Chapter 9
Patients and EHRs Tele Home Monitoring Reference Scenario

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Abstract. This scenario focuses on patients as users of Electronic Health Records (EHR) relevant information. The concrete field of applications is telemonitoring at home, a field where many new approaches and devices are showing up on the market in various countries, an indication of the perceived relevance and market potential of this type of patient involvement. After an introduction to key aspects of patients as users of EHRs, we describe the main application scenario. Generic considerations of telemonitoring at home, as well as the concrete context and application, the telemonitoring equipment presently in use, and screen shots of EHR patient data as seen by the physician (which will later be used for evaluation and validation purposes of patients' access to their vital data) are presented and discussed. We conclude with a vision of the empowered patient using his EHR data to improve his medical condition and quality of life.

1. The Shifting Healthcare Paradigm and Home Care

1.1 The Patient-Centred Healthcare Paradigm – A New Definition of "Patient"

The traditional health care model is based on a highly structured, hierarchical delivery system dominated by physicians and with patients as mere receivers of health services, which are usually provided by public or government institutions - with strict boundaries between local/GP services and stationary services in hospitals. This model is shifting towards a new paradigm accepting the citizen/patient as a self-determined individual.

The new paradigm of *patient-centred*, *seamless* healthcare processes requires - when taken seriously - the full involvement (as much as reasonably possible) of citizens in all aspects of healthcare and during all stages of the healthcare value chain, from health information and prevention all the way through to rehabilitation and long-

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term care. Such a paradigm also implies that the term "patient" is reinterpreted towards meaning "citizens concerned about their health or the health of their friends and relatives".

Under the new paradigm, citizens/patients are self-determined individuals with their own wills and aspirations, which may differ from what a doctor or nurse requests or expects from them, or what best medical practice, and guidelines suggest as optimal treatment in a given situation. This relates to the patient's own definition of quality of life which might imply, e.g., for severely chronically ill patients, a shorter, but from their point of view, more fulfilling life.

Additionally, the patient is a person who is well informed about his/her own illnesses or chronic disease, and discusses with health professionals the optimal treatment path and the interventions best suited to his/her situation. There are already today cases of patients suffering, e.g., from rare diseases, who exchange information and experiences through the Internet and who quite often are much better informed than medical professionals.

In such a context, the patient is part of a real dialogue, and is no longer only the recipient of information from a physician or a nurse. This collaborative model needs to be further developed towards a "tria-logue" model involving also the support network of the patient (spouse, other relatives, informal carers) and a "multi-logue" model (involving formal and community carers, paramedical supporters, social workers) to provide a comprehensive health and social/psychological environment with the primary objective to preserve health and, only as a second option, to treat diseases.

1.2 Rationale for Scenario Selection – Patient Communication and Home Care Lead to Better Medical Outcomes

Home care is a prime example to demonstrate the new paradigm of collaborative and collective organisation of healthcare. All industrial societies are ageing. This has profound socio-economic and health sector implications (Stowe, 2001a), underlined, e.g., by the dramatic increase of the old age dependency ratio - the ratio of the number of people aged 65 and over to the number of people between the ages of 15-64 - from 2000 to 2030 (85% and more in France, Germany, Italy and the UK; more than 100% in Japan) (Stowe, 2001b). As a consequence, an increasing number of older and very old people will suffer in the future from chronic diseases.

To cope with the resulting challenges to our societies, telemedicine and e-health applications hold promise to provide better care, and support independent living (Porteus and Brownsell, 2000). In parallel, the costs per service can be expected to decrease (Wootton, 2001). Research has shown that improved communication with patients, and the possibility for them to remain in an environment they are familiar with and comfortable in, leads to better medical outcomes and, at the same time, improves the quality of life for older people (Stroetmann and Erkert, 1999).

For patients who are actively involved by their physicians in the healthcare delivery process, better results were experienced (Miller, 2001). Patients of doctors who give more information and engage in more positive talk report higher satisfaction and compliance, better recall and understanding, and more favourable health status ratings and clinical outcomes (Hall, Roter and Katz, 1988). At the same time, distrust

is reduced, as well as the likelihood of complains, disputes and even lawsuits (Mechanic, 1998). On the other hand, in this context, ethical and legal implications, such as the patients' privacy and security concerns, including a fear of third party access to electronically recorded health and medical data, need to be taken into account (Stanberry, 2000).

1.3 Patients and Universal Access

Why access by patients to their health records is a Universal Access issue? As discussed above, many patients are already today highly interested in accessing their health data, e.g., via their EHR, and various empirical research results strongly support this (Stroetmann and Stroetmann, 2002). For individual and social (improved medical outcome, quality of life, empowerment of patients) as well as economic reasons (pressures to contain costs in the health system; ageing of our societies), strong support for this concept is expected in coming years. A pressing issue, which at this stage needs policy attention, is what we term the "medical divide". A quite considerable portion of the population, particularly many older, disabled and frail people, those with no or little education and/or on low income, people who have been disappointed by what they find (or cannot find) on the Internet, and who are not interested in e-health services, will be left out of these developments and cannot or will not participate in the benefits and advantages of e-health, unless user-friendly interfaces and design-for-all features are fully taken account of. Creativity, innovations and support are needed to integrate such patients, to progress towards a true Information Society for all, and to ensure cohesion and equality in access to medical and health services.

2. Reference Scenario: Patients, Their Context and Tasks

The scenario reported in this Chapter is based on a real application situation. The Chapter will, therefore, describe such an application and discuss the related medical issues from the point of view of the patient, introducing the measurement devices presently in use and describing the tasks of the patients. Subsequently, activities carried out at the nephrologist's office will be reported, and screen shots of patient vital data from their EHR will be presented.

2.1 The Application Situation

Our reference scenario is built around patients suffering from End Stage Renal Failure (ESRF) being treated by continuous ambulatory peritoneal dialysis (CAPD), and who, at the same time, also suffer from high blood pressure. End-stage renal disease (ESRD) (or end-stage renal failure - ESRF) is the stage in chronic renal disease in which renal replacement therapy, dialysis or kidney transplantation, is needed to sustain life. ESRD is generally an irreversible state. When being treated by continuous ambulatory peritoneal dialysis (CAPD), the patient empties a fresh bag of

dialysate into the abdomen. After 4 to 6 hours of dwell time, the patient returns the dialysate containing wastes to the bag. The patient then repeats the cycle with a fresh bag of dialysate. CAPD does not require a machine; the process uses gravity to fill and empty the abdomen. A typical prescription for a CAPD patient requires three or four exchanges during the day and one long overnight exchange when the patient sleeps. The dialysate used for the long overnight exchange may have a higher concentration of dextrose, so that it absorbs wastes for a longer time.

In what follows, we consider two designated categories of tasks, namely those carried out by patients at home and those carried out by professionals in the office.

2.2 Activities Carried Out by Patients at Home

Patients carry out tasks that enable measurement of certain vital signs on a daily basis. The vital signs measured are described below.

2.2.1 Body Weight

Being obese increases the risk for many diseases, especially heart disease, stroke, cancer, and diabetes. In addition, for conditions like severe heart diseases and for dialysis patients, increasing body weight is a very important indicator of a beginning decompensation, which is a highly critical situation. Cardiologists regard changes in weight as one of the most relevant vital signals for their chronic patients. In PD patients, attainment of target weight is based on clinical indicators.

2.2.2 Blood Pressure

Blood pressure is expressed in millimetres of mercury, or mm Hg. The systolic blood pressure is the top number of a blood pressure reading. This shows the maximum pressure in the blood vessels as the heart contracts and circulates blood throughout the body. The diastolic blood pressure is the bottom number of a blood pressure reading. It shows the lowest pressure in the blood vessels between heartbeats, when the heart is at rest. Both high blood pressure (hypertension) and low blood pressure (hypotension) are indications of a condition that might necessitate a medical intervention. High blood pressure is also called the silent killer. Chronically high blood pressure can cause blood vessel changes in the back of the eye (retina), thickening of the heart muscle, kidney failure, and brain damage. This condition is considered a (high) risk factor for the development of heart disease, peripheral vascular disease, stroke and kidney disease.

2.2.3 Pulse Rate

The pulse rate is the number of times a person's heart beats in one minute. The pulse rate can give important information about overall health and fitness, and is usually measured as part of a physical exam. Whenever a person has an appointment with a healthcare provider, the pulse rate is measured routinely. An irregular pulse often indicates an electrical problem in the heart. This may be normal for a given person or may indicate a life-threatening problem. For example, irregular pulse rates can be due to a heart attack or enlargement of the heart. Pulse rate is usually measured concurrently with blood pressure.

2.2.4 Electrocardiogram – ECG (1-lead to 12-lead)

An electrocardiogram, also called an ECG, is a graphic record of the heart's electrical activity. Healthcare providers use it to help diagnose heart disease. They can also use it to monitor how well different heart medications are working.

Though 9- to 12-lead ECGs can be taken at home, a 1-lead ECG (a so called rhythm strip, which reliably shows abnormal rhythms such as arrhythmias or dysrhythmias) can be much easier performed and more simply applied by lay persons.

Other information may concern:

- The patient's medication compliance and feedback on this to both the patient himself and the physician, and
- General information on the disease, its treatment procedures and options and lifestyle information and training material.

Users of all this information and data can be

- The physician or nephrologist looking after the patient
- The patient directly
- Family members or informal carers
- Formal carers or nurses

2.3 Presently Used Measuring Devices

For the described requirement and assessment tests, a modular set of TeleCare measurement devices has been being used. These measurement units have single-button or no-button operation. Each device is equipped with a radio transmitter, capable of sending the measured information reliably to a Home Hub. This eliminates the need to cable patients' living quarters, and also provides a degree of freedom to move the devices within the home.

The model of use for this equipment is based on automatic, not patient-initiated, data transmission.

Once the patient has completed a measurement, for example blood pressure, the data are automatically transmitted to the Home Hub. The Home Hub is a microcontroller communication link that uses TCP/IP, MSCHAP, plus encryption to send the data over conventional phone lines to an ODBC database, located in a hospital or other secure setting. No additional user interaction is required to enter the data into the database, or to match it with a patient.

The NT server, running a standard SQL database and a web server, automatically collects incoming patient data, presents it to the database for entry, and allows care providers with the appropriate authorisation to review the data as web pages via Intranet, or secure virtual private Networks.

Special attention was devoted to the fact that most patients are frail or elderly. The patients units therefore need to be unobtrusive, very simple to use, and robust. Special features of the physiologic measurement devices are:

- Large displays and numbers making it easy to read the measurements
- Only one button to run measurement
- Voice and light prompts to support required behaviour
- Battery powered to allow mobile use at home
- Fully automatic data transmission (no patient interaction required)

- No wiring between measurement devices and the home hub
  Examples of the three measurement devices are depicted in the following pictures.

Fig. 1. Blood pressure

Fig. 2. Scalemeasurement

Fig. 3. Scale

Fig. 4. Rhythm strip device

The scale (Figure 2, Figure 3) offers a very large, low profile platform (easy to step on), and a column with hand bars to hold on to, as well as voice announcements.

2.4 Context of Use for the Home-Based Tasks

The context of use from the patient's point of view is presently only the patient's home, usually a corner in the bedroom, or, in large homes/apartments, a separate room. If the bathroom is large, it may also be a small table/corner there, and during the day some of the measurements can also be taken in the living room or at a dining table. PD requires a considerable amount of supplies which are also heavy (e.g., dialysate) and may be stored in a separate room, the basement or elsewhere.

Before breakfast, the first task of the patient is to step onto the scale; he is "asked" by a synthetic voice to stand still (which is also indicated by a light on the display) for about 5 seconds (he/she may, of course, use the handle to keep balance without affecting the measurement result, which is particularly important for frail people) till the scale "talks" to him (and also provides a flashing light signal on the display) and tells him to step off the scale. Afterwards, the scale "tells" the patient his weight and this value is also displayed. The volume of the synthetic voice can be adjusted by a

separate key. The data is automatically transmitted to the home hub underneath the telephone.

Next, the patient attaches the cuff of the blood pressure device to his upper arm with a Velcro fastener, presses a large, round button on the front of the device, and then the device automatically pumps the cuff, allows the air pressure slowly to decrease and takes the necessary measurements (systolic and diastolic pressure, pulse rate), displays these data and also transfers them automatically to the home hub.

Then the patient attaches the two leads of the rhythm strip to his wrists, pushes a button on the measurement device, waits for about one minute, and takes the leads off. The device has no display to show the ECG, but it automatically transmits the data to the home hub.

All of these vital data are then automatically, without any action on the part of the patient, transmitted via the home hub and his telephone dialling into an "800" number to the server at the nephrologist's office or in a hospital or community care centre. Without action on either side, the vital data are added to and integrated into the EHR of the patient. In other words, the EHR is updated every time the patient takes new measurements.

In addition to taking these measurements, the patient has to empty his abdomen and allow the dialysate containing wastes from his blood to return to the bag by attaching the catheter implanted in his belly to the bag. After this, the patient fills his abdomen again with a fresh bag of dialysate. The bag with the waste is weighed on a small scale and the result recorded by hand on a piece of paper.

The exchange of fluid is usually repeated for another three times every day, and each time blood pressure and pulse are measured as well, but not weight and ECG.

Presently, input of patient data is made by the physician for those data and information collected during the visit of the patient to the ambulatory clinic or office of the nephrologist. In addition, in our scenario, vital data are measured in the described manner by the patient using telemonitoring measurement devices that automatically record and transmit the measurement data via a telecommunications connection. This is a new form of input made possible by telemonitoring technology.

Target users for the reference scenario are presently those high-risk PD 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 (German) PD patients, close monitoring would be medically indicated. When the system becomes available permanently and 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 when they have to visit the dialysis clinic three times a week (PD patients: usually once a month or every six weeks).

Beyond this, any patient who would benefit significantly from closer telemonitoring such data at home or while moving, particularly patients with a severe heart disease, qualify as target users in future.

2.4.1 Activities Carried Out at the Nephrologist's Office

The nephrologist's office is equipped with web-technology based service software, which allows review of a patient's medical condition. Simply by clicking on a patient's name, his or her individual record is accessed. On the standard interface, the physician sees the graphical trend of the patient's weight and, in tabular form, all other data measured. To have a closer look at any data or combination of data, he can click on the relevant buttons on his screen to select them, request a graphical presentation and adjust the time period reported on. These data can, if preferred by the medical staff, also be presented in tabular form. Additional files for medical history, laboratory results, medication régime etc. are available.

For security and privacy reasons, presently no external access to the server in the physician's office is possible. However, various screen shots of anonymous patient data as recorded by the system based on the telemonitoring data transmitted were obtained. In the following, they are presented and briefly explained. In principle, these data are already today also available to patients in printed form from their physician, and they could easily be made available via Internet technology.

Figure 5 shows a simple diagram of weight measurements for one month as a full screen without any other information:

Fig. 5. Weight measurements for one month

Figure 6 depicts are more complicated graphical design showing three measurement values over two weeks in parallel:

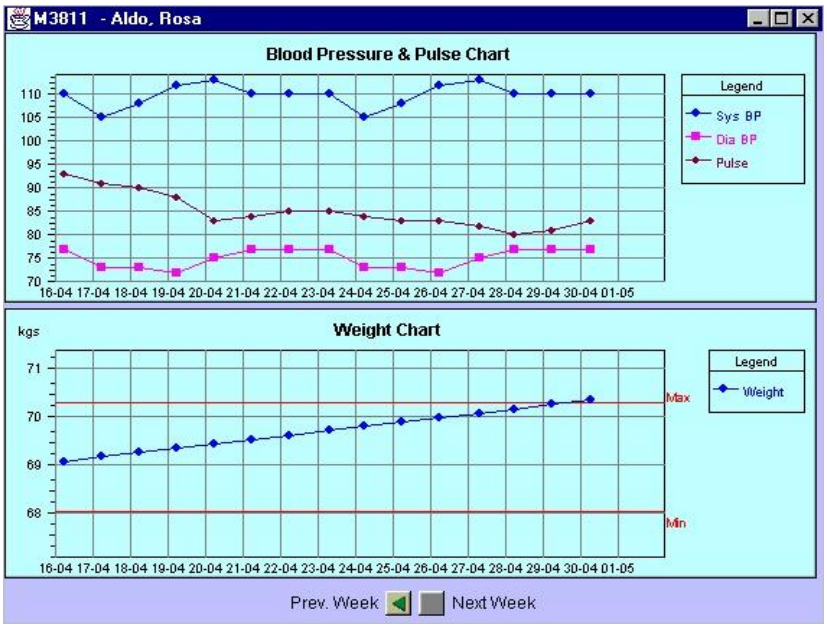

Fig. 6. Combination of blood pressure, pulse and weight chart on one screen

A further degree of complexity is shown in Figure 7.

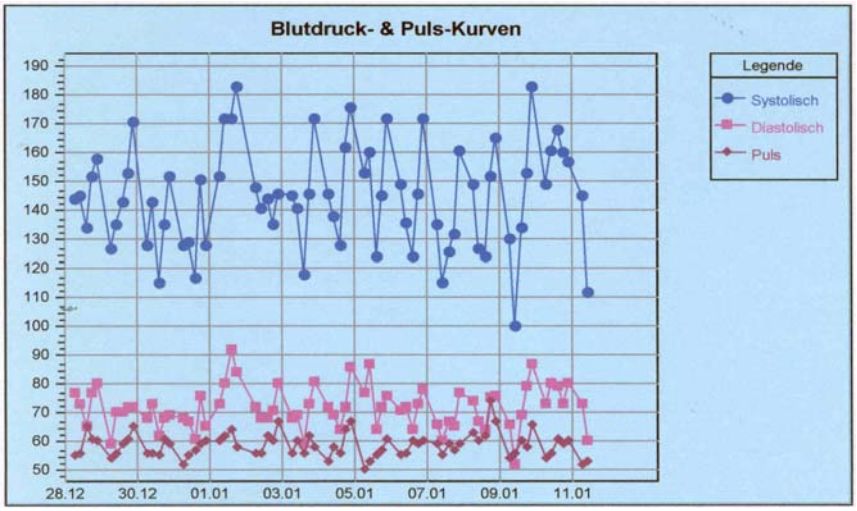

Fig. 7. Blood pressure and pulse values, measured four times a day for two weeks

As an alternative, a tabular presentation of these values was also offered to the patients as seen in Table 1:

Table 1. Blood pressure and pulse values, measured four times a day for six days

Trends für

Telefon: Alter: 56 Jahre Pat.-Nr.: Dias 1

Datum	Gewicht	Sys/Dia(Mitt)	Puls
22.07.2001	95.8 kg 10:56	161 / 92 (150) 00:44	75 00:44
		170 / 97 (155) 10:58	66 10:58
		159 / 90 (136) 13:44	69 13:44
		156 / 93 (131) 18:27	66 18:27
21.07.2001	95.8 kg 10:45	148 / 88 (119) 00:55	78 00:55
		155 / 92 (138) 10:46	68 10:46
		155 / 87 (107) 12:36	73 12:36
		156 / 84 (132) 16:52	72 16:52
		165 / 92 (144) 20:56	69 20:56
20.07.2001	95.20 kg 10:47	163 / 92 (147) 00:44	72 00:44
		152 / 96 (129) 10:49	72 10:49
		156 / 87 (126) 13:16	72 13:16
		146 / 85 (118) 21:15	80 21:15
19.07.2001	94.87 kg 10:13	159 / 91 (130) 00:51	76 00:51
		150 / 92 (137) 10:16	68 10:16
		151 / 91 (134) 13:04	66 13:04
		156 / 89 (137) 17:16	68 17:16
		154 / 88 (136) 21:45	69 21:45
18.07.2001	94.33 kg 10:14	160 / 94 (131) 00:59	72 00:59
		156 / 95 (134) 10:17	70 10:17
		145 / 92 (124) 13:58	65 13:58
		153 / 90 (132) 19:11	66 19:11
17.07.2001	95.20 kg 11:08	184 / 98 (143) 11:10	67 11:10
		145 / 90 (120) 13:16	69 13:16
		152 / 90 (121) 17:37	68 17:37
		152 / 87 (127) 21:37	75 21:37

Finally a representation of a 16 second rhythm strip (one-lead ECG) with a minor irregularity was selected as shown in Figure 8.

Fig. 8. 16 second rhythm strip (one-lead ECG)

3. Concluding Remarks

Experience with chronically ill patients engaged in the above reference scenario as well as reports in the literature (Cimino et al., 2001) show that patients having access to their vital data by whatever means are in a much better position to monitor their environment, their behaviour, their diet and their own compliance with medication. Both medical outcome and quality of life improve, and the patients feel more in control of their own health. Therefore, as a logical extension of such considerations, the need arises to identify ways and means to ensure that all those patients who want access to their EHR obtain information on those data which are of prime relevance for them and which they are able to interpret and translate into meaningful action to improve, or at least to stabilise, their physical and mental health status.