2005-01-01

Design of Mobile Phone Applications for Point-Of-Care test result validation.

John McGrory
Technological University Dublin, john.mcgrory@tudublin.ie

Owen Lynch
Technological University Dublin, owen.lynch@tudublin.ie

Eugene Coyle
Technological University Dublin, Eugene.Coyle@tudublin.ie

Recommended Citation

Lynch,O,McGrory,J. Coyle,E.:Design of mobile phone applications for point of care test result validation. IASTED International Conference on Telehealth (Telehealth 2005), held at Banff, Canada.

Funder: Technological University Dublin

DESIGN OF MOBILE PHONE APPLICATIONS FOR POINT OF CARE TEST RESULT VALIDATION

Owen Lynch, John McGrory and Eugene Coyle
School of Control Systems and Electrical Engineering
Dublin Institute of Technology
Kevin St.
Dublin 8
Ireland
{owen.lynch, john.mcgrory, eugene.coyle}@dit.ie

ABSTRACT
Patients with many different conditions are required to take the management of their condition into their own hands and perform Point of Care Testing (POCT) at home. However, this raises quality control issues that would not arise in a clinical setting, since the sample acquisition and testing procedures are not overseen by professional hospital staff. Another major issue, the main focus of this research, is that results from such tests are not clinically validated to ensure that they are plausible for that patient at the time of testing. In hospital, tests taken by clinicians are validated by hi-tech computerised validation systems, before a diagnosis is made. Patients at home must often use the results of tests they take to determine medication dosage or monitor their condition, but these results do not undergo a validation procedure. Thus, there is a need to implement a system of result validation, either locally or by the hospital validation system itself, for people testing at home with POCT devices. This paper describes how mobile phone applications may be used to link patients, who manage their condition in the home, with the hospital information system (HIS) to upload and validate their results.

KEY WORDS
Point of Care, Home Health Care, J2ME, Mobile Application, Clinical Validation, Data Transmission

1. Introduction

1.1 Point of Care Testing

Point of Care testing in the home is a rapidly growing area in the healthcare arena. It gives patients an opportunity to manage their own conditions and can reduce their length of stay in hospital. There is also a cost reduction associated with the release of patients to their home for continuance of their healthcare. With a rapidly ageing worldwide population, and the older share of the population set to double by 2030 [1], there is a need to increase POCT at home in the health care system. There are a variety of ailments of the aged for which doctors can utilise clinical laboratory tests, and providing POCT to homebound patients could have a significant impact on their condition [2]. The variety of test apparatus for patients who manage their conditions at home is as diverse as the ailments themselves, ranging from simple urine dipsticks and blood pressure arm cuffs to complicated ECG devices. Many patients also use blood-testing units, such as glucometers for diabetics taking insulin to check glucose levels or blood coagulation (INR) meters for people taking anticoagulant medication, such as warfarin. The management of diabetes in the USA costs $100 billion annually and has many secondary disorders associated with it. However, management of the condition with POCT would prevent many of these disorders [2]. It is not only chronically ill patients and the ageing who use POCT, women during pregnancy and patients recently released from hospital may also have to monitor biological signs.

1.2 Clinical Testing and Result Validation

In hospitals and other similar clinical settings, tests are often required to be performed on specimen samples, such as blood or urine, which are taken from patients. The results of these tests provide invaluable information to doctors and clinicians for assessing a condition or making a diagnosis. The samples are taken from the patient by trained staff and in a hygienic manner that is well established, labelled and sent to the lab where the requested tests are performed by high precision lab testing equipment. The clinical laboratory applies gold standard testing regimes on each sample to obtain a result. The gold standard is considered the most specific test for a given sample and is completed according to a strict workflow list. Test results are then validated by a computerised validation system to determine their plausibility. This validation system may be bespoke software rules written by the hospital's own professionals or a commercially available system such as LabRespond [3]. Clinical validation systems play an important role in large automated laboratories and allow professionals to concentrate on problematic cases. These systems typically use a rule base to validate the result data as well as

clinical information such as past result values, sex and age to determine the believability of the result [4]. If there is a problem with the result and it is deemed invalid, it is marked for closer inspection by a laboratory professional. Further action can then be taken or the test can be re-ordered.

1.3 Home Testing Issues

For patients who perform tests at home with POCT equipment, there are some major issues, which this research addresses. First, the testing quality achieved by patients operating self-monitoring instruments is less when compared to a technician using the same equipment [5]. Second, there is no independent validation of the test results as described above. Thus decisions made as a result of a home test may be the wrong ones, which could potentially lead to complications for the patient. The consequence of producing the wrong results for INR could result in haemorrhaging or death of a warfarin patient [2]. Finally, the hospital professionals and doctors are unaware of their patients' progress between hospital visits. Patients may be scheduled to report to the hospital for weekly or monthly check-ups. However if a complication arises between visits, it may go unnoticed. Another issue with home based POCT is that prescribed drugs may interact with and affect test results. If the hospital is aware of this, it can allow for it in the validation algorithm and make changes to its outcome if necessary.

1.4 Proposed Solution

A major challenge of POCT is the integration of test results into hospital information systems (HIS) and electronic patient records (EPR). The need for connectivity between POCT devices and HIS is well recognised and benefits have been documented [6]. This research endeavours to bridge the gap between the patient at home and the hospital responsible for the treatment of the patient. The technologies considered will be discussed and then some solutions proposed for connecting patients with the hospital system for validation of results and the population of data to their EPR, using a mobile phone.

2. Mobile Phone and Java Technologies

2.1 Introduction

With the worldwide mobile phone subscriber numbers passing the 1.5 billion mark in 2004 and predicted to hit the 2 billion mark as early as July 2006 [7], it is clear that mobile phones are now a familiar tool to nearly everyone and are a necessary tool in everyday life for some. Phones are now more than just simple voice communicators and are evolving into sophisticated mini-computers, capable of running small to medium sized applications. Research has been carried out to investigate different mobile technologies that could be used as part of the solution for validating results of patients using POCT equipment.

2.2 Relevant Mobile Phone Technologies

The available mobile technologies were investigated and compared to one another to see which would suit this problem the most. Three of the technologies considered for use as a possible solution were Short Message Service (SMS), Wireless Application Protocol (WAP) and Java 2 Micro Edition (J2ME).

SMS was first considered but was soon ruled out as a realistic solution. SMS is mostly associated with short text-based messages for simple communication between phone subscribers, but a stream of SMS messages can be used to transmit any digital data. However, SMS is a store-and-forward service and there is no guarantee that the information will be delivered in a timely manner [8]. As POCT is time critical, this would not be acceptable.

WAP is an open specification that lets wireless devices easily interact with services and allows users to access the Internet [9]. So it could be used, for example, by patients to access a hospital server, submit test results and have relevant information returned to them, both textually and graphically. It uses the GPRS network, which is an always-on service and provides the highest possible transmission rates in GSM networks. However, there are also big limitations in using WAP as a solution. It requires a constant connection to the network and thus an off-line solution for validation would not be possible.

2.3 Java 2 Micro Edition (J2ME)

J2ME is a lighter version of the standard edition of Java designed specifically for developing applications on wireless communications devices with limited memory sizes, such as standard mobile telephones. It is a rapidly developing technology; there are literally hundreds of phones capable of running J2ME [10] and it is becoming a standard feature on mobile phones. J2ME applications are developed as MIDlets, MIDlets are to wireless what Java Applets have been to the web. J2ME applications can run on the phone without a network connection and are capable of making secure HTTP (HTTPS) connections to Internet servers and parsing the response. They are capable of storing data persistently, displaying data graphically and can perform relatively complex computation. Another beneficial aspect to J2ME is its ability to handle and parse XML, a format for structured documents and data that facilitates the interchange of data between computer applications. Because of these and its many other features J2ME has been chosen to develop the applications for ensuring high quality result validation as will be discussed in the next section.

2.4 Java Servlets

As noted above, J2ME applications have the ability to make HTTP connections and can handle and parse XML documents. This means that they can wrap any data into an XML document and send it to a server. Java Servlet technology works using this technique. It provides a mechanism for extending the functionality of a web server and accessing business systems [11]. Java Servlets have access to all of the existing Java application programming

interfaces (APIs), so that powerful server programs can be accessed by simple client applications remotely. Java Servlet technology has been chosen to implement the test hospital server programs and will be used for validating the results, providing software updates for the client application and storing the patient results in the EPR.

3. System Design

3.1 Introduction

Three versions of the application have been considered as possible solutions to the problem. Each version of the system consists of a J2ME client application, which runs on the phone, and a server application, which will be implemented as a Java Servlet. In the first version, the application will perform the validation of the result on the phone, only connecting to the hospital to update the validation rules and algorithm if necessary and to upload the result to the hospital database. In the second version the hospital server will do all of the validation computation, making the mobile client application much smaller. The third version splits the workload between the phone and the server, so some initial computation may be done on the phone but the application can remotely call procedures on the server for more heavy computation and uploading of result data. All three versions will include some pre-test instructions or procedures to help ensure a more accurate and reliable test result is obtained.

3.2 Version 1: All Computation on the Phone

In this case the client application is equipped with the rule base and algorithm to validate the patient's result locally. The rules could be tailored specifically for a patient and their condition if necessary. This method is suitable for result types where the validation procedure is relatively simple. Once the validation is finished, the application connects to the hospital and transmits the result data in XML format for storage on the hospital database. In the case of an invalid result, it will be flagged so a clinician can view it and contact the patient with further advice. A simple workflow of the system is shown in Figure 1. If previous result values are needed to validate a result they will be stored locally on the phone but can be retrieved from the hospital database if necessary. The validation algorithm may need to be updated or changed by the hospital technicians from time to time, so the application is designed with this in mind and has functionality to check for an update. If one is available, it downloads the new data and uses it for validation of results. Although all three versions of the application will need to make network connections, this one will generally use the least "air-time" as it does not need to wait for a response from the hospital validation system to validate the results. However, due to the limited processing power on a phone it is only suitable for the more simple validation methods.

3.3 Version 2: All Computation on the Server

This version of the application means there is less work done by the client application on the actual validation of the result. Information entered by the user on the phone is wrapped in an XML document and sent to the server over the HTTP connection, the result is then validated on the server by the validation process. If the result is valid it is stored on the patients EPR. If invalid, it is marked for inspection by the relevant hospital staff. A response for the client is generated and the outcome of the validation is included in it. Figure 2 shows a simplified workflow of how the client and servers would work together in the system. As results are validated by the most up to date validation service on the hospital server, there is less need to continually check the client application for updates in this version.

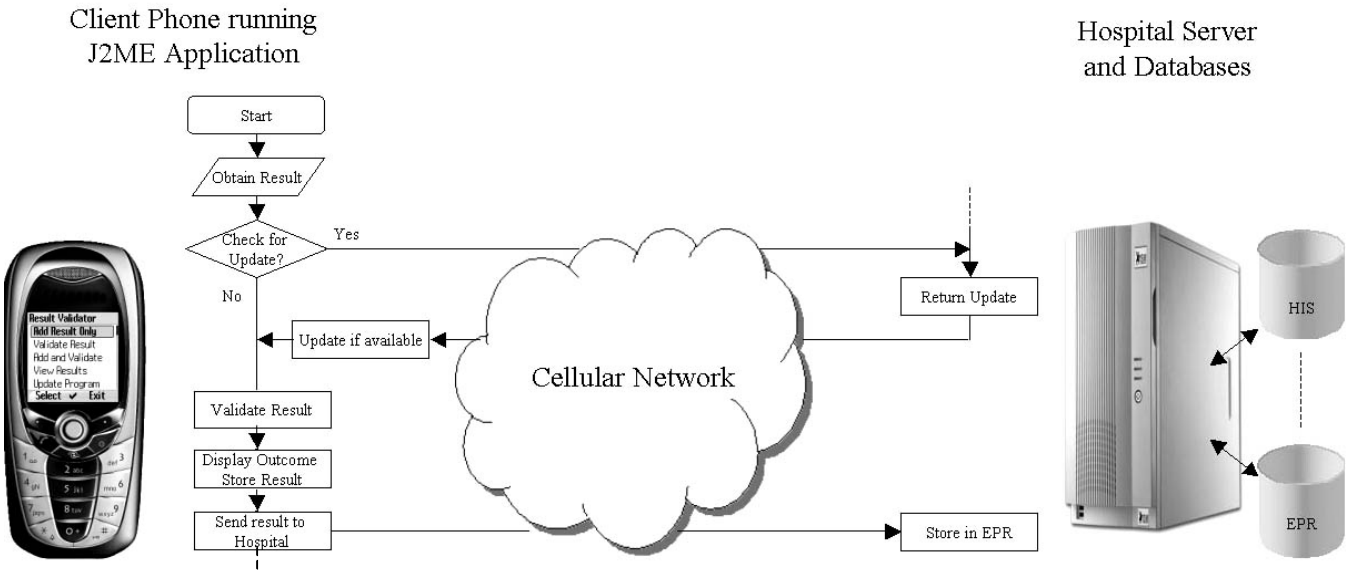

Figure 1: Simplified workflow of version one.

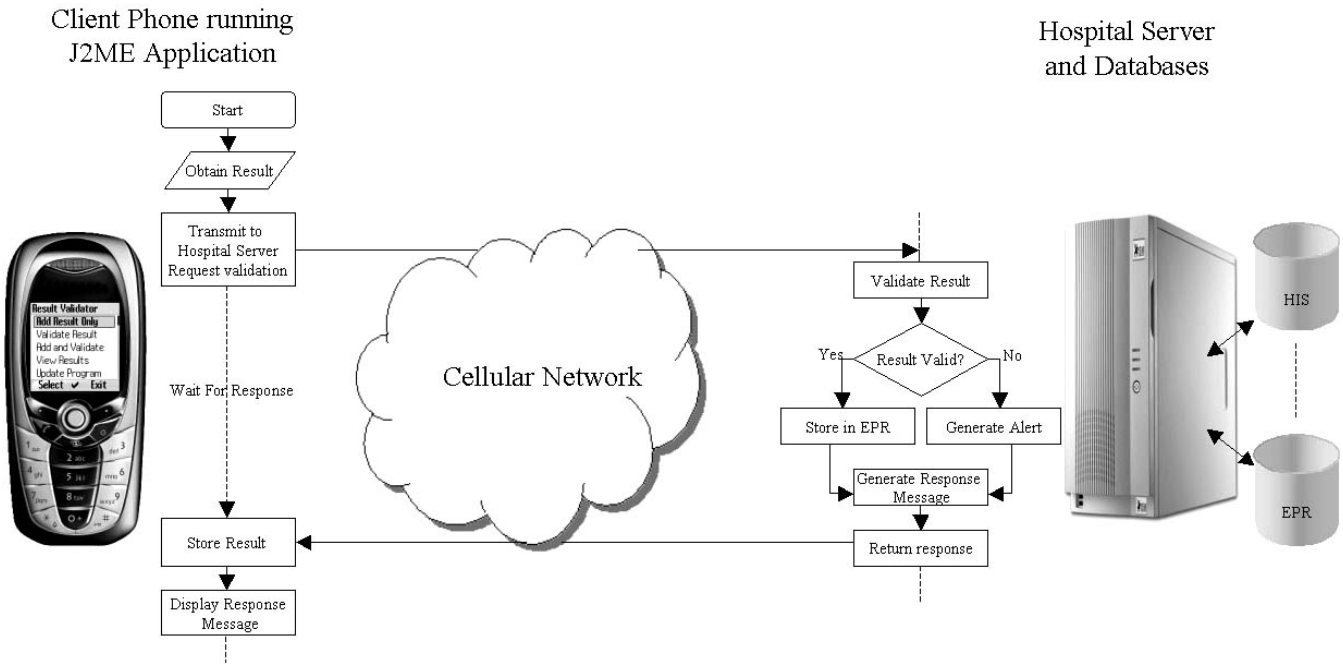

Figure 2: Simplified workflow of version two.

3.4 Version 3: Shared Computation

This version is potentially the most sensible one. It is similar to the second one but is a solution that utilises distributed computing technologies. When the result to be validated is entered this application will invoke the method for validation on the server remotely. To the user it will seem like the application is doing the computation locally but in fact it will be done by the server application. This distributed solution means the client application can be smaller than the first version, which is more suitable for a J2ME device. It also means, as in the previous version, that the result is being validated by the hospital validation service, which will always be the most up to date version. XML-RPC is a lightweight XML-based protocol for remote method invocation over HTTP and is being considered for use in this version of the system.

4. Implementation

4.1 Introduction

The basic designs for the three versions of the system have now been outlined. Proof of concept implementations for both the client and server side applications are being carried out. When finished, the three implantations will be tested and benchmarked against one another so that the strengths and weaknesses of each can be identified. With this information, the optimum version may be identified and improvements can be made. All three versions are designed with simplicity of use in mind so that the system will be manageable by elderly patients and people who are not technically educated.

4.2 Build and Test of The System

For the proof of concept, the J2ME applications are tested using various mobile phone emulators as well as the J2ME Wireless Development Toolkit. The Servlets written are running on an Apache Tomcat server. The Database on the server side has been built using the MySQL RDMS. The result data to be sent from client to server is wrapped to XML format and based on the HL7 format for laboratory results.

The selection of the optimal design from the three versions described will be based on the results of comprehensive testing and benchmarking of the systems. There are good reasons for implementing each version but testing each one and comparing the results of all three will confirm which ones are viable solutions. Factors being considered to determine the optimum system will be the accuracy of the result validation compared to the gold standard, the time it takes to receive a validation after the result is entered, and the efficiency in terms of network traffic.

4.3 Application Deployment

For all three cases the method for deploying the application will be the same. J2ME applications can be deployed to mobile phones over the air (OTA) and thus users are not required to have data cables for their handsets. Once downloaded, the application can be run on the phone without connecting to the network. The process will work as follows. The patient downloads the application to their phone from the hospital server. The application runs locally but can make HTTP connection to the hospital to upload data or validate the result. The client application receives data back from the hospital and

can perform additional computation if necessary and store the result locally.

5. Conclusion

With the increase in the demand for POCT in the home, there is a great opportunity for work in the area of patient-hospital communication. There is already much work being done on the communication of data between POCT units and wireless devices such as mobile phones and PDA's. The applications outlined in this paper take this communication to the next level and allow the results to be transmitted to the hospital. The three versions described in this paper give good guidelines as to how such a system may be realised The implementation of these applications will confirm the benefits. The wireless industry is rapidly growing and with the roll out of 3G networks already in operation there is great scope for expanding these applications, thus ensuring greater patient care and less wasted time.

References:

[1] K. Kinsella & D. R. Phillips, Global Ageing: The Challenge of Success*, Population Bulletin, 60*(1), 2005.

[2] C. A. Lehmann, The Future of Home Testing – implications for traditional laboratories, *Clinica Chimica Acta, 323*(1-2)*,* 2002, 21-36.

[3] W. P. Oosterhuis, J. L. M. Herman & H. M. J. Goldschmidt, Evaluation of LabRespond, a new Automated Validation System for Clinical Laboratory Test Results, *Clinical Chemistry 46*(11), 2000.

[4] G. Boran, P. Given & R. O'Moore, Patient Result Validation Services, *Computer Methods and Programs in Biomedicine, 50*(2)*,* 1996, 161-168.

[5] S. Skeie, G. Thue, K. Nerhus & S. Sandberg, Instruments for Self Monitoring of Blood Glucose: Comparisons of Testing Quality Achieved by Patients and a Technician, *Clinical Chemistry, 48*(7), 2002, 994-1003.

[6] M. Taylor, J.H. Nichols & J. Saltz, POCT Connectivity, Opening the door to a laboratory without walls*, American Clinical Laboratory*, July 2000.

[7] S. Josifovska, Where Next For The Handset?, *IEE Review, 50*(12), 2004, 36-39.

[8] T. Knyziak, W. Winiecki, The new prospects of distributed measurement systems using Java 2 Micro Edition mobile phone, *Computer Standards and Interfaces*, Article in press, available online at www.sciencedirect.com, 2005.

[9] K. Read & F. Maurer, Developing Mobile Wireless Applications, *IEEE Internet Computing 7*(1), 2003, 81-86.

[10] Java 2 Platform, Micro Edition (J2ME), http://java.sun.com/j2me/

[11] Java Servlet Technology, http://java.sun.com/products/servlet/