IST Programme

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Pre-Trial User Evaluation Report:

Pre-Trial #2 (November-December 2003)

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Contents

Executive Summary

This document reports on the results of the second pre-trial of the MobiHealth project from the perspective of the trial owners. As with the first trial, a trial owner is defined as the doctor, nurse, physiotherapist, administrator and technical provider involved in putting together and running the trial. A trial is a field test of the MobiHealth Body Area Network prototypes and the necessary communications infrastructure.

The trials follow the guidelines outlined in Deliverable 1.4 of the project. That deliverable determines the methodology used for evaluating the field trials.

Throughout December 2003 and January 2004, Pre-Trial #2 tested Version 3.1 and other minor upgrades of the MobiHealth system prototype in trials running in Barcelona (ES), Moenchengladbach (D), Enschede (NL), Luleå and Boden (SE). It was the purpose of this pre-trial to build on the work carried out in Pre-Trial #1 (summer and autumn of 2003) among trial owners and their clients (patients, care recipients) in using the BAN and communications; to evaluate the performance and user-friendliness of the equipment; and to provide data to the system providers for the final trials of the MobiHealth system in January and February 2004.

Following identical procedure for Pre-Trial #1, the user evaluation of Pre-Trial #2 is based on a questionnaire filled in by each trial owner having completed their pre-trial. The sections below quote directly from the answers given.

A brief description of each trial follows:

Germany

Trial 1 Secondary prevention in coronary heart disease

In the future trial the patient is able to transmit ECG and blood pressure 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 in these vital signs will be quickly detected and appropriate intervention can be effectuated. The trials are designed to determine whether 2.5-3G wireless communications can support such services. *In this pre-trial the unit was tested by several medical and technical personnel (cardiologists and technicians) and two cardiac patients, as well as persons at the call centre.*

Sweden

Trial 1: The Lighthouse alarm and locator

The purpose of the Lighthouse trial is to test the effectiveness of a new GPRS/UMTS-based personal alarm and locating device for clients of the care centre, especially the elderly, and the personnel, according to several determining factors: safety, convenience, empowerment of user, mobility of user and improvement in efficiency of care given. *In*

this pre-trial, the connectivity and positioning were tested by the trial owner and two care personnel in the Lighthouse, and two independent testers in the city and surrounding environment. This trial also provided more intensive testing of the UMTS capabilities.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

The aim of the trial is to follow the patients' activity level during the course of a week, by means of continuous monitoring of heart rate and self-reporting of the activity level, monitoring walking distance to determine the factors that impede the patient from performing those activities that she wishes to perform. The primary research question is to examine the correspondence of heart data and monitored activity to the self-reports of activity level. It is also intended to evaluate how the women experience using the mobile technological devices. *In this pre-trial the trial owner tested the system with a test subject at the Department of Health Science.*

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

The end trial is to examine whether mobile health facilities with monitoring of some relevant vital signs can contribute to an earlier detection and treatment of COPD and also reduce the need for check-ups and hospitalisation. *In this pre-trial, two professionals and one test-person wore and tested the unit over several days, performing different activities.Subsequently an elderly test subject conducted a test for six hours with the system under supervision of the trial owner.*

Trial 4: Home care and remote consultation for recently-released patients in a rural area

The end goal of this trial is to find a way to communicate vital signs from a person at home to an Registered Nurse and/or a physician for consultation and diagnosis in order to reduce visits to the hospital and give trustful and safe care at home. A subsequent aim is to use this methodology and evaluate the consequences in terms of experiences of healthcare and living at home with severe illness (quality of life, ethical considerations etc.) and also evaluate the consequences for the Nurse Aids, Licensed Practitional Nurses and Registered Nurses in their work. *In this pre-trial, two professionals tested the system in several different environments, at home, in a healthcare department, and in a car driving over a wide rural area. Subsequently the system was tested(including 12-lead ECG) by ten volunteer subjects at Sanden Health Care Centre in Boden, with a further back-up test for each subject. This trial also explored the possibilities with regard to UMTS.*

Spain

Trial 1 Support of home-based healthcare services

The end resulting trial involves use of GPRS for supporting home-based care for elderly chronically ill patients, usually suffering from more than two concurrent conditions. The MobiHealth Nurse-BAN will be used to perform patient measurements during nurse home visiting. *This pre-trial involved technical and medical personnel only, and was run exclusively in the hospital and between the hospital and the telecommunications services.Two technicians tested the system and two professionals evaluated the outcomes and measurements.*

Trial 2 Outdoor patients' rehabilitation

In the scenario description for the trials as originally designed, the patients involved in this trial are chronic respiratory patients who could benefit from rehabilitation programmes to improve their functional status. The study aims to check feasibility of remotely supervised outdoors training programs based on control of walking speed enabled by use of the BAN. The physiotherapist will receive on-line information on patient's exercise performance and will provide feedback and advice. *In this pre-trial exclusively technical and medical personnel tested the system, and the test was run in the hospital and between the hospital and the telecommunications service partner. The procedure was similar to the other Barcelona trial.*

The Netherlands

Trial 1: Tele Trauma Team

This trial is for a sensor, visual and transmission system for trauma/medical care delivered by an ambulance, at the scene or on the way to the hospital. The main objectives are to examine the feasibility and safety of monitoring various vital signs, recording the site of the accident and communicating with and guiding the paramedics, all by sensors put by a paramedic upon the patient or worn by himself, and relaying these data to the trauma hospital. *There was no pre-trial on this occasion, however, some testing of the UMTS network and connectivity was performed, and many of the technical usability tests from the other Enschede trial had application in this trial, so the results are merged in the evaluation.*

Trial 2: Integrated home care for women with high-risk pregnancies

The purpose of this study is to evaluate whether monitoring at a distance of vital signs (e.g. CTG, maternal blood pressure) is feasible, safe, and can postpone hospitalization for women with a high-risk pregnancy. *This pre-trial monitored ten healthy pregnant women at a hospital and two at home.*

Part One: Field Pre-Trial Details per Site

Please provide comments on the circumstances and procedures of the pre-trial(s) you ran, under the following headings:

Testing period

Germany

Trial 1 Secondary prevention in coronary heart disease

This pre-trial ran 12th December – 15th December.

Sweden

Trial 1: The Lighthouse alarm and locator

24th, 26th, 28th November, and 2nd December, a total of circa 25 hours.

Special UMTS trial: 9th December 2003 between 19:51-20:02.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

The trial ran on 12th December 2003, from 10.00 to 11.30.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

The first pre-trial of this phase took place on 27th to 28th November 2003.

The second took place on Saturday 29th November to Sunday 30th November 2003. This consisted of three sessions: Saturday – SESSION 1: one hour 08:35-09:35 and SESSION 2: six hours – 12:15-18:15. Sunday – SESSION 3: five hours 15:15-20:15.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

2nd December – 5th December 2003.

Spain

Trial 1 Support of home-based healthcare services

The testing has been performed since December 12th until January 5th. The testing was done periodically everyday several times at different hours. The testing concerning UMTS is being performed at the moment.

UMTS: The testing has been performed from January 10th and still going on. The testing was done periodically everyday several times at different hours.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

The trial was conducted from 15th November to 9th December 2003.

Location of test (all locations where BAN was tested/data read)

Germany

Trial 1 Secondary prevention in coronary heart disease

The trial took place at GesundheitScout24, Duisburg, and the practice of Dr. Metten in Mönchengladbach.

Sweden

Trial 1: The Lighthouse alarm and locator

The cities of Stockholm and Luleå.

Special UMTS trial: driving around the suburbs and centre of Luleå.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

The location of the test of the BAN was at the Department of Health Science, Boden.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

The first pre-trial took place in Stockholm, Sweden.

The second took place in the home of the trial owner, located in the city centre of Luleå. The first session was in the home of the trial owner and out walking in the city centre of Luleå, shopping and visiting a cafe, driving a car and visiting a friend (all in the city centre) and finally shopping at a large shopping centre. The second sessions were at the home of test person 2, situated at Lerbäcken, 5 km from the city centre of Luleå.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

The trials were conducted at Sandens Health Care Centre, Boden.

Spain

Trial 1 Support of home-based healthcare services

The BANs were tested in the Clínic hospital in Barcelona. The data was sent to the server placed in Telefónica (Madrid) and then the access to the information was done from portable PCs also at the hospital (Barcelona). This also applied to the UMTS test.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

The tests were conducted at MST in Enschede; also on the UT Campus, driving around Enschede, and in the town of Boekelo.

Person(s) testing BAN

Germany

Trial 1 Secondary prevention in coronary heart disease

Baerbel Krell (Cardiologist).
Rien Metten (Cardiologist).
Norbert Fischer (Patient).
Anna Lenzen (Patient).
Christian Hund (Technician).
Stefan Roedig, (Coordinator).

Sweden

Trial 1: The Lighthouse alarm and locator

Anna-Lena Andersson (trial owner, Director of Lighthouse Care Centre), Maria Porsberger (care personnel), Eeva-Kaisa Nilsson (care personnel), Anders Granström (independent test person, CEO of Centre for Distance-Spanning healthcare), and Stefan Kullberg (medical technology consultant).

Special UMTS trial: Erik Bertilsson (no ECG sensors applied).

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

One professional person tested the BAN, with a test-person at the Department of Health Science.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

In the first test, the test subject was Staffan Andersson, the doctor in charge of this trial.

In the second, Susanne Andersson, the trial owner, wore the BAN for one hour. Then test person 1, the trial owner's partner, wore it for six hours (as in Pre-Trial 1), instructed by the trial owner. Then test person 2, the trial owner's father, wore it for five hours (this had not happened in Pre-Trial 1), instructed by the trial owner.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Two trial owners did the testing. There were ten people participating in the trial as patients. A 12-lead ECG was carried out, using the regular ECG at Sandens Health Care Centre on each participant before testing the BAN. When the BAN was tested one or more test was done on each participant.

Spain

Trial 1 Support of home-based healthcare services

There were two technicians testing the BANs and the global system plus two professionals evaluating the results and the measurements done by the sensors.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

The trial owner, Dr. Rik Quartero.
Cees Sluimer.

BAN (Mobi serial number, iPAQ model, and extras)

Germany

Trial 1 Secondary prevention in coronary heart disease

Two BANs were tested:
1. Mobi serial number: 0924030053 IPAQ: 4G2ADW34N07C.
2. Mobie serial number: 0924030050 IPAQ: 4G2ADW34N082.

Sweden

Trial 1: The Lighthouse alarm and locator

Luth 010 4g2adw34n072
Luth013 4g2adw34n06e

Special UMTS trial: Mobi: 0924030048
MBU: 4G2ADW34N06M
UMTS telephone: Nokia 6650

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

iPAQ: 4G2ADW34NO6E
GPRS: 9V36KD41AMLE
Mobi: 0924030012

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

In the first trial, the BAN was LTU 020-2, with the RespInsuff package of sensors.

In the second, it was LTU018 ID-4G2RAW34N07D (Mobi SN 0924030021).

Trial 4: Home care and remote consultation for recently-released patients in a rural area

iPAQ: S/N 4g2adw34n089
Mobi: S/N 0924030026

Spain

Trial 1 Support of home-based healthcare services

IPAQ: 4G28DW34R05T
Mobi: 0924030018
IPAQ: 4G27DW34R04P
Mobi: 0924030036
IPAQ: 4G28DW34R05W
Mobi: 0924030044
IPAQ: 4G27DW34R04D
Mobi: 0924030037
IPAQ: 4G28DW34R05D
Mobi: 0924030015
GPRS/WLAN NOKIA D211 (PCMCIA provided by the hospital CSC)
SIMs for GPRS connection (provided by Telefónica Móviles)

UMTS: IPAQ: 4G27DW34R04R
Mobi: 0924030031

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

0924030061 (MST 005) + Ipac 4G2ADW3N06P
0924030062 (MST 007) + Ipac 4G2ADW34N03C
(MST 006) + Ipac …02X
(MST 008) + Ipac
Trauma Mobi was returned to UT + Ipac 4G24DW3V2ZO + Nokia 027459/6

Sensors tested (parameters measured)

Germany

Trial 1 Secondary prevention in coronary heart disease

ECG (3-lead).
Alarm button.

Sweden

Trial 1: The Lighthouse alarm and locator

Location marker, ECG, drop sensor and manual input.

Special UMTS trial: 4-lead ECG, activity sensor, marker (alarm button).

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

3-lead ECG
activity sensor

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

In the first trial, the parameters were pulse oximetry, 3-lead ECG and an activity sensor.

In the second, they were the activity Sensor (all sessions), pulse oximeter (all sessions) and 3-lead ECG (test person 2).

Trial 4: Home care and remote consultation for recently-released patients in a rural area

3-lead ECG and pulse oximeter.

Spain

Trial 1 Support of home-based healthcare services

SatO2
ECG
Movement

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

ECG leads on Pregnancy BAN.
Pulse oximetry on Trauma BAN.

Part Two: Outcome (Assessment)

Please indicate what occurred while carrying out the following activities on the current prototype (Version 3.1) of the BAN and communications system in the pre-trial(s) you ran, under the following headings:

Activating iPAQ

Germany

Trial 1 Secondary prevention in coronary heart disease

The activation of the iPAQs was in the current prototype version no greater problem. The iPAQ and Mobi still had to be rebooted after every measurement. This was acceptable for the trial, but not for a commercialisation.

Sweden

Trial 1: The Lighthouse alarm and locator

Activating the iPAQ was OK; one time 2 Mobis were together in the iPAQ that the trial owner had already switched on to test, at the same time as she was starting another BAN; while this was happening she was not touching the other iPAQ. When she looked at it there were 2 Mobis noted, and the display said "checking connections". She exited and noted that the presence of the other Mobi disappeared and "Mobi is sending" was displayed on the IPAQ.

Special UMTS trial: OK after resetting the iPAQ.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

The professional had to fill in login and password on the iPAQ every single time it was started up. Compared with Pre-Trial #1 it was much easier to activate the iPAQ. It takes about 2-3 min from login to MBU sending.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

In the first pre-trial, the Mobi-iPAQ-communication came on at start-up: Success rate was 80% (20% of the time the "check mobi" message appeared).

In the second, when starting up all of the three sessions the trial owner had to reset the iPAQ 2 times (in every session) before reaching MBU sending status. It was still necessary to fill in a password after every restart/reset. It was sometimes a bit difficult to reset/turn off GPRS.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

When activating the iPAQ, a reset was performed before each test. Only once was there a start-up failure: the remaining twenty times start-up was fine.

Spain

Trial 1 Support of home-based healthcare services

More stable than previous version, the establishment of the GPRS connection doesn't usually fail if the battery is charged enough.

UMTS: Much more stable than GPRS. In fact, UMTS never fails when stablishing the connection. Very reliable.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

No problems were encountered, except on MST 008, where accidentally Version 3.1.1 had been installed. The sensor viewer crashed.
Activating UMTS was faster than GPRS.
The system was sufficiently intuitive not to need the manual.

Sending

Germany

Trial 1 Secondary prevention in coronary heart disease

It takes about half a minute to get the Bluetooth connection between the Mobi and IPAQ. The connection and the sending of the data is then stable. Measurement breaks down after 30-60 minutes. Still the Mobi turns off from time to time without any reason.

Sweden

Trial 1: The Lighthouse alarm and locator

The sending period was short; during many of the tests only 2.5 minutes of data were sent.

Special UMTS trial: No problems after setting up the BlueTooth communication to the UMTS phone.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

Data was sending for about 1 ½ hours, data that was presented in PortiLab was 16 minutes long. The text on the iPAQ screen was (during the 1 ½ hours) "MBU sending".

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

In the first pre-trial, 10 minutes of data were sent on 27th November at 10.15 a.m. and 10 minutes were also sent on 27th November at 11:00. The system worked fine during those occasions. No sending was possible on 28th November.

In the second trial sessions, according to an independent observer data was sent for five hours continuously (= the whole session) on Sunday 30th November. Also on Saturday data was sent during the whole day, but not continuously (this needs correlation with Portilab). Indication on the iPAQ was that the MBU was sending, even when the Mobi had turned off spontaneously.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Three times when the device was sending, the sign "flushing data" was missing. One sending session stopped by itself during the test. All of the other sending sessions were good.

Spain

Trial 1 Support of home-based healthcare services

There were still problems when sending data. Many times, the indicator of data being sent does not appear on the screen of the PDA and therefore, data is not stored at the BEsys. There are some cases in which the data seems to be sent to the server because the message ‘sending data’ appears in the PDA, but when the stored data is accessed, only 1 or 2 K have been stored or no data has been stored. It is not stable at all.

UMTS: Usually data is sent without problems. In some very punctual cases it is needed to restart the iPAQ, and then you can send with no problems.

Trial 2 Outdoor patients’ rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

Duration of transmission was between two and four hours on GPRS, regardless of whether transmission was using sleeve or separate Nokia as a modem, and regardless of testing area. Each time, the iPAQ reported a normal sending mode, while the Mobi switched off. No reason for this is known.

Transmission with UMTS was up to 8 hours, depending on network coverage.

Mobi-iPAQ-Back-End system communication

Germany

Trial 1 Secondary prevention in coronary heart disease

The communication between the iPAQ and Mobi is widely stable; connection breaks down after 30-60 minutes of measurement.

Sweden

Trial 1: The Lighthouse alarm and locator

Communication has improved; however, there are still some disconnections between the systems, fewer than before. The Mobi still turns off sometimes, but again, fewer times than during Pre-Trial #1. For reasons unknown to this trial owner, data sending was limited to short periods of time several times.

Special UMTS trial: The communication seemed stable during the whole measurement. One test was performed while driving round in a car in Luleå (from the Lighthouse through the city centre to Sandviksgatan/the Bergnäset bridge). The test was not interrupted even though we were informed that the pre-commercial UMTS network could have problems with handover between the base stations.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

The MOBI did not turn off at any time during the 1½-hour trial. The file in the BE is 1½ hours but when viewing in the PortiLab one can only see 16 minutes.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

See under “Sending” above. On 28th November several trials resulted in “no communication” message every time. One spontaneous disconnection between Mobi and iPAQ occurred during the pre-trial.

In the second pre-trial sessions, during the sessions on Saturday the Mobi turned off spontaneously 5-6 times, but the message on the iPAQ was “MBU sending”. Half of the “turn offs” might be due to test person 1 forgetting to bring the iPAQ with him when leaving one room and entering another. During the session on Sunday there was only one turn off after five hours, when the session was about to end. The test persons were asked to keep an eye on the Mobi, to see that it did not turn off. There was connection to the Back-End System in all sessions.

There were some resets of the iPAQ during start up procedure in all sessions.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Checking with the Back-End System, there are valid signals on several files from the Remote Consultation BAN. The consulting doctor is to provide an opinion on the standards and safety in sending from the BAN to the Back-End System.

Spain

Trial 1 Support of home-based healthcare services

The communication between the iPAQ and the server when establishing the GPRS connection is OK. The communication between the Mobi and the iPAQ is complicated because the Mobi turns off after a few minutes of having been switched on. The communication between the iPAQ and the BEsys when sending data often fails and no data is stored in the BEsys.

UMTS: Very easy to stablish the connection between the three devices and it always works properly.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

No problems were encountered.

Sensor view on iPAQ

Germany

Trial 1 Secondary prevention in coronary heart disease

ECG measurements could be viewed on the IPAQ and seemed to be valid.

Sweden

Trial 1: The Lighthouse alarm and locator

This is now good.

Special UMTS trial: The sensor viewer crashed easily when changing between the sensors to view.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

There is no problem to see the signals on the sensor viewer.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 reports that the sensor view fully complied with the specification.

Trial owner 2 reports: when starting up the first session on Saturday, when pressing the button for the sensor viewer, the message “Check Mobi” came up. She pressed OK, and then a picture came up that she had never seen before (she took a photo of it and e-mailed it later on to Telia). She reported the error verbally on Monday or Tuesday to Telia. After resetting the iPAQ and GPRS there was no problem with the sensor viewer in any of the three sessions. The signals had good quality and were viewable.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Four times there were problems seeing in the sensor view. Not all 3-lead ECG readings or saturation were visible in the view. Once the curve stayed on the viewer for a minute after the sensor view had been closed.

Spain

Trial 1 Support of home-based healthcare services

The sensor viewer on the iPAQ shows the signals correctly but with no scale or axis. There are no changes with respect to the previous version. The results presented in the iPAQ do not permit a correct interpretation. The display of numerical results is satisfactory but the graphics are useless since no scale is available. The professional cannot base his/her whole evaluation on this information. As a conclusion this trial owner must say that the interaction with the iPAQ should be much more simple, stable and user-friendly.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

This was adequate, except for instability on the unit with Version 3.1.1.

Manual input

Germany

Trial 1 Secondary prevention in coronary heart disease

This was not yet tested.

Sweden

Trial 1: The Lighthouse alarm and locator

It was not possible to see the whole text in the iPAQ window.

Special UMTS trial: no extensively tested.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

First the ID must be filled in; then it is easier than Pre-Trial 1. To fill in ID should be in the login function, not in the manual input.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Only two manual inputs were performed in the first pre-trial. This is because of the complexity. Unfortunately it was not possible to specify only the activity because at each time a new activity is put in on the iPAQ you have to go through all fields for spirometry parameters (step length, FEV1, FVC, PEF) before sending.

In the second pre-trials, during the first session the manual input worked fine. In the beginning of session 2, the language was changed from English to Swedish. After this the “error-empty” message started to pop up. When changing back the language to English there was a problem in starting up the MH application again. Trial owner 2 changed batteries in the Mobi, reset and could after that use the manual input on and off (sometimes there was an error message). During session 3 (Sunday) it was not possible to use the manual input because the “error-empty” message popped up again.

It was not easy to find out where to change language, first after reading the English manual on the webpage she found out. She reports that it would be good if there weren´t any fields that you **have** to fill in before choosing an activity. The manual input part is a bit tricky to understand – which button to press, for example when filling in the text field and when changing language. But the good thing in Manual Input is that there now is a Send button, when choosing activity.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Manual input is a real problem. It seems that using manual input disturbs the sending from the Mobi. Once the sending stopped while the manual input was in use. The three sending sessions where the sign “flushing data” did not come up on the screen were the same sessions that the trial persons were using manual input. It is difficult to use the ID-applications; sometimes it was stuck on the screen for a long time. The parameters blood pressure, pulse, CRP and blood glucose were no problem to use and send.

Spain

Trial 1 Support of home-based healthcare services

OK. No problems with the manual input.

Trial 2 Outdoor patients’ rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

No problems were encountered, but this was not specifically tested.

Portilab

Germany

Trial 1 Secondary prevention in coronary heart disease

There were problems with storing and reviewing data from PortiLab2. The problem could not be specified. In general PortiLab2 is still not very user-friendly. One improvement seems to be that real-time measurement is now available.

Sweden

Trial 1: The Lighthouse alarm and locator

This is still not user-friendly.

Special UMTS trial: Since the configuration file for Portilab was not correct at time of trial, no detailed analysis of the data has been performed.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

It is easy to go to the PortiLab application. There is a problem finding the file when the file-name is figures and letters. One has to auto-scale every parameter; this is not good. For this trial owner the signals are of good quality but a problem is that one does not know if they are valid.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 had not yet downloaded and tested the latest version.

For trial owner 2, support was needed when installing Portilab and when viewing the data (support was given by phone). According to Portilab there were a total of 8 files from her Pre Trial 2 (Saturday and Sunday together). The longest file appeared to be 5 hours long, but when looking at it in Portilab, only 14.41 min are viewable in the Portilab, a dropout of 4 hours and 45 min.This was similar with most of the files. The longest file is around 45 min (as far as can be seen); so the total dropout of data is quite high.

Trial owner 2 can see that she only managed to send manual input on two occasions (first session and in the beginning of the second); but there are some drop alarms.

One very important question is whether the saturation is missing in Portilab (or in the configuration file for respinsuff); or if the trial owner just did not understand how it was presented. She could not find this out by reading the user manual.

Trial owner 2 also thought it was difficult to understand how one should read the values/graphs that you see in Portilab. For example, how does one analyse it? What do the values stand for? For example in manual input – is it which second the activity etc happened? Again she did not find out this by reading the user manual.

Trial owner 2 did not have a chance to use Portilab when collecting data, since there was no configuration file.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

This group has worked with PortiLab and has seen the curves etc. However, they feel the need for more training to understand and use PortiLab and be more comfortable with the system.

Spain

Trial 1 Support of home-based healthcare services

There are still the same problems with respect to the usability of the PortiLab from the professional point of view. There have been few changes with respect to the previous version.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

"With a little help from my friends", it works. All but intuitive.

Part Three: Usability and empowerment

Please provide an assessment of the performance of the current prototype (Version 3.1) of the BAN system and communications that you tested in this (these) pre-trial(s), according to the following factors:

Functionality

Germany

Trial 1 Secondary prevention in coronary heart disease

It still takes up to three minutes to activate the BAN. The IPAQ and the Mobi have to be restarted after every measurement. Starting functionality is nevertheless improved with respect to the previous version.

Sweden

Trial 1: The Lighthouse alarm and locator

No comment.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

The test person stated that it was convenient to carry the Mobi and iPAQ. The equipment did not hinder the person in his job as a teacher.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

The BAN/system is more stable than version 3.0. Start up is easier and more automatic. On the sensor viewer the signals are of good quality. Trial owner 2 cannot decide today if the data collected is possible to analyse and are of use for her in her daily work, since she had not yet been able to get in to Portilab. Unfortunately data collected was not possible for her to analyse from Portilab today, since she did not have enough information about what the values stand for (missing in the user manual) and the dropout of data was high.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

This version is better to work with. They could understand when the BAN was working and when it did not. It was easy to understand what the next step in the process would be, and they could se when the network was working. The BAN feels very stable.

Spain

Trial 1 Support of home-based healthcare services

Not very user-friendly. GPRS establishment has been greatly improved but still the percentage of data storage at the BEsys is pretty low.

UMTS: Much more friendly than GPRS, connection is greatly improved and the data is stored correctly at the BEsys.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

Functionality is good; much improved compared to the earlier version. But: direct Bluetooth connection between the Mobi and latest PortiLab version appeared impossible with all tested Mobis.

Ease of use

Germany

Trial 1 Secondary prevention in coronary heart disease

After a little training it is no problem for a patient or another test person to put on the sensors on his/her own. Sensor stickers never got loose during testing. Removal of ECG-sensors can be painful. Wearing of the BAN is convenient and does not affect activities of daily living.

Sweden

Trial 1: The Lighthouse alarm and locator

There are still too many steps to carry out.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

If things go well a connection between all the equipment is made the first time on start-up, and then the equipment is relatively easy to use.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 reports that it is acceptable except for the complicated manual input (see above).

Trial owner 2 reports that Version 3.1 is quite easy to use, with exception of the Manual Input, which shows errors. Comments from test person 1: thinks that the pulse oximeter sensor is in his way, the finger feels stiff when performing activities. Carrying the Mobi is ok. It is easy to forget to bring the iPAQ when moving around. It is sweaty on the fingertip at the end of a six-hour session. Comments from test person 2: would be nice with a little box for all the cables or perhaps a different construction.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

This BAN is very easy to use. The hourglass and the notice on the screen improved the BAN a lot. Also all applications on the screen were better than in Version 3.0.

Spain

Trial 1 Support of home-based healthcare services

It is definitely not easy to use for either a professional or a patient, as he/she does not know when data is being stored.

UMTS: It is not difficult to use if you have a minimum of support and have been taught how to deal with the devices.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

OK. But: battery charging remains a pragmatic problem. One is always looking for a wall plug.

Safety

Germany

Trial 1 Secondary prevention in coronary heart disease

Medical treatment of the patients during pre-trial and real trial is not based on the transmitted vital signs because the BAN system is in a testing phase. In this stage the monitoring of the ECG and blood pressure is an additional service for the patient and not a surrogate for treatment by the physician. Nevertheless transmitted ECG levels seem to be valid on the IPAQ viewer and there are no artefacts if the sensors fit properly.

Sweden

Trial 1: The Lighthouse alarm and locator

It is still considered not to be a safe system for care purposes.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

The system is not stable.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 believes this has to be defined.

Trial owner 2 comments that the Mobi still turns off spontaneously, which means that the test person has to check if the Mobi is still on. There is no indication on the iPAQ that the Mobi turned off = drop out of data. The iPAQ still says “MBU sending”. Comments from test person 1: is it possible for anybody to see the data on its way in cyberspace? If my saturation is low – will somebody come and help me?

Trial owner 2 thought she had sent data for longer periods than she actually did – as she could see in Portilab afterwards.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

This group wished to reserve answering the safety question until they could hear the opinion of the consulting doctor on the validity of the readings.

Spain

Trial 1 Support of home-based healthcare services

As the system often fails when sending the data to the BEsys, it is considered not safe enough for clinical use.

UMTS: As the system doesn't allow an interpretation of the results, it is considered not safe enough for clinical use.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

There are no complaints.

Mobility

Germany

Trial 1 Secondary prevention in coronary heart disease

Mobility was guaranteed during the pre-trials; patients and testing persons walked around taking the IPAQs with them. Distance to the iPAQ can be up to 10 meters. If the distance is more, there are first artefacts and then measurement breaks down.

Sweden

Trial 1: The Lighthouse alarm and locator

The iPAQ and GPRS device are still a little heavy.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

To get full mobility in this pre-trial, the critical factor is the battery consumption in the iPAQ. Participants may wish to be outdoors for many hours.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 reported that he could be fully mobile when carrying all equipment for 8 hours and 6 hours on 27/11 and 28/11 respectively.

In the second phase of sessions, comments from test person 1: feels a bit prevented in doing everything, mainly because of the pulse oximeter sensor. Wonders if there is a possibility to have an alarm/indication when the connection between Mobi and iPAQ is bad/nearly lost – to easier remember to bring the iPAQ. Comments from test person 2: avoids doing as much as he is used to during the five-hour session, because he is afraid of pulling the cables out of the Mobi. Is not as active as he normally is.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

All tested patients said that this instrument was much better than the regular ECG. It is smaller and with only four sensors to apply. The trial owners think that the mobility is very good because of its size and easiness.

Spain

Trial 1 Support of home-based healthcare services

The battery of the device must be full, or almost. The iPAQ has to be connected most of the time. The mobility is then reduced.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

This is OK, except for the charging issue. Also, there are too many leads and too long.

Part Four: Comparison to Pre-Trial #1 and Extent of Fulfilment of Expectations/Requests

With regard to Pre-Trial #2, please provide any details of the extent to which your expectations for improvements to Version 3.1 of the BAN were fulfilled. Please compare Version 3.1 and Version 3.0 with regard to the performance, usability, safety, functionality, and problems encountered in terms of:

Start-up function:

Germany

Trial 1 Secondary prevention in coronary heart disease

One of the largest improvements of the Version 3.1 is the advanced start-up functionality. It is not that cumbersome anymore to start the iPAQ by inserting the GPRS jacket at the right moment etc.

Sweden

Trial 1: The Lighthouse alarm and locator

This has now improved over Version 3.0.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

Starting up the system is much quicker than Pre-Trial #1. It is easy to use the manual input. The system is a little bit more stable than Pre-Trail #1 but not enough to use in the healthcare system. The trial owner needs more knowledge to analyze the signals in PortiLab before she can say anything about that.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 reports an 80% success rate now, a significant improvement Compare this with a 10% success rate in Pre-Trial 1 in August.

Trial owner 2 notes that it is much easier, more automatic, but still not perfect.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Much better in Pre-Trial#2. In one of twenty there was a startup failure. A great improvement.

Spain

Trial 1 Support of home-based healthcare services

Start-up has been greatly improved in terms of establishment of the GPRS connection between the iPAQ and the BEsys. It does not have to be manually tested if the communication has been established, which means a big step forward.

UMTS: It has been greatly improved in terms of establishment of the UMTS connection between the iPAQ and the BEsys. It doesn't have to be manually tested if the communication has been established, which means a big step forward.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

This is much improved.

GPRS connection stability:

Germany

Trial 1 Secondary prevention in coronary heart disease

During upgrade of the BANs a problem occurred with the SIM cards which were caused by a missing HTTP chunking functionality. At time of writing it was not clear if problems with sending of the data to BESys are caused by this missing functionality but it was considered to be very likely.

Sweden

Trial 1: The Lighthouse alarm and locator

The system still disconnects, but less than before.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 says it is better but not sufficient, see above.

Trial owner 2 says: “much better. Didn´t really have a problem with this now.”

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Seemed better in Pre-trial#2. The system worked much faster now than in Pre-trial#1.

Spain

Trial 1 Support of home-based healthcare services

The maintenance of the connection is not very stable. After a few minutes of sending data, the Mobi turns off and the data transmission is cut, which means that the iPAQ needs to be restarted.

UMTS: The maintenance of the connection is very stable. It only breaks if the battery of the Mobi or the cell phone is low.

Trial 2 Outdoor patients’ rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

This is better, but still most registrations do not last longer than two hours.

Batteries:

Germany

Trial 1 Secondary prevention in coronary heart disease

No changes from Pre-Trial #1. Mobi batteries last for around 8 hours. Again the battery of the iPAQ has to be almost full, otherwise no measurements can be done.

Sweden

Trial 1: The Lighthouse alarm and locator

Battery lifetime is not very long.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

It was not possible for trial owner 1 to comment.

Trial owner 2 notes that there is still too short a duration for the batteries in the iPAQ, if the test person wants to be outside.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

There were no problems with the battery in Pre-trial#2. The group speculates that they may have been better prepared with batteries this time.

Spain

Trial 1 Support of home-based healthcare services

Still, the batteries need to be almost full to have a more or less stable connection; if not, the chances of error are increased.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

No change.

Mobility:

Germany

Trial 1 Secondary prevention in coronary heart disease

Mobility is guaranteed like it was in Pre-Trial #1.

Sweden

Trial 1: The Lighthouse alarm and locator

The iPAQ and GPRS device are still a bit heavy, but otherwise this is OK.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 says mobility is similar to Pre-Trial 1, and sufficient.

Trial owner 2 agrees that it is the same.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Mobility was goos, as good as it had been in Pre-Trial #1.

Spain

Trial 1 Support of home-based healthcare services

Mobility is reduced due to the fact that the iPAQ needs to be charged periodically.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

No change.

Wearability:

Germany

Trial 1 Secondary prevention in coronary heart disease

Sensors and BAN are easy to wear. Length of cables is appropriate whilst doing daily activities.

Sweden

Trial 1: The Lighthouse alarm and locator

Wearability is fine.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 believes wearability is similar to Pre-Trial 1, and sufficient.

Trial owner 2 believes that the pulse oximeter is still the sensor that does not feel 100% ok, and the cables in both the pulse oximeter sensor and ECG sensors are too long (according to test persons).

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Wearability was also as good as in Pre-Trial #1.

Spain

Trial 1 Support of home-based healthcare services

No problems foreseen from this point; patients seem to feel comfortable with the devices in terms of wearability.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

No change.

Visibility of errors on iPAQ:

Germany

Trial 1 Secondary prevention in coronary heart disease

The only feature here is that one can see on the iPAQ when the Bluetooth connection between the iPAQ and Mobi fails.

Sweden

Trial 1: The Lighthouse alarm and locator

This has improved.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 thinks the visibility of errors is good.

Trial owner 2 thinks it is better, but it still does not indicate if data still is sending or if connection is lost.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

This was a great improvement in Pre-trial#2. In Pre-trial#1 you did not know if it was an error or if the BAN was working. The screen is more improved with details and signs to show what is happening under the test. The icon is easier to understand.

Spain

Trial 1 Support of home-based healthcare services

Difficult to identify, it is not shown in any way when data is not being correctly stored.

UMTS: Better than in previous versions. It gives you clues of where the error comes from.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

This has improved.

Security:

Germany

Trial 1 Secondary prevention in coronary heart disease

Version 3.1. is much more stable than the previous one. Nevertheless the whole system is not safe enough for clinical decision-making. The verification of the security of the system should be the aim of a larger pilot study.

Sweden

Trial 1: The Lighthouse alarm and locator

Security is not commented on.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

No comment.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

In trial owner 1's view this is not possible to define.

Trial owner 2 also could not really say, but test person 1 commented in general that anybody can get their hands on the data (this is still the same as for Version 3.0).

Dropout of data was high.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

For the first time the group has seen curves under the testing period on PortiLab2 now in Pre-trial#2. Other than that they cannot comment on security.

Spain

Trial 1 Support of home-based healthcare services

Same situation as with the previous version. It is not secure enough to do clinical trials.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

This is OK.

Logging functionality:

Germany

Trial 1 Secondary prevention in coronary heart disease

No comments were made.

Sweden

Trial 1: The Lighthouse alarm and locator

The logging functionality has improved over Version 3.0.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

No comment.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

For trial owner 1 the logging functionality was easier.

Trial owner 2 did not provide a comment, not being sure of the meaning of the question.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Logging functionality was the same in Pre-Trial #2 as in Pre-Trial #1.

Spain

Trial 1 Support of home-based healthcare services

The fact of not having to manually test the establishment of GPRS and UMTS connection is a great improvement in comparison to the previous version.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

This is OK.

General stability issues:

Germany

Trial 1 Secondary prevention in coronary heart disease

Measurements break down after 30-60 minutes but this is really a large improvement if compared with Version 3.0.

Sweden

Trial 1: The Lighthouse alarm and locator

In general, this is now better, but still not perfect.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

No comment.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

For trial owner 1 the stability overall was better.

Trial owner 2 agreed that the system is more stable than Version 3.0. Also test person 1, who had tested the earlier version, had this impression.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

The BAN feels more stable in Pre-Trial #2. The group got an "answer" every time they made some notes or sent something on the iPAQ. They felt that they could follow the process from measurements to sending, and to the BE-system much more in Pre-trial #2 than they could in Pre-trial #1.

Spain

Trial 1 Support of home-based healthcare services

There are problems with maintaining the connection between the Mobi and the iPAQ. The Mobi often switches off after a few minutes.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

This still needs improvement.

Portilab:

Germany

Trial 1 Secondary prevention in coronary heart disease

No data could be stored and reviewed in PortiLab2 during the last three days. This could however have been caused by using default HTTP calls (problems with German operator). Real-time display is available in Version 3.1 which is a big step forward. In general this version of Portilab2 was not very user-friendly.

Sweden

Trial 1: The Lighthouse alarm and locator

PortiLab is still not user-friendly.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

No comment.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 had not downloaded and tested the latest version.

Due to a disc crash in the Dutch Back-End System, trial owner 2 had also not been able to check the Portilab changes.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

In Pre-Trial #1 they could not see the curves at all. In this Pre-trial #2 they were able to see the curves and work with PortiLab#2. A real improvement in this version.

Spain

Trial 1 Support of home-based healthcare services

From the point of view of the user, no big improvements have been performed. There are still the same problems in usability and reliability.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

Without expert help around the corner, this would have been a major problem (the trial owner was in Enschede, where experts on PortiLab were close by).

Manual input:

Germany

Trial 1 Secondary prevention in coronary heart disease

Not tested.

Sweden

Trial 1: The Lighthouse alarm and locator

The whole text was still not visible on the display.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

No comment.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 said it functions but is not convenient for the RespInsuff trial(see above).

Trial owner 2 says that it is better in terms of being more automatic – with the send-button, but still not optimal. She could not really use it because of errors. It was not good to have fields that you have to fill in every time you are going to fill in an activity. There are still too many steps to remember.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Much easier to use in Pre-Trial #2. More easy to understand. A big improvement that ID was possible to use. But in this Pre-trial #2 they noticed that there was some sort of problem when they were sending and using manual input. It was something they had not expected.

Spain

Trial 1 Support of home-based healthcare services

OK.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

This is OK.

User manual:

Germany

Trial 1 Secondary prevention in coronary heart disease

The latest version of the user manual contains an extended section about PortiLab2. In general the manual is very helpful. A translation of the user manual in German was ongoing at time of writing and was scheduled for finishing before Christmas to be used by patients. Nevertheless it was to be feared that the manual overstrains the patients (most of them are older than 50 years).

Sweden

Trial 1: The Lighthouse alarm and locator

The user manual is good.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

No comment.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 had not yet read the latest version of the user manual.

Trial owner 2 found the latest version better and much clearer, except from the part about Portilab. She felt there has to be much more explanation for the users about how to use the graphs, data, values that you can see in Portilab. We have graphs – so what do they really say? How does one analyse??

Trial 4: Home care and remote consultation for recently-released patients in a rural area

The user manual has always been very good and important to use for doing the pre-trials.

Spain

Trial 1 Support of home-based healthcare services

No comment.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

For the BAN, no manual was needed. For PortiLab, it does not help a lot.

Part Five: Preconditions for Further Trials

Please indicate the conditions for development of the BAN system and communications, or any relevant factors, that you consider will be necessary in order to carry out an effective final field trial with valid conclusions.

Germany

Trial 1 Secondary prevention in coronary heart disease

Improvements in PortiLab2 which allow the trouble-free storing and reviewing of the data. It is till now not clear if these problems are caused by the problems with Vodafone Germany and the downgrade of the sample rate to 128 samples/sec.

Sweden

Trial 1: The Lighthouse alarm and locator

We still need fewer disconnections in the system, and longer data sending time.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

No comment.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Trial owner 1 declares that a real trial will start on 6th or 7th of December, but will not include predefined patients according to the primary inclusion criteria.

For trial owner 2, she believes it would be nice if the Manual Input worked better – otherwise they will not be able to use that in the real trial. Then only sending data via pulse oximeter and activity sensor will be used. But she would like to be able to correlate data from the sensors with the Manual Input.

After viewing data in Portilab, trial owner 2 was hesitant aboutusing this on real patients; but perhaps it would be all right on healthier Resp patients. On the other hand they could always evaluate the patients' experience of carrying the BAN; and if the dropout of data is high, that is also an evaluation....

Trial 4: Home care and remote consultation for recently-released patients in a rural area

The group has to know that the system is safe to use now for a final field trial with real patients .If the BAN is safe then they can start the field trial as soon as possible.

They hope that the manual input is better in the next version, that there are no problems with sending and using manual input at the same time and that they can use ID on each person. Also, they need some education in PortiLab2 or some help while doing the trial and also working with PortiLab2.

Spain

Trial 1 Support of home-based healthcare services

GPRS: It would be necessary to have a stable connection between the iPAQ and the Mobi, which means that the Mobi should not switch off after a few minutes, as was happening during this pre-trial.

GPRS: The transmission of the data to the BEsys should be more stable, it often fails and not data is stored, what means that a session has to be repeated several times to have results.

Problems and improvements come from the visualisation part involving both the sensor viewer and the Portilab.

In reference to the PortiLab, the interface should be improved from the clinical point of view. The graphics should appear with axis in order to be evaluated.

The problem of selecting a patient by his name still persists. It is difficult from the point of view of the professional to select a session based on a 12-digit code.

Trial 2 Outdoor patients' rehabilitation

See above.

The Netherlands

Trial 1: Tele Trauma Team

and

Trial 2: Integrated home care for women with high-risk pregnancies

The major issue to improve upon, apart from PortiLab, is the stability of the system. For the primary MobiHealth target, the current stability will do

marginally. To get a real view of the clinical potential, running times of eight hours at least are preferable.

Addendum to the Enschede comments:

The test procedure in Enschede was:

All BANs directly Bluetoothed to PortiLab.
GPRS BAN tested with pregnant volunteer; run time one hour maximum.
GPRS BAN with sleeve and GPRS BAN with Nokia, tested synchronously on Rik Quartero. Both drop out at one to four-hour interval.
GPRS and UMTS tested synchronously on Rik Quartero. UMTS failed because of (lack of) network cover. GPRS four-hour run time.
UMTS tested between UT and MST. Total run time six hours.
UMTS and GPRS tested on in-hospital patients. GPRS drop out after one hour (Mobi), UMTS run time eight hours, 127 MB data.

Conclusions

This pre-trial proved to be in a good position to compare the experiences of Pre-Trial #1 of Version 3.0 of the MobiHealth system (this trial ran in summer and autumn of 2003) with those experiences of using the upgraded Version 3.1 and enhanced functionality which was tested in December of 2003 and January of 2004.

Once again there was quite a lot of overlap in the experiences of the trial owners in different regions of Europe, and the partners could see a great deal of commonality to the issues which had been addressed based on the requirements from Pre-Trial #1 Report. A few are noted below.

Start-up: trial owners reported improvement in starting up the system. It was reported that the system was “much easier to activate”, “much quicker”, “more automatic”, and one owner reported an 80% first-time success rate, compared with 10% in Pre-Trial #1. Minor failures to start up were solved by simply repeating the process, and resetting the iPAQ.

GPRS connection stability: trial owners noted a greater stability and fewer incidents of break-off in connection when compared with Pre-Trial #1. With regard to the data transfer, there was quite a spectrum of experiences here. Connections were indicated on the iPAQ to last anywhere between 30 minutes and five hours; however, at the back-end much smaller time values for data transfer were indicated. For example, in one case “data was sending for 1 ½ hours, data that was presented in PortiLab was 16 minutes.”

UMTS connection stability: the use of UMTS in this pre-trial was limited, but a test of the UMTS system was carried out at the Lighthouse and its environs, with positive results on stability and connection, even during handover. Other limited tests in Sweden also provided positive results with UMTS, and in Enschede a similar experience was reported. The most promising results were reported from Barcelona, where a marked improvement was noted in the performance using UMTS over that recorded for GPRS.

Sensor viewer: again there were reports of improvement with the sensor-viewer. Some trial-owners expressed the wish for a scale in order to better determine the readings visually: ”The display of numerical results is satisfactory but the graphics are useless since no scale is available.”

Batteries: battery power was the same as with Pre-Trial #1. The relatively short battery life on the system meant it was advisable to leave it on the charger in some cases. Some trial owners noted that

the batteries needed to be almost full in order to establish a good connection.

Mobility: it was generally agreed that a person wearing the system could be mobile; the critical factor was the battery life. The factor that is important here is that if the iPAQ is charging, the maximum distance the user can have from it is dependent on Bluetooth. “To get full mobility in this pre-trial, the critical factor is the battery consumption in the iPAQ. Participants may wish to be outdoors for many hours.”

Wearability: with the greater amount of testing afforded by this pre-trial, there was general consensus that the MobiHealth system was easy even for a patient to put on by themselves and wear for long periods, and that in most cases it was unrestrictive to daily activities. One trial owner considered “the iPAQ and GPRS device are a little heavy” for elderly or infirm people to carry.

Visibility of errors on iPAQ: the request from Pre-Trial #1 that there be some kind of sign if the iPAQ was disconnected or not functioning properly was answered. Trial owners reported an improvement here, although there was the question of the “Sending” indicator and the relation between apparent sending time and actual data transmitted. One trial owner noted “This was a great improvement in Pre-Trial #2. In Pre-Trial #1 you did not know if it was an error or if the BAN was working”.

Security: the system was still generally considered to need greater reliability if it were to be considered a safe system for clinical application and decision-making.

Logging functionality: there seemed to be some confusion about the meaning of the expression “logging”. Some trial owners seem to have believed it related to “log-in”, i.e., start-up. They reported that it was easier to “log in”.

Portilab: PortiLab could be accessed easily enough; however, it was considered to be difficult to locate and review the correct file as the file name was made up of many figures and letters: “It was difficult to understand how one should read the values/graphs that you see in Portilab. For example, how does one analyse it? What do the values stand for?” It was felt by some trial owners that more training would be required to use PortiLab effectively. Greater transparency was needed. In general it was felt that PortiLab was not yet user-friendly enough.

Manual input: there were minor instances of improvement; there were still many steps to be taken and fields to be filled in before sending: “The manual input part is a bit tricky to understand – which button to press, for example when filling in the text field and when

changing language. But the good thing in Manual Input is that there now is a Send button, when choosing activity.”

User manual: this was a great improvement. Translations had been made locally and the overall manual was considered to be very helpful indeed. An exception for one trial owner was the section on PortiLab, where it was requested that there has to be much more explanation for the users about how to use the graphs, data, values that you see in PortiLab.”

In summary, this pre-trial revealed:

a) great improvements over the previous version of the MobiHealth system in the areas of start-up and user manual;
b) moderate improvements to GPRS connection stability and display of errors on the iPAQ; and
c) some minor improvements to the sensor viewer.

The pre-conditions for carrying out the next phase of trials as stated by the trial owners in the Pre-Trial #1 Report were generally answered in the technical delivery of the upgrade, while some elements left room for improvement.

The critical areas which the trial owners perceived to need further improvement were greater connection stability, longer run-time in sending data, and the usability of PortiLab and readability of the data stored there.

A note on connectivity: the bulk of the comments from the users regarding incidents of connection breakdown related to the use of GPRS. The use of UMTS in this pre-trial was limited, but a test of the UMTS system was carried out at the Lighthouse and its environs, with positive results on stability and connection, even during handover. Other limited tests in Sweden also provided positive results with UMTS, and in Enschede a similar experience was reported. The most promising results were reported from Barcelona, where a marked improvement was noted in the performance using UMTS over that recorded for GPRS.

The final phase of the trials will generate a final User Evaluation Report which will sum up the usability and applicability of the final version of the MobiHealth system prototype.