Exploring Complexity in Health: An Interdisciplinary Systems Approach
A. Hoerbst et al. (Eds.)

doi:10.3233/978-1-61499-678-1-185

A Smartwatch-Driven Medication Management System Compliant to the German Medication Plan

Andreas KEIL[a,1], Konstantin GEGIER[a],
Monika POBIRUCHIN[b] and Martin WIESNER[a]
[a] *Dept. of Medical Informatics, Heilbronn University, Heilbronn, Germany*
[b] *GECKO Institute for Medicine, Informatics and Economics, Heilbronn, Germany*

Abstract. Medication adherence is an important factor for the outcome of medical therapies. To support high adherence levels, smartwatches can be used to assist the patient. However, a successful integration of such devices into clinicians' or general practitioners' information systems requires the use of standards. In this paper, a medication management system supplied with smartwatch generated feedback events is presented. It allows physicians to manage their patients' medications and track their adherence in real time. Moreover, it fosters interoperability via a ISO/IEC 16022 data matrix which encodes related medication data in compliance with the German Medication Plan specification.

Keywords. Adherence, Medication Plan, Interoperability, Smartwatches

1. Introduction

Medication adherence is generally defined as "the extent to which patients take medications as prescribed by their health care providers" [1]. In the past, several concepts have been discussed how the use of information technology can increase the level of patient safety [2]. However, despite numerous digital opportunities, drugs are still often prescribed in a primarily paper-based way. Several drawbacks, such as readability, error-prone transcription or misinterpretation by different health care providers (HCPs) can pose a safety risk to patients.

In the near future, a uniform medication plan (MP) will be propagated on a nationwide scale in Germany [3]. The federal medication plan – referred to as *Bundesmedikationsplan* – provides a consensus-based data scheme and "compiles all the information in an electronic two-dimensional data matrix code thus facilitating the modification of these schedules by any HCP"[4]. Thus, such a standardized MP can foster the interoperability among different healthcare information systems by providing structured and machine processible information on a patient's current drug prescriptions. In this context, the emergence of ubiquitous mobile devices and the availability of smart medication reminder applications [5–6] in digital app marketplaces target an increasing number of patients with acute or chronic diseases. In the past, numerous smartphone based-medication reminders have been presented [7, 8].

[1] Corresponding Author: akeil@stud.hs-heilbronn.de, Twitter: @t4deon

However, these mostly consumer-oriented apps lack the support to (a) *create*, (b) *manage* or (c) *im- or export* MPs in structured nationwide data format.

In this paper, a first prototype of such a system is presented. It supports several use cases of the *Bundesmedikationsplan* and is part of a larger technology assessment study which will analyze the effects smartwatches might have on medication adherence.

2. Methods & Material

A digital medication management system involves different specifications and standards of which some are specific to the German healthcare system.

2.1. Medication Plan – BÄK specification

The German MP according to the BÄK[2] specification [3] describes a document format that encapsulates a detailed, patient specific drug listing. Besides basic patient information, it includes the trade names, active substances, doses and dosage forms of the drugs as well as the intake schemes with the corresponding intake units, for instance *drops*. The plan also provides the prescription cause and additional medical notes. There are different drug categories, e.g., *medication on demand*, *long-term medication*, *self medication* and several others. The MP can be modified and adjusted by clinicians, general practitioners or pharmacists. It has different objectives: i) a patient keeps track of prescribed drugs and related intake information, ii) a practitioner obtains a general overview of the current medication scheme and thus knowledge on potentially harmful drug interactions, iii) for a clinician the MP structures drug information involved in the therapy and rehabilitation process and iv) a pharmacist can advise well-priced alternatives based on active substance information.

On a semantic level, the BÄK MP offers a detailed feature specification on how drug prescriptions should be documented. It contains feature categories for *dosage forms*, *units* and corresponding characteristic values. Some features are rather fine-grained. For instance, three *dosage forms* exist describing drops: (a) *eye drops*, (b) *eye and ear drops* and (c) *ear drops*.

Still, the BÄK MP is oriented for a paper-based document use case. Yet, by design, it also offers a data matrix code which represents all medication data in a machine processible format for inter-exchange with other information systems.

2.2. Medication Plan – HL7/CDA specification

Another more standard-oriented specification is proposed and maintained by the German HL7 working group [9]. The *Patientenbezogener Medikationsplan*[3] (PMP) makes use of accepted international standards such as CDA or LOINC. It references standardized terminology as provided by *code-sets*. This specification is based on XML-structured documents and allows for complex integration and data transformation scenarios. However, at the time of this work and to the best knowledge of the authors, no freely available implementation of the PMP specification exists covering all required use-cases.

---

[2] *Bundesärztekammer*, engl.: German Medical Association (GMA)

[3] engl.: patient-oriented medication plan

2.3. Data Exchange - Data Matrix (ISO/IEC 16022)

According to the ISO/IEC 16022 specification [10], a "Data Matrix is a two-dimensional matrix symbology, which is made of nominally square modules arranged within a perimeter finder pattern". For the purpose of MP exchange, a 2D bar code can encode up to 3116 ASCII (256 byte) characters. Camera-equipped devices can scan and interpret this data for display or informational purposes. As defined in the BÄK MP specification (see Section 2.1), this standard is also used to exchange data among different HCPs.

2.4. Compendiums on Drug Data

There are several drug compendiums in Germany, e.g., *ifap Index* and *Scholz-Datenbank.* Another well known example is the *Rote Liste* (engl.: Red List, RL). It provides several information on drugs including their trade name, manufacturer, active substances, dosage forms and other information. Yet, not all information systems are connected to such compendiums due to commercial licensing and non-existent open APIs. Moreover, there are different concepts which actually refer to the same concept on a semantic level. For instance, there are dosage forms called (a) *eye drops* and (b) *eye drops suspension* or (c) *eye ointment and suspension.* All these terms describe similar concepts which have a slightly different meaning, but basically refer to *drop* or *ointment*. As there is no standardized German dosage form terminology, all those aforementioned concepts can't be interpreted in a precise and unambiguous manner by software systems.

3. Results

The presented prototype aims to support physicians in (a) managing medication plans, (b) tracking and (c) thus improving the medication adherence of their patients.

3.1. System Context & Architecture

For this purpose, a physician adds or modifies an existing medication entry via the web-based user interface (Web-UI) of the management system (1) (see Figure 1). Next, the modified medication plan is persisted into a database (2) and MP's digital representation (*Data Matrix*) is updated accordingly (3).

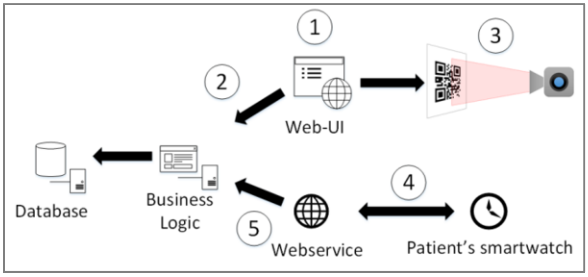

Figure 1. Workflow and system context of the medication management system. The primary system component (1) allows for structured medication data entry (2). The endpoints (3) and (4) represent external data consumers, i.e., other information systems interacting with digital MPs.

On the consumer side, a patient's smartwatch retrieves a current version of the medication schedule or pushes an event to a REST-ful web service, in case a medication has been taken or postponed (4). After this step, the updated information on this patient-generated drug event is processed and stored on the database side (5). In this context, the physician is thereby enabled to analyze a patient's medication adherence in real time via his/her account for the management web-based UI.

3.2. Medication Management View

The system offers a dedicated view to modify a patient's latest MP, shown in Figure 2.

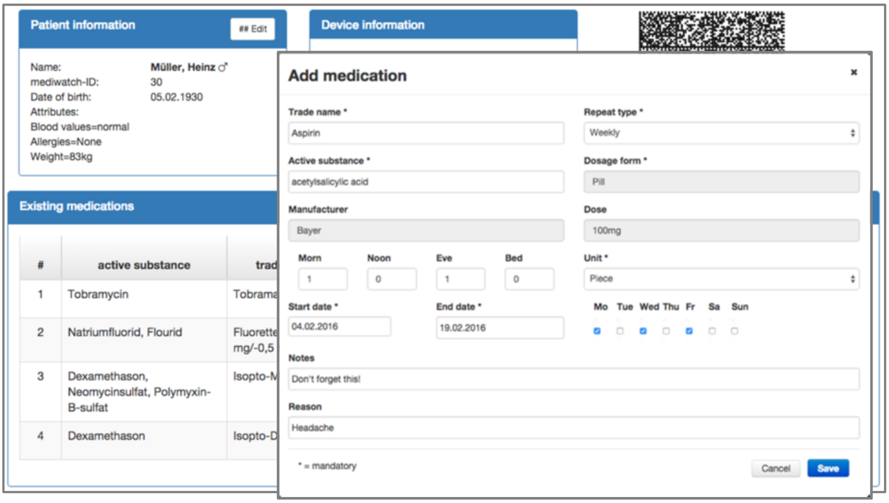

Figure 2. The medication prescription view of the system. To the right: Structured definition of entries with support for different medication schemes (once, hourly, daily, weekly, month).

The main medication entry dialog is displayed to the right side. In this dialog, an authorized health professional can enter trade names or active substances to select a drug which shall be prescribed. If only the trade name is entered, the corresponding active substance, dosage form, dose and manufacturer are auto-completed.

The intake scheme is then specified in the format: morning (*Mo*), noon (*Mi*), evening (*Ab*) and bed (*zN*).

As depicted in Figure 3, the associated Data Matrix code is directly updated after the medication entry process is completed by the clinician. In this context, the explicit and well-structured definition of all relevant MP data entries has a major benefit. It enables physicians to precisely track their patients' medication intake over time, given that the smartwatch of each participant sends back confirmation events. Thus, individual medication adherence might rise, potentially resulting in a better treatment outcome over time.

4. Discussion

In this paper we presented a medication management system supported by smartwatch generated feedback events. This system enables clinical health professionals and/or study nurses to manage individual medication schemes of their

```
MP|1|1|Heinz|Müller||19305705|
mediwatch||||Blood values=normal|
Allergies=None|Weight=83kg|
Tobramycin|Tobramaxin|3 mg|TRO|
0-0-1-0|MESSBECHER|Natriumfluorid,
Flourid|Fluoretten 0,25 mg/-0,5 mg/-1,0
mg|0,553 mg/1,106 mg/2,212 mg|UNKNOWN|
1-1-0-1|MESSBECHER|[…]|#@
```

Figure 3. Example MP Data Matrix code as generated by the MediWatch Management System. To the right: A shortened textual representation of the 2D bar code's content as defined by the BÄK-MP specification.

patient cohort. Even though it is designed for a German setting, the architecture of the system can be adapted to other national constraints or legislative settings. Still, several limitations need to be addressed. First, the mapping of dosage form and dosage units from the RL to BÄK-MP only reflects a limited amount of test data. As there is no agreed terminology for drugs and medication schemes in Germany, the manual mappings process conducted in our systems poses a barrier for direct integration into existing clinical settings. Second, in a routine scenario our system needs to be connected to primary data sources of the hospital information system to access the patients or the locally provided drug compendium.

As a next step, the authors plan to evaluate the system with a group of physicians or study nurses. For this investigation we intent to partner up with a regional study center and thus evaluate if the system is ready for routine use.

References

[1] L. Osterberg, T. Blaschke. Adherence to medication. *N Engl J Med*, ***353***(5) (2005), 487-497.

[2] E. Ammenwerth, A.F. Aly, T. Bürkle, P. Christ, et. al. Memorandum on the use of information technology to improve medication safety. *Methods Inf Med*. 2014;**53**(5) 336-343.

[3] Federation for improvement of safety of pharmacotherapy in Germany. Specification for an individual medication schedule (V2.0), Available at: http://goo.gl/GqqIGA Accessed 28 Jan 2016.

[4] J. Freigofas, H.M. Seidling, R. Quinzler, B. Schöttker, K.U. Saum, H. Brenner, W.E. Haefeli. Characteristics of medication schedules used by elderly ambulatory patients. *European J of Clinical Pharmacology*. 2015;**71**(9), 1109-1120.

[5] S. Becker, A. Kribben, S. Meister, C.J. Diamantidis, N. Unger, A. Mitchell. User Profiles of a Smartphone Application to Support Drug Adherence - Experiences from the iNephro Project. *PLoS one* 2013;**8**(10).

[6] A. Mertens, P. Rasche, S. Theis, M. Wille, C. Schlick, S. Becker. Influence of Mobile ICT on the Adherence of Elderly People with Chronic Diseases. *In Human Aspects of IT for the Aged Population. Design for Everyday Life*. 2015, pp. 123-133. Springer International Publishing.

[7] L. Dayer, S. Heldenbrand, P. Anderson, P.O. Gubbins, B.C. Martin. Smartphone medication adherence apps: potential benefits to patients and providers. *J of the Am Pharmacists Assoc*, **53**(2) (2013), 172-181.

[8] S. Becker, C. Brandl, S. Meister, E. Nagel, T. Miron-Shatz, A. Mitchell, A. Kribben, U.V. Albrecht, A. Mertens. Demographic and Health Related Data of Users of a Mobile Application to Support Drug Adherence is Associated with Usage Duration and Intensity. *PloS one*, 2015;**10**(1), e0116980.

[9] German HL7 WG. Implementation Guide for a patient-oriented medication plan (V.0.97). Available at: http://wiki.hl7.de/index.php?title=IG:Patientenbezogener_Medikationsplan Accessed 04 Feb 2016.

[10] ISO/IEC 16022:2006. Information technology - Automatic identification and data capture techniques - Data Matrix bar code symbology specification, 2006.
Available at: http://www.iso.org/iso/catalogue_detail.htm?csnumber=44230 Accessed 28 Jan 2016.