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Toward personal eHealth in cardiology. Results from the EPI-MEDICS telemedicine project

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Abstract

Despite many attempts to improve the management of acute myocardial infarction, only small trends to shorter time intervals before treatment have been reported. The self-care solution developed by the European EPI-MEDICS project (2001-2004) is a novel, very affordable, easy-to-use, portable, and intelligent Personal ECG Monitor (PEM) for the early detection of cardiac ischemia and arrhythmia that is able to record a professional-quality, 3-lead electrocardiogram (ECG) based on leads I, II, and V_2; derive the missing leads of the standard 12-lead ECG (thanks to either a generic or a patient-specific transform), compare each ECG with a reference ECG by means of advanced neural network–based decision-making methods taking into account the serial ECG measurements and the patient risk factors and clinical data; and generate different levels of alarms and forward the alarm messages with the recorded ECGs and the patient's Personal electronic Health Record (PHR) to the relevant health care providers by means of a standard Bluetooth-enabled, GSM/GPRS-compatible mobile phone. The ECG records are SCP-ECG encoded and stored with the PHR on a secure personal SD Card embedded in the PEM device. The alarm messages and the PHR are XML encoded. Major alarm messages are automatically transmitted to the nearest emergency call center. Medium or minor alarms are sent on demand to a central PEM Alarm Web Server. Health professionals are informed by a Short Message Service. The PEM embeds itself a Web server to facilitate the reviewing and/or update of the PHR during a routine visit at the office of the general physician or cardiologist. Eighty PEM prototypes have been finalized and tested for several weeks on 697 citizens/patients in different clinical and self-care situations involving end users (188 patients), general physicians (10), and cardiologists (9). The clinical evaluation indicates that the EPI-MEDICS concept may save lives and is very valuable for prehospitalization triage.

Keywords: Personal ECG monitor; Derived ECG; Embedded decision-making; EPI-MEDICS; eHealth

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1. Background: ambient intelligence and pervasive computing

Several new classes of miniaturized computing and communication devices such as smart cards, handheld computers (PDA), smart phones, and, more recently, intelligent and wearable medical devices have been designed during the past decade. Combined to the recent proliferation of wireless communication solutions, this presents exciting opportunities for the development of personal eHealth. For example, in Italy and in the United States, diabetic patients are currently using PDAs to collect and send critical medical data to a follow-up center or to their attending physicians who also have a similar handheld device connected to Internet by means of a wireless GPRS-enabled cellular phone [1]. The European EPI-MEDICS project [2–4] has developed an easy-to-use, low-cost Personal ECG Monitor (PEM) having the capabilities of recording anywhere and anytime a simplified but of professional-quality electrocardiogram (ECG); analyzing the successive ECGs of a given patient with reference to a baseline ECG stored in a Smart Card embedded in the PEM; detecting in almost real time the onset of an infarction and/or arrhythmias that are risky for the patient's health; and automatically transmitting an alarm message together with the ECGs and the patient's Personal electronic Health Record (PHR) to the nearest emergency center, 24-hour call center, or alarm server that in turn will send a Short Message Service (SMS) to the attending physician to warn him of the alarm message arrival (Fig. 1). In ambulatory situations, the PEM can also be used as a first-aid cardiology kit by the patient himself or by/for any citizen, whether at home, at work, in holidays, or in the street.

These smart devices together with the advances of wireless technologies such as Bluetooth, ZigBee, GPRS, or WIFI will allow the citizens to access and/or transmit their health data anywhere and anytime and to act as consumers responsible of their own health. This concept is called *pervasive computing*, where eHealth represents only one of the numerous application areas [5].

Another recent concept is *ambient intelligence*. Defined by the EC Information Society Technologies Advisory Group in 1999, this idiom describes a potential future in which we will be surrounded by intelligent objects and in which the environment will recognize the presence of persons and will respond to it in an undetectable manner [6]. Thus, the European PROTECTOR project aims at developing an intelligent system that is able to alert a pedestrian of the nearing of a danger even if he does not yet see the car. EPI-MEDICS has developed intelligent solutions based on artificial neural networks (ANN) committees embedded in the PEM that mimic a multiexpert decision-making approach capable of taking into account the patient's specificity and risk factors.

These new research domains, ambient intelligence and pervasive computing, arrive just in time to help satisfy new needs of citizens/patients: home care and self-care [7,8]. This general trend is especially perceptible in the field of cardiology.

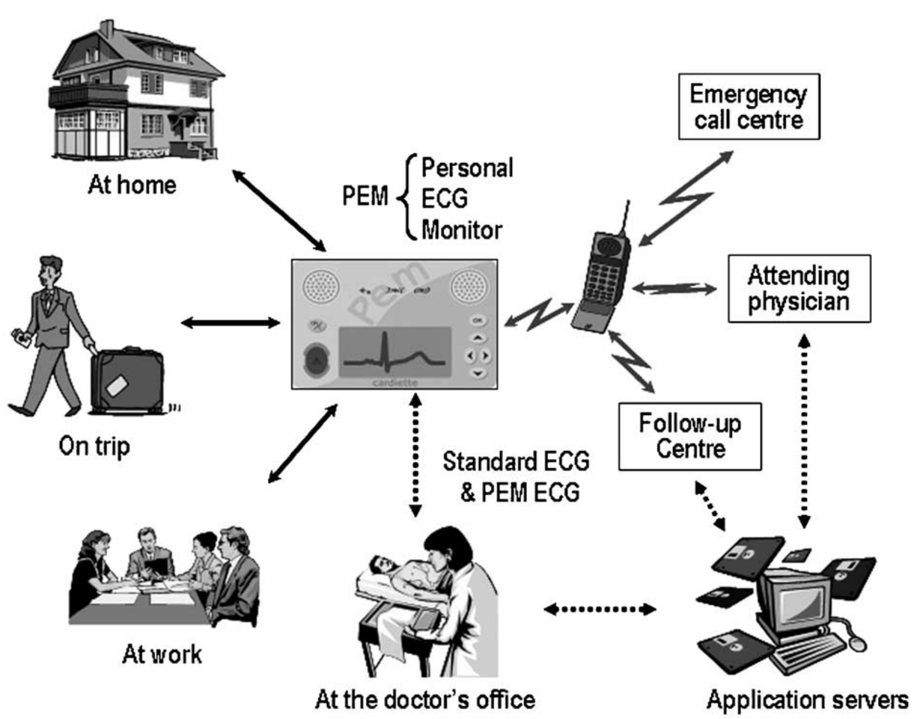

Fig. 1. Simplified model of the EPI-MEDICS concept. The PEM may be used on demand at different occasions at home, at work, or during a trip. Depending on the alarm level and/or on the scenario of use, the alarm message and the ECGs may be automatically sent together with the embedded PHR via a standard Bluetooth-enabled, GSM/GPRS-compatible mobile phone to an emergency call center, a competence center, or to the attending cardiologist or GP.

2. Toward a new paradigm in telecardiology: self-care

In western countries, heart disease is still the main cause of early disability and premature death, and almost two thirds of the cardiac deaths occur outside the hospital. Epidemiological data suggest that greater deployment of resources for prehospital care has more potential to reduce the fatality rate of acute myocardial infarction (AMI) than the intensification of treatment in hospital [9], and that the earlier treatment is given, the better: *when* matters more than *where* [10]. New strategies are thus needed to reduce the time between the onset of the first symptoms and the decision to treat.

However, correct and timely diagnosis of acute ischemia is a very difficult task. Chest pain may be caused by other diseases than AMI, and there are also ischemia episodes that are silent, like patients with diabetes. The only easy-to-use, immediately available, and useful diagnostic tool for assessing the probability of a cardiac event in the prehospital phase, for stratifying its degree (stable, unstable angina, AMI, risk of out-hospital or in-hospital death), and for guiding therapy is the ECG. Ambulances are increasingly being equipped with digital ECGs and means to transmit the ECGs to a coordination center for tele-expertise. But the sensitivity of the ECG for assessing acute ischemia is still limited. It might be considerably increased if a previous reference tracing would be available. The ECG is like a fingerprint and analyzing serial changes will allow to overcome intersubject variability and thus to considerably improve the sensitivity and the specificity of the diagnostic tool. But performing serial ECG analysis implies that the patient's reference ECGs and the relevant clinical information have been stored on an easy-to-access media such as a central database, a personal Smart Card, or a personal portable device such as a PEM device.

Attempts have also been made to improve the management of cardiac care by teaching patients to recognize symptoms of myocardial infarctions. Nevertheless, only small trends to shorter time intervals before treatment have been reported. Symptoms are often interpreted incorrectly.

Event recorders and transtelephonic ECG recorders are increasingly used to improve decision making by following patients at home or in ambulatory situations. But these systems are usually unable to capture transient ECG events such as infrequent arrhythmias or ischemic episodes. Moreover, all these systems 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 (~85% of patients with cardiac disease) and would be very expensive if adopted for every citizen at risk.

The challenge is thus 2-fold: (1) detect as early as possible the onset of ischemic or arrhythmic events, even for citizens who have not yet any known cardiac disease and (2) involve the health care structures without delay, but only if necessary.

3. The EPI-MEDICS solution

The solution designed by the European EPI-MEDICS project [2–4] is a novel, enhanced, portable, and intelligent PEM for the early detection of cardiac ischemia and arrhythmia (Fig. 1). The PEM is able to record a 10-second duration pseudo-orthogonal and 3-lead subset of the standard 12-lead ECG (DI, DII, and V_2); to derive the missing 5 leads (V_1, V_3-V_6) of the standard 12-lead ECG [11]; to store the derived 12-lead ECG according to the SCP-ECG standard [12] in an embedded SD memory card (hereafter called PemCard); to analyze and interpret the recorded 10-second ECG; to quantify its serial changes with reference to a baseline ECG previously stored in the PemCard; to generate different levels of alarms taking into account both the interpretation of the serial changes of the ECG signals and clinical information from the patient's PHR; and, in case of an alarm or on request of the patient or of an assisting person, to send by means of new generation wireless communication techniques (Bluetooth and GSM/GPRS) an alarm message, the PHR, the baseline ECG, and the last recorded (abnormal) ECG to the most relevant health care provider (Fig. 1). The ECG signals are compliant with the SCP-ECG standard [12]. The messages and the PHR are encoded in XML.

Major alarms (acute ischemia/infarction, severe arrhythmia) are automatically transmitted to the nearest emergency call center. To offset the relatively slow speed of GPRS transmissions (which depends on the quality of the transmission and the traffic intensity and may take from 30 seconds up to a few minutes), we designed an application software running on the call center personal computers (PCs) that displays the incoming information as soon as received [4]. The data transmitted by the PEM are sent in the following order: (1) alarm message indicating the reason and the severity of the alarm; (2) patient demographics and localization; (3) ECG that triggered the alarm (hereafter called the last ECG); (4) the patient's PHR, especially his cardiac history and risk factors; (5) if available, the most recent baseline ECG (also called the reference ECG); (6) clinical symptoms (if the patient or an assisting person had the time to document them); and (7) the second last ECG (if available and specified in the settings). The coordinating physician in the ambulance coordinating center and the cardiologist in the emergency center can display and/or print on demand any received information, call back the patient on his mobile phone, and forward the received ECGs and the PHR to the relevant cardiac center for action or advice [13].

In case of a medium alarm level (suspicion of ischemia and/or atypical arrhythmia), all information is sent to and temporarily stored on an alarm server (Fig. 2) that automatically sends an SMS to the attending health professional (cardiologist or general physician [GP]) stored in the patient's contact list of the PemCard. The SMS provides information about the reason and the level of the alarm, the patient's mobile phone number, the URL of the

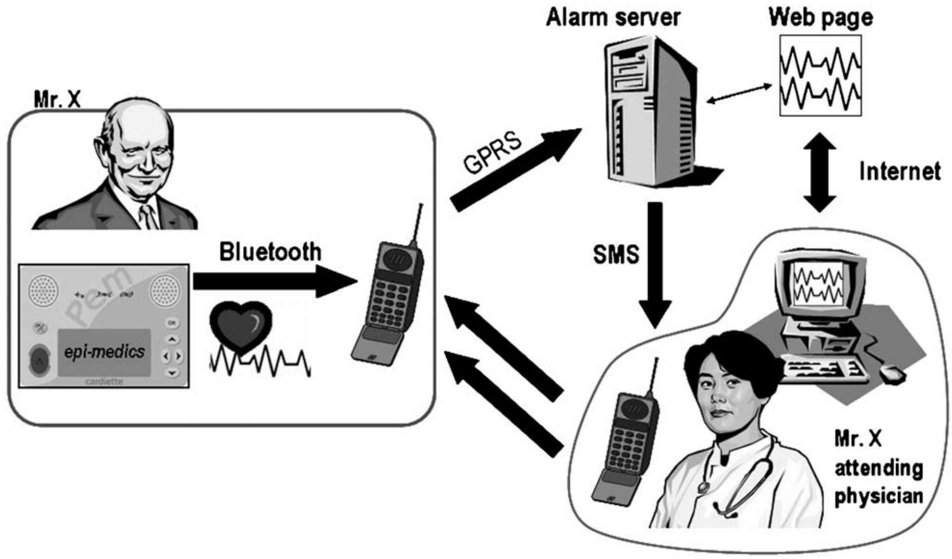

Fig. 2. Medium alarm scenario. The PEM sends the alarm message together with the last recorded ECG, the reference ECG, and the patient's EHR to the PEM alarm server, which in turn sends an SMS to the attending physician. The latter accesses the alarm server that automatically formats the data according to the type of equipment (PC, Notepad, etc) used to connect to the alarm server and takes the appropriate actions.

alarm server (currently http://pem-alarm.univ-lyon1.fr), a 6-digit random ID number, and a password selected at random from an 8-character word length dictionary. The attending physician then accesses the alarm server that automatically formats the data according to the type of equipment (PC, Notepad, etc) used to connect to the alarm server and takes the appropriate actions: contact the patient, change the alarm level to a major alarm and ask the alarm server to forward the totality of the information to an emergency call center, send a tele-expertise request to an expert, and transfer the ECGs stored on the alarm server to the patient's Electronic Health Record (EHR) repository. The information is temporarily stored on the alarm server and automatically erased after a customizable delay of 2 weeks.

In case of a minor alarm (small ECG changes), the PEM displays a short message inviting the user to report about the message at the occasion of one of his next visits to his cardiologist or attending physician. The message content and the automated interpretation results are stored in the PemCard together with the ECG.

Except in the case of a major alarm, the patient/citizen has always the possibility either to inhibit the sending of a medium alarm or to authorize the sending of his/her ECGs and PHR to the alarm server (thus to his attending physician) or to a follow-up call center even in the case when no changes have been detected.

Another scenario is a routine visit to the GP or the cardiologist (Fig. 3). Let us suppose that a citizen (Mr/Mrs X) has bought a PEM in a drugstore (or that a patient has given his PEM to a family member) and has recorded several ECGs and consults a physician who has never heard about the PEM. Mr/Mrs X complains about problems he/she thinks are of cardiac origin and asks his/her physician for advice. To consult the PHR and/or to update its content, the only tools that are necessary are a Bluetooth connection and a standard Web browser; no other software has to be installed on the PC of the health professional. The PEM embeds itself a Web server [4] that automatically generates HTML pages that can be displayed by any Web browser. Thus, health professionals can access the information stored in the PEM (contacts list, health record, ECGs, settings, backup tools, etc) in the same way they browse the Web; they are in a familiar environment and do not need to learn to use a new software.

4. Embedded intelligence

Decision making embedded in the PEM is performed at 4 different levels: detection of arrhythmias; diagnosis of ischemia; generation of alarms (if any) taking into account the severity of arrhythmia and/or ischemia and additional clinical information such as the patient's risk factors; and intelligent management of the alarm messages for handling any communication problem with the contacted health care providers.

Arrhythmia detection and ischemia diagnosis are based on the comparison of the last recorded ECG with a reference ECG. Any ECG stored in the PEM may be marked as a reference ECG by a health professional at the occasion of a consultation of the health record stored in the PEM. This ECG may be either a derived ECG previously acquired by the PEM or a standard 12-lead ECG acquired by any SCP-ECG–compliant digital ECG recorder and then downloaded by the health professional into the patient's PemCard. Arrhythmia detection is rule based. Diagnosis of ischemia is performed by a committee of 100 ANN for unary decision making and 75 ANN for serial analysis. Unary analysis is triggered only if no reference ECG is available.

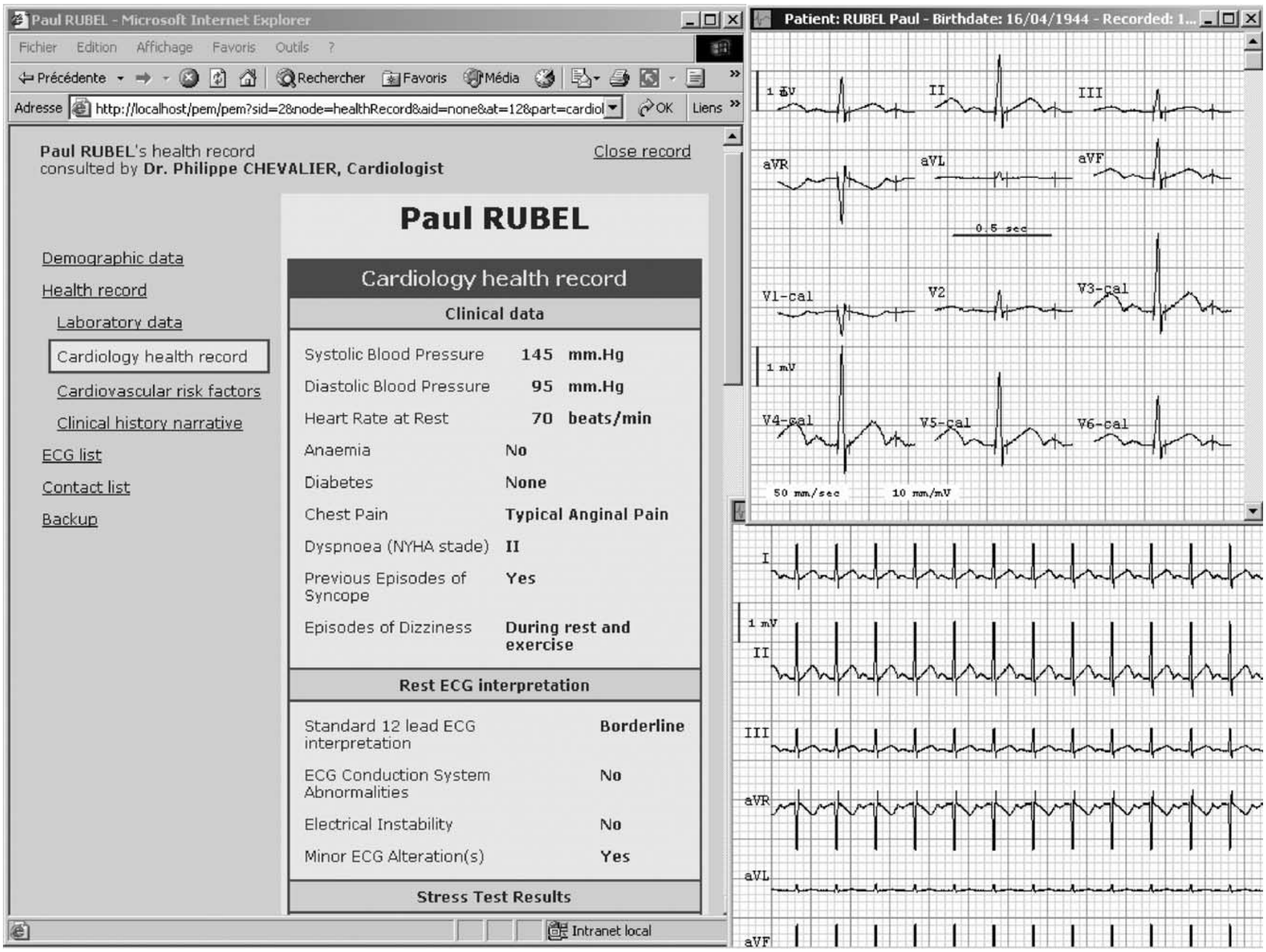

Fig. 3. Snapshot of the display of part of a patient's cardiology health record and of his/her latest ECG during a routine visit at the physician's office. Only a standard Web browser and RS232 or Bluetooth connectivity are required to access the EHR stored in the PEM Smart Media data card.

Overall evaluation results of the ANN's ischemia diagnosis capability have been reported by Ohlsson et al [14]. Using a multiexpert approach improves the ischemia diagnosis sensitivity by more than 10% when compared with a median ANN. This improvement is a direct consequence of the application of the central limit theorem. Performing serial ECG analysis adds another 10% improvement in sensitivity. Overall diagnosis accuracy is comparable with an expert cardiologist interpreting the same set of ECGs.

To ease ECG signal analysis and decision-making upgrades, we developed a multiplatform ECG processing software factory. Decision making may also be customized by adjusting the rule-based logic and the ANN output thresholds to the patient specificities in function of the history of false alarms and/or misdiagnoses.

5. An easy-to-deploy, high-performance self-care system

Thanks to the embedded decision making, care providers are involved only if the PEM detects an abnormality or if the patient wishes to have an authorized advice.

Another cost-reducing factor is the fact that no specific infrastructure is required. Communications are based on standard external tools: the mobile phones of patients and health professionals; standard Internet tools; and Web services for the setup or update of the health record and of the software embedded in the PEM devices, for the computation of a patient-specific 3- to 12-lead ECG transformation matrix, for the update of the ANN structure, weights, and biases, and for the customization of the embedded decision-making process to the specificities of the patient (adjustment of the decision making thresholds, weighting of the risk factors, etc) [4].

Mastering the software complexity has been overcome by embedding the totality of the software in the PEM devices and in the application servers. Thus, no specific software is required for the end user and/or for the workstations of health professionals. The PEM software and the decision-making rules are easy to upgrade via the Web servers. This approach facilitates the deployment of the EPI-MEDICS solution and guarantees that all PEMs will include the latest ECG signal analysis and decision-making components.

Eighty PEM prototypes have been finalized and evaluated between March and October 2004 according to different clinical use cases in different settings in France, Italy, and Sweden; in the areas of Lyon, Brescia, Catania, Trento, and Lund; and in emergency centers coronary care units, cardiology clinics, offices of cardiologists and GPs, home care and ambulatory care situations, and the like, both by health professionals (9 cardiologists, 10 GPs, ECG technicians, nurses, etc) and by the patients themselves. During the clinical trial, health professionals have recorded 1372 PEM ECGs and 787 standard SCP-ECG–compliant 12-lead ECGs on 794 patients. In self-care situations, the PEM has been used by 188 citizens and patients who have recorded 1287 PEM ECGs. This process is still continuing in the centers of Brescia, Lyon, and Trento on new patients selected according to their risk factors.

Fifty patients have been enrolled in Lyon for the self-care scenario assessment during the clinical trial. Each patient recorded 12 $\pm$ 6.1 ECGs (mean $\pm$ σ). One patient recorded up to 30 ECGs a day. All tracings except 3% were judged to be of professional quality. Twenty percent of the self-care patients displayed a paroxysmal arrhythmia episode (supraventricular tachycardia, atrial fibrillation, or flutter) during the follow-up period (mean $\pm$ σ = 19.4 $\pm$ 16.9 days; range, 3-79 days). One patient displayed an intermittent Wolff-Parkinson-White syndrome. Some of the patients with complaints of palpitations had never been diagnosed before even with 7 days of Holter monitoring.

The PEM and the associated software tools were judged extremely easy-to-use and user-friendly both by patients and by health professionals. The only problem has been in some rare cases an inversion of the left and right arm electrodes cables when using the Mason-Likar electrode positions. This problem will be solved in the next software release by introducing an automated electrode inversion detection module based on the serial comparison of the recorded signals with the reference ECG.

Another interesting result is of psychological order. Several usually anxious patients declared to be much less stressed when having been staffed with the PEM because they feel protected by this kind of equipment.

The capability of the PEM to detect acute infarction in self-care situations remains, however, to be demonstrated because no such event occurred during the clinical trial.

6. Conclusion

After decades of development of information systems and telemedicine applications dedicated to hospitals and health professionals, medical informatics is evolving to take account of new eHealth requirements, especially in the domain of home care, self-care, and cyber medicine [7].

We can imagine a near future in which citizens and patients will use, as in the EPI-MEDICS project, smart wearable technologies to produce, transmit, and/or access information anywhere and anytime and, above all, to act as health consumers who are responsible of their own health. They will be able to perform "medical" tests at the early stage of the onset of their symptoms without involving skilled personnel and call for assistance only when needed. Additional services like the flow management process of the PEM alarm messages and of tele-expertise requests to and between health professionals are also being implemented in emergency call centers and/or in the informatics departments of several hospitals [13]. All these software components will be driven by intelligent mobile agents to facilitate their communication via the XML format and to update the databases storing the patients EHRs with new data collected at home or in ambulatory recording conditions and for efficient data retrieval [13]. A new era has started: eHealth will become personalized, wearable, and ubiquitous.

Acknowledgments

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