

HOW TO EVALUATE HUMAN FACTORS AFFECTING WIRELESS BIOMEDICAL SENSORS

Identifying Aspects of Patient Acceptance based on a Preliminary Clinical Trial

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Abstract: In this paper, we highlight some important aspects of how to evaluate patient acceptance with wearable sensors recording vital signs information, used in a telehomecare environment. Questions of human factors and patient satisfaction need to be addressed, where the patient is able to carry out daily life activities in his own environment. We compare results from a preliminary clinical trial with patients using a wireless ECG sensor for three days out-of-hospital service, to available published results from telehomecare projects, and propose important aspects and plans for future investigations. It is important not only to observe the patient, but also the possible changes in the family situation when a sick patient is transferred to his own home for active treatment. At the same time, emotional barriers and stigmatisation are challenging factors where time is needed to let the patient adopt this new situation. Therefore, measures should be on an on-going basis with long-term use of the technological equipment in order for the patient to integrate this into his body scheme as well as daily activities. Of special importance will be the evaluation of the communication between the patient and the health professionals, as quick feedback from the doctor to the patient on his or her own measurements is of utmost importance.

1 INTRODUCTION

Several research projects have been focusing on wearable biomedical sensors and their benefits for ambient assisted living, where the patients are remotely monitored by different sensors placed on the body for vital signs recording (Jones et al., 2006). However, little efforts have been done investigating how the patients experience and manage this new technology.

Chronically ill patients experience a greater degree of freedom and are more involved in the treatment with daily monitoring of vital information during hospitalization in their own home, than with the traditional treatment procedures at hospital. Introducing advanced medical technology in the patient's own home will influence the patient's situation as it makes empowerment and self-management possible (Barlow et al., 2002).

At the same time, coordinated follow-up and new workflow procedures for the health-care services need to be implemented in order to give the patient

satisfactory support by virtual visits in his home (Wootton and Kvedar, 2006). However, this support also must be integrated in the self-monitoring of vital signs information performed by the patients, with understandable interpretations of the results.

The primary goal of developing wireless ECG sensors is to find ways of monitoring the everyday life of the patient as closely as possible. In other words, the rationale is to increase the quality of data being collected by decreasing the impact on the patient's everyday life when he or she is being monitored. When implementing such equipment it is therefore necessary to allow the patient to integrate it into his or her daily activities. Also, we argue that this integration concerns a person's body scheme, being a dynamic, and typically unaware, representation of the positions of one's body parts (Haggard and Wolpert, 2005). To monitor this process, measures should therefore be based on long-term use of the wireless equipment in an everyday life situation.

In this paper we will focus on how the technology acceptance can be monitored in order to highlight obstacles and possible improvements both in

the technology solutions and in coordination with the health care services. Based on experiences from a preliminary clinical trial, we try to identify some important aspects of patient acceptance and present plans for future projects involving observations of user acceptance.

1.1 Usability and Telehomecare

Home telehealth is a growing field of patient treatment and follow-up, but most research studies have focused on the technology, and so questions of human factors and patient satisfaction need to be addressed. A systematic review of studies of patient satisfaction with telemedicine was done by Mair and Whitten, arguing that *“available research fails to provide satisfactory explanations of the underlying reasons for patient satisfaction or dissatisfaction with telemedicine”*. They found that the studies concerning patient satisfaction mainly used simple survey instruments and that many of the studies had only a few participants (Mair and Whitten, 2000).

According to Friedman & Wyatt, usability studies can be useful in the evaluation of new biomedical equipment, with the aim of observing speed of use, user comments and completion of simple tasks (Friedman and Wyatt, 2006). They describe field function studies as useful in the validation of prototypes or released versions of new biomedical equipments, but the trials should be conducted in situations with real use of the equipment, and with the aim of observing speed and quality of data collected and accuracy of advice given from the devices.

The principles of user-centered design can be useful when designing new telehomecare devices. Adlam and colleagues describe how user evaluation can be implemented in the design process (Adlam et al., 2006). They start with discovering the “real problem” and the users’ requirements, which can be accomplished with a simple prototype demonstrating the actual functionality of a device. However, interacting with real users in their own environments will be a challenging task, and prototypes with limited functionality can give restrictions on the use of the new solution to be developed, resulting in preliminary tests, which do not reflect a more complicated use situation, i.e. the daily activities of the patients.

Kaufmann and colleagues developed a system design for both usability testing and usability inspection in the patient’s home for a diabetes telemedicine system. First, they used a cognitive walkthrough to identify goals and sequences of actions to anticipate potential user problems. Second, a field usability testing was performed as a series of tasks to be ac-

complished by the subjects in their home and closely followed by semi-structured interviews to reveal problems and barriers to efficient and safe use of the system (Kaufmann et al., 2003). A similar approach has been suggested by Kushniruk and Patel, who have developed a low-cost portable usability testing solution intended to be used by patients in their homes (Kushniruk and Patel, 2004).

In a study of the patient’s perspectives on high-tech homecare technology, Lehoux found that the user-acceptance was shaped by different types of anxiety, which mainly was related to the actual equipment and the procedures. At the same time, the patients complained of reductions in daily activities as well as feelings of stigmatization, as they tended to withdraw from social activities in order to hide the medical equipment from the eyes of visitors. For a patient wearing a permanent catheter, this will alter the patient’s body image (Lehoux, 2004). Lehoux found that good usability is dependant on competence, where lay people are supposed to use high-tech medical devices, as well as on technical and human dimensions, where the technology is integrated into the patients’ private and social lives.

Hopp and colleagues measured the outcome for patients receiving telehealth home-care and used a questionnaire at baseline and after six months, where they used a modified version of the SF-36 to measure Health Related Quality Of Life (HRQOL) (Hopp et al., 2006). In addition they used separate questions to ask about satisfaction with the telehealth equipment for the intervention group, with questions from the National Ambulatory Care Survey and modified for use in evaluating telehealth services. They found a high degree of satisfaction with the telemedicine equipment, but few patients reported that their family members had been taught how to use the equipment installed in their homes.

2 OBJECTIVES

In this paper, we present some ideas of how to evaluate human aspects of telehomecare solutions, which are based on preliminary results from a clinical study where patients have used wearable sensors for a three day period of out-of-hospital service. We focus on the impact on everyday life during the patients’ use of the wireless ECG-sensor; the experiences with daily behaviour as well as general patient satisfaction. The important question is which factors to include in future evaluations, and how to observe the degree of the patients’ influence on new telehomecare services, together with their perception

and possible adoption of the new technology.

3 METHODS

Patients referred to long-term ambulatory “Holter” arrhythmia procedures at the outpatient clinic at Sørlandet Sykehus HF in Arendal, Norway, were asked to participate in a study wearing our newly developed wireless ECG-sensor (Fensli et al., 2005). By signing the informed consent form, they participated in the study during their ordinary arrhythmia investigation. The inclusion criteria was patients with suspected arrhythmias, and the exclusion criteria was patients with dementia who were anticipated not being able to handle the equipment and contribute in filling out the required questionnaires.

After signing the informed consent form, the patients were given information of the research project and they received several questionnaires to be filled in during the time they used the wireless ECG-system as a usability study. Because influences from participating in a three day trial of the new recording solutions can be a bias in the evaluation of patient acceptance, a reference group with patients undergoing a “normal” routine investigation at the hospital using conventional “Holter” monitoring equipment (Huntleigh Healthcare) was established.

During the period from November 2006 to May 2007, 11 patients were enrolled in the study, and 25 patients were included in the reference group. The questionnaires focused on several topics, among them questions defining the Dimensions: Hygienic Aspects (3 items), Physical Activity (6 items), Skin Reactions (2 items), Anxiety (3 items), and Equipment (5 items) (Fensli et al., 2008). After a three day period of arrhythmia investigation with the use of the wireless sensor, 4 patients in the intervention group were followed-up with qualitative interviews, in order to discover more general experience with regard to the use of a wearable sensor.

4 EXPLORATORY RESULTS

In the questionnaire, the patients are asked about their experiences with the use of the equipment, where we have used an 11-point semantic differential scale. The patients should evaluate their experience of using the wireless equipment in terms of their agreement to the statements describing actual situations of the equipment usage. For some of the questions the scale was ranging from “0 – Extremely

problematic” to “10 – Without any problems”. Some items described a statement with scale values ranging from “0 – I completely disagree” to “10 – I completely agree”. In addition, they filled in some general characteristics, such as gender and age. The results are given in Table 1.

Table 1: Patients’ general characteristics and results from the calculated dimensions based on the questionnaires, Mean (SD). Calculations of Cronbach’s alpha for the dimension Hygienic Aspects was 0.83, for Physical Activity 0.88, for Skin Reactions 0.65, for Anxiety 0.80 and for Equipment 0.86.

| General characteristics and Dimensions | Wireless sensor (n=11) | Reference group (n=25) |
|--|------------------------|------------------------|
| Gender: Man/woman | 6 / 5 | 7 / 18 |
| Age | 40.2 (19.4) | 56.4 (13.2) |
| SAI | 8.2 (1.0) | 7.6 (1.9) |
| Hygienic Aspects | 8.6 (1.6) | 6.6 (2.9) * |
| Physical Activity | 9.2 (0.8) | 8.0 (2.8) |
| Skin Reactions | 6.3 (2.5) | 8.6 (2.4) * |
| Anxiety | 9.0 (1.3) | 7.3 (3.5) |
| Equipment | 8.0 (1.7) | 7.5 (2.8) |

* significant difference $p < .05$

The internal consistency, as calculated by Cronbach’s alpha, showed acceptable levels. The construct validity was evaluated by confirmatory factor analysis, giving reasonable factor loading according to our expectations. Calculations of a Sensor Acceptance Index (SAI) as an aggregated score showed a tendency towards a higher score for the wireless group compared to the reference group; however this difference was not at a significant level. For the dimension Hygienic Aspects regression analyses showed a significant difference between the two groups ($F(1,34)=4.51$; $p < 0.05$), with a higher score for the wireless group. The dimension Skin Reactions showed a significantly higher score for the reference group ($F(1,31)=5.95$; $p < 0.05$). With regard to the dimensions Anxiety and Physical Activity, the wireless sensor showed higher scores; however, this was not a significant difference.

In the interviews with four of the patients in the intervention group, we tried to discover some general experiences from the patients’ use of the wireless recording equipment. All patients reported some anxiety because of what they found to be a degree of uncertainty, as they did not receive any feedback from the recording system of the measurements made. They expected a quick feedback from the hospital, and two of the patients expressed the need for patient influence, while one of the respondents

said that he was not concerned with influence.

The hygienic factor focused on actual tasks related to the patient's ability to perform body wash and use of the equipment during the night while asleep, in order to obtain information about any problems relating to the wearable recording sensor. The survey showed a significant difference for the hygienic aspects, and the wireless solution obviously was preferable, since it is easy to wear and does not involve any hindrances like cables. This was confirmed both by responses to the open questions in the questionnaire and by statements in the interviews, as the patients generally expressed high satisfaction with the wireless solution compared to the existing "Holter" system. They felt free to carry out daily activities without any hindrance.

With respect to the equipment used, one patient complained about the "Holter" recorder, and said that he had "a feeling of being a living medical instrument", because of all the cables he had to wear. With regard to the wireless sensor, he said: "The wireless sensor was comfortable to wear, and most of the time I just forgot I was wearing this system". He said that the sensor after a while became "a part of me".

Another patient said the wireless system made it possible for her to participate in physical exercise. It was much easier to wear, especially during the night, and it did not prevent her from being able to take a shower. The Holter equipment was troublesome with all the cables, and made the hygienic activities more problematic. In her view, the differences in use between those two systems were huge, and they can not be compared at all.

One of the patients expressed some dissatisfaction with wearing this equipment, and she wanted to hide the equipment from other people. Similar expressions of embarrassment were also found in responses to the open questions in the questionnaire, and even if the calculated difference was not at a significant level, it showed a trend toward more anxiety regarding the use of the Holter equipment.

5 DISCUSSION

The results presented above are of interest in the evaluation of patient experience with wearable sensors attached to the chest for three days of continuous monitoring. Even though this clinical trial was limited both in terms of time and the number of patients, some interesting aspects have been discovered in relation to integration into the patients' everyday life. By comparing results and experiences

from the clinical trial with available published results from other telehomecare projects, it has been possible to discover some general aspects and point out ideas for future investigations.

First, our findings point to the issue of stigmatization, as some patients wish to hide the wireless recorder from the eyes of other people. This was similar to the findings by Myers et al., who studied the impact of home-based monitoring on patients with congestive heart failure, and followed up patients for a 2 month period. They found it necessary to train patients in telemonitoring procedures on an ongoing basis (Myers et al., 2006). During their study, 13.5% of patients withdrew due to anxiety or because they did not "like" the telemonitoring procedures or equipment. Their experiences of patient perception and ability to learn how to use the equipment indicate that the emotional barriers and stigmatization were a challenging factor and time was needed to allow the patients to adapt to this new situation. Our findings, however, also showed that when patients feel like the sensor is becoming "a part of me", as expressed by one of the patients, the stigmatization factor does not seem to represent any problems for the patient during daily activities, and can be adopted within his or her body scheme.

Second, our findings point to a need of constant feedback from the system or the health professionals to the patients. In this study we did not implement a daily reporting schema between the patient and the hospital, which was probably the reason why the patients expressed some worries about what the technology was measuring in terms of irregularities in their heart beats. Even though they trusted the equipment, they would like to see the results and the doctor's evaluation of the results when they felt irregular heart beats. These findings were in line with our experiences from an earlier study where patients underwent a 24-hour Holter recording procedure (Fensli et al., 2004), and quick feedback from the doctor was evaluated to be of utmost importance. However, although the patients appreciated good information during the research project, they expressed some uncertainty with respect to from whom they would receive an answer concerning arrhythmia findings. Their misperception of the health care sector as a "clear and strictly coordinated service", capable of giving them the desired follow-up, shows that organizational issues will be of utmost importance when introducing new telemedical solutions. If the co-ordination within the health care sector is not clearly defined, questions from the patients will not be correctly addressed and there will easily be situations where patients will suffer from not having

received the required feedback to the situation at hand.

Third, during the interviews the patients expressed overall good confidence with using the wearable sensor, mostly because of the ease of use during daily activities, which was confirmed by the significant difference calculated for the Hygienic Aspects. As a general measure of satisfaction (SAI), we found a relatively high score at 8.2 for the intervention group and 7.6 for the reference group. According to the intentions of home-based health care as expressed by Barlow and colleagues, those expressions of satisfaction were somewhat as expected (Barlow et al., 2002). This has also been confirmed by Whitten and Mickus in their study of patients with congestive heart failure in addition to chronic pulmonary disease, finding that the patients were satisfied with the technology (Whitten and Mickus, 2007). Wootton and Kvedar have also pointed to the importance of changes in the health care services (Wootton and Kvedar, 2006), and their findings are also in line with what was reported by Scalvini and colleagues in their study of chronic heart patients and the effects of home-based telecardiology (Scalvini et al., 2005). In our study, the scores for Anxiety were relatively high indicating a low degree of anxiety, with 9.0 in the intervention group and 7.3 in the reference group. The age of patients in the reference group was slightly higher and consisted of more female patients, which may represent a bias. However, being confident with using the wearable equipment combined with a feeling of safety is important to the patients.

Patient acceptance of home hospitalization equipment on a long-term basis does not seem to have been given the necessary attention in previous studies of telehomecare. Following a systematic study of observed effects in home telemonitoring of patients with diabetes, Jaana and colleagues found that studies should be extended in time and involve larger samples of patients in order to generalize the findings and obtain sufficient validity (Jaana and Pare, 2007). Long-term evaluation may probably also discover some underlying reasons for the feelings of anxiety as reported by Lehoux.

We therefore propose future studies to follow the patients' use of wearable sensors and telehomecare equipment for a relatively long time in order for the patient to adopt the technology into his/her daily activities and body scheme. Attention should be paid to the patients' ability to carry out hygienic activities such as body wash or even taking a shower, and it should be possible to participate in physical sports activities while using wearable sensor recorders.

Also, not only the patient but also his/her spouse or partner should be taken into account and given the necessary information about how the treatment should be performed and how to interact with the health care services in a coordinated manner using tele-medical equipment. As proposed by Kushniruk and Patel, multi-method evaluations can be important, and even the use of video-recording can be performed in the patients' home (Kushniruk and Patel, 2004). Hence, a multi-method approach can be employed, where questionnaires can provide some background information about the patients, their behaviour, and acceptance of the technology. In addition, interviews in the patient's home can be combined with video recordings and, later on, analysis of the process data to obtain a more thorough understanding of obstacles and barriers to the use of such solutions. Evaluating the communication between the patient and health care services will also be of special importance, and new e-health-based forms of communication should be investigated. As quick responses are required by the patients, quality factors in the communication between the patient and the health care service should be observed.

6 CONCLUSIONS

Implementation of wireless sensors for vital signs recording for the use in home hospitalization can be a great benefit for the patient, as this gives a feeling of freedom compared to ordinary hospital stay. During the use of wireless ECG-sensors, the patients in this study were satisfied with the ease of use in a daily life situation, and gave a higher score in the factor Hygienic Aspects than patients in the reference group. With respect to the factor Anxiety no significant differences were discovered. However, the use of wearable medical equipment can also affect the patients' everyday life situation in a negative manner, where they tended to hide the equipment from the eyes of other people, and they expressed anxiousness for not using the telemedical equipment in a correct manner. But at the same time, the patients also expressed confidence with the system and tended to adopt its use into their daily life.

During the interviews, the patients, however, expressed worries of not having immediate feedback and responses to irregular heart beats, and their expectations of instant follow-up by the health care sector were revealed. This can be a great challenge where necessary coordinated routines and workflow within the health care sector should be defined and established before implementing new telemedical

services. The feedback channels to the patients' questions and recordings should be timely defined and validated. In order to investigate the use of telemedical technology in everyday life situations, research studies should be performed in a relatively long-term manner. Also, by employing a multi-method approach, such studies should focus on observing to which degree the patient adopts this new technology into his or her everyday life as well as body scheme or body image. Additionally, such studies should take into account the interaction between the patient and the system, as well as the interaction between the patient and the health care professionals. Finally, it seems necessary to also investigate how the patient's partner or spouse experiences the technology in daily use.

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