Mobile Health Care: Towards Commercialization of Research Results

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Abstract: During the last fours years a consortium of universities, hospitals and commercial companies collaborated to develop innovative systems and services for mobile health care. The European Union financed two major projects allowing us to develop a complete mobile healthcare system and validate it with extensive medical trials. MobiHealth[1] and HealthService24[1] have developed an m-health service platform including a generic Body Area Network (BAN) for tele-healthcare. Biosignals measured by sensors connected to the BAN are transmitted to a remote healthcare location over public wireless networks (e.g. GPRS, UMTS), where care professionals can monitor, diagnose and provide advice to patients in real time. The developed system is in the last phase of the pre-commercial validation and a commercial product is expected to be available in late 2006.

1 Introduction

Today the health sector faces serious and increasing problems in the management of resources for disease prevention, follow-up and remote assistance of patients. The cost of in-patient care is increasingly creating problems for both patients and social security organizations, while out of hospital monitoring of the patients' health state is practically non-existent. The patient either has to measure different vital signs at regular intervals or has to visit the hospital. As a result, patients who need monitoring but are not at immediate risk are obliged to stay for long periods in hospital so that regular measurements can be taken. These results in high costs for the hospitals and health insurers, lost working hours and low morale of the patient.

On the other hand, citizens are becoming more health conscious and are demanding advanced health services, as can be seen from the ever-expanding para-health market, where health related services are becoming increasingly common and

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Project sites http://www.mobihealth.org and http://www.heathservice24.com
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available to every citizen. In the last few years, for example services and applications, such as physical state monitoring during sports training, the use of health call centres and on-line health consultations have been commercialized in almost all European countries.

Finally, citizen mobility at a pan-European scale is increasing, with thousands of citizens crossing European country borders daily for purposes of entertainment, leisure, shopping and business. This mobility is strongly supported by the widely available communication services, like mobile telephony and mobile internet access, available today in the most remote areas of the European continent (and the globe!). One of the major technological advances of the 21st century will be the implementation and wide availability of public broadband wireless networks, and specifically 3G (UMTS) and 4G networks.

The above described needs of the citizens and patients combined with the evolution and availability of wireless communication networks and the ever-advancing miniaturization of sensor devices and computers, will give rise to new services and applications that will have a major impact on health care. Citizens, being patients or non-patients, will not only be able to get medical advice from a distance but will also be able to send from any location full, detailed and accurate vital signal measurements, as if they had been taken to a medical centre, implementing the "ubiquitous medical care" dream.

Towards this direction we have completed a research project and are running a commercial validation project, for the development and deployment of innovative value-added mobile health services using 2.5 (GPRS) and 3G (UMTS) networks.

The **MobiHealth** research project (financed by the European Union under the IST programme (IST-2001-36006)), started in May 2002 and completed in February 2004, developed a technically validated and fully functional mobile services platform for ambulant patient monitoring with measurements transmitted over public wireless networks. This was achieved with the integration of sensors in a wireless Body Area Network (BAN). The BAN continuously measures and transmits vital signs to health service providers (e.g. hospital) or health brokers. This way the BAN facilitates remote monitoring of patients' vital signs and therefore enables proactive disease prevention and management by continuous monitoring of patients' health condition 'anytime and anywhere'.

With the completion of MobiHealth project, the very encouraging results and comments coming from the system users (i.e. hospitals and patients), we proceeded towards the first phase of the commercialisation of the system and services. A new 18th months project, **HealthService24**, under the eTen framework was launched in February 2005, with the goal to validate the existing service in the market in order to have a fully marketable solution at the end of the project. The HealthService24 project validates and fine-tunes the solution to such an extent, that it enables a sustainable market deployment at the end of the market validation phase.

1.1 Overview of the projects' results and targets

The use of health BANs together with advanced wireless communications enables remote management of chronic conditions and detection of health emergencies whilst maximising patient mobility. MobiHealth has developed a generic BAN for healthcare and an m-health services platform. The BAN incorporates a set of body-worn devices and handles wireless communication (via Bluetooth) amongst those devices. It also handles external communication (via GPRS/UMTS) with a remote location. The main devices used in the project are medical sensors like 3 to 7 lead ECG/EMG, respiration belts and oxygen saturation sensors. The remote healthcare location is a healthcare provider (i.e. hospital or medical call centre). Biosignals measured by sensors connected to the BAN are transmitted to the remote healthcare location over public wireless networks.

The results of the project include an architecture for, and a prototype of, a generic service platform for provision of ubiquitous healthcare services based on wireless Body Area Networks. The MobiHealth BAN and service platform were trialled in four European countries with a variety of patient groups. The MobiHealth system can support not only sensors, but potentially any body worn devices Hence the system has potentially very many applications in healthcare which allow delivering healthcare services to the community. In the last months of the project 9 different trials scenarios were implemented for different patient groups. These trials allowed us to identify problems and issues in the development of m-health services and to identify limitations and shortcomings of the existing and forthcoming public network infrastructures.

The HealthService24 project started in February 2004 and ends in July 2006. The main objective of HealthService24 is to test the feasibility of the deployment of the mobile healthcare services via trials that will validate the precise conditions to be fulfilled for the subsequent deployment of the services.

In HealthService24, three trial scenarios at different sites in Europe are used for the validation of the deployment conditions. It should be noted that an important part of the project is the introduction of the required adaptations in order to correct problems that were identified in the trials of the MobiHealth project.

2 The MobiHealth System and Services

MobiHealth has developed a mobile health BAN and a generic service platform for BAN services for patients and health professionals. Remote patient monitoring is only one of the services that can be provided.

The healthcare BAN is an innovative health-monitoring tool that incorporates a range of devices including sensors and actuators, together with communication and processing capabilities. Communication between entities within a BAN is called *intra-BAN* communication. To use the BAN for remote monitoring, external communication is required which is called *extra-BAN* communication. The gateway that facilitates extra-BAN communication is the *Mobile Base Unit (MBU).*

The MobiHealth system provides a complete end-to-end m-health platform for ambulant patient monitoring, deployed over UMTS and GPRS networks. The MobiHealth patient/user is equipped with different vital sign sensors, like pulse rate, oxygen saturation and ECG, interconnected via the healthcare BAN. The MBU is the central node of the healthcare BAN. It aggregates the vital signs measurements (intra-BAN communication based on wireless networks like Bluetooth[1] and Zigbee[2]) and transmits them to the back-end system (extra-BAN communication based on GPRS and UMTS), which may be located within the health broker premises or may be located at the wireless services provider's site. From there the measurements are dispatched to the health care provider or broker where the medical personnel monitor them life or store them for automatic processing. Figure 1 shows the architecture of a BAN. Sensors devices establish an ad-hoc network with the MBU. The MBU can be any device with sufficient processing power able to manage the BAN and provide extra-BAN communication services.

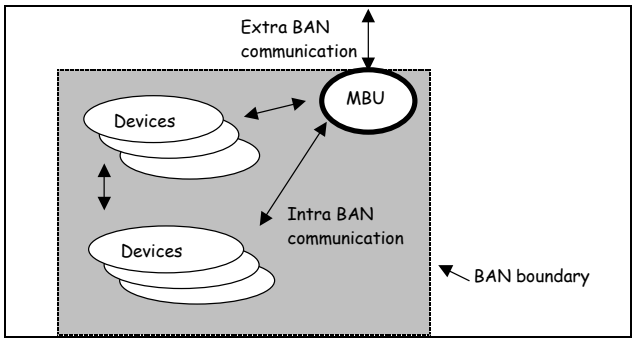

Figure 1 : BAN architecture

2.1 The MobiHealth Body Area Network

The concept of Body Area Networks originally came from IBM[3] and was developed further by many other researchers, for example at Philips [4], at the University of Twente [5], and at Fraunhofer [6]. In the Wireless World Research Forum's *Book of Visions*, we define a BAN as "*a collection of (inter) communicating devices which are worn on the body, providing an integrated set of personalised services to the user*" [11].

In the context of the MobiHealth project the **Healthcare BAN** is a health monitoring tool that consists of sensors, actuators, communication and processing facilities connected via a wireless network which is worn on the body and which moves around with the person (i.e., the BAN is the unit of roaming). A sensor is the starting point of the vital sign (data) acquisition process, ensuring that a physical phenomenon, such as patient movement, muscle activity or blood flow, is converted to an electrical signal. Next, a sensor device amplifies, conditions, digitise and transmits the data to the MBU.

The Healthcare BAN sensors can be self-supporting and/or front-end supported. Self-supporting sensors have a power supply and facilities for amplification,

conditioning, digitisation and communication. Self-supporting sensors are independent building blocks of a BAN and ensure a highly configurable healthcare BAN. However, each sensor runs at its own internal clock and may have a different sampling frequency. Consequently, mechanisms for the synchronization between sensors may be needed.

Front-end supported sensors share a common power supply and data acquisition facilities. Consequently, front-end supported sensors typically operate on the same front-end clock and jointly provide multiplexed sensor samples as a single data block. This avoids the need for synchronization between sensors.

A sensor is responsible for the data acquisition process, ensuring that a physical phenomenon, such as patient movement, muscle activity or blood flow, is first converted to an electrical signal. This signal is then amplified, conditioned, digitised and communicated inside the BAN.

2.2 Service platform architecture

Collecting and transmitting the vital signal measurements is only part of the healthcare service platform developed in the MobiHealth project and shown in Figure 2. The dotted square boxes indicate the physical location where parts of the service platform are executing. The rounded boxes represent the functional layers of the architecture. The M-health service platform consists of sensor and actuator services, intra-BAN and extra-BAN communication providers and an M-health service layer. The M-health service layer integrates and adds value to the intra-BAN and extra-BAN communication providers masking applications from specific characteristics of the underlying communication providers.

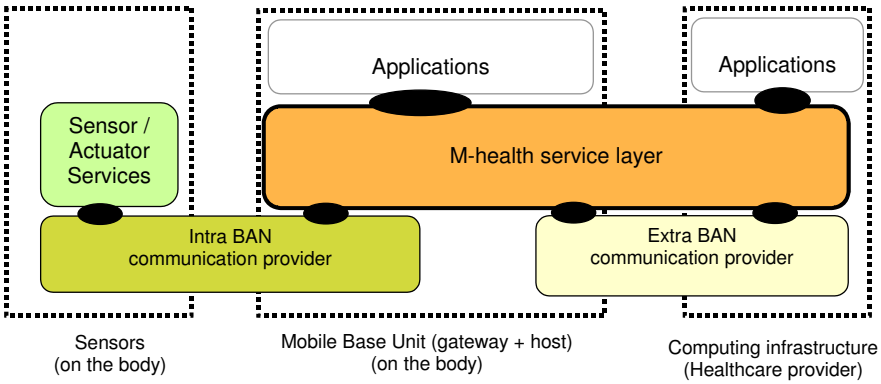

Figure 2 Service platform functional architecture

Applications that run on top of the service platform can either be deployed on the MBU (for on-site use e.g. by a visiting nurse) or on the servers or workstations of the healthcare provider, i.e. the call centre or the co-located secondary care centre in Figure 2. For this, the M-health service platform offers a number of services including:

- *BAN registration*: the service platform maintains a list of active BANs and allows applications to retrieve the specific configuration of a BAN.
- *BAN discovery*: applications can subscribe to the platform to receive a notification in case a BAN becomes active (i.e. a patient switches on a BAN).
- *BAN authorization and authentication*: the service platform authenticates BANs and only allows authorized BANs to convey data.
- *BAN data encryption*: the platform encrypts data that is conveyed over unsecured networks
- *BAN configuration*: the service platform allows online configuration and management of the BANs, such as (de)activation of specific sensors or modification of the sample frequency of a sensor.
- *Data acquisition control*: the service platform enables applications to start, stop or temporarily interrupt the data acquisition process of a BAN.
- *Query and modify actuator status*: applications can manipulate actuators from a distance.
- *BAN data storage*: the service platform can act as an intermediate storage provider to applications. Applications determine the minimal duration of the storage.
- *BAN data monitoring*: the service platform can apply filtering algorithms on the BAN data to determine if an interesting event has taken place (e.g. a patient has dropped on the floor) and report this event to the application layer.

A refined view of the m-Health service layer is shown in

Figure 3 for the case where the M-health service platform user (e.g. at a hospital) is not co-located remotely with the call centre. The arrows in the figure show the flow of the BAN data. The BANip entity is the BAN interconnect protocol protocol entity [7]. Peer entities can be found on the MBU and on the computing infrastructure (in the 'fixed' network). The BANip entities communicate through a proxy that authenticates and authorizes the BANs' connection.

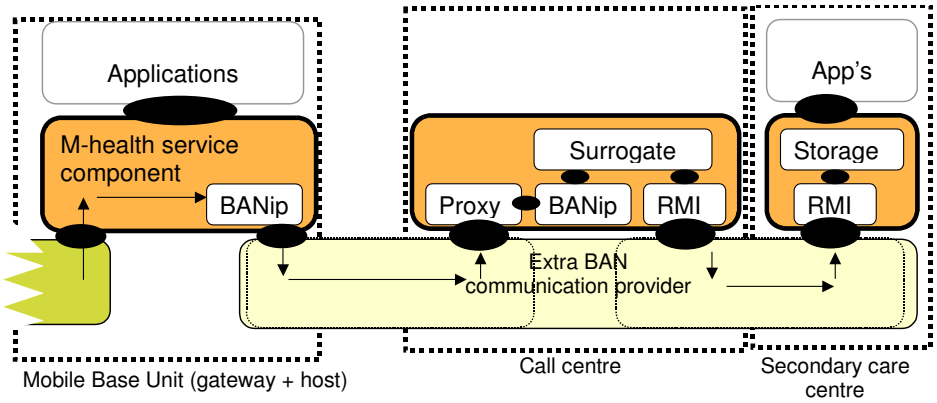

Figure 3. Refined view of the service platform

The surrogate component uses the BANip protocol to obtain BAN data. This component contains a representation of the BAN (i.e. the surrogate) and shields other components in the 'fixed' network from the BANip and direct interaction with the BAN. The surrogate component can be accessed by any application protocol, including Remote Method Invocation (RMI) as depicted in
Figure 3. The storage entity uses RMI to interact with the surrogate as if it interacts with the remote BAN at the location of the patient, without the burden of the discovery, registration and authentication of the BANs. The surrogate component is therefore the intermediary whereto BAN data from the location of the patient is pushed and wherefrom the data is pulled by the application component residing at the secondary care centre. The storage entity provides the BAN data storage service to the application layer. Configuration, discovery and monitoring services are offered as separate entities, with the same structure as the storage entity.

Applications that use the m-health service layer can range from simple viewer applications that provide a graphical display of the BAN data, to complicated applications that analyse and interpret the data. The M-health service platform consists of sensor and actuator services, intra-BAN and extra-BAN communication providers and an m-health service layer. The intra-BAN and extra-BAN communication providers represent the communication services offered by intra-BAN communication networks (e.g. Bluetooth) and extra-BAN communication networks (e.g. UMTS), respectively. The m-health service layer integrates and adds value to the intra-BAN and extra-BAN communication providers. The m-health service layer masks applications from specific characteristics of the underlying communication providers, such as the inverted consumer-producer roles.

2.3 Service platform technical requirements

To leverage the healthcare BAN for use as a *remote* monitoring tool several issues and considerations were taken into account in the design and development of the supporting healthcare service platform. These issues reflect both, commercial and social needs or restrictions, as well as technical limitations of underlying [8]. The most important ones being *scalability*, *security* and *extra-Ban network restrictions*.

Scalability: The healthcare service platform must be able to support services that cover niche healthcare cases that require the simultaneous monitoring of small numbers of patients (e.g., ranging from 10 to 100 BANs) to large-scale chronic disease management processes (e.g., 100.000+ BANs used to monitor COPD patients). In addition, geographical scalability, that is global coverage, should be supported.

Security: The healthcare service platform connects the BAN with the Internet. Consequently, the BAN is potentially vulnerable to attacks from malicious Internet users who may try to either break into the system or frustrate its use. Therefore, the healthcare service platform should be protected from attacks like Denial of Service (DoS). Mechanisms that ensure data integrity must be included to prevent corruption of BAN data. Each BAN should authenticate itself with the service platform, which should only allow authorized BANs to send BAN data (i.e. preventing masquerading)

and access controls are needed to prevent unauthorised access to BAN control signals and/or data.

Mask 'inverted-producer-consumer' problem. Traditionally, providers of data (such as web servers) are deployed on a computing infrastructure with sufficient network and processing capacity. Consumers of data (such as web browsers) assume that providers are available most of the time (except for maintenance) and have sufficient bandwidth to serve a reasonable number of consumers. This model was the one adopted by the public wireless network operators where the data consumer, i.e., the mobile device, initiates a network connection to the producer. Based on this assumption, most network operators of 2.5/3G networks hand out private IP addresses to mobile devices. Connection establishment initiated from a fixed host on the public Internet to a mobile device is therefore inhibited.

However, in the MobiHealth system each BAN *is a data producer*. For the service platform, the producer and consumer roles are thus inverted because the provider of data is deployed on a mobile device (i.e. the MBU) while the consumer of data is deployed on a fixed host with sufficient processing and communication capacity. The MBU may be temporary unavailable, due to the short lifetime of batteries or because it has moved to an area without coverage of the public wireless infrastructure. The service platform therefore masks the inversion of the producer-consumer roles from the BAN and the end-users (e.g., a patient wearing the BAN or a medical specialist analyzing the BAN data).

2.4 Implementation of the MobiHealth System

In the MobiHealth trials, the MBU was implemented on an iPAQ H3870. This device has built-in Bluetooth capabilities and can be extended with a GPRS extension jacket. The UMTS version used a Nokia UMTS telephone connected to the MBU via Bluetooth. Figure 4 shows on the left the GPRS system with a sensor device and sensors, and on the right the UTMS system (without the sensors).

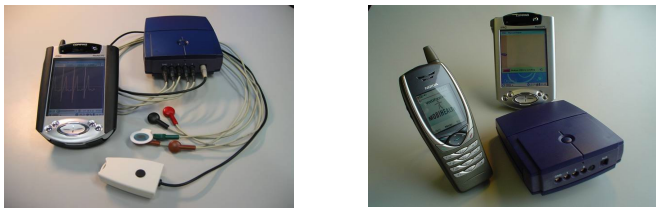

Figure 4: GPRS and UMTS systems

The BANip [7] has been implemented using Java 2 Micro Edition (J2ME) on the MBU as an HTTP client that collects a number of samples into the payload of an HTTP POST request and invokes the post on the surrogate. We have used a standard HTTP proxy to act as a security gateway of the surrogate. In case the surrogate needs to control the MBU, these control commands are carried as payload of the HTTP reply.

The surrogate was implemented using the Jini Surrogate architecture. Jini provides the implementation for auto-discovery and registration of the BAN. Other components, such as the BAN data storage component, are service users from the perspective of the surrogate.

The medical sensors integrated into the MobiHealth system allowed the measurement of six different biosignals, namely: ECG, EMG, Pulse Oximetry, Temperature, Marking, Respiration and Motion/activity. In addition, a number of derived signals were calculated, for example like heart rate and heart rate variability.

The signals could be viewed on the MBU (figures 4 and 5) and were also sent live to the health care organization, where they were presented to the medical personnel (figure 6) by means of the Portilab professional viewer application.

Figure 5. MBU display Respiration

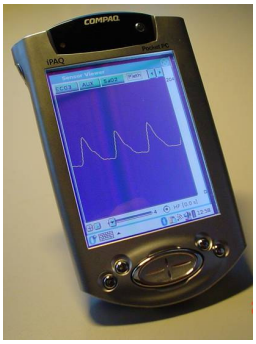

Figure 6. MBU display Pulse Plethysmogram

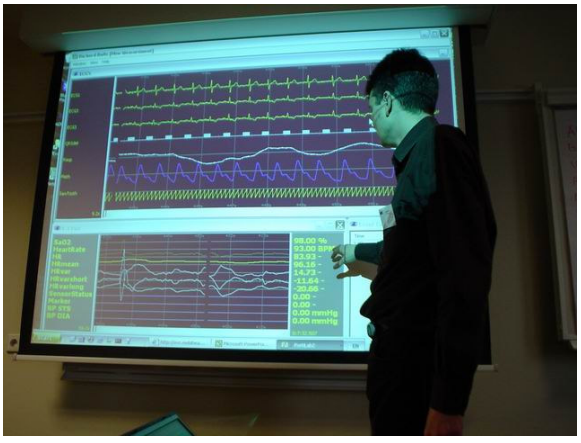

Figure 7. MobiHealth PortiLab end-user application

2.5 The MobiHealth Trials

The MobiHealth system and services were validated with a number of trials that spanned four European countries, and covered a range of conditions including pregnancy, trauma, cardiology, rheumatoid arthritis and respiratory insufficiency and made use of patient BANs and health professional BANs (nurse BAN, paramedic BAN). The trials were selected to represent a range of bandwidth requirements: low (less than 12 Kbps), medium (12 – 24 Kbps) and high (greater than 24 Kbps) and to include both non-real time (e.g. routine transmission of tri-weekly ECG) and real time requirements (e.g. eventss, transmission of vital signs in a critical trauma situation). For each application, the generic MobiHealth BAN was specialized by addition of the appropriate sensor set and corresponding application software.

Trial 1 - German : Telemonitoring of patients with cardiac arrhythmia

The target group in this trial are patients with ventricular arrhythmia who are undergoing drug therapy. In patients suffering from arrhythmia, ECG measurements have to be taken regularly to monitor the efficacy of drug therapy. By wearing a BAN, the patient's ECG and blood pressure are transmitted via GPRS from home or elsewhere to the health call centre, where the vital signs are monitored by a cardiologist. The intention is that irregular patterns will be detected quickly and appropriate intervention can be initiated.

Trial 2 - The Netherlands: Integrated homecare for women with high-risk pregnancies

The trial used the MobiHealth BAN to support integrated homecare for women with high-risk pregnancies. Women with high-risk pregnancies are often admitted to the hospital for longer periods because of possible pregnancy-related complications. Homecare with continuous monitoring is desirable and can postpone hospitalisation and reduce costs, as well as offering more security for the mother and unborn child. In this trial, patients are monitored from home using the MobiHealth BAN and the (maternal and foetal) biosignals are transmitted to the hospital. The trial uses both GPRS and UMTS networks.

Trial 3 - The Netherlands: Tele trauma team

MobiHealth BANs are used in trauma care by both patients and health professionals (ambulance paramedics). The trauma patient BAN measures vital signs, which are transmitted from the scene to the members of the trauma team located at the hospital. The paramedics wear trauma team BANs, which incorporate an audio system and a wireless communication, link to the hospital. The purpose of this trial is to evaluate whether mobile communications can improve quality of care and decrease lag-time between the accident and the intervention. The trial uses both GPRS and UMTS networks.

Trial 4 - Spain: Support of home-based healthcare services

This trial involves use of GPRS for supporting remote assistance and home-based care for elderly and chronically ill patients suffering from co-morbidities including COPD. The MobiHealth nurse-BAN is used to perform patient measurements during nurse home visits and the MobiHealth patient-BAN is used for continuous monitoring during patient rehabilitation at home, or even outdoors. Parameters measured are oxygen saturation, ECG, spirometry, temperature, and blood pressure.

Trial 5 - Spain: Outdoor patient rehabilitation

The patients involved in this trial are chronic respiratory patients who are expected to benefit from rehabilitation programs to improve their functional status. The study aims to check the feasibility of remotely supervised outdoor training programs based on control of walking speed enabled by use of the MobiHealth BAN. The physiotherapist receives online information on the patient's exercise performance and provides feedback and advice. It is expected that by enabling patients to perform physical training in their own local settings, the benefits, in terms of cost and social acceptance, can be significant. Parameters measured are pulse oximetry, ECG and mobility with audio communication between patient and remote supervising physiotherapist.

Trial 6 - Sweden: Lighthouse events and locator trial

The target group involved in the trials are patients at the Lighthouse care resource centre and also clients living at home, but with the common characteristic that all have an events system located in their room at the Lighthouse centre or in their home. The current system does not allow the patient any freedom related to mobility and forces the patient to be trapped at home or in their room at the Centre if they are to be in range of the events. By replacing the fixed events system with the mobile MobiHealth system the patient can move freely anywhere whilst still having the events facility. In addition, position and vital signs are monitored.

Trial 7 - Sweden: Physical activity and impediments to activity for women with RA

Trial subjects are women with Rheumatoid Arthritis. The use of the BAN together with the mobile communications had the goal of enabling collection of a completely new kind of research data to enhance understanding of the difficulties and limitations, which these patients face. The ultimate objective is to offer solutions that will make their lives easier. Parameters measured include heart rate, activity level, walking distance and stride length.

Trial 8 - Sweden: Monitoring of vital parameters in patients with respiratory insufficiency

The group of patients involved in the trial suffer from respiratory insufficiency due to chronic pulmonary diseases. These people need to be under constant medical supervision in case they suffer an aggravation of their condition. Besides needing regular check-ups, they are also dependent on oxygen therapy at home, which means oxygen delivery and close supervision. The use of the MobiHealth BANs is designed

to enable the early detection of this group of diseases but also to support homecare for diagnosed patients by detecting situations where the patient requires intervention. Parameters measured are pulse rate, oxygen saturation and signals from a motion sensor (accelerometer).

Trial 9 – Sweden: Home care and remote consultation for recently released patients in a rural area

Home care services and the possibility of monitoring health conditions at a distance are changing the way of providing care in different situations. If suitable, home-based services are provided and patients do not need to be in hospital, for example if they are recovering from an intervention. By investing in home care, hospitals have been able to significantly reduce pressure on beds and on staff time dedicated to the kind of patients named above. This trial tests enhancement of the offered home care services through transmission of clinical data from a patient BAN to a physician or a registered district nurse (RDN). The target group are patients recently released from hospital who are living in a rural, low population density area.

3 Results of the MobiHealth project

The MobiHealth project was completed successfully in February 2004 and a series of important results were obtained. First of all the project developed an architecture for, and a prototype of, a generic service platform for the provision of ubiquitous healthcare services based on wireless Body Area Networks and 2.5/3G networks. The developed system was used to validate the ability of the commercially available 2.5/3G networks to support advanced mobile health services. In addition, the performed trials allowed us to identify the usefulness and the user acceptance of the services in different medical specialties, as well as the problems and issues that need to be resolved for its deployment. Finally, the project trials allowed us to identify the market considerations and the different actors that need to be involved in a commercial deployment.

During the trials, the evaluation team responsible for evaluation of the results collected different types of data. The trials were evaluated using a methodology developed in the project. Specifically we evaluated the trials from the technical point of view (technical evaluation), the medical point of view (end-user and social evaluation) and from the business point of view (market evaluation).

The technical evaluation focused on the evaluation of the performance of the communication infrastructure characterized in terms of: availability, bandwidth characteristics, percentage of data loss/corruption, transmission delay and its variation ("jitter"). In addition to the network performance, the technical evaluation also assessed the overall system in terms of validity, accuracy and robustness of the Sensor Service and application, the BAN and the intra-BAN communications, time delays etc.

The system performance related parameters were logged at the BAN side, while the generated traffic was logged by the 2.5/3G network measurement system. Logs at the BAN side record any problems regarding access to the network and the process of

transmitting the data to the BEsys. The network log reports were used to verify if any of the logged problems at the BAN side could have been caused by the current status of the network during that time.

The performance characteristics of the MobiHealth communication infrastructure were derived in two ways: objective and subjective evaluation.

The *objective evaluation* of the infrastructure included active and passive measurements. For the active measurements an external data stream was generated (that is, we had no real MobiHealth data) and the performance characteristics of the communication paths were measured. The passive measurements were performed in the up-and-running MobiHealth system so that real MobiHealth data were used. During the passive measurement phase, the participating operators also performed core-network data logging of the MobiHealth traffic characteristics [10].

The *subjective evaluation* of the infrastructure's performance was done by the end-users (healthcare professionals) who expressed their perceptions of functionality and performance characteristics as experienced during the usage of the MobiHealth system.

The end user evaluation described the usability/acceptance of the MobiHealth Services seeking the subjective opinion of users regarding the new services, their usability, user interaction, satisfaction, suitability, usefulness, acceptance, independence and experiences. Also questions about *perceived* performance characteristics of the system, like: system accuracy, validity, robustness, its speed or availability of the service were addressed to the professional users. End users in this project were defined as the patients and the health care personnel who were involved in the trials and were using the MobiHealth system.

The end-user evaluation data were collected using diaries, questionnaires, interviews and some objective measurements, e.g. walking distance and step-length for mobility assessment. End-users' evaluation results were compared against the performance measurements of the platform to analyse existence of expected correlations. An example of correlation between user experience and measured technical performance would be the receipt of an unusable poor quality ECG, which cannot be interpreted by the professional, coinciding with large delays and packet drops in the system indicating communication throughput problems.

The goal of ***the market evaluation*** was to provide a set of criteria, which would allow valid statements and decisions regarding the market value and potential of the MobiHealth system in the respective trial settings to be made. The factors which were important and decisive in this context included: health political issues, existing market structures and processes, market players, business scenarios, value chains, potential users, users' characterization (behaviour, acceptance requirements), health economic relevance, realization of market potentials (how much and when), barriers of entry, opportunities and threats.

3.1 Technical evaluation results

One of the first problems that we encountered in the use of the UMTS (and GPRS) networks arose from another facet of the *inverted producer-consumer* model

described earlier. Although we were able to resolve the addressing space restrictions, an implication of the reversed roles in the MobiHealth system was that the available upstream bandwidth was far less than the available downstream bandwidth. Mobile operators anticipate that the user will mainly consume information and in consequence are implementing solutions that allow the fast downloading of large amounts of data. The consequence is that the network and terminal devices cannot support (in their present configuration) high bandwidth transmission *emanating from the end-user*. This is a limiting factor for the volume of clinical data measurements that the MobiHealth system can send to the health broker. Using double or higher number of channels for up-loading is not currently possible with the existing mobile terminals and many cases it is not even supported by the operators. We expect nevertheless that in the future this problem will be minimized, as the users will start producing and uploading high data content.

To enhance portability and compatibility with the operating systems available on portable telephones, the MobiHealth application on the MBU was programmed in Java under the CLDC Java Virtual Machine [15]. As a result we were forced to use the HTTP protocol for transporting biosignal data. However the current CLDC HTTP protocol implementation does not allow for persistent HTTP connections. That means that whenever the MBU needs to send data it must establish a new TCP/IP connection. This is very expensive, in terms of performance.

A second issue related to the use of the HTTP protocol is the fact that every time a request is sent, the communication is blocked until an acknowledgment or reply is received. To solve this problem we used a technique called *chunking* [16] where multiple requests are sent without having to wait for a reply. However not all operators allow the use of chunking for their GPRS network. This eventually might cause standardization problems for services and applications that transmit continuous real time data over the GPRS and possibly UMTS

A problem was also observed with the functionality available to the different PCMCI network cards. The available data bandwidth over GPRS (and UMTS) depends on the strength of the signal at the user location. Although the GPRS and UMTS telephones do indicate the signal strength during operation, this is not the case for the PCMCIA cards integrated with the iPAQ. PCMCIA cards allow the control of the signal strength using proprietary software, *but only during set up*. During data transmission the signal strength information is not available. However this information is of major importance for the MobiHealth application, since it will allow us to estimate the available bandwidth and to control the data transmission rate accordingly. Currently, we have the situation that when transmitting at a certain data rate from an area with a strong signal and we pass into an area where the signal is weaker, we are not able to lower the data transmission rate and as a consequence the connection breaks down. The signal strength as well as the encoding schema used during transmission should be thus available to the application under a standardized API for all types of GPRS/UMTS terminals, whether these terminals are PCMCIA cards or regular mobile phones.

3.2 User acceptance results

For evaluation of user acceptance, questionnaires were used for both the patients and the medical personnel. For the network performance, we conducted both passive and active measurements for the UMTS networks in Netherlands, Spain and Sweden.

The results of the user evaluation indicate that users see a clear need for such a mobile system, and have high expectations. However, the prototype delivered was evaluated as if it was a final product rather than a prototype and of course, some users were disappointed. What was interesting was that users (medical personnel and patients) that had good technical support were satisfied with the service and system and a good level of confidence of the services was finally achieved. Nevertheless in spite this initial disappointment, by the end of the project all users agreed that a stable product would be very useful.

The main remarks coming from the users were related to the user interface. For example the fact the user was not able to see when the network connection was on and when lost was considered an important aspect for the control of the service functionality. The complex menus and interfaces were also a problem for both medical personnel and patients, requiring a simplified version and automation of most of the tasks. Finally, problems like the length of the cables of the ECG sensors (1 meter), the "ugliness" of the oxygen saturation sensor etc were marked as areas where improvement is needed.

3.3 2.5/3G Network Evaluation results

The analysis of the network performance evaluation data collected during the trials provides interesting results regarding the performance of the UMTS networks and technical issues related to MobiHealth BAN. Although the current UMTS networks are stable and functional, there are many barriers and technological details that need to be resolved before stable and viable m-health services can be introduced into the market. Some of the most important problems are the restricted available data bandwidth for uplinks, delay variation, delays in transmission and handovers.

Delay variation

During the trials, we observed that the uplink delay variation (jitter) was in some cases very high. Possible causes can be error recovery and bearer switching (**Figure** 8). The implication of the high jitter is that buffering of data is required to compensate for the delays. This has consequences on the interactivity of the application and the Quality of Service specifications. Further fine-tuning of the network will be required in order to resolve this problem.

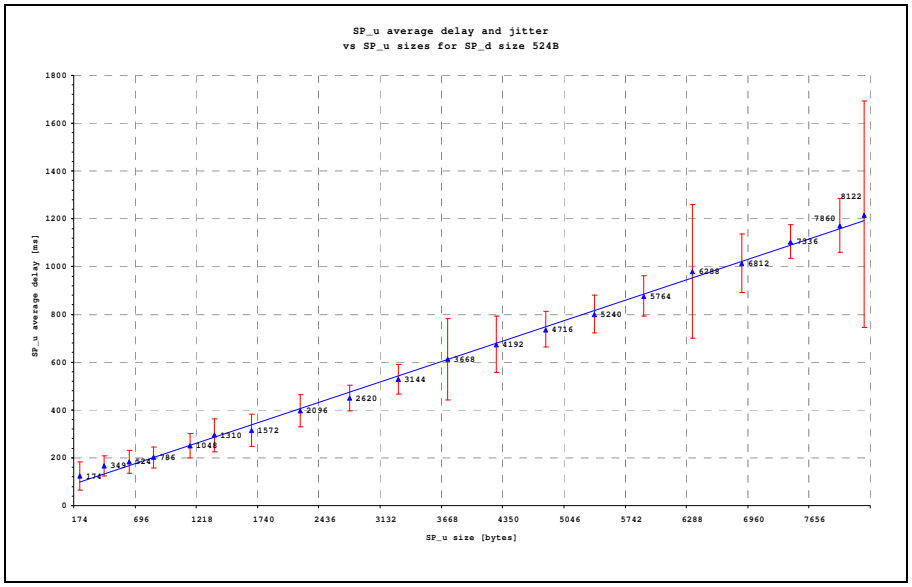

Figure 8: Delay and jitter (scale 0 to 1800 ms) fordifferent packet sizes (from 174 to 8022 bytes)

Handovers

On some occasions, we observed connection loss during horizontal handover. The reasons of this connection loss were not clear to us, and we were not able to consistently reproduce the problem. Further analysis is needed to identify and resolve this problem.

During the trials we had the opportunity to test GPRS-UMTS hard handover using dual mode terminals on a pre-commercial UMTS network. Although the handover worked correctly (i.e. the IP context remained the same), we observed a long delay during the handover process and a temporary interruption of the communications. The delay observed was between 10 and 20 seconds. This created problems in the MobiHealth application since during this time the data needed to be buffered leading in many cases to buffer overflow and data loss.

In addition we were not able to find out (neither our contacts in the participating operators were able to tell us) when and under what conditions the handover between UMTS and GPRS takes place.

Clearly, the hard handover delay will need to be resolved but in addition, information about the hard handover policy (when, what bandwidth will be next available etc) should be made available to the application designers.

Bandwidth

A major issue in our trials was the available UMTS bandwidth. At the moment the available bandwidth of the UMTS network is far bellow the “dream” 2 Mbps, the operators do not yet support this bandwidth. Nevertheless, we measured a steady bandwidth for downlink of 384 Kbps (net: 270Kbps due to overhead), and 64 Kbps (net: 57 Kbps) for uplink. These figures were stable and were tested also with moving terminals (up to 60 Km/h). However the traffic model of UMTS networks should be

reviewed by the operators and industry so that it takes into consideration the fact that end users can also be producers of information and not only consumers (inverted producer–consumer paradigm). This will have implications for bandwidth allocation and design of terminals, all of which disallow, for the time being, high data transmission from the user.

IP address allocation
Different operators have different policies regarding allocation of IP addresses to mobile devices. Some allocate public IP addresses, thus making them directly visible from the Internet, while others use private addresses making the mobile devices invisible from the Internet. Both solutions have advantages and disadvantages, depending on the application. We believe that the operators should allow the application providers to choose which model they want to use for their applications and not impose one or other model.

Communication costs
A major issue in the development of new medical services will be the communication costs. From our trials we have observed that continuous monitoring of vital signs can easily generate data in the order of 10 MB or more per day per user, (depending of course on the configuration and the required biosignals – the figure of 10MB is an indicative figure for a 4 lead ECG sensor) . With the existing cost policies the overall communication costs over a period of just one month will make the application cost prohibitive (around 1 Euro per MB). We expect that the operators will introduce a different cost model for continuous transmission applications, like for example a flat charge for unlimited data and usage (as is the case today where some operators offer flat cost unlimited use for GSM communications).

Clock drift
Our system incorporates a number of stand-alone devices (Portable PC, PDAs etc) interconnected via Bluetooth. Each device had its own internal clock and for the performance evaluation we time-stamped the packets and data at different points. However, the internal clocks of the different devices were drifting to the point where the measured delays were unrealistic. The drift was most probably due to environmental changes, like rise of the room temperature when the heating was turned on, in turn raising the temperature of the devices, causing the clock to drift. In addition, the regular automatic clock re-synchronization functions were forcing the clock to advance (by 50ms or more) creating artefacts and destroying the measurements (Figure 9).

To resolve this problem we stabilized the environmental conditions (no heating) and took care to re-synchronize the clocks more often. Nevertheless, the clock drift remains an important problem in the design of applications requiring high precision of timing between interconnected devices.

Power supply for the terminals

A major problem in the mobile medical applications is the limited power supply. A UMTS terminal (e.g. Nokia telephone) transmitting data continuously will empty its battery in less than 2 hours (at best). More research into alternative power sources needs to be conducted.

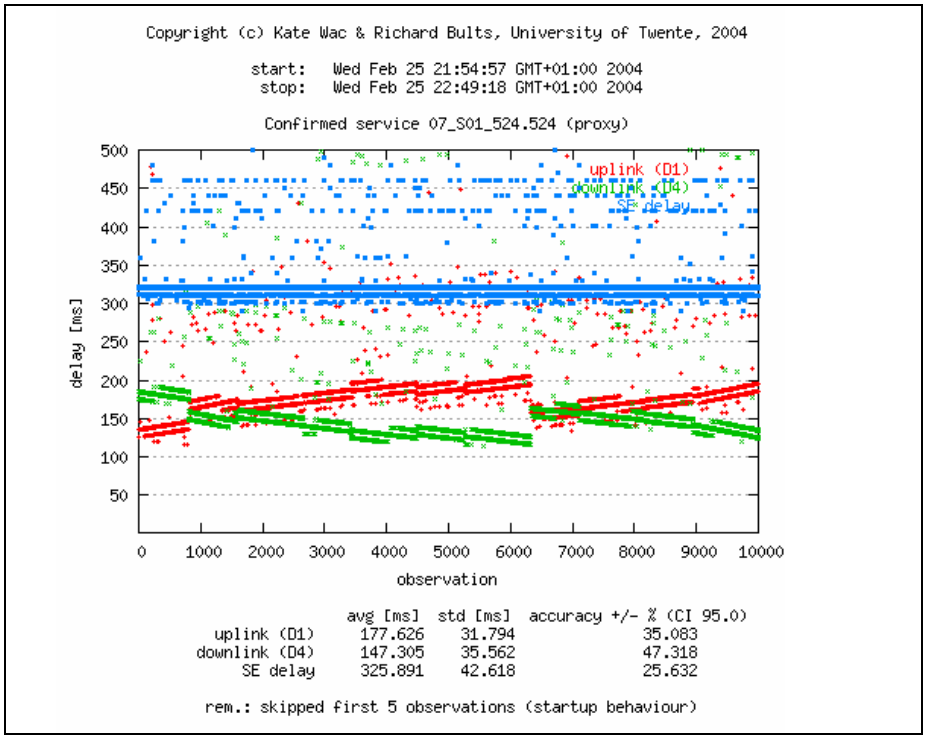

Figure 9: Clock drift influence on the measured delay over a period of 1 hour (uplink, downlink and total delay)

3.4 Market evaluation results

The main target of the market evaluation was to provide a set of criteria which will allow to make valid statements and decisions regarding the market value and potential of the MobiHealth system in the respective trial settings. The project first identified the relevant *market players* and stakeholders in a deployment of the MobiHealth Services, and then identified the market entry barriers for Mobile Health services.

To be noted that a number of these players were contacted during the course of the project and – especially in the later stages of the project – were involved in putting together scenarios and approaches that form the basis for marketing the MobiHealth solution. Based on their input and remarks we were able to better understand the related market deployment issues, the roles and interests of the players and the barriers to anticipate.

3.4.1 Mobile Health Stakeholders

Stakeholders are public or private organization and institutes that have a financial or other interest in the mobile health technology. We have identified the following stakeholders and their interactions (figure 10) that are related to healthcare services in care delivery infrastructures:

- end-users, i.e. the patients and the healthcare professionals (e.g. medical specialists, nurses, paramedics, physiotherapists in our trials);
- secondary care centres, e.g. the hospitals or revalidation centers; healthcare call centres, i.e. healthcare portals which intermediate or aggregate prime/secondary healthcare services and provide a one counter service to patients any time any place.
- Pharmaceutical industry, i.e research centres for the development and testing of new drugs.
- Internet service providers, i.e. the provider of Internet connectivity;
- 2.5/3G wireless network providers, i.e. the provider of public wireless networks with access to the Internet;
- Secure network providers, i.e. providers of a secure layer over the Internet. In our case, the responsibility to organize a secure layer over the Internet was delegated to the call centre.

The involvement of these stakeholders, each with their own security, usage, availability, pricing policies etc, complicates the medical data transfer from the BAN to end-user applications as well as the way the service can be provided and paid for.

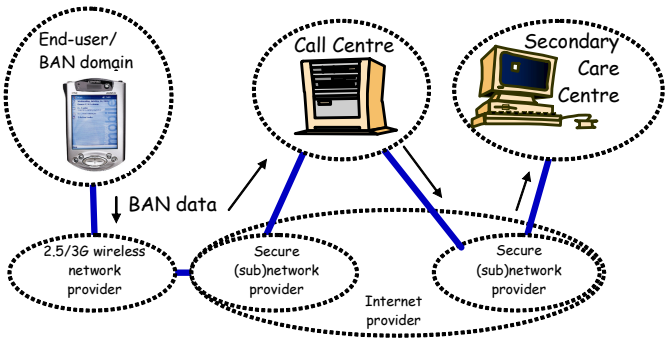

Fig. 10 Refined view of Service Provisioning Stakeholders.

3.4.2 Market Bariers

At the same time the main *market entry barriers* were identified and possible solutions were sketched. What was verified (once more!) is that the healthcare market is difficult to access, it is highly regulated, conservative and not very dynamic in embracing new technology, work methods or business models. In the case of telemedicine things are even worst since in most countries medical services are only reimbursed if there is face to face contact between the doctor/nurse and the patient.

Furthermore, experience has shown that most projects in hospitals are stopped if they are not regularly reimbursed, and as a result telemedicine projects and services remain at the level of proof of concept and rarely become fully functioning services. However, this problem having being recognized, solutions are slowly appearing in different countries. For example, in the Netherlands the government in collaboration with medical institutions are trying to define financial rules for internet consultations with general practitioners.

Other market barriers arise from the lack of health-political support. It is a very difficult and time consuming process for government to change the health related laws introducing new work methods covering new technological advances, since too many issues need to be taken into consideration, starting from the related costs, to the definition of the potential health hazards from wireless communication technology, covering medical data security hurdles as well as ethical and liability legal requirements. Finally one of the most important barriers comes from the fact that good technology solutions are not enough – management of complex value chains and processes is necessary in order to introduce new proposed services successfully, both from economic and medical perspectives.

The barriers of entry are characterized by changing rather traditional views and ways of working. On the other hand the factors of success deal predominantly with adaptation ability issues such as patient usability, technical integration, and process adaptation.

4 Towards commercialization : The HealthService24 project

One of the results of the MobiHealth project was the validation of the fact that today there is no concise mobile monitoring service available in Europe. There are various systems, services and applications available, which allow users to monitor their health status and transmit some type of vital signal information to remotely located medical personnel. For example, pregnant women can be monitored from home, instead of being admitted to the hospital, Rheumatoid Arthritis patients can be monitored remotely during rehabilitation exercises at home, the glucose level can be registered and the patient can download the data once a day/week to a PC and send it to the hospital. However, the currently available services allow patients to monitor and transmit their state over a wired phone (home services), meaning that the mobility of users is very limited, as they need a telephone line and electricity connection. The medical tools available today are only on the level of administrative information (the doctor has a PDA with which he can access the medical record of the patient and send information using GSM/GPRS). The mobile solutions that start appearing in the market either are simple technological solutions with no complete integrated service to support them or at best they simply provide the possibility for the patient to store the vital signal measurements and upload them at the evening to the hospital server.

HealthService24 aims to bridge this gap by offering a viable mobile health care service permitting healthcare professionals to remotely assess, diagnose and treat patients whilst the patients are free to continue with daily life activities. The HealthService24 services will allow patients and non-patients to monitor their

physical condition and obtain advice and information at any place and moment. Hence the service will enable patients to be fully mobile. The starting point is the system developed and validated during by the MobiHealth project.

We are aware of the fact that many former technological innovations in the field of mobile health applications were not successful in the longer run due to failure to address crucial issues such as social and economic aspects, changes in medical work practices and even standardization of technologies and integration with existing medical information systems. The HealthService24 project deals with the adaptation, customization and localization of the existing service prototype, the related social aspects and working conditions, and the related economic issues stemming from the deployment of the system on a larger scale, including the changes that will be brought to the processes and practices of the healthcare organizations and medical personnel. The HealthService24 will define the needs, expectations and requirements of all members of the value chain and will create added value and benefits for all value chain members, as only such an approach can make a sustainable market deployment possible. We aim to have a commercial product at the end of the project (Fall 2006).

4.1 The HealthService24 operation scenario

A HealthService24 patient/user is equipped with variety of vital constant sensors, like blood pressure, pulse plethismogram and ECG interconnected in a wireless Body Area Network managed by a PDA or mobile telephone and worn on the body, and thus moving around with the person. These way patients can stay mobile but be continuously monitored and receive advice when needed.

The measurements are transmitted wirelessly using GPRS (alternatively UMTS) to a data centre. The centre acts as an intermediary between patients/users and health care providers and provides three services: data repository (just collecting the received data), streaming service (forwarding data to a care professional), and event service (interpretation of the received data and sending of an event signal to a predefined destination (using SMS)). The data centre may also provide technical support and, if needed, act as the first-level medical support for the HealthService24 users.

From the data centre, the data is wirelessly transferred to health care providers. Data sent to a health care provider can be viewed (e.g. on a laptop). Healthcare professionals, to whom the patients' data is transferred, can remotely assess, diagnose and treat patients whilst the patients stay fully mobile and continue with their daily life activities.

4.2 Validation trials

In order to test and verify the system, the service and the network infrastructure for its suitability and the restrictions it imposes on mobile health care applications, nine validation trials will be conducted within the project in three different countries in Europe: Netherlands, Spain and Cyprus. Three different groups of patients will test the service: (high-risk) pregnant women, cardiac patients and COPD-patients

(Chronic Obstructive Pulmonary Disease) with respiratory problems. The (high-risk) pregnant women trials will be carried out in Netherlands, the COPD-patients trials in Spain, and the cardiac patients trials in Cyprus.

It is envisaged to conduct three validation trials at each test side. Each trial will last approx. 3 months followed by 1 month results analysis. As the market validation is an interactive process, the results obtained during the first set of trials will be fed into the next phases. Each set of trials will be carried out by a hospital/clinic specialised in the particular disease/health problem to guarantee the highest possible quality level and credibility of the results.

As the number of patients/ users needed per group for a validation trial varies depending on the expected hospital days, different numbers of patients need to be validated within each group. Taking the above into consideration and to assure reliable results from the validation trials, a minimum of 8 pregnant women per trial shall be monitored and 15 COPD- and cardiac patients, which means that in all three trials per patient group at least 25 (high-risk) pregnant women, 45 COPD-patients and 45 cardiac-patients will be monitored.

For the **(high-risk) pregnant women** trials, the trials will use the HealthService24 to support integrated homecare for women with high-risk pregnancies. Women with high-risk pregnancies are often admitted to the hospital for longer periods of time because of possible pregnancy-related complications. Admission is necessary for the intensive monitoring of the patient and the unborn child. Homecare with continuous monitoring is desirable and can postpone hospitalisation and reduce costs, as well as offering more security for the mother and unborn child. In this trial, patients will be monitored using the patient-BAN. The maternal and foetal bio-signals will be remotely transmitted to the hospital. An additional objective of the trial will be to evaluate if such a solution postpones hospitalisation and reduces costs. This trial takes place in Enschede, the Netherlands in the *Medisch Spectrum Twente* Hospital.

For the **COPD-patients trials**, the trials will use the HealthService24 to support remote assistance for elderly and chronically ill patients suffering from co-morbidities including the COPD. The MobiHealth nurse-BAN will be used to perform patient measurements during nurse home visits and the MobiHealth patient-BAN will be used for continuous monitoring during patient rehabilitation at home or outdoors. It is very important to facilitate patients' access to healthcare professionals without saturating the available resources, and this is one of the main expected outcomes of the HealthService24 remote monitoring approach. Parameters to be measured are oxygen saturation, ECG, spirometry, temperature, glucose and blood pressure. The trials take place in the Barcelona, Spain, at the *Hospital Clínic Provincial de Barcelona.*

For the **cardiac patients trials**, the HealthService24 will be tested by two groups of patients:

Group1: Patients who had an acute episode and have been admitted and stabilised but need continuing monitoring of condition and drug regime for a further few days. With the HealthService24 these patients will be allowed an earlier discharge, with an appropriate follow up (using the HealthService24) in the place of their choice.

Group 2: Patients in a suspected acute episode, brought in for examination; a decision needs to be taken whether to keep the patients at the hospital for observation, or to discharge them home. In case a patient is discharged, and there is a suspicion of an abnormal condition, the patient will be equipped with the MobiHealth patient-BAN enabling constant monitoring of the patient's state.
The cardiac patients' trial takes place in Agia Napa, Cyprus, at the *LITO Polyclinic*.

4.3 Evaluation procedure

Metrics for evaluating the test results will include general indicators such as quality of life (and care) for both patient and doctor, economic benefits for a patient/government of not staying in hospital (and freeing a hospital bed), overall costs of the service and adaptation issues to adjust the service to national requirements as well as reliability, accuracy and sensitivity of the equipment and ease of use for patient and health professional. A number of questionnaires will be prepared, issued and evaluated.

During the trials different types of data will be collected in view of an evaluation of the results. The targets of the evaluation include both technical and socio-economic aspects. From the technical side, the state of the UMTS (and GPRS) infrastructure and its suitability for mobile health applications will be verified, while from the socio-economic side the added value that the HealthService24 can bring to different healthcare domains will be explored and the related issues for its commercial deployment will be evaluated. The technical issues have already been addressed by the MobiHealth project, so the HealthService24 project will mostly just confirm that results and concentrate on the health-economic and socio-economic aspects to make the service ready for the market deployment.

4.4 Status of the HeathService24 project

From the first days of the project, we realized that the market is already mature and ready to accept the deployment of m-health services, as proposed by the HS24 project. As a result, the project objectives not only remain valid, but there is a need for a faster deployment in order to catch the present market opportunities. For this reason, an adaptation of the time frame of the short and long term objectives was made and, furthermore Ericsson adapted its internal structure and processes in order to fulfil in a shorter time the objectives of the project. As a result, we were forced to delay the start of the trials for 4 months and adapt the existing system, bringing it closer to a commercial product. Finally, in October 2005 the trials were started with an adapted system that was stable with additional functionality and with a simple and ergonomic user interface as requested by the users. The system allows for example the prioritization of the signals to be sent, so in case of low bandwidth the least "important" signals are not sent to the hospital but stored locally, allows for off-line operation in case of connectivity breakdown or for energy conservation, is able to store and retransmit historical data on request etc. Further secondary functionalities as well as administrative interfaces will be added to the system in the next few months.

Some of the items that were added in the user interface were basic information regarding pulse rate and/or oxygen saturation as well as an easy to read indication (for the pregnancy trial) that labour is highly probable and the woman should come to the hospital at once. In addition and most importantly, simply explained information on the connectivity status. The user knows at any instance if he is connected and if not where is the problem (see Figure 11. Mobile user interface).

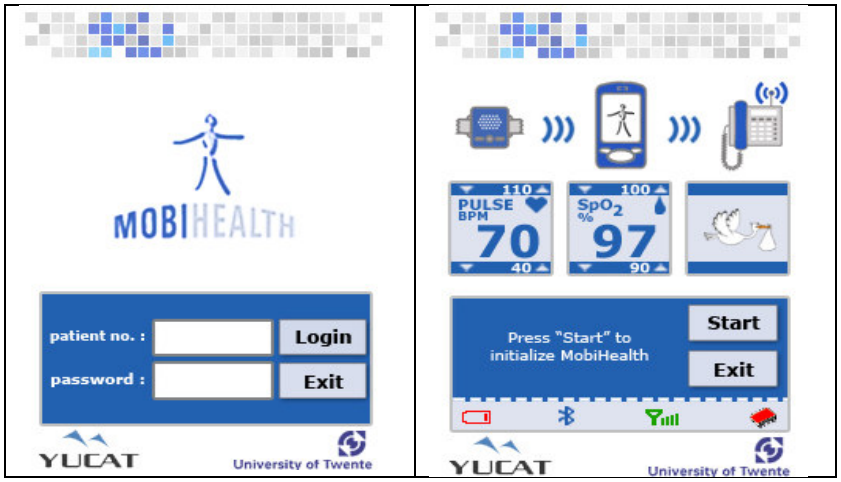

Figure 11. Mobile user interface

5 Conclusions

The results of the project indicate that several issues need to be resolved by both network operators and hardware manufacturers for a better support to mobile health services [9]. Ambulatory monitoring is more successful for some biosignals than others, for example some measurements are severely disrupted by movement artefacts. Some monitoring equipment is still too cumbersome for ambulatory use, because of the nature of the equipment or because of power requirements (Powering always-on devices and continuous transmission will continue to raise technical challenges for the next decade for mobile applications!). Furthermore, even with 2.5 and 3G, we still suffer from limited bandwidth for applications that serve many simultaneous users.

Other challenges relate to security, integrity and privacy of data during transmission to both local transmission (e.g. intra-BAN) and long range (e.g. extra-BAN) communications. Legislation differences between European countries do create some problems in the adoption of mobile systems. Some harmonization is expected in the future but it will take time to become reality.

Business models for healthcare and accounting and billing models for network services need to evolve if technical innovations are to be exploited fully. Standardisation at all levels is essential for open solutions to prevail. At the same time

specialization, customisation and personalisation are widely considered to be success criteria for innovative services.

The main problems identified relating to the introduction of new mobile health services based on Internet technologies into hospitals relate to the changes required to support these new services, in both technological level and work practices level. From a technology point of view, the introduction of new mobile services requires a modern ICT infrastructure with secure connections to the Internet. However, many hospitals today do not have this kind of ICT infrastructure. Some hospital IT departments didn't even accept the use of standard HTTPS (i.e. HTTP over secure sockets) to retrieve vital sign information. On the other hand other hospitals demanded that the mobile system fully integrates with their existing IT system, using the same data exchange standards and formats.

A second technology related problem concerns the precaution measures taken by the majority of the hospitals in the use of wireless communication devices inside the hospitals. Due to lack of serious studies regarding the interference of wireless communication devices, like telephones, with medical equipment, most hospitals prohibit the use of any such device within their premises. This has as an immediate consequence that any wireless medical system will have difficulties to be officially authorised to function inside the hospital.

Nevertheless, from the reactions and interest of the hospitals and the patients we are very optimistic that the proposed MobiHealth/HS24 system and services will be a commercial success.

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