

Towards Intelligent and Mobile Systems for Early Detection and Interpretation of Cardiological Syndromes

P Rubel¹, F Gouaux¹, J Fayn¹, D Assanelli², A Cuce³, L Edenbrandt⁴, C Malossi⁵

¹INSERM XR121/ERM107, France, ²University of Brescia, Italy, ³STMicroelectronics, Italy, ⁴University of Lund, Sweden, ⁵Elettronica Trentina, Italy

Abstract

Because of a continuously growing elderly population, the number of heart attacks is steadily increasing. Most victims do not survive long enough to receive medical help. The only useful early decision making supporting tool is the electrocardiogram (ECG). The solution proposed by the European IST-2000-26164 EPI-MEDICS project consists in developing a very affordable, easy to use but powerful, embedded Personal ECG Monitor (PEM) for the early detection and prevention of cardiac events. The PEM device shall be able to record, store and synthesize standard 12-lead ECGs, generate different levels of alarms, and forward the alarm messages with the recorded signals to the relevant health care providers by means of new generation wireless communication techniques. In this paper, we briefly describe the different use cases of the PEM and propose a global telemedical architecture for the follow-up of ambulatory patients. The paper also reports about the ins and the outs of the project and the results which have been reached so far.

1. Introduction

Medical informatics has expanded rapidly over the past years. After decades of development of information systems designed primarily for physicians and other healthcare managers and professionals, there is an increasing demand of personalized and non-hospital based care [1]. Citizens and patients will use information technology to access information and control their own health care, consulting professionals much less often. Developments in research are moving us away from institution-centric care towards the personalized, wearable, implantable systems that will become intelligent, communicating and ubiquitous. Professional care will be more and more viewed as the support to a system that emphasizes self care [2]. This general trend is especially perceptible in the field of cardiology.

The aim of the European IST-2000-26164 EPI-MEDICS project, which has started January 1st, 2001, is to develop and experiment a novel Enhanced, Personal,

Intelligent and Mobile system for Early Detection and Interpretation of Cardiological Syndromes (EPI-MEDICS) [3]. The first main objective is to design a very affordable, easy-to-use but powerful, embedded Personal ECG Monitor (PEM) for the early detection and prevention of cardiac events. It shall be able to record and store electrocardiograms (ECGs) from a pseudo orthogonal subset of ECG electrode positions chosen for their adequacy with home care or ambulatory recording conditions, and from these signals synthesize a so-called derived standard 12-lead ECG. A second main objective is to incorporate into the PEM device intelligent and robust data processing and decision-making methods having auto-learning and auto-adaptive capabilities, that are able to generate different levels of alarms and to forward the alarm messages with the recorded signals to the relevant health care providers. The last objective is to develop means and tools for wireless data communication between the PEM device and the health professional systems and infrastructures, from any-where, at any-time, allowing a seamless integration of personal health data and the patients signals for the enhancement of the continuity and of the quality of care.

In the following, we briefly describe the target population, use cases and the first results of the EPI-MEDICS project.

2. Target population

In Europe, heart disease is the main cause of early disability and premature death. Because of a continuously growing elderly population, the number of cardiac patients is steadily increasing and this trend is counterbalancing the benefit of the improvement of the quality of care and of preventive actions. The majority of deaths from coronary disease occur in the pre-hospital phase and most victims do not survive long enough to receive medical help [4]. The ratio of out-of-hospital deaths to in-hospital deaths for acute coronary events ranges from 15.6:1 in the youngest cohorts aged less than 50 to 2:1 for the elderly aged 70 to 74 [5]. Patients with acute myocardial infarction (AMI) who survive long enough to

enter hospital undoubtedly benefit from new treatments introduced into routine practice within the last decade or so. Unfortunately the impact on community mortality rates is influenced only marginally by this success, as a relatively small proportion of potential victims reach hospital to benefit from recent advances.

Epidemiological data suggest that greater deployment of resources for pre-hospital care has more potential to reduce the case fatality rate of AMI than has the intensification of treatment in hospital. The clear message of the different studies is the earlier treatment is given the better: when matters more than where [6]. New strategies are thus needed to reduce the time before treatment: campaigns to teach symptoms of heart attacks, use of the agreed common European emergency number (112), strategic positioning of ambulances, pre-hospital triage and arrangements for cardiac care based on advanced information from the ambulance or the patient.

A key symptom for diagnosing acute ischemia is chest pain. However, correct and timely diagnosis of acute ischemia is a very difficult task. Chest pain may be caused by other diseases, such as pericarditis, or due to other problems, such as muscle-skeletal or gastro-oesophageal problems. There are also other ischemia episodes, which are silent, like patients suffering from diabetes. The only immediately available and useful diagnostic tool for assessing the probability of a cardiac event, for stratifying its degree (stable, unstable angina, AMI, risk of out-hospital or in-hospital death) and for guiding therapy is the electrocardiogram [7]. The diagnostic power of the ECG may be further increased if a previous reference tracing is available. The ECG is like a fingerprint and analysing serial changes will allow to overcome inter-subject variability and thus to considerably improve the sensitivity and the specificity of the diagnostic tool.

3. Information technologies

Performing serial ECG analysis implies that reference ECGs and relevant clinical information concerning the patient have previously been stored, with the perspective of their future use, either on central databases or at the physician office, or on a personal portable device such as an EPI-MEDICS device or a SmartCard.

During previous European Framework Programmes, several solutions have been designed to improve cardiac patient health by providing seamless patient information availability and sharing throughout Europe. Within GEDIPE [8], a standard communication protocol for the ECG (SCP-ECG) [9] and a reference model for ECG databases have been developed and during I4C [10], a computer-based cardiology patient record for the follow-up of cardiac diseased patients has been designed. SCP-

ECG is now becoming an ISO standard and GEDIPE and I4C are becoming used in cardiac clinics and for the transmission of the patient record and of the ECGs from the ambulance or from home. Several Fifth Framework Programme projects (CHRONICS, CHS) are pursuing this work by designing home-based monitoring systems and home care services for the distant follow-up of heart failure patients.

However, all these systems are mainly designed for the follow-up of severe diseased cardiac patients either at home or in hospital. They require setting up new information technology infrastructures and medical services and need skilled personnel to interpret the ECG and take decisions for the patient care. This approach would be very impractical for patients with infrequent symptoms such as arrhythmias and ischemia, that represent 85% of the cardiac diseased patients, and would be very expensive if adapted for every citizen at risk.

The challenge is twofold:

- Detect as early as possible the onset of ischemic events, even for citizens that have not yet any known cardiac disease.
- Involve the health care structures without delay, but only if necessary.

This approach relies on the paradigm of moving from the traditional institution-centred care approach to a patient/citizen-centred one. Another paradigm is to directly involve the citizen in the health path as a first player able to act as a consumer responsible of his own health and able to perform relevant tests without involving skilled personnel from the beginning but only when a specialized action will be required.

The solution consists in developing an extremely friendly, highly intelligent but easy-to-use personal portable device for the early detection and interpretation of ECG based cardiological syndromes, that will be able to manage different levels of alarms, forward messages embedding the recorded signals and alarms to the relevant health care providers by means of any already owned communication device, embed internal computing and professional recording and analysis capability at an affordable price and embed self improving capabilities to take account of the specificities of the patient. A key issue in developing such a highly intelligent device will be to embed newly designed serial analysis algorithms and fuzzy, auto-adaptive decision rules.

In the following, we present typical use cases of the PEM device.

4. Use cases

Two different situations are possible: either the attending physician has recommended the patient to buy or to rent a PEM device (home care scenario), or the

patient has decided to take himself care of his health (self care scenario). From the first use of the embedded device, the EPI-MEDICS architecture will support the collection and the process of ECG signals and health data and will be capable of detecting arrhythmias and/or changes of the ECG signals that are consistent with either infarction or ischemia.

The PEM device is able to store several ECGs from the patient and his collaterals and to automatically call the citizen's attending primary care physician or cardiologist or an emergency service and upload the ECGs and the clinical information on the health professionals PCs or workstations (Fig. 1). Several instants where the device is used can be sketched as follows:

- Initial set-up

The citizen has received his equipment and performs his first ECG recording. The system detects that no previous ECG record has been stored and asks the patient to enter some data (age, sex, weight, patient-id...). The system checks for ECG abnormalities and reports any abnormal condition.

- Subsequent ECG recordings

The citizen wants to assess again his health status and performs an ECG record. The system automatically compares the new ECG with the previous ones and detects any significant changes. If there is no change, the system resumes by storing the last recorded ECG in its memory. If there are significant changes of the depolarisation phase, the system first asks the citizen to confirm his identity, then to check the electrodes positions, and to enter additional clinical information. Depending on the diagnosis and the device connectivity possibilities (GSM, other wireless connections...), the system will propose to call the citizen's attending physician or a cardiologist or trigger an alarm and page an emergency service, establish a digital link and upload the patients ECGs and the clinical history.

- Visit at the physician's office

An appointment has been made with a general practitioner or a cardiologist. The health professional may download the information recorded in the PEM device to his computer system, review and validate the diagnoses performed by the device and upload a part of the citizen health record to the embedded device.

- Recording of the collateral's ECGs

One of the citizen's collaterals has some difficulties in breathing after having climbed staircases and wants to assess his health status. The system records an ECG, detects that the ECG is quite different from the ECGs stored in the system and asks the subject to confirm his identity. The device proceeds as for the initial set-up phase and stores the newly recorded ECG as a reference ECG for the second citizens ID.

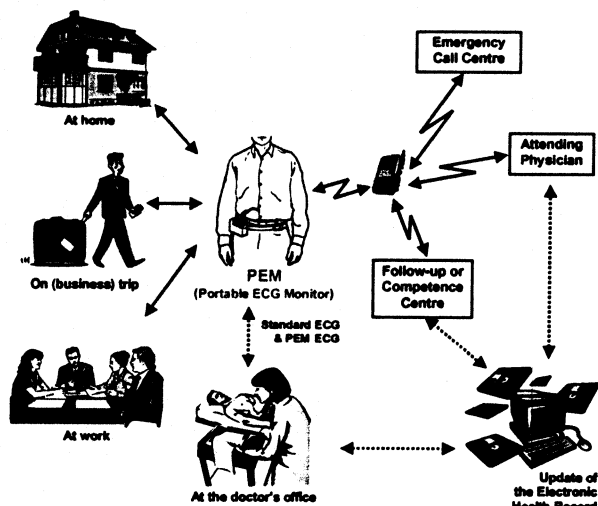


Fig. 1. Simplified Model of the EPI-MEDICS information flow.

- Data archival

The system runs out of storage memory and suggests either to introduce a new flashcard or SmartCard memory or to upload the less relevant ECGs to a central storage facility for subsequent retrieval by the health care professional, if needed.

- Assessment of care, drug studies, research

The device could be used to support large clinical or pharmacology trials by uploading the recorded data to a central database for statistics or research.

5. Potential target segments

The healthcare system is undergoing several series of changes of the standard approach: from traditional institution-centred care paradigm to a patient, citizen-centred one. The main segments that will be covered during the lifetime of the product can be expressed as follows:

Potential target segments

- Citizens with evidence of heart disease
- Citizens with cardiovascular risk factor
- Citizens "prevention oriented"
- Insurance and pharmaceutical companies
- First contact organisations: hotels, airlines...
- Virtual health centres
- Health care institutes and suppliers (public and private hospitals and clinics...)

6. Identification of users' needs

Generally, a new product or service should meet users' needs. Therefore the identification of the user needs is essential to develop a new system. The subsequent design and implementation of the system depend on reliable and accurate information.

For the EPI-MEDICS project, the users that could

potentially contribute to the discussions include different categories of medical staff, scientific and professional societies and of course patients. Besides this variety, another difficulty is that all these actors are geographically distributed all over Europe. And members of relevant scientific societies who could add a valuable contribution with specialist knowledge can be located anywhere in the world.

Given the complexity implied, and the innovative nature of the system, we assumed that a number of user needs would change all over the project, as a result of the experiences obtained from the users. These considerations pushed us to design a central repository for the collection and the management of the user requirements (UR) and to make these information accessible to any member of the user community by means of Internet [11].

As a consequence, we are expecting to collect a substantial amount of information about the functionalities and the use of the PEM device and the associated telemedical architecture. To be practically exploitable, these information have to be processed in a structured way, so that there will be no loss, no distorted information. The typical information we would like to collect in addition to each UR are the rationale of the requirement, its criticality (indicates if the requirement is either mandatory or only desired), and the skills of the author of the requirement. We found that the best solution to physically support the processes of user requirements collection and assessment was to use a relational database (SQL Server 2000) coupled to an active server page (ASP) web server for a dynamic access to the URs over the Internet. The present web site [11] describes the user requirements collected so far, the draft specifications of the PEM device and of the overall EPI-MEDICS architecture, the expected scenarios of use, and the user requirements assessment procedure.

7. Conclusion

It has to be pin-pointed that although limited because focused only on the detection of ischemia (and additionally of arrhythmia), the PEM devices that we are developing within the frame of the EPI-MEDICS project will have a much higher degree of intelligence than the one that has been embedded in the most recent, professional electrocardiographs. The reasons are twofold. First, the interest of embedding such algorithms in standard ECG equipment is still limited because of the difficulty to retrieve the previous tracings of the patient (within seconds). Second, it would be very difficult to store in a standard electrocardiograph as many decision rules sets as there are patients to analyse. These problems will be solved in the EPI-MEDICS devices which will

store all (or the most relevant) ECGs of the owner (and possibly of his/her collaterals) and will embed only the set of decision rules that are specific to the owner(s).

On the other hand, EPI-MEDICS will not necessitate to develop any new infrastructure or service. All what will be requested from the health care providers is that they are connected to Internet and use standard browsers and Internet tools.

The benefit will be an immediate acceptance by the health care actors, an easy to disseminate product, that will provide a significant step forward in the provision of new, improved, intelligent, ubiquitous, user friendly, cost-effective, any-where, any-time health care services.

References

- [1] Eysenbach G. Consumer health informatics. *BMJ* 2000;320:1713-1716.
- [2] Smith R. The future of healthcare systems. *BMJ* 1997;314: 1495-1496.
- [3] EPI-MEDICS project # IST-2000-26164, , CORDIS - IST page, <http://www.cordis.lu/ist/home.html>
- [4] Task Force report: the pre-hospital management of acute heart attacks. Recommendations of a Task Force of the European Society of Cardiology and The European Resuscitation Council. *European Heart Journal* 1998;19:1140-1164.
- [5] Norris RM. Fatality outside hospital from acute coronary events in three British health districts, 1994-5. United Kingdom Heart Attack Study Collaborative Group. *BMJ* 1998;316:1065-1070.
- [6] McMurray J and Rankin A. Cardiology--I: Treatment of myocardial infarction, unstable angina, and angina pectoris. *BMJ* 1994;309:1343-1350.
- [7] Estes NAM and Salem DN. Predictive value of the electrocardiogram in acute coronary syndromes. *JAMA* 1999;281(8):753-754.
- [8] Rubel P, Willems JL, Zywiets C, Fayn J, Assanelli D, Malossi C, Todd S. OEDIPE. Open European Data Interchange and Processing for Electrocardiography. In: Lares MF, Ladeira MJ and Christensen JP, editors. *Health in the New Communications Age*. Amsterdam: IOS Press, 1995:313-321.
- [9] ENV 1064:1993 Medical Informatics - Standard Communication Protocol - Computer-assisted Electrocardiography (SCP-ECG), <http://www.centc251.org>
- [10] van Bommel JH, van Ginneken AM, Stam H, Assanelli D, Macfarlane PW, Maglaveras N, Rubel P, Zeelenberg C, Zywiets C. Integration and communication for the continuity of cardiac care (I4C). *J Electrocardiol* 1998;31(Suppl):60-68.
- [11] EPI-MEDICS web site: <http://epi-medics.insa-lyon.fr/>

Address for correspondence.

P Rubel
INSERM XR121/ERM107
28, avenue du Doyen Lépine
69394 Lyon Cedex 3, France
rubel@insa.insa-lyon.fr