SAPHIRE - Intelligent Healthcare Monitoring based on Semantic Interoperability Platform - The Homecare Scenario -

Andreas Hein[1], Oliver Nee[1], Detlev Willemsen[2], Thomas Scheffold[3], Asuman Dogac[4], Gokce Banu Laleci[4]

(1) OFFIS e.V.
{andreas.hein, nee}@offis.de

(2) Schüchtermann-Klinik Bad Rothenfelde

(3) Institute for Heart and Circulation Research at the University of Witten/Herdecke

(4) Middle East Technical University, Software Research & Development Center

Abstract: The SAPHIRE project aims to develop an intelligent healthcare monitoring and decision support system on a platform integrating the wireless medical sensor data with hospital information systems. In the SAPHIRE project, patient monitoring will be achieved by using agent technology where the "agent behaviour" will be supported by intelligent clinical decision support systems which will be based on computerized clinical practice guidelines, and will access the patient medical history stored in medical information systems through semantically enriched Web services to tackle the interoperability problem. In this paper one of the two demonstrator environments – the homecare scenario – will be described from the medical and technical point of view.

1 Introduction – SAPHIRE

Progress in medicine has lowered the mortality for many diseases common in Europe's population to an astounding degree. This has led, and continues to lead, to an increasingly aging population and poses a new challenge to social and health services: Given limited resources, more and more people with complex diseases need to be treated efficiently. The increasing cost pressure resulting from is spurning a development resulting in shorter hospital stays towards ambulant care and rehabilitation. Recent advances in communications resulting in better connectivity at home offer a new option and make homecare a cost efficient way of continuing the treatment at the patients' homes. The EU-funded SAPHIRE project (IST-27074) aims to establish a framework for intelligent monitoring to increase efficiency in healthcare.

An intelligent decision support system (DSS) based on established clinical guidelines is a key component of the SAPHIRE system. This DSS uses agent technology and provides clinicians as well as patients and their relatives with relevant medical information. Its suggestions are based on medical knowledge embedded into the guidelines, on input from the treating physician, on the patient's history that is retrieved from the EHR. Vital parameters gathered from sensors and transmitted wirelessly, as well as patient feedback are both also used as input for the DSS.

If exercise is part of the patient's treatment plan, the SAPHIRE system can support this by integrating medical sensor data and actuators for the stabilization of the patient during training. This aspect is clearly an improvement from the traditional approach, where the patient is given a conservative training guideline and exercises under supervision. With SAPHIRE, the actuator is controlled by more than one kind of sensor data and not just the patient's pulse as with most current ergometers. Supervision is optional (especially for stable patients) and can take place remotely. In order to achieve this, agents monitor the sensor data, as well as performance data from the ergometer. Based on this data, a real-time patient model with discrete states is derived.

If the patient's state is identified as a potentially critical one, an alert is generated and propagated, triggering local reactions - such as lowering the ergometer resistance to zero and aborting the training session as well as reactions from the medical therapist who is supervising and assisting the patient remotely.

Sensor data, patient feedback and alerts are documented as part of the patient's history within the hospital's electronic healthcare record (EHR). Based on semantically enriched web services and exploiting technology from the ARTEMIS project [Do06], SAPHIRE can interface with virtually any EHR system.

Two pilot applications will be deployed to demonstrate and test the technologies implemented during the project, representing two scenarios: a hospital scenario and a homecare scenario. The hospital scenario will be tested by the Emergency Hospital of Bucharest, Romania (Spitalul Clinic de Urgență București, SCUB) while the homecare scenario will be demonstrated by the Schüchtermann-Schillersche Kliniken (SSK) in Bad Rothenfelde, Germany.

The hospital scenario will be tested with two sets of patients. The first set consists of patients suffering from an acute coronary syndrome (ACS) in a sub-acute phase. Patients from the second set are patients with decompensated heart failure (HF) of different aetiologies. Both sets need to be stable enough to avoid endangerment and be mobile enough to benefit from wireless sensor technology. In this scenario, long-term monitoring of vital parameters (ECG, blood pressure, oxygen saturation) is coupled with alert agents and an intelligent clinical decision support system. The SAPHIRE system allows patients to move freely within the ward while the system monitors the sensor data and alerts a Doctor if the data indicates medical problems.

Aim of the homecare scenario is the implementation of the infrastructure for homecare and individual home-based training of patients by closing the gap between the IT infrastructure of health care institutions and the local infrastructure of the patient's home. In this scenario, the system combines the aspect of alert and guideline agents with a component that controls the patient's ergometer to facilitate a training that is effective and that keeps the patient in a stable, non-critical state. This aspect is described further in section 3. The system design supposes a rental concept to solve cost-effective constraints. This is done by integrating the respective hardware and software on the so-called user-friendly multi-services home platform. Within the scope of the project, the multi-services home platform will be used as a residential gateway between the patient's home and the clinic. Additionally, the development of reliable communication protocols according to data privacy requirements, the semantically enriched patient data and their integration into the hospital information system (HIS) and the EHR.

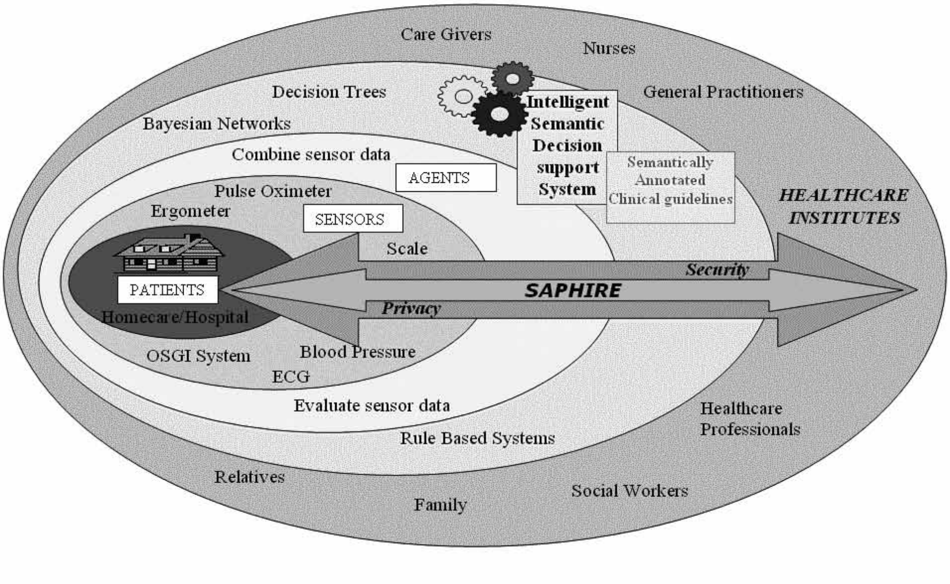

Figure 1: Conceptual Overview of the SAPHIRE project

Figure 1 gives a conceptual overview of the SAPHIRE project. The patient in the hospital (or at home for in the homecare scenario) is the very core of this project. Various sensors gather data from the patient. Sensor data is transmitted wirelessly to an Interoperability Platform called the Multi-Services HealthCare Platform (MSHCP). Agents combine and evaluate sensor and infer the patient's status. Based on this data, and taking into account the patient's history that is gathered from various healthcare institutes, an Intelligent Semantic Decision Support System based on semantically annotated guidelines modelled using the Guideline Interchange Format (GLIF) makes suggestions for the patient's treatment. Mechanisms that ensure privacy and security complement the system.

2 State of the Art

The following state of the art is divided into the description of architectural approaches for homecare monitoring systems and decision support systems.

(1) Homecare monitoring systems have been researched for several years, and there are already a few commercial solutions and business models. The existing solutions, however, often rely on medical call centres, transmit their data through telephones and are based on proprietary technology. Wireless sensor systems have only recently become available as Bluetooth and ZigBee became reasonable choices for wireless data transfer.

The first established system that should be mentioned is well@home, which is actually dubbed a “clinical management system” used by patients at home. Embedded measurements of blood pressure, pulse, oxygen saturation (SaO2), temperature, ECG, and respiration rate are taken through wired sensors and transmitted using a built-in modem. A physician reviews the data and returns a treatment plan that patients can see on a large touch screen that is part of the well@home device.

For wireless systems, there are several options for transmitting the data. A popular approach is to for a “Body Area Network” (BAN) to gather the sensor data and to use a “Mobile Base Unit“(MBU) for temporary data storage and data transfer. A MBU is often a PDA or a smart phone. Using the latter option uses GSM to transmit the data. The projects "Personal Health Monitoring" (PHM) and MobiHealth [Ko02], which is funded by the European Commission, can be named as representative projects for BAN-based monitoring systems. There are even systems where sensor technology is directly integrated into the smart phone, such as the “Vitaphone 2300” that is capable of generating 3-lead ECGs and that uses GPS to give the position to the medical call centre in case of an emergency. The "Citizens’ Healthcare System" (CHS) [Ma05] and many commercially available ECG home devices (like the "Vitaphone 100 IR") use a slightly different approach for data transfer. The patient uses a normal phone to transmit the collected data to the clinic. The data centre is called, and the patient holds the ECG unit against the phone's microphone. The ECG unit then sends the data via an acoustical signal (like it is done in analogue faxes or modems). However, this approach does not allow a local combination of data from different sensors. This combination can be done by the homecare provider after the transfer, which means that possible feedback to the patient can only be given after the data communication is completed.

Projects like WiPAM, Philips’ Motiva, and TOPCARE [Mi02] use Bluetooth to transmit the data to a concentrator that is often referred to as the "Home Care Unit"(HCU). This unit then uses the normal phone lines (analogue or ISDN), GSM or data lines (DSL, Ethernet) to transmit the sensor data to the healthcare provider.

Projects like "Universal Remote Signal Acquisition For hEalth"(U-R-SAFE) [Ca03] are combined approaches, relying on wireless sensors that use the BAN technique when the patient is not at home or the HCU if the patient is at home. This combination allows constant monitoring of the patient's vital signs.

(2) Decision Support Systems (DSS) are commonly defined as "active knowledge systems which use two or more items of patient data to generate case-specific advice" [Wy91]. The SAPHIRE system aims to combine patient data (the patient's history form the EHR and sensor data) with established clinical guidelines (modelled using GLIF) to give specific advice to doctors, to patients and their relatives. Decision Support Systems have been researched and used for three decades now, and there is a plethora of systems. However, due to space restrictions, we can only introduce two systems that apply DSS in a fashion that is similar to SAPHIRE's approach.

ISABEL is a web-based clinical decision support system and is described in [Ra04]. Like DxPlain [Ba87] it reminds clinical users of a significant diagnosis they might not have considered and helps prevent diagnostic errors. In addition to differential diagnoses, guidelines for the management of diseases are being offered to the user, as well as clinical images and a section where clinical experience can be shared among the users. The knowledge base was constructed in a speedy manner: A diagnostic tree with 3500 diagnoses was pre-designed and then populated with standard electronic medical texts. Several (unformatted) texts from different sources were collated under one diagnostic label. The texts were not modified, and no manual mapping or encoding was required. A commercial inference engine was used that creates "a unique signature of key concepts for each diagnosis". With each text that was added to a diagnostic label, the signature was updated. Based on key clinical features for a patient, ISABEL searches the text database and returns all diagnostic labels (and the documents collated under the label) that have a matching concept signature. The clinical features of a patient are entered as free text.

ATHENA (Assessment and Treatment of Hypertension: Evidence-Based Automation) is a decision support system for the implementation of widely accepted clinical guidelines for the management and treatment of hypertension. ATHENA's DSS is described in [Go00] and gives the clinician advisories that help plan a patient's high blood pressure treatment. The system is uses EON for guideline-based decision support and consists of two main components: a hypertension knowledge base modelled using the Protegé-editor and a guideline interpreter that retrieves clinical information from an EHR and applies the knowledge base to generate case-specific recommendations for a patient encounter. The system makes recommendations to add, substitute or delete drugs, or to change their dose depending on how well the patient's blood pressure is under control and whether or not there are co-morbid diseases that indicate the a change in medication. In order to be independent of the EHR database schema, a database mediator called "Athenaeum" was implemented that reconciles the EHR database schema with EON's relational data model. Athenaeum and the two knowledge bases used for mapping purposes are described in detail in [Ad99].

3 Approach – Assisted Home-Based Training

The proposed approach for the homecare scenario in the SAPHIRE project consists of a distributed assistant architecture that allows the data integration of each individual patient at the hospital site and a control loop for the stabilization of the patient during the exercise at home (Figure 2). The assistant will on one hand relieve the medical doctor from the time-consuming direct monitoring of the exercise and will restrict his/her activities to high-level interpretations (e.g. of ST segments in the ECG). The patient on the other hand can schedule his/her training individually and will carry out the training at home. To ensure an optimal training and derive high-quality diagnostic data the training at home will be controlled and stabilized by an individualized assistant. In case the process becomes instable and local operations are not sufficient for stabilization (e.g. due to technical problems during data acquisition or vital parameters out of range even if the training has been interrupted) alerts are transmitted to the hospital.

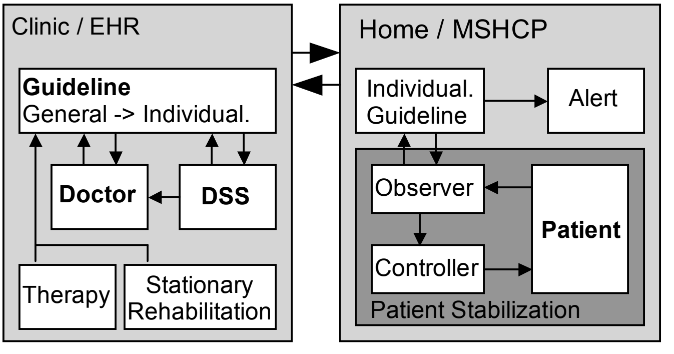

Figure 2: Concept of the Assisted Home-Based Training

The detailed description of the assisted home-based training is divided into the description of (1) the clinical requirements and the addressed patient population, (2) the software architecture of the multi-services home platform at home and (3) the control loop for the stabilization of the patient. The clinic site with the individualization of the guideline and the diagnostic support of the medical doctor by the DSS is not part of this paper.

3.1 Clinical Requirements

Within the homecare scenario a combination of exercise training as a diagnostic method and fitness training for the improvement of the heart condition will be implemented. The training is carried out on a cycle ergometer device (or a treadmill) with programmable exercise capacity. The difference between these training methods is the use of progressive (stepwise or linear) or constant (power over time) protocols and the sensor equipment for the patient monitoring.

Clinical guidelines for the exercise training have been published by the American College of Cardiology/American Heart Association [Gi02]. The potential population are patients suffering from cardiovascular diseases. This method has been proven as a cost-effective diagnostic method in comparison to imaging techniques. For the implementation of the guideline the following sensors data have to be acquired continuously:

- BP(t) … Blood pressure
- SaO2(t) … Oxygen saturation
- RR(t) … Respiratory rate
- HR(t) … Heart rate
- $ECG_{12}(t_x)$ … 12-lead ECG acquired at discrete times: before, during and after the training

Clinical guidelines defining the fitness training are not available at the moment. Nonetheless, it is an important part of the post-interventional treatment of patients that have been treated by a coronary angioplasty (PTCA). The assisted home-based training will be generally composed of two phases:

- *Inpatient phase*: Patients after a successful revascularisation procedure will carry out the training with the homecare equipment at the clinic under supervision of a physician. During this phase the self-handling of the equipment will be optimized and the parameters for the home-based training will be acquired. This phase will last approximately three weeks.
- *Outpatient phase*: After the inpatient phase the patient will proceed with the training at home. A physician will review the training protocol once per day, but immediate communication will not be necessary.

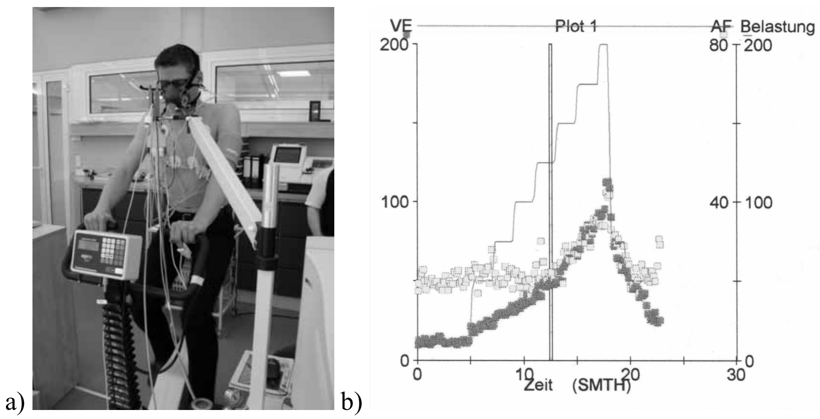

Figure 3: a) Patient during the exercise training at the clinic, b) none-linear behaviour of respiratory volume per minute (green) and respiratory rate (yellow) during an exercise training (stepwise increment of the ergometer's power)

3.2 Architecture of the Multi-Services HomeCare Platform

The Multi-Services HomeCare Platform (MSHCP) acts on one hand as a gateway between the clinic and the patient's home. On the other hand the MSHCP manages the execution of the individualized guideline. The MSHCP is implemented as an embedded PC with an operation system (Linux), a Java environment (J2SE), and an OSGi based middleware. OSGi (Open Services Gateway Initiative) is a standardized, component oriented computing environment for networked services. It is already used for home automation applications. Main components of OSGi are an execution environment, different module layers, a live cycle layer, and a service registry. In this way, this framework can manage remote control and secure communication (Figure 4):

- **Communication**: The MSHCP communicates with the clinic via the Internet using a secure (VPN - Virtual Private Network). Due to data privacy regulations the MSHCP initiates the communication only after the patient starts the training and acknowledges the transfer of personal data. Potential updates of the training guideline or of training parameters are downloaded from the clinic. After the training a structured report of the training according to the patient's guideline summarizing the most important parameters is sent to the clinic for review by the medical doctor. In case of an urgent alert communication paths can be defined (SMS via mobile phone or pager).
- **Guideline**: For the individualized training and diagnosis of the patient the general guidelines by e.g. the ESC (European Society of Cardiology) or ACC/AHA (American College of Cardiology/American Heart Association) have to be formalized to an executable model and parameters have to be set and updated according to the individual state of the patient. The guideline includes rules to define contraindications and termination of the training, the training sequence, parameters that have to be monitored, and rules for the computation of risk factors. The individual guideline infers discrete state changes from the patient's state, the patient's feedback through the user interface and decisions of the medical doctor at the clinic.

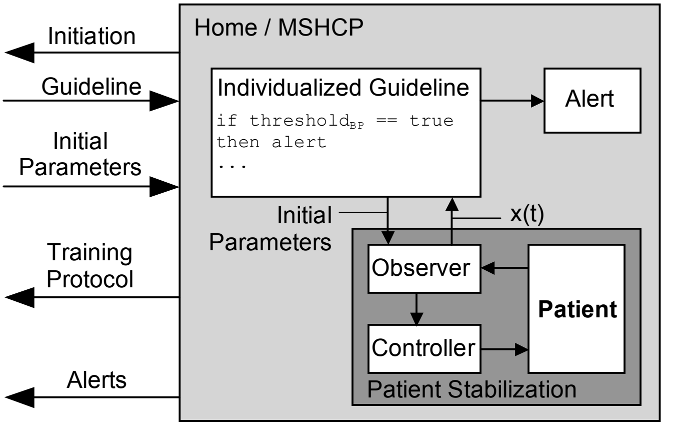

Figure 4: Architecture of the individualized assistant at the MSHCP

3.3 Patient Stabilization and Control Loop

The control loop for the patient stabilization during the training at home is shown in Figure 5. It consists of the patient, the ergometer, an observer, and a controller. The patient is modelled by its internal state $y_p(t)$ described by continuous values over the time of blood pressure (BP), respiratory rate (RR), heart rate (HR), oxygen saturation (SaO2), and the ECG signal acquired at 12 defined positions at the patient's limb and extremities. Depending on the patient state $y_p(t)$, the power $P_p(t)$ applied by the patient to the ergometer (measured and transmitted as $y_e(t)$) and initial parameters and thresholds the observer derives the system state $x(t)$ and the control difference $e(t)$. The control difference $e(t)$ is used by the controller to derive control output to the ergometer $u_e(t)$ and to the patient via visual display $u_p(t)$. In addition, the patient state $x(t)$ is used to initiate alerts and report the training results to the clinic.

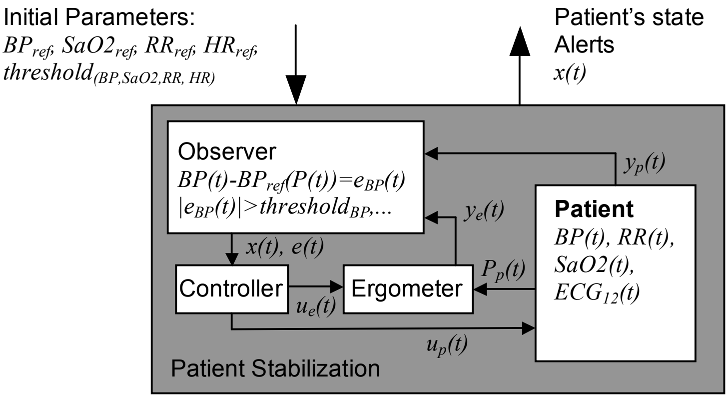

Figure 5: Architecture of the control loop for the home-based training consisting of the observer, the controller and the patient.

The patient stabilization is defined to reach the following aims:

1. *Improvement of patient's compliance to the predefined training plan*: Because of safety reasons there is only a weak coupling between ergometer and patient. That means, that neither the training itself nor the power transmitted from the patient to the ergometer during the training can be controlled directly. Due to this, reminder and visual information about the training requirements are transmitted to the patient to improve the training. In addition, the parameters as BP_{ref}, RR_{ref} or HR_{ref} can be used as input to the control loop and can be stabilized automatically by varying the ergometer's power.
2. *Determination of potentially critical states*: According to [Gi02] absolute, the differential and the relative thresholds can be used to derive the patient's state $x(t)$ from the observed parameters $y_p(t)$ to control the training:
   - Absolute thresholds are defined independent on the training state of the patient. Examples are respiratory rates (RR) < 8 min^{-1} and > 24 min^{-1} or oxygen saturation (SpO2) < 90%. These values can differ from patient to patient and have to be defined based on the initial training in the clinic.

- Differential and relative thresholds depend on one hand on the training state $y_e(t)$ of the patient (e.g. blood pressure (BP) before the training start should < 200/110 mmHg and during the training < 250/115 mmHg). On the other hand either the change of one parameter should not exceed a threshold (e.g. drop of BP by 10 mmHg despite increased workload) or the chronological sequence of one parameter should not be abnormal in respect to the reference curves recorded during the initial training in the clinic (e.g. respiration).

Depending on the identified deviation *e(t)* and classified risk (thresholds exceeded) either the training is eased by opening the ergometer's brakes and informing the patient to slow down or the training will be interrupted and the clinic will be informed via alert channels.

3. *Identification of technical problems*: The detection of sensor failure or erroneous sensor placement is of special importance to avoid false alerts. Critical are the problems during recording of ECG and blood pressure because these parameters are used as indicators for the termination of the training.
4. *Derivation of diagnostic parameters*: While fitness training only requires the stabilization of single parameters by the controller, the use of the system for diagnostic reasons requires additional sensor fusion and remote interpretation of the ECG signals in the clinic. Required parameters are derived form the ECG (e.g. maximum ST depression and elevation), the hemodynamic parameters (e.g. maximum heart rate, maximum systolic blood pressure and total exercise duration), and related symptoms (e.g. exercise-induced angina, etc.).

3.4 Guideline Modelling

In SAPHIRE's hospital scenario, selected paper-based guidelines for patients with acute coronary syndrome (ACS) are transformed into computer-interpretable guidelines (CIG) by using the Guideline Interchange Format (GLIF). GLIF was defined by the Intermed Collaboratory to facilitate the sharing of computer-interpretable guidelines. The specifications can be found at the [GLIF] homepage. Primitives used to model guideline flows are shown in Figure 6.

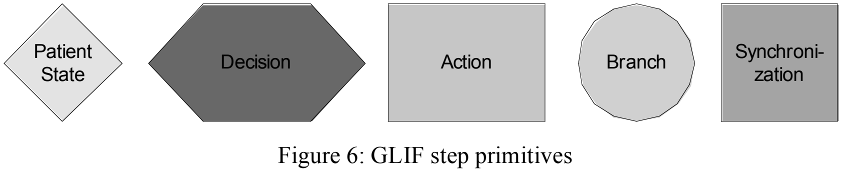

Figure 6: GLIF step primitives

Using these primitives, it is possible to describe the steps of a typical exercise session, as shown in Figure 7. The action steps in the flow are actually sub-guidelines that are executed. To give an example, Figure 8 shows the flow of the sub-guideline called "Measure Vital Parameters (2)". In order to describe the flow and the decision process completely, further refinements are necessary to a degree where expressions in GELLO, an object-oriented guideline execution language are entered.

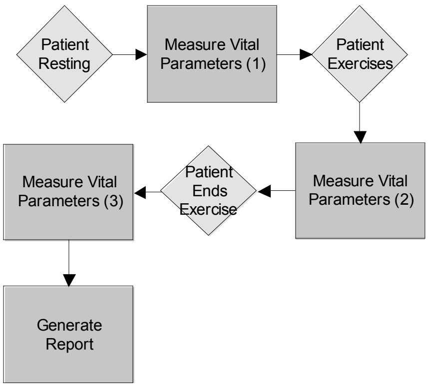

Figure 7: Exercise session modelled in GLIF

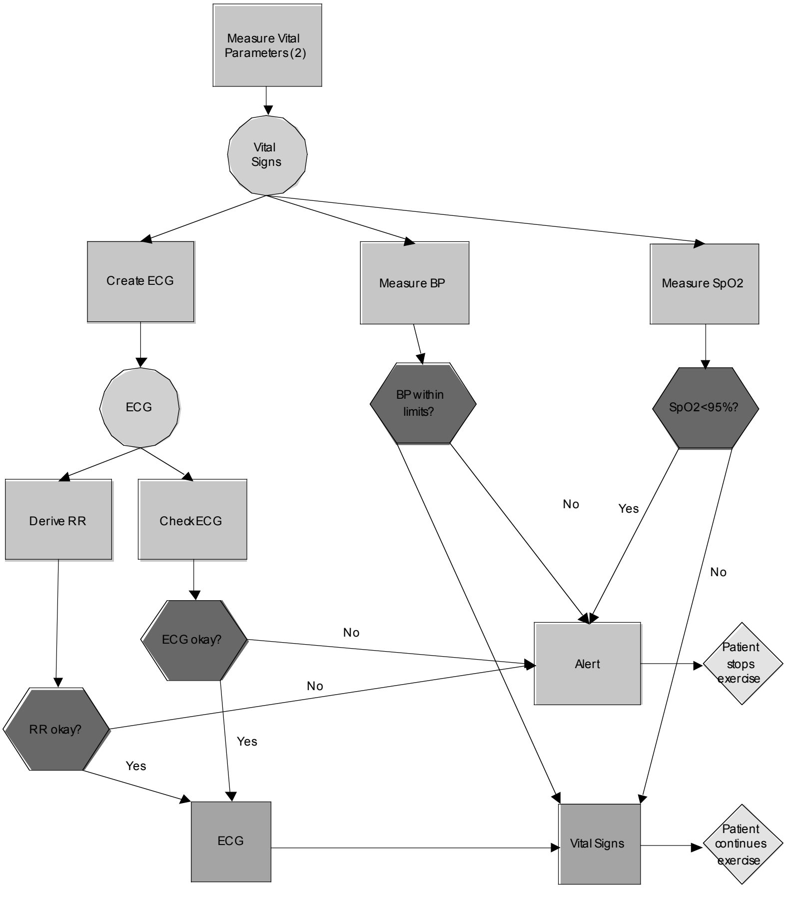

Figure 8: Sub-guideline "Measure Vital Parameters (2)"

4. Conclusions

In this paper the new concept of an assisted home-based training has been introduced. The technical specification and an architectural approach have been derived from a medical guideline. In contrary to existing monitoring systems it cannot be assumed that the patient is at a steady state during the monitoring but the dynamic changes of observable parameters during the training have to be compared with reference curves to derive potentially critical situations and to trigger alerts.

The assisted home-based training is part of a framework that aims to closing the bridge between software systems at the hospital site (medical guidelines and decision support systems) and a multi-services healthcare platform at the patient's home that acquires diagnostic data and stabilizes the patient.

References

[Ad99] Advani, A. *et al.*: Integrating a Modern Knowledge-Based System Architecture with a Legacy VA Database. Proceedings of the 1999 Annual Meeting AMIA, 1999;1-2:653-7

[Ba87] Barnett, G.O. *et al.*: DXplain. An evolving diagnostic decision-support system. JAMA. 1987;258(1):67-74.

[Ca03] Castinié, F. *et al.*: The U-R-Safe project: A multidisciplinary approach for a fully nomad care for patients. Invited paper for SETIT 2003, Tunisia, March 17-21, 2003.

[Do06] Dogac, A. *et al.*: Artemis: Deploying semantically enriched Web services in the healthcare domain. Information Systems 2006;5-6:321-339

[Gi02] Gibbons, R.J. *et al.*: ACC/AHA 2002 Guideline Update for Exercise Testing. A Report of the American College of Cardiology/American Heart Association. Circulation 2002; 106:1883-92.

[GLIF] The Intermed Collaboratory: Guideline Interchange Format (GLIF). http://www.glif.org (last accessed June 13th, 2006)

[Go00] Goldstein, M.K. *et al.*: Implementing clinical practice guidelines while taking account of changing evidence: ATHENA DSS, an easily modifiable decision-support system for managing hypertension in primary care. Proc AMIA Symp. 2000;1:300-4.

[Ko02] Konstantas, D. *et al.*: Mobihealth - innovative 2.5/3g mobile services and applications for healthcare. In Proc. Eleventh IST Mobile and Wireless Telecommunications Summit 2002, Thessaloniki, Greece, June 2002

[Ma05] Maglaveras, N. *et al.*: The Citizen Health System (CHS): a modular medical contact center providing quality telemedicine services. IEEE Trans Inf Technol Biomed. 2005 Sep;9(3):353-62.

[Mi02] Millan, J. *et al.*: TOPCARE - Implementation of a telematic homecare platform in cooperative health care provider networks. EMBS/BMES Conference, 2002.3:1869-1870

[Ra04] Ramnarayan, P. *et al.*: ISABEL: a novel Internet-delivered clinical decision support system. In: Bryant J, editor Current Perspectives in Healthcare Computing 2004, Harrogate, UK;2004 p.245-254

[Wy91] Wyatt, J.; Spiegelhalter, D.: Field trials of medical decision-aids: potential problems and solutions. In: Clayton P, ed. Proceedings of the 15th Symposium on Computer Applications in Medical Care, Washington 1991. New York: McGraw Hill, 1991:3-7