Engineering Management Field Project

A Proposal for the Use of Wireless Technology in Healthcare

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Executive Summary

- The annual healthcare cost in the United States is a staggering $2.6 trillion USD or over 17% of the gross domestic product (GDP). Research consultancy firm McKinsey reports that remote patient monitoring of chronically ill patients alone could reduce healthcare costs by as much as $200 billion per year.
- Enhancements in mobile communication devices and networks make them on par or more advanced than some of the standard instruments used in healthcare today. In addition, these devices are available at much lower costs than traditional healthcare devices. Thus, leveraging these devices and wireless networks could significantly reduce the cost of healthcare delivery and expand coverage. Wireless operators have the distribution channels and marketing capability to reach the majority of the population.
- Wireless operators are looking to vertical industries like healthcare for future revenue growth due to saturation in the consumer market (greater than 103% penetration). Mobile operators have networks that cover over 97% of the total US population. In addition, they have a large employee base to leverage for m-health trials. With their large employee base, mobile operators have influence over large health insurers such as United Healthcare, Wellpoint, Kaiser and others. Since healthcare insurers and the Center for Medicare and Medicaid Services influence the industry through reimbursements for services, gaining their acceptance is tantamount to success.

What is preventing the merger of healthcare and wireless technologies?

The primary challenge in exploiting the advantages of mobile healthcare solutions is a fragmented industry due to lack of agreed upon standards. This fragmentation limits healthcare providers' ability to exchange patient data for improved treatment and consistent data for broader analysis. It also limits healthcare providers' ability to deploy remote monitoring solutions, which would reduce hospital visits and improve patients' health data.

While work is underway in standards organizations such as Integrating the Healthcare Enterprise (IHE), Continua Health Alliance, the Healthcare Information and Management Systems Society (HIMSS) and other organizations, a baseline agreement still has not been reached. Baseline standards for an end to network would enable global interoperability much like that of cellular networks today. Standardization drives mass market solutions and the major changes needed to impact healthcare costs.

In addition, no large scale trial has been done and published to validate the reduction in healthcare cost resulting from m-health solutions. Mobile operators are well positioned to influence and execute these trials. They can also influence and drive the standardization of m-health solutions.

- Secondary research revealed the large-scale fragmentation in the industry with various proposals for mobile health solution but none standardized for global adoption. It also showed the huge potential revenue opportunity for mobile operators in the healthcare segment.
- Primary research confirmed the idea that wireless technologies can play a significant role in reducing healthcare costs if targeted to chronically ill patients. However, the lack of standardized approach is a huge inhibitor.
- This author designed a proposed Architecture for HL7, which recently initiated a work group to focus on the use of mobile technologies in healthcare. The proposal includes specification options for each component included in the architecture as well as the integration specifications.

Focus on Chronic Diseases

The treatment of chronically ill patients accounts for approximately 80% of the healthcare costs. Hospital related expenses are close to $800 billion a year and account for one of the largest components of overall healthcare costs. Remote monitoring solutions using the telecommunications network could reduce hospital visits, the length of hospitalization, and re-admissions, thus significantly reducing healthcare costs. Results of the research indicate that solutions adopted by the Center for Medicare and Medicaid services (CMS) will drive market adoption. Reimbursement for services is critical in determining which solutions are adopted by healthcare providers. CMS provides healthcare reimbursements and accounts for approximately 35% of healthcare expenditures. Therefore, solutions selected by CMS will be most impactful.

Replacing Traditional Healthcare Devices with Smartphone Applications

Examples of the capabilities of new technological applications include the resolution of a typical smartphone camera, which is greater than 300 pixels per square inch. This resolution exceeds that of some ultrasound machines. Some cell phones have processors in excess of 1GHz, which is similar to the top-of-the-line pacemakers and defibrillators. HD video cameras on many cell phones shoot images at 30 frames per second, making those more advanced than the colonoscopes doctors use to search for cancerous tissues. There are many more examples of how advances in cellular capabilities can be leveraged to reduce healthcare costs.

In addition, the widespread use of mobile phones means that most patients have a mobile device. Thus re-purposing these devices to enable patients to take a more active role in their healthcare will not require a major change in behavior or costs. Many cell phones can be converted to medical devices with simple attachments and applications. For example, a clip on eye piece can be attached to a smart phone to enable a refractive error test used by doctors to determine patients' vision. This device, with additional applications, allows for the delivery of optometrists' instruments for less than $30 USD, versus the $10,000 price of the traditional model. Blood pressure cuffs can be attached to cell phones to provide measurements and delivery of the data for optimized treatment and for trending and analysis. Using these devices enables patients to take a more active role in their own health, thus reducing the number of doctor visits needed.

Research Outline

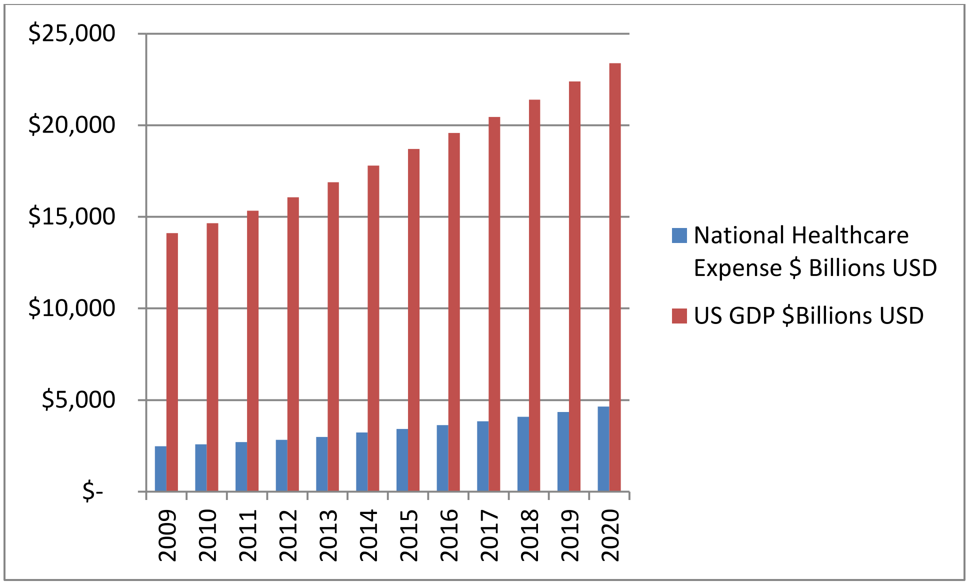
The first chapter of the report provides a high-level market overview and background information on the subject. Chapter 2 is the literature review, which is a broad survey of the research work done on m-health including articles and books written about the subject. A summary of the articles is provided along with insight into what additional work is needed in each area. Feedback on what the authors did well and not so well is also included. The overall findings of the secondary research are summarized in a conclusion. Chapter 3 covers the research methodologies used for the primary and secondary research. This chapter also includes the questionnaire used for primary research and resulting feedback. The results from the research are summarized in Chapter 4 along with the author's insight on the subject. The report concludes with areas for additional research.

1.0 Introduction

According to the Center for Medicare and Medicaid Services (CMS) report US Healthcare Expense 2010–2020, the cost of US healthcare was $2.6 trillion USD in 2010 and is expected to grow to $4.6 trillion by 2020. Growth in healthcare spending is attributed to an increase in healthcare enrollment, coverage expansion to include people below the age of 65, Exchange plan premiums (Part of the Affordable Care Act) and cost sharing subsidies as well as growth in the elderly population. For 2012, US healthcare cost is projected to account for 17.5% of the nation's Gross Domestic Product (GDP).

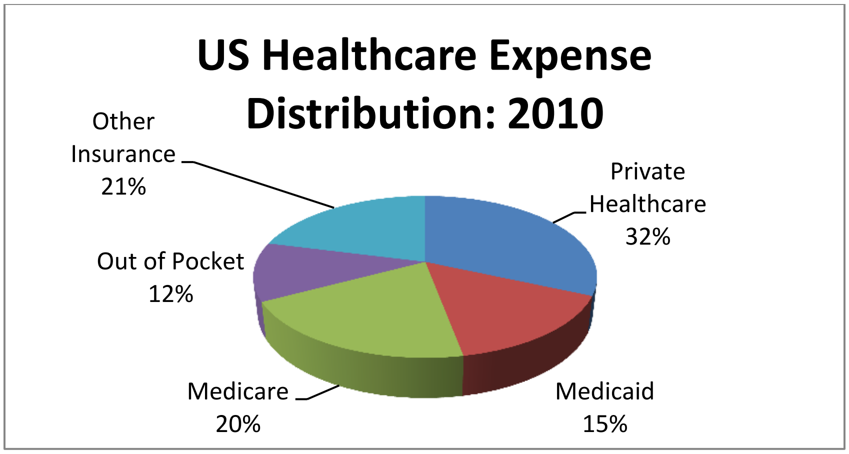
Chart 1: US GDP and Healthcare Expense 2010 - 2020

Source: (National Health Expenditure and Selected Economic Indicators: 2005 - 2020, 2011)



According to health expense data for 2010 (See chart 2), the US government paid approximately 35% of the overall healthcare expenses through Medicare and Medicaid services. Private insurance covered 32%, while 12% were out of pocket expenses from various households. Overall hospital expenses accounted for 30% or $794 billion USD of total expenses, physician and clinical services expenses accounted for 20%, or $518 billion, and prescription drugs accounted for 10% or $259 billion USD. The key point is that federal government and private health insurance cover 67% of healthcare expenses in the US and hospitalization costs make up a significant amount of the overall expenses. Thus, minimizing hospital visits and hospitalization can have an impact the overall cost of healthcare in the United States. Since CMS pays a significant portion of the costs, solutions adopted by CMS will largely influence the rest of the industry.

Chart 2: US Healthcare Expense Distribution – 2010



According to management consultancy McKinsey, the healthcare industry could save $175 to $200 billion annually by managing chronic diseases through remote monitoring. The objective of this project is to study the use of wireless technologies in the United States healthcare market. The research will focus on the drivers and inhibitors to integrating wireless and healthcare solutions.

The project will leverage a combination of primary and secondary research to study the use of wireless technologies in healthcare. Primary research includes the use of a questionnaire to interview four individuals associated with companies that are designing mobile health technologies or organizations that are working to standardize these technologies. Secondary research includes a review and discussion of up to nineteen sources on the use of wireless technologies in healthcare. The secondary research focuses on what others are saying about the subject and additional research needed in the respective areas. The report concludes with the author's input and a summary of findings related to the subject.

This report will provide a summary of the use of wireless technologies in healthcare. It will show how wireless technologies are being used in healthcare and the different use cases. The report will provide overall coverage of mobile health solutions including drivers, barriers, key enablers, and future direction. The report will conclude with the current impact and expected future impact of these technologies. It will also include recommendations for future analysis of mobile healthcare industry and its potential impact on healthcare costs.

1.1 Background

The field of remote healthcare monitoring is nascent, though it is gaining a lot of traction. The problem in the marketplace is the lack of a comprehensive, standardized, mass market solution. Some of the products in the market are proprietary or are incomplete.. Some companies provide small segments of the solution, but there is generally a lack of a more comprehensive solution.

Standardization will be the key to enabling mass market solutions. Organizations such as Continua Health Alliance and Third Generation Partnership Program (3GPP) are developing some standards on machine type communication, which includes m-health. 3GPP is an international wireless standards organization responsible for the leading wireless standards such as Long Term Evolution (LTE) and High Speed Packet Access (HSPA). The standardization work being done in 3GPP is not exclusive to m-health solutions but addresses the broader category of Machine Type Communication (MTC) or Machine to Machine (M2M) communications. Continua Health Alliance is leveraging existing standards and is focused on device standardization and working with operators. Integrating the Healthcare Enterprise (IHE) is working exclusively on m-health standards and is focused primarily on the healthcare domains. Direct health care standardization includes Health Level Seven (HL7), which defines health care applications protocols. HL7 is developing standards around data formats for the exchange of information in the healthcare domain. HL7 provides a framework but not a specific reference architecture, which makes it difficult to test for compliance. Actual implementation may vary, which could result in interoperability issues. Integrating the Health Enterprise (IHE) is also working on a framework for interoperability. However, it is more focused on the clinical area, using the existing healthcare domains such as radiology, cardiology, eye care, laboratory, patient care coordination, patient care devices and several others. IHE references standards such as DICOM for sharing electronic images and HL7, which defines the message or data format for healthcare records. There is also work underway through the Office of National Coordination of Health Information Systems. A subset of this work includes migrating healthcare providers to electronic medical records and establishing regional healthcare repositories for collecting health information. The information will later be shared among healthcare professionals to improve treatment through increased knowledge sharing. Thus, multiple efforts are underway centered on standardizing m-health. The industry needs to organize around a specific set of rules.

Solutions that leverage existing wireless operator networks to ensure wide service distribution and low cost as a result of larger volumes using existing infrastructure will be most effective. Leveraging the wireless operators will also ensure service consistency and continuity across different regions. In addition, United States wireless network penetration is currently above 103% according to the Cellular Telecommunications Industry Association (CTIA). Thus, leveraging mobile networks enables a mass-market solution.

Remote patient monitoring solutions will be an integral component in reducing healthcare costs. Remote monitoring will be used to gather data that can be sent to a patient's doctor and also to the regional repository with the consent of the patient. Solutions often include devices given to each patient to monitor a specific health care issue. For example, a patient with high blood pressure would be given a portable blood pressure monitoring device. The patient will be instructed at the provider's office on how to use the device to take his/her blood pressure and send the reading wirelessly to the server. There will be different peripheral devices depending on the patient's specific health condition. Each device will have a unique identifier that is linked to each patient. Additional security features will also include a changeable password. The information will be deposited in two data points. One will be used for the patient's healthcare provider to track the patient's condition for diagnosis and treatment. The other data point will be sent anonymously to the healthcare database repository for more generic analysis of patients with certain conditions, demographics and treatment options.

The overall goal is that access to continuous real-time data, as well of trending information will help physicians and healthcare practitioners to better understand and treat certain conditions. A more long-term view is that patients' homes will be covered with sensors that monitor multiple conditions such as heart rate, blood pressure, breathing and other vitals. This information will be collected on a continuous basis to be processed into meaningful information so that doctors can treat wellness verses sickness (Balakrishnan et. al 2009). Doctors will have access to databases of information based on real world data to make more intelligent and informed decisions. The information can also be shared across regions and the nation to provide a wider pool of patients with certain conditions. This information sharing will provide unprecedented insight into certain diseases and the ways to treat them. Doctors can then be paid to keep patients well rather than treat sickness.

2.0 Literature Review

2.1 Introduction

Numerous articles were found on the subject of m-health. Some were focused on the market opportunity, while others were focused on the specifics of the solution. The articles used for the literature review focused on three areas: the overall market for m-health, the use of wireless sensors in body area networks and the use cellular devices in mobile health applications. The literature review concludes with a diabetes use case. Diabetes represents one of the major chronic diseases, accounting for approximately $174 billion in annual healthcare costs (Balakrishnan et. al 2009). Thus, studying the use of mobile solutions for remote monitoring of diabetes patients is germane to reducing annual healthcare costs.

Many of the articles focused on solving specific issues such as the architectural framework for sensors. While addressing these issues is relevant in developing a comprehensive solution, it is a small subset of the work that needs to be done. Other research in the overall architecture was not comprehensive. The authors had strong knowledge in some domains but not in others. The overall goal of this paper is to build on the work done by the other authors and to present a more cohesive and comprehensive view of the problem and potential solutions.

2.2 The m-Health Market Revenue Projections

An aging population and an increase in chronic diseases has led to an increase in per capita healthcare costs globally, while not much progress has been made in improving the quality of healthcare delivery. The widespread availability and use of mobile phones provides an avenue to innovate and improve healthcare delivery. The author describes two paths to healthcare delivery, one being direct patient access and the other improving the efficiency of healthcare systems, administration, practitioner support and patient care delivery. The report proposed that by 2017, the global revenue related to mobile healthcare will be $23 billion USD. This cost is distributed across mobile operators, device vendors, healthcare providers and content and application providers. The lion's share of this revenue, 65% or $15 billion, will be directly tied to the monitoring services. Chronic disease monitoring and post-acute services are expected to account for 70% or $10.7 billion USD of the monitoring revenue. Diagnosis services will account for 15% or $3.4 billion USD, while HealthCare System strengthening services will account for 6% or $1.4 billion USD. Of the entire ecosystem, mobile operators stand to gain the lion's share of this revenue, 50% or $11.5 billion USD (Nawal, Vaidya, and Vishwanath 2012). The US and China represent the largest share of revenue, each accounting for about a third of the overall revenue. The US will account for approximately $5.9 billion in mobile healthcare revenue and China will account for $2.52 billion by 2017 (Bluestein 2011).

Overall success will depend on collaboration across the entire ecosystem and user acceptance. Government and regulatory support are seen as key requirements for the uptake of mobile healthcare solutions and delivery. Regulations will drive doctors, hospitals and key providers' behaviors. These regulations will also be key to driving standardization and interoperability. Usability and awareness are also key to gaining end-user acceptance.

In general, the article cites the rising cost of healthcare in developed countries (the US, Germany, Australia, Japan) due to an aging population and increasing rates of chronic diseases tied to lifestyle. Emerging countries such as Africa, Latin America, and others have younger populations. Thus, they are not impacted by certain diseases but by poorly developed healthcare delivery systems and not enough healthcare providers. Developed nations are more prone to non-communicable diseases, while developing nations have more communicable diseases.

Global availability of mobile cellular devices as well as increased smartphone adoption can help to close the disparity in healthcare availability. Many developed countries such as the US, South Korea, Australia, UK, Germany, Sweden and Japan have a mobile penetration rate exceeding 100%. Likewise, many developing countries have a high mobile penetration rate in the 80% range or above in some cases. Botswana, Brazil, Chile, Indonesia, and Malaysia all have over 100% mobile penetration rates. The increased adoption of smartphones with more advanced capabilities is also a strong enabler as well as wide-scale deployment of third and fourth generation networks with higher data delivery capabilities.
In developed countries, much of the focus has been on using mobile phones to track fitness, weight management and some monitoring of the chronically ill patients. In emerging markets such as Africa, the focus has been on improving efficiencies of the healthcare workforce and systems as well as distributing prevention and awareness information. Most of services in emerging markets leverage SMS capabilities to share information, while some use PDAs for data collection and access. In developed markets, the

focus is more on leveraging the cellular networks to enable monitoring to reduce hospital re-admissions and physician visits.

The report provides a lot of great information about the mobile healthcare market. The one area that the author failed to cover is the use of non-traditional wireless devices for healthcare such as sensors and the embedded cellular module in health monitoring devices such as glucose meters, scales, ECG devices and others. The cost of cellular chip sets has declined as a result; the chip sets can be used in many devices that were previously off limits due to cost. Some of the solutions being evaluated in the market will leverage embedded modules.

2.3 Body Sensor Networks

2.3.1 The Use of Grid Technologies and Sensors in m-Health

In the article “Ubiquitous Healthcare Computing with Sensor Grid Enhancement with Data Management System” addresses the use of sensor networks and grid computing in healthcare. The article discusses the architecture and use cases for emergency care, remote monitoring, the exchange of information to improve diagnostic capabilities, and remote surgery. The author’s main point is that sensor networks can be optimized by leveraging grid computing to compensate for limited storage, processing, and communication capabilities in sensor devices. Sensor devices are great for capturing healthcare data, while grid computing will enable aggregation, analysis and distribution of the data. Efforts are underway globally in developing these type of systems. However, one of the challenges is ensuring global interoperability of these systems. The article proposes a new architecture to ensure interoperability (Cao et al. 2010).

Sensor networks can be used to capture real-time vital signs for a large number of patients. This information can be relayed to emergency medical technicians (EMT), doctors, and nurses. Grid computing is the use of distributed computing infrastructure to quickly process and analyze data. The supporting architecture, which includes a database with patient specific information, storage, and application servers, would enable the collection, analysis, and presentation of this data in meaningful ways. The result is a system optimized for healthcare delivery and accuracy through shared information and resources.

Uniformity and interoperability of the data structure is critical. Standardization is needed for data format, structure and data model for national and international interoperability. Quality of Service (QoS) is also important to ensure that data is delivered according to appropriate response time. Some information is needed in real-time, while other data can be stored and forwarded for later access.

Another issue that the author addresses is security, which is important to protect the patients' privacy and access to data. The proposed security mechanism leverages user name and password to enable access to the entire database. Authentication, Authorization, and Accounting (AAA) is recommended to limit who has access to what data and to track who actually accessed the data. However, the challenge is that this mechanism is not well defined.

The author proposed the use of proxy servers with open standards framework of Health Layer Seven (HL7) and Open Geospatial Consortium (OGC) to optimize data delivery. Both standards provide the framework for interoperability. HL7 provides the standardized data framework to ensure interoperability across different healthcare provider networks, while OGC provides the framework for converting data from one format to another on the fly to eliminate the need for bulk conversion. The proxy acts as an intermediary between wireless sensor network and the grid network. Applications can be written to query the grid to determine availability of certain resources and coordinate network connectivity between the grid and the sensor networks.

The author's use of a standardized approach is necessary for mass market solutions. Healthcare is a global issue, so global interoperability will be necessary for mass market solutions. The use of a layered architecture model is also applauded since that is commonly used in most IT and telecommunication networks today to enable robust and scalable networks. The proposed use of a proxy server is also significant since it enables controlled access to resources and prevents flooding of requests that could impact the reliability of the network.

Some areas of improvement in the architecture could be the use of load balancers to optimize network performance and availability of resources. The use of firewalls was not addressed. Firewalls will also be needed to control the security of the architecture and limit access to certain data to a controlled group of users. Furthermore, multi-factor authentication is another area that could improve security, but it was not explicitly addressed in the paper. Multi-factor authentication, as the name implies, would require the use of more than one level of authentication in order to access certain data and information.

In general, more work can be done on the overall security of the network since this is required for HIPAA compliance. HIPAA is the Health Insurance Portability and Accountability Act of 1996. It was enacted in the United States to protect workers who lose their jobs or have changed jobs. The second part of the act is Administrative Simplification (AS), which requires the establishment of national standards for electronic health transactions and national identification for insurance plans, providers and employers. Part II also addresses security and privacy of health data. HIPAA specifies a series of physical, administrative and technical safeguards to assure confidentiality, integrity and availability of electronic protected health information. The author did not mention HIPAA at all in the document, so more work is needed in this area. He did touch on getting patients' authorization upfront; however, HIPAA requires much more than gaining permission. More work is also needed on sharing collected data in an anonymized way for global usage. Sharing data in this way would enable doctors to look at the efficacy of certain drugs across a large sample of patients as well as study how certain conditions have been treated across a large sample of patients while protecting the confidentiality of the patients.

This article explores the use of wireless body sensors to monitor patients without much intrusion on their daily lives. The technology is proposed for monitoring patients in the hospitals, remote monitoring chronically ill patients and gathering vital statistics of patients in more continuous manner. The solution proposes the use of 802.15.4, which is the use of low powered radios connected with sensors. The 802.15.4 standard is a lower OSI layer protocol (MAC) standard focused on the development of low cost, low speed, wireless personal areas networks (WPAN). This would enable constant communication of devices in this network with minimal power consumption. The framework is based on communication within 10 meters and data rates of up to 250 kb/sec, but typically 20 to 40 kbps. The overall intention is to enable embedded devices at reduced manufacturing and operational costs as well as technology simplicity (Center for Medicare and Medicaid Services, National Healthcare Expenditure 2011).

The use of wireless body sensor networks is proposed for blood pressure monitoring, which also incorporates ECG monitoring. These body sensor networks are proposed as an alternative to the use of the traditional blood pressure cuff. The challenge with this solution is the ability to accurately associate sensor devices and measurements to a specific person to ensure that all of the data collected is for a particular person. Another challenge is the complexity of setting up the network especially for older patients.

The authors proposed the use of Body Coupled Communication (BCC), which sends out a weak electronic coupling signal up to a few centimeters from the skin for identifications of the individual. The sensor nodes have the intelligence to detect other sensor nodes connected to the same body. The solution solves the identification issue by proposing a personal identification tag worn on the body via wristband or watch along with the medical sensor devices. This enables unique identification of the collected data to a specific person through wireless connectivity between the BCC and the sensors. The sensors use radio frequency (RF) to connect to a hub or router for sending the data to a centralized aggregator or a server. Wireless area body descriptor is used to identify sensors belonging to the same body. This information is provided by the BCC. Wireless sensors wait in sleep mode until other sensors try to access the network by requesting the descriptor from the BCC. This wakes up other sensors connected to the same BCC, and thus the same body, enabling communication between sensors. The BCC communicates with the sensor network either through application programming interface (API) if independent or through a serial bus if it is integrated with the sensor network. The sensors use up to 6mW of power in the active state and 1 mW if in the sleep mode.

The author cited previous work done in the area of body personal networks. Research of previous work revealed that poor ground coupling contributed to signal attenuation, which impacted data rates. Over the years further work resulted in improved data rates from 2.4kb/sec to current data rates of up to 250kb/sec. Early work began with Zimmerman in the 1990s, with later development in Japan by NTT and the Korean Advanced Institute of Science and Technology. The author replicated a system leveraging an 802.15.4 platform from Philips Research as the wireless technology for the sensors. The BCC was developed using an active digital aura (ADA) module. Two wireless sensor nodes were used for ECG and photoplethysmogram (PPG). This combination enables blood pressure monitoring based on pulse arrival time (PAT) measurements.

The author’s work revealed that identification was a key limitation of the technology. However, numerous efforts in this area now enable multiple identification mechanisms. The author also looked at the use of RFID but decided that this had too many limitations due to propagation range. The BCC approach addresses the identification as well as the ease of use issue. It enables a more plug and play architecture, which reduces simplicity for all users.

Further work should be done in the security for the overall architecture. The author did touch on this topic, but a more detailed discussion is needed especially since this is a health care application, which is prone to privacy and government regulation issues. How does one prevent unauthorized access to this data and what are the security mechanisms inherent in the 802.15.4 technology to prevent spoofing or re-direction of data? Also, more discussion is needed about the overall implementation of the system for mass scale data aggregation and analysis. How are sensor networks used to address the wider healthcare issue and its use in predictive healthcare treatment? More work is also needed in application layer capabilities required to improve the marketability of this type of solution.

This article addresses the use of sensor networks to deliver low cost, pervasive healthcare solutions from home e-healthcare providers to home healthcare users. The use of wireless technologies is expected to improve healthcare delivery to patients by enabling constant monitoring through sensors in the home. The author began with a discussion of previous research work done in e-health ranging from the likelihood of technology adoption to security and the use of orthogonal frequency division multiplexing (OFDM) to increase data rate. The likelihood of technology adoption was most closely linked to personal innovation versus job relevance, ease of use, and compatibility. The author then discusses the proposed architecture design and various components and intended use. The article wraps up with a summary of the findings (Doukas, Fourlas, and Liolios 2010).

The author proposes a system architecture that is composed of three main elements: the end user home health network, the control center and the e-health service provide access center. The home network consists of multiple health care peripherals (IP camera, or wireless vital sign sensors for blood pressure, heart, and other vitals) connected by various short range wireless technologies including RFID, Bluetooth, serial connection or USB to a router with cellular backhaul. The data is sent from the home network via cellular technology to a healthcare engine and local database.

The control center includes a messaging database that processes SIP messages and uses PUSH technology and a registrar's server for performing authorization, accounting and authentication (AAA). The control center along with the other two elements is connected to the network backbone. The e-health service provider architecture is also connected to the backbone network and includes the application server with third party web-based applications and tablets or smart devices for accessing data from the application.

The system collects the data, processes the data and then presents the data to various parties in the ecosystem. Notifications are sent if the data exceeds certain thresholds or if other abnormalities occur with the device. Data includes vital signs being monitored and trigger events for abnormal behavior. Trigger messages are delivered via instant messaging to the control center and hospital providers. The architecture also includes location servers, which track the location of the patients. These location servers are especially useful after a trigger notification is sent. The overall design enables mobile access to patient's data from anywhere at any time. A mobility manager is also included in the architecture.

E-Health Service providers also uses CANE, which is a system used between hospitals and emergency response technicians for advice on patient care while in transit to the emergency room and for hospitals to receive updated information on patients' conditions while in transit to the hospital. The application also maps patients' locations with the nearest emergency response teams based on geographical data gathered via the location database server. The GPS also provides directions, estimated arrival time, connectivity to satellites, as well as longitude and latitude information of the emergency response vehicle.

Future direction includes the use of the IP cameras to share a photo of injury to enable remote diagnostic capability. This capability could include the sharing of medical images such as MRI and x-rays to extend healthcare delivery to the underserved. The PDA images of the application are great for understanding the simplicity and usability similarly for the GPS images showing the ambulance location.

Overall, the author did well in discussing past research in mobile health as well as the proposed architecture. Further work could include the use of cloud computing to store, aggregate, and distribute the data. Standardization work around this architecture is also important for interoperability and wide-scale deployments. There should also be more discussion around how this architecture meets various security requirements for HIPAA and HITRUST.

The author reported on mobile healthcare trials done in Europe on the use of body are networks (BAN) and mobile health platforms leveraging the public wireless network in delivering tele-health care. The system evaluated used GSM and UMTS. The author learned that though the system proved to be a likely solution in reducing healthcare costs due to reduced doctors' and hospital visits, some optimization was needed for commercial success. One factor requiring improvement was the general design of wireless networks that includes higher downlink capacity and lower uplink capacity. These networks were designed based on past usage where users tended to download more information than they uploaded. However, with mobile healthcare, the user would be generating more uplink traffic than downlink traffic. Thus, GSM/UMTS networks would not be ideal. HSPA would be more likely an option due to its higher uplink and downlink data rate (Flack, Baldus, Espina, and Klabunde 2007).

The proposed system includes a healthcare Body Area Network. The body area network consists of the following: sensors, actuators, communication and processing facilities connected via short range wireless networks. The sensors would continuously monitor heart rate, blood pressure, electrocardiogram, respirations and other vitals. The BAN is worn on the patient and moves around with the patient. The BAN connects to a Mobile Base Unit, which aggregates the sensor data and sends it to the back-end systems.

The other system evaluated includes a front-end system, which includes an aggregator device with multiple ports for up to eight attachments to monitor different vital statistics. The system connects to HTC phones that send the data to the backend systems for billing, aggregation and analysis. The backend system can be located in the wireless operator network or healthcare provider's network.

The solution proposed by this author is in line with the work others are doing in this area and helps to validate the mobile healthcare architecture. The architecture typically includes sensors connected wirelessly or through ports on a hub that provide local area to wide area network connectivity. The data is then sent to an aggregation point for access via healthcare workers or patients. The author focused on some of the challenges with wireless technologies that have since been resolved through migration to HSPA and LTE, which both have much higher capacity. More work in needed in the details of the solution such as standardization and data presentation for wider scale compatibility.

2.3.2 The Role of Smartphones in m-Health

This article addresses the role that smartphones play in mobile healthcare. The smartphone will act as a hub for collecting data from peripheral devices. This will reduce remote monitoring cost since these devices will not require as much customization. They can leverage Bluetooth or other low power LAN technologies to connect to the smartphone hub. The report cites remote monitoring of cardiac patients as the leading area in mobile healthcare in the US (Hallwyler 2011). Diabetes and chronic obstructive pulmonary diseases (COPD) are expected to gain traction as they too become reimbursable through health insurance. While mobile health is gaining traction, more trials are needed as well a clearer direction on FDA regulations tied to this area. The electronic health record is not progressing as fast. To date, about one third of all physicians are using electronic medical records (EMR) (Bluestein 2011).

Another area for further development could include the impact of standardization on adoption of mobile health. One of the drawbacks is how the market is moving toward standardization to improve interoperability and mass market solutions. Access to the full report was not available so it is unclear if this area was addressed.

A Fast Company.com article published in December 2011 highlights how smartphones have evolved to the point that with simple attachments, they are capable of replacing many common medical devices at a much lower cost. The article points out that many smartphone features are so advanced that they are equivalent to, or more advanced than, existing medical devices. Cell phones with processors greater than 1GHz now make smartphones on par with top-of-the-line pacemakers and cardiac defibrillators. The resolution on many smartphones is greater than or equal to 300 pixels per inch, which makes them equivalent to hospital grade ultrasound machines. Many smartphones' video quality is at least equal or greater than 30 frames per second, which makes them more advanced than existing colonoscopes, which doctors use to search for cancerous tissues. Smartphones have the baseline capabilities, which when combined with application software and simple attachments, can function as low cost replacements for more costly medical devices. The article referenced the use of an application and a plastic iPhone attachment that can be used by eye doctors to determine patient's vision. The app and attachment cost approximately $30 and can be used to replace an auto refractor which typically costs about $10,000 and weighs about 40 pounds. The wide availability of smartphones and continuing adoption, especially in emerging markets, will lead to wider availability of medical devices and improved patient care (Herman, Pemmaraju, Segre and Polgreen).

This article explores the use of mobile technology in a tablet-based application developed to automate hospital bed management in New Zealand. The article focuses on the key success factors. The key case study includes a tablet computer connected to the hospital's IT system through its Local Area Network (LAN). Information is communicated over HL7, secure healthcare protocol from the IT system to the handheld device carried by the hospital bed manager. The bed manager application ties patient data and bed occupancy data together for bed allocation to new patients. The Windows-enabled tablet has limited battery life of 3 to 4 hours and the batteries need to be changed during a typical 8 to 10 hour shift. The application provides an occupancy indicator showing 0 to 100% occupancy rate throughout the day. The application is web-enabled and can be run from other wireless devices such as a regular PC, PDA, and smartphone. Other applications on the tablet include administrative and data collection as well as resource and surgery ward resource readiness. The application increases the efficiency and accuracy of the information and reduces the need for paper information as well as phone calls to update data (Lehmann, Prasad, and Scornavacc, 2008).

Some of the success factors evaluated include:

- Hardware selection was important for portability, ease of use, and adequate functions to match bed manager's tasks.
- Usability is also important. Use of color coding replicates the current system, thus improving learning curve and ease of use.
- Mobility was also a major factor. This mobility enabled usage from anywhere and anytime in the hospital, which reduces trips taken and overall efficiency.
- Ease of integration into a legacy system is also very important in driving adoption. Hospitals are typically slower to adopt new technology, so any solution needs to be easily integrated into existing systems.
- Efficiency improvements are also a major success factor. The system enables real time data on bed occupancy, which improves admittance and discharge time and well as bed allocation.
- Other success factors include improved patient care and organization's image. The bed manager felt that by using the application he/she was better able to accommodate patients and reduce wait time, thus improving the patient experience and overall image of the organization. The new tablet devices provide an image of a more technologically advanced organization.

- Good coverage and performance are also key enablers for increasing adoption rate and trust in new applications.

The author developed a new framework for evaluating information systems in healthcare. The new framework includes the following success factors:

- Quality of information: Is the information provided required to perform the task at hand? Is it timely to enable real-time action? Is the information accurate, consistent, relevant and complete?
- System Quality: Reliable, portable, flexible, ease of use. Coverage and data rate also improve system quality.
- Service Quality: IT governance, system readiness, ability for future enhancements and system modifications, vendor and hospital responsibilities for future enhancements and system management.

The framework used to evaluate the impact of mobile technology on healthcare provides a good base for analysis. However, the article could be improved with more quantitative data versus qualitative information. For example, it could have provided a patient survey to show the actual customer feedback on the use of the bed management system. This survey could have included a comparison of the actual wait times for a bed before using the system compared to the wait time after using the system. Other information could have included the time it took the bed manager to travel to a desktop system and make phone calls to update current bed information. This data would then be compared to reduced time to gather the same information with the bed management system. Specific data on the cost saving resulting from the use of the bed management system would also have been helpful in making the claims more valid. One major negative of the report is the lack of quantitative data to support the claims of improvements.

The article also cited the relatively old US healthcare cost of $500 billion. It is now estimated that the US healthcare cost is approximately $2.6 trillion USD. Using more current data increases the system's potential impact on the current state of healthcare in the US and globally. This also points to my previous point of lacking strong quantitative information to validate claims.

The next article cites the use of text messaging that expands m-health tools to any cell phone, not just smartphones. Text messages are now tools for expanding healthcare knowledge, thus improving healthcare coverage. Approximately 2,200 women in San Diego participate in text4baby, a free text messaging service for pregnant women and new mothers. The service sends out health information about fetal and newborn health. It also sends immunization and doctor visit reminders. Over 63% of users reported that the messages reminded them of appointments. Seventy-four percent reported that they were informed of medical warnings and over seventy-one percent reported that the text messages prompted them to discuss certain subjects with their doctors (Text4baby 2011).

2.3.3 Standardization Efforts

2.3.4 Integrating the Healthcare Enterprise (IHE)

IHE is an industry-wide approach to standardize how computerized systems are used to share healthcare information. It leverages existing standards such as HL7, DICOM and others to develop a standardized approach for each healthcare domain. Profiles are used to describe specific integration problems along with participants, standards and design details to solve the problem. The profiles are then organized according to a domain or the overarching category of the profiles. Example profiles include cardiology, eyecare, IT infrastructure, laboratory, patient care devices, patient care coordination, pharmacy and many other profiles. Profiles are categorized into three states: final text, trial implementation and retired. Profiles listed as final are stable. Trial profiles are frozen for trial use but can be changed prior to final text. Profiles listed as retired are no longer recommended or maintained by IHE (Nawal, Vaidya, and Vishwanath, 2012).

An example profile to demonstrate how it is used is the cardiac catheterization workflow. The cardiac catheterization workflow is complex and may involve a variety of imaging, measurements and reporting systems that need to be tied to the same patient id and procedure. The procedure may be used for diagnosis, intervention or therapy. Typically, the process is implemented in emergency situations with not much time for detailed preparation. The workflow integration profile ensures the continuity and integrity of the patient data in the context of the cardiac catheterization procedure. It ensures that the patient id is tied to the patients' images, measurements in the different analysis systems, and these records are stored reliably for reporting, further analysis and subsequent procedures. HL7 messaging is used across multiple systems, the patient registration, order placing, and order scheduling systems. Where DICOM is used, the profile ensures mapping of HL7 messages to DICOM messages to enable the systems to interact and transfer data as needed to associate the patient with images and measurements. DICOM is the standardization of medical images with the patient's demographics such as id, date, image series, and parameters for acquisition.

Benefits of the profile workflow include improving patient care, reducing charging delays, reducing time and errors typically associated with manual entries, ensuring proper demographics and procedure coding, ensuring real-time status on procedures to optimize facilities usage, ensuring that images are securely stored prior to deletion from the angio system and much more. In general, the profile workflows are effective in optimizing the process within a healthcare enterprise. The IT Infrastructure domain would expand on these workflows by addressing the sharing of health information via a Health Information Exchange. This would enable access to historical lab data and summaries. In addition, query capabilities would support the broader domains of Quality, Research and Public Health. More specifically, the XDS.b profile was developed to facilitate registration, distribution and access across health enterprises of patient electronic health records.

2.3.5 Challenge with HL7 and other Healthcare Standards

Standards such as HL7 are defining how to move healthcare data from one point to another. They are built on the premise of a closed healthcare enterprise network even though they include sharing across different healthcare domains and providers. Mobile devices operate outside of the closed healthcare networks, and thus would be excluded from existing standardized solutions.

Many of the current workflows do not include mobile devices, which is a severe limitation due to society's desire for connectivity and information access from anywhere and at anytime. In addition, mobility would enable coverage extension. Existing standards need to be updated to address the use of mobile devices in the architectural framework and workflow. Mobile devices can be leveraged not only to access the information but also to be used as a medical device tool to capture some images such as ultrasound. Within the same framework, the images could also be integrated with patient demographics to meet DICOM and HL7 requirements.

2.3.4. Chronic Disease Use Case (Diabetes)

Diabetes is one of the major chronic diseases impacting Americans. According to the latest data from the National Diabetes fact sheet, 8.3 %, or 25.8 million Americans, have diabetes; 18.8 million are diagnosed while 7 million are undiagnosed. Even more alarming, there are 79 million pre-diabetic Americans. Americans age 65 or older are the largest group affected, with 27% of people in this age group diagnosed with diabetes. Blacks have the largest percentage of diabetics by population at 12.8%. Heart disease and high blood pressure are tied to diabetes and diabetes-related deaths. Diabetes is also tied to blindness, kidney disease, stroke, and nervous system disease. In 2007, the cost for diabetes treatment was estimated at $174 billion, with $116 billion in direct costs (Mansfield 2012).

This paper discussed an approach to exchanging information across clinical and public health exchanges for monitoring diabetic patients. The information can be used by public health organizations (at the local, state and national levels) to survey the population of people with diabetes. This will enable intervention and continued care to control the disease.

The key participants include healthcare providers, labs, doctors, nurses, care managers, and patients. The primary focus is to standardize the exchange of information to enable population-based surveillance and quality reporting. The report included a framework to monitor patients though the glycemic and cholesterol tests. The framework includes the tests to be completed for glycemic and cholesterol results, frequency of the tests, if the test was completed, and results of the test. From the clinical level, the information is queried for a specific patients while on a public health level, the query is done to see the total number of patients with a certain condition perform the test, the results of the test, and the total number of participants who did not take the tests.

The HbA1c test is used to determine the longer term average blood glucose level over a period of time, while the blood glucose test is more of a snapshot at one period in time. Doctors and patients typically monitor blood glucose level, while clinics monitor the hbA1c levels. Non-diabetics usually have blood glucose levels in the range of 4-5.9%, while diabetics who have their diabetes under control have levels of about 6.5%. Those with higher risk conditions are in the 7.5% range. The HbA1c test should be done in three-month intervals to gain control of diabetes and in six-month intervals for diabetes already under control. In the framework under discussion, the goal is to keep the HbA1c levels below 7% for individual patients.

The low-density lipoprotein-cholesterol (LDL-C) is also measured to track diabetes conditions. People with diabetes are prone to unhealthy cholesterol levels, which are tied to cardiovascular diseases and bad cholesterol (LDL-C and triglycerides). The expected range of LDL-C is to be below 130mg/DL; normal is about 100mg/DL. Those with diabetes should work to keep their LDL-C below 70mg/DL.

The guidelines along with queries help to establish a chronic care framework for collecting and exchanging data across different providers and platforms. The overall framework provides guidelines for gaining patient consent, ordering tests, communicating test results, reporting, notifications and much more. This framework will enable the tracking of diabetes patients from a micro to macro level for monitoring and treatment.

Key query parameters include:

- Patient ID
- Care record time period
- Clinical statement time period
- Care provision codes

Value Sets would include:

- HbA1c data
- LDL-C data
- Patient ID

Once the data is collected in various databases, several standardized reports can be generated.

These reports include:

- Chronic Care Management Aggregate Surveillance Report
- Quality Measure Data

Conclusion

Leveraging a framework for the electronic exchange of health information will enable application developers and solutions providers to implement solutions with this standardized means to inputting and retrieving data. This will ensure consistency and accuracy of information. Database and servers will employ similar frameworks to ensure interoperability across different provider systems and networks. This is essential for mass market deployment and utilization.

This use case provides an example of the type of background work necessary for the overall success of mobile health. The framework is being defined in HL7. Without this level of detailed work, solutions will be available in islands that do not work well together and prevent wide scale level of information sharing.

2.4 Literature Review Conclusion

Most of the articles addressed a component of the solution, but there was a lack of a comprehensive picture of using mobile technology to improve healthcare. Some of the authors focused on the specifics of the technology architecture, while others spoke more about the potential market opportunities. A more comprehensive view would cover the broader market challenges, and then address specifics about the solutions, ecosystem partners and what is required to move mobile healthcare into mass market solutions. The reason for the failure to provide comprehensive coverage is tied to the lack of proven mass market solutions. There is work being done in other countries on mobile healthcare, but some of the work is region specific. In the US, where healthcare is more widely available, solutions will be more holistic versus informational. There will be more focus on reducing hospital and doctor visits through remote monitoring.

There is one study, however, that analyzed the impact of a free mobile health information service. Researchers at the National Latino Research Center at Cal State and the Department of Reproductive Medicine at UCSD studied the text4baby service. Text4baby provides pregnant women and new moms information about fetal and newborn health as well as connects them with national resource centers. Over 2,200 women in San Diego, California participated in text4baby and most reported high satisfaction with the service. Hispanic women were very happy with the service. Text4baby would be an example of using m-health solutions to expand healthcare coverage to women who may not have visited their doctors as often as they should or who forgot to keep up with immunization records.

Overall, most of the authors see mobile communication technologies as a means of extending healthcare services and capabilities. This is primarily based on the ubiquitous nature of mobile devices and advances in wireless technologies, which makes solutions possible. The declining cost of wireless modules needed for e-health solutions is also a significant factor. The primary drawback is lack of a cohesive approach to m-health.

3.1 Primary Research

Since the literature review did not provide the information desired for this project, primary research was conducted. The primary research included the distribution of a questionnaire to four companies, which are either developing mobile health solutions or working on the standardization of mobile health solutions. The questionnaire was completed via live phone interviews with a member of the four different organizations. The responses are presented in this section of the report.

3.1.1 Questionnaire

Questions

1. What are the key drivers for mobile or electronic healthcare?
2. What are the key inhibitors?
3. What role do you see wireless technologies playing in reducing healthcare cost?
4. Who are the key players impacting this industry?
5. What role will wireless operators play?
6. How much of an impact will wireless technologies have on healthcare delivery?
7. How will wireless technologies impact healthcare delivery to the underserved?
8. How will cloud technologies be used?
9. What will be the key differentiators?
10. What is the key to mass market solutions?
11. Which solutions will have the most impact?
12. What role will standardization play?
13. What role will the FDA play and how will this impact the m-health ecosystem providers?
14. What role will wireless standards organizations play?
15. Which organizations will drive m-health standardization?
16. What do you see as the primary near term solutions?
17. What do you see as the long term solutions?
18. When will mass market solutions be available in the market?

3.2 Primary Research Findings

3.2.1 Kansas City Quality Improvement Consortium

Johnny Simpson, board member of the Kansas City Quality Improvement Consortium, a health care quality improvement community based organization

1. The key drivers are President Obama's healthcare initiatives to deliver quality healthcare to all patients. Another driver is the need to get healthcare information to and from consumers. All of

these initiatives rest with the consumer. Mobile devices are key to getting this information to these people and to communicate with them and to develop the transmission of this data to healthcare organizations.

2. Cost is a primary inhibitor in getting mobile healthcare devices to the consumers. Education, teaching patients how to use the devices is another inhibitor as well as device availability.

3. Wireless technologies will play a major role in reducing healthcare costs. It is through wireless technologies that doctors will be able to communicate with patients regardless of the patient's location. Wireless technologies will provide constant access to healthcare records and enable patients to stay in contact with healthcare provider.

4. Telemedicine vendors, mobile operators such as Verizon, Sprint, and AT&T, all play a key part in defining tele-health. The hospitals, primary care physicians, and home health agencies also play a major role. Insurance companies will need to support mobile healthcare by providing coverage for these solutions. The doctors and physicians will be the ones who present the technologies to the patients. The Center for Medicaid and Medicare services (CMS) is key since it can enables reimbursement.

5. Wireless operators will be the primary delivery engine for mobile healthcare solutions. They will deliver the information to the patients and doctors.

6. Wireless technologies will have a great impact on healthcare delivery. They will enable doctors to track if patients are taking their prescription through remote monitoring with video capability.

They can be used to measure movement to determine if patients will have hip or back problems as well as monitor their sleep patterns. Real outcome is measured by whether or not the patients follow the directions. Wireless devices will be used to see if the patient actually took a blood sample or not. It will also be used to enable medical data storage.

7. Wireless technologies will impact healthcare delivery by increasing accessibility to the underserved by enabling low cost devices. Wireless devices improve access to physicians and health care providers due to lack of transportation and reduces waiting time. They also improve patient outcome.

8. Cloud technologies will be used to interconnect health information technologies and to share electronic medical records between practices. Cloud will reduce duplicated services by replacing individual servers with a centralized network of servers and databases. It will also be used as a means of gathering data from patients anywhere and enable access to real time patient data at any time.

9. Some of the key differentiators for m-health solutions are ease of access, cost, usability, and ubiquity across various platforms. Also solutions that can show a competitive return on investment to the practitioners.

10. The key to mass market solutions is ubiquitous healthcare applications on mobile devices. Technology is driven by application, not the hardware. The hardware is improved as more and more applications are available. The industry needs a baseline set of capabilities and features which are universally available.

11. Solutions which will have the most impact on reducing healthcare costs are those addressing the most critical conditions: heart conditions, diabetes, weight, COPD, asthma. These are also the most common ailments impacting baby boomers.

12. Standardization will help to reduce costs through the use of well-known procedures. Patients, physicians and insurance plan managers' expectations are managed through standardized processes and procedures. It also helps in research to provide a higher quality of healthcare.

13. The FDA has a key role in healthcare and wellness. A lots of health issues have to do with diet and what people consume, the types of drugs used and how they are available and the impact of medications. How medications interact with each other. Patients are taking multiple medications so they need to make sure they don't counter the others. They have to regulate the SAR of the devices, which could further impact patients.

14. Wireless standards organizations play a key role in ensuring that the applications and technologies are ubiquitous. Standards ensure that solutions meet minimum requirements of the healthcare industry.

15. Which organizations will drive m-health standardization?

    HL7, HIE, and organizations which lead in the marketplace. The medical industry, Center for Medicare and Medicaid Services (CMS), and medical associations will drive m-health standards. Doctors will need to approve the means of receiving data and will help to drive the standards.

16. The primary near term solutions will focus on individual monitoring of the big five chronic health conditions: diabetes, heart disease, asthma, arthritis and stroke. The home health agencies will be

able to share data with physicians and practices on the information that they will see so that when the data comes in it is accessible and available.

17. What do you see as the long term solutions?

    Over the longer term, wireless technologies enable real-time access to patients so that the data is collected in real-time. Wireless technologies are the key drivers in delivering video capabilities which will be more critical over time.

18. Three to four years from now, these solutions will become mass market solutions. This is due to the politics of m-health. Healthcare providers are waiting to see when the politics issues will be finalized. For example, if you file taxes in Massachusetts, then you are required to have healthcare. The issue is the minimum requirement for health insurance similar to auto insurance today, which requires a minimum of liability. This will limit the mass market aspects.

3.2.2 Verizon Wireless

William Gordon, manager of m-Health Solutions (Verizon Wireless)

1. The primary driver for mobile healthcare is the need to reduce cost. This has led the United States government to implement electronic health record mandates. Over seventy percent of healthcare workers use smartphones and tablets so migrating to mobile healthcare would not deviate from the norm. Accountable Care Organizations (ACOs) are required to go out and generate business and reduce costs. ACOs are hired by physicians groups to manage their business account for the financial results.

2. Primary inhibitors include the lack of understanding of wireless technologies, lack of reimbursement for m-health, need for proven return on investment (ROI), and a need for large scale market trials. Another challenge is the already slim margins in healthcare solutions.

3. What role do you see wireless technologies playing in reducing healthcare cost?

   Some wireless devices are more advanced than some of the existing medical devices. However, the challenge is the lack of reimbursement for using wireless solutions. If these solutions are reimbursable through CMS, then others will follow.

4. Key players in m-health are doctors, insurance companies, device OEMs Philips, Bosch, GE, Honeywell, Medtronics, and legacy device vendors.

5. What role will wireless operators play?

   Wireless operators can push ecosystem partners to develop plug and play m-health solutions. Operators will then need to get these solutions adopted at the enterprise level where companies are providing healthcare for their employees. Enterprise customers can offer incentives to gain consumer adoption. For example, employees who register to use these solutions would get a percentage off their health insurance premiums. Verizon has over 90,000 employees receiving healthcare insurance through Well Point—they can start by influencing these 90,000 people. Since congestive heart failure is the most serious and costly to treat, offer customers a rebate for staying out of the hospital and raise rates for non-conformance. Enterprises can use their insurance companies to place the devices into the patients' hands and tie incentives to staying healthy.

6. How much of an impact will wireless technologies have on healthcare delivery?

Wireless will have a significant role in delivering healthcare to targeted recipients, chronically ill patients who account for eighty percent of the healthcare costs.

7. How will wireless technologies impact healthcare delivery to the underserved?

   Text4baby is one example where wireless technology is used to reduce infant mortality rate. In addition, through wireless solutions, patients up to seventy five to one hundred miles from a hospital can connect to a specialist in cities. There is also the potential to use wireless video solutions to collaborate with specialists from remote locations.

8. How will cloud technologies be used?

   Everyone will use the cloud since it is too costly for healthcare providers to own and operate their own datacenters.

9. What will be the key differentiators?

   The companies which are first to the market with m-health solutions will be the market leaders. Cost for the solutions and ease of use are also differentiators.

10. What is the key to mass market solutions?

    Advertising and marketing are the keys to mass market solutions. For example, the Nike Fuel, fitness band which tracks the wearer's movements with the ability to connect the device to a computer for easy data upload. Strong marketing of this device resulted in shortage of these devices in stores even at the steep price of $149.

11. Which solutions will have the most impact on reducing healthcare costs?

    Solutions which are focused on healthcare delivery to chronically ill patients will have the most impact on reducing healthcare costs.

12. What role will standardization play in reducing cost?

    Application layer standardization is needed for data presentation. The secret sauce is needed to seamlessly integrate data. Device level standardization is needed more that health record level standardization.

13. What role will the FDA play and how will this impact the m-health ecosystem providers?

    The FDA plays a small role today but will play a much bigger role in the future. The FDA will help to ensure the safety of solutions to protect the public. These solutions will also provide a new revenue stream for FDA in terms of certifications.

14. What role will wireless standards organizations play?

    The role of wireless standards organizations is still unknown. They will provide guidelines but not direct standards or oversight. They will provide a consulting role.

15. Which organizations will drive m-health standardization?

    The FDA will drive healthcare standardization.

16. What do you see as the primary near term solutions?

    Solutions developed for treatment of chronically ill patients. Those solutions treating diabetes will have the most impact since this is the largest segment of top five illnesses.

17. What do you see as the long term solutions?

    - Doctors in a box solutions, plug and play with self diagnostic capabilities
        - Smartphone and tablets applications

- Applications to prioritize doctor's visits
- Applications to schedule doctor's visits
- Remote doctor consultations

18. When will mass market solutions be available in the market?

    In a year from now there will be applications for chronically ill patients served through smartphones.

3.2.3 Multi-tech

John Carnes, VP of Business Development

1. What are the key drivers for mobile or electronic healthcare?

   Chronic disease management is one of the primary drivers as well as the need to improve lifestyle. Cost is also a primary driver in the consumer market.

2. What are the key inhibitors?

   Payment is the largest inhibitor. Determining who should pay for m-health solutions is a challenge.

3. What role do you see wireless technologies playing in reducing healthcare cost?

   Wireless technologies will enable millions of home healthcare products using analogue, WiFi, and cellular networks.

4. Who are the key players impacting this industry?

   Government agencies need to develop the rules and regulations needed to deploy these solutions. Wireless operators, the private sector, and medical providers are also critical.

Standardization is needed for interoperability and this is driven by standardized data formats for integration.

5. What role will wireless operators play?

   Wireless operators have the network to reach consumers. They have expertise in working with vendors to create solutions.

6. How much of an impact will wireless technologies have on healthcare delivery?
7. See other responses
8. How will wireless technologies impact healthcare delivery to the underserved?
9. See other responses
10. How will cloud technologies be used?

    Ensure that data is secure and compliant.

11. What will be the key differentiators?

    Modem flexibility will provide differentiation as well as solutions targeted to specific demographics. Those targeted to treat the chronically ill will also have significant impact.

12. What is the key to mass market solutions?

    Usability and cost effectiveness are keys to mass market solutions.

13. Which solutions will have the most impact?

    Those targeted to treat the chronically ill will also have significant impact. These solutions will include treatment plans, monitoring, pill dispensers, etc.

14. What role will standardization play?

Standardization will have a significant impact due to the need for common format.

15. What role will the FDA play and how will this impact the m-health ecosystem providers?

    Unsure

16. What role will wireless standards organizations play?

    Not my domain

17. Which organizations will drive m-health standardization?

    Unsure

18. What do you see as the primary near term solutions?

    Not sure

19. What do you see as the long term solutions?

    Not sure

20. When will mass market solutions be available in the market?

    The market for m-health will increase rapidly in the near term.

3.2.4 Carecam Innovations

1. Mobile healthcare is being driven by the need for information quickly and efficiently. With the influx of smartphones/tablets in the hand of most anyone from 6 years old to 90 years old there is a need, if not expectation for information at our fingertips. As a society we expect for every professional to have all information to complete the task with excellence. From the person working on your car to the neurosurgeon fixing your memory. We expect them to have up the latest proven procedure, drug, process or tool to complete the job safely and effectively.

2. Connectivity/Hardware availability/Adoption. Though these barriers are diminishing daily there is always going to be another “great” thing on the horizon. Keeping up with and optimizing technology is an ever-changing challenge.

3. A bit off topic but very interesting, there was an article I read the other day that did a study on the hiring process in most companies. It was discovered that people with years of education and knowledge stored in their head were passed over for people who were “connected” and could use the tools available to find up to date answers/information just as quick as the other could recite it from memory. Key inhibitors include determining who will pay for mobile health solutions. Other inhibitors include connectivity, availability, and hardware specific to healthcare solutions. Technologies are constantly changing, so finding the right mix of solutions in the ever-changing landscape is challenging. This is what makes solution based on wireless technologies such as the cell phone more feasible for long term adoption. This will reduce the learning curve for those who are reluctant to change. Since people use cell phones in their daily lives and will be less resistant to keeping up with advances in this technology. Leveraging cellular technology will make it easier for those who are reluctant to change to more quickly adopt to using devices such as tablets to collect and retrieve data.

4. Wireless technology and the use of Cloud computing will also play a major role in reducing the cost of collecting, storing and retrieving healthcare data This will also increase the availability and accessibility of this data to wider segment of ecosystem players. Access control mechanisms used in wireless and wireline networks can be used to protect patients’ privacy by determining who has access to what information and to provide an auditable historical record of these transactions.

5. The mobile operator's role will be tied to its ability to reach the masses through its wireless networks and large customer base. Mobile operators will control the flow of revenue by controlling the distribution of information and data. Mobile operators will also play a role in the marketing and distribution of mobile healthcare solutions. The major operators in the US had significant national and regional reach. Verizon, the largest mobile operator's network covers over 290 million people or over 93 percent of the US population. The impact of the operator's role will be determined based on if they are simply a transport provider versus a solutions provider.

6. The government will play a major role in the evolution of m-health based on how tightly or loosely the segment is regulated. Government regulations requiring electronic medical records are already driving adoption by medical providers. Similar regulations will be needed to drive m-health overall. The private sector, healthcare providers and carriers will also have significant influence.

7. Standardization and interoperability will also play a major role in the proliferation of m-health solutions. Healthcare data format needs to be standardized in order for communication and information sharing between different providers systems. Collaboration between the leaders in Electronic Health Records/ Electronic Medical Records (EHR/EMR) systems such a Cerner, Epic, and others will also be vital.

8. Key market differentiators include flexible solutions with ease of use. In the near term, dedicated devices customized for a particular application with features like large button for seniors, will continue to lead in the market. More advanced solutions like body sensors with nano-technology

will take more time before they are widely adopted. Usability and cost effectiveness are two determinants for adoption. Non-intrusive solutions are also key differentiators. Solutions which can collect data in the background without much interaction from patients being monitored will be more attractive than those involving the patients interactions.

9. Today, many hospitals build and maintain their own datacenters or share with another provider. This results in very high costs. The use of secure public clouds dedicated to healthcare will significantly reduce healthcare data storage and retrieval costs due to economies of scale.

10. Scalable, standardized solutions will have the most impact in terms of gaining adoption and the biggest impact on reducing healthcare costs. This will simplify accessibility and accuracy of the information. Today, it is difficult to move data from one system to another since this requires mapping each bit of data to different fields in databases due to different configurations used by different providers. So, to share data means a lot of translations to conform to each implementation of HL7/HL6/HL5/DICOM, etcetera. Standardization would eliminate the need for costly data translation and manipulation and improve accuracy and security of data. All the key stakeholders need to level set on a common ground and accept a solution or set of rules going forward.

11. Chronic diseases like diabetes will be the area of focus since this will have the biggest impact on healthcare cost reduction. Solutions will include remote monitoring, pill dispenser, fall detection, wellness tracking through use of pedometers and other devices to ensure that the patients are staying active.

12. Solutions which are passive and non-intrusive will have the most impact. Simplification and accuracy. Currently we are forced to conform every bit of data to a different field or database

when moving from one system to another. Each hospital or healthcare office using HL7/HL6/HL5/DICOM ... differently. So each time data is shared it has to be conformed or transformed. Standardization would eliminate the need for translation or manipulation and would offer a much cleaner solution. This way you could have centralized access restrictions and security monitoring without having to worry about corruption or loss

13. No response
14. No response
15. I think it will become community driven like most other industries. We need to be more aware and involved in healthcare. I would like to see a day when we know our doctor like we know (or should know) our neighbor. Information about planting tulips can be shared and trusted like any other data. In the near term, the industry will focus on the testing and validations of m-health solutions. They will look to validate the benefits of using wireless technologies.

16. Over the long term, there will be a common ground for m-health ecosystem and acceptance by all of the stakeholders.

17. By far the long term solution is community organization and standardization. The last place you want to operate like the Wild-Wild West is healthcare. On the path we are going (if not there already) we will have too many fragmented records and no real picture of care. I know that eventually we will have a database structure that is available for all healthcare facilities worldwide that is flexible enough to allow a patient to be seen in Boston on Monday and Dubai on Thursday with all records available to both doctors.

18. There is a need for support for the open community like PDC Connectethon. Having regulations sent down from the ivory towers is not beneficial for the patient. The collaboration and continuous efforts to simplify and standardize is what will produce a mass solution.

3.0 Procedure and Methodology

After failing to find a suggested architecture for utilizing mobile technology in healthcare, the author designed a format to be presented to the HL7 Mobile Health Work Group (MHWG). The Mobile Health Work Group's mission is to develop standards for leveraging wireless technologies in healthcare.

4.0 Proposal

4.1 Original Thoughts

Wireless networks and devices will play a major role in reducing healthcare costs globally and more specifically in the United States. How wireless technologies will be used will differ depending on the region under study. More developed regions will leverage more advanced architectures with more robust infrastructure to deploy and support mobile healthcare. Less financially rich regions, such as rural counties and towns, will leverage the cellular network in its current capacity in addition to new enhancements. The cellular network will continue to be used to disseminate information and extend access to limited physical resources.

In addition, advancements in healthcare applications and attachments built for mobile devices will extend healthcare capabilities to remote areas beyond simple text messages. Devices costing tens of dollars to few hundred dollars can serve as medical instruments and can now be purchased and mailed to remote regions. These devices will provide the same function as their legacy counterparts, but will be less costly and smaller in size and weight. In addition, applications can be developed to train local healthcare providers on how to use the devices. These applications can be pushed to the user to extend education beyond the traditional group of practitioners. For example, teachers in rural schools can use a smartphone with the eye attachment to check a student's vision. The information can be recorded and shared in a report with the optometrist for a eyeglass prescription. This reduces the need to have a local optometrist present. Ultrasound photos can be taken outside of a hospital/clinic or doctor's office and sent to a server in the Cloud for retrieval and review by remote healthcare providers. This can reduce the number of visits a pregnant woman needs to make to a doctor and can ensure that a pregnant woman gets access to a doctor even if it is just for the ultrasound. Video or voice-based applications can be used to disseminate information to uneducated patients.

In general, mobile technology will widen the availability of healthcare providers and provide patients with more information and knowledge to help them. Wireless devices will enable the availability of non-traditional healthcare providers and extend the availability of healthcare workers. State, local and federal governments will have to work in concert along with other ecosystem partners for these solutions to be widely available, trusted, and accepted.

Mobile operators will play a critical role in m-health for several reasons. Mobile operators have the networks to reach as much as 97% of the total US population. Mobile penetration in the US market is above 103%, which means that most people have mobile phones and some have multiple connected devices. As a result of this high penetration rate, mobile operators need new revenue streams to drive the next hundreds of millions of connections. Verizon has re-aligned its business around top seven verticals, which include healthcare. AT&T has formed a "for health" division to focus on healthcare. Sprint is also supporting healthcare through solutions and sponsorships of HIMMS conferences. Mobile operators also have the means and influence to deploy and support large scale trials just by leveraging their employee base. Most operators use one or two Health Maintenance organizations (HMOs) and fund healthcare for their employees. Employers pay the majority of the 32% or $832 billion paid by private health insurance. Therefore, they can drive the large-scale trials needed and influence their employees to participate in these trials. In fact, several of the operators plan to do so. These trials will provide the real world data needed to substantiate the claims that m-health will reduce healthcare costs.

Figure 1: US Top Four Mobile Operators and Total Employees (December 31, 2011)

Operator	Employees	Retiree	Insurer
Verizon	193,900	209,400	Wellpoint
AT&T	256,000	335,000	United Healthcare
Sprint	40,000		United Healthcare
T-Mobile	32,709		

Source: Each company's quarterly SEC filings

4.2.1 Drivers for m-Health Solutions

Cost is the number one factor driving the migration to electronic healthcare delivery method. Second is the need for wide-scale healthcare availability. The cost to provide healthcare services in the US will continue to increase as more baby boomers reach retirement age. Currently, 13% of Americans are age 65 and older. This number will grow to 16% by 2020 due to improved quality of life and preventative care resulting in longer life span.

The government accounts for 35% of healthcare spending in the United States, or over $900 billion USD, which adds to the overall government deficit. The total cost of healthcare is expected to grow by another

$2 trillion over the next eight years if the status quo continues. It will be difficult for the economy to sustain this level of growth. Direct action to curtail healthcare cost is needed.

4.2.2 Inhibitors

One of the primary limiting factors is the lack of well-defined standards across the ecosystem. In order for solutions to attain mass market status, the standards have to be clearly defined. An example of this is reflected in cellular communications networks. If a person from anywhere in the world sends a text message, it can be retrieved and read by the intended party, from any other wireless-enabled device across technologies, anywhere in the world. This is the same for mobile voice communication. Similar standardization is needed for mobile healthcare solutions. A global team needs to determine the necessary standards and they must be clearly written and managed. This will require interoperability testing and certification to ensure that each ecosystem player meets the required standard. Device vendors would need to meet requirements for their devices and the network communications protocols would need to be standardized as well to ensure that data sent from one healthcare facility can be read and understood by the servers and applications in another healthcare facility.

The overall objective is to have systems developed globally that can be accessed by physicians and other healthcare providers to diagnose certain conditions and test the efficacy of certain drugs. The challenge is that different countries have different patient privacy laws and rules. Therefore, there will be a need to find a common denominator that is acceptable globally.

4.3 The Mobile Healthcare Ecosystem and Proposed Architecture

The mobile healthcare architecture as depicted in figure 3 will start with sensors or devices that capture patient's vital signs data, movement, environment air quality, vision, or numerous other data points. These sensors will range from those requiring patient interaction, such as a glucose meter, to motion or air quality sensors, which fit seamlessly into the patients' environments. The mobility of the sensors will enable their use in diverse environments or anywhere the patient is located. The main purpose of sensors is to collect and forward data. There are numerous sensor providers from traditional healthcare providers such as Philips and GE to newer companies like BL Healthcare and Multi-tech.

The next element in the architecture is the aggregator. The aggregator collects data from sensors and routes or forwards the information to servers in a datacenter, cloud, or other localized storage environment. The aggregator does not need to be a dedicated healthcare device. However, it will require routing function, wide area network capability such as Wi-Fi, cellular connectivity, or wireline connectivity. It will also need to support the short range wireless technologies supported by the sensors. Providers of gateways range from Cisco Systems, Digi, Multi-tech, Sierra Wireless and others.
The wireless or wireline network typically connects the data from the gateway to the servers. In healthcare applications, this will most likely be a private network connection, Virtual Private Network connection (VPN), or Secure Socket Layer (SSL) connection. The information will typically be routed to a database for aggregation and parsing. Then, an application server hosting the application will pull the information from the database into the application format for presentation. The application server and database can be stored in a secured public cloud, private cloud, and other secure datacenter. Redundant storage is recommended to protect the data in the case of manmade or natural disasters.

End-users such as the patient, doctor, nurse, or other healthcare providers typically access the data via web portal. This portal can be presented on a web-enabled desktop, laptop, tablet, or smartphone. Healthcare laws may require that VPN is used to access the data to protect the patient's privacy. The data may be presented in a snapshot view for a specific period of time or a historical view to show the data over a few days, weeks, or months. The information can be securely accessed from anywhere there is an Internet connection and at any time.

4.3.1 Healthcare Architecture Overview

Sensor Network

The healthcare architecture will include various healthcare sensors with different configurations. Some will have direct connection to a wide area network like those with cellular chips. Others will have local area network connectivity then connect to a hub. The baseline architecture includes sensors with direct or wireless connectivity to an aggregation device. The sensors will leverage low power, low range wireless protocols such as BlueTooth, Zigbee, Z-Wave, IPv6 over a low power personal area network (6lowPAN) to communicate from sensors to an aggregator. Sensor networks are currently used to monitor temperature, sound, vibrations, pollutants, motion, and pressure. They will be similarly applied in healthcare solutions. Sensor networks are a critical component for large scale, continuous collection of patient data.

Sensors typically operate in mesh network architecture to ensure communication between the nodes. These nodes typically use an IPV6 address and can send and receive IPV6 packets. Payload and processing capabilities are typically extremely limited. The nodes then connect to an edge router or aggregator. They can be connected through multiple edge routers to form larger networks or just to one for a simple network.

Figure 2: Sensor Options

Sensor Technologies	Voltage/Current	Security	Distance	Data Rate	Standards	Features
Zigbee 2.0		AES 128	10 – 75 meters;	256kbps	IEEE 802.15.4	IP over AMI and HAN; 2.4GHz
Blue Tooth	<20mA	128 bit	160 ft., 50	1Mbps	802.15.4 -	2.4GHz,

Low Energy 4.0		AES w/counter mode	meters		2006	time to send data 6ms
Z-Wave	5VDC		100 ft. or 30 meters		Proprietary	Home automation; 900MHz band; Closed
6loWPAN	3V(17.4Ma TX/19Ma listen)	AES Encryption/ No key exchange	10 meter range	256kbps	IEEE 802.15.4 with IP capabilities	IP to small, low power, low processing devices

Aggregation Device

The aggregation device communicates via local area network or personal area network protocols to the aggregator. The aggregator collects the local data and sends it via wide area network protocol to a database or databases for storage, parsing and presentation. The wide area network connectivity options include GSM/GPRS/HSPA/LTE or CDMA, WiMAX, Ethernet, or even WiFi. The aggregator will leverage different form factors. This will include dedicated routers or gateways and cell phones with applications to enable aggregation functions.

Figure 3: Sample m-health Aggregation Devices

Database and Application Server

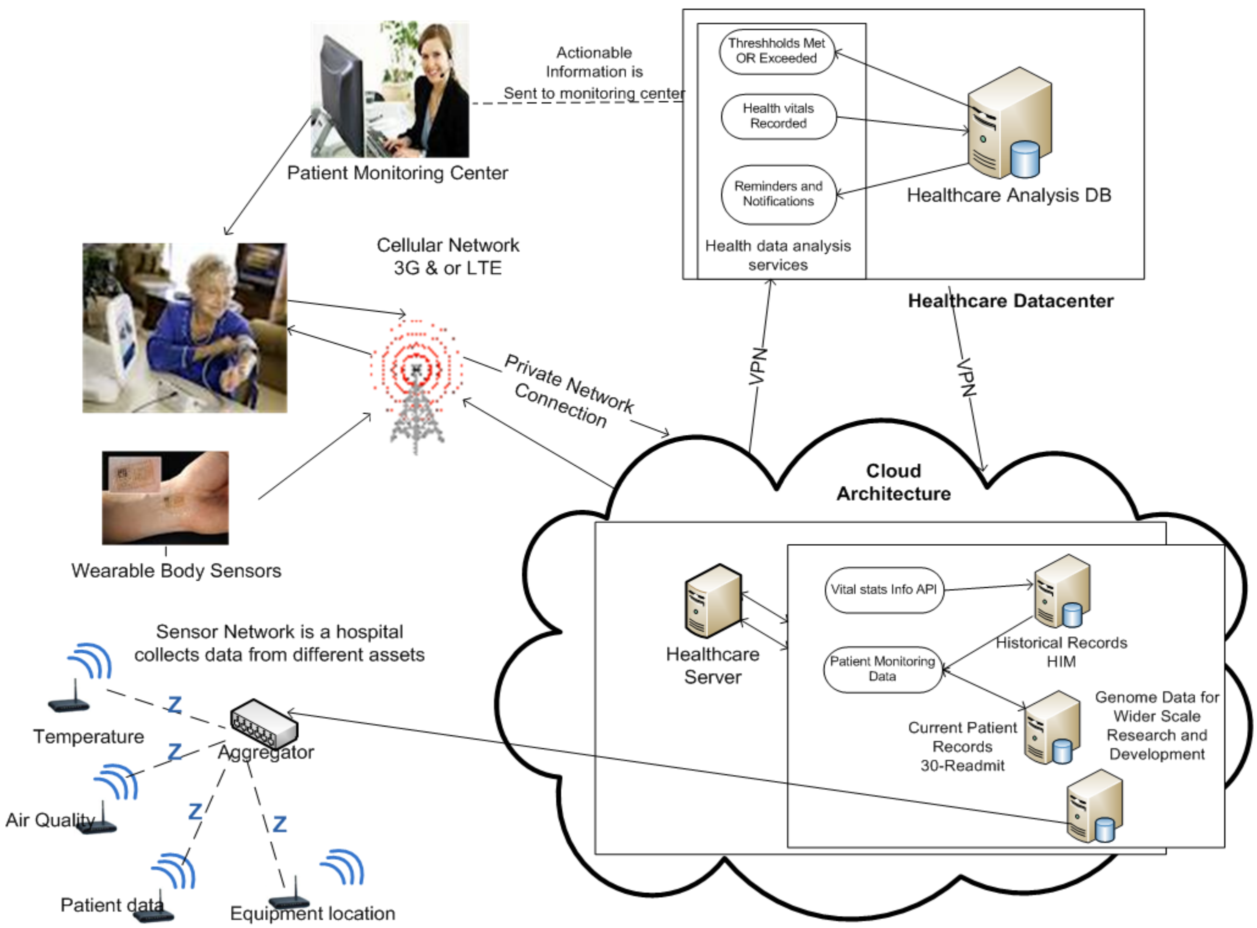
The database may also be connected to an application server that pulls the data and presents it in different views based on the user credentials. For example, a doctor may be able to see data from multiple patients with similar conditions, while the patient will only be able to see his/her specific data. The database and application servers will be centralized in a cloud network or other datacenter infrastructure. The application will be virtualized to enable multiple instances of the application to run in different cloud environments.

The cloud can be used to spin up a different database for different institutions while keeping hospital specific data in one or more servers, then sharing the same data without patient identification in a more generic database for wider scope analysis. The cloud infrastructure can enable easy database replication to ensure that all databases are the same. Healthcare-related data can also be isolated in its own environment, separated from other commercial data, to meet specified security requirements.

Other Network Elements

The network architecture will also include firewalls and protect and limit access to data based on user credentials as well as AAA/Subscriber database server to store user credentials and enable access based on credentials. End users will access the data via secured web-portal accessible via an Internet capable device with a VPN client for additional security. Data will traverse the wireless networks through private network connections for additional security. Private network connection will tunnel the data to the designated server or servers for storage. Medical Images will follow DICOM standards. Other data will follow HL7 formats. Databases will be stored in geographically redundant datacenters with on net connectivity for active backup in case of failure. This means that the same data will be replicated on both servers.

Figure 4: Mobile Health Network Architecture



5.0 Summary

Organizations like Continua Alliance and IHE are pushing for the global standardization of electronic healthcare data. These efforts will help to reduce time, errors, cost and improve the efficiency of healthcare delivery. They helped to move healthcare data from manual paperwork process to digital, automated processes. They have also enabled the electronic sharing of patient data, which was not widely available before. Now, patient data can be shared across departments and healthcare enterprises. However, a much larger transformation is needed in order to significantly reduce the cost of healthcare. Standardization of electronic data and how it is shared is just the first step in the process.

The next step is to extend healthcare delivery beyond the traditional bounds of hospitals, clinics, nursing homes and healthcare providers. These traditional care facilities have a large impact on healthcare costs. Hospitals alone account for costs of over $800 billion annually. Patient care needs to extend to incorporate the patients and other caregivers in the home and other less costly environments. Patient involvement means less doctor visits and more proactive care. Leveraging wireless requires the same standards organizations to define specifications and rules around how to use cellular devices for remote healthcare services.

Low cost, ubiquitous wireless devices provide a means to transform healthcare delivery and management. Second generation and third generation wireless chipsets are now available in the $20 to $40 price range, making it possible to develop low cost devices with these chipsets for wide area connectivity. This means that devices can be developed for less than $100 USD. The reduction of one doctor visit can pay for the cost of the device. Health Maintenance Organizations and Medicare and Medicaid services may be willing to fund these devices in order to save on more costly doctor visits.

The great advantage of the cellular networks is that they are already built, they are highly stable and reliable, and can reach the vast majority of the population, over 97 percent. Most cellular networks are also interoperable, so data sent on one network will safely be delivered to a user on another network. In addition, most people know how to use cellular devices. This will reduce the learning curve and adoption rate. It will take some time for people to adjust to using cellular devices for healthcare, but education will be the key. In addition, some solutions will leverage different form factors and will require little to no interaction with the patient.

The proposal is for IHE to expand healthcare data delivery model to incorporate the use of wireless networks and devices. The aim is to expand the ecosystem to include mobile network operators, mobile device vendors, gateway vendors and cloud or Infrastructure as a Service (IaaS) providers. While the existing healthcare ecosystem addresses the current healthcare delivery model, wireless devices and networks are outside of their core competence and should be delegated to the experts. In order to transform the business of healthcare, the participants must also be transformed traditional healthcare ecosystem along with a wireless ecosystem, can help to transform the healthcare delivery model. Government regulations will also need to support the transformation efforts. Since the government currently pays 35% of the overall $2.6 trillion dollars, it has a vested interest in reducing healthcare costs. Only then, will healthcare standardization enable the evolution needed to dramatically reduce healthcare costs.

6.0 Suggestions for Additional Work

While the theory of using wireless networks and devices to reduce healthcare costs seem logical and practical, it is still largely unproven due to the lack of large scale trials. Therefore, future work should include the analysis of large scale deployment of mobile health solutions. The results of using these solutions and the associated cost should be well documented for comparison of the new system versus the cost to continue using the existing systems.

To notice a significant difference in cost, the study should focus on chronically ill patients such as those with asthma, diabetes, heart disease, or other chronic conditions. Chronically ill patients are typically more costly to treat due to more incidents of hospitalization and re-admittance. Diabetes results in costs of approximately $174 billion annually. Thus, leveraging solutions that reduce doctor visits and hospitalization of chronically ill patients should be a key area of focus.

Remote monitoring and its impact on reducing patient's hospital visits should be evaluated. One contributor to hospital costs is thirty day re-admit. Thirty day re-admit is when a patient who is recently released from the hospital has to be re-admitted within thirty days. The Center for Medicare and Medicaid Services (CMS) reports that approximately $15 billion dollars of Medicare's annual costs is related to re-admittance and of that, $12 billion is preventable. Remote monitoring should be incorporated into transitional care from hospital to home to reduce patients' re-hospitalization. The study should focus on hospitals with high rates of readmission.

Other work can also be done on the standardization of the wireless system for healthcare data delivery. Once the standards are defined, then interoperability testing will be needed to ensure wide-scale sharing of information as needed. This testing would also be supported by the trial mentioned earlier. More information is also needed on the typical healthcare instruments that are now replaceable with mobile, simplified versions. An online catalog of these devices should be made available by healthcare organizations.

Large enterprises such as the mobile operators and telecommunication equipment vendors will also play a key role in promoting m-health solutions since they pay 32% of healthcare expenses. They can influence employees' decisions by offering subsidies to those employees who use m-health solutions. They can help to support large scale trials by referring employees. They will also need to participate in the m-health standardization efforts.

7.0

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