# Patient-centric Handling of Diverse Signals in the mHealth Environment

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Abstract: In the context of the Mobile Health (or Telemedicine) many signals (data items) are exchanged between the medical devices, data storage units and involved persons. They are often treated as a uniform mass of "medical data", especially in the Big Data community. At a closer look, they unveil various characteristics, like type (single / continuous), required quality and tolerance for missing values. As in medical care time is crucial, real-time characteristics are important, like the sampling rate and the overall reaction time of the emergency system. The handling of data depends also on the severity of the medical case. Data are transferred and processed by external systems, therefore the overall function depends on the environment and the persons involved: from the user/patient to a dedicated medical emergency team. The collected data can be anonymously reused to gain or verify knowledge, what calls for a fair trade-off between the interests of the individual patient and the community. This paper discusses the semantics of mHealth data, like medical requirements, physical constraints and human aspects. This analysis leads to a more precise mathematical definition of the required data handling that helps to construct mHealth systems that better fulfill the health support function.

## 1 INTRODUCTION

A mobile health system, serving to treat a serious medical case has to meet many demands. For a designer, it is easy to be biased by his/her own experience. A developer of smartphone applications, a Big Data analyzer, a sensorics specialist - each of them has a different viewpoint and puts stress on different aspects of the problem. As the technical issues are truly challenging and crucial for the success, they tend to play the dominant role, especially in small and young enterprises. We will try to connect various technical viewpoints with the medical perspective in order to build a unified picture.

Mobile health systems generate and process large amounts of data. It is important to see their medical significance which is not equal for all of them. Some of them are required in a predefined frequency, some are helpful but optional. Some need a certain precision, some serve only as orientation values. Some have to ensure guaranteed reaction times, for some timing constraints are irrelevant. Some, when analyzed statistically, need a well balanced, unbiased sample, for some sheer quantity makes them valuable.

This paper takes a closer look at the above mentioned aspects of mHealth data and brings to a technically-oriented reader a better view on their *meaning*. This semantic view allows in the next step to formalize the requirements regarding time constraints and data extraction, conversion, transmission and storage. The final goal is to help the reader to construct better *patient-centric* medical systems.

Remark: We use here interchangeably the terms signals or data (items). The word *signal* stresses the capture from sensors, whereas *data* emphasizes the information content. We also use the term *patient*, although in the case of fitness tracking *user* would be more correct. As the borders between the application areas are not sharp, we stay with the first term.

## 2 RELATED WORK

There are several good overviews of today's mobile health technology and applications (Baig et al., 2015), (Islam et al., 2015), (Silva et al., 2015), (Soh et al., 2015). A detailed analysis of remote blood glucose monitoring is given in (Lanzola et al., 2016). Cardiovascular health and disease is discussed in (Eapen et al., 2016). The authors also propose a roadmap for mobile health in this area. An Android-based system for ECG arrhythmia classification and heart rate variability analysis is presented in (Xue et al., 2015).

It is useful to look at the mHealth from the medical perspective. (Itrat et al., 2016) discuss the

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telemedicine in prehospital stroke evaluation. (Agboola et al., 2016) presents a bitter reality check for smartphone apps. A top-selling app for managing and diagnosing skin cancer was only able to accurately classify 10 of 93 biopsy-proven melanomas. As for insulin dose calculation, 67% of the apps gave inappropriate output dose recommendations that put users at risk (Huckvale et al., 2015).

If we analyze the function of the systems not in the lab, but in real life, practical experience is of use. (Espinoza et al., 2016) present the design of a telemedicine management system in Ecuador where specific local challenges of a rural environment in a less developed country had to be addressed.

# 3 SIGNAL TYPES

## 3.1 Basic Signals

We can divide the basic signals in following categories:

- Single measurements: *(t, value)*
- Point events: *(t, type)*
- Continuous waveforms: $(y = f(t))$

If we take a closer look, the divisions between them are blurred. In the case of a chronic disease, single measurements form a sequence of values. Point events may be entered as such, like an epileptic seizure or tumbling. If they are detected by sensors, they are derived from other measurements, as shown below. Continuous signals are created by sampling a property, so formally they are sequences of values, at a high sampling rate. When we speak of such signals like ECG (electrocardiogram) or EEG (electroencephalogram), they may come from a single sensor (in a very basic version) or from a set of sensors placed on the chest or on the head in well defined locations. In the latter case we obtain a set of synchronized waveforms.

## 3.2 Derived Signals

From the basic signals we can derive more condensed information. It is especially useful in the case of continuous signals the volume of which is too large to store or transfer. Equally, in the raw form it is not yet very useful. For the electrocardiogram, a well known condition is the ST Segment Elevation Myocardial Infarction (STEMI). The cardiac cycle has characteristic points P-Q-R-S-T, and the elevation of the S-T segment is a signal warning about the risk of a myocardial infarction, i.e. heart attack. Similarly, irregularities of the cycle frequency can be identified as arrhythmia, in several variants, like tachycardia or bradycardia (heartbeat too fast or too slow). For arrhythmia to be detected, the basic signal has to be analyzed over many cycles. The severity of the case depends on the intensity and duration of the abnormal condition.

As mentioned above, a point event can be detected by sensors. For example, tumbling of the patient can be detected by accelerometers, e.g. in a smartphone. In this case, an algorithm extracts a characteristic waveform from a continuous signal.

When we monitor vital signals, we have to treat adequately missing values. The fact that the measurement is missing may be an information itself. For example, missing a required value for a prolonged time may indicate that the device is not working (e.g. battery empty), that something has happened to the patient or that the patient is not using the device because it is obtrusive, he/she went on travel and: has forgotten it at home / has left it because of its weight / has no plug adapter for the charger. In a similar way, systematic outlier values may mean a health problem or a wrong placement or poor body contact of the device. We list those cases in order to stress that the same observed situation may have very different causes. Some of them may require intervention of the system operator (hospital).



## 3.3 Complex Signals

Until now we have discussed signals coming from single sources. From the medical point of view, it is often useful to combine information from many sources. One of the main reasons is making sharper distinctions between the cases and eliminating false alarms. There are many papers presenting methods to detect patients' falls with the use of the accelerometers. Typically the accelerometers built in the smartphones are considered as described in (Sannino et al., 2015). They are reasonably ubiquitous, however the assumption that they are worn all the time seems not to hold. In any case, if such a device detects the patient tumbling on the floor, it is useful to verify it with more data. Especially if the detected condition is severe, requires an action and this action is costly - like sending an ambulance - it is crucial to detect only real cases. False alarms, even not frequent, will erode the confidence in the service.

If we want to design a novel architecture that connects various devices from unrelated producers, we face the problem of the interoperability. Such devices - microphone, ECG sensor, EEG headset - typically are delivered with a connection to the smartphone or the cloud and visualization and/or analysis application. If we want to connect them into a combined device, we have to go on the level of the internal interfaces (rarely disclosed) and to write our own application. The system described in (Sannino and De Pietro, 2014) detects fainting and falling of patients by connecting the heart rate variability in the ECG with the information from accelerometers and other body and environmental sensors. In this way the decisions generated by the system take the context into account what increases their reliability.

Not only data formats may pose a problem, also communication protocols may be different (periodic sending / on demand), time and data granularity or measurement precision. When detecting complex events, we need synchronized data. If they come marked by internal timestamps, we have to compensate possible differences or to force the synchronization of the clocks.

# 4 CASE SEVERITY

The treatment of the signal depends on the severity of the medical case. We can list here following classes:

- fitness, general health, behavior modification
- chronic disease
  - mild
  - severe
- life saving

The influenced factors are:

- required quality
- necessity, sampling rate
- reaction time

If the devices are used for ***fitness improvement***, the measurements are performed or checked according to the interest of the user. The value is rather used for general information, and there are no timing requirements. The user often loses interest for the measurements after a certain time. If in meantime he/she changed to a healthier lifestyle, the basic goal has been achieved.

There is however a risk that the user gets obsessed with the fitness goals. Some people measure their weight on bathroom scales many times per day, not taking account of normal daily variation and measurement errors. In the same way, trying to constantly increase the daily step count, especially when comparing to the group and obtaining (verbal) rewards from the device, may pose a health risk. There is a certain optimum and not always more is better. On the other hand, the device typically just counts steps, so climbing a mountain is like walking, or even of smaller value, as the covered distance is smaller. Equally swimming, when the device is left in a locker, does not count at all. Therefore the user has to be aware that his/her virtual health is only an imperfect model of the real one.

This becomes a problem, if the user has an agreement with an insurance company to have a healthy lifestyle in exchange for lower primes. A simple device, like an accelerometer in a smartphone, registers only certain types of activities. On the other hand, the user may be tempted to cheat the device, by simulating realistic oscillations.

In a case of a ***chronic disease***, the device is typically used to monitor the state of the patient, detect the abnormalities and inform the doctor or hospital that handles his/her case. For a mild condition, the measurement can be done occasionally, more or less periodically or if the patient does not feel well. Therefore missing values are not problematic, possibly the patient feels no necessity to act. He/she should not be burdened too much by reminders. He/she can be called for a periodic check, as it is for apnea patients using a ventilator. The measurement should have a reasonable precision, determined on the basis of the medical science. It is necessary to eliminate the variability caused by imprecise placement of the sensor, too high (or too low) humidity of skin, wrong operating mode of the device, or similar. If - as we assume - the measurement is performed by the patient at home, the handling should be entirely simple and clear. The device has to be approved by the doctor what eliminates most cheap sensors and easily downloadable smartphone applications.

For a severe chronic disease, the requirements for quality and regularity of the measurements are more stringent. Regular measurements may show the increased risk before the actual event occurs and the patient may come for an extensive check or a preventive hospital stay. As the deterioration of the health state may be rapid and serious, time plays an important role. Ergonomics has to be carefully designed, as in an emergency the patient's capabilities are impaired. For example, during an insulin shock the patient is dizzy and nervous and his/her vision is blurred. If the patient is not able to act on his/her own and has no assistance, an automatic communication with the hospital is necessary.

For a ***life saving*** condition, the precision and reaction times are even more important. Let us fix our attention on a patient with a cardiac disease, having one or more wearable / implantable devices connected via a wireless Body Area Network (BAN) to a smartphone that can alarm the hospital in case of emergency. The devices are active, i.e. can induce a life saving action locally. As the patient is at risk, he/she has to adapt his/her life habits accordingly. As the emergency call system depends on functioning communication, the loss of the phone signal or of data roaming is a problem. This may occur in a rural area, in a location not properly covered by the patient's provider or in a restaurant restroom in the basement under a thick concrete floor. Therefore the patient should avoid such locations, limit the stay and take care. The current risk level may be evaluated by the devices and communicated to the patient. In a better phase less precautions have to be taken. The user interaction design is delicate, as the patient has to know about the increased risk but on the other hand should not be overwhelmed by messages. Too many warnings will themselves increase his/her anxiety or with time will be ignored. An intervention is costly, possibly includes sending an ambulance, therefore making a clear distinction between real and false alarms is extremely important. When in doubt, the emergency team may try to contact the patient. However, if the risk condition is generated by a complex algorithm combining many factors, the hospital emergency team may know about the upcoming event earlier than the patient him-/herself. This evidently is true if the measurement system is reliable and the algorithm is correct. We see that taking quickly correct, resolute decisions is not easy.

# 5 REAL TIME ANALYSIS

In the systems that handle serious medical conditions where emergencies may occur, reaction time is essential. At the lowest level we treat basic communications issues, like network architecture, data quantity, channel capacity and similar. Several papers discuss these problems and propose various feasible architectures (Thelen et al., 2015), (Castellano et al., 2015), (Hossain and Muhammad, 2016), (Kang et al., 2015).

Let us analyze the sequence of events (Figure 1) that if not handled on time, can lead to a catastrophic outcome, like death or a durable health damage.

We monitor the health state of the patient with periodic measurements. The time from the occurrence of the emergency state to a catastrophic outcome is a medical fact, as well as the possible outcome itself (risk level). The time from noticing the emergency to an intervention depends on technology. The period of the measurements has to be adapted adequately. For fast events, like a heart attack, where the time limit

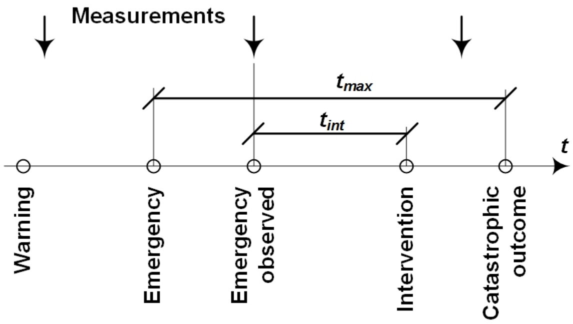

Figure 1: Timing of a medical intervention.

for an intervention is around one hour, the monitoring should be continuous (measurement period reduced to almost zero) and the intervention delay reduced to a minimum. For slow events, like breast cancer, where the disease develops in months, the measurement period is decisive. Not observing this limits makes the monitoring system virtually useless.

Under *warning*, as indicated in the figure 1, we understand some early signals that suggest an increased risk (*yellow alarm*). Early warning permits to extend our time reserve for action. As the indication in this stage is less decisive, full scale intervention is not appropriate. The patient may however reduce the risk by taking a rest, performing additional tests or visiting a doctor.

Breast cancer screening with mammography is a well studied example of risk analysis (Wegwarth and Gigerenzer, 2013). The authors show we should be wary of overdiagnosis and overtreatment.

When deciding what and how to measure and what actions to take, following factors have to be considered:

- disease
  - development time
  - medical risk when not treated on time
  - cost of intervention
- measurements (possible overdiagnosis)
  - cost (financial and organizational)
  - medical side effects
- false positives (overtreatment)
  - probability
  - cost of unnecessary treatment
  - medical side effects

The figure 2 depicts the basic trade-offs in this process. Mobile health technology mainly permits to reduce the cost of the measurement and in this way to make more frequent measurements without visiting a doctor - at home and in travel. It also permits to send

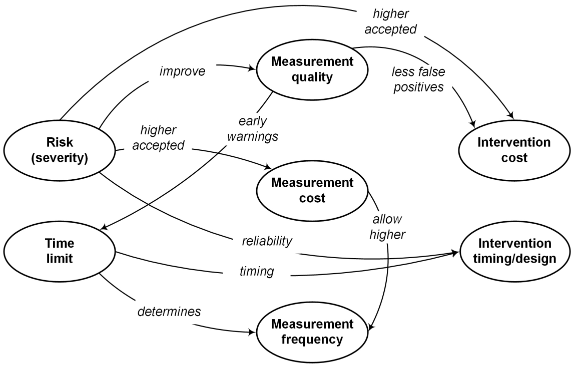


Figure 2: Trade-offs between various factors influencing a successful intervention.

quickly the data and emergency alarms, allowing the patient to maintain the same risk level even having an active life.

In the case of a disease with high risk and short required reaction times (like heart disease), it is important to design carefully the emergency service, ensuring high reliability and respecting the time limits. As this problem goes beyond the desine of the device itself, it will be treated in the following section, regarding the Cyber-Physical-Social Systems.

# 6 CYBER-PHYSICAL-SOCIAL SYSTEMS

It is important to see that mHealth systems consist of more than the purely technical elements. They interact intensely with the physical world. The sensors themselves are material - they need electrical power, their probes can break, sensing surfaces can have poor contact to the skin, output nozzles can be clogged. If we speak of Body Area Network, we have to remember that tissue and clothing damp the wireless signal.

If the patient moves in the environment, the wireless signal connecting him/her with the server may be blocked by obstacles (e.g. when visiting the restroom in a restaurant's basement). He/she can also move into the area where his provider has a poor signal or data roaming is impossible.

The emergency systems (Figure 3) are operated

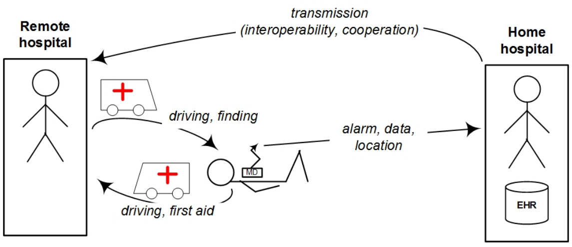


Figure 3: Emergency service.

by humans (*Human in the Loop*) and depend on their cognitive skills and information state. For example, if a heart monitoring system issues an alarm and the ambulance scheduler has no experience with automated systems, his/her thinking time adds directly to the delay of the rescue. The hospital that sends the ambulance is located near to the current position of the patient is not necessarily the same that handles his/her case and owns his/her health record. This requires to arrange the cooperation in advance, including a smooth interoperable data transfer and financial agreements. In the case of a heart attack the whole process has to be concluded during *the golden hour* and leaves no reserve for doubts and clarifications.

This shows that we should ensure that our assumptions about the system reliability and availability are not simplistic. We have to remember that in real life even a trivial cause (empty battery of a sensor, dry skin under the sensor patch, loosened contact of a cable) may have dramatic consequences for the patient's health. Therefore when analyzing the system with formal methods we should be aware that the model and the real object are different and imagination and common sense will be helpful.

# 7 VERIFICATION OF HYPOTHESES

Data generated in an mHealth supported therapy can be reused to verify our assumptions and obtain new knowledge. Let us consider a heart monitoring system issuing alarms and warnings in emergency cases. If the system is working continuously, it can detect significant events also if the patient is not aware of anything. They may consist of changed ECG waveforms, slower / faster / less periodic frequency or else. The intensity and duration of such events may play a role, as well as their sequence. Combining them with other vital signals will make the detection more specific.

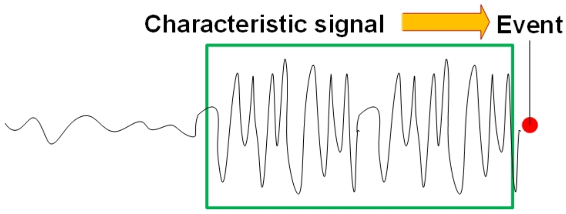


Figure 4: Using knowledge / hypothesis.

Normally, as shown in the figure 4, we assume that we *know* the rules and just *detect* the characteristic signals that indicate that an emergency event is imminent.

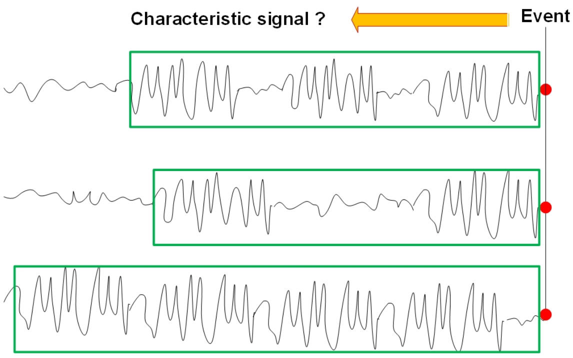

Figure 5: Searching for a new hypothesis.

The area of continuous ECG analysis, especially combined with other signals, is however fairly new. Therefore such event detection rules have to be verified, possibly on many patients, in many situations. Mobile health systems provide us such opportunity. We can analyze the actually occurring events and *look back* at the signals (Figure 5) searching for telltale data events, determine their characteristics and verify if the correlation is significant. In this way, we can create new hypotheses based on data. Evidently, quantifying variability of continuous signals is not easy, especially if we do not know beforehand what are we looking for. This shows that storing raw data (or extensive excerpts of them) for later analysis is useful, even if the benefit is not immediately evident.

# 8 COMMUNICATION AND STORAGE - SECURITY

Data collected from a mHealth device are sent to a receiver. Locally, it may be a smartphone or another data aggregator. A device can also have a direct connection to a server in the cloud. It is interesting what happens to those data later: where are they processed and stored, who owns them, for which purposes can they be used.

## 8.1 Architectures

Following factors are important in the analysis of the transmission and processing of data:

- data quantity
- network independence
- local use of data
  - user feedback
  - local action
- data reuse at a server
- cost of local computation
- cost of transmission

Especially in handling continuous signals there is a trade-off between storage, computation and communications. For taking decisions, we are interested in global parameters (pulse frequency, oxygen saturation) or special states or events (arrhythmia). If the rules to extract such condensed information are well defined, it is better to do the processing locally on the strongest device that can handle this task. This could mean that the implanted sensor device sends raw data to the smartphone, and the smartphone executes the complex calculation. This reasoning is only an example, in a specific case a precise analysis of computational power, transmission channel capacity, energy costs, etc. has to be performed.

Measurements can be used for local action with strong requirements for precision and reaction time, like in glucose management system. It is essential to ensure this function locally, also in the absence of the connection with the remote system. In this case we often speak of Fog Computing - like in Cloud Computing we have storage and processing nodes but not *high in the sky*, but rather locally, *near to the ground* (Gia et al., 2015), (Chakraborty, 2016).

## 8.2 Security

As mobile health systems handle very personal data, they have to be properly secured. This concerns both data transmission and storage. It is easier said than done. Sensor and actuator nodes are low power devices and handling strong security is costly. Basically all exposed networks should be properly managed - this includes applying security patches if necessary. However distributing software updates via network is itself an attack vector.

We have a set of heterogeneous devices coming from different sources, with different lifetimes. Establishing secure communications with the Public Key Infrastructure (PKI) is difficult. We have also to be aware of the trade-off between security and function. On one hand, the devices should be sure they talk to trusted partners. On the other hand, if the security certificate expires on a node and the communication is blocked, this would stop the proper function of the device that may be critical for the health or life of the patient.

Various architectural options, also in the context of the Internet of Things (IoT) and cloud computing, with the stress on the security aspects are presented in (AlTawy and Youssef, 2016), (Gejibo et al., 2015), (Samie et al., 2016), (Suciu et al., 2015), (Larburu et al., 2016) and (Sukor et al., 2015).

## 9 INDIVIDUAL PATIENT AND POPULATION - PRIVACY

Data regarding individual patients can be collected and reused for many purposes. Fitness tracking applications typically permit to send own data to the pool and to compare personal results with the community. This community has some basic stratification, e.g. with respect to gender and age. The quality of input data is unproven, no sources of bias are considered. The power of the solution lies in quantity of data. Such comparison is used mostly for personal satisfaction and motivation for further effort. It has to be mentioned that more effort is not always good, especially for elderly with osteoporosis and worn-out knees. The competition may cause an addiction where gaining points and virtual rewards count more than the actual health.

In order to participate, the patient has to agree, i.e. to express consent to share data. However, the exact conditions of this consent, if published, are never consulted. All detailed data reside on the servers of the provider and the patient somehow assumes that exact times and locations of his/her walks will not be disclosed to third persons or sold.

In the treatment of more serious medical cases, data can be aggregated and analyzed in order to obtain and verify knowledge. This can help to identify risk factors or to issue recommendations for healthy behavior.

If statistics based on collected data are used for generating decisions (actionable knowledge), we have to ensure adequate quality and statistical validity. Various aspect of medical data reuse are discussed in depth in (Sliwa, 2016b). If the decisions apply to the entire population, we should eliminate bias. If the population shows strong variations, it should be properly stratified, and the statistics for each category have to satisfy the quality criteria. This is not easy, as it is more practical to observe the population than to execute a formal clinical trial. To put it simply: if mostly young, technically oriented patients are willing to share their data, those data should not be used as a benchmark for the entire population, including the elderly.

Evidently, the system provider has access to all data and can use them at least to improve the service. Due to the fast pace of the technical development, much faster than the legislation, from formal legal point of view the area of reusing mobile health data is a gray zone. The question of data ownership in a multi-party Internet of Things (IOT) system, with smart medical devices as one of the examples, is discussed in (Sliwa, 2016a).

## 10 CONCLUSIONS AND FUTURE WORK

The basic goal of this analysis is to raise awareness for the semantic aspects of data processing in mHealth systems. It is important to understand the properties of the signals flowing from the sensors and their relevance to the overall health support function of the system. Their properties are determined by the medical factors, like the severity of the case, the possible outcome. the necessary intervention and its time constraints.

After the semantic analysis the elementary properties of the signals can be extracted, which permit to build a formal model:

- data type
- conversion algorithm
- timing requirements
- data quantity
- duration and location of storage
- ownership and protection

Nevertheless, it has to be stressed that for complex Cyber-Physical-Social-Systems, as in Mobile Health, the formal model is only an approximation and has to be constantly verified. The environmental conditions are diverse, the technology changes rapidly and human behavior is difficult to predict, therefore the usage of such systems has to observed and the design assumptions have to be periodically reviewed.

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