

EFFICACY AND FEASIBILITY OF A MOBILE ECG DECISION SUPPORT SYSTEM – A PRELIMINARY CONCEPTUAL MODEL

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Abstract

The mobile network-based Electrocardiography (m-ECG) system to be developed is expected to improve the overall referral processes and treatment of cardio vascular patients remotely located from physicians by eliminating or minimising the unpredictable elements such as poor sound quality, delay in transmission time and speed. The earlier physicians can treat heart attack patients, the lower the risk of permanent heart muscle damage. The main aim of the project is to develop a cardiac health decision support system to transfer ECG data via wireless technology through a mobile phone network where it can be read reliable by cardiologist, hospital staff and general practitioner (GP). Thus this research develops a conceptual model that will test an interface system for transmission of ECG information between patients and carers. Once developed, the efficacy and operational feasibility of the system will be investigated. The research describes the theoretical base using Information System (IS) success model to underpin one part of the conceptual model of a larger project.

Keywords: mobile network-based Electrocardiography (m-ECG), Information System (IS) success model, DDS, Health Informatics

1. INTRODUCTION

One of the rapidly growing areas of telemedicine is long term and long range cardiovascular disease patient monitoring at a distance from hospital or clinic. This is made possible with emerging electrogram instruments which are used to records arrhythmia when it happens or records ECGs readings allowing a cardiac expert to review trends. An ECG is the primary tool used for diagnose and to understand the severity of a myocardial infarction or heart attack. It is important for patient survival for the clinician to receive patient information of detrimental change of condition as quickly as possible but it must be accurate. This research focuses on development of a cardiac health decision support system for analysis of ECG data that will be transmitted using the application of mobile phone technology to overcome the distance gap between patient and doctor. Research has shown that reducing the time between assessment and hospital admission reduces treatment time by one-third (Cheng et al 2006).

Recent advances in mobile technology, computing power and memory size of mobile devices have increased the application of technology to ECG monitoring (Fang, Sufi & Cosic 2008). A wireless ECG instrument has the ability to work with mobile phone technology specifically by ameliorating patient monitoring and sharing details between GP and specialist physician in private and public hospitals, enhancing the speed of assessment and efficient decision making about the treatment required.

The study focuses on using a 12 lead ECG instrument, a new representation of the heart's electrical activity recorded from 12 points on the body's surface. With the new generation of mobile technology attached to the 12 lead ECG instrument, cardiovascular diseases and other existing heart diseases can be detected accurately and earlier. In case of a heart infraction, an ECG recording can be transmitted immediately through an advanced wireless ECG system (m-ECG). This m-ECG system will be able to transmit recording details to doctors and present the information for evaluation and diagnosis. Doctors and nurses can successfully use the portable wireless mobile phone attached to the 12 lead ECG instrument to transmit a patient's ECG recording to a specialist doctor for a more detailed diagnosis and treatment instructions without having to visit the hospital or community clinic.

Mobile phones can also play an integral role in remote care of patients with chronic illnesses (Olga 2008). An approach to distant monitoring of patients using m-ECG will be developed by this study. However, once developed and tested the efficacy, operational feasibility and acceptance of this system will be evaluated before it can be implemented. These two phases are part of larger study. This paper focuses on efficacy and operational feasibility only.

2. RESEARCH OBJECTIVES AND PURPOSE

Electrocardiography (ECG) instruments are currently used in general practices and hospitals. The interval between individual segments from an ECG can be analysed to confirm a suspect infraction case. The use of integrated data transfer and storage has made it possible to associate it with an individual patient's data, such as name, age, past history and medications.

A study by Engin et al (2005) identified that telemedicine applications are becoming very popular because of an increasing aged population and insufficient personnel capacity in hospitals. The use of telemedicine capabilities to manage chronically ill patients is becoming more and more clinically relevant and economically cost-effective. Engin et al's study presented a design of a prototype telemedicine system which provides human electrocardiogram (ECG) signals transferred via a telephone network. The system they developed covered the management of electronic records of patients and access to patients' details from hospitals.

The advanced m-ECG system to be developed by this research allows a physician to diagnose and understand the severity of a heart attack much earlier and prepare for treatment before a patient arrives at hospital or clinic. It has been shown that patients who received pre-hospital ECG assessments had an average door to balloon time (a time measurement in emergency cardiac care) of

79 minutes, 37 minutes faster than those who did not receive a pre-hospital ECG reading (Cheng et al. 2006).

Given this finding it is important to reduce the delay in getting a heart infraction signal to a health carer. It is purported that the more that can be done to reduce this time, the more chance the patient has of survival. This research focuses on an efficient way for patients to be in contact with health professionals anytime and anywhere. The m-ECG system will consist of 12-lead ECG miniature sensors, which measure more accurately the heart activity that can then be wirelessly transferred as data to a doctor's mobile phone. The ECG information will also be transferred in real time by using secure wireless connection to a health care provider and data stored on computer for future reference. The collected data can be retrieved and analysed by specialist doctors and other carers as and when needed.

The purpose of the research is to develop a mobile 12 lead ECG (m-ECG) telemonitoring decision support system, which features capabilities of long distant communication through a high level interactive m-ECG interface notification assistant. The interface design will be user friendly and reside on a ubiquitous device, such as a smart phone. Once the system and interface are developed and pilot tested, this research will investigate the efficacy and operational feasibility of this system in general and specialists' practices and hospitals.

3. REVIEW OF THE RELATED LITERATURE

Since the introduction of Electrocardiography (ECG) by Einthoven at the turn of the 20th century, its use, importance has rapidly expanded. A non-invasive, simple, inexpensive and reproducible procedure allows the ECG signal to be recorded and provides sufficient cardiac information to permit an initial, tentative diagnosis (William 2000). Due to logistical problems of obtaining ECGs from hospital inpatients, Einthoven also presented an approach in 1906 characterized by the transmission of ECG information over telephone wires. The general principles of remote ECG transmission were established although there was no advanced telemedicine at the time. From improvements in network service developed in virtually a century, technological developments have given advanced portable recording systems for ECG use, the application of mobile technology as a telemonitoring device and standard desktop personnel computers (PCs) as the display instrument.

3.1 Usage of ECG Telemonitoring (m-ECG) Systems and 12 Lead ECG Instrument

A mobile technology, incorporating technologies such as Bluetooth, GPRS, GSM or Wi-Fi, allows wireless communication with health centres. Several groups (Rodriguez et al. 2005) have developed applications to monitor the ECG using mobile devices, where the samples have been obtained from standard data bases or they have developed the ECG module to maintain ECG data from wireless transmission. Work of researches has shown the implementation of the acquisition module with wireless technology capabilities (Bluetooth, GPRS/GSM and Wi-Fi) in the real time ECG visualization of mobile devices.

The initial ideas of connecting the ECG system to a mobile phone and making an application for graphical presentation of data were found to be most difficult to develop a standard solution (Georgios and Ivan 2008). What would be nice to implement would be an advanced and reliable alarm function for 12 lead mobile ECG system, connected to Bluetooth, GPRS/GSM or perhaps to GPS depending to the handheld mobile phone's inbuilt functions and software applications.

3.2 Advantage of 12 Lead ECG Instrument

Previous studies emphasise the importance of ECG telemonitoring systems during and after implementation (Rodriguez et al (2005), Cheng et al (2007), Georgios et al (2008), Fang et al (2008) and Ekström (2006)). In the past decade, there were a number of researchers who focused on allowing the ECG instruments to communicate with mobile devices and transmit data through wireless

technology. Moreover, ECG instruments have increased a number of leads to attach to the body's surface (3 leads to 12 leads of ECG) and produced a better quality data for monitoring.

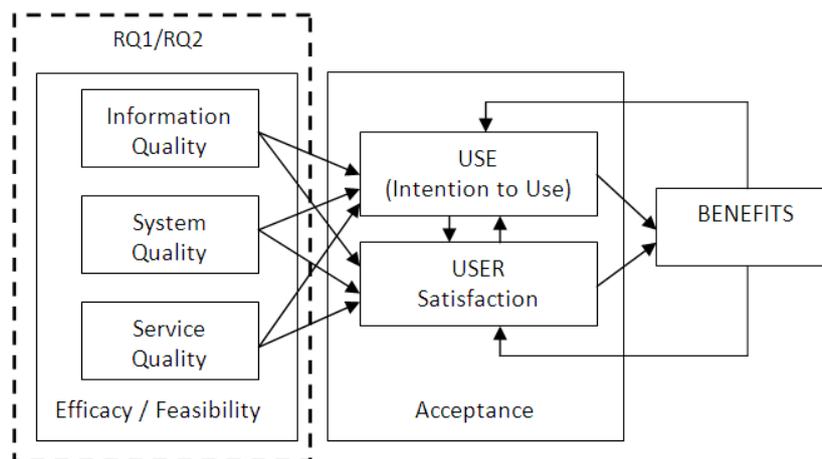
The ECG library (2009) has defined three standards of ECG instruments. 3-lead ECG is usually used on transport monitors, and monitors two different areas of the heart (one lateral, two inferior). 5-lead ECG is preferred in an ICU (intensive care unit), to monitor the third (anterior) area. With the 5-lead ECG, nurse can keep an eye on the three areas of the heart and identify changes in any area. 12-lead ECG gives a more detailed look at the heart's three areas (anterior=front, lateral=side, inferior=back), and changes in certain segments of the ECG in the related leads for each area suggest the area of concern.

There are immediate advantages of 12-lead monitoring for the detection and localization of cardiac disease in patients. Kligfield (2001) indicated that 12-lead recording represents a potentially unified signal acquisition method that can be utilized for bedside monitoring, for ambulatory recording or telemetry, for exercise testing, and, with modification, also for standard electrocardiography.

3.3 Efficacy and Operational Feasibility of Mobile ECG System

A number of studies in ECG telemonitoring evaluation have been reviewed to gain a better understanding of mobile ECG evaluation domains and factors that lead to successful implementations and use of mobile ECG systems. Jen-Hwa (2003) mentioned that evaluation of telehealth system success or effectiveness is a fundamental challenge to healthcare organizations. Maryati et al (2006) also suggested examples of system quality measures as usefulness, availability, ease of use, ease of learning, response time, reliability, completeness, system flexibility, and easy access to help. Rodriguez et al. (2005) stated that mobile ECG has potentially resolved the difficult problem for human heart function monitoring in special mobile environments, and the developed system is expected to improve efficacy and feasibility of telemonitoring used in various medical and health care areas.

According to Hu (1999), telehealth could greatly depend on information system (IS) in most cases. Delone and McLean's IS success model (1992) appears to be a significant framework to evaluate system success in the telehealth area. Therefore, this study has adopted an IS model (Figure 1 – only left-hand side discussed in this paper) based on a review of relevant IS success models to evaluate efficacy and feasibility of mobile ECG system.



- Information Quality: Information accuracy, legibility, availability, output timeliness, reliability, completeness, relevancy and consistency.
- System Quality: usefulness, availability, ease of use, ease of learning, response time, reliability, completeness, system flexibility and easy to help
- Service Quality: guarantee a certain level of performance

Figure 1: The reformulated IS success model (Source: Delone & McLean 2002)

Telemedicine interventions must be shown to achieve at least equivalent patient outcomes, ideally at similar or reduced costs. According to William et al. (2002), the strongest evidence for the efficacy of telemedicine for diagnostic and management decisions came from specialist.

Feasibility evaluation based on four factors: operational, time, economic and technical criteria. According to Judi et al. (2009), the ability to attract customers and opportunity to acquire latest infrastructure and skills justify the need of telemedicine in hospital. Successful implementation of telemedicine is related to the availability of three factors: strong fundamental knowledge and infrastructure, planning and management of health information and technology, fulfilment of legal and ethical issues, and constant evaluation of telemedicine implementations (Judi et al. 2009).

3.4 Gaps in the Literature

Based on the literature review, there appears to be no competed model that has evaluated efficacy and feasibility of an m-ECG decision support system (DSS) based on 12 lead ECG system. Various points of view in the literature (e.g. Galbiati et al. 2009; Cheng et al. 2006 & William et al. 2002) promote the ability and development of ECG telemonitoring systems that can be implemented with wireless technology for data transmission. According to Galbiati et al. (2009), it was only less than 10 years ago researchers from Texas demonstrated the efficacy and feasibility of transferring ECG data via wireless technology to hand-held computers where it could be reliably interpreted by cardiologists. However, new innovations of network services bring the potential to offer better mobility and ubiquity of service by using mobile technology, which enable a large range of application scenarios.

Little literature addresses efficacy and feasibility of mobile ECG decision support systems, particularly within 3G/3.5G networks of mobile technology and 12 lead ECG telemonitoring systems. In order to provide more patient care, mobile communication and localization technology are able to perform automatic monitoring for human ECG signal at any time and place through a number of wireless transmission methods and assessment of patient through a user friendly interface with a ubiquitous device (Rodriguez et al. 2005).

4. CONCEPTUAL MODEL AND METHODOLOGY

The research uses mobile phone network with ECG technology as an approach in collecting and analysing the ECG recording data to help physicians diagnose patients faster and mobilize resources in anticipation of a patient's arrival, rather than reacting once the patient is already in hospital or clinic. According to Williams (2000), a mobile ECG (m-ECG) device will become a major mode of health care delivery for cardiac patients, but patient and clinician acceptability, system efficacy, and supporting infrastructure feasibility need to be assessed. The conceptual model (Figure 2) will test the two dimensions of efficacy and feasibility of m-ECG decision support system in order to improve the quality of care for cardiac infraction sufferers.

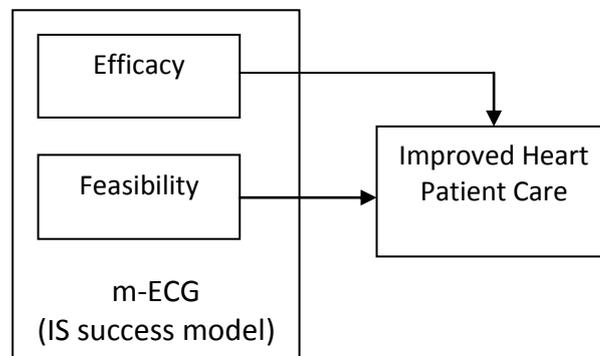


Figure 2: Conceptual model for m-ECG system

For this research, the user group is defined as clinicians, nurses and hospital administrators. No real patients will be involved. It will use anonymized electronic records of patients so that the system developed can be tested to see how well it distributes a patient's detail to clinicians. Implementing and analysing a mobile ECG decision support system to communication with real cardiac patients would be extremely valuable, providing future validation of the conceptual model developed. Qualitative and quantitative approaches combining several data collection methods will be used in this research.

A methodology for m-ECG development (pilot testing with focus group for the m-ECG system to be developed) is shown in Figure 3. The focus group will also expect to assist in guidance of qualitative data analyses.

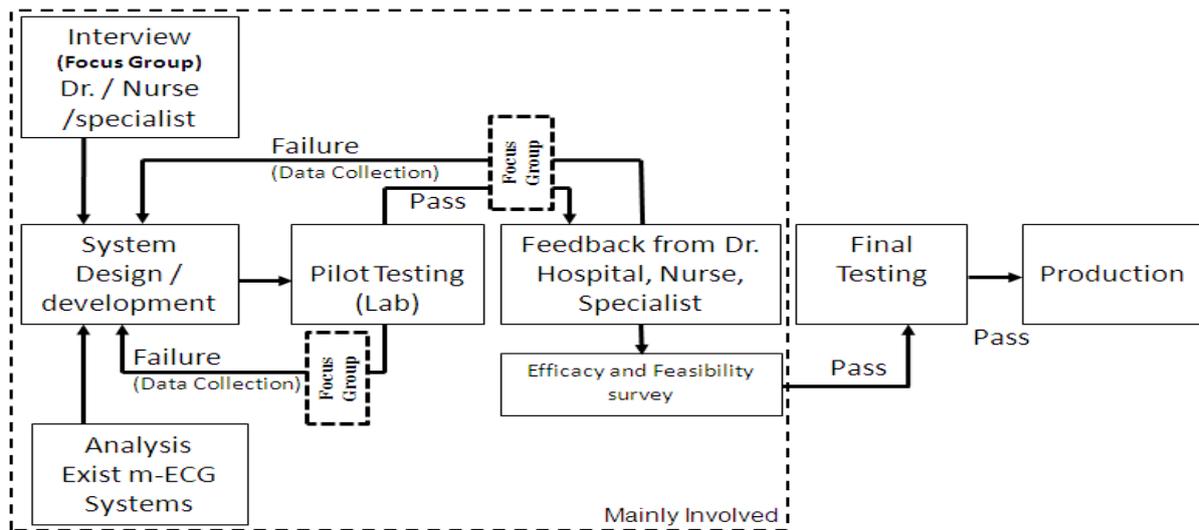


Figure 3: A preliminary pilot testing for the research

4.1 Sample and data collection

The research will first interview doctor, nurse and specialist to see what the specification of m-ECG are needed and analyse existing ECG systems to explore the functional requirements of m-ECG decision support system from selected users. A small number of users (8-10 users) will be interviewed including doctors (5 users), nurses (2 users) and hospital administrators (3 users). Existing mobile ECG systems (3-5 systems) will also be selected to evaluate current m-ECG used. Up to ten clinical staffs and administrators who are applying best practice in cardiac patient care will provide as case studies and be part of interviews.

During the development of the mobile ECG (m-ECG) application, conducting a qualitative data (pilot testing) is suggest as an effective means of initiating a wider development. Qualitative data will be gathered during pilot testing of m-ECG using focus groups. Based on focus groups' feedback gathered during testing sessions the m-ECG system will be modified to arrive at a better solution to users. According to Robert and Reiss (2007), the protocol for operation aliasing a pilot testing will address the parameters to be analyzed, equipment to be tested, operational procedures, the start-up/shut-down/cleaning procedures, and testing matrix. A pilot study is a representation of the project vision and serves as a key planning tool to fill in details related to finance, design, permitting, and public outreach (Robert and Reiss 2007).

Once the function requirements have been identified from users, this research will develop the application of mobile ECG technology and then pilot test the system in the laboratory. This research will then use Information System (IS) Success Model to evaluate whether the level of efficacy of transferring ECG through mobile technology can bring specific attributes for monitoring cardiac patients in remote locations and the operationally feasible of monitoring cardiac patients in remotely. To collect quantitative data on efficacy and feasibility of m-ECG, it will solicit acceptance of the

system developed from doctors (5 doctors who were interviewed + 5 new doctors), nurses (2 nurses who were interviewed + 2 new nurses) and hospital administrator (3 hospital administrators who were interviewed + 3 new hospital administrators) using survey questions to identify users' attitudes, opinions and points of views of new systems.

5 SUMMARY AND CONTRIBUTIONS

Heart disease is one of the most serious diseases that threaten human beings. According to Better Health (2008), heart disease is the leading cause of death, causing nearly 36 per cent of all deaths in Australia. ECG monitoring and transmission can play an important role in the prevention, diagnosis and rescue of heart disease sufferers. In the absence of telehealth technology, presurgical service requires patients to visit doctors in regional or metropolitan hospitals. Auscultation of a patient's heart echo via ECG mobile phone technology is an efficient method to carry out preadmissions' consultations for GPs and cardiologists. Problems of existing ECG transmission through Bluetooth technology as identified by medical practitioner included sound quality, real-time connectivity, and transmission speeds associated with limited band width. Subsequent examination of these difficulties concluded that with wireless communication heart attack victims could receive potentially life-saving treatment significantly faster than standard practices (Engin, 2005). The idea behind a new system of managing patient care in conjunction with modern telecommunication applications using wireless devices is to improve the quality of patient care (Gururajan et al., 2005).

There are three main expected contributions from this research: 1) decision support system for distant monitoring of cardiac patients through the mobile-based transmission of 12 lead ECG information; 2) an appraisal on new mobile 12 lead ECG systems implementation; 3) an understanding of how to increase the use of health technologies. As stated earlier, this paper reports on only one area of a larger study.

The research is expected to contribute to existing studies in telehealth evaluation. It contributes to existing knowledge by applying IS success model to telemedicine and forms part of evaluating the efficacy and feasibility of a mobile ECG (m-ECG) system. Other contributions to the health informatics literature will come from data collection and analysis methodologies used for evaluating the framework of this research. As the research is at its first stage, contributions stated are predicted expectations but further insights may be revealed.

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