

Tele-Homecare for Chronically Ill Persons: Pilot Trials, Medical Outcomes and Future Perspectives

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Abstract: Socio-economic trends including the ageing of populations in the developed world have led to markedly increased interest in improving society's ability to deliver effective care to older and chronically ill patients at home. The paper reports progress from recent European research on three key fronts faced in the diffusion of tele-homecare: Pilot applications to explore the features of as yet untried care domains, full clinical trials to present hard evidence of desired medical outcomes, and R&D to expand the capability of tele-homecare systems to meet the needs of a yet wider variety of chronic illnesses and patient groups.

1. Introduction and Objectives

Globally, and particularly in Europe, the population is ageing. To cope with the impact on health and social care systems and to improve the quality of life for older citizens, home care is increasing in importance. The objectives of this paper are to

- outline trends underlying an increasing interest in homecare
- briefly report on recent research projects dealing with key topics in care for chronically ill and older persons
- sketch perspectives on further developments needed in the care for older people.

The research reported on - an application study in a cost-intensive treatment environment, a world-first clinical trial of tele-homecare in heart failure, and an R&D project to make real use of broadband communications in home-care systems - relates to three essential components of successful introduction of home care into new fields: gaining experience in new applications of existing systems, providing hard evidence of benefits to decision-makers and further improving the capabilities of the technology available to care providers. Already for more than 15 years, telemedicine and telemonitoring approaches have been identified as a key element in this context [1,2,3,4].

2. Impact of Ageing Trends on Health Systems and Social Care

Population ageing is consistent across the globe. 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 (or 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 50 years [5,6].

An ageing population will have considerable impacts on a wide variety of socio-economic aspects, such as economic growth, capital markets, pension systems, but also on technical progress and innovations, education and human capital, family and household

structures - and last, but not least, on health and social care systems [7]. It implies that the prevalence of chronic diseases will grow and the absolute number of disabled persons rise. "Evidence of age-related rationing of health interventions has been documented in some countries in the European Region. ... One can expect that the age-related rationing would become more prominent because of the pressures on the health systems created by the increasing proportion of older people." [8]

On the other hand, "much of the economic contribution of the older population goes unrecognised. Older people make substantial contributions in unpaid work in such areas as agriculture, informal care giving and services. Many European economies depend on these activities, but include few of them in their assessment of gross national product, often leaving the contributions made by older citizens unnoticed and undervalued." [8] Europe will indeed need considerably more informal carers if health and care systems are to remain sustainable [5]. The fastest growing population segment are those 80 years and older, who are also most in need of supportive care at home and in institutions.

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. In many countries there are now moves to better integrate the medical and social aspects. The ageing of the population and the desire to reduce expensive and inappropriate institutional and/or in-patient care are encouraging this. Home care by social care professionals and by non-professionals is becoming increasingly important.

It is against this background that the following short reviews of recent research and technology developments in the context of tele-homecare for chronically ill persons have to be seen.

3. Selected Research Results

3.1 Advanced Trial in a Cost-Intensive Treatment Environment

End stage renal failure (ESRF) and the resulting need for dialysis cause very high costs for treatment, up to € 50,000 and more per annum. And, in the context of other diseases like diabetes or coronary diseases, the incidence of ESRF is rising globally at rates between 3% and 7%.

Research has shown that home dialysis can produce improved medical perspectives for patients [9]. In addition, more flexibility allows for many patients - particularly peritoneal dialysis patients - a better adaptation both to a changing work environment and to leisure activities, which in turn translates into a higher quality of life. In addition, research results indicate that home dialysis (be it haemo dialysis or peritoneal dialysis) leads to a reduction in overall treatment costs [10].

Based on a small study of user requirements (from the physicians' point of view) to see whether telehealth applications could be expected to improve the treatment of patients suffering from ESRF, a small pilot experiment was devised for home monitoring of peritoneal dialysis patients to learn more about the potential benefits. The eight patients selected were at a higher risk due to coronary co-morbidity. This research, the ESRF pilot application, was undertaken in the context of the TEN-HMS project, research partly supported by the European Union Trans-European-Networks (TEN-Telecom) Programme.

All patients measured blood pressure and pulse four times a day during each exchange of the dialysate; in addition, weight and ECG (1-lead rhythm strip) were measured in the morning before the first exchange. All data was transmitted via radio frequency (RF) sig-

nals from the measurement devices to a home hub connected to the patient's telephone line. From there data was automatically transmitted to the central server located on the desk in a nephrologist's office in the dialysis clinic. A printer attached to the server allowed printing of charts and reports for filing or for providing visiting patients with their data.

The daily data transmission indeed 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. Integration of the system into routine daily care processes did not pose any problems. The physician reported having the impression that patients indeed had a feeling of being better looked after and cared for. Home monitoring may become applicable to an even wider dialysis population, i.e. patients for which home dialysis presently is not suited due to their unstable situation, if additional data like temperature, urine output etc. could be closely monitored as well.

Not unexpectedly, close monitoring turned out to be particularly useful for those patients where changes in blood pressure (hypertension, which is difficult to adjust) and weight (i.e. patients who have problems with their fluid balance - either the filtration is too low or they tend to drink too much) can be expected to occur within a short time period. It is estimated that for about 10% of all present PD patients close monitoring is medically indicated. When appropriate systems become available for general introduction, it can be expected that the market potential will be considerably expanded: Perhaps 10% to 20% of all new (hitherto haemo) dialysis patients may then, in addition, qualify for PD treatment. Presently, their unstable health requires close monitoring which is only assured if, as required for haemodialysis today, they visit the dialysis clinic three times a week (PD patients usually visit their physician only once a month or every six weeks).

The high reliability of the monitoring system used - coupled with very efficient technical support - made it an ideal instrument for closely monitoring patients at risk, adjusting their therapy on the spot and in (experimental) steps as needed, and for balancing the medication regime such that the established boundary values for the vital parameters were not exceeded and the quality of life of patients enhanced.

3.2 World-First Full-Scale Clinical RCT with High-Risk Patients

The second study we report upon concerns a chronic disease many citizens are affected by. It is estimated that currently there are more than 4 million patients with heart failure in the European Union. The annual risk of a patient with heart failure being admitted to hospital is about 40%, with worsening of heart failure the predominant cause [11]. Admission to hospital with an episode of worsening heart failure predicts a high risk of recurrent events and death. Heart failure is costly to manage, consuming between 1% and 2% of all health system costs in developed countries, and about 70% of costs are due to hospital admissions [12].

Telecare is a feasible technology that may assist the delivery of care to patients with heart failure; the benefits for patients as well as the cost savings for the care system could be substantial [13]. The aim of the TEN-HMS (Home care Management System) project was to scientifically test whether telehealth home-monitoring can improve medical outcome for heart failure patients as well as their quality of life and the efficiency of healthcare processes. The feasibility of such a trial as well as the usability and reliability of the technical equipment had been examined in a pilot trial [14].

For this prospective randomised controlled clinical trial, 426 patients with a recent exacerbation of chronic heart failure were selected. 12 university and regional hospitals in

Germany, the Netherlands and the United Kingdom as well as local specialists and GPs were involved. By a random selection process, guided and controlled by an outside specialised institute, patients were allocated at a ratio 1:2:2 to one control and two intervention groups:

- (1) The Usual Care (UC) group comprised 85 patients: The primary care 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: The primary care physician was responsible for implementing the patient management plan, plus additional monthly telephone contacts from a heart failure nurse to help increase effectiveness and adherence.
- (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 (vital data [weight, blood pressure and pulse, rhythm] using home monitoring equipment interfaced automatically through cordless communications with the telephone; data were transmitted through secure networks to a medical service centre).

Standard best care is well understood for heart failure patients, therefore the UC group was smaller to improve the overall efficiency of this costly trial. - To allow for comparable results across different countries and health systems and to secure methodological rigor, strict patient selection criteria were established. It is estimated that up to 20% of patients with heart failure fulfil the entry criteria set.

Patient recruitment started in June 2000 and continued until March 2002. Collection of patient follow-up data ended in November 2002, yielding data for more than 205,000 patient-days for analysis.

For methodological reasons, particularly so as not to influence the behaviour of the physicians and nurses participating, no interim results were made available. The data obtained indicate that heart failure patients supported by telecare, either via monthly telephone calls or telemonitoring, have indeed a substantially and significantly lower mortality rate compared to patients obtaining usual care (best medical practice based on a patient management plan). E.g., at 360 days follow-up, the usual care (UC) group lived, on average, about 263 days, compared with 307 days for the nurse telephone (NT) and 303 days for the telemonitoring (TM) group. The numbers of admissions into hospital were slightly higher for the TM than for the NT group, but the mean duration per admission was considerably lower, up to 25%. Overall, total days in hospital were considerably and consistently, although not statistically significantly, lower for the TM group. Further data analysis indicate that the cost saving of the overall reduction in hospital bed-days more than offsets the increased cost of telemonitoring compared to nurse telephone monitoring. Nearly all (some 90%) of telemonitored patients were very enthusiastic about this kind of support, stating that they felt much safer regarding their health management.

The TEN-HMS project was the first large (426 patients), long-term (240 to more than 600 days of follow-up) randomised controlled trial of telemonitoring for heart failure patients. The data suggest that increased patient support by some form of telecare can significantly improve the survival rate of high-risk heart failure patients. It is interesting to note that regular telephone contact and support may lead to a significant improvement in *days alive and out of hospital* and that compared to nurse-telephone support, telemonitoring may lead to a further improvement.

The slightly higher admission rate for the TM group indicates that closer surveillance may lead to an earlier, but perhaps more timely detection of a worsening health status. This may also explain the significantly lower mean duration per admission.

The initial results of this world wide unique study provide a strong argument for the wider introduction of telecare. Considering the significantly improved survival rate of high-risk patients supported in this way it becomes an ethical imperative to improve the organisation of the delivery of health care to patients with heart failure.

3.3 Broad-Band Services in the Home Environment

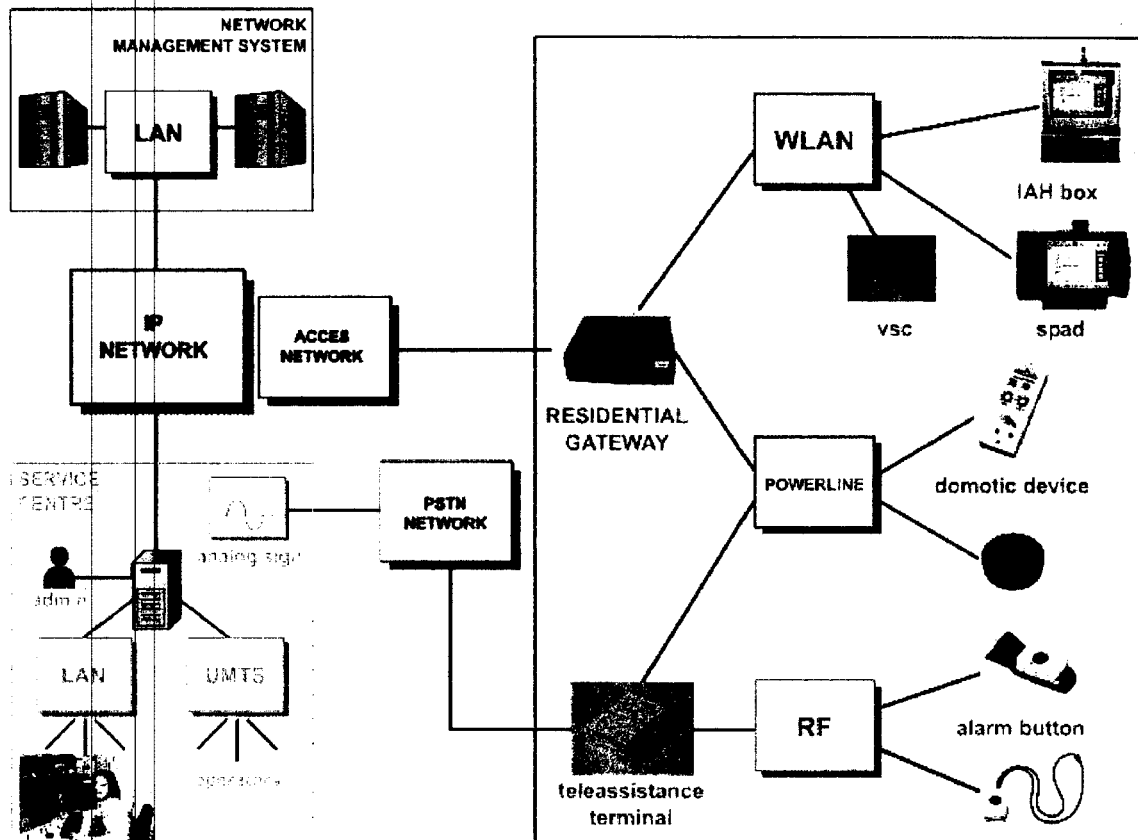
Clinical trials of tele-homecare must make use of technology which is mature enough for months of use with patients who may be at real risk. Today this means systems which use the facilities of the public switched telephone network and perform limited integration of simple data capture functions. At the same time trends such as the explosive growth of internet technology and the extension of broadband access to private homes offer the potential for radical improvement in the ability of clinicians and nurses to interact with patients at home. These improvements can open home-based treatment to new groups. As was seen in the case of dialysis, simple technology could make a qualitatively more attractive treatment regime accessible to those otherwise exposed to long periods of specialist care away from home.

Particularly visual communication, bringing the ability to interact comfortably with patients at home, watch their reactions and behaviour, reassure and inform in a trustworthy manner is expected to extend significantly the reach of tele-homecare to groups requiring more intensive contact to care staff. High-quality video-telephony was, for reasons of price, previously limited to rare applications promising particularly high levels of cost saving or quality improvement. IST@HOME, 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) set out to take the next steps in providing usable, affordable systems fit for the purpose of caring for chronically ill patients at home, continuing a tradition of research bringing powerful media closer to clinical and patient needs, to affordability and hence to everyday practice.

The figure on the next page shows the architecture of the IST@HOME system, in which Set-Top and Service Pad are connected to the telecare centre via wireless LAN and Residential Gateway (RG). A power-line network is used for the domotic functions device control and sensor connection, with signals tunnelled securely via the RG to the tele-care 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 PSTN to ensure all alarms are 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 media provided.

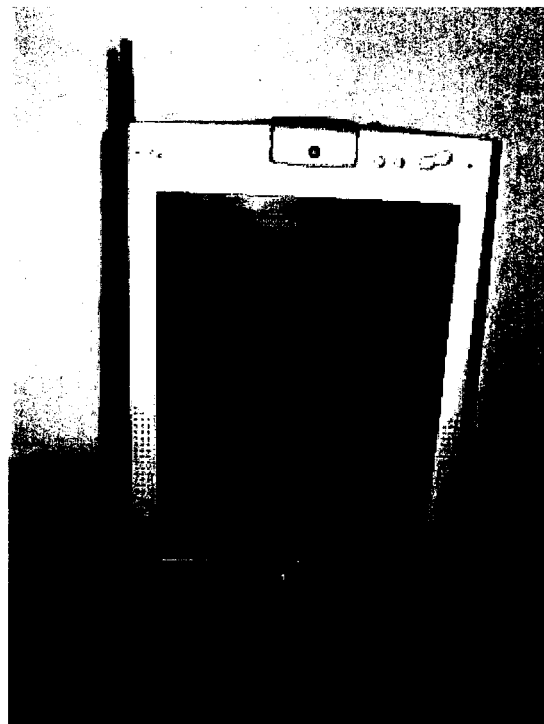
A vital signs device captures discrete values under user control. The user is guided in the use of the two buttons by sound feedback and text prompts. The prototype measures blood pressure, oxygen saturation and pulse, and the unit is upgradeable to include peak expiratory flow (PEF), body-weight or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



Pulse is measured between 18 to 255 pulses per minute, oximetry is via a finger clip showing saturation up to 100% at 2% accuracy. Blood pressure is measured through an automatically inflating cuff and records from 25 to 260 mmHg or 10 to 130 mmHg for infants. The small device weighs under 1kg and transmits values captured via the wireless LAN to the service centre along a pathway secured by encryption.

The Set-Top is based on the common platform designed in a previous IST project (HAS-Video) 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 projects 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 (right) 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 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 overall defence against attack.

Evaluation of the IST@HOME system was designed to complement the development process, which was segmented in 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 deployed to make usability comparisons along the development process. The instrument used was the System Usability Scale (SUS) [15]. SUS 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 in some cases between positive and negative item formulations.

SUS was deployed 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 was tested with a group of users at four sites across Europe. All service components including messaging, video-telephony and web information access were tested. Results were mixed: though picture and sound quality on the set-top were found by most to be good, these features were found to be poor on the Service Pad. Legibility of text was good on both devices. Though feedback from users was positive in terms of the services offered, this positive 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.

Observation of use of interim prototypes 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 then 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, showing 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 at once and users could be calmed down if needed - seen by staff as 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 functionality. 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.

4. Outlook

Based on our experience so far we strongly believe that tele-homecare has a realistic potential to ensure and improve the self-assurance of chronically ill and older people, their ability to communicate and socially interact, their medical support and their safety. At the same time, it can be a means to alleviate the burden on professional people and home carers, to organise their work better and more efficiently, and to spend a higher proportion of their time actually caring for those who are in most urgent need of their attention.

However, our experience also indicates that present technology needs further development to tap the full potential of tele-homecare. Systems must be easier to be installed in homes by non-technical staff, be easier to integrate in legacy systems, provide better performance, be carefully designed for ease of use by both care staff and patients at home, and provide a full range of communication media to enable a maximum of care tasks to be performed remotely thus reaching all possible patient groups.

Perhaps most urgently - to really prove a business case for such applications - large scale experiments and implementation projects are needed in which the various aspects of such services are integrated into one holistic approach. Moving from a perspective focusing on functional disabilities of older people to an orientation to meeting market demands arising from the variety of clinical needs of chronically ill patients will prove a key success factor. We expect that advances in telecare technology as well as changes in reimbursement systems will in the near future provide important incentives and opportunities for teleservices which, at the same time, hold the potential for improving the quality of life for quite a few members of this growing patient population. In Germany, new reimbursement schemes based on Diagnosis Related Groups are under discussion and will be implemented soon in hospitals. It is expected that this will also have an impact on the ambulatory sector in general, 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 as well as providing new business opportunities and jobs in public and private health and home care services and enabling unpaid voluntary help to be given much more effectively. We have met great interest in improved homecare not only among medical and social service providers but also in social housing and local government.

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