Development, implementation, and operation of mobile medical apps

D. Schmoldt, Department for Information Systems, Philipps-University Marburg, Germany, dschmoldt@raie.de
W. Mondorf, Haemostas-Frankfurt, Germany, wmondorf@web.de
H. Pollmann, ITH, Münster, Germany, pollmann@haemophilie-zentrum.de
A. Rösch, Rösch & Associates Information Engineering GmbH, Germany, aroesch@raie.de

Introduction

Documentation of hemophilia home treatment is usually done by analysis of paper based substitution calendars. Transferring written entries into databases is time consuming and bears the possibility of errors. Bleeding or treatment problems are often identified months later than they occur following regular patient consultations. In contrast, telemetric tools allow real-time surveillance of treatment and bleeding episodes as well as automated online analysis of these data.

Methods

A telemetric system for documentation of home treatment called “smart medication” was developed in collaboration between the Philipps-University in Marburg, medical experts, the IT Company Rösch & Associates GmbH and the society for advancement of telemedicine in the haemostaseology (VFTH e.V.). Based on Google’s Android and HTML5, an application was built for real-time surveillance of treatment and bleeding episodes and online analysis of these data. It consists of three components:
1 - Patient’s App
2 - Patient’s Website
3 - Medical Centre’s App
4 - Medical Centre’s Website

Results

Within two years 300 patients with haemophilia A/B transmitted 21300 treatment entries. The difference between prescribed and documented concentrates was low demonstrating a high rate of adherence to the electronic documentation format. Higher bleeding frequencies could be identified within less than one week since occurrence allowing early initiation of education and subsequent improvement of home treatment.

Conclusion

We hereby introduce a smartphone application for documentation and analysis of treatment and bleeding episodes and easy medication management. Online surveillance in hemophilia home care allows early identification of current treatment and bleeding problems. The development of possible target joints may be identified and treated much earlier.
Apps in medical usage – current situation and developments

Martin Braecklein, DGBMT Fachausschuss mobile Diagnose- und Therapiesysteme - mHealth, Germany, martin@braecklein.de

Introduction

Apps play a more and more import role in daily life. This holds also true for the medical usage. Most apps are fitness and wellness related used for prevention. However, by now are gaining importance in diagnosis and therapy of patients through the continuum of care. They can be found in preclinical setting, in hospitals and rehabilitation clinics as well as at home and especially with mobile patients.

Methods

To provide an overview of the current situation the main application areas of apps in medical usage will be described with advantages, challenges and the acceptance by the relevant stakeholders. Additionally current trends and developments will be presented. The focus will be on apps for diagnosis, monitoring and therapy.

Results

Apps in medical usage can provide a lot of advantages in different settings and open up a new level of support for patients, care givers and insurance companies. Some already show proven outcomes in terms of patient- or cost-benefits. Generally they can provide relevant information at the right time at the right place. However, there are also questions, like the quality and the regulation of health apps, data security and privacy, evidence and how to provide this evidence. Also the reimbursement is still a challenge.

Conclusion

Often it seems that there is a hype around apps in medical usage. While they provide advantages they cannot solve every problem in healthcare delivery. They also come with risks, which need to be addressed. To profit from the advantages there is discussion required especially on how to handle the fast development cycle while ensuring patient safety and solving the challenges. While this discussion is underway in North America it is just starting in Europe.
Ethical and Legal Implications on Apps in Clinical Trials

U.-V. Albrecht¹, O. Pramann²
¹ Hannover Medical School, Peter L. Reichertz Institute for Medical Informatics University of Braunschweig - Institute of Technology and Hannover Medical School, Germany
² Kanzlei34 - Rechtsanwälte und Notare, Hannover, Germany, Pramann@Kanzlei34.de

Abstract

Using smart devices and apps in clinical trials has great potential: this versatile technology is ubiquitously available, broadly accepted, user friendly and it offers integrated sensors for primary data acquisition and data sending features to allow for a hassle free communication with the study sites. This new approach promises to increase efficiency and to lower costs. This article deals with the ethical and legal demands of using this technology in clinical trials with respect to regulation, informed consent, data protection and liability.

1 Introduction

1.1 Smartphones, Tablet-PCs and Apps in a Health Context

Mobile devices have become an integral part of our daily life, often also for highly sensitive areas, ranging from keeping track of personal everyday tasks to social media, or governmental services to healthcare: there has been a shift from data management in a purely stationary setting to mobile devices and mobile applications – so called apps – and the devices they run on are continually gaining importance. The medical field is no exception [1]: Here, mobile applications help with researching specific information as well gathering and aggregating information from many different sources. They also support the management and evaluation process of the acquired data. When used appropriately, they have the potential to increase efficiency and to lower costs, which makes them especially attractive for use in today’s cost-conscious health care systems. Depending on the circumstances, they may also lead to better patient empowerment, e.g. by giving patients the opportunity to take a more active role in their own care process.

1.2 Apps in Clinical Trials

Mobile devices are ubiquitously available, user friendly and they offer integrated sensors and data sending features. It seems logical that such devices are considered as promising instruments for future research and clinical trials. Besides assisting with filing electronic case report forms (eCRF), Smartphones, Tablet-PCs and other smart devices can also be helpful in primary data collection with internal or external sensors [2].

1.1 Medical Device - or Not?

Health related apps can be roughly divided into regulated (mobile) medical apps and non-regulated (mobile) medical apps: Regulated (mobile) medical apps are applications that are provided by the manufacturer with an official medical purpose, e.g. for diagnostic purposes, therapy or treatment and have to conform to regulatory constraints according to the federal medicinal product act. Apps that could fall within this category could for example be provided and advertised by a manufacturer with the purpose of supporting doctors in the evaluation of radiographs. The same applies to apps that acquire vital signs or other medically relevant sensor data using external hardware or adapters that are connected to the mobile device (e.g. for taking a temperature, blood pressure, pulse or performing a blood glucose test) and evaluate them. This contrasts with a variety of other applications, that can potentially be used in a medical context but that have not officially been designated as having a medical purpose by the manufacturer. This includes for example health information apps, reference apps with the sole purpose of providing information, such as medical dictionaries, drug information systems or lifestyle apps that help users in improving their health or the perception of their body’s functions, such as pedometers and fitness programs.

2 Regulatory aspects

Whether an application or a smart device may be classified as a medical device is determined by their intended use.

Before the manufacturer is allowed to bring a medical app to market or to use it in a clinical trial, a CE label has to be obtained, the only exception being clinical trials that are required for obtaining a CE label. The CE label may only be assigned after the appropriate conformity assessment procedure. The details of the procedure depend on the potential risk of the medical device.

In the MEDDEV Guideline 2.1.1/6 of January 2012, the European Commission provides criteria for an application to qualify as a medical device. The Guideline is not legally binding and addresses manufacturers in the European Market. In the US, the Food and Drug Administration also published a guidance document in 2013 that provides both manufacturers and the FDA personnel with information on a planned regulation of mobile medical apps [3].

If the app is a medical device, the manufacturer needs a premarket notification according to FDA regulation on medical devices. A letter of substantial equivalence from
FDA provides the manufacturer with permission for commercial distribution of his device.

3 Clinical Trials on Apps

For scientific research in the area of human pharmaceuticals that includes human test subjects, the EU Directive 2001/20/EC and EU Directive 2007/47/EC (MDD) for medical devices and their integration national laws are applicable to assure patient’s safety. The Declaration of Helsinki, revision Fortaleza 2013 (DoH) [4] and professional codes also apply. As the MDD only refers to a documentation to hand in for informed consent, the Directive 2001/20/EC is more precise. If there is no pharmaceutical or physical intervention to be applied within a trial, it still needs to be designed in a manner that ensures that pain, discomfort and fear are minimized. Corresponding scientific guidelines of the Agency have to be followed. If minors are involved, according to the EU Directive 2001/20/EC, this warrants special justification, and minors must directly benefit from the participation, independent of whether they are enrolled in the interventional or non-interventional arm of the study. Also, trials should directly relate to the specific clinical condition the participants suffer from. The interests of the patient always prevail over those of science and society. Except for compensation, no incentives or financial inducements should be given.

4 Informed Consent

According to international and national law, study participants capable of giving consent will only be included after they have given their informed consent. The participants have to confirm their participation in written form, dated and signed voluntarily after having been duly informed of the nature, significance, implications and risks of the study by a physician. If any minors are involved, with respect to Article 4 of the directive, staff that is experienced in dealing with minors will have to appropriately inform them about the trial, the risks and the benefits according to their capacity of understanding. Furthermore, an explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation or to withdraw from the clinical trial at any time must be considered by the investigators if appropriate. The informed consent of the parents or legal representative needs to be obtained and the consent must represent the minor’s presumed will and may be revoked at any time without detriment to the minor.

5 Data Protection

According to the Data Protection Directive 94/46/EC, data may only be collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. The collection process may only take place within the limits of what the participants (who are able to give consent) consented to as this signifies their agreement for personal data relating to them to be processed. At a level that is appropriate for the sensitivity of the data, technical and organizational measures have to be taken, both at the time of the design of the processing system and at the time of the processing itself, to maintain security and to prevent any unauthorized processing. The data has to be processed by a health professional who is subject to national law or rules established by national competent bodies under the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.

All this is meant to strengthen the digital privacy rights of EU citizens, improve the EU’s online economy and strengthen the free market. Besides other changes, the key element of the regulation is that individuals must give explicit consent for data to be processed. Furthermore, individuals are granted easy access to their data and receive the “right to data portability” that will enable them to more easily transfer acquired data from one service provider to another.

6 Liability

Liability risks exist for the sponsor with regard to the patients whenever these suffer damages when using the software according to the instructions [5]. This explicitly concerns the contractual relationship that obliges the sponsor to conduct a study in a proper way: the sponsor is required to ensure the safety of the participating patients and is responsible for the use of the application. On the one hand, no damage should occur and, on the other hand, validity of data must be ensured. With regard to the data to be collected, it is not recommended that the sponsor solely relies on the results generated by the appropriate hardware of a smartphone.

7 Conclusion

Using mobile (smart) devices for clinical research inherits several risks, e.g. technical issues or inadequate validity of content in the sense of false or flawed information being integrated in the app. For example, as a result of incorrect programming, medical calculators may store erroneous calculation algorithms, which then leads to an incorrect calculation of medication dosage, which in turn can lead to over- or underdosage. Finally, a device defect is possible so that faulty internal and/or external sensors are used resulting in incorrect values and erroneous interpretation of the actual situation. The manufacturer will be held accountable in all these cases. He bears the common civil responsibility that already exists in the context of liability for medical devices and in the context of the liability for software in accordance with the common pattern. For medical devices, a distinction is made between the particular error categories like constructional fault, manufacturing defect, instruction error and observation obligation [6]. Due to the various legal pitfalls, the use of the private devices of study staff for study purposes is not recommended. [7, 8, 9]
Conducting mobile device and app related research to retain complete and unbiased data sets is a methodological challenge that is cannot be solved by jurisprudence alone.

7 References


Readout: Health Apps and Their Data Sending Behaviour

U.-V. Albrecht1, O. Pramann2, T. Jungnickel1, U. von Jan1
1 Hannover Medical School, Peter L. Reichertz Institute for Medical Informatics University of Braunschweig - Institute of Technology and Hannover Medical School, Germany, albrecht.urs-vito@mh-hannover.de
2 Kanzlei34 - Rechtsanwälte und Notare, Hannover, Germany

Abstract

In the medical field, mobile devices and apps are continually gaining importance for medical professionals as well as for patients. Key aspect of their success lies within their capability to collect and process personal and health related data at the point of care. Mobile devices simplify this collection process. But the aggregation of reliable information about the usage patterns or personal information of any clientele is an alluring possibility for service providers. Regardless of the application, this behavior is often undesired. We conducted a preliminary examination of the data sending behaviour of a small amount of health related apps and compared the results to the provided information by the manufacturers on data protection.

1 Introduction

Mobile devices have become an integral part of daily life, often also for highly sensitive areas, ranging from keeping track of personal everyday tasks to social media, or governmental services to healthcare: there has been a shift from data management in a purely stationary setting to mobile devices [1] and mobile apps and the devices they run on are continually gaining importance. The medical field is no exception: Here, mobile applications help with researching specific information as well gathering and aggregating information from many different sources. They also support the management and evaluation process of the acquired data. When used appropriately, they have the potential to increase efficiency and to lower costs, which makes them especially attractive for use in today’s cost-conscious health care systems. Depending on the circumstances, they may also lead to better patient empowerment, e.g. by giving patients the opportunity to take a more active role in their own care process.

But in many cases, the medical app label seems to be assigned rather haphazardly and so called apps cover a wide spectrum ranging from software having only a pretended or very basic medical purpose to those designed for professional use – thereby misleading the users. Another important factor is that adequate levels of quality for the content and functionality of the provided apps must be assured, but often, users do not receive enough information to be able to make an informed decision about whether they can trust an app or not. Especially for a field such as medicine, where acquired information is mostly of a highly personal and sensitive nature, such behavior is highly undesirable. Users often trust that apps available via official distribution channels, i.e. official app stores, are secure since apps being distributed in this way have to undergo undergo an “official” review process. In the past, this has not always proven sufficient [2]. In other fields of application, in the recent past, many mobile apps have already gambled away the trust of their users. Many apps contain unintentional security flaws, but some even openly deceive their users, for example by covertly accessing the data available on the devices without the user’s consent, requesting data not necessary for the purported purpose or by handling (i.e. storing and transmitting) the entrusted data in an insecure manner [3, 4, 5]. One of the reasons behind this data hunger of both application developers and service providers is that insights about the usage and consumption behavior of any clientele – independent of whether business or private areas are concerned – offer an enormous market potential.

Not all of the aforementioned problems are due to “intentional” security breaches, e.g. caused by malware – which is something an educated user might even expect; often, there are simply issues with the security model of the mobile operating system or other seemingly harmless software components running on the device [3, 4]; but sometimes also with intentional attacks [5] or improper or careless use (Figure 1).

![Figure 1 – Factors contributing to security and trustability in a mobile setting](image-url)
In this paper, the authors choose to address security issues as one prominent and important aspect to rate the level of trust that can be placed on medical apps.

2 Methods

2.1 App Selection

Different users have different expectations, depending on whether they are medical professionals or laypersons. Therefore, to at least basically appraise the current overall situation, random app information texts from the German medical section of Apple’s App Store (and their Android pendants if available) were presented to three reviewers (physicians/computer scientists) who selected the first eight applications (convenience sample) that met the following criteria: at least on a basic level, the apps had to have a medically sound purpose; in addition, selected apps had to either require or have at least the potential for recording, storing or transmitting sensitive information (Table 1).

Table 1. Apps selected for the examination

<table>
<thead>
<tr>
<th>#</th>
<th>OS</th>
<th>Objective</th>
<th>Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>iOS &amp; Android</td>
<td>Record and evaluate blood pressure values</td>
<td>free</td>
</tr>
<tr>
<td>2</td>
<td>iOS &amp; Android</td>
<td>Determine and log the user’s heart rate</td>
<td>charged</td>
</tr>
<tr>
<td>3</td>
<td>iOS</td>
<td>Record vaccinations</td>
<td>free</td>
</tr>
<tr>
<td>4</td>
<td>iOS</td>
<td>Record and evaluate blood pressure + weight using devices</td>
<td>free</td>
</tr>
<tr>
<td>5</td>
<td>iOS</td>
<td>Keep track of blood glucose levels, allows direct access to measuring equipment connected directly to the phone</td>
<td>free</td>
</tr>
<tr>
<td>6</td>
<td>iOS</td>
<td>Remind users of regularly taking their birth control pills</td>
<td>free</td>
</tr>
<tr>
<td>7</td>
<td>iOS</td>
<td>Keep track of laboratory values</td>
<td>charged</td>
</tr>
<tr>
<td>8</td>
<td>iOS &amp; Android</td>
<td>Provide emergency responders with medical information directly on the mobile device</td>
<td>charged</td>
</tr>
</tbody>
</table>

Since the goal was to appraise the current situation and possibly reveal some of the most common shortcomings regarding data protection and security to be able to sensitize users in general rather than to point a finger at specific app developers, the selected apps themselves are not named at this time (but are available upon request, including detailed results).

2.2 Used Devices

For evaluating the iOS based apps, they were installed either on an iPhone 3GS (iOS 4.3.3) or an iPod Touch 3G (iOS 5.1.1). For the Android platform, an HTC Desire HD (Android 2.3.3) as well as a Sony Ericsson xperia mini pro (Android 2.3.4) were used. Subsequently, an analysis of the network traffic generated by each application was performed. For the network analysis of each selected app, the devices were first reset to factory settings. After the respective app was installed, the device was connected PC (Linux, Ubuntu 12.04) containing a dedicated wireless LAN adapter running in master mode, thus allowing the computer to act as a wireless access point (WAP) for other devices.

2.3 Analysis of Network Traffic

While each app was running, Wireshark\(^1\) [6] was used to listen to and capture the complete network traffic running over the aforementioned access point. The transmitted data packages were later analyzed from the generated protocols. In cases where an unencrypted transmission of data was detected, the gathered data was directly scrutinized with regard to possible privacy concerns. In case of encrypted transmission, no further evaluation of the transmitted data was performed since we abstained from deeper cryptographic analysis, i.e. by using ARP spoofing [7]; simpler tools such as the free (Java based) analysis tool Burp\(^2\) did not prove sufficient in the case of the two apps found to be using encrypted connections. In this case, only the server(s) involved in the data exchange were noted. It was also noted whether the amount of data used in the exchange was consistent with the purported purpose. If available, privacy statements and/or user agreements were also scrutinized.

2.3 Aspects of Analysis

In summary, the most important aspects considered during the evaluation of each selected apps were:

- Does the app require information (e.g. personal data and/or ID) that is unnecessary for the stated purpose? Even if it is not required to enter personal identification, a user can easily be tracked based on a unique device id.
- Is there a potential for data transfer without the user's knowledge?
- If necessary for the app’s purpose: is the data handled according to current data security standards?
- How well do the privacy statements or end user agreements mirror the way the data is really handled?

3 Results

Figure 2 shows the analysis results for the eight selected medical apps. In our analysis, three serious security issues were noticeable: Data, including personal and medical information, were often transmitted in readable text format without employing even basic encryption. Even if possible, the anonymity of the collected data was rarely observed: often, the device’s ID and other identifying information

---

\(^1\) http://www.wireshark.org/, last access 12/10/2012
\(^2\) http://portswigger.net/burp/proxy.html, last access 12/10/2012
were included. Although users are basically made aware of the data collection, transmission and storage on internet servers, a major concern is that standard security mechanisms, e.g. the HTTPS protocol for web-based transfers, were not consistently applied. It is remarkable that in some cases, data was sent without the user explicitly being aware of it; the user was not always given the chance to give or deny his consent, even if a privacy statement was available. Also, the reviewed statements vary in their structure and quality – i.e. what they cover and how well they are adapted to the specific purpose of the app. In some statements, the makers of the apps gave themselves extensive rights for collecting data, but only provided little or misleading information about the nature and extent of the data collection and evaluation process and the security aspects of the data transfer. Headlines should be discontinued basically left. Without incurring too large spaces between words, as in this example.

Factors contributing to the trustability of medical apps to check without technical analysis in an easy self-assessment should contain the following items [8]:

- Does the app openly collect any data or does it have the potential to collect and evaluate data in a hidden manner?
- Is the data transferred in a secure manner (HTTPS)?
- If data is being collected, is the acquisition process voluntary?
- Is a statement available that provides detailed information about data protection and privacy issues?
- Does it cover:
  - the purpose for which the data is being acquired
  - who (besides the user) potentially profits from the data (e.g. if it is evaluated by the provider of an online service)
  - the geographical location (country) of the servers where the data is being stored
  - measures for ensuring data protection and privacy (e.g. encryption levels, anonymity/pseudonymity)
  - if applicable, for network transfers as well as local or online storage
  - contact addresses as well as options for terminating the relationship between the service provider and the user, including deletion options and deletion periods for any collected data
- Does the app provide options for cancelling data collection and storage?

Figure 2 - Evaluation of eight exemplary medical apps. Ratings were assigned for (encrypted) data transmission, handling of sensitive information and availability and quality of a privacy statement.

4 Conclusion

For medical apps not being covered by the scope of regulation, there will still be no official regulatory instance to check apps for accidental or even intentional security breaches. Developers should at least provide users with transparent information regarding their data management policy, beginning with specifically adapted privacy statements. An average user must be able to easily find, read and understand such a statement. In a clear and transparent way, it should describe the reason, nature and extent of the data collection, when and how often the collection and transmission is carried out, who the beneficiary firm is and how this company handles and stores data. Also, the level of data protection and encryption during all steps of processing the data and their storage should be declared. The user should be informed about his right to change the data entries regarding her personality or the right to withdraw her data from the collection if applicable. For contact purposes, the beneficiary companies must provide the user with a postal address, telephone number and email address. Besides the data privacy statement to make an informed consent possible, the developers should establish methods within the app that allow the user to turn off any data collection or transmission. At least, the users should be made aware of any data transmission taking place. Also, users should not to be forced to create any additional accounts that are simply deemed “necessary for usage of the application” by the producers of the app unless this is a requirement to provide them with the promised service. Non-voluntary actions like hidden data collection and transmission must be banned from developments. Also, server-side tools for analyzing the data should not be employed without the knowledge of the user.
5 References


[3] Burns J. Developing secure mobile applications for android; 2009. iSec Partners.


Customer-enabled orchestration of complex services:
A new paradigm even for health care?

A. Winter, Universität Leipzig, Institut für Medizinische Informatik, Statistik und Epidemiologie, Leipzig, Germany
alfred.winter@imise.uni-leipzig.de
R. Alt, Universität Leipzig, Institut für Wirtschaftsinformatik, Leipzig, Germany
J. Ehmke, FU Berlin, Department Wirtschaftsinformatik, Berlin, Germany
R. Haux, TU Braunschweig und Med. Hochschule Hannover, Peter L. Reichertz Institut für Medizinische Informatik, Braunschweig, Germany
D. Mattfeld, TU Braunschweig, Institut für Wirtschaftswissenschaften, Braunschweig, Germany
A. Oberweis, Karlsruher Institut für Technologie, Institut für Angewandte Informatik und formale Beschreibungsverfahren, Karlsruhe, Germany
B. Paech, Universität Heidelberg, Institut für Informatik, Heidelberg, Germany

Introduction
In our economies the service sector becomes increasingly important. In parallel nearly ubiquitously accessible information reinforces people’s desire for self-determination. As client e.g. in the education, finance and mobility industry or as patient in health care people want to select and compile even complex services self dependently. Information technology (IT) has to support such kind of customer-enabled orchestration of complex services. It is a paradigm shift having widespread consequences since many needs and areas of life are affected and many different service providers may be involved. Our aim is
1. to explain the differences between provider- and customer-enabled orchestration of complex services;
2. to show the imperative on better support of customer-enabled orchestration especially in the health care sector;
3. to describe current need for research on information technology related fundamentals of customer-enabled orchestration;
4. to highlight the potentials of a transdisciplinary cooperation.

Methods
Originated in different disciplines like informatics, medical informatics and business informatics the authors met regularly since 2008 to discuss differences and similarities about their respective research fields and research methodologies.

Results
In health care, tools especially for supporting chronically ill patients as in oncology are needed. In oncology therapy plans are complicated and different types of health care providers take part for a longer period of time. Patients need support to orchestrate the bundle of services they need.
As a prerequisite we identified 8 fields of transdisciplinary research. Among them research on eBrokers, standardized context definitions describing custumers’/patients’ needs and standardized service descriptions are of special interest in health care.

Conclusion
There is a strong need for research in different disciplines in order to be able to manage and design this paradigm shift. Research and training has to become more and more transdisciplinary. This holds especially for informatics, medical informatics and business informatics.
Using AAL-data for health care decisions – necessity of systematic information management

P. Knaup, Institute of Medical Biometry and Informatics, University of Heidelberg, Heidelberg, Germany, petra.knaup@med.uni-heidelberg.de
H. Demski, IBMI - Institute for Biological and Medical Imaging, Helmholtz Zentrum München - Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH), Neuherberg, Germany, demski@helmholtz-muenchen.de
M. Ganzinger, Institute of Medical Biometry and Informatics, University of Heidelberg, Heidelberg, Germany, matthias.ganzinger@med.uni-heidelberg.de
AH. Helmer, R&D Division Health, OFFIS - Institute for Information Technology, Oldenburg, Germany, axel.helmer.job@gmail.com
Sven Meister, Fraunhofer Institute for Software and Systems Engineering, Dortmund, Germany, sven.meister@isst.fraunhofer.de
M. Schablowski-Trautmann, InterComponentWare AG, Walldorf, Germany, matthias.schablowski-trautmann@icw.de
L. Schöpe, Smart Living - Anwendungen für Service-Wohnen GmbH, Dortmund, Germany, lothar.schoepe@smartliving.com.de

Introduction
At the background of changing demographics numerous research projects were initiated investigating the potential of assistive technology to support people with special care needs in their home environment. Data acquired via assistive technology can complement electronic health records providing a good basis for informed decisions. This involves both the provider and the patient, empowering the latter to participate more actively in his care. Information management in that context currently faces two major challenges: (i) Sensors usually gather continuous time series. To support medical decisions these data have to be aggregated, preprocessed and visualized adequately according to information needs. (ii) Context based integration of sensor data together with data from electronic health records is still in an early stage of research.

As a step to meeting these challenges a reference-process was defined to model the pathway from sensor to medical decision making. It helps identifying common aspects on a general level and can be adapted for particular projects.

Methods
A group of AAL and medical informatics experts identified the steps of the reference-process in a metaplan approach. The process will be validated by analyzing existing AAL solutions.

Results
The following steps were identified: measurement, digital output, data gathering, pre-processing, integrating different sensor modalities, data correlation and consolidation, integration with data from health information systems, analysis for medical decision making.

While the reference-process models the information flow from sensor to medical decision making in an abstract way, it does not define the necessary technical infrastructure, communication interfaces, and long term storage of data.

Conclusion
The reference-process illustrates the wide-spread importance of systematic information management in the AAL context. Interdisciplinarity of biomedical engineering and medical informatics approaches is crucial for using data from AAL components for medical decisions. Generalization of methods and advancing standardization are important research topics for the near future.
Using workflow based patient centric activity lists for monitoring patients in the ambulatory setting

M. Schablowski-Trautmann
InterComponentWare AG, Walldorf, Germany, Matthias.Schablowski-Trautmann@icw.de

Introduction
There is growing interest in applying distributed acquisition of patient data via assistive devices to enabling self-determined lifestyle to persons that otherwise would need help from other people during daily routine. This is viewed as one of the sub-disciplines of ambient assisted living. Similar concepts of distributed patient monitoring do exist in the field of care management and care coordination. The current paper presents a novel application which enables close collaboration between a central care coordinator and the patient using an integrated workflow engine.

Methods
An existing software (ICW Care Manager) was extended by a patient portal to closely involve the patient in the care process by giving access to specific education material and by enabling collection of patient generated electronic form based questionnaires. An essential component of this novel solution is a patient centric activity list which enables a well-timed collaboration between the patient and the care team. The technical infrastructure behind this is a configurable workflow engine allowing for processes to be modeled on the basis of guidelines, clinical pathways and organization-specific standards (care plans).
To underline practical applicability, the combined solution (care manager / patient portal) was applied to a scenario involving post-acute therapy monitoring for a breast cancer patient persona.

Results
As shown in the application scenario of the demo setting, involving both the care coordinator and the patient in the same care process instance provides new options for monitoring of follow-up care in breast cancer patients. This setting may be transferred to other monitoring settings as well including AAL like scenarios.

Conclusion
A demo scenario taken from the emerging field of care coordination is presented which can be taken as a blue print for AAL based application scenarios. Future research is required to understand parallels and differences between the two fields in more details.
Predicting falls in people with dementia using accelerometry –
A one-year prospective multi-center field study

M. Gietzelt1, K.-H. Wolf2, M. Marschollek3, R. Haux2
1Institute of Medical Biometry and Informatics of the University of Heidelberg, Heidelberg, Germany, 
   Matthias.Gietzelt@med.uni-heidelberg.de
2Peter L. Reichertz Institute for Medical Informatics of the University of Braunschweig - Institute of Technology and 
   Hannover Medical School, Braunschweig, Germany
3Peter L. Reichertz Institute for Medical Informatics of the University of Braunschweig - Institute of Technology and 
   Hannover Medical School, Hannover, Germany


Abstract
Falls in older people are one of the major key problems and can lead to injuries, fractures, immobility, or even to death. Thereby, dementia increases this risk. Aim of this research was to estimate fall risk in older people with dementia during their everyday life in a one-year cohort study using accelerometry-based gait analysis. Fifty-five subjects were recruited from nursing homes. It was possible to classify gait parameters in combination with the age of the subjects, which resulted in an accuracy of 86.3% for a 3 month, 88.8% for a 6 month, and 93.0% for a 12 month prediction.

1 Introduction
About 30% of people aged 65 years and over fall at least once a year. Falls can acutely worsen the health status and severely restrict the self-contained mobility in older people. They can cause injuries, fractures, or in the worst case they can even lead to death. In this context, dementia is highly significant, because people with dementia have a higher risk of falling, which is about 50%. If falls could be predicted with sufficient accuracy, the risk of falling could be decreased by adequate (physio-) therapeutic interventions.

1.1 Related Work
There are a number of sensor-based studies related to measure fall risk. Most of them use the recent fall history of the subjects in order to make a fall prognosis (e.g. [1]). A recent fall history might be a good indicator for a higher risk of falling, but is not a robust predictor that a fall will actually happen in the near future. Other authors use a variety of fall risk assessment tools and scores for prognosis [2-4]. These tools, however, may have a limited capability to determine fall risk.

Sensor-based studies in which falls are documented prospectively are rare [5-8]. These studies used an accelerometry-based gait analysis and their hypothesis was that there are archetypical gait patterns, which are predictive for falls. The subjects were called by phone in a follow-up after one [5-7] or two years [8], respectively. This might be a methodological flaw, because the subjects may have overlooked a fall happened during that time and there is no way to control the information of the subjects. Furthermore, subjects tend to exclude or ignore fall events, which caused no or little injuries. Therefore, it seems to be necessary to have access to a professional documentation of fall events for these kinds of studies.

The mentioned prospective fall risk studies were conducted in a supervised setting. But people tend to change their behavior including their gait in supervised settings. Therefore, it could be advantageous to measure human gait unobtrusively during their everyday life. This may reduce the effect of feeling observed by the study personnel.

1.2 Objective
Aim of this research is to determine the risk of falling for short-term (3 months), mid-term (6 months), and long-term (12 months) periods in older people with dementia during their everyday life using accelerometric gait parameters.

2 Methods
2.1 Study Design
A prospective one-year cohort study was conducted in four nursing homes in Braunschweig, Germany, specialized in dementia care. Subjects were recruited in nursing homes, because these institutions document falls as Quality Assurance. The inclusion criteria were:
- Age ≥ 65 years when joining the study;
- Dementia (MMSE < 24 points [9]);
- Recurrent falls;
- Signed written informed consent by the subjects’ legal guardians.

The exclusion criteria were immobility and wheel chair mobility. The participants were followed-up every 3 months and measured for one week in each phase. This allows for fall prediction for short-term (3 month), mid-term (6 month) and long-term (12 month). In each measurement phase, a Timed “Up & Go”-test (TUG) was conducted as a clinical reference fall risk assessment tool [10].
2.2 Sensor Equipment

Accelerometers were chosen, because they are small and cheap, and there are already positive results of fall prediction studies using accelerometry [6-8]. Accelerometers were worn by the study participants at the hip, because this wearing position induces less measurement artifacts than other positions. The nurses were instructed to take care that the sensor systems were worn by the study participants. The SHIMMER platform Rev 1.3 [11] (see Figure 1) was used to capture the data on a microSD card. This sensor system is equipped with an MMA7260QT accelerometer, which was configured at a sensitivity of ±4 g and a sample rate of 51.2 Hz.

![SHIMMER sensor node](image1.png)

Figure 1: The SHIMMER platform used as accelerometric sensor platform in this study compared to a 2 Euro coin.

2.3 Gait Analysis

Gait episodes were automatically detected by an autocorrelation method, whereby only gait episodes of at least 20 seconds were analyzed [12]. Gait parameters (e.g. velocity, compensation motions etc.) were extracted from the gait episodes and served as a basis for classification. Please refer to [12] for the complete and detailed list of gait parameters. The accelerometric signal of each gait episode was aligned to the axes of the human body (see Figure 2) using the “depitch-algorithm” [13].

![Definition of human axes](image2.png)

Figure 2: Definition of human axes: anterior-posterior (ap), left-right (lr), and superior-inferior (si).

2.4 Data Analysis

Gait parameters and fall protocols were merged in a MySQL database. Each gait episode was interpreted as instance and annotated with information whether the study participant has fallen, or not. WEKA version 3.6.8 [14] and the integrated C4.5 decision tree induction method were used for analysis [15]. Thereby, decision trees with gait parameters only, and decision trees with gait parameters in combination with the age were induced for each prognosis period (short-, mid- and long-term). The models were evaluated using a 10-fold cross-validation.

3 Results

3.1 Subjects and Falls

Fifty-five subjects were included in this study (sample size estimation was 40), which were 83.1±7.0 years old (minimum 65 years, maximum 99 years) on study admission. The MMSE score was 16.4±5.2 points. During the study, altogether 76 falls occurred in 26 subjects. This is a fall incidence of 47.3%. Altogether, 6.722 gait episodes were detected. Figure 3 shows a study participant wearing the SHIMMER sensor node in a case fixed on a belt.

![Study participant wearing SHIMMER sensor node](image3.png)

Figure 3: Study participant wearing the SHIMMER sensor node in a case fixed on a belt.

3.2 Model Predictions

The age of the study participants could not predict falls for short- and mid-term (Area Under the Curve (AUC) of 0.51 and 0.50, respectively), but satisfyingly for long-term prognosis (AUC of 0.86). The AUC of the TUG was 0.58 (short-term), 0.55 (mid-term) and 0.74 (long-term).

Table 1 shows the summary of the model predictions regarding falls. For reasons of comparison, the rate of correct classified instances was computed for short-, mid-, and long-term fall prognosis of the age with a cut-off at 80 years and the TUG at 20 seconds, which are typical cut-off values regarding fall prediction.
In this paper, only a decision tree induction method was used for classification, because this was prospectively planned in the study protocol. The choice of the decision tree was based on the hypothesis that gait parameters have a hierarchical interrelationship regarding gait problems and hence to the fall prognosis. That means that a high step frequency associated with small steps may indicate festination, which can typically be observed in patients with Parkinson’s disease. One can also imagine that a gait may be instable, if there is a low velocity and a low step frequency. The most interesting point with decision trees is that not all parameters have to be computed at once, because only the parameters on the path of the decision tree are needed. This might save computing time on small sensor nodes or smart phones with limited resources, which could be a future platform to predict falls in everyday life.

Because of the instance-based approach to classify gait episodes, the information about intra-individual changes of gait could not be covered. This may contain further information and may lead to better results.

4 Conclusion

In this paper, we described a sensor-based, unobtrusive and objective method, which is able to determine the risk of falling in people with dementia in their everyday life. We presented the results of a cohort study conducted as field study.

The number of detected gait episodes was very high, especially in comparison with supervised clinical trials, where usually only one or a few gait episodes per subject are measured. Thereby, it has to be discussed that the number of gait episodes per study participant varied and could have biased the results. This might have led to an over-representation of some specific archetypical gait patterns.

The results showed that very small decision trees could be induced, especially in the focus of the large amount of available instances (gait episodes) to classify. Interestingly, neither the models with the gait parameters nor the age alone were able to predict falls well. But the combination of both showed a high rate of correct classified instances. The reason for this effect remains unclear. Maybe there are effects of the group composition.

4.1 Limitations

Regarding the current study there are a number of limitations to state:

- The nursing homes document fall events because of reasons of Quality Assurance using fall protocols. Although this documentation is done in a professional manner, it might have happened that some falls remain undiscovered and undocumented. Furthermore, the quality of the fall protocols can vary due to experience and medical expertise of the assessor.
- The selection of the subjects was not random, but the subjects were selected by the nursing staff according to the given inclusion and exclusion criteria. This makes it clear again that this study was a technical feasibility study.
- The nursing homes were not selected randomly. The choice of the nursing homes depended on organizational reasons.
- The flows in the everyday work routine may differ between the nursing homes. This may have an influence on the observational equivalence.
- The study design was chosen as field study. Thereby, the impossibility of controlling the setting is a huge problem. It remains unclear, if all detected gait episodes were actually gait episodes and if they could be assigned to the correct study participant.
- Another goal of the study design was to reduce the impression of the study participants of being observed. It is hard to estimate whether this was the case and what influence this had on the participants of the study.

### Table 1: Summary of the rates of correctly classified instances.

<table>
<thead>
<tr>
<th>Prognosis term</th>
<th>Short-</th>
<th>Mid-</th>
<th>Long-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥ 80 years</td>
<td>40.0%</td>
<td>40.5%</td>
<td>76.7%</td>
</tr>
<tr>
<td>TUG ≥ 20 seconds</td>
<td>46.1%</td>
<td>43.0%</td>
<td>48.5%</td>
</tr>
<tr>
<td>Model gait parameters only</td>
<td>74.7%</td>
<td>68.5%</td>
<td>78.5%</td>
</tr>
<tr>
<td>Model gait parameters + age</td>
<td>86.3%</td>
<td>88.8%</td>
<td>93.0%</td>
</tr>
</tbody>
</table>

### Table 2: Sensitivity, specificity, positive and negative predictive values for short-, mid-, and long-term prognosis of the models combining gait parameters and age.

<table>
<thead>
<tr>
<th>Prognosis term</th>
<th>Short-</th>
<th>Mid-</th>
<th>Long-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>93.4%</td>
<td>93.3%</td>
<td>91.1%</td>
</tr>
<tr>
<td>Specificity</td>
<td>68.6%</td>
<td>80.0%</td>
<td>96.5%</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>88.2%</td>
<td>90.1%</td>
<td>97.9%</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>80.5%</td>
<td>85.8%</td>
<td>85.5%</td>
</tr>
</tbody>
</table>

In this table, the values for sensitivity, specificity, positive and negative predictive values are provided for short-, mid-, and long-term prognosis of the combined gait-parameters-and-age model.
5 Acknowledgments

The authors would like to thank Armin Koch and Ralph Scherer from the Institute for Biometry at Hannover Medical School for assisting in the conceptual design of the study. The authors would also like to thank the following nursing homes and their employees who were involved:

- Elin Schriever, Mandy Stephan, Martina Dietrich, and their team of the nursing home “DRK-Seniorenwohnheim Steinbrecherstraße”, Braunschweig, Germany
- Britta Östermeyer, Jeanette Berndt, and their team of the nursing home “ambet e.V., Haus Auguste”, Braunschweig, Germany
- Valentina Büssow, Carmen Bauer, Sandra Wiersma, Isa Vollstädt, and their teams of the nursing home “ambet e.V., Haus Amalia”, Salzgitter, Germany
- Arnold Sebök, Frank Wenzel, Yvonne Smyzek, and their team of the nursing home “AWO Wohn- und Pflegeheim Am Inselwall”, Braunschweig, Germany

6 References

Event based communication Architecture Model for living quarters

M.Sc. Sebastian Thiele 1 a, Prof. Dr. Anke Häber 1
1 University of Applied Sciences Zwickau, Dr. Friedrichs-Ring 2A, 08056 Zwickau, Germany
a sebastian.thiele@fh-zwickau.de

Abstract

From an organizational view the coordination of a transinstitutional process of patient treatment among different health care providers is difficult. If the care process includes home monitoring the problems like data dispatching and -usage by health care providers (HCP) increase. Specialized service providers are helpful to collect and provide gathered data from the persons home area to the IT systems of the HCPs. The communication process is triggered by events of sensors in the residential area which are categorized based on an event classification model.

1 Introduction

In the research project Ambient Assisted Living in Intelligent Controlled Environments (A²LICE) [1], apartments in a living quarter are upgraded with building automation sensors and medical devices. The main objective is to support elderly people with special care needs, in long-term living in their own home. To achieve this, functionalities such as activity detection and monitoring of health parameters (vital signs) are provided with options to communicate the resulting data to the health care providers. Stakeholders in the project are a nursing care service, general practitioners and a local hospital. The data of medical parameters and recognized activities of daily living (ADL) [2] gathered in the home area of the resident have to be processed to support a long term health monitoring. A software-component processes the data and transmits them to the care givers information system. Additional requirements regarding to the data encoding and quality are provided by the partners of different healthcare sectors. For this scenario, interface specifications have been drafted by standardization organizations, such as Continua Health Alliance (CHA) [3] or Integrating the Healthcare Enterprise (IHE) [4]. Since external service providers use very different information systems, the exchange of data between them and application systems in the persons living area is difficult. Considering care providers more accurately, it is clear that each of them need data for different monitoring tasks in different situations and therefore requires different data. Thus, it is not clear at what time which data must be transmitted to which HCP. In addition, considering an architectural approach on a living quarter level it is not necessarily known which project partners must be supplied with data, but in principle any external service providers with its own application system must be connected. This paper presents communication architecture for data transmission between the home area and service providers of health care sector. The interfaces, communication standards and information systems used are presented and classified in the architectural model. The communication triggering events are identified and systematized in an event classification model.

2 Methods

2.1 Application systems

Health care providers use a variety of application and information systems. These are, depending on the sectoral orientation, of different complexity. A²LICE uses the application systems of a general practitioner (ixx.concept), a hospital (SAP IS-H/ishomed) and a nursing care service (MediFox live).

2.2 Communication standards

A communication between the participants within an IT infrastructure can only be successfully if a common vocabulary and standardized communication schemes are used. The following communication standards are used in health care sector and the A²LICE project. Health Level 7 (HL7) describes a standard that is used predominantly in the clinical sector and is currently available in version 3. A purely ASCII based version of HL7 has been maintained up to version 2.7. A variety of scenarios in the AAL domain can be formulated by means of event-, message type (ETMT) combinations using HL7 v2.

In the general practitioner sector the Kassenärztliche Bundesvereinigung (KBV) started early to develop standards for data transmission between laboratories and the practitioner’s office. A product of these standardization efforts is the Labordatenträger (LDT), to transport microbiology reports. Especially systems of smaller software manufacturers for certain areas of the health care sector (e.g. nursing services) are often dispensed with the support of common communication standards due to politics of product-pricing [5].

2.3 IT infrastructure

In the German health care system, extremely heterogeneous IT landscapes with a variety of not coupled application
systems exist. The scope of these systems is often limited to specific problem areas, therefore extending them is time and cost consuming. In addition, uniform implementation guidelines for the construction and operation of major IT infrastructures in healthcare doesn’t exist. Standardization initiatives such as the IHE are engaged in developing best practice approaches e.g. for a facility wide communication of patient data among application systems. In general the focus for such guidelines lays on the clinical sector, the general practitioners sector is not considered. However, there is a variety of isolated applications that allow couplings between the health care sectors. By operating point-to-point solutions an additional complexity is generated. So called middleware solutions between the sectors could provide data integrity and reliable exchange of electronic data but are missing. In the AAL Domain only a few projects operate online platforms offering monitoring of measures and therefore interchange the data between caregivers.

2.4 Technical conditions
From the perspective of an individual HCP, the integration of already elsewhere in the health care sector collected data into their own documentation- and management systems is difficult. Results are increased costs and time consumption for reobtaining information (patient histories, treatment data). To ensure integration, interfaces are required between its own and third-party systems. The information systems used in the facilities maintain electronic medical records or case files for storing treatment relevant information. An import of information into these structures is only possible to a limited extent, since the semantic integration of externally generated data can only be ensured with increased effort.

2.5 Telemedical center (TMC)
A telemedical center is a facility for the telemedical support of particular chronically ill people. Beside of the professional expertise the TMC provides technical resources for monitoring the health status of patients. For this reason it uses a specialized software system (TMC-System, TMCS) which assumes the data from the domestic areas of the residents, process and store these in patient specific records such as electronic case record or electronic medical record stores. Through a coupling of the TMZS with the systems of the HCPs a long term health monitoring can be optimally supported. An establishment of telemedical centers has been made to date only in pilot projects [6], [7].

2.6 Event classification
The sensors in the home area produce a high amount of data. Transfer all of them directly to one or more HCPs, is not possible and useful for reasons of data protection and due to the resulting payload. The data must be assessed in terms of their semantics. Current standards in the AAL environment do not consider event classifications. Moreover, it is necessary to distinct between AAL- and telemedical events which also need to be classified and contextualized. For this reason event chains of sensor messages are composed to allow a conclusion about the potential risk they express. A categorization of anticipated events is required. The actual recognition of events and situations is done by upstream processes (probabilistic methods).

3 Results

3.1 Communication architecture
The developed communication architecture is modeled on the provisions of the Continua Health Alliance to build an architecture for monitoring medical parameters. The communication network consists of home areas, a telemedical center and individual health care providers from different sectors utilizes various defined interfaces for data exchange. To fulfil the monitoring tasks in each area different application components are used.

3.1.1 The Continua Health Alliance approach
The Continua Health Alliance is a standardization organization which is active in the area of AAL and telemedicine. Continua defined Integration Profiles and processes for telemonitoring of elderly persons and summarized them in the Continua Design Guidelines. It avails itself of the communication standards HL7 v2 and v3. The Primary focus is currently on the transmission of measured values of medical devices to a Health Record Network (HRN). The HRN refers to an institution independent electronic health record system (EHR) which can be used by health care providers to monitor patients with mainly chronic diseases. CHA utilizes HL7 and web services as interfaces between application systems. IHE provide the frameworks IT Infrastructure (ITI) and Patient Care Devices (PCD) with subsequently defined profiles, which define the necessary actors and transactions between those systems. The transmission of data from the apartments of the elderly persons to the HRN is defined by the Device Enterprise Communication profile (DEC) of the PCD Framework. The framework provides functionalities such as the query for new measurement results in the home of the patient by a health care provider and ensuring transport safety and data security (web service security).

3.1.2 Processes between homearea and TMC
Once the data is collected in the home they are communicated either directly to the participating provider or (based on the type of data, expected use and configurations) to a TMCS. In the direct scenario of data transmission to the systems of service providers, the collected data must be transformed into the correct data formats and distributed through various interfaces. This is associated with a high configuration overhead of the application system used in the home. In addition to the development of interfaces target systems, access credentials, data formats and necessary encodings need to be set up. By using various adapters, the
above mentioned target systems of practitioners, the nursing service and the hospital can be served with the collected data prototypically. A more consistent approach causing significantly lower development and configuration efforts (particularly in the home area) is the choice of coupling to a TMCS. Analogously to the CHA approach web services are used for the transmission of the data. HL7 version 2.6 is used as the general communication standard. Here the ETMT ORU_R01 is used (Order Result), which is intended for the transmission of test results such as laboratory tests. By the TMCS offered HL7 web services responds to the inbound message processes them and (if configured) forward it to health care providers.

3.1.3 Processes in the TMC
Apart from the technical tasks such as acceptance of the data from home areas, processing, transformation and routing, organizational functions such as the steering of processes are perceived. This process preceding rules sets, which react on the content of the message (measured values, situations, ADLs) are responsible for the pre-processing of the data in the TMCS. By maintaining a patient specific electronic health record a consistent record can be built. An alarm of the service provider (doctor, nurse, relatives) in case of health related problems based on the event classification (threshold exceeded at measurement results) and intervention by them becomes possible. A threshold evaluation can take place directly in TMCS or in the home of the patient. By the patients selected strategy for forwarding the data to the service provider will also determine which data are transmitted from TMCS to the service provider.

3.1.4 Processes between TMC and HCPs
Typical processes between the TMC and the health care providers describe the transmission of in the home area measured vital signs, recognized activities and situations. The TMCS has a (patient specific) knowledge of which system the data must be transferred to and in which format they must be provided. For this purpose, transformations of the received data into the target data formats and optionally a translation of the terminologies used in the target systems are necessary. In the A^LICE project the system of a practitioner is served with a LDT-File and the ISHishmed via an HL7 v2.6 message, MediFox uses a proprietary data format. For example, it is possible to transmit blood pressure measurements and blood glucose monitoring data to the general practitioner and ADL data to the application system of the nursing service.

3.1.5 Data processing at the HCP
Depending on the performance of the care provider’s application systems processing of the data received from the TMCS may be extensive. A general practitioner can import the received LDT-File directly into his application system and assign a patient reference. As a result, graphical analysis and time series comparisons for the development of selected parameters are possible. In the clinical sector making use of clinical pathways (CP) is a further option to take advantage of the latest health related data. In a specific scenario, a patient with type II diabetes could be located in treatment path that is traversed by the hospitals workflow system cyclically. The CP can access the latest data of the blood sugar levels of the patient and consider his/her specifics such as diagnoses, medication and other known health related problems.

3.1.6 IT infrastructure
The overall infrastructure is modeled based on the CHA-specified infrastructure guidelines. This means to use the same technical concepts for coupling the residential home application system to the TMCS via HL7 interface and web service. The main processes in the home describe tasks of collection, persistence, evaluation and transformation of sensor data as well as publishing. These tasks benefit from the developed event classification. Through events raised in the home, communication is initiated. Different strategies to disseminate the data based on the classification schemas allow the preservation of privacy.

Another differing aspect to the original specification is to support the coupling to different service providers in the form of point-to-point connections for the benefit of data transmission. The approach of TMCS-coupling is considered to be preferable. In this case, extensive configuration procedures in application systems of the residents are moved into the TMCS. These procedures can be easily done by specially trained employees. In the present scenario, the communication relation aimed primarily from the domestic sector to the health care provider’s. The reverse channel (back to the person’s home areas) is not yet finally determined. The following figure (Image 1) illustrates the proposed overall architecture.

![Image 1 Conceptual Architecture](https://example.com/image1.png)

The health care providers are responsible for defining and implementing robust interfaces or use (standardized) pre-defined ones from their application system manufacturer. CHA defines the usage of web services for the overall communication. The application systems ixx.concept and MediFox live in A^LICE do not support them. That's why other approaches such as the provision of a secure FTP server (S-FTP) or a proprietary database interface have...
been chosen. Only IS-H/ishmed allows the implementation of own web services for the discussed scenario.

3.2 Event classification
The developed model of event classification provides the categorization of events according to the hazard potential of sensor events. The potential risk for an event derives from the nature of used sensors such as Heat- or CO₂-sensors. Linking individual events to situations accordingly allows the derivation of the hazard. Provision is made for a four-stage classification according to the scheme of not critical (C1), medium critical (C2), highly critical (C3) and unknown (C9). An automated classification is done accordingly to a predefined threshold which the emergence of several critical sensor messages takes into account. Telemedical data (blood pressure, blood sugar levels) can be evaluated accordingly to an existing personal health profile. Exceeding the specified values in this profile implies an alarm situation.

A semantic integration of so raised (critical) events can be achieved by building a terminology for events in the AAL environment. The authors propose the use of a unique event identifier and an associated event description which is to be embedded in a suitable XML schema. As a result, employees at the TMC are presented with a traffic light alike functionality through the above presented classification system. Dispatching of further actions becomes possible in situations of moderate and high risk. Specifically it was semantically determined which potential danger is associated with the triggering of a sensor. In situations of high risk (red light) the transfer of the concrete situation is absolutely necessary to initiate appropriate actions by the TMC employee.

4 Conclusion
The developed communication architecture for residential areas benefited from the use of standardized interfaces. The components used within the architecture are operated on residential or residential block level and exchange messages with the mentioned service providers of the health care sector. The data processing is carried out by means of different strategies for processing measurements of medical parameters (vital signs), activities of daily living and the energetic data of the each flat. An exchange of the data collected by the sensors in building automation and medical technology is based on data usage guidelines, which are determined by the actual residents.

The target system for collected data is a centralized software instance which refers to a telemedical center. This organization offers different services for the residents for monitoring the person's health status as well as energetic data. For this purpose it uses web services, data analysis technologies and standardized communication architecture. Within this system, the data are processed and distributed on the basis of person specific configurations to the health care providers of different sectoral affiliation. In a later phase of the project this central software instance will be operated within the Gesellschaft für Intelligente Infrastruktur Zwickau mbH (GIIZ) [8] and is a target for energetic and health data from the home areas of the residents.

Acknowledgment
The authors gratefully thank the European Social Fund (ESF) for supporting the junior research group and the doctoral scholarship at the University of Applied Sciences Zwickau.

References
Professional Use of Mobile Devices at a University Medical Center

Kristin Illiger¹, Ute von Jan¹, Urs-Vito Albrecht¹

¹Peter L. Reichertz Institute for Medical Informatics, University of Braunschweig – Institute of Technology and Hannover Medical School, Germany, illiger.kristin@mh-hannover.de

Abstract

This article describes an analysis of the expectancy, acceptance and use of mobile technologies at a university medical centre in Germany. Using an online questionnaire, in a longitudinal study performed at two points in time (2012 and 2014), we explored whether doctors use mobile devices in their everyday clinical setting and where they see chances or risks when using them while collaborating with colleagues or when dealing with patients. Based on the results obtained for the two surveys, a comparison was performed with respect to changes that had taken place over time with respect to presence of mobile technologies in the clinical setting, general usage of these technologies and concerns voiced by the participants of both surveys. We were also interested in whether age, gender, work experience or the place someone has within the hospital’s hierarchy play a role in this context. The results show a noticeable increase in general usage of mobile devices in daily clinical practice. At the same time, at both points in time, the devices were mainly used for communication as well as for looking up information. The participants mainly voiced concerns with respect to data protection, reliability and hygiene. Altogether, the aim of the presented study is to contribute to the discussion about the use of mobile devices in the medical field.

Keywords. mobile technologies, technical acceptance, doctors, hospital

1 Introduction

Mobile devices such Smartphones and tablet PCs have a value for supporting doctors in their daily work and offer possibilities for optimizing and facilitating routine tasks amongst others [1,2]. Some developments in the international context indicate that mobile devices will certainly become a key part of communication and management processes in modern healthcare settings amongst others [3,4].

Altogether, this gives cause for critically discussing the such developments, especially considering the differing needs of all parties concerned, namely patients as well as members of the medical staff.

This longitudinal study takes a closer look at the expectancy, usage and acceptance of mobile technologies at a university medical centre in Germany. The results show the current situation in a university hospital specifically Hannover Medical School, and may provide first indications for future trends regarding the potentials and limitations of mobile devices from a doctor’s perspective.

2 Methods

A standardized interview of physicians was conducted via an anonymous online questionnaire at the Hannover Medical School in Germany at two points in time: first in 2012, and again in 2014. The questionnaire consisted of 16 items in total, including aspects of actual usage, usage ideas and possible concerns about using the devices while interacting with patients and colleagues. This questionnaire was provided via an online evaluation platform that is available as an in-house installation at the Hannover Medical School. The obtained data were entered into an electronic survey system and exported to Microsoft Excel 2007 for further descriptive analysis. Pearson’s chi-squared test (2-sided) was used for testing significance of differences between expectancy, usage as well as acceptance of mobile technologies and demographic factors (IBM® SPSS® Statistics Version 21.0, IBM-Corp). Demographic factors that were included were age, gender, work experience (categories: up to two years, up to four years, up to six years, up to 10 years, up to 20 years, up to 30 years, more than 30 years) and the participant’s place within the hospital’s hierarchy (consultant, specialist registrar, house officer).

All physicians currently employed at Hannover Medical School were invited to participate in the study. The return rate was 23% (248/1077) in 2012 and 18% (205/1151) in 2014. Demographics of the respondents corresponded to the overall data available for the Hannover Medical School [5].

3 Results

3.1 Presence of mobile technologies in a clinical setting

In 2012, 70% of the doctors who had answered the survey were using at least one mobile smart device (which we defined as a device that is capable of downloading, installing and running mobile apps). In 2014, corresponding rate of those who had answered had risen to 82%. When asking about whether they were using the devices for work purposes, in 2012, 22% of those questioned confirmed this and in 2014, the percentage had grown to 38% of those who had answered the survey. 37% of respondents stated...
that their employer did not specifically support use of mobile devices; in 2014, this number had fallen to 29%.

3.2 Usage of mobile technologies

The majority of the participants who use a mobile device state that they mainly use it for electronic communication, e.g., for reading and sending emails or for chatting (2012: 52%, 2014: 61%) as well as researching medical information (2012: 44%; 2014: 57%).

Less often, the devices are being used when dealing with patients: in 2012, only 13% were using their mobile devices as an aid for diagnostics while they were caring for patients and in 2014, users who did so were still a minority with only 18% admitting to doing so.

When asking about usage of the mobile devices in the context of treatment, the rates are even lower (8% in 2012, 4% in 2014).

Relatively few (9% in 2012 and as in 2014) of the participants were using the mobile devices in the context of patient education and patient information.

A dependence between work experience (P=.461) or age (P=.101) and anticipated usage of mobile devices at work in the coming years could not be confirmed.

3.3 Concerns regarding the use of mobile technology

In 2012, users primarily voiced concerns related to security and privacy of patient data (45%) and hygiene (36%). As before, in 2014, participants remained concerned about security of patient related data (62%) and hygiene (39%), but also about reliability and trustworthiness of the software (32%). In 2012, 11% refrained from using mobile devices during contact with patients since they thought their patients might be unfamiliar with them or might not have access to such technology; in 2014, this percentage had slightly fallen to 8%. Only a minority of the doctors state that a lack of interest or too much time required to become familiar with the technology would be a reason for them not to use mobile devices in their work with patients or colleagues (2012: 4%; 2014: 3%). A statistically significant connection between the major concerns voiced by the users and the different positions within the hospital’s hierarchy could not be identified (P=.050 to .915).

4 Conclusion

The results of the study show which chances but also limits doctors in general perceive for mobile devices in their everyday work. Main areas of usage were communication as well as information research. In contrast to the growing number of so-called “health applications” or “medical applications” that are readily available in the app stores of various mobile platforms, such apps still only play a minor role for the participants of our study. Major concerns voiced by the participants fall into the categories of data protection, reliability and hygiene.

Potential ethical issues are not really perceived as a problem for using mobile devices. Personal lack of interest also does not seem to be a hindering factor.

Considering recently uncovered issues regarding data protection and privacy that have been in the focus of the media in recent times, the qualms users have in this area are adequate and show that users are at least basically aware of the risks posed by using mobile technologies in a medical setting [6,7] and are careful when using them for work purposes.

Also, it can be assumed that, similar to other groups of users nowadays, most doctors have at least a basic personal interest in using them. This is a promising development considering the potentials mobile technologies offer for not only for private but also for professional applications.

The information we collect may possibly be helpful as a basis for implementing successful strategies for officially deploying mobile technologies in a major health care facility such as Hannover Medical School.

Nevertheless, the available data does not allow to paint a complete picture regarding acceptance of mobile technologies or the actual future utilization of such devices for the near future. A closer look at the concrete intents and wishes of using mobile devices for work purposes was not taken.

Unfortunately, the return rate for both surveys was not as high as we would have wished. The evaluated sample was no randomized and is thus not necessarily representative. It may be possible that those doctors who participated in the surveys were generally interested in the matter and specifically in the current status as well as future developments regarding mobile devices as well as their professional deployment. This might have biased our results.

In addition, due to privacy issues, we were unable to confirm whether those doctors who had answered in 2014 had already participated in 2012 or not.

Therefore, altogether, in its current form, the results of our study can only show tendencies and cannot be used for meaningful conclusions.

Lastly, it must also be noted that when evaluating mobile devices in the medical, it is not sufficient to solely look at the doctors’ perspective. Rather, it is also important to consider the needs and concerns of the patients as well. This is currently subject of an additional study being performed by the Peter L. Reichertz Institute for Medical Informatics that deals with acceptance of mobile devices from a patient’s perspective.

Acknowledgments

We would like to thank employees of Hannover Medical School for participating in this survey.
Registration

The study was conducted with approval by the Institutional Review Board of Hannover Medical School, study number 1206-2011.

5 References


Personal Diabetes Management Tools based on hybrid Neural Nets

M. Reuter¹, S. Bohlmann⁴
¹Department of Computer Science, TU Clausthal/IngB RT&S, Clausthal-Zellerfeld, Germany, matthias.reuter@ingb-rts.de
²Department of Computer Science, TU Clausthal/IngB RT&S, Clausthal-Zellerfeld, Germany, sabine.bohlmann@ingb-rts.de

Abstract

In the last years we developed and tested a special software tool for personalized diabetes management. On basis of a large range of filled questionnaires from American and German diabetes patients we trained special neural nets to create a personal finger print for each patient to enable an individual therapeutically support and guaranty a continuous monitoring over time. Especially our categorizers differ between social, educational and ethnic background and, based on a class oriented four level statistic, the states of the patients factoring the different psychological, physiological, familiar and social factors. In such way our system leads to a supervision and guiding system for patients and the attending physicians and guarantees an over all cost reduction of factor 5 - 7.

1 Introduction

Diabetes (diabetes mellitus) describes a group of metabolic diseases in which a person has high blood glucose, either because insulin production is inadequate, or because the body's cells do not respond properly to insulin, or both. Diabetes can be divided in two forms: Diabetes Type I and Diabetes Type II. As both forms differ, every diabetes management system also has to distinguish both groups generally, as same as (general) cultural, sociological and familiar background together with the attitude of the patient regarding this form of disease [2],[3]. It is this enumeration of fundamental different parameters which leads to the finding that common expert system or simple software are unable to handle all different parameters in the necessary context of an individual handling of the patients' disease.

Rather, it is necessary to use new algorithm to combine all the different parameters and - out of them - to form an individual personal finger print of the patients' behaviour and the medical treatment for effective supervision and therapeutically guidance. Such algorithmic structures can be realized by using the methods and procedures of the so called computer-based intelligence (CI) as on one hand the CI enables scientist and applicants to categorize diffuse or incomplete data sets by self learning algorithm, on the other hand the CI enables to combine information automatically from unequal sources and formats. In so far, CI can be seen in the context of Big Data and Data Warehouse too.

2 Methods

2.1 Basis Modules of the System

Our personal diabetes management system consists of four different basis modules:

- Data Base Module (DB), storing all questionnaires and their corresponding answers, personal data, trends, neural net structures and labels for the different country versions.
- Online and Printing Module (OPM), enabling the connection to the World Wide Web, the mailing function, the report generator and the communication to the printer equipment of doctor’s office.
- The Graphical User Interface Software (GUI), enabling the Man-Machine-Interaction (Patient to Computer Dialog, PCD), the help functions and the choice of the individual language of the country where the system is momentary used.
- The CI-Module, involving the neural net structures, the special categorization algorithm, the learning procedures for the system and the and evaluation and visualization modules for testing on confidence.

All these modules are running combined in background, where the system itself has the following three main working modes:

- Patients’ Mode (PM)
- Doctors’ Mode (DM)
- Maintenance Mode (MM)

2.2 Basis Functionalities of the System

To ensure that data security is given, every patient and the doctor’s office personal stuff have a 9 letter password, which ensure the patient (and doctor) to see all personal data the results of all questionnaires and trend analysis results only. Furthermore the doctor and/or the doctor’s office stuff is able to create new patient’s “cards”, means new patients, stored in the data base.

If a new patient’s card is created, first all necessary personal data are evaluated by an interactive PCD-dispute, where the systems check all data on logic and completeness. In the second step the patient is lead through the questionnaire. In our system this questionnaire is divided in eight logical categories. This enable to analyse different items of patients’ life and behaviour. These categorise are disease status and history, physical, psychological, social and familiar status, self and foreign assessment.
After a patient has answered all questions (or optional one or more categories) the system categorises the patient via its neural network structure. On demand these categorisation results can be posted to the doctor’s office and/or to the patient via internet and/or mobile devices, where the results are bundled in pdf-reports.

In the doctors mode the system can be conditioned, means special neural nets can be created and trained. Furthermore in this modus the doctor is able to create a statistical- and neural- overview of all his patient data together.

2.3 Principle of the Neural Net based Categorizer

Surely the core of the system can be found in the neural network structure, which is the underlying data analysis algorithm of the personal diabetes management system. Therefore we explain here some basics of these Cl-oriented methods. Neural net are more or less a simulation algorithm of central nervous functionalities. Therefore they can be divided in several neurons, which are combined via synaptic connections. These connections can be conditioned in a special training modus. The training itself can be done in two modes: supervised and unsupervised. Supervised training can be done easily if one knows everything about the system to be categorised and examples of all possible states of the system are know. As we don’t know, how many different classes of patient or (different) states of the disease are existent, this method is not sufficient for a diabetes managing system.

As a result, for our intention the second method to train a network - the unsupervised training - is more sufficient. If this learning method is used, the fundamental algorithm separates all categories of the data, presented to the net during the training phase by itself. Unfortunately with common self organizing neural nets this proceeding leads to a well known problem: At least for every different state of the system/patient, one single neuron has to be implemented, or - if we don’t know how many states exist - more neurons then existing states have to be implemented in the network. To work around this principle bottleneck, we developed a new kind of processing and interpretation strategy of these nets, called “Computing with Activities” (CWA-Method) [1]. Out of this theory, we don’t interpret the activity of a single neuron, but the overall activity structure of the whole net. We are sure that this interpretation is near by the neurological assumption, that neuron ensembles activity pattern represents different items like objects or minds of the cortex and an example will show, how powerful this new theory is: Following the classical information theory of the simulated neural nets we can store in a 200 neurons containing net 200 different states of a system/patient. But if we use the CWA-Method and define that our simulated neurons can assume five different states (such like five different firing modes over a fixed time interval) we can store and code 5^{200} states of a system/patient in the same net. This is more information as all films ever produced together!

Beneath this nearly unlimited storing volume, the CWA-method also ensures that slightly changes in the data sets lead to slightly changes in the categorisation result too and vice versa; means by CWA great differences in patient states lead to great differences in the activity pattern of our basic categorisation results and vice versa. Images 1a and 1b show some examples of such an activity based categoriser. The upper examples show a small difference in the data sets, the lower a bigger difference. It is important to mention, that the data sets used have the dimension of 20, means 20 parameters (here 20 different answers to 20 different questions) have been combined to categorise different patients regarding their similarity in behaviour and status.

Image 1a/1b CWA-Method explained by similar patients and unequal patients categorization

2.4 Categorization criteria and trend analysis

We saw, that the neural nets are a very powerful categorizer. But it is needless to say that our system needs an adequate machine-user-interface which enables to interpret the neural based categorization in intuitive and quick way. For that reason we implement a special interpretation module, which analyze the neural activity pattern in that way that four different general categorization classes are describing the momentary states of a patient. These classes are combined with a kind of “to do list”, means containing a reference of therapeutic interventions. In detail these categories and therapeutic interventions are:

- **Green**: patient’s state is ok, non action is needed
- **Yellow**: patient’s state is more or less ok, but has to be supervised and improved
- **Orange**: patient’s state is not ok, action is needed
- **Red**: patient’s state is alarming, prompt action is needed

In that way the doctor/medical stuff at least have a tool which enables the inquiry of the patient’s state via a simple (quick) view, as exemplified by Image 2

The neural based personal diabetes management system includes three different levels of patient evaluation as shown in Image 2, too. First of all - represented by the left hand side block - the overall state of the patient is visualised. In Image 2 everything is ok, indicated by the green colour of the three columns of the left hand side block. The block in the middle shows the patients trend over time. In the left hand side column a yellow categorisation is
shown, the middle and the right hand sided columns show a green categorisation. We use these three different categorisations to evaluate, which kind of categorisation fits the real state of a patient best.

In detail the left columns of each block point out the average of the analysis of all data (here the over all analysis and the trend analysis of the patient’s data), the middle column represents the neural net categorisation of the states following the four classes: green-yellow-orange-red.

**Image 2** Color-coded patient state analysis

At least the right column represents the categorisation of the neural nets by corresponding rainbow colours. Surely the rainbow colour representation of a patient’s state is more significant than all other representations, but for a quick overview it is helpful if a categorisation of our fixed four colours is presented for reference too. This argument can be pointed out more clearly on hand of the categorisation of the single questions (right hand side block). In this block on the left hand side the traditional four colours coding is shown, the right column shows the categorisation by the corresponding rainbow colours. As our investigations show the chosen colour coding enables a more detailed analysis of patients within “one view”, where especially the break down from the global categorisation of the over all state of the patient to the single questions leads to an effective (adequate) estimation of diabetes management. The overview of Image 2 describes only the momentary status of a patient. To ensure that therapeutic treatments are successful over the time, or to identify deteriorations on one or several areas, we implement a statistical module which analyses the categorisation results over the time. Based on the database entries of the patients, this module identifies three different trends – again on basis of our colour coding – and visualise them in special charts, as exemplary shown in Image 3. Out of this charts another module calculates a trend prognosis, where statistical blips are taken into account (neglected) too. Furthermore different time intervals for the trend prognosis can be chosen, which gives the medical staff the opportunity, to analyse momentary and longsome changes. Moreover the medical staff or the patient itself can choose alternatively the categorisation of the global status or the categorisation of the single questions. In that way our tools enables to indentify the weak or the strong points in patient’s behaviour and/or patients handling of the disease. At least by the methods and trends we described, the doctors, the medical stuff, the social environment and the patient itself are empowered to supervise and interpret the momentary and past states of the patient/the diabetes running.

In detail Image 3 shows the chart of the colour coded categorisations of the blood glucose control of a patient over 20 examinations (left hand side). Easily it can be pointed out, that at the beginning of the examinations the values have been very low, than improved and at least get worse again. The middle block shows – again colour coded – the statistical parameters, here the centre of gravity (means the overall middle value), the FactorK, which is a prognosis for the next weeks and the momentary trend over the next 10 days. At least our tool contains a report generator, enabling to archive the categorisation results and trend analysis charts in Word or pdf-documents. The documents generated by the report generator, can be stored in an anonymous or personalized form, can be printed out directly and/or be sent via email to the patient or a medical centre. Furthermore the report generator enables the doctor and/or the patient to select further examination results for printing and/or controlling. A standard form of a report is shown in Image 5. At the top of the report the personal data are (optional) given, followed by the legend of the color coding. Next the different questions text and their classical and neural based categorization results are listed. The report of the questions ends with the chart of the completed questionnaires and the long and short time prognosis, coded again by three colors and a short text segment.
3 Results

We condition and test the system with two different data sets to explore the data sets of the partner company SMO Networks, which also provided the questionnaires. The first data set, collected in the USA, contained 1024 patient’s questionnaires data, 501 of Diabetes Type I and 523 of Diabetes Type II. The second data set, collected in Germany, contains 612 patient’s questionnaires data of Diabetes Type I and 564 of Diabetes Type II. Different social, ethnic and educational groups have been recorded to empower the neural nets to differ adequate between the wide ranges of data. After the training phase of the neural nets, the statistical distribution of the categorized data sets were evaluated and compared with literature to ensure our system reflects reality. Image 4 shows a net, based on a well balanced data set.

Next we evaluate the final system regarding its “safe time”-factor; means, we asked test persons to supervise and assess patients by common methods like (paper or computer based) patient’s medical files, Excel data sheets or conversation and by using our system, or, at least, by the personal reports, exemplary shown by Image 5.

After a short training phase, our test personal needed a factor ten less time for a patient evaluation; means the system enables a cost savings of more or less factor seven.

4 Conclusion

We presented a computer- and computer-intelligence based system for Diabetes management and patient trend analysis. Core of this system are small effective neural networks, trained by patient data of different social, ethnic and disease-related environments. Due to its structure, the system can be continuously adapted and sensitized by means of new data. In that way over time regional influences are incorporated automatically into the systems behavior, reps. into the systems categorization behavior.

5 References

Ultrasound communication for intelligent implants

D. Laqua\textsuperscript{1}, T. S"uhn\textsuperscript{1}, K. Kring\textsuperscript{1}, K. Albrecht\textsuperscript{1} and P. Husar\textsuperscript{1}

\textsuperscript{1} Biosignal Processing Group, Technische Universität Ilmenau, 98693 Ilmenau, Germany

Abstract—Wireless communication is an essential part of body area networks (BANs). Ultrasound waves can be used as an alternative to radio frequency (RF) transmission. Nowadays RF telemetry is an established solution and there are several companies selling their products. In contrast, for medical implants the use of ultrasound telemetry is an unconventional and experimental method. This work presents a transmission line including an active sensor and a receiver. The microcontroller based sensor generates a 1 MHz ultrasound wave using a piezo crystal. At the receiver, a piezo crystal transforms the ultrasound wave into an electrical signal. The following analog processing reconstructs the transmitted information. The digital signal processing of the microcontroller extracts binary digits and visualizes them on a display. The complete signal chain is evaluated by temperature measurements with additional ultrasound transmission through tissue substitutes. The transmitted information is extracted and presented by the receiver circuit.

I. INTRODUCTION

Body area networks (BAN) are miniaturized sophisticated bio-medical devices, which can be implanted or worn by humans [1]. Due to the fact that transcutaneous connections raise the infection risk, a tethered telemetry or power supply for medical implants is inappropriate and not justifiable in the majority of cases. The information of an intra-body area network (IBAN) can be transmitted via in-body and along-the-body communication. In most cases an in-body sensor is connected to a fixed access point outside the body [2]. Wireless communication mostly bases on radio frequency (RF) electromagnetic waves. Depending on frequency, biological tissue could have high levels of attenuation for electromagnetic waves. In contrast biological tissue is a very good acoustic transmission medium.

To avoid a denaturation a low power in-body transmission prevents the tissue from heating up. This takes effect for mechanical and electromagnetic transmission lines. A high-energy ultrasound beam could induce a mechanical destruction of the cells by disrupting the cell membranes or cell structure. In consequence the transmission energy should be as low as possible. Energy harvesting with the human body requires ultra low power consumption for the used electronic parts. This is also the premise for the functionality with a weak input power. As well it is still a challenge to guarantee a continuous operation of battery-powered implanted devices over longer periods of time. On medical implants the exchange of batteries is either not possible or imposes high strain on the patient and it is still a risk for an infection.

RF telemetry enables wireless data transfer over the air or through obstacles, while phase transitions mostly have a minor impact on the signal. There is a wide field of available products using RF transmission for communication. For BANs the high electrical attenuation in liquids is problematic. In contrast to RF transmission, phase transitions have a remarkable effect to ultrasound waves. This is used in medical imaging to differentiate the anatomic structures. However, that may be a reason for the lack of commercial products for communication via ultrasound.

Ultrasound communication, as method for intelligent implants, has the potential for being a realistic, low power alternative to RF communication, which could have a high attenuation in tissue.

In the work Measuring the attenuation characteristics of biological tissues for enabling low power in vivo RF transmission [3] the attenuation depending on transmission frequency is presented. The work of Schwiebert et al. [4] gives a detailed overview of the opportunities of BANs. An artificial retina implant or an implantable glucose monitoring system are presented as possible applications. Davilis et al. [5] and Galluccio et al. [6] investigated interferences, absorption and attenuation of ultrasound waves in biological tissue. The frequency range, the type of transducer (piezoelectric element), the communication network architecture and the data encoding method are specifications. Both papers summarize their work independently from each other with the essay, that ultrasound communication has a high potential for application in the human body.

II. METHODS

This work presents a concept for transmitting vital parameters from an intelligent implant via ultrasound. For energy harvesting with the human body a discrete sensor value, like temperature or pressure, is needed. Fig. 1 presents the concept of an implemented ultrasound transmission line including an active sensor and a receiver. Gelatin is used as a sub-
stitute for biological tissue.

A. Active sensor

For wireless telemetry the active sensor generates an ultrasound wave with a frequency of 1 MHz. Therefore, a microcontroller generates a square-wave output signal with its integrated timing modules. The voltage amplitude of 3.3 V, which is the same as the power supply voltage, is not sufficient to drive the piezo crystal. A MOSFET circuit amplifies the square-wave output signal for piezo 1. A switching boost converter boosts the supply voltage from 3.3 V up to 20 V. The supply voltage of 20 V causes a larger oscillation amplitude in the transmitting piezo, which improves the signal intensity in the receiving piezo.

B. Receiver

When the ultrasound wave reaches piezo 2, the piezoelectrical crystal starts to oscillate. This generates an alternating voltage in the crystal. To avoid a load to piezo 2, a operation amplifier with a high impedance buffers the input signal for further processing. An active high-pass filters the lower frequencies and the DC voltage. Without removing the offset, the low level will be amplified above the logical zero threshold voltage. For information extraction the 1 MHz ultrasound frequency is filtered by a fourth order low-pass. An active high-pass removes the offset voltage caused by the low-pass filter. At the end of the signal processing chain, the microcontroller analyses the signal and visualizes the result on a display.

C. Firmware

C1 Signal generation

The clock system of the microcontroller MSP430F2619 provides an internal timer module, which generates the carrier frequency of 1 MHz for the ultrasound wave. The temperature information is transmitted as a binary code, where the binary digits are coded by switching the basic frequency on and off. The length of the pulse train defines the corresponding digits. A logical zero is a pulse train with a duration of 250 µs and logical one has a duration of 750 µs.

C2 Signal processing

The receiver uses a microcontroller for signal processing. The microcontroller provides a port interrupt module, which is able to detect a falling or rising edge at the pins. The preprocessing is described in the subsection above. The rising edge at the pin induces an interrupt routine, which starts the internal timer counting up. The falling edge stops the timer. A comparison with defined threshold value decides, whether it is a logical 0 or a logical 1. The result is presented on the display, which is connected to the microcontroller.

III. RESULTS

Fig. 2 presents the main components of the built prototype on a breadboard. The active sensor, depicted in the lower row, consists of a DC/DC buck-boost switching regulator module for the power supply voltage of 3.3 V. The microcontroller MSP430F2619 (Texas Instruments) operates as temperature sensor and signal generator. For power supply of piezo 1 (transmitter) a DC/DC boost converter is used and the MOSFET amplifier switches the piezo 1. The receiver circuit, shown in the upper row, consists of a buffer for high impedance decoupling of the piezo 2 (receiver), an active high-pass for removing the offset and the low frequencies and a fourth order-low pass for filtering the 1 MHz carrier fre-
waves are amplified. Fig. 5 visualizes the raw signal of piezo 2 and the gained signal after the active high-pass. The complete 8 bit sequence is shown in Fig. 6. After analog preprocessing, the filtered and amplified signal is provided to the MSP430F2619 (Texas Instruments) for measuring the pulse width and displaying the information.

IV. CONCLUSION

Ultrasound waves propose a paradigm shift for wireless transmission with BANs. The work of L. Galluccio et al. [6] proposes a strong potential for communications in and out of the human body. This work presents a complete ultrasound transmission line with an active sensor and a receiver. The active sensor has only one power input with two implemented DC/DC switching regulators. One of them is a voltage booster for the needed high voltage supply of the piezo crystal. Experimental transmissions through a tissue substitution with automatic information extraction were successful. A further experiment with a transmission through the human hand was successful, as well. The backscatter technique proposed by Mazzilli et al. [8] is able to improve energy con-
sunction for the active sensor. For the backscatter technique, the ultrasound wave is injected into tissue and reflected by a second piezo. A third piezo receives the reflected signal and extracts the information. Modifying the mechanical characteristics of the reflecting piezo crystal, between attenuator and reflector, encodes the information. A big advantage of the backscatter technique is the very low energy consumption. A better filter design can improve the information extraction and make the transmission more robust against noise and artifacts. It is also possible to optimize the energy consumption with low power operation amplifiers. Energy harvesting provides only a small amount of energy and it is not possible to ensure a continuously supply. Therefore, the system uses low power components and has a low power consumption. The presented work includes a temperature sensor but alternatively pressure or chemical sensors are imaginable. A half-duplex communication with the same amount of piezo crystals is possible, as well. For storage or mHealth applications, the receiver can be coupled with a smartphone or tablet.

REFERENCES

Standardization of ENT Oncological Anamnesis and Evaluation using Levenshtein Distance Measure

Jens Meiera, Andreas Boehm², Thomas Neumuth³

¹Innovation Center Computer Assisted Surgery (ICCAS), Universität Leipzig, Leipzig, Germany
²Department of ENT Surgery, University Medical Center Leipzig, Germany
Email: {firstname.lastname@iccas.de, andreas.boehm@medizin.uni-leipzig.de}

Abstract
The documentation of clinical results for diagnostics, therapy planning, retrospective studies or quality management is crucial. Especially in tumor treatment a preferably complete electronic patient record builds the basis for finding the best possible therapy for the patient. Currently used hospital information systems are poorly integrated into daily clinical routine and provide little support for the documentation of the results made by physicians and surgeons. The clinical information system oncoflow has been tailored to the oncological workflows in ENT tumor therapy and provides structured documentation of results during the first consultation. A workflow analysis that compares the documentation workflow within the currently used hospital information system SAP i.s.h.med and the new oncoflow system has been performed at a clinical site. The study comprises the anamnesis documentation of 16 patients with suspected tumor in SAP and 11 patients in oncoflow, respectively. Study results show that physicians perform a highly standardized documentation in oncoflow which is significantly improved by 71% compared to the usage of SAP i.s.h.med.

1 Introduction

1.1 Motivation
Tumor therapy is a long-lasting, complex and challenging process for both patients and physicians. Due to a wide variety of possible treatment options physicians and surgeons need as much information as possible to be able to choose the best possible therapy for the patient. Therefore, the information should be available immediately and well-structured for the clinical staff in a centralized information system. Unfortunately, at the moment, different information systems are used in daily clinical routine that are not well integrated into the clinical workflow and only provide basic support in the different treatment phases. Hence, three major drawbacks can be identified in head and neck tumor therapy at the university medical center Leipzig: 1.) There are no standardized questions available for the first patient consultation. Each physician uses a word-document with a slightly varying set of questions. 2.) The results documentation is done in SAP i.s.h.med in a free-form text field in an unstructured way. 3.) The information is not instantly usable for further electronic processing, clinical studies or quality management. It is not possible to apply filters on the database for selecting patients with a certain attribute e.g. patients with positive risk factors.

In order to improve the information quality and to establish standardized clinical procedures we developed a clinical information system oncoflow that supports the entire oncological therapy process for patients with head and neck cancer and is well integrated into daily clinical routine [1]. This paper focuses on the first consultation of the patient. In this step important information about the current medical status is acquired such as smoking or alcohol habits, allergies, comedication or former surgical interventions. In a tight cooperation with physicians and surgeons we developed a web-based, standardized form for the convenient and structured documentation of the anamnesis results. During a clinical study we documented 16 consultations where the attending physician used SAP for documentation and 11 consultations with oncoflow, respectively. Afterwards, we used the Levenshtein distance measure in order to show improvements in the documentation process so that the acquired data is more structured and exhaustive [2].

1.2 Clinical Context
The clinical workflow for patients with head or neck cancer is grouped into three major phases. The tumor therapy starts with a clinical diagnostics phase to acquire important patient-specific information. This phase starts with a consultation, where a detailed anamnesis and clinical examination is performed. Morphological as well as functional medical imaging such as Computer Tomography (CT), Magnetic Resonance Imaging (MRI) or Positron Emission Tomography (PET) is also performed. Afterwards, during a panendoscopy tissue samples from potential tumor tissue are taken and sent immediately to a histopathological examination. The local tumor board then decides on the most appropriate therapy for the patient based on the previously acquired information. Subsequently, the patient goes into the therapy phase. During this phase the patient receives (neo-) adjuvant radio- or chemotherapy, a surgical intervention or a combination of them. After each therapy the patient case is discussed again in the tumor board. Based on the previous therapy results further therapies are applied or the patient

¹ The tumor board is an institution where physicians from different medical disciplines such as surgery, radiation therapy, radiology and pathology meet to discuss the patient cases and different therapy approaches.
is released into follow-up. During this last phase of the tumor treatment process the patient joins regular follow-
up consultations to identify recurring tumors as early as possible. The process is briefly depicted in Figure 1.

![Clinical workflow](image)

**Figure 1:** Clinical workflow for the treatment of patients with head and neck tumor.

### 1.3 Related Work

The improvement of clinical documentation as well as information quality in electronic Patient Records (ePR) is already addressed in various research projects. Davis et al. developed a template within the ePR that improves significantly the documentation of asthma severity and the appropriate treatment [3]. Bordowitz et al. state that physicians underdocument and undertreat obesity and implemented an ePR that automatically calculates the body mass index and supports obesity documentation [4]. The documentation quality and also the treatment of obese patients have been improved significantly. Menke et al. implemented a computerized clinical documentation system in a pediatric intensive care unit resulting in an improved completeness of documentation, better accessibility and accuracy of information and no change in time spent for patient care by clinical staff [5].

An appropriate IT infrastructure is especially important in tumor documentation to provide physicians useful information, evaluate standards of care and get an impression about the effectiveness in cancer care [6]. Furthermore, the certification as comprehensive cancer center is important with regard to legal regulations and financial means [7]. Therefore, a centralized ePR and supporting tools for tumor therapy and cancer center certification have been developed at ICCAS aiming at targeting the previously mentioned drawbacks [8]–[10].

### 2 Methods

#### 2.1 Workflow Standardization

In order to find a standardized documentation of the first consultation we conducted several interviews with all physicians and surgeons from the local ENT department that are involved in tumor treatment. During these meetings the relevant questions to the patients, the order in which they are posed and all supporting documents have been acquired. Afterwards, a consolidated document containing a standardized sequence of questions has been developed. Finally, the agreed set of questions has been implemented in oncoflow as a web-based form (see Figure 2). The form consists of free text fields for unstructured information as well as predefined checkboxes and dropdown fields for important therapy-related information such as nicotine consumption, pain or Karnofsky index.

![Structured oncoflow anamnesis documentation](image)

**Figure 2:** Structured oncoflow anamnesis documentation.

### 2.2 Background: Levenshtein Distance

The Levenshtein distance has been developed to compare the similarity between two strings [2]. Schumann et al. compared the Levenshtein distance to three other distance measures with regard to the application in quantitative workflow evaluation [11]. The authors conclude, “that the Levenshtein and Adjacency distances are best suited for measurement of distances between the activity sequences of surgical process models”. Thus, we used the Levenshtein distance in this project. This distance measure takes into account the minimal number of insert, delete or replace operations to convert one string into another one.

\[
d^L = \min \begin{cases} +0 & \text{if } equal \\ +1 & \text{replace} \\ +1 & \text{delete} \\ +1 & \text{insert} \end{cases}
\]

Given two strings \(X = "ABCD\text{EF}"\) with \(|X| = 6\) and \(Y = "ABB\text{CDM}"\) with \(|Y| = 6\). For converting String \(Y\) into String \(X\) the following procedure could be applied. At first the second \(B\) from String \(Y\) has to be removed. Afterwards the \(M\) has to be replaced with an \(E\) and finally a \(F\) has to be added to String \(Y\). The applied operations are not unique so that there may exist different ways for string transformation. The Levenshtein distance in this example equals \(d^L = 3\) and is finally calculated as the minimal number of necessary operations.

#### 2.3 Study Design

The clinical study has been performed at the department of ENT surgery at the university medical center Leipzig. A human observer attended the consultation and used the s.w.a.n workflow editor [12] for the documentation of the physicians’ questions to the patient as well as the docu-
mentation process in SAP i.s.h.med and oncoflow, respectively. The workflow analysis focused on the points depicted as captions in the web-based anamnesis form and which are also explained in detail in Table 1.

The study hypothesis is as follows:

“A structured documentation with a predefined set of questions results in a more structured and standardized clinical workflow, an ePR containing more relevant patient-specific data, hence, a higher information density.”

Existing information will also have a higher quality due to the restriction of user inputs with the help of checkboxes or dropdown fields.

Table 1: Study-relevant observation parameters depicted in ideal chronological order (“gold standard”).

<table>
<thead>
<tr>
<th>Question type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual anamnesis</td>
<td>• Reason for going to clinic</td>
</tr>
<tr>
<td></td>
<td>• What are actual problems</td>
</tr>
<tr>
<td>ENT anamnesis</td>
<td>• ENT specific questions</td>
</tr>
<tr>
<td>Common anamnesis</td>
<td>• Information apart from ENT, e.g. herpes, cramps</td>
</tr>
<tr>
<td>Interventions</td>
<td>• All former interventions</td>
</tr>
<tr>
<td>Allergies</td>
<td>• Information about allergies</td>
</tr>
<tr>
<td>Drugs</td>
<td>• Which drugs the patient uses regularly</td>
</tr>
<tr>
<td>Profession</td>
<td>• Profession of the patient</td>
</tr>
<tr>
<td></td>
<td>• Interesting in the case of potential tumor risk factors</td>
</tr>
<tr>
<td>Family anamnesis</td>
<td>• Diseases from family members, especially tumor diseases</td>
</tr>
<tr>
<td>Nicotine</td>
<td>• Nicotine consumption</td>
</tr>
<tr>
<td>Alcohol</td>
<td>• Alcohol consumption</td>
</tr>
</tbody>
</table>

2.4 Implementation and Postprocessing

The evaluation has been performed with a text-based Java application and a study file format especially developed for this project. The input file consists of a gold standard describing the ideal order of questions in the first line and the patient-specific observations in the following lines. The ideal order of questions equals the order used in Table 1 with a total number of 10 observations. The Java program processes two separate input files containing SAP and oncoflow results and calculates the Levenshtein distance for each patient-specific observation with respect to the gold standard. The program also performs a statistical evaluation of the results. It calculates mean and median values, variance, and standard deviation. Afterwards, a Mann-Whitney U test is performed in order to show the statistical significance of the results.

3 Results

The clinical study encompasses 16 anamneses documented within the SAP i.s.h.med free text field as control group as well as 11 anamneses documented with the structured oncoflow form as study group. In Table 2 the number of documented information entities, the Levenshtein distance for each anamnesis compared to the ideal sequence of questions, the mean value and the standard deviation are depicted. The Levenshtein distance of SAP i.s.h.med will be denoted as \( d_{\text{sap}} \) and for oncoflow it will be referred to as \( d_{\text{of}} \).

Table 2: Levenshtein distances comparing gold standard with anamneses from SAP and oncoflow.

<table>
<thead>
<tr>
<th>Anamnesis</th>
<th>( d_{\text{sap}} )</th>
<th>( d_{\text{of}} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>5</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>6</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>7</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>9</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>10</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>11</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>12</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>13</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>14</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>15</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>16</td>
<td>9</td>
<td>7</td>
</tr>
</tbody>
</table>

Mann-Whitney-U tests have been applied to the number of documented information (\( p = 0.0023 \)) and the Levenshtein distances (\( p = 0.0001 \)) which means that the populations show significant differences.

However, the Levenshtein distance without additional knowledge provides no information about the real differences between the gold standard and the actually documented amount of information in the current observation set. Hence, the number of documented data entities has to be considered in the evaluation.

The results for the documentation in SAP show a mean Levenshtein distance with \( \mu = 6.50 \), thus, a significant difference to the ideal documentation workflow. Considering the mean number of documented data entities (\( \mu = 7.44 \)) less information as defined in the optimal workflow has been documented.

The oncoflow results show significant workflow improvements. The usage of the web-based anamnesis form results in a reduction of the mean Levenshtein distance by 4.59 to \( \mu = 1.91 \). The mean number of documented information entities increased to \( \mu = 10.18 \) which shows that basically all questions, which are important for the treatment process, are asked by the physician.
In Figure 3 the recorded information and Levenshtein distances are depicted in a boxplot representation.

Figure 3: Boxplot representation of left: # of data elements; right: Levenshtein distances.

The boxplots show that the number of datasets increased through the usage of oncoflow, but also that the standard deviation strongly decreased. One can also see that the Levenshtein distance shows a high decrease in oncoflow, but the standard deviation is equally high as in SAP.

4 Conclusion

In this paper we presented a study about the value of a web-based clinical documentation system for the first consultation in oncological patient care. Within a clinical study the system has been used in daily routine at a clinical site. Afterwards the Levenshtein distance has been used to evaluate if the documentation of results has been improved compared to the usage of SAP i.s.h.med.

We standardized the complete anamnesis workflow and found out that the physicians follow the standardized set of questions; hence, more patient-specific information is recorded within the new system. The number of documented information entities could be increased from 7.5 questions with SAP to 10 questions in oncoflow. This is an improvement of 25%.

Standardized and transparent workflows are important for the certification as cancer center, outcome documentation and quality management, and finally for evidence based medicine. Due to the usage of a structured documentation form physicians perform an anamnesis whose structure could be improved by 71%.

A further clinical study investigated the time differences caused by the usage of a structured reporting template in contrast to a free-form text field [1]. This study shows that there are no significant differences between these two workflows. Thus, the improvements in information quality shown in this paper do not cause unfavorable additional timely costs for clinical personnel.

Due to the promising results future work will focus on the establishment of systematic and patient-oriented tumor documentation. Follow-up results are especially important for the evaluation of previous tumor therapies. Thus, standardizations in this area seem to be very fruitful.

5 References

Creating gesture controlled games for robot-assisted stroke rehabilitation

A. Basteris\textsuperscript{3}, E. Johansson\textsuperscript{1}, P. Klein\textsuperscript{1}, N. Nasr\textsuperscript{2}, S. Nijenhuis\textsuperscript{2}, P. Sale\textsuperscript{6}, F. Schätzlein\textsuperscript{1}, A. Stienen\textsuperscript{4},

\textsuperscript{1}User Interface Design GmbH, Ludwigsburg, Germany, peter.klein@uid.com
\textsuperscript{2}Roessingh Research and Development, Enschede, the Netherlands
\textsuperscript{3}University of Hertfordshire, Hatfield, UK
\textsuperscript{4}University of Twente, Enschede, the Netherlands
\textsuperscript{5}University of Sheffield, Sheffield, UK
\textsuperscript{6}IRCCS San Raffaele, Rome, Italy


Abstract

Regular training exercises are fundamental to regain functional use of arm and hand control after a stroke. With the SCRIPT system, the patient can practice hand exercising independently at home by playing gesture controlled games using a robotic glove (orthosis). The system could offer prolonged rehabilitation out of the clinic, with low cost treatment. In the first version of the system (Script 1), a set of therapeutic games were developed within the project and tested in formative and summative evaluations. The main findings indicate that motivational aspects play a major role. The main issues detected concern the challenge for the patients to understand and remember the correct gestures. Following a User Centered Design process, these findings helped to improve the new version of the system (Script 2).

1 Introduction

The SCRIPT (Supervised Care and Rehabilitation Involving Personal Tele-robotics) project aims to create a rehabilitation device to be used by stroke patients in their homes for training wrist and hand movements. One goal of the project is to make training more motivating and therefore more effective/efficient. For this purpose, gesture controlled games are used for training, including an orthosis to support and measure the movements.

1.1 Background

Many patients after stroke have impaired arm and hand function, which limits them in performing activities of daily living independently. Intensive and active training is important to regain functional use of the arm and hand after a stroke. Due to high costs and limited availability of health care professionals, intensity and/or dosage of rehabilitation is often limited. Hence, any technical device that can prolong neurorehabilitation out of the clinic, with low cost treatment, plays an important role in the health management systems [1]. One of such applications is rehabilitation robotics, since it can provide more independent, repetitive, task-specific, interactive treatment of the arm with high treatment intensity [2-4]. In order to increase the treatment dosage even more, such a treatment is preferably applied in the home situation, via remote monitoring and supervision [5].

1.2 User Centered Design Process

When following a User Centered Design (UCD) process as described in ISO 9241-210, the needs of the user are in focus, as well as the whole context in which the product will be used. To gather reliable information, it is advised to include users in the development process. The process consists of iterations of four phases: (1) analyzing the context of use, (2) defining the requirements, (3) concept and creation and (4) evaluation. This feedback will help to improve the system iteratively. The UCD process applied to the Script project is described in chapter 2.4.

1.3 About SCRIPT

The SCRIPT system consists of a user interface (UI) on a touch screen, a set of games for training and an orthosis which supports the patient’s movements. The patient’s system is remotely connected to a therapist application for supervision. Defined user groups of the Script system are chronic stroke patients with affected hand or arm movements, as well as treating therapists. This paper focuses on the patient user group.

In the project, two versions of prototypes are created and tested: SCRIPT1 includes a passive orthosis [6], while SCRIPT2 works with an active orthosis. This paper mainly describes evaluation of SCRIPT1 and subsequent improvements realized for SCRIPT2.

2 Methods

2.1 SCRIPT orthosis

The SCRIPT Passive Orthosis (SPO) is a wrist, hand and finger orthosis that assists individuals after stroke, suffering from impairments caused by spasticity and abnormal synergies. The SPO offsets these undesired torques with passive springs that pull the joints towards extension. The user carries out voluntary muscle activation to perform movements and thus stays actively involved. The SPO is
equipped with sensors to measure the joint rotations and applied forces at the joints, which are used to interact with a gaming environment. It also provides information on the user's forearm posture and movements.

2.2 Games
As a part of the SCRIPT project, a set of games for stroke rehabilitation is developed. Three games have been delivered in year one of the project, six in year two and again four will be delivered in year three. Feedback on the first set of games was used to improve the concepts of the next set. When creating a game concept several aspects are considered, along with the game idea and the scenario: (1) the goal of the game, (2) which gestures to include from a therapeutical point of view, (3) how many levels are needed and how they differ and (4) how the difficulty is to adapt within one level.

2.3 Patient UI
In therapy, suitable games are assigned to the patient by the therapist. There is a game description in the patient UI (game details screen) to explain the game and to help the patient to decide which game to play. Movement performance is likely to change dramatically between sessions, due to subject’s both inter- and intra-individual variability. Shorter, smaller movements can be expected from more severely impaired subjects and the way that one person performs a movement can change due to motor (re)learning. Hence, a calibration phase (calibration screen) was inserted for each of the gestures performed within a game. The subject is asked to perform a few repetitions of the desired movement(s), for a maximum of 30 seconds. Movement duration and amplitude are measured, which provides a way to evaluate subjects’ improvement. The calibration procedure also allows fitting the game to the individual skills and needs. The parameters for gesture recognition and game speed are adjusted based on the calibration outcome, so that objects appear on the screen at a position, distance and velocity which makes successful performance neither impossible nor too easy.

2.4 UCD in SCRIPT
SCRIPT project follows a UCD process and several studies have been conducted for evaluation of the system, so far mainly for SCRIPT1. The feedback on the UI and the games has been used to improve the SCRIPT2 system.

2.4.1 Formative Evaluation
A set of formative evaluation activities were carried out in order to gather feedback for improvements on the Script1 system. Participatory formative evaluation methods were used, such as cognitive walkthrough and cooperative evaluation [7]. Evaluations were carried out across three clinical sites. Feedback was collected from members of the steering group committees including patients, carers and stroke professionals. In addition, usability issues were identified during evaluations in participants’ homes. Six households were visited, where participants and their carers were asked to try out the system by performing a series of tasks while also encouraged to think aloud.

2.4.2 Summative Evaluation
Twenty-one subjects (10 males, 11 females) were included in the clinical study. Mean age was 59 years, mean time post stroke was 19 months. The chronic stroke patients used the SCRIPT1 system for training at home, for six weeks. All subjects trained independently, and were remotely supervised, offline, by a healthcare professional. The feasibility of the SCRIPT1 system (including the games, motivational UI and orthosis) was assessed, to investigate validity and usefulness of the system. Evaluation of feasibility involved compliance in terms of actual use (training duration in minutes), usability measured by the System Usability Scale (SUS) [8], and user acceptance of the total SCRIPT1 system by a semi-structured interview.

2.4.3 Usability Test (SCRIPT2)
Results of formative and summative evaluation of SCRIPT1 were used to improve the next version of the system, SCRIPT2. Before the next clinical study, a usability test was planned and conducted to prove updated concepts. The patient UI for SCRIPT2 was evaluated in a usability test (UT) with three patients. The participants were all male and the time of the stroke was between eight and 22 months ago. The tests focused on the UI, and the device of the orthosis as well as the control of the games was not included in the test set-up. The UI was presented on a 21.5” touch screen.

First half of the test sessions was spent to find out basal needs of the patients when interacting with the system, by using the Valence method [9]. Patients were allowed to interact freely with the UI and were instructed to set positive and negative markers whenever they liked or disliked something they were experiencing. The markers were then reviewed and discussed together with the patient. Afterwards, the patients performed specific tasks like running the calibration process. Before the closing interview the games were shown to the patient, and the gestures used to control the games were explained.

3 Results

3.1 Evaluation Results
During evaluation, feedback was given concerning the games and parts of the UI which were directly associated with the games (e.g. the calibration screens and game details screen). The results implied the following conclusions:

Games
- Patients had problems to understand and remember what gestures to perform in some situations.
- It is important to clearly indicate when a gesture is successfully performed and scores are earned.
• The orientation of grasps must relate to the orientation of the corresponding objects, e.g. if a banana is shown horizontally the grasp has to be performed horizontally.
• Clear feedback in the games is a must, e.g. visual or acoustical hints to indicate when an object is selectable, or was successfully handled. This is also a matter of motivation.
• It has to be directly visible how to pause or end a game. Touching the screen to pause or stop the game was not clear enough.
• One of the games was perceived as monotonous, because of too little variation. On the other hand, games must not require gestures that are too difficult to perform.

Patient UI
• The gestures presented on the game details screen were not clear to the patients, e.g. the combined gesture visualization for flexion and extension of the wrist.

Calibration
• The calibration process was experienced as too long and it was not clear when to start performing a certain gesture. Some patients did not understand the word “calibration”.

Technical issues
• Patients were annoyed by poor controls of the movements in some of the games, e.g. when the game did not react on patients’ movements.

Main positive feedback about games as assessed by the semi-structured interview of the summative evaluation:
• The scoring element. Most patients liked to improve their previous earned scores, which motivated them to practice more and more.
• The variation in difficulty, like the automatic speed correction of the obstacles.
• The variation in activities available in one of the games, with different and more arm/hand movements in higher categories available. This keeps the game challenging and motivating.

During the summative evaluation, the average training duration was concluded to 105 (± 66) minutes per week, which comes down to about 15 minutes of self-administered practice at home per day. However, the individual training duration per subject varied considerably, ranging from 13 up to 284 minutes per week.

The group average SUS score was 69%, indicating that usability of the SCRIPT1 system is promising with a good chance of acceptance in the field. Individually, three subjects scored ‘usability difficulties in the field’ (SUS <50%), whereas ten subjects scored the SCRIPT1 system as promising or high acceptability (SUS >70%) [10].

3.1.1 Usability Test results (SCRIPT2)

Above all, patients want to feel competent while using SCRIPT. In this context especially the following needs were identified: to complete tasks independently, get along unaided and be in control. Patients wished for physical activity as well as learning and trying new things (need: curiosity) and having fun. More positive than negative mark-

ers were set, which indicates that the patients’ needs are mainly fulfilled. In the tasks part of the test, patients had difficulties conducting the calibration process: Patients performed the correct gestures, but did not know when exactly they had to perform the gesture. In the screens showed, the corresponding game actions were described in the calibration screen, but test results showed that this still is not enough to remember the gestures. Confronted with the games, two of the patients mentioned a wish for games that also challenge the brain.

3.2 Implications on the games

Analyzing the results of the evaluations, the following aspects are taken into consideration when developing new games for SCRIPT:
• Show images of the requested gestures as hints in the games. With this solution, the patient does not have to remember the correct gesture and can concentrate on performing the movement (see image 1).
• Gestures of the patient must be recognized reliably by the system. Any technical issues or bugs leads to frustration and must be avoided.
• Carefully prove that objects in the game correlate with the real grasping gestures, e.g. grasping a stick with a cylindrical grasp. Orientation of the object needs to correspond with the orientation of the gesture.
• To support motivation, always display the scores and motivational messages at the same place consistently throughout all games.
• Include a visible Pause button in all games.
• Give clear visual and/or acoustic feedback when an object is selected or when an action was performed correctly.
• In the next generation of the orthosis, the interface to the fingers will be improved to apply pure torques and to get a higher measurement accuracy. This should further improve the control the users have during the games.

3.3 Improvements on patient UI

3.3.1 Game details screen

The issue for the patient to remember what gestures to use in a game, also affects the game details screens. The de-
scription of the game and its gestures are now displayed more clearly, the game icon has been replaced with a screenshot from the game and gesture visualization has been simplified, e.g. by splitting wrist flexion/extension into two separate gestures, when used separately for different activities in the game (see image 2 and 3).

Based on the results on the evaluations and the usability test, improvements have been carried out for Script2 regarding the UI, the orthosis and the existing games, and in addition six new games have been developed. The whole system will again be tested by patients at home in a second summative evaluation, using an active orthosis this time. A new set of games will be developed for Script in year three of the project. During the concept phase and development, the evaluation feedback received so far will again be considered. Aspects of learning and motivation will be taken into account, as well as the request to include more challenges for the brain, in addition to the training of hand and arm movements.

5 References

Determining Reaction Times Using Touch Screen Devices – A Comparison of Various Methods

U von Jan¹, J Teske², UV Albrecht¹
¹Peter L. Reichertz Institute for Medical Informatics, University of Braunschweig - Institute of Technology and Hannover Medical School, Hannover, Germany
²Institute of Legal Medicine, Hannover Medical School, Hannover, Germany

Abstract

The use of mobile devices is becoming increasingly popular and this does not stop at tasks previously thought difficult to implement for a professional mobile setting, such as performing reliable reaction time based test that are often included in psychophysical test suites. For stationary (PC-based) settings, various implementations of such test suites exist. When using mobile smart devices for such purposes, special care must be taken to standardize evaluation of reaction times as the way users handle such devices can differ greatly, for example depending on user’s familiarity with mobile devices or personal preferences while handling them. Values obtained for reaction tests with mobile may also be influenced by the setting where testing takes place. Nevertheless, standardization is an important aspect to allow for conclusive values. This paper compares five different methods for obtaining reaction times using the touch screen of mobile devices that where evaluated in order to determine the best method to use for inclusion in a mobile test suite we are currently implementing with the intent to be able to provide objective parameters in settings where good reaction times are essential.

1 Introduction

Although many traffic accidents simply due to carelessness of those involved, many are of them caused by drivers who are under the influence of drugs or alcoholic beverages. Preventive measures include roadside tests administered by the police during general traffic controls. While misuse of alcohol can be assessed with relative ease, e.g. by using a breathalyzer, the same does not hold true for other drugs [1]: drug wipes, saliva or urine tests are not always to identify these substances (e.g., in case of a synthetic cannabinoid). Nevertheless, even if the substance itself cannot be measured, its influence on the person who is to be assessed is what is really important at the roadside: if a police officer has the impression that someone is not fit to drive, he will initiate the appropriate procedures for performing laboratory tests. However, such an “impression” is quite subjective. To be able to somehow “quantify” this, police in many countries use methods derived from the field impairment tests (FIT) used in the UK [2] or the standardized field sobriety tests (SFT) that was developed and evaluated in the US [3]. For example, these tests include a Walk-and-Turn test or the One-Leg Stand test. The current way used for conducting such tests often still leads to subjective results and may also not be applicable for all suspects (e.g., if someone has orthopedic problems). For a more reliable quantification, using apporative methods for administering appropriate tests, e.g. found in psychophysical test suites may be a solution, but these are usually found in a laboratory setting and often, they also suffer from complexity and other factors preventing them from being used for roadside testing.

On the other hand, nowadays, mobile devices are readily available and include many features (touch screens, accelerometers etc.) that support the idea of using them for roadside testing. We therefore decided to build a mobile test battery [1] that includes a number of psychophysical tests (e.g., sustained attention, go-no go, distractibility) as they are also found in established test suites [4] and implemented it for Android based devices.

While implementing and testing the preliminary version of the test suite with volunteers at our lab, it was noted that reaction times obtained asking the test subjects to react to the presented stimuli via simple touch events differed greatly between individuals and even for the same individuals. This variability to stem from differences in how individuals handled the mobile test devices and a number of factors seemed to have an influence. Differences could especially be noted with respect to how the devices were held (hand-held or laid down on a stable surface, e.g. a table) and how users chose to react to the stimuli they were presented with. While some barely lifted their fingers between different touch events, others chose to hover above the screen at a greater distance or even varied their approach while taking the tests, leading to highly variable (and sometimes unexpected) results. Altogether, these differences necessitate a closer look at standardizing the setting for mobile reaction tests as similar problems can also be expected in a roadside setting for the next stage of our app, i.e. field testing.

2 Methods

Five different methods were implemented in a mobile app and used for assessment. Testing was performed on an Android based device, specifically an 8 inch tablet (Samsung Galaxy Tab 3 8.0 3G, Android 4.2.2) as this conforms to the class of device that will be used when deploying the aforementioned test suite later on. All
methods were evaluated by 3 users (ages: 31-42) who were presented with 30 visual stimuli (white square on black screen, always shown in the same location) in random intervals of 1-3 seconds for a duration of 1 second each, amounting to a maximum of 2 minutes per test. The random interval was chosen in order to prevent habituation effects by simply “tapping a steady rhythm”. Prior to each test, the volunteers were allowed to practice each method using a test round that was not included in the results. Each participant was asked to perform each of the tests three times with a break of one minute in between. The participants were asked to place the device on a table and to sit in a relaxed manner in front of this table, i.e. with their lower arm comfortably resting on the table with device within reach of their fingers.

The five methods for evaluation differed in the way the test subjects were told to react to these stimuli (Figure 1):

1. First, they were asked to react to each stimulus by touching the screen in the way they felt most comfortable, similar to what many recreational reaction test available on the app stores of mobile platforms require. They were allowed to hold the device or put it down on a table and were not given any specific instructions on how to perform the test. The app took note of the differences in time between the presentation of each stimulus and the initial touch event.

2. For the second test, users were instructed to put the device on a stable surface (table) and to place the index finger of their dominant hand on the screen. This time, lifting the finger was the expected reaction to the visual stimulus. The next visual stimulus was presented at a random interval (as for all other tests, after 1-3 seconds) after the finger had been placed back on the touchscreen of the device. For each round, the app took note of the timespan between appearance of the stimulus and the time the finger was lifted from the screen.

3. The third test again required the participants to react to the visual stimuli but this time, the app made use of multi-touch events: one finger of the dominant hand (e.g., the middle finger) had to be kept on the screen throughout the test and a second finger (e.g., the index finger) of the same hand had to be used for touching the screen as soon as the visual stimulus became visible (similar to the first test). Again, the app took note of the differences between the presentation time of the stimulus and initial touch event.

4. The fourth test also made use of multitouch events. Again, one finger (middle finger) had to be kept on the screen throughout the test. For starting each round, the second finger (index finger) had to be placed on the screen as well. Similar to method two, the expected reaction was lifting this second finger and the timespan between appearance of the stimulus and the time the finger was lifted was recorded. The next round only started once after the second finger had been placed back on the screen.

5. The fifth method we tested was an extension of method 4: similar to before, one finger had to be kept on the screen throughout the test. Again, at the beginning, the second finger had to be placed on the screen as well, but this time, the expected reaction was to lift that finger and to put it back down on the screen as quickly as possible. For each round, the app recorded the timespan between presentation of the stimulus and the initial finger lift (5.1) and also the timespan between the presentation of the stimulus and the final touch down event (5.2).

For all five tests methods, it was noted whether there were any misses (no reaction to the visual stimulus).

Fig. 1: Presentation of visual cue and expected reaction for each of the 5 methods.

3 Results

For each participant and test, median values and interquartile ranges were calculated for evaluation of the obtained test results. There were no misses.
Tab. 1. Median values for tests 1-5, three test runs (3 runs, altogether 90 stimuli, no misses). For test 5, finger lift (5.1) and touch down (5.1) events are noted.

<table>
<thead>
<tr>
<th>Test</th>
<th>Participant 1</th>
<th>Participant 2</th>
<th>Participant 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>328.5 ms</td>
<td>355 ms</td>
<td>373.5 ms</td>
</tr>
<tr>
<td>2</td>
<td>332 ms</td>
<td>346.5 ms</td>
<td>295 ms</td>
</tr>
<tr>
<td>3</td>
<td>331.5 ms</td>
<td>369.5 ms</td>
<td>367.5 ms</td>
</tr>
<tr>
<td>4</td>
<td>318 ms</td>
<td>347 ms</td>
<td>318 ms</td>
</tr>
<tr>
<td>5.1</td>
<td>327 ms</td>
<td>367 ms</td>
<td>317.5 ms</td>
</tr>
<tr>
<td>5.2</td>
<td>408.5 ms</td>
<td>479 ms</td>
<td>417.5 ms</td>
</tr>
</tbody>
</table>

As can be seen in Tables 1 and 2, an evaluation of the median values (Table 1 and Figure 2) and IQR ranges (Table 2 and Figure 4) for the three participants gave hints for test 4 (placing two fingers on the screen at the beginning, then lifting the index finger once the visual stimulus is being shown) being the most reliable test with the smallest variability between participants.

4 Conclusion

While the median reaction times appear somewhat stable between all five tests (with the exception the 2nd event recorded for test 5), the same does not hold true for the interquartile ranges: Surprisingly, results for the initial finger lift event (5.1) for test number 5 have a much higher variability between the participants, although one might have expected results in a comparable range to tests 4 since both test evaluate finger lift events. The same holds true for test 2, where the finger lift event is also recorded, although in contrast to test 4, this test only makes use of only a single finger.

The perceived differences in variability between all five test methods may be due to a number of factors. For test method 1, which is widely used in many reaction tests of the recreational type that are available on the app stores of various mobile platforms, variability may be introduced since there is no standardized position – and thus, also no standard distance, even for a single person – from which users start to move the hand and finger they use for touching the screen.

In contrast, test method 2 certainly uses a defined start location, i.e. the touch screen itself as the user is expected to simply lift the from the screen to react to the stimulus. The relatively high variability that was noted for two of the participants may be explained by inadvertently tensing the muscles of the hand when solely lifting the index finger as required: in order to prevent inadvertent touch events by other fingers of the same hand, the middle-, ring- and little fingers were often curled up to keep them out of the way.

The use of two fingers, as required by methods 3 to 5, is meant to provide users with a relative fix point: by keeping one finger, i.e. the middle finger on the screen throughout the test, the hand remains in a stable position. The variability still noted for test 3 may again be explained by differences in the distance from which the index finger moves down, although these can be expected to be smaller than for method 1, this may still have an influence and again, while performing the tests, inadvertent tensing of the muscles was also noted by the participants and may contribute to the variability for this method.

On the other hand, by requiring users to keep two fingers on the touch screen and to lift the index finger to react to each stimulus, the hand is kept relatively relaxed when using test method 4. Also, users are not required to place the finger back on the screen as quickly as required for method 5, but rather, they are allowed to do so at their own pace. In contrast to method 5, this may prevent unnecessarily tensing the muscles which may explain the differences between methods 4 and 5.
A limitation of our preliminary test setup is certainly the small number of participants and further testing needs to need to be performed for confirmation; before carefully planning a larger scale evaluation of the 5 test methods with an adequate number of users of different age cohorts (as it can be expected that reaction times will be longer for older test subjects [5]), for the initial testing described here, we were mostly interested in two aspects, ie. wether the chosen test methods are a) usable and b) wether there are hint to differences in variability between test methods for users who are rougly in the same age range. Once the test methods presented here have a more undergone careful evaluation (including usability testing), the method having obtained the lowest variability and highest usability scores will be integrated in our mobile psycho-physical test suite as mentioned in the beginning.

5 Acknowledgement

Special thanks go to the “Bund gegen Alkohol und Drogen im Straßenverkehr” (B.A.D.S) for giving support.

6 References

Electro-Optical Cardiovascular Diagnostic Assistant in Portable Pocket-Sized Format for Ubiquitous Applications

Y. Zhao, M. Mend, T. Bischof, B. Kessler, W.H. Kullmann
Institute of Medical Engineering Schweinfurt (IMES), University of Applied Sciences Wuerzburg-Schweinfurt, Schweinfurt, Germany
Ying.Zhao@fhws.de

Introduction

First cardiovascular diagnosis of patients in case of telemedical applications at patients’ home, in medical nursing centres or in case of outdoor emergency situations requires a mobile diagnostic system of small size, simple handling, and high usability.

Methods

The portable electro-optical cardiovascular sensor system of pocket-sized format enables the data acquisition of a twelve-channel electrocardiogram and the photoplethysmographic detection of the finger pulse wave in the red and infrared spectral region. The data acquisition of the electrocardiogram and the pulse wave detection is electronically synchronized by a microcontroller. The sampling rate of all detector modalities is 1000 samples/s. After analog-digital conversion with 12 bit resolution the detected signals are transmitted to a data evaluation laptop via the USB transmission protocol. The diagnostic interpretation of the detected vital data is carried out with a multimodal self-explaining diagnostic software on the data evaluation computer.

Results

On basis of the detection of only few ECG channels and the simultaneous acquisition of the photoplethysmographic finger pulse wave the system permits a first overview and diagnostic assistance of heart function, a hint at the occurrence of a heart infarction, information on heart rate variability, a view into the the autonomous nervous system, blood oxygen saturation, and arterial pulse wave analysis (pulse contour, pulse transit time, pulse wave velocity).

Conclusion

The mobile electro-optical cardiovascular diagnostic assistant system in pocket-sized format enables a quick overview over the cardiac and vascular state of a patient. The system of high usability is well adapted for providing a first diagnostic view on the cardiovascular system outside of clinical environment or the physician’s practice.
Development of a Telemonitoring System for Improved COPD Care

M. Kaiser1, B. Schwarz2, L. Mursina2, 3, V. Gross2, H. Schneider2, 3, K. Sohrabi2, 3

1Technische Hochschule Mittelhessen – University of Applied Sciences, Giessen, Germany, markus.kaiser@mni.thm.de
2Technische Hochschule Mittelhessen – University of Applied Sciences, Giessen, Germany
3Competence Centre for Information Technology, Giessen, Germany

Abstract

Telemonitoring solutions are increasingly relied on for the care of chronically ill patients, due to their ability to provide substantial quality of life improvements for the patients as well as cost reduction on the side of healthcare systems. While chronic diseases of the respiratory system, particularly COPD, are considered a strong indication for the adoption of telemonitoring, a system that combines the early recognition of critical degradation and therapeutical support within the patient’s home is not currently available. A solution is presented here that combines medical devices and smartphones via a communication infrastructure to provide a secure telemonitoring service for COPD patients.

1 Introduction

Telemonitoring describes the regular acquisition and transmission of vital signs as well as device data. The datasets are then used to monitor the health of chronically ill patients within their domestic environment. Professionals see chronic diseases of the respiratory system, especially chronic obstructive pulmonary disease (COPD), as an important indication for the use of innovative telemonitoring solutions [1]. Chronic respiratory diseases carry a risk of a sudden aggravation of the patient’s health, up to life threatening conditions. Telemonitoring allows to detect such events at an early stage, enabling the initiation of countermeasures. While individually set indicators could possibly deliver warnings ahead of time, the tools necessary to implement such a solution are not currently available.

In addition to the patient-centered benefits of telemonitoring applications, there are considerable advantages over conventional approaches for the healthcare providers in utilizing the significant cost-saving potential [2].

2 Methods

The telemonitoring system presented here offers a web-based platform for the control and evaluation of data collected from different medical devices such as a pulse oximeter and an integrated COPD screening device containing sensors for PTT, respiratory frequency and wheezing along with other relevant parameters.

The systems screening capabilities are accompanied by a video feedback system supporting rehabilitation exercises performed by the patients.

The proposed architecture relies heavily on established technology standards for connection encryption, mobile device and interface integration to allow building a stable and secure system that is open to change and easy to maintain.

3 Results

The current development release contains an Android [3] app incorporating the medical devices and sensors via the Bluetooth Medical Device Profile[4]. Additionally, the app provides communication from the patient to the control center based on the secure encrypted web communication protocol HTTPS (Hypertext Transfer Protocol Secure).

The monitoring and control center is implemented in C#.NET [5] and contains a communication server based on ASP.NET MVC 4 web technologies [6] for unified patient-side communication. The control center contains additional standardized external interfaces like HL7 (Health Level Seven) [7] and provides datastore capabilities for all incoming data using Microsoft SQL server [8].

Image 1 shows the basic architecture layout for the system. Vital parameter data is read from connected bluetooth-capable devices and collected by the smartphone app, which is responsible for the initiation of a secure connection to the control center server. To enhance the data security, no identifiable patient related data is included in this transmission.

The data can be either viewed directly in the control center web application or relayed to other systems running in the background, such as electronic health records located at affiliated hospitals or medical practices. It is possible to set up an emergency messaging system that alerts emergency units and technicians with standard short messages (SMS) if certain related events, such as a sudden degradation of a patient’s condition, are detected.

The video feedback system on one side provides a direct feedback for the patient about vital parameters and therapeutical accomplishments. On the other side, the system provides attending physicians with information about the patient’s status and performance in therapy.
5 Acknowledgement

We thank the Hessian Ministry for Science and Art for financial assistance under the state program LOEWE (Landes-Offensive zur Entwicklung Wissenschaftlich-ökonomischer Exzellenz).

6 References


4 Conclusion

The system introduced in this paper combines proven technology to allow highly location-independent care, especially for patients suffering from COPD. It combines the monitoring of COPD-specific vital parameters and rehabilitation measures for maximum efficiency in a secure environment. With COPD currently being the 4th leading cause of death [9], ongoing demographic changes [10] suggest that with an ageing society, the incidence of chronic deseases will continue to rise. It is therefore imperative to devise solutions that assure the adequate care of chronically ill patients, while still controlling the emerging costs. Technical solutions like the one presented here contribute to the first step. They still need to be proven in the field and will have to be integrated into organizational structures and healthcare systems that explicitly support such solutions.

Image 1 Telemonitoring System Architecture Overview
Secure Mobile Communication Systems for Telemedical Stroke Care – From Theory to Practice

René Hempel, Institut f. Automation u. Kommunikation e.V., Werner-Heisenberg-Str. 1, 39106 Magdeburg, Germany, rene.hempel@ifak.eu
Franziska Wolf, Institut f. Automation u. Kommunikation e.V., Werner-Heisenberg-Str. 1, 39106 Magdeburg, Germany, franziska.wolf@ifak.eu

Introduction

Stroke is the third leading cause of death, and largely responsible for permanent disability and dependency [1]. In 81% of strokes immediate medical intervention could offer a better success of treatment [2]. Because of a therapeutic time window of only about 3 hours, this therapy achieves only 2% of all stroke patients. An acceleration of the procedures in cases of emergency could increase this rate significantly. Therefore the goal of the ASTER project [3] was to develop a telemedical platform for ambulance vehicles to optimize the emergency care focussed on stroke emergencies. The platform provides a link from mobile emergency medical services to hospitals and transport telematics using secure and distributed communication [4]. An regular ambulance vehicle was equipped with different modules of telematics as a prototype for demonstrations and tests. The design of the telemedical platform allows to be extended for other emergencies such as heart attack and highly integrates into the workflows of other entities such as emergency departments, emergency management and logistics.

From Prototype to Product

At the end of the project, the prototypic ambulance vehicle (see figure 1 and 2) allowed for eletronical handling of patient data, teleconsultation services, secure communication with all connected devices and stakeholders as well as advanced navigation with automatic traffic light control [5], [6]. The presentation will give an insight into the process of transforming the telemedical prototype into a (medical) product making it usable for many kinds of emergency services such as rescue service, police, fire service and even civil protection. As a conclusion from the ASTER project especially the obstacles and challenges to optimize the whole development process for production.

Acknowledgement

The authors would like to express their acknowledgement to the German Federal Ministry for Education and Research (BMBF) for granting the national ASTER (code 03WKP20F). The results of which contributed to this paper.

References

[1] Heuschmann, P. U. et al. (2010): Schlaganfallhäufigkeit und Versorgung von Schlaganfallpatienten in Deutschland (Frequency and Care of Stroke in Germany), Akt Neurol 2010, Thieme Verlag, Stuttgart, Germany


A multisine signal generator based on FPGA for broadband bioimpedance spectroscopy

Yuxiang Yang¹, Fu Zhang¹, Lianhuan Wang¹, Xiufang Yang¹, He Wen², Zhaosheng Teng²
¹Department of Precision Instrumentation Engineering, Xi’an University of Technology, Xi’an, China, yyyflyinger@gmail.com
²Department of Instrumentation Science and Technology, Hunan University, Changsha, China

Abstract

Multisine with low crest factor (CF) is desirable for multifrequency simultaneous measurement of bioimpedance spectroscopy. In this paper, the Van der Ouderaa’s multisine with a CF of 1.405 is adopted, and the approach to generate the multisine based on a field-programmable gate array (FPGA), a digital to analog converter (DAC) and a passive seven-order Butterworth low-pass filer is described.

1 Introduction

Bioimpedance spectroscopy (BIS), which performs measurement of bioimpedance over a certain frequency range [1], has recently been widely adopted in medical diagnoses. Traditionally, the frequency-sweep (FS) approach is the most adopted BIS measurement technique for its simplicity, but it can not grasp the instantaneous impedance spectra and may lost important diagnostic information [2]. In recent years, the multifrequency simultaneous (MFS) measurement technique has been becoming popular, in which the time to perform a complete BIS is drastically reduced [3].

Broadband excitation is crucial for the MFS approach. Previous researches have typically employed either aperiodic excitations such as sinc and chirp pulses [4], or periodic excitations such as maximum length binary sequences (MLBS) [5], multifrequency mixed (MFM) signal [6], and multisines [3]. An intuitive comparison among the four types of signals is illustrated in Figure 1.

In Figure 1, the chirp, MLBS and MFM signal all contain a great number of undesired harmonic components, which may degrade the measurement precision [7]. Multisine, however, has clean (no undesired) spectrum and the flexibility to create arbitrary harmonic components [8], and is regarded as the best suited broadband excitation [9].

2 Method

2.1 Multisine generator

The multisine as shown in Figure 1 (at the bottom) was proposed by Van der Ouderaa et al. [10, 11], which has 31 equidistant and flat amplitude spectrum and a near optimum CF of 1.405. The multisine is realized based on a field-programmable gate array (FPGA) EP1CT100C8 (Altera Corporation, San Jose, CA) and a 12-bit digital to analog converter (DAC) and a passive seven-order Butterworth low-pass filer.

2.2 Low-pass Filter

In order to suppress the high frequency noises produced by the FPGA and DAC, a passive seven-order Butterworth low-pass filer (LPF) is designed, as shown in Figure 2. In Figure 2, the LPF, which is made up of 4 capacitors, 3 inductance and 2 resistors with elaborately selected parameter values, has a cutoff frequency of 5 MHz and an input and output impedance of 100 Ω. The amplitude-frequency characteristic of the LPF is shown in Figure 3, which has a...
flat gain in passband (0~5 MHz) and sharp attenuation in the stopband (higher than 5 MHz).

Figure 2: Structure of the seven-order Butterworth low-pass filter (LPF)

Figure 3: The amplitude-frequency characteristic of the seven-order Butterworth LPF

3 Results

The multisine signal is generated periodically with the fundamental frequency 32 kHz, and the 31 frequency components in the multisine span linearly from 32 kHz to 992 kHz, which covers the main frequency range in most BIS measurements. Figure 4 shows the real waveform of the generated multisine, captured by an oscilloscope.

Figure 4: Oscillograph of the generated multisine signal

4 Conclusion

This paper provides a practical approach to generate a multisine signal, and establishes a good broadband excitation signal for multifrequency simultaneous (MFS) measurement of BIS.

Acknowledgment

This study has been supported by two grants from the National Natural Science Foundation of China (No. 30900317, 61273271).

References


Optimal Adaptive Wireless Body Area Networks for High Speed mHealth Services

M. Sudjai, L.C. Tran, F. Safaei, S.L. Phung
School of Electrical, Computer, and Telecommunication Engineering, University of Wollongong, Wollongong, Australia, email: ms917@uow.edu.au

Abstract

Adaptive ultra-wideband wireless body area networks have been proposed as one of feasible mHealth platforms offering a high-speed, robust mobile health service. The error performance of such systems outperforms non-adaptive systems by up to 4 dB. To further improve the error performance, the optimization of adaptive parameters is investigated in this paper. Simulation results show that the proposed optimal adaptive systems achieves a 2 dB gain with respect to bit error rate (BER). This improvement is equivalent to extra reduction of the power consumption up to 37% in these networks, thus increasing the longevity and reliability of mHealth services.

1 Introduction

Mobile health (mHealth) fosters the advancement of personal and mobile healthcare services. It promises an effective health monitoring system which is potentially capable of reducing the ever-increasing healthcare cost of the ageing society [1]. A reliable array of tiny, lightweight medical sensors and a robust energy-efficient communication system are keys for the success of mHealth delivery [1]. Therefore mHealth services could be promoted by the development of advanced Wireless Body Area Networks (WBAN). A WBAN consists of wearable and implantable sensors to continuously monitor physiological conditions and feedback real time data wirelessly to the doctor and/or the patient [3]. These WBAN features give rise to some challenges. First, the monitoring and communication systems have to be reliable and accurate. Second, the devices have to be small, light, and highly power efficient to ensure their suitability and longevity. Third, the systems also have to provide high capacity to support many sensors and to cater for future bandwidth-hungry services.

To address these issues, we proposed a Space-Time-Frequency Coded Multi-Band Orthogonal Frequency Division Multiplexing Ultra-Wideband (STFC MB-OFDM UWB) system as an alternative high data rate physical layer for a WBAN system, which can achieve significantly better BER performance, compared to the conventional MB-OFDM system [4]. The system improvements by adaptive approaches for WBAN are hardly found in the literature [1]. Hence, we proposed for the first time in [5] a novel BER-based adaptive STFC MB-OFDM UWB systems. This proposed adaptive algorithm selects a suitable set among three possible sets of modulation, STFC coding rate, and Tx signal power. Each set of adaptive schemes is determined by two BER thresholds, namely the lower and upper thresholds. This adaptive scheme results in a performance improvement by up to 4 dB, meaning a possible 60% reduction of the total transmitted power, hence reducing the dimension of WBAN devices and prolonging their battery life. However, parameters of the adaptive algorithm in [5] have not been optimized. To pursue maximum performance and power reduction, further refinement is needed. Hence, this paper aims to optimize the aforementioned adaptive WBAN system to gain extra performance improvement and power saving for mHealth services.

2 Methods

We consider a WBAN employing the MB-OFDM UWB technology, which allows the data rate up to 1 Gbps [2]. This rate is far higher than an Impulse Radio (IR) UWB WBAN system proposed in [3], where the maximum data rate is 15.6 Mbps. Due to the severely dispersive body area propagation channel [6], we utilize the Multiple-Input Multiple-Output (MIMO) technique [7,8] to increase the diversity order and enhance the performance against channel fading. In particular, we have proposed the STFC MB-OFDM UWB system for a high speed WBAN physical layer [4]. Readers are recommended to refer to [4,9] for a thorough description of the system. The adaptive scheme is later added to the system in order to improve the BER performance and power efficiency while keeping high throughput in body-to-external links of a WBAN [5]. This paper mainly focuses on the optimization of adaptive parameters to further improve the performance and power saving.

2.1 System model

Figure 1 Adaptive STFC MB-OFDM UWB WBAN.
The system model with $M$-Tx antennas and $N$-Rx antennas is depicted in Figure 1. The transmitter consists of an adaptive block that controls three possible sets of modulation, signal power, and STFC coding, referred to as *Set-l* ($l = 1, 2, 3$) [5]. The channel quality is measured by a BER estimator. The measured BER is not fed back directly to the transmitter, but is compared to the preset upper and lower thresholds, resulting in one out of three possible sets of adaptive schemes to be selected. Hence, to indicate which set of adaptive schemes should be used in the next transmission, only two bits are required to be fed back to the transmitter. Assuming that the non-adaptive system employs QPSK, STFC rate 1.0, and normalized power 1.0, thus providing a 2 bps/Hz spectral efficiency. In the adaptive system, *Set-l*, is designed to take advantage of the best channel by maximizing the throughput, i.e. by using QPSK, STFC rate 3/2 and power 1.5, providing a 3 bps/Hz spectral efficiency. *Set-2* is used for the average quality channel, hence employing the same scheme as the non-adaptive system. *Set-3* is aimed to tackle the worst channel by employing more powerful BPSK modulation, STFC rate 1.0, and power 0.5, providing a spectral efficiency of 1 bps/Hz. Assuming that the three sets are equiprobable and signal powers are selected as above, the average spectral density and total transmitted power in the adaptive system is equal to those in a non-adaptive system, resulting in a fair comparison.

Let $\bar{x} = [x_1, x_2, ..., x_{N_{RF}}]^T$ be the symbol vector, where $N_{RF}$ is the FFT/IFFT size. The adaptive STFC block in Figure 1 creates a space-time code either with full rate or 3/2-rate. The full rate code, i.e. the Alamouti code [7], converts two consecutive symbol vectors into a STFC block

$$X = [\bar{x}_{t,m}]_{T \times M} = \begin{bmatrix} \bar{x}_1 & \bar{x}_2 \\ -\bar{x}_2 & \bar{x}_1 \end{bmatrix}$$

(1)

For a 3/2-rate STFC, three symbol vectors are encoded following the Sezginer-Sari code [10]

$$X = [\bar{x}_{t,m}]_{T \times M} = \begin{bmatrix} a\bar{x}_1 + b\bar{x}_2 \frac{b}{\sqrt{2}} - (c\bar{x}_1 + d\bar{x}_3) \frac{d}{\sqrt{2}} \\ a\bar{x}_2 + b\bar{x}_1 \frac{b}{\sqrt{2}} + c\bar{x}_1 + d\bar{x}_3 \frac{d}{\sqrt{2}} \end{bmatrix}$$

(2)

where $\bar{x}_1$ and $\bar{x}_2$ are symbol vectors transmitted from the first and the second antenna at a given time slot, respectively. Here, $(\cdot)^*$ denotes complex conjugate, $t$ indicates time slot and $m$ indicates the $m^{th}$ Tx antenna. $a, b, c, d$ and $d$ are complex-valued design parameters. We use the optimal parameters $a = c = \sqrt{2}$, and $b = d = (1 + j\sqrt{2})/4$ as determined in [10]. The received signals can be written in a matrix form as [5, 8]

$$R = X \circ H + N$$

(3)

where $H$ is the FFT transform of the channel matrix, and the operation ($\circ$) denotes the matrix multiplication similar to the conventional matrix multiplication, except that each entry in $R$ and $H$ is not a single number, but a vector [4, 5, 9]. The detected vectors are decided by the following Maximum Likelihood (ML) rule

$$\{\bar{x}_{t,m}\} = \arg\min_{\{\bar{x}_{t,m}\}} ||R - X \circ H||_F^2$$

(4)

Readers may refer to [5] for a more comprehensive analysis of the system model.

2.2 Transmission model

For clarity, it is assumed that a person wearing WBAN devices makes a clockwise angular movement with respect to a fixed external transceiver. Different angles of the body direction experience dissimilar radio propagation characteristics, leading to different channel fading [6]. During each frame transmission, the BER is measured in the portion $f$ of the frame, $(0 < f < 1)$, where *Set-2* is selected as the default modulation and STFC coding scheme.

![Figure 2 Adaptive frame transmission models.](image)

The receiver measures the quality of the channel, i.e. BER, for this portion, compares it to the preset thresholds, and then decides which *Set-l* to be suggested to the transmitter via a two-bit feedback link to update the modulation and STFC coding scheme for the remaining portion $(1 - f)$ of that frame. Note that this *Set-l* is known to the receiver.

2.3 Adaptive algorithm

The adaptive scheme is controlled by the measured BER and BER thresholds [5]. Two BER thresholds, i.e. upper and lower thresholds, are defined that determine the selection of one among three possible *Set-l*. The upper and lower thresholds are derived from the average non-adaptive BER performance as the benchmark. The thresholds are linearly defined to reflect a constant deviation in the whole range of SNR w.r.t. to the non-adaptive average BER performance as the reference point. The lower and upper linear thresholds are defined as

$$BER^{(g)}_L = BER^{(g)}_{NA} - k \times BER^{(g)}_{NA}$$

(5)

$$BER^{(g)}_U = BER^{(g)}_{NA} + k \times BER^{(g)}_{NA}$$

(6)

where $BER^{(g)}_{L}$ is the lower threshold, $BER^{(g)}_U$ the upper threshold, and $BER^{(g)}_{NA}$ is the non-adaptive average BER performance for the $g$-th SNR value. $k$ is a constant, whose value will be optimized later in this paper.

The algorithm for each frame transmission is as follows:


\[
\begin{align*}
\text{Start} \\
\text{Measure BER in the initial portion;}
\text{If BER < BER}_L \\
\text{Set\_Modulation} = \text{qpsk}; \\
\text{Set\_Power\_Tx} = 1.5; \\
\text{Set\_STFC\_rate} = 1.5; \\
\text{Use Set\_1 for next portion of the frame}
\end{align*}
\]

\[
\begin{align*}
\text{else if BER \geq BER}_L \text{ and BER \leq BER}_U \\
\text{Set\_Modulation} = \text{bpsk}; \\
\text{Set\_Power\_Tx} = 0.5; \\
\text{Set\_STFC\_rate} = 1.0; \\
\text{Use Set\_2}
\end{align*}
\]

\[
\begin{align*}
\text{else} \\
\text{Set\_Modulation} = \text{qpsk}; \\
\text{Set\_Power\_Tx} = 1.0; \\
\text{Set\_STFC\_rate} = 1.0; \\
\text{Use Set\_3}
\end{align*}
\]

\text{End}

\section{2.4 Optimization of parameters}

Performance of the adaptive system depends on the selected Set-l on a frame-to-frame basis. During \(q\)-th frame transmission, where \(q = 0, 1, 2, ..., Q - 1\), and \(Q\) is the number of frames, the measurement of BER and adaptation occurs during the \(f\) portion of the frame, as defined in Section 2.2. Hence, the BER of the system is affected by the selected value of the \(f\)-factor. At the same time, BER is also affected by the selection of Set-l, which is done by comparing the measured BER of the current received frame with the thresholds, which are, in turn defined by the \(k\)-factor. Hence the system performance depends on both \(f\) and \(k\). It is obvious that \(0 < f < 1\) and \(0 < k < 1\). For simplicity, but without loss of generality, we consider a set of limited discrete values of \(f\) and \(k\) as detailed in (7) and (8). Note that \(f\) and \(k\) are independent from each other.

\[
f_i = 0.1i, \quad i = 1, 2, ..., 9
\]

\[
k_j = 0.1j, \quad j = 1, 2, ..., 9
\]

We denote a variable \(u^q_i\) where \(u^q_i = 1\) if a certain portion of the frame \(f_i\) is selected to measure the BER, and \(u^q_i = 0\) otherwise. We define a variable \(v^j_k\) where \(v^j_k = 1\) if a certain value of \(k_j\) is selected to determine the upper and lower BER thresholds as mentioned in (5) and (6), and \(v^j_k = 0\) otherwise.

We also denote \(z^q_k\) to be the cost associated with the selected \(f_i\), and \(w^j_k\) is to be the cost associated with the selected \(k_j\). The costs here mean the BER performance. Since the maximum likelihood decoding is used, the cost could be expressed as \(\arg\min_{(u^q_i, v^j_k)} \| X - Y \times H \|_F^2 \). The throughput is fixed to 1.8 bps/Hz or 90% of maximum capacity, since this is sufficient to support the current and foreseeable future mHealth monitoring applications.

Our objective is to optimize the overall average BER of all \(Q\) frames. Hence, The total cost function is defined by

\[
\text{cost} = \sum_{q=0}^{Q-1} \sum_{i=1}^{9} \sum_{j=1}^{9} (z^q_i \cdot u^q_i + w^j_k \cdot v^j_k) \tag{9}
\]

The first term of (9) represents the average BER performance associated with a given value of \(f\), provided that a value of \(k\) is arbitrarily chosen. While the second term is likewise for given value of \(k\), provided \(f\) is arbitrarily selected.

Note that only a single pair of values of \(f\) and \(k\) is chosen during each frame transmission. This is equivalent to selecting a single optimum value of \(u^q_i\) and \(v^j_k\) from their possible values. Thus, the constraints are determined by

\[
\sum_{i=1}^{9} u^q_i = 1, \forall i = 1, 2, ..., 9
\]

\[
\sum_{j=1}^{9} v^j_k = 1, \forall j = 1, 2, ..., 9
\]

\[
u^q_i \geq 0, v^j_k \geq 0
\]
3 Results

Figure 3 Optimal adaptive and non-optimal adaptive performances in a $2 \times 1$ MIMO configuration.

Figure 4 Optimal adaptive and non-optimal adaptive performances in a $2 \times 2$ MIMO configuration.

This section compares system BER performance of the non-adaptive system, the non-optimal adaptive system, and the optimal adaptive system. It is assumed that a perfect channel state estimation is available at the receiver. We use the IEEE’s WBAN channel model 4 (CM4) that takes into account the effect of angular body movements [6]. CM4 represents links between body-worn devices and fixed external transceivers such as wireless access points. MB-OFDM UWB employs 128 subcarriers with a 37-zero padding, and bandwidth of 528 MHz. The STFCs are implemented in the $2 \times 1$ and $2 \times 2$ MIMO configurations.

Figure 3 shows the performance comparison in the $2 \times 1$ MIMO, while Figure 4 is for the $2 \times 2$ MIMO. In the medium to high SNR range, the non-optimal adaptive $2 \times 1$ MIMO system provides a 1–4 dB gain over the non-adaptive counterpart. The optimal adaptive system enhances the performance further by 1–2 dB in the whole SNR range. Meanwhile, the non-optimal adaptive $2 \times 2$ MIMO WBAN provides a near constant 1–2 dB gain in the whole range of SNR, compared to the non-adaptive WBAN as shown in Figure 4. Again, optimizing the adaptive parameters provides an additional 1–2 dB improvement.

Therefore, in these two MIMO configurations, the optimal adaptive WBAN result in a gain of up to 2 dB over the non-optimal adaptive WBAN, and up to 6 dB over the non-adaptive WBAN. Translating to the power saving, the optimal adaptive approach provides a power consumption reduction by up to 37% and 75%, compared to the two counterparts respectively.

4 Conclusion

The proposed adaptive STFC MB-OFDM UWB WBAN is one of feasible effective mHealth platforms. By the optimization of its adaptive parameters as shown in this paper, the performance of the system is improved considerably. The improvements provide critical power reduction of WBAN devices, thus extending the battery life and enhancing the reliability of mHealth services significantly.

References

A Concept for Semi-Automatic Generation of Digital Patient Models

Kerstin Denecke¹, Mario Cypko¹, Yihan Deng¹
¹Innovation Center Computer Assisted Surgery, University of Leipzig, Leipzig, Germany, name.lastname@iccas.de

Abstract
Clinical decision making becomes more complex due to the increased availability of clinical tests and corresponding results. A digital patient model tries to address this issue. It integrates information related to a specific medical condition and makes it available for various applications such as decision support. Information entities characterising a medical condition are associated to each other and form the model. Such patient conditions can be realised as probabilistic models. NLP methods can be used to extract information entities characterising a disease from evidences as well as information from the electronic health record. To facilitate the model generation process, we introduce a concept and architecture for exploiting natural language processing (NLP) methods in the context of digital patient modelling.

1 Introduction
New technical and medical findings led to an increased development of methods supporting clinical procedures and diagnosis in the last years. They are continuously integrated into daily practice since they have the potential to improve treatment and even to individualize treatment for example by considering -omics data within diagnosis and treatment decisions. However, the new methods provide very complex results that hamper the quick manual analysis and interpretation by doctors. Besides clinical data such as laboratory results and radiological images, DNA sequences and lifestyle information from the patient are to be considered in decision-making, to be weighted and to be correlated with clinical data. Such analysis requires comprehensive background knowledge regarding dependencies and correlations between single examination results. For example the efficacy of a drug can depend on the genomic information. Such knowledge need to be present at the time of decision making. In order to realize a reproducible and evidence-based clinical decision making, digital patient models can be exploited.

A digital patient model integrates various information entities that need to be considered within therapy planning and clinical decision making. It further describes relations between clinical parameters and sociological factors related to a specific clinical pathology. Normally, patient models are focussing on a specific medical condition, organ or disease. They can occur in different facets [3]:
- Geometric patient models (e.g., 3D-images / 3D patient model of specific organ such as 3D panendoscopy or Patient-specific modeling of the heart,
- Dynamic or functional patient models,
- Patient models for diagnosis (e.g. Presentation characteristics of esophagus cancer [6], causal probabilistic model for diagnosis of bacterial urinary tract infection [7]),
- Predictive patient models for disease progress,
- Predictive patient models for therapy planning.

We are considering digital patient models for therapy planning. In this context, the model is exploited to determine and visualize information entities and their direct dependencies, but also serves as reference for communication between clinicians or with patients. The personal viewpoints of the clinicians can be confronted with an evidence-based and integrated viewpoint provided through the model which leads to a more objective and transparent therapy decision. Within a clinical decision support system such digital patient model can provide hints to missing examination results that are important to make a proper decision.

The construction of a digital patient model bases upon clinical and scientific evidences that can be collected through expert interviews and literature review. Additionally, to build a patient-specific model, relevant clinical data need to be extracted from the electronic health record. Since the process of collecting the relevant information can be very comprehensive, we study the applicability of NLP methods to support the modeling work. In this paper, we describe a concept of using natural language processing methods within the modelling generation process, to identify relevant information entities for patient modelling. Use cases for natural language processing in the context of digital patient modeling are identified and a framework for integrating NLP methods into the digital patient modeling process is introduced.

The paper is structured as follows: In section 2, we describe the underlying approach for creating a digital patient model and review NLP methods in the medical domain. Section 3 introduces the architecture for creating systems that build patient
models, or update them. The paper finishes with conclusions and future work.

2 Methods

2.1 Developing a Digital Patient Model

Probabilistic modeling utilizes presumed probability distributions of certain input assumptions to calculate the implied probability distribution for chosen output metrics. Probabilistic models have been proven to be successful in modeling diseases for the use in diagnostic systems [11-13]. Our approach for creating a digital patient model as defined above also relies upon that technology. More specifically, we use acyclic graphs, so called Multi-Entity Bayesian Networks (MEBN [1]) to generate a patient model based on which patient specific Bayesian Network (PSBN) can be constructed. MEBNs are probabilistic graphical models based on Bayesian probability theory and allow to determine complex cause–effect relationships. In the MEBN’s graphical structure, nodes represent information entities (IE) from the domain of interest, such as medical examinations, medical imaging, patient behavior, genetic factors, and patient characteristics (e.g. age, gender, tobacco and alcohol consumption), whereas directed edges represent causal dependencies between IEs. Additionally, each node contains possible states of an IE, as well as a conditional probability distribution (CPD). The CPDs reflect causal influences and are required for automatic inferencing and reasoning based on the network.

In our previous work, we constructed the graph in close collaboration with health experts who identified relevant literature and guidelines, selected information entities and connected them appropriately to build the graph [14]. Weights were assigned manually by experts to the relations between IE.. In that way, we constructed within one year a patient model based on MEBN for laryngeal cancer. Information entities were identified and linked by an ENT physician. As of now, the laryngeal cancer patient model contains more than 800 IE with more than 1,100 direct dependencies. Each IE contains all possible events, and all medical sources used in the model have been referenced as additional information.

As it can be seen, the model generation process is very time-consuming and there is a substantial risk of missing relevant information. Additionally, the model needs to be updated regularly to consider latest research results which provokes additional workload when done manually. To reduce the workload, we suggest a semi-automatic approach. At least in the model generation and update process human expertise will always be necessary to ensure a high quality of the model. Quality of natural processing tools for processing biomedical literature increased in the last years [5] which makes such application realistic. In the context of digital patient modelling as considered in this work, natural language processing can support in three ways:

1. **Model generation**: Identifying relevant information entities and relations that describe medical conditions and related factors from research literature and (free-textual) guidelines,
2. **Model instantiation**: Extracting patient information from the electronic health record to be integrated into the graph for generating a patient specific Bayesian network,
3. **Model update**: Reviewing literature for collecting updates in information entities and relations to find clinical evidences (evidence-based medicine).

Extraction of information from the patient record includes gathering diseases, symptoms and medical procedures as well as medications as they are documented. Additionally, complications that occurred and sentiments or attitudes can be extracted from the documents and considered in the model. In the next section, we provide an overview on natural language processing in the context of medicine. From there, we develop our concept for building a digital patient model using NLP which is described in section 3.

2.2 Natural Language Processing in Medicine

There are mainly two types of information sources in the medical domain which are also relevant in digital patient modeling. One source of information comprises clinical documents, i.e. patient reports or clinical notes. Various document types exist: radiology reports, discharge summaries, surgical reports, nurse letters etc. There have been efforts to extract information and consequently encode the patient data in order to use it in data mining, decision support systems, patient management systems, quality monitoring systems, and clinical research. A second source of information comprises the huge repositories of scientific literature in the biomedical domain. MEDLINE, a literature database, contains over 19 million abstracts of biomedical publications and is a critical source of information, with a rate of approximate 60,000 new abstracts appearing each month. Language in both types of textual sources differs significantly which led to the development of algorithms for either clinical documents or biomedical literature [4]. Additionally, clinical guidelines exist, also written in natural language.

In the field of NLP, Information extraction targets at identifying relevant information from texts. Normally, the type of information of interest is specified in advance (e.g. an interest in symptoms). Information extraction comprises several tasks,
including named entity recognition, coreference resolution, relation extraction and template filling. Named-entity recognition (NER) aims at identifying within a collection of text all of the instances of a name for a specific type of thing [10]. Examples of named entity categories in the medical domain include diseases and illnesses, symptoms, procedures or drugs. More general named entity categories are person names, organizations, or locations.

In the domain of medicine, the systems cTakes [9] and MetaMap [8] are frequently exploited. Both tools were successfully tested on clinical documents and biomedical literature. They extract terms from unstructured text and map them to concepts of the Unified Medical Language System (UMLS, http://www.nlm.nih.gov/research/umls/). A concept represents a single meaning. Due to the flexibility in language usage, the same meaning can be expressed in different ways, e.g. through a noun, its synonym, an abbreviation etc. Through mapping of terms to concepts of a terminology, texts can be represented semantically and become interpretable for computer algorithms. For example, the UMLS Metathesaurus is organized by concepts: each concept has specific attributes defining its meaning. It is linked to the corresponding concept names in the various source vocabularies. We intend to exploit existing clinical information extraction tools to extract relevant information for semi-automatic patient modelling.

3 Results

In this section, we describe our concept for generating semi-automatically disease or organ-specific patient models according to our definition (i.e. Information entities linked according to their dependencies to each other). The key idea is to exploit natural language processing to extract relevant information for model generation, instantiation and update and in this way, to facilitate the model generation process and to reduce manual work (see Fig. 2). We identified five components that are required to build applications that can create a digital patient model (see Fig. 1): Data Collector, Filtering and Preprocessing Module, Extraction and Classification Module, Model Generator and Updater, Visualization Module. These modules are described in the following.

The Data Collector collects textual content from various sources, e.g. from the electronic health record, from the Web or from knowledge repositories (e.g. guidelines). The data collector needs to be able to start external applications or to interact with them for data collection purposes. Data collection requires specification of the repositories to be searched or keywords based on which large-scale collection can be performed. Collected texts need to be filtered and preprocessed realized by a second module. More specifically, relevant texts are selected from the data collection. This is implemented using classification techniques from machine learning. Third, from the relevant texts, information needs to be extracted and classified. It needs to be clearly specified, which information needs to be extracted (e.g. information entities that are represented as nodes in the digital patient model, clinical evidences for these information entities or clinical data for a specific patient extracted from the clinical documents of the EHR).
model update or inclusion of patient data into the MEBN. Model generation requires a concrete definition of nodes, what they contain and how to link them. In our previous work we came up with a specification of the MEBN graphs with results published elsewhere. For updating the model, relevant new information will be integrated into the graph, e.g. pointers to the clinical evidences will be updated in the graph. When generating a PSBN, this component adds information extracted from the electronic health record into the graph. Afterwards, the created, updated or individualized model can be exploited by decision support systems or can be directly visualized using 3D-visualizations [2].

4 Discussion and Conclusions

This paper identified use cases to automatize the process of digital patient modelling using natural language processing. So far, our work concentrated on using MEBN for patient modeling where relevant information items and relations were identified by experts manually. In contrast to other approach for modeling complex information and dependencies such as Neural networks, MEBN have the advantage of representing knowledge in an understandable way and computation is reproducible. Many study groups already approached the issue of clinical application of Bayesian networks. The TREAT study group well explored the feasibility and applicability of Bayesian networks in clinical settings mainly in the field of antibiotic treatment of patients with bacterial infections [11]. Onisko [13] described the impact of precision of Bayesian network parameters on accuracy of medical diagnostic systems highlighting the fact, that Bayesian networks tolerate a high degree of inaccuracy and still produce reasonable statements. Pitchforth [12] proposed the validation of expert elicited Bayesian networks utilizing psychometric techniques. However, all existing approaches exploited manpower to build the network graphs. Given the increasing quality of NLP tools in the biomedical domain, we believe that NLP could support in model generation and in particular in collecting relevant information for model updating. In future work, we will realize the architecture to collect relevant information entities for building a disease-specific digital patient model for a specific disease.

5 References