Wireless Health: Making Your Devices Talk

A Review, Solution, and Outlook for Wireless Health Connectivity

Stephan Hengstler

MeshEye Consulting
Campbell, California, United States
hengstler@alumni.stanford.edu

Abstract—**With the technological revolution in digital communications and connectivity over the past two decades, the healthcare sector is at the beginning of a dramatic overhaul. These technologies have already made their way into our everyday lives and thus changing the way we do things. The healthcare industry with its resistance to change has started considering, evaluating, and embracing the way connectivity can change medical treatment and personal health. In this paper, we review the state-of-the-art in medical device connectivity with a focus on wireless solutions. Throughout the paper, the discussion primarily applies to the United States and it separately studies its three major care delivery settings: clinical, office, and home. Based on the challenges and requirements that each of these settings present, we discuss the key aspects needed for medical device connectivity to succeed from both a technological and financial perspective. Cellular connectivity can satisfy many of these key aspects. Therefore, we have proposed and operated a testbed for cellular-enabled upload into Electronic Health Record (EHR) systems, which we present here and outline its implementation in detail. The paper concludes with a longer term outlook on the adoption of digital communications and connectivity in the healthcare sector.**

Keywords-cellular; connectivity; devices; health; wireless

I. INTRODUCTION

There is much excitement in the electronic health (eHealth) and mobile health (mHealth) industry about the promise that wireless technologies can bring to healthcare. Many grassroots efforts are underway promising everything from vital sign monitoring to aging in-place. Naturally, one may ask which technologies and solutions truly create value, which will survive in the end and ultimately benefit us humans?

The business environment feels similar to the beginnings of cellular technology in the mid to late 1990s. Many companies offer complementary, overlapping, or competing product solutions for improving healthcare through the use of wireless connectivity—the same kind of wireless connectivity we already use on a daily basis in our laptops, tablets, and cell phones. Although they share the same base technology, the rules of engagement differ for the healthcare sector in many aspects from consumer markets. It is us, as the end–user, driving market success in consumer markets and hence deciding the fate of a product solution or technology. A consumer product succeeds if it meets the needs of the consumer in terms of cost, features, and usability. Not so in the healthcare industry: the success of a medical product is driven by multiple other factors such as distributor alliances, marketing efforts, insurance reimbursement, quality reputation and regulatory track record. With all the parties involved in the chain of treatment, who have a stake in deciding the means of treatment, it is us, as the patient, who has the least say in the medical devices that facilitate our diagnosis and treatment.

The research presented here expands upon our seminal paper [1] on wireless health and our presentation [2] given at the mHealth Summit 2013. In this paper, we will cover and discuss the deployment and usefulness of wireless connectivity technology in a variety of medical instruments primarily in the United States. The paper starts out in Section II with a survey of existing connectivity solutions used in medical devices today. In Section III, we introduce several key aspects that are necessary for a connectivity solution to succeed in the healthcare market. Section IV applies these keys to cellular connectivity exclusively and presents our technology solution for connecting medical devices equipped with cellular modems to Electronic Health Record (EHR) systems. In Section V, we discuss the direction that we see the market taking and our view of what the future holds for connectivity solutions in healthcare. Section VI concludes the paper with a summary of the insights gained and final remarks.

II. EXISTING CONNECTIVITY SOLUTIONS

The deployment of wireless technology in healthcare delivery settings today is widespread. Many solutions already exist or are under development aiming to streamline the healthcare system [3]. But, as varied as the patient groups are, so are the treatment options. Today, wireless solutions in healthcare are highly fragmented with little standardization beyond the medium access layer. While this fragmentation facilitates a high degree of targeted solutions, which address specific needs, it makes it difficult for medical instrument companies to capitalize on their R&D investments.

Two different ways of categorizing solutions in use today help to shed light on wireless deployment: (i) grouping by the intended healthcare setting (clinical, office, and home

setting) and (ii) grouping by the target patient group (teenagers, baby boomers, and general population). Grouping solutions by target patient group will lead to a separation by health condition, whereas categorizing them by healthcare setting will result in a separation by treatment and usage environment. The latter grouping is more meaningful with respect to medical device functionality and connectivity. Therefore, let us take a closer look at which connectivity solutions have made their way into the three different care delivery settings.

A. Clinical Setting

In clinical settings, i.e., clinics and hospitals, the objective of connected devices lies in preventing medical errors and reducing the cost of treatment. Connected devices facilitate this through streamlining the flow of admission, diagnosis, billing, and release information.

Clinical healthcare providers still prefer wired solutions for most of their medical instruments. Table I lists the main advantages and disadvantages of wired versus wireless connectivity in medical devices. For one, wired solutions are more secure, reliable, and easier to maintain once installed and configured. Such wired instruments include for example vital sign monitors, surgical instrumentation, and hospital lab equipment. The use of mobile devices that doctors and nurses carry around is limited to smart phones, tablets, personal digital assistants, and most notably bedside monitors [4]. Both wired and wireless devices that are used in diagnosis and treatment typically integrate into the facility's Health Information System (HIS) and Laboratory Information System (LIS) through the use of instrument middleware.

With few exceptions, IEEE 802.11 Wi-Fi [5] is the preferred connectivity technology for such devices. Cellular technology [6] is only used for text message notifications to personnel involved in patient care activities. So far, wireless connections only make sense for instruments that doctors and nurses carry with them to perform routine tasks or for patient bedside monitors according to a clinical laboratorian at the Palo Alto Medical Foundation. A prime example of such a patient bedside monitor is Abbott's i-STAT 1 Wireless System [7]. It is a handheld blood analyzer that, for instance, allows quantitative point-of-care measurements of Cardiac Troponin I, which is used in the diagnosis and treatment of heart attacks. The handheld analyzer can transmit measurement results via Wi-Fi into the patients' electronic medical records. The primary motivators for connecting medical devices into electronic medical records lie in the reduction of the overall cost structure, prevention of transcription errors, and, in the United States, by federal mandate [8], in the reduction of the rate of readmission.

The deployment of cellular technology in clinical settings still faces strong opposition. A frequently encountered argument against cellular technology is weak reception or no coverage. Cellular coverage largely depends on the network carrier. One thing to keep in mind is that coverage can only improve over time—if paying customers reside at any given location, at least one cell phone carrier will be there to go after them. Some hospitals and clinics are installing indoor Distributed Antenna Systems (DAS) thus actively improving cell coverage to the benefit of caregivers and patients alike.

TABLE I. WIRED VERSUS WIRELESS CONNECTIVITY

	Advantages	Disadvantages
Wired	• Robust, stable and reliable • Access control on premise • Simple to monitor security	• Higher cost of installation • More complicated to scale • Upgrade can be expensive
Wireless	• Easy to install and deploy • Supports device mobility • Readily upgradable to latest wireless standard	• Access control challenging • Devices need to be configured individually • Requires coverage testing

B. Office Setting

Doctors' offices are currently undergoing a fundamental change. The federal incentives and mandate towards the adoption and meaningful use of electronic health records [9] causes smaller doctors' offices to switch from primarily paper-based record keeping to electronic health records for their patient base. With it, the use of instrumented testing becomes also more lucrative as test results can automatically find their way into a patient's digital medical record. However, very few of such devices are in use today; let alone advanced devices offering cellular connectivity.

Especially for smaller practices, the main hurdle is the affordability of diagnostic test instruments and their limited insurance reimbursement. Test labs service most diagnostic testing needs arising in doctors' offices with an established cost structure for reimbursement. This flow of patient testing is more cost efficient as long it remains below the cost of ownership of in-house instrumented testing. This is primarily dependent upon the volume of tests run in a doctor's office. Furthermore, if an instrumented test has not been waived through the Clinical Laboratory Improvement Amendments (CLIA), a staff member of the doctors' office needs to undergo training to be authorized to perform this particular test. Another hurdle lies in that doctors, who have run their practice paper-based for most of their career, are unlikely open to adopting new technology and change the way they have been practicing medicine. This hurdle will diminish over time as more and more younger doctors take over—especially "digital natives" [10] who are accustomed to computer, internet and smart phone usage. Note that the implied assumption here is that younger doctors bring with them a comparatively higher willingness to try new technologies in patient treatment.

The situation is very different in an adjacent point-of-care setting: minute clinics. They specialize in the rapid diagnosis and immediate treatment of only the most commonly occurring infections such as Influenza or Streptococcus, and diseases such as diabetes, high cholesterol, high blood pressure or asthma. Their volume of tests performed is large enough to justify the use of instrumented testing. Therefore, medical instruments have started to make their way into these point-of-care facilities. Instrument connectivity is of little value thus far unless it can relay the prescribed drug treatment through the patient's health record to the pharmacy or send reminders of dosage or refills to the patient's cell

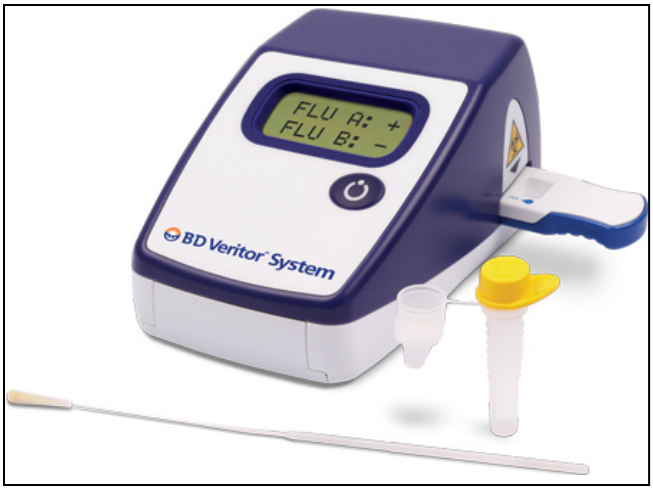

Figure 1. The BD Veritor™ System.

phone [11]. Since several of these minute clinics operate under the same business as pharmacy services, forwarding the prescribed drug treatment immediately to the pharmacy does make business sense—it saves paper and avoids human transcription errors.

C. *Home Setting*

There is a plethora of solutions already available in the wireless health market today. The industry has come up with enticing catch phrases to market the products in this market segment: quantified self, patient-centric, personalized medicine, and aging in place. Products ranging from vital sign monitoring, such as body weight, body fat, heart rate, blood glucose, and oxygen saturation to dieting, fitness and sleep trackers are readily available. They generate massive amounts of data which, in most cases, are continuously uploaded via Bluetooth, WiFi, or USB to an associated smart phone app, which analyzes and visualizes the data. The ultimate objective has to be the improvement of one's individual personal health [12] through changes in behavior and lifestyle. A reduction in healthcare cost is often a desired side effect for the people using these devices on a regular basis.

There are two sizeable markets in the United States for these personal health products: the teenage population and the baby boomers. The two population groups have different health challenges and hence the solutions are tailored to their needs. Baby boomers are entering the retirement age and with it come the onset of several health concerns such as congestive heart failure, hypertension, and diabetes. Hence, baby boomers spend money on solutions that enable graceful "aging in place," i.e., solutions that detect, prevent, or manage such chronic conditions in the convenience of their homes [13].

In case of the teenage population, who are sometimes referred to as "the Fat Kids of America," the primary health concerns are obesity, diabetes, and asthma. The objective here is not only the management of these chronic conditions under the supervision of the teenager's parents, but to maintain or improve his or her overall health through enforcing medication adherence and ultimately creating a persistent change in behavior. A representative example of a personal health monitor with cellular connectivity is Telcare's cellular-enabled Blood Glucose Meter [14]. To our knowledge, this is the first product in the personal healthcare market that directly uses cellular connectivity to upload glucose measurements in real-time to the patient's diabetes record, which resides on a secure Telcare server. In case of a minor, the parents as well as authorized doctors are given access to the diabetes record to review glucose level charts. Moreover, Telcare's server provides instant feedback and coaching to patients via the smart phone style glucose meter.

III. KEYS TO SUCCESS

Table II summarizes our review of medical device connectivity in the three care delivery settings. With these opportunities and challenges in mind, let us take a closer look at the keys required for a solution to succeed in each of these setting. The overarching key for success of any new healthcare solution is overall cost reduction in the healthcare delivery process. And that is the premise of wirelessly connected medical devices: their attraction lies in cost reduction, measurement objectivity, and ease of use. While the above mentioned keys are common across all care delivery settings, each setting weighs them differently or has additional keys to success.

For illustration and consideration purposes, a good example of a medical device that exhibits measurement objectivity and ease of use is the BD Veritor™ System [15], which the United States Food and Drug Administration (FDA) approved in 2010 for the clinical as well as the point-of-care care (POC) care delivery setting. It is a rapid testing platform for the detection of infectious diseases such as Influenza Type A and B and Group A Streptococcus. The BD Veritor System [16], as shown in Fig. 1, consists of the device and the consumables, that is, the mobile reader and the sample extractor, test tube, and test cartridge (in the figure, the cartridge is shown inserted in the reader). The reader is priced at around $300 USD; however, in its current version it is lacking the option of connectivity into HIS or LIS installations.

To perform a test with BD Veritor System, the physician mixes the patient sample (nasal fluid for an Influenza test and saliva for a Strep test) that resides on the sample

TABLE II. WIRELESS CONNECTIVITY IN HEALTHCARE SETTINGS

Care Setting	Opportunities	Challenges
Clinical	• Bedside monitoring during routine patient visits • Patient self-monitoring after hospital discharge	• Clinics are slow in adopting new technologies • Reduction in overall cost of care not yet proven
Office	• Facilitate adoption of electronic health records • Seamlessly relay treatment to pharmacy or insurance	• Insurance reimbursement limits return on investment • Smaller offices not setup for wireless connectivity
Home	• Detect, prevent, and manage chronic conditions • Self-tracking to create persistent lifestyle changes	• Monitoring products lack standard and aggregation • Gap between tracking and persistent behavior change

extractor with the reagents in the test tube. Three drops are then dispensed into the sample well of the test cartridge. After ten minutes, the physician inserts the cartridge into the reader. Finally, the BD Veritor System reader analyzes the test strip for ten seconds and displays the final test result.

A. Clinical Setting

Since the hospital's clinical lab along with external central labs cover most of the testing needs arising in patient treatment, there is not a great deal of potential for adding wireless medical devices in the hospital setting. As discussed in Section II, the exceptions are devices that doctors and nurses use in routine patient treatment or patient bedside monitors.

There is however another emerging class of devices that can greatly benefit from wireless connectivity: devices that track the state of health of a patient after his or her release from the hospital. To achieve this, the patient could be given a monitoring device that facilitates home testing and wireless data upload into the hospital's HIS or LIS. One advantage is that the patient could recover in the comfort of his or her own home while the critical parameters of his or her state of health are still being monitored by the hospital's medical staff. The other benefit is that this would lower the readmission rate—in line with the United States' Affordable Care Act [8]—while reducing the cost of care at the same time.

The key to making this a reality is to combine a test approved for home usage with an easy-to-use device that is able to wirelessly transmit the patient's health parameters reliably and securely into the hospital's HIS or LIS.

B. Office Setting

To successfully place wireless medical devices in the point-of-care setting, minute clinics or physician offices, requires foremost that the solution makes financial sense. In this setting, a patient testing service has a fixed reimbursement amount no matter how the test is performed, i.e., visually read, instrument read, or by a central lab. Hence, doctors' offices will have a difficult time financially justifying the expense of instrumented testing if the per annum test volume for that particular test is low. In other words, wireless medical instruments can only succeed in this market if they prove to be less expensive to purchase, install, and operate than the already existing solutions in place. Although the federal mandate towards the use of medical health records may aid in deploying more wired and wirelessly connected instruments, most instruments are just too expensive to be financially viable testing solutions for most doctors' offices.

Nevertheless, rapid tests that occur frequently such as for infectious diseases (Influenza, Streptococcus, sexually transmitted diseases, etc.) may justify usage of wireless medical instruments. The keys here are that such instruments are cleared for the point-of-care setting, i.e., Clinical Laboratory Improvement Amendments (CLIA) waived, and that their cost of ownership lies approximately below $500 per year. A BD Veritor System that features connectivity into EHR systems would meet these requirements satisfactorily.

C. Home Setting

While each of the solutions offered for home deployment may address a particular health issue quite adequately, there are many challenges facing the wireless health home market today. For one, there is little to no standardization. Each solution works on its own independent of other health products in use. Each solution also requires frequent interaction and manual data entry by its user—something a society governed by convenience strongly shuns. For this reason, the average duration of regular usage does not exceed 30 days for the majority of these health improvement apps: just 5% of all apps (including health apps) are still in use 30 days after download [17]. In short, they are too intrusive to many people's already hectic and packed life.

Decentralized storage of data collected through different personal health solutions creates another significant challenge. How is one to get a comprehensive picture of one's health if the data resides in several different, unique applications? There are of course a few solutions like Google Health (discontinued as of January 2013) and Microsoft HealthVault [18] attempting to address the need of centralized data storage through offering a single landing page service. But, most personal health products do not interface with them and hence data would have to be entered manually. Therefore, a major key to succeed in this market is easy and seamless integration of the medical sensing devices, that is, the ones that provide personal health metrics, into personal health record systems. This can only be achieved effectively through standardization of the health data interfaces. The Continua Health Alliance [19] and the Institute of Electrical and Electronics Engineers [20] for instance are actively pushing this standardization and have been issuing design guidelines and standards for interoperability in personal healthcare [21].

Another fundamental issue of personal health tracking is that it is not sufficient to create persistent and lasting lifestyle changes. Living in a society of instant gratification, we expect solutions with this promise of success; but behavior change is a process of perseverance—very much in contradiction to instant gratification. In fact, Joseph Kvedar [22] has found "that only a small portion of the population, around 10 percent, will change their behavior based on tracker information alone." Knowing the right thing and doing the right thing are worlds apart. Even if personal health trackers provide us with vital information of what foods to avoid for example, we are still subjected to the marketing exposure of unhealthy eating habits. In the United States, good examples are the Carl's Jr. TV commercials for its selection of big and juicy burgers [23]. How can one not watch one of these commercials without leaving with the thought that relishing one of these irresistibly delicious burgers results in tremendous pleasure? Knowing that they are an unhealthy diet will likely not kill that thought! It is like running a marathon with a rock tied to one's ankle.

In essence, our lifestyle choices are not only impacted by reading our personal health statistics, but also by what we expose ourselves to in the form of billboards, commercials, and magazines. And to extract oneself from this omnipresent

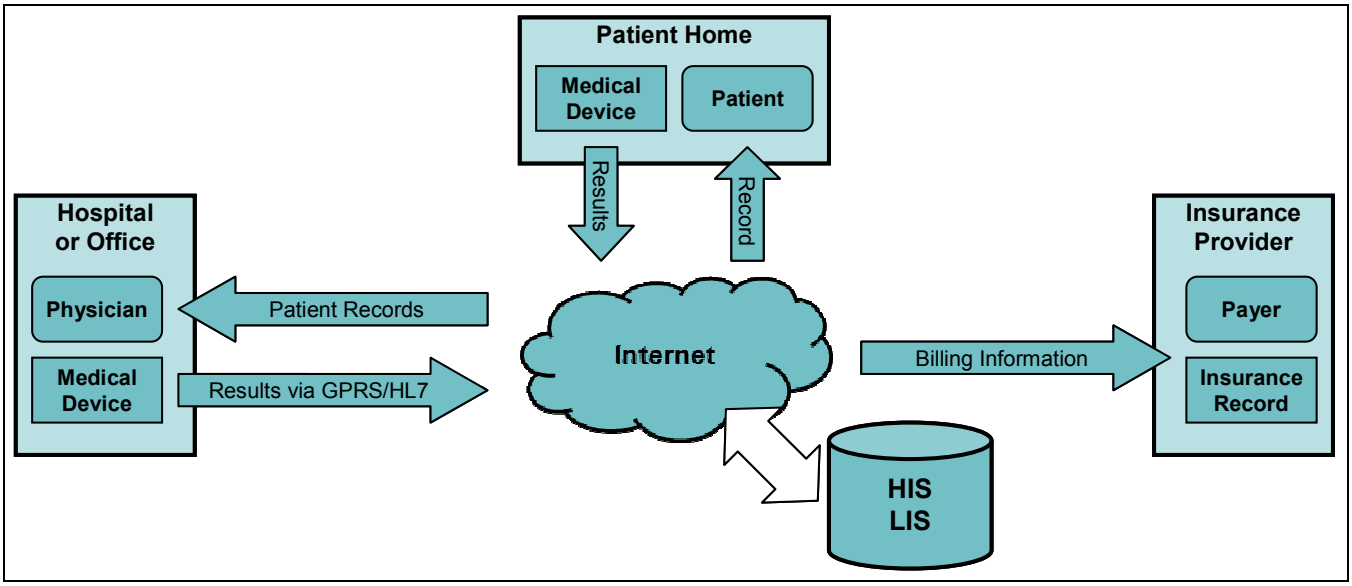

Figure 2. Healthcare information flow with cellular connectivity of medical devices.

exposure in the United States is a deliberate effort that has to be made daily. To assist us in this effort, our personal health systems would also have to tie into our flat panel TVs and web browsers and block out commercials and banner ads that are inappropriate for our current health condition. But, in reality, the opposite is happening. The marketing industry exploits our internet browsing behavior for the most part to entice us into buying and consuming more and more.

IV. THE CASE FOR CELLULAR

At this point, it should have become clear that there is no one-size-fits-all solution. The three care delivery settings considered have overlapping but also diverging requirements, which cannot be met by one solution all at once. Therefore, there are many product offerings from small to large companies, which focus on one or a few aspects in the healthcare delivery process. In short, the market is highly fragmented and proprietary solutions are prevalent.

But for solutions to be cost effective and scalable demands standardization and interoperability that in turn can proliferate integrated solutions [24]. Therefore, in the near-term, healthcare solutions will have to target seamless integration into the flow of care from patient over provider to payer [13]. Clearly, this is a good idea in theory but not enough to succeed in the healthcare market. The present reality is that the adoption of mHealth connectivity standards has been inconsistent [25].

We are convinced that the adoption of cellular connectivity in medical devices is the starting point to enabling higher levels of standardization and interoperability—at least at the front-end, where patient health data needs to make it into the digital medical record. It is crucial for subsequent treatment to consistently store this data digitally in a secure and reliable manner. But, if the interface method is lacking any of these attributes, the patient data will not be stored consistently leading to patchy health records. While there are several connection technologies and dataflow models conceivable, cellular technology is already dominating the personal consumer space and, as a result, has been widely adopted, is standardized, and continuously increases in data throughput and geographical coverage. Moreover, cellular hardware cost is held down by the large scale consumer market and service providers continue to drive down data transmission cost. Therefore, medical devices equipped with cellular modems can meet several of the keys for success discussed in Section III.

Let us discuss this cellular connectivity solution in more detail. Fig. 2 illustrates the flow of healthcare information when medical devices are equipped with a cellular GSM modem. This enables them to directly communicate with the HIS/LIS, or, more generally, the EHR system, through a General Packet Radio Service (GPRS) Internet connection. Test results can then readily be uploaded into the patient health record via the HL7 protocol [26]. Note that this direct connection eliminates the need for and expense of middleware software, a “middle man”, which, for the most part, reformats the device’s proprietary data output to the standardized EHR data format. Even more importantly, this dataflow model does not depend on another database server or cloud service operated, for instance, by the device manufacturer. Once the patient results have been uploaded to the EHR, which can either occur from a hospital, physician office, or the patient’s home, other need-to-know parties can readily access or be notified of the results. Such parties are the primary care physician, the insurance payer, as well as the patient itself.

A. Testbed Implementation

To explore and validate the feasibility of this cellular connectivity solution, MeshEye Consulting has been operating an Electronic Medical Record (EMR) connectivity testbed with an HL7 portal for test record upload since November 2010. The testbed deploys the open-source EMR software FreeMED [27] in lieu of HIS/LIS software. The

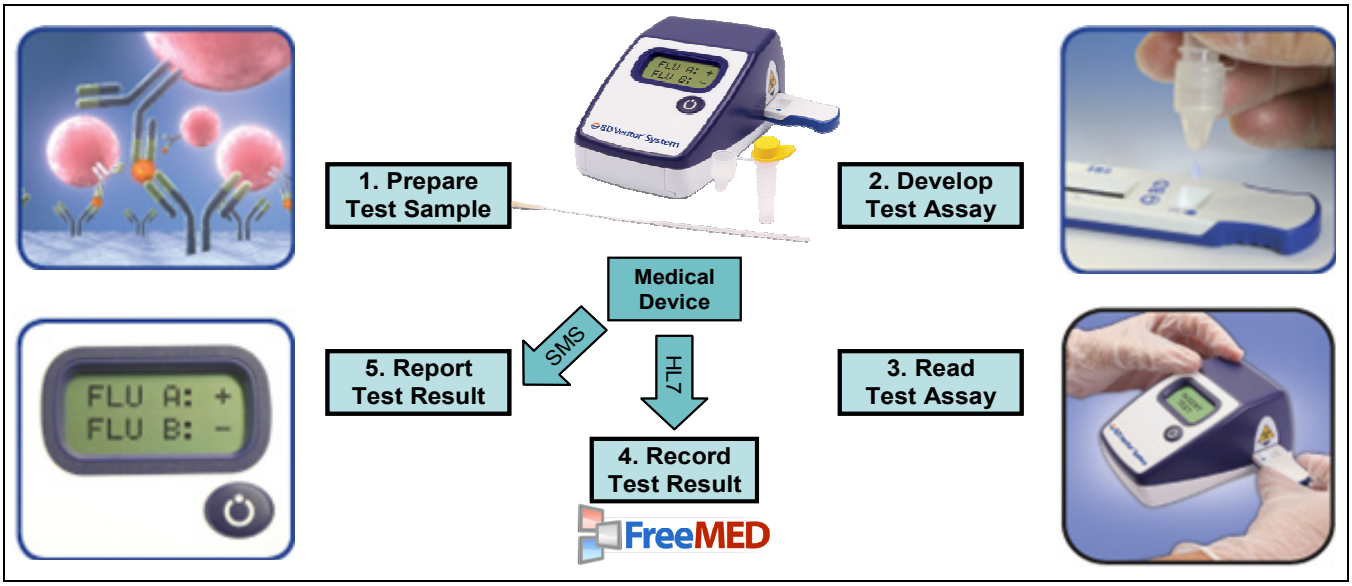

Figure 3. Process steps from patient sample to test result in the MeshEye EMR Connectivity Testbed.

FreeMED installation has been modified to accept test records from medical devices in the form of HL7 Version 2.3 messages encapsulated in XML-RPC requests. A medical device prototype equipped with a cellular GSM modem was designed to upload its test records to this EMR system via GPRS. The testbed has proven that this approach is feasible and easy to implement.

To generate the HL7 messages, the test result fields first needed to be mapped to fields in an HL7 ORU-R01 observation result message. The results of this field mapping are shown in Table III for Influenza test results that the BD Veritor System reports. To import the HL7 ORU-R01 messages into FreeMED v0.8.1.1, we used Java to invoke the FreeMED XML-RPC call

TABLE III. FIELD MAPPING OF VERITOR RESULT TO HL7 MESSAGE

HL7 Field Identifier	Veritor Result Field(s)	HL7 Message Field
MSH-10	Index of test result	Message Control ID
PID-4	Barcoded patient ID	Alternate Patient ID – PID
ORC-12	Reader serial number	Ordering Provider
OBR-2	Reader serial number and index of test result	Placer Order Number
OBR-4	"UPPER RESPIRATORY SAMPLE" and "INFLUENZA"	Universal Service ID
OBX-3	"UPPER RESPIRATORY SAMPLE"	Observation Identifier
OBX-5	Display of test result: "FLU A: [+/–] FLU B: [+/–]"	Observation Value
OBX-6	None	Units
OBX-7	[+/–]	Reference Range
OBX-8	[+]	Abnormal Flags
OBX-11	"F" for final result	Observ Result Status

```
FreeMED.Transport.parse('HL7v2', message);
```

where *message* is the HL7 message in string format.

To notify the physician of completed tests, the EMR connectivity testbed has been configured to send out text messages with the test results. The end-to-end delay commonly encountered is in the order of 10 to 20 seconds. Considering that rapid diagnostic tests typically take at least 10 minutes to complete, such quality of service (QoS) would be acceptable. But cellular network carriers do not make any guarantees of end-to-end delay for text messaging, and hence it is only a solution good enough for demonstration purposes but not for professional field deployment. Moreover, text messaging does not lend itself to encryption, which brings us to another area of frequent concern: compliance with the Health Insurance Portability and Accountability Act (HIPAA).

HIPAA compliance requires the implementation of reasonable safeguards for the protection of patient-identifiable information. Although the EMR connectivity testbed does not transmit any information that would allow identification of a patient by name, only an assigned patient identifier, it makes sense to encrypt the entire payload. This usually diffuses any concerns around patient privacy but adds the burden of encryption key management.

The process steps necessary to turn a patient sample into a test result notification in the MeshEye EMR connectivity testbed are shown in Fig. 3. In the first step, the patient sample is mixed with the test reagent in a test tube, which takes no more than five minutes. Next, the sample mixture is dispensed onto the test cartridge and the test assay develops within 10 minutes. In step 3, the cartridge is then inserted into the reader which reads the test assay and determines the test result with a read time of 10 seconds. Finally, the reader uploads the test result via HL7 transparently to FreeMED, the MeshEye EMR system, and reports the test result in the

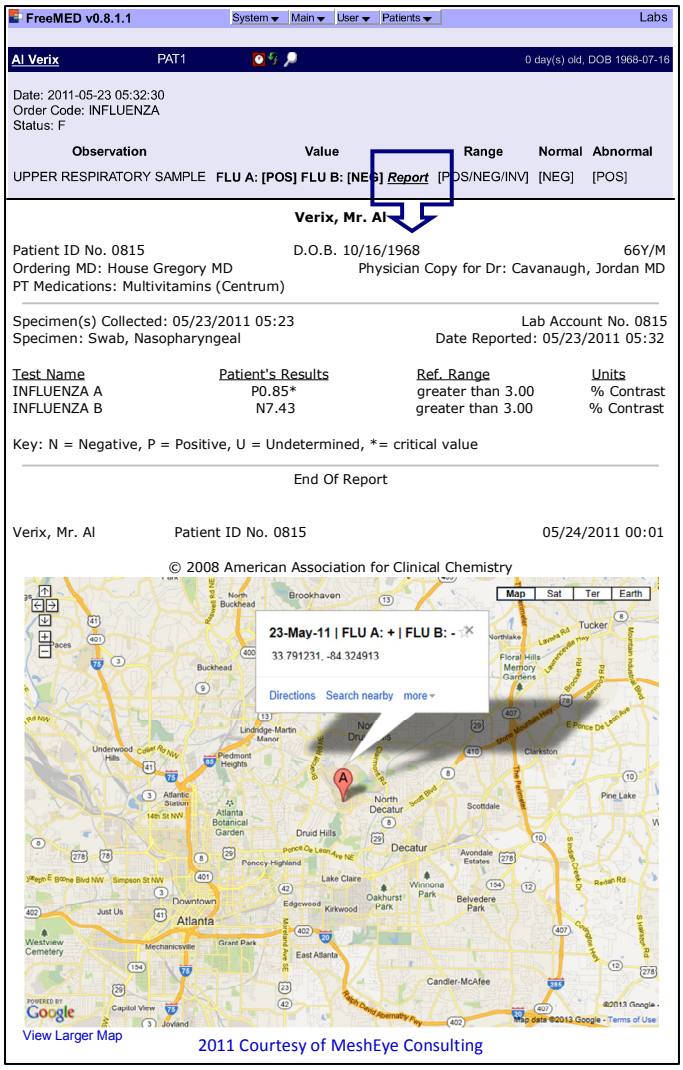

Figure 4. Patient test record (top) and instrument test report (bottom) of the MeshEye EMR Connectivity Testbed.

form of a text message notification to one or more cell phones. Steps 4 and 5 typically take just under a minute when cellular coverage is available. Thus, the entire process from test sample preparation to test result reporting approaches 15 minutes. Such test process duration is well suited for diseases and infections that benefit from being detected and treated during a single patient visit.

B. *Testbed Demonstration*

The EMR connectivity testbed was demonstrated to several hospitals in California as well as to the Centers for Disease Control and Prevention (CDC) in Atlanta, GA, in May 2011. Fig. 4 shows the patient test record and instrument test report that the testbed generated during the demonstration. The top of the figure shows the view of the patient's test result entry while the bottom of the figure shows the automatically generated instrument test report. The report contains all the fields expected of a lab test report. In addition, it maps the rough location of the testing site, which is derived from the cell tower identifiers within communication range of the modem. Most importantly, the test result upload completes in real-time, i.e., it usually takes less than a minute. This solution would allow the CDC to publish their "Influenza Surveillance Report" in real-time rather than with data lagging by two weeks. Especially CDC's recently launched influenza app [28] could benefit greatly from real-time reporting of infectious disease testing.

Further advantages of uploading and storing test results that have been patient de-identified but tagged with geo-location information, are their value for data mining purposes. In case of Influenza testing, this would allow monitoring real-time progression of the infection and spotting of pandemics early on. In case of diseases that are not seasonal, but chronic in nature, availability of such data could help to establish correlations between geographical area and the likelihood of developing such diseases. Maps that predict the likelihood of developing and progressing asthma for instance have already been generated and serve as an example of the value of such maps. Taking it even one step further, these likelihood maps could help shedding light on prevalent factors causing chronic diseases, that is, whether they are primarily hereditary or predominantly location dependent.

C. *Testbed Limitations*

While deployment of our EMR connectivity testbed was straightforward, we found that its deployment in the real world is far from this simple. More specifically, we came across three major challenges to real-world deployment: (i) HIS/LIS installations sit behind a tight firewall, (ii) HL7 is not really a universal standard, and (iii) healthcare providers may not accept unsolicited observation results. The following paragraphs will give more details on these challenges.

Since healthcare providers have to protect patient information from unauthorized access, HIS/LIS installations are only accessible from within the organization's intranet or at least sit behind a tightly configured firewall. That means that it is impossible for our cellular-enabled reader to directly upload test records via HL7 over Transmission Control Protocol (TCP)/Internet Protocol Suite (IP). Virtual Private Network (VPN) tunnels to the organization's intranet are typically established to overcome this obstacle. Nonetheless, running a VPN client inside the reader is not feasible given its limited computational resources. An alternative would be to open up a TCP/IP port in the organization's firewall although this would increase the vulnerability to unauthorized intrusion.

Anyone dealing with HL7 messaging quickly realizes that HL7 is not really a universal standard. The saying among experts goes "If you have seen one HL7 interface, you've seen one HL7 interface." One reason behind this is that every HIS/LIS installation configures the mapping of HL7 message fields to HIS/LIS database fields differently.

The third challenge comes from the reader sending an HL7 ORU-R01 observation result message without the order number issued for the diagnostic test. Therefore, this is considered an unsolicited result message which not all HIS/LIS installations accept. This challenge could be

addressed by scanning the order identifier instead of or in addition to the patient identifier.

We are currently working on finding solutions to the above mentioned limitations of our EMR connectivity solution. The success depends to a large degree on the flexibility of healthcare providers to make changes to their IT infrastructure. How much value the set of tests performed by a particular instrument creates will primarily drive the willingness for such changes.

V. LONGER TERM OUTLOOK

There is no doubt that interoperability through standardization will continue to increase in healthcare solutions. From a technology perspective, that is what is required to make any medical device talk to any EHR system [29]. It also makes sense from a business perspective since interoperability is an essential component for a scalable connected health market [25]. In short, interoperability through standardization will likely pave the way for widespread use of connected medical devices. Not surprisingly, the history of digital technology already features numerous examples of standards that triggered widespread use: Ethernet, GSM, Wi-Fi, and UMTS to name just a few.

But, knowing the right thing does not necessarily translate into doing the right thing. In fact, the healthcare industry in the United States is known for its resistance to change and slow rate of technology adoption. For instance, Thompson states that "I feel frustrated that physicians don't quite seem to be practicing in the 2012 world of technology I see on the exhibit floor [at the annual AACC Clinical Lab Expo 2012]" [30]. Healthcare investor G. Kurtzman puts it this way [31]: "Unless there is a "pull" from customers, patients, providers, or payers, an entrepreneur in healthcare IT won't be able to capitalize on just a good idea." Along these lines, the two parties that still need to drive the idea of connected health with more conviction are the payers and the regulators. The roadblock, that regulatory agencies and healthcare payers pose, and the outlook, that we anticipate for them, are summarized in Table IV.

TABLE IV. THE REGULATORY HURDLE AND THE INSURANCE BATTLE

	Regulatory Agencies	Healthcare Payers
Road-block	• Regulations are uncertain and approval process is slow	• Payers not convinced about overall reduction in cost
Outlook	• Issue clear guidance around connected medical devices • Simplify submission and speed up approval process	• Conclusive case studies and clinical trials needed • Account for entire chain of healthcare services in studies

The regulatory agencies' mandate includes issuing regulations for marketability of medical devices and enforcing them in the marketplace. There still remains a lot of uncertainty concerning the regulation of mobile health applications and related connected health devices. Therefore, the regulatory agencies have to clarify the approval process of these emerging technologies. In the United States, the FDA already took a big leap forward towards more clarity in 2013 when it issued its final guidance on mobile medical apps [32]. The next step is to speed up their approval process. This will also make the pursuit of connected health solutions more attractive to the investment community.

With respect to regulatory approval of wireless medical devices, there is an important distinction between unidirectional and bidirectional communication of the device to a web server or a cloud service. When the device only transmits data to the web server but does not receive any data back, regulatory approval is generally only required for the medical device as an autonomous, stand-alone device. But once the wirelessly connected device receives any information back from the web server or cloud service that could alter its functionality, the approval process applies to the system encompassing both, the medical device and the web server or cloud service.

The healthcare payers, that is, the insurance providers, have to be persuaded that connected healthcare solutions not only make sense but also reduce the overall cost of treatment. This is especially important in the United States, which has the highest cost structure in healthcare. It will require several more case studies and clinical trials to make a convincing case for the overall reduction in healthcare cost. Such studies and trials are however intricate and costly since the entire chain of healthcare services involved in patient treatment has to be accounted for.

Finally, a strong push for wireless connectivity in healthcare is coming from several players at the bottom of the food chain of healthcare reimbursement: medical device manufacturers and cellular network providers. Device manufacturers have an increasing interest in equipping their products with connectivity. This would provide them with instrument quality control (QC) data as well as access to test results, which may allow them to move up in the food chain. Network providers see the opportunity in high-volume data contracts in machine-to-machine (M2M) communication, which is viewed as their next big market after the cell phone market volume has started to level off. This alliance between device manufacturers and network providers is however not without challenges. Device manufacturers will have to negotiate pricing for cellular data subscriptions that meet their revenue models without directly transferring increased cost to healthcare providers. In other words, network providers prefer per monthly billing whereas healthcare providers purchase medical devices in one time transactions. This is the cash flow gap that device manufacturers will have to bridge.

With respect to cellular connectivity in medical devices, the outlook is the same as for connectivity in general. Nevertheless, it has to bear the additional burden of subscription fees paid to cellular network service providers. But, there is hope in sight [33]: "[…] The number of devices with integrated cellular connectivity increased from 0.73 million in 2011 to about 1.03 million in 2012, and is projected to grow at a CAGR rate of 46.3 percent to 7.1 million in 2017." And by the laws of supply and demand, increased deployment will result in lower cost of cellular connectivity in medical devices. Certainly, in-home monitoring devices, which we mentioned in Section III for

the clinical setting, will contribute to this market growth [33]: "For example, in the U.S., readmission penalties established by the Centers for Medicare & Medicaid Services will drive hospitals to adopt telehealth solutions for monitoring post-discharge patients." However, most likely countries other than the United States will lead the way—countries, in which cellular subscription fees adapt more rapidly to market supply and demand, as is the case in most countries across Europe and Asia.

VI. Conclusion and Future Work

We reviewed the current state of connectivity technology for medical devices in the healthcare sector giving special attention to wireless connectivity. The review highlighted the diversity and fragmentation of existing solutions to address the demands in the clinical, office, and home care setting in the United States. Therefore, the one key aspect to increase adoption of connected medical devices is interoperability through standardization. Cellular connectivity can enable standardized, seamless, and ubiquitous integration of medical devices into EHR systems. For this reason, we proposed and presented a cellular connectivity testbed that confirms and demonstrates the validity of this approach. Our EMR connectivity testbed indicates that medical devices can be seamlessly integrated into the flow of patient treatment across all three healthcare delivery settings. However, it remains to be seen whether wireless connectivity can actually lead to an overall reduction in the cost of care and change towards healthy lifestyle choices. Moreover, regulators and payers still have a long way to go before wireless connectivity becomes the norm in everyday patient diagnosis and treatment.

Acknowledgment

The author gratefully acknowledges the discussions, inspiration, and involvement of his colleagues at Alverix Inc. in San Jose, California, and the Becton, Dickinson and Company (BD) Diagnostics Group located in Baltimore, Maryland, and San Diego, California.

References

[1] S. Hengstler, "Wireless Health: Making Your Devices Talk," Proceedings of the Fifth International Conference on Emerging Network Intelligence (EMERGING 2013), Sept. 2013, pp. 19–25.

[2] S. Hengstler, "Making Your Devices Talk: The Case for Cellular Connectivity," Fifth Annual mHealth Summit (mHealth '13), Dec. 2013.

[3] "mHealth in an mWorld: How mobile technology is transforming health care," Deloitte Center for Health Solutions, Deloitte, 2012, pp. 1–21.

[4] P. B. Luppa, C. Müller, A. Schlichtiger, and H. Schlebusch (2011), "Point-of-care testing (POCT): Current techniques and future perspectives," TrAC Trends in Analytical Chemistry, vol. 30, no. 6, Jun. 2011, pp. 887–898.

[5] Wi-Fi® in Healthcare: Security Solutions for Hospital Wi-Fi Networks," White Paper, Wi-Fi Alliance, Feb. 2012, pp. 1–11.

[6] S. Saw, T. P. Loh, S. B. L. Ang, J. W. L. Yip, and S. K. Sethi (2011), "Meeting Regulatory Requirements by the Use of Cell Phone Text Message Notification With Autoescalation and Loop Closure for Reporting of Critical Laboratory Results," American Journal of Clinical Pathology, vol. 136, no. 1, Jul. 2011, pp. 30–34.

[7] Abbott Point of Care i-STAT 1 Wireless System, Product Website, [retrieved: December, 2014] Available: http://www.abbottpointofcare.com/Products-and-Services/iSTAT-Wireless.aspx

[8] United States Department of Labor, Affordable Care Act, [retrieved: December, 2014] Available: http://www.dol.gov/ebsa/healthreform/

[9] Government Health IT, Policymaking, Regulation, & Strategy: Meaningful Use, [retrieved: December, 2014] Available: http://www.healthit.gov/policy-researchers-implementers/meaningful-use

[10] M. Prensky (2001), "Digital Natives, Digital Immigrants Part 1", On the Horizon, vol. 9, no. 5, Oct. 2001, pp.1–6.

[11] I. Sachpazidis, S. Fragou, G. Sakas, "Medication adherence system using SMS technology," Proc. Intelligent Sensors, Sensor Networks and Information Processing Conference (ISSNIP 2004), IEEE Press, Dec. 2004, pp. 571–575.

[12] P. Sonnier, POLL RESULTS: What is the single greatest health benefit afforded by Digital Health solutions? [retrieved: December, 2014] Available: http://popperandco.com/2012/07/

[13] L. C. Baker, S. J. Johnson, D. Macaulay, and H. Birnbaum (2011), "Integrated Telehealth and Care Management Program for Medicare Beneficiaries with Chronic Disease Linked to Savings," Health Affairs, vol. 30, no. 9, Sept. 2011, pp. 1689–1697.

[14] Telcare Cellular-Enabled Blood Glucose Meter, Product Website, [retrieved: December, 2014] Available: http://www.telcare.com

[15] A. Paxton, "Rx for optimizing rapid flu test performance," CAP Today, vol. 27, no. 1, Jan. 2013, pp. 1–5.

[16] BD Veritor System, Product Website, [retrieved: December, 2014] Available: http://www.bd.com/ds/veritorsystem/

[17] R. Gary, "Why 95% of Mobile Apps are Abandoned—and Tips to Keep Your Apps from Becoming Part of that Statistic," Nuance Communications Inc., iss. 20, Nov. 2011, pp. 1–2.

[18] Microsoft HealthVault, Product Website, [retrieved: December, 2014] Available: https://www.healthvault.com

[19] Continua Health Alliance, Organization Website, [retrieved: December, 2014] Available: http://www.continuaalliance.org

[20] IEEE Standards Association, IEEE Standard 11073-10103-2012 – Health informatics—Point-of-care medical device communication, [retrieved: December, 2014] Available: http://standards.ieee.org/findstds/standard/11073-10103-2012.html

[21] D. Bowman, "Continua Health Alliance Releases 2011 Design Guidelines," FierceHealthIT, iss. 9, Sept. 2011, pp. 1–2.

[22] E. Waltz, "How I Quantified Myself: Can self-measurement gadgets help us live healthier and better lives?," IEEE Spectrum Magazine, vol. 49, no. 9, Sept. 2012, pp. 43–47.

[23] Carl Karcher Enterprises, Inc., Company Website, [retrieved: December, 2014] Available: http://www.carlsjr.com

[24] J. Hatcliff et al., "Rationale and Architecture Principles for Medical Application Platforms," Proceedings of the 2012 IEEE/ACM Third International Conference on Cyber-Physical Systems (ICCPS '12), Apr. 2012, pp. 3–12.

[25] "Interoperability: An essential component for scalable mHealth," mHealthInsights, PwC, Mar. 2013, pp. 1–3.

[26] Health Level Seven International, Introduction to HL7 Standards, [retrieved: December, 2014] Available: http://www.hl7.org/implement/standards/

[27] FreeMED Electronic Medical Record Software, Product Website, [retrieved: February, 2014] Available: http://freemedsoftware.org

[28] G. Slabodkin, "CDC's influenza app should be more reliable," Editor's Corner in FierceMobile Healthcare, iss. 15, Jan. 2013, pp. 1–2.

[29] B. Malone, "The Cutting Edge of Lab Connectivity: Will New Standard Deliver Plug-and-Play Solutions?" Clinical Laboratory News, vol. 38, no. 9, Sept. 2012, pp. 1–5.

[30] B. Malone, "Spotlight on Point-of-Care Testing: Innovation, Expansion Evident at AACC Clinical Lab Expo in Los Angeles," Clinical Laboratory News, vol. 38, no. 10, Oct. 2012, pp. 1–8.

[31] G. Kurtzman, GUEST POST: The question every healthcare IT startup must answer, [retrieved: December, 2014] Available: http://venturebeat.com/2012/08/25/healthcare-it-startup-tips/

[32] U.S. Department of Health and Human Services Food and Drug Administration, "Mobile Medical Applications," Guidance for Industry and Food and Drug Administration Staff, Sept. 2013, pp. 1–43.

[33] G. Slabodkin, "Research predicts strong growth of patient home monitoring systems by 2017," FierceMobile Healthcare, iss. 18, Jan. 2013, pp. 1–2.