https://doi.org/10.2352/ISSN.2470-1173.2018.06.MOBMU-406
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Development of a mobile deployable technical system for the secure and paperless exchange of information between general practitioners and doctors' practices out in the field and laboratories

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Abstract

This paper deals with the description of our new development of a mobile system for general practitioners and doctors' practices. It is Intended to simplify the complex and error-prone work process of a home visit to patients and to Ensure a high degree of accuracy and correctness.

The system besteht of a technical device (similar in size to a smartphone) and a customized software.

The hardware component is to realize the connection and reading of the medical analyzers used in the practices (eg. Blood glucose, blood lipids, blood oxygen equipment, etc.).

The software component is Intended to Ensure the secure, paperless exchange of information between home doctors and doctors' offices in the field of external use and laboratories.

Overall Document Guidelines: Head

In 2015, the National Regulatory Control Council (NKR) published within the project "More time for treatment," an inquiry carried out by the Federal Statistical Office inventory measuring the cost of contract doctors and psychotherapists. The result was that the state emerged in 2013 outside the actual treatment costs at the federal level annual costs of more than 2 billion euros. This corresponds to around 55 million hours that were not as therapy time for the treatment of patients. The main share of this from the cost of compliance with bureaucratic requirements for compliance with information obligations of joint self-government.

For everyday work in general practices caring for patients is one of the living environment. These are in addition to patients who are visited at home, on a large scale patients living in residential institutions such as nursing homes or in assisted living. To perform a proper site survey, the doctor has a very high technical, work and organizational effort. GPs work an average of 56 and specialists 53 hours a week. Many of the costs incurred in the course of an investigation undoubtedly necessary work must currently be performed manually and with different, mutually incompatible technical systems.

The doctor needs to collect and sort all patient data and preliminary findings and create a patient order it by hand in the preparation phase. He also has to hold a lot of extra work materials and technical examination devices and take them to the patient. This includes material for blood collection, a smart card reader, point-of-care devices and various documents. Locally, the electronic health card is read, bled and made further investigations. In the doctor's office all information must be processed, sorted and stored after the examination. The patient order is completed with the accrued patient information and sent to an appointed laboratory. Because of these many manual steps, which are caused by different and mutually incompatible technical systems throughout the workflow many sources of error may arise. The associated labor, time and cost is very high and at the loss of treatment time. The resident doctor is not only physicians, but also an entrepreneur. He must think and act economically and use the reserves, he has to ensure the optimal treatment optimal.

After practitioner surveys a home visit lasts with all upstream and downstream tasks currently an average of 45 minutes (without drive). Of this amount, approximately 20 to 25 minutes for the actual therapy time. If the product is developed in the project employed can be the time and labor required for the preparation time by about 45 - 50%, which are about 9 - reduce 10 minutes. Thus the trend began around 2012 is still supported for paperless practice.

According to the CBD were 2,015 throughout the country about 52,000 family doctors - either in independent practice or as salaried doctors in group practices involved. In monthly average of 15 home visits, where the number is regionally very different, there is a - computational - savings of approximately 1.5 million hours. Based on the average annual turnover of a general practice corresponds to a monetary value of approximately 13.5 million euros.

Our product development is to act as an interface between the various technical applications, which employs a doctor's office. There are a variety solved currently existing technical problems in doctor's offices and laboratory areas. The challenge in the development of the system is the combination of many different analytical devices such as blood sugar, blood oxygen devices (point-of-care devices, referred to below as POC), barcode scanners, barcode printers, smart card reader and other medical examination equipment. They are connected not only with each other but exchange the collected and analyzed data and information with each other. These include the automated creation, management and analysis of laboratory orders at a central location and compliance with modern IT security and data protection standards such. B. OWASP or BSI Baseline Protection / ISO 27001.

motivation

leading competitive products / procedures, international and current state of the art, indicating the characteristic technical data in comparison with their own development objectives

As in paragraph 1.1. already mentioned, the technical and labor time required to perform a home visit and the associated creation of a laboratory order is very high and prone to error.

Mirth Connect
poctGate
labGate

According to today's state of the art, the doctor takes a lot of different technical systems to perform a home visit and to prepare a laboratory order. To prepare the necessary patient data from the operated by the doctor doctor information system are often still manually documented on paper. The physician information systems used such as CGM MediStar, x.Concept or QuincyWIN are either not able to provide data beyond practice electronically available or can only view through a web portal. But the data required can be edited either directly, be taken for further processing in a laboratory order.

The reason for this is often due to the nature of the software implementation of the products. These were developed years ago for a certain functionality and location (desktop or in the laboratory practice) and were from a technological perspective never designed for mobile to be used.

To be developed in this project is novel product from a technological point of view, because it is very modular. It is designed not only for one application, but can be used for many future areas of application depending on requirements and implemented modules. It is designed from the outset as a mobile application and is therefore very well suited to such. To be served as smartphones or tablets.

Locally, the doctor needs another work equipment and technically compatible with each other analyzers in addition to the laboratory order form. These include acceptance materials (blood collection tube), point-of-care equipment for determination of z. B. blood sugar, iron and blood oxygen levels and a health card reader. Bar codes are used for the personalization of sample tubes that have to be glued to the tube on site for each patient. Are point-of-care equipment used on site, the results must be transmitted mostly by hand, as this date is technically not able to give the data directly on.

Currently, the data is either stored internally on the devices and software can put in practice with the, usually by the manufacturer are available to be read. Here is the cause, similar to the doctor information systems, the former objective in the development of the devices. Originally, these devices have been developed for use in laboratories and surgeries and needed for this purpose only certain hardware and software features. These functions (or interfaces) were not designed in this case for the analysis of data to be released mobile.

We use proprietary hardware box here to be solved this problem. The POC devices usually have a USB or network interfaces that are not well suited for connection to a smartphone or tablet constructional reasons. The hardware box will include all standard interfaces such as USB, network or COM and spread over an area in the mobile and standardized interfaces to pass (Bluetooth, Wi-Fi).

After the completion of the home visits, the data and results collected must be entered again manually in the medical information systems and a laboratory order are generated.

For the commissioning of laboratory orders an order entry system as labGate, CGM Channel, MIPS or Cyberlab Dorner exists in many doctors' offices. This order-entry systems are currently able to communicate with certain other technical systems and to transmit it to a lab laboratory orders. However, the connection in this case only within a practice and not across and mobile. The communication of order and finding is currently therefore possible only within the practice. In these systems, there is currently an opportunity through a web portal to access the data and retrieve information on the current laboratory orders. The web portals are not include new data in the location or further processing. The reasons for this match the descriptions to the doctor information systems.

From these descriptions, a variety of errors can occur in everyday practices. By the incompatibility of the various technical systems patient names are reversed because no unique sample identification is possible. There are recorded incorrect information to the patients of the documents by manually filling or entire records assigned to the wrong patient. In addition, a very large proportion of working time and costs spent for exchanging by data between the various technical systems. Often, the preliminary findings and patient data must be collected manually, the laboratory orders are filled manually and assigned to these samples those taken to create it an order for a laboratory.

Another problem is in the secure transmission and storage of particularly sensitive personal data, resulting from the described procedures. Through the various technical systems that are not properly compatible with each other, it is very difficult to implement or comply with all data protection and absolutely necessary IT security requirements. This addition to the very high administrative costs results in a high data protection and IT security risk to the personal data of patients.

Compared to the presented competitors in a technical system that is able to connect many different devices and applications with each other and to process the data collected in this project arises. It ensures accuracy over the entire work process and optimizes the time requirements.

To be developed in this project product will contain the following important parts and combine:

- Mobile full access to the medical information system
- mobile reading and processing of data from point-of-care systems using hardware box
- mobile reading and processing of the information of the health card
- Clear and accurate personalization of the sample tubes with RFID / NFC
- direct connection to the order- entry system and automatic generation of a laboratory order

- observance and application of current IT security and data protection standards, such as OWASP and BSI basic protection / ISO 27001

The aim is to develop a technical system that optimizes the entire workflow of a home visit. The challenge and the focus be primarily on the compound of the hardware box with the POC devices and the optimization of technical processes. The results of development (product and process innovation in e-health area) will be portable and meet the current IT security and data protection standards. With our development, the existing technical applications, such as medical information systems or order entry systems to be connected through their own interfaces. This concerns in particular the analysis systems in laboratories.

Implementation

Project objective and content is to develop a mobile deployable technical system for the safe and paperless exchange of information between family doctors / clinics out in the field and laboratories. It will simplify the complex and error-prone work process of a home visit to the patient's strong and ensure high accuracy.

The system consists of a technical device, the size comparable to a smartphone and a customized software. The hardware component is to realize the connection and the reading of the medical analysis equipment used in the practices (eg. As blood glucose, blood lipid, blood oxygen equipment, etc.). The software component will ensure the safe and paperless exchange of information between primary care physicians and medical practices out in the field and laboratories.

1.3. Targeted technical capabilities and relevant parameters with associated approach

in the project to develop a software application for the most common mobile operating systems (Android, iOS, Windows) hardware for the connection of currently available laboratory equipment (POC) and. The hardware box will read the wired medical instruments (eg. As via USB, network port) and pass via Bluetooth or Wi-Fi to the software application. The choice of optimum standards is part of the project. These technical solutions, complexity and security issues are among others contrasted and compared.

Concept for reading the unknown proprietary data formats. The example whether data of POC can ever be transferred. The basic concept for reading the POC devices based on the development of a middleware for each POC device. The middleware is a "translator" that converts the questions raised by POCGerät available proprietary data in a known protocol. A middleware is a layer between the POC device and the standardized protocol used (eg. B. POCT1A, HL7) in this case, and must be able to convert the data into an understandable format. It can be understood as a kind of translator. If, for example, the POC device XYZ be connected to the mobile app, in the first step examines the hardware interface it has (USB, LAN, etc.). Does the POC device via a hardware interface (USB, LAN, etc.) must be checked if it is addressed with this, so data can be read. If so, the read data is analyzed (study the nature, scale and accuracy) and a translator (middleware) developed that converts this data into a protocol understandable. If the read data in a known (text or database-based) format, they can be converted and processed. This includes the examination of the scope of data: for example, all data that is displayed on the screen of the device or entered on the device also included in the read data and error-free.

The following interfaces are implemented in the hardware box:

- Infrared
- USB
- RS232
- RJ45 LAN
- Wi-Fi
- Bluetooth
- NFC

via these interfaces the various analyzers can be connected to the box. For processing the data of the individual devices, the device-specific protocols must be analyzed and implemented. The following protocols are implemented:

- POCT1A
- ASTM
- MicroINR
- Proprietary data
- HL7
- LDT

Demands on to developing mobile application is to support as many known protocols that are commonly used in the medical development environment. Such as:

- POCT1A
- ASTM
- MicroINR
- HL7

These protocols are documented and standardized. By supporting a high functional results for the mobile application. In addition, the quality and credibility increased with respect to potential customers. Unfortunately talk, as in other technology sectors, not all manufacturers of these protocols. Often you use your own or modify the known specifications. Therefore it will be necessary for connecting the POC devices to the mobile application to develop mechanisms that can translate these proprietary protocols in an understandable format (next to paragraph).

If the data in an unknown or non-readable format, processing is more complex. Is a contact with the manufacturer possible and gives this information to its devices out, these devices can be integrated. If this is not the case, there is the possibility to analyze the data by a code analysis, or reverse engineering techniques, however, this is very time consuming and labor intensive. The focus is on the connection of the POC devices whose protocol is documented and accessible.

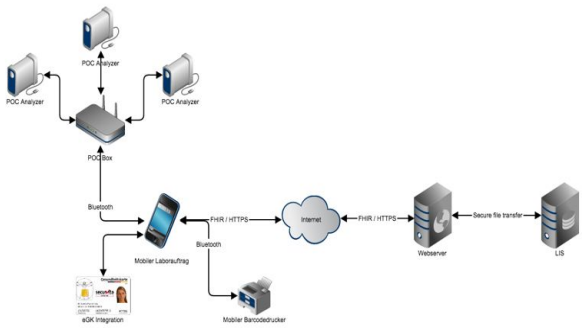

Figure 1. *Overview Graphic of the entire system*

The individual components are shown again in Fig. 1 and FIG. 2. The POC devices to be connected to the mobile app using the hardware box. Health card and the barcode printer can exchange data expected to directly, or with an adapter, with the mobile application.

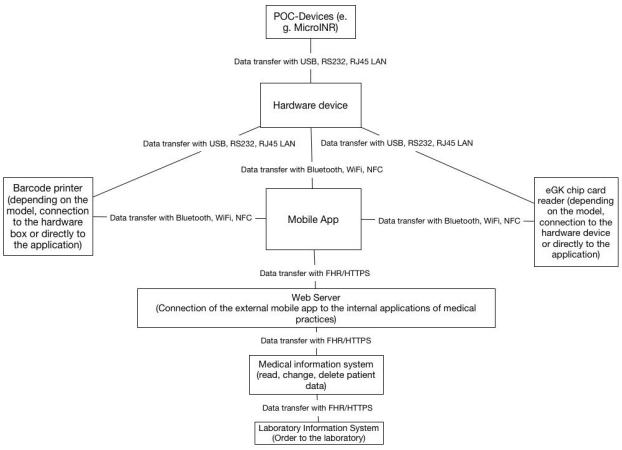

Figure 2. *Data flow of the individual components*

Several new interfaces are developed for the application to be created along with the hardware box and implemented.

In the first step, an interface for connecting selected point-of-care devices is developed. These must be capable of evaluating the various technical output logs of point-of-care devices and transfer them into the existing system.

A common POC device is z. As the MicroINR the AXON LAB. This is a portable analyzer for determining blood coagulation time. The INR value indicates how long it takes for the blood to clot. The MicroINR finds its use in the professional sector (hospitals, physicians' offices, outpatient care facilities) as well as in the private sector for patient self-management (see Fig. 2).

Are often carried:

- blood sugar,
- •, blood fat
- Blutgerinnungszeit-,
- Blood oxygen devices

Figure 3. *MicroINR the AXON LAB*

Although the MicroINR is designated by the manufacturer as smart, it has only one USB port and a proprietary proprietary data format (as MicroINR USB protocol called).

In the project an interface that is designed for this and other POC devices which is able to transmit the acquired data on the hardware box to the mobile app.

The second interface will ensure the link to standard medical information systems. You will be able to read not only the content of such a technical system, but also support the changing, adding and removing data.

To a method for reading of the health card is implemented in due course. This makes it possible to take on new patients locally in the system or update in the new quarter. For implementing a card reader is needed. In the project several possible devices are tested for their suitability and implemented where appropriate. By way of example, there are by the company IDENTOS a reader that can be connected directly to a smartphone (designation: ISO 7816 Crypto terminal, see Fig. 3). The functions of this unit must then be implemented for mobile applications.

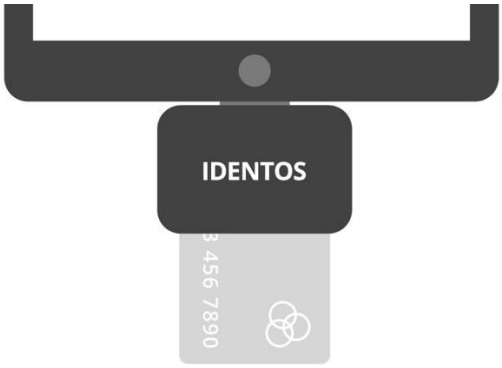

Figure 4. IDENTOS ISO 7816 Crypto Terminal

According to recent reports from industry and research, the need for an error-free system for labeling and classification of the sample tube, the z. For example, during a blood collection, very high. This is to be realized with new sample tubes that have integrated an RFID chip or stickers. Therefore, an RFID / NFC interface is integrated into the product. Thus, each sample can be detected by an RFID chip on the sample tubes and associated error-free to the respective patient.

For the currently used test tube with barcode connection to a bar code printer is also integrated and the application can directly read the bar codes affixed and processed.

Another interface must be implemented for the connection to selected order entry systems. This must also have data etc. the functionality to read, edit, remove. The emphasis here is on the automatic creation of a laboratory order directly on the mobile device.

The entire development process is carried out taking into account modern and established standards such as HL7 Fhir. Here, current data protection and IT security measures such as OWASP and BSI basic protection / ISO 27001 are considered and implemented.

The development projects (hardware and software) includes the following modules:

Hardware:

The hardware box handles communication between the POC devices and the mobile application. She uses for the connector module. It consists of a micro-computer (such. As Raspberry Pi, Arduino), which is equipped with different interfaces (USB, Wi-Fi, Bluetooth). It must have its own power supply available (battery) and be as light as possible and work energy efficient. It is connected to the individual POC devices and sends the read data wirelessly to the mobile application (see Fig. 1).

Connector module

using the connector module is the app to connect in conjunction with the hardware box, capable of different laboratory equipment via different standards. These are often to USB interfaces with proprietary protocols (eg. As Axonlab MicroINR via USB). When the module is to be developed to existing industry standards secure resorted (z. B. HL7 IHE, HL7 Fhir). The implementation is modular here, since future use is sought in similar applications.

Commissioning of POC orders

over the phone, it is possible to scan a patient's wristband. About this scanning function, it is possible to transmit the case or patient number directly without manual error sources to the POC device. In the scope of the project must be checked which support analyzers this bidirectional connection. For this functionality, a module for capturing patient and order codes must be developed and implemented. This must be able to read data reliably and to pass on to the other features.

Commissioning of laboratory results for a central laboratory

is implementing a module that allows a family doctor laboratory profiles may engage directly via smartphone when connected central laboratory. To this end, barcode labels or collection systems are required with RFID chips. Within the project it is necessary to specify the appropriate hardware and protocols and to integrate the interfaces in the mobile application.

Smart card reader for the integration of the electronic health card

To all payroll-relevant patient information for the laboratory order to obtain it is necessary to identify these automated. These mobile readers are evaluated and integrated interfaces to these devices in the mobile laboratory order.

Finding representation of POC results

The finding representation is used for tabular and graphical representation of measured laboratory values. Measurement results can be checked in case of need for a better visualization in pathological laboratory values to achieve. In addition, targeted multimedia data (Elektrophoresekurve, etc.) represent via smartphone. The data source is a secure web portal serves. In this portal, the measurement results after each measurement be safely imported. If necessary, the medical staff has read access at any time to these results. In pathological abnormalities alarm via push notification directly to the user takes place.

Server side

for the connection of the individual modules and the display of the collected information is standardized server applications and server systems implemented (Web server, laboratory information systems (LIS)).

Implementation of current data protection and IT security measures

manufacturer or developer of healthcare apps that the Medical Devices Act (MPG) subject to undertake quality assurance among others its development, risk-aware, user meet and perform for the West German laws. For e-health apps laws and standards apply to medical devices.

For manufacturers and developers has the Düsseldorf Circle, a meeting of the top data supervisors in the private sector, issued instructions for the development and operation of apps in June 2014 based on the German data protection law. This guidance refers to the basic principles of data protection and regulations that must be followed during the integration of content and in the technical design of an app. Developer and manufacturer is noted

that during the planning and development phase of an app these regulatory aspects must be considered. Unless the app vendors have their headquarters in the Federal Republic of Germany, they must abide by § 1 BDSG to the German data protection laws. Content to other data protection regulations are among others in the Telemedia Act (TMG) application.

The following principles are used for the implementation used:

- prohibition permission title (§ 4 1 BDSG.)
- Data reduction and data economy (§ 3a Act)
- a direct survey(§ 4 2
- Purpose bond (including § 4 3 BDSGBDSG.)., § 14 para. 1 BDSG, § 28 para. 1 sentence 2 BDSG)
- principle of necessity
- access control
- access control
- access control
- relay control
- input control
- order control
- Availability control
- separation bid

concept for the development of the security architecture for the individual system components. The basis for the concept of the BSI basic protection catalogs and the ISO regulation 27001. These include the basic and general rules for designing the safety concept. Based on these rules, a must for the specific case, are developed a hardware box and mobile app, tailored concept and then implemented. The following diagram illustrates the general procedures are shown.

Figure 4. concept of security architecture ISO 27001

Within each of the steps shown an individual approach must be developed. In the first step of the entire project and in the further course of the project specifically for each hardware and software component of the project.

In general, the individual steps include:

- Analysis of
  - o All components of the project detect

all components of the individual components, functions, interfaces detect

- protection requirements
  - o determining the need for confidentiality, availability, integrity for all components of the project,

determining the need for confidentiality, availability, integrity for all components of the individual components, functions, interfaces

- selection of measures, security check
  - o modeling and development of appropriate IT Sicherheitsmaßnehmen and development of the first security checks for components of the project

modeling and development of appropriate IT Sicherheitsmaßnehmen and development of the first security checks for all components the individual components, functions, interfaces

- Supplemental security analysis
  - o Check for additional analysis needs and development of this, for all components of the project

check for additionalcozy analysis needs and development of this, for all components of the individual components, functions, interfaces

- Risk analysis
  - o identifyrisks, assess and treat for all components of the project

to identify, assess and handle all components of the individual components, functions, interfacesrisks

- Consolidation of measures
  - o develop lack of action andofon all components of the project to merge

develop lack policiesand bring together all the components of the individual components, functions, interfaces

- safety check II
  - o development of new, revised security checks for all components of the project

development of the new, revised security checks all the components of the individual components , functions, interfaces

- implementation of the measures
  - o performing all developed measures for all components of the project

performing all developed measures all Components of the individual components, functions, interfaces

Spoken in the list of development, making it the new development (R & D) meant these components. The BSI standard documents used as a basis do not include concrete contents or examples on the individual measures. Sie geben nur den theoretischen Rahmen vor.

Es muss also für jeden Teil des Projektes (z. B. für die Funktion der Datenübertragung zw. App und Hardwarebox) eine eigene, mit konkreten Informationen gefüllte, Vorgehensweise entwickelt und umgesetzt werden.

Bei der Umsetzung und Anwendung der entwickelten Maßnahmen auf die einzelnen Bestandteile, müssen diese Maßnahmen stetig überarbeitet oder neu entwickelt werden, um eine fehlerfreie Durchführung zu gewährleisten.

Bei der Entwicklung von Hard- oder Software-Produkten gibt es bekanntlich eine Vielzahl von Problemen, die sicherheitsrelevant sind. Für die Entwicklung dieser Produkte

müssen viele Teile und Module für die Hard- und Software implementiert werden. Diese Module und Funktionen sind sehr komplex, da sie viele sicherheitsrelevante Funktionen (wie z. B. Verschlüsselung, Kompression, Speicherung, Steuerung ...) enthalten und diese auch fehlerfrei ausführen müssen.

Daraus ergibt sich eine Problematik: auf Grund der hohen Komplexität und Kleinteiligkeit enthalten viele der entwickelten Produkte Implementierungsfehler sowohl in den Hard- als auch in den Software-Bestandteilen, die im späteren Verlauf der Entwicklung oder sogar erst in der Vermarktungsphase zu großen Sicherheitsproblemen führen können.

Dieses Problem betrifft nicht nur Entwicklungen von kleiner und mittlerer Produktkomplexität, sondern auch große Unternehmen wie Microsoft oder Samsung kämpfen bekannterweise mit Sicherheitslücken in ihren Soft- und Hardware-Produkten.

Ziel der Projektarbeiten an der THB ist die Entwicklung einer maßgeschneiderten Testumgebung, die mögliche Implementierungsfehler in Soft- und Hardware aufspürt. Sie thematisiert dabei auch die Überprüfung auf spezielle Fehler die in diesem Projekt (Entwicklung im medizinischen Bereich) auftreten können. Eine solche Testumgebung ist am Markt nicht verfügbar.

Diese geplante neuartige Test-Methodik (Testsoftware) erlaubt eine semiautomatische Prüfung und Analyse von Hard- und Softwarefehlern (fehlerhafte Datenformate, Kompatibilitätsprobleme, Synchronisationsprobleme).

Die dabei zu entwickelnden intelligenten Algorithmen sollen die Produktbestandteile analysieren, testen und auswerten können. Weiterhin müssen die Algorithmen in der Lage sind die anfallenden komplexen Untersuchungen zeitnah durch zu führen.

Die Algorithmen müssen modular und erweiterbar aufgebaut sein, da neue Analysemethoden hinzukommen können und die daraus entstehenden neuen Daten ausgewertet werden müssen. Die darauf basierenden entsprechenden Datenstrukturen müssen flexibel aufgebaut sein, um neue und optimierte Regelsätze leicht hinzufügen zu können.

Die THB besitzt ein innovatives IT-Sicherheitslabor mit einer umfangreichen Ausstattung und auf dem neuesten Stand der Technik. Der verantwortliche Professor und die am Projekt beteiligten Mitarbeiter verfügen über langjährige Erfahrung und Know-How auf dem Gebiet der Sicherheits- und Schwachstellenanalyse. Aufgrund dieser Eigenschaften ist eine Entwicklung zeitnah und konkurrenzfähig möglich.

Für die zu entwickelnden Bestandteile und Funktionen (Algorithmen) siehe Tabelle AP 5.

Zusammengefasst ist das Ziel dieses Projektes, die Erstellung eines mobilen technischen Systems, das aus den folgenden Modulen und Schnittstellen besteht:

- Hardwarebox zur Ansteuerung der POC, eGK, Barcodedrucker Geräte
- mobile Applikation auf Android-Smartphones
- Schnittstelle zu Arztinformationssystemen (AIS)
- Schnittstelle zu Point-of-Care-Geräten (AXONLAB, MicroINR via USB oder Netzwerkanschluss zu Bluetooth)
- Schnittstelle zur elektronischen Gesundheitskarte (Chipkatenlesegerät) (eGK)
- Schnittstelle zu Laborinformationssystemen (Order-Entry)
- Schnittstelle zu RFID/NFC
- Schnittstelle zu Barcodedrucker (von USB oder Netzwerk zu Bluetooth)
- Anpassung neuer Standards wie HL7, FHIR
- Umsetzung aktueller Datenschutz- bzw. IT-Sicherheitsmaßnahmen wie OWASP bzw. BSI-Grundschutz/ISO 27001

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