Introduction

Currently heart failure is one of the main causes of disability and mortality in western countries. Due to the severity of this illness, as well as the number of clinical interventions necessary (particularly the high frequency of hospitalizations), heart failure comprises a major health expense. Specifically, it accounts for 5% of total hospitalization costs and 1-2% of total healthcare expenses [1]. Better therapies for myocardial infarction (MI) and an increasingly older population will eventually result in even larger numbers of patients with chronic heart failure (CHF). Obviously, the increase of patients will necessitate new interventions and support models, including multi-pharmacological prescriptions and close monitoring of clinical conditions over extended periods. Because a patient’s psychological condition can influence the course of cardiac disease and therapeutic compliance, the interventions also will need to monitor behavioural and life-style modifications, requiring extensive education efforts, both for the patients themselves and for their families.

Disease Management (DM) interventions have been extensively tested and found to be more effective than traditional interventions in improving the prognosis of patients with diabetes, congestive heart failure (CHF) and myocardial infarction (MI). DM consists of a system of coordinated healthcare interventions and patient communication for populations with a high incidence of medical conditions involving patient self-care. A recent meta-analysis that included 102 studies (10 of which were conducted on CHF patients, with a total of 2000 subjects and follow-ups ranging from three months to one year) evaluated the impact of DM as part of a multi-disciplinary approach for treating chronic conditions [2-29]. Results showed that, for the management of CHF, the most common interventions were [2]:

• training patients before dismissal on activities that were to be continued at home (pharmacological therapy, diet, exercise);
• telephone contacts;
• home-based interventions (HBI) involving GP or a trained nurse.
Results confirmed that an integrated management (including multifunction center activities and continuous monitoring) were the most effective interventions. These findings are in marked contrast to the high noncompliance to therapy usually observed in CHF patients after hospital dismissal, a situation that leads to instabilization and a worsening of the clinical condition.

Several studies have focused on the characteristics associated with the likelihood of instabilization. In an Italian sample, for example, it was shown that 46% of CHF and left ventricular dysfunction patients that had been hospitalized for an acute event were re-hospitalized within a year, and that 50% of these re-hospitalizations were due to the lack of adherence to therapy. Moreover, 80% of “unstable” subjects are re-hospitalized within three months from dismissal. Thus, it is clear that patient monitoring during this critical period may have a crucial impact on stability.

New wireless technologies represent a very important resource for managing the complex activities required by DM interventions. There is evidence that some DM programs may reduce disease-associated costs up to 30-40%, mainly in terms of fewer re-hospitalizations, which makes investments in technologically advanced DM interventions extremely worthwhile. New technologies allow easier and better data management. Information can be more easily accessed and distributed, thus improving the productivity-effectiveness relationship. Moreover, the availability of a large amount of data allows advanced statistical analysis (such as Artificial Neural Networks), a capability that, eventually, will lead to better understanding of the variables involved in disease prognosis and even better assistance models.

Up to now, no studies focusing on the integrated management of CHF patients through the use of advanced technologies have been conducted in Italy. The ICAROS (Innovative architecture based on wireless and intelligent technology for the cardiological and psychological care of heARt disOrderS)-FIRB project has developed a home-based telecare system for CHD patients, using advanced Internet, as well as emerging wireless and mobile, technologies.

The ICAROS - FIRB Project

The ICAROS project was sponsored by the Italian Ministry of University and Scientific Research, with a FIRB (Italian Funds for Base Research) – New Medical Engineering 2001, in co-operation with the following research units:

a) Department of Medicine, Prevention and Applied Biotechnologies of Milano-Bicocca University;
b) Department of Psychology of Università Cattolica del Sacro Cuore, Milan;
c) Istituto Auxologico Italiano.

The technological partner was Mobile Medical Technologies (MMT)¹, a soci-

¹ Mobile Medical Technologies s.r.l. (http://www.m-mt.net, email info@m-mt.net)
ety that offers innovative services in the field of disease management through proprietary Internet and wireless technologies. Not only did MMT provide the technology for wireless clinical monitoring, therapy and acute episode management, they also served as a consultant for developing the project’s protocol, implementing the project, and providing the logistic management, training and first-level support needed by the clinical staff.

The project was awarded the CNR (National Research Center) Special Prize for the 6th edition of FORUM P.A. Sanità, issued by the Italian Ministry of Health and other organizations. The FORUM P.A. SANITÀ Prize acknowledges public healthcare organizations who take advantage of Information & Communication Technology (ICT) in creating more efficient healthcare, particularly in terms of managing clinical data as a means of controlling healthcare costs. The CNR special prize was awarded to the ICAROS Project because of its use of ICT in the active prevention of chronic diseases through the administration of complex healthcare programs.

To date, the ICAROS project has been presented at a number of national and international meetings, such as:
- 2nd international e-GOVERNMENT & e-HEALTH conference and exhibition, held in Milan, Italy in July 2005;
- Critical Issues in eHealth Research Conference, held in Washington D.C. (USA) in June 2005;
- Other meetings and exhibits sponsored by the Ministry for Innovation and Technologies.

The project is also a pilot study for a larger investigation, sponsored by a European Commission grant, to be conducted by an international group consisting of researchers from Italian, Spanish and Greek universities and institutions. The larger European project is intended to investigate a universal service for monitoring and managing the cardiac and psychological health of European cardiac patients, and it will include e-Health and advanced mobile services designed to help overcome existing financial and social barriers related to launching such a service at a trans-European level. The project will use trans-European telecommunication network-based applications, exploiting the potential of broadband, advanced mobile networks and multiple platforms in areas of public interest. Its methodology will incorporate the advantages of open standards, interoperability and trusted, secure frameworks. The project will also foster the modernization of related existing public services (eEurope 2005).

As noted by the World Health Organization (WHO), the “…majority of CVDs are preventable and controllable. However, millions are dying in middle age. Activities to prevent this should include strengthening collaborative work with various organizations and community groups involved in this area, promoting the formation of coalitions between key stakeholders, and developing initiatives based on best practices by supporting information exchange among countries.” FOR ALL, comprised of groups from several European
nations dedicated to enhancing the efforts of present cardiologic disease management and psychosocial support services, is strongly positioned to accomplish this goal. FOR ALL is backed by the existing service from the Istituto Auxologico of Milan, which will be adapted and customized for the market validation phase at the trans-European level, supporting exchange of best practices among European countries. Partners in the project include APIF Moviquity S.A. (Spain); ISTITUTO AUXOLOGICO ITALIANO (Italy); DIANOEMA S.p.A (Italy); ALTEC Information and Communication Systems S.A. (Greece); ATTIKON University Hospital (Greece); and Hospital de Terrassa (CST) (Spain).

The ICAROS study uses a randomized design with parallel groups. Patients are enrolled in the study at three Italian research centers and monitored for one year in order to compare the evolution of clinical and functional conditions between the Integrated Management (IntM) group \( (n = 30) \) and the Conventional Management (CM) group \( (n = 30) \). Upon dismissal from the hospital, patients in the CM group will receive treatment supervised by their GP, and they will undergo clinical check-ups and psychological visits every three months at the HF center. Patients in the IntM group will be monitored daily through a PDA, and they, also, will undergo quarterly visits at the HF center.

The study sample consists of CHF hospitalized systolic dysfunction patients with an ejection fraction lower than 40%, in III-IV NYHA class at hospitalization and with a previous history of HF. In addition, the patients are required to have had one or more hospitalizations during the previous 12 months, or a peripheric edema at dismissal.

The study aims are to:

- Reduce disease progression in terms of clinical events.
- Improve patients’ clinical conditions and functional states.
- Monitor psychological state and identify psychological conditions associated with cardiovascular risk in a timely manner.
- Improve CHD patients’ quality of life.
- Optimize and personalize therapy, while achieving better cost/benefits efficiency.
- Improve the efficacy and timeliness of interpreting and identifying important clinical signs of acute events that require costly intervention.
- Improve compliance as well as the identification of non-compliant patients.

## System Description

The core aspect of the DM model developed for ICAROS-FIRB is therapeutic continuity, i.e., improving the patients’ feeling of being cared for by medical staff, while being completely free to move about and go anywhere. Mature Internet technologies and emerging multi-channel and wireless technologies allow patients to maintain the interactions and communications established with medical staff during hospitalization.
Overall System Architecture

The service, Mobile Medical Technologies, provided to the ICAROS-FIRB Project, is headed by the Istituto Auxologico Italiano and Università Cattolica Sacro Cuore, and aimed at improving both the effectiveness and efficiency of chronic disease management. By providing a continuous interaction between patient and doctor, based on new technologies (Internet, mobile, wireless), Mobile Medical Technologies provides continuous monitoring of key medical parameters and psychological conditions using an Internet-based software application, which serves as both a medical aid and a psychological care and diagnostic tool.

The front-end designed for the patient provides a portable solution for the day-to-day management of the patient's healthcare needs, while the clinical front-end provides both medical and psychological web-based software designed to facilitate care-related decisions (Figure 1).

The data repository and the core applications are hosted at a remote server farm. The patient front-end consists of a health organiser resident on the patient's PDA or smartphone. This system is designed to help individuals better manage their lifestyle, medical care and drug intake, to track treatment progress, and to enter information about their therapy by inputting actions performed (e.g., drug intake, exercise, questionnaires). All information collected is automatically report-

![Fig. 1. Remote monitoring system](image-url)
Part II - Psychological Treatments in Cardiac Rehabilitation

ed through synchronisation/downloading to their healthcare professional. Each action that the patient performs and enters in the PDA/smartphone is time stamped, which can be viewed by the clinician. Patients are also able to receive printed information regarding their therapies and medical conditions, and to schedule and organise followup visits. Questionnaires are submitted periodically in order to monitor and evaluate psychological conditions. The device used by the patient provides the all information needed for managing the disease, and it allows data input through system prompts. Electronic patient records are available to nurses and/or physicians through a desktop Internet browser. At the initial visit, the physician classifies the patient on the basis of his or her clinical profile and the key variables to be continuously monitored. The physician then initialises the system and loads the key parameters and the therapy into the central repository.

The back end consists of a database and diagnostic software for analysing and comparing data sent by the patient. The collected data will also become the basis for building an integrated, proprietary statistical system that interprets the patient’s key clinical symptoms and proposes adjustments to drug intake, exercise and diet. Based on key clinical parameters, the software is designed to be continuously updated with the latest disease-specific information using an evidence-based medical approach and optimal therapeutic targets.

Patient information is entered into the system’s medical record database either through synchronisation of the patient’s PDA or through a real-time connection with the server. Once the patient has synchronised the device, the doctor receives the information sorted by priority/urgency of each case, and, as appropriate, he or she can update therapy or send messages to the patient (e.g., to schedule visits, warn patients of high-risk behaviours, etc.). Automatic control of adherence to physician instruction (compliance) through analysis of actual data is enabled. Identification by the doctor of out of range parameters/behaviours through automatic data verification will activate an alarm system that facilitates specific action. As soon as the synchronisation takes place, the patient receives new instructions from the system.

The system integrates and stores all clinical data, to provide doctors with a continuous stream of both current and historic information. The objective is to support the doctor in interpreting data and managing the patient. At a given time, for example, the physician may receive a list of priority patients alerting the him or her to the most urgent cases; a list of potential treatment options for a specific patient; charts on key clinical data and forecasts; and information pertaining to patient compliance with respect to diet, physical exercise and drug consumption. Information on when each action was performed, and on medical treatment, safety and tolerability, is also provided.

The ICAROS FIRB Project services – headed by the Istituto Auxologico Italiano – are supplied via a remote software custom application on a remote computer server hosted in a server farm that runs a Java application server and a relational database; the application (an enhanced Electronic Patient Record) is accessible via Internet through a standard browser, Java Runtime Environment enabled, in a secure mode (HTTPS).
The overall architecture is protected by a firewall; and the server farm service provides standard features, including SNMP, data back-up, antivirus, uninterruptible power supply, intrusion detection and so on; a service level agreement for maintenance and recovery had been signed.

Help desk operators, nurses, physicians and psychologists are able to interact with the application through Desktop clients; the availability of broadband connections (xDSL/LAN) in the clinical center is required to obtain high performances; the browser uses a Java runtime environment (Java Applet technologies enabled) in order to reach platform independence.

Every desktop client is provided with PDA synchronisation software, making it possible to set up and manage the handheld devices before delivering them to the patients. Mobile devices access the Internet and then go to the application server through a GPRS/EDGE connection supplied by a national Mobile TelCo Operator, as well as by the standard mobile Internet Gateway. The PDA device runs a Windows Mobile 2003 custom application. Data are exchanged between PDAs and the Application Server using a compress XML file format, lowering costs associated with data transmission.

The Electronic Patient Record application. The system adopted for the ICAROS FIRB project is build upon an existing clinical software layer: an Electronic Patient Record (EPR), which is a web-based application developed with Java technologies. This system runs on an Oracle database, in contrast to the mobile application, developed with MSFT Net technologies. The interface between the two layers is managed by a Java servlet and an XML file. Specifically, the ICAROS-FIRB project runs on a customized version of eHealth®.Solutions from GMD mbh (Berlin, Germany), controlled by DN Group (Bologna, Italy); and the custom features consist of proprietary solutions created and owned by Mobile Medical Technologies.

The current release of eHealth®.Solutions runs on a Microsoft Windows Server platform, and the application server is Tomcat. The reason for adopting an established electronic patient record software framework comes from both the wide diffusion of the software in clinical organizations and the opportunity to rapidly deploy new functionalities for the mobile wireless front end, thanks to the embedded developer tools. Main eHealth® solutions offer further advantages in terms of the high reliability of the EPR, the ability of clinic organizations located in different regions to access the EPR over the Internet, the availability of a document repository for uploading/downloading information, a high degree of usability and data security (involving encryption and authentication, compatibility with both standard HIPAA2 and stricter Italian privacy laws).

All the EPR and mobile tools the project uses are considered current state-of-the-art technologies.

The application can be run from the ICT department inside the clinical center or from the remote server, without any difference in performance.

2 HIPAA (http://www.cms.hhs.gov/hipaa/) Health Insurance Portability and Accountability Act
**Handheld device application.** The handheld section of the ICAROS–FIRB project is developed with MSFT .Net Windows Mobile 2003 Second Edition, Phone Enabled. The device used by patients:

1. provides all the information necessary for data management (drug intake, diet, exercise, registration parameters, check-up visits); and
2. allows data input when required by the system.

The Windows Mobile devices are equipped with a standard GSM/GPRS Sim Card; some limitation in the functionalities have been activated (only preset telephone numbers are reachable); ICAROS FIRB PDAs could be used also as regular GSM mobile phones and to transmit ECG in acoustic connection thought special purpose devices.

The application serves as a diary for the collection of clinical and vital data, and completed psychological questionnaires. It also serves as a reminder to facilitate adherence to therapy. Collected data can be either locally stored (in the memory of the PDA) or sent to the central repository.

## Medical and Psychological Monitoring

### Assessment

At intake, physicians classify patients based upon clinical profile, and then they initialise the system with the main variables to be monitored (such as blood pressure) and the pharmacological treatment. This initial phase also includes a psychological assessment, which may occur during either hospitalization or day-hospital rehabilitation. Patients are administered a clinical interview regarding personal history, habits and their social network, and they later complete self-report questionnaires. The psychological assessment process usually occurs over a period of two to three one-hour sessions. The psychological constructs investigated are anxiety, depression, quality of life perception, illness perception and behaviour, and anger. Personality traits are investigated as well, with an emphasis on evaluating Type A and D behaviour patterns (for further information regarding personality traits, refer to chapter XX, “Type A, Type D, Anger-Prone Behaviour and Risk of Relapse in CHD Patients”). After completing the assessment process, the psychologist at the HF centre compiles a profile, focussed on whether psychological risk factors have emerged.

### Patient’s Front-End

On a daily basis, patients are required to enter vital parameters on the PDA, including weight, heart rate, diastolic and systolic pressure, liquid intake and diuresis. Patients benefit from an enlarged keyboard that shows up on the PDA display when they need to input numbers or letters. A range-control system prevents the input of improbable data, thus avoiding unnecessary alerts. Figure 2 shows the display for entering vital parameters, as well as the display that serves
as a therapy reminder. PDA screenshots are in Italian, as, thus far, the project has been implemented using an Italian sample.

![Fig. 2. PDA displays for vital parameters collection and pharmacological therapy administration](image)

Patient’s front-end presents, at regular intervals, questionnaires aimed to evaluate depression, anxiety and perception of quality of life. Data synchronization occurs in the same way as it does for medical data. Table 1 lists administered questionnaires, including timing, psychological constructs investigated, and response modality.

<table>
<thead>
<tr>
<th>Psychological Construct</th>
<th>STAI-short form</th>
<th>PGWB-6</th>
<th>PHQ-9</th>
<th>GENERAL - B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration Frequency</td>
<td>Weekly</td>
<td>Monthly</td>
<td>Bi-weekly</td>
<td>Weekly</td>
</tr>
<tr>
<td>Type of answer</td>
<td>Multiple choice</td>
<td>Multiple choice</td>
<td>Visual Analogic scale</td>
<td>Visual Analogic scale</td>
</tr>
</tbody>
</table>
**Anxiety** is measured weekly using a short form of Spielberger’s State Trait Anxiety Inventory (STAI -6). Six items were selected by the authors from the state scale, which measures anxiety in terms of feelings of insecurity and powerlessness in front of a perceived threat [30, 31].

**Depression** is evaluated using the Patient Health Questionnaire (PHQ-9). The PHQ is frequently used to diagnose depressive conditions in medical settings. It consists of nine items for evaluating DSM-IV criteria for major depression. Two studies, one involving 3000 patients with a number of medical problems, and the other, also conducted on 3000 patients at gynecological-obstetric clinics, show the instrument’s diagnostic value in relation to measures comprising a larger number of items. Moreover, PHQ-9 not only helps to establish the presence of a depressive condition, but also provides an index of severity of depressive symptomatology [32-34].

**Perception of Quality of Life** is measured monthly through PGWB-6, the short form of a standardized self-report instrument developed by Dupuy (Perception of General Well-Being Inventory, or PGWBI) [35-37]. The questionnaire is composed of six sub-scales (anxiety, depression, positivity and well-being, self-control, general health and vitality). The 22-item scale has high internal consistency (Cronbach alpha 0.90-0.94) and has been used in a number of samples varying greatly in terms of socio-demographic variables, health conditions and age. The PGWB-6 has also been used to evaluate changes in subjective well-being after psychotherapy. A study conducted by Università Cattolica of Milan, in cooperation with Bracco, compared the original and the short version, and found a high statistically significant correlation between the two ($r = 0.887, p<.0001$). Finally, a multi-trait analysis showed that Cronbach alpha was .93 for the standard scale and .92 for the short version. Hence, reliability and validity data strongly support the implementation of PGWB-6, which has thus far proved a convenient instrument for monitoring quality of life.

**Psychological General Screening B-PGS**: Patients also receive a weekly questionnaire used to evaluate psychological well-being (for example, “I feel anxious”). Patients are asked to state what an acceptable condition would be (“Normal/acceptable anxiety for me should be...”). This questionnaire was developed by the group of psychologists involved in the project, and one of the study’s aims is to validate it.

Questionnaires can be multiple-choice (an example is shown in Figure 3), or Visual Analogic Scales (VASs) (an example is shown in Figure 4). All measures, except for GSB, use normal population indexes as a comparison.

VASs (Figure 4) provide patients with a response system that is more perceptively immediate, making it easier for them to identify the degree of a particular emotional state. Moreover, numeric data expressed on a continuous scale is without doubt more precise, compared with scales involving the forced choice of a specific number.
Windows Mobile 2003 allows the use of Landscape mode to increase the horizontal scale dimensions and hence questionnaire sensitivity.

**Fig. 3.** Display for one of PGWB-6’s items

**Fig. 4.** Visual Analogic Scale for one of STAI-6’s items
Staff Eront-End

Medical and psychological visits at the CHF centre are conducted at intake and every three months; physicians may also perform unplanned visits based upon information collected through the system.

Patients are enrolled and randomly assigned to the treatment or control group. When registering the patient into the system, the relevant data are collected and input, including demographic data and information related to mobile devices and SIM card.

As soon as the patient synchronizes the device, the healthcare staff receives information organized by priority/urgency. The system allows medical and psychological staff to identify irregular parameters or behaviours through an automatic verification routine that activates an alert system to facilitate appropriate action. Based upon the information collected, healthcare staff may decide to contact the patient, modify therapy, send the patient a text message or plan a visit. The patient will receive the feedback as soon as he/she performs the next synchronization.

An automatic control system is activated in order to check treatment compliance through analysis of relevant data.

The system holds and integrates all medical and psychological data, and provides health and psychological care staff with a continuous stream of updated and historic information. The aim is to provide an optimal method for interpreting clinical data and managing patients.

Collected data include:
- List of patients with active alerts.
- List of different options for treatment of a specific patient.
- Graphs reporting important data related to clinical picture and development of the condition.
- Information regarding patient compliance, including diet, exercise, drugs intake.
- Information regarding security and tolerance to pharmacological treatment.
- Psychological questionnaire outcomes.

Figure 5 shows the system architecture that allows for the communication of patient information, as well as medical staff-patient exchanges.
Psychologist’s Desktop. The answers to self-report questionnaires provided by patients through the PDA are sent directly to the database, along with data regarding vital parameters. The system automatically scores the answers. Total scores for anxiety and depression scales are transformed into percentiles and rated according to clinical significance as follows:
- scores under the 90th percentile are considered normal and reported in a green-coloured cell;
- scores between the 90th and 95th percentile are considered moderate and reported in a yellow-coloured cell; and
- scores corresponding to the 95th percentile or higher are the labeled “High” and reported in a red-coloured cell.

Figures 6 and 7 show displays that track the clinical history of two patients as far as anxiety and depression are concerned. The relevant information was transmitted to the system through PDA questionnaires the patients completed. Data for each questionnaire, including numerical index and qualitative label, are recorded in a dedicated cartel, from most to least recent observation, thus showing the course of patient’s condition over time for a specific psychological dimension.
Fig. 6. Database screenshot: depression levels reported by one patient

Fig. 7. Database screenshot: anxiety levels reported by one patient
Figure 8 shows the protocol to be followed by the psychologist in charge, based upon alerts regarding the patient’s anxiety and depression levels.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Observation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>Normal Level</td>
<td>No action to be performed</td>
</tr>
<tr>
<td></td>
<td>Moderate Level</td>
<td>Verify the presence of two consecutive alerts of moderate level. If trend is confirmed, call patient for psychological inquiry</td>
</tr>
<tr>
<td></td>
<td>High Level</td>
<td>Call patient and plan visit with psychologist. Cardiologist should be alerted as well</td>
</tr>
<tr>
<td>Depression</td>
<td>Normal Level</td>
<td>No action to be performed</td>
</tr>
<tr>
<td></td>
<td>Moderate Level</td>
<td>Call patient to verify condition. In case depressive symptomatology is confirmed, plan a visit with psychologist</td>
</tr>
<tr>
<td></td>
<td>High Level</td>
<td>Call patient and plan visit with psychologist. Cardiologist should be alerted as well</td>
</tr>
</tbody>
</table>

Fig. 8. Psychological reports and types of intervention for anxiety and depressive condition alerts

Medical Staff’s Desktop. The visit management part is composed of eight different data files: Anamnesis, Pharmacological Anamnesis, Objective Examination, Neuro-hormonal, ECG, Chest RX, Ultrasound and Ergo Test. Other visits, including psychological visits, can be stored in a database of electronic documents (text documents, letters, computation sheets, imaging files or scanned documents) as attachments. The visit management section is the same for both treatment and control groups. A separate panel is provided for monitoring each patient in the Integrated Management group. This panel allows access to a number of data files that help control each patient’s condition and eventually modify the intervention.

The Episode sheet briefly summarizes the information on the registration card for each patient. The Diary sheet is a sort of planner that helps staff to register future events, such as visits or telephone calls. The Active Problems sheet is extremely important, as it records whether pharmacological prescriptions have been regularly followed and whether vital parameters fall into the acceptable
range. From an IT perspective, this sheet is log-file already analyzed from a medical standpoint, reporting information that patients have sent following the PDA-central system synchronization. All clinical data received from the PDA feed appropriate algorithms capable of generating alerts. Figures 9 and 10 show examples of database sheets that report alerts.

![Fig. 9. Patients with alerts](image)

![Fig. 10. Alerts specification for a specific patient](image)

The Current Therapy and Questionnaires sheets allow for the management, respectively, of pharmacological therapy and psychological questionnaires, with specific interfaces for administering or modifying therapies and questionnaires as far as parameters such as quantity, timing and so forth, are concerned.

The SBP-B (related to PGWB-6 instrument), Anxiety, Depression and General B sheets report numerical indices and generate graphical evaluations of responses to individual questionnaires.

The PDA Data sheet reports all medical values collected from patients and is referred to for vital parameters details when the Active Problems sheets generate a warning message.

The last two sheets, Adverse Events and End Points, are used to record cardiac events that occur to patients during the one-year monitoring period; these sheets also contain information on why patients might have left the study.
Final considerations

Today, electronic patient record technology is widely used in healthcare organizations even if not all the capabilities are exploited. The interest in, and diffusion of, handheld wireless technologies have increased dramatically thanks to technological improvements, especially in terms of and reliability, and to the integration of handheld wireless technology with mobile telephony, Bluetooth and wi-fi. Until now, these technologies were used primarily by sales organizations to automate the operations of their sales forces. The ICAROS Project is solid evidence that the innovation of a complex information system need not result in resistance from staff not trained in information technology methodologies.

In clinical institutions, particularly those that care for elderly CHF patients, the real challenge is the ability to develop very simple systems and devices. Another critical issue involves the training of both system operators and patients. It is essential that this training be provided by qualified professionals, in a step-by-step manner. Although the adoption of a new technology always represents a challenge, we have witnessed the ease with which this process can occur, as demonstrated by the wide diffusion of mobile phones (whose complexity is much greater than that of the ICAROS-provided device).

In the ICAROS project, in-hospital patient training was assigned a key role; sometimes, depending on circumstances, training was also extended to the patient’s family. The role of nurses was found to be very important. When they are skilled at information technology (office procedures, data entry) and call-center procedures, nurses are able to solve minor problems in managing the telecare, such as reminding patients to recharge PDA batteries.

The usability of remote monitoring systems obviously involves the ability to simplify data acquisition processes. Technologies capable to acquiring multiple patient inputs through a set of wearable sensors and peripheral special purpose devices located in the patient’s home will likely, in the near future, be routine. Also, the continued efforts of computer professionals will result in increased advances in the simplification of the protocol languages used to communicate between computers, computerized devices, and patients and nurses and/or physicians.

At the same time, all the regulations related to more “intrusive” patient management systems will be consolidated to guarantee privacy of the target of care and to improve the confidence in making appropriate use of the increasing amount of data to be analysed.

In a time when population aging is one of most important issues to be solved by welfare systems, it is fundamental to find cost-effective intervention plans. IT systems have proven their usefulness in terms of economic benefits in a number of different fields. Yet, it is not always easy for users to understand related benefits; this becomes even more pronounced for DM interventions, due to their complexity. It is therefore necessary to progressively introduce DM programs, in a process that directly involves patients and clinicians. Ultimately, this will result in a continuity of care not currently provided. For patients, knowing that
they are monitored on a daily basis by the clinical center is both comforting and motivating at the same time, thus impacting clinical adherence. It is plausible that using the PDA helps establishing trust between patients and clinical staff. At the same time, patients feel more autonomous in managing their therapy and daily activities, as the PDA also serves as a self-monitoring instrument that increases patient responsibility with respect to pharmacological treatment, subjective psychological well-being and risk factors directly and indirectly related to disease prognosis.

Preliminary information about the ICAROS-FIRB project supports the feasibility of the implementation of DM on a large scale, despite the acknowledged complexity and challenges that are involved.

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CEQ1: Shouldn’t this be referenced?  
CEQ2: Please note chapter to be supplied  
CEQ3: Information to be included in table below?  
CEQ4: Correct initial?  
CEQ5: Footnote needs to be translated and incorporated into document