AHRQ Healthcare Horizon Scanning System – Potential High-Impact Interventions Report

Cross-Cutting Interventions and Programs

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www.ahrq.gov

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Prepared by:
ECRI Institute
5200 Butler Pike
Plymouth Meeting, PA 19462

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Statement of Funding and Purpose

This report incorporates data collected during implementation of the Agency for Healthcare Research and Quality (AHRQ) Healthcare Horizon Scanning System by ECRI Institute under contract to AHRQ, Rockville, MD (Contract No. HHSA290201000006C). The findings and conclusions in this document are those of the authors, who are responsible for its content, and do not necessarily represent the views of AHRQ. No statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

This report's content should not be construed as either endorsements or rejections of specific interventions. As topics are entered into the System, individual topic profiles are developed for technologies and programs that appear to be close to diffusion into practice in the United States. Those reports are sent to various experts with clinical, health systems, health administration, and/or research backgrounds for comment and opinions about potential for impact. The comments and opinions received are then considered and synthesized by ECRI Institute to identify interventions that experts deemed, through the comment process, to have potential for high impact. Please see the methods section for more details about this process. This report is produced twice annually and topics included may change depending on expert comments received on interventions issued for comment during the preceding 6 months.

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

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Financial Disclosure Statement

None of the individuals compiling this information has any affiliations or financial involvement that conflicts with the material presented in this report.

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Preface

The purpose of the AHRQ Healthcare Horizon Scanning System is to conduct horizon scanning of emerging health care technologies and innovations to better inform patient-centered outcomes research investments at AHRQ through the Effective Health Care Program. The Healthcare Horizon Scanning System provides AHRQ a systematic process to identify and monitor emerging technologies and innovations in health care and to create an inventory of interventions that have the highest potential for impact on clinical care, the health care system, patient outcomes, and costs. It will also be a tool for the public to identify and find information on new health care technologies and interventions. Any investigator or funder of research will be able to use the AHRQ Healthcare Horizon Scanning System to select potential topics for research.

The health care technologies and innovations of interest for horizon scanning are those that have yet to diffuse into or become part of established health care practice. These health care interventions are still in the early stages of development or adoption, except in the case of new applications of already-diffused technologies. Consistent with the definitions of health care interventions provided by the Institute of Medicine and the Federal Coordinating Council for Comparative Effectiveness Research, AHRQ is interested in innovations in drugs and biologics, medical devices, screening and diagnostic tests, procedures, services and programs, and care delivery.

Horizon scanning involves two processes. The first is identifying and monitoring new and evolving health care interventions that are purported to or may hold potential to diagnose, treat, or otherwise manage a particular condition or to improve care delivery for a variety of conditions. The second is analyzing the relevant health care context in which these new and evolving interventions exist to understand their potential impact on clinical care, the health care system, patient outcomes, and costs. It is NOT the goal of the AHRQ Healthcare Horizon Scanning System to make predictions on the future use and costs of any health care technology. Rather, the reports will help to inform and guide the planning and prioritization of research resources.

We welcome comments on this Potential High-Impact Interventions report. Send comments by mail to the Task Order Officer named in this report to: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to: effectivehealthcare@ahrq.hhs.gov.

Richard Kronick, Ph.D.
Director
Agency for Healthcare Research and Quality

Yen-pin Chiang, Ph.D.
Acting Director
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Elise Berliner, Ph.D.
Task Order Officer
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

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Background

Horizon scanning is an activity undertaken to identify technological and system innovations that could have important impacts or bring about paradigm shifts. In the health care sector, horizon scanning pertains to identification of new (and new uses of existing) pharmaceuticals, medical devices, diagnostic tests and procedures, therapeutic interventions, rehabilitative interventions, behavioral health interventions, and public health and health promotion activities. In early 2010, the Agency for Healthcare Research and Quality (AHRQ) identified the need to establish a national Healthcare Horizon Scanning System to generate information to inform comparative-effectiveness research investments by AHRQ and other interested entities. AHRQ makes those investments in 14 priority areas. For purposes of horizon scanning, AHRQ's interests are broad and encompass drugs, devices, procedures, treatments, screening and diagnostics, therapeutics, surgery, programs, and care delivery innovations that address unmet needs. Thus, we refer to topics identified and tracked in the AHRQ Healthcare Horizon Scanning System generically as "interventions." The AHRQ Healthcare Horizon Scanning System implementation of a systematic horizon scanning protocol (developed between September 1 and November 30, 2010) began on December 1, 2010. The system is intended to identify interventions that purport to address an unmet need and are up to 3 years out on the horizon and then to follow them up to 2 years after initial entry into the health care system. Since that implementation, review of more than 18,000 leads about potential topics has resulted in identification and tracking of about 2,000 topics across the 14 AHRQ priority areas and 1 cross-cutting area; about 550 topics are being actively tracked in the system.

Methods

As part of the Healthcare Horizon Scanning System activity, a report on interventions deemed as having potential for high impact on some aspect of health care or the health care system (e.g., patient outcomes, utilization, infrastructure, costs) is aggregated semi-annually. Topics eligible for inclusion are those interventions expected to be within 0–3 years of potential diffusion (e.g., in phase III trials or for which some preliminary efficacy data in the target population are available) in the United States or that have just begun diffusing and that have completed an expert feedback loop.

The determination of impact is made using a systematic process that involves compiling information on topics and issuing topic drafts to a small group of various experts (selected topic by topic) to gather their opinions and impressions about potential impact. Those impressions are used to determine potential impact. Information is compiled for expert comment on topics at a granular level (i.e., similar drugs in the same class are read separately), and then topics in the same class of a device, drug, or biologic are aggregated for discussion and impact assessment at a class level for this report. The process uses a topic-specific structured form with text boxes for comments and a scoring system (1 minimal to 4 high) for potential impact in seven parameters. Participants are required to respond to all parameters.

The scores and opinions are then synthesized to discern those topics deemed by experts to have potential for high impact in one or more of the parameters. Experts are drawn from an expanding database ECRI Institute maintains of approximately 150 experts nationwide who were invited and agreed to participate. The experts comprise a range of generalists and specialists in the health care sector whose experience reflects clinical practice, clinical research, health care delivery, health business, health technology assessment, or health facility administration perspectives. Each expert uses the structured form to also disclose any potential intellectual or financial conflicts of interest

(COIs). Perspectives of an expert with a COI are balanced by perspectives of experts without COIs. No more than two experts with a possible COI are considered out of a total of the five to eight experts who are sought to provide comment for each topic. Experts are identified in the system by the perspective they bring (e.g., clinical, research, health systems, health business, health administration, health policy).

The topics included in this report had scores *and/or* supporting rationales at or above the overall average for all topics in this priority area that received comments by experts. Of key importance is that topic scores alone are not the sole criterion for inclusion—experts' rationales are the main drivers for the designation of potentially high impact. We then associated topics that emerged as having potentially high impact with a further subcategorization of "lower," "moderate," or "higher" within the high-impact-potential range. As the Healthcare Horizon Scanning System grows in number of topics on which expert opinions are received and as the development status of the interventions changes, the list of topics designated as having potentially high impact is expected to change over time. This report is generated twice a year.

For additional details on methods, please refer to the full AHRQ Healthcare Horizon Scanning System Protocol and Operations Manual published on AHRQ's Effective Health Care Web site.

Results

The table below lists five topics for which (1) preliminary or published phase III data were available; (2) information was compiled and sent for expert comment before May 15, 2014, in this priority area; and (3) we received five to eight sets of comments from experts between July 1, 2013, and May 23, 2014. (Seven topics in this priority area were being tracked in the system as of May 15, 2014.)

We present summaries on four topics (designated by an asterisk in the table below), which were deemed to have high-impact potential at this time on the basis of expert comments. The material on interventions in this Executive Summary and report is organized alphabetically. Readers are encouraged to read the detailed information on each intervention that follows the Executive Summary.

Priority Area 15: Cross-Cutting Interventions and Programs

Topic	High-Impact Potential
1. * Computer-assisted system (Sedasys) for propofol sedation during gastrointestinal endoscopy procedures	Lower end of the high-impact-potential range**
2. * Digital medicines (Proteus Digital Health Feedback System) for chronic conditions requiring long-term drug therapy	Lower end of the high-impact-potential range
3. * Hospital postdischarge clinics to provide transition care	Lower end of the high-impact-potential range
4. Internet-based clinic electronic visits for diagnosis and treatment of simple conditions	This prior high-impact topic (December 2013) was archived in the system April 2014 because it has now widely diffused
5. * Senior-specific emergency departments for treatment of elderly patients	High

**This topic was previously included in the Cancer priority area because the topic's initial focus was its use for screening colonoscopy. We have now categorized the topic in the Cross-Cutting area because it may also be used during gastrointestinal endoscopy procedures for benign conditions, such as peptic ulcer disease.

Discussion

We created this priority area to capture cross-cutting interventions that affect two or more of AHRQ's 14 priority areas. Some of these interventions are health care technologies and others are programs, services, or care-delivery innovations. The topics that emerged as having a potential high

impact are care-delivery innovations that might shift providers' roles or settings. They also use technology to integrate care across settings or to automate processes.

Prior High Impact Topic Archived Since December 2013 Report

- **Internet-Based Clinic Electronic Visits for Diagnosis and Treatment of Simple Conditions:** In the December 2013 report, this topic was deemed by expert comments to have potential for high impact (on the lower end of the high-impact-potential scale). They saw it as having potential to improve access to primary care and reduce care costs. Since that time, we identified many additional online clinics in operation nationwide, including Virtuwell®, The Doc Now, Zipnosis, and NowClinic®. We consider this mode of care delivery as having passed a tipping point to wide diffusion (and perhaps fulfilling projected impact). Thus, we have archived it from the system because the intervention has become widely available to residents in most states (assuming patients have Internet access). We archived the topic in the horizon scanning system as of April 30, 2014.

Computer-Assisted System (Sedasys) for Propofol Sedation During Gastrointestinal Endoscopy Procedures

- **Key Facts:** Sedasys® (Ethicon Endo-Surgery [EES], Inc., a unit of Johnson & Johnson, New Brunswick, NJ) is a computer-assisted personalized sedation (CAPS) system intended to aid clinicians in delivering propofol for minimal to moderate sedation during routine colonoscopy and esophagogastroduodenoscopy (EGD) procedures. Of the millions of routine endoscopies performed each year in the United States, the majority have been performed using a combination of a benzodiazepine and an opiate to achieve conscious sedation. However, an increasing number of endoscopies are being performed using propofol-mediated sedation, which purportedly has the benefits of improved patient experience and faster patient recovery times. Although propofol may be preferred for these reasons, its use is complicated by safety concerns. These concerns have required that the drug be administered by an anesthesia professional who is not involved in performing the endoscopy procedure. This requirement substantially increases the cost and staffing mix required for these procedures, potentially limiting propofol use. The Sedasys system is intended to allow physician-led teams to administer propofol during routine endoscopy procedures (although an anesthesia professional needs to be available in case of emergency). The Sedasys system was studied in a randomized controlled trial that compared propofol-mediated sedation delivered using Sedasys to benzodiazepine/opiate-mediated sedation. In this trial, Pambianco et al. reported that patients undergoing Sedasys-mediated propofol sedation experienced less hypoxia than patients undergoing benzodiazepine/opioid sedation, suggesting a reduced risk of hypoxia-induced sequelae. The Sedasys system was approved more than 1 year ago—in May 2013—by the U.S. Food and Drug Administration (FDA) through the premarket approval process. The technology has yet to be introduced in clinical care, according to the manufacturer, which indicated the company plans to introduce it slowly and in limited geographic areas. This is likely because of the controversy among clinical specialties (gastroenterology versus anesthesiology) about its safety and use. The product labeling states that the system is intended "for the intravenous administration of 1% (10 mg/mL) propofol injectable emulsion for the initiation and maintenance of minimal to moderate sedation, as defined by the American Society of Anesthesiologists (ASA) Continuum of Depth of Sedation, in ASA physical status I and II patients ≥18 years old

undergoing colonoscopy and esophagogastroduodenoscopy (EGD) procedures." The system's manufacturer is initiating a limited rollout of the system in late 2014. The cost impact of the technology is not yet known, although its potential impacts have been discussed in trade publications. EES issued a self-funded cost study stating that the anticipated per-procedure costs of using the Sedasys CAPS system were expected to be less than 30% of the cost of an anesthesia professional administering propofol.

- **Key Expert Comments:** Overall, experts commenting on this topic expressed views that the Sedasys system has significant potential to disrupt the current methods of delivering propofol-mediated sedation, which could also have a big impact on the way endoscopy centers operate. However, they were unsure whether the potential benefits of wider access to propofol-mediated sedation were significant enough to offset safety concerns about potential oversedation of patients in a setting without an anesthesiologist present and thought adoption might be hindered by these concerns and pushback from anesthesiologists. If adopted, expert commenters thought, the system could significantly change costs associated with propofol-mediated sedation by obviating the need for anesthesiologists to be present in the room for every propofol procedure.
- **Potential for High Impact:** Lower end of the high-impact-potential range

Digital Medicines (Proteus Digital Health Feedback System) for Chronic Conditions Requiring Long-Term Drug Therapy

- **Key Facts:** The Proteus Digital Health™ Feedback System (Proteus Digital Health, Inc., Redwood City, CA), a form of "smart-pill" technology or "digital medicine," has been developed for use with oral pill or capsule medications prescribed for chronic diseases. The intention is to track medication adherence in patients with chronic conditions such as tuberculosis, diabetes, heart failure, HIV, hepatitis C virus infection, and mental health disorders. The technology consists of an ingestible sensor (made of silicon, copper, magnesium, and cellulose, which are commonly used food ingredients) taken with a medication, a personal monitor, and a Bluetooth-enabled data device such as a smartphone. The patient ingests the medication along with the sensor, and digestive fluids activate the sensor in the stomach. The activated sensor transmits its unique signature to the personal monitor, which records and timestamps the event and physiologic data. The personal monitor is a miniature, battery-operated, data-logging device in the form of a patch worn on the torso. It records heart rate, activity, sensor ingestion, and patient-logged events such as symptoms. The monitor transmits the data to the patient's Bluetooth-enabled smartphone or other computerized device. Encrypted data are forwarded to a secure database that clinicians can access to review the patient's status. In a trial published in 2011 by Au-Yeung et al., 111 patients ingested 7,144 monitored pills, and investigators reported that the system's positive and negative ingestible-marker detection accuracy was >97%, and medication adherence was >85%. The most common adverse effect was mild skin rash from the monitor patch's electrodes; no serious adverse events were reported. The company received FDA marketing clearance for the monitoring device in March 2010 and for the ingestible sensor in July 2012. The company is working with selected pharmaceutical manufacturers to choose medications for sensor integration and has also partnered with Oracle Health Sciences, a division of Oracle Corp., which conducts trials on behalf of many pharmaceutical companies, to embed the technology in medications for more complete results in clinical trials. Lack of patient adherence to the medication regimens tested in clinical trials has been implicated as a significant reason that many phase II and III trials do not meet their

endpoints. Costs of using the technology have not been published and would involve more than the device itself because equipment and staffing for collecting, monitoring, and reviewing the additional patient data would have costs. Thus, whether this would add to overall costs or offset costs of nonadherence to medication regimens is not known at this time.

- **Key Expert Comments:** This technology could significantly impact many health system parameters if adopted, experts commented. Variables affecting adherence (e.g., medication affordability, access, side effects) caused some skepticism among experts about this technology's potential to improve medication adherence and health outcomes. Patient acceptance of the technology might be low, although one expert thought that elderly patients living alone might be more likely to adopt this technology. Experts thought clinicians would more readily accept the technology because it could offer more insight into patient behavior and issues of which clinicians might not otherwise be aware. Some clinician resistance might arise due to the increased time required for patient monitoring, followup, and education without additional reimbursement, experts noted.
- **Potential for High Impact:** Lower end of the high-impact-potential range

Hospital Postdischarge Clinics to Provide Transition Care

- **Key Facts:** Postdischarge clinics are intended to increase access to care after hospitalization through a primary care-based, hospitalist-staffed approach to transitional care. Staff from the emergency department (ED) or inpatient hospital setting refer patients to a postdischarge clinic for an appointment within 2 days of discharge. At a postdischarge visit, typical activities are as follows: the discharge worker reconciles medications, reviews medication use with the patient, arranges for prescriptions to be filled, assesses patients for any new symptoms, discusses pending test results, and schedules any necessary referral appointments. Staff also address case management, insurance status, and durable medical equipment needs during these visits. Staff may spend extensive time teaching the patient about self-diagnosis and personal health. The visit concludes with patients referred to or reconnected with their primary care providers. Three studies from discharge clinics at major urban health facility settings (Denver, CO; San Francisco, CA; and Boston, MA) have reported on various aspects of their programs during the past 2 years, including show rates at followup visits, comparative outcomes among different followup settings (discharge clinic, primary care, urgent care), and time between discharge and access to followup care. Costs to establish and maintain a postdischarge clinic vary depending on the institution or health system's business model and existing resources. Developers of established postdischarge clinics have indicated that space and a dedicated support staff are needed for the operation. Newbold et al. (2012) stated that postdischarge clinics can generate revenue for parent facilities through additional billing for patient visits.
- **Key Expert Comments:** A need for providing prompt care after hospital discharge exists, but experts varied on this intervention's potential to fulfill that need. Experts were particularly enthusiastic about the potential of this intervention to increase access to followup care for populations affected by health disparities and thought these populations could benefit the most from these visits. Experts also noted the potential for cost savings from a possible reduction in hospital readmissions. However, some experts were skeptical of its impact because high-quality data on health outcomes and readmissions were lacking.
- **Potential for High Impact:** Lower end of the high-impact-potential range

Senior-Specific Emergency Departments for Treatment of Elderly Patients

- **Key Facts:** Between 2008 and 2011, several health systems began to offer or planned to build EDs designed to cater to the special needs of the senior population (people aged 65 or older). Since 2011, the number of reports of openings of these demographically targeted EDs exceeds 50, with an estimated 150 in development. The intent is to improve seniors' safety, clinical outcomes, and quality of care and to reduce admissions and lengths of stay, especially in intensive care units. Senior-specific EDs approach design, equipment, and processes of care with a focus that is different from that used for standard EDs. Senior-specific EDs use furnishings and equipment designed to provide comfort, reduce injury risk, and enhance cognitive orientation (e.g., reclining chairs, padded/lined stretchers, large-faced clocks, calendars, and large-print signage.) Fall-prevention design provides nonskid floor surfaces, extra handrails, more aisle lighting, bedside commodes, and other visual and lighting aids. Protocol interventions include screening for cognitive impairment, delirium, risk of adverse health outcomes, return visits, or hospitalization; practicing minimal use of urethral catheters and "tethering" devices; and creating a position for a nursing discharge coordinator to improve continuity of care, decrease risk of return visits, and increase patient satisfaction. Several institutions that have implemented senior-specific EDs have informally reported positive impacts in outcomes such as medication improvement, significant decreases in return visits to the ED for the same illness, an decreases in ED falls by seniors, (Holy Cross Hospital, Silver Spring, MD; St. Joseph's Regional Medical Center, Paterson, NJ; Mount Sinai Hospital, New York, NY). Additionally, after we received expert comments on this topic, two occurrences of note are that researchers from three separate hospitals published study results from their senior EDs, and a task force of several medical societies developed and published guidelines for establishing senior-specific EDs. Costs for outfitting a senior ED vary widely according to the approach taken and size (new wing/structure or retrofitting existing space). For example, a facility created by Newark (NJ) Beth Israel and composed of eight beds, reported a cost of $3.2 million for building and outfitting its senior ED. However, Holy Cross Hospital stated that it spent $150,000 to create its senior-specific ED by adapting existing space.
- **Key Expert Comments:** Senior-specific EDs seek to address a very important unmet need, experts commented. Experts were highly optimistic about the potential of these EDs to improve quality of life and health outcomes in elderly patients presenting at EDs, based on preliminary reports on outcomes. A positive disruption in care could result from senior-specific EDs by reducing lengths of stay, achieving more appropriate hospital admissions, and improving diagnoses, experts suggested. Experts anticipated widespread adoption and acceptance of senior-specific EDs by hospital administrators, providers, and patients alike, although outfitting such EDs will require up-front investments in infrastructure and staff training and recruitment of clinicians with geriatric expertise.
- **Potential for High Impact:** High

Cross-Cutting Interventions and Programs

Computer-Assisted Personalized Sedation System (Sedasys) for Propofol Sedation during Gastrointestinal Endoscopy Procedures

Unmet need: Approximately 55 million endoscopy procedures (i.e., colonoscopy and esophagogastroduodenoscopy procedures) are performed each year in the United States.[1] Endoscopists (e.g., gastroenterologists) and endoscopy nurses perform most endoscopic sedation procedures and use either benzodiazepine alone (e.g., midazolam, diazepam) or benzodiazepine in combination with an opiate (e.g., meperidine, fentanyl) to induce moderate sedation.[2] However, approximately 25% of endoscopies performed in the United States use propofol, and this percentage is projected to increase substantially in the coming years.[3,4] Compared with benzodiazepine/opiate sedation, propofol has the advantage of having a more rapid onset and a more rapid termination of the sedative effect, leading to faster patient recovery from sedation.[5] However, propofol also has higher potency than benzodiazepines/opiates and, therefore, carries an increased potential for the unintended induction of general anesthesia and/or hemodynamic and respiratory depression.[2] Due to these safety concerns, the U.S. Food and Drug Administration (FDA)-approved labeling for propofol states that the drug "should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure."[6] This effectively prohibited physician-led endoscopy teams from administering propofol and required the presence of an anesthesia professional.[7] The Sedasys® computer-assisted personalized sedation (CAPS) system would allow the administration of propofol by such teams during routine endoscopy cases, which could represent a significant shift in the personnel by whom and settings in which propofol-mediated sedation is performed.

Intervention: Sedasys is a CAPS sedation system intended to aid clinicians in delivering propofol for sedation during routine endoscopy procedures. The system integrates patient monitoring and drug delivery with the intention of maintaining appropriate levels of sedation. To perform the desired minimal to moderate level of sedation using the Sedasys system, a clinician selects a propofol dose rate intended to that level. Based on the dose rate and patient weight, the Sedasys system calculates a loading dose, which is delivered over the course of 3 minutes. After administrating the loading dose, the system continues to administer propofol at the physician-prescribed dose rate.[7]

The system performs routine monitoring of multiple patient vital signs: (1) oxygen saturation by pulse oximetry; (2) cardiodynamics by noninvasive blood pressure monitoring and electrocardiogram; and (3) respiratory activity by capnometry. Additionally, the system monitors patient responsiveness using an automated responsiveness monitor, which consists of a handset that the patient is prompted to squeeze by audio or tactile stimuli.[7] The Sedasys system is designed to interrupt propofol infusion if the patient's oxygen saturation level or respiration rate falls below certain levels.[8] Upon return of the patient's oxygen saturation level and respiration rate to normal, the Sedasys system is designed to resume propofol administration at a lowered dose or, in the case of more severe deficits in ventilatory function, prompt the clinician to make a decision on whether to resume propofol administration.[5,8] Besides monitoring the automated administration of propofol, the clinician may transiently increase the patient's sedation in response to patient discomfort. After infusion of such a transient increase, the system is designed to prevent administration of a second such bolus for 90 seconds.[8]

Clinical trials: The Sedasys system was studied in an open-label, randomized controlled trial.[9] In this trial, 1,000 adults undergoing sedation during a routine colonoscopy or

esophagogastroduodenoscopy (EGD) were randomly assigned to propofol-mediated sedation delivered by the Sedasys system or to benzodiazepine/opioid-mediated sedation. Endoscopist/nurse teams administered both sedation methods. Patients of American Anesthesiologist (ASA) physical performance status IV (patients with severe systemic disease that is a constant threat to life) or V (a moribund patient who is not expected to survive without the operation) were excluded from the trial. Only a small number (n=17) of the overall patient population had an ASA performance status of III (severe systemic disease). The primary endpoint was a composite safety measure (area under the curve of oxygen desaturation [AUC_{Desat}]) that served as a surrogate for potential hypoxia-induced injury. AUC_{Desat} was calculated as "the difference between the threshold (90%) and actual oxygen saturation summed every second during which oxygen saturation was below threshold." On the primary endpoint, patients receiving the Sedasys-delivered propofol had a statistically lower AUC_{Desat} than patients receiving benzodiazepine-based sedation: 23.6 s·% versus 88.0 s·% (p=0.028). Among the 496 patients receiving Sedasys-delivered propofol, no serious adverse events were reported. However, a higher percentage of patients receiving Sedasys-delivered propofol experienced deep sedation/general anesthesia (3%) than patients receiving benzodiazepine/opiate sedation (1%).[9]

Manufacturer and regulatory status: Ethicon Endo-Surgery (EES), Inc., a unit of Johnson & Johnson (New Brunswick, NJ), developed the Sedasys system. FDA approved the system in May 2013, 5 years after EES submitted the marketing application.[10] The product labeling states that the system is indicated "for the intravenous administration of 1% (10 mg/mL) propofol injectable emulsion for the initiation and maintenance of minimal to moderate sedation, as defined by the American Society of Anesthesiologists (ASA) Continuum of Depth of Sedation, in ASA physical status I and II patients ≥18 years old undergoing colonoscopy and esophagogastroduodenoscopy (EGD) procedures."[7] Sales of the system are being limited to facilities at which an anesthesia professional is "immediately available to the user for assistance or consultation as needed."[7] Additionally, potential users of the system must complete an EES-approved training program before the Sedasys can be used.[7]

The FDA approval requires that EES conduct two postmarketing studies on safety in routine clinical use. The first trial will assess trained users' responses to alarms generated by the system during its use. The second trial will determine the percentage of subjects who require rescue intervention by an anesthesia professional when receiving Sedasys-delivered propofol. Results of this second trial will be used to determine whether to maintain the requirement that an anesthesia professional be immediately available during Sedasys-mediated sedation.[10] EES indicated that distribution of the system would begin sometime in 2014 with initial distribution limited to a few metropolitan areas.[11]

Cost implications: The cost of the system itself has not been released by the manufacturer. The potential cost of the procedure has been discussed in various non-journal publications. Because sedation induced by an anesthesia professional using propofol is becoming more common,[3,4] introducing the Sedasys system has important cost implications. No formal cost-effectiveness studies have been published in peer reviewed journals, but a study funded by EES reported that the anticipated per-procedure costs of using the Sedasys system is expected to be less than 30% of the cost of an anesthesia professional administering propofol.[12] The study also reported that the United States health care system has the potential to save about $160 million by 2015 by using Sedasys systems during the millions of routine colonoscopy procedures performed in low-risk patients each year.[12] However, this study did not take into account costs associated with training or the need to have an anesthesia professional immediately available for emergencies.

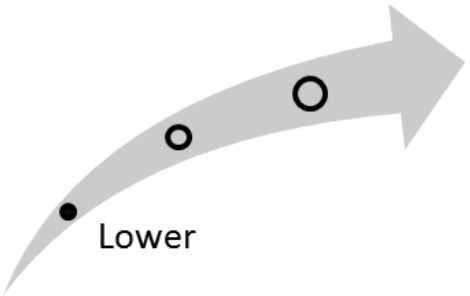
Currently, reimbursement for sedation during endoscopy procedures is typically handled in one of two ways.[13] If the sedative (typically a benzodiazepine) is administered by the endoscopist performing the procedure, the reimbursement for administration of the sedative is bundled in the reimbursement rate for the endoscopy procedure itself. However, if a sedative (typically propofol) is administered by an anesthesiologist, the anesthesiologist is reimbursed under a second procedure, termed monitored anesthesia care (MAC). MAC is billed separately from the endoscopy procedure and cannot be billed by the clinician performing the endoscopy. Although third-party payers typically reimburse endoscopy procedures (e.g., screening colonoscopy) and the associated endoscopist-delivered sedation, several third-party payers have begun to limit reimbursement for MAC in patients who do not have anesthesia-related risk factors.[6] Whether the use of the Sedasys system will be reimbursed separately from an endoscopy procedure (similar to MAC, but billable by the endoscopist) or will be absorbed into the reimbursement rate for endoscopy is unclear.

Our searches of 11 representative, private, third-party payers that publish their coverage policies online (i.e., Aetna, Anthem, Blue Cross/Blue Shield Alabama, Blue Cross/Blue Shield Massachusetts, CIGNA, HealthPartners, Humana, Medica, Regence, United Healthcare, Wellmark) identified only one payer (Humana) with a policy specific to Sedasys-administered sedation. Humana's policy states that "Humana members may NOT be eligible under the Plan for Sedasys® Computer-Assisted Personalized Sedation System. This technology is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language."[14]

Clinical Pathway at Point of This Intervention

During endoscopy procedures, patients are typically sedated to ensure their comfort and procedure success.[2] Diagnostic and uncomplicated endoscopies (e.g., colonoscopies, EGDs) are usually performed with the patient under moderate sedation (previously known as conscious sedation), in which the patient retains the ability to make purposeful responses to tactile or verbal stimuli and retains normal cardiovascular function and spontaneous ventilation.[2] About three-fourths of endoscopic sedation procedures in the United States are performed by endoscopists and endoscopy nurses and use either benzodiazepine alone (e.g., midazolam, diazepam) or benzodiazepine in combination with an opiate (e.g., meperidine, fentanyl) to induce moderate sedation.[2] Approximately 25% of endoscopies performed in the United States use propofol; however, the current propofol labeling requires that it be administered by physicians trained in the administration of general anesthesia.[3] The Sedasys system could potentially allow administration of propofol by physicians or nurses who are not trained in the administration of general anesthesia.

Figure 1. Overall high-impact potential: computer-assisted personalized sedation system (Sedasys) for propofol sedation during gastrointestinal endoscopy procedures



Overall, experts commented that the Sedasys system has significant potential to disrupt the current methods of delivering propofol-mediated sedation, which could also have a big impact on the way endoscopy centers operate. However, experts were unsure whether the potential benefits of wider access to propofol-mediated sedation were significant enough to offset the concern about potential oversedation of patients in a setting without an anesthesiologist present, and thus adoption might be hindered by these concerns and pushback from anesthesiologists. If adopted, the system could significantly change costs associated with propofol-mediated sedation.

Results and Discussion of Comments

Seven experts, with clinical, research, health systems, and health administration backgrounds, offered perspectives on this intervention.[15-21] We have organized the following discussion of expert comments by the parameters on which they commented.

Unmet need and health outcomes: The significance of the unmet need Sedasys purports to address was seen as having minimal to moderate importance by the majority of expert commenters. These experts suggested that the unmet need addressed by Sedasys was of moderate importance and cited patient preference for propofol sedation coupled with the high cost of anesthesiologist-delivered propofol as a substantial burden on the health system. They suggested that the ability of endoscopist/nurse teams to deliver propofol sedation using CAPS could drive wider availability of propofol for sedation during endoscopies. Conversely, expert commenters who viewed the unmet need potentially addressed by CAPS as having only minimal or no importance cited the availability of anesthesiologists and nurse anesthetists to administer propofol as already being capable of addressing function of CAPS systems. Multiple experts observed that no trial comparing Sedasys-administered propofol sedation to anesthesiologist-administered propofol sedation has been conducted and suggested that this was an important comparison to fully examine the risk-benefit profile of the Sedasys system.

With regard to health outcomes, experts thought the Sedasys system has little potential to improve patient health outcomes. In fact, multiple commenters suggested that the switch from anesthesia professional-administered propofol to propofol given by physician-led endoscopy teams had the potential to increase risks of adverse events to patients. Still, some commenters suggested that use of the Sedasys system could expand access to patient-preferred propofol-mediated sedation; one commenter with a research background suggested that this might increase patient compliance with colonoscopy screening recommendations for patients who prefer propofol. However, commenters overall viewed the technology's potential for improving patient health as minimal.

Acceptance and adoption: Significant controversy surrounds the adoption of Sedasys-delivered propofol, as indicated by expert comments. Generally, gastrointestinal endoscopists were seen as likely to promote wide adoption of the system while anesthesiologists were seen as likely to resist. Experts suggested that patient preference for propofol sedation would drive adoption. However, multiple experts thought the majority of patients might not know the differences between sedation methods and would not know to ask for propofol, thus the system could have limited adoption. Further, one clinical commenter suggested that patients aware of propofol administration methods would prefer an anesthesia professional to deliver propofol rather than a CAPS system, again limiting adoption.

Health care delivery infrastructure and patient management: Experts identified many potential shifts in the health care delivery infrastructure that could result from adopting Sedasys-delivered propofol. Multiple commenters cited the substantial training requirements in airway management and Sedasys system use that would be required of physician/nurse endoscopy teams. Additionally, multiple commenters suggested that adoption of Sedasys could change staffing

requirements at endoscopy centers, suggesting that fewer anesthesia professionals would be needed. However, one health systems expert noted that the definition of having an anesthesia professional "immediately available" needs to be clarified. Other experts suggested that Sedasys has the potential to increase case throughput due to the decreased patient recovery time associated with propofol sedation compared with benzodiazepine/opioid sedation.

Cost: The cost of using the Sedasys system has not been released by the manufacturer, but it could have significant potential to reduce costs associated with propofol-mediated sedation because an anesthesia professional would no longer be required in every procedure, suggested the majority of experts. However, multiple commenters indicated that the per-procedure costs of Sedasys-delivered propofol have not yet been clearly defined and may vary depending on the number of patients seen at a given endoscopy center. One clinical expert suggested that the equipment, disposables, system maintenance, and requirement of having an anesthesia professional available for emergencies could actually increase costs relative to anesthesiologist-administered propofol.

Digital Medicines (Proteus Digital Health Feedback System) for Chronic Conditions Requiring Long-Term Drug Therapy

Unmet need: Effective medical therapy for many chronic diseases depends on patient adherence to prescribed medication doses at the correct times. According to the World Health Organization, however, the average medication adherence rate among patients with chronic diseases in developed nations is only 50%.[22] This suboptimal rate compromises treatment outcomes.[23] Therefore, an unmet need exists for technologies that assess, manage, and improve patient adherence to medication regimens for chronic diseases.

Intervention: The Proteus Digital Health Feedback System is a networked medication adherence-monitoring system—or digital medicine technology—intended "to confirm the ingestion of individual oral medications and doses, to integrate this adherence data with physiological parameters and wellness metrics, to offer patient-directed sharing of health information with caregivers and providers, and to incorporate individualized behavior support tools."[23] Developers state that one benefit of the system is its ability to improve providers' "knowledge of a patient's adherence."[23] With access to objective medication-adherence data, providers could determine whether their clinical management "should focus upon improving medication adherence, dose adjustment, drug substitution, or polypharmacy"[23] or other factors affecting adherence, such as cost or side effects.

Three main components comprise the system:[24]

1. Ingestible sensor (formerly known as Ingestible Event Marker or IEM): a 1 mm^2 microfabricated chip sensor that can be embedded in an inactive tablet swallowed by the patient with the medication or into the active medication itself.[23,25,26] The company states that the sensor is made of "materials found in the food chain," such as silicon, copper, magnesium, and cellulose. When swallowed, stomach fluids activate the sensor. Once activated, the sensor transmits digital information regarding the drug taken, its dose, and time of ingestion.[23,25] The system's wearable personal monitor captures the data, and after about 7 minutes of activation, the sensor becomes inactive and is subsequently excreted through fecal elimination.
2. Personal monitor: a wearable, adhesive, soft foam, skin-patch device (5 by 11 by 1 cm) that looks like an adhesive bandage and records information sent from the ingestible sensor. The monitor also records additional physiologic metrics, such as heart rate, respiration, activity, body position, and monitor-wearing compliance. The battery-operated monitor transmits this information via Bluetooth telemetry to a computing device and is designed to be worn for 7 days.[23,27]
3. Smartphone or Web-based communication platform: a device used to view transmitted sensor data captured by the personal monitor. Encrypted data are sent securely to either a smartphone or Web-based platform for viewing by the patient, and with patient approval, by family members, caregivers, or health care providers.[23]

Clinical trials: Investigators reported results of a clinical trial of 111 subjects who ingested 7,144 ingestible markers.[23] "The system's positive detection accuracy and negative detection accuracy in detecting ingested markers were 97.1% and 97.7%, respectively. It differentiated 100% of multiple drugs and doses taken simultaneously by type and by dose. Medication adherence was >85%. The most common adverse effect was mild skin rash from the monitor's electrodes. No definitive marker-related adverse effects were reported."[23] Another report from a clinical trial of 30 patients stated similar detection accuracy of the system.[28] These investigators reported four adverse events related to the device, of which three were skin rashes and one was nausea.[28] The company

also has entered a collaboration with Oracle Health Sciences (a division of Oracle Corp., Redwood Shores, CA) "to work together in clinical trials exclusively to provide clinical investigators worldwide the ability to measure information about medication ingestion, dose timing, and associated physiologic response continuously and precisely for patients enrolled in clinical trials."[29] According to a recent Forbes magazine article, Proteus expects this alliance to significantly influence the success of pharmaceutical trials because "patient adherence to prescribed drug regimens is often as low as 50 percent. That undermines the statistical analysis of trial results and makes it difficult to determine the 'dose response curve,' which represents the maximum tolerable dose and the minimal effective dose. Failure to determine these thresholds during Phase 2 is believed to be one of the main reasons for Phase 3 failures."[30]

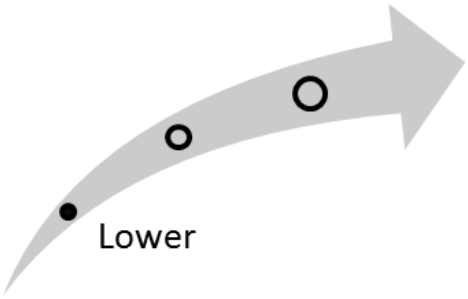
Manufacturer and regulatory status: Proteus Digital Health, Inc., (Redwood City, CA) makes the system. The manufacturer worked with FDA to determine the regulatory pathway because its components are regulated separately.[26] In March 2010, FDA cleared for marketing the Raisin Personal Monitor (an earlier name of the wearable monitor) to record heart rate, activity, and patient-logged events.[31] In July 2012, FDA granted a 510(k) de novo clearance for the Proteus Ingestible Event Marker.[26] In May 2013, FDA reclassified the ingestible sensor as a Class II device subject to special controls.[32,33] The entire system is now available for sale and use in the United States; however, each medication embedded with the sensor is expected to be subject to FDA marketing clearance. In August 2010, the company received Conformité Européene (CE) mark approval to market the complete system in the European Union.[34] The company announced collaborations with Novartis International AG (Basel, Switzerland) and Otsuka Holdings Co., Ltd., (Tokyo, Japan) to develop and commercialize digital medicines.[35]

Cost: The cost of embedding the technology is unknown at this time. However, using the sensors will require use of technology to collect the data, and staff to monitor, interpret, and act upon the data collected as appropriate to followup with patients. Whether these added costs would offset costs of medication regimen nonadherence is unknown at this time.

Clinical Pathway at Point of This Intervention

The company states that tablets can be delivered to patients in one of three ways, "depending on the pharmacy's capabilities and the physician's prescription: (1) Using stand-alone packaging, with patients directed to co-ingest one sensor-enabled inactive tablet each time they take their medication of interest; (2) Co-packaged in specialty blister packets or sachets, with one sensor-enabled inactive tablet in the same compartment as one dose of the medication of interest; or (3) Inside capsules that co-encapsulate a sensor-enabled inactive tablet and the medication of interest."[36,37] Patients can ingest up to 30 sensors per day.[38] Patients take oral medications along with sensors as prescribed by a physician. Patients wear a monitoring patch on the skin and receive training on how to access transmitted information using a computer or smartphone. Clinicians can access objective, accurate, and timely data about patient adherence, to monitor patients' physiologic parameters, understand more about medication response, and prescribe any necessary adjustments in the regimen.[39]

Figure 2. Overall high-impact potential: digital medicines (Proteus Digital Health Feedback System) for chronic conditions requiring long-term drug therapy



Most experts who commented on this topic thought this intervention could have a significant impact on many health system parameters, although one expert was skeptical about its potential to improve patient medication adherence and health outcomes. Its ultimate impact may depend most on patient acceptance or lack thereof. Experts are eager to see more clinical utility data to ascertain whether this technology can improve patient health outcomes. Based on this input, our overall assessment is that this intervention is in the lower end of the high-impact-potential range.

Results and Discussion of Comments

Seven experts, with clinical, research, health systems, and health administration backgrounds, offered perspectives on this intervention.[40-46] We have organized the following discussion of expert comments by the parameters on which they commented.

Unmet need and health outcomes: An important unmet need exists for ways to improve patient adherence to prescribed medication regimens, the experts agreed, and they thought that a direct monitoring system might be one tool to accomplish this. One clinical expert noted multiple indirect monitoring systems (e.g., electronic bottle caps, refill data, pill counts) also address the unmet need. Experts also acknowledged that digital medicines do not address several other adherence variables (e.g., medication affordability, access, side effects).

This device's potential to improve patient health outcomes is uncertain, the majority of experts thought. They cited a paucity of data and uncertainty about its true impact on adherence. These experts were eager to see more and longer-term data. Health outcomes for some conditions (e.g., HIV, immunosuppression after organ transplant) more critically depend on medication adherence, some experts noted, and thus patients with those conditions might benefit more from this intervention. Although most experts focused on individual health outcomes, one clinical expert stated that this intervention might be particularly useful for drug-resistant tuberculosis and other diseases in which medication adherence has a direct effect on public health.

Acceptance and adoption: Patients might resist accepting the technology due to perceived intrusiveness, most experts thought. Several experts cited cost as a potential barrier to patient adoption as well. One expert speculated that patients who are nonadherent due to memory deficits or dementia might accept this intervention as a memory aid, although another expert thought it might be too complex for some patients. Most experts agreed clinicians would readily accept this technology, although some clinicians might have concerns about the burden of additional time required to monitor data, educate patients, and perform additional patient followup. One research expert explained that clinician acceptance might increase if reimbursement for this technology and the additional time required to use it were available and if it saved health care costs by improving patient outcomes.

Health care delivery infrastructure and patient management: Patient management might improve due to increased engagement between doctors and patients, experts speculated. If the onus of improving patient adherence falls on the provider, staffing needs might increase due to additional time needed for monitoring data and counseling nonadherent patients.

Experts suggested the technology would have minimal effect on health care costs if adoption is highly selective or limited; however, if adoption focuses on patients with the most complex medication regimens and who are most likely to have adherence issues, it could reduce care costs by averting health complications and hospitalizations.

Health disparities: This technology is not likely to reduce health disparities, the experts generally agreed, citing per-patient costs anticipated with use of the system. Further, several experts thought this technology might increase disparities between technology-naïve and technology-savvy patients. One expert suggested patients with poor literacy who cannot understand written instructions might benefit from digital reminders to take medicine. Socioeconomically disadvantaged patients, who are disproportionately affected by tuberculosis and HIV, might benefit from increased engagement with clinicians through this technology but may also be more likely to object to its intrusiveness, experts noted.

Hospital Postdischarge Clinics to Provide Transition Care

Unmet need: Discharge from hospital to a patient's home involves a transfer of responsibility of care from the inpatient provider to the patient, his or her home caregivers, and primary care or specialist physician.[47] The immediate period at home after hospitalization is a vulnerable time for patients and can lead to high rates of health services use and health care spending. Ineffective planning and lack of an effective transition can lead to lapses in the quality of care, bad outcomes, readmission, and decreased patient safety.[47,48] During the transition, medications may be altered and self-care responsibilities increased. The National Institute for Health Care Reform reports that one-third of adults discharged from a hospital did not access followup care (with a physician, nurse practitioner, or physician assistant) within 30 days of discharge. Thus, a large unmet need exists to increase access to transitional care after hospitalization.

Intervention: Postdischarge clinics, such as those at San Francisco General Hospital, CA, and Beth Israel Deaconess Medical Center, Boston, MA, focus on increasing access to transitional care through a primary care–based, hospitalist-staffed approach.

At the Bridge Clinic of San Francisco General Hospital, hospital residents refer patients to the clinic by text messaging a hospital-run system to set up the appointment. Residents are required to prepare a discharge summary immediately so it is available for the patient's clinic appointment. Before official discharge from inpatient care, patients receive a contact number for the clinic in case they need to reschedule the appointment or ask any questions. At the postdischarge visit, the discharge worker reconciles medications, reviews medication use, arranges prescription refills, assesses patients for any new symptoms, discusses pending test results, and makes any necessary referral appointments. The discharge worker also spends time educating patients regarding self-diagnosis and personal health promotion. Case management, insurance status, and durable medical equipment needs (e.g., walkers, special beds, chair lifts) are addressed. Finally, patients are referred to or reconnected with primary care providers.[49]

The postdischarge clinic at Beth Israel-Deaconess Medical Center runs in a similar fashion. However, a computerized algorithm identifies patients for postdischarge clinic referral who have no listed primary care provider or for whom a followup appointment cannot be made with the listed primary care physician within 2 weeks of discharge. Visits at the clinic are 40 minutes long and consist of "reviewing the hospitalization, medication reconciliation, and outstanding tests."[50] The clinic staff may also schedule home health care services or skilled nursing facility care for patients. Clinic staff see the majority of patients once and schedule a followup visit with a primary care provider. Patients discharged from the emergency department (ED) are scheduled for 30-minute appointments within 48 hours of the ED visit. Everything done at the clinic is documented and accessible via the medical center's electronic health record system.[50]

Clinical trials: Three studies evaluated different aspects and effects of postdischarge clinics. In one retrospective study from the Denver VA Medical Center, CO, Burke et al. (2013) evaluated the effects of postdischarge clinics on hospital readmission rates, ED visits, and mortality (within 30 days after initial hospital discharge). Investigators reported on patients (n=5,085) who were discharged from the hospital and had a followup visit at a postdischarge clinic (n=538), urgent care center (n=2,699), or primary care practice (n=1,848). As reported by the study authors, "hospital length of stay (LOS) significantly varied between groups, with LOS 2.4 days shorter in [postdischarge clinic] (PDC) than primary care followup (PDC, 3.8 days; urgent care, 5.0 days; primary care, 6.2 days; p=0.04 between groups). Despite this, outcomes at 30 days were not statistically different between groups in unadjusted analysis (19.9% in PDC, 18.3% in urgent care, and 17.5% in primary care,

p=0.42); there was similarly no difference between PDC and primary care followup in propensity-adjusted multivariate analysis, adjusting for baseline differences between groups."[51]

In a prospective study at Beth Israel Deaconess Medical Center, Boston, MA, Doctoroff et al. (2012) examined the length of time between hospital discharge and access to followup care at its newly established postdischarge clinic and primary care followup by Health Care Associates (HCA). Study authors reported, "The median duration from hospitalization to first visit was 7 days in the PDC and 15 days elsewhere in HCA (adjusted difference = 8.45 +/- 0.43 days; P < 0.001). From 2009 to 2011, among 10,845 discharges of HCA patients, patients were more likely to be seen within a week when the PDC was open than when it was closed…. Patients seen in a PDC based in a large academic primary care practice had far earlier followup than those seen elsewhere in the same practice, leading to a substantially greater proportion of all patients in the practice being seen within a week of discharge."[52]

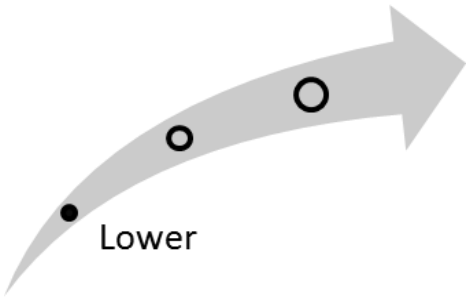
At San Francisco General Hospital, Thomas et al. (2012) conducted an initial pilot study of its discharge clinic to evaluate the show rate at the hospital's Bridge Clinic and map it to patient demographics in terms of presence of an established primary care provider and health insurance coverage. Study authors reported, "During the pilot period, we had a 70% show rate, with 78 patients seen in the clinic. The majority of patients did not have a primary care provider (88%) or access to health coverage (79%)."[53]

Program developers and funding: The number of postdischarge clinics across the United States has been increasing, possibly in response to Medicare rules preventing payment for readmissions within 30 days of discharge.[49,50,54] The inputs and costs required to establish and maintain a postdischarge clinic vary based on the hospital's needs, patient load, and available resources. Developers of established postdischarge clinics have indicated that space and a dedicated support staff are needed for an effective operation.[50] Established postdischarge clinics can generate revenue for the parent hospital through billing for patient visits, according to some implementers.[49]

Current Approach to Care

Postdischarge clinics compete most directly with traditional primary care followup visits. Several other interventions may be used for postdischarge followup care, including providing more comprehensive discharge planning, having a medical professional make followup phone calls, ensuring the patient leaves with a followup appointment with a primary care practice, and sending an alert to the primary care provider that the patient has been discharged from inpatient care.[55] However, these interventions have not satisfied the unmet need for effective postdischarge, transitional care. As public payers such as Medicare seek to limit reimbursement for readmissions within 30 days of discharge, health systems are seeking more innovative approaches to transitional care to prevent readmissions and improve patient health outcomes.

Figure 3. Overall high-impact potential: hospital postdischarge clinics to provide transition care



Experts commented that the unmet need is great to provide prompt postdischarge care, but views were mixed on the potential for these clinics to fulfill that need. Experts commented on the lack of data at this time to show conclusively the impact of postdischarge clinics on readmissions and patient outcomes relative to other strategies. However, experts were particularly enthusiastic about the ability of these clinics to increase access to followup care for health disparate populations, citing these populations as most likely to benefit. Experts also noted the potential for cost savings by averting hospital readmissions. Based on this input, our overall assessment is that this intervention is in the lower end of the high-impact-potential range.

Results and Discussion of Comments

Six experts, with clinical, research, and health systems backgrounds, offered perspectives on this program.[56-61] We have organized the following discussion of expert comments by the parameters on which they commented.

Unmet need and health outcomes: A great need exists to provide transitional care after hospitalization, particularly to reduce 30-day hospital readmission rates, the experts generally agreed. But their views were mixed on the potential for these clinics to meet this need. Some experts thought the intervention's ability to provide rapid followup care could prevent relapses and ensure recovery. One clinical expert noted that patients with complex diseases could benefit in particular because "the current system has no means of aiding patients like these with health care professionals and instead relies entirely on the patient and the family."[56] Another expert with a research perspective concluded, "Providing more rapid follow-up [care] may be important in keeping patients more engaged in their care and more likely to follow discharge guidelines and recommendations."[58] However, other experts thought the intervention lacked substantial and high-quality data at this point to demonstrate positive impact on health outcomes and readmissions.

Acceptance and adoption: Clinicians would readily accept and adopt postdischarge clinics for transitional care, the majority of experts thought. The potential for reducing readmissions (and cost savings), enhancing care coordination, and reducing complications, experts cited, would fuel widespread implementation. However, a few experts suggested that funding and possible perceived intrusion on primary care physicians' scope of practice could be barriers to adoption. Patients would welcome the postdischarge clinic model, experts generally agreed. They noted that patients without regular access to care or established primary care providers would be particularly inclined to accept and use postdischarge clinic services.

Health care delivery infrastructure and patient management: Experts did not anticipate much disruption to health care delivery, except potentially directing patients away from primary care physicians. Case management would be most affected, experts thought, for patients who have no regular source of health care. Experts anticipated a postdischarge clinic could manage such patients more efficiently and effectively.

The potential cost savings from reduced hospital readmissions would be the greatest area for potential cost impact with postdischarge clinics, experts suggested, which could offset the initial cost of establishing a postdischarge clinic.

Health disparities: Postdischarge clinics could reduce disparities by increasing access to care in health-disparate populations, the majority of experts agreed. Patients without established primary care access are disproportionately of low socioeconomic status. One clinical expert remarked, "This intervention targets this population at a critical health care moment at the time when a patient is moving from the acute to subacute setting. This is a moment when a good number of negative outcomes could be avoided through coordinated care efforts."[56]

Senior-Specific Emergency Departments for Treatment of Elderly Patients

Unmet need: As the U.S. population ages and the proportion of the population that is elderly increases, emergency departments are seeing more seniors (i.e., individuals aged 65 years or older) seeking care. However, EDs are typically not optimally equipped to handle this population's unique needs. The ED's physical layout may pose a risk of falls for elderly patients, narrow and thin mattresses increase the risk of developing pressure ulcers, fluorescent lights and a lack of windows foster disorientation in cognitively impaired older adults, and noise pollution from alarms, staff, and patients contributes to communication difficulties in elderly patients who may be more likely to have some hearing impairment than younger patients. After an ED visit, seniors are at greater risk for medical complications, functional decline, and poor health-related outcomes than they were before the ED visit. EDs designed to cater specifically to the needs of the senior population have been proposed to help address these challenges.[62]

Intervention: Several institutions that have established senior-specific EDs since 2008 have published their experiences in implementing multiple interventions to improve patient satisfaction, safety, comfort, and health outcomes.[62-64] To standardize the implementation of senior-specific EDs, a task force comprising members from the American College of Emergency Physicians, the American Geriatrics Society, the Emergency Nurses Association, and the Society for Academic Emergency Medicine developed criteria for geriatric EDs and published guidelines in March 2014 after a 2-year collaboration.[65]

Although experts commented on this intervention before the guidelines were released, the guidelines incorporate many of the same elements on which our experts commented. The guidelines focus on six areas to be modified or established for a senior-specific ED, as follows:[65]

- Staffing and administration: geriatric ED medical director, geriatric ED nurse manager, and geriatric-trained staff physicians and nurses are needed; specialists in geriatrics, cardiology, general surgery, gastroenterology, neurology, orthopedics, geriatric psychiatry, and radiology should be available for consultation; case managers, physician extenders, occupational and physical therapists, and pharmacists should be available to provide ancillary services and social services
- Followup care and transition: discharge protocols that include how to communicate with patients, families, and caregivers should be created and use followup phone calls or telemedicine and connect to community resources for home care
- Education: residency and continuing medical education should include unique physiology, atypical disease presentation, and psychosocial needs of senior patients
- Quality improvement: data on admission rates, readmission rates, revisit rates, and patient satisfaction should be collected and monitored
- Equipment and supplies: mobility, incontinence, behavioral needs, memory cues, and visual and auditory deficits, natural lighting, contrasting colors, large signage, nonskid flooring, handrails, white boards, thicker mattresses should be integrated as appropriate
- Policies, procedures, and protocols: patient delirium, dementia, functional decline, fall risk, medication interactions, transitional care, catheter use, and palliative and end-of-life care should all be addressed

Senior-specific ED interventions can be implemented in the whole ED and used as needed or housed as a separate unit serving referred patients.[65] Patient referral varies by hospital. It may be solely age-based (i.e., patients 65 years and older) or also based on patient complaint and overall health screens.[65,66]

Clinical trials: Several institutions that have implemented senior-specific EDs informally reported positive findings initially, and experts based their comments on these informal reports. After we received comments, three studies were published in journals.

Holy Cross Hospital (Silver Spring, MD) reported in January 2012 that about 11% of patients of the hospital's geriatric ED "were prescribed five or more medications, and through the pharmacist referral, it was recognized that 20 percent of the population were taking inappropriate medications or doses."[67] Furthermore, the hospital reported, "Inpatient volume increased, signifying appropriate admissions and return emergency department visits within 72 hours decreased to 3 percent."[67]

Also, Dr. Mark Rosenberg, chairman of emergency services at St. Joseph's Regional Medical Center (Paterson, NJ), noted that, "a year after St. Joseph's opened its geriatric ER in 2009, the hospital's return rate for seniors who came back within 30 days of treatment for the same illness or injury had decreased from 20 percent to less than 1 percent."[68] Dr. Andy Jagoda, emergency medicine chairman at Mount Sinai Hospital (New York, NY), reported that "up to eight elderly patients a month were falling in the regular emergency room…none have fallen in the geriatric E.R."[66]

After we received expert comments on this topic, researchers from three separate hospitals formally published study results. One study reported no difference in time to return after 30 and 180 days or in average length of hospital stay. Patients treated in the senior-specific ED were less likely to be admitted than those treated in the conventional ED.[69] In another study, authors noted admission rates significantly decreased from 59.8% to 49.0% after establishing senior-specific protocols.[70] A third study reported trends toward decreased admissions, length of stay, and revisits.[71]

Program developers and funding: Multiple hospitals across the United States have developed senior-specific EDs. Hospitals incorporating a senior-specific ED would be responsible for the cost of constructing or updating the ED, which varies based on the institution's needs and resources. For example, Newark (NJ) Beth Israel's facility, composed of eight beds, cost a reported $3.2 million.[72] However, Holy Cross Hospital stated that it spent $150,000 to create its senior-specific ED and that it raised the money through an annual fundraising event.[73] The hospital states that patients do not pay an extra fee to use the ED and its officials hope that the initial financial outlay will be recovered by reducing the rate of hospital readmissions.[73] Clinical services and tests conducted in the senior-specific ED are expected to be reimbursed according to normal insurance schedules and policies.

Diffusion: The prevalence of these EDs appears to be steadily growing. The first senior-specific ED in the United States was opened at Holy Cross Hospital in 2008.[74] St. Joseph's Healthcare System and Newark Beth Israel Medical Center opened geriatric EDs in 2009 and 2011, respectively.[72,75] No registry of senior-specific EDs in the United States exists; however, reports from health systems and health care news articles indicate that more than 50 have emerged across the United States since 2011, with an estimated 150 in development.[76]

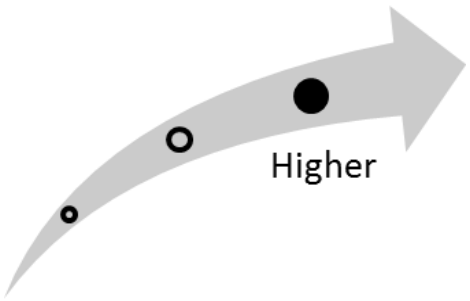
Current Approach to Care

Traditional EDs may incorporate cognitive screenings (usually administered on an as-needed basis to ED patients) and other geriatric clinical tools or best practices into routine examinations for seniors. However, to realize the goal of a senior-specific ED, staff also need to work closely with other hospital departments and community health programs to ensure seamless transitions of care for elderly patients after discharge from the ED.

From a clinical point of view, traditional ED practice is not optimally suited for the senior population, according to ED experts in geriatrics. For example, rapid triage and diagnosis—hallmarks of ED care—are difficult with older patients, who might have multiple comorbidities, take multiple medications, and have functional and cognitive impairments. Clinical researchers state that these

challenges, combined with the pressure to make rapid diagnoses, can increase the risk of incorrect or missed diagnoses. Further, in an effort to reduce fall risk and the time and energy devoted to cleaning bedpans or changing diapers, ED staff often insert bladder catheters into these patients, which increases patients' risk of developing delirium and infection.[62] Other design features that might pose a risk to the elderly include the narrow stretchers with thin mattresses that patients lie on while awaiting admission or tests; these mattresses can increase risk of pressure ulcers. Fluorescent lighting and a lack of windows can promote disorientation in cognitively impaired older adults, and noise from monitor alarms, clinical staff, and other patients can contribute to worsening delirium and communication difficulties in the potentially hearing-impaired population.[62]

Figure 4. Overall high-impact potential: senior-specific emergency departments for treatment of elderly patients



Most experts commenting on this intervention agreed that the need for senior-specific ED care is an important unmet need. Although they thought that sufficient supporting data were needed (some of which was published after they submitted comments), experts were highly optimistic about the potential for improved quality of life and health outcomes in elderly patients treated in this setting. Experts anticipated widespread adoption and acceptance of senior-specific EDs by hospital administrators, providers, and patients alike. Based on this input, our overall assessment is that this intervention is in the higher end of the high-impact-potential range.

Results and Discussion of Comments

Seven experts, with clinical, research, and health administration backgrounds, offered perspectives on this program.[77-83] We have organized the following discussion of expert comments by the parameters on which they commented.

Unmet need and health outcomes: The infrastructure of the traditional ED is ill equipped to satisfy the special needs and demands of elderly patients, experts agreed. They cited architectural layout changes, lighting changes, and specialized staff as helping senior-specific EDs to fulfill this unmet need. Although substantive supporting data were lacking at the time of comment, experts concluded the potential for improved quality of life and health outcomes in the target population is great with this care delivery innovation. Experts anticipated shorter lengths of stay, fewer medication errors, improved communication, and decreased patient anxiety and confusion would result from senior-specific EDs, compared with traditional EDs. Experts called for more concrete information on health outcomes and recommended that in-depth cost-benefit analyses be completed; however, they tempered this recommendation, saying that formalized studies on this invention would be difficult.

Acceptance and adoption: Clinicians would readily accept senior-specific EDs, experts generally agreed. However, two experts proposed the potential for initial resistance.[80,81] One expert with a clinical perspective suggested, "Some clinicians would be leery of working in a senior-specific

ED because of [the] increase challenge of the elderly (being more complex, having atypical presentation, multiple medication use, medical complications, and high rate of poor outcomes)."[80]

Experts concluded the care delivery innovation would be widely accepted by patients and suggested elderly patients would gravitate towards hospitals offering this type of service.

Infrastructure and staffing: Staff training and environmental changes are needed to implement this care-delivery innovation, experts noted. Widespread implementation would result in an initial, positive shift in patient management, experts anticipated. They cited reduced lengths of stay, more appropriate hospital admissions, reduced readmissions, and improved diagnoses as contributing to this disruption. One clinical expert viewed senior-specific EDs as beneficial to both elderly and younger patients, stating, "If the conventional EDs only have the younger patients that are less complicated, [and who] need less medical services/tests, and have better outcomes, there will be lower throughput times; decreasing the wait times and improve the patient's satisfaction."[80] This expert also suggested that senior-specific EDs could potentially decrease inpatient stays by improving communication and subsequent diagnosis, which would also reduce unnecessary testing. Experts generally agreed the environment established by senior-specific EDs would facilitate improved communication and allow for better understanding of discharge instructions.

Initial costs for establishing a senior-specific ED could be high, experts agreed. Some experts thought these costs would be offset by reduced readmissions, reduced adverse events (e.g., falls), and improved health outcomes. Overall, experts did not anticipate that long-term costs would differ from those of the traditional ED.

Health disparities: The ED's legal obligation to provide care to any patient regardless of ability to pay would negate any potential effects on health disparities, experts stated. However, experts suggested that the up-front costs required to establish a senior-specific ED may result in adoption in more affluent areas. This would adversely affect senior citizens of health-disparate areas who may be unable to access care at those senior-specific EDs, some experts anticipated.

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