Patient Monitoring for Cardiovascular Diseases

Description of the problem domain

Abstract

The goal of this project was to design a patient monitoring system for cardiovascular diseases. In this document, we describe the problem domain of the project. We start with an overview of the context: cardiovascular diseases and e-health. Then, we describe the overall goals of the system, the involved stakeholders and additional constraints. Finally, we provide an example scenario of the system in use.

Contents

1 Context

Cardiovascular diseases. Heart diseases or cardiovascular diseases (CVDs) are the class of diseases that involve the heart or blood vessels (arteries and veins). While the term technically refers to any disease that affects the cardiovascular system, it is usually used to refer to those related to atherosclerosis (arterial disease). This is a condition in which an artery wall thickens as the result of a build-up of fatty materials such as cholesterol. Arterial disease can lead to heart attacks and strokes. Other pathologies are hypertension, congestive heart failure, heart transplantation, etc.
Population based studies in the youth show that the precursors of heart diseases start in adolescence. CVDs are slow, in the sense that they develop over decades, and therefore CVDs are associated to the patients age. Although some symptoms can be treated (for example, obstructed heart vessels can be bypassed), prevention is of utter importance (for example, change in diet). Smoking, hypertension, and other conditions can increase the risk by several times.
As the western world faces population aging, the impact of CVDs increases continually. Most countries face high and increasing rates of cardiovascular disease. Cardiovascular diseases (CVD) kill over 2 million people per year in the European Union and cost the EU economy over 192 billion euros annually with 268.8 million of lost working days [1]. These trends shift the priority in CVD treatment (i) to prevention and timely diagnosis of the disease, and (ii) to management of the disease; i.e. prediction and prevention of malignant events (e.g. heart failure) after diagnosis.

E-health. *Electronic-health* has large potential for increasing the quality of care delivered to patients, while decreasing overall healthcare costs. It can therefore mainly contribute to the management of CVDs, less to the primary prevention and timely diagnosis. The term "e-health" is defined broadly, grouping all types of healthcare practice supported by electronic processes and communication. It ranges from medical knowledge management (medical journals, etc) to software solutions for appointment scheduling and patient data management [2].
Another instance of e-health is the centralization of patient data in an *electronic health record (EHR)* which enables different healthcare professionals to communicate patient data in a fast, efficient and reliable way. *Telemedicine* is another instance of e-health, which enables the remote treatment and monitoring of patients, for example at home. As opposed to treatment and monitoring at the hospital, telemedicine has the potential to drastically cut costs in hospitalization.
A patient monitoring system focuses not so much on active treatment, but on monitoring of the patient and the disease. It offers extensive and up-to-date information to the physician without being overly obtrusive in the patients' day-to-day life. By continually monitoring the patient, the physician can predict and therefore prevent malignant events, for example by changing the diagnosis or adapting the treatment.

Positioning

In this project, we assume the point-of-view of a software company that has been contracted by a specific hospital (our client) to develop a patient monitoring system for cardiovascular diseases. Although this platform is being built with one specific hospital in mind, it would evidently be beneficial for our company if we can later sell this product to other hospitals as well.
The goal is to offer the patient monitoring system as a service: instead of developing and selling the software as-is, our company will provide and maintain a patient monitoring infrastructure together with additional services such as a callcenter. The system is in fact the middleman between the patient and the hospital. The system itself will be located outside of the hospital infrastructure. However, it is well-integrated in the existing hospital infrastructure or Hospital Information System (HIS), for example to access patient records, offer decision support functionalities to the cardiologist, for invoicing, etc.
Although this assignment presents in fact a simplification of reality, the requirements and description of the problem domain are based on a number of actual research projects in the e-health space.

Figure 1: A possible setup for the heart sensor.

2 Description of the problem domain

2.1 Overall System Goals

The patient monitoring system becomes relevant after primary diagnosis of CVD. The primary goal of the patient monitoring system is to offer a sound solution for continuous and remote monitoring, timely decision making and prediction of malignant events:

- **Continuous and remote monitoring.** Patient monitoring is a very powerful tool in treatment and management of long-term diseases such as CVD. Automated continuous patient monitoring can give physicians a detailed and up-to-date view on the evolution of the disease. Current technologies allow patients to be monitored 24/7 without the need for the patient to be in a hospital bed.
- **Timely decision making.** Continuous patient monitoring also aids healthcare professionals in their decision making, offering them an extensive and up-to-date view on the patient's status. This leads to improved diagnoses, possibly even without meeting the patient in person.
- **Prediction of malignant events.** Furthermore, continuous monitoring of the patients health status can predict malignant events such as heart attacks. By automated prediction of such events, healthcare professionals can be notified in a timely fashion, and the occurrence of malignant events such as hearth attacks can be prevented.

The remainder of this chapter zooms in on these three aspects of the patient monitoring system.

2.2 Monitoring

To monitor CVD patients, many parameters are of relevance, such as the heart rate, weight, blood pressure, body temperature, etc. In the patient monitoring system, these measurements are provided by electronic sensors and by the user itself.

Wearable unit. The most important enabler for monitoring CVD patients is the *wearable unit*. This device bundles a number of sensors for CVD, and is worn by the patient close to the heart, for example as a chest band (see Fig. 1). The wearable unit has a battery lifetime of at least 8 hours and is minimal in size in order to not hinder the patient.
The wearable unit continually measures a number of medical parameters:

- the **heart rate** in beats per minute (bpm). Normal levels for a healthy person are between 60 bpm and 100 bpm. For correct interpretation, the heart rate values should be correlated with the activity level of the patient.
- a continuous **electrocardiograph** (ECG) which plots the electrical activity of the heart over time (see Fig. 2). The fundamental parameters to evaluate are the **maximum ventricular rate** (maximal heart rate) in bpm, the presence of **ventricular arrhythmias** (abnormalities of the heart rate and rhythm) and the presence of **ischemia signs** (restriction in blood supply).

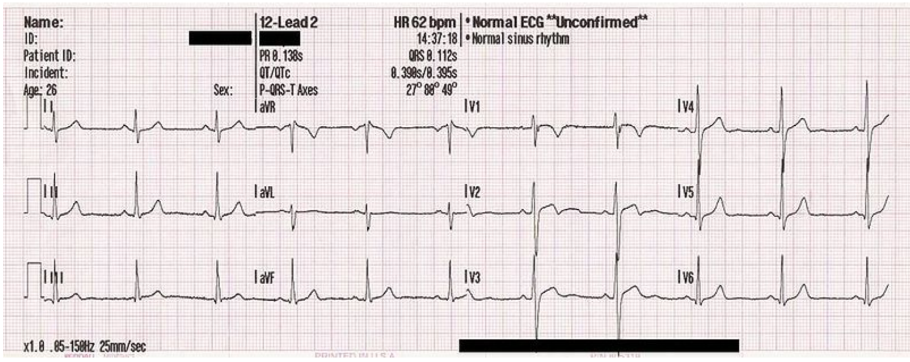

Figure 2: An ECG of a 26-year-old male.

- the **respiratory rate** (based on sound). Normal levels for a healthy person are within 12 and 20 breaths per minute. This value also needs to be correlated to the activity level of the patient.
- the **blood oxygen level** in percentage. Normal levels for a healthy person are within 90% and 100%.
- the **blood pressure** (the pressure exerted by circulating blood upon the walls of blood vessels) in millimeters of mercury (mmHg). Normal levels for a healthy person are within 85 mmHg and 140 mmHg.
- the **activity level** using the accelerometer. The activity level is expressed as a single number.
- the **temperature** in degrees Celcius. Normal levels for a healthy person are within 35 degrees and 37 degrees.

Other inputs. Next to the wearable unit, other measuring devices or sensors are in scope of the patient monitoring system. For example, the patient's weight is obtained (in kg.) with a scale, and reported by the patient. A GPS chip (e.g. in a smartphone) delivers info about the geographic location of the patient. Furthermore, a questionnaire filled in by the patient provides less tangible kinds of information, such as how he is feeling. Combined, these sensors can be used to give an idea of the mental state of the patient: if for example the patient hasn't left the home for few days and the questionnaire indicates a sad mood, it probably is a good idea to send a family member or volunteering neighbor to pay the patient a visit.

Gateway. Sensors will not communicate directly with the system themselves, but an intermediate device is introduced near the patient: the *gateway.* Every sensor communicates directly with the gateway, which makes abstraction of specific communication technologies and protocols (as shown in Fig. 3). For example, the wearable unit uses BlueTooth for wireless communication but the gateway also offers a USB port to connect to other devices.
The data collected from the sensors and other inputs are packaged by the gateway and transmitted to the patient monitoring system. The transmission can happen in multiple ways. When inside the house, the gateway could use the local WiFi network, when outside, it could use a 3G network. Additionally, the gateway can be one of several types of devices, for example a home computer or a smart phone. Note that this device could also be used to gather other types of patient data. For example, a smartphone is able to to gather location data with a GPS and the home computer could be used for a patient questionnaire.
The gateway never transmits raw data to the system, only processed values in packages. The exact contents of a data package and the transmission rate can be configured on the gateway. By default, the configuration is determined by the patient's risk level (see Section 2.4). For example, in case of low risk, only a single average blood pressure value for the monitoring period is required during the planned transmission. In case of high risk, it can be useful to acquire the maximum, minimum and average daily values. Table 1 gives an overview of the default configuration for high

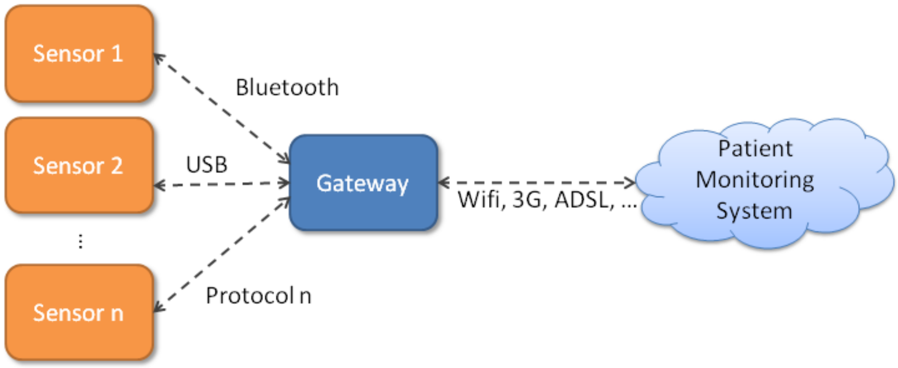

Figure 3: The sensor setup with a gateway.

risk, which has the highest transmission rates. These default rates can be explicitly overwritten by a physician.

Parameter	Transmission rate	Derived measure
Heart rate	48/day	Avg, max, min, variance
ECG	24/day	Full ECG of 30 sec.
Respiratory rate	48/day	Avg, max, min
Oxygen level	24/day	Avg, max, min
Blood pressure	48/day	Avg, max, min
Activity level	4/day	Single value
Temperature	6/day	Avg
Questionnaire	1/day	Full answers
Weight	4/week	Momentary value

Table 1: Default configuration for high risk.

Next to periodically transmitting the measurements, the gateway also supports transmitting data on demand. The physician has the ability to request the measurements instantly, in which case the systems sends the request to the gateway. For example, the physician can pull the latest data from the wearable unit or request the patient to enter his weight or fill in a specific questionnaire.

Invasiveness in the patient's day-to-day life. A consequence of these technological advances in patient monitoring and wearable sensors is that the patient should not be bound to one place for the monitoring to happen. These technologies allow him to remain mobile, and for example leave the hospital or his home without losing any data. Furthermore, the patient should not be hindered by the system and the monitoring happens automatically without having the patient fill out several forms each hour.

2.3 Risk estimation and notifications

The system employs the monitoring data sent by the gateway to continuously make estimates of the patient's current status. The underlying goal is to predict upcoming malignant events (such as a heart attacks) and keep the appropriate parties (physicians, trustees, home caretakers, etc.) up-to-date by sending notifications.
To achieve this, patients are divided into *risk levels* (low, medium and high risk). The physician determines the initial risk level of a patient depending on the primary diagnosis. After that, the system monitors the patient and continually estimates whether or not a patient's risk level should

change, using *clinical risk models*. These models combine different technologies such as data mining, machine learning, probability models (e.g. Bayesian networks) and ontologies to model the data and derive a risk estimate combining all given inputs. The inputs for the clinical risk models are: (i) the new data sent by the gateway, (ii) the old data in the system, (iii) the pathologies of the patient (as determined by the physician) and (iv) the current risk level.
Because it is generally accepted that no single risk model fits all cases, the system supports and is able to combine multiple models. For example, HeartScore [3] is targeted at the general population and not at known high-risk CVD patients. Therefore is is not suitable for event detection but it can be suitable for decision support and is definitely useful for patients as it shows their progress. Because of this, the system provides multiple risk models, which can be deployed by physicians on a per-patient basis.
To give an understanding of how this works, we provide one example clinical risk model. This model estimates a patient's risk using *thresholds* for each medical parameter, determined on a per-patient basis. These thresholds determine whether the monitored values are normal, worrisome or dangerous. Default values for each of these thresholds depend on the risk level of the patient, but the physician is able to override each of the threshold values. Table 2 shows the default threshold values for the blood pressure.

Risk level	**Normal**	**Worrisome**	**Dangerous**
Low	105-120	90-105, 120-150	80-90, 150-190
Medium	95-135	90-95, 135-160	80-90, 160-190
High	90-150	85-90, 150-170	80-85, 170-190

Table 2: Default thresholds for blood pressure (mmHg).

The risk models only estimate the risk level of a patient, but cannot actually change it. Only the physician can actually change the risk level of the patient in the system. The main goal of the patient monitoring system is to aid their decision making, *not* to make actual medical decisions. If the system estimates that a patient's risk level should change, the physician is notified in order to assess the estimation and approve or decline it.
In general, there are three notification levels: green, yellow and red. A red notification is sent when the patient's status changes seriously and requires immediate attention. A yellow notification is sent when the patient's status changes non-critically, but potentially dangerous. A green notification is sent when the patient's status reverts to a lower risk level. Of course, the exact content of the notification depends on the precise event.
Note that next to the physician, a lot of parties might receive notifications. For example, a yellow notification concerning the activity of a patient can best be sent to his trustees of the home caretakers so that they can also keep an eye on the situation.

2.4 Physician decision support

The medical models used for the estimation of patient risk levels are also used to aid physicians in their decision making, for example on a consultation. When a physician checks the status of a patient, the most important and relevant information should be shown in a structured and efficient way. For this, the system has to be able to evaluate the patient's status. Through the implementation of standard clinical models and by applying medical guidelines, routine clinical consultations are made more consistent and informative. For example, the system knows that the physician was recently notified of a malignant event with the patient. Now, the system shows the current risk estimate of the patient, together with all the information relevant to the event (for example, a graph of the blood pressure or an ECG). Of course, the physician is still able to request the exact information he wants.

2.5 Patient support

Similarly to physicians, patients can also make use of the medical models. When a patient wants to check his own status, he also expects to see the most important and relevant information in a structured and efficient way. Of course, there is an important difference in the way this data is presented to these actors: in case of the patient, this data must not be too technical or clinical. The system offers him a customized view on his data, for example a simple graph indicating the percentage improvement since last week.

2.6 Emergencies

As an extension to the green, yellow and red notifications, the system can also send *emergency notifications*. An emergency notification is sent to the Hospital Emergency services (cf. Section 4) in case of a life-threatening event such as a heart attack. Emergency notifications are sent in case of *ongoing* emergencies, while other notifications are sent when malignant events are *predicted*.
Normal notifications are sent by the system after analyzing new data using medical risk models. For emergencies, this system is too slow since the fastest transmission rate is 48 times per day. Therefore, the gateway is extended with a general-purpose, light-weight, medical emergency model, which is also threshold-based (as the one presented in Section 2.3). Similar to the risk models, default threshold values depend on the patient's risk level but can be explicitly overwritten by a physician.
The gateway uses this model to interpret the measurements itself and alerts the system of a possible emergency, along with the necessary data. The system rechecks the data for an emergency using more extensive models and sends out an emergency notification if needed.
Note however, that we are not building a live-saving device. Handling emergencies is not a primary goal of the system and the timely delivery of an emergency notification does not have to be guaranteed in every case.

3 Main stakeholders

Patients. The system applies to patients who have already been diagnosed with CVD and now need to be monitored for treating or controlling their disease (which does not hold for every CVD patient). They want the system to help them in their treatment and would like this to happen in the most comfortable way.

Physicians. The system will be used by multiple types of physicians. In practice, cardiovascular diseases are treated by cardiologists, thoracic surgeons, vascular surgeons, neurologists, and radiologists, depending on the organ system that is being treated. General practitioners (GPs) also form a large group of physicians in the system.
The system should support physicians in their job, primarily by aiding their decision making. Physicians want the information they need in a structured and efficient way, for example by being notified of important updates of a patient's status or a clean graph of the patient's evolution. Also note that we are building a system for use by a hospital, but not every physician needs to be on that same location. A GP probably has his own independent practice, so can a radiologist.

Nurses. Nurses are responsible for the more practical part of the patient's treatment. In general, nurses at the hospital do not take part in the system. However, a specialized team is responsible for the setup and configuration of the sensors after a patient has been diagnosed and recommended to use the system. For example, depending on the diagnose of the physician, the measuring rate of parameters to be measures can differ from patient to patient. The sensor settings also need to incorporate the patient's body structure and specific needs.

Home caretakers. Home caretakers visit the patients at home and help the patient in several ways. For example, a caretaker can help the patient doing his daily chores or can help with washing, clothing etc, but they can also perform more medical care operations such as administering medication or doing kinesthetic exercises. Moreover, as home caretakers acquire a very personal connection to the patient, they obtain a clear view of the current health situation of the patient. They could clearly use information about the patient's status and can also provide useful input to the system.

Trustees. Patients can allow their trustees to use the system. A trustee can be anyone, ranging from their family and friends to their neighbors who want to help. Amongst others, trustees can be allowed to keep up-to-date of the patient's status by checking his status using the system or by being subscribed to notifications. Moreover, each patient can assign one of their trustees to be their *buddy*. A buddy plays a similar role to home caretakers: he or she visits the patient on a regular basis and is able to estimate the current situation of the patient correctly. They can also input their estimations in the system.

Emergency callcenter. The emergency callcenter in the hospital receives all emergency calls and responds appropriately, for example by dispatching an ambulance to the scene. They also receive emergency notifications from the monitoring system. With an emergency, they want as much information as possible to get a clear view over the situation. Therefore, they also want to access the monitoring information. Moreover, an emergency needs to be entered in the system so other appropriate parties (the specialist, the GP etc.) can be notified to be kept up-to-date.

Telemedicine callcenter. The telemedicine callcenter takes on every sort of question about the system from the end-user side, ranging from a patient who notices his sensor went dead, to a hospital administrator who is having troubles integrating the system with his own system (the Hospital Information System (HIS)). The callcenter is a service offered by our company, not by the hospital itself.

Telemedicine operators. The telemedicine operators follow up the system from the hospital point of view. They are notified by the system when a patient's sensor hasn't sent in data for a long time or the data seems incorrect and they handle notifications where human assessment is needed to determine further actions.

The hospital. The hospital is our company's main client. More specifically, we – as a telemedicine company – have been contracted for a pilot project, involving only a limited number of CVD patients. If successful, the hospital will deploy and apply this monitoring system to a larger patient base in the future.
The hospital's main stake is that the patient monitoring system will aid them in raising the quality of CVD treatment, thereby increasing the efficiency and effectiveness of CVD treatment. Furthermore, by introducing CVD patient monitoring from home, CVD patients are kept out of the hospital and this frees up space and resources allocated previously for on premise patient monitoring.

Legal departments. Both the legal department of our company as that of the hospital need the system to comply to healthcare regulations. More information about the precise healthcare regulations can be found in section 4.4. It is important that the system is not only compliant to these regulations by design, but is provably compliant throughout its operation.

Hospital financial department. The hospital financial department is responsible for sending the bills to their customers, the patients. It is imperative that the systems provide clear usage and billing reports so that this is done correctly.

Telecom operators. Telecom operators provide means for the sensors and the gateways to communicate with the system. A service level agreement between our company and the telecom operators determines the capabilities of these communication channels.

4 Additional constraints

Next to the general problem domain description, there are a number of specific constraints highly relevant to the patient monitoring system.

4.1 Hospital Information System (HIS)

As mentioned in Section 1, the patient monitoring system will be deployed and maintained as a service by our company. Nonetheless, it should integrate tightly with the existing Hospital Information System (HIS) currently in use at the hospital. The desired integration covers a number of dimensions:

Patient data. Evidently, the hospital has full ownership of patient records and patient data and the patient monitoring system (PMS) will not change this. This implies that the measurements gathered by the PMS must be integrated in the patient record storage of the hospital itself. However, keep in mind that some of the measured data (cf. Section 2.2) is very fine-grained and updated frequently.

Physician workstation. As part of the existing HIS, the physician (e.g. a cardiologist) already has a means to connect to the hospital, either through his personal workstation or remotely (if they have their own practice). As the patient monitoring system offers the physician with a number of new functionalities related to decision support, remote configuration of the sensors, daily patient follow-up and receiving notifications, these must be integrated in the physician's workstation.

Patient registration. When a patient is first introduced to the monitoring system, he received a set of sensors. First, these must be paired or linked to the specific patient. Secondly, they must be initialized and calibrated according to the patient's context, and this setup must be tested before sending the patient home. This process of patient registration happens at the hospital (e.g. after a check-up), and is conducted by a trained nurse.

Emergency situation. When the automated decision support identifies an emergency situation (cf. Section 2.3), it must be able to trigger an emergency procedure by contacting the emergency services already offered by the hospital (e.g. 112) and possibly also the other stakeholders involved in the patient's treatment, such as his physician and GP.

Accounting. Finally, for purposes of accounting, the hospital must be kept aware on a day-to-day basis of the costs incurred during operation of the patient monitoring system. Typical costs include the maintenance of the platform (e.g. repairing sensors), bandwidth, operation costs of the callcenter, etc.

4.2 Electronic Health Record integration

As mentioned earlier, the *electronic health record (EHR)* is a common enabler in e-health. In this system, a patient's medical record is available electronically to allow healthcare professionals from different medical institutions to communicate patient data in a fast, efficient and reliable way.
For example, if you visit the GP on call in the weekend, this physician can get access to all the information about you just as easily as your main GP. A lot of effort has been put into researching and developing this field and the first practical implementations have been set up.
The data collected by the patient monitoring system should be integrated in the patient's EHR. Note that the EHR is not intended for storing raw data, but for storing and sharing structured and summarized patient data. Also, events and intermediate diagnoses have to be present. The EHR can also be a source of information, for example when a physician prescribes medication relevant to CVDs.
The EHR itself can be a complex system. One reference implementation allows hospitals to keep their patient and personnel data on premise and provides a central registry with references to all patient records. The whole system is accessible through one service, which combines the different

data sources into one clear patient health record. Moreover, there are European initiatives [4] that aim to incorporate all national initiatives into one service, accessible from every country within the EU.

4.3 Financial constraints

Evidently, setting up and maintaining a pilot project such as the one described in this assignment is a costly operation. For this project, our company has negotiated a million-euro contract with the hospital. Since the pilot project involves monitoring of actual CVD patients, a Service-Level Agreement (SLA) has been enclosed as part of this contract. This agreement stipulates certain quality requirements (in terms of performance and availability). For example, there should be an upper limit in the time it takes for an emergency notification to reach its destination.
Also, our company has to negotiate a number of service-level agreements with several of third parties: the telecom operator to ensure the desired degree of patient connectivity, the hardware manufacturer for acquisition, maintenance, upgrade and repair, etc.
Another relevant aspect is the billing of patients (typically done by the hospital, as part of the treatment costs). Especially beyond the scope of the pilot project, when the patient monitoring system will be applied to a larger CVD patient base, the billing policy should take into account other concerns. For example, abuse of telemedicine services (e.g. by a lonely patient continually contacting the callcenter for no specific reason other than social interaction) should be prevented.

4.4 Legal issues

Because the data handled in the system is medical data, the system has to comply to several laws. In the EU, medical information is regarded as personal information and falls under the European Data Protection Directive[1] [6]. In the US, there is a specific law regarding the processing of medical data: the *Health Insurance Portability and Accountability Act (HIPAA)*[7]. Amongst others, both acts determine the following similar rules:

- Health information cannot be used and disclosed without explicit patient consent, unless processing is necessary to protect the vital interests of the patient or for treatment, payment or healthcare operations.
- Identification should be minimized when disclosing it: if the data can be anonymized, it should be.
- The patient should be able to locate and view all of his health information. He should also be able to delete and modify all personal administrative information.
- Health data should be stored for a number of years, depending on the country (30 years in Belgium, 6 years in the US).
- Anytime the patient's data is disclosed to someone, this event should be monitored and logged.

The system should apply to all rules stated above.

4.5 Security

Considering the nature of the patient monitoring system (patient health information is highly sensitive information) and the legal implications listed above, it is evident that security is key concern in the system. Security in itself is a very complex subject that affects many layers of the system, and it should therefore be considered very early in the development process. In this assignment we limit the scope to *user authentication* and *user action logging*.

[1] A directive is a legislative act of the European Union which requires member states to achieve a particular result without dictating the means of achieving that result. It can be distinguished from regulations which are self-executing and do not require any implementing measures[5].

User authentication. Authentication is the process of ensuring the identity of the different actors. It should not be possible for a user to act as another user (spoofing) and users should not be able to access the system unauthorized. It is clear that the patient monitoring system has a large variety of types of users, and it is realistic that the concrete realization of authentication will differ highly between these users: for example, a physician uses a badge to authenticate himself, a home caretaker uses a username and password and the patient is authenticated implicitly, because he is using a wearable unit that is linked to his identity.

User action logging. Logging is the process of storing information about every action performed by the actors and the system itself. It enables the checking of system compliance to business or security policies, or in case of security-related incidents, trace the incident to a user. A log contains information such as the identity of the actor, the action, the object on which the action is performed, a timestamp etc. Note that user action logging depends on correct user authentication.

5 Scenarios

This section presents a set of concrete scenarios concerning the typical treatment and monitoring of a CVD patient, called Stef Aerts. Fig. 4 provides a high-level overview of this scenario.

5.1 Primary diagnosis

Stef Aerts is a 63-year old man, living in Leuven. He has always enjoyed eating and drinking well, but has quit smoking at the age of 31, when his first son was born. He now enjoys the quiet life on retirement with his wife, Jeanne.
At the age of 57, Stef started feeling a bit off. His GP noticed hypertension ($T1$) and ordered a blood test. This test indicated that Stef suffers from hypercholesterolaemia, i.e. high cholesterol levels. Therefore, he prescribed appropriate medication, and adviced Stef to lay back a bit on the butter and salt.
Since several weeks, Stef has been troubled with chest pains ($T2$). He finally decided to consult his GP again, who recognized the severity of the problem and forwarded Stef to the hospital for further testing. After an ECG and some X-rays, the cardiologist, dr. Huis, observed narrowed arteries near the heart, an indication of arterial disease (CVD). One artery in particular was obstructing the blood supply to the heart and dr. Huis schedules a bypass surgery right away ($T3$).
The surgery went well. The obstruction has been taken care of and worse outcomes have been avoided. The cardiologist now recommends Stef to sign up for the patient monitoring system that the hospital is testing on CVD patients. This system allows Stef to go home three days after the surgery while still being monitored. This helps keeping the arterial disease near his heart under

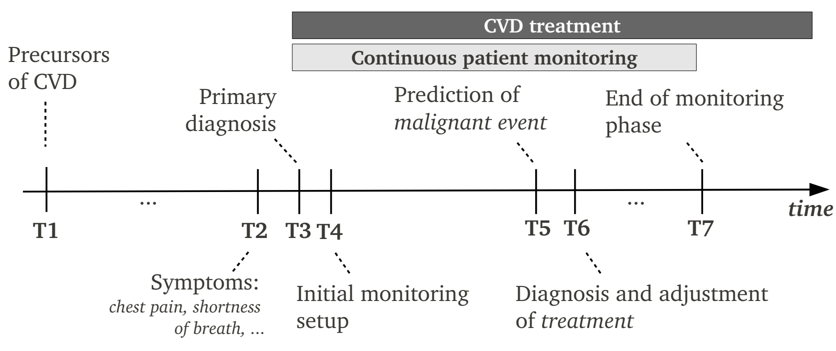

Figure 4: High-level overview of the treatment of a CVD patient.

control and allows for detailed monitoring of his recovery from the surgery. Stef agrees to take part in the system.

5.2 Initial setup

After Stef agrees to sign up for the monitoring system, Dr. Huis determines the correct monitoring configuration (e.g. sampling frequency, measured parameters, etc) and passes these on to the nurse responsible for patient registration and the initial setup ($T4$ of Fig. 4). This nurse has received specific training for this. As a first step, she signs up Stef for the monitoring system. She explains the system to him and shows him the wearable unit and the possible gateway devices. Stef chooses to get a smartphone since he would like to be able to still leave the house and doesn't already own one. Next, the nurse configures the wearable unit for Stef, incorporating his specific body structure and the configuration dr. Huis has requested. From this point on, Stef will be wearing the wearable unit constantly. The nurse also pairs the wearable unit with the gateway. Afterward, she runs some primary tests and verifies that the sensors function as expected. She also asks Stef to appoint a buddy: someone responsible in case of emergencies. Stef chooses Jeanne, his wife, for this.

At home, Stef is trying to get used to the system. He explores the functions of the smartphone. He also has a home computer, on which he tries to customize some system settings: the nurse told him he could add trustees to the system and Stef would very much like his children to stay up-to-date of his health status. Stef cannot find what he is looking for, and the manual does not seem to help either. He decides to call the telemedicine callcenter. They offer him to enter the trustees by phone or want to aid Stef through the procedure on his computer. Stef chooses the latter and eventually, he manages to enter the e-mail addresses and phone numbers of his children.

5.3 Normal monitoring

Starting from the initial setup, Stef wears the wearable unit at all times. He only takes it off to take a bath, or to change the (rechargeable) batteries. When Stef leaves the house, he always takes his smartphone with him. The system constantly takes measurements and sends them to the system. Stef also has to fill in a questionnaire every day, asking him whether he feels any pain, and in which physical activities he takes part. The GP can use the monitoring information combined with regular check-ups to keep a close eye on Stef's evolution. Stef only needs to visit dr. Huis when the GP considers it a good idea.

5.4 GP check-up

As said, Stef needs to visit his GP (who also is a user in the system) regularly for check-ups. On one such consultation, the GP examines Stef and uses the system to take a closer look on his evolution since last time. The system returns the information in a clear and structured way, showing graphs and summaries with only the most important information. Since Stef has had surgery and suffers from narrowed arteries near his heart, the system focuses on the ECG and heart rate. The GP is also interested in Stef's blood pressure and queries this data too. The graphs seem normal for Stef's case and the GP enters his findings in the system after the check-up. The other physicians (e.g. dr. Huis) are notified of the results. In the other case, the GP could have redirect Stef to the hospital for further tests.

5.5 A malignant event

For more than a month, everything remains normal and Stef seems to be recovering well from surgery. But then the clinical risk models indicate that his heart is having more and more problems and, as a result, the system estimates that Stef's risk level should be raised. The systems sends a notification to dr. Huis, and after reading the notification he uses the system to get some more details. What worries him is that the obtained data show recent changes in the heart rate patterns (visible on the ECGs). This might indicate that Stef's other arteries are also in trouble, which might lead to ischemia (restriction in blood supply) and oxygen shortage. He updates Stef's

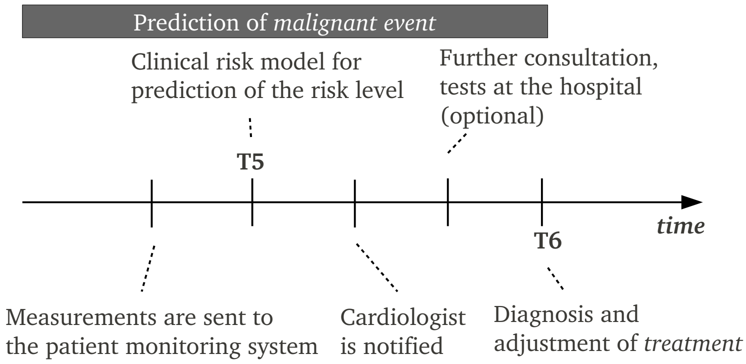

Figure 5: Zoom-in on the prediction of a malignant event.

risk level and orders a consultation at the hospital for some more elaborate tests. The event is automatically added to Stef's EHR after confirmation by dr. Huis. A timeline of these events is presented in Figure 5.
At consultation, Dr. Huis performs a coronary catheterization, a minimally invasive procedure to access the coronary circulation and blood filled chambers of the heart using a catheter. The resulting coronary angiogram visualizes the narrowing and obstructions in the heart vessels, and in Stef's case these tests indicate that dr. Huis has interpreted the data correctly: Stef is suffering from additional myocardial infarction (narrowed or blocked arteries). To address this, Dr. Huis decides to adjust Stef's treatment by changing his medication (β-blocker treatment). He also increases Stef's risk level in the patient monitoring system and recommends him to hire a home caretaker to visit him regularly. This home caretaker would help him to do some exercises and would assess his situation. After each visit, he or she would fill in a questionnaire about him using their PDAs. His son, in the hospital to support his father in these difficult times, also offers to keep an eye on his father and would also like to fill in such a questionnaire from time to time. Stef agrees to both measures.

5.6 EHR

In a weekend after the malignant event, Stef gets the flu. He visits the GP on duty, which is not his regular GP and moreover, does not have access to the monitoring system. The GP examines Stef, makes his diagnosis and adds the diagnosis, symptoms and prescribed medications to the EHR. After that, the patient monitoring system notices that Stef was diagnosed with the flu. Although this does not directly relate to CVDs, the clinical models do point out that it could be important information for the involved physicians. Therefore, the system sends notifications to the GP and the cardiologist in order to get them up-to-date.

5.7 Troubleshooting

Stef recovers from the flu. Three weeks later, the patient monitoring system notices that no data has come in from Stef for half a day. The system notifies the telemedicine operators, and they contact Stef by telephone in order to inform him of this and to find the cause of the problem. Firstly, they ask Stef to take a look at the little indicator light on the wearable unit, which indicates the battery status. At first sight, the battery seems to be the problem. Stef admits that he forgot to change the batteries that morning. He immediately replaces the batteries with fully charged ones, but the wearable unit still fails to work. The operators make an appointment with the nurse who performed the original setup at the hospital. At this appointment, the nurse replaces the wearable unit.

5.8 Accountancy

Since Stef has signed up for the patient monitoring system while it is still in the pilot phase, he only has to pay a small fee, which occurs on the hospital bill for his CVD treatment (part of this is covered by the mutuality, but that is out of scope of this assignment).

5.9 End of the monitoring

After three months of monitoring, Stef's status seems to have stabilized. At a consultation, dr. Huis explains to Stef that at this point in the treatment, the monitoring is not strictly required, as the new medication seems to work and a regular check-up with his GP should suffice. Although Stef could still choose to continue to use the system for his safety, he chooses not to (he is tired of changing the batteries so often). Stef returns the wearable unit and is signed out of the system. He does choose to keep the smartphone now that he has learned to work with it (and he doesn't want to lose face to his grandchildren).

References

[1] "MEP Heart Group — The Cost of Non Heart Health in Europe, 26 February 2008," February 2008. [Online]. Available: http://www.mepheartgroup.eu/meetings-activities/item/6-costs-of-non-heart-health-in-europe.html

[2] "eHealth - Wikipedia, the free encyclopedia," February 2011. [Online]. Available: http://en.wikipedia.org/wiki/EHealth

[3] "HeartScore: cardiovascular disease (CVD) risk assessment and management," February 2011. [Online]. Available: http://www.heartscore.org/

[4] "epSOS: Home," February 2011. [Online]. Available: http://www.epsos.eu/

[5] R. Folsom, R. Lake, and V. Nanda, *European Union law after Maastricht: a practical guide for lawyers outside the Common Market.* Kluwer Law Intl, 1996.

[6] "Justice - Data Protection - Homepage," October 2010. [Online]. Available: http://ec.europa.eu/justice/policies/privacy/index_en.htm

[7] U. Government, "Health Insurance Portability and Accountability Act of 1996," 1996.