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Mobile and ubiquitous architecture for the medical control of chronic diseases through the use of intelligent devices: Using the architecture for patients with diabetes

Vladimir Villarreal [a,*], Jesus Fontecha [b,1], Ramon Hervas [b,1], Jose Bravo [b,1]

[a] Technological University of Panama, Lassonde, 6th West Avenue, David, CH, POB 6-2894, Panama

[b] Modelling Ambient Intelligence Research Lab, University of Castilla-La Mancha, Paseo de la Universidad, 13071, Ciudad Real, Spain

HIGHLIGHTS

- We define an application to allow the patient monitoring.
- We offer a solution that will help the improvement of life for patients.
- We design ontologies to enable obtaining the knowledge of the field of study.
- We define patterns for the generation of applications.
- Defining layers we facilitate the development and maintenance.

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ABSTRACT

This manuscript presents a mobile monitoring application to allow a patient to monitor a chronic disease using mobile devices. This application is developed according to three components that enable the semi-automatic development of software, independent of the target disease and adaptable to the particular user needs. First, we present ontologies that classify medical elements such as diseases, recommendations, preventions, foods, mobile devices and diet suggestions. The second element is the distribution of the devices in layers, allowing the generation of final applications distributed in a medical context. These layers are defined to develop and maintain the set of applications. The third and most important element is developing patterns known as MobiPatterns. A MobiPattern defines the schema of each control module that is a part of the final application. These elements include formal models that seek to uncover fundamental principles and essential features and algorithms, which need to be revisited in the context provided by mobility. Aspects of the application such as the functionality, user interface, and response time for a group of patients have been evaluated in a final application targeting patients with diabetes. The design focuses on simplicity, extensibility, scalability, heterogeneity, and application customization.

1. Introduction

The concept of Ambient Intelligence (AmI) has emerged to describe interactions between a multitude of network-enabled devices, services, and artifacts. The technology will be nearly invisible, embedded in all types of objects and everyday environments, such as the home, office, car, and train.

Advances in sensing, mobile, and embedded devices have made patient monitoring possible, and they have also provided medical treatments and other assistance in health care. Aging populations will benefit from reduced costs and improved health care through assisted living based on these technologies [1]. This concept denotes an intelligent environment customized for monitoring and assisting adults and elders with disabilities while they live alone at home.

This is a common situation for patients with chronic diseases: "*Liz is a woman diagnosed with diabetes. She uses a glucose meter to control the level of sugar in her blood. Every day, she maintains an adequate level of glucose through several measurements of the disease. As part of the process, she needs to make annotations in her notebook. Whenever a measurement is performed, she annotates the irregularities and changes presented during the day. If she has a problem, she has to call the doctor to consult about what has happened. Liz would like to obtain constant feedback about her measurements, obtaining recommendations and messages whenever the levels of glucose in her blood change. Additionally, she would like to manage all the incidents that she has presented in the last few days,*

* Corresponding author. Tel.: +507 7754563; fax: +507 7753012.
E-mail addresses: vladimir.villarreal@utp.ac.pa, vladvill22@gmail.com (V. Villarreal), jesus.fontecha@uclm.es (J. Fontecha), ramon.hlucas@uclm.es (R. Hervas), jose.bravo@uclm.es (J. Bravo).
1 Tel.: +34 926295300x96675.

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without the need to register them in her notebook. She wants to send these incidents to her doctor automatically. This would provide her with a better quality of life and a more constant monitoring of her disease''.

This represents the ideal situation for a patient who suffers a chronic disease and needs constant monitoring. This is the main issue that these people face. We developed and implemented an application to facilitate continuous monitoring tasks allowing patients to lead normal lives without worrying about how to manage these medical tasks. This is a non-intrusive application with a low level of interaction. Once a vital sign has been measured, the application can process and visualize the results. This application is developed based on the patterns, layers and ontologies that are defined in our research. The objective of this application is to allow constant monitoring of patients with chronic diseases through the use of biometrics and mobile devices.

This application is remote and mobile, based on an adaptive system. The system can collect data while the patient is at home using a mobile phone and a biometric device. The remote application means that medical staff will be able to access all the collected data in a non-intrusive manner. This will facilitate a greater intimacy with patients. A mobile device, allowing continuous monitoring, can also receive this information.

We have indicated that the application will be mobile because the solution is based on the integrated or embedded hardware of portable and wireless devices; the patient does not have to carry heavy devices. Additionally, the system is adaptive, and the development will provide not only information about biometric values but also control activities for each of the patients. Therefore, medical staff will obtain their patients' biometric values and several notifications when patients may be at risk.

The hypothesis of our research is as follows: ''*Is it possible to develop a mobile application that offers services that allow patients to use biometric devices to provide data and information to mobile devices (e.g., mobile phone, PDA, Internet tablet, or small computer) that collect information, evaluate trends, provide advice on health and diet or suggest ways to evaluate symptoms of a disease using a transparent and redundant data link between the patient and the personal mobile device?*''.

The results of this hypothesis define our contribution in the area of ambient assisted living and mobile computing as well as provide an application to help people based on software engineering techniques related to the definition of interfaces, communication technologies, and medical knowledge.

This application can be adapted to some diseases, such as diabetes, high blood pressure, and fever, through biometric devices such as glucometers, tensiometers, and thermometers. When the application is running on the mobile device, the patient can add a new disease. The application development is evaluated in a medical context for patients with diabetes and blood pressure issues, always with the recommendation of a doctor.

This paper is organized into seven sections. After this introduction, Section 2 introduces the related work and compares it with our proposal. Section 3 presents a general proposal for generating mobile monitoring applications that link information to the patient's profile, contain medical modules and generate alerts. Section 4 describes the application of our architecture for patients with diabetes. We describe the evaluation of our application in Section 5, and in Section 6, we include a discussion of our proposal. Finally, Section 7 presents the paper's conclusions.

2. Research background

Some research has been developed for use in both indoor and outdoor environments. Most of the monitoring systems are focused on a single task, such as simple vital sign monitoring, fall detection, environment customization, or locating a person. Some devices may have a limited effectiveness because during a heart attack or a stroke, a patient may not be able to push the panic button. Other systems are based on a public or mobile phone or a pager-like device. This research proposes the development of software elements implemented in medical situations.

2.1. Researchers' contributions

Nirmalya [2] offers the idea of an architecture that supports a mix of efficient context-aware information for healthcare applications with an ambiguous context. It provides a systematic approximation to derive fragments of the context and to handle the probability of ambiguity in this context. This framework has been evaluated to monitor elderly people in small home environments. This design has been developed and labeled using Dynamic Bayesian Networks (DBNs) and a rule-based model. In our case, we do not have ambiguity in the data. To achieve this, we defined an individual profile for each patient, and the functionality of this architecture lies in the profile.

Mei [3] proposes the development of a framework for representing patients' vital signs. This framework facilitates the representation of the different notations for vital signs [4–6]. He proposes an XML schema to design the representation of the vital signs framework, specifying the existing standards of representation. Additionally, he proposes the creation of data sheets that contain the representations of vital signs that result from the mobility of the (patient) users in heterogeneous environments. Our proposal is not based on the representation of vital signs but rather on their control and interpretation.

Kebler [7] discusses how to use the context information to improve the analysis of similarity. He talks about three uses measurements of similarity in the geospatial domain and investigates which aspects of Dey and Abowd's definition of context (e.g., identity, activity, location or time) play a crucial role in defining the similarity in each of them. This alignment makes it possible to relate the structure of a shared vocabulary in the base of knowledge and the context information. The context parameters examined by the study are used to influence the results of the similarity analysis. The fundamental key that permits the care handling modules is the behavioral record in the patient's profile.

Preuveneers [8] investigates how the mobile phone platform can help individuals diagnosed with diabetes handle their blood glucose levels without resorting to additional systems (beyond the equipment they currently use) or without adding any additional activity sensors, such as pedometers, accelerometers, or heartbeat monitors. Participants in this study were patients with Type-1 diabetes. Our proposal focuses on patient monitoring; it is not necessary to know the location of the patient, but it is crucial to know the activities the patient was carrying out at a specific moment. This allows our system to learn for future situations. Our study is not only for diabetes; we can monitor many different chronic diseases using biometric devices to obtain the measurement.

Mamykina [9] presents MAHI (Mobile Access to Health Information), an application that monitors patients diagnosed with diabetes. This application is capable of acquiring reflexive thought skills for social interaction with diabetes educators. In our proposal, only the endocrinologists become involved because they are the only ones who know the patients' specific profiles. Managing the reflexive analysis of past experiences is one of the most essential skills in managing diabetes.

Bravo [10] proposes a patient tele-monitoring process. He proposes using a monitoring device that a person (patient or assistant) could activate by touching an NFC (Near-Field Communication) tag with the phone to launch the mobile phone application. As a result, the monitoring device should be active, and the measurements are sent to the mobile phone through a Bluetooth connection. When the mobile phone obtains the measurements, it is in a position to make a recommendation. The use of such technologies is contemplated due to the low cost and energy consumption. In our proposal, we use technology such as Bluetooth for more extend communication. Bluetooth communication is superior to NFC.

At Georgia Tech [11,12], the Aware Home project created a home environment that monitors its occupants' whereabouts and activities. The services provided by Aware Home range from promoting enhanced social communication by providing a digital portrait of an elderly person to relatives to storage aids that assist users in resuming interrupted activities by using playbacks of video recordings of past events. Next, in [13], related research to home health monitoring using a smart phone was presented. We have developed an application that allows the use of different mobile devices with different biometric devices. This application uses interfaces based on the diseases as inputs to the healthcare system.

At the University of Virginia [14], researchers developed a smart in-home monitoring system to collect data using a suite of low-cost, non-intrusive sensors. The collected data are stored and analyzed in an integrated data management system. The system collects information in a passive manner and does not directly interact with the person being monitored. We collect data from each patient through mobile devices when this patient uses the biometric device. These data are stored on a server that permits patient control, and the application provides suggestions for the prevention and control of the progression of diseases.

Intel [15] is focused on improving care in clinical environments, advancing personal health technologies at home, identifying new care models and work practices, and promoting standards and policies that enable innovation and interoperability across the healthcare ecosystem. Some research developments of Intel are focused on technology research for independent living (TRIL), everyday technologies for Alzheimer's care (ETAC) and aging services.

In the Center for Future Health (CFH) at the University of Rochester [16], there is a smart medical home prototype that consists of infrared sensors, computers, bio-sensors, and video cameras. The key services are medical advisory, which provides a real-time conversational interface between the patient and a health care expert, motion and activity monitoring, pathogen detection, skin care, and a personal health care record for consumer–provider decision support.

The ElderCare [17] platform aims at providing a holistic ICT infrastructure for AAL at any home or residence. It is affordable, unobtrusive, easily deployable, usable, accessible, and available. It describes the architecture and components of an AAL-enabling platform centered on an interactive TV (ITV) that combines OSGi middleware, RFID and NFC. The primary focus is on improving the day-to-day experience of dependent or semi-dependent elderly people as well as of their caregivers and relatives.

For the analysis and evaluation of each of the related work, we have defined a set of criteria that will enable us to assess and locate the aspects of design, adaptability, communication, security and costs in each investigation with regard to our work. The evaluation criteria for each evaluated work are as follows:

- *Design*
  - *Cohesion*: the ways in which a system that we have physically divided into parts (particularly in relation to the structure of the problem) can significantly affect the structural complexity of the resulting system, as well as the total number of inter-modular references. Within the evaluation of the related work, we analyzed the degree of cohesion of applications that are designed for the monitoring and control of patients. The weights for this sub-criterion have been defined as (High (HG) = 3, Average (AV) = 2, and Low (LW) = 1).
  - *Coupling*: if two modules are strongly coupled, there is a high probability that the programmer needs to understand one of them to try to make changes to the other. The weights for this sub-criterion have been defined as (High (HG) = 1, Average (AV) = 2, and Low (LW) = 3).
  - *Usability*: the usability of the system consists of a component's functionality (functional utility) and the modes users can use to access this functionality. We can define usability as the extent to which users can use a product to achieve objectives with highly specific effectiveness, efficiency and satisfaction in a particular context. The weights for this sub-criterion have been defined as (High (HG) = 3, Average (AV) = 2, and Low (LW) = 1).
- *Adaptability*
  - *Capacity for change over time*: this feature allows us to know the capacity that an application has to adapt to changes that occur in the environment, i.e., the capacity that applications have to evolve over time. This is the ability to adjust to changing needs with respect to the initial idea of its implementation. Many proposals are developed as a point solution, limiting their ability to evolve in the future. The weights for this sub-criterion have been defined as (High (HG) = 3, Average (AV) = 2, and Low (LW) = 1).
  - *Domain application migration*: in addition to the evolutionary ability, we find it is important to evaluate an applications' ability to migrate to another domain. This is the ease with which an application can adapt to use in an area other than the one for which it was developed. In our case, it could refer to the ability to operate with more than one disease. For some applications, it is not possible to implement all or part of the developed architecture in a different application domain. The weights for this sub-criterion have been defined as (High (HG) = 3, Average (AV) = 2, Low (LW) = 1).
  - *Technological migration*: in medical environments, an application may need to adjust to new technological changes. If an application is not developed with this in mind, it may make further development or migrations to new technology difficult. This criterion evaluates the ability of developed applications to migrate easily to new devices or operating systems. The weights for this sub-criterion have been defined as (High (HG) = 3, Average (AV) = 2, and Low (LW) = 1).
- *Communication*
  - *External communication or transmission technology*: for technologies that reference patient monitoring, this criterion evaluates the data transmission technologies. It takes into account the type of data that is transmitted and the supported technologies for sending and receiving data, where relevant. The weights for this sub-criterion have been defined as (High (HG) = 3, Average (AV) = 2, and Low (LW) = 1).
- *Security*
  - *Data treatment*: currently, treatment of patient data is one of the primary disadvantages when developing this type of application. This criterion evaluates the aspects related to the treatment of private data if data protection guidelines are included. The weights for this sub-criterion have been defined as (High (HG) = 3, Average (AV) = 2, and Low (LW) = 1).
  - *Data transmission*: this criterion evaluates aspects of security during the data transfer between each of the involved devices. This aspect is of great importance because we will analyze each proposal and determine which solutions maintain secure communication among the elements. The weights for this sub-criterion have been defined as (High (HG) = 3, Average (AV) = 2, and Low (LW) = 1).
- *Costs*
  - *Implementation*: this criterion evaluates the aspects related to the costs of application development, i.e., the cost of the devices or hardware and software needed for development. The weights for this sub-criterion have been defined as (High (HG) = 1, Average (AV) = 2, and Low (LW) = 3).

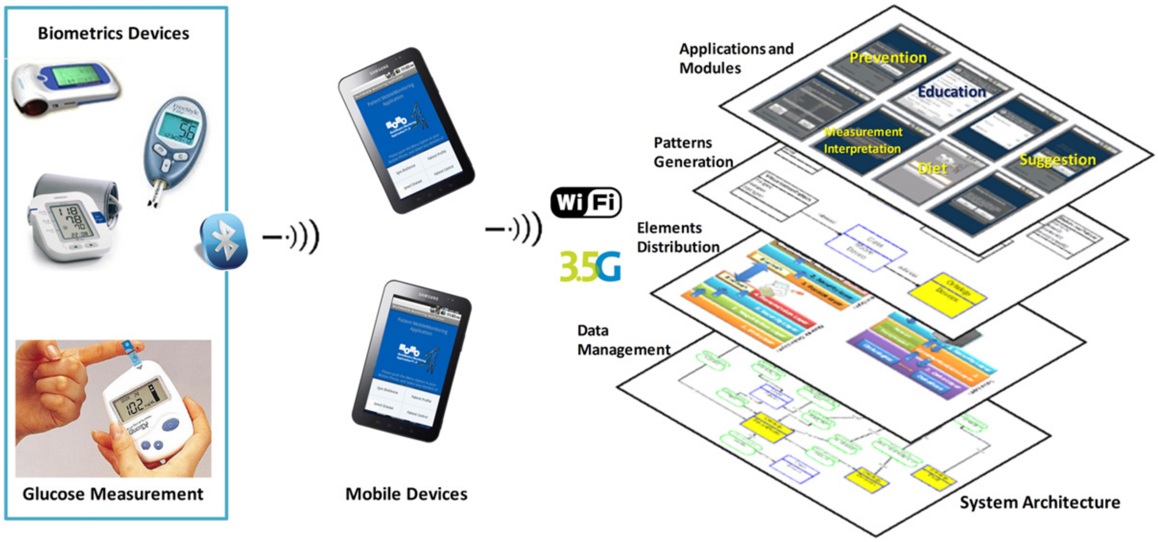

Fig. 1. Relationship between the distributed proposal and multiple devices.

- *Maintenance*: this cost refers to the effort required to update, change or improve the initial proposal for other environments or new requirements in the same environment. It is important for this position to be clear, not only to the initial developers but also to all the elements in such a way that it is easy to identify the involved parties and facilitate the readjustment of the initial application without having to review all of its structure. The weights for this sub-criterion have been defined as (High (HG) = 1, Average (AV) = 2, and Low (LW) = 3).

Table 1 shows a comparison of the evaluated criteria for each of the previously mentioned proposal. Each criterion has been weighed in such a way that you can compare it with our proposals. The criteria are specified in the previous paragraphs, along with the weight assigned to previously studied research.

We can summarize the most important criterion for each of the evaluated research projects. With respect to the degree of cohesion, Preuveneers and MoMo's research had the highest degree of cohesion. Generally, usability is the primary concern when developing mobile applications for patient monitoring. The level of adaptability, as we have mentioned previously, allows the developed applications to coexist with new changes in the application or technological domain and the ability to change over time. Nirmalya, Mei and MoMo's proposals had the highest degree of adaptability. Mamykina and ElderCare's proposals were less adaptable.

None of the analyzed proposals consider data processing security or mention it in the explanations of their proposals. MoMo offers high levels of safety in data transfer and treatment. Similarly, only Georgia Tech's proposal specifically mentions data transfer security. They use technological aspects to maintain the integrity of the data to be transmitted.

The cost of application development is another important criterion to analyze. In other words, it is important to state which proposal has the lowest cost of implementation (use of technologies for development). As for the cost of maintenance (ease of modifying an application), the majority of proposals have a middle grade of maintenance. In MoMo's research, the cost is categorized at a medium level. This is due to the use of current technologies whose cost/benefit ratio is very high.

3. Software engineering aspect of the development of a mobile monitoring application

The proposed mobile monitoring application integrates heterogeneous devices; some are directly connected with mobile devices through communication technology (Bluetooth) or manual interaction. Together, these devices inform the healthcare provider about the patient's health condition. Data are collected, aggregated, pre-processed and stored using a variety of sensors and devices. The interaction between the biometric devices, mobile devices, and full system is the primary objective of patient monitoring. These activities can be performed by obtaining vital signs and appropriately interpreting them to generate medical monitoring applications.

Fig. 1 shows the elements of the proposal. On the left, a number of healthcare and monitoring devices are connected to Bluetooth mobile devices. In the center, these biometric devices are linked to a mobile phone to process sensor data, manage applications, and ensure redundant connectivity via 3G and WiFi data networks. Information is transmitted to a central database and advisory system for evaluation and monitoring by the medical server (right). Further subsections explain each element of the system architecture.

3.1. Applications and modules

Mobile devices provide richer interfaces for real-time and historical data. This application works like a bridge between the patient and the monitoring modules. It starts when the system boots-up and loads the applications, passing them through the parameters defined in the configuration files. The application developed is illustrated in two specific areas: the first corresponds to the needs of the doctor and the second corresponds to the needs of the patient.

The physician's application is installed on a mobile phone, and it allows the control of all of their patients' records organized by the patient's profile, including the last measurement obtained from the biometric device. In the patient application, the program is installed on their mobile phone. We have developed the application using the Android operating system with remote connectivity to a database in MySQL.

3.2. Development-based pattern generation

An implementation pattern that allows the rapid, flexible, and guided development of applications is important to develop general application structures. Software designers adapt the pattern solution to their specific project. Patterns use a formal

Table 1
Comparison of the defined criteria for the proposals of researchers evaluated.

Related works	Design						Adaptability						Communication		Security				Costs			
	Cohesion		Coupling		Usability		Change capability with time		Domain application migration		Technological migration		Transmission technology		Data treatment		Data transmission		Implementation		Maintenance	
Nirmalya	AV	2	AV	2	AV	2	HG	3	AV	2	AV	2	LW	1	LW	1	AV	2	LW	3	AV	2
Mamykina	AV	2	AV	2	AV	2	LW	1	LW	1	LW	1	AV	2	LW	1	AV	2	AV	2	LW	1
Preuveneers	HG	3	AV	2	HG	3	AV	2	AV	2	AV	2	HG	3	LW	1	LW	1	AV	2	AV	2
Kebler	AV	2	HG	1	AV	2	LW	1	LW	1	LW	1	LW	1	LW	1	LW	1	AV	2	AV	2
Bravo	AV	2	AV	2	AV	2	AV	2	AV	2	AV	2	AV	2	AV	2	AV	2	LW	3	HG	1
Mei	AV	2	AV	2	HG	3	HG	3	AV	2	AV	2	HG	3	LW	1	AV	2	AV	2	AV	2
Georgia Tech	AV	2	AV	2	HG	3	AV	2	AV	2	AV	2	AV	2	AV	2	HG	3	AV	2	AV	2
Center for Future Healthcare	AV	2	AV	2	HG	3	AV	2	LW	1	LW	1	AV	2	AV	2	AV	2	AV	2	AV	2
ElderCare	AV	2	AV	2	AV	2	LW	1	LW	1	LW	1	AV	2	AV	2	AV	2	AV	2	AV	2
MoMo	HG	3	AV	2	HG	3	HG	3	HG	3	AV	2	HG	3	HG	3	HG	3	AV	2	AV	2

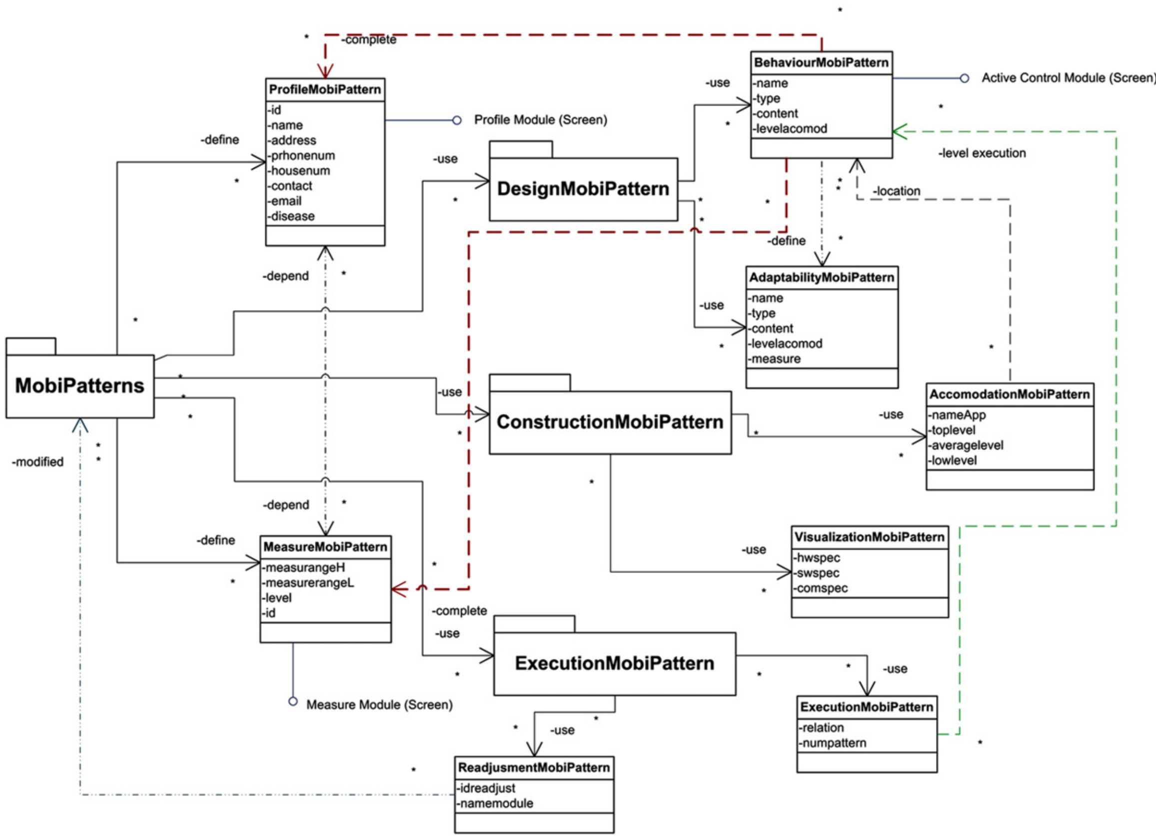

Fig. 2. MobiPattern distribution and relationship with other MobiPatterns.

approach to describe a design problem, its proposed solution, and any factors that might affect the problem or the solution.

Some researchers define software pattern structures to develop applications and data exchange [18,19]. We have developed interactive applications to be embedded in a mobile device (PDA, mobile phone, etc.). For the creation and integration of these modules into the mobile devices, we have defined and developed a set of patterns known as MobiPatterns. In any MobiPattern, we need to consider that all the interpretations are generated after a measurement. These MobiPatterns define the schema of each screen of the final application and the functional structure. We defined generic patterns for use in any application that allows patient monitoring. Then, we grouped all measurements obtained by the biometric device in five levels of ranges: alert (very low), low, acceptable, ideal and high. This classification allows the generation of a more accurate medical control for the patient.

Fig. 2 presents the distribution of these MobiPatterns and the relationships among them. One MobiPattern always depends on another MobiPattern based on the following sequence: (ProfileMobiPattern) "*depends on*" (MeasureMobiPattern) *and* (MeasureMobiPattern) "*is related to each of*" (FunctionalityMobiPattern) *then* (ProfileMobiPattern) "*is related to each of*" (FunctionalityMobiPattern). Their relationships are very important when establishing the application's communication protocol.

Some examples of MobiPatterns are presented in this section. Each MobiPattern allows the generation of modules that form the final application. We design MobiPatterns for the generation of final applications for different diseases. Each disease has a name, e.g., blood pressure, diabetes, or temperature, and a specific number of measured values. The definition of each *MobiPattern* is generic, and it depends on the requirements of each disease.

3.2.1. Elements of the MenuMobiPattern

To generate the final application, we designed and developed another MobiPattern to complement the first MobiPattern explained in Section 3.2. This pattern defines the first screen or module of the mobile monitoring application and organizes all the modules or components of the final application. This is known as *MenuMobiPattern*. This pattern readjusts the menu for each monitored disease. In Fig. 3(a), we present the architecture of this MobiPattern and one example of the main screen related to a menu application. The menu can activate six main functions. The functions are the following:

- Patient profile: this option allows the application user to visualize and modify data.
- New disease: new diseases may be added to the monitoring application.
- Self-control: a follow-up based on the inputs of the monitoring devices for different diseases.
- Synchronize Bluetooth devices: this function may be added if a monitoring device for a particular disease has Bluetooth functionality. When the patient uses a Bluetooth device, it automatically communicates with the application and submits its recorded measurements.
- Adding new measures: the display shows an icon with the sign "+". With this function, patients may add measurements and other parameters related to the monitoring of the disease, e.g., physical activities. The notifications area is located on the bottom bar; it displays pending alarms (triggered by a measurement that indicates risk) and notifications, e.g., messages from doctors, because this area is accessible from the screen that shows these notifications.

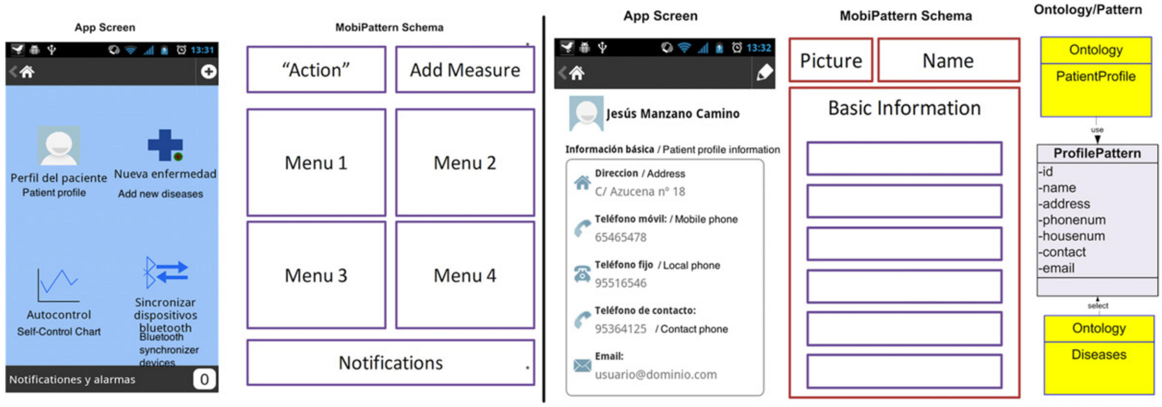

Fig. 3. (a) The menu screen and the MenuMobiPattern schema, and (b) the patient's profile screen and the ProfileMobiPattern schema with the ontologies relation.

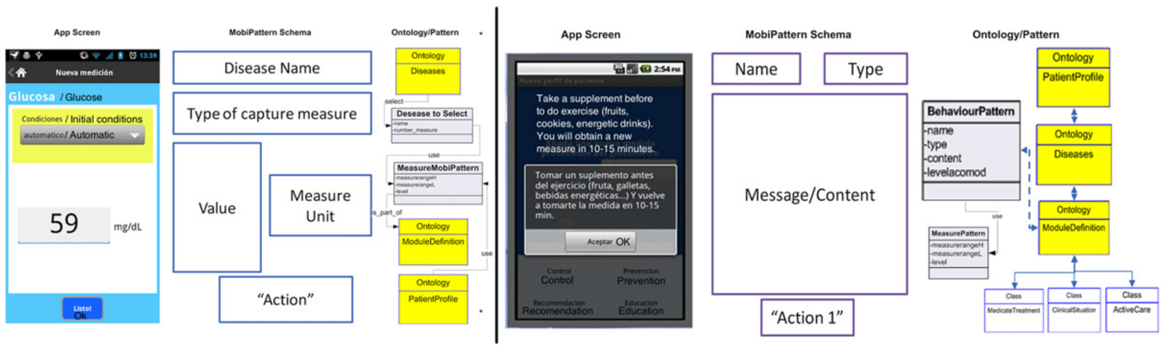

Fig. 4. (a) The measure screen and the MeasureMobiPattern with the ontologies relation, and (b) the functionality screen recommendation and a FunctionalityMobiPattern schema with the ontologies relation.

- Settings menu: from the main menu, you can access other sections of the application:
  - Preferences: the application parameters can be modified here. These include choosing the input (manually or automatically obtaining measurements) and the language of the application.
  - About: this item shows information about the application, the development team, and the help page.

3.2.2. Elements of the ProfileMobiPattern

The *ProfileMobiPattern* is responsible for generating the patient's profile. The profile is associated with the patient's disease. Fig. 3(b) presents the structure of the patient profile module and its relationship with the MobiPattern to generate the patient's profile. This MobiPattern is related to two ontologies—the patient profile ontology and the disease ontology. We explain the main structure of the ontologies in Section 3.3.5.

In the first use of the application, the user will enter their data. The system compares the id introduced with the id in the database. If all the fields of the patient's profile are completed and if the patient is a new user of the application, it can complete the remaining fields with data already stored in the system.

Importantly, there is a field to enter the phone numbers of emergency contracts; if the user has a high-risk measurement; the application sends an SMS warning to these contacts. In this case, the message is sent to the doctor and the patient's relatives. Data will be kept updated on the database located in the phone memory and on the database in the central server.

3.2.3. Elements of the MeasureMobiPattern

This MobiPattern reads each of the vital signs from biometric devices, providing constant patient monitoring. Fig. 4(a) presents the relationship between the "*add measure screen*" and this MobiPattern. MeasureMobiPattern is related to the "*disease_to_select*" class and the diseases, ModuleDefinition and PatientProfile ontologies. The "*disease_to_select*" class is used to select and add a new disease for the application.

Fig. 4(b) provides an example of a functional module, in this case a recommendation module. The screen shows a recommendation message for the patient, and the MobiPattern schema identifies each element of the MeasureMobiPattern. Additionally, we explain the relationship between the ontologies and the class that compounds this MobiPattern.

A glucose sensor is used as the primary input for the patient's application. The data received show the trend values, but we do not exclude the use of an old-fashioned glucose meter. These data need to be compared to the average values set by an endocrinologist (80–180 mg/dl). For these values, the application provides a suggestion or positive reinforcement (suggestion module). These data are also stored in the mobile device, packaged according to the frequency specified on the profile by the endocrinologist and sent through the communication module to the doctor's application.

3.2.4. Elements of the FunctionalityMobiPattern

This module is responsible for the communication between the doctor and the patient. This module has several functions, such as sending the glucose values, special recommendations from the doctor, profile updates, and alerts. The alert module is continuously supervising the glucose levels. If it records a high-risk value, it communicates with emergency services to assist the patient. The suggestion module uses the diet module to present suggestions about food habits. The diet module has a list of healthy and prohibited foods; to generate this list, it can read the profile data about allergies and foods for other types of diseases that the patient may suffer. The diabetic education module presents information

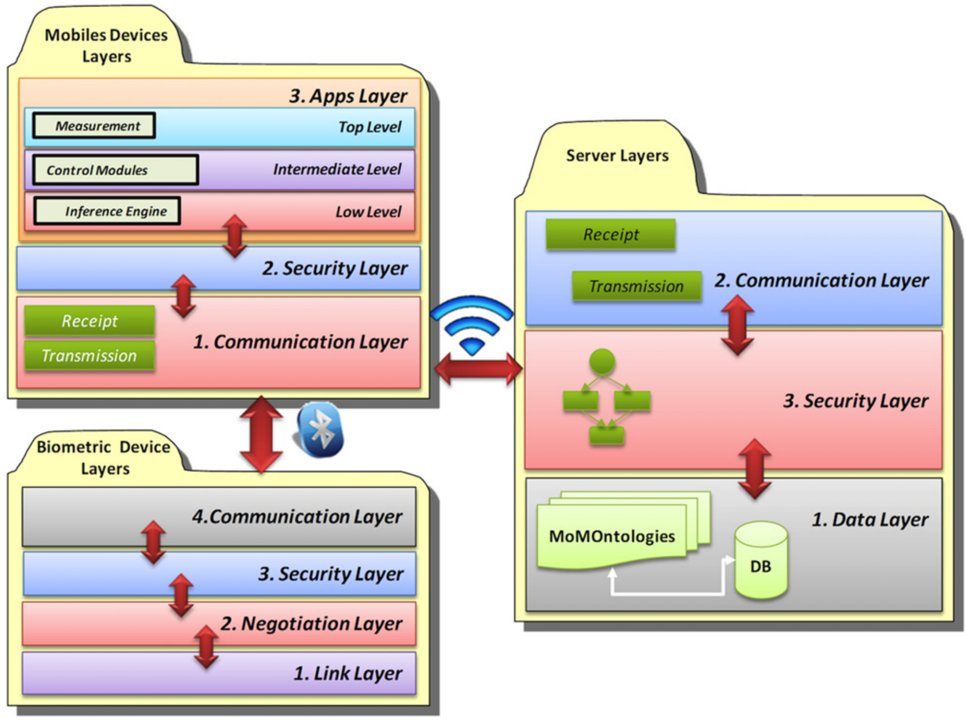

Fig. 5. Distribution of each element of the layer structure.

about the illness, habits, and preferable behaviors to prevent health complications.

The prevention module analyzes the glucose level, and it also associates defined activities with dangerous glucose values and triggers the suggestion module to avoid a reoccurrence. To develop the suggestions, the module uses a calendar in which the user records their schedule activities, and the application analyzes the glucose levels registered during the activity. If the activity causes the patient to have abnormally high or low levels, this is learned, and the application will trigger the suggestion module the next time this activity is scheduled. The patient profile has data related to age, sex, diabetes onset, weight, allergies, physical activity, diseases related to diabetes, and physical disabilities. This sort of information, as well as the required daily carbohydrates intake, is provided by the endocrinologist. The profile will progressively grow as the user interacts with the system.

3.3. Distribution of elements

We have distributed the elements of the application in layers. In different areas [20,21], some architectures have been implemented using a layered architecture to promote the interoperability of the entire architecture, facilitating standardization in the development.

We have defined and developed a set of layers as part of our developed application (Fig. 5). This application has three main group layers: biometric distributed layers, mobile distributed layers and server distributed layers. Each layer and sub-layer is evaluated according to aspects such as communication, security, application development, heterogeneity, and data management.

3.3.1. Communication

The communication item is related to the technical possibility of communication between biometric and mobile devices. This communication is based on negotiation and transmission. There are two methods to enable communication between devices: Bluetooth and WiFi/3G. The first is used for communication between the biometric device and the mobile device; the second is used for transmission between mobile devices and the system architecture.

The communication channel negotiates the terms of communication, which establishes the formal aspects of each device and the package delivery specifications (size, headers, encryption type, etc.). After the negotiation phase occurs, the data transmission between the biometric device (as the transmitter) and the mobile device (as the receiver) takes place.

We present the structure of the communication layer. Some functionalities of the communication components are the following:

- enable the channel of communication between the server and the mobile device;
- provide security services for the transmission of data;
- provide access to the services offered by the layer of data;
- receive encrypted requests for passing to the security layer;
- enable n-numbers of channels for simultaneous access by several mobile devices.

When the contact between the patient and the specialist begins, the profile is stored with the distributed glucose levels. This transmission occurs via a mobile Internet connection, e.g., WiFi. The frequency with which data are sent depends on the profile. A person whose trend charts indicate very irregular glucose levels needs to be checked more frequently, for example, this person needs more attention than a person whose trend charts show regular levels. The alerts launched by the system are stored in a permanent record in the patient's profile. The data stored in the patient's profile allows the endocrinologist to monitor them, justify the measurements and find out why the alerts were triggered, even if they were caused by failure to follow the suggestions of the system. The specialist's statistics module works with the suggestion data. These items are received, establishing a priority, providing a better care to the patients, and facilitating the doctor's tasks.

If the patient uses a biometric device with Bluetooth connectivity and this connection fails, the measure can be obtained manually. The patient introduces the measurements obtained at the application. However, the problem is with the biometric device because the patient needs to replace the device and connect a new biometric device with the application. The doctor, depending on the type of the patient's biometric device, initially explains this connection.

3.3.2. Security

Some researchers proposed solutions that we evaluated before choosing the most appropriate solution for our application. Berkeley University in California proposed a security method for a *WSN* (*Wireless Sensor Network*) known as "*TinySec*", which provides encryption and authentication [22,23]. It consists of two submodules—one for encryption and the other one for authentication.

The security in our application is related to the transmitted data captured by the biometric device and the subsequent transmission from the biometric device. We use Bluetooth; we will implement security protocols when transmitting data between the mobile and biometric devices.

The functionalities of the security component are as follows:

- ensure the integrity of the data to transmit from the data layer;
- evaluate each request for access to the data, depending on the access role;
- offer access to the data layer FEC (Flow and Errors Control);
- restrictions for patients who are not logged in;
- offer cryptography services to ensure the integrity of the data received from the data layer.

We use the *javax.crypto* library, included in the java standard SDK, to encrypt and decrypt the data transmitted between the mobile devices and the central server. This library establishes secure communication with Web services.

3.3.3. Application development

Each generated module will be located on the same level as the source application for each application in the layers proposal. This occurs because each developed application (module integrated in the final application) must be located in a specific level.

The application development defines three levels of operation. They are low, the location of the control measures; middle, the location of the patient's profile module; and high, the location of the active control module (recommendations, prevention, alarms, diet, and education). These standards specify the location of each of the modules generated based on the MobiPatterns.

3.3.4. Heterogeneity

Many devices with diverse communication capabilities work or are placed in the same environment. Additionally, these devices communicate with biometric devices. In this research, the communication technology used is Bluetooth. Bluetooth communication allows the integration of new communication technologies and data transmission at the lowest levels of our layers proposal. If the biometric device has another communication technology, the mobile application would permit the manual entry of the measured values.

3.3.5. Data management

The use of ontologies in Ambient Intelligence provides several benefits and additional functionalities. For data management, we developed a complete ontology to define all the elements of the application. We have previously explored the use of ontologies as a runtime adaptation of applications and personalization to the particular user needs [24]. The ontological definition is based on the proposals of Hervás [25]; they include a user-centered classification compounded by the user, environment, devices, and services. We have enhanced those ontologies with information about the diseases, biometrical devices, and module generation.

In [26], we defined a general ontology that includes the taxonomical organization based on the principal elements and the type of data stored in augmented objects.

Depending on the information stored in the patient's record, different modules are upgraded with new data. All activity development for the patient is stored on a server, making it possible for the doctor to review information from each patient. The doctor receives information about the last measurement, activities, generated recommendations, and alerts with dates and hours to improve patient monitoring.

In Fig. 6, we show the structure of the upper ontology for mobile monitoring application. The doctor and the patient are the actors who interact with the application. The patient has a profile that offers information to the application (classified under the CommonProfile and IndividualProfile ontologies). This individual profile allows this module definition (the MedicateTreatment, ActiveCare and ClinicalSituation ontologies). In addition, this module definition obtains information about the diseases and food ontologies. According to this classification, each of the elements is related to the initial definition of the patient profile. The definition of the modules generates the application structure for the doctor and the patient based on each of these patterns and the relationships between the modules' definition structures.

- *Monitoring*: defined in [27] as controlling the patient's vital signs via monitors. We will focus on monitoring by means of mobile devices.
- *Entities*: stakeholders who are involved in the patients' mobile monitoring process and interact with the application. They are the doctor, the patient, and the sensors.

The application contains the following ontology classifications:

- *Patient's Profile*: defines each patient's data: Common Profile and Individual Profile.
- *Common Profile*: this profile stores the information about the patient's diseases.
- *Diseases*: defines a classification of diseases. In this case, a disease-classification ontology has been developed with the following criteria and aspects of the disease. These diseases are classified depending on the duration of the diseases (Class "ForRapidityandDuration"): acute or chronic; by the frequency in which they appear (Class "ForFrequency"): sporadic, endemic, or epidemic; and by their origin (Class "ForOrigin"): infectious or non-infectious.
- *ModuleDefinition*: elements generated according to each patient's profile. We distribute the module in care activities (Class "ActivitiesCare") that manage the prevention, education, self-control, suggestion and diet modules, defined for the pathology particular to each patient. The clinical state (Class "ClinicalSituation") defines the typical characteristics of a disease (diseases ontology) and establishes checkpoints for the interpretation of the data obtained by the different sensors. The medical treatment (Class "MedicateTreatment") can be either an activity or a pharmaceutical and is always prescribed by a specialist.
- *Food*: defines a classification of the different types of food to be consumed by the patient. The ontology proposed by Cantais [28] reflects a food classification for patients with diabetes, depending on their energetic content. We use an adaptation of this ontology with the recommended (advisable) food component, a forbidden food, and a restricted food section.

4. Applying the proposal through the developed elements: a case study on diabetes

We selected diabetes because it is currently one of the most common diseases. We evaluated this application in the area of

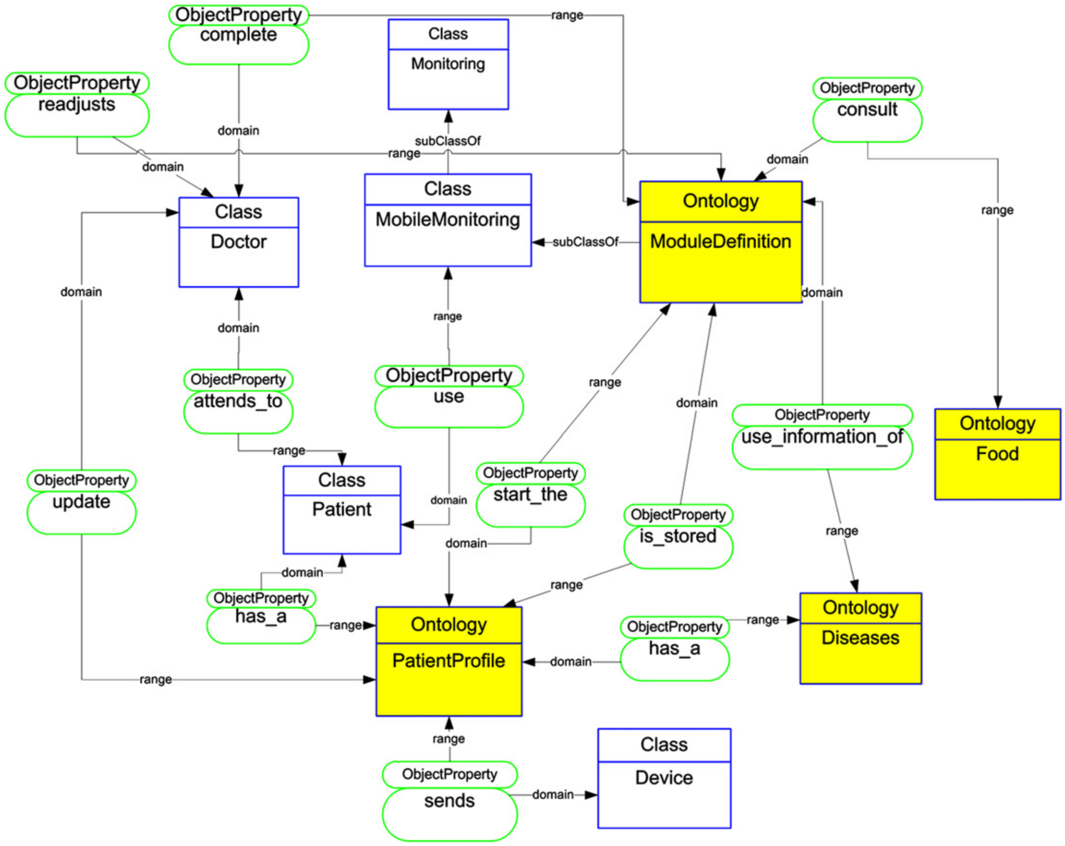

Fig. 6. Ontologies diagram for the patient mobile monitoring architecture.

blood pressure. When you use the application with a different disease, only the type of disease and the number of measurements change. The application can be implemented to control diseases that have one or two measurement units. In each case, the final application only updates the measurement module. When the application is installed in the mobile device, it defines the relationship between each MobiPattern and the ontologies through the application core. Then, each module is generated and adjusted to each type of disease, and an application is installed in the patient's mobile device. This application is synchronized with the biometric device if the device supports data transfer. If the patient does not have a biometric device with communication technology, the data will be entered via the keyboard of the mobile device. Thus, the monitoring functionality starts.

After a glucose level is obtained, the system places the glucose value in three different ranges (low, normal and high) according to the values established for diabetes (Fig. 7(a)). Each group has an associated range of values that allow patients to know whether the value has changed from expected glucose levels (Fig. 7(b)). This incidence is stored in the database to be analyzed by the physician at the next visit.

A patient with diabetes should combine the diet and exercise to control their glucose levels. The application asks if the patient wants to exercise. Depending on the level of glucose obtained from the glucose meter, a recommendation of whether the patient should exercise is generated (Fig. 7(c)).

If the patient's measurements are in a range where the exercise is not permitted, the application will recommend that the patient monitor the measurement in a few minutes to detect changes in the level of glucose. When glucose levels are within an acceptable level, the application asks what type of exercise the patient would like to do; depending on the type and duration of each exercise, it will show different recommendations for controlling glucose levels (Fig. 7(e)). For example, it may recommend the amount of carbohydrates to be eaten depending on the mass and weight of the patient, as shown in Fig. 7(f). In Fig. 7(g), the patient and doctor can see the historical data of each measurement for each patient. In addition to generating recommendations and suggestions for patient management, our architecture offers patients the appropriate resources to show the history of their measurements taken at any time during the day.

This history allows the patient to analyze the behavior of their disease based on medical controls for variations in their glucose measurements. As shown in Fig. 7(d) and (h), the mobile application displays a table with information about the day when the measurement was obtained and the value of this measurement with respect to the range in which it is located (low, acceptable or high). In the same manner, the application shows charts related to the behavior of glucose at different times of the day, allowing the detection of changes in the health surveillance.

This group of applications has been developed as a demonstration prototype. The aim of this prototype was to collect vital signs from the devices and transmit them to a server via Ethernet or WiFi. The data collected should be displayed in a set of graphical interfaces.

The patient uses the glucose meter "*GlucoTel*" with Bluetooth communication. *GlucoTel* is a glucose meter with Bluetooth technology that allows real-time transmission of blood glucose measurements. These results are stored and sent online to the central server database through the mobile phones. The server has a MySQL database to store all the data from the architecture. The data transmission and reception from the server are performed using Web Services. The biometric device sends the value of the blood glucose to the mobile phone. We use "*GeeksPhone One*" mobile phone with the following specifications: Android 2.2 operating system, Bluetooth and WiFi connectivity and a touch

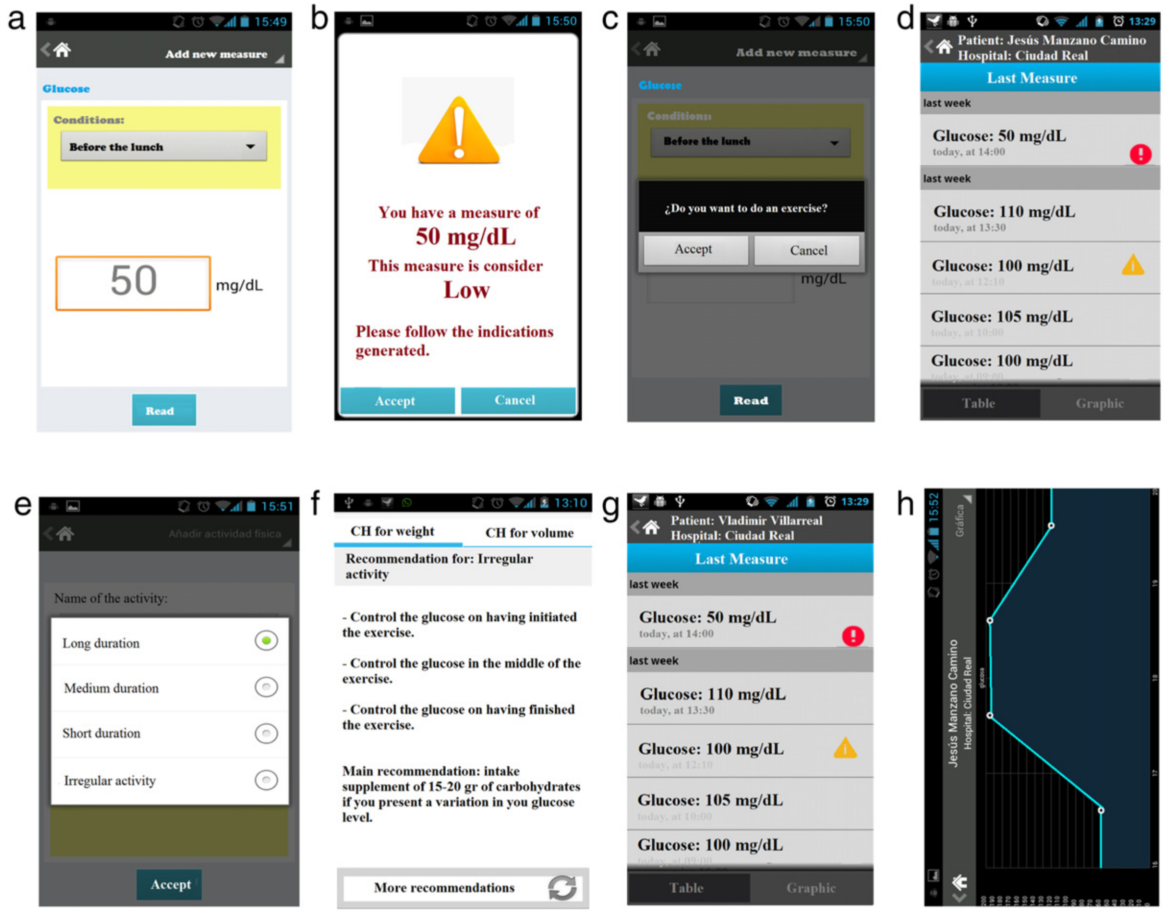

Fig. 7. Screenshots related to the complete functionality of the application for a patient with a normal measurement.

screen. The mobile phone sends all data to the server through web services. The glucose measurement is sent to the mobile phone, which interprets it according to the ranges established for diabetes and shows the recommendations and suggestions for the patient. Then, the mobile application starts interacting with the patient by providing advice to monitor and control the disease. The patient can see the list of recommendations for diet, exercise, medications, and preventive care activities by touching the mobile phone screen.

5. Applying a software architecture evaluation

5.1. For user expertise

We evaluated how a patient with diabetes uses the mobile monitoring application to control their glucose. For this evaluation, we used general and specific technologies. General technology is any technology used in the application independent of the monitored disease, while a specific technology is used to implement the architecture of a specific disease. The specific technologies that we have used in this evaluation are the central server that handles the patients and doctors' information and the mobile phone used to install the application.

First, the patient extracts a blood sample and puts it in the glucose meter. Once the blood sample is read, the glucose meter displays the patient's current glucose level. This solution has been designed, evaluated, and validated considering a group of 20 patients. The goals of this evaluation were to determine if the patients accept this solution and to evaluate the functionality of the mobile monitoring application. This evaluation was applied to patients with diabetes, where the phone was used to monitor their blood glucose in conjunction with their diabetic notebook annotations.

We used scales from 1 to 3 with the following ratings (1 = low, 2 = medium, 3 = high). The ages of the patients ranged from 40 to 50 years, having an average of three years of experience managing their disease. Based on the first prototype, patients provided their feedback, comments and recommendations on the design of the current solution. As shown in Fig. 8, the following the aspects were evaluated:

- *Response time of the application*: this aspect evaluates the time it took the application to provide answers for medical surveillance after the glucose levels of the patient were obtained. After this aspect was evaluated, eight patients provided a rating of good, while two patients rated it moderate.
- *Assessment of the recommendations generated*: the results obtained show that the application provides recommendations that are useful for each patient, and each generated recommendation is directly related to the measurement range of the patient at a particular moment. This is very helpful for the subsequent maintenance of the application, offering the patient real tips and a great value for controlling the disease.
- *Usability of the application*: the usability of the visual and functional aspects was evaluated. The visual aspect includes the ability to use the application according to the developed interfaces or how friendly the interfaces are for patients. The functionality includes the application's accessibility and improvement. In the results obtained, six patients said the application's visual and functional aspects were easy to use, while four patients said its use was average. It is important to mention that the patients had never used a mobile device before.

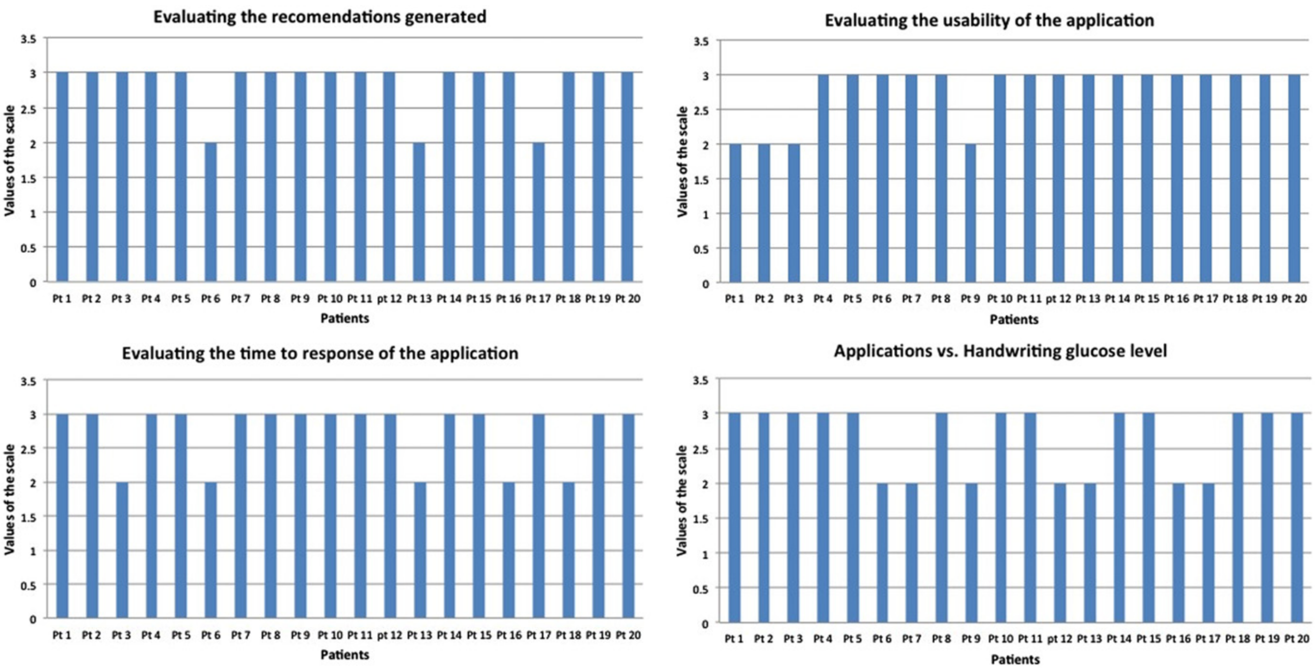

Fig. 8. Summarized results about the use of the applications to monitoring patients with diabetes.

- *Assessment of the application in comparison to handwriting the glucose levels*: patients with diabetes record their glucose measurements in a notebook. This allows the patient to have a constant control in the case of an emergency, and it helps the doctor to obtain information about the patient. We can check if the application has integrated the same functionalities as handwriting the glucose level. Seven patients thought the application has a better function than handwriting their glucose level, while three patients said that the application has the same functions as the notebook.

In terms of ease of use, patients feel that the application is easy to use because it only requires simple, short interactions, and the application responds almost automatically.

5.2. Using a software engineering method: ALMA

The developed application can be specialized for different diseases (diabetes, blood pressure, temperature) using several biometric devices (glucometer, tensiometer, thermometer) as it is able to adapt its functionality in the form of interconnected modules for multiple configurations. The overall design of the application has been adapted in such a way that much of it can be reused when performing future work based on the design and initial development. Thus, several applications that rely on the architecture have been developed to evaluate their validity for mobile monitoring of patients.

After using the application, we have implemented an evaluation of the software architecture's quality based on some methods recognized by the scientific community that facilitate the evaluation of the developed prototypes. Each method is evaluated as a specific aspect according to the final requirements of the application. Evaluation of software architectures is an open, continually expanding field and non-quantitative or objective methods currently exist. Despite containing a subjective factor, some selected methods have had a remarkable impact and acceptance in the scientific community, and for this reason, they have been selected to evaluate this application.

There are many aspects that can be evaluated. However, for this paper, we are interested in the following. First, facilitating modification is one of the most important aspects of the application, and the application should evolve over time to ensure compliance with the goals and objectives for which it was developed. The second is to evaluate the performance of the application based on the medical follow-up of patients. It must provide timely responses, and their performance must be as efficient as possible. We are also interested in evaluating the architecture's usability. We would also like to take into account the time at which the application development began in relation to the usability for the programmer, i.e., a developed application may be used by patients of any age range; therefore, the goal is to offer an easy-to-use and easy-to-understand environment.

Table 2
Factors that are amenable to modification in the application.

Component	Relation between components	Weight
Patient profile	ModuleDefinition, self-control and measuring	3
Module definition	PatientProfile and measuring	4
Self-control	PatientProfile, measuring and ModuleDefinition	2
Measuring	PatientProfile, ModuleDefinition, self-control and communication structure	5
Communication structure	Measuring and PatientProfile	1

The ALMA method is a method aimed at targets, which provides three types of goals: to predict the cost of maintenance, to assess risks and select from a set of architectures, and to evaluate them. ALMA has four steps to perform an analysis of an application:

- Set goal: determine the aim of the analysis.
- Software architecture description: provide a description of the most important parts of the application.
- Elicit scenarios: select the set of relevant scenarios.
- Evaluation scenarios: determine the effect of the set of scenarios.

In Table 2, we have organized each element, the relationship with other elements within the application and the weight assigned according to their importance to the function of the final application.

The estimates were expressed as lines of code (LoC) and time (in seconds) in the final software architecture.

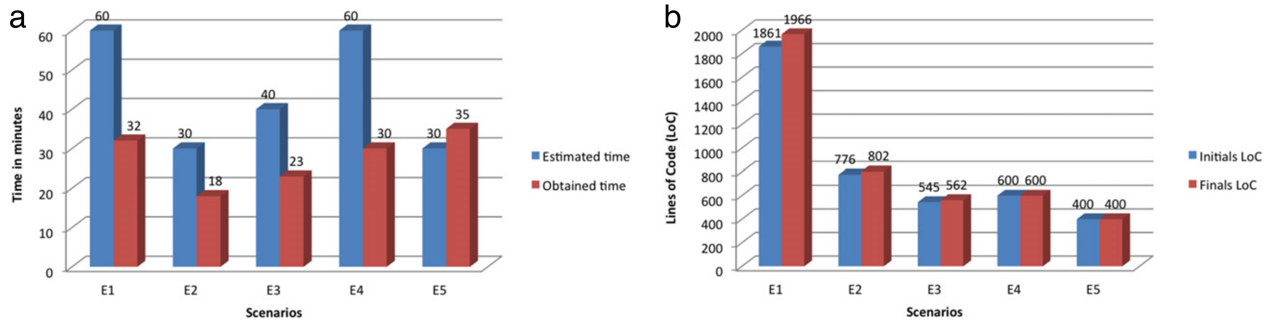

Fig. 9. Result obtained with ALMA method: (a) estimated time and (b) lines of code—LoC.

Table 3
Results of the assessment of each scenario based on the ALMA method.

Scenarios	Estimated time (min)	Obtained time (min)	Initial LoC	Finals LoC	Effort percentage
E1	60	32	∼1861 LoC	∼1966 LoC	53.3%
E2	30	18	∼776 LoC	∼802 LoC	60.0%
E3	40	23	∼545 LoC	∼562 LoC	57.5%
E4	60	30	∼600 LoC	∼600 LoC	50.0%
E5	30	35	∼400 LoC	∼400 LoC	116.7%

5.2.1. Elicit scenarios

The next step is eliciting a set of change scenarios. First, we selected possible stakeholders. The principal stakeholders selected in this evaluation are the architecture designers. This stakeholder is responsible for the development, implementation, and evaluation of the final software architecture. He or she evaluates the main aspects to be modified based on the method used. The elicitation technique used in this evaluation is bottom-up because the stakeholder has knowledge of the software in each scenario. We identified 15 change scenarios and presented five change scenarios for this paper:

- E1. Change the structure of the patient profile related to the module definition and measuring.
- E2. Add a new list of ten suggestions for a disease.
- E3. Change the visual format of the self-control module.
- E4. Add new types of disease with two measurement units without affecting the control module operation.
- E5. Add a new Bluetooth biometric device to replace the old device.

5.2.2. The probability that the scenarios will occur must be estimated

To determine the final results, we assign each scenario a weight that predicts the probability. We estimated two aspects in the scenarios: time to make the change and lines of code (LoC) that are needed for the change.

5.2.3. Interpretation of results: obtaining the conclusions based on the analysis scenarios

After eliciting the scenarios and their weights, we evaluated each change scenario with each stakeholder, applying the change to the known modifiability of each component.

In Table 3, we provide the results of evaluating each scenario in estimated time and the initial lines of code (LoC). After applying the evaluation, we obtained the time and line of code (LoC) for each scenario. We have also specified the percentage of effort to make the change, with respect to the maximum time estimated to complete it. Taking into account the fact that the estimated time (ET) corresponds to one hundred percent of estimated effort (PEst) and the obtained time (OT) corresponds to the percentage of effort achieved (PEsf), we estimate the effort as described below:

$$\mathrm{PEsf} = (\mathrm{OT} * \mathrm{PEst})/(\mathrm{ET}). \quad (1)$$

In Fig. 9(a), note that most changes required less time than we initially predicted. In scenario 2, the changes made to the final application are minimal, requiring little intervention in the developed final structure. Scenarios that needed more time were 1 and 3 (patient profile and graph of self-control, respectively). The profile change required more time because it is the module that customizes the features of the application, and it requires more detail and attention when making any changes. Stage 5 required more time than we estimate due to the biometrics. The architecture complies with the aspects of analysis of modifiability proposed by the method of assessment that we have used, in this case, the ALMA method. In addition, to evaluate the time it takes for a component of the application to be amended, the number of Lines of Code (LoC) that are affected and added to make the change are also evaluated. The graph of Fig. 9(b) shows the results of the assessment with regard to the initial number of LoC before applying the scenarios and the final number of LoC after the applying the scenario.

6. Discussion about the proposal developed

This paper presents an application to allow patient monitoring through mobile and biometrics devices. It uses MobiPattern to define the interface, layers to distribute the application to the mobile devices and server, and ontologies to define the knowledge. We designed a set of layers distributed in the three elements that interact with the final application: the mobile devices, biometrics devices, and central server. This distribution is performed to identify each element that interacts with the application, to identify where the application needs changes and to add new elements to the application.

Additionally, we defined ontologies. This design is important to understanding the complete information about the mobile monitoring process and to acquiring new information that helps generate recommendations. The ontologies define the data management and the relationships with the next element of the application, the MobiPattern. A MobiPattern is a schema that allows the definition and generation of each module and screen of the application. We discuss how the application allows the monitoring of many diseases (we evaluate the application in diabetes and blood pressure patients) with the interfaces generated based on MobiPatterns. For each disease, the application always has the same structure, but the functionality of each medical module depends of the specifications of the disease.

The application allows constant patient monitoring through biometrics and mobile devices for chronic diseases. We add new diseases to this application based on the ontologies defined in our research. The mobile monitoring application is developed based on the three software engineering aspects defined in this paper. These elements contribute to the developed application and offer additional values to be implemented in other environments—i.e., to develop applications considering other diseases based on the ones proposed. Our application offers significant benefits in the daily activities of patients, such as real-time monitoring, adding a new disease, and generating suggestions and education modules according to the last measurement obtained. These activities have specific requirements to evaluate the effective functionality of the application. The following aspects are very important for us.

6.1. Transparency

The patient must take measurements using the biometric device that are then read by the mobile device. The mobile device captures the vital signs, analyzes them, and then compares their measurements with measurement ranges established for the patient's disease. Once the tests are read and interpreted, they are transmitted by the control modules embedded in the mobile device. All this activity is transparent to the patient. This application is easy to use. The patient only needs to use the mobile and biometric devices.

6.2. Vital sign measurement and interpretation

With the development application, vital signs, e.g., glucose level, blood pressure, and temperature, can be measured and transmitted via Bluetooth technology between the mobile and biometric devices. If the biometric device does not have Bluetooth technology, the patient can enter the vital sign measurements manually.

6.3. Activity control

The control of activities includes those physical activities recommended by the doctor, which are detailed. These activities allow us to adjust future definitions of modules used for patient monitoring according to a schedule of the patient's activities. The system learns automatically based on the patient's behavior during an activity, establishing a relationship between measurements, trends, and performance of the activity. The patient is also educated based on the information provided during the treatment. In the recommendation system, the application offers the patient recommendations based on particular activities performed or variations in the measurements taken at a given moment. The recommendations may include suggestions related to diet, the use of a specific medical treatments, and others.

6.4. Self-control

Self-control provides information from a patient's history of actions and trends. This is stored in individual profiles. Users can view information through charts and tables about the last measurement. The data regarding the glucose levels are stored in the profile as a permanent record. This module accesses this information and uses it to display charts and statistics about the monitored disease.

6.5. Privacy

Medical and personal data are protected with different levels of security based on an individual's role or relationship with the patient (e.g., health care providers, medical specialists, relatives, etc.). The system will be evaluated based on the degree to which these technologies help people in their daily lives at home or in assisted living facilities and their willingness to use these technologies. We started by selecting a group of five patients with diabetes. These patients used the application for two days, and from these results, we can determine whether our application can provide a good solution in living assistance.

In the introduction, we explained that this application is a multi-mobile technology. In this paper, we developed the application in the first scenario of a patient with diabetes. It is very important to evaluate this architecture in other medical situations. For a new disease, the architecture would have the same functional elements defined in Section 2. The parameters to change will be the number of units of measurements to capture. That is, a patient with diabetes only has a single measure to obtain; in this case, the application generated was based on the patterns that were developed. If the application uses two units of measurement, for example, blood pressure, the architecture identifies this parameter and readjusts the MeasureMobiPattern in such a way that it captures the two units of measurement of the biometric device. All the functional behaviors of the application remain the same and interact with the new information ontologies implemented for the new disease. In this case, the application does not depend on a specific disease. Instead, the disease depends on the core of the application, using each MobiPattern to automatically develop each module.

The architecture would need to be redesigned if a patient needs to generate an application for a disease with more than two units of measurement. A weakness of our application is that it has been implemented only to generate applications for Android-based devices. If patients want to use other platforms, the application should be migrated completely. We are sure that the use of this application in other scenarios would be very important to the improvement of our research.

7. Conclusions

This application provides continuous patient monitoring to improve the communication between patients and doctors. The application generates individual patients' profiles, self-control and education modules for their chronic diseases. This has been developed for the mobile monitoring of patients via biometric devices and a mobile phone.

An ontologies classification has been created. These elements are the patient's profiles, where the personal details of the patient are specified, and the definition of the modules for the mobile phone as well as for the doctor. A diet definition, medical treatments, care activities, and the patient profile are some of the aspects that have been modeled in the ontologies.

The use of mobile monitoring applications for patients with chronic diseases – in our case patients with diabetes – is very necessary to monitor patients and facilitate their daily activities. This application provides scalability for use in different mobile devices and with a variety of diseases.

We are confident that good communication will help doctors and patients make better decisions in different situations and conditions.

Our contribution is marked in two specific areas. The first is the use of a mobile monitoring solution that allows the monitoring of patients at any time or place using a mobile and a biometric device. The second is the promotion of the easy day-by-day life for people who need assistance. It is a very intuitive and transparent application for the user with real-time functionality.

We are working on developing the application for other mobile devices, provided they have sufficient capabilities to run the application.

Acknowledgments

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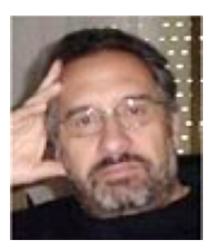
Vladimir Villarreal, Graduated in Programming and System Analysis Technologies from Technological University of Panama (2002) and received Ph.D. from the Castilla-La Mancha University. He is a full-time professor at the same University. He is a member of Modelling Ambient Intelligence Research Group (MAmI). He is an author of several articles on Ambient Assisted Living, eHealth and Ubiquitous Computing.

Jesus Fontecha, Graduated in Computer Engineering (2008) and is a Ph.D. Candidate for the Castilla-La Mancha University. He is a full-time professor at the same University. He is a member of Modelling Ambient Intelligence Research Group (MAmI).

Ramón Hervás, Computer Science Engineer (2004) and Ph.D. for the Castilla-La Mancha University and he is an associate professor at the same University. His research interests include the Visualization of Information, Shaped of Context and Ontologies inside of Ambient Intelligence area. He has taken part in several research projects like CICYT MOSAIC Learning Project and SERVIDOR Project about m-learning, and the PROFIT, ALIADO and AmITACA Project applying beginning of the ambient intelligence to the Medical Context and leisure respectively.



José Bravo, Graduated in Physics from the Complutensian University of Madrid and Ph.D. in Industrial Engineering for the UNED. He is the Modelling Ambient Intelligence (MAmI) Research Group Director in the Castilla-La Mancha University. He is a promoter of initiatives on AmI like it there demonstrates the organization of several editions of the Symposium on Ubiquitous Computation and Environmental Intelligence (UCAmI) and International Workshop in Ambient Assisted Living (IWAAL). His group develops several projects in this area and is specializing in AmI and Health. He is an IEEE Senior Member.