bwHealthApp: A Software System to Support Personalized Medicine by Individual Monitoring of Vital Parameters of Outpatients

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Abstract: Continuous monitoring of individual vital parameters can provide information for the assessment of one's health and indications of medical problems in the context of personalized medicine. Correlations between parameters and health issues are to be evaluated. As one project in this topic area, a telemedicine platform is implemented to gather data of outpatients via wearables and accumulate them for physicians and researchers to review. This work extracts requirements, draws use case scenarios, and shows the current system architecture consisting of a patient application, a physician application with a web server, and a backend server application. In further work, the prototype will assist to develop a vendor-free and open monitoring solution. A conclusion on functionality and usability will be evaluated in an imminent first study.

1 INTRODUCTION

Personalized medicine (PM) focuses on the person themselves, their characteristics, and needs, ideally supported by enriching existing patient information with continuously collected health data. There are indications of the medical potential of such non-specific health monitoring (Dusheck, 2017).

The increasing use of wearables with an unmanageable variety of sensors leads to self-assessments and a new type of appropriate medical consultations. To prove medical evidence and to enable a systematic approach, a large-scale evaluation in a real clinical environment is necessary, which requires a suitable and freely adaptable software system for data processing.

Understanding patterns of vital signs and diseases is an emerging application for large data analysis and machine learning. Continuous monitoring of various health data using case studies, including medical outcomes, is the basis for supporting diagnosis for precision medicine. A solution is needed that combines flexible and case-specific sensor composition with the interpretation of medical data in a clinical care environment. This additional data can be used to supplement the current diagnosis, therapy planning, monitoring of the patient's condition, clinical evaluation, and research. Further, the actually needed type, quality, and quantity of vital data and for monitoring relevant patient-reported outcomes (PROs) as well as their correlation with pathophysiological processes are current objects of research (Dusheck, 2017; Dias and Cunha., 2018; Ohri et al., 2017).

To realize such a solution, the ministry of social affairs and integration state of Baden-Württemberg (Germany) initialized this project to develop a telehealth system for PM, that enables individual configuration for body area networks (BAN) for eligible medical use cases. Tools for data recording by arbitrary, commercially available sensors as well as examination and validation are provided alongside interfaces to systems for automated data analysis, alarming, or deep learning for predictors. The principal application underlying this work is the monitoring of patients undergoing chemotherapy treatment in medical oncological daycare units. Here, continuous monitoring of vital parameters can support the detection of critical situations or overall changes in the patient's condition (Ohri et al., 2017).

Medical partners of the bwHealthApp project are the Center for Personalized Medicine (CPM) and the Clinic of Internal Medicine of the university hospital of Tübingen, Germany, with its daycare units. An upcoming, cooperative clinical trial shall determine which sensors are useful for monitoring health param-

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eters in the oncological setting. Effects concerning human life by monitoring health data and resulting diagnosis must be identified and secured.

In order to provide flexibility, the platform is developed in an open form, so that sensors from different vendors can be used. This work presents the requirements analysis and the implemented prototype.

2 RELATED WORK

With the availability of 2.5G and 3G mobile telecommunications networks in the first years of the 21st century, bandwidth was sufficient to examine the applicability of decentralized individual vital data capturing from BAN for patient monitoring (van Halteren et al., 2004), and has since been an ongoing field of research for individual health assessment. With the constant growth of the wearable market, consumer devices for various vital parameters became widely spread (Dias and Cunha., 2018; Statista, 2019). Their suitability for medical purposes is currently evaluated. Preliminiary results indicate that the quality for some parameters (e.g. heart rate) is partly sufficient (Turakhia et al., 2019; Raja et al., 2019). In contrast to current comparable home care solutions using specific medical devices, the bwHealthApp also applies consumer wearables. They are cost efficient and part of an increasing number of peoples' everyday life, which is expected to ensure a sustainable coverage of monitoring time and manageable need for support. The trade-off between usability and data quality is to be evaluated.

For PM, the long-term collection of data from ambulatory patients in their home environments provides information about the progress of a disease that would not be available during short hospital stays. For instance, in the case of chemoradiotherapy, the analysis of activity data by a step counter between the weekly visits in daycare may help to avoid hospitalization (Ohri et al., 2017). An advantage of the bwHealthApp is the continuous transfer of data to the central server for closer monitoring and quicker response times.

By long-term monitoring, further, yet unknown correlations between vital parameters, environmental influences, and progress of a disease may be uncovered. For cancer treatment, several correlations between parameters and patient outcomes have been examined (Friedenreich et al., 2016; Guo et al., 2015). Until now no operational integrated mobile health solution is known to the authors which makes sensor data from oncological outpatients' everyday life available for clinical routine. Here the bwHealthApp supports the emerging concept of integrating routine data and clinical research, as applied in PM (Vogenberg et al., 2010). The system further allows for adaptive variation of vital parameters to be monitored.

Making vital data available requires connectivity and sensors which are manageable by patients without a technical background, as well as tools that allow physicians to check the data during a regular patient visit. For this purpose home care monitoring provides practical solutions for nearly two decades (Lin et al., 2007). This experience, existing tools and concepts are used to establish the bwHealtApp software. Counteracting cancer is one of the current main challenges in medicine. There are international efforts taken to make use of digital possibilities, such as the new ONCORELIEF project¹ funded within the EU H2020 framework since 2020. The novelty of the bwHealthApp is the application of well established remote patient monitoring approaches for oncological treatment adapted to PM.

3 APPROACH

The aim of the project stage presented is to establish an initial prototype accepted by physicians and patients within the domain of chemotherapy.

3.1 Design Process

First, principal use case scenarios considering the routine operation of the system were obtained by interviews and workshops with the CPM stakeholders, identifying important functional and quality requirements regarding changeability, extendibility, configurability, and flexibility. For a more specific system presentation, influential factors and boundary conditions were defined. The concrete architecture, consisting of a smartphone application for patients' use, a backend server application for storing and exchanging data, and a frontend web application for physicians, was developed and implemented. The open-source paradigm is applied to enable sustainability and avoid dead ends by closed-shops. As characteristic for PM, the boundaries between patient care and research are blurred. For individual data examination, the collection, organization, processing, and visualization of raw data are fundamental requirements. High-level analysis and machine learning have not yet been integrated, except the data model and service architecture, allowing for specific data extraction.

¹https://oncorelief.eu/

3.2 Functional and Qualitative Requirements

The core task of the bwHealthApp is the centralized recording of individual health data from decentralized data sources and to provide attending physicians with a possibility to analyze and correlate different vital parameters, PROs, and findings to detect unusual changes within the patients' individual profile during their stay at home.

To support the main goal of keeping a patient in his regular environment, data collection must be flexible and need to avoid interference with daily life wherever possible. Thus, easily available and userfriendly wearables should be prioritized for integration. Wearables should be combined individually concerning medically required parameters and independent of specific vendors. For personal involvement of the patients, an appropriate compliance considering the application of the tools can be assumed.

All data the patient wants to provide should be retrievable for the treating physicians. Although continuous data collection would be ideal in the medical setting, the patients have sovereignty of their data and can terminate the data monitoring. The whole system should be generic, modular, integrative and open.

3.3 Aspects of Realization

The bwHealthApp is a new digital health care application, which is not fully covered by German legislation since medical data is collected and processed beyond an a priori defined medical question. Therefore, it can currently only be applied in clinical trials.

The performance of smartphone and server processors must be considered, as well as technical limitations, such as battery lifetime, memory, or network connectivity, and different versions of mobile operating systems. Other relevant factors are handling offline and online modes, and essential external systems needed for the running system.

Concerning the evolving requirements regarding sensors, vital parameters, and medical questions, an agile development approach, as well as DevOps paradigms, have been adopted. The principal components are developed for open source and framework availability, giving importance to versioning and monitoring of patches and security issues. The overall risk of dying frameworks and components has to be matched by a modular architecture, which in turn affects deployment pipelines.

The Bluetooth low energy (BLE) protocol, being the current de facto standard for consumer wearables, is used to set up the BAN. BLE still being under development leads to frequent changes in the applied frameworks of the android platform, requiring a flexible and modular design of the smartphone app. The implementation of the BLE protocol stack has to be monitored by the android developers, and resulting version limits for android will exclude smartphones with older OS installations.

Further, sensors cannot be integrated if vendors do not provide their specifications, leading to the Cosinuss One² as the sensor of choice for initial development and testing.

4 USE CASE SCENARIOS

4.1 Patient Registration and Authentication

The first step for using the bwHealthApp in treatment is the patient registration and authentication. Patients are registered by an attending physician in the medical daycare unit. After registration, the authentication of the patient takes place via QR code scans, linking the patient's personal information with the smartphone to be used as the BAN gateway. This makes the patient, their monitoring cases, and medical data as associable as possible. The smartphone is further used for identification during operation.

4.2 Measurement Configuration and Evaluation

For the measurement configuration, the physician selects a set of vital parameters and/or questionnaires from a catalog, defining sampling rates for each element. The configuration is then persisted on the server and transferred to the patient's smartphone. Physicians can also create individual questionnaires and add them to the catalog. After the configured data is collected, it can be reviewed by the physician. The corresponding web application offers a selection of tools for visualization and data filtering.

4.3 Device Initialization and Data Collection

After a patient has been registered, authenticated, and corresponding measurements are configured by the physician, the smartphone application and used wearables must be initialized. If the medical question does

²https://www.cosinuss.com/en/products/one/

not need uniform devices, patients can use any preferred wearable that is supported by the system.

When launched, the smartphone app scans for available devices in the environment and connects to selected wearables. The app scans which configured health care parameters are covered by which connected device. Missing components trigger notifications and request feedback. In parallel, configured questionnaires are downloaded automatically. Sensor parameters are sampled and questionnaires are displayed automatically in accordance with the configured sampling rate and are persisted on the backend server. After initialization, a dashboard offers an overview of the sampling process. The user can decide if and when they want data to be recorded.

4.4 Connectivity and Operation

During data collection, further functionalities are needed to handle broken connections, error feedback, and reconnects. These have to be individually realized by each client application. In contrast to the current, more supervised monitoring approaches (e.g. Holter monitor), this will need to be evaluated with respect to clinical viability. A fundamental challenge will be general usability for people with limited capability to operate the smartphone app. Further, processes need to be implemented to guarantee data synchronicity across all sub-systems.

5 SYSTEM ARCHITECTURE AND FUNCTIONALITY

The project's three essential systems are summarized in figure 1. Note that wearables, smartphone, and patient app are part of the system for patients, while both web server and physician application are part of the system of physicians. External systems are excluded by the horizontal swim lane divider. All three components are required for the entire application to function as intended, yet each individual system should be replaceable, serving the modularity desired for opensource software.

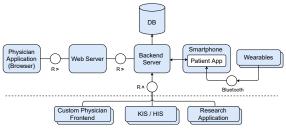


Figure 1: System architecture overview.

5.1 Wearables and Patient Application

Wearables represent external sensor systems for data collection and are combined into a BAN, for which the smartphone app acts as a data integration system with sensor management, data management, and user interaction. Figure 2 shows the basic architecture of the smartphone application.

The measurement scheduler extracts configured vital parameters and searches for appropriate sensors to connect to. After the connection has been confirmed, the sensor manager establishes the BLE connection and provides a handler for each sensor. A specific GATT service (e.g. heart rate) is assigned to each sensor. The handler extracts the desired value, interprets the raw data according to the GATT implementation, and transfers it to the data manager component in the configured interval. Error messages and invalid values are handled here. The measurement module regularly pools the current values for display. This is the only implementation of polling, all other data changes are using the observer pattern. Accordingly, the questionnaire scheduler handles the download and timely display of configured questionnaires.

Data is not streamed to the server. Instead, sensor data is buffered into packets and transmitted at regular intervals. PROs on the other hand are submitted after the questionnaire has been filled in. Currently, data is only held in RAM temporarily in support of data economy. An offline mode temporarily moving data from RAM to app may be introduced in the future.

5.2 Web Server and Physician Application

The web server, as seen in Figure 3, serves as an interface between the backend server and the physician application. It establishes a one-way connection to the

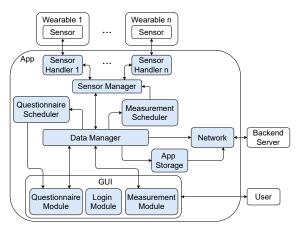


Figure 2: Smartphone application overview.

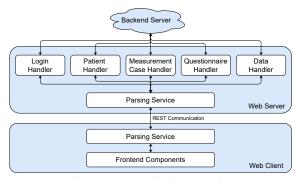


Figure 3: Web application overview.

backend server and forwards all client requests via a REST interface. The web server hosts the physician application and provides it with static resources. For each incoming client request, the server forwards it to a separate handler, where the route to the backend server is defined. The returning request is then received by the same handler and forwarded to the client. If requests take too long or cause errors, timeouts and error handling are available.

Purpose of the physician application is the management of monitoring cases. The system provides visualization of individual health data and is used for manual evaluation during consultations. The current lack of medical guidelines on the use of individual monitoring in PM marks the current system boundary. Data visualization is processed in the browser, without any external services.

The frontend is divided into functional components, providing tools for patient registration and authentication, monitoring case creation, view and editing, and most prominently data evaluation. For the latter, data from sensors and PROs can be viewed as raw data and rendered into a graphical representation, as well as exported for integration into external tools.

5.3 Backend Server Application

The server application functions as both a gateway for the aforementioned client applications and a controller managing subsystems, as is shown in figure 4, providing REST-like interfaces for client systems. Access to resources and corresponding operations is limited, as per usual, by provided URLs and their corresponding HTTP-methods, thereby offering a first layer of (role-based) access control. With respect to system evolution and interoperability, data is transmitted to and from the server application in JavaScript Object Notation (JSON).

Data security of both incoming and outgoing messages will be ensured by encoded communication protocols (e.g. HTTPS) and established authentication

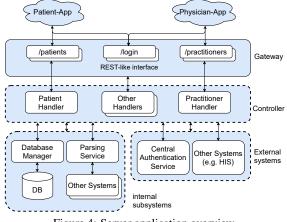


Figure 4: Server application overview.

mechanisms (e.g. X.509). Those messages are then forwarded to the receiving handler, where they are dispatched to the appropriate internal (e.g. database management) or external (e.g. central authentication service) subsystems, if given authorization requirements are met. Communication with external subsystems may require the use or provision of medical standard interfaces (e.g. HL7, DICOM) to allow for a flexible replacement of such subsystems as well as extensibility with additional components. The internal and specific subsystems of the project cover the administration of management data such as user identities, registered devices, and individual parameter configurations, as well as run-time data such as assigned sensors and measured values or PROs. External subsystems will include a centralized authentication service, which is currently under development, and may be extended by further systems for data visualization, diagnosis support, and messaging for notifications.

The server application is designed with interoperability in mind, specifically concerning external applications for clinical information processing such as hospital information systems (HIS) or tumor boards. It's also supposed to serve as a data source for research applications like machine learning, or evidence-based medicine.

5.4 Persistence and Data Management

Persistence and data management are fundamental tasks within the project, handled by an internal subsystem of the server application. Central to the persistence are monitoring cases, which encases a patient, treating physicians, and an array of related data.

As a server application subsystem, the database cannot be accessed directly, but only via appropriate REST routes. By this means, the previously mentioned role-based access control provided by the

Item creation						
Question	Group	Display				
	Close item					
Preview						
Grouping term Question*		Delete				
Question details						
riee lexi		\checkmark				

Figure 5: Questionnaire creation.

REST interface is extended to the database. Furthermore, access control within the database is to be extended by discretionary access control (DAC), introducing the concepts of data ownership and individually governed access control to personal data.

In a first step, the introduction of DAC will allow both patients and physicians to consult further physicians, and in monitoring cases involving several physicians, for each of them to access and review the patient's data. Later on, data (specifically medical outcomes) can be provided to external subsystems for learning of predictors, ensuing automated alerting, and currently unspecified research applications. All while maintaining the patient's data ownership.

6 UI AND USER PROCESSES

6.1 Patient Registration and Authentication

The physician registers the patient in the web application with personal information. After the information is sent to the server, the physician is forwarded to the authentication page. Upon receiving a new patient, the server will generate an authentication code, which is then sent to the physician's client as a response to the creating request. The patient can enter said code (as QR code) into their mobile app for verification.

6.2 Device Initialization and Configuration

Physicians can create a configuration containing vital parameters and questionnaires. Measurements parameters consist of the type and sampling interval. Questionnaires can be created from existing templates or from the editor shown in figure 5. A questionnaire consists of at least one item: a question, a grouping of further items, or a display text. Each questionnaire

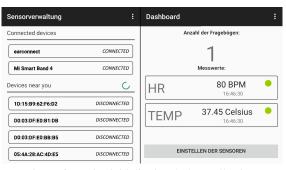


Figure 6: Device initialisation & data collection.

has a sampling interval, too. A measurement case consists of any combination of questionnaires and vital parameters. After the configuration is saved, it is loaded onto the patient's smartphone.

To measure vital parameters, wearables must be connected to the application. The user can search for and connect to available BLE wearables (figure 6, left side). For connected devices, the app automatically checks whether the configured features are available.

6.3 Data Collection and Evaluation

If a configuration has been downloaded, data collection is started directly after sensor initialization. The newest interpreted value gets shown in the application (see figure 6, right side). In this case, the parameters heart rate (HR) and temperature (TEMP) are queried and for each of these parameters, a device is connected (green dot). Missing features will be visualized by a red dot instead. Polling times are automatically set for scheduling the PROs. When the app is opened in the foreground, the questionnaire is dis-

Measurement parameter							
	Measurement parameters	Average	Minimum	Maximum			
	7: TEMP (0000-00-00 00:00:01)	37.6 °C	36.17 °C	38.61 °C			
	7: HR (0000-00-00 00:00:01)	66.4/min	0/min	101/min			
Questionnaires							
L	Physical activity: (Measurement case 7)						
0	Quality of life: (Measurement case 7)						
F	low long did you sleep last nig	iht? •	06 / 10 / 2020 12:00	9			
١	Unit	lours	05 / 10 / 2020 12:00	4			
			04 / 10 / 2020 12:00	3			
ŀ	low well did you sleep? •		06 / 10 / 2020 12:00	Really well			
	● Really well ● Well ● Ok ● Not so well ● Bad	:	05 / 10 / 2020 12:00	Bad			
L			04 / 10 / 2020 12:00	Bad	J		

Figure 7: Tabular data evaluation.

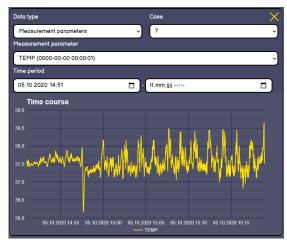


Figure 8: Graphical data evaluation.

played immediately. If the app is in the background, a notification is created that allows the user to open the questionnaire. The user can always decide whether he wants data to be recorded or not. By default, data is recorded in the background once the app is opened in the foreground or background. However, when the user closes the task, this process is terminated. This means that the user has the data sovereignty and can determine at any time whether or not data is recorded.

The data that gets saved to the backend server can be evaluated in the physician's client application. The physician can filter the data by the associated case, the vital parameters and questionnaires included, or the time period in which the data was collected. Figure 7 shows the raw data evaluation as tables. Additionally, a graphical evaluation is available for all vital parameters and some selected questionnaire items (figure 8).

7 CRITICAL ANALYSIS

Integrated and clinically approved solutions for specific vital parameters are only available for certain medical use cases and diagnoses. In contrast to these restricted monitoring applications, the depicted approach needs to combine changeable and case dependent sensor composition with medical data interpretation. The presented data integration solution was developed to enable the clinical validation of this open approach in the clinical environment. The designed system architecture depicts a vendor-free and open solution consisting of a centralized server and decentralized BAN gateway applications, demonstrating the feasibility of collecting wearable data independent of the used sensors and supported value types. In reality, however, independence from vendors and compatibility with any sensor are mutually exclusive, due to closed shops built by most sensor manufacturers.

Additionally, the wider the array of supported sensors, the more critical the question of sensor data reliability and precision becomes. The naive approach to this problem would be to argue that even if the data produced is lacking precision, simply having a lot more data presents value in itself. While there may be some truth to that, this argument won't hold up once incorrect data leads physicians to false diagnoses, especially considering false negatives. Many sensors accumulate additional data, such as skin contact, that could be used to narrow down the precision of measurements, e.g. the better the skin contact, the more reliable the corresponding measurement. If or in what capacity this suffices to counterbalance the risk of incorrect data will require own research. However, the presented platform will be available to assist in such research, providing a framework by which necessary tests can be supported.

Next to the reliability of data, privacy and security are ever-present topics for well-justified doubts and criticism. One major key aspect here is user consent, an internationally recognized problem, mostly with national-specific implications. Bolstered by German federal minister of health Jens Spahn, the European General Data Protection Regulation, and many big players from both IT and medical contexts, data ownership, and sovereignty, as well as the infamous 'transparent citizen', have been recent topics of controversy in Germany. While some criticize the general idea of data collection without immediate cause, others argue for such data to be of high medical necessity. It is clear that in addition to technical concepts, robust and adequate solutions for various legal questions will be required.

8 CONCLUSION

A final conclusion cannot yet be drawn but should be available after testing the application in a real-world scenario, i.e. with actual patients and physicians in a real treatment situation. In an imminent first study, we will evaluate operations, user acceptance, and sensor connection stability according to the chemotherapy use case. Initial vital parameters are general physical activity (e.g. step-count), weight and body fat percentage, cardiac values (heart rate, blood pressure), and body temperature. In addition, an UV sensor and skin conductance measurement will be made available. Until now our advances suffice to show the practicability of such an application.

A first small non representative user-study with physicians indicates a general approval of the pilot

implementation, but in detail the number of clicks needed to fulfill the tasks has to be reduced.

One driving factor throughout implementation was to aim for genericity. This contributed to the benefit of the current system being applicable in a wide array of use cases. While desirable for developing our application, some of the valued flexibility needs to be toned down to enter a testing phase. Especially considering that such a generic approach gives way to plenty related problems, such as volatility of standards or frameworks, or the closed shop mentality of many wearable device distributors.

A first measure of toning down flexibility will be to settle for a selection of vital data points relevant to the use case of oncology, selecting appropriate sensor types for measuring said data points, and choosing devices that offer the required services. The selection of appropriate sensors, or rather devices, presents a somewhat harder challenge. In addition to technical requirements, user acceptance is crucial for the success of both testing and operation of the project, including factors such as comfort, ease of use, aesthetics, or even brand loyalty.

As expected in the current stage of development, some additional questions remain open, and some decisions may be overthrown in the future. For example, the mobile application for patients currently stops sending data once the user closes the application on their phone. While this is an easy way to give control to the patient, this design decision may deviate from the user's assumption of the app, or create a conflict between the wish to keep the list of opened applications tidy while still passively sending out data. There are several alternate approaches, each of which needs to be checked with user compliance. While the functionality and basic structure of the bwHealthApp is clear and functioning it is not evaluated if and how the system is accepted in the field. In a subsequent study the usability and overall practicability of the presented approach will be examined.

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