AHRQ Healthcare Horizon Scanning System – Potential High Impact Interventions Report

Crosscutting Interventions and Programs

Potential High Impact Interventions Report

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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. HHSA29020100006C). 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 closer to diffusion into practice in the United States. Drafts of 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 those interventions that experts deem, 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 six 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 the horizon scanning, assessing the leads for topics, or provide 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 target technologies and innovations in health care and to create an inventory of target technologies 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 the analysis of 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 utilization 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 7,000 leads about topics have resulted in identification and tracking of more than 900 topics across the 14 AHRQ priority areas.

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 twice annually. Topics eligible for inclusion are those interventions expected to be within 0 to 4 years of potential diffusion (e.g., in phase III trials for pharmaceuticals or biotechnologies or in phase II or a trial with some preliminary efficacy data on the target population for devices and programs) 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 a profile on topics and issuing topic profile 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 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 high impact potential designation. We then associated topics that emerged as having potentially high impact with a further subcategorization of "lower," "moderate," or "higher" within the potential high impact 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 potential high impact is expected to change over time. This report is being 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 material on interventions in this Executive Summary and report is organized according alphabetically by disease state. Readers are encouraged to read the detailed information on each intervention that follows the Executive Summary. The table below lists the four topics for which (1) information was compiled by November 2011 in this priority area; *and* (2) we received six to eight sets of comments from experts between February and November 1, 2011. (A total of 14 topics in this priority area were being tracked in the system as of November 2011.) For purposes of the Potential High Impact Interventions Report, we aggregated related topics for summary and discussion (e.g., individual drugs into a class). We present four summaries on four topics (indicated below by an asterisk) that emerged as potential high impact on the basis of experts' comments and their assessment of potential impact.

Priority Area 15: Crosscutting Interventions and Programs
1. Barbershop-based medical screening and education programs
2. *Intelligent pills to monitor patient medication use
3. *Medical homes network (South Side Healthcare Collaborative) to link emergency department patients to community care
4. Online placeholder system for emergency care visits
5. *Partnering urban academic medical centers and rural primary care clinicians for treatment of complex, chronic conditions
6. Patient group appointments with physicians for management of chronic conditions
7. Portable Doppler ultrasonography for monitoring status of intrathoracic omental flap transposition
8. *Senior-specific emergency departments for treatment of elderly patients

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.

Intelligent Pills to Monitor Patient Medication Use

- **Key Facts**: The Raisin System™ (Proteus Biomedical, Inc., Redwood City, CA), a form of smart-pill technology, is being investigated for use in the treatment of chronic diseases requiring ongoing medication, such as tuberculosis, diabetes, heart failure, and mental health disorders and to reduce organ rejection after transplantation. 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 detection accuracy and negative detection accuracy in detecting ingested markers was over 97% and medication adherence was >85%. The most common adverse effect was mild skin rash from the monitor's electrodes, and no serious events were reported. The company has received FDA marketing clearance for the monitoring device in March 2010, but not yet for the IEM.
- **Key Expert Comments**: Some experts commenting on this topic remained skeptical about this intervention's potential to actually improve compliance, but all the experts predicted that this intervention could have a significant impact on many health system parameters. Experts though that the intervention's greatest impact would likely be the controversy it might inspire, due to concerns about "Big Brother" monitoring. Experts also predicted, 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**: High

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

- **Key Facts**: The University of Chicago's Southside Medical Homes (SMH) Network is intended to link patients who overuse or misuse the emergency department (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 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 ER Community Portal, which allows community physicians to access the 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 a potentially high 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 in shifting patient care from the ED to the primary setting. However, most experts noted that greater patient adherence to the program will be necessary for it to reach its full potential.
- **Potential for High Impact**: 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, NM) 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 normally fall within the realm of specialty care. A specialist (likely 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 currently being investigated for its viability to improve management of patients with hepatitis C virus infection or other chronic conditions.
- **Key Expert Comments**: Though experts 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, several experts were skeptical about the program's ability to be rolled out on a large scale. This skepticism stemmed from unanswered questions about reimbursement and the potential infeasibility of equipping rural physicians' offices with the technology needed to sustain this program.
- **Potential for High Impact**: Moderately high

Senior-specific Emergency Departments for Treatment of Elderly Patients

- **Key Facts**: Some hospitals are now offering senior-specific EDs. These EDs are designed to cater specifically to the special needs of the senior population in an effort 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, 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 senior-specific ED care represents an important unmet need, that this model might improve outcomes in the target population. They also agreed that this innovation might dramatically impact hospital infrastructure and the manner in which patients are managed. However, experts' enthusiasm for the model was somewhat tempered by the paucity of available outcomes data at this time.
- **Potential for High Impact**: Moderately high

Crosscutting Interventions and Programs

Intervention

Intelligent pills to monitor patient medication use

Effective medical therapy for many chronic diseases depends on patient adherence in taking prescribed medications in the proper sequence and 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%.[1] Therefore, an unmet need exists for technologies that might help improve patient adherence with medication dosages for chronic disease.

The Raisin System™ (Proteus Biomedical, Inc., Redwood City, CA) is a form of smart-pill technology that is being investigated for use in the treatment of chronic diseases requiring ongoing medication such as tuberculosis, diabetes, heart failure, and mental health disorders and to reduce organ rejection after transplantation.[2] The system is comprised of ingestible event markers (IEMs), which are tiny microchip sensors that are affixed to conventional pharmaceuticals (i.e., pills), and a personal monitor. The IEMs are made from common food ingredients and 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 physiological data such as heart rate. The personal monitor transmits collected patient data to the patient's Bluetooth-enabled cell phone or other computerized device. The data is then encrypted and forwarded to a secure database that physicians can access to review the patient's condition.[2]

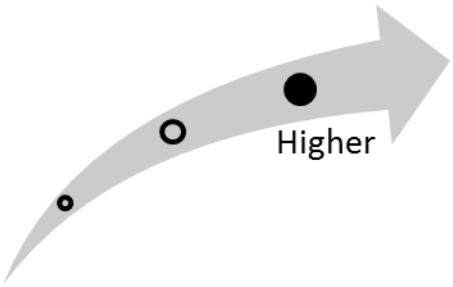
In results of a clinical trial of 111 subjects who ingested 7,144 ingestible markers, investigators published the following: "The system's positive detection accuracy and negative detection accuracy in detecting ingested markers were 97.1% and 97.7%, respectively. It differentiated 100% of multiple drugs 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."[3]

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.[4] 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.[5]

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.[2]

Figure 1. 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, they generally predicted that this intervention could have a very 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 predicted 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 is in the higher end of the high potential impact range.

Results and Discussion of Comments

Seven experts, with clinical, research, health systems, and health administration backgrounds, offered perspectives on this intervention.[6-12] 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 substitution 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 predicted 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 usually 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 compliant their patients are 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."[12] 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, though 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 does fall 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.

Program

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.[13] The University of Chicago's Southside Medical Homes (SMH) Network is intended to link patients who overuse or misuse the ED with community-based, primary care providers.[13] This model, if proven effective, might serve as a template for other hospital systems facing the same challenges.

The University of Chicago Hospital's (UHC) 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."[13,14] According to the SMH project developers, specific goals of the program include: (1) to build a sustainable safety net system that links ED patients 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.[13]

The SMH program was established in 2005, in partnership with local community-based health centers.[13,15] According to program developers, the project's foundation is a collaborative organization between the UCH-ED and 18 community-based health care providers.[13] When patients visit the ED, they are flagged if they are identified as lacking a medical home.[13] ED-based patient advocates (or "navigators") visit these patients, either while the patient is awaiting medical care or before discharge from the ED.[13]

The patient advocates are members of the ED staff who are recruited from the community and trained in the UCH-ED.[13] 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.[13] 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.[13] 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.[13] Patients who leave the ED without being seen are contacted by a patient advocate via telephone.[14]

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.[14,16] Some of the partnering community health centers reserve certain appointment slots for SMH-referred patients.[14]

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 ED patients: (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.[13]

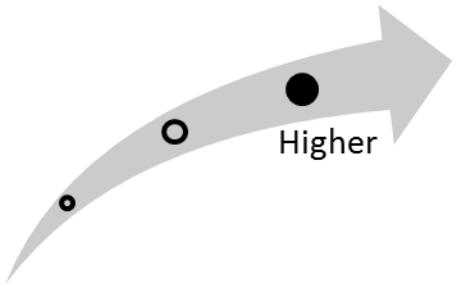
According to the program's sponsor, in the first 5 years of the program (initiated in 2005), the SMH has educated 27,000 patients on the health care resources available in the community, and more than half of those patients have been successfully connected to primary care doctors on the South Side of Chicago.[15] However, only about 35% of the approximately 16,000 primary care appointments made through the project were kept by patients.[17] In a 2008 study of the program, which involved 950 patients and six 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."[13]

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.[13] 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.[13]

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



Experts viewed this program as having potential high impact because of the sizable burden of ED overcrowding and underutilization of primary care services. 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 greater patient adherence to the program would be necessary to reach its full potential. 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

Seven experts, with clinical, research, health systems, and health administration backgrounds, offered their perspectives on this intervention.[18-24] 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 health system resources and patient outcomes.

Experts generally predicted that this intervention has great potential to improve patient health outcomes by giving patients access to ongoing appropriate primary care, especially by reducing acute exacerbations associated with chronic conditions. However, many 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.

Most experts predicted that this program would have a significant impact on health disparities, for two reasons: (1) access to primary care would improve for patients who are underserved, and (2) chronic conditions that can be improved by this model disproportionately affect minority populations. One clinical expert noted even broader implications: "…the effects of a medical home on individuals' health…would also affect their quality of life, earning potential, and the well-being of their families."[18]

Experts predicted that this model might cause moderate disruption to current health care infrastructure and patient management models, but in a positive way. Patient care would shift from the ED setting to the primary care setting. This shift might, in turn, increase staffing and other resources needed in community clinics, though some experts predicted that current staffing/resource levels would easily absorb the increase in patient volume. EDs would need to hire and train patient advocates to effectively implement the program. Relationships with community providers would need to be established. If patients are successfully diverted to community primary care providers, wait times and care for ED patients with truly emergent conditions might be reduced.

In terms of clinical acceptance, most experts suggested that providers (both in the ED and in community health centers) would readily adopt the program, though one research-based expert commented, "Based on the existing patient load and staff resources [in community health centers], there might be some pushback."[21] Similarly, one clinical expert suggested that ED physicians might be reluctant to accept the program if too many of their patients were diverted.

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 having to keep appointments and visit the clinic during set office hours, transportation issues, and out-of-pocket costs.

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.

Program

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.[25] 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 community.[25]

Project ECHO is a health care delivery model developed at the University of New Mexico Health Sciences Center (Albuquerque, NM). 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."[25] 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 the program's 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."[25]

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."[25]

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.[25] 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.[25,26] 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.[25] 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.[25,26] Lastly, patient outcomes are monitored through a centralized database.[25]

According to the 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.[25,26]

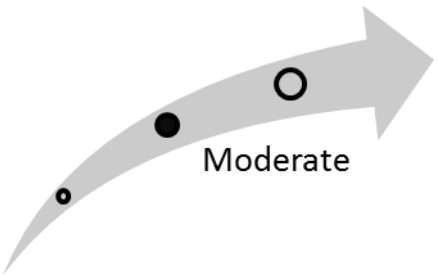
Project ECHO is currently under study as a way to improve management of patients with HCV infection or other chronic conditions.[25] In a trial comparing the treatment of 407 patients with chronic HCV infection (who had received no previous treatment for the infection) at the University of New Mexico 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."[26]

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.[25] 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.[27]

Figure 3. Overall High Impact Potential: Partnering urban specialists with rural primary care clinicians (Project ECHO) for treatment of complex, chronic conditions



Though experts 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, several experts were skeptical about the program's ability to be rolled out on a large scale. This skepticism stemmed from unanswered questions about reimbursement and the potential infeasibility of equipping rural physicians' office with the technology needed to sustain this program. Based on this input, our overall assessment is that this intervention is in the moderate high potential impact range.

Results and Discussion of Comments

Seven experts, with clinical, research, and health systems backgrounds, offered comments on this program.[28-34] Experts 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. However, experts offered differing opinions on whether this program has potential to truly meet this need. Most experts predicted that this intervention has potential to improve patient outcomes, based on both the limited trial data available and the underlying theory. As one expert with a clinical and research background stated, this program "provides the needed tools (i.e., education, protocols, networking, outcomes analysis) that primary care physicians practicing in rural areas need to care for patients with complex chronic diseases."[30] However, one health systems-based expert suggested that this model has too many barriers to implementation: "Given the limitations of connectivity and reimbursement for patient contact time, not to mention the education time [involved], the intervention as designed has minimal potential to improve patient health."[29]

Experts agreed that this intervention has potential to dramatically affect health disparities, especially because it is intended to improve access to specialist care. One research-based expert stated, "The program seems to target patient populations [with] limited access to care and to better equip health care staff in these communities."[34]

Several experts suggested that this program would have a significant impact on the way patients are managed, across several dimensions. First, specialty care would be available in previously underserved areas, which would "bring quality treatment to the patient, rather than requiring the patient to travel long distances for care, or go without."[33] Secondly, this program could equip "health care staff with the knowledge/tools to identify and treat diseases in the early stages of development," which might lead to changes in the clinical pathway that patients follow.[34] Finally, the incorporation of technology into patient management is considered a relatively novel approach: "Treating patients by 'remote control', [during which] specialists do not assume the care of patients and onsite primary care providers need to develop skills and gain patients' trust, is a significantly different way to manage patients."[28]

Most experts noted that for implementation, this program might require several adjustments to the infrastructure of rural primary care offices, including "internet access, telephone services, fax, speaker phone…teleconferencing capability…2-day orientation and commitment from faculty to participate in the program, which [requires] weekly 2-hour teleclinics."[30] Several experts predicted that the technologic requirements (e.g., broadband Internet) would pose the greatest barrier to the program's uptake in rural areas.

Several experts also suggested that unanswered questions about reimbursement would pose a significant challenge to this program's implementation. The pilot program described above is funded by grant monies, and experts were skeptical about the sustainability of the program without long-term funding. Experts predicted that creating integrating the program's services into a reimbursement schedule would be necessary for the program's continued sustainability.

Intervention

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.[35] 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.[35] 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.[35]

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 elderly patients.[35-37] 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.[35]

GEDIs can be divided into two main types: structural modification and protocol interventions.[35] (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.)[38]

According to the 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.[35]

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 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.[35]

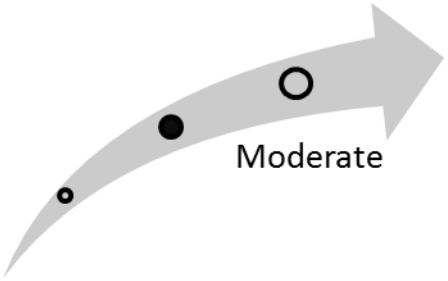
The first "Seniors Emergency Center" implemented in the U.S. (Holy Cross Hospital, Silver Spring, MD) illustrates how these interventions might be put into practice.[37] The hospital created a separate, enclosed area of the ED specifically designed to meet the needs of seniors.[37] Structural and environmental 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.[37] The hospital also states that the care team that works in the center includes (in addition to physicians) a geriatric nurse practitioner, registered nurses trained in geriatrics, and a geriatric social worker.[37] The hospital claims that unit staff receive training in both geriatrics and communication with elderly adults.[39]

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.[35] 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 contribute to worsening delirium and communication difficulties in the potentially hearing-impaired population.[35]

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.[35] Clinical researchers state these challenges, combined with the pressure to make rapid diagnoses, can increase the risk of incorrect or missed diagnoses.[35] 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.[35]

Figure 4. Overall High Impact Potential: Senior-specific emergency departments for treatment of elderly patients



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 somewhat tempered by the lack of outcomes data. Based on this input, our overall assessment is that this intervention is in the moderate high potential impact range.

Results and Discussion of Comments

Eight experts, with clinical, research, and health administration backgrounds, offered perspectives on this program.[40-47] Experts generally agreed that the need for senior-specific EDs is important, for several reasons: (1) the elderly population is sizable and growing; (2) the elderly population has multiple medical, social, and psychological needs that might not be identified or addressed in the traditional ED, and (3) outcomes in this patient population are suboptimal.

Despite a paucity of outcomes data thus far for this program, most experts appeared optimistic about its potential to improve health outcomes in seniors. As one research- and clinical-based expert stated, one expects "that specialty care of this sort would improve patient safety by providing a more senior-friendly environment, assessment of needs, and education on current prescription medications."[42] More than one expert likened the senior-specific ED to the pediatric ED, and predicted that the senior-specific ED would be similarly successful in improving outcomes. However, most experts suggested that outcomes data are needed before this approach would diffuse widely.

However, one expert, speaking from a health administration viewpoint, suggested that this innovation is "more of a marketing effort than a genuine intervention," because "most of the description is about amenities," "many EDs currently employ discharge planners to help arrange a safe

discharge," and "many of the physical enhancements would be more useful on [a] nursing unit, where geriatric patients spend more time."[46]

Experts predicted that creating a senior-specific ED would disrupt existing hospital infrastructure and, in some cases, this disruption might pose a barrier to implementation. Creating the ED would require structural modifications (i.e., renovation of existing space or construction of a new space). The model requires a novel staffing mix and staff training program, and hospitals would need to purchase specialized equipment for a senior-specific ED. However, as one research-based expert pointed out, "these [changes] could be incrementally implemented depending on [the] fiscal, physical, and demographic challenges of hospital systems."[47]

Several experts predicted that senior-specific EDs would noticeably alter patient management protocols for this population. First, "a large culture change is anticipated," in that "patients over 65 would be assessed in a different way to take into account [their] special needs."[42,43] As one research-based expert commented, "The 'treat and street' adage for most general EDs will not apply. Instead, closer patient management with a goal of reducing patient readmission will be required." Some experts also noted that this innovation might shorten lengths of stay, reduce readmissions, and shift some care to the outpatient setting.

In terms of cost, most experts agreed that creating a senior-specific ED would require substantial initial cash outlay. However, most experts also suggested that hospitals might recoup some of these costs by reducing readmissions through this model. One health administration expert suggested that this intervention might financially "backfire on hospitals by generating increased payer denials for medical necessity," or by increasing the number of "social admissions."[46] Another research-based expert expressed concern that hospitals will pass along to the elderly patients the cost of constructing the ED and providing senior-specific care.

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