

The background features a central sunburst of light rays in yellow and orange, surrounded by concentric circles of semi-transparent, overlapping squares in shades of blue, teal, and green. The overall effect is a dynamic, multi-layered geometric pattern.

**2015 | TOP 10
HOSPITAL C-SUITE
WATCH LIST**

2015 Top 10 Hospital C-Suite Watch List

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Introduction

ECRI Institute's 2015 Top 10 Hospital C-Suite Watch List discusses a blend of novel, new, and emerging technologies that will demand attention and planning over the next 12 to 18 months, plus important issues and programs affecting care processes and delivery in 2015 and beyond. We used our Institute's intellectual capital across our 450 interdisciplinary staff to identify these new and emerging technologies and care delivery issues. Our mission is to help decision makers understand the hype versus the evidence and the important issues to consider when deciding whether to be early adopters, middle adopters, or no-adopters.

Our list differs from others' top 10 technology lists. That's fine with us. We have no vested interest in the technologies and issues we discuss other than to fulfill our mission to improve patient safety and cost-effectiveness of healthcare. Our decades of experience as an independent evaluator of technologies and our participation in helping solve health systems issues affecting patient safety and cost-effective care drive us to look at the horizon with an eye toward helping the healthcare community understand what to think about before adopting and implementing the next "new" intervention or care strategy.

To compile this list, we looked across the continuum of care at new and upcoming developments in major clinical service lines. For our 2015 Watch List, we focus on infection control, cancer care, obesity, surgery, and diabetes. We also focus on a number of health information system issues and technologies such as middleware for alarm management, Google Glass for various clinical applications, wearable wireless sensors, and future directions for telehealth services. Additionally, we address a care model issue pertaining to efforts to improve adolescent and young adult cancer care and outcomes. Some of the technologies are commercially available (recently FDA approved), and others are on the 2015 or early 2016 horizon and will require planning now. As always, we offer straight talk about cost factors with these new technologies and services.

We welcome discourse and other perspectives. New this year is our LinkedIn group, "[Emerging Healthcare Technologies in Patient Care](#)," which we invite you to join so we can continue the discussion about these technologies and care innovations. ECRI Institute will continue to provide new evidence and insights throughout the year. We look forward to hearing your thoughts on these technologies.

Please feel free to contact ECRI Institute's experts to discuss your unique clinical and technology needs at (610) 825-6000, ext. 5655, or consultants@ecri.org.

1

Disinfection Robots: A Front-line Assault on Hospital-acquired Infections?

Battles may be lost or won on the hospital-acquired infection (HAI) front, but the war wages on as pathogens mutate to resist the latest antibiotics and disinfectants. HAIs are a significant problem. According to the U.S. Centers for Disease Control and Prevention (CDC), a survey of acute care hospitals found 1 in 25 hospital patients has at least 1 HAI on any given day and that 75,000 deaths per year are due to HAIs.¹ The thoroughness of terminal cleaning of patient rooms (i.e., thorough environmental cleaning and disinfection of patient rooms after patient discharge or transfer) in acute care hospitals is one area of focus to reduce HAIs and improve patient care. Recently, some hospitals have adopted portable enhanced environmental disinfection systems (robots) that feature ultraviolet-C (UV-C) light or hydrogen peroxide vapor (HPV) to complement infection control protocols already in place to battle hospital-acquired *Clostridium difficile* (*C. diff*), methicillin-resistant *Staphylococcus aureus* (MRSA), and other multi-drug-resistant organisms.²

Disinfection robotics evolved out of the need to reduce HAIs without incurring additional labor costs. While disinfection robots are new, the two methodologies for disinfecting rooms during terminal cleaning procedures—hydrogen peroxide and ultraviolet processes—are not.³ UV-C light has been used to decontaminate drinking water and air handling systems for many years, and UV-C and HPV have been used in clean room environments by the pharmaceutical industry for more than a decade. UV-C deactivates DNA and RNA, and HPV utilizes oxidative processes to kill microorganisms, including spores.²

Which Technology to Choose: Ultraviolet Light and Hydrogen Peroxide Vaporization

One supplier, Lumalier Corp. (Memphis, TN, USA), offers a UV-C system—the TRU-D® SmartUVC™ with its proprietary Sensor360™—that calculates the UV time and dose required based on room size, geometry, surface reflectivity to UV-C, and equipment in the room. In a single-patient room, decontamination takes about 25 minutes for MRSA and 45 minutes for *C. diff*. The robot is wheeled into a room that has already undergone terminal cleaning. The machine is activated remotely because no one can be in the room during system use. A large circular shaft featuring long UV-C tubes shines UV-C light on all room surfaces and objects to kill pathogens. Published environmental-surface study results have indicated the technology eradicates pathogens, and Lumalier has stated that an ongoing study of the TRU-D system (funded by CDC) is comparing HAI rates after standard chemical cleaning plus UV-C disinfecting with the TRU-D.²

Another UV-C device, the Xenex®, by Xenex Disinfection Services (San Antonio, TX, USA), uses pulsed xenon. According to Xenex, the system requires five-minute cycles in multiple positions in a typical patient room to kill *C. diff.*, and in this time frame all other pathogens are eliminated.² Several hospitals have released data on reduced *C. diff* and MRSA infection rates in conjunction with this pulsed xenon UV-C system.² While the technology is important, it is also critical to implement a bundled approach to reducing HAIs. Education, enhanced hand-hygiene protocols, advanced cleaning procedures, and contact precautions all lead to a safer hospital environment.²

In addition to light technology, HPV can be used for disinfection purposes. Bioquell, Inc. (Horsham, PA, USA) markets its Q-10 robot system to healthcare facilities. The system uses two machines: the first unit releases a 35% hydrogen peroxide solution into the air, and the second aerates the room. The robots resemble portable air-conditioning units. As with the UV-C devices, this system features remote activation because no one can be in the room during use. In



While disinfection robots are new, the two methodologies for disinfecting rooms during terminal cleaning procedures—hydrogen peroxide and ultraviolet processes—are not.

WHAT TO DO

- ▶ Consider introducing disinfection robots into intensive care units and other high-infection-risk patient care areas, but understand these technologies do not obviate the need for other infection control practices.
- ▶ Smooth introduction requires that infection control/prevention departments and hospital value analysis and technology assessment departments work together when considering whether to implement disinfection robots.
- ▶ These technologies are costly. Consider trialing the robots to assess their optimal value in terms of type of technology and locations in which to use them.
- ▶ For the trial, collect data on pre- and post-implementation hospital infection rates (including number and types of pathogens), patient clinical and infection information, readmission rates, disinfection time, and room downtime.
- ▶ If you move forward with acquiring the technology, decide how many to acquire, where to place them, and whether to purchase or lease them.
- ▶ Create a phased-in implementation approach that includes staff training to ensure understanding of the technology and its implications for other aspects of infection control to ensure consistent infection prevention protocols.
- ▶ Training staff for proper terminal cleaning, robotic cleaning, and infection prevention practices are key to a successful infection prevention program. A patient area may be disinfected well, but if a staff member does not follow appropriate infection prevention protocol, any patient area a staff member touches may be recontaminated.
- ▶ Monitor the clinical literature for evidence of effectiveness. Most cleaning and monitoring modalities are not well studied in clinical settings. The evidence base is limited by weak study designs, lack of consensus around important concepts (such as cleanliness thresholds and delineation of high-touch surfaces), and reliance on nonclinical outcomes.
- ▶ Watch for technology enhancements, including built-in UV-C and/or HPC disinfection systems, for newly constructed hospital areas and high-ion areas.

addition, air conditioning and heating vents, as well as spaces around the door, must be sealed during use. The process does not harm electronic equipment. According to the company, a single-patient room without a bathroom takes 90 minutes to decontaminate.²

Whatever the technology, note that the available “no-touch” technologies such as UV-C light irradiation and vaporized/aerosolized hydrogen peroxide can be used only for *terminal* room disinfection because they are hazardous to patients and staff.⁴ Also, the number of robots you decide to acquire should be determined according to your room turnover needs and the time required to disinfect.

Another Technology Option: Antimicrobial Coatings

Besides HPV and UV-C, light-activated antimicrobial coatings are being studied for the *continuous* disinfection of surfaces.⁴ These novel technologies, especially those employing nanotechnology, have dramatically improved the likelihood of developing a self-disinfecting surface, which has tremendous possibilities.⁴ Also, antimicrobial sealants are extremely durable, remain effective for years, and reduce labor costs, toxic chemicals, and water usage.⁵ Most importantly, the use of such surfaces could minimize the impact of inadequate cleaning and disinfecting practices during both routine and terminal room cleaning and disinfection.⁴

Implementing disinfection robotics might not only improve patient health outcomes, but also bring about significant savings and cost avoidance for healthcare systems.

Costs and Reimbursement

While disinfecting robot technology is costly, there's a direct correlation to reducing infection risk for inpatients, costs for treating HAIs, and patients' length of stay.³ According to ECRI Institute's SELECTplus pricing database, Bioquell's Q-10 HPV system has an average price of approximately \$47,000, the Xenex UV-C system costs approximately \$81,000, and the TRU-D UV-C system costs \$125,000.² Service contract costs should also be considered as part of any lifecycle cost analysis.

The U.S. Centers for Medicare & Medicaid Services (CMS) assesses hospitals' readmission payment adjustments using three readmission measures endorsed by the National Quality Forum: heart attack, heart failure, and pneumonia. CMS is finalizing its proposal to add two new readmission measures, which will be used to calculate readmission penalties beginning in fiscal year 2015: readmissions for hip/knee arthroplasty and chronic obstructive pulmonary disease.⁶ Disincentives, such as lower reimbursement payments, are expected to continue, and any higher costs incurred due to HAIs may not be reimbursed at all.

Introducing these technologies could have large positive implications for infection prevention practices and capital and operational budgets. In addition, administrators could see a return on investment due to fewer staff-contracted infections and loss of work time. Implementing disinfection robotics might not only improve patient health outcomes, but also bring about significant savings and cost avoidance for healthcare systems.

Related ECRI Institute Publications

- ▶ **Hotline Response.** Automated Technologies for Patient Room Disinfection and Decontamination of Biosafety Level 4 Infectious Agents, Including Ebola Virus, December 2014.
- ▶ **Procurement Trends.** UV Room Disinfection, July 2014.
- ▶ **Product Brief.** Pulsed Xenon UV Disinfection System (Xenex Disinfection Services, LLC) and R-D Rapid Disinfector (Steriliz, LLC) for Environmental Disinfection, April 2014.

2 Three-dimensional (3-D) Printing Buzz: How Many 3-D Printers Should You Plan on in 2015?

Three-dimensional (3-D) printers are all the rage in healthcare these days. So much so that the U.S. Food and Drug Administration (FDA) held a major town hall meeting in October 2014 to explore potential regulatory issues. 3-D printers in healthcare are being explored for use in three ways: 1) making anatomic patient-specific models for planning and practicing delicate surgery before the real procedure, 2) fabricating custom implants for patients, and 3) creating human tissues and organs by layering cells.

Researchers at the University of Michigan Health System (Ann Arbor, MI, USA) have used 3-D printing techniques under compassionate use approval to fabricate customized, resorbable implants to repair failing airways in two children. Other centers have used the technology to create 3-D models of the skull, jaw, and heart to allow surgeons to plan intricate surgeries to repair congenital heart defects, restore normal facial structure, and correct other anomalies. Some medical device manufacturers are producing orthopedic implants on-demand using 3-D printers to hold down product inventory costs.

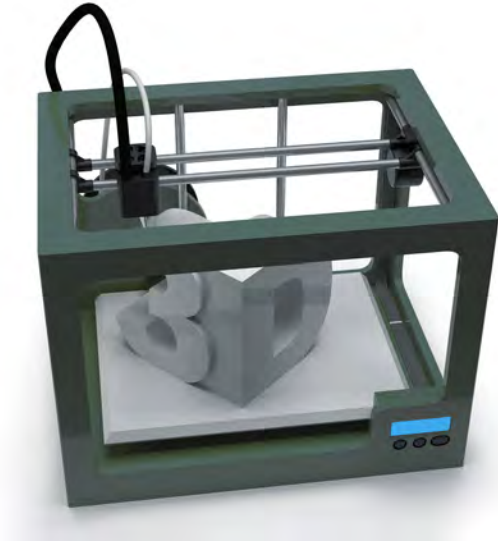
Amid these developments, FDA is asking questions and seeking to define its appropriate role in regulating 3-D printing in healthcare, trying to strike a balance between protecting patient safety while not stifling innovation in emerging healthcare technologies. Some analysts have predicted that U.S. hospitals will buy an average of two 3-D printers each in 2015. How should health facilities respond?

3-D Printing: The Basics

Although relatively new to healthcare, 3-D printing, also called additive manufacturing, has been used in some form since the early 1990s, primarily in heavy industry such as jet engine construction. Designers use computer-aided design and 3-D modeling software to plan the printing process, which builds objects from plastic, metal, or other materials by adding successive layers onto each other until the object is complete. Essentially, 3-D printers build products from the bottom up by heating raw materials to facilitate spraying them through a nozzle or jet to create multiple layers in thin slices as directed by the software instructions. The 3-D printing process contrasts traditional reductive manufacturing that subtracts from a wooden block or other raw material to reach a finished product.

Numerous 3-D printers are commercially available, ranging widely in size, complexity, and price from tabletop models for hobbyists under \$1,000 to large industrial models, which range in cost from tens of thousands of dollars to a million dollars, but no standards have yet emerged for clinical applications of 3-D printing. Companies marketing 3-D printers that are purportedly well-suited for healthcare applications include 3D Systems, Inc. (Rock Hill, SC, USA) and Stratasys, Ltd. (Eden Prairie, MN, USA). HP (Palo Alto, CA, USA) has announced plans to introduce a “revolutionary” 3-D printer in 2016 using its proprietary “Blended Reality Ecosystem” that promises faster and cheaper printing options than those currently available. Companies such as Medical Modeling, Inc. (Golden, CO, USA) reportedly offer 3-D printing services as outside suppliers. Investigators have reported using conventional 3-D printers and modifying them to investigate different materials and applications. In general, 3-D printing involving plastics, metal alloys, or other inorganic materials for healthcare applications is further along in development than 3-D bioprinting (i.e., layering living cells to generate new tissue or organs).

WHAT TO DO



- ▶ Closely monitor FDA moves to regulate 3-D printing in healthcare, particularly 3-D printing done by hospitals, so your facility does not risk running afoul of regulations.
- ▶ Assign teams in your health system to keep current about 3-D printing research in their clinical fields.
- ▶ Evaluate the feasibility of establishing a 3-D printing program at your facility and the applications that might make the most sense for your patient populations and clinical service lines (e.g., enhanced surgical planning, customized orthotics).

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Effects on Healthcare Delivery and Patient Outcomes

One of the most dramatic examples of 3-D printing's potential to directly alter patient care occurred at the University of Michigan. Surgeon Glen Green, MD, and biomedical engineer Scott Hollister, PhD, used 3-D printing to create customized, bioresorbable airway splints to treat severe tracheobronchomalacia, a rare but potentially fatal softening of tracheal and bronchial tissue leading to collapsed airways with no real curative therapy. They completed the procedure in two children (as of November 2014) under FDA compassionate use exemptions. In March 2014, investigators at University Medical Center Utrecht (The Netherlands) reported a 23-hour surgery to implant the first complete 3-D-printed skull in a 22-year-old patient with a progressive, bone-thickening disorder. Elsewhere, collaborators at Princeton University (NJ, USA) and Johns Hopkins University (Baltimore, MD, USA) completed a proof-of-concept study using 3-D printing to create bionic ears that interweave biologic tissue with functional electronics. A University of Toronto (Ontario, Canada) team is evaluating the feasibility of 3-D printing sheets of skin grafts using a burn patient's own cells.

Researchers at Wake Forest University (Winston-Salem, NC, USA), with support from the U.S. military, want to use 3-D printers to apply new autologous cells directly onto burn wounds. At Children's National Medical Center (Washington, DC, USA), pediatric cardiologists and surgeons are using 3-D-printed models to study congenital heart defects to plan intricate corrective surgeries in children.

Other applications have received less media attention but appear to be diffusing more broadly at this early stage. Such uses include creating customized prosthetic devices, especially dental crowns and bridges, as well as prosthetic limbs, using anatomic data obtained with noninvasive imaging rather than molds and oral impressions.

The Evidence Story

At this point, most published data on 3-D printing are limited to case reports and very small case series describing early 3-D printing experience. Most reports involve craniofacial and mandibular surgery and dental procedures. Typically, these reports describe 3-D printing used to create detailed surgical models and templates to facilitate surgical planning, with fewer reports describing 3-D-printed models for cardiac, neurosurgery, and orthopedic surgery. To a lesser extent, the clinical literature cites 3-D printing to create customized implants used in craniomaxillofacial and mandibular surgery and dental surgery. A couple studies compared 3-D-printed ankle-foot orthoses to conventionally fabricated orthoses.

Costs, Reimbursement, and Regulation

At this stage, how 3-D printing might affect healthcare costs overall remains unclear. Ultimately, costs could be affected by how 3-D printing is regulated. According to General Electric Aviation (Cincinnati, OH, USA), which has been using 3-D printing and additive manufacturing since the 1990s in some form to produce jet engines, 3-D printing can potentially allow faster and cheaper development of new products compared to traditional manufacturing techniques. Device manufacturer Renovis Surgical Technologies, Inc. (Redlands, CA, USA) reports that it has FDA marketing clearance for two metal-alloy orthopedic implants produced with additive manufacturing. Manufacturers and hospitals could view 3-D printing as a cost-cutting technique that allows them to reduce product inventory costs with more "just in time" production.

With regard to coverage and reimbursement, such customized health technology will change the evidence paradigm and require a different approach to coverage policy and reimbursement by third-party payers. The idea of having evidence from randomized controlled trials goes out the window with such highly customized uses of 3-D printing for patients.

From a regulatory perspective, among the questions FDA raised at an October 2014 public meeting on 3-D printing were whether the 3-D printing process fundamentally alters raw materials' chemical or biomechanical properties in unforeseen or unsafe ways. Some patient safety issues raised included printer calibration and maintenance, sterilization of printers and materials, infection risk, and risk of delamination of layered print products over time. FDA has sought public input as it prepares to develop industry guidelines for 3-D printing in healthcare. Other questions raised included whether FDA might consider hospitals to be manufacturers—held to the same regulatory standards—if and when they use 3-D printing to create individualized implants for patients.

Related ECRI Institute Publications

- ▶ **Health Technology Trends.** FDA Questions Stakeholders on 3-D Printing Process, Validation Practices, November 2014.
- ▶ **Health Technology Trends.** 3-D Printing in Healthcare: Devices, Tissues, and Regulatory Issues, April 2014.
- ▶ **Health Technology Trends.** All the Better to Hear You With: Researchers 3-D Print First Pair of Bionic Ears, April 2014.
- ▶ **Health Technology Trends.** Life-saving 3-D Printed Technology Emerges in Pediatrics, April 2014.
- ▶ **Health Technology Trends.** Regenerating Skin Cells for Burns: Can 3-D Printing Improve the Process? April 2014.
- ▶ **Hotline Response.** Clinical Applications for 3-dimensional Printing Technology, January 2014.

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were whether the 3-D printing process fundamentally alters
raw materials' chemical or biomechanical properties
in unforeseen or unsafe ways.*

3 Middleware Is Everywhere: Can It Help You Meet the National Patient Safety Goal on Clinical Alarms?

Middleware is on the minds of health information technology (IT) experts everywhere. The term has wormed its way into the lexicon of the healthcare industry as the use of personal communication devices (PCDs) in health systems increases. But what exactly is middleware? How are PCDs, like smartphones, being used to change the face of alarm management?

Until a few years ago, healthcare alarms were typically localized. They either emanated from the medical device itself or, in the case of physiologic monitors, came from both the monitor and its central station. Can the use of middleware change how alarms are sent out and managed? Will it be able to create a personal notification environment for clinicians that is as simple to use as texting?

Middleware has been described as software that allows for communication and data management between two different systems. Used especially in IT networks, middleware provides messaging services so that different applications can communicate—it tries to glue everything together. While middleware can also facilitate the automation of clinical documentation, perform remote surveillance, and perform data aggregation for retrospective review and analysis, our focus is how its use can revolutionize alarm management and notification.

Alarm Management and Notification

In 2013, the Joint Commission (TJC) published a Sentinel Event Alert citing 98 reports of alarm-related events over a 3.5-year period, with 80 of those events resulting in deaths and 12 in permanent loss of functions.⁷ TJC then issued the 2014 National Patient Safety Goal (NPSG) for hospitals and critical-access hospitals. The NPSG focuses on managing alarms more effectively to reduce alarm fatigue and is to be implemented in two phases:⁸

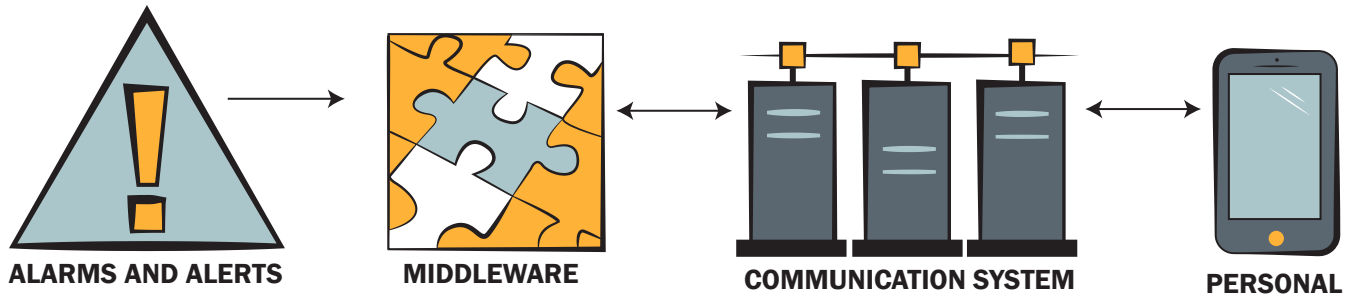
- ▶ Phase 1: During 2014, healthcare providers were required to identify the alarm hazards that organizations will address based on their individual situations.
- ▶ Phase 2: As of January 1, 2016, organizations will be expected to have developed and implemented specific policies and procedures to combat hazards and educate staff.

In addition to TJC's efforts, ECRI Institute has also identified clinical alarm hazards as the number one issue in its "[Top 10 Health Technology Hazards for 2015](#)."

How Does Middleware Fit into All This?

Alarm management is very complex, and making the most of emerging technologies like middleware may be a critical part of how your hospital responds to the NPSG. A middleware solution can help organizations collect alarms and data for analysis and in turn help them recognize problematic alarms.

Middleware provides messaging services so different applications can communicate—it tries to glue everything together.



System Design

Using PCDs to manage alarms can turn the complex alerting process into a simple one—or at least a less complex one. Alerts and alarms from different applications and medical devices (e.g., an electronic medical record system, a nurse call system, patient monitors) may be routed to the middleware. The middleware can relay the alarms to the communication system that then propagates the messages to PCDs carried by medical personnel. Voice-over IP (VoIP) phones, Wi-Fi phones, smartphones, and pagers can now receive alarms that were once limited and localized. With the advance in technology, these PCDs can now also receive specific information related to the alarm device or alerts from different sources, which can lead to better alarm management.

Middleware’s Critical Functions

Middleware performs critical functions, such as:

- ▶ Prioritization of alarms
- ▶ Assignments (staff assignments, schedules)
- ▶ Alarm escalations
- ▶ Routing assignments
 - Individual: the system sends the message to an individual only
 - Group: an alarm condition, such as a code blue, is set to propagate to a team
- ▶ Report generation and information logs
- ▶ Complex event processing: combines messages from multiple sources to infer events or patterns that suggest more complicated circumstances

WHAT TO DO

- ▶ Assess alarm loads to see how middleware can be used to prioritize alarms and reduce alarm fatigue.
- ▶ Review the IT Strategic Plan to determine whether alarm middleware can be accomplished to support your hospital’s work in meeting the NPSG on clinical alarms.
- ▶ Determine which systems may need middleware.
- ▶ Inventory PCDs, and determine whether one platform is suitable for all communication needs.
- ▶ Alarm response time depends on using PCDs. PCDs should be able to handle multiple priority levels for incoming alerts. Using two-way communication devices with an “acknowledge” option is preferable.
- ▶ Consider your architectural layout. Smaller areas are easier to cover and typically produce faster response times.
- ▶ Consider the nurse-to-patient ratio. Getting this right means having enough coverage during shift changes and peak census times.
- ▶ When using alarm middleware, customize with care and test extensively before deploying.

Properly implemented, these systems can expedite alarm notification and response times, improve alarm management, reduce alarm fatigue, and create a quieter healing environment for patients by directly notifying clinicians or caregivers via PCD and sending multiple alerts to a PCD from different alarm sources.

Of the many critical functions the middleware performs within an alarm management system, the following require great attention:

- ▶ **Prioritization:** The alarm management system *must* have a built-in prioritization capability. More than one alarm may emanate from a single device, and guidelines must clearly state which alert takes precedence. Accurate mapping of priorities is necessary for the system to work effectively.
- ▶ **Escalation:** Alarm escalation schemes are critical to the successful implementation of an effective system. It is essential to narrow down which alarms and alerts are to be transmitted via the middleware to the PCD. Proper implementation of an alerts system takes into account how alarms are escalated and to whom they are sent. Failover redundancies should be built in, and alarms should automatically be escalated within a certain time frame if the primary caregiver does not acknowledge an alarm.
- ▶ **Reporting:** Reducing the number of problematic alarms requires robust alarm management strategies and data analysis. Alarm systems using middleware are built to collect just that type of data. They can create reports specific to a particular care unit, to an individual device, or even based on a particular alarm priority level. This ability is vital, as it allows organizations to parse their data to find problematic alarm areas. This level of reporting can also arm an organization with audit trails to track alert delivery and response times. Alarm reports generated through a system's middleware help educate a facility's staff and helps them understand how to customize the type of alarms they receive.
- ▶ **Managing assignments:** Using middleware in your alarm management system allows staff to create appropriate correlations between caregivers and their assigned patients, between caregivers and their PCD, and between caregivers and their backup "buddy," which can include other members of their group who can provide coverage, the Code Blue Team, and others.

Other implementation factors to consider are:

- ▶ Which communication devices can be interfaced to the system (smartphones, VoIP phones)
- ▶ Which medical devices can be interfaced with the system
- ▶ Whether other information systems (e.g., ADT) can be interfaced to ease the assignment process

Working with your middleware vendor and your alarm consultant is important to discuss the types of care models that are already established in your organization. Nursing care delivery models like centralized monitoring (i.e., in which an organization utilizes monitor watchers to manually provide alarm notification by contacting the caregiver's PCD), decentralized monitoring (i.e., in which the caregivers are directly responsible for responding to alarms on the devices monitoring), or a hybrid of the two will affect your choice of how your system is designed and what middleware is required.

Alarm middleware is highly complex and very customizable. Because the cost of these systems depend on their configurations, it's not uncommon for a hospital to spend more than \$100,000 to implement them. To make sure you are getting the right system for your hospitals and their nursing care delivery models, it's imperative to have a good design team in place. A good multidisciplinary team should include not only members of the clinical staff, but also IT, facilities, and biomedical engineering.

One of the biggest considerations the team must consider is testing the middleware alarm management system. It is imperative to exhaustively analyze the system to ensure that alarms are transmitted and received properly. A "sandbox" testing environment should be set up to evaluate how well the escalation scheme functions when priority level alarms are sent and will help identify potential glitches during software and hardware upgrades. Alarm integration is one technology in which performance improvements can be great—or devastating. Deep analysis, planning, and testing are essential to its success.

Related ECRI Institute Publication

- ▶ **Health Devices.** 2015 Top 10 Health Technology Hazards, November 2014.

*In addition to the Joint Commission's efforts,
ECRI Institute has also identified
clinical alarm hazards as the number one issue in its
"Top 10 Health Technology Hazards for 2015."*

4 Postdischarge Clinics: Do They Prevent Readmissions and Save You Money?

Patients discharged from hospitals are often in a vulnerable health state and are at risk of adverse events and readmissions that might be preventable with better postdischarge planning and execution. Until recently, hospitals may have under-emphasized comprehensive discharge planning and tended to view this as the responsibility of the patient's physician or other providers. A comprehensive discharge planning process is one of the key ways to reduce avoidable readmissions. However, all too often when patients are discharged they cannot schedule an appointment or get to their primary care or referred physicians in a timely manner. Patients are still recovering from their hospital stay and become overwhelmed trying to manage their own care. Postdischarge clinics are an initiative intended to create smoother care transitions, address patient needs, and prevent hospital readmissions.

Readmission Penalties Go Up in 2015

Several federal initiatives have caused hospitals to change perspectives on patient discharge procedures. In May 2013, CMS updated its interpretive guidelines for surveyors for discharge planning and provided "advisory practices," urging hospitals to voluntarily use them as references and resources for process improvement. CMS holds hospitals accountable for complying with its discharge planning as a condition of participation in the agency's strategy to reduce preventable hospital readmissions. Initially, CMS required hospitals to publicly report their 30-day readmission rates for acute myocardial infarction, heart failure, and pneumonia. A financial incentive for hospitals to reduce readmission rates for certain conditions was added under the Patient Protection and Affordable Care Act, which established the Hospital Readmissions Reduction Program (HRRP), effective for discharges that began two years ago. Under the program, CMS reduces payments to inpatient prospective payment system hospitals with "excess" readmissions. After the program's first month of operation, CMS data indicated a rapid reduction in the all-cause national rate of 30-day readmissions for Medicare patients, from a persistent 19% to 17.8%.⁹

The 1% excess readmission penalty assessed in fiscal year 2013 by HRRP resulted in more than 2,200 hospitals being assessed about \$280 million. The penalty increases to a maximum 3% in 2015 and includes readmissions for chronic obstructive pulmonary disease and elective hip or knee replacements.¹⁰

Barriers to Needed Postdischarge Care

Basing its analysis on 2000–2008 data from the Medical Expenditure Panel Survey, the National Institute for Health Care Reform (NIHCR) reported that more than 90% of people admitted to the hospital have a primary care physician. However, having a usual source of care (e.g., a primary care physician) does not guarantee easy access or access when needed: 1 in 10 people reported difficulty accessing his or her primary care physician. Barriers include lack of after-hours care (nights and weekends), lack of transportation, and long travel times.¹¹ NIHCR reports that one-third of adults discharged from a hospital did not access follow-up care (with a physician, nurse practitioner, or physician assistant) within 30 days of discharge. NIHCR's findings have shown that nonelderly adults with public coverage were no more likely to seek follow-up care within 30 days of discharge than the privately insured.¹¹

Some early evidence does show that postdischarge care clinics can shorten the time to first visit after hospitalization.



WHAT TO DO

- ▶ Any provider with serious readmission penalty issues should consider implementing a postdischarge clinic model.
- ▶ To determine your need for such a clinic, first assess your compliance with CMS requirements and identify deficits.
- ▶ Adopt an enterprise risk-management approach when considering strategies to improve discharge planning.
- ▶ Design and implement a screening process to identify patients unable to self-manage their postdischarge care plan and likely to experience adverse health consequences as a result.
- ▶ Identify patients admitted for clinical conditions that correlate with higher readmission rates.
- ▶ Use checklists consistently with all patients in the clinic, and consider social and economic factors that can affect the discharge plan.
- ▶ Review cases of discharged patients periodically to determine gaps in postdischarge clinic services.
- ▶ Tailor a discharge plan to each patient's needs.
- ▶ Ensure that the postdischarge providers include medication reconciliation and patient education about their discharge medications.

Turning the Process on Its Head: New Postdischarge Clinic Model

Some hospitals have turned discharge planning on its head by creating postdischarge clinics that focus on increasing patient access to posthospital care through a primary care-based, hospitalist-staffed approach to transitional care. In the old model, ineffective planning and lack of care coordination and follow-up often undermined patient health and safety, decreased patient satisfaction, and contributed to hospital readmissions. In effect, the hospital (or an Accountable Care Organization), assumes greater responsibility for patient care when the patient leaves the hospital.

Transitions of care, encompassing a patient's discharge back into the community, are frequently associated with clinically and financially costly adverse events. Timely follow-up by a clinician familiar with the patient and hospital course is critical for reducing the risk of postdischarge adverse events. However, the increased demand for primary care services and the decreased supply of primary care physicians make timely follow-up difficult. Typical problems that can occur for patients include:

- ▶ Medication prescriptions being miscommunicated
- ▶ Hospital discharge information not being communicated to the primary care physician
- ▶ Test results not being forwarded, leaving the patient susceptible to unresolved medical issues

Hospitalists are increasingly being used to improve postdischarge care access and continuity after discharge in a postdischarge clinic.¹² The postdischarge clinic, also known as a transitional care clinic or after-care clinic, bridges medical care coverage between the hospital and ongoing primary care.

Examples that appear to be working provide models to consider. At the Bridge Clinic of San Francisco General Hospital (CA), patients are referred by hospital residents who can text message a hospital-run appointment system to set up the postdischarge appointment. Residents must prepare a discharge summary immediately so it is available for the patient's appointment at the clinic. Before being officially discharged from inpatient care, patients are provided with a contact number for the clinic in case they need to reschedule the appointment or ask any questions. At the postdischarge visit, medications are reconciled, medication use is reviewed, prescriptions are refilled, patients are assessed for any new symptoms, pending test results are discussed, and any necessary referral appointments are made. Extensive time is spent on patient education regarding self-diagnosis and personal health promotion. Case management, insurance status, and any durable medical equipment needs are addressed. Finally, patients are referred to or reconnected with primary care physicians.¹³

Another model, at Beth Israel Deaconess Medical Center (Boston, MA, USA), is run in a similar fashion. However, patients are directly referred to the clinic by a computerized algorithm that identifies patients without a listed primary care physician or for whom a follow-up appointment cannot be made with the listed primary care physician within two weeks of discharge. Visits are 40 minutes long and consist of "reviewing the hospitalization, medication reconciliation, and outstanding tests."¹⁴ The clinic staff may also establish home healthcare services or skilled nursing facility care for patients. The majority of patients are seen at the clinic only once and are then scheduled for a follow-up visit with a primary care physician. Patients discharged from the emergency department are scheduled for 30-minute appointments within 48 hours of the emergency department visit. Everything done at the clinic is documented and accessible via the medical center's electronic health record system.¹⁴

The Evidence Story

Recent research on hospital readmissions by the Dartmouth Atlas Project found that only 42% of hospitalized Medicare patients had any contact with a primary care clinician within 14 days of discharge.¹⁵ Postdischarge clinics are trying to rectify this, but little clinical evidence has been published reporting whether postdischarge clinics lead to lowered hospital readmission rates. However, some early evidence does show that postdischarge care clinics can shorten the time to first visit after hospitalization. One recent study of a dedicated hospitalist-staffed postdischarge clinic indicated the clinic is associated with markedly shorter time to first visit after hospitalization. The postdischarge clinic improved the proportion of patients seen within one week across the entire practice. The clinic was used particularly by vulnerable subgroups of patients for whom access tends to be most fragmented. Many other important outcomes are still to be determined; for example, it will be important to understand the effect of postdischarge clinics on adverse events related to discharge such as medication errors, interventions on outstanding tests, readmissions, and postdischarge mortality.¹⁶

The Cost Equation

Hospitals incorporating a postdischarge clinic into their care delivery process bear the financial cost of constructing or updating space for the clinic. Costs vary based on the institution's needs, patient populations served, and available resources. Developers of the Bridge Clinic reported that no extra funding was needed to establish and maintain the clinic; patient care and case management were provided by nurse practitioners already on staff.¹³ Developers also note that the clinic generates revenue for the parent hospital through billing for patient visits.¹³ Developers of the postdischarge clinic at Beth Israel Deaconess have not yet tested the financial model but have indicated that the revenue the clinic generates is "less important than the costs saved by avoiding readmissions."¹⁴

Related ECRI Institute Publications

- ▶ **Guidance Article:** Discharge Planning, September 2014.
- ▶ **AHRQ Healthcare Horizon Scanning System Potential High-Impact Interventions: Cross-Cutting Interventions and Programs.** Hospital Postdischarge Clinics to Provide Transition Care. Rockville, MD: Agency for Healthcare Research and Quality, June 2014. <http://effectivehealthcare.ahrq.gov/index.cfm/>

Some hospitals have created postdischarge clinics that focus on increasing patient access to posthospital care through a primary care-based, hospitalist-staffed approach to transitional care.

5

Google Glass—Dead for Consumers but Maybe Not for Healthcare: Will Your Clinicians and Patients See Any Benefits?

Since Google launched a trial version of its Google Glass in 2013, the technology has become “uncool” among many techies, as their dream of a Google Glass consumer version may never materialize. In November 2014, Reuters reported that more than half the companies it contacted that had been developing Google Glass consumer applications had essentially pulled the plug on their projects with the dwindling prospects for a mass-market version; consumer trade publications soon echoed the death knell. However, in healthcare, rumors of Google Glass’s demise appear to be premature. Based on early user feedback, Google is refocusing Google Glass on the business market, especially for healthcare applications. Some developers of healthcare-related Google Glass applications report securing additional venture capital funding. The two biggest applications could be hands-free documentation and information review, and telerenting (or teleproctoring) (e.g., allowing experienced surgeons to remotely coach novice surgeons via a Google Glass telemedicine link). Will Google Glass soon be a line item in your technology budget like laptops, iPads, and handheld ultrasound devices?

What Exactly Does Google Glass Do?

Worn like a pair of eyeglasses, Google Glass sits above the right eye and contains a computerized central processing unit and a small optical head-mounted prism display with wireless connectivity through users’ Bluetooth-enabled Android or iPhone. A right-temple touchpad allows users to scroll and select displayed menu items. A camera allows users to take pictures and record video. The titanium frames, described as “feather light,” can be worn with or without prescription lenses. Users can control the device with voice commands, such as “OK, Glass, record video,” or “OK, Glass, take a picture,” and subtle head movements. Users can also use ear buds with Google Glass.

How Can Google Glass Alter Healthcare Delivery and Patient Outcomes?

Some providers have expressed optimism about results from their initial Google Glass experience. In January 2014, Dignity Health (San Francisco, CA, USA; formerly Catholic Healthcare West) began a pilot study in collaboration with software firm Augmedix (San Francisco, CA, USA) to evaluate whether Google Glass could help family practice physicians redirect more time to patient care and less time to data entry for electronic health records (EHRs). According to Dignity Health, Google Glass let its physicians who were testing the device increase direct patient care time from 35% to 70%, while decreasing daily time spent on EHR data entry from 33% to 9%. Physicians report Google Glass facilitates patient record review without the need to turn away from patients to view a computer screen. Most patients seem to view Google Glass favorably, based on reports that less than 1% of patients in the study asked physicians to remove Google Glass during their visits.

However, early feedback from clinician explorers (i.e., clinicians testing clinical use of the device in various settings) suggests that, although Google Glass has the potential to improve aspects of patient care, a new version designed specifically for healthcare applications would be required to fully realize its potential.

Used during surgery, Google Glass could allow experienced surgeons located off-site to provide real-time guidance to novice surgeons by giving them the same patient view remotely. During surgery, Google Glass could theoretically allow a remote pathologist to view a tumor through a surgeon’s eyes and discuss whether or where further tissue excision would be required.



WHAT TO DO

- ▶ Monitor ongoing research of Google Glass devices and healthcare software applications.
- ▶ Explore what Google Glass applications might make the most sense for your facility.
- ▶ Monitor federal regulatory bodies that could assert regulatory authority over Google Glass and the software applications, including FDA steps that might affect Google Glass use at your facility.
- ▶ Form collaborative teams of clinicians and IT staff to weigh Google Glass adoption options and all the relevant steps required for implementing specific applications. Identify early-adopter clinical testing groups.
- ▶ Develop a protocol for testing each application of interest to your health system and a formal, structured method of collecting and analyzing data from your clinical groups testing each application of the device.

Early feedback suggests a new version of Google Glass designed specifically for healthcare applications would be required to fully realize its potential.

In another application under clinical study, researchers at the University of California, Los Angeles, have been testing whether Google Glass could be combined with lab-on-a-chip technology and mobile phones to perform rapid laboratory testing to identify possible disease outbreaks in specific populations.

The Evidence Story

The few available studies of Google Glass describe users' initial experience and perceptions of Google Glass. Meunsterer and colleagues (2014) tested the technology for four consecutive weeks during rounds, clinic, and in the operating room of a pediatric surgery department at Children's Hospital at Montefiore (New York, NY, USA).¹⁷ Investigators found Google Glass useful for hands-free photo/video documentation, hands-free telephone calls, looking up billing codes, and Internet searches for unfamiliar medical terms or syndromes. However, investigators cited several device shortcomings, including short battery life, data protection issues, poor overall audio quality, and slow data transmission combined with interruptions during videoconferencing. They recommended substantial hardware improvements and development of specialized medical applications before wider Google Glass adoption.¹⁷

Wu and colleagues (2014) compared Google Glass–assisted ultrasound-guided placement of a central venous access catheter (CVAC) to conventional ultrasound-guided CVAC placement among 40 clinicians of varying experience levels.¹⁸ Investigators observed that all clinicians were able to complete CVAC placement, but Google Glass users, on average, took longer to gain venous access and had more needle redirections but made fewer head movements.¹⁸

Russell and colleagues (2014) evaluated whether Google Glass telementoring from remote experts using Google Hangout (an online tool for group collaborations and meetings) would allow novice ultrasound users to approximate ventricular ejection fraction in healthy subjects using bedside cardiac ultrasound.¹⁹ Investigators observed no statistical difference in ability to obtain adequate images or image quality between Google Glass novice ultrasound users and novice users receiving traditional bedside mentoring from the same cardiac ultrasound expert. Investigators recommended further confirmatory studies involving different patient populations.¹⁹

Costs, Reimbursement, and Regulation

Google reportedly charged the 8,000 select clinician explorers \$1,500 each for the Google Glass test version. Little information is available detailing additional costs for any healthcare-related software applications available for Google Glass. These costs would add to technology costs for health systems, but in some cases might offset other costs when used for telemedicine applications. If it improves both clinician and patient satisfaction during patient visits, as described previously for enabling EHR documentation during patient visits, it might be considered a worthy investment.

*The two biggest applications
could be hands-free documentation
and information review, and telementoring.*

Addressing Privacy Concerns

Maintaining patient privacy is critical to the future use of Google Glass in healthcare. Software developers such as Pristine Software Company LLC (Austin, TX, USA) and CrowdOptics, Inc. (San Francisco, CA, USA) offer applications that comply with the Health Insurance Portability and Accountability Act of 1996 (HIPPA) and that purportedly let healthcare providers use Google Glass to stream audio and video across a hospital's network in accordance with all regulations. At the Children's Hospital at Montefiore, Meunsterer and colleagues had to disable Google Glass's Wi-Fi connection to prevent the device from uploading video and picture data to the Google cloud. Other researchers at Beth Israel Deaconess Medical Center reported removing all Google components from the device to prevent patient data from traveling over Google servers, thus retaining all patient data within their hospital's firewall.

At this early stage, it remains unclear whether FDA or any other federal agency would consider Google Glass subject to its oversight. In June 2014, FDA updated a list of "mobile apps that may meet the definition of a medical device but for which FDA intends to exercise enforcement discretion." Without naming specific products, FDA describes one technology potentially subject to discretionary enforcement as mobile apps that allow a user to collect, log, track, and trend data such as blood glucose, blood pressure, heart rate, weight, or other data from a device to eventually share with a healthcare provider or upload it to an online (cloud) database or personal EHR. Google Glass may be used for similar activities, so it may be subject to similar regulatory enforcement.

As the technology develops, health systems will need to keep up on how FDA and other regulatory bodies regulate Google Glass applications and the implications if hospitals modify Google Glass or software used on the device.

Beyond patient privacy, using Google Glass could raise major patient safety concerns that remain largely unexplored in initial user experience. Potential safety issues include whether clinicians could safely substitute Google Glass for another conventional technology and how glasses are kept sterile between uses in operating rooms or other hospital areas, especially areas with patients vulnerable to infection. Numerous media reports cite foil delamination as a frequent cause of Google Glass failure, especially in high humidity conditions, a technological hurdle that could be critical for proper sterilization procedures in healthcare settings.

Related ECRI Institute Publications

- ▶ **Health Technology Trends.** Is Google Glass the Next Breakthrough Technology in Healthcare? August 2014.
- ▶ **Health Technology Trends.** Wearable, Measurable, Mobile: Vital Signs of the Times from Apple, Google, and Others, August 2014.
- ▶ **Health Technology Forecast News Brief.** Is Google Glass a Surgeon's New Best Friend? June 2014.

6 New Anti-obesity Devices: Should You Add Them to Your Bariatric Armamentarium?

According to CDC, 34.9% of U.S. adults were obese in 2012, up from 32.2% in 2003. Three years ago, FDA came under intense pressure to more quickly approve several novel anti-obesity drugs in development. As of late 2014, three of four new anti-obesity drugs received FDA approval and the fourth was recommended for approval. Developers of anti-obesity devices issued a similar call to FDA to create a more hospitable climate for approval of novel minimally invasive anti-obesity devices, given the growing prevalence of obesity and the need for options for patients who are not suited for invasive bariatric surgery or who do not want to undergo the surgery. Another factor urging action is that the newly approved drugs have achieved mixed results and less uptake by patients and clinicians than anticipated. Thus, the broad therapeutic gap between lifestyle modification (i.e., diet, exercise), medical therapy, and bariatric surgery has heightened interest in new minimally invasive interventions, potentially obviating the need for bariatric surgery in some patients.

Three Devices on the Near Horizon

Minimally invasive anti-obesity devices in development target weight loss using different technical approaches, although all try to reach this goal without permanently altering the gastrointestinal tract like bariatric surgery. Three different devices are in late-phase development, and some have been reviewed by the FDA advisory panel for obesity devices (Gastroenterology-Urology Devices Panel), which makes recommendations to the agency about approval for anti-obesity devices.

The Maestro[®] System for VBLOC[®] vagal nerve blocking (EnteroMedics, Inc., St. Paul, MN, USA) is designed to achieve weight loss by sending low-energy electrical impulses from an implantable pulse generator to block normal vagus nerve signals in the abdominal region. According to the company, vagus nerve blocking works through several mechanisms, including reducing appetite and increasing satiety, inhibiting stomach expansion and contraction (gastric motility), and cutting caloric absorption by restricting secretion of digestive enzymes. To deploy the technology, a surgeon implants the neuromodulation device under the skin and places the system's two internal electrodes on the anterior and posterior vagal nerve trunks, just above the junction of the esophagus and stomach. Patients are placed under general anesthesia during the laparoscopic implantation procedure, which usually takes about 60 to 90 minutes. Clinicians wirelessly program, modify treatment parameters, and retrieve diagnostic data from the neuromodulator using proprietary software running on a standard laptop computer. A rechargeable lithium ion battery powers the neuromodulator while the patient is awake. Patients typically recharge the battery overnight using an external mobile charger that uses radiofrequency waves to supply energy transcutaneously.

During clinical trials of the Maestro system, clinicians programmed the device to block vagus nerve signals for about 13 hours per day, and patients were instructed to check power levels daily and recharge batteries as needed. According to EnteroMedics, the Maestro system is indicated to induce weight loss in patients with a body mass index (BMI) of 40 to 45 kg/m² or a BMI above 35 kg/m² with major obesity-related comorbidity such as diabetes.

The ReShape Duo[™] (ReShape Medical, Inc., San Clemente, CA, USA) uses two balloons placed in the stomach, intended to limit the stomach's capacity for food intake and increase satiety. During the 15- to 30-minute outpatient implantation procedure, a physician uses an endoscope advanced through the mouth to deploy the balloon, with the patient under



WHAT TO DO

- ▶ Of three minimally invasive devices in late development, two could receive FDA approval in 2015.
- ▶ Plan now with your bariatric clinical staff whether you want to adopt these new technologies.
- ▶ Consider cost implications for your health system and how you will manage the additional patients seeking these devices.
- ▶ Decide what training clinical teams would need to provide the technology and necessary follow-up care.

These minimally invasive devices could represent a new revenue stream for facilities attracting patients with less severe obesity.

conscious sedation. When the operator confirms proper balloon location, each balloon is inflated with 450 cc of saline (900 cc total). According to the manufacturer, the dual-balloon design conforms to the stomach's contours better than similar 400 to 700 cc single-balloon devices, thereby reducing the chance of device migration and gastric obstruction while occupying a greater internal volume without distending the stomach. The ReShape Duo balloon is intended to stay in place for six months. To retrieve the device with the patient under conscious sedation, a clinician uses an endoscope fitted with a proprietary suction tool advanced through the mouth to drain the saline and snare the deflated balloons for removal. Clinical trials of the ReShape device have evaluated its weight-loss effectiveness in patients with BMI between 30 and 40 kg/m².

The EndoBarrier® (GI Dynamics, Inc., Lexington, MA, USA) is a 60 cm long impenetrable fluoropolymer sleeve placed in the small intestine intended to promote weight loss by partially blocking absorption of nutrients through intestinal walls. A surgeon deploys the sleeve through the mouth and into the small intestine using a proprietary delivery catheter under fluoroscopic and endoscopic guidance with the patient under general anesthesia. A barbed stent at the top of the sleeve anchors the device within the duodenal bulb, just beyond the stomach. The sleeve extends down the first section of the small intestine (i.e., through the duodenum and proximal jejunum). The sleeve is intended to remain in place for 3 to 12 months. To recover the device, a surgeon advances a retrieval catheter to the small intestine to release the anchoring stent using drawstrings and removes the sleeve through the mouth. In the United States, GI Dynamics is studying EndoBarrier to treat type 2 diabetes mellitus (T2DM) in obese patients. In the European Union, EndoBarrier has marketing approval to treat obesity and T2DM.

How Do They Change Patient Care?

These minimally invasive devices might give bariatric surgeons and endoscopic gastroenterologists new therapeutic options that could represent a new revenue stream for facilities attracting patient populations with less severe obesity who would not typically be indicated for bariatric surgery and who do not want to undergo laparoscopic adjustable gastric banding (e.g., Lap-Band,[®] Apollo Endosurgery, Inc., Austin, TX, USA).

The Evidence Story

Overall, most trials on these devices have been relatively small (about 20 to 40 patients per trial), and patients treated with these minimally invasive technologies experienced between 20% and 25% excess weight loss (i.e., not total weight, but excess weight) over approximately 6 to 12 months. However, in November 2014, preliminary results from the largest U.S. randomized clinical trial (REDUCE study, n = 326) on one of these devices, the ReShape Duo intragastric balloon, reported positive results. These results formed the basis of the regulatory submission to FDA for approval of this device. Key results included that 55% of patients treated with the balloon lost at least 25% of their excess weight. The authors reported significant and sustained improvements in comorbidities through the 24-week treatment phase and 24 weeks after the balloons were removed. These improvements included better numbers for triglycerides, high- and low-density lipoproteins, systolic and diastolic blood pressures, and waist and hip circumferences. A key question is whether weight loss is sustained after balloon removal. The author reported that two-thirds of the mean weight loss achieved while the balloons were present was maintained for 24 weeks after removal.

Patients receiving the Maestro VBLOC system dropped about 25% of their excess body weight after one year. These patients also showed some treatment benefit, expressed as improved blood glucose levels and modest blood pressure reductions. Adverse effects included heartburn and mild to moderate abdominal pain.²⁰⁻²²

Recent studies of the EndoBarrier suggest that patients who completed the trials lost about 20% of excess weight through 12 months.^{23,24} Patients receiving the EndoBarrier also showed improvement in blood sugar levels, lessening the diabetes burden.^{23,24}

Ponce and colleagues (2012) reported that patients treated with the ReShape Duo had a mean 31.8% excess weight loss six months after device implantation; at six months after balloon removal, this patient group maintained 64% of achieved total weight loss.²⁵

Costs, Reimbursement, and Regulatory issues

Costs, coverage, and reimbursement for these technologies have not been established in the United States because no devices have received marketing approval yet from FDA. In June 2014, an FDA advisory panel (Gastroenterology-Urology Devices Panel) voted that the Maestro system was safe (8-1 in favor) and that its benefits outweighed its risks (6-2). However, the panel voted 5-4 against whether available data offered “reasonable assurance” of the Maestro system’s effectiveness in treating obesity. The manufacturer estimates that costs for the Maestro system and implantation procedure will be comparable to bariatric surgery. The Maestro system has had marketing approval in the European Union since 2011, where the device costs an estimated \$20,000. FDA’s final decision is pending.

ReShape Medical submitted a premarket approval application to FDA for the ReShape Duo in July 2014, and a date for the FDA advisory committee has not yet been announced. Estimated costs for the dual balloon, implantation, and subsequent device removal are approximately \$7,400 in the United Kingdom and about \$8,000 in Canada.

GI Dynamics is conducting late-phase clinical trials of the EndoBarrier under an FDA investigational device exemption and expects the trial’s final data collection to be in June 2015, after which it hopes to submit a premarket approval application for regulatory approval, so this device is likely farthest from FDA approval of the three devices. The EndoBarrier has European marketing approval for three separate indications: 3-, 6-, or 12-month treatment of obesity and T2DM. The manufacturer estimates that EndoBarrier treatment will cost about half that of laparoscopic adjustable banding, or about \$7,500.

Related ECRI Institute Publications

- ▶ **Health Technology Forecast Profile.** Vagus Nerve Blocking (Maestro System VBLOC) for Treating Obesity, January 2015.
- ▶ **Health Technology Forecast Profile.** Endoluminal Sleeve (EndoBarrier) for Preoperative Weight Loss or Treating Obesity, April 2013.

7 Caring for Millennials with Cancer: Should You Create Adolescent and Young Adult Cancer Centers to Improve Outcomes?

Each year in the United States, about 70,000 adolescents and young adults (AYAs) receive a diagnosis of cancer. The most common cancers in this population include lymphoma, leukemia, germ cell tumors, melanoma, and tumors of the central nervous system. Although we think of Millennials as starting with better health than previous generations, the cancer survival rates for patients in the 15 to 24 age group have not improved to the same degree as it has for patients both under 15 and over 50 during the past several years.²⁶ Some healthcare systems are looking at whether treatment location is an important factor in their care and are creating dedicated treatment facilities that cater to the AYA population.

The National Cancer Institute (NCI) has stated that cancer is not a single disease with a one-size-fits-all approach and that patients should seek treatment at a cancer center that specializes in their particular type of cancer. AYAs with some form of cancer may fare better if they are treated with protocols tailored to their specific age group, with amenities and support programs tailored to their needs.²⁷

NCI calls the lack of treatment facilities for patients between pediatric and adult oncology a “no-man’s land.” Currently, most AYAs are treated at either a pediatric or an adult cancer center, usually depending on their age. Unfortunately, these patients do not identify with either of these populations.

A study recently performed by the City of Hope (Duarte, CA, USA) that included nearly 1,350 patients, including older AYAs, concluded that when these patients were treated at NCI-designated comprehensive cancer centers, they had better results than patients who sought care at adult community facilities. However, the AYA population is less likely than families with younger children with cancer to seek care at an NCI-designated center. The study found the following factors played into seeking an NCI-designated cancer center:

- ▶ Age, especially those over 22 years
- ▶ Low socioeconomic status
- ▶ Covered by insurance
- ▶ Residence greater than five miles from the nearest center

The researchers believe that one way to improve AYA outcomes is to look at and find ways to overcome the barriers keeping these patients away from proper care.²⁸

Several AYA cancer centers exist in the United States, and more health systems with cancer centers are exploring their feasibility. Most of these centers feature programs that include:

- ▶ Program-specific patient navigators
- ▶ Physicians who have expertise in germ cell tumors, which are one of the most common forms of cancer seen in the AYA population
- ▶ Access to the latest clinical trials
- ▶ Age-specific education using multimedia devices (smartphones, tablets) to which the patient can better relate

One early AYA model has been championed by Roger Daltrey and Pete Townshend of the English rock band The Who in Great Britain, and the model has also moved “across the pond.” Who Cares: Teen Cancer America is a program described as “a charity devoted to improving the lives of teenagers and young adults with cancer.” Teen Cancer America is the American affiliate of Teen Cancer Trust, originally started in the United Kingdom by Daltrey and Townshend. Launched in November 2012, Teen Cancer America has collaborated with seven hospitals throughout the United States.



WHAT TO DO

- ▶ Determine the AYA cancer population in your service area, and perform a needs assessment for the services.
- ▶ Engage your cancer center clinicians to obtain their perspectives.
- ▶ Identify and assess availability of existing AYA cancer services in your area, if any, and the model(s) being used.
- ▶ If you decide to offer an AYA care model, determine whether you need to build new infrastructure or renovate existing infrastructure to suit the specific needs of the program.
- ▶ Research and review existing models to see what might be appropriate to adapt or modify to provide AYA cancer care in your setting.

The program's goals are to:

- ▶ partner with hospitals nationwide to provide guidance in establishing AYA units and services,
- ▶ advocate for young people with cancer to have equal access to optimum treatment,
- ▶ assist hospitals in developing staff,
- ▶ facilitate collaboration between hospitals over similar services,
- ▶ influence health systems and the pharma community to invest in research and clinical trials, and
- ▶ develop educational materials aimed at the young adult population served.²⁹

Most health systems with cancer centers that offer AYA-specific programs have similar features targeting this population. Infrastructure features offered in patient lounge areas and often in patients' rooms include large-screen televisions, video games, computers, electronic musical instruments, and pool and ping pong tables.

Memorial Sloan Kettering Cancer Center (New York, NY, USA) has taken the next step in the continuum of AYA treatment by establishing the Adult Long-Term Follow-Up Program, which is part of the center's Adult Survivorship Program. Kettering's philosophy is that "long-term care can help prevent, detect, and treat any delayed complications—known as late effects—that arise."³⁰ The AYA program at Roswell Park Cancer Institute (RPCI) (Buffalo, NY, USA) has a strong focus on preserving the fertility and sexual health of patients. Jacob Madonia, RN, a cancer survivor now working at RPCI thinks "a very important and yet sometimes overlooked aspect of cancer treatment is the impact on fertility and sexuality. This topic is very important to the AYA population, yet the subject is often ignored due to a lack of knowledge or discomfort. While this issue is not easy to discuss, it is a necessary conversation."³¹ Both programs help the AYA patient achieve the full spectrum of care.

The AYA population is underserved, with dedicated centers only in large metropolitan areas at academic-based medical centers such as Rainbow Babies and Children's Hospital in Cleveland (OH, USA), Oregon Health and Science University (Portland, OR, USA), Northwestern Memorial Hospital (Chicago, IL, USA), Johns Hopkins Hospital (Baltimore, MD, USA), and Tufts Medical Center (Boston, MA, USA), among others. These centers serve the AYA population by identifying the unique needs of patients and their families, guiding them toward support resources that are specifically tailored to their needs, and empowering young adult patients and their families to take an active role in their disease. The need is growing for additional cancer centers dedicated to the special medical and emotional needs of this underserved population—will your hospital tackle this complex program?

Related ECRI Institute Publication

- ▶ **AHRQ Healthcare Horizon Scanning System Potential High-Impact Interventions:** Priority Area 02: Cancer. Specialized Care Model for Adolescents and Young Adults with Cancer. Rockville, MD: Agency for Healthcare Research and Quality, June 2014. <http://effectivehealthcare.ahrq.gov/index.cfm/>

8 Fecal Microbiota Therapy: New Hope for Other Serious GI Disorders?

Clinical use of fecal microbiota transplantation (FMT), a nonpharmacologic procedure for treating recurrent *Clostridium difficile* (*C. diff*) infection by transferring donated fecal matter from a healthy patient to an ill patient, has spread widely and has even been proposed in a recent published cost-effectiveness study from Johns Hopkins as first-line therapy for *C. diff*. FMT is intended to reestablish normal microbial diversity in the colon, and its use has grown markedly in the past few years because of the increased incidence of recurrent *C. diff* infection, the growing body of evidence of its cost-effectiveness, and payment penalties introduced in the United States regarding readmissions for hospital-acquired infections. As of 2015, clinicians have performed several thousand FMTs worldwide, including in the United States, where about half of hospital-based and 15% to 25% of private/group practices now offer the procedure.³² Some clinicians believe it will become even more widely available if the material becomes standardized, licensed, and ready to use (off the shelf).³³ And now FMT is under study for treating Crohn's disease and ulcerative colitis, two extremely debilitating conditions that lack cures and effective treatments for many patients.

FDA Weighs Regulation of FMT

After much debate between specialty societies and FDA over how to regulate FMT, FDA initially encouraged physicians who wanted to perform it to submit an Investigational New Drug (IND) application for FMT products and obtain informed consent that details potential procedure risks. However, in March 2014, FDA's revised guidance indicated that an IND application is not necessary if the FMT product is obtained from a donor known to the patient or the treating licensed healthcare provider and the donor and stool are qualified by screening and testing performed under the direction of the licensed healthcare provider. After review of public comments on this proposed guidance, FDA expects to issue final regulatory guidance in 2015; FMT products in development will likely be subject to stricter regulatory oversight.

Other FMT Uses in Development

Researchers have been exploring other clinical indications, including inflammatory bowel diseases (IBDs) (i.e., ulcerative colitis, Crohn's disease) and systemic conditions (e.g., obesity, metabolic syndrome) believed to have a pathogenesis related to microbial imbalance in the gastrointestinal (GI) tract.³⁴ The greatest FMT research interest is as potential therapy for ulcerative colitis and Crohn's disease because intestinal microbiota composition and diversity are altered in patients with these bowel diseases.^{35,36} Clinicians typically treat ulcerative colitis with anti-inflammatory drugs with varied success, and no long-term cure or treatment strategy besides surgery is available to prevent debilitating periodic flare-ups. In addition to exploring use of FMT for treating IBDs, researchers are also exploring its use for obese patients with metabolic syndrome who are thought to have an imbalance in their lower intestinal tract flora that could contribute to insulin resistance.³⁷

The Procedure: How Is It Done? Can It Be Simplified?

FMT involves using one of several methods to introduce fecal matter from a healthy donor into the GI tract of a patient with *C. diff* infection. To ensure that the donor is healthy, prospective donors undergo prescreening by interview and extensive laboratory testing for contagious transmissible diseases. Although donated stool is relatively simple to



WHAT TO DO

- ▶ Watch for FDA final regulatory guidance in 2015 for FMT products, and meet with your clinical staff to determine what your health system needs to do to comply.
- ▶ Develop specific FMT treatment protocols for each clinical indication for which your health system uses the treatment.
- ▶ Monitor research and development of FMT standardized products (oral capsules, synthetic stool, and pre-made suspensions that can be purchased).
- ▶ Look for publication of clinical studies of FMT for new indications for irritable bowel disease, obesity, and metabolic syndrome.

FMT is now under study for treating Crohn's disease and ulcerative colitis, two extremely debilitating conditions that lack cures and effective treatments for many patients.

prepare, published reports describe different preparation methods. A gastroenterologist can instill prepared donor fecal suspension via a nasogastric tube, nasoduodenal/jejunal tube, upper tract endoscope, colonoscope, retention enema, or a combination of upper and lower approaches. The procedure takes 5 to 25 minutes, depending on the delivery method. Hospitals or clinics wishing to offer the procedure may need to create dedicated laboratory facilities to process the donor stool and facilitate administration. Centers offering FMT also need specific treatment protocols that include patient counseling, donor testing, stool donation, stool processing, and transplanting of processed fecal material.

To further expand access and simplify the procedure, several companies and research groups are developing standardized FMT products, such as oral capsules, synthetic stool that does not look or smell like stool, and pre-made suspensions. In particular, oral capsules are a source of intense interest to patients, physicians, and industry because they eliminate donor identification, donor testing, and sample preparation and avoid some of the uncomfortable social aspects of current FMT technology.

Dedicated to expanding access to FMT therapies, OpenBiome (Cambridge, MA, USA) opened the first public stool bank in October 2013. OpenBiome is providing stool screening services similar to those for blood products and organ transplant. Since opening, it has provided more than 400 prescreened, filtered, frozen fecal transplant samples to 42 hospitals and clinics in the United States.³⁸

The Evidence Story

Evidence for new indications for FMT is limited thus far, but ongoing trials may provide further insight into the procedure's safety and efficacy in the patient population targeted for the new indications.

Borody et al. retrospectively reviewed cases of 62 patients with ulcerative colitis who underwent FMT at a center in Australia over 24 years. The study reported a response rate of 92% and a clinical remission rate of 68%. However, researchers found that the patients required multiple FMT infusions.³⁹ An ongoing study evaluating the durability of clinical response and safety of standardized FMT in China is enrolling 60 patients with moderate to severe ulcerative colitis. This one-year study, for which reported results are expected in June 2015, is comparing standardized FMT performed once with traditional ulcerative colitis treatments established in clinical guidelines.⁴⁰ Another ongoing controlled trial is assessing FMT for treating children with ulcerative colitis; reported results are expected in 2019.⁴¹

Vermeire et al. reported results of a four-patient pilot study of FMT to treat Crohn's disease and found no clinical or endoscopic improvement at eight-week follow-up.⁴² An ongoing trial enrolling 18 patients with Crohn's disease in France is comparing FMT with a sham procedure; reported results are expected early in 2016.⁴³

Vrieze et al. reported results from the Fecal Administration To LOSE weight (FATLOSE) trial that included 20 obese male patients with metabolic syndrome. This single-center, randomized controlled trial compared FMT using donor stool from a lean volunteer with a control group receiving FMT using their own stool. The six-week study, which measured insulin resistance and fecal flora composition, found that FMT from lean donors significantly improved insulin sensitivity in the obese male patients and increased the number of butyrate-producing intestinal bacteria, a type of bacteria that patients with IBD lack.³⁷

Several companies and research groups are developing standardized FMT products, such as oral capsules, synthetic stool, and premade suspensions.

The Cost Equation

Reported costs associated with screening donor blood and stool for contagious agents and preparing the donor fecal sample are about \$1,000.⁴⁴ The cost of FMT depends on the procedure used for introducing the donor stool: about \$1,000 for retention enema, \$1,100 for sigmoidoscopy, \$1,300 for nasogastric tube insertion, and \$1,600 for colonoscopy.⁴⁴ Thus, the estimated per-patient cost for FMT ranges from \$2,000 to \$2,600.

OpenBiome, the public stool bank, operates on a not-for-profit basis, charging hospitals and clinics a processing and shipping fee of \$250 per specimen.⁴⁵ Ultimately, the company aims to have screening and other operational costs of \$3,000 per donor covered by the \$250 fee. Collecting multiple samples from each qualified donor helps to spread screening costs over many treatments.⁴⁵

Although several large third-party payers (e.g., Aetna, Humana, HealthPartners) cover the procedure for treating recurrent *C. diff.* infection, reimbursing its use for other clinical indications is uncertain until more evidence accumulates. In the meantime, be aware that in the same way that FMT initially gained momentum as a last resort for treating *C. diff.* infection several years ago, it may likewise gain momentum for treating severe IBDs that aren't responding to other interventions.

Related ECRI Institute Publication

- ▶ **Emerging Technology Report.** Fecal Microbiota Transplantation for Treating Recurrent *Clostridium difficile* Infection, August 2014.

9

Artificial Pancreas Device Systems: What's Coming after the First-generation System?

Demand is high for a new externally worn insulin pump and glucose monitoring device known as a threshold-suspend system for treatment of type 1 diabetes mellitus (T1DM). The system is intended to automatically stop insulin delivery from the pump for up to two hours when sensor glucose values reach a preset level and when the patient does not respond to an alarm. The system includes the pump, six-day-wear disposable sensors for continuous glucose monitoring, a sensor insertion device, and a blood glucose meter that transmits fingerstick blood glucose results wirelessly to the insulin pump.⁴⁶ However, this is only the first step toward total artificial pancreas device systems (APDSs). FDA has taken several initiatives to speed development of true APDSs, and you can expect to see more devices on the way within one to three years.

Who Is It For? Who Is It Not For?

Many patients do not achieve desired blood sugar control goals and receive intensive diabetes management. But this places patients at increased risk for hypoglycemia (blood glucose <70 mg/dl), which can be life-threatening. Some patients are unable to recognize the symptoms of hypoglycemia and may not awaken from sleep when it occurs. To optimize glucose management for these patients, many experts believe that the best therapeutic option is an APDS that can mimic normal pancreatic beta cell function and restore normal metabolic homeostasis without causing hypoglycemia.⁴⁷ An APDS is intended to provide a complete system, known as a closed-loop system, by combining several technologies: a glucose monitoring device, an external or implantable insulin pump, and a glucose sensor with advanced-algorithm software designed to deliver appropriate doses of insulin from the insulin pump.⁴⁸

FDA is facilitating APDS development efforts. Its efforts include prioritizing the review of research protocol studies, providing clear guidelines to industry, setting performance and safety standards, fostering discussions between government and private researchers, sponsoring public forums, and finding ways to shorten study and review time. Although fully automated APDSs are a few years away from clinical availability, in September 2013, FDA granted marketing approval for a first-generation threshold-suspend insulin delivery system (i.e., MiniMed[®] 530G system with Enlite[®] sensor [Medtronic, Inc., Minneapolis, MN, USA]) for “continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for patients 16 years of age and older requiring insulin and continuous monitoring and trending of glucose levels in the fluid under the skin.”⁴⁹ This system is the first to be approved under FDA's new product classification, “OZO: Artificial Pancreas Device System, Threshold Suspend.” Additional FDA categories of APDSs include control-to-range systems that reduce the likelihood of a hypoglycemic or hyperglycemic event by adjusting insulin dosing only if a person's glucose level approaches the low or high thresholds and control-to-target fully automated systems that set target glucose levels and try to achieve these levels at all times.

What impact will the threshold-suspend insulin delivery system have on existing diabetes management teams? Does it improve patient outcomes? Will payers reimburse for APDSs? Do they bend the cost curve for treating patients with diabetes? What comes next?



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WHAT TO DO

- ▶ Implement APDS technology only if you have a multidisciplinary diabetes team directed by an experienced endocrinologist/diabetologist.
- ▶ Be aware that additional and longer patient visits are likely for those using the technology, which will affect patient scheduling, wait times, and number of patients that can be seen.
- ▶ Select patients who are highly motivated and able to learn how to maintain system components and recognize potential problems.
- ▶ Have a trained diabetes team member available 24 hours a day to provide patient support and guidance.
- ▶ Develop clinical protocols for use of new APDSs as they become commercially available.

Overall cost-effectiveness will depend on whether APDSs improve clinical outcomes compared with current methods of intensive insulin management.

The First Step

The MiniMed 530G with Enlite sensor is intended to automatically stop insulin delivery for up to two hours when sensor glucose values reach a preset level and when the patient does not respond to an alarm. The system consists of an insulin pump, six-day-wear disposable sensors for continuous glucose monitoring, a sensor insertion device, and a blood glucose meter that transmits fingerstick blood glucose results wirelessly to the insulin pump.⁴⁶ Clinicians and patients can also use proprietary software to monitor blood glucose levels and manage diabetes care. According to Medtronic, these features may reduce the severity and duration of hypoglycemia, help determine patterns in glucose values by tracking and trending information, and facilitate long-term adjustments in individual treatment plans.

Medtronic commercialized a similar system in Europe in May 2010.

Prepare for Complex Patient Training and Monitoring

Don't proceed with this technology unless you have the essential multidisciplinary team and understand that patients using this technology may need more and longer appointments than other patients using a diabetes pump. A multidisciplinary team under the direction of an experienced endocrinologist or diabetologist should train patients on use of threshold-suspend insulin delivery systems. Team members are responsible for initial training, retraining when switching to a new pump model, periodic reeducation to address knowledge gaps and troubleshoot any pump or

glycemic control issues, and periodic reevaluation of the appropriateness of therapy. Approximately 2,000 centers with multidisciplinary diabetes teams already in place have adopted the MiniMed 530G system. Only motivated patients should be considered for the MiniMed 530G, and they must be able to troubleshoot common problems and self-monitor how well the device is working.

In cooperation with healthcare providers, Medtronic offers a training program for patients that consists of online modules, printed material, and in-person hands-on education conducted by a certified product trainer. For ongoing technical support, Medtronic also provides a 24-hour helpline and a StartRight program, which comprises proactive coaching, education, and technical support for 3 months.⁵⁰

Nonetheless, facilities with diabetes management programs will need to develop clinical protocols to monitor and provide continuing guidance for patients using threshold-suspend systems. Patient follow-up may require more frequent and longer patient visits, which may affect patient throughput.

The Evidence Story

Published evidence is limited so far. FDA assessed the safety and effectiveness of the MiniMed 530G device using data extrapolated from studies of the Medtronic Veo™ system and Sof-Sensor™ deployed in Europe. In 2012, Garg and colleagues published results of the in-clinic portion of the multicenter Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial that assessed the efficacy of automatic suspension of insulin delivery in reducing exercise-induced hypoglycemia in patients with T1DM.⁵¹ In this randomized crossover study, 50 patients exercised while using MiniMed Veo with the pump's threshold-suspend feature set to suspend insulin delivery for 2 hours when a sensor glucose value of ≤ 70 mg/dL was detected or with the pump set to deliver basal insulin regardless of the sensor glucose value. Mean duration of hypoglycemia was significantly shorter by about 30 minutes during periods when the threshold-suspend feature was activated than during periods when it was turned off. Mean glucose during and after exercise sessions was significantly higher when the threshold-suspend feature was activated than when it was off. It concluded "that automatic suspension of insulin delivery significantly reduced the duration and severity of induced hypoglycemia without causing rebound hyperglycemia."⁵¹

In June 2013, Bergenstal and colleagues published results from the ASPIRE in-home trial, which evaluated the safety and efficacy of the technology when used in a home setting. In this trial, 247 patients with T1DM and documented nocturnal hypoglycemia were randomly assigned to receive sensor-augmented pump therapy using the MiniMed Veo with the threshold-suspend feature activated or standard sensor-augmented pump therapy.⁵² Compared to the control group, the group using the activated threshold-suspend feature had a significantly lower mean AUC (area under the curve) (a composite measure for duration and severity of nocturnal hypoglycemia), significantly fewer nocturnal hypoglycemic events, and significantly fewer episodes of severe hypoglycemia.

In addition to the studies of threshold-suspend systems, many APDS proof-of-concept trials are ongoing in the United States and internationally. Much of the research is supported by JDRF (formerly the Juvenile Diabetes Research Foundation), the leading global organization focused on T1DM research.

The Cost Equation

APDSs will likely cost more than previously marketed insulin-delivery systems, as evidenced by the higher costs associated with the MiniMed 530G system; however, marketing of competing systems and improved sensor technology may ultimately decrease overall device costs. The retail cost of the MiniMed 530G system is \$7,350, and the retail costs of disposable supplies (i.e., sensors, infusion sets, syringes) can be as high as \$4,500/year. About 95% of patients using insulin pumps have private insurance with copays of up to 50%, so patients and insurers bear a portion of the costs. Medtronic is offering substantial financial incentives to current pump users who want the integrated system. Most payers cover insulin pump therapy for patients who have poorly controlled T1DM, and some payers (e.g., CIGNA, Blue Cross/Blue Shield [BC/BS] Alabama) have issued policies describing coverage for the MiniMed 530G. However, other payers (i.e., BC/BS Massachusetts, Humana, Medica, Regence) list threshold-suspend technology as “investigational” and ineligible for reimbursement.

Overall cost-effectiveness will depend on whether APDSs improve clinical outcomes (i.e., quality of life and reduced hospital stays, emergency department visits, and incidence of acute and secondary diabetes complications) compared with current methods of intensive insulin management.

Race to Market a Fully Automated APDS

JDRF has committed significant resources to developing a fully automated APDS, and three companies are competing to bring next-generation APDSs to market. By April 2015, Medtronic expects to launch a predictive threshold-suspend system in Europe that suspends insulin delivery about a half hour before a hypoglycemic event.⁵³ Medtronic is also conducting phase II trials of a fully automated control-to-target APDS that consists of a MiniMed insulin pump, a continuous glucose monitor, and an Android phone, which houses the algorithm.⁵⁴ This system automatically adjusts insulin delivery to achieve a predetermined glucose value. Animas Corp. (West Chester, PA, USA), a division of Johnson & Johnson, in collaboration with Dexcom, Inc., (San Diego, CA, USA) and JDRF, is conducting feasibility studies for its control-to-range APDS, which includes an insulin pump, a continuous glucose monitor, and a control algorithm used to predict changes in blood glucose.⁵⁵ Lastly, Tandem Diabetes Care, Inc. (San Diego, CA, USA) partnered with JDRF to develop a dual-chamber, fully automated, control-to-target APDS that simultaneously delivers insulin with other drug therapies used for diabetes management (e.g., glucagon, meal-time Symlin®).⁵⁶

Related ECRI Institute Publication

- ▶ **Health Technology Forecast Profile.** MiniMed 530G with Enlite Sensor Low-glucose Suspend Insulin Delivery System (Medtronic, Inc.) for Treating Diabetes, March 2014.

10 Telehealth: Have We Passed the Tipping Point in Clinical Use?

Is telehealth—or telemedicine—finally about to break free of the return-on-investment concerns that hobbled its use? After all, many hospitals have been participating in a telestroke program either as a hub or a spoke member of a network for some time. Grant-funded services to improve rural healthcare have been operating for years, and remote services provided to the incarcerated are another well-developed program. At the same time, information software and hardware development have spawned remarkable advances in monitoring technologies that include use of wearable sensors, making both telehealth and wearable sensors markets with potential for huge growth. Most telehealth services, however, have been developed in isolation from each other, often at the request of an individual clinician and with little strategic analysis. Is telehealth now an imperative service rather than a niche application?

Wearable Sensors Fuel Telehealth Growth

Wearable sensors previously referred to large, bulky devices that recorded vital signs as a patient lay in a hospital bed. Now, wearable sensor technologies for healthcare use are significantly smaller and allow both healthy individuals and sick patients to monitor vital signs from home and other locations. These sensors come in different forms, from wristlet devices to skin patches to head domes designed to track vital signs from the head. The market for healthcare sensors is expected to grow tenfold, from \$3 billion to at least \$30 billion, in the next five years.⁵⁷ This anticipated growth can be attributed to a focus by companies on remote monitoring of specific diseases (e.g., diabetes, heart failure) to enable just-in-time healthcare management—if the data are actively monitored clinically so that timely action can be taken.

Companies not typically associated with healthcare are developing wearable sensor technologies, such as electronics and appliance maker Samsung and video game platform maker Nintendo Co., Ltd. (Kyoto, Japan).⁵⁸ New healthcare sensor technologies include glucose monitors and monitors for daily activity, medication adherence, and blood pressure, all of which feed information to both the patient and clinical team. Technology companies are also partnering with providers to help understand health data, patient practices, and the role of social media in health.⁵⁷ The idea is that a collaboration between technology companies and healthcare providers will change the wearables description from fitness and wellness devices to healthcare and chronic condition management devices.⁵⁷ For instance, along with the September 2014 release of Apple Watch, Apple is working with Mayo Clinic, Mount Sinai Hospital, Cleveland Clinic, and Johns Hopkins Medical Center to develop HealthKit. HealthKit will be a cloud repository that uses a single tool to enable all health and fitness apps to work together and all health data to be shared seamlessly among the various apps.

Getting a Grip on Telehealth Guiding Principles

While hardware, software, and individual niche uses are down in the weeds of telehealth, one question remains: who is looking at the overall aims of telehealth in clinical care? With all the activities driving the explosive use of telemedicine, the American Medical Association (AMA) decided at its June 2014 annual meeting to approve a list of guiding principles. These principles are intended to help foster innovation in telemedicine use, protect the patient-physician relationship, and promote improved care coordination and communication with medical homes. The American Telemedicine

New care locations enabled by advancing technologies like telehealth require new processes, practices, and products.



WHAT TO DO

- ▶ Interview stakeholders beyond your hospital's credentialed medical staff to assess what clinical services the community needs. Also, include your physicians, but go further than that.
- ▶ Develop a plan to address setup and maintenance of telehealth technologies in care settings other than the acute care hospital. Many patient users will need retraining after initial setup, and whether this is live in-home or via telepresence is an important program service question.
- ▶ Look at the telehealth marketplace to see what various platforms offer, and determine whether they will fit into your organization's sourcing requirements, patient-related information transit and storage requirements, IT security needs, and training programs.
- ▶ Identify staff to champion the program. Medical, nursing, risk management, and IT all need to be involved. Value analysis committees may require some reconfiguring to engage on the technologies used to deliver telehealth services.
- ▶ Plan how and which clinical staff will monitor the data received, and develop protocols for action steps expected for various scenarios. Make plans to discuss the implementation and monitoring of the software and data warehouses.
- ▶ Assess what metrics your organization will use to judge success. Number of patient encounters, demonstrated patient outcome improvements, reduced readmissions through better remote monitoring postdischarge, and more are essential to "prove" that telehealth is a success for your organization.
- ▶ Plan patient education strategies that also include at-home caregivers and families; develop responses to resistance that may occur because of "Big Brother is watching" perceptions.
- ▶ Implement a technology management program to calibrate, retrieve, and repair technologies, such as wearable sensors, deployed in home and community settings. This may require adding a new position within the technology management group to support these new technologies.

Association, in partnership with another 12 organizations, is spearheading the development of telehealth coverage. It specifically calls authorization of the following:

- ▶ The use of telehealth for all Accountable Care Organizations (ACOs) and bundled payment programs
- ▶ Telehealth payments for population health management to include all critical access hospitals and all federally qualified health centers (FQHCs)
- ▶ Remote patient monitoring for chronic obstructive pulmonary disease and congestive heart failure, and at FQHCs, remote monitoring for patients with diabetes
- ▶ The facilitation of care by allowing video visits and remote monitoring for Medicare patients such as those undergoing home-based kidney dialysis

Additionally, the Alliance for Connected Care is pushing lawmakers to allow telehealth services to be substituted for in-person care and that current Medicare restrictions on telehealth services be waived for ACOs.⁵⁹ (The Alliance is composed of leading companies across the healthcare and technology spectrum, representing insurers, retail pharmacies, technology and telecommunications companies, and healthcare entrepreneurs.)

The future of telehealth programs looks rosy and may mimic successfully operated telestroke programs that have been in use for some time. Telestroke is the delivery of neurologic care via remote video conferencing from a neurologist at the base—or hub—site to patients in outlying hospitals—the spokes—who may be having a stroke. Telestroke is often viewed as the poster child for telehealth success by providers, payers, and patients.⁵⁸ Telestroke solved a particular need—coverage by an expert neurologist to hospitals that could not provide coverage 24/7. Regional programs using hospitals or a neurology physician group as the hubs have strived to improve stroke care.

Now, in addition to calls for payment reform from industry groups, more momentum has been shown by the Veterans Administration Health System (VAHS). It reports that in fiscal year 2014, it delivered more than 2 million telehealth visits to more than 690,000 veterans.⁶⁰ Also, the annual cost of treating veterans via telehealth fell 4% between 2009 and 2012. VAHS has achieved scalability, and it is looking for more use of telehealth as it expands from fixed-based telehealth access sites to mobile programs using cell phones.

Google also announced it is conducting a trial of live-video medical advice.⁶¹ Google has partnered with several telehealth companies to provide the service to those online searching for medical information and to ensure that the participating clinicians are appropriately credentialed and licensed. While it does not offer live advice on every medical search, this basic telehealth application might break down barriers even further among the patient population.

So while telehealth barriers remain (e.g., reimbursement, licensure), the concept is beyond proof, though hard evidence that it provides benefits for all clinical applications is not yet conclusive. Hospitals and clinicians are trying to figure out how best to proceed. In 2013, FDA and the Association for the Advancement of Medical Instrumentation held a joint Summit on Healthcare Technology in Nonclinical Settings. One of the summit's chief messages was that new care locations enabled by advancing technologies like telehealth require new processes, practices, and products, not just processes tweaked from traditional hospital care delivery processes.⁶² Any hospital with pilot telehealth programs has probably encountered this phenomenon—that tweaked traditional processes are not the solution that works best. To develop best practices for telehealth services, services need to be developed programatically so that best practices can be shared easily among services.

One of these best practices relates to the technical platform used for implementation. Healthcare systems are realizing that one of the criteria for success lies in the software that supports the clinical workflow. As hospital administrators know from experience, one software platform will likely never be perfect for all clinical specialties and their appropriate workflows and documentation needs. Flexibility is needed and wanted. While the convenience of a single vendor/platform may look attractive from a telemedicine hub site's perspective, it is not necessarily the best plan for telemedicine program development. Having a contractual agreement with just one telehealth platform supplier may not make sense to support all possible clinical applications of telemedicine.

As healthcare changes to a patient-centered model, which in turn drives many program development questions, healthcare leaders need to be ready to implement telehealth to improve patient care, optimize staffing, and maximize what reimbursements are available for care provision.

Related ECRI Institute Publications

- ▶ **Health Technology Trends.** Improved Outcomes Demonstrated with Telemedicine for Chronic Diseases, October 2014.
- ▶ **Health Technology Trends.** Core Operational Guidelines Issued from American Telemedicine Association, September 2014.
- ▶ **Health Technology Trends.** Telemedicine Guidelines from State Medical Boards Aim to Remove Barriers, Protect Patients, September 2014.
- ▶ **Health Technology Trends.** Telemedicine Practice Sees Proposed Reimbursement Initiatives, Bandwidth Funding, September 2014.
- ▶ **Health Technology Trends.** Telemedicine Sees Renewed Interest with Updated AMA Guidelines, September 2014.
- ▶ **Health Technology Trends.** VA Investigators Report Telemedicine for Chronic Disease Lowers Treatment Costs, Mortality, September 2014.

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