An Innovative Technology Profile:

Mobile Cardiovascular Tools

Class IV

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:

[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.

- 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:
  - 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]
  - 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]
  - 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:
  - 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]
  - 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.
  - In these programs, heart rate, blood pressure and body weight measurements were transmitted daily to a telemonitoring service center.
  - 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]
  - 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:
  - 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.