Personalised mobile services supporting the implementation of clinical guidelines

Val Jones¹, Valerie Gay², Peter Leijdekkers³, Rienk Rienks³ and Hermie Hermens⁴

¹ University of Twente, PO Box 217, 7500 AE Enschede, The Netherlands
v.m.jones@utwente.nl

² University of Technology, Sydney, Faculty of Engineering and IT
University of Technology, Sydney, PO Box 123, Broadway, NSW 2007, Australia
{Valerie.Gay, Peter.Leijdekkers}@uts.edu.au

³ Heart Lung Centre and Central Military Hospital, Heidelberglaan 100, 3584 CX Utrecht,
The Netherlands
r.rienks@chello.nl

⁴ Roessingh Research and Development, Roessingh Research and Development, P.O. Box 310
7500 AH Enschede, The Netherlands h.hermens@rrd.nl

Abstract. Telemonitoring is emerging as a compelling application of Body Area Networks (BANs). We describe two health BAN systems developed respectively by a European and an Australian research team and discuss some issues encountered relating to formalization of clinical knowledge to support real-time analysis and interpretation of BAN data. Our example application is an evidence-based telemonitoring and teletreatment application for home-based rehabilitation following myocardial infarction. The proposal is to establish the patient’s individual baseline risk profile and, by real-time analysis of BAN data, continually re-assess the current risk level in order to give timely personalised feedback. Static and dynamic risk factors are derived from the literature. Many sources express evidence probabilistically, suggesting a requirement for reasoning with uncertainty; elsewhere evidence requires qualitative reasoning: both familiar modes of reasoning in KBSs. However even at this knowledge acquisition stage some issues arise concerning how best to apply the clinical evidence.

Keywords: Telemonitoring/treatment, Body Area Networks, biosignal processing, Clinical Decision Support, clinical guidelines.

1 Introduction

Telemedicine services such as patient monitoring and treatment are emerging as some of the most compelling applications of Body Area Network (BAN) technology. We are beginning to investigate in what circumstances it is feasible and useful to apply clinical decision support technology to the problem of analysis and interpretation of BAN data. In this work-in-progress paper we refer to the example of dynamic risk assessment for patients undergoing cardiac rehabilitation. The intention is to build on our current mobile
monitoring systems for cardiac patients and develop a more intelligent, evidence-based monitoring and treatment application for home-based rehabilitation following myocardial infarction. The idea is that the cardiology team establishes the patient’s individual baseline risk profile and equips the patient with a cardiac rehabilitation BAN. This extension of the cardio BAN incorporates a set of body worn sensors and transmits the captured biosignals to a remote healthcare location. Analysis of biosignals is performed locally on the BAN and/or remotely. As well as providing continuous cardiac monitoring, as the current systems do, the proposed BAN application will also continually reassess the patient’s current risk level, enabling the system and/or a remote clinician to give appropriate personalized, timely advice, support and if necessary, intervention. The intention is to support secondary prevention by optimizing rehabilitation activities and minimizing dynamic risk whilst maintaining vigilance in respect of adverse events or trends (the latter being already implemented in the existing cardio BANs).

In section 2 we introduce the two existing health BAN systems, one from Sydney and one from Twente. Each has been prototyped and trialled on different patient groups. In section 3 we outline the example application, namely BAN-based support for patients in home-based cardiac rehabilitation. This application could be implemented as an additional service running on either of the BAN systems. In section 4 we raise some of the issues which were encountered in the knowledge acquisition phase.

2. Mobile monitoring and treatment systems

First we describe the monitoring systems developed by two research groups. The Telemedicine Group at the University of Twente in The Netherlands and the Personal Health Monitor Group at the University of Technology, Sydney, are both researching the use of Body Area Networks to provide mobile health services to patients and health professionals. Both the European BAN and the Australian BAN incorporate a set of body-worn devices including one or more sensors and a processing and communication platform (a mobile phone or PDA). Fig. 1 shows one variant of the European MobiHealth BAN [1-4] and Fig. 2 shows the Australian PHM system [5-8].
At Twente the emphasis has always been on telemedicine, i.e., using “extraBAN” communication between the patient BAN and a remote healthcare organisation or clinician. A generic architecture for Body Area Networks (BANs) and a supporting m-health service platform have been developed, referred to respectively as the MobiHealth BAN and MobiHealth MSP. Based on the generic architecture, a series of specialised BANs and software applications have been developed for different patient groups from a number of specialties including cardiology. Biosignals measured by body worn sensors are transmitted to a remote healthcare location where they can be viewed by clinicians. Automated or clinician-initiated feedback and treatment completes the (macro) loop for BAN-based m-health services. Since 2002 several telemonitoring and teletreatment applications for a variety of (chronic and acute) clinical conditions have been trialled on different patient groups over the course of a number of collaborative projects (IST MobiHealth, IST XMotion, eTEN HealthService24, Freeband Awareness, eTEN Myotel).

The group at the University of Technology, Sydney, began researching a contrasting approach where the original emphasis was on local (micro-loop) processing, offering local monitoring and personalised services to patients to support self-care. The PHM has been trialled on 70 low-medium risk cardiac patients at the Sydney Royal North Shore Hospital (Cardiology Department) in Australia and is currently under commercial development. An extensive description and comparison of the two systems can be found in [9].

Both systems can be classed as health BANs according to the Twente definition. In both systems captured biosignals undergo a series of processes starting with low level signal processing and ending with high level clinical analysis and interpretation to various levels of abstraction in order, for example, to detect medical emergencies or adverse trends. Both systems include detection of cardiac arrhythmias as one of the offered clinical applications (the Sydney Personal Heart Monitor and the Twente cardioBAN).

The sensors that are currently integrated in the Personal Health Monitor are: ECG, weight scale, accelerometer, blood pressure monitor, blood glucose meter, pulse oximeter and GPS. The sensors that have been integrated into the MobiHealth BAN to date are: electrodes for measuring 3, 4 and 9 channel ECG and surface EMG, pulse oximeter,
respiration sensor, temperature sensor and activity sensors (step-counter, 3D accelerometer).

For certain clinical interpretation tasks, such as detecting when certain pre-specified thresholds are exceeded, an algorithmic approach suffices. Other interpretation tasks require a more sophisticated approach, involving fusion and analysis of data from multiple sensors. At a certain point algorithmic approaches may not be appropriate and both research groups have come to realize the necessity, in some applications, of adding more intelligence including context awareness to the analysis and interpretation of BAN data [10-12, 3].

3 Example application: cardiac rehabilitation BAN

Participation in cardiac rehabilitation programmes post MI “has been shown to reduce all-cause mortality and cardiac mortality when compared to usual care” [13]. The vision of [14] was to implement continuous risk assessment for this patient group by means of real-time analysis and interpretation of BAN-captured biosignals together with context data. As well as detecting clinical emergencies and trends this extended cardiology BAN would estimate the current risk level and give appropriate feedback and encouragement to support compliance (eg exercise and medication reminders) to the patient. The advice would attempt to minimize risk levels at any one time for example by rescheduling exercise not to coincide with elevation of risk levels caused by other factors such as stress.

The American Heart Association lists the major non-modifiable risk factors for cardiovascular disease as: age, gender, heredity (family history, race). These factors play a major part in determining an individual patient’s baseline risk. The major modifiable risk factors (cigarette smoking, obesity, hypertension, high blood cholesterol, diabetes mellitus and physical inactivity) can be influenced by life-style changes and/or medication. However the impact of changes in lifestyle will usually be gradual (over weeks or months). Risk of mortality by myocardial infarction or coronary heart disease can be estimated based on these modifiable and non-modifiable risk factors. Risk is usually expressed in terms of percentage of mortality over a 10 year time span [15]. Other so-called “contributory factors” are stress, alcohol, diet and nutrition, but “their significance and prevalence haven’t yet been precisely determined” [15]. In addition to the static or relatively slowly changing factors, the literature also refers to factors elevating risk in the short term. These ‘triggers’ include time of day, physical exertion, weekly and seasonal variations, eating a heavy meal, smoking, and “meteorological stress” (ie exposure to extreme temperatures). All these triggers may lead to ischaemia, which could be detected directly through ST segment changes on the ECG. However we did not find an algorithm for detecting ST segment changes that could be implemented on the BAN at present.

The proposal was to extend the existing cardiology BAN from Sydney (the PHM system) and its software in order to monitor, where possible, these short term risk factors and dynamically estimate the changing risk for an individual patient. (The proposed application could similarly be implemented by extension of the European MobiHealth
cardio BAN.) The baseline risk would be set and regularly reviewed by the cardiologist and the system would calculate the dynamic risk on the basis of sensor data and context information and give appropriate feedback. The cardiac rehabilitation BAN proposed in [14] would consist of an extension of the PHM system, consisting of a processing platform (a mobile phone) which communicates wirelessly with sensors and context sources to continuously update the current risk estimate. The sensors would be electrodes (to measure ECG and derive heart rate), accelerometer (to detect falls and to measure duration and intensity of physical activity), temperature sensor and blood pressure monitor. Context sources would include the internal clock of the mobile phone (time of day) and calendar (for seasonal variation in risk). For some factors the patient would be required to enter data (e.g., heavy meal, cigarette). Note: not all dynamic risk factors identified can currently be measured using existing sensors or external context sources.

At Sydney a first selection of static and dynamic risk factors was established following a literature search and a first attempt at formalisation of the knowledge was attempted, resulting in a model for dynamic risk assessment and an algorithm incorporating a scoring system [16]. The concept was to define a personal baseline risk based on the cardiologist’s assessment including the particular fixed and voluntary characteristics of the individual patient, and then on a moment-by-moment basis to dynamically increment or decrement the current risk score according to changing factors known to influence risk in the short term. SCORE risk functions [17] were preferred over Framingham [18] since the target group are already diagnosed with cardiac disease or have suffered a cardiac event. The resulting model can be regarded as a first approximation based on a literature search only, still requiring validation by clinical experts. However even at this early stage many issues emerged; here we discuss some points arising from the evidence relating to the role of exercise during rehabilitation.

3.1 Exercise during cardiac rehabilitation

Exercise is a central component in cardiac rehabilitation. The NICE clinical guideline on secondary prevention following a myocardial infarction includes as a key priority that “Patients should be advised to undertake regular physical activity sufficient to increase exercise capacity” and that “Patients should be advised to be physically active for 20–30 minutes a day to the point of slight breathlessness” [13]. Some health authorities offer a hospital-based rehabilitation programme including exercise sessions which are monitored closely by clinical staff. According to the definition of phases of comprehensive cardiac rehabilitation found in the UK National Service Framework for Coronary Heart Disease, (Appendix F of the full guideline [13]), “structured exercise sessions to meet the assessed needs of individual patients” are introduced for eligible patients in Phase 3 of rehabilitation, four weeks after the acute cardiac event. Since physical exertion itself can be a trigger for further cardiac events, the exercise prescription must be adapted to the individual patient and carefully monitored. Phase 3 is usually implemented as a hospital based outpatient programme. After this phase, exercise and other lifestyle
recommendations will be made for Phase 4: “long-term maintenance of changed behaviour”. Long term regular exercise has been “shown to reduce all-cause and cardiac mortality in patients after an MI” [13]. However the guideline notes that “Maintenance of these lifestyle changes in patients after an MI has been shown to decline following the end of the patient’s participation in coordinated comprehensive cardiac rehabilitation” and identifies the key research question: “What encourages the maintenance of regular exercise … beyond the period of comprehensive cardiac rehabilitation?”

We investigate whether a BAN-based monitoring application could provide patients in Phase 4 with support in maintaining and optimizing their long term home-based rehabilitation by helping to track and minimize dynamic risk levels and by giving monitoring and feedback, and encouragement, reassurance and a sense of safety. Currently we are examining the complex set of rules in [16] to see if a Clinical Decision Support (CDS) approach could offer a better solution than the algorithmic approach.

4 Extension with a CDS component

Many of the sources express clinical evidence in terms of probabilities, suggesting a requirement for reasoning with uncertainty; in other cases the medical evidence requires qualitative reasoning. A KBS/decision support approach would seem to be appropriate and address at least some of the issues. The concept is illustrated in Fig. 3.

Fig. 3 CDSS with real time biosignal input from Body Area Network

5 Discussion and Conclusions

The preparatory work to date on the cardiac rehabilitation application has been largely concerned with the knowledge acquisition phase, involving searches of the medical literature including relevant clinical guidelines to provide the base clinical knowledge. Knowledge engineering was initially attempted taking an algorithmic approach, by
expressing individual risk factors as rules and defining a scoring system. Currently we investigate expressing the knowledge in a suitable KR formalism for processing using CDSS technology to analyse and interpret BAN data and context data. Some issues we encountered are outlined below.

**Degrees of uncertainty.** Probabilistic evidence on some of the risk factors is sometimes expressed with large ranges, variance or margins of error. An example is the estimation of ventilatory threshold based on HR$_{\text{max}}$. The threshold is used in one of the rules in [16]. At first sight this appears to be a simple question of estimating and applying a threshold. Although both ventilatory threshold and HR$_{\text{max}}$ can be measured directly by a cardiac stress test, such tests are inadvisable in post-MI patients (indeed this would violate the rules in which they are referenced). Therefore an estimate is used in [16] where ventilatory threshold is estimated on the basis of HR$_{\text{max}}$, which is in turn estimated by the formula commonly used in exercise physiology of 220 minus age in years. However this HR$_{\text{max}}$ formula has been criticised in [18] as being clinically unfounded: “Research since 1971 has revealed the error in HR$_{\text{max}}$ estimation, and there remains no formula that provides acceptable accuracy of HR$_{\text{max}}$ prediction.” A number of alternative formulae are reviewed in [18], but the conclusion is that more research is required to establish a more accurate method of estimation. Furthermore, the formula for estimating ventilatory threshold in relation to HR$_{\text{max}}$ is itself expressed with a wide margin of variability: “The ventilatory threshold corresponds with approximately 85% of HR$_{\text{max}}$. But this may vary between 50% and 90% of HR$_{\text{max}}$” [16]. The concern is that such high degrees of uncertainty or imprecision will multiply up casting doubt on the likelihood of reaching useful conclusions.

Another point is general lack of consensus over risk factors “Risk factors for cardiovascular disease have been defined by various groups and experts for decades. Unfortunately, the lack of consensus among these groups and the periodic changes in risk factor listings have led to confusion among health care professionals” [19].

Finally separate items of clinical evidence, often expressed probabilistically, were found in the literature but the issue of finding evidence supporting how to combine, normalize and weight these separate items however seems to us to be problematic, and the weights assigned in [16] were in many cases arbitrary first ‘guess estimates’. We feel the need for expert opinion or further evidence in order to combine, normalize, weight and tune the knowledge base relating to the different risk factors.

To summarise this work-in-progress, we pose the general question: in what circumstances it is feasible and useful to apply CDSSs in connection with BAN monitoring and treatment applications? Further, in the particular case of real-time cardiac risk assessment, we ask if the cardiac rehabilitation BAN concept itself is clinically valid, useful and achievable given present knowledge and technology. If the concept is valid, we see potential for cost efficient delivery of effective cardiac rehabilitation. NHS Lothian’s Heart Manual programme has demonstrated that properly planned and managed home-based cardiac rehabilitation can be as effective as hospital-based rehabilitation programmes [21]. Augmenting this with real-time monitoring and feedback systems for home use by patients could further enhance such home-based programmes, hence the
proposed BAN-supported home-based rehabilitation application might have the potential not only to support Phase 4 cardiac rehabilitation, but possibly to replace the hospital-based Phase 3 of current programmes. The application also has potential for monitoring health under extreme circumstances, e.g. for deep sea divers repairing oil pipe lines, or workers at high altitude, athletes in training or military personnel on the battlefield. In Twente we also investigate another application of CDSSs using Actor-Agent Communities (AAC) based on Bayesian networks. This study [22] focuses on rehabilitation for chronic pain patients.

If the concept is valid, but (in the cardiac rehabilitation application or other applications) insufficient clinical evidence is currently available to support the application, an alternative contribution by our technology might be found in data aggregation. Data routinely collected from patient health BANs can furnish large collections of clinical data with the potential for data mining in order to yield more statistically powerful and accurate clinical evidence. Such data aggregation effort however requires standards relating to representation of biosignal data and the associated metadata needed to compare and interpret them.

References


