

# Research and Engineering Roadmap for Development and Deployment of Smart Medical Devices

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**Keywords:** Smart Medical Devices, Interoperability, Translational Medicine, Evidence Based Medicine, Cyber-Physical Systems, Research Roadmap.

**Abstract:** The actual clinical use of smart wireless, software-based, mobile medical devices does not meet the recently raised expectations. First, current low level of interoperability calls for setting and enforcing open standards from the device level to the national/global collaboration structure. Second, heterogeneous and frequently changing devices, operating in various natural, technical and human environments, do not match the classical approval model. In addition to a time-limited set of clinical trials, they need a system of continuous quality monitoring. Third, *ad-hoc* deployment, without dedicated staff with well defined, novel skill sets is not scalable. A proper organizational structure is necessary. In this paper we present a modular software structure and a framework of a system supporting both the direct health care and the continuous quality evaluation. We expose the location of interfaces crucial for assuring multivendor interoperability. We then define a roadmap giving structure to the necessary development effort. The structure we propose should permit to coordinate the actions of independent teams tackling the immense number of multifaceted and interrelated tasks.

## 1 INTRODUCTION

In spite of brilliant visions of the wireless future of the medicine<sup>1</sup> the actual adoption of smart medical devices into the clinical practice lags far behind expectations. In this paper we discuss the obstacles impeding this adoption and propose ways to overcome them. We focus our attention on the chosen basic scenario: patients with wearable and implantable medical devices, connected via an aggregator (typically a smartphone) into a larger infrastructure. We discuss the challenges to the development of a versatile ecosystem of interoperable devices and support systems and to their deployment in the actual clinical practice:

- Interoperability at all levels
- Configuration and deployment to the patients
- Servicing the deployed systems
- Ongoing quality control

Then we propose an organizational framework that provides a viable reference structure that enables to decompose the overall problem into manageable tasks. The solution is not only technical but to a

great extent organizational and requires a cooperation of many partners, willing to open their systems or to share their data. Their interests are legitimate and their concerns have to be treated with respect. Therefore we discuss the driving forces that should motivate them to enter into such collaboration.

On the basis of this framework we set a research and development roadmap that identifies main problem areas to be solved. The definitions of interfaces and data structures deserve a particular attention, since they are decisive for the current and future interoperability and flexibility. If well designed, they will permit a development of solution elements by independent teams that eventually will match into an encompassing superstructure.

In the conclusion we invite fellow researchers to discuss the proposed roadmap and to collaborate in using it as a scaffold for the actual project plan.

## 2 RELATED WORK

Mobile medical devices are currently an important research area. We present here only a selection of papers relevant for our subject. A good starting point

<sup>1</sup>[http://www.ted.com/talks/eric\\_topol\\_the\\_wireless\\_future\\_of\\_medicine](http://www.ted.com/talks/eric_topol_the_wireless_future_of_medicine), accessed May 7, 2014

is the roadmap<sup>2</sup> of the Healthcare Information and Management Systems Society. A broad picture of future possibilities is given in (Kumar et al., 2013a) and (Alemdar and Ersoy, 2010). The paper (Bergsland et al., 2014) presents various barriers faced by medical innovation - related to economy, mentality differences, healthcare organization, inadequate regulatory process, intellectual property and ethical issues. A deeper analysis in the context of Ambient Assisted Living (AAL) is presented in (Memon et al., 2014). This paper discusses important issues like interoperability and gives a sobering overview of actually implemented systems.

The problem of technology evaluation is addressed in (Kumar et al., 2013b), (Tomlinson et al., 2013) and (Mohr et al., 2013). A novel approach is crowdtesting (Speidel and Sridharan, 2014). One of the main topics of this paper, medical registries, is treated in the paper (Amit et al., 2014) that presents the Israeli implantable cardioverter-defibrillators registry, and (Wolpert et al., 2011) that exposes the necessity of a cardiac registry and the barriers that hinder their implementation. An approach to protect the data privacy in a registry<sup>3</sup>, based on a physical separation of personal and medical data is presented in (Sliwa and Benoist, 2012).

At the side of the integration of the patient's sensors with a smartphone, we witness two major initiatives: Apple's Health app<sup>4</sup> and Samsung's wearable sensor device Simband<sup>5</sup> with corresponding software on the smartphone. They should define ultimate (competing) personal health monitoring platforms. As for now, it was impossible for us to verify the claims regarding their validity as open systems. In any case, they position themselves in the consumer market segment.

Various approaches to create integration frameworks for system operation and device comparison are proposed in (Wagner et al., 2013), (Pawar et al., 2012), (Seeger et al., 2013), (Viswanathan et al., 2012) and (Franke et al., 2013). Open mHealth Architecture, similar to our goal, is proposed in (Estrin and Sim, 2010).

The European project "Renewing Health" (REGioNs of Europe WorkINg toGether for HEALTH)<sup>6</sup>

<sup>2</sup><http://www.himss.org/mobilehealthit/roadmap>, accessed May 7, 2014

<sup>3</sup><http://memdoc.org/>, accessed May 7, 2014

<sup>4</sup><http://www.apple.com/ios/whats-new/health/>, accessed Oct. 20, 2014

<sup>5</sup>[http://www.samsung.com/us/globalinnovation/innovation\\_areas/](http://www.samsung.com/us/globalinnovation/innovation_areas/), accessed Oct. 20, 2014

<sup>6</sup><http://www.renewinghealth.eu/en/>, accessed Oct.20, 2014

has delivered several pilot projects related to the management of chronic diseases with telemedicine. In particular, the Telemonitoring for Chronic Heart Failure project in the Veneto Region<sup>7</sup> shows an organizational structure including explicitly various human participants.

### 3 REFERENCE SETTING

In this paper we concentrate on systems of implantable and wearable devices, connected via a Body Area Network to a data aggregator, currently typically a smartphone (Fig. 1). This set is to be considered as a virtual multi-element device, performing a common task in a coordinated way.

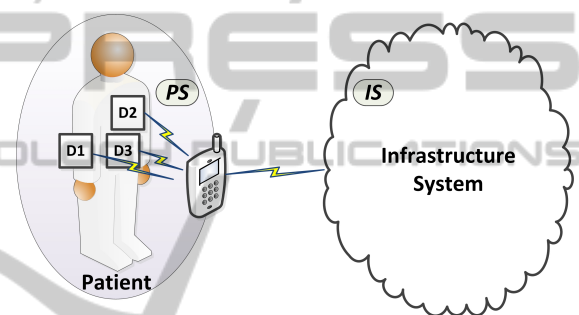


Figure 1: Basic configuration.

They have a specific medical purpose, like monitoring of vital health signals in a chronic disease, possibly expanded with direct life saving functions. The latter may be performed by the device itself, like a pacemaker, defibrillator or an implantable insulin pump, or may involve alarming qualified medical personnel. Therefore they do not work in isolation, but rather are integrated into a well defined infrastructure. They are selected and *prescribed* by medical specialists as an integral part of a therapy. In the face of the severity of the medical condition treated, of the importance of the provided function and of the degree of risk in case of a malfunction, they are subject to the regulatory oversight of the relevant authority.

We deliberately leave aside the thriving field of consumer devices used for fitness, promoting a healthy lifestyle and preventive health monitoring. Those devices do not have to meet stringent requirements and are not in the focus of the approval authorities. In this field the market forces and the consumer's satisfaction will play the decisive role.

<sup>7</sup><http://www.renewinghealth.eu/documents/28946/9c9db1d1-8ace-4b07-bc08-8a7a68f55d05>, accessed Oct.20,2014

## 4 CHALLENGES

### 4.1 Interoperability

Technically, one of the major problems is interoperability. It is necessary if we want to flexibly configure the systems, selecting the best elements for every function from any producer. It has an economic background, as many producers prefer to protect their ecosystems with proprietary, undisclosed data formats and protocols. In consequence, the hospital and the patient may be forced not to include necessary devices that are not supported by a chosen supplier. In the same way, if we want our devices to communicate directly with the hospital Electronic Health record (EHR) system, the EHR system chosen will limit us to only certain suppliers. Such connection exist or can be developed on demand<sup>89</sup>, the effort is however substantial and provides only a 1:1 communication path. This does not scale into an vendor independent, open solution.

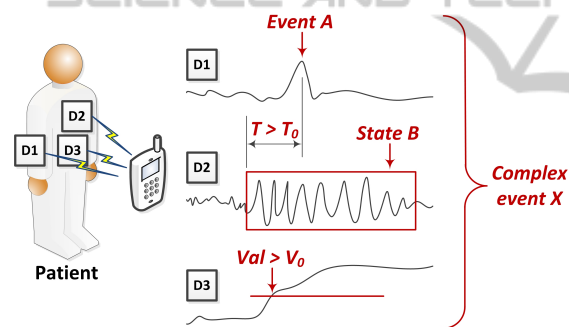


Figure 2: Complex event.

We also may want the devices to operate in a coordinated way. An important case is the detection of complex events (Fig. 2). In this figure the device D1 detects a peak of the measured value (point event), D2 assesses a prolonged waveform as an abnormal state, and the parameter measured by D3 exceeds the limit value. The combination of those measurements establishes a medical condition (e.g. an emergency) with a much better precision than each of them alone, reducing in that way significantly the frequency of false alarms. In the case of cardiac monitoring, D1 could be an accelerometer, D2 - an ECG monitor and D3 - pulse meter.

From the position of the system designer the necessity of an open, interoperable system is evident. If the best sensors of the classes D1, D2 and D3 are available from different producers, we want to be able

<sup>8</sup><http://nanthealth.com/>, accessed May 7, 2014

<sup>9</sup><http://www.isirona.com/>, accessed May 7, 2014

to connect them into a closely coupled system - with one communication device executing the event detection algorithm and with well synchronized clocks.

As far as possible, existing standards have to be respected. They currently form a multicolor patchwork of partly overlapping initiatives backed by various organizations (St Cyr, 2013). The list of ECG formats alone is overwhelming (Bond et al., 2011). Over the time, the technology and market forces will determine the optimal solutions, whereas open standards will still coexist with proprietary standards enforced by major players. In the area of data exchange with medical devices, the predominant standard on the semantic level is HL7<sup>10</sup>. At the lower level the major standards are ISO/IEEE 11073<sup>11</sup> (Yao and Warren, 2005), (Trigo et al., 2014) and ASTM F2671<sup>12</sup>. It is to be examined which competing standards will eventually predominate and to what extent they are applicable to low power micro/nano sensors.

### 4.2 Configuring and Distributing the Devices

Distributing smart medical devices to the patients is a complex task. It is difficult from the medical point of view, especially when the device has to be implanted (Kramme, 2007), (Lemke et al., 2013). Configuring a device like a defibrillator requires a special blend of medical and technical knowledge. This knowledge is today available in good hospitals. However, if the composite device has to be configured from individual sensors into a working Body Area Network together with an application on a commercial smartphone, we enter a new domain. In order to set a wireless network, a good network supporter is necessary. Just trying to assign the tasks of installation and support to the clinical staff is unfeasible (Wagner et al., 2013). On the other hand, working with frail and elderly patients is not a common skill among the network supporters.

### 4.3 Support

Similarly, establishing a support service is not trivial. We have to remember that not only the patients' calls have to be handled. The data coming from the devices may also indicate problems that are not visible to the patients but require an intervention. For example, missing or wrong values (outliers) suggest a

<sup>10</sup><http://http://www.hl7.org/>, accessed Oct.15,2014

<sup>11</sup><http://www.continuaalliance.org/> accessed Oct.15, 2014

<sup>12</sup><http://www.astm.org/Standards/F2761>, accessed Oct.15, 2014

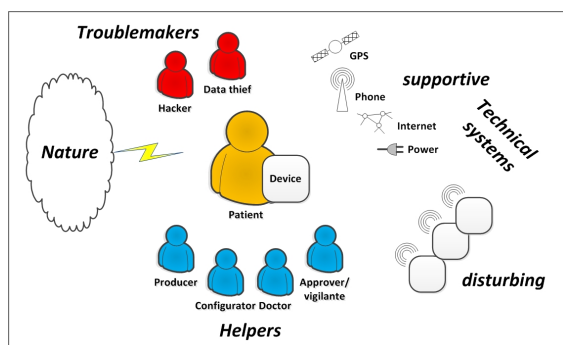


Figure 3: Medical device and its environment.

wrong fixation of the device, empty battery or a similar cause. In this case the medical personnel has to contact the patient, and depending of the severity of the disease it may be urgent. With a limited number of patients, normal personnel is sufficient, but above a certain limit a special organizational unit is necessary, especially that such cases will require not only medical knowledge but also profound technical skills.

## 4.4 Quality Control

### 4.4.1 Smart Medical Devices as Complex Cyber-physical Systems

A device does not work on its own, but is a part of an environment that has to be included in the quality assessment (Fig. 3). It consists of humans, nature and other technical systems.

The patients are biologically different and may respond differently to the same therapy. In general, the device may be adequate for their medical condition or not. If they have to perform some operations themselves (attach the device, input settings, read and interpret the messages), the result will depend on their motoric and cognitive skills.

Among other participating humans we have several groups of helpers, whose services will be of value if they master the necessary novel mixture of approaches and skills that are currently provided by various isolated communities (Fig. 4).

As the software based, networked medical devices communicate electronically with the external world, they are susceptible to attacks from hackers. They store and transmit valuable patient data which are interesting to various sorts of data thieves. Aside from the electronic attacks, the devices can be physically stolen or destroyed.

The forces of nature play an important destructive role - the devices break, they corrode inside the body, fixations loosen, sensors get dirty and nozzles get clogged. Flesh, bones and cloth attenuate the sig-

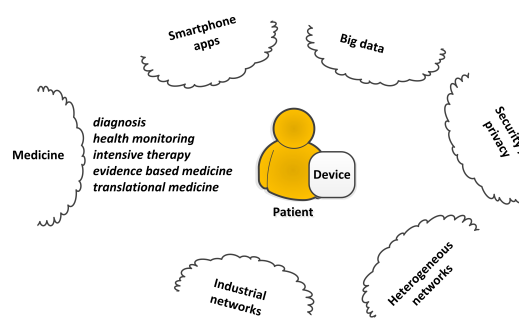


Figure 4: Merging approaches and skills.

nal propagation in the Body Area Networks. Landscape and buildings obstruct the phone signal.

Networked devices depend on other technical systems. They need electrical power, phone signal and Internet connection, possibly also GPS positioning. We cannot take their existence for granted. On the other hand, nearby systems may introduce noise and jam the useful signal. Other wireless systems may use the same bandwidth and compete for channel capacity.

### 4.4.2 Formal Approval and Reimbursement

The approval process of medical devices is relatively new, compared with the process for the drugs (Yin, 2012). In every market the respective regulatory agency defines precise rules of approval for the medical devices (Abdel-Aleem, 2009). They are divided in several classes, depending on the possible risk to the patient. Usually only for the high risk (Life-Saving and Life-Sustaining) devices the results of a well-controlled clinical investigation have to be provided. FDA has recently issued the guidance regarding the mobile medical applications<sup>13</sup> that defines which apps are the focus of regulatory oversight, which may meet the definition of medical device but are exempt from enforcement and which are not considered medical devices. Similarly, the European Commission is working on the update of its regulatory framework<sup>14</sup>. A good analysis from technical and legal point of view can be found in (Sorenson and Drummond, 2014). As the process is highly dynamic, we will not comment it here in detail.

In the design phase a risk analysis has to be performed. The main standard used in this context are ISO 14971:2007 (Application of risk management to medical devices) and IEC 80001-1:2010 (Applica-

<sup>13</sup><http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>, accessed Mar. 26, 2014

<sup>14</sup><http://ec.europa.eu/health/medical-devices/regulatory-framework/>, accessed Oct. 10, 2014



tion of risk management for IT-networks incorporating medical devices). The paper (Alemzadeh et al., 2013) provides an in-depth analysis of this process. A complex example of its application for hemodialysis devices is shown in (Lodi et al., 2010). The results depend however on the actual assiduity of the people who perform the assessment, on their technical knowledge and capacity to imagine rare and novel risks.

The most trusted method is a randomized control trial. A double-blind experiment with medical devices is difficult to implement (Potapov et al., 2011), (Lipton et al., 2010) and (Castro et al., 2010) as it is not easy to construct such a fake device that it is not noticed by the patient. The paper (Zannad et al., 2014) presents an extensive analysis of the challenges facing the trials using the example of cardiovascular medical devices. The approval process is however far from perfect (Teow and Siegel, 2013) and risky devices may reach the market (Hauser, 2012).

Another important factor is the reimbursement of the therapies by insurances or government authorities. There is a large market for consumer devices that are useful in prevention, e.g. supporting a healthy life style. The professional devices are however more expensive and their large scale use is only possible if they are reimbursed. Therefore the respective payers require a proof of their medical efficacy as well as of economic efficiency (what therapy improvement for what price). The new devices not only induce costs - extensive use of medical devices may increase the possibilities of ambulant treatment and hence have a positive influence on the general costs of the system.

#### 4.4.3 Continuous Monitoring

For many reasons a one-time clinical study is not sufficient for a thorough evaluation of smart medical devices. The devices operate in a variable, undefined environment consisting of natural and technical conditions, as well humans that use and support them. A patient can be allergic to the used material, another can misunderstand the instructions. During travel phone signal can be missing or bad roaming contract may inhibit the data transfer.

All detected problems may lead to an update of the device - its mechanical part (e.g. fixing) or software. The operating procedures may be changed or the personnel and the patients may be better instructed. In all such cases the compound (device + environment) is not the same, what formally invalidates the previous tests.

Assessing the quality of updated software is a hard statistical problem. Let us assume that the basic medical algorithm is correct, but due to bugs the software

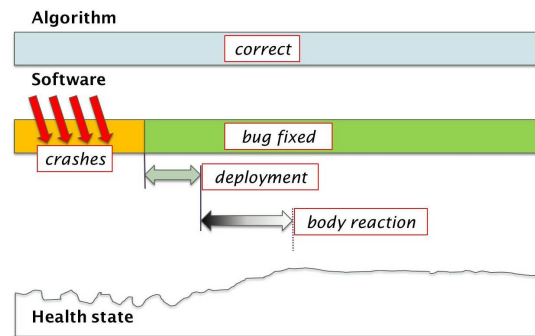


Figure 5: Software versioning.

crashes from time to time (Fig. 5). As said before, a device with a changed software is not the same device. We have however already collected a valuable set of data, and resetting the measurements would be wasteful. Only some well known negative effects were caused by the bug, the rest is unchanged.

Another factor is time. The device may wear out with time. The quality of unchanged software, e.g. without security patches, deteriorates with time<sup>15</sup>.

We want to know the long term effects of the therapy but the necessity of a long clinical trial collides with the pace of technical progress. Especially if we require - correctly - that during all conditions remain *exactly* the same, the result will be of no value. Moreover, we need to notice any change in the infrastructure, the deployment of new features (software and/or hardware) to be able to statistically assess the effect of the changes.

We therefore advocate to collect data during the operation of the devices for continuous surveillance of installed devices in order to detect hidden flaws, rare defects and results of material wearout and other forms of degradation. On one hand, we will obtain problem notifications regarding specific patients that require contacting them, i.e. knowing their identities. On the other hand, we will have general results concerning the efficacy of therapy methods and quality of device classes and models. This information (with identities removed) will be analyzed by good statisticians and forwarded to the producers and to the approval authorities.

Those issues are well understood by the medical community. (Sedrakyan et al., 2013) present the rationale for an international registry of cardiovascular devices, (Kesselheim et al., 2014) even argue for compulsory postmarket research. Several organizations and initiatives are active in this field. In the USA we can name the Institute of Medicine

<sup>15</sup><http://www.wired.com/2014/01/theres-no-good-way-to-patch-the-internet-of-things-and-thats-a-huge-problem/>, accessed Oct. 20, 2014

(IOM), Patient-Centered Outcomes Research Institute (PCORI), FDA’s Sentinel Initiative, Medical Device Epidemiology Network Initiative (MDEpiNet) or MedWatch, The FDA Safety Information and Adverse Event Reporting Program. Even if their number suggests overlapping competences, it shows also a growing importance of the issue.

## 5 ORGANIZATIONAL FRAMEWORK

### 5.1 Basic Scenario

Having discussed the challenges we face, we pass now to the presentation of the outline of a solution we propose in this paper. The proposed organizational units cover the tasks described before. The information flow ensures a smooth functioning of the system and permits to all participants to produce and receive necessary data.

We consider here a health support system regarding a single medical problem, or a group of related problems, e.g. cardiovascular diseases. It can be subdivided in following parts (Fig. 6):

- Patient’s System: the set of devices delivered to the patient, the local network and installed software
- Infrastructure System: hospitals and other supporting entities, communicating with the patients via Wide Area Network
  - Direct Health Support
  - Quality Control and Evaluation

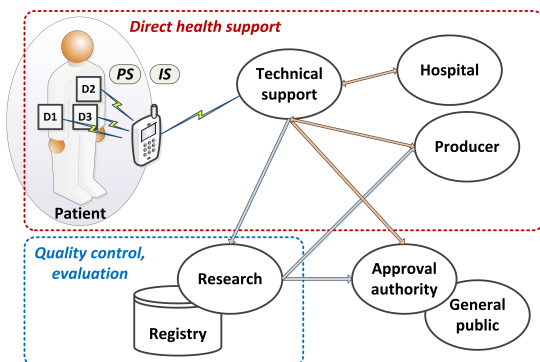


Figure 6: Subsystems: patient (PS) and infrastructure (IS); actors and data flows.

It has to provide following functionality:

- deployment and support
  - configuring and delivering to patients
  - network operation (connection with devices)
  - contacting patients
- notifying producers, distributing updates

- quality assurance and effectiveness evaluation
  - monitoring technical state
  - detecting failures
  - measuring medical effectiveness
- extracting medical knowledge for better therapies

### 5.2 Actors and Roles

The partners that cooperate in the structure outlined above are:

- Patients

- Hospitals
- Technical support
  - Configurators
  - Operators
  - Call centers
- Producers
- Approval authorities
- Research institutes

We will further discuss the motivation of the partners driving them towards the cooperation outlined here.

#### 5.2.1 Patients

The patients are the ones that should profit from the novel therapies. Their feedback will be very useful in finding and eventually fixing the problems not detected in the laboratory setting. In cases when the supporters see surprising data or detect data losses, the help of the patients will permit to connect the IT problems to the events from real life and to identify their actual causes. Moreover, sharing anonymous data for research will enable a better understanding of the process, provide evidence based medical knowledge and help to evaluate and improve the deployed devices.

#### 5.2.2 Hospitals

Every patient is related to a hospital, handling his/her case. We will use the term “*home hospital*”. This hospital keeps the patient’s record - on paper or in electronic form.

#### 5.2.3 Technical Support

In order to assure the operation of the system, a number of functions has to be performed (Fig. 7). These functions require special technical equipment and a novel set of skills that may exceed the current capacities of a typical hospital. They may be delivered by one or several organizations, depending on the necessary skills and equipment, and whether a direct contact to the patients and hospitals is needed.

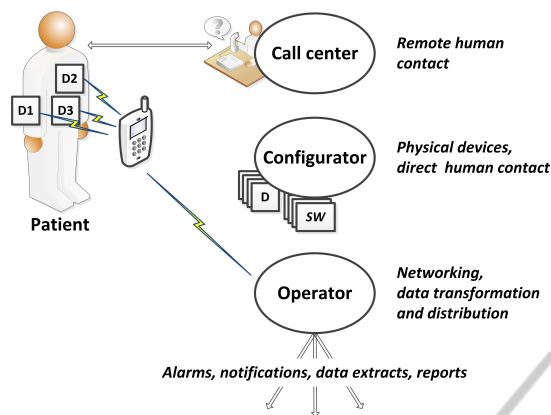


Figure 7: Technical support - subunits.

**Configurators** A configurator is a unit that configures the complete set of devices received by a patient. It cares that all hardware components can effectively communicate and that all software packages run on the data aggregator used by the patient. This aggregator may be a device (e.g. a smartphone) owned by the patient or a special device preconfigured for this task. The configurator performs also the final delivery to the patient and gives him/her the necessary instruction. Having a supply of physical devices, the configurator will be contacted if a service or replacement is needed. The configurator acts on behalf of the hospital and provides the necessary technical expertise, missing at the hospital. As the configurators interact with patients, they need to maintain local offices. In case of implantable devices, the operation is performed at the hospital, this however seems not to require the presence of the configurator. Actual connection into a functioning Body Area Network (BAN) will rather be done later, after the scar is healed. This geographical distribution permits various forms of organization - as separate, local companies or connected in one enterprise.

**Operators** An operator is a unit that supports the continuous function of the system of distributed medical devices. We think here mostly of assuring the network connection between the patients' aggregator devices and the hospital and other data destinations. The operator has to perform all transformations on data received from the patients and distribute them according to the predefined scheme. The operator has to know all communications partners. It also has to know the types and versions of all devices (sensors, actuators) used in the system and their producers in order to generate the status and malfunction notifications. Likewise, the information about the actual configuration of the device sets delivered to the patients is necessary for specific service functions, e.g. status inquiries or software updates.

**Call Centers** The first function of a call center is receiving remarks, complaints and service requests from the patients. Equally important are contacts with the patient initiated by the service providers (Fig. 8). The device set delivered to the patient may automatically inform about a problem of which the patient is not aware. Sensor values systematically out of range suggest a wrong position or weak contact with the body. This again can be caused by dirt, humidity or a loosened fixation. Signal from a device will be missing if its battery is drained or if the device was uncomfortable and has been removed. It also could be broken, lost or stolen. The effective cause is unknown to the service providers. Therefore the patient has to be personally contacted, otherwise his/her system will not be working. The patient can correct the installation of the devices, but if the problem is caused by a property of the installed devices, like weight, size or noise, it rather gives a valuable input to the producers who should improve the design.

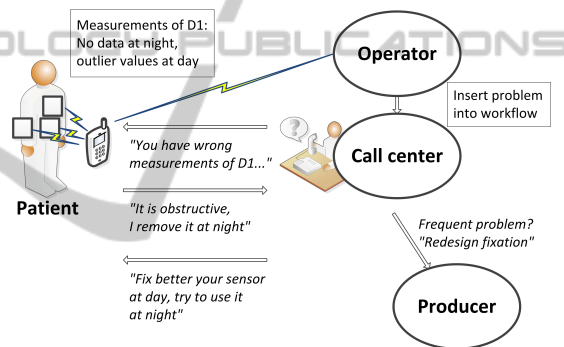


Figure 8: Call center - active contact.

Evidently, if the contact has to be efficient, the patient has to be available and be in the position to concentrate on the problem. Therefore a second call at another time of the day may be needed, or a follow-up call if the problem persists or reappears after a certain time. We see that the tasks of a call center are very similar to a Customer Relationship Management (CRM) System. A 24 hours / 7 days operation is recommended. In addition to the technical and medical fundamentals, the personnel needs local language skills and the ability to interact with ill, elderly, uncertain or angry people.

**Producers**

The individual devices (sensors, actuators) have various producers. Typically, they will provide their own means for reading the status and data recorded in the devices or for updating the software. In our case, it is important that the patient's set of devices is treated as a system. The operator should know about the deployed software versions, in our design it is also the main distributor of the information. This does not

exclude sending data directly to the producer who has own established programs for data analysis and quality control. It is also possible that in the initial phase the procedures deployed in the system proposed here are not equally mature. It is understandable that the producer is interested in keeping its trade secrets and in treating the faults in its products discreetly. On the other hand, we promote here openness, and this finally serves all. It is to be decided if the producers should have a direct commercial relationship with the end users (and consequently know them) or not. We endorse the solution where they are isolated from them by the interface of the configurators and operators of our system.

They should be informed about the performance of the devices, mechanical, electrical and networking issues. The software update process has to be defined: in what cases the producer is obliged to deliver an update (e.g. software crash, new security leak) and what are the test and approval procedures.

#### Approval Authorities

The proposed system should be integrated in the postmarked surveillance program of the approval authorities. It can generate automatic warnings about the malfunction of the devices. One goal is ensuring the patients' safety. Therefore emergency cases that put their health in danger have to be reported immediately. Another goal is to evaluate the effectiveness of the methods and the quality of specific devices. In the proposed system, long term progress reports can be generated. They should not be treated as the sole basis for decisions, they can however be useful in providing sound quantitative foundation. If the therapies are refunded, their cost-effectiveness should also be evaluated. The exact contents and frequency of reports are subject to an individual agreement. In the case of internationally marketed products, many authorities may be involved.

#### Research Institute

The main task of the research institute is to support the registry. The goal of the registry has been presented in the section 4.4.3. The researchers have to define the logical structure of registry items that is a reasonable compromise between diverging requirements: heterogeneity, variability and stable structure for comparison and research. The actual implementation and hosting may be provided by a partner with stronger IT skills. The researchers use this data collection to answer questions leading to better medical and economical decisions. They publish scientific papers and produce reports for cooperating medical societies, government offices or for general public.

The researchers have to bring skills in relevant medical fields and in statistics. The environment is

very far from a clean randomized trial. The patients represent a known, but neither predefined nor balanced assortment of age, gender, life-style and other properties. The devices are applied as decided by the hospital, their elements are replaced, software is fixed and updated. This makes producing truthful statistics extremely challenging.

### 5.3 Driving Forces

The proposed scheme is based on the cooperation of many partners. It will never function in real life if they are not sufficiently motivated to participate.

The *patients* want to receive the best treatment possible and the *hospitals* want to provide it. Both of them want to have freedom of choice of therapy and devices and to avoid a vendor lock. With the registry, we propose a secondary use of patients' data, not aimed directly to support their own health. Ultimately the goal of collecting those data is to serve them better in optimizing the therapy and eliminating device faults. This approach corresponds to the trend towards the predictive, personalized, preventive, participative (P4) medicine (Hood, 2013).

Strong, established *device producers* often prefer to protect their market share with proprietary standards. This is a winning strategy only for dominant players, as for the less strong ones it would limit the possible options to own products, what may reduce their chances for new customers. For small, innovative producers, participating in open standards is the only way to reach the market.

The producers may be reluctant to participate in the quality monitoring scheme, as it discloses the defects of their devices. On the other hand, not hiding the issues makes the impression of playing a fair game and should eventually increase the trust of the patients towards such producers.

In many countries there is a growing pressure from the side of the official bodies, like *approval authorities* to cooperate in the evaluation of medical effectiveness and financial efficiency. This pressure may be a decisive argument for participation.

The framework proposed here intends to provide solution for several basic cases, each of them having slightly different participants with different interests and motivations. The following diagrams show those participants and the respective information flows for the considered cases:

- Health support (Fig. 9)
- Quality assurance (Fig. 10)
- Medical research (Fig. 11)



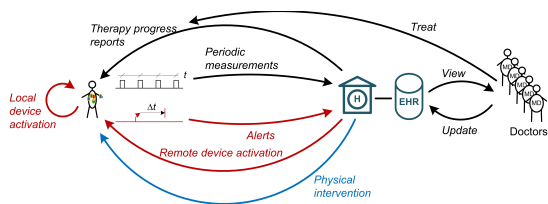


Figure 9: Data flow for health support.

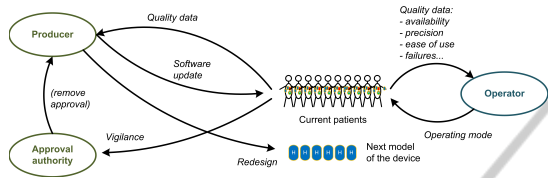


Figure 10: Data flow for quality assurance.

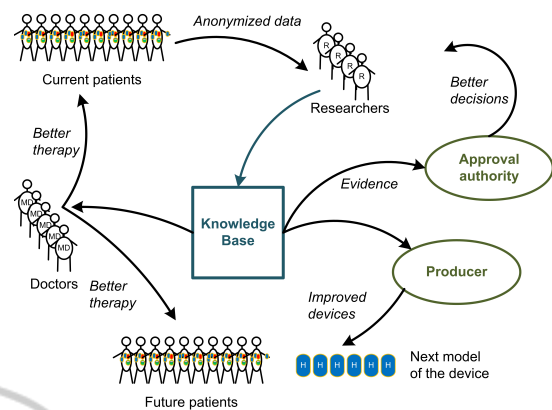


Figure 11: Data flow for medical research.

## 6 DEVELOPMENT ROADMAP

In the preceding sections we have presented the issues hindering the widespread adoption of smart medical devices and shown an organizational structure that should facilitate this adoption. Now we want to outline a roadmap that sets the overall structure of a solution permitting to construct flexible healthcare systems based on smart medical devices. We aim at open systems where all producers can concentrate on their core capacities and deliver elements of best quality that can be selected by the configurators without being locked by vendors' proprietary, undisclosed standards. Our goal will be achieved if these ideas will help to focus the future development or serve as a basis for discussion. The terminology used in the following text relates to the proposed organizational structure, as shown in Fig. 6 and Fig. 7.

- Building Composite Devices
  - Combining personal device clusters into composed multi-element devices
  - Selecting / expanding current interoperability standards
  - Creating a generic structure for smartphone applications for sensor/actuator networks

A modular smartphone application should be able to integrate various devices from different vendors. The devices have common features on various levels. They send or receive several data types: events, single values, waveforms. They can send data spontaneously (asynchronously or in a time raster) or when requested. The semantics can be categorized into a limited (but extensible) number of classes: blood pressure, oxygen saturation, electrocardiogram. On all those levels modular software structure has to be

defined. It is also to be analyzed to what extent the emerging de facto standards (e.g. from Apple and Samsung) are really applicable, flexible and extensible in the open environment.

- Integrating devices in the healthcare system
  - Defining data extracts for various recipients
  - Implementing data transformations and splitting data flow
  - Solving related security and privacy issues

Data sent from the composite medical device to the network operator module consist of a sequence of items: events and measurements. The operator software distributes them to the registered recipients (hospital, producer, quality control, approval authority or other). The recipients may register for certain types of items related to various sources (patients). Depending on the recipient, the forwarded items may be processed, e.g. anonymized. A recipient may also submit an algorithm for processing the sequence of items to detect interesting events. In such a case the sequence would be processed locally at the operator on behalf of the recipient that would be informed only if a defined event occurs. For security and privacy protection, the data flow has to be verified and approved by qualified (human) administrators. If basic access limitations for a recipient are defined, he/she can also submit an algorithm that will be automatically attached to the system if those limitations are respected. Such a modular structure will permit to construct the operator software with no knowledge about the underlying semantics.

- Monitoring quality
  - Defining a flexible and expandable ontology permitting to compare heterogeneous, evolving devices

- Establishing a vendor-independent infrastructure for continuous assessment of devices quality and therapy methods effectiveness

The devices we want to integrate into our scheme are heterogeneous, they come from various vendors and their hardware and software may be frequently updated. They show however certain similarities. For example, implantable devices face similar problems: short battery life, erosion by body fluids, mechanical/chemical/electrical harm to the body, etc. Wireless nodes can lose data packets, their signal can be attenuated by body tissue or clothing. They can also be subject to malicious human actions like eavesdropping or impersonation. We see that a device, because of its properties may belong to many classes. The goal of the design of the registry is to capture these similarities and to generate standardized data structures in the database that will permit to make some founded statements about the (absolute and relative) quality of the devices and the efficacy of the therapy methods.

- Organization
  - Organizing device configuration and distribution
  - Establishing efficient data exchange between deployed devices and healthcare institutions
  - Setting an organization for handling special cases initiated by patient or by hospital
  - Solving international approval issues
  - Ensuring a correct reimbursement for specific medical cases

The tasks described above are necessary if we want to pass from a technically possible solution to a solution that is actually applied. Only if we succeed here, the patients will effectively benefit from our efforts. As the experience shows, overcoming organizational hurdles and convincing potential partners to enter into a cooperation may be more difficult than providing the technology. However, a working technical solution is a condition for

- Statistics

Until now we have discussed the methods to ensure the data flow for the system operation and quality assurance. The next step is to process the collected data in order to obtain meaningful insights, helping to choose the best devices and to evaluate the medical efficacy of the therapies, also with respect to the costs. The setting is far from a clean clinical trial. The composition of the patients' cohort is statistically balanced. The condition tested is not a simple yes or no - during a treatment the device can be replaced with a

new model, some elements can be updated, software bugs can be fixed. Also the result is not reducible to a single parameter. The algorithm of an insulin pump may be correct, but the software may crash from time to time. After a patch, this problem is solved. On the other hand, the composition of the substance used may be not optimal for some patients. The device may be rejected by some patients as too obtrusive. The tip of an implanted sensor may break. How to determine which parts of the result are conserved when system elements are modified? All this is an immense challenge to the statisticians.

## 7 CONCLUSION AND FUTURE WORK

In this paper we have presented the technical and organizational obstacles that curb the widespread adoption of mobile medical systems. We have then proposed a modular framework of a solution. In the following we have outlined a roadmap that will permit to channel the activities of the developers and other partners into a well coordinated effort. It defines the main tasks and pinpoints the elements critical for the interoperability. In our opinion, it can be used as a draft of an actual project plan. The list of tasks is long, therefore they have to be executed by many teams over a longer period of time. We intend to be a part of it.

Achieving interoperability of smart medical devices and reliable functioning of systems built upon them is a tremendous challenge. However, without engaging in this endeavor we will remain at the stage of isolated solutions and the promising technologies will not meet our justified expectations.

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