A feasibility study and recommendation of technology and solutions for wireless monitoring of biomedical data

by

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Abstract

This report contains the results of a study on wireless remote monitoring technology that has been conducted for Contel AS, though it applies to a much wider audience. The study was started because there was need for, and interest in, broad sighted information about the subject. This information has been collected and organized into this report, in addition to our own evaluations and proposals.

Remote monitoring of patients is an interesting subject. There is a lot of ongoing research and development, and many exciting new ideas and technologies are under way. This technology has the potential to change the way health care is done, letting the health sector take part in the wireless revolution. The technological evolution in this field lies far beyond the reality of today, and not a lot of wireless remote monitoring system have yet been taken into use. Improving health care requires significant changes, and changes are not done quickly when persons, and not technology, must remain in focus.

The applications and benefits of wireless remote monitoring are many and diverse. They range from greatly improved home care for chronic and post-operative patients, and improved emergency care, to letting the patient return sooner to his home and family, and free valuable hospital resources.

To get an overview of the current state of the field we have conducted a study of the available products on the market, and the plethora of ongoing reasearch effort into this field. There are many exciting products available that could benefit the health service and its patients in many ways. Yet, we have seen that the utilization of wireless remote monitoring is remarkably low. Apart from the slow process of adopting new technology, there is also the issue of lack of knowledge between both health care instances and political authorities. This may be due to the over-complex multitude of independent and proprietary solutions. A lack of established standards, and lack of utilization of those available, inhibit interoperability between products and prevents the possibility of a free market and custom solutions.

With any system handling sensitive data there are strict requirements to information security. There are laws and regulations giving a framework to protect the privacy of patients. To be familiar with these requirements is essential when developing solutions for health care. An introduction to existing laws and other requirements to remote monitoring systems is given.

An essential part of wireless remote monitorig is the wireless communication capabilities. A number of communication technologies exist with varying properties. An overview of the most used technologies is presented, and these technologies are evaluated for suitability with different types of applications. This provides a method for selecting communication technologies for different cases of remote monitoring.

In the light of the observations we have made during the study, and a dialogue with Sørlandet Sykehus Arendal, a solution for remote monitoring of oxygen saturation during sleep disorder screening is proposed. This solution will make it easier for the patient to do an overnight oxygen saturation measurement while sleeping at home. Combining results from different simultanious measurements can make better founded diagnoses. Larger scale systems that can receive data from many different sensors would be beneficial. But it still has some issues against it, like lack of standardization of communication, before it can become viable.

Introducing technology that has the potential to bring healthcare out of the hospital and into the patient's home, replace nurses with tecnical devices, and collect sensitive information will

bring many ethical considerations. These must be dealt with in order to ensure that any changes made in the health service are for the better for the patient.

Wireless remote monitoring is really an underdeveloped area today in the health care service. It will continue to become more and more important and revolutionizing for the way patients are treated in the years to come.

Preface

This thesis is part of the last stage in completing the Master of Science degree in Information and Communication Technology at the Faculty of Engineering and Science at Agder University College in Grimstad, Norway.

It has been written for Contel AS and we have spent most of our time at their office at the Research and Development (FoU) facilities in Grimstad. We would like to thank Contel AS for the opportunity to write about such an interesting subject like wireless remote monitoring, and for the resources we have been privileged to use in relation to the thesis.

We would also like to use this opportunity to thank our supervisor Rune Fensli at Agder University College for valuable help and inspiration both in prosperous and more difficult times.

At Sørlandet Sykehus Agder we would like to thank Susanne Hernes for comments on our work, valuable ideas, and for aiding our understanding of how remote monitoring systems are utilized in the health care service today.

Grimstad 26.06.2003

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1 Introduction

1.1 Background for the thesis

Contel AS is a company involved in communication technology applications, with focus on mobile solutions. As Contel has expertise in wireless communications and sees a market in health care there is interest in obtaining more knowledge of how wireless communications are being utilized in the heath care service.

This assignment was specified in cooperation between Contel and the students. The field of wireless remote monitoring was selected for its strong reliance on wireless communication technology. This report aims at providing information about the current state of this field as to what technologies and solutions are available or under development and what is in practical use today.

The intended audience of this report is not limited to Contel. It is objective enough to contain information that can be of interest to the health care service and also other health related or communication technology related companies, within or outside of Norway.

1.2 Work description

This is the official project description:

> *"There are systems and solutions currently under development for collecting medical data from patients residing outside health institutions. It is desired that such systems are based on wearable sensor devices using wireless data transfer to send measured biomedical parameters to a central storage. Different types of sensors can be used for biomedical measurement, event monitoring and data driven alarms. Both the medical staff and the patient may have access to whole or part of the monitoring results. This will give the patient freedom of movement, increased involvement in monitoring their condition and more control over their own care. Such a system also enable medical staff to actively and frequently follow up patients when electronic communication can be used between the patient and the health care service.*
>
> *A study shall be conducted regarding what products and projects exist today within wireless collection of biomedical data, i.e. available sensor devices for use in a Body Area Network (BAN), and the feasibility of different mobile technologies for data transfer to the central storage. The study will contain what standards and technologies existing products are based upon and what demands such a system must meet. Further, different possibilities and technological solutions shall be discussed, relating them to the needs of selected cases of biomedical data monitoring. Recommended solutions shall be stated for the selected monitoring cases."*

1.3 Delimitations

The amount of information that can be relevant to this report is enormous, and some limitations must be made.

This report is focused on a feasibility study and recommendation of technology. Therefore:

- The report will not recommend specific equipment vendors or products. There are far too many products available and the market evolves rapidly, so a recommendation of a specific product at one time will be obsolete soon after. A technological solution will be recommended, and specific products can then be evaluated according to that.

- The report will focus on the wireless transmission of measured data from the patient to the receiving information system. The aspect of how sensors physically measure biomedical parameters, or how the collected information is analysed and presented, is beyond the scope of the report.

- The medical aspect of patient handling and monitoring will not be covered. We are looking at technological tools that medical staff can utilize, not how the results they provide are to be interpreted medically.

1.4 Value of this report

This report will give an overview of the technological aspect of wireless remote monitoring of health care patients. This information can be valuable to several parties.

- Technology companies, within or outside of Norway, that recognize health care as a market, and value information about remote monitoring technology.

- The health care service, who recognize remote monitoring as a good approach to gain many benefits, including cost savings and increased patient service.

The value of the report lies in how relevant information is collected and presented objectively, and how possible solutions are discussed.

1.5 Report structure

This report is structured as to first establish what remote monitoring is, how it can be used and what is required of such systems. The second part will provide information about available products, projects, relevant standards, and a reference to communication technologies. The last part of the report establishes a method for evaluating the different communication technologies, evaluates different cases of remote monitoring use, and ends up with recommended solutions. In closing there is a discussion of ethical considerations.

2 Wireless remote monitoring

This chapter gives an introduction to understanding wireless remote monitoring. A definition of the term is given, before the purpose of this technology is discussed. A technical overview of the different parts of the system is shown, and lastly a list of applications and benefits of wireless remote monitoring is presented.

2.1 Definition

The project description establishes what is meant by wireless remote monitoring as "*collecting medical data from patients residing outside health institutions*" and that "*such systems are based on wearable sensor devices using wireless data transfer to send measured biomedical parameters to a central storage*".

This definition clearly states that the patient is residing outside the health institution. The patient's medical data, the measured biomedical parameters, are collected by wearable sensor devices, and that these measurements are wirelessly transferred to some central storage facility.

2.2 Purpose

The purpose of monitoring patients outside the health institution has no single answer. There are multiple reasons for moving part of health care to the patient, rather than moving the patient into the institution.

In one aspect, the patient can be monitored without being hindered in normal activities. Many patients have the need for monitoring of their health condition. To be able to continue with their everyday lives while being monitored will increase quality of life, and also help monitor symptoms in the patient's natural setting. This will reduce missed days at school and work, and health related restrictions on daily activities are minimized. Remote monitoring also often leads to increased security and comfort on part of the patient and other family members as the patient can stay at home.

Another reason is that the quality of the care may be improved. As described in an article concerning the Citizen Health System (CHS) [3]:

> *"Health delivery practices are shifting towards home care. The reasons are many, including better possibilities for managing chronic care, controlling health delivery costs, increasing patient's quality of life and quality of health services. In addition there is added the distinct possibility of predicting, and thus avoiding, serious complications"*

Yet another purpose of letting the patient be monitored outside the institution is that the hospital bed that would otherwise be taken now remains free for other patients to use. This can increase hospital capacity and increase revenue.

Evidently there are many reasons for implementing remote monitoring. Yet it seems that the technology is not as widespread as it perhaps should be. Quoting the same CHS article as before:

"Even though the technology is now becoming more mature, affordable and manageable, widespread application of such solutions are not yet accomplished. In fact, awareness of the public and the physicians is low when it comes to use the use of ICT based health delivery solutions, and even more important, politicians' awareness is even lower."

Even if this article now is getting a year or two old the situation seems not to have changed remarkably. This may be due to several reasons, but one is that though the technological evolution is quickly moving ahead, working with people is a slower process. The health care service is all about working with persons in focus, and any new technology must be fit to the persons needs rather than the other way around.

For a more extensive list of the applications of wireless remote monitoring refer to chapter *2.4 Applications and benefits*.

2.3 Technical overview

In this report the term wireless *remote monitoring* is used to mean a system where medical data is collected from a patient outside an institution for use by some medical professional.

A system for remote monitoring can be designed in numerous ways. A system can send medical parameters from the patient to a central storage, perhaps in real-time for constant surveillance, or once a day for later analysis. Another option is for the sensors to, at the patient, analyze automatically measured data and transmit to medical professionals only if there is detected a problem. In other cases the patients themselves do a manual measurement, i.e. by holding an ECG instrument over their heart and send the recorded data via a cell-network. With this solution the patients are free from hospitalization, while still being able to record information about their heart condition when they feel unwell.

In all of these systems the information is sent from the patient to medical professionals in some form, and this is the essential concept of remote monitoring even if the technological perspective can be very different. Her is one example of how such a system can be depicted:

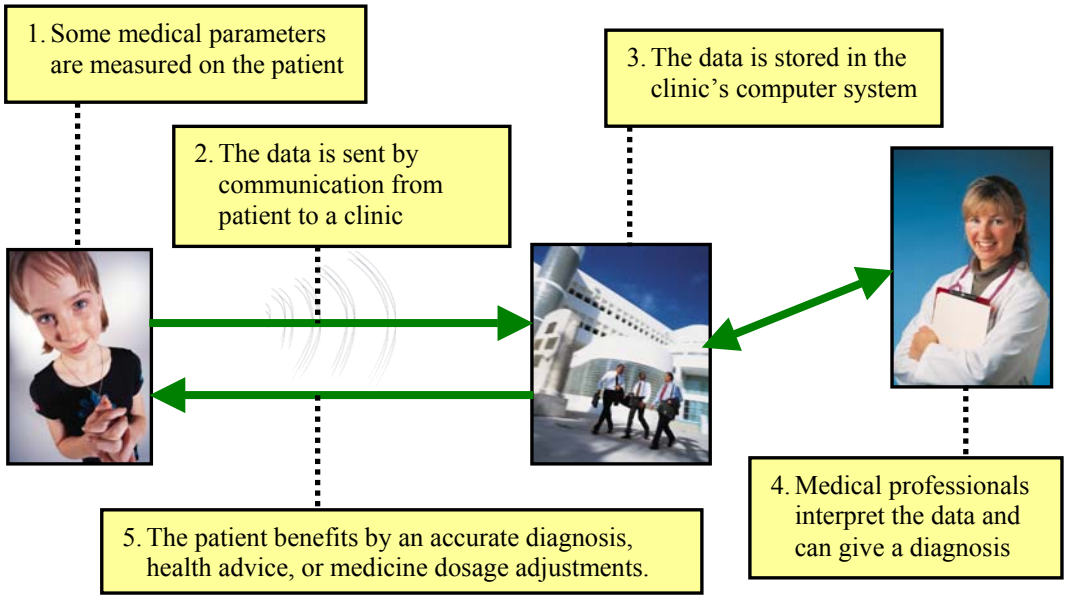

Figure 1 Remote monitoring system overview

A remote monitoring system will in general implement the following components:

- Health monitoring sensors measuring one or more biomedical parameters
- Communication technology to transmit the measured information
- Data storage of patient records, including automatic processing and analysis
- User interface to the measured information

These parts are discussed in the following sections.

2.3.1 Health monitoring sensors

The current state-of-the-art technology in medical sensors allows for easy and unobtrusive electronic measurement of several health conditions. The sensors are often stand-alone devices, and sometimes comprised of two or more elements connected by a cable or wireless technology. Medical sensors have the capability to measure vital signs such as blood pressure, pulse rate, respiration frequency etc. Based on these medical parameters the medical professionals can monitor the patient's health condition, and act in case of an anomaly.

The most useful monitoring sensors are the ones that can be worn on the patient's body, accurately measuring vital parameters throughout the day, while the patient is continuing with daily life activities. This places some demands on the sensor devices:

- Easy to use for the patient when health staff is not available
- Clinically approved by a trusted authority
- Durable and robust
- Accurate in its measurements and reliable in use
- Mobile and light-weight so it will not bother the patient unnecessarily

For more information on these points see 3.3 Requirements to sensor devices.

2.3.2 Communication technology

The medical parameters measured on the patient are transmitted to a central storage by some sort of communication technology. When considering a technology to be used in a specific case, issues like bandwidth, latency, availability, security and ubiquity are key. (See 3.2 Requirements to communication technology*)*.

Demands for each of these vary depending on the context it is to be used in, as there are, for example, higher demands to capacity when transferring ECG measures in real time than sending a daily measure of your blood glucose level. (See 8 Method for technology evaluation).

Some examples of widely used communication technologies with varying properties could be fixed telephone, GSM cellular network and Wireless LAN. For a reference to technologies see 7 Communication technologies.

2.3.3 Data store

For the medical information to be useful it must be stored for inspection and analysis. Data is often stored in a patient record database, and may hold information on for instance measured medical data, personal details and medical history. The crucial point of the data store is to

make the medical information available and secure. (See 3.1 Requirements to information security*)*.

In addition, automatic processing and analysis may be implemented working on the stored data providing more useful data to the medical professionals.

2.3.4 User interface

The user interface is an important part of the system and is what enables the persons involved to utilize the collected data in the data store. It must meet strict requirements to security and access control since the information accessed is of highly personal nature. (See chapter 3.1 Requirements to information security*)*.

The user interface becomes a tool for the medical professionals to view the medical data measured in detail, and help them to make decisions like a diagnosis, medical advice or medicine dosage adjustments. In some cases patients are given access to view whole or some part of the medical data collected, and they can therefore participate more in the process of evaluating their own medical condition.

Several user interfaces can be used in different types of remote monitoring solutions depending of the specific needs that system must meet. Some examples could be hospital journal systems, secure web applications or even automatic telephone menus (IVR). Some important properties of a user interface are its presentation capabilities, data security, ease of use, reliability and availability.

2.4 Applications and benefits

Remote monitoring can benefit a wide range of patients within the health care service. As an example, three large groups of patients stand out as having a clear benefit from this type of aid:

- **Heart condition patients**
  Heart parameters like ECG and blood pressure can be closely monitored and aid physicians in diagnosis and treatment of heart patients.

- **Asthma/respiratory patient**
  Parameters like blood oxygen levels and respiratory rate can be monitored to aid physicians in setting diagnosis.

- **Diabetes patients**
  By monitoring blood glucose levels or insulin levels physicians and patients can be aided in diagnosis and treatment of diabetes and its symptoms.

There are also many other patient groups that can benefit from this kind of technology. A remote monitoring system has many applications in the health care service. Here are mentioned some examples:

1. Assistance in case of accidents and emergencies
2. Increased capacity and lower costs for hospitals
3. Assistance and monitoring in a home-care setting
4. Monitoring of chronically ill patients
5. Patient involvement in setting diagnosis

6. Medicine dosage adjustment
7. Physical state monitoring in sports
8. Monitoring of sporadically occurring symptoms
9. Emergency alarms

These applications are described in the following chapters.

2.4.1 Assistance in case of accidents and emergencies

In some cases there are need for emergency assistance from medical professional in case of accidents etc. If the medical professional that arrives the place of emergency does not have the competence to state diagnose, biomedical measurements of the patient can be sent to experts via a remote monitoring system. The expert can evaluate the biomedical parameters collected and assist the emergency personnel in making the right decisions.

In some areas the distance to the hospital is long. I.e. in north Norway the population have to rely on helicopters, planes or boats to get adequate health care, and the time it takes for the help to reach the patient can be quite long. The home care service is often more locally available, and can benefit greatly from remote monitoring solutions where the time before help arrives can be utilized more efficiently by getting expert opinions and instructions earlier.

Pre-hospital services in many countries are now required to carry 12 lead ECG and other diagnostic equipment that can transmit information directly to the receiving hospital for an expert opinion, a second opinion or to update a central database. Such a system is already implemented in several ambulances, ships, airplanes and oil platforms. The system helps the medical professionals be more prepared to assist the patient when he arrives at the hospital by evaluating the patient's vital signs remotely as he is arriving in the ambulance [4].

In England ambulances will be equipped with the latest technology in remote monitoring in case of accidents and emergencies [5]:

> *"Every single front line NHS ambulance in England is to be equipped with more of the latest technology aimed at treating heart attack victims as quickly as possible.*
>
> *£14 million of new funding has been made available to:*
> - *Equip all front line ambulances with 12-lead electrocardiogram (ECG) machines, which help diagnose heart problems;*
> - *Provide communications equipment so the ECG diagnosis data can be transmitted quickly from the ambulance while on route to hospital;*
> - *Provide paramedics with life-saving thrombolytic drugs; and*
> - *Train England's 8,500 paramedics in diagnosis and in the use of thrombolysis equipment & drugs.*
>
> *By giving them ECG equipment and training in thrombolytics, paramedics can diagnose heart attacks accurately and the results can be transmitted to A&E departments. If patients are able to get thrombolysis an hour sooner than if they had to wait to be taken to hospital, 3,000 lives a year will be saved."*

This type of solution is also in use at Sørlandet Sykehus Agder. See 10.1.1 Ambulatory Prehospital ECG.

2.4.2 Increased capacity and lower costs for hospitals

For measurement of medical parameters patients often must be hospitalized over some time. A patient dispatched earlier to remote monitoring leaves an empty bed, which can be occupied by another patient. The patient will also be monitored in his natural habitat. By making good use of remote monitoring a hospital therefore has the potential to treat more patients.

By using remote monitoring technology, physically ill patients treated in a hospital will be able to return home sooner as their doctors will be able to monitor their progress remotely. According to the @Home project (See 5.8) presentation [6], the period of hospitalization may be reduced by as much as 30%.

In the same presentation, assuming a busy clinic, it is estimated that hospitals may treat as many as 10% more patients per year without any new buildings, using remote monitoring. The potential of increased income is evident from the potential of increased capacity. In this respect, an increase in income of 10% for busy hospital wards is expected.

In a study conducted by Tillinghast – Towers Perrin which assessed the clinical efficacy and cost-effectiveness associated with the AlereNet system (See 4.3), the result was a 62% reduction in all-cause inpatient hospitalizations and a 45% reduction in all-cause emergency room visits. Total direct costs for hospitalizations and ER visits were reduced by 62% and total savings in claims paid per patient equaled $6,196. [8]

2.4.3 Assistance and monitoring in a home-care setting

As mentioned in the preceding paragraph shorter hospital stays mean increased capacity for the hospitals. There is an ongoing trend of shorter hospital stays in the modern health care service. This is often done as a result of cost-cutting, and means that hospitals are dispatching patients that are still in need of care. In [97], a submission to the New South Wales Health Council, there is expressed concern about this trend:

> *"There is an ongoing reduction in the average length of stay in hospital in NSW. This dropped from 6.1 days in 1993-4 to a projected 4.8 days in 1999-2000."*
>
> *"Shorter hospital stays mean more people leaving hospital while they are still very sick and in need of care. There is a huge increase in the demand for post-acute care, and there are indications that there is demand for more complex care.*
>
> *Interviews undertaken with consumers, NGO community care providers and many health staff indicate that there is a widespread view that consumers are not receiving this care."*

This trend leaves the patient in need of home care, and in this area use of remote monitoring could be very beneficial. When patients are recovering at home, there is a nurse in charge of their healthcare. However, in many situations, these nurses need to consult a physician in order to make decisions. Remote monitoring systems are used to aid this communication by enabling transmission of patient data via communication technology from the patient's home to the specialized center.

New wireless technologies that cater to patients suffering from diabetes, cardiovascular disease, and other serious ailments, help physicians and clinicians provide the monitoring and

preventive care that can stop or slow complications. For the patients, these home-monitoring technologies promise to help them live longer and better lives. [9]

Some doctors argue that good psychological spirits can account for dramatic improvements in the patient's health after illness and traumatic treatment. This accounts for another reason to use remote monitoring in a home-care setting. By moving the patient at home during the final, less critical stages of the recovery, for remote monitoring purposes, the healing process is expected to speed up. [6]

2.4.4 Monitoring of chronically ill patients

In the United States today, 90 million people suffer from chronic medical conditions like diabetes, asthma, and heart disease. Chronic illnesses account for approximately 75% of total healthcare costs in the United States. As a result, healthcare organizations, realizing the importance that successful management of these patients has on overall cost-effectiveness and patient satisfaction, need innovative methods to manage these patients. [10]

It is very important to facilitate patients' access to healthcare professionals without saturating the available resources, and this is one of main expected outcomes of the remote monitoring approach. Monitoring of chronically ill patients involves use of remote monitoring for supporting home-based care for chronically ill patients including remote assistance if needed.

Remote monitoring systems make use of sensor devices that can measure a patient's blood pressure, glucose, temperature, etc. If the physician feels the need for a follow-up based on the measurements, he or she can call the patient and make further arrangements.

The Health Hero Health Buddy Appliance (See 4.1) is an example of an internet based application that collects data that provides health care providers important information about a patient's chronic condition on a daily basis – right from the comfort of their homes.

Patient survey results from multiple studies of Health Buddy [12] shows:

- Patient satisfaction increases over time
- 97% of patients reported having no difficulty using the Health Buddy to answer daily questions
- Over time, patients reported feeling more connected to their doctor, nurses and hospital

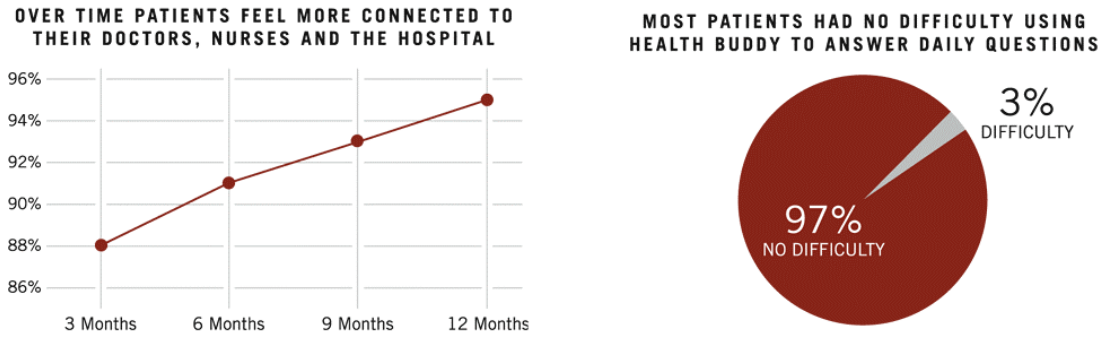

Figure 2 Health Buddy patient satisfaction survey

The Health Buddy asks patients numerous questions about medication compliance including reminders to take prescribed medications on a regular basis. In a recent study, medication compliance increased from 34% of the patients reporting no problems missing medication doses to 94% of patients reporting no problems missing medication doses.

2.4.5 Patient involvement in setting diagnosis

By letting the patient view and/or update information via his or her home computer the patient can be more involved in his or her own diagnose or treatment. As an example a web interface can provide communication between the patient and the medical personnel. Patients can review their medical history and keep tabs on their own health data by viewing their health charts and sharing them with health care providers or family members.

Health Buddy Web (See 4.1) is an example of an application where the care providers can analyze the patients' vital signs, symptoms, behaviors etc. measured by inputs from the patient. Each day, Health Buddy Web will ask a series of questions about vital signs, symptoms and behaviors. Patients answer these questions by clicking on the appropriate answer with their mouse.

Health Buddy Web will respond to the patients' answers with education, messages that prompt patient action, and reinforcement promoting improved self-management and behavior change.

Throughout the entire program, patients are encouraged to learn self-management skills and to become more involved in the management of their own health condition. Health Buddy Web offers patient's additional in-depth health information and interactive illustrations about their condition. These illustrations and text hyperlinks can enhance patients' learning and ultimately help them better manage and educate themselves about their condition.

Figure 3 Patient education

2.4.6 Medicine dosage adjustment

The effect of prescribed medicine can be monitored and dosage can be adjusted based on measurements collected by monitoring.

One example can be taken from the TopCare project (See 5.7). Patients on oral anticoagulant[1] therapy need to have regular controls of their PT[2] values in order to avoid complications. In the routine management of oral anticoagulation therapy, patients visit once a month either the general practitioner or the anticoagulation clinic, have a blood sample drawn from the vein and sent to the laboratory. Patients have to wait for results, and then contact their doctor again to discuss the results in case of a dosage adjustment.

[1] Anticoagulation is the term used to describe the process that makes a patient's blood less likely to clot.
[2] The prothrombin time, or PT, test measures the time it takes your blood to form a clot.

The TopCare project will allow patients to test their PT values at home from a finger puncture. The PT results are sent directly to the Anticoagulation Clinics or to the doctors, depending on whom follow-up the patients. Moreover patients indicate his current anticoagulant drug dosage and any change that may have occurred since the last measurement (changes in the diet, travels, taking of new drugs, emotional changes). These results are added to the database of the patient and reviewed by the doctor. The doctor then sends the dosage adjustment to the patient if necessary and gives him the date for his next PT test. [13]

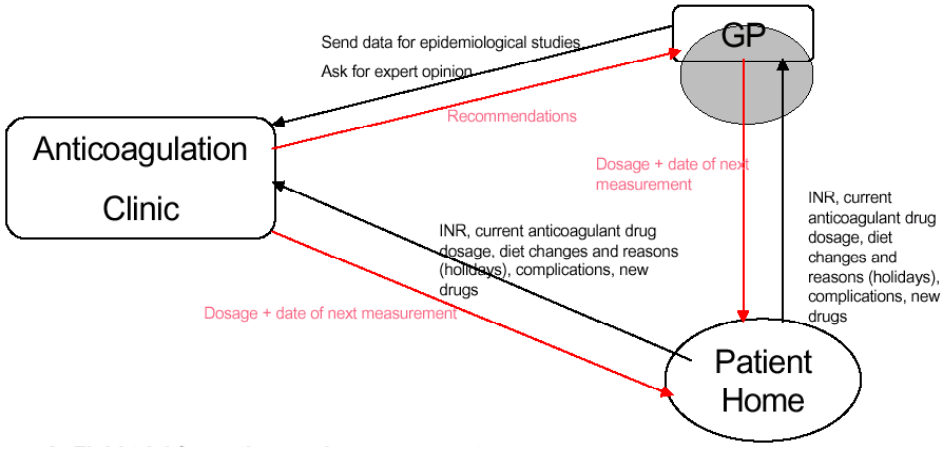

Figure 4 Medicine dosage adjustment

2.4.7 Physical state monitoring in sports

Physiological monitoring in sports and training allows for trainers and coaches to monitor their athletes' fitness in real-time. Remote monitoring is used for data collection, storage and analysis. It is hoped that such a system will give coaches valuable information of the athlete's condition, and prevent any accidents that can happen in a highly competitive training situation.

In relation to a research project called Coach's Companion [14], useful measures collected from the player's physical condition could be:

Sensor	Interpretation of data
Heart rate	Sustained high heart rate levels may lead to over-exertion. Rapid pulse is one of the signs of heat exhaustion and heat stroke.
Accelerometer	The peak levels of acceleration can be monitored. If the level of peak acceleration begins to drop, the player may be becoming tired.
Moisture	The lack of perspiration is a sign of dehydration, which can lead to heat stroke and heat exhaustion.
Temperature	High body temperature levels can indicate overheating of the body.

Table 1 Coach's companion measures

2.4.8 Monitoring of sporadically occurring symptoms

Medical conditions with irregularly appearing symptoms can be monitored for different parameters including frequency, metrics and time of occurrence. By analyzing statistics and history of the measurements the medical professionals have a collection of data that can help

them to make a better-founded diagnosis. One example use of this is Holter monitoring as described here by Children's Hospital of Wisconsin [15]:

When symptoms such as dizziness, fainting, low blood pressure, prolonged fatigue, or palpitations continue to occur without a definitive diagnosis obtained with a resting ECG, your child's physician may request an ECG tracing to be run over a long period of time. Certain arrhythmias (a fast, slow, or irregular heartbeat) which can cause the symptoms noted above may occur only sporadically, or may occur only under certain conditions, such as stress. Arrhythmias of this type are difficult to obtain on an ECG tracing that only runs for a few minutes.

A prolonged type of ECG tracing, called a Holter monitor, provides the physician a better opportunity to capture any abnormal heartbeats or rhythms that may be causing your child's symptoms. The Holter monitor test is used to record your child's ECG tracing continuously for a period of 24 hours or longer. Event monitoring is very similar to Holter monitoring, and is often performed for the same reasons. With an event monitor, your child wears ECG electrode patches on his/her chest, and the electrodes are connected by wire leads to a recording device. However, unlike the Holter monitor, which records continuously throughout the testing period of 24 to 48 hours, the event monitor does not record until your child feels symptoms and you or your child trigger the monitor to record the ECG tracing at that time. [16] By using communication technology, the testing period can be extended from the usual 24 to 48 hours.

In recent years, 30-day arrhythmia monitoring has proven to be an effective tool for detecting arrhythmias in patients with infrequent symptoms. Unlike Holter Monitoring, which is generally used to record cardiac rhythms over a continuous 24 hour period, 30-day arrhythmia monitoring provides a means to monitor the patient over an extended period of time, during which the patient is more likely to experience symptoms.

Patients are given a pager sized monitor which they typically use for up to 30 days. The patients activate the monitor to record their ECG whenever symptoms occur, and to transmit the recording by telephone to a monitoring center. The technician receiving the signal prepares a report containing the symptomatic ECG and forwards it to the ordering physician for review. [17]

2.4.9 Emergency alarms

Monitoring devices can be installed in the home or on the patient to monitor a wide range of biological functions or parameters and notify a monitoring center in the event of an alarm. When special conditions are detected an alarm can be sent by the sensor allowing critical help to be available to the patient.

Alarms are an important part of home telecare applications. Here is a definition from The Medical Journal of Australia:

Home telecare technologies have been reviewed by several authors, and fall broadly into three generations.

- **First-generation systems** are designed to reduce anxiety among elderly and high-risk patients and reduce their use of primary healthcare services. Typical technologies include personal alarm systems and emergency response telephones that make a voice connection between the patient and the response centre whenever a pendant alarm button is pressed.

- **Second-generation systems** can generate alarms without the intervention of the patient, on the suspicion that something may be wrong. These systems can continuously monitor a large number of variables sensitive to changes in functional health status, and generate an alarm when significant changes are observed. With an intelligent decision-support system using robust algorithms, false alarms are unlikely.

These second-generation systems are unobtrusive, do not require direct patient participation and can be integrated with evolving "smart home" technology for home automation, security and environmental control. New developments include sensor arrays worn by the patient and capable of measuring factors such as temperature, respiration, electrocardiogram and skin blood flow. Ambulatory data can be transmitted to a local computer or specialised controller via low cost telemetry before transmission to a central computer. Local intelligence can be used to detect emergencies and long term trends in health status can be identified and acted upon at the response centre. [18]

3 Requirements

There are several issues to consider regarding remote monitoring systems. This is a technology that moves part of the health care service out of the hospitals and into the patient's home and daily life. As the health care system handles highly private and sensitive information it is crucial to ensure that this information will be secure and under secrecy.

The different involved technologies have an impact on many aspects of the system, including information security, the system's ease-of-use, and the patient's freedom of movement. Therefore specific requirements must be met by these technologies, and the system as a whole, in order to amount to a satisfactory solution.

The next chapters will describe requirements for three aspects of a remote monitoring system:

1. Requirements to information security
2. Requirements to communication technology
3. Requirements to sensor devices

3.1 Requirements to information security

This chapter will give an overview of what is required of a system that is to be considered secure in dealing with sensitive medical information. First an overview is given on the aspects of information security in the health care system. This includes problems it presents, and some well known measures to counter these problems.

Then there is presented an overview of the laws and regulations to information security in Norway. This includes a list of relevant laws and regulations acting in Norway, and a list of organizations and inspectorates involved with health information systems.

3.1.1 Information security in the health care system

Security refers to the range of technical and procedural mechanisms that aim to preserve confidentiality, restricting information access to authorized "knowers" for authorized purposes. Security modalities also have the goal of assuring the accuracy and timely availability of data for the legitimate user set, as well as promoting failure resistance in the electronic systems overall. [19]

Electronic communications have two potential weaknesses: they can be intercepted in transit, data can be read or altered, or it may be difficult to be certain of the origin and authorship of the message, thus arising concerns in regards to integrity and authenticity of the contents. Several measures can be taken to protect patient data [20]:

- Electronic healthcare records can be protected by applications and servers that incorporate authenticated, authorized and audited access control.
- Encryption can protect the integrity of data while in transit.
- User authentication and screen locks can prevent improper access and accidental disclosure.

- Enterprise security policies consistent with emerging recommendations can help ensure that appropriate technical, administrative and procedural measures are employed to protect patient data.

- Legislative and regulatory measures can provide guidelines for protection of electronic health information and provide punitive damages for violations.

Cindy Zakoworotny is a member of AHIMA's Task Force on Information Security and Director of the Medical Record Department at Hartford Hospital in Hartford, Connecticut. She presented issues regarding health care information security issues to the Subcommittee on Health Data Needs, Standards and Security National Committee on Vital and Health Statistics (NCVHS) in August 1997 [21].

According to her statement there is no absolute right policy for information security and data accessibility, and says that each institution needs to evaluate its information resources and threats, and determine its own course. Related to "Protecting Electronic Health Information" the report states:

> *"The prospect of storing health information in electronic form raises concerns about patient privacy and data security, for although information technology allows the use of advanced technical mechanisms to limit access to health information, it also introduces new vulnerabilities".*

The statement reports these issues as policies that are important to data store and data accessibility:

- **Access and Protection:** Information should be readily available and must be protected against destruction and unauthorized modification.

- **Authorized Users:** Define who is authorized to write in the record, or create an entry in a computerized information system. Authentication policies and error corrections need to be well defined to ensure the creation of complete and accurate information.

- **Information Removal:** An organization should have a policy outlining under what circumstance information may be removed. Under what conditions is an organization allowed to remove computers or media that contain confidential information?

- **Employee Responsibilities:** A policy should document employee responsibilities in protecting patient confidentiality. This policy should include a statement of the consequences of inappropriate access and release of information.

- **Downloading Patient Information:** There should be a policy prohibiting the downloading of patient data files, unless this activity is specifically part of an employee's job responsibilities. A prohibition should also exist against loading unauthorized software onto workstations or downloading programs from the Internet, as these may contain viruses that can infect the organization's information system network

- **Network Access Standards:** Network access standards should be delineated in policy to ensure the security of the organization's networks--

including all wide-area and local-area network--and that they are under the general control of the network supervisor. This reduces the risk of "backdoor" access to the networks that finds its way around the protection built into firewalls and the documented network configuration.

- **Vendor Access:** If the organization has hired outside contractors or vendors to provide services that allow or require access to patient information, it must take reasonable steps to protect information held by these contractors and their employees against theft, loss, unauthorized destruction, or other unauthorized access. If on-line access to the organization's information systems will be granted to employees of a contractor or vendor, the agreement should specify which employees would have this capability.

- **Recycling:** Make certain that the organization's recycling programs provide for secure disposal of all patient-identifiable information. Such storage media as disks and tapes should be properly erased and overwritten before they are disposed, and hard drives should be erased or destroyed before they are discarded or sold outside the organization.

The report *Use and Disclosure of Medical Data* [22] defines two actions that can be taken to relax the sensitivity of medical data. These actions separate the information from the identification of an individual. The two actions are called anonymization and pseudonymization:

- "By anonymisation is meant the effectively permanent removal of personal identifiers from personal data. Typically this occurs when data are aggregated with a view to the production of statistics (for instance the proportion of the population which has contracted a particular disease). Anonymisation only occurs if there is no reasonably possibility that data from which the personal identifiers have been removed will not in the future be linked once again with the data subject to whom the data related. Data could not be described as anonymised, for instance, if a patient's name were removed from a record before passing them to a researcher who could link them back to the patient through a postcode or because the patient's condition was sufficiently unusual that it would allow him or her to be identified."

- "Pseudonymisation occurs when a true identity (e.g. name, address, National Health number etc) is replaced by a pseudonym, that is an identifier by which the patient is known within a system but which does not readily identify him or her as a person in the real world. Pseudonymisation is typically reversible in that information linking the pseudonym to a real identity is held in a secure part of a computer system (or away from the system as a whole)."

3.1.2 Laws and regulations to information security in Norway

This chapter gives an overview of the acting laws and regulations in Norway relevant to health information security, and a list of organizations and inspectorates involved with health information systems.

3.1.2.1 Laws and regulations

All health applications in Norway has to be in compliance with Norwegian laws and regulations regarding The Personal Data Act [23], and other Acts for the health personnel regarding patient confidentiality.

> *"Privacy is a fundamental human right. It underpins human dignity and other values such as freedom of association and freedom of speech. It has become one of the most important human rights issues of the modern age."* [25]

3.1.2.1.1 Personal Data Act of 2000

Medical information that is treated in a remote monitoring system is considered as sensitive according to the Personal Data Act of 2000 Chapter 1, Section 2 no. 8c [25], and must meet the demands of this Act. The Personal Data Act of 2000 was approved on April 14, 2000 [26]. According to Privacy International [28], the Act is designed to update Norwegian law and closely follows the EU Directive, even though Norway is not a member of the EU. The new law also sets specific rules on video surveillance and biometrics. It replaces the Personal Data Registers Act of 1978 [25]. [30]

Personal Data Act, Section 1 Purpose of the Act [23], states:

> *"The purpose of the Act is to protect natural persons from violation of their right to privacy through the processing of personal data.*
>
> *The Act shall help to ensure that personal data are processed in accordance with fundamental respect for the right to privacy, including the need to protect personal integrity and private life and ensure that personal data are of adequate quality."*

3.1.2.1.2 Right to privacy in the Norwegian constitution

According to Privacy International there is no provision in the Norwegian Constitution of 1814 dealing specifically with the protection of privacy [30]. The closest provision is section 102, which prohibits searches of private homes except in "criminal cases." More generally, section 110c of the Constitution places state authorities under an express duty to "respect and secure human rights." The Norwegian Supreme Court has held that there exists in Norwegian law a general legal protection of "personality" which embraces a right to privacy. This protection of personality exists independently of statutory authority but helps form the basis of the latter (including data protection legislation), and can be applied by the courts on a case-by-case basis. This protection was first recognized in 1952. [30]

3.1.2.1.3 Automatic processing of personal data

Norway is also a member of the Council of Europe and has signed and ratified the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (ETS No. 108) [31]. This convention extends the safeguards for everyone's rights and fundamental freedoms, and in particular the right to the respect for privacy, taking account of the increasing flow across frontiers of personal data undergoing automatic processing.

Chapter II, article 6 states health as a special category of data:

> *"Personal data revealing racial origin, political opinions or religious or other beliefs, as well as personal data concerning health or sexual life, may not be processed automatically unless domestic law provides appropriate safeguards. The same shall apply to personal data relating to criminal convictions."*

Regarding data security chapter II, article 7 states:

> *"Appropriate security measures shall be taken for the protection of personal data stored in automated data files against accidental or unauthorised destruction or accidental loss as well as against unauthorised access, alteration or dissemination."*

The laws and regulations in Norway must meet the demands of this convention regarding storage and automatic processing of health information such as in remote monitoring systems.

3.1.2.2 Organizations and inspectorates involved with health information systems

There are several organizations and inspectorates working with health care solutions in the Norwegian health care system. In the process of developing health applications these organizations could provide necessary information about laws and regulations on health information security. This overview contains information on:

1. The Data Inspectorate
2. The Norwegian Centre for Telemedicine
3. KITH
4. The Norwegian Society for Medical Informatics

3.1.2.2.1 The Data Inspectorate

The Data Inspectorate (Datatilsynet) [23] is an independent administration body set up under the Ministry of Justice in 1980. The Inspectorate accepts applications for licenses for data registers and evaluates the licenses, enforces the privacy laws and regulations, and provides information.

The Data Inspectorate has for example recommended a ciphering strength of DES128 when personal information is transferred over external networks [26].

3.1.2.2.2 The Norwegian Centre for Telemedicine

The Norwegian Centre for Telemedicine (NST) is a resource centre that aims to gather, produce and provide telemedicine information both nationally and internationally. The NST works actively to ensure that telemedicine services are taken into use in modern medicine [32].

The Norwegian Ministry of Health officially opened the Department of Telemedicine at the University Hospital of North Norway in 1993, and identified the NST as a national competence centre for telemedicine research and development activity for the nation. In 2002 the World Health Organization (WHO) designated the NST as its first Collaborating Centre for Telemedicine. The University Hospital of North Norway has been involved in a variety of telemedicine activities since the late 1980s. Today the NST has about 110 employees [32].

Through telemedicine, the NST aims to contribute to excellent and effective health services that are equally accessible to everyone who needs them. According to NST [33]:

> *"The NST is a resource centre for everyone who seeks cooperation, knowledge and support in telemedicine in Norway and abroad.*
>
> - *The NST's expertise is available without charge to the public Norwegian health sector*
> - *The NST's expertise can be shared with non-profit organizations*

- *The NST's expertise can be exported to a global market*
- *The NST organizes courses and conferences in telemedicine."*

3.1.2.2.3 KITH

KITH focuses on communication and information technology in the health care system in Norway. According to the KITH website this is their mission statement [34]:

> *"KITH shall be the main centre of competence in Norway for the extensive, efficient and secure implementation and use of information and communication technology in health care."*

Their main objective is presented as follows:

> *"KITH has as its main objective to ensure the implementation and use of information and communication technology that enables the health care services to fulfill their common needs and objectives for efficient and secure information management, collaboration and development."*

Regarding security they are involved in [36]:

> *"**Secure information management***
> *Security, privacy and quality of information management in health care, focussing both on technological, organisational and ethical aspects"*

More information about KITH can be found in chapter 6.1.

3.1.2.2.4 The Norwegian Society for Medical Informatics

According to their official website [37]:

> *"The Norwegian Society for Medical Informatics – Forum for Databehandling i Helsesektoren (FDH) was established in 1972 as a special interest group of The Norwegian Informatics Society – Den Norske Dataforening (DND). Since 1989 FDH has been an independent society with primary interest in medical informatics and an associated status to DND."*
>
> *"FDH organizes meetings, seminars and courses to share knowledge and information with the members as well as to promote involvement of medical informatics in the Norwegian health care system."*
>
> *"FDH arrange seminars and meetings regularly on topics like EPR, Data Security, Thrusted Third Parties, Legal Issues and Healtcare Legislation, Healtcare Politics..."*

3.2 Requirements to communication technology

There are many factors to consider when you are choosing a communication technology for a remote monitoring system. All of these factors must be considered specifically depending on the selected medical context.

The report *Networking Health: Protecting Electronic Health Information* [38] has listed a series of factors that are important to consider in specifying demands of communication

technology. The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

The five primary factors specified in the report are bandwidth, latency, availability, security, and ubiquity. These factors and demands are described as follows:

1. **Bandwidth** is the rate at which information is transmitted through a network, measured in bits (or kilobits or megabits) per second. The amount of bandwidth a particular application demands is determined by the amount of data to be transmitted and the time in which that transmission must be completed. From the point of view of an individual user (e.g., a consumer, a doctor, or a nurse), the demand for bandwidth is a demand not so much for a uniform increase in the bandwidth of the entire network but for access to sufficient bandwidth when needed. Applications that must transfer large amounts of data quickly demand much greater bandwidth than do applications that transfer smaller amounts of data (such as e-mail) or transfer data more slowly (e.g., if a response is not needed quickly).

2. **Latency** is the time required to transmit data across the network (i.e., the delay between a sender transmitting a message and a recipient receiving it). The latency an application demands can vary tremendously. Real-time, interactive applications demand low latency so that users can interact with each other easily. Applications that do not demand real-time interactions between users - - so - called asynchronous applications such as e-mail and store-and-forward messaging systems -- have only weak demands on latency requirements.

3. **Availability** refers to the continuous availability of the network, the individual links of which it is composed, and the services it offers. Availability can be measured in terms of the percentage of the time the network (or a particular link) is operational or by the average time between failures. Some applications cannot function properly if the performance of the network is degraded; and many time-critical applications cannot tolerate network failures, even if very brief.

4. **Security**, in the computer science community, generally encompasses three elements: system availability, confidentiality, and integrity. The first of these is addressed above. Confidentiality refers to the ability to prevent communications from being disclosed to unauthorized parties in violation of disclosure rules. Integrity refers to the ability to prevent malicious or accidental alteration of data. The need for confidentiality and integrity varies greatly across applications. Both are important concerns in applications involving exchanges of personal health information. Integrity is of paramount importance for some applications, such as setting levels on dosimetry equipment that delivers drugs to patients and preserving the authenticity of medical images.

5. **Ubiquity** refers to the relative accessibility of a network. The ubiquity of a network is influenced by the network's geographic scope (i.e., whether it can be accessed from many places) and by rules regulating participation (i.e., whether it is open to the general public or to members only). The telephone network, for example, is highly accessible because roughly 94

percent of U.S. homes have telephone connections, and anyone is allowed to subscribe to the service. Applications that serve the general public usually demand high levels of accessibility (ubiquity), whereas those that serve limited populations do not, although there may be interest in allowing access by members from multiple locations.

3.3 Requirements to sensor devices

With remote monitoring, measurements of a patients vital signs is often moved from a secure environment in the hospitals into the patients home. This means that there are some other security issues to consider when putting these systems in use. In a patient's home the patient himself is responsible for using the equipment correctly, and the need for assistance in case of failure or malfunction is not as accessible as in a secure hospital environment.

We have not discovered any official requirements to the sensor devices beyond those that apply to the system as a whole. Therefore we have set up a list of factors that may be taken into consideration when evaluating such devices. This list is not complete or the result of any research, it is only a list of more or less obvious observations.

We consider a suitable sensor device to be:

- **Easy to use:** A device that is to be used by the patient should be easy enough to use so that the measurements can be done correctly. In other cases, where the monitoring equipment is to advanced for the patient to manage, home care professionals will be needed for assistance.

- **Clinically approved:** When monitoring sensors are clinically approved by some reliable authority, the device has been tested and should be working according to the authority's requirements.

- **Durable:** The sensor should be as durable and robust as possible as the device will be used by patients with little or no training, and in the patients daily life environment. It should be resistant to common mishaps, like being dropped on the floor.

- **Accurate in its measurements:** The more accurate and trustable the measurements are, the more usable the results will be and the patient will gain more from the monitoring.

- **Mobile and light-weight:** The mobility of the sensor affects the mobility of the patient when the sensor is physically attached to the patient. The most important factor is often the wireless transmission range. If the device is to be worn it is beneficial for it to be small and light-weight.

4 Available products

This chapter gives an overview of some of the many different remote monitoring products that exist on the market today. We have found that there is a lot of research going on that will lead to more products in the future. Some of this research is described in chapter *5 Research projects.*

The products described in this chapter are:

1. Health Buddy
2. Vitaphone Hertz Handy
3. AlereNet
4. WelchAllyn MicroPaq
5. e-San Asthma monitoring solution
6. e-San Diabetes monitoring solution
7. LifeLink Telemonitoring
8. HomMed Monitoring System

4.1 Health Buddy

The Health Hero [11] Health Buddy automates data collection to allow health care providers to actively manage, educate, and track a patient's chronic condition. Early intervention and education allows patients to become an active member in their own health care while allowing health care providers to increase quality of care and decrease health care costs.

4.1.1 Health Hero Platform

The Health Hero Platform is a one-to-many, two-way communications link between healthcare providers and chronically ill patients. It consists of the Health Hero iCare Desktop, a web-based application used by the nurse/care manager to deliver and review patient responses and the Health Hero Health Buddy appliance, used by the patient to receive and respond to the nurse/care manager.

Figure 5 Health Hero Platform

To use the Health Hero Platform, healthcare providers simply need a computer with a standard Internet connection and patients only need a working telephone jack.

Through the Health Hero Platform, healthcare providers gain a resource to do their jobs more efficiently so they can focus their care on the patients who need it most. At the same time, meaningful caregiver involvement educates and motivates patients to more actively participate in their own self-care.

4.1.2 Health Hero iCare Desktop

Medical providers use the Health Hero iCare Desktop to develop queries, reminders, and tips for groups of patients. These provider-patient "dialogues" can be customized for different disease populations and personalized for individual patients, so each day patients receive messages tailored to their needs. Healthcare professionals also use the web to view current or historical patient information or print out reports. Health Hero includes notification features so care providers can be alerted if a patient's response falls outside a parameter specified by the provider.

Figure 6 Health Hero Web

4.1.3 Health Buddy Appliance

Each patient enrolled in the Health Hero service receives a Health Buddy appliance, a simple, in-home messaging device that plugs into the patient's existing phone line. When it fits their schedule, patients view new information from their healthcare provider on the Health Buddy screen and respond to the queries using the appliance's four buttons. The simplicity of the Health Buddy appliance ensures it is accessible to all patients, regardless of their familiarity with or ability to use technology.

Figure 7 Health Hero Appliance

4.1.4 Utilized standards and technologies

The Health Buddy Appliance uses an analog modem for its communication. On the receiving end, the iCare Desktop uses a standard internet connection. The user can also use a web interface.

There is not mentioned any use of open data format standards, so the communication must be considered proprietary.

4.2 Vitaphone Hertz Handy

The Vitaphone Hertz Handy [64] is a complete system for patients to measure an ECG signal, and then transmit this data to a central location called the Vitaphone Service Center where the data can be stored and processed.

The device itself is a combination of an ECG sensor put together with a fully functional GSM mobile phone and a built-in GPS positioning device. This combination ensures the patients can carry the Vitaphone with them anywhere they go and be confident that they can use the device wherever GSM coverage is present.

Figure 8 Vitaphone Hertz Handy

On the backside of the Vitaphone there are four electrode points which, as you press them against your chest, can record an ECG signal. This is then with a few simple key presses transmitted to the Service Center. In case of emergency a button on top of the device can be easily reached and will send an alarm signal to the Service Center along with the patient's current GPS position.

4.2.1 Utilized standards and technologies

This product bases its communication on GSM technology, and its position tracking ability is based on GPS. There is not mentioned any use of open data format standards, so the communication must be considered proprietary.

4.3 AlereNet

AlereNet [7] web-based technology functions as a data portal that provides clinicians secure, password-protected, encrypted access to collected patient information via the Internet. Clinicians can obtain objective clinical information in a timely fashion to accurately assess their patients and most importantly, identify a need for clinical intervention as soon as trends indicate a change in the patient's health status.

Caregivers have the possibility to closely monitor a large number of patients without the inefficiency and time-consuming need for office visits, home visits or phone calls. The AlereNet system is available as a hosted model or a full-service solution, depending upon individual customer needs.

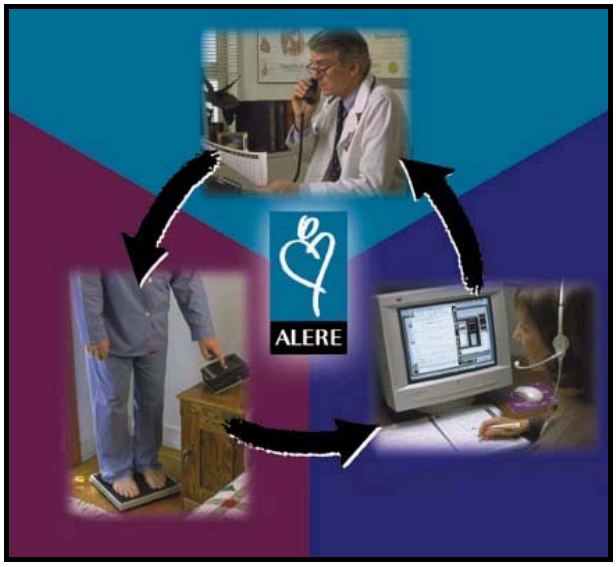

Figure 9 AlereNet System

4.3.1 AlereNet System Components

4.3.1.1 DayLink Monitor

Consists of a biometric measurement device with an easy-to-use interactive display and communications appliance. Placed in a patient's home or other care setting, the DayLink monitor asks patients physician-specified questions about their symptoms, via audible voice and visual display. The patient answers the questions by pressing YES or NO keys. Accurate measurements and patient responses are then sent via the patient's regular phone line to the Alere Data Exchange Network. Alere technology translates the raw data into user-friendly, personalized information that is exchanged between the patients and their caregivers, creating an interactive patient care experience.

4.3.1.2 Nurse Station

Provides a secure, password-protected connection for access to patient data organized to facilitate review and artifact resolution. Nurses can view current and historical weight and symptom information, as well as patient medical history, comorbidities, current and historical medications, and other important demographic information. In addition, Nurse Station allows the user to enter and act upon parameters about which a physician wishes to be notified, to

generate Alert and Status reports, to enter notes regarding patient communications and to remotely modify the patient's target weight and symptom questions.

4.3.1.3 MD Station

Allows physicians to review patient data and status remotely. Information is organized such that physicians can easily retrieve data and symptom trends over time. MD Station allows the physician to access all the information found through Nurse Station, while the functionality is modified for their needs. Future functionality includes personalized patient content, care regimen changes, drug compliance and interactive connectivity.

4.3.1.4 Data Exchange Network

Allows clinicians to access Alere's proprietary Data Exchange Network via the Internet. This dynamic data management structure permits users to proactively analyze the objective and subjective disease information collected via the DayLink monitor. Timely, accurate and actionable information can be readily accessed by all members of the patient's care network, including physicians, nurses, case managers and other key caregivers. Data integration is possible with customers' existing systems.

4.3.1.5 Outcomes Reports

Automatically tracks and reports individual and aggregate information needed to assess a variety of outcomes measures, including program enrollment, utilization of hospital and emergency department resources and patient health-related quality of life and functional status. Alere enables database queries and custom report generation because the AlereNet system uses an applications layer and a rules engine interface. Available reports include physician profiles, demographic variation and best practices analyses, patient and physician satisfaction and documentation to satisfy regulatory requirements from organizations including NCQA and HCFA.

4.3.2 Utilized standards and technologies

This product bases its communication on internet technology via the phone line. This probably means there is a built-in analog modem. There is not mentioned any use of open data format standards, so the communication must be considered proprietary.

4.4 WelchAllyn Micropaq

The Micropaq [65] combines features such as waveform display, multi-parameter monitoring, and patient alarm capabilities into a small, rugged, lightweight, patient-wearable device.

The Micropaq displays ECG waveforms, heart rate, and SpO_2, as well as alarm messages from the Acuity Central Station. Micropaq also protects and extends patient care by providing patient alarms when it is out-of-range or not connected to the wireless network.

Other features include:

- One or two ECG channels for five-lead ECG monitoring.
- Pulse oximetry (SpO_2) monitoring with Masimo SET technology [96] for accuracy under motion and low perfusion conditions.
- Nurse call capability.

Figure 10 WelchAllyn Micropaq

4.4.1 FlexNet

Welch Allyn's comprehensive FlexNet patient monitoring network uses technology supplied by Symbol Technologies to integrate the Micropaq into wireless Ethernet Local Area Networks. This two-way communication allows you to monitor, assist and reassure ambulatory patients at the point of care, while also monitoring from the Acuity Central Station.

Figure 11 WelchAllyn FlexNet

FlexNet links multiple devices such as ambulatory wireless monitors and hardwired and wireless bedside monitors to Acuity Central Monitoring Stations.

4.4.2 Utilized standards and technologies

FlexNet uses Symbol Technology's Spectrum24® radio module that operates in the 2.4 GHz band using spread-spectrum modulation. This technology conforms to IEEE 802.11 wireless Ethernet LAN standards [66]. There is not mentioned any use of open data format standards, so the communication must be considered proprietary.

4.5 e-San Asthma monitoring solution

The e-San solution for asthma monitoring [67] uses a combination of an electronic peak flow meter and a PDA mobile handset which transmits the readings to a central server over a GPRS connection. [68]

Careful monitoring of lung function using peak flow meters improves the control of asthma and reduces the risk of an acute asthma attack. A problem is that most sufferers do not always record the peak flow values accurately in their patient diary, which is reviewed retrospectively at the Asthma Clinic every three months, and often go for several days at a time without recording any readings at all.

Figure 12 e-San asthma monitoring solution

With the e-San solutions, asthma sufferers use the peak flow meter at home in the morning and evening and the system transmits the readings in real time to the server. An electronic patient diary on the PDA also allows the patients to enter information describing their symptoms and this information is transmitted at the same time as the peak flow readings. Whenever no readings have been received for more than a day, a text message is automatically sent to the patient's phone.

At any time, GPs or Practice Nurses can access their patients' data stored on the server, enabling them to monitor the patients' condition with up-to-date, accurate and reliable data. This means the e-San solution allows the treatment of asthma to be more proactive, and provides benefits both to the patient, such as greater reassurance and ultimately improved quality of life, and to GPs and the National Health Service as fewer avoidable emergency hospitalizations and call-outs will result in time and cost efficiencies.

The e-San solution is currently undergoing trial in a 100-patient study. The results of the trial will be published in relevant Medical Journals and interim results will be published in GP publications.

4.5.1 Utilized standards and technologies

This product transmits the readings to a central server over a GPRS connection. There is not mentioned any use of open data format standards, so the communication must be considered proprietary.

4.6 e-San Diabetes monitoring solution

e-San has developed an integrated monitoring device for diabetics [67], which combines an electronic blood glucose meter and a GPRS mobile phone. The patient switches the blood glucose meter on, connects the cable from the meter to the phone and places a drop of blood onto the reagent strip. Within a few seconds, the blood glucose reading is available at the central e-San server. A few seconds later, the entries from the patient diary regarding insulin dose, meals and physical activity are also available at the server.

The long-term complications of damage to the eyes, kidney or nerves are related to hyperglycemia (high blood sugar levels) and occur from the second decade onwards after diagnosis. These complications are, however, potentially preventable. Unfortunately many patients in their late teens and early twenties have poor glycaemic control and are at substantially increased risk of long-term complications.

Figure 13 e-San diabetes monitoring solution

To optimize glycaemic control patients need to alter their insulin dose to take account of their energy intake and anticipated physical activity. Blood glucose tests provide feedback but the recognition and interpretation of patterns of test results is complex because they occur in the context of changes in diet and physical activity.

The e-San solution is being evaluated in a randomized controlled trial in a group of 100 young adults with Type 1 diabetes. The incoming readings are monitored on the server and intelligent software will automatically alert a Diabetes Specialist Nurse when required. This will allow the nurse to offer support to individuals at a time when blood glucose levels have moved outside a personally targeted zone.

4.6.1 Utilized standards and technologies

This product transmits the readings to a central server over a GPRS connection. There is not mentioned any use of open data format standards, so the communication must be considered proprietary.

4.7 LifeLink Telemonitoring

LifeLink Telemonitoring [69] offers physicians and patients a powerful suite of telemonitoring services to combat chronic diseases such as hypertension, congestive heart failure and diabetes. We provide immediate feedback to patients and accurate and timely data to clinicians.

Patients are enabled to monitor blood pressure & heart rate, weight, blood glucose and hemoglobin A1c at home, and to send objective data to clinicians over the telephone. Patients also report their subjective symptoms and medication compliance. Also under development are services for spirometry (respiratory function), thermometry (temperature), PT/INR (anti-coagulant level), SpO_2 (pulse oximetry), lipids (cholesterol) and microalbuminurea (urine protein).

Figure 14 LifeLink Telemonitoring

4.7.1 Patient feedback

As soon as the data are sent, the hub signals the patient to pick up the phone for a message. An Interactive Voice Response (IVR) system tells patients their recent readings, and congratulates them if they are at goal. The IVR also asks questions about symptoms and medication compliance. If readings exceed critical levels the IVR prompts patients to call their doctor or nurse.

4.7.2 Results sent to clinicians

The results are sent to clinicians by fax or email, or directly interfaced with an electronic medical record or case management system. Reports can be sent as soon as a patient sends data, or readings that are within limits set for that patient can be batched and sent at regular intervals. If readings exceed those limits, reports are sent immediately.

A primary care physician may elect to receive weekly reports by fax to make treatment decisions for non-acute patients with hypertension or diabetes. For a pregnant woman with hypertension, blood pressure reports are sent daily. A case manager will have home monitoring data from congestive heart failure patients on his or her computer within minutes of the patient sending readings. This daily home surveillance frees the case manager to focus on the sickest patients, secure in the knowledge that daily telemonitoring provides rapid notification if another patient is getting into trouble.

4.7.3 Utilized standards and technologies

This product sends its reading “over the telephone”, which most probably means through an analog modem. Also the solution utilizes IVR technology, and fax and email. There is also mentioned that the results can be “directly interfaced with an electronic medical record or case management system”, but not what data formats are supported.

There is not mentioned any use of open data format standards, so the communication must be considered proprietary.

4.8 HomMed Monitoring System

The HomMed Monitor [70] is a vital-sign monitoring and communication device which:

- Reminds patients every day that it's time to take their vital signs, then guides patients through the simple, 3-minute procedure with a gentle, friendly voice.
- Measures patients' weight with a hospital-grade digital scale for early detection of fluid retention. The scale is accurate up to 1/10 of a pound and can weigh patients up to 500 pounds.
- Has a custom-designed blood pressure cuff that can be easily positioned with one hand and accurately measures systolic, diastolic, and mean blood pressure.
- Has a simple-to-use, non-invasive finger probe that accurately measures heart rate and oxygen saturation.
- Is compact and weighs less than 3 pounds.
- Thermometer accurately measures temperature.

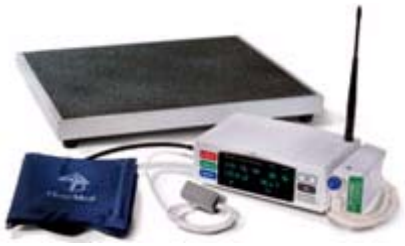

Figure 15 HomMed Monitoring System

- Asks patients up to 10 subjective questions about how they feel, to which they answer yes or no. These questions can be customized to assist in further evaluating their conditions.
- Uses dual communication modes to automatically transmit patient information via wireless pager technology or standard phone lines.
- Utilizes software that alerts clinicians to vital sign parameter "breaks."
- Allows for customized reports, giving detailed patient trending data presented in graphical or tabular formats.
- Has additional accessories that can be added as required for customized patient monitoring. These multiple peripherals can be attached simultaneously.

4.8.1 Utilized standards and technologies

This product, as mentioned above “uses dual communication modes to automatically transmit patient information via wireless pager technology or standard phone lines”. There is no further information on what exact technology this refers to.

There is not mentioned any use of open data format standards, so the communication must be considered proprietary.

5 Research projects

This chapter gives an overview of some of the current research effort that is going on today.

Many of the projects described here are IST funded projects. An enormous number of health related research and development projects are defined under the Information Society Technologies (IST) Programme [71] under the European Commission [72]. Many of these aim to solve different problems within remote monitoring. An introduction to some of the most relevant projects is given in this chapter.

To find more information about a particular project, refer to the IST Website [71] and search for the IST project reference number. Also refer to the project's official website where given, or contact the project's contact person.

Result reports from completed projects are seldom released to the public on the projects' website, as most results are meant to be exploited commercially by the participants.

The projects that are described in this chapter are:

1. Broadband technology in home care service in Alta, Norway
2. A Body-Monitoring System with EEG and EOG Sensors
3. AMON
4. EPI-MEDICS
5. e-ReMedy
6. HealthMate
7. TOPCARE
8. @HOME
9. DAPHNE
10. BodyLife
11. CHS
12. CHRONIC
13. D-LAB
14. MOEBIUS
15. M2DM
16. MOBI-DEV
17. TelemediCare
18. MobiHealth

5.1 Broadband technology in home care service in Alta

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Alta commune, Norway, was responsible for this project witch was completed in collaboration with the National Center of Telemedicine and Telenor Research and Development. Additionally, the project was connected to a local group of scientists at NORUT Finnmark. The project was executed in the period from spring 2000 until 2002.

5.1.1 Project description in three phases:

1. A broadband radio network was established in Alta, and there was developed and tested a mobile version of an electronic patient record system. Thus, there was established mobile access to written patient information.

2. A solution was developed that made it possible to attach image information to the patients record, and to send inquiries to municipal doctors and skin specialists. The purpose was to strengthen the quality of wound treatment in the home care service by help of digital images.

3. E-mail communication between the home care service, doctors and pharmacy was enabled for ordering of prescriptions.

5.1.2 Results

Phase 1: Mobile patient record system
The nurses' experiences with having access to patient data in the field are exclusively positive. They emphasize the availability of up-to-date information as very positive. When they are carrying the computer they do not have to ask other people to retrieve the data for them, and they do not have to drive back to the office to retrieve it themselves. Easier access to information increases their decision basis. It reduces the strain of needing to remember a lot of information at the same time and reduces the use of "sticky-note systems", thus eliminating potential sources of error.

Experiences also show that it is possible for the users to participate in the writing of reports together with the nurses. Users that want to and are able to, can participate and therefore practice access to their own medical record without requiring additional effort from them in form of other contact like telephone, letter or physical meeting.

Phase 2: Strengthening the quality of wound treatment in home care
Through use of images attached to the medical record the nurses were able to document the wound healing process. They have seen changes from the first to the last image, and have documented healing and deterioration through images and text. The solution has also opened for the opportunity to evaluate wound images in collaboration with others. Visualization of

wounds through digital images contributes to an increased professional awareness related to wound treatment. The solution may also form the basis of internal evaluation and competence development, it was said.

Phase 3: E-mail communication

A reason for why making contact through e-mail is easier is that the nurses do not need to be waiting in a ”telephone-queue”. By using e-mail they can send inquires asynchronously, and the doctors can answer the inquiries after the patient consultations at the doctors office has concluded for the day. The system was evaluated as being practical, answers are available for the nurses the next day and they do not have to be waiting in a telephone-queue. The experiences with e-mail communication with the pharmacy in Alta also was positive. The themes that were communicated dealt with prescription problems.

5.2 A Body-Monitoring System with EEG and EOG Sensors

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http://www.ercim.org/publication/Ercim_News/enw51/bielikova.html	

A team of four students from the Slovak University of Technology in Bratislava has developed a prototype mobile sleep laboratory - a body-monitoring system with EEG and EOG sensors. The students explored the concept of intelligent data collection from human body sensors, and with this system, won third prize at the annual IEEE Computer Society International Design Competition (CSIDC 2002 [73]) World Finals.

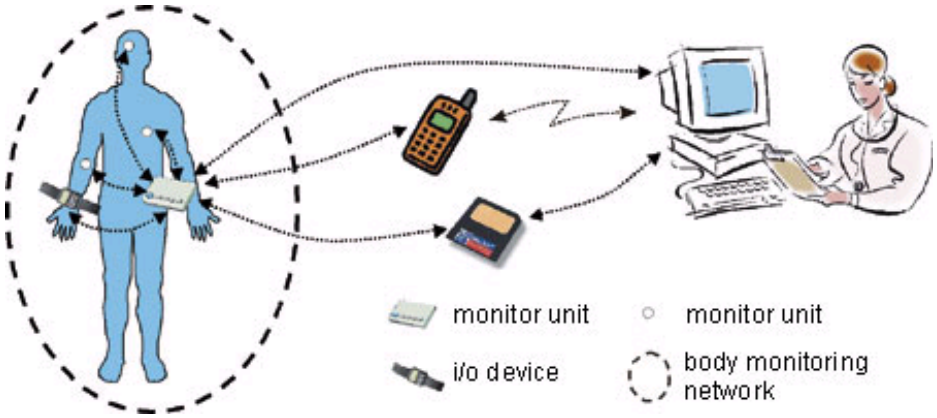

Figure 16 Overview of the Body Monitoring System

The Body-Monitoring System (BMS) is designed as a mobile device that is able to collect measured data and to act according to instructions set by a supervisor. The system consists of a body-monitoring network. In order to recognize the monitored person's state, the monitor unit connects to various body sensors and i/o devices using either wired or wireless communication technologies. Data from all sensors is collected, stored and analyzed in real time and, according to the analysis, actions may then be performed. A computer is used as an interface to the body-monitoring network, and developed software allows a supervisor to configure the monitor unit for the monitored person, to connect sensors and I/O devices, define and upload instructions for monitoring and download collected data.

To validate the system design the students tested it in a specific field of medicine - sleep research. To cope with the problem of sleep disorders, sleep laboratories in hospitals are used to monitor patients overnight. However, patients are influenced by the hospital environment, and usually show different sleep patterns to patients at home. As a solution to this problem a prototype mobile sleep laboratory was developed for home use. The prototype employs an electroencephalograph (EEG, which monitors brain waves), an electrooculograph (EOG, which monitors eye movement) and a thermometer. Analysis of EEG and EOG data allows identification of all sleep stages.

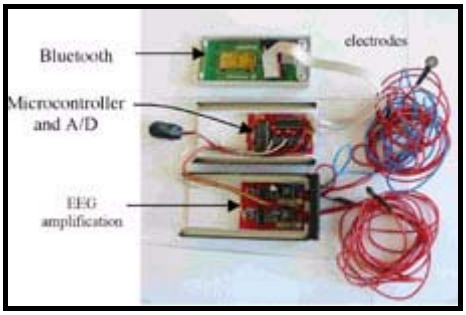

Figure 17 EEG sensor protoype

Figure 18 The EOG sensor in action

Sensor implementation goes out from a common sensor platform designed in the course of this project. The common platform contains a detecting element, amplifiers and filters, an AD converter, a microprocessor and a Bluetooth module. Figure 2 depicts the EEG sensor prototype. The developed EEG sensor could also be used for continuous EEG examination. Such an examination is necessary for patients suffering from epilepsy.

Although the students concentrated on monitoring the human body for medical purposes, the design of the Body-Monitoring System could also be used in many other fields (e.g. pulse rate monitoring in sports science, prevention of Sudden Infant Death Syndrome and monitoring of people working in dangerous environments).

5.3 AMON

"Advanced care and alert portable telemedical MONitor"

The AMON project is funded by the EC under the IST Programme with reference number "IST-2000-25239". It was started in January 2001 and was completed by end of December 2002.

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5.3.1 Project Definition

AMON aims to research, develop and validate an advanced, wearable personal health system that will monitor and evaluate human vital signs using advanced bio-sensors. The system will gather and analyze the vital information and transmit the data to a remote telemedicine centre, for further analysis and emergency care, using GSM/UMTS cellular infrastructure. The Wrist-mounted Monitoring Device (WMD) will include sensors such as heart rate, heart rhythm, 2-lead ECG, blood pressure, O2 blood saturation, skin perspiration and body temperature.

Figure 19 AMON Wrist-mounted Monitoring Device

AMON will enable patients (including the high risk and elderly) who are not confined to a hospital to monitor continuously and analyze their vital signs. AMON will provide care at the point and time of need, giving patients the freedom of movement and enhancing their quality of life.

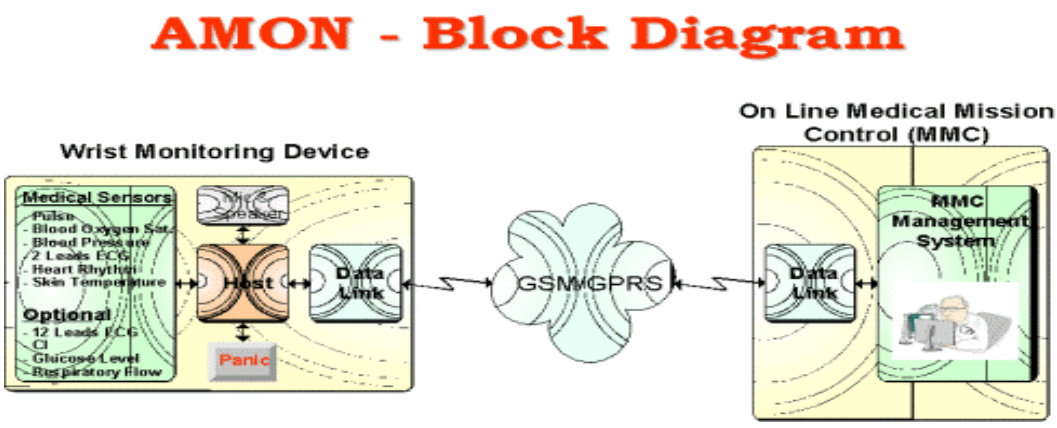

Figure 20 AMON Block Diagram

5.3.1.1 Objectives

The main objective of the AMON project is to perform the necessary research, development and validation for an advanced wearable, personal health system. The system is designed to monitor and to evaluate human vital signs such as: heart rate, heart rhythm, 2-lead ECG, blood pressure, O2 blood saturation, skin perspiration and body temperature.

The Wrist Monitor Device, the wearable component of AMON, will utilized an advanced bio-sensors and gather vital information, analyze it automatically using a built-in expert system, and transmit the data to a remote telemedicine centre, for analysis and emergency care, using GSM/UMTS cellular infrastructure. The scientific and technological challenge is to design a wearable monitoring device that will be small, dependable and contain the necessary data for an impending medical emergency.

5.4 EPI-MEDICS

"*Enhanced Personal, Intelligent and Mobile system for Early Detection and Interpretation of Cardiological Syndromes*"

The EPI-MEDICS project is funded by the EC under the IST Programme with reference number "IST-2000-26164". It was started in January 2001 and is to be completed by end of December 2003.

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5.4.1 Project Definition

Because of a continuously growing number of cardiac patients in Europe, the only practical way to decrease the overall cardiac mortality and morbidity is to supply the citizen with a portable care device that will allow him to monitor his health status and early detect cardiac events such as ischemia and arrhythmia.

EPI-MEDICS will design a solution based on the interpretation of ECG derived cardiological syndromes and develop a friendly and easy-to-use, cost-effective and intelligent personal device that may be used anywhere, anytime. The device will be able to record and store ECG signals with a professional quality level, incorporate intelligent self-adaptive data processing and decision-making techniques, generate different levels of alarms, and forward the alarm messages with the recorded signals to the relevant health care providers by means of new generation wireless communication devices.

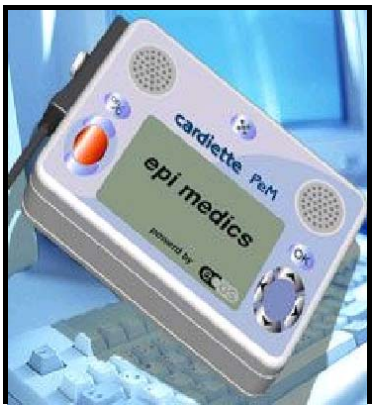

Figure 21 EPI-MEDICS Portable ECG Monitor

5.4.1.1 Objectives

Heart disease is the main cause of early disability and premature death in western countries. Moreover, because of the ageing of the population, the number of cardiac deaths is steadily increasing. However, the only available diagnosis tool useful for assessing the probability of cardiac events is the electrocardiogram (ECG). But, most of the cardiac deaths occur outside of the hospital. So, new strategies are required to reduce the time before treatment.

The challenge is two fold: detect as early as possible the onset of arrhythmias and schema events by monitoring the changes of the ECG of the citizen at risk, and then involve without delay, but only if necessary, the health care structures. The aim of the EPI-MEDICS project is to develop and experiment a novel "intelligent" Personal ECG Monitor (PEM) for the early detection and management of cardiac events. The objective is to design a very affordable,

easy-to-use but powerful, embedded device that shall be able to record, store and synthesize standard 12-lead ECGs, incorporate intelligent self-adaptive data processing and decision-making techniques, generate different levels of alarms, and forward the alarm messages with the recorded signals to the relevant health care providers by means of new generation wireless communication techniques.

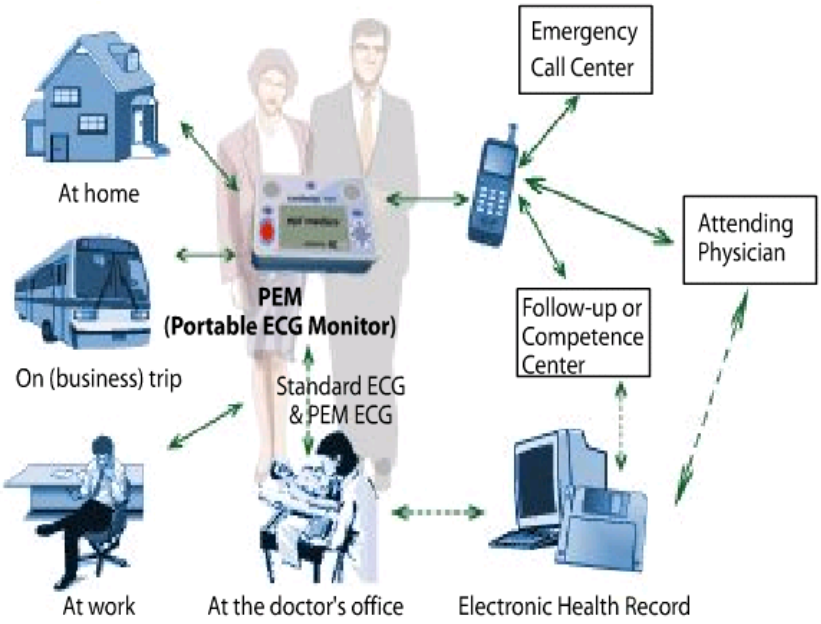

Figure 22 EPI-MEDICS System Overview

5.4.1.2 Work description

Determine an easy to use, pseudo-orthogonal subset of ECG electrode positions that is adequate for home care or ambulatory use, capable of synthesizing standard 12-lead ECGs for integration in the electronic patient record and for control by the cardiologist, develop computerized serial ECG analysis methods that are compliant with the clinical scenarios, and determine the most relevant ECG measurements for the detection of ischemic events and arrhythmia's, elaborate robust integrated decision-making methods having auto-learning and auto-adaptive capabilities for the generation of alarms.

Another work item is to develop means and tools for wireless data communication between the PEM devices and the health professional systems and infrastructures, from anywhere, at anytime, allowing a seamless integration of personal health data and the patients ECG signals in the patients' health record for the enhancement of the continuity and of the quality of care.

The last step will be the evaluation of a series of around 200 prototypes that will be distributed to different categories of patients and assessed by a network of cardiologists and GPs interconnected by Internet.

5.4.1.3 Expected results

The main expected result will be the design of an enhanced, intelligent and portable PEM prototype that will be able to detect cardiac arrhythmias and ischemias, generate different levels of alarms, and forward them to the relevant health care providers. The prototypes will be assessed on a series of ambulatory normal and cardiac patients from almost three countries. The PEMs will also contribute to build up the electronic patients records by providing additional, useful and reusable ECG information for the remote assessment of the citizens' cardiac status and their pre-hospitalization triage.

5.5 e-ReMedy

"Tele-Medicine Platform to support Home Rehabilitation based on Internet Technologies"

The E-REMEDY project is funded by the EC under the IST Programme with reference number "IST-2000-25146". It was started in January 2001 and was completed by end of December 2002.

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5.5.1 Project Definition

e-ReMedy is a project planned to enable patients who need rehabilitation to manage the necessary therapies at home with the goal to improve quality and decrease costs. The project aims to plan, realize and experiment a range of home use equipment remotely connected with an external supervisor system. The use of Internet technology make also possible the exchange of data necessary to run the rehabilitation protocols.

5.5.1.1 Objectives

The overall objective of the e-ReMedy project is to dramatically increase the quality of the rehabilitation services provided by EU hospitals and rehabilitation centers to patients, while at the same time reducing the costs incurred. To achieve the above goals, the project intends to design, develop, test, validate in pilot installations and commercially exploit an innovative infrastructure to support rehabilitation processes with most part performed at home, without reducing, and possibly increasing, the medical monitoring level.

The infrastructure will exploit a number of technological advances, among which, in particular: advanced sensors, real-time internet connections, wireless connections, tele-conferencing, decision support systems.

5.5.1.2 Description of the work

Technically, the system that will be developed is composed of:

- Rehabilitation machines: highly sensorised, open to external connections and programmable machines.

- Innovative sensors able to perform the measurement of critical physiological variables like air-flow, oxygen consumption, blood pressure.

- An internet-based, distributed software system, made up of a real time Internet connection between the central system and the client system, allowing the run-time supervision of patients connected to the Centre through the transmission of data relevant to the exercises being performed and the establishment of a video-conference link; a client system, able to collect and store the acquired data, perform filtering and computations,

display the variables via animated graphics, detect alarms; a central system able to visualize the patient data, send alerting messages to the specialists at the centre, store patient data, provide workflow management aids and a Decision Support System.

The system developed will be deeply evaluated by three end-users within the consortium.

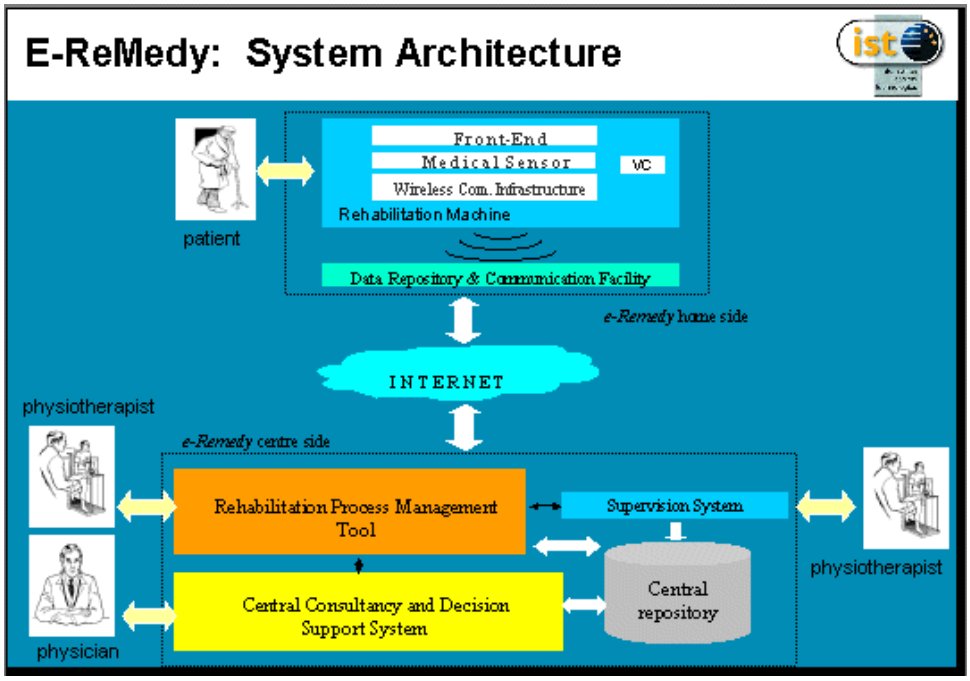

Figure 23 E-ReMedy System Architecture

5.5.1.3 Expected results

Improved quality and safety standards of the rehabilitation service. Improved safety of the rehabilitation process. More strict contact between patients and physicians. Reduction of the hospitalization period. More informed decision making therefore higher accuracy and efficiency in taking decisions about the rehabilitation treatments. Improved management of medical information, including remote access of patients' data and electronic exchange of patient cases among centers. Reduction of time wastes for physicians and physiotherapists. Improved patient quality of life.

5.6 HealthMate

"Personal intelligent health mobile systems for Telecare and Tele-consultation"

The HealthMate project is funded by the EC under the IST Programme with reference number "IST-2000-26154". It was started in January 2001 and is to be completed by end of June 2003.

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5.6.1 Project Definition

A significant proportion of the health demands will be soon satisfied through mobile networks (m-health). This project contributes to the definition of a new generation of GPRS/UMTS portable personal systems, taking advantage of EU predominant position.

The project will develop four tele-care innovative platforms to cope with a large number of potential client groups and health needs: Navigation/positioning personal terminals; programmable terminals to hold well-defined protocols for tele-assistance or the management of emergency situations; data capture mobile personal devices; and multi-modal high dialogue capacity terminals. The project optimizes the market value of the targeted products by innovative: high usability interfaces; privacy and security tools; high reliability designs; scalability and interoperability to enlarge market segments; and powerful evaluation tools.

5.6.1.1 Objectives

Develop portable personal systems for health Tele-care and Tele-consultation based on new generation of wireless communication networks; integrating advanced, innovative wireless technologies to configure a secure information exchange media between the personal systems and the health service providers. And to assure service continuity at any time and place. The systems will also include the elements to facilitate a mass-market take-up of diverse wireless personal terminals and intranet-based services. Legal and ethical aspects involved are also addressed.

5.6.1.2 Expected results

Four tele-care platforms will be developed for a large number of client groups and health needs:

- Services to access at any time and any place the right health information
- Services to manage predictable emergency situations, based on the capture of pertinent information from the user and the environment
- Services to assess the geographical position of persons requiring orientation help
- Services of tele-monitoring to assess patient status

5.7 TOPCARE

"Implementation of a telematic homecare platform in cooperative health care provider networks"

The TOPCARE project is funded by the EC under the IST Programme with reference number "IST-2000-25068". It was started in January 2001 and is to be completed by end of December 2003.

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http://www.topcare-network.com/	

5.7.1 Project Definition

The overall objective of TOPCARE is to develop technical devices and telecommunication structures and to lay the organizational groundwork for bringing co-operative health care services into the home of patients.

A telematic homecare platform will be established and evaluated in European cooperative health care environments for following scenarios: home monitoring and treatment of patients needing:

- Infusion therapies
- Controlled ventilatory support
- Monitored medication adjustment and adherence control when treated with anti-coagulants.

A 24h accessible telemedical centre is integral part in each of the proposed caregiver networks.

5.7.1.1 Objectives

The overall objective of TOPCARE is to develop technical devices and telecommunication structures and to lay the organizational groundwork for bringing co-operative health care services into the home of patients. Telematic communication technologies and modern vital sign monitoring is applied in order to enhance post-clinical treatment in an out-patient setting, foster the communication between patient, practitioners and clinics, and to provide electronic assistance in documentation management for improved quality assurance.

TOPCARE will address the need for reliable and safe ambulatory devices and services that foster patient compliance in the home environment. Continuity of care will be achieved by integrating the home based services into a network of health care providers. Three ambulatory scenarios will be initiated in three European countries. The joint efforts in TOPCARE are expected to lay the groundwork for generating a telematic based European homecare market.

5.7.1.2 Work description

The work in TOPCARE is divided into seven work packages that include workflow definition for homecare services, the development of the telematic homecare platform and of telematic modules that serve the particular medical application, the design of a health telecenter, the initiation of at least three pilot trial, as well as the development of concepts for sustainable telematic ambulatory healthcare services.

Technical work for implementing a generic telematic homecare system comprises the design of a telematic homecare platform (THP) backbone, the development of telematic home stations (THS) and health professional stations (HPS) and a communication server that will manage the net administration, the health professional registration at the THS, the device communication, and the Internet access.

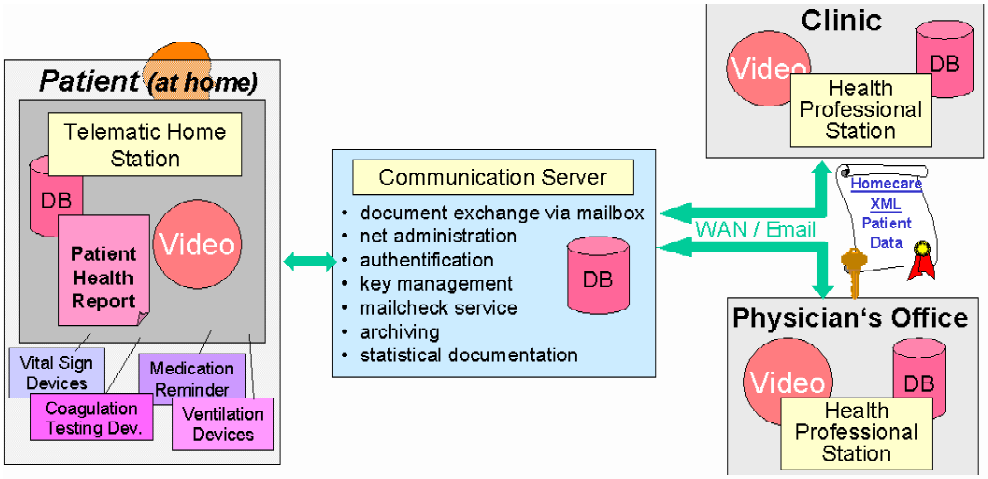

Figure 24 TOPCARE Architecture

Telematic homecare application modules will be integrated for three medical homecare scenarios:

- Ventilation/oxygen therapy
- Infusion therapy
- Medication adherence control demonstrated on anticoagulation treatment.

For the latter, a telematic medication adherence device will be developed. After the definition of structure and organizational procedures for a Health Telecenter modules will be designed and integrated to have the platform work as ambulatory care / homecare call centre.

After technical evaluation, the homecare platform and the application modules will be tested in real co-operative caretaker environments. For each of the three medical applications pilot trials are initiated. Finally, business concepts will be developed for sustained establishment of ambulatory homecare services.

5.7.1.3 Expected results

Technical: An operational and successfully tested generic homecare platform demonstrating data exchange between the client stations THS and HPS. Demonstration of successfully handling telematic services for each of the three homecare applications in a multiple care provider environment employing a health telecenter.

Organizational: Setting up a co-operative caretaker environment in which telematic ambulatory patient care and homecare services can be evaluated under real world conditions.

5.8 @HOME

"Remote Home Monitoring of Patients"

The @HOME project is funded by the EC under the IST Programme with reference number "IST-2000-26083". It was started in January 2001 and was completed by end of March 2003.

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http://www.at-home-medic.net/	

5.8.1 Project Definition

The @HOME project aims to enhance patient welfare and quality of life across the EU. The project introduces next-generation, user-friendly, cost-effective and interoperable general-interest health services by ensuring hospitals make best use of state of the art technology in communications (UMTS, Bluetooth, data privacy and secure connections) and ubiquitous medical sensors.

The @HOME system is primarily addressed to European hospitals and their patients. It is envisaged as a post-stationary application, i.e. it will come into play once the patient has received hospital treatment and is recovering. During the recovery phase, the patient is often hospitalized in order to monitor critical, but often simple to measure, parameters, such as temperature, blood pressure, pulse rate etc. Another parameter which is of interest and which will be investigated is treatment compliance.

5.8.1.1 Objectives

The objective of the project is to equip clinics with state of the art infrastructure, which will allow for continuity in patient treatment at home and, often, a faster dispatch of patients. By the end of the project, the @HOME platform will enable hospitals to perform remote regular and reliable health monitoring of patients residing and recovering at their homes and will promptly advise the clinic staff in case of an emergency. Reciprocally, @HOME will provide information services regarding the recovery of the patients to the patients themselves and their carers/ relatives.

The @HOME project will produce a robust platform for real-time remote monitoring of patients at their home by their doctors at the hospital. @HOME will be addressed to two patient groups and their doctors: patients recovering after hospital treatment and chronically ill patients. The @HOME system will be evaluated within two pilot applications: Post-surgery Pilot and Psychiatry Pilot.

The objectives of the @HOME application are highlighted below:

- Lower relapse rate for chronically ill patients. Monitoring of treatment compliance will enable the doctors to intervene when chronically ill patients do not conform. This rate currently stands at the very high fraction of 60%. @HOME expects to reduce this to 40%.

- Shorter hospitalization period for patients. Physically ill patients treated in a hospital will be able to return home sooner. Their doctors will be able to monitor their progress remotely in real time by using the @HOME infrastructure. The period of hospitalization may be reduced by as much as 30%.

- Lower cost for patient treatment. This is true for both chronic disorders and post-surgery cases. Cost reduction will be of the order of 10%-20%.

- Quality of life for the patient. @HOME will be a high-tech application in the service of citizens. Its use will result to less frequent/ shorter hospitalizations of patients.

- Health Information for the patient. @HOME will feature an Internet-based service where patients and their carers will be able to monitor their progress and obtain useful advice and information for their recovery.

- Increased capacity and income for hospitals. A hospital that makes good use of @HOME has the potential to treat more patients. A patient dispatched earlier leaves an empty bed, which can be occupied by another patient. It is estimated that hospitals may treat as many as 10% more patients per year without investment on new buildings.

5.9 DAPHNE

"Detection of Activity Performances for Health with New Equipment"

The DAPHNE project is funded by the EC under the IST Programme with reference number "IST-2000-25107". It was started in January 2001 and was completed by end of December 2002.

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5.9.1 Project Definition

One of the most growing progressive neuromotory diseases is Parkinson disease that affects young and elderly people; the researches carried out in the framework of neuromotory pathologies have generated methodologies for multiparametric analysis, allowing a quantitative measurement of neurological and psycho-physical health state.

Albeit the first application of the mentioned studies was the monitoring of Parkinson progress state as well as other neuromotory pathologies, such methodologies can also be applied to monitor the soundness of healthy citizens. These measures are an excellent method to show reactive parameters changes caused by stress, fatigue, emotional states, drugs and alcohol; therefore, the aim of the present project is to develop a system able to quantify reactive parameters creating a system that can be put in a small equipment with data wireless transmission to operational health centers.

5.9.1.1 Objectives

The main objective of the present project is to promote the self care trough the development of a portable and computerized instrument that measures some fundamental parameters of citizen's reactive capabilities.

The aim is to give the possibility of performing continuous and autonomous monitoring of the health state at home assuring, thanks to a telecommunication system, a constant remote control. Therefore on one hand, the patient affected by a neuromotory pathology (like Parkinson disease) can be daily assisted by clinicians who can intervene if the parameters are out of range or change the therapy; on the other hand, the healthy citizen can prevent any possible illness by constantly screen his/her health state acquiring awareness on how the life style can influence the psychophysical soundness.

5.9.1.2 Expected results

Final product realization with clinical validation after the system revision by means of end user feedback. The expected result is the development of a portable system oriented to self-care, with clinical validation and a high technological value.

5.10 BodyLife

"Intelligent system monitoring the body composition for better healthy life style and illness prevention"

The BodyLife project is funded by the EC under the IST Programme with reference number "IST-2000-25410". It was started in January 2001 and was completed by end of December 2003.

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5.10.1 Project Definition

There is a real medical need for non-invasive, but reliable and simple method for measuring body composition since weight measurement is largely insufficient. The increase of quality and type of data available for the determination of the actual status of the body is a key point for the optimization of these non-invasive techniques.

BodyLife aims at developing a system that will measure the body composition for the whole body and separately for different parts of it (arms, legs, trunk) at home, surgery, clinic or hospital. The use of the equipment in more advanced level, will involve more sophisticated equipment with imaging tools.

5.10.1.1 Objectives

The main objective of the project is the development and the validation of reliable methods, intelligent instrumentations, sensors and software for determination of the body composition for better life style and illness prevention. The scientific and technological methods through which those objectives are to be achieved will be:

- Innovative ultrasonic and electromagnetic ones as well as
- Sensors coupled with an intelligent platform or system with an appropriate representation of the data for non-expert end-users, and interfaced with a medical multimedia database.

Ultimately it is hoped that body composition data combined with the overall clinical and psychological profile of the individuals will contribute to the improvement of their respective health provision and as well as their quality of life.

5.10.1.2 Work description

Two kinds of intelligent systems will be developed, one compact home PC platform (portable PC, desktop PC or PC rack) to be used by the doctors and their patients in close collaboration, in health care centers, surgeries or clinics. The second system will be a battery-operated device that will enable patients to perform some measurements themselves at home. It will be

equipped with adapted software for easy interpretation by the patients and will have the ability to connect via an RS232 serial port with an external PC and printer.

This second equipment will be more dedicated to healthy-lifestyle and illness prevention with limited functions analysis. The system as a whole will integrate different data acquisition, processing and imaging electronic boards. It will include a large range of sensor configurations (electrodes and inductive sensors adapted for analyzing different parts of body), including a large coil for total body measurement, as well as different ultrasonic probe configurations.

Punctual ultrasonic and electromagnetic sensors will give local information for the parts tested; encircling coils will be mainly used as TOBEC system to determine the total water content of the whole body, or of its individual part tested (specific coils adapted to arms, legs, trunk). By moving the coil along the part of body, the doctor can also observe the different variations of composition observed.

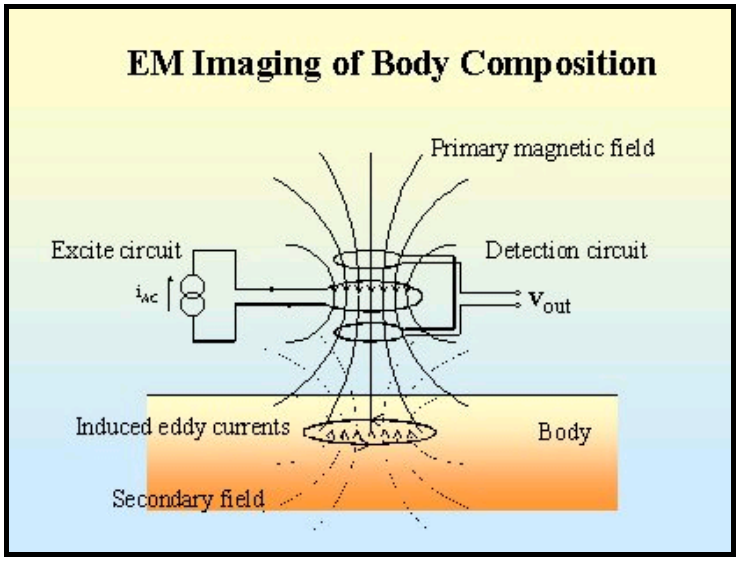

Figure 25 BodyLife EM Imaging of Body Composition

As to the possible migration of the project, there is a plan to further exploit opportunities arising from other potential medical or industrial applications and to promote the Consortium's scientific and technological excellence as well as the collaboration with other research centers.

5.10.1.3 Expected results

- A demonstrator platform (for hospitals, clinics and surgeries) and system with adapted (electromagnetic or ultrasonic) sensors connected to a medical information software package platform for use by the patients

- Medical multimedia database with adapted software interface to communicate with the equipment developed

- Medical knowledge information systems that will connect body composition data to health combined with the overall clinical and psychological condition of the patient e.g. recommendations on lifestyle, on-line medical services.

5.11 CHS

"Distance Information Technologies For Home Care - The Citizen Health System (CHS)"

The CHS project is funded by the EC under the IST Programme with reference number "IST-1999-13352". It was started in January 2000 and was completed by end of December 2002.

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5.11.1 Project Definition

CHS deals with the development of systems and services for the citizen. More specifically, it aims in the development of personal health services that can be used from home that communicate with the rest of the information infrastructure. These personal health systems shall be developed in the areas of diabetes, heart failure and post-trauma patients.

CHS is expected to support the EU policy on health promotion through the increase of awareness to the citizen of the use of micro-devices and it solutions for monitoring and consulting. The project also aims in developing new generation telemedicine systems and services for tele-consultation and provision of tele-care diabetes, heart failure and post-trauma patients.

5.11.1.1 Objectives

CHS will develop a new generation telemedicine services for home care that will improve quality of health care an and create a large new IT market by involving every single home and every single health care provider.

Development of user acceptable MMIs and GUIs for easy and error free data fusion, browsing, education, new genera generation decision support systems for artifact rejection and finally integration techniques for developing a comp complete health system for home care are CHS's IT related objectives. Cost effectiveness, citizen involvement in health care delivery via micro-devices, a continuing education process, better diagnosis opportunities for the clinical staff and the development of a transatlantic network for home care delivery and exchange of data and experiences are the quality of health care objectives of CHS's. Finally the economic and business objectives of CHS aim at the creation of a major market for health care delivery, analogous to that of the INTERNET market.

5.11.1.2 Work description

CHS will consist of a clinical centre unit (deployed where home care is coordinated) and a home care unit at the patients' home.

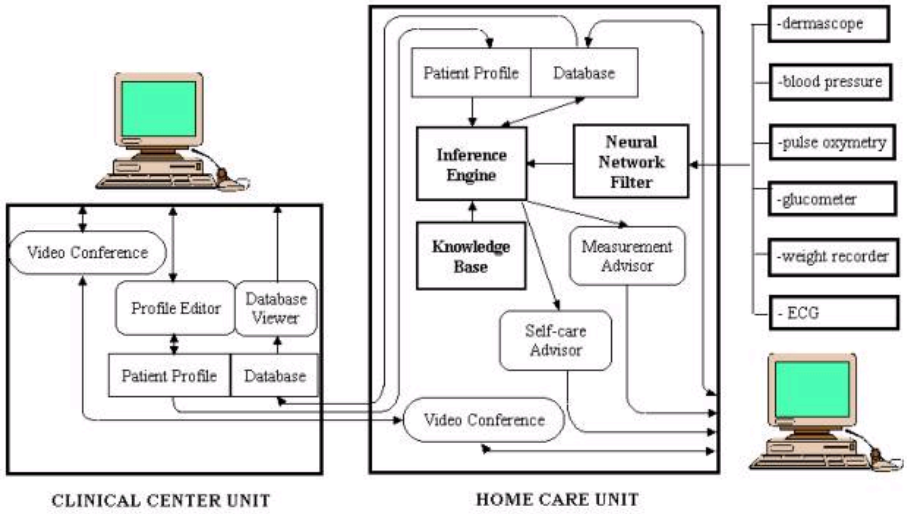

Figure 26 Overview of the Citizen Health System (CHS)

The home care unit will be a mobile personal computer equipped with telemedicine measurement devices, data management and decision support software, and connection with the hub unit of the supporting clinical centre. It will provide a variety of care support functions including:

1. Reception of information from a variety of measurement devices
2. Step-by-step instruction for the patient to perform measurements
3. Decision support to identify and correct measurement problems
4. Storage of collected information in a patient data base
5. Forwarding and downloading data to and from the clinical centre unit
6. Decision support to treat simple clinical problems that do not require direct consultation with clinicians (physicians or nurses).

Data management will integrate the patient profile, a home monitoring database, and store-forward technology while two types of decision support technologies will be applied in the home care unit of the system: a neural networks to recognize artifacts and faulty measurement situations; and a rule-based decision support system for the management of measurement errors and assistance in correcting measurement problems.

The clinical centre unit will assist a variety of functions in co-operation with the home care unit through profiling of patients and identifying their particular health care needs, including monitoring, selecting and configuring the home care unit for the patient to use, educating patients about measurements and the use of home care unit, providing ongoing support in form of regular home visits and telephone consultations, periodic download from home care units and review of collected information, and emergency telephone/video conferences and other support in case of unexpected problems.

5.12 CHRONIC

"An Information Capture and Processing Environment for Chronic Patients in the Information Society"

The CHRONIC project is funded by the EC under the IST Programme with reference number "IST-1999-12158". It was started in January 2000 and was completed by end of June 2002.

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5.12.1 Project Definition

Our goal is to develop an information environment for the care of chronic patients as an efficient alternative to conventional institutional care, that will improve their quality of life while reducing the huge healthcare costs in the European Union and getting an optimum benefit of information systems technology and culture.

5.12.1.1 Objectives

We propose an innovative information environment based on two elements: A chronic care management network (the entry point to any requirement for health resources) and a patient monitoring environment (to capture and process at home all relevant information).

The objective of this proposal is to develop a new European model for the care of chronic patients, based on an integrated information technology environment, that consist of:

1. Safe, friendly and reliable personal home-based health monitoring systems, providing unrestrained non-intrusive connectivity to the patient with efficient communication packaging. They will include sensors and intelligent devices for data handling, decision making and patient status assessment.

2. Information systems in open communication platforms, adapted to the wide heterogeneity of user needs and profiles, based on available infrastructure, that will allow the access to information for case management, teleconsultation, advising, rehabilitation and patient training programmes.

3. Tools and systems, connectable to already available health information systems, to support the daily work of service providers and managers: diagnostic/therapeutic decision making, clinical guidelines and protocols, and services quality assessment.

The application to other scenarios (acute, terminal patients, elderly, healthy) is emphasized. The chronic care platform proposed will facilitate the outsourcing of services, and thus the growth of new health-related industries. The results will be evaluated in three pilots focused on highly prevalent chronic disorders: cardio-vascular, neurologic and respiratory, the top three causes of mortality by 2020. This chronic care model can be also extended to other scenarios like acute patients or even in a healthy environment, for prevention.

5.13 D-LAB

"Organising The Decentralisation Of Clinical Testing Outside Laboratories"

The D-LAB project is funded by the EC under the IST Programme with reference number "IST-1999-12502". It was started in January 2000 and was completed by end of December 2001.

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5.13.1 Project Definition

The project D-LAB focuses its research on the organization, control and management of diagnostic tests outside the traditional Central Laboratory, in Points of Care Testing (POCT). In this area D-LAB aims also at contributing to a paradigm shift in the organization of the services of diagnostic testing, through the development of the concept of Virtual Laboratory to integrate and monitor all the testing activities performed inside Hospitals, at Medical Offices, at Pharmacies and at Health Care Centers in general.

5.13.1.1 Objectives

Development of the concept of Virtual Laboratory, centered on:

- the issue of integration of information through the development of a "middleware" that integrates the information produced at distributed POCT's with Information Systems of the Healthcare Organization
- the interconnection and usability of POCT equipments
- "standardization" issues with the definition of clinical protocols and guidelines for POCT activity in a distributed environment
- defining guidelines for the development of an end-user interface for POCT medical equipment, as this is a critical issue for the acceptability of the D-LAB platform by non-specialized operators (non-laboratory staff).

5.14 MOEBIUS

"MObile Extranet Based Integrated User Services"

The MOEBIUS project is funded by the EC under the IST Programme with reference number "IST-1999-11591". It was started in January 2000 and was completed by end of December 2001.

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5.14.1 Project Definition

Recent time has witnessed the explosion in the business world of the concept of Intranet and, as a natural evolution, of extranet, i.e., the use of Internet Communication paradigms to allow access to relevant (private) information to closed user groups from the outside world, over the public Internet. Typical extranet application scenario involves employees of a company, or more generally of a structured organization (e.g. a hospital) who need to access internal information or services when physically far from the organization's home premises.

In this context, the MOEBIUS proposal seeks to identify an integrated mobile service platform, i.e. the Mobile Extranet platform focusing on a global co-ordination of micro- (i.e., Layer 2) and macro (i.e., Layer 3) mobilities provided by the state-of-the art and future mobile systems (SMS, GPRS, circuit data, Cellular IP, etc.) with Mobile IP, as well as on the provision of security mechanisms for this service platform supporting a variety of application sectors..

5.14.1.1 Objectives

- To integrate an IP-based, Mobile Extranet platform, exploiting state-of-the art technologies in the telecommunication and in the information technology areas
- To use the platform for applications in different sectors, i.e., health care, and remote control, in order to demonstrate the benefits for end users in public health, business and residential environments
- To verify, on the overall platform, the inter-operations of the different technologies
- To identify the impact on the terminal side protocols and implement the relevant changes
- To provide of the security infrastructure at both network and application level;

- To contribute to relevant standardization bodies

5.14.1.2 Work description

GPRS will be mainly considered in the experimental phase of the project for Layer 2 mobility, since it is the most attractive solution in the short to medium term. Nevertheless, the Mobile Extranet concept defined in MOEBIUS will not be confined to the use of GPRS. Evolutionary solutions, such as Cellular IP and UMTS, will be considered by the study as part of the project from an architectural and systems engineering point of view.

The Mobile Extranet will be defined as an open platform to be supported by many network operators in a cost effective, competitive environment and the users can move among the various areas during their communication in a seamless way.

Project experiments will be mainly performed with applications deriving from one of the most mobile sensitive sectors, i.e. the healthcare sector. Additional applications will be considered in business and residential areas to prove the generality of the Mobile Extranet approach.

5.15 M2DM

"Multi-Access Services for telematic Management of Diabetes Mellitus"

The M2DM project is funded by the EC under the IST Programme with reference number "IST-1999-10315". It was started in January 2000 and was completed by end of December 2002.

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5.15.1 Project Definition

This project intends to provide a sustainable service care to residential and mobile diabetic patients aiming to increase the quality of patient's care through improving communication between patients and caregivers.

M2DM incorporates new telemedicine services that emphasize the provision of personal health care 24 hours a day and provides new means to information access to physicians and patients. A Multi-Access Server (MAS) is defined in the project comprising a full range of non-expensive and widely accepted information technologies offering to users a universal, easy-to-use, on-line and cost-effective access to telemedicine and information services.

M2DM aims at providing diabetic patients and health care providers with the Multi-Access service with the goal of increasing the quality of care through improving communication between patients and caregivers. This service will be based on Computer Telephony Interfaces and Web-based technology.

M2DM will provide the capability of effectively managing the knowledge necessary for the complex and distributed process of chronic disease care, providing technological instruments and infrastructures to give the right knowledge to the right people in the right form at the right time.

A distinguished feature of M2DM will be its capability of managing the knowledge necessary for Diabetes Management. Several advanced methods for data analysis, evidence- and knowledge pooling and knowledge management will be investigated in the project, and finally integrated in the Multi-Access services. Moreover, the services will be customized to meet the needs of final users by exploiting the knowledge management approach studied in the project.

5.16 MOBI-DEV

"Mobile devices for healthcare applications"

The Mobi-Dev project is funded by the EC under the IST Programme with reference number "IST-2000-26402". It was started in January 2001 and was completed by end of June 2003.

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5.16.1 Project Definition

Mobi-Dev is a European effort which addresses the long standing and increasingly demanding need of health professionals to effectively, accurately, securely, from anywhere, anytime and in user-friendly way communicate with patients' databases located within hospitals, private offices, laboratories or pharmacies.

To this end, an innovative integration of state of the art but also upcoming enabling technologies will be combined to combine the new generation mobile communication palm device for health professionals. Natural language understanding, electronic signature, smart card reader and UMTS and Bluetooth transceiver technologies will be integrated. Access restrictions and secure data transmission will be guaranteed.

Mobi-Dev's marketable product will be exploited by business partners beyond the end of the Project in the European market, to the benefit of health care industry and quality of health of European citizens.

5.16.1.1 Objectives

The objective of Mobi-Dev Project is to provide the new generation mobile devices for health care professionals. Mobi-Dev will ease and improve at many levels the daily routine of doctors, nurses, researchers, both inside and outside healthcare organizations, thanks to its innovative integration of new technologies, including mobile communication devices, natural language understanding and electronic signature.

It will provide:

- Unlimited availability of patients data with the possibility to edit them any time and from everywhere
- Possibility to retrieve in real time lab analysis results, without having to go to the information database storing them
- Possibility to input data into structured format by direct speech in natural language
- Input data authentication by electronic signature of the person that inputs them
- Alarm features (early warning or red flag) which can be customized to patients clinical needs
- Possibility to reuse the same Mobi-Dev by different health professionals

5.16.1.2 Work description

The Mobi-Dev system consists of a platform with a client-server architecture integrated with SW applications. It will provide the clinical staff with portable devices (based on palm PCs) wirelessly connected to different information databases, able to perform real time data management. An Internet based system will be set up to exchange clinical data between the Mobi-Dev portable devices and various kind of relevant information databases (HIS, GPs personal databases, clinical laboratories and pharmacy databases).

Web interfaces with HIS will be realized using standard database interfaces products. The palm PC with microphone will be integrated with a smart card reader, a Bluetooth transceiver and an UMTS one. Central servers will manage the mobile devices and perform the time/memory consuming tasks, as the language understanding; the smart card will permit electronic signing input data. Bluetooth connection will permit the use of Mobi-Dev inside the hospitals in conformity with the most restrictive and recent security requirements.

Security and privacy issues are of the main importance for the Project and put under the strict control of well-established experts. Accordance to the user requests and market demand will be assured by users involvement in the system definition and by a user centered system evaluation.

5.16.1.3 Expected results

Key aspects of the project's development will be the successful achievement of the main objectives described above (assessed in measurable way). There is the possibility to affect the information flow in the clinical management of the patient, and the hospital management and to reduce costs and to increase the efficiency, comprehensive management and quality of care for European citizens.

5.17 TelemediCare

"Telematic Support for Patient Focused Distant Care"

The TelemediCare project is funded by the EC under the IST Programme with reference number "IST-1999-10754". It was started in January 2000 and was completed by end of June 2002.

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5.17.1 Project Definition

The TelemediCare system will improve the quality of home-based care and medical treatment, through the development of a new generation of open platform telemedicine solutions.

The project will introduce Medical Net Instruments, which implies that patients will receive 24-hour real-time medical monitoring in their own home. Advanced and reliable sensors on the body will supply high quality medical data. These data are sent to the patient's computer through wireless communication. The computer will analyze and store the data. Intelligent software will trigger medical supervision, treatment or care by establishing two-way communication over the Internet with remote, "arrive-on-call" treatment/care providers.

5.17.1.1 Work description

The TelemediCare project involves several areas of research and development in the field of telemedicine:

- Four, miniaturized, non-intrusive medical sensors on the patient's body will provide high quality real-time data on ECG, blood pressure, oximetry and temperature. The technological platform for these sensors will be open for later development of a wider range/family of medical sensors.
- The Local Patient Computer (LPC) will be the bridge between each patient and the surrounding treatment and care infrastructure. The computer will store high-resolution data in a Local Patient Record.
- Reliable wireless communication between sensors and the LPC. Freedom from wires improves well-being and mobility of monitored patients.
- Software services enable integration of binary objects, such as raw/analyzed data, images etc., into the remote health care information system.
- The LPC will comprise an artificial intelligence that is able to trigger services from the treatment/care infrastructure on the basis of the evaluation of single or multiple elements in the patient's medical status.
- The project will develop a secure web-based interface between the LPC and the monitoring treatment/care providing infrastructure. This will also allow for seamless integration with existing Hospital Information Systems.

5.18 MobiHealth

"Mobile Health Care"

The MobiHealth project is funded by the EC under the IST Programme with reference number "IST-2001-36006". It was started in May 2002 and is to be completed by end of October 2003.

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http://www.mobihealth.org/	

5.18.1 Project Definition

According to the MobiHealth website, the "MobiHealth project aims at developing and trialing new mobile value-added services in the area of healthcare, thus bringing healthcare to the patient".

5.18.2 The MobiHealth BAN system

The project is focused around developing what they call a generic Body Area Network – BAN. This is a network of connectable sensors that are worn on the patients' body. Measurements are done continuously, and results are transmitted wirelessly to their doctor, hospital or health call center while the patients remains free to live their daily lives.

Figure 27 MobiHealth Operational Overview

As of the website, "The MobiHealth system will allow patients to be fully mobile whilst undergoing health monitoring. The patients wear a lightweight monitoring system - the MobiHealth BAN (Body Area Network) - which is customized to their individual health needs. Sensors and actuators will continuously measure and transmit vital constants along with audio and video to health service providers and brokers, improving from one side the quality of life of patients and allowing, from the other side, the introduction of new value added services in the areas of disease prevention, disease diagnosis, remote assistance,

clinical research, para-health services, physical state monitoring (sports) and even clinical research."

"The MobiHealth BAN system will also target the support of fast and reliable remote assistance in case of accidents, enabling paramedics to send reliable vital constants data as well as audio and video from the accident site to a health care centre."

5.18.3 Generic BAN software platform (BAN OS)

From a technical point of view the MobiHealth project aim to develop a generic software platform (BAN OS) that will take care of all issues related to sensor connectivity, security, quality of service and hand-over across diverse hardware platforms. The options for hardware to support the OS include programmable mobile phones and PDAs.

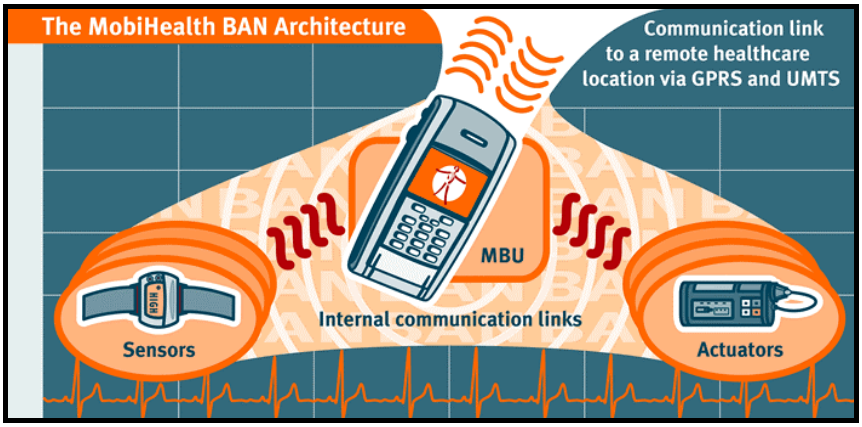


Figure 28 MobiHealth BAN Architecture

"The MobiHealth service and application platform enables monitoring, storage and transmission of vital signs data coming from the patient BAN. The platform supports flexible personalization of services and ensures appropriate intervention in response to certain conditions or combinations detected in the vital signs measurements."

5.18.4 Trials

A great focus of the MobiHealth project is to perform trials to evaluate the system. Trials are to be conducted within areas of acute trauma care, chronic and high-risk patient monitoring and monitoring of patients in home-care settings.

Randomized controlled trials are performed in Germany, the Netherlands, Spain and Sweden and are scheduled to start in May 2003 and go into result evaluation in July-September 2003. The trials are evaluated in terms of accuracy and validity of measurements, usability of the GPRS and UMTS networks, business and market potentials and also for social and ethical effects.

6 Standards and organizations

Standards are crucial for interoperability between products. When products use the same standard interface they can be used together and the buyer is free to choose between alternative products to select one that best suits his needs.

In this chapter we list relevant standards and standards organizations. Organizations are developing or evaluating and suggesting standards for various medical equipment. This list is not fully complete, but shows some of the most important standards and organizations. The list include:

- KITH
- HL7
- IEEE 1073
- DICOM
- EDIFACT
- NCCLS
- CEN/TC251
- MoHCA
- ebXML
- MedCom
- CEN pre-standard ENV 12538
- CEN VITAL ENV 13734

6.1 KITH

KITH is a collaborative effort within the Norwegian health care service whose core services are standardization, requirements specification and counseling. According to the KITH website [34], KITH shall be the main centre of competence in Norway for the extensive, efficient and secure implementation and use of information and communication technology in health care.

KITH has as its main objective to ensure the implementation and use of information and communication technology that enables the health care services to fulfill their common needs and objectives for efficient and secure information management, collaboration and development.

KITH is owned by the health care services. The owners are The State/The Ministry of Health (40%), The Norwegian Association of Local and Regional Authorities (30%) and The County of Sør-Trøndelag (30%).

KITH is establishing the fundament for extensive, efficient and secure use of ICT in health care:

- **Electronic commerce and co-operation**
  Seamless electronic commerce and co-operation between the health care actors using EDI, e-mail, WWW and other technologies

- **Common information resources**
  Information which is used frequently, in various contexts and by many

actors, should be regarded as common resources and should be made sharable in an effective and secure manner

- **Information networks**
  Establishing and developing a common, secure and Internet-based ICT-infrastructure in health care - a national health information network

- **Health information systems**
  Clinical, patient administrative and administrative information systems, including electronic health care records

- **Secure information management**
  Security, privacy and quality of information management in health care, focusing both on technological, organizational and ethical aspects

- **Strategic planning**
  We initiate and participate in processes for strategic planning in health care, focusing on the prospects (and limitations) of ICT in relation to the strategic objectives.

6.2 HL7

Health Level Seven develops specifications. The most widely used being a messaging standard that enables disparate healthcare applications to exchange key sets of clinical and administrative data.

According to the HL7 website [74], Health Level Seven is one of several ANSI-accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. Most SDOs produce standards (sometimes called specifications or protocols) for a particular healthcare domain such as pharmacy, medical devices, imaging or insurance (claims processing) transactions. Health Level Seven's domain is clinical and administrative data. Our mission is: *"to provide standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services. Specifically, to create flexible, cost effective approaches, standards, guidelines, methodologies, and related services for interoperability between healthcare information systems."* [75]

In an article published in Healthcare Informatics April 2000, David John Marotta, co chair of the Health Level Seven Education and Implementation Subcommittee, talks about HL7 [76]:

> *"As a standard, HL7 is widely accepted and used. Since its creation, this standard has grown from a user-based consensus standard to an international standard with affiliate groups in Australia, Canada, Finland, Germany, India, The Netherlands, New Zealand, South Africa and the United Kingdom. Named as the most widely used standard among healthcare providers in a 1998 survey of 153 CIOs sponsored by the College of Healthcare Information Management Executives (CHIME) and HCIA Inc., HL7 has cut costs and facilitated interconnectivity.*
>
> *A 1998 survey found the HL7 standard in use in more than 95 percent of hospitals with more than 400 beds. Overall, more than 80 percent of the respondents in that study reported using HL7 in their IS departments with another 13.5 percent planning to do so.*

In recent years, HL7 has grown to be much more than the clinical messaging for which it was originally developed. XML technology offers users of the HL7 standard a plethora of additional possibilities to tighten medical interface specifications and expand data exchange possibilities. XML functionality will extend HL7 to support both HL7 messages and HL7 document encoding. The strengths of XML allow users to write a tagged document once but use it in various ways to give an HL7 XML document extended life beyond that of the Internet and a traditional HL7 message.

In HL7 XML, everything from a patient's online medical record to a pharmacy's formulary could be represented and exchanged in an HL7 XML document. HL7's Patient Record Architecture in version 3.0 will allow a standard format for exchanging a patient's medical records between different hospital systems or even different hospitals."

6.3 IEEE 1073

IEEE 1073 [77] standards for medical device communication provide plug-and-play interoperability at the point-of-care, optimized for the acute care environment. The IEEE 1073 General Committee is chartered under the IEEE Engineering in Medicine and Biology Society, and works closely with other national and international organizations, including HL7, NCCLS, ISO TC215, CEN TC251, and ANSI HISB. [78]

Medical device communication standards are works in progress and hold the promise of universal communication among medical electronic devices and information systems.

To address the medical device plug-and-play interoperability problem, a single communications standard is needed. Software engineers designing medical equipment could use such a standard to implement external interfaces once for all models. POC MDC, or MIB (medical information bus), standards are poised to fill this need. MIB is the common name for a series of standards published or under development by the Institute of Electrical and Electronics Engineers as the IEEE 1073 standard for medical device communications. Intended to bring a wide range of medical devices under its purview, these standards aim to encompass transparent plug-and-play interoperability, ease of reconfiguration, and ease of use. [79]

6.4 DICOM

DICOM [80] is an acronym for Digital Imaging and Communications in Medicine.

The American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) formed a joint committee to develop a Standard for Digital Imaging and Communications in Medicine.

This Standard is developed in liaison with other Standardization Organizations including CEN TC251 in Europe and JIRA in Japan, with review also by other organizations including IEEE, HL7 and ANSI in the USA.

ACR and the NEMA formed a joint committee in 1983 to develop a standard to:

- Promote communication of digital image information, regardless of device manufacturer

- Facilitate the development and expansion of picture archiving and communication systems (PACS) that can also interface with other systems of hospital information

- Allow the creation of diagnostic information data bases that can be interrogated by a wide variety of devices distributed geographically.

This Standard has been developed with an emphasis on diagnostic medical imaging as practiced in radiology, cardiology and related disciplines; however, it is also applicable to a wide range of image and non-image related information exchanged in clinical and other medical environments. [81]

6.5 NCCLS

NCCLS [82] is a global, interdisciplinary, non-profit, standards-developing and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. NCCLS is based on the principle that consensus is an efficient and cost-effective way to improve patient testing and services.

NCCLS develops and publishes standards and guidelines through a unique consensus process involving government, professions, and industry. All NCCLS consensus documents are voluntary, but in certain instances, regulatory agencies or accrediting bodies will require that a specific NCCLS standard or guideline be followed. Therefore, in order for an institution to meet the regulatory or accreditation requirements, following the standard or guideline becomes mandatory.

6.6 CEN/TC251

CEN/TC 251 [83] is the body within Europe mandated to develop standards for Health Informatics.

The organization defines it's own scope as:

> *"Standardization in the field of Health Information and Communications Technology (ICT) to achieve compatibility and interoperability between independent systems and to enable modularity. This includes requirements on health information structure to support clinical and administrative procedures, technical methods to support interoperable systems as well as requirements regarding safety, security and quality."* [84]

The objective of CEN/TC 251 is to develop standards required in the field of Health Information and Communications Technology (ICT) to support the existing clinical practices of European healthcare and emerging new ways of providing services to the citizens in the information society. It is recognized that in the era of the global information society, it is

important that while focusing on the European needs of health actors and suppliers of systems, we should promote international solutions through ISO whenever feasible.

6.7 EDIFACT

EDIFACT (Electronic Data Interchange For Administration Commerce and Transport) is an organization which develops the United Nations rules for Electronic Data Interchange. These rules consist of a set of internationally agreed standards, a directory and guidelines for the electronic interchange of structured data. This applies in particular to data related to goods and services exchanged between independent computerized information systems. Recommended within the framework of the UN, the rules are published in the United Nations Trade Data Interchange Directory (UNTDID).

Electronic Data Interchange facilitates the electronic exchange of structured business and engineering data between trading partners using standard messages. It is used, for example, between manufacturers, wholesalers, distributors, retailers, shippers, consignees, carriers, banks, insurers and government agencies. EDIFACT aims to harmonize all the EDI standards that currently exist across the numerous industrial and commercial sectors. One can anticipate that EDIFACT will be adopted as the EDI language used by all industrial and commercial sectors and administrations worldwide. [85]

6.8 MoHCA

The Mobile Healthcare Alliance is a not-for-profit association that tries to create communication between different parties within health care regarding mobile healthcare. As described in the document *Introduction to MoHCA and Mobile Health* [86], the mission of MoHCA is to:

> *"Promote the adoption of mobile technologies to support the delivery of higher quality healthcare."*

Their vision is defined in the same document:

> *"MoHCA provides an active forum in which all interested healthcare industry participants can identify and advance common priorities relating to the implementation, standardization, security, and regulation of portable devices, wireless technologies, and mobile workflow processes."*

MoHCA provides a forum for vendors and providers, organizations and individuals, public and private sectors to [87]:

- Exchange ideas, promote learning
- Identify healthcare issues, needs and requirements
- Seek and share solutions
- Develop best practices, guidelines and model policies
- Promote development and use of wireless standards
- Influence and respond to government regulations
- Develop and communicate positions

In a press release on the MoHCA website [88] the positive effect of the diversity of the members is mentioned:

"The diverse membership of MoHCA is unified by a shared interest of ensuring that mobile applications are incorporated into healthcare processes with appropriate regard for the privacy, confidentiality, and security of health information.

MoHCA Members include wireless carriers, application developers, device manufacturers, system integrators, technology consultants, practitioners, healthcare professional societies, and healthcare organizations."

6.9 ebXML

The mission of ebXML is stated on their website [89]:

"To provide an open XML-based infrastructure enabling the global use of electronic business information in an interoperable, secure and consistent manner by all parties." [90]

The same website describes ebXML in this way:

ebXML (Electronic Business using eXtensible Markup Language), sponsored by UN/CEFACT and OASIS, is a modular suite of specifications that enables enterprises of any size and in any geographical location to conduct business over the Internet. Using ebXML, companies now have a standard method to exchange business messages, conduct trading relationships, communicate data in common terms and define and register business processes.

ebXML Value

- Provides the only globally developed open XML-based Standard built on a rich heritage of electronic business experience.
- Creates a Single Global Electronic Market Enables all parties irrespective of size to engage in Internet-based electronic business. Provides for plug and play shrink-wrapped solutions.
- Enables parties to complement and extend current EC/EDI investment expand electronic business to new and existing trading partners.
- Facilitates convergence of current and emerging XML efforts.

ebXML delivers the value by

- Using the strengths of OASIS and UN/CEFACT to ensure a global open process.
- Developing technical specifications for the open ebXML infrastructure.
- Creating the technical specifications with the world's best experts.
- Collaborating with other initiatives and standards development organizations.
- Building on the experience and strengths of existing EDI knowledge.
- Enlisting industry leaders to participate and adopt ebXML infrastructure.
- Realizing the commitment by ebXML participants to implement the ebXML technical specifications.

Other industry organizations, such as the Automotive Industry Action Group, Health Level Seven, Open Applications Group, Open Travel Alliance, SWIFT and formal international and North American EDI standards bodies, have also been active participants in the ebXML initiative.

7 Communication technologies

This chapter is a quick reference to a number of communication technologies. The details for each technology will be described according to the requirements to communication technology established in chapter 3.2.

The technologies that are described in this chapter are:

1. GSM
2. GPRS
3. UMTS
4. SMS
5. MMS
6. Bluetooth
7. ZigBee
8. WLAN IEEE 802.11b
9. Analog modem and ISDN

7.1 GSM

GSM – Global System for Mobile Communications – is a digital cellular communications system developed in order to create a common European mobile telephone standard. It has been rapidly accepted worldwide, and GSM is now the most popular mobile phone system in the world, accounting for more than 72 % of the world's digital mobile phones. According to a press release by the GSM Association in January 2003 [39], there are more than 787 million mobile phones in use in 190 countries today. The phenomenal success in mobile telecommunications is due in large to GSM.

7.1.1 Bandwidth

GSM users can send and receive data at rates up to 9600 bps in normal operation. High Speed Circuit Switched Data (HSCSD) [40] operation is also supported utilizing up to four traffic channels. In this way data rates between 28.8 kbps and 43.2 kbps are achieved.

7.1.2 Latency

Data transfer across an established line is done in real-time. The establishment of the line may take anywhere from a second to minutes depending on the distance of the call and how quickly the call is answered in the receiving end.

7.1.3 Availability

In general the GSM network is highly available and reliable. Although, as with any wireless technology, there is the possibility of loss of radio link due to coverage problems or interference.

7.1.4 Security

From the outset, GSM has been a system designed with stringent levels of inbuilt security. With constantly enhanced transmission protocols and algorithms added to the flexible and future proof platform, GSM remains the most secure public wireless standard in the world. [43]

7.1.5 Ubiquity

The GSM network is open to the general public.

One of GSM's key strengths is its international roaming capability, giving consumers a seamless service in over 168 countries. Roaming is the ability to use your own GSM phone number in another GSM network. You can roam to another region or country and use the services of any network operator in that region that has a roaming agreement with your GSM network operator in your home region/country.

7.2 GPRS

According to the article *What is General Packet Radio Service* at the GSM World website [43], The General Packet Radio Service (GPRS) is a new non voice value added service that allows information to be sent and received across a mobile telephone network. It supplements today's Circuit Switched Data and Short Message Service.

Rather than sending a continuous stream of data over a permanent connection, packet switching only utilizes the network when there is data to be sent.

It brings Internet Protocol (IP) capability to the GSM network for the first time and enables connection to a wide range of public and private data networks using industry standard data protocols such as TCP/IP and X.25. GPRS is extremely efficient in its use of scarce spectrum resources and enables GSM operators to introduce a wide range of value added services for market differentiation.

7.2.1 Bandwidth

Theoretical maximum speeds of up to 170 kilobits per second (kbps) are achievable with GPRS using all eight timeslots at the same time. This is about three times as fast as the data transmission speeds possible over today's fixed telecommunications networks and ten times as fast as current Circuit Switched Data services on GSM networks.

Achieving the theoretical maximum GPRS data transmission speed of 170 kbps would require a single user taking over all eight timeslots without any error protection. Clearly, it is unlikely that a network operator will allow all timeslots to be used by a single GPRS user. Additionally, the initial GPRS terminals are expected be severely limited - supporting only one, two or three timeslots. The bandwidth available to a GPRS user will therefore be severely limited. As such, the theoretical maximum GPRS speeds should be checked against the reality of constraints in the networks and terminals. The reality is that mobile networks are always likely to have lower data transmission speeds than fixed networks.

GPRS does impact a network's existing cell capacity. There are only limited radio resources that can be deployed for different uses- use for one purpose precludes simultaneous use for another. For example, voice and GPRS calls both use the same network resources. The extent of the impact depends upon the number of timeslots, if any, that are reserved for exclusive use

of GPRS. However, GPRS does dynamically manage channel allocation and allow a reduction in peak time signaling channel loading by sending short messages over GPRS channels instead. [43]

In reality, neither phones or networks will give you the theoretical bandwidth of 170 kbps. The Nokia 3650 phone states a GRPS transfer rate of up to 40.2 kbps. [98]

7.2.2 Latency

GPRS packets are sent in all different directions to reach the same destination. This opens up the potential for one or some of those packets to be lost or corrupted during the data transmission over the radio link. The GPRS standards recognize this inherent feature of wireless packet technologies and incorporate data integrity and retransmission strategies. However, the result is that potential transit delays can occur.

GPRS facilitates instant connections whereby information can be sent or received immediately as the need arises, subject to radio coverage. No dial-up modem connection is necessary. This is why GPRS users are sometimes referred to as being "always connected". [43]

7.2.3 Availability

In general the GSM network is highly available and reliable. Although, as with any wireless technology, there is the possibility of loss of radio link due to coverage problems or interference.

7.2.4 Security

The air interface ciphering in GPRS is at the same level as in an ordinary GSM network without GPRS. The encryption algorithm in GPRS is GEA. The strength of GEA is roughly equivalent of A5 used in ordinary GSM. The authentication process is also done in a similar fashion. [44]

7.2.5 Ubiquity

The GPRS network is open to the general public, but is not as widely available as the GSM network in some countries. In Norway thought, the GPRS radio coverage is nearly identical to that of GSM.

7.3 UMTS

Standing for "Universal Mobile Telecommunications System", UMTS represents an evolution in terms of services and data speeds from today's "second generation" mobile networks. As a key member of the "global family" of third generation (3G) mobile technologies identified by the ITU, UMTS is the natural evolutionary choice for operators of GSM networks. [45]

7.3.1 Bandwidth

The principal advantages of UMTS are the flexible bandwidth, high data rate and high mobility. These features mean that UMTS is suitable for all types of multimedia service. Data rates up to 2 Mbps can be achieved on the basis of CDMA technology. [46]

The actual bandwidth you can achieve with UMTS depends on how many subscribers that are connected to the same network cell as you are, and what type of cell that is.

The cells can offer a maximum data rate of [48]:

Macro cell - 144 kbps in rural with max. speed of 500 km/h
Micro cell - 384 kbps in suburban with max. speed of 120 km/h
Pico cell - 2 Mbps with max. speed of 10 km/h

The data rate is also limited by the available terminals. The Siemens U10 offers a maximum data rate of 384 kbps. This is enough to take full advantage of a Micro cell.

7.3.2 Latency

Real-time classes are defined in UMTS to serve time-critical applications, which require small delay and delay variations. In other situations the need for reliability (correct data) makes the real-time class infeasible to use, and instead data transfer that incorporate radio link retransmissions should be used. [49]

7.3.3 Availability

The UMTS network has not been well tested in practice yet due to delayed development, but in theory the UMTS network is supposed to offer the same high availability and reliability as the GPRS and GSM networks.

7.3.4 Security

The security functions of UMTS are based on what was implemented in GSM. Some of the security functions have been added and some existing have been improved. The application of authentication algorithms is stricter and subscriber confidentially is tighter. [46]

The main security elements that are from GSM [46]:

- Authentication of subscribers
- Subscriber identity confidentially
- Subscriber Identity Module (SIM) to be removable from terminal hardware
- Radio interface encryption

Additional UMTS security features [46]:

- Security against using false base stations with mutual authentication
- Encryption extended from air interface only to include Node-B to RNC connection
- Security data in the network will be protected in data storages and while transmitting ciphering keys and authentication data in the system.
- Mechanism for upgrading security features

7.3.5 Ubiquity

UMTS is conceived as a global system, comprising both terrestrial and satellite components. Multi-mode terminals operating also via 2G systems (e.g. GSM 900 and 1800) will further extend the reach of many UMTS services. With these terminals a subscriber will be able to roam from a private network into a picocellular/micro-cellular public one, then into a wide

area macrocellular network (e.g. a 2G network), and then to a satellite mobile one, with minimal break in communication. [50]

7.4 SMS

The Short Message Service (SMS) is the ability to send and receive text messages to and from mobile telephones. [41]

It is a service within the GSM family of technologies, and is carried by the GSM network and thus has the same availability, security and ubiquity.

7.4.1 Bandwidth

The bandwidth of an SMS message is quite limited. An SMS message can contain 140 bytes of data (or often 160 7-bit characters). This is transmitted in roughly one or two seconds.

7.4.2 Latency

The messages are delivered in a store-and-forward fashion. This means that the network stores the messages until they can be delivered to the destination. The time between sending and delivery can vary from a few seconds and up to a week. There is also a possibility that the message will not be delivered at all. In the usual case the messages are delivered within a few seconds of sending.

7.4.3 Availability

Since the GSM network is used, SMS benefits from the same high availability. In some circumstances where radio coverage is poor, SMS is able to get though when a call can not. This is due to the lower data rate and shorter time span of an SMS message than a voice call.

7.4.4 Security

Again, as the GSM network is used, SMS benefits from the same high level of security.

7.4.5 Ubiquity

The ubiquity of the SMS service is also the same as its bearer technology, GSM. The service is open to the general public, and has roaming capabilities in most of the world.

7.5 MMS

According to GSM World [41], Multimedia Messaging Service (MMS) is a store and forward messaging service that allows mobile subscribers to exchange multimedia messages with other mobile subscribers. As such it can be seen as an evolution of SMS, with MMS supporting the transmission of additional media types:

- text
- picture
- audio

- video
- combinations of the above

It is a service within the GSM family of technologies, and is carried by GSM, GPRS or UMTS, and thus has the same availability, security and ubiquity as these technologies.

7.5.1 Bandwidth

The bandwidth of an MMS message is given by the bearer service, either GSM, GPRS or UMTS.

There is no specified maximum size of an MMS message, but in practice the handset limits the messages by its available memory. As mentioned in the MMS – Frequently Asked Questions as the GSM World website:

> *"There is not a network limit but initial devices are specifying minimum support for 30k - it's really a manufacturer limit concerning the amount of memory"*

7.5.2 Latency

The messages are delivered in a store-and-forward fashion. This means that the network stores the messages until they can be delivered to the destination. The time between sending and delivery can vary from a few seconds and up to a week. There is also a possibility that the message will not be delivered at all. In the usual case the messages are delivered within a few seconds of sending.

7.5.3 Availability

MMS benefits from the same high availability as its bearer services.

7.5.4 Security

MMS benefits from the same high level of security as its bearer services.

7.5.5 Ubiquity

The ubiquity of the MMS service is also the same as its bearer technologies. The service is open to the general public, and has roaming capabilities in most of the world.

7.6 Bluetooth

Bluetooth is a low power radio technology being developed with the objective of replacing the wires currently used to connect electronic devices such as personal computers, printers and a wide variety of handheld devices such as palm top computers and mobile phones.

The development of Bluetooth began in early 1998 and was led by a number of telecommunications and computer industry leaders. The Bluetooth specification will be open and royalty-free, and available to anyone who wishes to use it in their products. [51]

7.6.1 Bandwidth

Although Bluetooth is known to have 1Mbps transmission rate, this is the symbol rate not the realistic file transfer rate. Also the Master-Slave configuration makes Bluetooth not a good real-time, high data rate wireless connectivity compared to other high data rate system. This is not a fault with Bluetooth itself, since it is intended to do relative low-speed wireless connections, with low cost. [52]

Bluetooth operates in the 2.4GHz ISM (Industrial, Scientific, Medical) band and devices equipped with Bluetooth should be capable of exchanging data at speeds up to 720 kbps at ranges up to 10 meters. This is achieved using a transmission power of 1mW and the incorporation of frequency hopping to avoid interference. If the receiving device detects that the transmitting device is closer than 10 meters it will automatically modify its transmitting power to suit the range. The device should also shift to a low-power mode as soon as traffic volume becomes low or ceases altogether. [51]

7.6.2 Latency

Data transfer over a connected link is done in real-time, but there can be some latency in the connecting phase.

Turning off the receiver for longer periods saves power. Any device can wake up the link again, with an average latency of 4 seconds. This is defined by the Link Manager and handled by the Link Controller. [53]

7.6.3 Availability

Designed to operate in a noisy radio frequency environment, the Bluetooth radio uses a fast acknowledgment and frequency hopping scheme to make the link robust. Bluetooth radio modules avoid interference from other signals by hopping to a new frequency after transmitting or receiving a packet. Compared with other systems operating in the same frequency band, the Bluetooth radio typically hops faster and uses shorter packets. This makes the Bluetooth radio more robust than other systems. Short packages and fast hopping also limit the impact of domestic and professional microwave ovens. Use of Forward Error Correction (FEC) limits the impact of random noise on long-distance links. The encoding is optimized for an uncoordinated environment. [54]

7.6.4 Security

Bluetooth is extremely secure in that it employs several layers of data encryption and user authentication measures. Bluetooth devices use a combination of the Personal Identification Number (PIN) and a Bluetooth address to identify other Bluetooth devices. Data encryption (i.e., 128-bit) can be used to further enhance the degree of Bluetooth security. The transmission scheme, fast frequency-hopping spread spectrum (FHSS), provides another level of security in itself, allowing only synchronized receivers to access the transmitted data. [55]

7.6.5 Ubiquity

Bluetooth is designed for very low power use, and the transmission range will only be 10 meters. High-powered Bluetooth devices will enable ranges up to 100 meters. Considering the design philosophy behind Bluetooth, even the 10 meters range is adequate for the purposes Bluetooth is intended for. Later versions of the Bluetooth specification may allow longer ranges. [55]

In the near future Ericsson envisions that users will roam while the system automatically selects the most appropriate technology, whether it is widespread 2G and/or 3G for wide area coverage, wireless LANs in the offices or short range Bluetooth. [56]

7.7 ZigBee

The ZigBee technology is a low data rate, low power consumption, low cost, wireless networking protocol targeted towards automation and remote control applications. ZigBee was created to address a market need for an industry standard to support these applications, as opposed to proprietary solutions. Philips, Honeywell and Invensys joined forces to draft a Market Requirements Definition for ZigBee. The IEEE 802.15.4 committee started working on a low data rate standard a short while later. The ZigBee Alliance and the IEEE decided to join forces and ZigBee became the commercial name for this technology. There are presently more than 20 companies, including major semiconductor manufacturers, IP providers and OEMs active in the ZigBee alliance and helping to define this standard.

The technology fills the need for a simple, easy to deploy low cost wireless network that can provide a battery life of 6 months to 2 years using just 2 AA batteries. No other wireless standard was designed from the start to meet this need. [62]

7.7.1 Bandwidth

The technology can operate in any one of three bands, the ISM band at 2.4 GHz worldwide, the European 868 MHz band, and the US 915MHz ISM band. The data rate at 2.4 GHz is 250 kbps; for the lower bands it is 20 kbps and 40 kbps respectively. [62]

7.7.2 Latency

The MAC layer software offers options for guaranteed time slots for low latency applications, dynamic device addressing and a handshake protocol for transfer reliability. [63]

7.7.3 Availability

There are issues for every protocol operating in the 2.4GHz band. The IEEE 802.10 and 802.15.2 committees are dealing with the coexistence issues. The ZigBee technology is actually sleeping most of the time (lowrate). Other technologies send packets - 1000s per day. With ZigBee technology, the packets are small and infrequent, so the probability of interference is very low.

ZigBee employs collision avoidance and guaranteed time slots for reliability. The ZigBee protocol further ensures reliable delivery of messages because every message is acknowledged. [62]

7.7.4 Security

Data integrity and authentication are supported by the ZigBee protocol. Encryption methods are currently defined by the IEEE, and these will be incorporated into ZigBee devices that require it. The ZigBee Alliance is in the process of specifying security options that may be used as required per application. [62]

7.7.5 Ubiquity

The range is 10 to 75 meters nominally, which is dependent on the power output (consumption) required for a given application and can be increased by various methods.

7.8 WLAN IEEE 802.11b

The IEEE 802.11 standard specifies the requirements for implementing wireless Local Area Networks. There are two approved IEEE 802.11 specifications, and two more are being developed. IEEE 802.11 was ratified in 1997 and supports a data rate of 2 Mbits/second. It is not widely implemented because of its low speed and the availability of a faster alternative. IEEE 802.11b specifies rates up to 11 Mbits/second, was ratified in 1999, is supported by multiple vendors, and is widely accepted in the marketplace. [59]

7.8.1 Bandwidth

IEEE 802.11b "High Rate" standard wireless local area network (WLAN) operates in the 2.4GHz (2.4 to 2.483 GHz) unlicensed Radio Frequency (RF) band and can transmit up to 11Mbps (Megabits per second). [60]

7.8.2 Latency

The latency of a Wireless LAN is measured in nanoseconds, so this is neglectable for all practical applications.

7.8.3 Availability

This depends on the setup and the equipment used, but the availability should be very high within the coverage area of the transmitter.

7.8.4 Security

Two security services are specified in IEEE 802.11, the authentication service and the privacy service. The privacy service is provided by Wired Equivalent Privacy (WEP) algorithm. The authentication service provides two basic levels of security. The first, Open System Authentication (OSA) is mandatory, but provides essentially no security. The second is shared-key authentication that provides the highest level of security available and uses the WEP algorithm.

OSA simply exchanges messages between a station and the wireless access point. Any station that can successfully send and receive compliant messages is permitted to associate with and enter the network. [59]

7.8.5 Ubiquity

The ubiquity of a wireless LAN is limited by the signal coverage range:

When indoors, 802.11b signals can travel as far as 150 meters. Outdoors, 11b range is over three times greater -- 500 meters. The outdoor ranges are higher because there are fewer obstacles, like walls, to absorb or block the radio signal.

For 802.11b to operate in its maximum bandwidth mode of 11Mbps, the distance indoors can be no more than 50 meters, outdoors it should be 250 meters. [61]

7.9 Analog modem and ISDN

Analog modems use a telephone network. They simply allow digital data to flow over the telephone company's already existing analog network by performing a digital to analog conversion for transmission onto the network and vice versa on the receiving end. The only necessity for analog modems is that each end of the call must have a compatible modem. This makes analog modem connections the most ubiquitous form of data communications available today.

ISDN has been around for many years, but its popularity is only now beginning to increase due to the limitations of analog modems and the rise of Internet usage. ISDN requires the phone company to install services within their phone switches to support this digitally switched connection service. [57]

7.9.1 Bandwidth

Analog modems are limited by the telephone company's voice bandwidth service. Current analog modems are struggling to achieve rates of only 56 kbps. ISDN provides digital service typically in increments of 64 kbps channels. The maximum being two at a total of 128 kbps. [57]

7.9.2 Latency

The latency of analog modems and ISDN is the same as the latency of the supporting telephone network, which is neglectable for short distance communication, and may be up to a few seconds when calling across the globe.

In the traditional Public Switched Telephone Network, the round-trip latency for domestic calls is virtually always under 150 milliseconds. At these levels, the latency is not noticeable to most people. Many international calls (especially calls carried via satellite) will have round-trip latency figures that can exceed 1 second, which can be very annoying for users. [58]

7.9.3 Availability

The availability of the telephone network is normally close to 100%.

7.9.4 Security

There is no protection against wiretapping in the analog network, so the security in this aspect is quite low. Tapping of phones and internet communication is a well known phenomena, and any needed security should be provided by the application.

7.9.5 Ubiquity

In any developed country most homes are connected to either the analog telephone network or ISDN.

8 Method for technology evaluation

To realize a certain remote monitoring application a choice of communication technology must be made. Some technologies are better suited than others, depending on the nature of the application. In this chapter a method for evaluating the suitability of technologies in relation to the demands of applications is established. The method is based on finding some criteria that separates different types of applications by what requirements they have to communication technologies.

Based on the information presented in *3.2 Requirements to communication technology,* a number of criteria are defined, and the technologies from chapter *7 Communication technologies* are evaluated according to these.

Last in this chapter a couple of example evaluation cases are presented to show the use of the evaluation method. An application is described, and the communication technologies are evaluated by the chosen criteria to see what technologies are suited for the application.

8.1 Evaluation method

First we select evaluation criteria based on the five primary factors that are important for communication technologies as specified in chapter *3.2 Requirements to communication technology*. Then the communication technologies described in chapter *7 Communication technologies* are evaluated according to the resulting classification. Finally a number of sample applications are evaluated according to their different communication requirements.

Comparing the requirements of the applications and the evaluated communication technologies gives an indication to what technologies are more suited for a specific application. This procedure is demonstrated by doing a complete evaluation of communication technologies for two applications: a peak air flow measurement application and an ambulatory prehospital ECG application.

8.2 Selection of evaluation criteria

As we have described in chapter *3.2 Requirements to communication technology*, there are several factors to consider when taking communication technology into use in remote monitoring systems. The five primary factors specified in the report are:

- Bandwidth
- Latency
- Availability
- Security
- Ubiquity

These factors are discussed below as to whether they are relevant for evaluating the use of technologies in applications.

Bandwidth denotes the data transmission rate required. As transmission rate requirements are very different to every single application and technology there is no good way to generalize bandwidth into classes. The application's bandwidth requirement or technology's bandwidth support will be numerically specified as an evaluation criteria.

Latency can be divided into two main classes: Real-time and delayed. We classify a technology as real-time if data reaches its destination while it is being transmitted, as opposed to being stored for later, delayed delivery. Applications that require an immediate response from medical staff, i.e. responding to an alarm or a live video consultation, are classified as real-time applications. If the data transmitted is not critical to an immediate response, the application is classified as delayed.

Availability can be measured in terms of the percentage of the time the network (or a particular link) is operational or by the average time between failures. It is critical for some remote monitoring applications to have a high or 100 percent availability to function properly. All of the technologies we have studied in this report do offer high availability, and we have therefore decided to eliminate this factor as an evaluation criterion.

Security is according to chapter *3.2 Requirements to communication technology* generally composed of three elements: system availability, confidentiality and integrity. As described above, availability has been eliminated as an evaluation criterion because of high availability in all of the selected technologies. A remote monitoring system transmits highly sensitive data, and should therefore not rely on the confidentiality services offered by the communication technology, but apply its own security on top of this as needed. Usually at least anonymisation is used. The integrity of the transported data is considered high in all of the evaluated technologies. A data integrity check is also supported in higher level transport protocols, such as TCP/IP, often used above the communication layer. Considering this, security is also eliminated as a criterion for evaluating the communication technology.

Ubiquity is the last evaluation criterion that would be useful to consider while choosing a suitable communication technology for a certain remote monitoring solution. The ubiquity of a network is influenced by the network's geographic scope and by rules regulating participation. When evaluating this criterion we will not take the rules regulating participation into consideration. If an application makes use of technology not open to the general public, the legitimate users will be given access. We therefore only consider the network's geographic scope. We define this as *mobility*. By this we mean how the user is limited geographically by the communication technology. If the patient is to wear sensory equipment at all times, it is important that the solution will allow the patient to continue with normal activities and not be confined to a limited area of equipment operation.

We divide mobility into two classes: High and Low level of mobility. A technology with a high level of mobility can be accessed within a wide geographical area, and a technology with low level of mobility has limited geographic range and the user is therefore confined to a limited area of equipment operation. As an example, a Wireless LAN offers a low level of mobility because it's area of radio coverage is limited to the building and its immediate surroundings. On the other hand, GSM has a wide geographic coverage area and therefore offers a high level of mobility.

This leaves us with the following evaluation criteria:

- **Bandwidth:** Transmission rate in kbps.
- **Latency Real-time:** Data reaches its destination while it is being transmitted and the application can get an immediate response.
- **Latency Delayed:** Data is being stored for later delivery.
- **Mobility High:** Offers a wide geographical range of operation.
- **Mobility Low:** Confined to a limited area of operation.

8.3 Evaluation of technologies

In this section we will try to evaluate the technologies from chapter *7 Communication technologies* by the criteria developed in chapter 8.2. The chosen criteria are bandwidth, latency, and mobility. This evaluation is displayed in the table below. The table can be used to find a proper technology from the requirements of a specific application. The columns denote maximum supported values, and a higher bandwidth technologies may be used when a lower bandwidth is required, but not vice versa. The same goes for the latency and mobility.

Technologies	Bandwidth	Latency		Mobility	
		Real-time	Delayed	High	Low
SMS	1.12 kbps		✓	✓	
MMS *	40,2 kbps		✓	✓	
ZigBee	250 kbps	✓			✓
GSM(HSCD)	43.2 kbps	✓		✓	
GPRS	40,2 kbps	✓		✓	
UMTS	384 kbps	✓			✓
WLAN	11000 kbps	✓			✓
Bluetooth	1000 kbps	✓			✓
Phone line	56 kbps	✓			✓

Table 2 Technologies evaluated by criteria

* MMS can utilize both GSM, GPRS or UMTS for transmission. In this table we have selected GPRS since this is the most used MMS bearer today.

8.4 Evaluation of applications

A number of examples of remote monitoring applications are classified based on their requirements in the table below. Other applications can be quite easily classified into the same system.

To find a suitable technology for a specific application we evaluate its needs by the same criteria as with the technologies, and compare the resulting requirements to those in Table 2.

The properties of some example applications are displayed in the table below:

Applications	Bandwidth	Latency		Mobility	
		Real-time	Delayed	High	Low
Blood glucose measurements	Low *		✓		✓
Continuous heart rate monitoring	≈ 2 kbps	✓		✓	
Peak air flow measurements	Low *		✓		✓
Ambulatory Prehospital ECG	≈ 40 kbps		✓	✓	
Video consultation	≈ 128 kbps	✓			✓
Daily weight measurements	Low *		✓		✓

Table 3 Applications evaluated by criteria

* Low: Bandwidth requirement is so low that this is eliminated as a criterion.

8.5 Example evaluation: Peak air flow meter application

This is an example of how we can use the tables from the previous chapters to evaluate technologies for one specific medical application. The peak air flow meter is an important part of

any asthma management plan. It can quickly measure respiratory capacity and assist in early detection of asthma attacks. Measurements with a peak air flow meter can help you and your doctor monitor your asthma. These measurements can be important and help your doctor prescribe medicines to keep your asthma in control. This procedure can be integrated into a remote monitoring system where the data will automatically be sent to the patient's doctor for further analysis.

The following arguments for selecting the criteria per application are used:

- **Bandwidth:** A peak air flow meter measures respiratory capacity as a single value parameter. In addition, we may need to send some more data like a patient identifier and perhaps a time stamp. This indicates a total data of only a few bytes per measurement. With so little data, bandwidth is not a limiting factor and can be safely eliminated as a criteria for selecting a suitable communication technology.

- **Delayed delivery:** There is no need for immediate response from the doctor. The data will be stored for later analysis.

- **Low level of mobility:** The patient will make use of the peak air flow meter from within his private home, so mobility is not a requirement.

This results in the following table:

Application	Bandwidth	Latency		Mobility	
		Real-time	Delayed	High	Low
Peak air flow measurements	Low *		✓		✓

Table 4 Peak air flow measurement evaluation

* Low: Bandwidth requirement is so low that this is eliminated as a criterion.

From the table above we can find the requirements for the peak air flow measurement application. To select a proper technology we compare this to *Table 2 Technologies evaluated by criteria*.

Since the application requires only a few bytes of bandwidth, no real-time delivery and a low level of mobility it is evident that this is not a very demanding application. We find that the peak air flow measurement application can make use of all the technologies evaluated in Table 2. As there are no specific requirements to the communication technology any of the evaluated technologies may be selected. This leaves us with the freedom to pick based on other factors, like cost or simply preference.

The following example in chapter 8.6 shows a more demanding application which is more restrictive in its choice of communication technology.

8.6 Example evaluation: Ambulatory prehospital ECG

As described in chapter 10.1.1, SSA has implemented ambulatory prehospital ECG:

> *"The hospital is equipping their ambulances with ECG remote monitoring devices. When a patient is being transported in the ambulance, the health care personnel have the opportunity to send an ECG "snapshot" of the patient's hearth condition to the ER. Specialists at the ER can then study the ECG snapshot sent from the ambulance and give a report to the ambulance personnel on how to best treat the patient. This way the patient can get earlier and better treatment by utilizing the time where he is being transported to the hospital."*

A typical electrocardiogram monitoring device generates massive volumes of digital data. Depending on the intended application for the data, the sampling rate ranges from 125 to 500 Hz. Each data sample may be digitized to a 8 to 12 bit binary number. Furthermore, up to 12 different streams of data may be obtained from various sensors placed on the patient's body. Even at the lowest sampling rate in the range and assuming just one sensor that generates 8-bit data, we would accumulate ECG data at a rate of 7.5 KB per minute or 450 KB per hour. At the other extreme (12 sensors generating 12-bit values at 500 Hz), data is generated at a rate of 540 KB per minute or more than 30 MB per hour. [91]

We assume for the sake of the example a snapshot by 4 sensors that generates 10-bit data at a sampling rate of 250 Hz over a period of 4 minutes. The complete ECG snapshot will be of:

250 Hz * 10 bit * 4 sensors * 240 seconds = 293 KB

With a typical time limit of 1 minute for transmission there is need for a technology with a transmission rate of at least:

293 KB * 8 bit / 60 seconds = 39 kbps

The following arguments for selecting the criteria per application are used:

- **Bandwidth:** 39 kbps
- **Real-time:** There is need for immediate response from health personnel. The data will be analyzed and feedback will be given to ambulance personnel on how to best treat the patient.
- **High level of mobility:** The application will be used from the traveling ambulance and needs wide geographic coverage.

This results in the following requirements table:

Application	Bandwidth	Latency		Mobility	
		Real-time	Delayed	High	Low
Ambulatory prehospital ECG	39 kbps	✓		✓	

Table 5 Ambulatory prehospital ECG evaluation

By comparing the requirements for this application with what the technologies in Table 2 can offer, we find that a limited set of technologies are suitable:

Technologies	Bandwidth	Latency		Mobility	
		Real-time	Delayed	High	Low
GSM(HSCD)	43.2 kbps	✓		✓	
GPRS	40,2 kbps	✓		✓	

Table 6 Ambulatory prehospital ECG technologies

Both technologies have wide geographic coverage, operate in real-time, and have similar transmission speed. Here ends the method for evaluating technologies, and the final choice of technology is up to the implementer of the system.

9 Sleep disorder screening at SSA

In this case we look at how sleep disorder screening is done at Sørlandet Sykehus Arendal (SSA) today, and discuss how a wireless remote monitoring solution can improve this method.

As a result of the study of research projects worldwide, we found that a couple of students from the Slovak University of Technology in Bratislava have developed a prototype mobile sleep laboratory (See 5.2). The prototype employs an electroencephalograph (EEG, which monitors brain waves), an electrooculograph (EOG, which monitors eye movement) and a thermometer. Analysis of EEG and EOG data allows identification of all sleep stages.

The prototype developed is a quite advanced wireless sleep laboratory and is tested in a specific field of medicine-sleep research. As mentioned above we have looked at how sleep disorder screening is done at SSA. This hospital does not have a sleep laboratory, but does a rough screening of patients by measuring the blood oxygen level during sleep. The prototype developed by students from the Slovak University of Technology in Bratislava identifies problems related to the patients' sleep stages, but are not capable of detecting respiratory problems. By measuring the blood oxygen level of the patients during sleep we will be able to, to some extent, detect these problems.

The AMON project (See 5.3) is another project that aims to monitor and evaluate human vital signs using advanced biosensors. The AMON monitoring application consists of a wrist monitor device, cellular communication technology for data transfer and a telemedicine center system that enables to manage input from multiple wearable medical devices. The system is designed to monitor and to evaluate human vital signs such as heart rate, heart rhythm, 2-lead ECG, blood pressure, O_2 blood saturation, skin perspiration and body temperature. Even though this project was completed by the end of December 2002 we have not been able to find any available product on the market.

In this chapter we have discussed how measuring of the blood oxygen level of patients during sleep can be done by a remote monitoring system. First there is a quick introduction to sleep disorders and how these can be diagnosed. We then look at how this is done at SSA, and how a wireless solution can be beneficial. Then follows a technical solution of such a system, and a discussion of choice of technologies.

In chapter *2.4 Applications and benefits*, we have described three large groups of patients that stand out as having a clear benefit from remote monitoring. The sleep disorder screening wireless monitor application described in this chapter falls into this group:

- **Asthma/respiratory patient**. Parameters like blood oxygen levels and respiratory rate can be monitored to aid physicians in setting diagnosis.

9.1 Sleep disorders are a serious health problem

Snoring, sleep apnea, and upper airway constricted breathing are common breathing disorders that occur during sleep. It is estimated that between 4% and 7% of the general population have some form of sleep-related breathing disorder. Snoring is the most well known disorder that occurs during sleep.

Sleep apnea is a more serious condition associated with complete blockage of the airway causing the individual to stop breathing.

In addition to sleep apneas, there is a form of mild interruption of breathing that may appear obstructive called hypopnea. This is an episode of shallow breathing where the airflow is decreased by 50% or more during sleep, lasts for ten seconds or longer, and may be associated with a fall in the blood oxygen level. [92]

Regardless of the condition the potential for a decrease in blood oxygen level and sleep interruption are the basic problems. Usually the oxygen saturation level is around 95%. With sleep disorders, it is not uncommon for the blood oxygen saturation level to reach 80% or lower. This can lead to a serious problem over an entire night and over a prolonged period of time. In addition, the snoring and apnea can cause a disruption in one's sleep that results in constant interruption called sleep fragmentation. These constant interruptions result in the failure to achieve a restful night's sleep.

Cardiovascular and cardiorespiratory conditions may be linked to sleep disorders including elevated blood pressure, irregular heart rate, and over prolonged periods, heart attack and stroke. [92]

9.2 Diagnosing sleep disorders

The best way to find out what's going on with you when you sleep is to spend a night in a sleep clinic.

The procedure is called polysomnography, or undergoing a polysomnogram. It's totally safe and painless -- although a bit weird, going to sleep in a strange room with dozens of wires and devices stuck to your body. By the next morning, if all has gone well, the clinic will have at least five hours of data which will tell them everything about the way you sleep, including data on:

- Airflow at your nose and mouth
- Oxygen levels
- Respiratory effort signaled from monitors on the chest wall and abdomen
- Oxygen levels
- Leg movements
- Body position (supine, prone, side)
- Electrocardiogram (measurement of heart muscle activity) [93]

At Sørlandet Sykehus Arendal there is no sleep clinic to do a full polysomnography. We have talked to Susanne Hernes [1] about how patients with suspicion of a sleep disorder are tested. The patient is tested by measuring the blood oxygen level during sleep. A drop in the O_2 level is an indication of a breathing disorder, and though this will give no conclusive diagnosis it can give an indication of some kind of sleep apnea.

To avoid occupying a bed at the hospital the patients are allowed to bring a small oxymeter to their home. This oxymeter uses a finger clip to non-invasively measure the oxygen saturation during sleep. The information is stored in the device which is returned to the hospital the following day for analysis.

9.3 Use of remote monitoring

By using a remote monitoring solution in this area there can be some improvements. Often the oxymeter data give no clear indication from the measurements of one single night's use, and the process is repeated a few times before a conclusion is drawn. Between each nightly recording the patient must return the data to the hospital for analysis, wait for the results, and then again bring the oxymeter back home for another night. If the data can be transmitted wirelessly back to the hospital without the patient leaving her home, the expert can analyze the data and let the patient keep the oxymeter one more night if necessary.

With oxymeters recording information within the device the amount of data is limited to the available storage space. This can limit the frequency of measurements, and the time span of recording. When the data can be transmitted out of the device this limitation is overcome, and measurements can give more detailed information over an extended time. If the clinic has more available data it will be easier to weed out faulty measurements caused by accidental displacement of the finger clip or other sources of error that can occur.

9.4 Technical solution

To solve this technically there are three system components that must be provided:

- An oxymeter device with a satisfactory degree of accuracy, and that integrates some form of wireless communication
- A choice of communication technology that fits the requirements of the system
- Some computer system at the receiving end that can store the data for analysis and user access

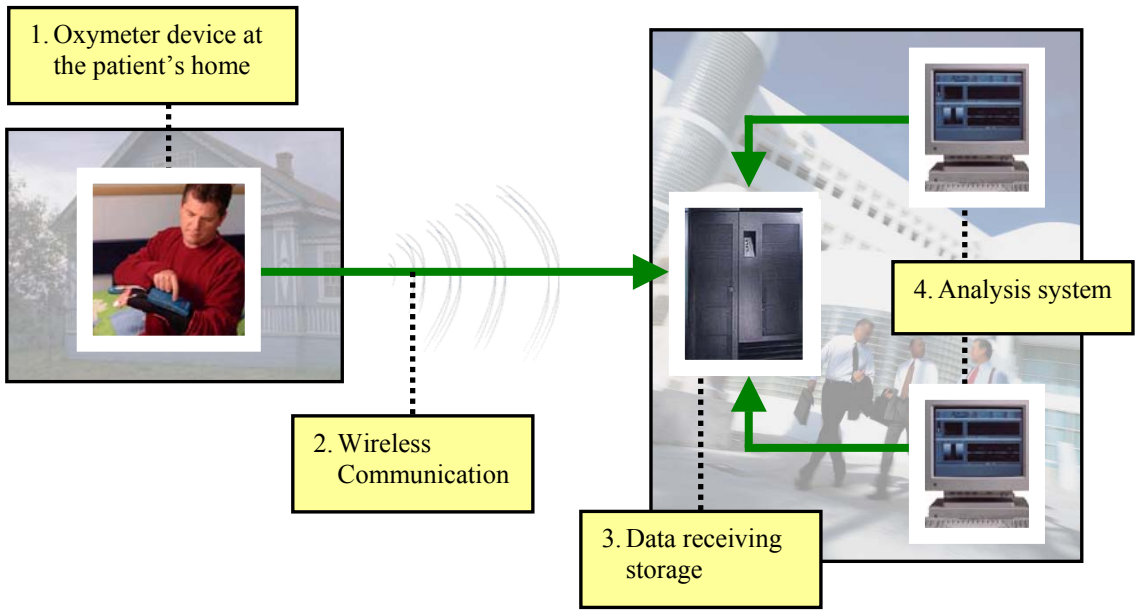


Figure 29 Sleep disorder screening technical overview

9.4.1 Oxymeter device

As mentioned above, the oxymeter device should have a satisfactory degree of accuracy, and integrate some form of wireless communication. More and more equipment manufacturers are adding wireless technology to their sensors, but it is beyond the scope of this report to recommend a specific manufacturer.

9.4.2 Communication technology

To make a choice of communication technology we follow the method established in chapter *8.2 Selection of evaluation criteria*.

First, a few criteria should be evaluated. These are:

- The bandwidth requirement of the transmitted data
- The transmission latency requirement of the data
- How mobile the patient will need to be

Measuring oxygen saturation does not result in any large amounts of data per time unit, so the bandwidth requirements are quite low. There are also no strict requirements for low latency transmission. If the data is delivered before the next morning it will be sufficient.

Focusing on mobility of the patient, we can see that the relevant location of the patient will be in her own home, mostly in bed, but she should be able to move around in the house. She should not be limited by wires, but no large area mobility is required.

This results in the following table for this application:

Application	Bandwidth	Latency		Mobility	
		Real-time	Delayed	High	Low
Oxygen saturation measurements	Low		✓		✓

Table 7 Oxygen saturation measurement evaluation

Comparing these requirements with the technologies evaluated in *Table 2 Technologies evaluated by criteria*, all of those technologies can actually be considered. Neither the bandwidth, latency or mobility restrict the choice as all of them meet or exceed the requirements.

Technologies	Bandwidth	Latency		Mobility	
		Real-time	Delayed	High	Low
SMS	1.12 kbps		✓	✓	
MMS	40,2 kbps		✓	✓	
ZigBee	250 kbps	✓			
GSM(HSCD)	43.2 kbps	✓		✓	
GPRS	40,2 kbps	✓		✓	
UMTS	2000 kbps	✓			✓
WLAN	11000 kbps	✓			✓
Bluetooth	1000 kbps	✓			✓
Phone line	56 kbps	✓			✓

Table 8 Technologies available for consideration

The evaluation method showed us that all of the technologies in Table 8 are suitable for this application. To arrive at one of these technologies, other factors must be evaluated. Some of

the technologies are short-range wireless technologies, and using these will require an additional appliance to relay the signal further through a longer range technology. This second technology does not need to be wireless as the patient's freedom of movement has already been provided. As this is just as functional as any other solution, it will give the patient more hassle by having to mind two units instead of just one. This also adds an extra source of error and makes the solution more difficult to manage. Therefore a long-range wireless technology that could communicate directly to the receiving end would be the best choice, as long as this does not make the patient-wearable device too large, heavy or power consuming.

Going for the long-range communication, this will narrow the choice down to SMS, MMS, GSM, GPRS and UMTS. SMS and MMS is quite expensive per byte of data in relation to the other technologies. UMTS is not widely available yet, so this is not a real option at the moment. This leaves GSM and GPRS as the better choices. Both are well suited for this application, and they both have the same degree of signal coverage, which is mostly everywhere. The deciding factor between the two is that GPRS is packet-switched, while GSM is circuit-switched. This leaves GPRS as the better choice for repeatedly sending small bits of information. As the oxymeter takes measurements the data can be transmitted whenever the device's memory is getting filled. This relaxes the memory requirements on the device.

9.4.3 Receiving system

On the receiving end there is needed a storage system connected to the communication channel. By using GPRS as the communication, the receiving system needs only be connected to the internet. With other communication technologies there may be needed some third party to access the data, like a telecom company.

The receiving system can be implemented at vastly different scales, ranging from a single desktop computer at the doctors office with analysis software installed, to an distributed patient record database. The system can be hosted at the hospital or doctors office, or by some third party where the hospital is allowed access. See the next chapter, chapter *10 Implementing remote monitoring systems* for more discussion about this.

9.5 Larger perspective

The technical solution presented above is not limited to sleep disorder screening. Any patient that can benefit from measuring oxygen saturation could use this solution. Also, combining oxygen saturation measurements with additional measurements, i.e. respiration or ECG, could give both better sleep disorder diagnoses, and many other uses of the system. A discussion of implementing larger scale systems follows in chapter *10 Implementing remote monitoring systems*.

10 Implementing remote monitoring systems

This chapter discusses the problem of how to implement remote monitoring systems in the existing health care system. First there are presented some examples of how such systems are implemented today by observing the use of remote monitoring at Sørlandet Sykehus Arendal.

Next, two general implementation scenarios of different scale are discussed. One small-scale scenario that is easily set up and cost effective, where there are only a few people involved, and only one monitored parameter. And then a large-scale scenario is discussed, where multiple measured parameters, and a large number of patients and specialists demand a more complex and scalable system. Finally, the vision of a national-scale shared patient record system is discussed with a discussion of why this is still far from being realized.

10.1 Remote monitoring in use today

To get an idea of how remote monitoring is being used in today's practice we have spoken to health care personnel at SSA (Sørlandet Sykehus Arendal). This may not be sufficient to say much about the state of things in hospitals in general, but it will give a look into what is actually being used in real life.

Remote monitoring systems as we are describing in this paper are not widely used at SSA. We were given a description of two cases where remote monitoring is being used:

- Ambulatory Prehospital ECG
- Home oxygen saturation monitoring.

10.1.1 Ambulatory Prehospital ECG

The hospital is equipping their ambulances with ECG remote monitoring devices. When a patient is being transported in the ambulance, the health care personnel have the opportunity to send an ECG "snapshot" of the patient's hearth condition to the ER. Specialists at the ER can then study the ECG snapshot sent from the ambulance and give a report to the ambulance personnel on how to best treat the patient. This way the patient can get earlier and better treatment by utilizing the time where he is being transported to the hospital.

10.1.2 Home oxygen saturation monitoring

At SSA they often use monitoring equipment that can monitor patient's oxygen saturation through a finger clip. This is used in relation both to sleep disorders and epileptics. The available equipment is without the benefit of wireless data transfer. The device is given to a patient who will bring it home with him for some period of time. There, it will record and store the measurements within the device as it is being used. When the patient is finished recording his biomedical data, the oxygen level, he will return the device to the hospital. There the health care personnel transfer the data from the recording to a computer for analysis. The results are printed to paper and is sent to the primary physician, who has in the first place ordered the monitoring. As we have understood, there is no way of accessing these data from a remote location except for receiving a copy of the printed data.

This is a good, and quite sufficient solution even without wireless data transfer. There is no need for investment in transmission infrastructure, and thus the added complexity often accompanying high-tech solutions is avoided. On the other side, the absence of wireless data transfer will limit measurement recordings to the available storage capacity of the device. This could limit both accuracy of measurements, the frequency at which measurements are taken, and the time span of the recording. Also it will require the patient to return the equipment to the hospital before any analysis can be performed. If the recording does not give sufficient information, and more measurements are required, the patient may need to return to the hospital multiple times.

The inaccessibility of the analysis results can be both beneficial and limiting. Issues of access control and professional secrecy are dealt with by the disconnected nature of the system.

10.2 Different implementation scenarios

There are many ways in which to take advantage of remote monitoring technology within the health care service. In the following section we will present three general scenarios of increasing scale and complexity:

1. Small-scale isolated remote monitoring system
2. Large-scale centralized remote monitoring system
3. National-scale shared patient record system

10.2.1 Small-scale isolated remote monitoring system

A small scale system has the benefit of low-cost, low maintenance and easy implementation when a small number of such systems are used, and there is no need for intricate communication between different systems.

The two cases of remote monitoring taken from SSA described above are examples of small-scale remote monitoring systems. The systems will achieve their purpose without any unnecessary complexity. They are isolated from the environment and can not combine recorded data with data from other systems. The figure below shows a case of wireless remote monitoring of blood oxygen saturation of a patient at home.

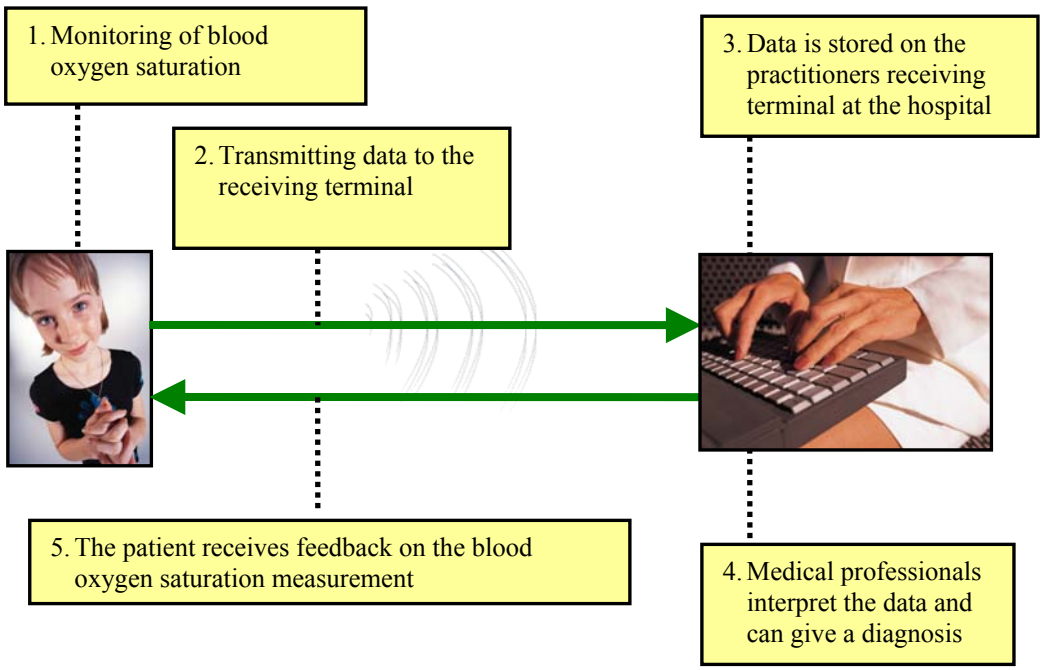


Figure 30 Small-scale isolated remote monitoring system

The system does not interact with other systems, and does not allow access to the recorded data other than on the receiving terminal at the hospital.

Benefits of this implementation is that it is relatively straight-forward to set up, both technically and administratively. The specialist is given a set of monitoring devices to hand out to the patients, and a terminal system where the monitoring results can be analysed and reports printed. Professional secrecy is not compromised in any way as only the specialist will have physical access to the receiving terminal.

The downside of this kind of arrangement is evident when there are more than a few monitoring solutions running at the hospital. Especially if patients need to use more than one of them at a time. It would be beneficial to allow the systems to combine their data during analysis to be able to discover composite anomalies. To achieve this, a larger scale system is needed.

10.2.2 Large-scale centralized remote monitoring system

By centralizing the receiving system and combining the hospital's different remote monitoring solutions into one single system a number of benefits can be gained at the expense of simplicity. Benefits include:

- Improved scalability
- Combining of data
- Improved communication
- External hosting

10.2.2.1 Improved scalability

This type of solution is better suited than the small-scale isolated solution in handling larger amounts of data, and a large number of specialists, patients and different monitoring systems.

Management is focused on one single system rather than many different, smaller systems at various locations. The data storage, security and access policy are also managed at a single location, and lower the complexity and costs of maintenance.

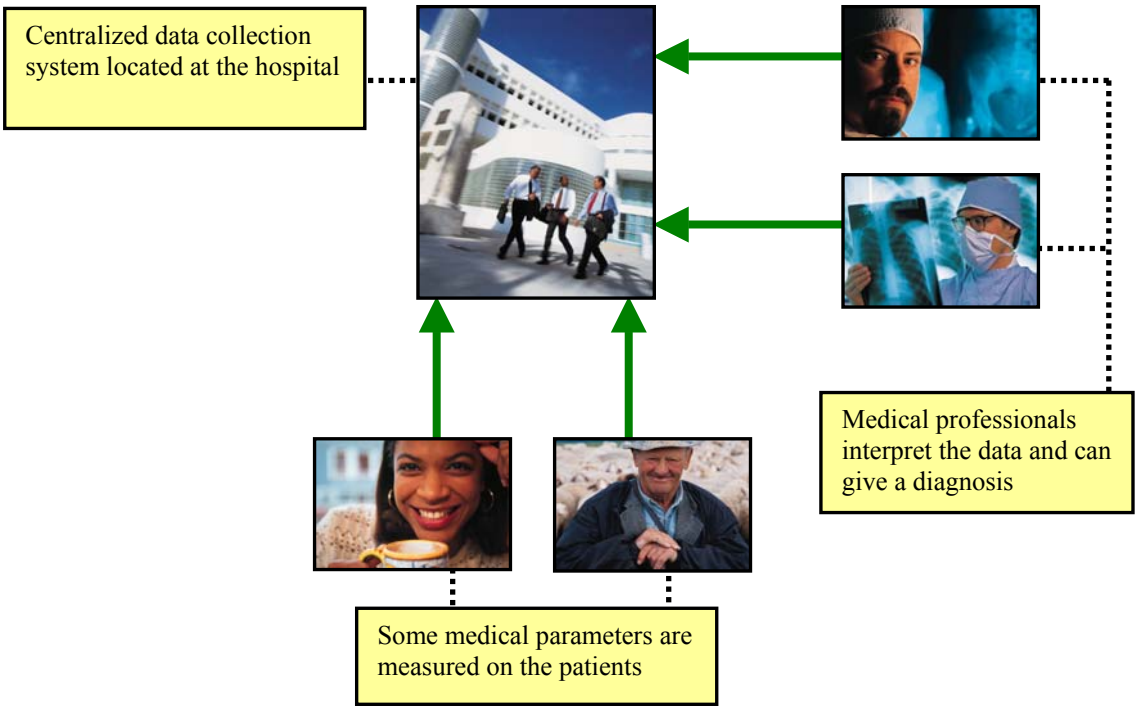


Figure 31 Large-scale centralized remote monitoring system

10.2.2.2 Combining of data

When the data from multiple monitoring systems are collected at one location there is the option to combine these data to generate more informative analyses and reports. A patient can be monitored by multiple sensors -- i.e. oxygen saturation, ECG and air flow -- and the results can be combined to give a more confident diagnosis. Automated analysis tools can discover connections between readings, rather than having the specialist interpret separate reports.

10.2.2.3 Improved communication

As all the specialists have access to the same system there is no need to exchange reports by paper print-outs. Reports can be accessed within the system and remain interactive. Comments can also be kept together with the report rather than in a separate system.

10.2.2.4 External hosting

This centralized system may be hosted internally within the institution, or externally by a trusted third party. By hosting the system internally the institution will have complete control over it, and can shield their sensitive data from the outside world. On the other hand, external hosting reduces the need for technical staff at the medical institution, and can cut the costs substantially. Such a third party may offer their services to multiple health care institutions and therefore split the expenses among these. For a third party system to be used, the security issues of letting people outside the hospital's organization manage sensitive data must be solved (See *10.2.3.1 Security hierarchy*).

10.2.2.5 Reasons why large-scale monitoring systems are not favoured today

10.2.2.5.1 Lack of standardization

To be able to realize a system where different remote monitoring equipment is communicating with a common storage there must be real interoperability between equipment measuring different parameters, and delivered by different vendors. These standards are not fully available as of today. A lot has been standardized, but still a lot is missing or under development.

10.2.2.5.2 Not widespread use of remote monitoring

Wireless remote monitoring systems are not widespread throughout health institutions today, so the small-scale systems are still favourable for reasons both of cost and simplicity. Only when multiple monitoring solutions are being used, or the monitored patient mass grows large, will there be a need for larger scale solutions.

10.2.3 National-scale shared patient record system

By further extending the scale of medical data systems it can be imagined an even larger system where a patient's information can be registered in a single system and accessed by multiple health instances. This will have several benefits for the patient when his health record is consistent and complete rather than spread across many hospitals and doctor's offices.

The article "An open, component based information infrastructure for integrated health information networks*"* [94] gives an overview of some of the benefits of such a system:

> *"There are a number of envisaged benefits from the development and deployment of an I-HER(integrated electronic health record) service, provided that the need for citizen consent, user authentication, and the required levels of security is properly addressed. Envisaged benefits include the following:*
>
> - *Vital health information would be available and accessible 24 hours a day, 7 days a week, regardless of where the person requiring care happens to be.*
>
> - *Since healthcare practitioners would be able to view a patient's relevant medical history, they would be better positioned to offer more effective and efficient treatment, and could spend more quality time with the patient. Contrast this with the current situation, where medical practitioners have access, if at all, to a partial or inaccurate patient history and may recommend a course of treatment that could potentially be life-threatening.*
>
> - *Access to information on previous medical or lab examinations would reduce the number of redundant procedures and result in greater cost savings. Certain procedures may also pose a health risk to patients, if repeated unnecessarily, and ought to be avoided.*
>
> - *The information that an I-EHR would provide to researchers (with safeguards built in to protect the identity of patients and obtain their consent) would result in improved quality of care, based on an enhanced ability of health planners and administrators to develop relevant health-care policies for the*

future. Population health statistics, developed from the information contained in the I-EHR, can be instrumental in the formulation of such policies.

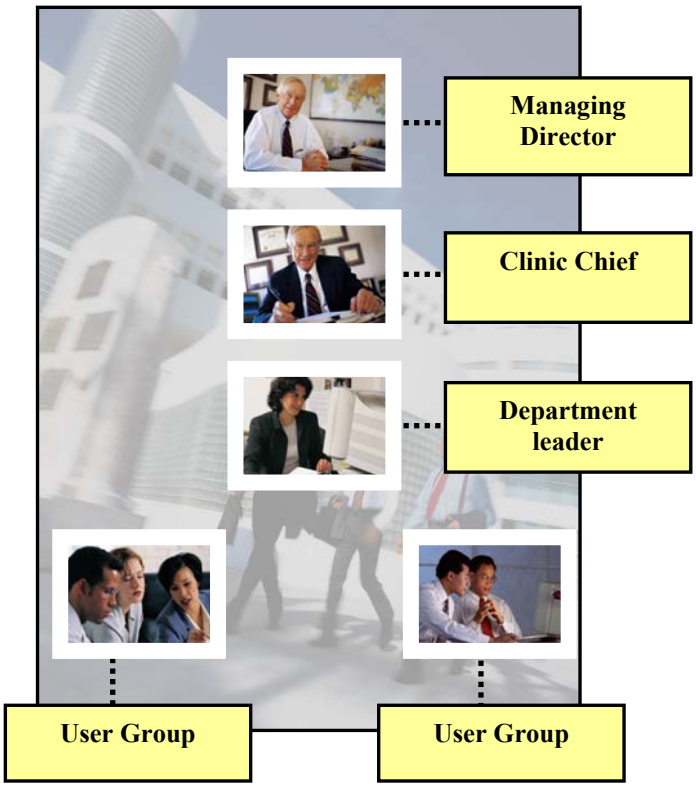
- *An I-EHR would greatly empower individuals by giving them access to their own personal health records. It will enable them to make informed choices about options available to them and give them the opportunity to exercise greater control over their own health."*

10.2.3.1 Security hierarchy

There are serious issues that keep this vision from being realized any time soon. One of these concern the way security is maintained within the health care service, as mentioned in the above cited article:

> *"provided that the need for citizen consent, user authentication, and the required levels of security is properly addressed".*

Security policies in medical information systems have to be based on existing laws and regulations. In the Norwegian health care system the security responsibilities are built in a hierarchical structure. Responsibilities within a hospital are delegated according to a structure similar to the figure below [2]:



- Managing Director is the top administrative responsible person.
- Normally the nearest leader has a delegated responsibility for following up his/her employees. This includes information of security aspects and internal regulations as well as training with respect to information security.

Figure 32 Levels of responsibility for hospital security

Depending on a persons' position within the organization they are given access to the information they need. The authorization to access secured data, like health records, is distributed in a hierarchical structure within an organization, and because of this, persons

residing outside of the hospitals responsibility cannot be authorized access to those data directly, as illustrated below:

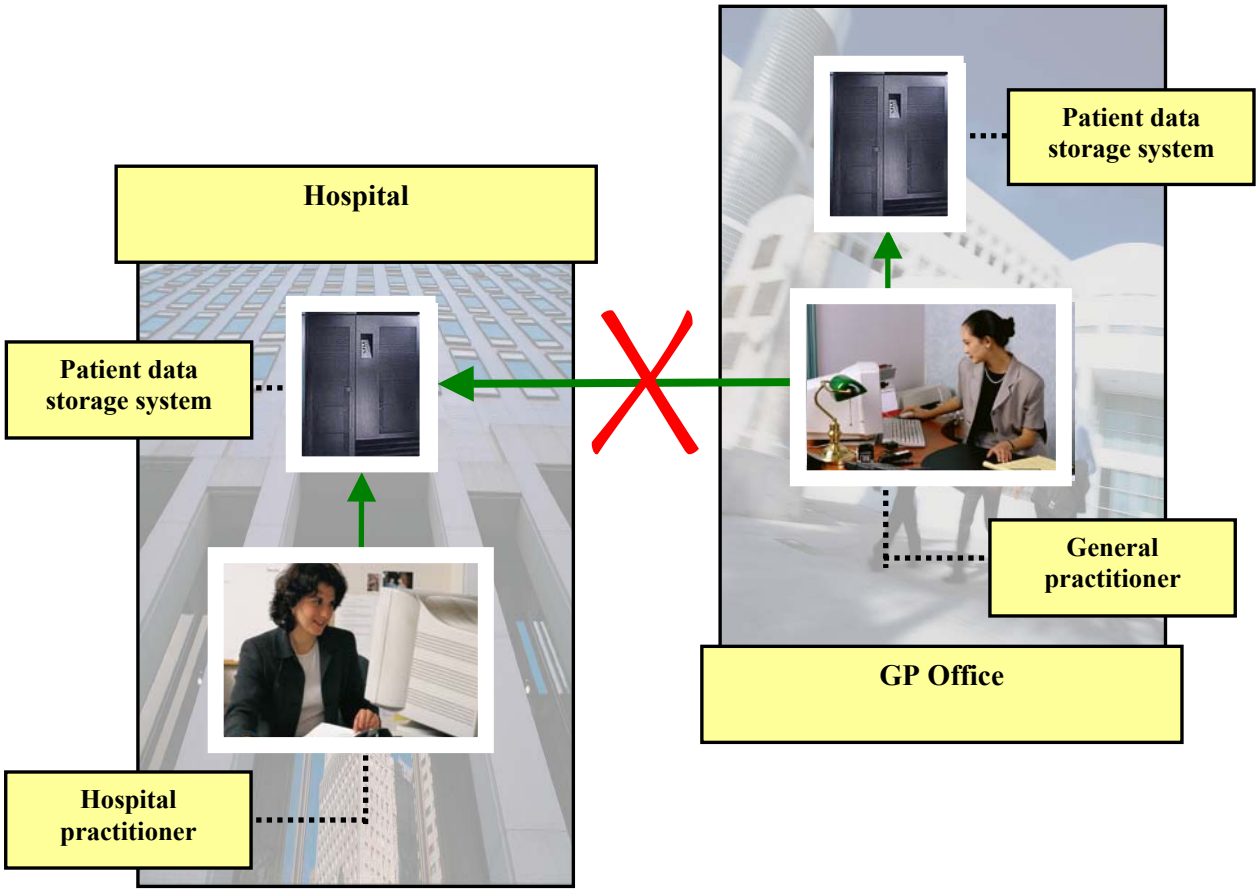


Figure 33 No access outside hospital's security responsibility

Since the general practitioner resides outside the hospital's security responsibility hierarchy, the practitioner is not allowed to log on to the hospital's system and gain access to internal patient data [2]. Today, sending a request to the hospital solves this; as a result the general practitioner will be sent the requested patient data.

This hierarchical structure raises concerns of how to solve the security responsibility of large-scale centralized remote monitoring systems that possibly function across hierarchy boundaries.

11 Ethical considerations

Any change in the way one thing is done results in changes in other areas. Implementing remote monitoring systems results in introducing new technology into the health care system, and thus sparks changes to how health care is conducted in many ways.

This leads us into the ethical side of remote monitoring technology. This is a broad field that reaches far beyond the scope of this report. Anyway, a few considerations are mentioned in the following text:

- Remote monitoring must benefit health care, not add to negative trends
- Hospitals and specialists must adjust to different modes of service delivery
- Patient demands for greater role in shared decision making
- Technology must not replace human care.
- Personal information must not be subject to unauthorized access or used for purposes other than intended
- The data measured must be reliable

In chapter *2.4.3 Assistance and monitoring in a home-care setting* there was mentioned a trend of shorter hospital stays, and this meant dispatching patients at an earlier stage in their healing. Remote monitoring solutions should not be used to add to this trend, and to cause patients to be dispatched prematurely. Though, when patients have to be dispatched early in any circumstance, remote monitoring solutions provide a valuable tool to give the patient increased care in the home.

According to Branko G Celler, Nigel H Lovell and Daniel K Y Chan in their article *The potential impact of home telecare on clinical practice,* monitoring patients at home requires fundamental changes in the health care system [18]:

> *"Implementation of home telecare will require fundamental changes in every sector of the healthcare services as GPs, hospitals and specialists adjust to different modes of service delivery, often based on the transfer of data and information and telemedicine diagnosis and consultation, and driven by patient demands for a greater role in shared decision making."*

They also point out that this technology must come in addition to the existing health care, not as a replacement. Also the patient must be certain that the personal data monitored is not used for any other purpose than intended:

> *"Ethical issues arising from home telecare and the storing and accessing of clinical data by multiple providers are complex. Implementation of home telecare services requires informed consent, must be voluntary and must complement, not exclude, traditional methods of healthcare delivery. Moreover, individuals are entitled to assurance that personal information will not be subject to unauthorised access, and will be used only for the purposes it has been collected for. This requires procedures and processes to ensure that personal data can only be accessed by those authorised to do so. Automatic*

encryption of data should be mandatory for any transmission of identified patient data.“

On the same thought that this services must complement the current health care, Chris Tweed and Gavan Quigley mentions in their article *Some ethical considerations of dwelling-based telecare systems for the elderly* that letting technology do what nurses are doing manually today can fall both ways [95]:

“*We have identified two principal broad categories of technological intervention: first, technology can be used to satisfy needs that are currently ignored or only partially fulfilled by human carers; and second, technology can be used to take on some of the functions and responsibilities that currently fall within the remit of human carers. The former are mainly needs for safety and security which are best addressed through constant monitoring and appear to be positive additions to the care providers armoury. The latter, however, could pose serious ethical problems related to responsibility. In both cases, telecare can only work if the technology is reliable, users know how to operate it and if human agents are willing and able to shoulder the ultimate responsibility for individuals’ well-being.*”

Another consideration they present is one of how well the care can be performed when patients are abstracted from persons to monitoring results, and how trustable the results can be:

“Monitoring systems of either kind present the usual interpretative problems associated with any technical instrument: what exactly is the sensor sensing, and how representative is that of the state of the environment or the person being monitored? There are hermeneutic issues to consider too. How does one gauge what is happening from the necessarily limited information which can be gathered (at specific temporal intervals in specific spatial locations) and transmitted, perhaps to a distant central monitoring station? This is the kind of problem which Borgmann (1999) attributes to the gap between the malleable world of information and brute physical reality.”

12 Conclusion and further work

This chapter presents the conclusions of this report, and suggests some fields that would be interesting to explore further.

12.1 Conclusion

The thesis presents results from a study of what products and research projects exists today within wireless remote monitoring and collection of biomedical data. This includes many different types of biomedical sensor devices, communication technologies and relevant standards. The requirements and demands that such systems must meet are also discussed. Some selected cases of remote monitoring are described, technical solutions are evaluated, and recommendations stated. In closing, there are many ethical considerations to adopting remote monitoring in the health care service. It is important that these are listened to in order to utilize the technology in a beneficial way.

One of the main challenges in this thesis was to find a good balance between a highly technological approach, and the health related aspects of this work. The technological aspect focuses on how to develop a remote monitoring solution versus the health related aspect that focuses more on the applicability, ethical considerations, and how to integrate such a system according to laws and regulations.

We have studied applications and benefits of wireless remote monitoring, and can conclude that this technology can be of great value in many circumstances. We have looked at a number of available products, and see that use of standards is not in focus. In addition to the available products, we have looked at a number of research projects. The future of health care is very exciting as there is much research into this area. It should be noted though that very little published results from these products were found.

Looking at standards, there are many standards operating on the application layer, but on coding and storage of medical parameters much is missing. The need for communication technology is met by the many different available technologies. Most applications should be able to find a suitable communication technology. A method has been developed to aid in selecting one that is appropriate. Based on the requirements evaluated for remote monitoring systems we were able to classify communication technologies into categories. By then classifying application requirements by the same criteria we are able to find the most suitable communication technologies for different remote monitoring applications.

A solution for screening of patients with respiratory sleep problems is presented. This solution is based on the assumption that the blood oxygen saturation decreases when a patient is having trouble breathing while asleep. It is modeled after a system in use at Sørlandet Sykehus Arendal and extended to take advantage of wireless communication. A wireless monitoring system is able to send data to the hospital continuously as it is being collected. This eliminates the restriction of memory capacity on the measurement frequency and time span. The equipment can be used continuously, and the nightly measurements can be repeated until a satisfactory amount of data has been collected, and without the patient taking trips back and forth to the hospital.

There is presented a large-scale centralized implementation of remote monitoring systems, in contrast to the straight-forward small scale solution usually depicted by many products and research projects. Successfully implementing such a centralized system demands standardized

communication interfaces between the sensors and the storage. This is a great barrier at the current time as many needed standards are still not available. Existing products are often completely proprietary in their communication. Close to none of the products described in this report inform of having used any standard data formats or protocols. The use of standards is crucial in achieving a flourishing market of different system components that can seamlessly interconnect.

Wireless remote monitoring is only one of many technologies that has emerged from applying information- and communication technologies to healthcare. Now, the healthcare service is starting to move into the mobile age, and wireless remote monitoring systems are at the cutting edge of this development.

12.2 Further work

In the course of this work we have identified some aspects that would be interesting to look further into:

- **Realization of an O_2 saturation measurement prototype**
  It would be interesting to go more into details, and develop a prototype for testing. A study could also be conducted on what effects introducing such a system into the health care system has.

- **Conduct a study on why remote monitoring solutions are not widely adopted**
  Remote monitoring is not a widely used technology in the health care system. This may come from fear of technology, security issues, lack of understanding of what exists on the market, reluctance to braking a traditional work method, etc. Conducting a study to get answers to what is holding back the development would give valuable insight into how this can be overcome.

- **External provider of remote monitoring services**
  It might be interesting to explore the possibilities for a company to position itself as a technology provider between the health care institutions and the patients. By lending out wireless monitoring equipment to hospitals, and giving them authorized and secure access to the collected data, the company can relieve the hospitals of large investments in technical staff. This requires that the security issues described in chapter 10.2.3.1 *Security hierarchy* are solved.

- **Make a study on how to overcome security obstacles between healthcare instances**
  By introducing large-scale monitoring systems as described in chapter 10.2.3, some security obstacles has to be overcome. This relates especially to the levels of responsibility for security in the Norwegian health care system described in chapter 10.2.3.1 *Security hierarchy*. A study on how to overcome these obstacles would be of great interest, and perhaps to propose changes to laws and regulations in order to fulfill the demands of such solutions.

- **Standards for transfer of biomedical data**
  Standards for transfer of biomedical data is of utmost importance to the development of interoperable solutions. As a result of lack of standards many proprietary solutions exists on the market today, and therefore different equipment is hard to integrate.

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