Wearable Sensors for Cardiac Rehabilitation

Insights in Engineering Leadership White Paper

Abstract

A confluence of events presents the opportunity to apply a wearable sensor based approach to increase participation, improve effectiveness, and reduce cost of cardiac rehabilitation. Cardiovascular disease (CVD) is the number one cause of death within the United States and globally, and projected to continue to rise. The direct and indirect cost of CVD in the US is projected to increase from $656 billion in 2015 to over $1.2 trillion in 2030. Patients benefit greatly from cardiac rehabilitation. Unfortunately participation in cardiac rehabilitation programs is low. New cardiac rehabilitation strategies are desperately needed to decrease the current CVD impact trend.

Number: 2014.4.10
Date: April 10, 2014

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This paper was created in an open classroom environment as part of the Engineering Leadership Professional Program (ELPP) developed and led by Prof. Ikhlaiq Sidhu at UC Berkeley. There should be no proprietary information contained in this paper. No information contained in this paper is intended to affect or influence public relations with any firm affiliated with any of the authors. The views represented are those of the authors alone and do not reflect those of the University of California Berkeley.
CVD is the number one cause of death in US: **780,000** deaths (2010)

Direct and indirect cost of CVD **$315bln** (2010)

Projected total cost of CVD is expected to rise to **$1,200bln** in 2030 (2012$). Even a 1% cost reduction results in **$multi-billion savings!**
Main Hypothesis and Topic

Wearable sensors have various healthcare applications. An emerging area is facilitation of outpatient rehabilitation. There is great opportunity to increase participation, improve effectiveness, and reduce cost for cardiac rehabilitation by leveraging wearable sensors.

Section I: Introduction

A confluence of events presents the opportunity to apply a wearable sensor based approach to increase participation, improve effectiveness, and reduce cost of cardiac rehabilitation (CR) through outpatient use. Cardiovascular disease (CVD) is the number one cause of death within the United States (and globally), and projected to continue to rise. The direct and indirect cost of CVD in the US is projected to increase from $656 billion in 2015 to over $1.2 trillion in 2030.

Patients benefit greatly from cardiac rehabilitation. The Mayo Clinic defines CR as

“a customized program of exercise and education. Cardiac rehabilitation is designed to help you recover from a heart attack, other forms of heart disease or surgery to treat heart disease.”

The National Institute of Health’s Heart, Lung, and Blood Institute (NIHLBI) is one of the many references that states: “Cardiac rehab can improve your overall health and prevent future heart problems and even death.”

The economic benefits of CR are also known: an article in the European Journal of Preventive Cardiology estimates cost savings of CR to be in the range of thousands of dollars per QALY (Quality Adjusted Life Year). Unfortunately participation in cardiac rehabilitation programs is alarmingly low at less than 30% of eligible patients. A 2012 American Heart Association Science Advisory concludes:

“CR and secondary preventive services have been well documented to reduce morbidity and mortality.

Despite the well-documented benefits, outpatient CR referral and participation rates remain disappointingly low. Therefore, greater efforts must be made to reinforce the importance of outpatient CR among healthcare systems, providers, and the public and thus to increase referral rates.”

A December 2013 Journal of the American Heart Association article concludes:

“New strategies for promoting participation in cardiac rehabilitation are desperately needed. Initial evidence supports the feasibility and acceptability of using mobile technology for cardiac rehabilitation.”
An American Heart Association Presidential Advisory states that given the high rate of heart attack recurrence

“preventing secondary cardiac events is an essential part of the care for patients with cardiovascular disease (CVD).

Health reform offers a unique opportunity for the reengineering of CR/SPPs to move beyond the traditional clinical center model toward new models of service delivery that can help expand the provision of high-quality comprehensive cardiac rehabilitation to all patients with CVD.”

Section 2: Existing Market

Opportunity exists in the market today for an effective product that leverages wearable sensors for outpatient CR.

At the 2011 American Medical Association IEEE conference, Dr. Luca Pollonini and Dr. Clifford Dacso presented a poster titled “Wearable Sensing Device for Home Monitoring of Cardiac Rehabilitation”. This poster concludes:

“This preliminary validation on healthy subjects shows that our device gives users relevant, personalized information about their conditioning status in real-time - when there is time to adjust their ongoing exercise to meet their rehabilitation goals.

We plan to refine and perfect the prototype sensing system by adding wireless EKG and PPT to maximize wearing comfort and quality of the readings. Additionally, multiple miniature muscle NIRS probe will be used to enable simultaneous reading on different groups of muscles. We plan to validate the device in a more extended clinical trial with CAD patients enrolled in standard and non-standard rehabilitation programs. Our long-term goal is promoting home-based, self-assessed rehabilitation programs to reduce mortality and increase well-being of the CAD population.”

Dr. Pollonini and Dr. Dacso are continuing their effort through the startup Blue Box Health. Blue Box Health was founded in 2009 and is privately held. From linkedin.com, Blue Box Health and their product is described as:

“The Company has developed a prototype sensor, Blue Scale, for chronically ill heart failure patients' use in the home. The Company has designed a clinical trial for the purpose of securing approval of its product by the FDA.

The Blue Scale will further the delivery of therapeutics by providing real-time monitoring and reporting as well as daily feedback thus improving medication compliance, decreasing complications, preventing decompensation events, and markedly decreasing the cost of care of this disease that accounts for $39 billion in
direct costs. The system will reduce total rehospitalization costs in the U.S. by $6 billion."

During a phone discussion Dr. Dacso (Blue Box Health CEO) claimed that the price point for their Blue Scale product is around $200 and that it is not expensive to build. A challenge for Blue Box Health has been reliable prototype creation, but Dr. Dacso is confident that the main technology challenges are behind them. One of the market challenges is the current “fee for service” healthcare payment system in the US, since it promotes doctor/patient face-to-face office visits, and doctors do not want to do “free” work. Exceptions to this payment model barrier are institutions that have “global risk”, where the institution both employs the doctors and provides medical insurance to patients, for example, HMO’s such as Kaiser, Veterans Health Administration, or the National Health Service in UK. Blue Scale plans to do product validation and achieve initial market acceptance through assisted living facilities, cardiologists, and health care providers.

Competitors to Blue Box Health include Corventis’s AVIVO Mobile Patient Management (MPM) System, intended to continuously measure, record, and periodically transmit physiological data, and Cardiocom’s Telescale, a home tele-monitoring system that can reduce acute care hospital admissions for heart failure. Both of these lack the broad applicability of the Blue Scale product, its analytics, and ease of use.

There are other existing products which attempt to provide remote monitoring of CVD-related vitals, however they do not address the outpatient CR market. An example is smartheart from SHL, an Israeli company dedicated to telemedicine. This personal mobile 12-lead ECG device enables the detection of heart attacks. It is claimed to be the first, the only, and the smallest 12-lead ECG in the world. SHL website describes their service as:

“Our cardiac monitoring service has been in operation for more than a quarter of a century. SHL Telemedicine will provide you with one of the easy-to-use hospital grade ECG devices developed by our Company. As well as our technology strengths, we have supportive, professional staff available 24/7 to check your newest ECG and pick up any change since your last one. They will contact you if necessary according to medical guidelines that were determined by professional physicians and cardiologists and are constantly examined and reviewed by our medical board.

We keep a record of all your ECGs, supplementary tests, hospitalizations and medication data in your online Personal Health Record, for immediate access at any time. This means that you can go on business trips or holiday travel without taking your medical files with you. We manage all our information on the Internet (according to HIPAA rules), which is handy if you need to see a doctor when away from home.”

Section III: Technology

Effective cardiac monitoring relies on accurate measurement of some of the following:
• **Weight** – maintain healthy weight;
• **Physical activity** – regular exercise;
• **Diet** – increase intake of Omega-3 (oily fish diet supplement);
• **Blood pressure** – maintain BP within proper range;
• **Medicine intake** – confirm that patient takes medicine;
• **EKG**;
• **Heart rate** – normal and in response to exercise;
• **Alcohol** – do not exceed the recommended daily limits;
• **Smoking** – if you smoke, it is strongly recommended you quit ASAP.

Multiple sensors or devices already exist in this space, for example iHealth BP Monitor, Samsung Gear Fit with heart rate monitor, and Proteus smart pill. However, to date, no company has successfully applied these devices to Cardiac Rehabilitation. Some of the technology factors that need to be addressed to facilitate the adaption of wearable sensors include:

- Form factor;
- Processing power & power consumption;
- Data transmission and security;
- Data processing.

For continuous monitoring, any wearable sensor should not obstruct or interfere with the patient’s daily activities, therefore more sensors in a smaller device are desired. The Edison platform, to be introduced in the Summer of 2014 by Intel, is designed to address some of the form factor considerations for wearable sensors:

> "Edison is intended for use in small, flexible electronics that can be worn around the body. While smartwatches, fitness trackers and health monitors are grabbing the most attention, Intel hopes Edison will be used as a launching pad to experiment with new wearable product designs."

One of the primary goals of the Edison platform is to allow multiple sensors to be connected or integrated, while minimizing power consumption. An additional goal is to field-test the wearable devices before defining future chip designs. Mike Bell, vice president and general manager of the New Devices Group at Intel, says “The improvements will future-proof Edison”, adding that “the company will look at how wearable devices turn out before defining future chips”.

Other hardware manufacturers are also active in this space. Freescale’s Warp is a hardware development platform designed primarily for prototyping wearable computing devices:

> “Freescale Semiconductor, a maker of small, low-power processors, has announced an effort based on a $149, Android-powered, open-source electronics board to try to help hardware developers build its chips into wearable computing devices.”
Learning from platforms such as Edison and Warp will allow more sensors to be integrated into a convenient power efficient form factor.

Another technology factor that needs to be considered is how sensors and devices communicate with each other and transmit data. The chart below shows a typical ecosystem consisting of multiple sensors and/or devices, using different and sometimes proprietary connectivity standards, connecting to various different systems.

The connectivity issue is seen as a barrier to extending care beyond traditional settings. The Contunua Health Alliance (CHA), a non-profit attempting to define standards in this area, notes:

“Various technologies could help by extending treatment and care beyond traditional clinical settings into personal and home settings. However creating such a personal telehealth ecosystem will require interoperability. Device connectivity to enterprise services is currently very proprietary.”

Devices that have the CHA certificate make use of the ISO/IEEE 11073 Personal Health Data (PHD) standards. To address security concerns, access to CHA design guidelines requires signing a non-disclosure agreement. CHA member companies include
semiconductor manufacturers, pharmaceutical companies, health care providers, and device manufacturers. Adoption of standards should help evolve the required ecosystem for effective home-based rehabilitation using wearable sensors. CHA certified sensors and devices should all be interoperable in the telehealth ecosystem.

Finally, doctors require actionable data, not more raw data. Therefore, some post-processing of the raw sensor data, either on the sensor device or on an aggregator of the data is desired to mine the raw data for actionable data. Monitoring systems should be able to take advantage of data mining algorithms to mine the raw data. Recent research shows that data mining techniques in the diagnosis of heart disease are giving acceptable results. The techniques were studied primarily in hospital environment, where the proposed algorithms are used as a “second opinion”, health professionals still monitor all data.

This brings up a potentially big technological challenge that needs to be considered – the cost of false-negatives in cases when the algorithm misses a critical diagnosis. There are no 100% accurate algorithms, so the question of acceptable risk and liability needs to be addressed. Such risk may be reduced by using larger sample sizes to train supervised learning based algorithms, but risk is still an issue. A barrier to using a larger sample size is the “privacy of records and ethical use of patient information”.

“Further, there may be ethical, legal and social issues, such as data ownership and privacy issues, related to healthcare data. The quality of data mining results and applications depends on the quality of data.”

The patient privacy issue may not be a barrier in organizations such as Kaiser, since the patient data already exists in the Kaiser medical IT system and may be mined without privacy concerns.

Section IV: Broad Contextual Factors

Wearable sensors and software platforms must be FDA approved prior to healthcare use. Several of the current devices available in the market, e.g. Corventis NUVANT cardiac monitor, Qualcomm Life 2net software platform, are already in compliance with FDA. Many more devices are in the process of FDA certification and approval. Our research indicates that FDA approval is not going to be a major obstacle for adoption of this technology.

A recent article in the International Journal for Equity in Health notes:

“rural inhabitants and patients of low SES” (Socio-Economic Status) “experience greater barriers to CR utilization when compared to their urban, high SES counterparts”

Use of wearable sensors in CR has the potential to increase participation of rural population without easy access to traditional rehabilitation centers and should contribute to making the healthcare system in the US more equitable.
While in-hospital cardiac healthcare is typically covered by insurance plans, outpatient CR often is not. The newly-adopted Obamacare law mandates that all insurance plans cover rehabilitation services as part of requirements of the “essential benefit package”. This is likely to greatly increase participation in CR of patients of low SES, i.e. of women and minorities.

Section V: Today vs. Future

Today outpatient CR requires patients to make one or more weekly visits to hospitals or rehabilitation centers for many weeks or months, making it difficult or inaccessible for many patients. In the future the use of wearable sensors will allow a large portion, but not all of CR, to be shifted to patients’ homes. We envision a “wearable CR” program of the future to start in the hospital, as it does today with Phase 1 (Inpatient CR), but during this phase the team of healthcare providers would train and supervise the patient in the use of the required wearable sensors and in data collection procedure to make the transition to Outpatient CR smooth. After being discharged from the hospital, the patient would start the Phase 2 (Outpatient CR) at home. During the initial 30-day period of Phase 2 patient may be required to visit the rehabilitation center a few times for on-site monitoring, as this is the most unstable period during the recovery from a CVD event. Thereafter, visits to the rehabilitation center may be become much less frequent or not necessary at all.

We expect the following considerations to apply to the future users of this technology: insurance companies, hospitals, doctors, and patients.

While it is logical that both the insurance companies and hospitals should be most interested in the wearable CR, since it can lower costs and improve outcomes, the current “fee for service” payment system needs to be modified to compensate doctors and hospitals for services not requiring face-to-face doctor/patient contact. Per comment from Dr. Dacso’s of Blue Health Box, “such system may be many years away.”

This, in turn, may slow down the rate of adoption of wearable CR among doctors. Other concerns for doctors are the liability for the decisions made based on the collected data (especially in cases of false-negatives, see Section 3) and a potential data overload, since doctors need more actionable data, not raw data. Interestingly, the need for actionable data may result in creation of a new category of medical IT professionals, “medical data technicians”, whose task will be to analyze and present to doctors the data collected by sensors.

Hospitals have several incentives to use wearable CR. Most importantly, because it can lower the 30-day readmission rate, for which they are presently not paid by insurance companies. Another reason is that wearable CR may allow more efficient use of nurses and physical therapists administering CR, since they will be able to service more patients. And, finally, use of cutting edge wearable CR technology may be good for marketing purposes.

But the biggest beneficiaries of the wearable CR will be the patients themselves, especially since under Obamacare CR coverage by insurance plans becomes mandatory. A very
important side benefit of wearable CR will be increased patients’ awareness and involvement in their own health: in the words of Dr. Dacso, this would allow them to “turn a 2am emergency into a 10am urgency!”

In the light of the above considerations, the likely first adopters of the “wearable CR” technology are organizations with “global risk” (see Section 2), i.e. HMO’s, such as Kaiser, and national health services, such as NHS in UK. Such organizations can financially incentivize the doctors whom they employ to use this technology, securely handle all of the collected CR data within internal medical IT departments, and subsidize the cost of the device to proliferate its use among patients.

On the other hand, these medical organizations likely lack the know-how to develop the sensor technology and all of the required data storage, communication, and analysis infrastructure. Hence, they are likely to partner with wearable device makers, such as Blue Box Health, and with data platform providers, such as Qualcomm Life.

Qualcomm Life is uniquely positioned to benefit from the introduction of wearable CR technology and may be a big winner in this field, since its 2net cloud-based system can provide the middleware layer between wearable sensors on one side and the medical IT departments of the hospitals on the other side. Additionally, Qualcomm Life has the scale to be the preferred reliable turn-key service provider for large HMO’s such as Kaiser.

Manufacturers of the wearable sensors, such as Blue Box Health, will attempt to capture a larger portion of the value by not only supplying the hardware, but also by providing the CR data analysis algorithms and software applications to hospitals and doctors. The abundance of data previously not available to doctors during the CR process will undoubtedly improve the outcomes and further lower the costs.

Section VI: Summarize and Predict Opportunity

The main challenge in applying wearable sensors to Cardiac Rehabilitation is in creating a seamless ecosystem, consisting of simple-to-use, unobtrusive wearable sensors, secure data transmission and storage infrastructure, data analysis algorithms to make the raw data actionable, and a system of payment to deliver this new service. While all of the needed technology already exists today, integrating the pieces and working out the rules for this ecosystem may take a few years. The best opportunity for this ecosystem to materialize is within the confines of a “global risk”, HMO-like organization.
“So, Doc, what would it take to make my little ‘problem’ disappear?”

“We need to replace your pinky ring with a wearable heart rate monitor.”
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