Home Telemonitoring of Chronic Heart Failure Patients: Novel System Architecture of the Home or Hospital in Heart Failure Study

GD Pinna[1], R Maestri[1], M Roma[1], JL Scanferlato[2], A Giordano[3], F Comazzi[3], M Ferrari[1], D Andrews[4], P Johnson[4], S Capomolla[1], A Mortara[5]

[1]S. Maugeri Foundation, IRCCS, Montescano and [3]Veruno, Italy, [2] Appel Elettronica, Torino, Italy, [4]University of Oxford, Oxford, UK, [5]Policlinico di Monza, Monza, Italy

Abstract

The HHH (Home or Hospital in Heart failure) study is a European Community multicenter trial aimed at assessing in a population of chronic heart failure patients 3 incremental home telemonitoring strategies against usual clinical practice. End points are rehospitalization, quality of life, mortality and cost-efficacy. Easy accessibility by the patient and low management costs are the two basic criteria that have guided the design of the architecture of the HHH telemonitoring system. Voice messages, vital signs and long-term cardiorespiratory data are periodically transmitted by the patients at home to a centralized interactive voice response system shared by several hospitals. From there, relevant data are automatically routed to the pertaining medical staff. The HHH technical infrastructure has been completed and tested in the 3 countries involved in the study and enrolment is in progress. Preliminary results on the feasibility of the HHH telemonitoring model are available.

1. Introduction

Chronic heart failure (CHF) is a growing public health problem in industrialized countries, afflicting > 1% of the general population and near 5% of the elderly. Besides being a disease with high morbidity and mortality, CHF is also accompanied by frequent rehospitalizations [1], as clinical instabilizations are likely to occur during the clinical progression of the disease. More effective treatment strategies directed at preventing clinical deterioration and consequent rehospitalization are then urgently needed, and great efforts have been done in the last years to identify and evaluate new home-care strategies capable of reducing unplanned hospital readmissions and improving quality of life. Home-based strategies based on periodic visits by a cardiac nurse have shown to be promising, yet their costs are high and they don't allow to monitor closely the patient's clinical status and the effect of changes in therapy.

Home telemonitoring of clinical and physiological parameters together with medical/nursing telemanagement might thus represent a potential alternative to traditional home care models. The feasibility, efficacy and cost-utility of this new approach, however, has to be tested in rigorous trials.

Among the physiological signals that are worth being monitored at home, respiration and heart rate variability (HRV) are of great importance, as both the presence of severe breathing disorders and a depressed HRV are independent markers of poor prognosis in CHF patients [2,3].

The HHH (Home or Hospital in Heart failure) study is a European Community multicountry randomized controlled clinical trail (QLGA-CT-2001-02424) aimed at comparing three different strategies of home telemonitoring against usual clinical procatice and assessing the prevalence and clinical impact of breathing disorders and abnormalities of HRV.

The strategies of home telemonitoring are based on i) simple monthly voice contact by telephone plus full time answering machine, ii) as (i) plus weekly monitoring of vital signs, iii) as (ii) plus monthly 24-hour monitoring of respiration and HRV.

The study is running in 3 European countries (Italy, UK and Poland), involving a total of 11 hospitals. This paper gives a general description of the HHH home telemonitoring architecture.

2. Methods

2.1. System requirements

The overall architecture of the HHH telemonitoring system has been designed following 2 basic requirements: easy accessibility by the patient and low management costs. The first criterion has been met by the utmost simplification of all the equipments necessary to collect clinical and physiological data at home (vital signs and 24-hour cardiorespiratory signals) and transmit them to the medical staff. This is crucial in order to ensure a high compliance in a population of patients which is on average over 65 years old. Most of these equipments are prototypes developed in strict

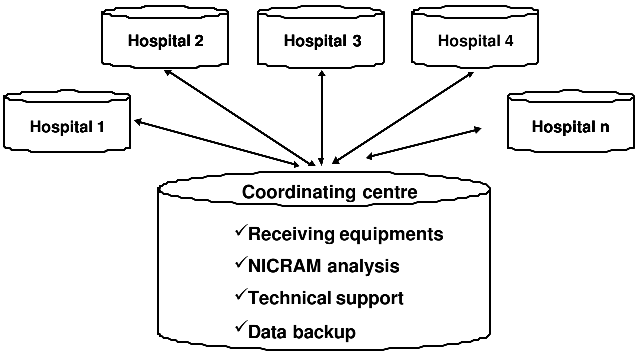

Fig. 1. Service model used in the HHH project.

cooperation between the HHH technical staff and external partners/providers. The second criterion has been met by using an automatic interactive voice response (IVR) system for receiving all data collected at home by the patients (vitals signs and cardiorespiratory signals), and a 24-hour digital answering machine to allow the patient to leave a voice message in case he/she needs help or advice. These two equipments were chosen in order to avoid a full-time phone answering staff (call center). In addition, all vital sign data are managed through a patient-oriented, double-check, automatic alarm system aimed at early detecting an incoming clinical instabilization. Moreover, cardiorespiratory recorders are shared between different patients (3:1) and an express courier is used to bring them to/from the patient's home. Finally, we have centralized in each country all equipments for receiving patient data as well as the technical staff needed to support and maintain the system and perform signal analysis (fig. 1). The health care model underlying this choice is a consortium of hospitals that share technical infrastructures and human resources in order to reduce management costs.

2.2. System architecture and data flow

The HHH project deals with several types of information which are coded and structured into coherent ensembles of data stored in the study databases:

1. *Demographic and clinical data*. They include all data collected at enrolment and follow-up controls, as well as those collected through periodic phone calls.
2. *Vital signs*. They include: weight, heart rate, systolic pressure, dyspnea score, fatigue score, peripheral edema, changes in therapy (Y/N) and blood test results (BUN, Na^+, K^+, Bilirubine, Creatinine). In order to transmit vital signs, the patient dials a toll-free number and enters collected data on the phone keyboard in reply to the questions asked by a recorded voice. A confirmation is requested for each of them.
3. *Voice messages*. Each message, being stored in digital form, becomes integral part of the overall patient's data set.
4. *NICRAM raw signals*. They include 24-hour ECG, respiration, body movement, body position and events recorded at home.
5. *NICRAM telemonitored signals*. They include those signals that are actually transmitted through telephone lines, namely the RR interval time series, respiration and body movement/position. Analysis of these signals is carried out in the coordinating centre by the signal analyst.
6. *NICRAM parameters*. These are the parameters derived from signal signals, nameley: i) time- and frequency-domain indexes of HRV, ii) indexes quantifying breathing abnormalities, iii) a physical activity score and iv) the 24-hour heart rate trend.
7. *Resource use information*. All data relevant to the computation of the costs of care (e.g., number and duration of hospital readmissions, number of specialist consultations etc.) and of management costs related to the telemonitoring system (e.g., the time spent by the medical and technical staffs, the costs of telemonitoring devices etc.).

The schematic diagram in figure 2 shows the data flow in the HHH study according to the three different telemonitoring strategies considered in the study.

When a new patient is enrolled in the study, baseline clinical and demographic data are entered into the local database of the enrolling centre. Monthly, all patients are contacted by phone by the nurse and asked about clinical status, occurrence of events and resource use (if any). Data are entered into the local database and periodically sent to the country coordinating centre for back-up purposes and countrywide data analysis.

All patients are allowed to send a voice message 24-hour a day to the answering machine (IVR) located in the coordinating centre. All received voice messages are transferred to the country database and then automatically sent to the pertaining enrolling centre to be listened to by the nurse using a dedicated software. Patients following strategy 2 and 3 send weekly vital signs parameters entering them on the phone keyboard As for voice messages, vital signs parameters are transferred from the IVR to the country database and then automatically routed to the pertaining enrolling centre to be analysed by the nurse.

Cardiorespiratory and activity signals collected monthly at home by patients following strategy 3 are transmitted to the country co-ordinating centre via telephone lines using a smart modem specifically designed for the project. Signals are received by the same IVR being used for the transmission of vital signs and transferred to the country database.

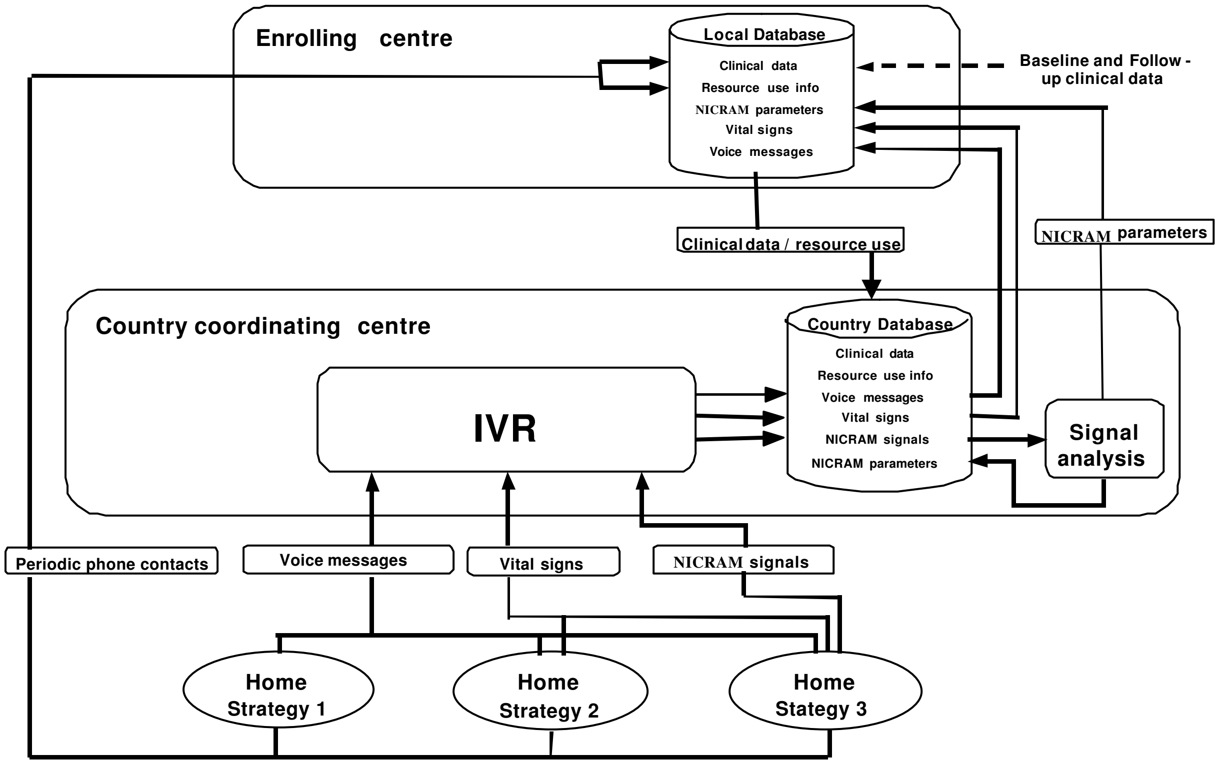

Fig. 2. System architecture and data flow in the HHH study.

The report containing the parameters derived from the analysis of cardiorespiratory and activity signals is then automatically sent to the pertaining enrolling centre.

2.3. Preliminary results

The HHH technical infrastructure has been completed and tested in the 3 countries involved in the study and enrolment is in progress. The first patient was enrolled in September 2002. The trial is expected to be completed by the end of 2004.

Ad interim results on the feasibility of the HHH model as regards the telemonitoring of vital signs are available for Italy, where 77 patients have been enrolled so far. Out of 578 vital signs transmissions scheduled till now, 542 (94%) were feasible (i.e., the patients were alive and at home). Four hundred eighty three (89%) of feasible transmissions were actually carried out by the patient, for a total of 3628 received parameters. Unexpected (i.e., not scheduled) transmissions and voice messages were respectively 37 and 78. Blood test results were successfully transmitted on 90 occasions. Preliminary results on cardiorespiratory telemonitoring are presented in another paper of these proceedings.

3. Conclusion

Preliminary results from the HHH study clearly indicate that home telemonitoring of vital signs in CHF patients is feasible and compliance is high. If proven to be capable of reducing rehospitalizations and other cardiac events compared to usual clinical practice at an affordable price, the HHH model could be extended to other chronic diseases where the continuity of care is the key factor in determining the long-term outcome.

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Address for correspondence.

Ing. Gian Domenico Pinna,
Servizio di Bioingegneria
Fondazione S. Maugeri
Istituto Scientifico di Montescano,
I-27040, Montescano (PV), ITALY
gdpinna@fsm.it