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Design and Evaluation of a Multimodal mHealth based Medication Management System for Patient Self Administration

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***Abstract*—The intake of prescribed medication presents a challenge, in particular for elderly people and in cases where a variety of medications have to be taken in accordance to a complex schedule. To support patients with this task, an mHealth-concept was developed and evaluated in the course of a clinical trial. The system used a multimodal user interface concept, i.e. both RFID tags and barcodes to identify and document the intake of medications. Results of the clinical study with 20 patients indicate that the multimodal mHealth concept utilizing barcode and RFID tags enabled easy-to-use medication management. Although further clinical evaluation is needed to assess whether such a tool can also enhance adherence, the system shows the potential for targeting the problem of medication management with mHealth methods.**

I. Introduction

Medication adherence, i.e. the degree to which patient behaviour coincide with therapeutic regimen plays a major role for the success of drug based therapies. The lack of adherence may cause worsening of the health of patients in general, increase the risks of hospitalization [1], and, as a consequence, also increase costs [2].

A number of systems have been devised for adherence management. Examples are systems based on electronic pillboxes, bottles and blisters. Such systems often feature wireless communication capabilities that allow communicating the data to a host system for adherence analysis and evaluation [3].

On the other hand, an increasing number of healthcare related apps became available for smartphones in recent years, with apps for medication management accounting for a significant part of those (for example 1.7% of all healthcare related apps for Apple's iOS based devices deal with medication aspects [4]).

Those apps are supposed to support patients in their daily medication management, although very few of them have been evaluated thoroughly, let alone in clinical trials. Moreover, most of them lack a connection to telehealth systems and processes that would allow healthcare providers to keep well maintained medication lists and to help in medication management as part of their healthcare services.

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The identification of all medicinal products used by the patient is one of the pivotal issues that need to be solved in the first place by any medication management system. A particular challenge in this context is to provide patients with easy-to-use capabilities to self-administer the medication list, including information to as when is which medicinal product to be taken.

Near Field Communication (NFC) is a wireless interface increasingly available in current and future mobile phones and smartphones. It is a short range (<10cm) wireless technology evolving from radio frequency identification (RFID) [5]. NFC is well positioned to support any activity of users that can be mapped to a "tap and go" paradigm, e.g. where users need to "touch" items in their environment to initiate and perform a brief communication with this item, for example to read out sensor data. NFC is, therefore, one of the enablers of the "Internet of Things" [6].

We previously had utilized NFC in a number of projects to empower mHealth-based systems in support of chronically ill patients [7, 8] and research [9].

Recently, we reported on the evaluation of the technical feasibility and usability of a prototypical system based on NFC enabled electronic blisters (e-blisters) in an mHealth-based medication management solution [10].

Since those blisters are not yet available on a routine basis for all or at least the most common medicinal products, this concept was found not to be ready for routine and widespread use. Huge challenges as regards the logistics necessary to supply patients with electronic blisters are still unsolved.

The aims of the present work have been to design, develop and evaluate a multimodal medication management system utilizing two short-range data acquisition capabilities of contemporary smartphones, i.e. NFC to read RFID tags and the mobile phone cameras to scan barcodes. The hypothesis was that such a system can be established that is both easy to use by patients and based on already available technology so as to keep potential costs in an affordable range to eventually allow application in a wide variety of therapeutic settings.

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II. Material and Methods

A. Medication Identification

Figure 1 shows both methods used for identification of medicinal products. These are:

- barcodes (EAN-13) readily available on all medication boxes that are available on the market in Austria and
- RFID tags (put there in the course of this work).

We used Mifare Classic 1K tags (NXP semiconductors N.V., Eindhoven, The Netherlands) that adhere to the ISO/IEC 14443 standard. Those tags can be read and written using the NFC feature of smartphones, in particular utilizing an openly available NFC Developer App [11]. The content of the RFID tag was derived from the respective EAN-13 barcodes and, thus, allowed to unequivocally identify the medicinal product in the same way as the barcode did.

Figure 1. Example for a medication box with barcode and RFID tag

B. Medication Management

The medication management was supported by an android based software application. The software was developed to run on NFC enabled smartphones (LG L5, LG, Seoul, South Korea). The documentation of medication intake could be started by touching the medication box with the NFC enabled smartphone (Figure 2).

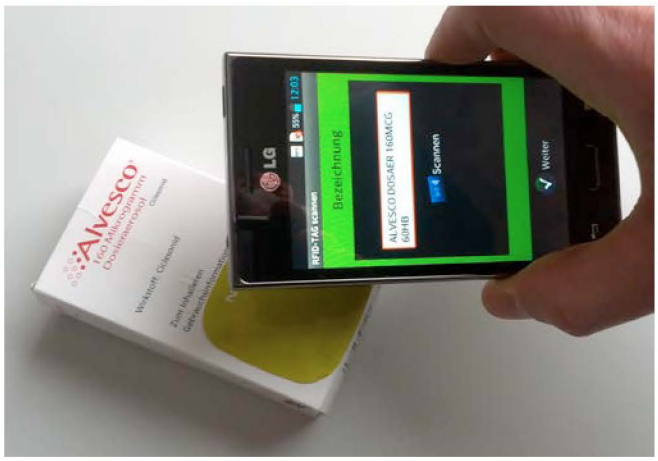

Figure 2. Action of identifying a medicinal product by touching the medication box with the NFC enabled smartphone.

When the RFID tag was read out for the first time, related information like intake characteristic, (regularly or on demand) intake schedule and, - if desired - an additional question had to be defined by the patient after scanning the barcode. This additional question was then asked each time after documentation of that specific drug.

The documentation of intake was initiated either by touching the application button on the display or by touching the RFID tag. In both cases, the main menu was shown where a barcode scan can be initiated.

The documented intake of medication was stored in a SQLite database on the smartphone. The architecture of the database consisted of tables for the drug, the prescribed schedule, the linkage between unique ID stored on the RFID tag and the drug, and the table to keep track of the adherence, i.e. store the data on the intake as documented by the patient. In the drug table, all relevant data from the Austrian "Apothekerverlag" pharmaceutical database was stored like the name of the drug etc.

The documentation of medication intake was clustered in specific time-slots for morning, midday, evening and night (Figure 3).

Figure 3. Defined time slots for each time of day category.

In the main menu of the application only drugs were listed that had been prescribed for the actual time slot. After documentation of the intake the drug disappeared from that list. Additionally, the total medication of the actual day could be displayed by the patient (Figure 4). Symbols were indicating the various time slots. The symbol "B" indicated drugs that were to be taken "on demand", i.e. based on autonomous decisions by the patients.

Figure 4. Left: main menu with the medication schedule for morning; Right: total medication schedule of the actual day

When the documentation of an intake was not done within the scheduled time slot, a reminder dialog appeared after any further action until the patient provided the required

information. Thus, prescribed medication that was not taken had to be dealt with, too. If a drug was taken out of schedule, a warning was issued.

III. RESULTS

In the course of a clinical trial, patients evaluated the usability of the proposed medication management system using NFC enabled smartphones and RFID tags as well as the phone's camera to scan barcodes. The subjects were asked to document their medication for the duration of a week and to answer a questionnaire regarding the usability of the system.

The main focus of the trial was on the multimodal drug identification process, facilitated by barcodes and RFID tags. In order to assess both elements, the subjects were asked to document the intake of one drug by barcode scan and the rest of the drugs with RFID tags.

After having obtained approval from the Ethics committee, patient recruitment started at the cardiology outpatient clinic of the Medical University of Graz. A total of 20 patients were enrolled to the study (four women and 16 men). Sixteen patients completed their questionnaires and 15 provided datasets that could be analyzed.

The mean age of the study subjects was 51.3 ± 20.4 years (min=20 years, max=81 years). Before the start of the study, all subjects already had a mobile phone in use. However, subjects over the age of 59 years used their mobile phone exclusively for phone calls. Four out of six subjects younger than 40 years used mobile apps as well as the internet on the mobile phone. In the age group 40 to 59 years, two out of five were using mobile apps and three out of five the internet on their mobile phone.

For most subjects, learning how to operate the smartphone and the medication application was very easy without any help (Figure 5).

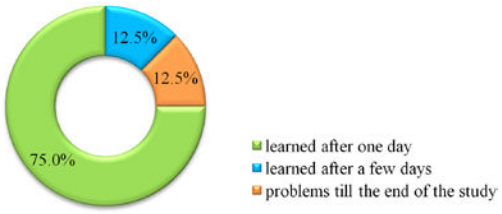

Figure 5. Usability of the medication self-management system

After one day, 12 (75%) of all subjects were able to operate the system and two (12.5%) after a few days. Only two patients (12.5%) had problems until the end of the study. Three patients had problems with the identification of a drug using the barcode scan and two by reading-out the RFID tag. The design of the application was found to be good (mean 2.1 ± 1 on a scale of 1 to 5, with 1 being the best).

The prescription of the medication of all subjects spanned all time-slots, i.e. morning, midday, evening and night. Figure 6 shows the number of prescribed drugs in each time-slot. Most of the drugs were taken in the morning and in the evening and one drug on average at midday. Some subjects had also prescribed drugs at night.

The results of medication adherence documentation are shown in Table 1. Overall, 559 data entries of the 15 datasets were analyzed. On average each subject was able to register 3.6 ± 2.3 drugs correctly after 0.7 ± 1.1 failed attempts. The person with the most daily intakes (12 intakes per day) documented 100 single intakes successfully. The average number of single entries was 37.3 ± 24.3 intakes per subject. Since patients were asked to document the intake of one type of medication by barcode scan and the rest of the drugs with RFID tags, 63.5% of all documentation entries were done by RFID and 36.5% by barcode scan.

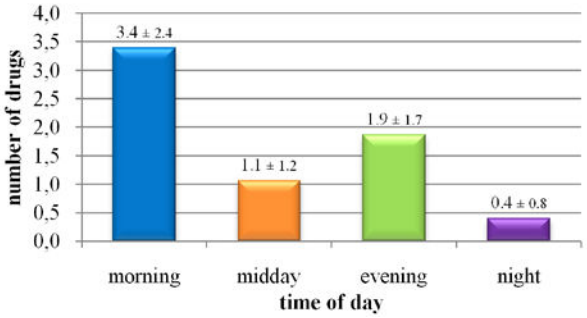

Figure 6. Number of drugs prescribed within a particular time-slot

All prescribed drugs were documented to 100% without any documentation gaps. Overall 26.6% ± 18.6% of all entries were documented with a delayed, i.e. outside of the designated time-slots. Three subjects did all documentation in time and one subject documented 58.6% outside of the designated time-slots.

TABLE I. RESULTS OF MEDICATION MONITORING

	Number of Different drugs correctly registered	Initial number of failed trials	daily intakes	single intakes/ entries
Mean	3.6	0.7	4.9	37.3
standard deviation	2.3	1.1	3	24.3
minimum	1	0	1	7
maximum	9	4	12	100
Total	55	11	74	559
with Barcode scan	55	-	15(20.3 %)	204(36.5 %)
with RFID tag	40	-	59(79.7 %)	355(63.5 %)

Figure 7 shows the details of intake over the whole study period of one week in a single subject. One drug was taken in the morning between 6 o'clock and 10 o'clock. The other drug was taken at midday as well as in the evening ranging between 12 o'clock and 20 o'clock over a time period of 7 days. Although some medication intake was changed

between the defined time-slots, most of the daily intake was prescribed in the middle of the time-slots (morning 07:34 ± 00:54; midday 13:15 ± 01:17; evening: 18:46 ± 01:09; night: 21:34 ± 00:53).

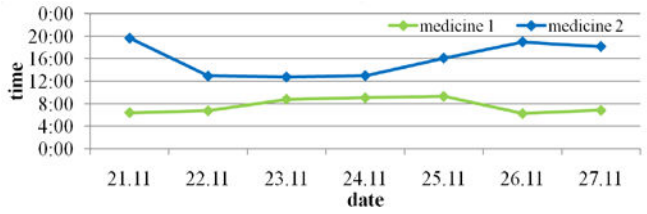

Figure 7. Example of daily intake over each day of one subject

With 0.4 ± 0.7 drugs per person, the possibility to document "on demand" medication was used only occasionally. Two subjects documented a modification of the prescribed dosage in 7.1% of their intakes.

IV. Discussion

Most of the subjects were able to document their medication intake and also to register their drugs at the beginning of the clinical study autonomously. This was the case despite the fact that the majority of patients did previously not use advanced features like Apps and the Internet on their mobile phones. In our view, pivotal factors which made this high rate of success possible were the intuitive menu design of the application and the easy and intuitive handling of barcode scan and RFID tags.

During the recruitment of study some patients were interested in participating in the study, but were afraid that they might not be able to register the medication list and schedule by themselves. This was particularly the case for people older than 60 years. A solution to this challenge could be a connection between the application and a telehealth system or an Electronic Health Record system like the upcoming "e-Medikation" system in Austrian. Such systems operated by healthcare providers should be linked and used to complement the mHealth concept and assist the patient by automatically maintain the list of medication.

Some of the subjects also noted that the used prototype isn't able to support patients, who sort their pills in drug dispensers. For these cases, the system needs to be extended towards using one RFID tag per time and pill dispenser compartment.

V. Conclusion

The obtained results indicate that multimodal medication self- management utilizing two short-range data acquisition capabilities of contemporary smartphones, i.e. NFC to read RFID tags and the phone's camera to scan barcodes is feasible. Before large scale adoption, however, some improvements like integration of pill dispensers are required. Our next activities will aim at the integration of this mHealth concept with telehealth systems and to assess whether such infrastructures can help to increase medication adherence in chronically ill patients.

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