GETTING TO VALUE:

ELEVEN CHRONIC DISEASE TECHNOLOGIES TO WATCH

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ACKNOWLEDGEMENTS

ABOUT NEHI

NEHI is a national health policy institute focused on enabling innovation to improve health care quality and lower health care costs. In partnership with members from all across the health care system, NEHI conducts evidence-based research and stimulates policy change to improve the quality and the value of health care. Together with this unparalleled network of committed health care leaders, NEHI brings an objective, collaborative and fresh voice to health policy. For more information, visit www.nehi.net.

INTRODUCTION

Confronted with shrinking budgets and growing costs, the U.S. health care system is under pressure to create value-based health care. Innovative health care technologies play a critical role in the quest for value; they offer the potential to lower costs while enhancing clinical outcomes, all the while expanding the reach of care to at-risk populations.

Despite their potential, high-value technologies are under-used, held back by systemic barriers that hinder technology adoption and innovation. This report seeks to address that missed opportunity and identify technologies with both clinical and financial benefits. Each of the profiled technologies has the potential to improve quality, reduce costs and positively impact the health of chronic disease patients, especially those from safety-net and at-risk populations. The report also identities cross-cutting lessons learned about the role of technology in creating value and an overview of some of the barriers that hold back their adoption.

This report was created to serve as both a resource and guide for state and national policy-makers, institutional decision-makers, and other influencers of technology adoption. These stakeholders can drive greater adoption of these eleven technologies and implement changes at both the institution and policy level to inspire future innovation and adoption of other high-value technologies.

BACKGROUND

Scan for Innovative Technologies

The scan was undertaken to identify promising, but underused, mobile and telehealth technologies with the potential to reduce the cost and maintain or improve the quality of care for the target population of chronic disease patients with a special focus on California's safety-net and underserved patient populations.

Chronic diseases, including cardiovascular conditions, diabetes and asthma are among the most costly, deadly and debilitating medical conditions facing Americans. Nearly one in two American adults has at least one chronic disease[1] and more than 75 percent of the nation's total medical care costs are spent on chronic diseases.[2] The burden of chronic diseases often falls on the safety-net and underserved populations.

The safety-net delivery system is underfunded, understaffed and often lacks the financial resources, human resources and information technology infrastructure needed for proper chronic disease management. Compounding the challenge, the safety-net population is all too often uninsured or underinsured. As a result, many lack access to resources to properly manage their diseases, leading to frequent use of health care services and contributing to unnecessary spending. Adding to the difficulty, the safety-net population faces additional challenges that may limit access to and adoption of mobile and telehealth technologies. Additional challenges include literacy, language barriers, housing instability and mobile technology and internet access.

Despite these challenges, innovative technologies designed for chronic disease care can support better monitoring and management of chronic conditions for underserved populations, and can reduce unnecessary hospitalizations and lower the cost of chronic disease care.

Scan Process: From Eighty to Eleven

The technology scan process was developed by NEHI, building on significant experience identifying promising technological innovations that are under-used, but show promise in improving the quality and reducing the cost of health care. NEHI's technology scan process seeks to expedite the identification and adoption of technologies, "disruptive innovations" and new models of technology-enabled care for chronic disease patients, especially those in underserved populations.

The scan process began by identifying over eighty technologies highlighted in the literature and/or mentioned in expert interviews that had the potential to address the target population of chronic disease patients, especially those in California's safety-net population. These 80 technologies were winnowed down to 11 through a process that

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[1] CDC (2011). Chronic Disease and Health Promotion, Retrieved from: http://www.cdc.gov/chronicdisease/overview/index.htm, Last accessed February 2012.
[2] American College of Physicians. (2009). Costs and Quality Associated with Treating Medicare Patients with Multiple Chronic Conditions. Internal Medicine, May 18, 2009. Retrieved from http://www.acponline.org/advocacy/events/state_of_healthcare/costs_quality.pdf. Last accessed December 2011.

identified those technologies with the highest potential for clinical benefit, cost savings and adoption. This down-selection process utilized criteria including low current adoption, future potential for benefit, alignment with the safety-net population, low cost, broad application, identifiable barriers, positive user experience and multiple products/manufacturers.

Since the scan was created to identify *emerging* technologies that have the potential to improve both cost and quality, there were few published articles with irrefutable data on their efficacy and proven cost-reduction capabilities. Instead, there was a range of data about the innovations that spanned the spectrum from anecdotal evidence (for those technologies still in development) to demonstration project outcomes to peer-reviewed articles with randomized controlled trial evidence. A global perspective was employed to evaluate the financial benefits of these technologies. Some technologies may require significant upfront investment and appear too costly to implement; however, they have the potential for long term efficiencies and future cost savings. Those technologies that met the basic evidence criteria listed above were included in the detailed analysis phase and profiled in this report. Details of the specific down-selection criteria are provided in the Appendix.

Technologies Profiled

The eleven profiled technologies all share the potential to lower cost and maintain or improve clinical outcomes for the target population, but vary considerably in terms of the quality and quantity of supporting evidence and current level of adoption. To illuminate these differences, NEHI placed these technologies on an "adoption readiness spectrum" ranging from those with less evidence or more significant barriers to technologies with strong evidence, minimal barriers and potential for early widespread adoption.

CLASS I	*These technologies have significant evidence supporting clinical and financial benefits; however, a small number of non-evidence barriers stand in the way of widespread adoption. If successful policy interventions are undertaken, the technology is primed for widespread adoption in the near-term.*

Extended Care eVisits   *Home Telehealth*   *Tele-Stroke*

| **CLASS II** | *These technologies leverage a well-established clinical intervention that is recognized in the literature to have clinical or financial benefit <u>and</u> to have some evidence to support the impact of the technology itself. They are generally closer to adoption, but still require further study of clinical or financial benefit and face significant non-evidence adoption barriers.* |

Mobile Clinical Decision Support

Virtual Visits

| **CLASS III** | *These technologies leverage a well-established clinical intervention that is recognized in the literature to have clinical or financial benefit. These technologies are the mobile health extension of these proven interventions so one can assume there are clinical and financial benefits; however, further study is needed to robustly verify this assumption for each individual technology.* |

Mobile Diabetes Management Tools

Medication Adherence Tools

Mobile Asthma Management Tools

CLASS IV	*These technologies are promising ideas with minimal evidence to support clinical or financial benefit at this point in time. Most have a several-year horizon before widespread adoption is feasible as the technologies need to be refined and evidence needs to be generated.*

In-Car Telemedicine

Social Media Promoting Health

Mobile Cardiovascular Tools

Detailed profiles for each of the eleven technologies follow, including their use cases, clinical benefits, financial benefits, barriers to adoption and next steps to implementation to facilitate adoption.

TECHNOLOGY PROFILES

NEHI

An Innovative Technology Profile:

Extended Care eVisits

Image Courtesy of InTouch Health

Class I

Extended Care eVisit technologies enable physicians to consult with nursing home patients who require physician services. Most physicians are unable to make routine visits to extended care facilities as they are often seeing patients at many facilities and maintain a community practice as well. As a result, most patients receive physician care in a hospital setting often resulting in overuse of the emergency department (ED) among the elderly. A survey of physicians revealed the startling reality that nursing home physicians spend on average less than two hours per week on site.[1] Extended Care eVisit technologies address the physician shortage challenge providing around-the-clock on-call physician coverage and timely access to physicians.

The technologies vary in sophistication but all have voice and/or videoconference functionality connecting a physician hub to nursing home residents at their bedside. Some products consist of simple push carts the nurse can bring during rounds, while others are robotically enabled carts that do not rely on the nurse's assistance.

Vendors continue to emerge on the market and include PhoneDOCTORx and InTouch Health.

Use Case

- The demand for long-term care continues to grow:
    - In the United States, 1.5 million people inhabit nursing homes.[2]
    - As the baby-boomer generation ages the number of extended care residents will increase.
- Extended Care eVisit technologies enable remote interactions between residents and providers when physicians are scarce.
    - These technologies provide around-the-clock audio and/or video consultations for non-urgent, urgent and emergent issues, decrease the burden on primary care physicians after-hours and on weekends and reduce avoidable transfers to the ED.
    - They can also be used for new admissions, laboratory and radiology test reviews, provision of short-term prescriptions for pain and other medications, review of admission orders and medication lists for patients being admitted, management of behavioral and pain control issues, family consultation and staff education.
- The number of installed units for these technologies continues to grow:
    - One manufacturer has logged 29,000 physician-patient encounters and enrolled 15 facilities to date.[3]

Clinical Benefit

- Extended Care eVisit technologies may reduce unnecessary ED visits and hospital admissions:
    - Eight percent of U.S. nursing home residents had an ED visit in the past 90 days.[4]

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[1] Dembner, A (2006). Nursing Homes Seen Deficient on Basic Care. The Boston Globe, July 3, 2006. Accessed January 2012.
[2] Kaiser Family Foundation (2011). Medicaid and the Uninsured: Medicaid and Long-Term Care Services and Supports, March 2011. Retrieved from http://www.kff.org/medicaid/upload/2186-08.pdf. Accessed January 2012.
[3] PhoneDOCTORx (2011). PhoneDOCTORx Product Overview. Retrieved from http://phonedoctorx.com/includes/docs/ADOL_One_Pager.pdf. Accessed January 2012.
[4]CDC (2004). Potentially Preventable Emergency Department Visits by Nursing Home Residents: United States 2004. Retrieved from http://www.cdc.gov/nchs/data/databriefs/db33.htm. Accessed January 2012.

- o Among nursing home residents with an ED visit in the past 90 days, 40 percent had a potentially preventable ED visit. Falls accounted for over one-third of preventable visits, heart conditions (mainly chest pain, pressure, burning, and heart failure) accounted for almost 20 percent, pneumonia for 12 percent and the remaining one-third included mental status changes, urinary tract infections, gastrointestinal bleeding symptoms, fever, metabolic disturbances, and skin diseases.[5]

- Evidence showing the clinical benefit of these technologies is growing; however, additional studies generating robust data are needed. For the most part clinical benefit has only been shown by manufacturers to date:
  - o One manufacturer claims that use of their technology can reduce transfers to the ED and hospital admissions and readmissions by more than 35 percent.[6]
  - o One case study of nursing home eVisit technology resulted in a 57 percent transfer prevention rate.[7]
  - o Another case study yielded positive results. Of 2,500 calls taken in one year, 37 percent were urgent cases where an ED visit was avoided (manufacturer, n=110).[8]

Financial Analysis

- Long term care accounts for a significant amount of health care spending:
  - o In 2006, nearly $178 billion was spent on long-term care services.
  - o Nursing home care averages $72,000 per year, assisted living facilities average $38,000 per year, and home health services average $21 per hour.[9]

- Many extended care residents are dually eligible for Medicare and Medicaid complicating the ROI for these technologies; however, the financial burden is largely placed on Medicaid:[10]
  - o Medicare covers hospital care, physician services, diagnostic tests, and limited SNF services in nursing homes following hospitalizations.
  - o Medicaid pays the deductible and coinsurance for Medicare-covered physician and hospital care, and covers long-stay services in nursing homes for low-income beneficiaries or those with high medical costs. In some states, bed-hold policies allow nursing homes to capture partial per-diem payments while a resident is admitted to the hospital.
  - o Medicaid accounts for 40 percent of total long-term care spending, Medicare provides limited post-acute care accounting for slightly less than one-quarter of spending and direct out-of-pocket care spending accounts for 22 percent of spending.[11]

- Evidence for the financial benefits of these technologies is strong:
  - o The New York state study stating 40 percent of nursing home hospitalizations were avoidable also suggested avoidance of hospitalizations would amount to $223 million in savings (based on a cost estimate of ~$12,000 per hospitalization).[12]
  - o An unnecessary hospital admission can cost upwards of $13,000, while the cost of an eVisit consultation can be as little as $40.[13]

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[5] CDC (2004).
[6] PhoneDOCTORx (2011).
[7] PhoneDOCTORx (2011).
[8] PhoneDoctoRX (2008). PhoneDoctoRX Interview, October 17, 2008.
[9] Kaiser Family Foundation (2011).
[10] Polniaszek, S (2011). Hospitalizations of Nursing Home Residents: Background and Options, U.S. Department of Health and Human Services, June 2011. Retrieved from http://aspe.hhs.gov/daltcp/reports/2011/NHResHosp.htm. Accessed January 2012.
[11] Kaiser Family Foundation (2011).
[12] Grabowski, D (2007). The Costs and Potential Savings Associated With Nursing Home Hospitalizations. *Health Affairs,* 2008; 26(6): 1753-61.
[13] Donnelly, J. (2011). Dial-a-Doctor: Service is Gaining Traction at Nursing Homes, Boston Business Journal December 16, 2011. Retrieved from http://www.bizjournals.com/boston/print-edition/2011/12/16/dial-a-doctor-service-is-gaining.html. Accessed January 2012.

- A health plan for dual eligibles in Massachusetts pays for these services per member per month and reduced unnecessary hospitalizations by 57 percent.[14]
- These technologies require a fixed cost investment and a management fee over time. The return on investment for a 110 bed skilled nursing facility after one year is described below:[15]
    - The fixed cost investment for a unit is ~$10,000.
    - A representative management fee structure for an average skilled nursing facility is $2/bed/day (~$80K per year)
    - Therefore, the total first year cost is $90,000 (equipment plus management fee), total savings from reduced ED visits alone is approximately $283,000 and net savings to the system is $193,000 (not including savings from reduced hospitalizations) per 110-bed SNF.

Barriers to Adoption

- *Financial Barriers*: The current reimbursement structure for long term care is complex and extended care facilities are already resource constrained.
- Business Model: The system requires access to an extended care facility or insurer that offers this service.
- *Legal and Licensure Barriers*: Medical licensure regulations limit cross state medical consultations.
- *Privacy Concerns*: Patients and providers may be concerned when information is shared over the internet.
- *IT Infrastructure*: Many are not interoperable with EHRs at this point in time.
- Limited Data: More research is needed to quantify cost-effectiveness and net savings accrued by using the eVisit technologies, and on the validity of the presumed benefits of the system.

Next Steps to Implementation

1. Implement a Gain-Sharing Model: Due to the complicated reimbursement challenges for nursing facilities, they often are hesitant to make the capital investments and pay for the ongoing service fees when insurers are likely to see the financial benefit. The development and implementation of a gain-sharing model similar to the approach taken by providers in Accountable Care Organizations, is one approach to addressing this funding challenge. In this new model, nursing facilities are more likely to invest upfront if they have a greater stake in the savings.

2. Address Cost Shifting Issues for Dual Eligibles: Address the reimbursement challenges and misaligned incentives created by Medicare and Medicaid. For example, some studies have found that bed-hold policies may inadvertently incentivize hospitalizations.

3. Create Public Networks: To ensure these services are available to underserved populations, the government should subsidize the development of physician hubs for this purpose. With this approach, the upfront investment is minimized ultimately making the technologies accessible to more patients.

4. Consider Developing a Licensure Requirement: The implementation of regulations or guidelines that require nursing facilities to meet certain physician access standards would likely promote the adoption of extended care evisits. For example, extended care facilities should guarantee access to physician services within an hour of an event. With this approach, regulators could offer a "Seal of Approval", initially moving towards more stringent guidelines when the reimbursement issues are resolved.

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[14] Donnelly, J (2011).
[15] PhoneDoctoRX (2008).

Home Telehealth

Home Telehealth (HT) technology provides a telemedicine tool for patients to take an active role in the management of their chronic diseases. HT works by allowing patients to transmit vital health data from their home to physicians' offices and, in turn, receive health coaching from their providers based on the clinical data they transmit. A HT system generally consists of a standalone hub device that collects physiologic data from peripheral devices and connects the patient to the provider via interactive/audio/video capabilities.

HT tools include audio and video conferencing capabilities, allowing remotely located health care professionals to interview, observe and educate the patient. In addition, HT tools assist in the use of the peripherals or other medical devices. Furthermore, advanced HT tools have the ability to show full-motion video, which can be used to provide patient education.

A representative sample of these tools includes Bosch Health Buddy and Philips TeleStation.

Use Case

Telemedicine approaches may not be appropriate for all Americans suffering from chronic disease, but recent estimates suggest a sizeable portion may benefit.

- The Veterans Health Administration (VHA) estimates that 75,000, or about 50 percent, of its total patient population could be cared for with home telemedicine technologies.[1]

- HT tools, with their interactive capabilities, offer the potential to positively impact a broader segment of the chronic disease population compared to other approaches like traditional remote patient monitoring (RPM), which have been shown to be effective primarily for the most serious chronic disease patients.

Despite the large number of HT technologies available in the marketplace, the current installed base of HT devices still remains relatively small, particularly in light of the immense target population of chronically ill patients. The majority of HT devices currently in use are still part of pilot or demonstration projects.

- The Health Buddy technology is currently being used by the Department of Veterans Affairs in 50 different health management programs across 18 Veterans Integrated Service Networks. The technology is also being used in the Medicare High Risk Demonstration project with approximately 1,000 patients in California.

- Centura Health at Home, Colorado's largest health care system, is currently offering LifeView to 167 Medicare members with heart failure, COPD and diabetes.

Some HT devices are more well-known and well-established.

- IDEAL LIFE Wireless devices have been used by The Roanoke Chowan Community Health Center (RCCHC) in more than 28 counties throughout North Carolina and by CareMore, a California-based company operating 26 care centers serving more than 50,000 Medicare Advantage patients.[2]

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[1] Darkins, A., Ryan, P., Kobb, R., et al. (2008). Care Coordination/Home Telehealth: The Systematic Implementation of Health Informatics, Home Telehealth, and Disease Management to Support the Care of Veteran Patients with Chronic Conditions. *Telemedicine and e-Health*, December 2008, 1118-1126.
[2] IDEAL LIFE. Interview. January 2012.

It has been well-established in the literature that HT tools promote improved clinical outcomes by providing patients with a means to actively monitor their condition. Specifically, HT tools have been found to improve health status by reducing the risk for emergency room visits and hospital readmissions, decreasing hospital length-of-stay and improving survival rates.

- Reduction in Emergency Department (ED) visits:
  - In a study of 40 in-home patients conducted by RCCHC those who used the Health Buddy HT over a six-month period had 69 percent fewer ED visits compared with the previous six months.[3]
  - A pilot study for the LifeView device found a 100 percent reduction in ED visits over a six-month period with the use of HT.[4]
  - In a yearlong study of 791 chronic disease patients who used the Health Buddy system through the VHA, a 40 percent reduction in ED visits was achieved.[5]

- Reduction in hospitalizations and hospital readmissions:
  - The largest study of HT to date, conducted by the VHA over an 18 month period, found a nearly 20 percent reduction in hospital admissions for the HT study group, compared to a 4.6 percent decrease in the entire VHA (non-telemedicine) population.
  - The RCCHC study noted a 71 percent reduction in hospitalizations with the use of HT over approximately one year.[6]
  - A Tufts Medical Center study of 188 heart failure patients over a 90-day period following the initial hospital stay found that hospitalizations related to heart failure were reduced by 72 percent with the use of HT and by 63 percent for other cardiovascular conditions.[7]
  - A Community Health Partners in North Carolina study of IDEAL LIFE Wireless found the total number of emergency room visits during the six months before implementation was 127 as compared to only 49 visits during implementation and 27 during the three months after discharge (n=73).[8]
  - A CareMore study reported a hospitalization rate 24 percent below average.[9]

- Reduction in hospital length of stay:
  - The VHA study also found a 25 percent reduction in the number of bed days.[10]
  - A separate, year-long study found a reduction of 60 percent in hospital bed days.[11]
  - The RCCHC conducted a three-year feasibility study using IDEAL LIFE Wireless devices of 198 patients and found that the total number of hospital-bed days was 199 during the six months before implementation as compared to only 99 during the six months of implementation and 70 during the 24 months after discharge.[12]
  - A CareMore study reported hospital stays 38 percent shorter in length using IDEAL LIFE'S devices.[13]

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[3] Britton, B. (2008). Telehealth Unbound: From Home Health Care to Population Based Care. Program Abstracts from the 13th Annual American Telehealth Association Meeting on April 7, 2008 in Seattle, WA. Retrieved from http://media.americantelemed.org/conf/2008/Presentations/225.pdf. Last accessed January 2012.

[4] Denholm, E. (2008). Telemedicine in Healthcare: Be Ready for the Future. Webinar Series: Healthcare Moves Home. *Health Tech*. Retrieved from http://www.healthtech.org/content/webinar_healthcaremoveshome. Last accessed January 2012.

[5] Meyers, M., Kobb, R., and Ryan, P. (2002). Virtually Healthy: Disease Management in the Home. *Disease Management*, 5(2):87-94.

[6] Britton, Bonnie (2008).

[7] Brookes, L. (2005). SPAN-CHF II: Specialized Primary and Networked Care in Heart Failure II. In Weintraub AJ, Kimmelstiel C, Levine D, et al. A multicenter randomized controlled comparison of telephonic disease management vs automated home monitoring in patients recently hospitalized with heart failure: SPAN-CHF II trial. Program and abstracts from the 9th Annual Scientific Meeting of the Heart Failure Society of America in Boca Raton, Florida.

[8] IDEAL LIFE. 2012

[9] Ibid.

[10] Darkins, Ryan and Kobb. 2008.

[11] Meyers, Kobb and Ryan. 2002.

[12] IDEAL LIFE. 2012.

[13] Ibid.

- Better survival rates:
    - In the Trans-European Network Homecare Monitoring Study, survival rates were substantially better for patients receiving RPM compared to usual care (27 percent greater for RPM patients).[14]

Financial Analysis

The cost of HT technology can be split into two portions: device costs and service fees.

- Device Costs:
    - One-time device costs include the purchase of all required devices including the main appliance (or base unit) and any additional peripherals (blood pressure monitors, scales, etc.).
    - The cost of HT devices varies substantially based on the level of sophistication.
    - Advanced devices, such as LifeView, cost several thousand dollars, whereas devices at the lower end of the cost spectrum are only about $100 per device.
- Service Fees:
    - HT technologies also incur ongoing service fees, usually billed on a monthly basis.
    - This covers the use of the IT systems which collect, manage and disseminate data collected from patients.
    - This often includes access to web-based tools and integration with electronic medical records.

Overall, the costs of HT technology must be considered inclusive of device and service fees, and over an extended period of time. According to an estimate by the VHA, the cost of care coordination/home telehealth is around $1,600 per patient, per year. Despite the high price tag, HT technology is perceived as cost effective for two reasons.

- First, it reduces hospital costs.
    - A meta-analysis of three programs using the Health Buddy technology showed that patients who used the device to manage heart failure experienced a decrease in hospitalizations and emergency room visits (for all types of illnesses), reducing average annual costs from $11,549 to $3,263.[15]
    - The RCCHC study found a similar reduction in hospital charges; hospital charges for the 40 patients followed prior to the use of telehealth amounted to $1,240,506 over six months, compared to charges of $229,919 during six months of HT use, an 81 percent reduction.[16]
- Second, HT can reduce the need for intensive home health service and institutional care services, such as 24-hour monitoring at a nursing home.
    - The VHA estimates that the cost of comprehensive home health services for chronic disease patients is approximately $13,121 per patient per year and the cost of nursing home care averages around $77,745 – high costs compared with the $1,600 per-year cost for HT.[17]
    - An analysis of the Trans-European Network Homecare Monitoring Study resulted in an ROI of 2.1 for the home telemonitoring program compared with similar services through a nurse telephone support program.[18]

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[14] Philips Medical Telemonitoring Services (2003). TEN-HMS Study Demonstrates Clinical and Financial Efficacy of Home Telemonitoring. Accessed December 2008 from http://www.medical.philips.com/goto/telemonitoring.
[15] Health Hero Network (2000). Clinical and Financial Analyses of Programs in Congestive Heart Failure. Retrieved from https://www.healthhero.com/papers/studies/Meta-Analysis_CHF_Outcomes.pdf. Last accessed January 2012.
[16] Britton. 2008.
[17] VHA Home Based Primary Care (HBPC) is provided by an interdisciplinary team of practitioners including nurses, social workers, physicians, therapists and dietitians. The services provided are more intense and frequent than traditional models of home health service provision and are intended for patients with complex, chronic, progressive diseases.
[18] Philips Medical Telemonitoring Services. 2003.

- *Cost of Supporting Devices:* Most HT technology requires substantial upfront acquisition costs, oftern much as several thousand dollars per device.

- *Reimbursement Issues:* Widespread adoption is dependent on the reimbursement model, and many third-party insurers do not cover the cost of these tools.

- *IT Infrastructure:* While the prevalence of EMR systems is increasing and is likely to accelerate with additional government funding, smaller primary care practices are unlikely to have such technology.

- *Behavioral and Cultural Change:* A concerted effort on the part of providers is required to aid physicians, as incorporating HT technology into their existing workflows and clinical activities represents a shift in professional practices.

- *Legal and licensure barriers:* As larger, multi-state integrated care networks begin to implement HT, legal and licensure issues may become more prominent over the long-term.

Next Steps to Implementation

1. Advocate for Reimbursement: Data suggest that HT technologies are clearly effective in improving both clinical and financial outcomes. A fundamental question, however, is who pays for these technologies? In turn, a next step is to address payment challenges by advocating for reimbursement under current fee-for-service models and future bundled payment models where providers will be rewarded for cost effective care. This could be aided through the development of cross-cutting strategies that emphasize the importance of HT technologies.

2. Make it Opt-Out, Not Opt-In: For HT technologies to be widely adopted, a standard protocol should be created in which providers are automatically enrolled in HT technologies within their institutions. Currently, HT technologies follow an opt-in, voluntary approach. The development of an opt-out standard protocol for HT technologies would help to increase adoption by providers, which in turn would improve clinical and financial outcomes for patients.

3. Opportunity for the Safety-Net: A critical question surrounding the topic of HT technologies is who pays for them, but perhaps equally important is the question of who pays for HT tools when there is a lack of money available? Advocating for reimbursement, therefore, should not just be generally focused on current fee-for-service models and future bundled payment models. Rather, strategies should be developed around how to incentivize reimbursement for HT tools within the Medicaid population, specifically those that live in rural areas.

Tele-Stroke Care

Class I

Every year, 795,000 Americans suffer from a stroke resulting in 137,000 deaths, making it the third leading cause of death for all Americans.[1] The most common type of stroke is the ischemic, or closed vessel, variety, occurring in 87 percent of cases.[2]

While ischemic strokes can be deadly and debilitating, the timely use of a clot-busting drug called a tissue plasminogen activator (tPA) can significantly reduce mortality rates and improve long-term speech and motor function. Unfortunately, the use of tPA is not without risk; the drug must be administered within four and a half (recently increased from three) hours of stroke onset and cannot be used for hemorrhagic (open vessel) stroke patients. If used incorrectly, tPA can cause an intracerebral hemorrhage, a serious and sometimes fatal complication. As a result, tPA use is normally limited to stroke centers staffed by specialist stroke neurologists.

Tele-stroke technology works to "virtually" bring the expertise of the stroke centers and provide enhanced stroke care, most notably the administration of the critical tPA, to smaller, rural and community hospitals.

Products on the market include the REACH Telestroke application and InTouch Health's Telestroke Networks.

Use Case

- Tele-stroke technology uses a video-conference link and electronic data sharing to allow specialist neurologists at the stroke center "hub" command center to communicate with "spoke" community hospital emergency departments.
    - Each "spoke" hospital uses a battery powered, portable cart with a PC, monitor, webcam and Internet access in the emergency department to allow the specialist neurologist to conduct a real-time consultation of the patient along with the ED physicians.
    - The specialist neurologists also have access to computed tomography (CT) scans and other tests conducted at the hospital though an electronic data sharing link.
    - Working collaboratively, the specialist and the emergency department staff develop a care plan based on established stroke protocols including, if appropriate, the administration of tPA, which can be undertaken by the hospital staff.

Clinical Benefit

- In certified stroke centers, around 10-20 percent of ischemic stroke patients are treated with tPA. Given that many patients are not appropriate for tPA therapy, a rate of around 20 percent rate is considered the current best practice standard. Outside of centers, the rate of tPA therapy is reported to be around 1-2 percent.
    - Data show that the number of patients receiving tPA therapy increases by approximately 10 fold over previous levels when tele-stroke technology is applied.[3]
- *Time to treatment:* Tele-stroke technology reduces the amount of time required to assess a stroke patient and administer tPA compared to non-stroke center hospitals without tele-stroke technology. This "door-

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[1] American Stroke Association (2009). Stroke 101. http://www.stroke.org/site/DocServer/STROKE101_2009.pdf Accessed 1/26/2012

[2] American Stroke Association (2009).

[3] Audebert H et al (2006). Comparison of Tissue Plasminogen Activator Administration Management between Tele-stroke Network Hospitals and Academic Stroke Centers. *Stroke*, Jul; 37(7):1822-7.

to-needle" time for community hospitals using tele-stroke ranges from 106 to 127 minutes, comparable to the performance of stroke centers.[4,5]

- *Mortality:* A retrospective study based on the National Institutes of Health's STRokE DOC trial found that patients treated at hospitals that used tele-stroke technology had similar mortality outcomes as patients in stroke centers, along with good six-month outcomes.[6]

- *Long-term morbidity:* Finally, tele-stroke technology produces better long-term patient outcomes. Long-term progress of 1,938 patients with ischemic or hemorrhagic strokes who were admitted to clinics taking part in the TEMPiS (Telemedicine Pilot Project on Integrated Stroke Care) project between July 2003 and March 2005 were compared to 1,122 patients admitted to nearby hospitals not using tele-stroke during the same period. Among stroke patients admitted to TEMPiS hospitals using telemedicine, the probability of a poor outcome (defined here as death, nursing home admittance or a lasting disability) 12 months after stroke was 35 percent lower than for non-TEMPiS patients. After 30 months, the risk of a poor outcome was still 18 percent lower for other hospital patients than for patients who were treated at hospitals without telemedicine links.[7]

Financial Analysis

- *Infrastructure and Acquisition Costs*: Infrastructure required for tele-stroke includes a high-speed internet connection for videoconferencing, CT or brain image transfer capability, a videoconferencing device that supports standard protocols and encryption, and a desktop computer. Costs for community hospitals are moderate; while a videoconferencing system is needed, only one such device is required. In addition, many hospitals have a PACS image transfer system already in place, reducing startup costs. Hub costs are higher; the videoconferencing device used by the hub hospitals typically costs about $20,000 to $25,000. Other technology acquisition costs for the hub facilities are proprietary information and not available.

- *Operational Costs*: Operations costs, including network fees and training doctors and support staff who interact with stroke patients, vary among networks. The REACH system uses this approach and charges spoke hospitals $3,500-$4,500 per month for a neurologist, and $2,000 to $3,000 per month for technical support, for a total cost to the spoke facility of $69,300 to $93,300 per year. [8]

- *Costs of the Condition*: In 2005, the average hospital stay for ischemic stroke, including both tPA and non-tPA treated patients, was 5.6 days at an average cost of $9,100 per stay.[9]

- *Reimbursement*: Since 2005, Medicare has reimbursed tPA-treated patients at a higher rate than conventionally treated patients (new DRG 559 covers reimbursement for the use of tPA at a rate of $11,540, while DRG 014 covers non-tPA stroke services at a rate of $6,417). As a result of this change, the use of tPA has become more financially viable for many hospitals.

- *Cost Effectiveness*: Recently published research has shown that, while costs are higher on average for tele-stroke patients (driven by technology costs), they tend to have more quality adjusted life years (QALYs), a measure of the improvement in both length and quality of life. The incremental cost-effectiveness ratio for tele-stroke compared to usual care is $2,449 per QALY over the lifetime of the patient, a very favorable result.[10]

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- *Stroke Center Regulations*: Some states have implemented regulations that require patients believed to have had an ischemic stroke to be transported to a "stroke center," hospitals with the specialized staff and training to care for stoke patients; non-certified facilities are bypassed. Smaller hospitals in jurisdictions without regulations on stroke centers have less incentive to invest in tele-stroke technology, often the most effective way for these facilities to become certified.

- *Physician Licensure*: Tele-stroke networks that work across state boundaries often are required to meet different physician licensure requirements in each state, adding cost and complexity and reducing staff flexibility.[11]

- *Staff Coordination:* Successful tele-stroke networks require a high level of coordination among a variety of staff in both the community and hub hospital: neurologists, emergency physicians, nurses or physician's assistants, radiology technologists, IT and administrative support staff and administrative assistants, financial analysts, operations managers and research coordinators. Effective coordination among these staff is key to a successful network

- *Reimbursement*: Medicare has significant limitations on reimbursement for telemedicine. While the requirement of a two-way video link (as opposed to store-and-forward technology) is not a concern for tele-stroke, the requirement that the recipient, the spoke hospital, must not be located in a metropolitan statistical area or its location must qualify as a rural health professional shortage area is a significant barrier. However, the Centers for Medicare & Medicaid Services (CMS) have been willing to develop new reimbursement approaches on a case basis: members of the REACH network in New York State have established reimbursement rates for telemedicine services equal to in-person consultations.[12]
  - Reimbursement challenges for tele-stroke in California have been reduced by Assembly Bill 415, which removes some of the most onerous restrictions on telehealth reimbursement for MediCal and private payers. In particular, it stipulates that "any service otherwise covered under standard contract terms (e.g. covered benefit, medically necessary) must be covered whether provided in-person or via telehealth."[13] Given that stroke neurologist consults are covered for in-person circumstances, this modification should allow for their reimbursement via tele-stroke approaches as well.

Next Steps to Implementation

1. *Implement Stroke Center Regulations*: In states where regulations require emergency services to transport patients with a suspected ischemic stroke only to stroke centers, such as Massachusetts, tele-stroke update has been significant. Such regulations, and associated loss of patients and revenue by hospitals, are a major trigger for investing in tele-stroke technology and the creation of tele-stroke networks.

2. *Address Infrastructure Costs*: High upfront costs can be a barrier to the implementation of tele-stroke, especially in safety-net hospitals. However, publicly funded models, such as the Arizona Telemedicine Program, have been created to reduce this burden. In this model, most infrastructure costs, purchased in bulk, are covered by the government, and a relatively small membership fee covers part of the ongoing service costs, with the remainder subsided from state funds.[14] Such public models should be examined in jurisdictions with significant numbers of safety-net facilities.

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Mobile Clinical Decision Support

One of the greatest obstacles a provider faces is the availability of proper information at the point of care, whether it is in a primary care, ambulatory care or other setting. This becomes especially critical if the patient is in an emergency condition. Clinical decision support systems (CDSS) have repeatedly been suggested as a useful tool for improving guideline adherence and mobilizing evidence-based knowledge into daily clinical practice. Mobile solutions may help to further facilitate this process.

Mobile clinical decision support tools are more frequently being leveraged to provide clinical decision support for physicians. For example, cell phones are loaded with the latest clinical decision support to aid physicians in making better diagnoses for patients in all care settings, and mobile and web-based clinical decision support resources provide physicians with easy to access information on appropriate treatments. Mobile technologies can assist clinicians to reduce preventable hospital readmissions, prevent medical errors and reduce adverse drug events.

A representative sample of these tools includes Health eVillages, Clinical Pharmacology Mobile and NaviNet Mobile Connect.

Use Case

- Mobile clinical decision support tools are targeted to physicians, but could also be used by nurses, retail pharmacies, managed care agencies, pharmacy benefit managers, pharmaceutical manufacturers and others.

- There are a number of mobile clinical decision support tools currently represented in the marketplace, all of which have similar but slightly different foci.
  - Mobile and Web-Based: Several tools use mobile and web-based clinical decision support resources to provide physicians with easy access to the latest information on evaluation, diagnosis, clinical management, prognosis and prevention.
  - Smartphones: Smartphones and other mobile devices, loaded with medical texts, drug guides and other reference tools offline, are used by health professionals in low-income regions of the world.

Clinical Benefit

It has been well-established that clinical decision support systems can facilitate clinician decision-making and guideline use by generating preventive reminders, ensuring the use of appropriate orders and assisting in diagnosis.[1,2] CDSSs have resulted in improvements in clinical performance through increasing screening and vaccination rates as well as clinician knowledge and adherence to guidelines, among other improvements.[3]

Handheld devices and smartphones have demonstrated limited but early successes in providing mobile clinical decision support that improve guideline adherence and mobilize evidence-based knowledge.[4,5,6,7]

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- In 2009 a Randomized Control Trial (RCT) found that a handheld decision-support system improved diagnostic decision-making for patients in emergency departments with a suspected pulmonary embolism (n > 1,000).[8]
  - Using a mobile CDSS led to significantly greater improvements than use of paper guidelines, increasing the proportion of patients who received an appropriate diagnostic work-up by 19.3%.
- Another RCT in 2009 looked at the proportion of obesity-related diagnoses in clinical encounters documented by nurses with and without obesity decision support features and found positive results (n=1,874).[9]
  - The experimental group encounters had significantly more obesity-related diagnoses (11.3%) than did the control group encounters (1%) and a significantly lower false negative rate (24.5% vs. 66.5%).
- Independent studies of web-based drug information databases in 2008 and 2007 found that one of these tools scored highest for clinical dependability, completeness of information and highest overall composite score.[10,11]

While clinical decision support systems are well-known to provide clinical benefits, there are still a number of mobile clinical decision support systems where the evidence is not yet clear, as published results were not yet available.

- In 2011 one of these tools was offered to physicians in order to provide them with mobile access to electronic health record and patient management data (n > 2,000).[12]
  - Data from this tool is being mined on a weekly basis and is compared against thousands of evidence-based care guidelines that have been adopted within the medical community as the standard of care.
- Some of these tools that use smartphones have been piloted internationally, including in Haiti, Uganda and Kenya, as well as here in the U.S., in impoverished and underserved Gulf Coast communities.[13]
  - One nursing school brought six Haitian nursing professors to the U.S. to train them on smartphones, and the professors then brought their newfound expertise back home to teach other nurses.[14]
  - Smartphones have also been provided to volunteer nurses at a clinic in one country, and based on their successful use of the technology, additional devices were sent there to expand upon their initial work.[15]

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[7] Roy, P., Durieux, P., Gillaizeau, F., et al. (2009). A computerized handheld decision-support system to improve pulmonary embolism diagnosis: A randomized trial. *Ann Intern Med*, 2009; 151: 677-86.
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- Although a number of studies have clearly shown the clinical benefits of CDSSs, the current evidence on return-on-investment (ROI) and overall cost-effectiveness of CDSSs is not as clear.[16,17]

  o Studies in 2008 and 2005 found that CDSSs improved medication adherence for congestive heart failure and high cholesterol, and cost-savings per member per year ranged from $4 to $35, respectively.[18,19]

  o A recent 2011 study, however, found that implementing CDSSs is not a cost-effective way to treat patients with Type 2 diabetes, as researchers found that the system costs about $160,845 per quality-adjusted life year and noted that it would need to cost less or deliver better results to be cost effective.[20]

- There has been almost no research done on ROI and cost-effectiveness of mobile CDSSs.

  o One 2004 study did, however, find that mobile clinical decision support tools can reduce operational costs by saving up to $15,700 per year, per physician, via automating prescriptions.[21]

- These tools have the potential to reduce preventable hospital readmissions, prevent medical errors, and reduce adverse drug events.

Barriers to Adoption

- *Ease of Use Issues:* Smartphone apps and web-based interfaces could be confusing for those not as technologically savvy or those without internet access. Additionally, most CDSSs are standalone products that lack interoperability with reporting and electronic health records.[22]

- *Limited Data:* Studies have shown the clinical benefits of CDSSs, and a few studies have demonstrated promise for mobile CDSSs. However, research on the clinical and financial benefits of mobile CDSSs is severely deficient.

- *Cost of Devices:* Smartphones and other hand-held devices could be cost-prohibitive to physicians and organizations working in impoverished and rural areas.

- *Reimbursement Issues:* Widespread adoption is dependent on the reimbursement model. If these tools are not covered by insurance, it is unlikely that clinicians will purchase them out-of-pocket, as they are expensive.

- *Behavioral and Cultural Change:* These tools require a concerted effort on the part of providers and organizations to fit these new technologies into their workflows.

- *Lack of Clinical Guidelines:* CDSSs have been shown to improve clinical outcomes, and mobile CDSSs show promise as well; however, there is a lack of standardized clinical guidelines on how mobile CDSSs should be used.

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1. Develop Meaningful Use Criteria Strategies for All Systems: In an environment of Meaningful Use (MU) criteria, a fundamental question is how smaller delivery systems can adhere to these criteria without the financial support and technologies that are available to larger systems, such as access to electronic medical record (EMR) systems that are capable of performing the required functions. This is particularly a question for community health clinics, visiting nurses, and small primary care clinics. Strategies should be developed which focus on the integration of MU criteria into these often forgotten but equally important delivery systems.

2. Look Ahead to Reality of Meaningful Use Requirements and Create Appropriate Use Cases: Strategies for the successful adoption of mobile CDSSs should also have an eye to the not-too-distant future of MU requirements. Stage 1 of MU requirements (2011 and 2012) sets the baseline for electronic data capture and information sharing, while Stage 2 (expected to be implemented in 2013) and Stage 3 (expected to be implemented in 2015) will continue to expand on this baseline and be developed through future rule making. As a result, strategies here should be forward-thinking in the development of future use cases for these technologies.

3. Opportunity for the Safety-Net: Through the development of MU criteria strategies for all systems and the creation of appropriate use cases for the future, there is a significant opportunity here to specifically focus on the safety-net population and build the use case for safety-net providers going forward.

NEHI

Virtual Visits

Virtual visit technologies create opportunities for patients and providers to interact remotely. With many of these technologies, patients can log their clinical data and share information with their provider in real-time, enhancing the dialogue between patient and provider. These technologies are web based platforms that allow interactions between patients and providers. Unlike Home Telehealth, these platforms do not require a hub device; instead, virtual visit technology can be accessed from smartphones, personal computers and kiosks.

Patients often delay or avoid primary care and chronic disease management services because they are costly, time consuming and difficult to come by as physicians' time is increasingly constrained. As a result, conditions often worsen, requiring costly interventions and trips to the emergency room. Virtual visit technologies remediate this issue by making physicians more accessible through web based interactions using physicians' time more efficiently.

Some examples of products on the market include American Well's Online Care Mobile, Stratus Video's Video Waiting Room and Ideal Life's Interactive Kiosks.

Use Case

- Virtual visit technologies encompass the breadth of technologies that enable remote interactions between patients and providers. Many technologies require both the patient and provider to have access to an internet-enabled personal computer or Smartphone to participate.
  - o Mobile and web based patient portals give patients access to e-consultations, e-prescriptions and e-health records.
  - o Kiosks in high traffic areas survey patients, collect routine clinical data and chronic disease endpoints such as blood glucose and pulmonary function, and connect patients to providers.
- Virtual visit manufacturers employ a variety of business models to reach patients:
  - o Many patient portals were developed for providers, health plans and home health organizations as a medium for consultations of acute conditions and chronic diseases.
  - o Many kiosks employ a retail approach where the patient can stop in at a kiosk located in a high traffic area and pay for a single consultation.
  - o Some kiosks were installed by businesses wanting to improve the health of their employees or members.
- The number of installed units for these technologies continues to grow:
  - o American Well has publicly announced Blue Cross Blue Shield of Hawaii, Blue Cross Blue Shield of Minnesota, TriWest, HealthNow New York, WellPoint, Optum/UnitedHealth, US Department of Veterans Affairs, Patient Advocates and Rite Aid as customers.
  - o Another manufacturer announced a partnership with Sprint to launch kiosks across the country.
- Both patients and providers are becoming increasingly receptive to virtual visits:
  - o Almost 90 percent of physicians would like their patients to monitor their health independently.[1]

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[1] Gullo, C (2011). Sprint, Ideal Life Offer Wireless Biometric Kiosks. Mobihealthnews, October 11, 2011. Retrieved from: http://mobihealthnews.com/13781/sprint-ideal-life-offer-wireless-biometric-kiosks/. Accessed December 2011.

- About three-quarters of consumers are interested in viewing their medical records and lab results online and exchanging emails with their doctor; however, only one quarter are willing to pay extra to do so.[2]

Clinical Benefit

- Virtual visit technologies may reduce unnecessary hospital readmissions, especially in cases where there is limited or no access to these services in their communities.
  - 12 percent of the more than 7 million yearly 30-day hospital readmissions are preventable.[3]
- Remote interactions between patients and providers has been repeatedly shown in the literature to be equally as effective as face-to-face consultations for routine primary care and chronic disease management:
  - Over a three year period, Kaiser Permanente of Hawaii was able to reduce outpatient visits by 25 percent and increase virtual visits eight-fold while maintaining patient satisfaction (n=225,000).[4]
  - In a Veterans Affairs study, diabetic patients were given stand-alone two-way messaging devices, where patients routinely answered questions about their health and received messages daily. Findings showed reduced diabetes-related hospitalizations and clinic visits (n=800).[5]
  - Another study compared face-to-face visits with videoconferencing visits using web cameras. Results showed that videoconferencing was equally as effective for the evaluation and management of acute, non-urgent issues, such as upper respiratory infections or back pain (n=175).[6]
- The clinical benefit of specific virtual visit technologies has not been robustly quantified to date. Case studies from vendors suggest positive results; however, there are no published data available at this time:
  - A case study revealed that those who utilized remote monitoring technologies that routinely prompted vital signs and medications showed a 40 percent improvement in medication adherence (n=50). [7]
  - One manufacturer has partnered with the University of Miami Miller School of Medicine to study the clinical benefit of wireless remote health monitoring for individuals with hypertension.[8]

Financial Analysis

- The financial benefits of reduced hospital readmissions are well established:
  - Treatment and management of chronic diseases account for more than 75 percent of U.S. health care spending.[9] Preventable hospital readmissions cost an estimated $25 billion annually.[10]
- A robust analysis of the financial benefits of these technologies has not been quantified to date; however, research suggests that remote monitoring of patients can lead to significant cost savings:
  - The Health Research Institute suggests that remote monitoring of chronic diseases could amount to $21 billion in savings annually due to a reduction in hospitalization and nursing home costs.[11]

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[7] Interview with Continuity Health. Conducted 12/11.

[8] Ideal Life (2010). Ideal Life and University of Miami Miller School of Medicine Collaborate on NIH-Funded Telehealth Program. Press Release April 27, 2010. Retrieved from: http://www.ideallifeonline.com/newsroom/uofm.pdf. Accessed December 2011.

9 PriceWaterhouse Coopers' Health Research Institute. (2008). The Price of Excess: Identifying Waste in Healthcare, 2008. Retrieved from http://www.pwc.com/us/en/healthcare/publications/the-price-of-excess.jhtml. Accessed October 2011.

10 PriceWaterhouse Coopers' Health Research Institute. (2008). The Price of Excess: Identifying Waste in Healthcare, 2008. Retrieved from http://www.pwc.com/us/en/healthcare/publications/the-price-of-excess.jhtml. Accessed October 2011.

- A study of congestive heart failure patients showed remote monitoring reduced hospitals readmissions and cut associated medical costs by more than half; specifically the cost for hospital admissions was reduced from $1.26 million to $540,000 (n=200).[12]
  - An actuarial study suggests that online care can save $3.36 for commercial plans and $6.95 for Medicare per-person per-month.[13]
- Many virtual visit technologies require access to larger organizations or have some direct-to-consumer costs:
  - In many cases patients must be employees or members of physician practices, health plans or home health organizations that offer these services.
  - In some cases, the service is available for a small co-pay of about $10, while the employer, provider or health plan is charged a fixed monthly fee.[14,15]

Barriers to Adoption

- *Business Model*: Most require an association with an organization that offers this service and aren't direct-to-consumer products.
- *Cultural Resistance*: Requires a behavior change in health care, where both patients and providers are comfortable with remote consultations and patients take an active role in monitoring their condition.
- *Financial Barriers*: The current fee-for-service payment mechanism often does not pay for remote consultations.
- *Legal and Licensure Barriers*: Medical licensure regulations limit cross state medical consultations.
- *Privacy Concerns*: Patients and providers may be concerned when information is shared over the internet.
- *IT Infrastructure*: Many systems are not interoperable with EHRs at this point in time.

Next Steps to Implementation

1. Advocate for Reimbursement: There is sufficient evidence suggesting the financial benefit of these technologies. To encourage widespread adoption, the logical next step is to address the fundamental payment challenges by advocating for reimbursement under current fee-for-service models and future bundled payment models where providers will be rewarded for cost effective care, particularly in terms of reimbursement for safety-net populations.
2. Understand the Liability Challenges: Addressing physician's liability concerns is a necessary next step to ensure that physicians and patients are comfortable with this new medium for health care services. Only when physicians feel they will not be penalized for providing care remotely, will they widely adopt this practice.

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[11] Gullo, C (2011). Sprint, Ideal Life Offer Wireless Biometric Kiosks. Mobihealthnews, October 11, 2011. Retrieved from: http://mobihealthnews.com/13781/sprint-ideal-life-offer-wireless-biometric-kiosks/. Accessed December 2011.
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An Innovative Technology Profile:

Mobile Diabetes Management Tools

Class III

Mobile diabetes management tools encompass the breadth of technologies that enhance patients' abilities to monitor their disease using their mobile phone. These technologies use mobile devices as a medium to collect and log blood glucose readings, provide real-time reminders and alerts, and translate and interpret data over time. Many applications include interfaces where data can be shared with caregivers and physicians and provide educational materials based on trends identified. They come in many forms, but all leverage mobile technology to either collect, log or transmit clinical data.

There are many mobile diabetes management tools on the market today with varying functionality and business models. A representative sample of tools include Telcare's Blood Glucose Monitor, Sanofi Aventis' iBGStar, Glooko's MeterSync Cable, Positive ID's iGlucose and WellDoc's DiabetesManager.

Use Case

- Currently, 25.8 million people in the U.S. have diabetes.[1]

- These technologies use mobile devices to collect and log blood glucose readings, provide real-time reminders and alerts, and translate and interpret data over time. When a wireless signal is unavailable, these devices will continue to function, uploading data when a signal is available:

  o "Enhanced Blood Glucose Monitors" are able to collect blood glucose readings, transmit data wirelessly and provide real-time feedback from a single device eliminating the need to manually log readings with your smartphone. These are designed to replace the widely adopted current blood glucose monitors.

  o "Data Transmission Devices" are add-on devices and cables that transmit clinical data from traditional blood glucose monitors to a smartphone or personal computer, also eliminating the need to manually log data, but still requiring the user to physically plug in the device. These are designed for patients already utilizing blood glucose monitors, but aim to enhance these devices.

  o "Mobile Diabetes Management Platforms" can be accessed with smartphones and are able to interpret trends in manually logged clinical data and send real-time alerts, actionable messages and educational materials to patients based on their clinical data. Some diabetes management platforms have targeted larger customers like health plans, large employers and pharmaceutical companies offering a more systemic approach to diabetes management.[2]

- Cell phone users are increasingly receptive to using their mobile devices to manage their care:

  o Nine percent of cell phone users have at least one software application on their phone to track or manage their health. Of cell phone users, minorities and younger generations are more likely to use health apps.[3]

  o One manufacturer estimates that about 1 to 3 million people within the iPhone market might have diabetes. The market grows if you consider the iPad and iPod touch devices, which are trending among older populations who are replacing their PCs.[4]

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[3] Fox, S (2011). The Social Life of Health Information, 2011. Pew Internet and American Life Project, May 12, 2011. Retrieved from: http://pewinternet.org/Reports/2011/Social-Life-of-Health-Info.aspx. Accessed November 2011.

[4] Dolan, B. (2011). Glooko Picks Up Where Lifescan Left Off. Mobihealthnews, November 23, 2011. Retrieved from: http://mobihealthnews.com/14861/glooko-picks-up-where-lifescan-left-off/. Accessed December 2011.

- Highly controlled blood glucose levels have been repeatedly shown in the literature to have significant clinical benefit:
  - It is widely recognized that a single percentage point drop in A1C level can reduce the risk of heart, kidney and eye disease by up to 40 percent.[5]
  - Evidence overwhelmingly supports intensive insulin therapy having long-term beneficial effects on the risk of cardiovascular disease.[6]
- While studies of mobile diabetes management tools are limited and on a small scale, manufacturers of these tools have shown that their products can improve A1C control:
  - Results from a manufacturer study showed that intervention patients exhibited a 1.9 percent decline in A1C compared to 0.7 percent for the usual care group after one year. All patients had private insurance coverage and access to the internet (manufacturer, n=163).[7]
  - In a separate manufacturer study, patients displayed a 2.03 percent decline in A1C compared to 0.68 percent for the usual care group after three months. These patients were 3.5 times more likely to have their medications titrated or changed by their provider and reported improved patient provider interactions (manufacturer, n=30).[8]
  - Users of mobile diabetes management tools reduced their ER visits and hospital stays by 58 percent over 12 months compared to the 12 months prior to the program (manufacturer, n=32).[9]
  - Korean patients using mobile diabetes management tools showed improved blood sugar control, a 1.05 percent decrease, after six months (South Korea, n=51).[10]

Financial Analysis

- As of yet, there is no specific evidence on the financial benefits of mobile diabetes management tools. However, the cost of diabetes is growing exponentially and the financial benefits of properly controlled blood glucose is well established:
  - The total cost of diagnosed diabetes in the United States was $174 billion in 2007.[11] By 2034, annual diabetes-related spending is expected to rise to $336 billion.[12]
  - A diabetic hospitalization can cost on average $10,937.[13]
  - One report suggests insurers may save $4,000 per patient annually if their patients are compliant with their blood glucose testing.[14]
- Because many of the mobile diabetes management tools have only recently entered the market, a robust analysis of the financial benefits of these tools has not been completed to date.
- Many of these mobile diabetes management tools will require some direct-to-consumer costs:
  - Mobile blood glucose monitors are aiming for price parity with current monitors and strips and are seeking reimbursement to eliminate additional costs for the consumer.[15]

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[5] Centers for Disease Control and Prevention. (2011).

[6] Centers for Disease Control and Prevention. (2011).

[7] Quinn, C (2011). Cluster-Randomized Trial of a Mobile Phone Personalized Behavioral Intervention for Blood Glucose Control, *Diabetes Care,* 2011; 34:1934–1942.

[8] Quinn, C (2008). WellDoc™ Mobile Diabetes Management Randomized Controlled Trial: Change in Clinical and Behavioral Outcomes and Patient and Physician Satisfaction. *Diabetes Technology & Therapeutics*, 2008; 10(3):160-168.

[9] WellDoc. (2011). The WellDoc DiabetesManager Cuts Hospital and ER Visits in Half. BusinessWire, December 6, 2011. Retrieved from: http://www.businesswire.com/news/home/20111206005830/en/WellDoc%C2%AE-DiabetesManager%C2%AE-Cuts-Hospital-ER-Visits. Accessed December 2011.

10 Kim HS (2007). A nurse short message service by cellular phone in type-2 diabetic patients for six months. *J Clin Nurs*, 2007; 16(6): 1082–7.

[11] Centers for Disease Control and Prevention. (2011).

[12] Huang, ES (2009). Projecting the Future Diabetes Population Size and Related Costs for the U.S. Diabetes Care. *Diabetes Care*, 2009; 32:2225–2229.

[13] WellDoc. (2011). The WellDoc DiabetesManager Cuts Hospital and ER Visits in Half.

[14] Telcare, (2011). Company Overview. Retrieved from: http://www.telcare.com/how-it-works/. Accessed December 2011.

[15] Telcare, (2011). How It Works. Retrieved from: http://www.telcare.com/how-it-works/. Accessed November 2011.

- Data transmission devices to mobile devices require some additional non-reimbursable investment from the consumer. The less sophisticated MedSync cable retails for $39.95,[16] while the wireless iGlucose device is projected to retail for $90 with a monthly subscription of $10.[17]

Barriers to Adoption

- *Financial Barriers*: Widespread adoption is dependent on the reimbursement model. If these new devices are not covered by insurance, its unlikely patients will purchase these technologies out-of-pocket, especially safety-net populations.

- *Cultural Resistance*: Many of these tools require patients to take an active role in data transmission, either by manually entering data into a platform or plugging in their device.

- *Cultural Resistance*: Patients may be comfortable with their current blood glucose monitors and unwilling to adopt new versions.

- *IT Infrastructure*: Compatibility issues between devices may be a barrier for many of these add-on devices.

Next Steps to Implementation

1. Incorporate Tools into Disease Management Programs: Rather than viewing these tools as immature stand-alone technologies, these tools should be viewed as enhancements to already established diabetes management programs. By shifting the focus to showing that these tools can benefit these programs, many reimbursement challenges for patients and particularly the safety-net can be sidestepped as most diabetes patients already have access to them. As stand-alone technologies, the evidence may not be mature enough to support reimbursement, so leveraging existing programs is essential.

2. Leverage Technologies for Public Health Interventions: These tools have clear epidemiological value as patient data can now be collected over time. The public health community must develop an approach to compile and interpret data for targeted public health interventions.

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[16] Glooko, (2011). Purchase. Retrieved from: http://www.glooko.com/purchase/logbook/. Accessed November 2011.
[17] Positive ID (2011). October Investor Presentation, October 10, 2011. Retrieved from: http://files.shareholder.com/downloads/ABEA-3Y7P8E/1571461936x0x497237/2a57d70a-42be-4366-83ce-0ddcb26bfb65/PositiveIDInvestor_Presentation_Oct_2011.pdf. Accessed December 2011.

An Innovative Technology Profile:
Medication Adherence Tools

The rise of chronic disease is one of the nation's most pressing and expensive health care concerns. Tens of millions of Americans suffer from chronic conditions, resulting in billions of dollars in health care spending and significant morbidity and mortality. Despite the financial and human toll, many of these diseases can be effectively managed with the use of prescription medications. Unfortunately, many patients do not take their chronic disease medications as prescribed – up to half all patients in the U.S. do not take their medications as prescribed by their doctors.[1]

Medication adherence tools represent an opportunity to save hundreds of billions of dollars. Technologies leveraging existing cell phones to remind patients and caregivers to take their medications continue to grow. In addition, an emerging technology space is the use of mobile applications for patients' medication adherence, known as *mHealth* technology, which seamlessly integrates into daily routines and provides alerts when medications should be taken. Furthermore, pill bottle caps provide effective medication management quickly and easily for patients.

A representative sample of these tools includes Pleio BuddyTips, MemoText and Vitality GlowCaps.

Use Case

- As many as 2 billion cases of poor medication adherence each year are avoidable, and one-third to two-thirds of medication-related hospital admissions are linked to poor adherence.[2,3,4]

- 133 million Americans are affected by at least one chronic condition, and 75 percent of health care spending goes toward the care of those with chronic conditions.[5]

- Poor adherence disproportionately affects the elderly, those with chronic conditions and low-income individuals; for diabetes and hypertension, which disproportionately affect minorities, proper adherence averages only 50-65 percent.[6,7]

There are a number of medication adherence tools currently represented in the marketplace, all of which have similar but ultimately different foci:

- Smartphone Apps: Smartphone applications list patients' medications, schedule pill reminders and help patients to order refills.

- Internet-connected Pill Caps: Internet-connected pill caps light up, play music and ring phones so patients do not forget to take their medication. The pill caps also send emails to remote caregivers, create adherence reports and refill prescriptions.

- Blister Packaging: Pharmaceutical packages designed to enhance patient adherence to medications have calendars printed on medication cards, or "blisters," which are designed to help patients follow their drug regimen.

[1] NEHI (2009) Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease. Retrieved from http://www.nehi.net/publications/44/thinking_outside_the_pillbox_a_systemwide_approach_to_improving_patient_medication_adherence_for_chronic_disease Last accessed November 2011.
[2] Osterberg and Blaschke. 2005.
[3] IMS Health. (2010). National Prescription Audit PLUS. Retrieved from http://www.imshealth.com/deployedfi les/imshealth/Global/Content/StaticFile/Top_Line_Data/2010_Top_Therapeutic_Classes_by_RX.pdf. Last accessed November 2011.
[4] Osterberg and Blaschke. 2005.
[5] American College of Physicians. (2009). Costs and Quality Associated with Treating Medicare Patients with Multiple Chronic Conditions. Internal Medicine, May 18, 2009. Retrieved from http://www.acponline.org/advocacy/events/state_of_healthcare/costs_quality.pdf. Last accessed December 2011.
[6] World Health Organization (2003). Adherence to Long-Term Therapies: Evidence for Action. Retrieved from http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf. Last accessed December 2011.
[7] Osterberg and Blaschke. 2005.

- Other Tools: Medication reminders also come in the form of automatic pill dispensers, pill boxes, watches and alarm clocks, among others, which assist with medication management.

Clinical Benefit

It has been well-established in the literature that a variety of medication adherence tools have improved adherence for several chronic diseases, including asthma, glaucoma and hypertension.[8]

- In 2011, early results were released from a Randomized Control Trial (RCT) that showed a 16 percent increase in adherence via SMS-texts and voice calls to ensure adherence to glaucoma treatment regimens (n=428).[9]

- A seven-month research study in 2011 looked at the efficacy of the Pill Phone application to improve medication adherence among hypertensive patients and found that it had positive results (n=50).[10]
  - Patients had a high level of acceptance and sustained use of the Pill Phone application, and refill rates increased with the use of the application and decreased after the application was discontinued.

- In June 2010, Partners Healthcare's Center for Connected Health announced results from a six-month clinical study measuring a 27 percent increase in adherence for users of an internet-connected pill cap (n=139).[11]

- In February 2009, a three-month study looked at the adherence rates of an internet-connected pill cap and found that the average adherence rate was 86 percent, significantly higher than the World Health Organizations' often-cited average adherence rate for the developed world of 50 percent (n=50).[12,13]

- Universities and pharmaceutical companies are administering their own RCTs to quantify the impact and value of internet-connected pill caps to specific populations, conditions and therapies.[14]

- In 2009, an analysis of the Pleio GoodStart program, in which BuddyTips e-mails, texts or phone messages are a component, found that it had been very well-received (n=2,628):[15]
  - 70 percent of participants say it helped them with their medication regimen, and prescription refills increased by 29 percent over patients' first 9 months of therapy.

- According to many experts, medication reminders in the form of automatic pill dispensers, pill boxes and alarm clocks provide the most accurate and valuable data on adherence, especially in difficult clinical situations.[16,17]

- Studies have shown the adherence benefits of calendar-based blister packaging:[18]

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[8] Figge, H. (2011). Electronic Tools to Measure and Enhance Medication Adherence. *US Pharm*, 2010; 36(4) (Compliance & Adherence suppl):6-10.
[9] Dolan, B. (2011). Automated med reminders boost adherence. Mobihealthnews. June 8, 2011. Retrieved from http://mobihealthnews.com/11146/automated-dosing-reminder-study-finds-increased-adherence/. Last accessed December 2011.
[10] PRNewswire. (2011). Research Study Looks at Benefits of 3G Wireless Technology for Hypertensive Patients in Underserved Urban Communities. February 9, 2011. Retrieved from http://www.fiercehealthcare.com/press-releases/research-study-looks-benefits-3g-wireless-technology-hypertensive-patients-. Last accessed December 2011,
[11] Partners Healthcare. (2010). Wireless Medication Adherence Study Conducted at the Partners Center for Connected Health Shows Promising Initial Findings. Center for Connected Health. June 23, 2010. Retrieved from http://www.connected-health.org/media-center/announcements/wireless-medication-adherence-study-conducted-at-the-partners-center-for-connected-health-shows-promising-initial-findings.aspx. Last accessed December 2011.
[12] Vitality. (2009). GlowCaps achieved an 86% rate of adherence. Retrieved from http://www.vitality.net/research_betaresults.html. Last accessed December 2011.
[13] Byrne, C. (2011). Wireless pill cap makers Vitality bought by pharma billionaire. VentureBeat. February 4, 2011. Retrieved from http://venturebeat.com/2011/02/04/glowcap-vitality-patrick-soon-shiong/. Last accessed December 2011.
[14] Vitality. 2009. GlowCaps achieved an 86% rate of adherence.
[15] Center for Health Transformation. (2010). The 21st Century Intelligent Pharmacy Project: The Importance of Medication Adherence. Retrieved from http://www.mirixa.com/pdf/CHTMedAdhrWp.pdf. Last accessed December 2011.
[16] Osterberg and Blaschke. 2005.
[17] Urquhart, J. (1997). The electronic medication event monitor: lessons for pharmacotherapy. *Clin Pharmacokinet,* 1997; 32: 345-356.
[18] Center for Health Transformation. 2010.

- o   A 2008 study demonstrated that the percentage of on-time refills and the medication possession ratio were 13.7 and 6.2 percent higher, respectively, for the study group as compared to the control group.[19]
- o   A 2006 RCT showed that blister packaging of blood pressure medication combined with pharmacist counseling improved adherence by nearly 40 percent compared with regular vials and no counseling; these elderly patients also experienced significant reductions in their systolic blood pressure.[20]

Financial Analysis

- Medication adherence represents a $290 billion opportunity to reduce costs.[21]

- Not taking medications as specifically prescribed costs over $100 billion a year in excess hospitalizations.[22]

- There has been minimal research done on return-on-investment (ROI) and cost-effectiveness of these tools.

- Smartphones can be expensive for safety net populations, but for the most part the technologies themselves are free applications to use, which means little up-front costs for the phones and no recurring costs after that.

- Third-party insurers typically do not cover the cost of these tools, although in some states, such as New York, certain medication adherence tools are covered by Medicaid.[23]

- Internet-connected pill caps have low up-front costs, as they usually only require a one-time fee of about $10.

Barriers to Adoption

- *Ease of Use Issues:* Many of these technologies use smartphone applications, which could be confusing for the elderly or those not technologically savvy.

- *Limited Data:* More rigorous controlled studies are needed to study ROI and cost savings.

- *Privacy Concerns:* In the absence of clear guidelines, the transfer of medical information over the internet is likely to raise privacy concerns with patients.

- *Cost of Supporting Devices:* Smartphones could be cost-prohibitive to elderly, minority and low-income populations.

- *Reimbursement Issues:* Widespread adoption is dependent on the reimbursement model, and most third-party insurers do not cover the cost of these tools.

Next Steps to Implementation

1. Advocate for Reimbursement: Data suggests that these technologies are effective in improving medication adherence, which leads to reduced costs and improved quality. A fundamental question, however, is who pays for adherence? In turn, a next step is to address payment challenges by advocating for reimbursement under current fee-for-service models and future bundled payment models where providers will be rewarded for cost effective care. This could be aided through the development of cross-cutting adherence strategies that emphasize the importance of these technologies. In addition, the

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[19] Schneider, P., Murphy, J., Pedersen, C. (2008). Impact of Medication Packaging on Adherence and Treatment Outcomes in Older Ambulatory Patients. *Journal of the American Pharmacists Association*, 48(1), 58-63.
[20] Lee, J., Grace, K., Taylor, A. (2006). Effect of a Pharmacy Care Program on Medication Adherence and Persistence, Blood Pressure and Low-Density Lipoprotein Cholesterol: A Randomized Controlled Trial. *JAMA*, 296, 2563-2571.
[21] NEHI. (2009). Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chorionic Disease. Retrieved from http://www.nehi.net/publications/44/thinking_outside_the_pillbox_a_systemwide_approach_to_improving_patient_medication_adherence_for_ chronic_disease. Last accessed October 2011.
[22] Sokol, M., McGuigan, K., Verbrugge, R., et al. (2005). Impact of medication adherence on hospitalization risk and healthcare cost. *Med Care*, 43(6), 521-530.
[23] In New York, Section 3621 of the Public Health Law authorizes a telemedicine demonstration program in Medicaid.

case for reimbursement could be made through the creation of adherence partnerships and coalitions, such as the Partnership to Fight Chronic Disease and Script Your Future.

2. Encourage Research on Specific Adherence Tools: It is clear that, overall, medication adherence tools work. However, what is less clear is which specific adherence tools are the best or most effective? As a result, more research should be undertaken to assess which technologies have the best financial and clinical outcomes.

3. Opportunity for the Safety-Net: A critical question surrounding the topic of medication adherence is who pays for it, but perhaps equally important is the question of who pays for adherence when there is a lack of money available? Advocating for reimbursement, therefore, should not just be focused on current fee-for-service models and future bundled payment models. Rather, strategies should be developed around how to incentivize reimbursement for adherence specifically within the Medicaid population.

An Innovative Technology Profile:

Mobile Asthma Management Tools

Mobile asthma management tools include novel technologies that empower patients to better understand where and what triggers asthma attacks in order to better prevent and treat asthma complications. This information enables patients to work with their providers and, more broadly, to support public health initiatives in their communities. These tools include GPS attachments to inhalers which record when and where inhalers are used, mobile logging applications where patients can manually enter asthma data, and early warning software that can alert patients to potential asthma attacks based on environmental factors like allergens and pollutants.

A representative sample of these tools includes the SpiroScout attachment by Asthmapolis, the mobile application AsthmaMD and early warning software from Asthma Signals.

Use Case

- According to the CDC, nearly 25 million people in the U.S. have been diagnosed with asthma, which is approximately 8 percent of the population.[1]

- Asthma is a chronic disease characterized by pervasive disparities:
  - Asthma is higher among multiracial (14.8%), Hispanic (14.2%) and non-Hispanic Blacks (9.5%), as compared to non-Hispanic Whites (7.8%).[2]
  - Disparities are also seen in age, gender and socioeconomic status: current asthma prevalence is higher among children (9.3%) than adults (7.3%); higher among females (8.6%) than males (6.9%); and higher among the poor (11.2%) than the near-poor (8.4%) and non-poor (7.0%).[3]

- According to the 2010 Behavioral Risk Factor Surveillance System (BRFSS), 5.9% of children (n=530,690) and 7.7% of adults (n= 2,155,879) in California currently have asthma.[4,5]

- Mobile asthma management tools target those who suffer from asthma attacks, especially children, in order to help them avoid attack-inducing allergen areas and help them better control and treat their asthma symptoms.

- There are a variety of mobile asthma management tools currently represented in the marketplace, all of which have similar but slightly different approaches:
  - Inhalers with GPS Technology: Several tools affix GPS tracking technology and a wireless link to the internet to the bottom of inhalers to help pinpoint the exact location and cause of an asthma attack.[6]
  - Inhalers with Audiovisual Reminders: Other tools use audiovisual reminders on inhalers to help improve asthma management.[7]
  - Smartphone Apps: Various tools use a Smartphone app to allow users to quickly and easily log their asthma activity, their medications and causes of their asthma in a diary which can then be shared with their physicians.[8]

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[1] Newman, J. (2011). High-tech inhaler from Madison company would help doctors track asthma attacks. June 15, 2011. Wisconsin State Journal. Retrieved from http://host.madison.com/wsj/business/article_e79d070e-9791-11e0-a329-001cc4c002e0.html. Accessed November 2011.
[2] CDC. (2011). Current Asthma Prevalence — United States, 2006–2008. *MMWR* 2011; 60(Suppl): (No.84-86).
[3] CDC. 2011.
[4] Behavioral Risk Factor Surveillance System (BRFSS). (2010). Child Current Asthma Prevalence Rate (Percent) and Prevalence (Number) by State or Territory: BRFSS 2010. Retrieved from http://www.cdc.gov/asthma/brfss/2010/child/current/tableC1.htm. Accessed November 2011.
[5] BRFSS. 2010.
[6] Halepis, H. (2011). GPS Inhalers Offer A Breath of Fresh Air. April 18, 2011. Retrieved from http://www.rmtracking.com/blog/2011/04/18/gps-inhalers-offer-a-breath-of-fresh-air/. Accessed November 2011.
[7] Charles, T., Quinn, D., Weatherall, M., et al. (2007). An audiovisual reminder function improves adherence with inhaled corticosteroid therapy in asthma. *J Allergy Clin Immunol,* 2007; 119: 811-816.

o Web and Mobile Phone Interfaces: Other applications connect patients and providers to recommendations through web and mobile phone interfaces.[9]

Clinical Benefit

A few mobile asthma management tools have been shown to have a number of positive clinical outcomes, such as helping patients get their asthma symptoms under control, improving the effectiveness of inhaler therapy and decreasing flare-ups, which result in fewer hospitalizations and trips to the emergency department or physician's office for uncontrolled asthma.

- A five-month study in 2010 focused on rural adults with asthma in 12 states and showed that many of them were able to get their symptoms under control after being given baseline data collected from a rescue inhaler with a GPS attachment (n=42).[10][11]

- Another study in 2009, looking at the same tool over a four-month period with a different population, showed that 75 percent of the patients improved their level of asthma control to some degree (n=40).[12]

- A 2007 study examined the effectiveness of audiovisual reminders in promoting adherence to inhaler therapy and demonstrated positive results, with 95.5% of patients who received reminders taking more than half of their prescribed medication compared to only 71.7% for patients not receiving reminders. (n=110).[13]

- Some asthma demonstration projects have shown that about 90 percent of attacks experienced by children with poor control of their asthma can be eliminated with appropriate information and action.[14] Other mobile asthma management tools have shown promising anecdotal evidence regarding clinical outcomes, but published results were not available.

- One asthma management tool has tracked over 50,000 users and improved the health of some asthmatics, though a randomized trial has not been conducted.[15]

Financial Analysis

- Asthma is a significant cost to our society, as annual expenditures for health and lost productivity due to asthma are estimated at over $20 billion.[16]

- Return-on-investment (ROI) for asthma management programs suggests positive potential financial savings: one review found that $2.72 was saved for every dollar spent on asthma disease management programs.[17]

- Another six-month study looked at an asthma management program and found net cost savings of $202,991.00, or 37.4 percent, compared to baseline costs. (n=258). Participants in this study also

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[8] AsthmaMD. (2011). About AsthmaMD. Retrieved from: http://www.asthmamd.org/about/#/resources/iphone_chart.jpg. Accessed November 2011.

[9] Asthma Signals. (2011). Asthma Signals, Inc. and the Asthma and Allergy Foundation of New England collaborate on an innovative mobile technology designed to tackle Pediatric Asthma. Press Release: May 24, 2011. Retrieved from http://www.asthmasignals.com/partners.htm. Accessed November 2011.

[10] Newman. 2011.

[11] Klein, S. (2011). Quality Matters Q&A – Asthmapolis: Improving Asthma Control with Mobile Technology. The Commonwealth Fund. October/November 2011. Retreived from http://www.commonwealthfund.org/Newsletters/Quality-Matters/2011/October-November-2011/Q-A.aspx. Accessed April 2012.

[12] Ibid.

[13] Charles, Quinn and Weatherall. 2007.

[14] Asthma Signals. 2011.

[15] Ghose, T. (2011). New Tech Boosts Science: From iPhone apps to cloud computing, everyday digital technologies are helping advance drug discovery, conduct clinical trials, and improve medical care. The Scientist. October 1, 2011. Retrieved from http://the-scientist.com/2011/10/01/new-tech-boosts-science/. Accessed November 2011.

[16] National Heart, Lung, and Blood Institute. (2009). Chartbook on Cardiovascular, Lung and Blood Diseases. U.S. Department of Health and Human Services, National Institute of Health. Retrieved from http://www.nhlbi.nih.gov/resources/docs/2009_ChartBook.pdf. Accessed November 2011.

[17] Goetzel, R., Ozminkowski, R., Villagra, V., et al. (2005). Return on investment in disease management: A review. *Health Care Financing Review*, 2005; (26)4: 1-19.

reported an 85.8 percent reduction in emergency room visits, a 57.5 percent drop in unscheduled physician visits and a 54.5 percent drop in hospitalizations.[18]

- Although studies have looked at asthma management programs and found cost savings as well as a positive ROI, there have been almost no studies done on the cost effectiveness of mobile asthma management programs.

- Widespread adoption is dependent on insurers paying for mobile asthma management programs; if they are not covered by insurance, it is unlikely that patients will purchase them out-of-pocket, especially safety-net populations.

- Mobile asthma management programs can help to reduce asthma attacks, which could reduce the overuse of emergency departments, prevent unnecessary hospital readmissions and decrease the number of hospital admissions due to preventable asthma complications.[19]

Barriers to Adoption

- *Ease of Use Issues:* Many of these technologies use smartphone applications, which could be confusing for the elderly or those not as technologically savvy.

- *Limited Data:* These programs are largely untested, especially regarding outcomes and possible ROI and cost savings of these technologies.

- *Privacy Concerns:* In the absence of clear guidelines, GPS-tracking and the transfer of medical information over the internet are likely to raise privacy concerns with patients.

- *Cost of Supporting Devices:* smartphones can be cost-prohibitive to elderly, minority and low-income populations.

- *Reimbursement Issues:* Widespread adoption of this technology is highly dependent on the reimbursement model. If these programs are not covered by insurance, it is unlikely that patients will purchase them out-of-pocket, especially safety-net populations.

Next Steps to Implementation

1. Develop Strategies that Address the Challenges of Patient Involvement: Many of these technologies may be burdensome for the user. For example, convincing patients to manually enter asthma data into a smartphone app multiple times a day as part of their daily routine might be a tough sell. In addition, GPS-tracking of patients, whether via an inhaler with Bluetooth technology or a smartphone app, might create privacy and security issues. As a result, strategies must be developed with the patient in mind in order to minimize disruption to the patient's routine and ease concerns about privacy.

2. Leverage Technologies for Public Health Interventions: These programs have clear epidemiological value, as asthma data can now be collected over time. In turn, public health and academic communities should work in partnership to develop an approach to compile and interpret data for targeted public health interventions.

3. Opportunity for the Safety-Net: Asthma is a chronic disease characterized by pervasive disparities, particularly in regard to minority and socioeconomic status. Strategies for the successful adoption of these technologies should also incentivize community interventions that focus on the safety-net population and make the business case for bundled payment models in Medicaid.

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[18] Owens, MK. (2006). State Medicaid Resource Kit: Maintaining Quality and Patient Access to Innovative Pharmaceuticals in Challenging Economic Times. National Pharmaceutical Council. December 2006: 12. Retrieved from http://www.npcnow.org/App_Themes/Public/pdf/Issues/pub_related_research/pub_disease/State%20Medicaid%20Resource%20Kit%202006.pdf . Last accessed April 2012.
[19] NEHI. (2008). How Many More Studies Will It Take? A Collection of Evidence That Our Health Care System Can Do Better. Retrieved from www.nehi.net/publications/30/how_many_more_studies_will_it_take. Last accessed October 2011.

The automobile is synonymous with American life and, increasingly, synonymous with America's growing obesity epidemic. Given that 119 million Americans, or 86% of all commuters, use a car and that the average commute by car is 24-28 minutes, Americans spend more than 47 million hours in the car each year driving to and from work alone.[1] Some health care technology manufacturers are developing systems to make use of this "lost" time for health management purposes.

In-car telemedicine is an emerging class of technologies that leverage recent advancements in automobiles to monitor and manage chronic diseases. As more cars are equipped with information technology systems and wireless capabilities, car manufacturers are beginning to leverage these new capabilities to actively monitor patients' health while driving.

Both Ford, with their "Sync" technology, and Toyota are actively developing in-car telehealth technologies. Ford, in particular, is developing its technology in partnership with other traditional health care companies including device manufacturer Medtronic, e-health provider WellDoc, and allergy management website developer SDI Health.

Use Case

- In-car telehealth can offer a safe and effective way to utilize mobile telehealth technology while patients are driving.
  - Portable medical devices, be they stand-alone or smartphone-based, face significant and growing legal limitations on use while driving.
  - Advanced information technology and mobile data connectivity have become increasingly common in automobiles. Voice recognition and wireless connectivity (Bluetooth) technology currently allow drivers to make phone calls, use GPS mapping and manage more traditional functions.
  - In-car telehealth uses the built-in automotive systems in conjunction with wireless health measurement devices and cloud-based data systems.
- The system is designed to support the management of chronic conditions.
  - Example Use Case 1: A diabetic patient's wireless glucose monitor communicates with the system, alerting that the driver is borderline hypoglycemic. The driver is prompted by the vehicle to remind him of the need to manage his blood sugar and to, if necessary, pull over and stop driving. Such an approach can enhance the consistent maintenance of glucose control or, in extreme cases, prevent loss of consciousness and resulting accidents.
  - Example Use Case 2: An asthma patient, driving through a known asthma attack-inducing allergen area, is warned by the system and the vehicle automatically switches the HVAC system to recirculate and closes the windows. These steps can prevent an asthma attack or prompt the driver to have a rescue inhaler at the ready.
  - Example Use Case 3: A patient with a known cardiovascular condition can be continuously monitored by integrated heart monitors. These data can be used to provide alerts to patients of impending heart attacks or to collect data for analysis.
- The system is wirelessly linked to cloud-based data management systems, allowing for the collection, analysis and use of data collected in the vehicle and from other sources.

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[1] McKenzie, B and Rapino, M (2011). Commuting in the United States: 2009, American Community Survey Reports, ACS- 15. U.S. Census Bureau, Washington, DC.

- The system also allows for real-time patient coaching, behavioral education and medication adherence support information to be "pushed" to the driver based on collected data.

Clinical Benefit

- No published data currently exist on the clinical benefits of in-car telehealth.

- However, data do suggest that general mobile telehealth interventions for diabetes can be clinically effective:

  o In one study, intervention patients exhibited a 1.9 percent decline in A1C compared to 0.7 percent for the usual care group after one year. All patients had private insurance coverage and access to the internet (manufacturer, n=163).[2]

  o The probability of surviving the first year after a heart attack was more than double for patients using cardiac telemonitoring services compared to those who did not use the service (mortality rate of 4.4 percent compared to 9.7 percent) (Israel, Intervention = 699, Control = 3,899).[3]

Financial Analysis

- No published data currently exist on the financial benefits or return-on-investment for this technology.

- Technology costs are not yet known, but it is anticipated that the majority of the system costs would be covered in the purchase of the vehicle and, as such, not require financial support from the health care system.

  o Given the use of standard connectivity technology protocols, the costs of health care devices which connect into the system should not be higher than other connected devices.

  o Ongoing service/monitoring fees will likely be necessary, but specific costs are currently unknown.

Barriers to Adoption

- *Availability*: None of the technologies are currently available to the public.

- *Regulatory Approval*: Significant unanswered questions remain regarding need for FDA 510(k) regulatory approval for these systems, perhaps even the vehicle – is it a " 4,000 pound medical device?"

- *Limited Data*: No clinical trials or significant pilot programs have been conducted to test this technology.

- *Reimbursement Issues* There is, as yet, no clear financial model for the ongoing funding of this technology and its associated service. It also remains unclear whether any costs would be borne by the patient themselves or paid for through traditional health insurance models.

Next Steps to Implementation

1. Clarify Regulatory Issues: A proactive approach to clarifying outstanding regulatory approval issues is required to advance the prospects of in-car telehealth. Manufacturers should begin conversations with the FDA regarding the regulatory framework for these "devices" as well as with the appropriate automotive regulatory agencies.

2. Identify Patient/Consumer Need: Significant effort is needed to develop compelling use cases for in-car telehealth from the perspective of patients/consumers. Given that consumers are responsible for much of the financial investment in this technology, via the purchase of the vehicle, the technology must have a compelling benefit to them, not simply to the health care system.

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[2] Quinn, C (2011). Cluster-Randomized Trial of a Mobile Phone Personalized Behavioral Intervention for Blood Glucose Control, *Diabetes Care,* 2011; 34:1934–1942.
[3] SHL Telemedicine (2007). Results from The Israeli Heart Society (ACSIS), April 2007. Accepted for Publication in the European Heart Journal. Investor Presentation. Accessed December 2011.

Social Media Promoting Health

Promotion of personal fitness, nutrition and general well-being through social media is an emerging approach to prevent and manage chronic diseases. These new social media sites engage and educate patients in personal health care, connect patients with their peers, implement evidence-based interventions, and change behavior over time. For some, their goal is to give simple daily challenges or "micro-actions" that add up to significant health improvements over time, all the while earning points and developing relationships with others on a similar pursuit. In some cases, points can be exchanged for discounts and rewards on consumer goods.

Many of these technologies leverage existing social media platforms like Facebook and Twitter and can be accessed on different internet-connected devices such as personal computers, smartphones or mobile phones. There are many social media sites that promote health in some way. A snapshot of sites on the market today includes MeYou Health, DailyFeats, BodiMojo and Zamzee.

Use Case

- Health-promoting social media target the masses rather than individual disease populations by promoting healthy actions aimed at addressing determinants of health and are free to the consumer.
- The focus for each site varies, but all of them connect patients and provide a health platform for inspiration and accountability. They take a holistic approach to health care and view many chronic diseases, such as diabetes and obesity, as systemic issues that require changes in how people live their daily lives.
- They have only been available to the public for the past few years, but the number of users has grown significantly in a short period of time. Based on interviews with two manufacturers, user demographics slightly skew towards women between the ages of 25 and 65.[1]
- A survey reported that use of web-based content, like wikis, blogs, and social networking, has significantly increased over the same time period, especially among safety-net populations and the chronically ill.
    - o Minority adults are more likely than their White counterparts to use cell phones and mobile devices to access the Internet, use instant messaging, engage social networking sites, look up health information, and track or manage their health with specialized applications.[2]
    - o Social network site users who are chronically ill are more likely to gather health information from these sites compared to those with no chronic conditions (20 percent vs. 12 percent). [3]
- Some of these sites have targeted or plan to target health plans, employers and physician groups to promote healthy behaviors among their employees, members and patients.
- In the near future, one vendor plans to leverage its technology to partner with pharmaceutical companies to incentivize and monitor healthy behaviors and compliance to care regimens of patients, while gathering data for the FDA.
- These platforms have significant public health implications, using social networks to gather clinical data which can be leveraged to implement population-based interventions.

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[1] Interviews with DailyFeats and MeYou Health, Conducted 12/11.
[2] Pew Internet and American Life Project (2011). Who's On What: Social Media Trends Among Communities of Color. Slideshare: January 25, 2011. Retrieved from: http://www.slideshare.net/PewInternet/whos-on-what-social-media-trends-among-communities-of-color. Accessed November 2011.
[3] Fox, S (2011). The Social Life of Health Information, 2011. Pew Internet and American Life Project, May 12, 2011. Retrieved from: http://pewinternet.org/Reports/2011/Social-Life-of-Health-Info.aspx. Accessed November 2011.

Clinical Benefit

- The clinical benefit of health-promoting social media has not been publicly quantified. Anecdotal data from vendors suggest positive results; however, no published data were available when this report was written.

- One vendor is planning a randomized control trial (RCT) of over 1,000 new members to demonstrate efficacy, while another vendor is currently surveying the impact of its product on the development of health habits on a weekly basis.

- Field tests of different types of social media platforms have shown that individuals using health-promoting social media have improved clinical outcomes compared to those who do not:

    o Smokers using the smoking cessation website, QuitNet, which includes social support through thread platforms, email and chat rooms, had a self-reported 7-day point prevalence abstinence rate of 7 percent and 30-day point prevalence abstinence rate of 5.9 percent after 3 months. This study had no control, but according to the CDC less than 5 percent of Americans will maintain abstinence for 3 months (n=385).[4]

    o Adults with Type 2 Diabetes or coronary heart disease enrolled in an online community for a walking program involving pedometers showed greater engagement in the program over a longer period of time (n=324).[5]

    o Teens demonstrated improved attitudes towards physical appearance after one month (n=178).[6]

- Scientists at MIT and Harvard are investigating the optimal social network structures to facilitate the spread of health information; their findings have been the building blocks of these sites:

    o One study suggests that individual adoption of healthy behavior was much more likely when participants received social reinforcement from multiple neighbors in the social network (n=1528).[7]

    o A controlled study on the spread of health innovation suggests that similarity in social contacts significantly increases the overall adoption of new health behavior among obese populations.[8]

- These platforms have shown value from a public health perspective in their ability to gather patient data. An international online diabetes community was overwhelmingly receptive to using a "Facebook-like" platform to chart and share A1C levels; 81.4 percent of users shared their data on the community display.[9]

Financial Analysis

- A robust analysis of financial benefits has not been completed to date.
- These sites are free to users, making them almost universally accessible, even to safety-net populations. Individuals only require internet access and 75 percent of adults in the U.S. go online.[10]
- Vendors have employed varying levels of marketing to recruit users, some investing little to no resources in marketing while others have invested in targeted marketing on Facebook.

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[4] Cobb, N (2005). Initial Evaluation of a Real-World Internet Smoking Cessation System. *Nicotine Tob Res*, 2005; 7(2): 207–216.
[5] Gibbons, MC (2011). Exploring the Potential of Web 2.0 to Address Health Disparities. Journal of Health Communication. August 15, 2011. Retrieved from: http://www.tandfonline.com.ezproxy.library.tufts.edu/doi/abs/10.1080/10810730.2011.596916?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed. Accessed November 2011.
6 BodiMojo (2011). BodiMojo launches "My Confidential," Girls-Only Confidence Dashboard. Press Release: October 30, 2011. Retrieved from:
http://www.bodimojo.com/press-release/bodimojo-launches-my-confidential-girls-only-confidence-dashboard.htm. Accessed November 2011.
[7] Centola, D (2010). The Spread of Behavior in an Online Social Network Experiment. *Science,* 2010; 329(5996):1194-1197.
[8] Centola, D (2011). An Experimental Study of Homophily in the Adoption of Health Behavior. *Science,* 2011; 334:1269-72.
[9] Weitzman, E et.al. (2011). Sharing Data for Public Health Research by Members of an International Online Diabetes Social Network. *PLoS ONE*, 2011; 6(4): e19256.
[10] Fox, S (2011). The Social Life of Health Information, 2011. Pew Internet and American Life Project, May 12, 2011. Retrieved from: http://pewinternet.org/Reports/2011/Social-Life-of-Health-Info.aspx. Accessed November 2011.

- *Limited Data*: Clinical evidence and financial return on investment (ROI) are unknown at this point in time.

- *Privacy Concerns*: Sharing clinical data in the public domain has inherent risks and users may be unaware or overlook the risk if they are desperate for information or support.

- *Cultural Resistance*: Patients need to be interested in leading healthy lives and choose to engage in health-promoting social media. Similarly, a subset of patients may be hesitant to share their personal experiences online.

- *Questionable Content*: Physicians are hesitant to recommend these sites to patients because they can't "trust" the content because it is not monitored.

- *Supporting Technologies*: Users require supporting technologies such as internet connectivity, personal computers, mobile phones and social media accounts such as Facebook and Twitter.

Next Steps to Implementation

1. Establish a Code of Conduct: To address patient privacy and confidentiality concerns, manufacturers should collaborate to define industry-wide standards for sharing patient data. These standards could be outlined in a unified "Code of Conduct".

2. Demonstrate Clear Evidence: For health-promoting social media to be taken seriously by more patients and providers, a robust clinical trial is needed to gather clear clinical benefit directly attributable to social media. Due to the inherent skepticism of some, the need for clear evidence is even more important. With regard to the safety-net population, social media is already used by many in the safety-net and they entail minimal to no upfront cost for the user. A targeted study for safety-net users would yield the needed evidence to promote widespread adoption for this patient population in particular.

An Innovative Technology Profile:
Mobile Cardiovascular Tools

Mobile cardiovascular tools represent the class of technologies that enable patients with cardiovascular disease (CVD) to monitor and share their vital signs with caregivers and providers using wireless technology. These tools come in many forms, ranging from mobile blood pressure (BP) monitors and electrocardiogram (ECG) monitors to body sensors, and all enable remote monitoring of critical cardiovascular data.

Often CVD patients will not recognize or will ignore symptoms leading to costly interventions sometimes resulting in mortality. These tools give patients insight into their disease, allowing them to manage their disease and identify clinical aberrations before they become serious problems.

There are many devices on the market today with varying levels of functionality. A representative sample includes Withings and Hammacher Schlemmer's mobile BP monitors, AliveCor's AliveECG and SHL Telemedicine's SmartHeart, and Delta's ePatch.

Use Case

- Cardiovascular disease (CVD) is a serious and costly condition for many Americans:
    - In 2006, an estimated 80 million American adults had at least one type of CVD.[1]
    - Heart disease is the leading cause of death for people of most ethnicities in the U.S., including African Americans, Hispanics and Whites.[2]
- Mobile cardiovascular tools encompass the range of technologies that enable patients to remotely monitor their vital signs. Many require the patient to have access to a Smartphone, while others are stand-alone devices with internet access:
    - "Mobile BP Monitors" attach to smartphones, allowing patients to collect and monitor their BP throughout the day, recognizing patterns more effectively than a single BP reading taken in the clinic as status inherently changes over time.[3]
    - "Mobile ECG Monitors" similarly utilize the built-in functionality of smartphones to measure and record electrocardiograms or transmit data to smartphones. The data can be used to diagnose CVD and may enable detection of a cardiac event.
    - "Mobile Body Sensors" are typically patches that adhere to the body collecting an array of vital signs such as heart rate, physical activity and sleep patterns. Data are then transmitted to smartphones or computers where patients and providers can view trends.
- Manufacturers employ a variety of business models to reach patients:
    - Manufacturers target both individual and larger customers like health insurers, hospitals, care organizations, medical device manufacturers and service companies to spread their technologies.[4]

Clinical Benefit

- Controlled BP has been shown in the literature to have significant clinical benefit:

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[1] Jones, D (2008). Heart Disease and Heart Statistics, 2009. Journal of the American Hearth Association, December 15, 2008. Retrieved from: http://circ.ahajournals.org/content/early/2008/12/15/CIRCULATIONAHA.108.191261.full.pdf+html Accessed December 2011.
[2] Centers for Disease Control and Prevention, (2010). Heart Disease Facts. Page Last Updated December 21, 2010. Retrieved from: http://www.cdc.gov/heartdisease/facts.htm. Accessed November 2011.
[3] Gianfranco, P (2008). European Society of Hypertension guidelines for blood pressure monitoring at home: a summary report of the Second International Consensus Conference on Home Blood Pressure Monitoring. Journal of Hypertension, 2008; 26:1505–1530.
[4] AT&T (2011). BlueLibris to Launch New Mobile Monitoring Devices on AT&T Network, Press Release: March 22, 2011 http://www.att.com/gen/press-room?pid=19397&cdvn=news&newsarticleid=31713. Accessed December, 2011.

- o Controlled BP has been associated with a 35-40 percent mean reduction in stroke incidence, 20-25 percent mean reduction in myocardial infarctions and more than 50 percent reduction in heart failure, according to a manufacturer.[5]
- The clinical benefit of specific mobile cardiovascular tools has not been robustly quantified to date.
- However, small manufacturer case studies suggest remote BP monitoring may have some prognostic value:
  - o A hypertension management program that required real-time readings resulted in an average BP reduction of 9 mmHg, from 147 mmHg to 138 mmHg over 6 months (manufacturer study, n=904).[6]
  - o Remote BP monitoring was more closely associated with the risk of cardiovascular mortality in two population studies, but in another it was not a significant predictor for hypertensive patients.[7]
  - o Remote BP monitoring was more closely associated with the risk of stroke in one population study, but in another population study, no prognostic superiority was found. [8]
- Similarly, small manufacturer case studies suggest that remote ECGs may improve cardiac event detection:
  - o Home ECG monitoring of high-risk post-myocardial infarction patients resulted in an average number of alarms per day of 0.39, with a positive predictive value of 0.106 (manufacturer study, n=10).[9]
  - o A manufacturer study testing the AliveECG is currently underway (n=100).
- There were no case studies available for "mobile body sensors" when this report was written. However, international programs that used cardiac telemonitoring services similar to body sensor technologies have successfully reduced the number of hospitalizations for CHF patients.
  - o In these programs, heart rate, blood pressure and body weight measurements were transmitted daily to a telemonitoring service center.
  - o The probability of surviving the first year after a heart attack was more than double for patients using cardiac telemonitoring services compared to those who did not use the service (mortality rate of 4.4 percent compared to 9.7 percent) (Israel, Intervention = 699, Control = 3,899).[10]
  - o Patients using cardiac telemonitoring services had a 66 percent reduction in total hospitalization days compared to the year preceding study entry (Israel, n=118).[11]

Financial Analysis

- As of yet, there is no specific evidence on the financial benefits of mobile cardiovascular tools. However, the cost of CVD is growing exponentially:
  - o In 2009, the estimated direct and indirect costs of CVD were $475.3 billion.[12] A major contributor to medical spending is inpatient hospital days reaching $71.2 billion, approximately one-fourth of the total cost of inpatient hospital care in the U.S.[13] As such, there is potential for significant savings if patients can be kept out of the hospital.

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[5] IDEAL LIFE (2009). White Paper: Hypertension, July 2009. Retrieved from:
http://www.ideallifeonline.com/whitepapers/WhitePaper_HTN.pdf. Accessed December 2011
[6] IDEAL LIFE (2009).
[7] Gianfranco, P (2008).
[8] Gianfranco, P (2008).
[9] Tomcsanyi, J (May 2009). Home ECG monitoring of high-risk post-myocardial infarction patients. Retrieved from:
http://www.ncbi.nlm.nih.gov.ezproxy.library.tufts.edu/pubmed/19443307. Accessed December, 2011.
[10] SHL Telemedicine (2007). Results from The Israeli Heart Society (ACSIS), April 2007. Accepted for Publication in the European Heart Journal. Investor Presentation. Accessed December 2011.
[11] Roth, A (2003). Telecardiology for patients with chronic heart failure: the 'SHL' experience in Israel. *International Journal of Cardiology,* 2004; 97(1):49-55.
[12] Jones, D. (2008).
[13] Jones, D. (2008).

- Through there are no financial data for these tools in the U.S., the same international programs that successfully reduced hospitalizations for CHF patients using cardiac telemonitoring services were shown to result in significant gross savings:
  - In Israel, gross savings were about $885 per 10,000 members annually.[14]
  - In Germany, a sick fund reported an average reduction in hospitalizations of 60 percent and a gross savings of more than $7,000 per CHF patient annually.[15] A different sick fund estimated that a 66 percent reduction in total hospitalization days would result in savings of at least $6.5 million annually.[16]
- Currently, most mobile BP and ECG monitors are not reimbursed, requiring the patient to pay out-of-pocket.
  - Mobile BP monitors range in price from $100-150
  - Mobile ECG monitors range from $100-500.[17,18]

Barriers to Adoption

- *Financial Barriers*: Widespread adoption is dependent on reimbursement. It is unlikely that patients will pay out-of-pocket, especially safety-net populations.
- *Financial Barriers*: The current fee-for-service payment mechanism does not pay for remote interactions.
- *Cultural Resistance*: Whether or not patients will take an active role in their health care remains to be seen.
- *Legal and Licensure Barriers*: Medical licensure regulations limit cross-state medical consultations.
- *Limited Data*: Additional studies are needed to verify the clinical and financial benefits of these tools.

Next Steps to Implementation

1. Clearly Define the Use Case: The use case for mobile cardiovascular tools is difficult to define. Some might argue that these technologies were designed first and paired to chronic disease management after. Only after the use case is clearly defined can the clinical and financial benefits be accurately quantified.

2. Consider Human Factors: Many of these technologies require an added effort from the patient and may be burdensome for many. Using patient focus groups to understand barriers to adoption may help inform future design decisions. In the future, these technologies should be developed to minimize disruption to the patients routine such as incorporating these devices into shirts or devices already used routinely.

3. Define Use Case for Safety-Net: These technologies may address a fundamental issue for the safety-net population: access to routine and specialty services. Because these tools allow patients to monitor their vital signs remotely, there is potentially a stronger use case for this population in particular.

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[14] Roth, A (2006). Telecardiology for patients with acute or chronic cardiac complaints: the 'SHL' experience in Israel and Germany. *Int J Med Inform,* 2006; 75(9):643-5.

[15] SHL Telemedicine (2007). Results were published by DKV Deutsche Krankenversicherung AG, July 1, 2004. Investor Presentation. Accessed December 2011.

[16] Roth, A (2006).

[17] Dolan, B. (2011). Interview: iPhoneECG Ready for Android, Too. MobiHealth News Press Release, January 17, 2011. Retrieved from: http://mobihealthnews.com/9955/interview-iphoneecg-ready-for-android-too/. Accessed December 2011.

[18] Empson, R. (2011). SmartHeart Turns Your Mobile Phone Into A Heart Monitor. May 24, 2011. Retrieved from: http://techcrunch.com/2011/05/24/smartheart-turns-your-mobile-phone-into-a-heart-monitor/. Accessed December, 2011.

CROSS-CUTTING LESSONS LEARNED

In addition to the specific analysis of the profiled technologies, NEHI's research uncovered several cross-cutting themes among the high-value technologies, each with significant implications for health care stakeholders including manufacturers, payers, patients and policymakers. These cross-cutting themes emerged from the research and interviews conducted during the scan process, and build on NEHI's extensive past experience with identifying and facilitating adoption of innovative technologies.

High-Value Technologies Leverage Existing Technologies and Consumer Products

- o **Lesson Learned**: In the past, similar scans have predominantly identified stand-alone devices that provide medical services to patients. In this scan, a new trend has emerged. Rather than building stand-alone devices, manufacturers are creating technologies that leverage existing consumer products found in patient's homes, cars and pockets. Because technologies increasingly leverage existing platforms, the upfront costs may be lower, an important benefit for the safety-net population. As mobile phones, smartphones and personal computers become increasingly ubiquitous, health care technologies that leverage these devices will continue to grow.

- o **Recommended Action**: Stakeholders should take note of the technology patients currently have at their fingertips and work to leverage these devices in their designs, reimbursement and policies.

New Technologies Have Entered an Unclear Regulatory Environment

- o **Lesson Learned**: As health care technologies move from stand-alone devices to systems that leverage smartphones and personal computers, the regulatory environment is increasingly unclear. Questions remain about when FDA 510(k) regulatory approval is required for such products; in many cases, it is up to the manufacturer to decide whether to seek regulatory approval, a process that can be time consuming and resource intensive. This inconsistent approach creates uncertainty for patients, providers and manufacturers.

- o **Recommended Action**: The FDA should address the changing face of medical technologies by clarifying their regulatory approval process for mobile and telehealth technologies.

"Better Mousetraps" Do Not Necessarily Mean Successful Technologies

- o **Lesson Learned:** The research and development environment for medical devices is in stark contrast to the landscape of drug development. Drugs are often discovered by small companies, which are later purchased by larger companies with the skills and resources to bring a product to market. Medical devices, on the other hand, are often developed <u>and</u> brought to market by small entrepreneurs who lack the human capital and financial resources to invest in clinical studies and financial analysis.

- o **Recommended Action:** Incubator structures and other outsourcing models can help small health care technology companies with clinical research, financial analysis and assistance with the regulatory process.

The Safety-Net Population Is Technology Savvy

- o **Lesson Learned**: Research increasingly points to the fact that the safety-net population is more similar to the general population in terms of technology adoption than previously assumed. Cell phones have become ubiquitous and even smartphones have become increasingly accessible to people of lower socioeconomic status. In fact, many low income individuals choose to use a smartphone as their single source for internet access rather than purchasing a personal computer and paying for internet access in the home. Contrary to common belief, many of these technologies are ideally suited for the safety-net population because they directly address the resource challenges and access issues paramount in the safety-net delivery system and many of the assumed hurdles for technology adoption may not be as significant as previously thought.
- o **Recommended Action:** Manufacturers should continue to innovate for and market to underserved populations as the adoption rate of mobile technologies continues to increase for this population and they are likely to benefit significantly from high-value innovations.

Societal Norms for Appropriate Use of Patient Data Are yet to be Determined

- o **Lesson Learned**: Innovative technologies are increasingly focused on clinical data collection and translation, creating more usable and actionable information for both the patient and provider. This new approach to health care is extremely powerful and data can be used to drive patient behavior and target interventions. However, the new age of "big data" brings with it real concerns of misuse, especially for vulnerable populations. The technology development process is moving faster than the development of societal norms for appropriate use of patient data.

- o **Recommended Action**: Manufacturers and the health community will need to make the case to each patient that using their data will benefit them personally along with others; but, societal benefit alone may not be sufficient to drive participation.

CROSS-CUTTING BARRIERS AND TARGETED NEXT STEPS

Health care stakeholders and policymakers often tout technology innovation as the panacea for clinical outcomes and cost savings. However, time and again, promising technologies fail to achieve their true potential because of the myriad barriers to their adoption. In the scan process, NEHI has identified a number of cross-cutting barriers that limit adoption of the profiled technologies and future high-value technologies as well. These barriers, if unaddressed, will continue to hold back the adoption of high-value technologies and should be a focus of policymakers and health care stakeholders.

Overcoming High Upfront Capital Costs

o **Barrier**: Health technologies with long-term value for the patient and the health care system may not be adopted if they require large upfront capital investments. Despite long term benefits, many technologies are not adopted because the health care system can't afford their implementation.

o **Recommended Action:** Business models that amortize upfront investments like rental agreements or rent-to-own models, as well as infrastructure banks where safety-net providers can apply for assistance with capital investments, help to address this challenge. The latter approach would allow providers and patients within the safety-net to realize the long term benefits of many of these technologies.

Generating Return on Investment (ROI) Data

o **Barrier**: It's the exception rather than the norm that a manufacturer will have adequate financial data, including an ROI calculation to support reimbursement and adoption of their product. Manufacturers too often assume that clinical benefit alone will drive sales. This is rarely the case; purchasers require clear financial evidence of net savings to warrant investment and reimbursement.

o **Recommended Action:** Manufacturers must study the financial benefits of their technology, as well as the clinical benefits, to identify ROI and support purchasing decisions.

Easing Cross-state Licensure for Telehealth Technologies

o **Barrier:** Medical licensure varies from state to state and limits telemedicine hubs from serving multiple jurisdictions. These hubs are integral to efficient telemedicine solutions where data are monitored remotely by a provider or caregiver. In the current environment, providers in these hubs would need licensure in every state where they remotely provide services even though the care they provide is fundamentally the same.

o **Recommended Action**: To maximize the efficiency of telemedicine technologies, states should work to harmonize medical licensure requirements to the extent possible.

Overcoming Misaligned Incentives from Fee-For-Service Payments

o **Barrier:** Fee-for-service payment models often drive volume rather than value in the use of health care. These models also have a negative impact on the adoption of technologies, failing to incentivize the widespread adoption of valuable mobile and telehealth technologies.

o **Recommended Action:** Continued progress towards bundled payments and Accountable Care Organizations will ease this barrier as providers increasingly consider value in their decision-making.

Incorporating Ease of Use into Technology Design

o **Barrier**: A patient's willingness and ability to use innovative technologies is vital to their success. The most successful technologies are often those that seamlessly fit into a daily routine of a patient and require little additional effort. For patients to continue to use a technology, it's important that they see progress and benefit; otherwise, their motivation to continue may be short lived.

o **Recommended Action**: Product design should encourage adoption by patients through prioritizing human factors above "flashy" technology requirements.

Addressing Concerns for Misuse of Patient Data

o **Barrier**: Some patients and providers are understandably skeptical regarding the collection and use of personal health data. Manufacturers will need to ensure that patients and providers are well informed about why their data are being collected and what they will be used for now and in the future. Current industry standards are limited and do not provide sufficient protections for some stakeholders.

o **Recommended Action**: In order to limit misuse of data and create more clarity in the industry, manufacturers, providers and the public health community should band together and create a "Code of Conduct" describing appropriate use of health data in telemedicine.

Addressing Provider Resistance to Telemedicine

o **Barrier**: Many providers remain uncomfortable and resistant to the use of telemedicine as a medium for health care delivery, continuing to focus on in-person interactions and the tactile nature of practicing medicine. However, as budget pressures grow, the need to implement low-cost solutions for health care delivery is growing. Rather than resist, providers should move to incorporate telemedicine into their practices and recognize that these technologies enhance their consultations, particularly for safety-net populations with access and affordability challenges.

o **Recommended Action:** To engage physicians and allay their fears, telemedicine approaches should be incorporated into medical education and ongoing training.

Addressing Provider Resistance to Engaged Patients

- o **Barrier:** Many providers remain uncomfortable and resistant to the changing paradigm of the provider-patient relationship. Patients are increasingly taking a more active role in their own health, using web-based resources to become informed about their disease. Providers should embrace this new era of patient engagement rather than resist.
- o **Recommended Action:** Similar to telemedicine, the evolving provider-patient relationship should be incorporated into medical education and ongoing training.

Overcoming Data Integration Challenges for the Safety-Net Delivery System

- o **Barrier**: A major challenge for technologies is the integration of remotely collected data into the patient's electronic medical record. These technologies will have far less impact if data exist in a vacuum, solely on a personal computer or mobile device. Hospitals and providers have ramped up their investments in information technology infrastructure in recent years; however, many of the small practices and community health centers that serve the safety-net populations still lack a sufficient IT infrastructure to effectively utilize this growing wealth of health data.
- o **Recommended Action**: To ensure that rural health clinics and community health centers can benefit from these new sources of patient data, continued public funding for regional HIT hubs that small clinics can leverage is critical.

APPENDIX: OVERVIEW OF PROCESS

A rigorous process was employed to identify the eleven promising yet underused technologies that were profiled in this report. This replicable process was designed to identify, assess and aid the adoption of transformational technologies for chronic disease management. A graphical depiction of the scan process can be seen below.

Figure 1 Graphical Depiction of Scan Process
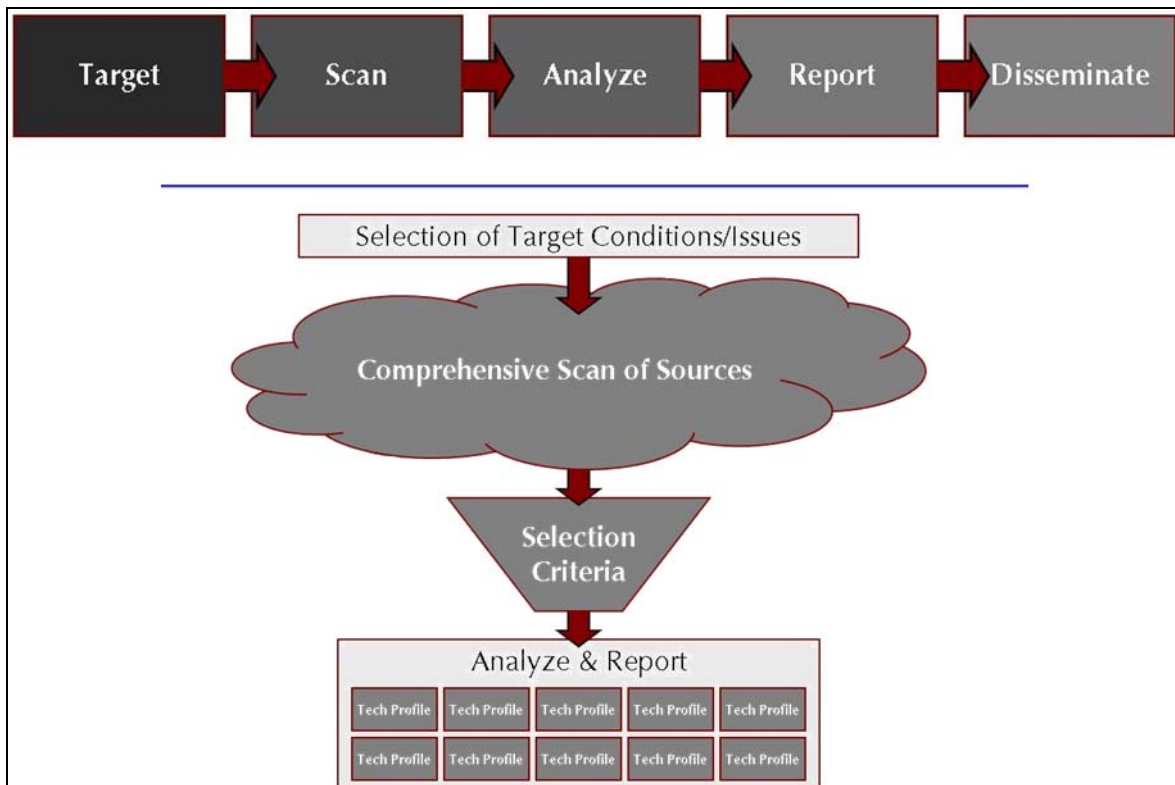
Step 1: Target

NEHI and CHCF developed a target audience and selection criteria to narrow the search parameters allowing for a more efficient scan while generating a more comparable set of candidate technologies. Formulation of the target was guided by the policy priorities of CHCF and the intended use of the final report to increase the affordability and accessibility of health care for underserved patient populations in California.

Chronic diseases, especially cardiovascular disease, diabetes and asthma, were chosen as the focus of this scan. Currently, the United States devotes significant resources to care for individuals with these illnesses, but much of this spending is avoidable with proper prevention measures such as early detection and disease management. With proper prevention, individuals can lead healthier, more productive lives, while saving dollars for the United States health care system.

California's safety-net patients, especially those with complex chronic conditions, were chosen due to the priorities of CHCF and the potential for significant clinical and financial benefit for this population. Safety-net patients drive significant and often avoidable costs due to their frequent use of health care services such as the emergency department for basic care. This population is often overlooked in technology innovation due to additional systemic barriers. However, there is significant opportunity for targeted technologies to have both clinical and financial benefit.

Step 2: Scan

A variety of sources including publications, conference programs and press releases were reviewed to identify innovative technologies with the potential to address the target populations. The high-level scan resulted in a diverse list of over 80 technologies that required additional research in the form of literature reviews and expert interviews to complete a technology profile.

Step 3: Select

The NEHI team applied a jointly developed and agreed upon set of selection criteria to identify eleven promising technologies. The selection criteria were developed based upon prior scan experience and the specific goals of this scan. Only technologies with prima facie evidence of the selection criteria and the greatest potential to address chronic disease care for safety-net populations were selected. The following selection criteria were applied in no particular order.

- Low current adoption, future potential. The technology is currently not widely adopted or has disparities in dissemination for specific populations defined by age, insurance, geography, or other parameters. The technology must have a potential path to future widespread adoption.

- Safety-net alignment. The technology and/or its target population must be aligned with or adaptable to the requirements and policies of safety-net delivery systems.

- Low cost. The technology has low up-front and recurring costs. Applicability to the safety-net systems implies technologies are feasible, affordable and "not too heavy a lift" for adoption by safety-net providers.

- Broad application. The technology must be able to demonstrate value in a broad application and address a condition or health policy issue with a target population of sufficient size to result in significant impact.

- Identifiable barriers. The barriers to broader adoption of the technology are identifiable. These may be payment, reimbursement, legal, regulatory, cultural or behavioral.

- Positive user experience. The technology has positive (if limited) data on patient experiences and user acceptance.

- Multiple products/manufacturers. The technology has more than one product and/or manufacturer in the marketplace, or more than one product and/or manufacturer are likely to be available in the near future.

Step 4: Analyze

Once the promising technologies were identified, the NEHI team conducted extensive research to create a profile for each of the eleven technologies. The information presented in the report was primarily gathered through case interviews with individual manufacturers and researchers since many of the technologies profiled are new to the market and lack extensive market research and peer-reviewed findings.

Each technology profile generally summarizes the technology grouping and highlights a limited set of products on the market today. Each profile captures the following information:
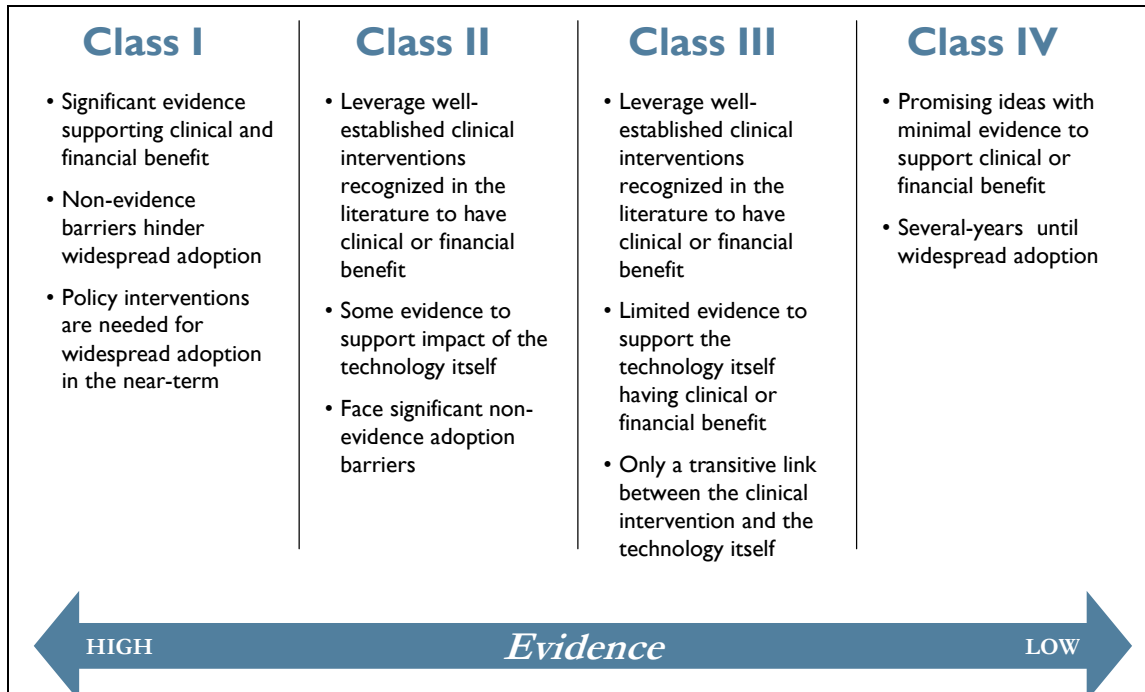
o *Use Case.* This section captures an array of information designed to describe who, what, when and how a patient would use the technology. Information includes the target audience, the technology's clinical intervention, the means to access the technology, the supporting technologies and the number of installed bases.

o *Clinical Benefit.* This section captures the clinical evidence in favor of the clinical intervention and the technologies themselves. In many cases, evidence for the technologies is gathered from small case studies rather then well designed clinical trials.

o *Financial Analysis.* This section captures any financial calculations that suggest return on investment for this class of technologies. In many cases, the technology itself lacks substantial financial analysis, but the clinical intervention that the technology supports may have significant financial benefit both in the short and long term.

o *Barriers to Adoption.* This section lists the key barriers that currently limit widespread adoption. They range from financial barriers to cultural resistance, but many are common among technologies profiled.

o *Next Steps to Implementation.* This section lists two to three targeted actions that if implemented, would facilitate adoption. These next steps range from design recommendations to policy level interventions, but are focused and achievable actions rather than broad sweeping reforms.

Each technology profile makes reference to a number of products and manufacturers. These examples are for illustrative purposes only and are not intended to represent a comprehensive list of the products available in the marketplace nor to endorse any specific products or manufacturers.

The eleven technologies profiled vary in terms of the quality and quantity of supporting evidence and current level of adoption. NEHI created an "adoption readiness spectrum" ranging from those with less evidence or more significant barriers to technologies with strong evidence, minimal barriers and primed for immediate widespread adoption. The spectrum includes four classes and though not a perfect correlation, one could say that Class I and Class II technologies, those technologies with the strongest evidence and

fewest barriers, have the highest promise for successful implementation into safety-net populations. A graphical depiction of the scan process can be seen below.

Figure 2 Adoption Readiness Spectrum

Class I	Class II	Class III	Class IV
• Significant evidence supporting clinical and financial benefit	• Leverage well-established clinical interventions recognized in the literature to have clinical or financial benefit	• Leverage well-established clinical interventions recognized in the literature to have clinical or financial benefit	• Promising ideas with minimal evidence to support clinical or financial benefit
• Non-evidence barriers hinder widespread adoption	• Some evidence to support impact of the technology itself	• Limited evidence to support the technology itself having clinical or financial benefit	• Several-years until widespread adoption
• Policy interventions are needed for widespread adoption in the near-term	• Face significant non-evidence adoption barriers	• Only a transitive link between the clinical intervention and the technology itself	

HIGH ⟵ *Evidence* ⟶ LOW

Step 5: Disseminate

The final report and recommendations will be shared with a broader audience of stakeholders interested in innovation and cost containment strategies for chronic disease patients in California's safety-net population and across the country.

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