Crosscutting Interventions and Programs

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
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Contract No. HHSA290201000006C

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June 2012
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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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 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 e-mail to effectivehealthcare@ahrq.hhs.gov.

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Executive Summary

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 7 years out on the horizon and then to follow them for up to 2 years after initial entry into the health care system. Since that implementation, more than 11,000 leads about topics have resulted in identification and tracking of more than 900 topics across the 14 AHRQ priority areas and a cross-cutting area.

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 quarterly. Topics eligible for inclusion are those interventions expected to be within 0–4 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. 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 350 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 (COI). 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 seven or 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.” 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 potential high impact is expected to change over time.

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 eight topics for which (1) information was compiled by April 15, 2012, in this priority area; and (2) we received six to eight sets of comments from experts between February 2011 and April 26, 2012. (Fourteen topics in this priority area were being tracked in the system as of May 2012.) We present summaries on five topics (indicated below by an asterisk) that emerged as potential high impact on the basis of experts’ comments and their assessment of potential impact. 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.

<table>
<thead>
<tr>
<th>Priority Area 15: Crosscutting Interventions and Programs</th>
<th>High Impact Potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Barbershop-based medical screening and education programs</td>
<td>No high-impact potential at this time</td>
</tr>
<tr>
<td>2. *Community paramedicine to improve care access in rural areas</td>
<td>High</td>
</tr>
<tr>
<td>3. *Intelligent pills (Raisin System) to monitor patient medication adherence</td>
<td>Moderately high</td>
</tr>
<tr>
<td>4. *Medical homes network (South Side Healthcare Collaborative) to link emergency department patients to community care</td>
<td>Moderately high</td>
</tr>
<tr>
<td>5. Online placeholder system for emergency care visits</td>
<td>No high-impact potential at this time</td>
</tr>
<tr>
<td>6. *Partnering urban academic medical centers and rural primary care clinicians for treatment of complex, chronic conditions</td>
<td>High</td>
</tr>
<tr>
<td>7. Patient group appointments with physicians for management of chronic conditions</td>
<td>No high-impact potential at this time</td>
</tr>
<tr>
<td>8. *Senior-specific emergency departments for treatment of elderly patients</td>
<td>Low</td>
</tr>
</tbody>
</table>

Discussion

We created a priority area to capture crosscutting interventions that affect multiple priority areas. Some of these interventions are healthcare technologies and others are programs, services, or care-delivery innovations.
Community Paramedicine to Improve Access to Care in Rural Areas

- **Key Facts:** For many reasons, primary care access in rural and remote regions is limited, and this shortage can prompt patients to inappropriately use emergency medical service (EMS) and ambulance transport to the emergency department (ED), especially for nonemergent medical issues, conditions of a home-health or social-service nature, and medical issues that could have been prevented if the patient had regular access to primary care. The community paramedicine model uses EMS personnel (paramedics) to provide specific primary care services in a patient’s home, with the ultimate goal of improving health outcomes among medically vulnerable populations and reducing unnecessary ambulance transports, ED visits, and hospital readmissions. Several versions of this model are being implemented in the United States, and we describe one of those models in this report. Although the community paramedicine model is not intended to replace current home-health services, it is intended to provide a means for extending the reach of primary care providers to patients who otherwise would not have access to these services.

- **Key Expert Comments:** Experts thought that this model will successfully meet the need for improving primary care access in rural areas. The program’s most dramatic effects are expected to be seen reduced health care costs, improved health disparities, and better patient management and health outcomes.

- **Potential for High Impact:** High

Intelligent Pills to Monitor Patient Medication Adherence

- **Key Facts:** The Raisin System™ (Proteus Biomedical, Inc., Redwood City, CA), a form of smart-pill technology, is being investigated to treat chronic diseases requiring ongoing medication, such as tuberculosis, diabetes, heart failure, AIDS, hepatitis C virus infection, and mental health disorders. The system comprises ingestible event markers (IEMs), which are tiny microchip sensors that are affixed to conventional pharmaceuticals (i.e., pills), and a personal monitor. The IEMs, made from common food ingredients, are activated by digestive fluids upon reaching the stomach. The personal monitor is a miniaturized, battery-operated, data-logging device that patients wear as a patch on the torso to record heart rate, activity, ingestion of monitored medications, and patient-logged events such as symptoms. When patients ingest a monitored smart pill, the activated IEM transmits its unique signature to the personal monitor, which records and timestamps the event along with physiologic data such as heart rate. The personal monitor transmits collected patient data to the patient’s Bluetooth-enabled cell phone or other computerized device. Data are then encrypted and forwarded to a secure database that clinicians can access to review the patient’s condition. In results of a trial of 111 subjects who ingested 7,144 ingestible markers, investigators reported that the system’s positive and negative detection accuracy in detecting ingested markers was more than 97% and medication adherence was more than 85%. The most common adverse effect was mild skin rash from the monitor’s electrodes, and no serious adverse events were reported. The company received marketing clearance from the U.S. Food and Drug Administration for the monitoring device in March 2010, but not yet for the IEM.

- **Key Expert Comments:** Experts commenting on this topic agreed that this technology could have a significant impact on many health system parameters, although some of the experts were skeptical about this intervention’s potential to actually improve adherence and health outcomes. Experts thought the intervention would generate much controversy because of concerns about “Big Brother” monitoring. Experts also thought, however, that this
technology has potential to improve patient adherence and health outcomes, even though it might increase time and infrastructure requirements on the part of clinicians to review data and shift patient management as a result.

- **Potential for High Impact**: Moderately high

**Medical Homes Network to Link Patients in Emergency Departments to Community Care**

- **Key Facts**: The University of Chicago’s South Side Medical Homes (SMH) Network is intended to link patients who overuse or misuse the ED with community-based, primary care providers. In the ED, patient advocates identify patients who do not have a regular primary care provider in the community, and assist them in setting up a primary care referral with collaborating community clinics. If the patient accepts the referral, appointments are scheduled either immediately or during a followup phone call. To maintain continuity of care, patient ED medical information is either faxed to the community clinic, or shared electronically through a recently developed ER Community Portal that allows community physicians to access medical records of patients referred from the ED. Some of the partnering community health centers reserve certain appointment slots for SMH-referred patients. Experts viewed this program as having significant impact because of the sizable burden of ED overcrowding and underutilization of primary care services.

- **Key Expert Comments**: Experts suggested that this program might be particularly impactful in improving health disparities and shifting patient care from the ED to the primary setting. However, most experts noted that patient adherence to the program will be necessary for it to reach its full potential.

- **Potential for High Impact**: Moderately high

**Partnering Urban Specialists with Rural Primary Care Clinicians (Project ECHO) for Treatment of Complex, Chronic Conditions**

- **Key Facts**: Project ECHO (Extension for Community Healthcare Outcomes, developed at the University of New Mexico Health Sciences Center, Albuquerque) is intended to address the unmet need of access to specialty care by aiding primary care clinicians in rural or underserved areas to develop more capacity to safely and effectively manage patients with chronic, common, and complex diseases in their community. The program uses telehealth technology and clinical management tools to train and support rural primary care providers in developing knowledge about diseases that would typically fall within the realm of specialty care. A specialist (e.g., from an academic medical center) guides a primary care provider in developing the skills and self-efficacy necessary to treat the patient. Additionally, during case-based teleclinics, ECHO specialists make brief didactic presentations that are typically relevant to specific issues that arise, with these presentations intended to improve content knowledge. Finally, patient outcomes are monitored through a centralized database. Project ECHO is being investigated for its viability to improve management of patients with hepatitis C virus infection or other chronic conditions.

- **Key Expert Comments**: Experts commenting on this topic agreed that this intervention is intended to fill an important gap and is likely to have a significant impact on patient management models and access to care in rural areas, although some skepticism about the model’s sustainability exist because of unanswered questions about long-term funding.

- **Potential for High Impact**: High
Senior-Specific Emergency Departments for Treatment of Elderly Patients

- **Key Facts:** Some hospitals are now offering EDs designed to cater specifically to the special needs of the senior population to improve safety, outcomes, and quality of care for elderly patients in the ED. Senior-specific EDs offer equipment such as reclining chairs and padded/lined stretchers to improve patient comfort and reduce risk of pressure ulcers; large-faced clocks for better visibility; calendars and boards with the names of hospital and clinical staff to reduce risk of patient disorientation and delirium; fall prevention design such as nonskid floor surfaces, extra handrails, more aisle lighting, and bedside commodes; and visual and lighting aids. Protocol-based patient care interventions include screening for cognitive impairment and delirium as part of routine practice, adopting minimal use of urethral catheters and other “tethering” devices to reduce patient immobility and risk for nosocomial infection and delirium, and creating a staff position for a nursing discharge coordinator to assess the patient’s postdischarge care situation and needs.

- **Key Expert Comments:** Experts agreed that the need for senior-specific ED care represents an important unmet need and that this model might improve outcomes and health disparities in the target population, although experts were divided on whether the latter would be a positive change. Experts’ enthusiasm for the model was somewhat tempered by the paucity of available outcomes data at this time.

- **Potential for High Impact:** Lower range of high impact potential
Crosscutting Interventions and Programs
Community Paramedicine To Improve Care Access in Rural Areas

Primary care access in rural and remote regions is limited by several factors, including physician shortages, hospital and clinic closures, limited transportation, aging populations, increasing cultural and ethnic diversity, economic disadvantage, and poor health status. Limited access to primary care can prompt patients to inappropriately use emergency medical service (EMS) and ambulance transport to the emergency department (ED), especially for nonemergent medical issues, conditions of a home-health or social-service nature, and medical issues that could have been prevented if the patient had regular access to primary care.

The community paramedicine model may close this access gap by using EMS personnel to augment available services. In community paramedicine, EMS personnel (paramedics) provide specific primary care services in a patient’s home. The reader should note that while one program in particular (Community Paramedic Program, Western Eagle County, CO) is described in detail herein, several other community paramedicine models are being implemented across the United States. While certain aspects of each of these programs differ, their underlying frameworks are similar.

The goals of the Western Eagle County Ambulance District (WECAD) community paramedicine program are to “improve health outcomes among medically vulnerable populations and to save healthcare dollars by preventing unnecessary ambulance transports, [ED] visits, and hospital readmissions.” According to the WECAD program handbook, the community paramedicine model has two components: primary care services (ordered by a physician and conducted in a patient’s home) and community-based prevention services (planned and provided in conjunction with the local public health department).

In the WECAD community paramedicine pilot program, these components are carried out by EMS workers, who have a lot of downtime between emergency calls. During these periods of downtime, EMS workers visit patient homes and provide specific primary care services that are within the paramedic’s legal scope of practice and skill set. These services may include assessment (vital signs, blood pressure, labs, medication compliance), treatment (wound care, medication reconciliation), prevention (immunizations, fall assessment), and referral (medical and social services). Patients are referred to the program via physician order. Care provided under the WECAD program is not intended to be of an ongoing nature, and each visit requires a separate physician’s order. After each visit, the paramedic completes a patient care report and faxes it to the ordering provider for the patient’s chart. If the paramedic deems that immediate physician intervention is necessary, he or she calls the ordering physician while at the patient’s home. The WECAD program developers note that community paramedicine is not intended to replace current home-health services, such as home-health care of primary care physicians. Instead, the program is intended to be an “extension of the primary care provider to provide care to patients without access.”

Although no ongoing trials of these paramedicine programs were identified in the National Clinical Trials database, researchers who studied the outcomes of a paramedicine intervention in an England-based trial of 3,018 patients older than 60 years of age, concluded that, “Overall, patients in the intervention group were less likely to attend an emergency department (relative risk 0.72, 95% confidence interval 0.68 to 0.75) or require hospital admission within 28 days (0.87, 0.81 to 0.94) and experienced a shorter total episode time (235 v 278 minutes, 95% confidence interval for difference −60 minutes to −25 minutes). Patients in the intervention group were more likely to report being highly satisfied with their healthcare episode (relative risk 1.16, 1.09 to 1.23). There
was no significant difference in 28 day mortality (0.87, 0.63 to 1.21). Costs, funding, and reimbursement policies vary from program to program. Patients enrolled in the WECAD program are not charged for services; the program is funded by State monies.

**Current Approach to Care**

EMS personnel are intended to be emergency responders who provide acute care. However, nationwide shortages of primary care physicians often lead to patient use of an EMS to access EDs for routine health care services, despite the fact that a primary care setting would provide patients with more appropriate and cost-effective care. Community paramedicine might increase access to primary and preventive care, provide wellness interventions within the medical home model, decrease ED use, save health care costs, and improve patient outcomes.

**Figure 1. Overall High Impact Potential: Community paramedicine to improve care access in rural areas**

Experts were extremely enthusiastic about this program’s potential to address the unmet need for improved provider access in rural areas. Experts thought that this program will have marked effects on health disparities and is likely to improve patient health outcomes over the long term. Experts also note that if the program is successful, it will fundamentally alter the way patients are managed, and could effect significant cost savings by reducing unnecessary or inappropriate ED visits and hospital admissions. Based on this input, our overall assessment is that this intervention is in the higher end of the high-potential-impact range.

**Results and Discussion of Comments**

Six experts, with clinical, research, and health systems backgrounds, offered their perspectives on this intervention.

Generally, experts agreed that the unmet need this intervention attempts to address is important. This opinion was based on the large number of patients affected by lack of primary care resources, the associated poor health outcomes, and the costs affiliated with unnecessary emergency medical resource use. Most experts also agreed that this intervention will be successful in meeting this need, although more experts appeared to base this opinion on the theory underlying the intervention, rather than on available trial data. For example, one clinical expert noted that “This program has the potential to offer a bridge to the challenge of accessing fundamental services at lower costs and under safe conditions,” and that the program may “significantly improve patient health because it may allow for more frequent monitoring of complex patients and may also offer ready access to some preventive services.”

Only one expert, speaking from a clinical perspective, suggested that this intervention may not be effective, stating that “EMS and its providers are inappropriate for primary care delivery even under the supervision of a physician. EMS staff are minimally trained professionals and could
provide only marginal primary care services.” This expert suggested that a preferable strategy would be to expand the availability of primary care nurse practitioners, because they are “geared toward primary care delivery in a way that EMS is fundamentally inappropriate for.”

Experts thought that this intervention’s greatest impact will be in the realm of improving health disparities. Although experts suggested several mechanisms (e.g., patient education, medication monitoring) through which this improvement might occur, the most commonly stated mechanism was by improving access to primary care for patients who otherwise would not receive it.

Experts thought this intervention will have a notable impact on the way patients are managed, for several reasons. First, this intervention will shift care from the ED to a home care setting. Secondly, it will shift the responsibility for patient care from emergency physicians and primary care physicians to paramedics. Thirdly, an additional emphasis will be placed on ongoing and preventive care, rather than on episodic emergency care.

Although most experts agreed that this intervention will be accepted by both patients and physicians, some experts suggested that there may be some pushback from clinicians, who may see this program as “competition” or may be inconvenienced by phone calls and managing care through EMS personnel. Most experts appeared to believe that physicians would be grateful for the improved patient care and reduced workload that this program may offer.

Experts suggested that this program may have important cost ramifications. Although costs will increase in the short term, as the program is implemented, several experts noted that this initial financial outlay would be recouped over time as inappropriate ED visits, hospitalizations, and readmission are reduced. As one clinical expert noted, this “could have a significant impact on healthcare costs by allowing for less expensive services to be delivered in a home setting rather than an expensive ER.”
Intelligent Pills To Monitor Patient Medication Adherence

Effective medical therapy for many chronic diseases depends on patient adherence to prescribed medication regimens in the proper sequence, dosage, and 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%. Therefore, technologies are needed that could improve patient adherence with medication dosages for chronic disease.

The Raisin System™ (Proteus Biomedical, Inc., Redwood City, CA) is a networked adherence monitoring system intended to aggregate data regarding patient medication adherence (and other metrics) into tools that can be used by patients and health care providers. Three main components comprise the system. The first component is the ingestible event marker (IEM), which is a microfabricated chip that a manufacturer can embed into any oral medication to be swallowed by the patient. The IEM is 1 square millimeter in size and is made of “materials found in the food chain,” such as silicon, copper, magnesium, minerals, and cellulose. When the patient swallows the IEM, the chip is released from the medication and activated by stomach fluids, which provide power to the IEM. Once activated in the body, the IEM transmits digital information regarding the drug taken, its dose, and time of ingestion. This information is captured by the system’s second component, a wearable personal monitor. After about 7 minutes of activation, the IEM becomes inactive and is excreted through fecal elimination.

The personal monitor is a wearable, adhesive, soft foam, skin-patch device (measuring 5 by 11 by 1 cm) that records the information sent from the IEM and that can also be used to measure additional physiological metrics, such as heart rate, respiration, activity, body position, and monitor-wearing compliance. The personal monitor then transmits this information (via Bluetooth telemetry) to a computing device. The personal monitor, which is battery operated and looks similar to an adhesive bandage, is designed to be worn for 7 days.

The third component is the mobile phone or Web-based communication platform that is used to view the data transmitted by the IEM and captured by the personal monitor. The data is sent securely to either a mobile phone or to a Web-based platform, where it can be viewed by the patient, family members, caregivers, or health care providers.

According to researchers investigating this product (several of whom are employed by the manufacturer), the intended purpose of this system is: “[T]o 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.” The researchers state that one benefit of the system lies in its ability to give health care providers “improved knowledge of a patient’s adherence.” With access to objective adherence data, providers will potentially be able to determine whether their clinical management of a patient “should focus upon improving medication adherence, dose adjustment, drug substitution, or polypharmacy.”

In results of a clinical trial of 111 subjects who ingested 7,144 ingestible markers, investigators published the following: “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.”

In March 2010, the manufacturer received 510(k) clearance from the U.S. Food and Drug Administration to market the Raisin Personal Monitor to record heart rate, activity, and patient-logged events. The IEMs, however, are not approved for marketing in the United States. The
company received Conformité Européene (CE) mark approval to market the complete Raisin System, including the ingestible sensor and personal physiologic monitor, in the European Union in August 2010.\textsuperscript{17}

**Clinical Pathway at Point of This Intervention**

The use of this intelligent pill technology would be incorporated into long-term medical management of patients with some forms of chronic disease. Patients would continue to take their medications in the same manner as before, as instructed by their physicians. However, using the personal monitoring technology provided through a “smart” pill is intended to provide physicians with more timely data on how patients are taking their prescribed medications, so that physicians might monitor changes in patients’ physiologic parameters in response to their medication use.\textsuperscript{18}

**Figure 2.** Overall High Impact Potential: Intelligent pills to monitor patient medication use

While some experts who commented on this topic remain skeptical about this intervention’s potential to actually improve patient compliance and by association, health outcomes, they generally thought that this intervention could have a significant impact on many health system parameters. These experts anticipate controversy that use of such a device could inspire, because of concerns about a “Big Brother” type of monitoring. These experts also believe that this technology has the potential to improve patient health outcomes, increase time and infrastructure requirements on the part of clinicians, and shift patient management models. Based on this input, our overall assessment is that this intervention has moderate high-impact potential.

**Results and Discussion of Comments**

Seven experts, with clinical, research, health systems, and health administration backgrounds, offered perspectives on this intervention.\textsuperscript{19-25} These experts agreed that an important unmet need exists for monitoring systems that might improve patient adherence to prescribed medication regimens. Some experts noted a driver for the need is the aging population, the increasing prevalence of chronic conditions, and the growing importance of medication management for treating these conditions. One community health expert stated that this intervention might be particularly useful where medication adherence has a direct effect on public health, such as in cases of drug-resistant tuberculosis or HIV, or in transplant cases, because donated organs are a scarce public resource and antirejection therapy adherence is an important concern in maximizing available resources. Additionally, this expert opined, this technology might play an important role as a substitute for or complement to directly observed therapy.

Experts agreed that the theory underlying this intervention is technologically sound. However, several were skeptical about whether increased patient monitoring, regardless of its specificity and sensitivity, would actually translate to improved patient-centered outcomes, such as disease control.
At the time they commented on the topic, these experts had access only to specificity and sensitivity data on the smart pill. They did not have access to more recently published adherence data described in the Intervention section above.

The experts overall believe that this intervention has potential to have a dramatic impact on several health system parameters, if it is proven to improve compliance. They believe this intervention has the potential to improve patient health outcomes, particularly for patients with conditions that require 100% adherence, such as tuberculosis, HIV, or organ transplants. Because patient outcomes are a function of medication compliance, the outcomes would improve over time with this monitoring system, most experts commenting on this topic thought. Furthermore, some of these experts noted that patients are not always honest or accurate in reporting to their clinicians their adherence to their regimens. Thus, experts thought, this system might offer clinicians an objective means for determining how well their patients adhere to treatment recommendations and help them to treat patients more effectively. As one commentator who is a pharmacist stated, “Clinicians might alter or change a medication based on the way the medication is prescribed, not necessarily on the way it is actually taken. [With this intervention,] better disease state management could occur.” However, two other experts noted that it is up to the patient to improve adherence to recommended therapy, and that this intervention’s primary function is simply to identify patients who are failing to adhere to their medication schedule. Presumably, patients identified as nonadherent would receive specific instruction from their providers, which might improve adherence. Experts speculated that the technology has the potential to affect patient management models, although they agreed that the various ways in which clinicians would intervene with nonadherent patients remains to be seen. If the onus of improving patient adherence falls on the provider, staffing levels might change, because a staff member might need to spend additional time counseling nonadherent patients.

Experts agreed that this intervention would require both additional infrastructure and time investments on the part of the medical provider, citing the following: An electronic health or medical record system would need to be in place to receive the transmitted data from the patient; employees would need to be trained on the use of the system; and clinicians or other staff members would need to analyze the significant amount of data the system captures about each patient, which would place new demands on time.

Experts suggested that this intervention’s greatest impact might lie in its potential for creating controversy. All noted that this intervention has the “feel of Big Brother” or breach of privacy, which might generate backlash from patients or society. Furthermore, some experts suggested that ethical issues might arise if insurance companies insist that patients use the system to determine financial responsibility for expensive interventions that could have been avoided if patients had fully adhered to treatment. Finally, some experts suggested that patients might be wary of ingesting a microchip, despite that fact that it is made of food products.
Medical Homes Network To Link Patients in Emergency Departments to Community Care

Emergency departments (EDs) are often used as a safety net for patients who are underinsured or not insured, who might view the ED as a “substitute for access to primary physician care” and present to the ED with exacerbations of chronic diseases that could be more appropriate managed in the outpatient, primary care setting.\textsuperscript{26} The University of Chicago’s South Side Medical Homes (SMH) Network is intended to link patients who overuse or misuse the ED with community-based, primary care providers.\textsuperscript{26} This model, if proven effective, might serve as a template for other hospital systems facing the same challenges.

The University of Chicago Hospital’s (UCH) ED developed the SMH, a care delivery innovation “to connect patients with community-based, primary care providers,” and enable them to “build a lasting relationship with a primary care physician in their neighborhoods.”\textsuperscript{26,27} According to SMH project developers, specific goals of the program include: (1) to build a sustainable safety net system that links patients visiting the ED who lack a “medical home” to community-based primary care; (2) to enhance linkages to community dental, mental health, substance abuse, and other social services; and (3) to strengthen and improve the program through continued self-assessment and patient feedback.\textsuperscript{26}

The SMH program was established in 2005 in partnership with local community-based health centers.\textsuperscript{26,28} According to program developers, the project’s foundation is a collaborative organization between the UCH-ED and 18 community-based health care providers.\textsuperscript{26} When patients visit the ED, they are flagged if they are identified as lacking a medical home.\textsuperscript{26} ED-based patient advocates (or “navigators”) visit these patients, either while the patient is waiting for medical care or before discharge from the ED.\textsuperscript{26}

The patient advocates are members of the ED staff who are recruited from the community and trained in the UCH-ED.\textsuperscript{26} These advocates seek out flagged patients in the ED and conduct a public-health needs screening that includes the following: (1) an inventory of patient medical problems needing primary care, such as hypertension or diabetes; (2) mental health history; (3) substance abuse status; and (4) current living situation.\textsuperscript{26} If the patient’s presenting symptoms and acuity level allow, the advocate then “initiates a discussion emphasizing the difference between acute healthcare needs addressed in the ED and preventive healthcare provided by a primary physicians,” and offers the patient a primary care referral with one of the partnering community clinics.\textsuperscript{26} Most of the referral clinics are staffed by UCH clinicians and are chosen for each patient based on his or her individual needs and neighborhood location.\textsuperscript{26} Patients who leave the ED without being seen are contacted by a patient advocate via telephone.\textsuperscript{27}

If the patient accepts the referral, appointments are scheduled either immediately or via a followup phone call. To maintain continuity of care, patient ED medical information is either faxed to the community clinic or shared electronically via a recently developed ED Community Portal, which allows community physicians to access the medical records of patients referred from the ED.\textsuperscript{27,29} Some of the partnering community health centers reserve certain appointment slots for SMH-referred patients.\textsuperscript{27}

Often, the patient advocates identify patients who would benefit from contact with social-work staff. Under the program model, the work of the patient advocates is complemented by the UCH-ED social-work staffers, who provide the following resources to patients in the ED: (1) a brief motivational interview addressing psychosocial needs, substance abuse counseling, and family support networks; (2) outpatient home health care; and (3) direct nursing home placement.\textsuperscript{26}
According to the program’s sponsor, in the first 5 years of the program (initiated in 2005), the SMH educated 27,000 patients on the health care resources available in the community, and more than half of those patients have been successfully connected to primary care doctors on the South Side of Chicago. However, only about 35% of the about 16,000 primary care appointments made through the project were kept by patients. In a 2008 study of the program, which involved 950 patients and 6 patient navigators, published results state: “Data through 01 July 2007 show a monthly average of 950 ED patients surveyed and 80% of these accepting follow-up referral services. Of those patients with ED-scheduled appointments (43%) in community clinics, network data shows patients returning to their referred providers: 39% of patients have been ≥2 times. The navigator role is evolving with the expansion of SMH to include: (1) frequent-user population referrals; (2) preventive health education; and (3) utilization of community resources.”

Current Approach to Care

Chronic, ambulatory-care-sensitive conditions such as alcohol abuse/dependence, bronchitis/asthma, and diabetes are best managed with ongoing care by primary care providers. However, many patients at the UCH-ED present with exacerbations of these conditions; many of these patients might view emergency treatment for these exacerbations as a substitute for ongoing primary care to control the conditions.

The SMH project is intended to link patients to primary care physicians. Therefore, partnerships with community-based health providers are considered important complementary components of this program. If the program is extended to address urgent care needs (as opposed to primary or emergent care), urgent care clinics might also be considered complementary additions to the project. The SMH could be used in tandem with other community-based health outreach programs.

Figure 3. Overall High Impact Potential: Medical homes network to link patients in emergency departments to community care

Because of the sizable burden of inappropriate ED use on both health care costs and patient health outcomes, experts generally agreed that the unmet need this program is purporting to address is important. Experts suggested that this program might be particularly impactful in improving health disparities and shifting patient care from the ED to the primary setting, where patients might be more appropriately managed over the long term. However, most experts noted that greater patient adherence to the program would be necessary to reach its full potential, and that more data is necessary to determine whether this intervention actually improves patient outcomes. Based on this input, our overall assessment is that this intervention has moderate potential for high impact.

Results and Discussion of Comments

Six experts, with clinical, research, and health systems backgrounds, offered their perspectives on this intervention.
Experts agreed that the need to link ED patients to primary care providers in the community is an important one, especially in light of the negative impact that ED overutilization (and community health underutilization) has on the health care system (e.g., excessive costs, long wait times) and patient outcomes.

Experts generally thought that this intervention has great potential to improve patient health outcomes by helping patients connect to ongoing appropriate primary care. However, several experts noted that only 35% of patients in the program actually kept their primary care appointments and opined that for this program to reach its full potential, efforts must be made to improve this percentage. Furthermore, some experts mentioned that for full evaluation of this program, data must be collected on how the new primary care relationship actually affects long-term health outcomes for patients.

Most experts thought that this program might have a significant impact on health disparities, particularly because, as one clinical expert pointed out, vulnerable populations (e.g., those of low socioeconomic status and racial or ethnic minorities) are less likely to be well-connected to a primary care physician. Experts generally agreed that this model has the potential to improve access to primary care for patients who inappropriately utilize the ED, and in turn, improve community health outcomes.

Experts thought that this model might cause moderate disruption to current health care infrastructure and patient management models, but in a generally positive way. Patient care would shift from the ED setting to the primary care setting, where patients would build a relationship with clinicians and be managed over an extended period of time, rather than being treated episodically in the ED. Experts appear to view these potential changes as a shift back to the way health care was intended to be delivered; as one clinical expert noted, this program “would facilitate the functioning of the existing health care infrastructure rather than disrupt it.”

In terms of clinical acceptance, most experts suggested that providers would accept this program, if it is proven to facilitate appropriate care for patients. However, several experts noted that for this program to be readily accepted by physicians, reimbursement policies and administrative work would have to be acceptable to the physicians involved.

Experts’ opinions on whether patients would readily adopt this program were divided. Some experts suggested that patients would appreciate the continuity of care and improved outcomes that primary care clinics could provide. Other experts suggested barriers to patient acceptance, including the difficulty of changing patient culture of ED use, the potential inconvenience of long wait times, and transportation issues. Several experts noted that to be adopted by patients, this program would need to address these barriers and ensure that the patient’s primary care experience is satisfying.

Most experts agreed that this program is likely to reduce long-term costs of care if ED visits are reduced. Some experts noted that initial costs (to implement the program) would likely be borne by the hospital, but that these upfront costs would likely be offset by future savings that might arise from the benefits of preventive care delivered in the primary physician setting.
Partnering Urban Specialists With Rural Primary Care Clinicians (Project ECHO) for Treatment of Complex, Chronic Conditions

Patients with chronic or complex diseases living in rural or medically underserved areas (e.g., prisons) where specialty care is in short supply or unavailable might experience substandard care because of access barriers, specialist shortages, geographical isolation, and other factors. Project ECHO™ (Extension for Community Healthcare Outcomes) is intended to address the unmet need of access to specialty care by aiding primary care clinicians in rural or underserved areas to develop more capacity to safely and effectively manage patients with chronic, common, and complex diseases in their communities.

Project ECHO is a health care delivery model developed at the University of New Mexico (UNM) Health Sciences Center (Albuquerque). It is intended to help develop rural communities’ “capacity for safe and effective treatment of chronic, common, and complex disease in rural and underserved areas while monitoring outcomes to ensure quality of care.” The program uses telehealth technology and clinical management tools to train and support rural primary care providers in developing knowledge about diseases that would typically fall within the realm of specialty care. According to program developers, this model enables providers to “deliver best-practice care for complex health conditions in federally qualified health centers and other community-based sites where this specialty care was previously unavailable.”

Project developers created the model to address the problem of hepatitis C virus (HCV) infection in New Mexico and have used that disease as a framework for describing the model’s execution. A partner site (e.g., a rural primary care practice) joins the network, at which point ECHO staff visit the site and conduct an orientation. This orientation includes an explanation of the HCV treatment protocol, the communications technology to be used, and the “case-based presentation format for the weekly 2-hour telemedicine clinics.”

Then, clinicians are organized into “disease-specific learning networks that meet weekly via videoconference to present cases.” For the HCV model, the specialty team included a hepatologist, a pharmacist, a psychiatrist, and a nurse. Also called “virtual grand rounds” or “teleclinics,” these conferences are led by specialists at academic medical centers who review and discuss cases with the rural clinicians and work with them to manage patients’ care according to evidence-based protocols. The program developers note that the specialists do not assume the care of patients, but instead guide the primary care provider in developing the skills and self-efficacy necessary to treat the patient. Additionally, during the case-based teleclinics, ECHO specialists make brief didactic presentations that are typically relevant to specific issues that arise, with these presentations intended to improve content knowledge. Lastly, patient outcomes are monitored through a centralized database.

According to project developers, the model’s case-based approach is designed to create a multilevel “learning loop” that allows primary care providers to: (1) “learn by doing,” using the guided feedback from specialists; (2) “learn from each other,” by interacting with other community-based primary care providers through the network; and (3) “learn from specialists,” through the didactic presentations given by ECHO specialists.

Project ECHO is under study as a way to improve management of patients with HCV infection or other chronic conditions. In a 2011 trial comparing the treatment of 407 patients with chronic HCV infection (who had received no previous treatment for the infection) at the UNM HCV clinic
or primary care clinicians at ECHO sites in rural areas and prisons in New Mexico, published results state: “A total of 57.5% of the patients treated at the UNM HCV clinic (84 of 146 patients) and 58.2% of those treated at ECHO sites (152 of 261 patients) had a sustained viral response (difference in rates between sites, 0.7 percentage points; 95% confidence interval, -9.2 to 10.7; p=0.89). Among patients with HCV genotype 1 infection, the rate of sustained viral response was 45.8% (38 of 83 patients) at the UNM HCV clinic and 49.7% (73 of 147 patients) at ECHO sites (p=0.57). Serious adverse events occurred in 13.7% of the patients at the UNM HCV clinic and in 6.9% of the patients at ECHO site.”

Current Approach to Care

Ideally, chronic, complex diseases (e.g., HCV infection) are treated by specialty care clinicians in academic medical centers or major hospitals. Project ECHO is intended to extend the reach of such specialty care to patients in rural or underserved areas where patients would otherwise face barriers to receiving this care. Because of the program’s focus on technologic communication, the program might compete with or complement other telemedicine programs, such as those initiated by the Indian Health Service and the Veterans Health Administration, which use telemedicine delivery systems to serve large underserved populations.

Figure 4. Overall High Impact Potential: Partnering urban specialists with rural primary care clinicians (Project ECHO) for treatment of complex, chronic conditions

Experts agree that this intervention is intended to fill an important gap in the health care system and is likely to have a significant impact on patient outcomes and access to care in rural areas. Health disparities may be particularly affected, and clinicians and patients alike are expected to accept this program. Some experts suggested that the long-term viability of this program will depend on whether funding is available, either from the government or other sources. Based on this input, our overall assessment is that this intervention is in the higher end of the high-potential-impact range.

Results and Discussion of Comments

Six experts, with clinical, research, and health systems backgrounds, offered comments on this program. Experts strongly agreed that the unmet need that this intervention purports to address is very important, citing the considerable lack of access to specialty care in rural or otherwise underserved areas compared with other areas. As one clinical expert pointed out, this access gap is likely to become even more pronounced in the future, because fewer medical students are choosing to enter primary care practice, but recent policy changes will increase the number of patients seeking care.

However, most experts believe that this intervention has potential to improve patient outcomes, based on both the limited trial data available and its underlying theory. Multiple experts pointed out
that although evidence is limited to one trial, the data collected from this trial showed improved patient health outcomes with Project ECHO, and may actually show better outcomes than care received in academic medical centers.

Experts agreed that this intervention has potential to dramatically affect health disparities, especially because it is intended to improve access to specialist services for patients with barriers to receiving this care. As one research-based expert stated, “the proposed intervention brings care to patients who otherwise will go without treatment.” Furthermore, two experts pointed out that this intervention would provide a mechanism for delivering culturally appropriate care for various subpopulations.

Several experts suggested that this program would have a notable impact on the way patients are managed, across several dimensions. First, patients would be able to receive care closer to home, and thus might be expected to seek care sooner. Additionally, patient volume in rural practices might be expected to increase as more patients participate in the program. However, a couple of experts stated that because the rural physicians would be, to a large degree, providing standard and accepted chronic care, that patient management may not change in terms of care protocols.

Although experts were extremely optimistic about this program’s potential to improve access to specialist care for patients in rural areas and its potential to improve health outcomes, several experts also expressed skepticism about the long-term sustainability of the program. Most experts raised the issue of funding and noted that this program will require either government funding or favorable reimbursement policies from third-party payers. Other experts suggested that the initial technology infrastructure, training, and new staffing resources that this program can require will pose a small, but likely not insurmountable, obstacle to diffusion.
Senior-Specific Emergency Departments for Treatment of Elderly Patients

As the U.S. population ages, seniors (i.e., individuals aged 65 years or older) are increasingly seeking care in EDs. However, EDs are not typically optimally equipped to handle the unique needs of this population, and 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 that are designed to cater specifically to the special needs of the senior population might help address these challenges and improve care for elderly patients in the ED.

Authors from several institutions, including Brookdale Department of Geriatrics and Adult Development at the Mount Sinai School of Medicine (New York, NY), and Holy Cross Hospital (Silver Spring, MD), have described models for senior-specific EDs, which are intended to “use specific interventions to improve patient satisfaction, comfort, and outcomes” in patients who are elderly. Although approaches to constructing or repurposing an ED space for seniors varies, one model described by researchers at the Brookdale Department of Geriatrics and Adult Development and the Mount Sinai School of Medicine illustrates the sort of design and approach (geriatric emergency department interventions [GEDIs]) that a senior-specific ED might entail.

GEDIs can be divided into two main types: structural modification and protocol interventions. (Other authors have described different category dimensions; for example, the Ontario School of Medicine’s framework divides interventions into those that address the physical environment, the social climate, hospital policies and procedures, and the health care system.)

According to clinical researchers, structural GEDI modifications that will make an ED more “senior-friendly” include reclining chairs or padded/lined stretchers to improve patient comfort and reduce pressure ulcers; large-faced clocks for improved visibility; calendars; boards with the names of hospital and clinical staff to reduce risk for patient delirium; fall prevention measures such as nonskid floor surfaces, handrails, aisle lighting, and bedside commodes; and visual and lighting aids that might reduce risk for delirium.

Clinical protocols that have the potential to improve senior patient outcomes include screening for cognitive impairment and delirium as part of routine practice, to identify early the patients who are at risk for these conditions and to assist in disposition, treatment, or discharge planning. Also deemed important is routine screening for risk of adverse health outcomes, return visits, or hospitalization; minimizing use of urethral catheters and other “tethering” devices that reduce patient immobility and increase risk for nosocomial infection and delirium; and creating a staff position for a nursing discharge coordinator to improve continuity of care, decrease the need for return visits, and increase patient satisfaction.

The first “Seniors Emergency Center” implemented in the United States (Holy Cross Hospital, Silver Spring, MD) illustrates how these interventions might be put into practice. The hospital created a separate, enclosed area of the ED specifically designed to meet the needs of seniors. Structural and environmental modifications include the use of special lighting, soft colors, and noise abatement features, handrails, flooring that is less likely to cause falls, thicker bed mattresses, telephones with larger buttons, and speakers in the bed pillows. The hospital also states that the care team at the center includes (in addition to physicians) a geriatric nurse practitioner, registered nurses trained in geriatrics, and a geriatric social worker. The hospital claims that unit staff receive training in both geriatrics and communication with elderly adults.
Current Approach to Care

According to clinical researchers from the Brookdale Department of Geriatrics and Adult Development and the Mount Sinai School of Medicine, space in the ED is designed for quick patient evaluation and turnover, with a physical layout designed to maximize use of available resources. However, this design poses many risks to the elderly population, including falls. 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, which increases risk of pressure ulcers; fluorescent lighting and a lack of windows, which promote disorientation in cognitively impaired older adults; and noise from monitor alarms, clinical staff, and other patients, which contributes to worsening delirium and communication difficulties in the potentially hearing-impaired population.

From a clinical point of view, traditional ED practice is not optimally suited for the senior population. For example, rapid triage and diagnosis—hallmarks of ED care—are difficult for older patients, who might have multiple comorbidities, polypharmacy, and 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. Furthermore, 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 this patient population, which increases the risk for developing delirium and infection.

Figure 5. Overall High Impact Potential: Senior-specific emergency departments for treatment of elderly patients

Most experts agreed that senior-specific ED care represents an important unmet need, that this model might improve outcomes in the target population, and that this innovation might dramatically impact hospital infrastructure and the manner in which patients are managed. However, expert enthusiasm for the model was tempered by the lack of outcomes data, and the opinion that all EDs should incorporate these changes for the benefit of the general population, rather than creating a separate ED with the described upgrades. Based on this input, our overall assessment is that this intervention is in the low high-potential-impact range.

Results and Discussion of Comments

Seven experts, with clinical, research, and health administration backgrounds, offered perspectives on this program.

Most experts agreed that the need for senior-specific EDs is important, because the elderly population is sizable and growing, and because the elderly population has multiple medical, social, and psychological needs that might not be identified or addressed in the traditional ED. However, a couple of experts suggested all EDs could benefit from improvements, and that rather than create
senior-specific EDs, hospitals might want to consider upgrading general EDs with the interventions described in this report.

Although several experts noted the lack of outcomes data regarding this intervention, most experts appeared optimistic about its potential to improve health outcomes in seniors. This support was based on the opinion that offering senior-specific care is “common sense” and is likely to “have a big health impact by improving patient safety (structural changes), focusing care delivery (protocols), and improve follow-up (staff to assist with discharge planning) of geriatric patients.”53,58 However, some experts suggested that most of these interventions could be implemented in general EDs, without creating a separate senior-specific ED, and that outcomes for the elderly population would still be expected to improve.

Experts agreed that this intervention will affect health disparities, although they were divided on whether this change would be positive. On one hand, some experts noted that this intervention would likely improve access to and quality of care for seniors visiting an ED. However, other experts expressed concern for worsening disparities, because only some hospitals would offer this program, which may widen disparities within the senior population; furthermore, diverting financial resources to this approach may reduce funds needed to close disparities gaps for other vulnerable populations.

In terms of cost, most experts agreed that creating a senior-specific ED would require a substantial initial cash outlay and that much of this expenditure would be realized through the structural modifications, staff training, and other infrastructure changes that implementing this intervention would require. However, some experts also suggested that hospitals might recoup some of these costs by reducing readmissions through this model. Although some experts expect that this intervention will be readily accepted by seniors who will enjoy being treated in a senior-specific facility, some experts stated that seniors would be unlikely to travel to a senior-specific ED if other EDs are located in closer proximity, and that the success of these EDs would require heavy marketing efforts on the part of the hospital.
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