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Tele-homecare for Chronically-ill Patients: Improved Outcomes and New Developments

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ABSTRACT

Objective: To evaluate the benefits of tele-homecare for chronically-ill patients and to explore the application of advanced tele-homecare technology.

Design: Prospective randomised controlled trial for patients with heart failure, pilot study for patients with renal failure and prototype trials with older patients for advanced systems solutions.

Setting: Telemonitoring was performed in the homes of citizens in three European countries, supervised by specialist nurses and physicians based in hospital and in primary care.

Methods: For the heart failure study, 426 patients with a recent exacerbation of their heart failure were recruited in Germany, the Netherlands and the United Kingdom. Patients were randomised into one of three groups, a control group receiving standard care, a group receiving monthly telephone calls from a specialist nurse and a telemonitoring group. In this group, ongoing support was provided by twice-daily monitoring of weight, blood pressure, heart rate and heart rhythm using devices interfaced through cordless communications with a medical service centre via the telephone network. Outcome parameters assessed included survival, number of hospital admissions and length of hospital stay. For the renal failure study, eight patients transmitted their blood pressure and heart rate four times a day during each exchange of dialysate. In addition, weight and an electrocardiogram (ECG) rhythm strip were recorded before the first exchange.

Results: For the heart failure study, over a 1 year follow-up period, improved survival was demonstrated with both telephone support and telemonitoring compared to standard care. Telemonitoring also reduced the number of days spent in hospital, providing savings which more than off-set the costs of telemonitoring. In the renal failure study there were no problems associated with integration of the system into routine daily care processes. Daily data transmission allowed closer monitoring of patients and enabled more timely reaction to changes in their medical requirements. In the technology study older patients were found to be able to use advanced technologies including stylus-driven interfaces and high-quality video telephony.

Conclusion: Mature tele-homecare technology and proven techniques have been shown to be ready for routine implementation. In a variety of settings, physicians, nurses and patients have confirmed the benefits. In particular, for patients with heart failure, more intensive monitoring at home improves survival and tele-homecare increases the number of days alive spent out of hospital. Further studies are warranted to evaluate the role of telemonitoring in improving outcomes and reducing care costs in other groups of patients with chronic disease.

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INTRODUCTION

Globally, and particularly in Europe, the population is ageing. At the start of the twenty-first century, the world population included about 600 million people aged 65 and older (10% of the world population), triple the number recorded 50 years earlier (8% of the world population in 1950). By mid-century, there will be some 2 billion older persons (21% of the world population), once again a tripling of this age group in a span of fifty years[1,2].

An ageing population will have considerable impact on a wide variety of socio-economic aspects, such as economic growth, capital markets, pension systems, but also on technical progress and innovations, education, family and household structures – and last, but not least, on health and social care systems[3]. Since the current age distribution of chronic disease and disability is not expected to shift commensurately, if expenditure is not increased significantly or rationing of health interventions introduced[4], health services will be under even greater pressure to provide cost-effective services to these groups.

Traditionally, there has been a tendency to draw fairly clear boundaries between 'medical' and 'social' services and between hospital and ambulatory care. Often this has resulted in poor communication across the sectors, with a lack of co-ordination and continuity of care for patients. Encouraged by a combination of an ageing population and the desire to reduce expensive and inappropriate institutional and/or in-patient care, there are now moves in many countries to better integrate medical and social aspects of care, and to improve the quality of care which can be provided at home. These developments help cope with the impact of demographic change on health and social care systems and can be expected to improve the quality of life for older citizens with chronic disease. For more than fifteen years, telemedicine and telemonitoring approaches have been identified as key elements in this context[5–8].

Two chronic diseases affecting elderly patients are end-stage renal failure (ESRF) and heart failure. Both these diseases significantly affect patients' quality of life and they usually require frequent hospital attendance. The annual risk of a patient with heart failure being admitted to hospital is about 40%, the predominant cause being a worsening of their heart failure[9]. Heart failure is costly to manage, consuming between 1% and 2% of all health system costs in developed countries, 70% of which are due to hospital admissions[10]. Renal failure patients usually receive hospital dialysis three times a week at an expense of some €50,000 per patient per annum. Dialysis can be performed at home by patients who are able to carry out the necessary steps reliably without assistance or supervision. Patients who meet these and other criteria for home dialysis enjoy a number of benefits, including increased flexibility with respect to work and leisure activities. In addition, home dialysis (either haemodialysis or peritoneal dialysis) leads to a reduction in overall treatment costs[11,12]. Today, many

more patients could be managed by home dialysis if home monitoring and assistance could be improved.

Tele-homecare may assist in the delivery of care to both these groups of patients and has the potential to produce substantial cost savings[13]. We report here on two studies which test this hypothesis. The first was a small pilot experiment devised to learn more about the potential benefits for home monitoring in peritoneal dialysis patients. The aim of the second study was to scientifically test whether tele-homecare can improve medical outcomes and quality of life for heart failure patients as well as increase the efficiency of healthcare processes. The feasibility of such a study, as well as the usability and reliability of the technical equipment, have previously been examined in a pilot trial[14].

METHODS

Telemonitoring in Patients with End-stage Renal Failure (ESRF)

Eight patients with ESRF and ischaemic heart disease were selected for the pilot study. All patients measured their blood pressure and heart rate four times a day (Figure 1) during each exchange of the dialysate. In addition, weight (Figure 2) and ECG (1-lead rhythm strip) were recorded in the morning before the first

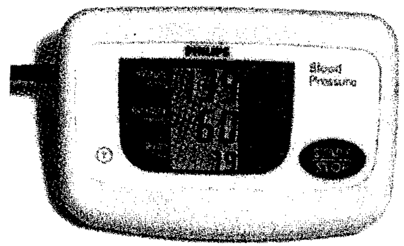

Figure 1. *Blood pressure and heart rate measurement device*

Figure 2. *Electronic scales*

exchange. All data were transmitted via radio frequency signals from the measurement devices to a home hub connected to the patient's telephone line. From there data were automatically transmitted to a central server located in the nephrologist's office in the dialysis clinic. A printer attached to the server allowed printing of charts and reports for filing and for providing visiting patients with their data.

Tele-homecare for Heart Failure

This study was a randomised controlled clinical trial involving 426 patients with a recent episode of exacerbation of their chronic heart failure. Recruitment and care of the patients was carried out through twelve university and regional hospitals in Germany, the Netherlands and the United Kingdom as well as local specialists and general practitioners (GPs). The study design defined three patient groups:

1) The control or Usual Care (UC) group comprised 85 patients. A specialist physician was responsible for implementing the patient management plan with usual support provided by the GP.
2) The Nurse Telephone (NT) group comprised 173 patients. A specialist physician was responsible for implementing the patient management plan and, in addition, patients were contacted every month by telephone by a heart failure nurse.
3) The Telemonitoring (TM) group comprised 168 patients. A heart failure nurse or physician was primarily responsible for implementation of the patient management plan. Ongoing support was provided by twice-daily telemonitoring of vital signs (weight, blood pressure and heart rate and rhythm) using the home monitoring equipment described above.

The mean age of the patients was 68 years and 78% were male. Patients were randomly allocated to the UC and the two intervention groups in the ratio 1:2:2. The reason the UC group was smaller is because the benefits of standard care are fairly well established for heart failure and thus fewer patients in this group reduced the cost of this expensive trial. Patient recruitment started in June 2000 and continued until March 2002, guided and controlled by an outside specialised institute. To allow for comparable results across different countries and health systems and to secure methodological rigor, strict patient selection criteria were established. These included amongst others – NYHA CHF classes II–IV, minimum treatment levels with certain drugs, and a planned or recent (<6 weeks) discharge to the patient's home following a hospital admission for exacerbation of heart failure. It is estimated that up to 20% of all patients with heart failure fulfil these criteria. Collection of patient follow-up data ended in November 2002, yielding data on more than 205,000 patient-days for analysis. Statistical analysis was performed using the Student-Newman-Keuls test for variables with normal distribution, and the Kruskal-Wallis test for other variables. Analysis was performed using SAS software. For methodological reasons, and particularly to avoid influencing the behaviour of the physicians and nurses participating, no interim

results were made available. All patients received full instructions and signed consent forms. They were 18 years or older and had no major cognitive defects.

RESULTS

ESRF Patients

The daily data transmission allowed closer monitoring of patients and enabled more timely reaction to changes in their medical requirements. This became obvious in various specific instances involving patients whose state of health deteriorated over a very short time period. Close monitoring turned out to be particularly useful for those patients where labile blood pressure or weight changes can be expected to occur within a short period of time. Integration of the system into routine daily care processes did not pose any problems. The physician reported the impression that patients felt better cared for.

Heart Failure Patients

The study demonstrated that heart failure patients supported by telehomecare, either via monthly telephone calls or telemonitoring, had a significantly ($p < 0.05$) lower mortality rate than patients receiving usual care (best medical practice based on a patient management plan). At 360 days follow-up, average survival in the usual care group was 263 days, compared with 307 for the nurse telephone group and 303 days for the telemonitoring group. The numbers of admissions into hospital was slightly higher for the TM group compared to the NT group, but the mean duration per admission was consistently lower ($p < 0.05$ for 240 days of follow-up). Overall, total days in hospital were considerably and consistently, although not statistically significantly, lower for the TM group. Further analysis of the data indicated that the cost savings from the overall reduction in hospital bed-days more than offset the increased cost of telemonitoring compared to nurse telephone monitoring. Nearly all (approximately 90%) of the telemonitored patients were very enthusiastic about this kind of support, stating that they felt much safer regarding their health management.

DISCUSSION

The results of both these studies have demonstrated the potential benefits of telehomecare in improving patient outcomes and reducing the costs of care in chronically-ill patients. For the renal failure patients the daily transmission of data allowed closer monitoring of patients and enabled more timely reactions to changes in their medical requirements. The system proved to be highly reliable and, with the addition of temperature and urine volume measurements, could be used to significantly extend the home dialysis population. Current systems enable the rapid adjustment of treatment, in (experimental) steps where appropriate, help in balancing medication regimes, ensure that established boundary values for vital parameters are not exceeded and enhance the quality of life of patients. It is estimated that close monitoring is medically indicated for about 10% of all present PD patients. In addition, approximately 10% to 20% of all new patients who initially receive haemodialysis may be suitable for PD treatment when combined with adequate close monitoring.

Data from the heart failure study indicate that increased patient support through the use of tele-homecare improves patient survival. Regular telephone contact and support led to an increase in days alive and out of hospital. This benefit was also conferred by telemonitoring. Although there was a slightly higher admission rate to hospital for the TM group compared to the NT group, the number of days spent in hospital was lower in the TM group. A possible explanation for this is that the closer surveillance associated with telemonitoring leads to earlier and more timely detection of deterioration in health status, and consequently earlier appropriate intervention.

These studies show that first-generation tele-homecare technology can effectively support the provision of routine tele-homecare for chronically-ill patients. The equipment is mature enough to be used for months with patients in their homes and requires only an ordinary telephone line for access. Though this technology provides good facilities for monitoring vital signs, communication with patients at home is often limited to the telephone. Broadband internet access, already available in many private homes, offers the potential for significantly improving the ability of clinicians and nurses to interact with patients. Visual communication with patients in the comfort of their homes, enabled by high quality video telephony, gives carers the ability to respond rapidly to patient concerns, communicate their interpretation or clarify open questions regarding vital data and when appropriate, observe patient reactions and behaviour, reassure or inform. The integration of high-quality video telephony with the Internet, vital signs, social alarms and domotic environment control to provide advanced tele-homecare systems is the focus of our research on Information Society Technologies at home (IST@HOME – for details see appendix). Evaluation of IST@HOME prototypes has demonstrated the usability of complex systems and touch-screen tablets even by older patients, and shown, for instance, that patients have a high level of confidence in information given to them personally through live video. It follows, that use of these emerging technologies can be expected to significantly extend the reach of tele-homecare, particularly among groups requiring more than minimal personal contact with care staff during treatment.

Crucial factors in ensuring wide-spread implementation of tele-homecare will be further reduction in the costs of systems and maximising their ease of use and functionality. As IST@HOME has concluded, tele-homecare systems should:

- Be easily installed in homes by non-technical staff
- Be readily integrated in legacy systems

- Provide reliable and effective performance
- Be carefully designed for ease of use by both care staff and patients
- Provide a full range of communication media
- Enable a maximum of care tasks to be performed remotely
- Reach all possible patient groups

Another important factor is the need to prove a business case for such applications. This requires large scale studies and implementation projects to demonstrate both the clinical and cost–benefits of systems. Advances in tele-homecare technology as well as changes in reimbursement systems may in the near future provide important incentives and opportunities. In Germany, new reimbursement schemes based on diagnosis related groups are being implemented in hospitals. It is expected that this will also have an impact on the ambulatory sector in general, which is still dominated across much of Europe by fee-for-service reimbursement. Providing effective tele-homecare can improve the quality of life, health and security of many older and chronically-ill people and assist family members and friends caring for them. These systems provide new business opportunities and jobs in public and private healthcare, as well as enabling voluntary help to be given much more effectively.

CONCLUSIONS

Our experience indicates that tele-homecare can improve both healthcare outcomes and the quality of life of patients with heart disease and renal failure. Our research into new systems developments indicates that tele-homecare can soon be extended to many groups who currently require hospital treatment or management. Further studies are warranted to assess the clinical and cost–benefits of tele-homecare across all groups of chronically-ill patients.

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APPENDIX: THE IST@HOME PROJECT

IST@HOME is a collaborative research and development project located in the Networked Audiovisual Systems and Home Platforms area of Information Society Technologies (IST, EU Fifth Framework Programme) that has developed and tested next generation tele-homecare systems. The project continues a tradition of EU research bringing powerful media closer to clinical and patient needs, to affordability and hence to everyday practice.

Figure 3 shows the architecture of the IST@HOME system, in which Set-Top and Service Pad are connected to the telecare centre via wireless local area network (LAN) and Residential Gateway (RG). A powerline network is used for the

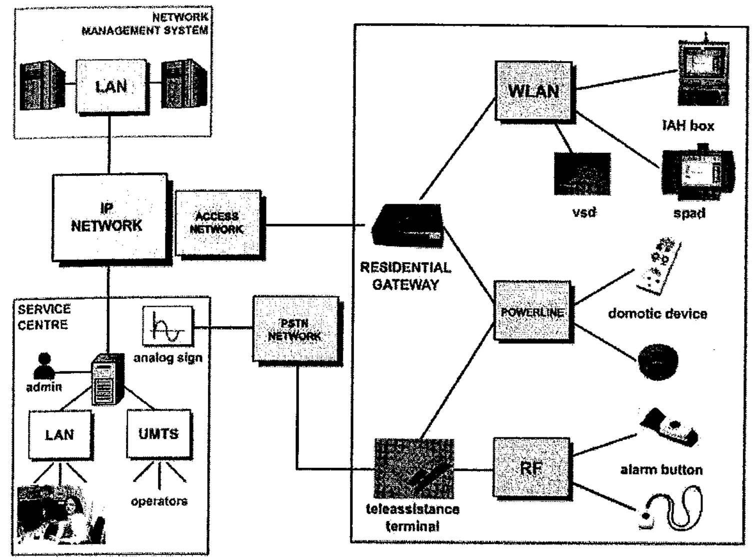

Figure 3. *IST@HOME service architecture*

IAH = IST@Home; IP = Internet Protocol; LAN = Local Area Network; PSTN = Public Switched Telephone Network; RF = Radio Frequency signals; UMTS = Universal Mobile Telecommunications System; VSD = Vital Signs Device; WLAN= Wide Local Area Network.

domotic functions device control and sensor connection, with signals tunnelled securely via the RG to the telecare centre. The RG incorporates Open Services Gateway Initiative (OSGi) software for services and provides the home's interface to wide area access networks (S.HDSL / DOCSIS).

The implementation of the alarm service maintains use of the public telephone network to ensure all alarms are reliably received at the alarm centre, which is typically located close to the telecare centre. Tele-assistance terminals are used which conform to legal specifications in the different countries. The alarm signal is also sent via the domotics link to the telecare centre, where staff can, depending on the case at hand and the procedural rules of the service, take over responsibility for responding to the alarm call and in doing so use the powerful communications media provided.

A vital signs device captures discrete values under user control. The user is guided in the use of the two buttons by sound feedback and text prompts. The prototype measures blood pressure, oxygen saturation and heart rate, and the unit is upgradeable to include peak expiratory flow (PEF), body weight or other measurements.

Heart rate is measured between 18 to 255 beats per minute, oximetry is via a finger clip showing saturation up to 100% at 2% accuracy. Blood pressure is

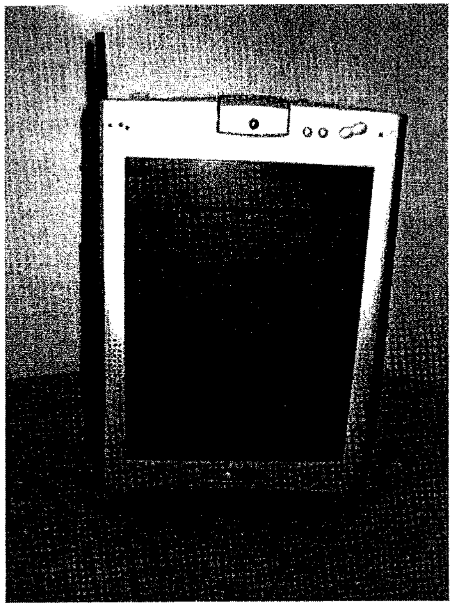

Figure 4. *IST@HOME Service Pad*

measured through an automatically inflating cuff and records from 25 to 260 mmHg (10 to 130 mmHg for infants). The small device weighs under 1kg and transmits values via the wireless LAN to the service centre along a pathway secured by encryption.

The Set-Top is based on a platform designed in a previous IST project in which signals are converted for output to the TV set. An external camera with integrated microphone was chosen for flexibility in selecting the field of view for the service centre. Design of the remote control for service access used results from previous research which had shown that users of video-based services on the TV have a clear preference for a small number of buttons linked to very simple dialogue options. The IST@HOME Service Pad (see Figure 4) is similar in functionality to the set-top box, but is fully portable and the user is provided with a touch-screen interface.

High quality video telephony poses stringent timing and bandwidth requirements on the networks used. Service sessions containing video telephony were configured for a 256Kbps payload and required a total 384Kbps bi-directional bandwidth for each such session. In regions where commercial ADSL (asymmetric digital subscriber line) today provides only 128Kbps upstream bandwidth, healthcare service providers should be aware that high bandwidth access such as DOCSIS CATV or S.HDSL (2.048Mbps bi-directional) must be used. Even given

adequate access bandwidth, sophisticated mechanisms are required to ensure overall service quality on shared pathways. The chosen architecture, combining RSVP and DIFFSERV, was successfully tested using OPNET simulation with different link types, congestion levels and packet delay.

Security requirements were met in the prototype system by the combination of IPSec from service centre to residential gateway and wired equivalent privacy (WEP) for the home network. In addition, firewall functions located in the RG contribute to the overall defence against attack.

Evaluation of the IST@HOME system was designed to complement the development process, which was segmented into two iterative steps to enable interim results to be taken into account in the design of the final prototypes. In addition to interviews and observation of ongoing use, a scale for measuring usability based on subjective overall assessment was employed to make usability comparisons along the development process. The instrument used was the System Usability Scale (SUS)[15], which has been reported to correlate well with other subjective measures of usability, and to be suitable for use with older people. Suitability was confirmed in the project, where the scale was found to be easy to use, rapid to complete and to pose low memory requirements. However, there was some confusion evident among some users between positive and negative item formulations.

SUS was employed in IST@HOME to assess usability of the system for first time users. Test persons were given a general description of the services they could access using the Set-Top and/or Service Pad but no training or introduction to the user interface. Tasks relating to the services were set verbally, e.g. to make a call to the service centre, or to reply to a message received. Support was given only when a test person had, despite encouragement, given up on a task. SUS items were responded to by users immediately after the use session, and debriefing and discussion took place only once this had been completed.

The interim release of the IST@HOME system, providing messaging, video telephony and Web information access, was tested with groups of users at four sites across Europe. The results were mixed. Although most found picture and sound quality on the Set-Top to be good and text legibility good on both devices, audio and video quality was poor on the Service Pad. Feedback from users on the services offered was generally positive, but this assessment did not extend to the alarm clock service. Users found they could not record the reason for setting an alarm, e.g. for medication, and the alarm setting procedure itself was difficult to perform. Observation of use of interim prototypes also revealed a number of problems in the user interface. These were traced back to inconsistencies in dialogue feature operation – e.g. some buttons or icons could be activated but others could not – lack of a path backward in some screens, unnecessary differences in layout between similar menu screens, ambiguous meaning of some icons and the inappropriateness of some status and failure messages. Use of the video telephony service was impaired through the fact that self-view was switched off automatically soon after the service was started, leaving staff to instruct users how to position themselves to be seen. In addition, the system exhibited some instability, including frozen pictures, loss of function of dialogue features and system crashes with no apparent connection to user behaviour. SUS results from the evaluation of the interim system release reflected the problems users had encountered.

In the final development phase, system modifications were made and prototypes finalised. Subsequent tests with a different set of users showed a number of improvements: picture and sound quality of both Service Pad and Set-Top were now both rated 'good' on average. Users also got stuck less frequently and navigated more rapidly, as a result of the significant improvement in menu design, navigation and status messages. The problems with self-view had been removed; this was now well integrated and fully functional.

Vital data capture had not been available in the interim version, and this functionality was strongly welcomed by all users. To be in picture contact with the service centre while the data are measured was seen as an additional benefit. The correct usage could be controlled, vital data could be commented on at once and users could be calmed down if needed. The latter feature was perceived by staff as being potentially very useful in emergency situations. Not all services had improved however. Due to decisions taken on on-screen management of application windows, browser access was limited to less than full screen, which made overview of information pages more difficult. Users were also still not satisfied with the usability and in some cases utility of the alarm clock function. Some users expressed requirements beyond those set for the system such as being able to see their own vital data on screen and to store it themselves.

Overall, the project showed that advanced systems providing monitoring, control and very acceptable person-to-person communications can be built today, with affordable components, and that these can be used even by older citizens throughout the home. Products currently planned by major manufacturers with many of the IST@HOME features can be expected to be offered soon as a next generation of tele-homecare systems.