

***A TEN YEARS EXPERIENCE OF THE “FONDAZIONE MAUGERI”  
NETWORK FOR CARDIOVASCULAR DISEASES***

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## **Summary**

The use of telemedicine appears particularly promising in cardiovascular disease, because the cost/effectiveness ratio of an early, tailored intervention, in terms of life-saving and functional recovery is demonstrated. Boario Home Care project was born in 1998, with the aim of applying the new models of disease management and the new technology on the territory. In the first phase the project was to realize a telematic network for the General Practitioners in a mountain territory; In the second phase the project was extended to the regional and then national territory and the number of enrolled General Practitioners increased. In the third phase, that is nowadays, the structure of the Service Center has been implemented with new broad band technologies (HDLS) and with an innovative teleworking model has been adopted for the professional figures involved. Different types of services are now available: multispecialty second opinion for General Practitioners, Home Telenursing for chronic patients, Home Telerehabilitation, Telediagnosis for palpitations and Call Center Services for hospitals.

In conclusion, Boario Home Care project has reached its maturity and many results even if we can consider them preliminary in the field of Telemedicine. Boario Home Care project won e-health Awards with the honourable mention and it was presented at the “eHealth 2003: ICT for Health” in Brussels, Belgium.

Key words: telemedicine; telecardiology.

## **Introduction**

Cardiovascular disease is the major cause of morbidity and mortality in Western countries. Despite progress in early diagnosis and intervention, in Europe ischemic heart disease is still the leading cause of mortality in males over 45 years and in females over 65 years. Cardiovascular diseases play a major role in general morbidity and disability, representing one of the major burdens to our health care system. Furthermore, the aging population, linked to greater efficacy of medical and surgical treatments, is contributing to a continuing increase in the number of cardiovascular patients and consequently of resources allocated to cardiovascular pathology (in terms of hospital admissions or specialist referrals).

Telemedicine can reduce the pressure on medical experts, who are limited in number, and extend their expertise to patients in isolated remote locations. Telecardiology has advantages for the individual patient in the interaction between primary and secondary care. In addition, general practitioners (GPs) gain educationally and hospital follow-up appointments may be reduced in number, because the GPs can handle more advanced medical problems. Telecardiology has been widely used in the diagnosis of arrhythmias and for the management of patients with chronic cardiovascular conditions. It is important to note that in many cardiovascular conditions, for example acute coronary syndromes, the opportunity to offer prompt diagnosis and treatment will improve outcomes in terms of mortality and functional recovery.

The Scientific Institute of Research and Care at Fondazione Salvatore Maugeri and the telemedicine service provided by Health Telematic Network, has been researching the clinical impact of Telecardiology on patients and health services in Italy since 1998 and providing direct telecardiology services. They have assembled the clinical and technological evidence-based platform for the telecardiology services now available throughout Italy. The collaboration supports the core philosophy of the initiative: to convert clinical evidence into practice, and so benefit citizens, healthcare professionals and healthcare provider organisations.

This Italian experience, named Boario Home Care project, was born in 1998, with the aim of applying the new models of disease management and the new technology on the territory.

## **Methods**

Since its inception in 1998 the history of Boario Home Care Project can be characterized as consisting of three major phases. Each phase has been closely linked to significant advances in Information Technology and Telecommunication.

### ***Service Center (Figure 1)***

In the first phase the project was to realize a telematic network for the General Practitioners in a mountain territory particularly hard to reach (Vallecamonica, a valley in the PreAlps) and to give them the possibility, over a 24 hour basis, of monitoring cardiovascular diseases of their patients using a mobile electrocardiographer. The recorded ECG could be sent by a fixed and mobile GSM telephone to the receiving station in Boario Terme where a Cardiologist reported the trace, offering an interactive teleconsultation and prescribed therapy, if necessary. The Cardiologist was “physically” present and worked directly at a workstation in the call center.

In the second phase the project was extended to the regional and then national territory and the number of enrolled GPs increased. At the same time a new way of disease management for chronic cardiac patients started. The vast amount of work generated by the call center obliged us to imagine the following “telework” flow: the call center operator received the call, asked the patient’s data (Figure 2) and received the ECG. Afterwards the user was put through to the Cardiologist who received the trace at home on his PC by FAX, reported the trace and provided teleconsultation.

In the third phase, that is nowadays, the structure of the Service Center (SC) has been implemented with new broad band technologies (HDLS) to connect all the network of cardiology divisions. Technology allows us to tailor the hospitals' network with specific requirements: xDSL always-on connection; access to the infrastructure of service (guaranteeing that all centres could carry out the program together with particular attention to data security and data access; development and management of the different services with application service provider (ASP) modality as outsourcing of high quantity and quality services. The network of cardiology divisions used an unique 24-hour working SC, by means of an advanced web-based platform. The SC functions as a receiving and sorting station, as a database and as a monitoring centre for patients. The SC was implemented with new broad band technologies (HDLS). It was equipped with 4 Hewlett Packard servers (with back-up hardware to avoid activity interruptions), a WEB server for Internet connection, firewall for data security, a computerized call-centre, 15 LAN workstations with 4 printers (over a network) and a central fax-maker. The SC uses a software application that implements a computerized medical record. Personal data folder of each patient can be created by the SC operators, who take care of linking each patient with his reference nurse. As a consequence each nurse can access only the personal data of their patients so as to guarantee patients' privacy. Each patient is linked to their clinical data records, including medical history, clinical history, telephone calls, all clinical examinations (such as ECG, oximetry) and therapy. The reference nurses and the cardiologists can examine and modify the clinical data of their patients. The *devices* used by the patients or by GPs provide a recording of several biological signals.

### ***ECG (Figure 3)***

The SC provides to the patients different kind of electrocardiographs. Using these devices and operating instructions supplied by the SC, patients at home can record an ECG trace and send it to the SC through the ordinary telephone line. In the SC's software platform, there is an application that enables the users to receive and directly elaborate ECGs; anyway the software gives the SC operators the possibility of importing ECGs from any kind of device and linking them as images to the medical records of the patients.

### ***Oximetry***

Some patients received devices to measure their oxygen saturation. This biological signal, registered for at least 2 hours a day and at least 2 hours a night, was transmitted to a website through the ordinary telephone line, using a provided modem. After transmitting the recorded signal to the website, patients called the SC and informed the operators. Once connected to the website, SC operators downloaded the patient's oxygen saturation and attached it as an image to their medical record.

### ***Operative flow-chart (Figure 4)***

The SC allows teleconsultation between hospital and territory with a teleworking model through a terminal server (with an encrypt and web-based VPN or web-based directly in https/ anonymous personal data). Terminal stations were implemented in the hospitals, functionally linked with the SC by a secure and encrypted VPN connection, configured to share the application program interface of the Central Station. The SC provides the technological and organizational support, while health activity is managed by the cardiologists and the nurses of the hospital. Before hospital discharge patients received a portable device transferring a one-lead trace by a fixed or mobile telephone to a receiving station, where a nurse or doctor were available for 24-hour and 365-day reporting and interactive teleconsultation. Teleconsultation provided two different possibilities: scheduled appointments (telemonitoring), managed by the nurse to collect information about the patients' general clinical condition, to receive the ECG trace and to reinforce compliance and education; occasional appointments (teleassistance) in which the patients, in the presence of symptoms or signs of possible decompensation or with any doubt about therapy, called the nurse. The operative flow-

chart is the same for telemonitoring with particular attention to the symptoms and signs referred by the patients. The system information flow is the following: a telephone-call arrives from the patient and the user is automatically identified through the stored telephone number or his identity code. Then the telephone-call is transferred to a free operator who recalls the previously-stored patient data stored in the enrolment phase and activates the “new call procedure”, inserting new data relative to this call (a control one or a call made in presence of symptoms). At this point the ECG trace can be received; the user is put through to the cardiologist or the nurse on duty (a three actor’s call takes place) who is at home or at the hospital and is connected to the central database through Internet. The specialist or the nurse examines the stored informatics clinical report and compares the trace with the baseline one; they collect information about patient’s history and clinical symptoms, providing teleconsultation and/or nursing triage. At the end the reported ECG trace and all patients’ data are stored.

### ***Organization***

Each hospital provided assistance from Monday to Friday from 08:00 to 16:00. The emergency service organized by the SC provided assistance during the rest of the day, linking the patients with a reference nurse or cardiologist.

### ***Staff training***

Detailed staff training in using the software applications is provided both to the SC operators and to the medical staff, in order to assure a high quality service.

SC operators: the first training period for a SC operator lasts two months. Each new SC operator has to practice for two hours a day and for three days a week. The period is organized in three stages. In the first stage the SC manager explains to the SC operator how to answer the telephone, how to use the software applications and how to use the devices. In the second stage the SC operator answers the telephone under the supervision of the SC manager. In the third stage the SC operator works for one month together with expert staff. All SC operators are subject to updating each month. During the updating meetings, the SC manager checks the SC operators’ background and gives a personal judgment to each SC operator.

### ***Medical staff training***

The SC’s medical staff manager selects just qualified personnel with the fit personal and professional properties to assure a high quality service. The staff training is organized in several stages: starting test, course of electrocardiography, sharing of the guidelines about cardiac diseases, explanation of the operative flow-charts, assessment of 50 clinical cases using an educational CD-ROM, explanation of the working procedures, communication and counselling course, training in using the computerized medical report and closing test. The staff training is repeated every two months with refresher courses and with an assessment of applicants every year.

### ***Quality control***

Each step was processed in an accurate quality control system. According to UNI EN ISO 9001:2000 standards each nonconformity was stored in a dynamic database to monitor any discrepancy from standard. The Quality Assurance Manager led a weekly assessment to evaluate how effectively performance improvements were working.

## Results

Different types of services are now available:

### ***Cardiological second opinion for General Practitioners***

1224 General Practitioners (GPs) received a portable 12 leads electrocardiographer which can be interfaced with a fixed or mobile telephone and transfer the recorded ECG trace to the receiving station where a cardiologist reports the trace and offers a teleconsultation (1-2).

Up to today the GPs asked for a teleconsultation for 103.050 patients: 35 cardiologists are involved. The analysis of a sample of 13177 patients showed that teleconsultation solved the GPs' problems for 10606 patients (80.4%), in 5% of cases the patient were addressed to the Emergency Department and in 14.7% of cases a request for further diagnostic test was made.

The diagnostic accuracy of the service (as for the Emergency Department referral) (3) was tested on a sample of 3456 patients and was of 94.5%, showing the substantial diagnostic value of the Service. The same accuracy was tested for the chest pain symptom and the result was that the telecardiology service showed a sensitivity of 97,4%, a specificity of 89,5 % and a diagnostic accuracy of 86,95 versus ED admission for chest pain (4).

Moreover the potential reduction of costs for the National Health Service through a telecardiology service has been estimated. In a group of 891 patients there was a reduction of 47% of Emergency Department referral and of 95% of the cardiologic consultations in comparison with the normal procedure followed by GPs (5). The same potential reduction of costs was tested in a subgroup of 311 elderly patients: there was a 37% reduction in referrals to the Emergency departments and a 94% reduction in the number of requests for cardiological consultations (6). Successful results was reached even in the diagnosis of atrial fibrillation or in the home follow up of elderly patient with atrial fibrillation (7)

The good results, even if they are preliminary, must be attributed to the effective teleconsultation which takes place after the ECG transmission, between two professional figures, an experienced cardiologist and the GP who knows his patients very well; this aspect confirms the impression of the reciprocal reliance and compliance of GPs and specialists in managing problems and possibly in following diagnostic and therapeutic common protocols. Improving this professional relationship, telecardiology can aid the appropriateness of hospital admissions and referrals to the Emergency Department, of diagnostic tests demands and of chronic disease home management. Now, multispecialty second opinion (Dermatology, Pneumology, Diabetology) are present.

### ***Chronic cardiac patients***

Chronic cardiac diseases such as chronic heart failure profit by multidisciplinary approaches, which are able to reduce hospitalization and improve the patient's quality of life at the same time and to reduce costs for National Health Service.

Home Telenursing is an integrated approach which must involve the patient, his family the GP and Specialized Cardiac Centers. The physiologic data and biologic signals transmission gives objective data which may show the need of an intervention of a physician or a nurse; the possibility of real time transmission of these objective data by telephone in association with subjective data given by the patient allow telemedicine to become a new and unique approach to the problem (8). 660 patients underwent this program; the patient receive a device which was able to record a 1 lead trace; the trace could be transmitted to the SC where especially trained and experienced nurses were available for the evaluation of the trace and for an interactive teleconsultation about the patient's state of health, symptoms, weight, diuresis and therapy. Teleconsultation provided two different possibilities: scheduled appointments (Telemonitoring), every week for patients with severe heart failure (III-IV NYHA class) or every fifteen days for patients with moderate heart failure (II NYHA class) and calls in the presence of symptoms (Teleassistance), in which the patients could call the SC 24 hours a day all year round and talk with the nurse. The GP and the cardiologist of the

reference Hospital were informed about the patient's situation and could intervene at any moment about diagnostic and therapy arrangements. This group of patients was compared with a group of 150 patients with an usual follow-up. The preliminary results of the project are characterized by a significant reduction in decompensation (22.9% in the group followed with telemedicine in comparison with 55.4% of the group with normal follow-up) and in hospitalizations (17.6% vs. 36.5%) (9-11). Another experience was done with patients after an acute myocardial infarction after primary PTCA (12). Nowadays we applied this approach to patients with chronic respiratory diseases (sometimes mechanically ventilated) (13) and to patient with amyotrophic lateral sclerosis.

### ***Post cardio surgery rehabilitation***

Home exercise rehabilitation should be promulgated as an alternative, however, because of its lesser cost, increased practicability, convenience, and potential to promote independence and self-responsibility. For low-risk patients, medically directed, home-based rehabilitation and supervised group programs have shown comparable safety and efficacy. The degree of electrocardiographic (ECG) surveillance should be linked inversely with the cardiac stability of the patient. Self-monitoring (e.g., pulse rate, symptoms, perceived exertion) may suffice for many low risk patients exercising at home or in community recreation facilities. Utilization of continuous or transtelephonic ECG monitoring will be increasingly scrutinized.

A whole cardiac rehabilitation program at home were organized for patients after coronary artery bypass graft surgery (CABG) and or cardiac valve replacement, to facilitate post operative return to work and social life. All patients, discharged 5 days after surgical procedure, were send at home with the possibility to call a SC where sending biological signals (as one lead or 12 lead ECG) and connecting themselves with the own hospital and personnel (cardiologist, cardiac surgeon, nurse, physiotherapist etc..). The rehabilitation program lasted 28 days; telemedicine contacts with the SC were done (two times a day for scheduled appointment); during the same period the patients were visited directly at home by the physiotherapist, by nurse, by physicians; if the patients has arrhythmias or problems which cannot be solved at home, he can be hospitalized.

### ***Telediagnosis for arrhythmia***

Palpitation is a common symptom that sometimes results from a substantial cardiac arrhythmia. Establishing the cause of palpitations may be difficult because historical clues are not always accurate. A 24-hour Holter monitor is usually used, but the yield of this instrument is low in patients whose symptoms occur infrequently. Another instrument used to study palpitations is a transtelephonic event recorder. This hand-held device was given to patients and they could apply it to the chest when the symptoms occurred. The patient pressed a button to record about 30 record of cardiac rhythm, which was stored in the memory of the device. The recording was later transmitted over the telephone for printing and interpretation to a call-center working 24 hours a day. Here a nurse compared the trace with the baseline one, checked the pt's symptoms, and decided to end the telephone call or, in presence of major arrhythmia, to request the cardiologist's intervention. 310 pts were randomly assigned to receive an event monitor (ER) or a 24-hour Holter monitoring. ER were used for 7 days or until two recordings were obtained while symptoms occurred. The percentage of patients in whom Event recorder was able to record the ECG trace during palpitations was 76.8 % in comparison with the Holter monitoring in which the percentage was 47.8% (14-15). In conclusion, more patients reach a clear diagnosis in real time when use ER in comparison with Holter for palpitation. In our experience 920 patients replace Holter monitoring with Event Recorder and reach the diagnosis.

### ***Call center service for hospitals***

Twenty-three cardiology divisions have been involved in the network from 2000- 2006. Terminals have been implemented in University and public hospitals, functionally linked with the SC, configured to share the application program interface of the Central Station with "on site/on

line” license. After hospital discharge the patients with cardiac diseases (chronic heart failure or arrhythmia) receive a telecardiology device and they can contact their cardiac division with a telephone call (the user’s telephone number is automatically identified); the operator recalls the stored patient’s data, view of them on the monitor and activates the “new call procedure” during which he inserts new data relative to this call (a control one or a call made in presence of symptoms). The patient can now transmit his biological signals (as ECG) and he is automatically connected with the Nurse or the Cardiologist of their own Cardiological Division who provide teleconsultation and triage activity (for example comparison of the ECG with the previous ones) with updating of informatic clinical report. At the end of all the procedures, the data are stored, transferred to the web-server and available on the net only for password owners. The SC provides the technological and organizational support, while health activity is managed by the Cardiologists and the Nurses of the hospital.

### ***Training staff***

Since the starting of the telemedicine service 42 SC operators, 79 specialists (49 Cardiologists), 71 nurses and 4 physiotherapists have been trained. At this moment 14 SC operators, 49 specialists, 39 nurses and 4 physiotherapists are still engaged in providing the telemedicine service.

### ***Developed scientific research***

Telemedicine service has been provided for nine years and it has been related with an accurate collection of data and experiences. This allowed us to develop a fruitful scientific research activity: 15 publications in international journals, 7 publications in national journals, 35 abstracts in international congresses, 71 abstracts in national congresses, 6 chapters in scientific books.

## **Conclusion**

Boario Home Care project (16) has reached its maturity and many results even if we can consider them preliminary; in fact in the field of Telemedicine, although claims about the utility and the efficacy of new telecommunication systems have been widely made, these are not founded on strong evidence. In December 2005, the Lombardy Region decided to implement telecardiology for some patients with chronic heart failure in classes III and IV of the New York Heart Association, and with an ejection fraction <40%, and having had one hospital admission in the previous six months. It also agreed to pilot services at a price of €660 for six months, for every patient in appropriate diagnosis related groups in VIII/1375, issued on 14 December 2005.

Boario Home Care project (16) won e-health Awards with the honourable mention and it was presented at the “eHealth 2003: ICT for Health” in Brussels, Belgium.

In 2005, after the first two eHealth evaluations by the Association of Chartered Certified Accountants, the European Commission commissioned the eHealth Impact (17) project. The eHealth Impact methodology is consistent with the evaluation models used for the first of the Association of Chartered Certified Accountant’s eHealth Impact reports with the European Commission in 2004, and is used to evaluate the research into telecardiology since 1998 and its future use in Lombardy up to 2012. It provides data for an eleventh eHealth Impact site. In this way, the Association of Chartered Certified Accountants, Health Telematic Network and the Fondazione Salvatore Maugeri are enhancing the European Commission’s eHealth Impact findings and knowledge.

Telecardiology is one of the fastest-growing fields in telemedicine (18). There is already a significant quantity of published clinical data, with some randomized multi-centre trials to answer the most important questions in definitive way. The contribution of telecardiology in some fields such as emergency and chronic care undoubtedly improves the quality of health care and helps to contain rising costs. Telecardiology has yet to reach maturity, but the evidence to date indicates that it has made a good start.

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