

Improved Surveillance of Haemophilia Home Treatment Using Mobile Phones

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Abstract—Haemophilia is an inherited blood coagulation disorder which results in permanent disability due to repeated bleeding and early death. The availability of plasma derived or recombinant coagulation concentrates reduces the symptoms of this disease and allows the patient to live an almost normal life. The missing coagulation factor is administered intravenously on demand in case of bleeding symptoms or as prophylactic regimen mostly three times per week. The German law and also the law of many other countries require thorough documentation of in-hospital and patient home treatment. The common way of documentation is by paper diary. Professional control of home treatment is delayed until presentation at the haemophilia center and does not allow immediate monitoring of bleeding and treatment measures. Only the use of telemetric systems may provide possibilities for online documentation and therefore early recognition of critical bleeding episodes or concentrate use. In collaboration with medical experts on haemophilia treatment and on the basis of experiences with the electronic diary system “Haemoassist™”, as well as the use of the modern smartphones technology, a new telemetric system was developed at the Philipps-University in Marburg (Germany). This paper provides an overview of the new concept named “smart medication”.

Keywords—*Telemedicine; mobile phones; mobile application development; home treatment; chronic disease; Haemophilia.*

I. INTRODUCTION

Haemophilia is a rare x-chromosomal inherited disease with a prevalence of 1 in 20,000 males worldwide. The disease is characterized by the missing coagulation factor VIII (Haemophilia A) or IX (Haemophilia B) which untreated leads to spontaneous bleeding in major joints or soft tissue. Prior to the availability of factor VIII or IX

concentrates the average life expectancy was below 20 years of age. Repeated bleeding episodes led to progressive hemarthrosis and finally to often lethal cerebral hemorrhage. Since factor VIII and IX concentrates were available, life expectancy and quality increased dramatically. Unfortunately transmission of HIV and Hepatitis C virus by plasma derived factor treatment in the early 80th led to a dramatic drawback. As the coagulation factor has to be administered on a regular base (prophylactic treatment) mostly three times per week or immediately in case of suspected bleeding (on demand) the patients are trained for self home treatment from early childhood on. However, haemophilia treaters need to monitor home treatment according to German law, to assure cost effective treatment. In spite of the small number of patients haemophilia treatment required nearly 1.5 % of the overall German health care budget in 2010 [1]. Documentation and monitoring of self home treatment is done by paper based protocols presented during consultation in the haemophilia center. They don't allow immediate surveillance at the time of bleeding or treatment. Analyses of bleeding and treatment regimens are difficult and time consuming to obtain. Electronic devices have shown to be useful for online surveillance and further documentation [2]. Our aim was to improve and facilitate the use these devices.

At first this abstract gives a short overview about the current situation in haemophilia home treatment. The second section explains the need of treatment documentation, its requirements and specifics. The third section describes the platform “smart medication”, with its three applications, security issues in handling patient data, and planned future extensions. Finally a conclusion is given in section four.

II. HAEMOPHILIA HOME TREATMENT

Because of the contamination of the concentrates with blood-borne viruses (e.g., hepatitis viruses and HIV) in the past, every injection with human blood, plasma, and plasma-derived products must be recorded [3]. In Germany, the Transfusion Act (“Transfusionsgesetz”) regulates the documentation and requires the following data:

- Identification number of the patient, full name, date of birth, and address;
- Batch number;
- Date and time of the injection.

“The responsible haemophilia care center has to ensure that the data of the documentation can be used product- and patient-related” and that it can find and trace back any potential contaminated product [4]. The common way of documentation by the patient is to use a paper diary. Because of only occasional consultation (2-3 times per year) at the haemophilia center, bleeding and treatment problems are identified much later than they occur and are difficult and time consuming to analyze. As patients often live far away from the treatment center a higher frequency of consultation is not feasible. Patient hand written entries into the paper diary are often difficult to read and incomplete [5].

In contrast, entries into electronic devices allows the doctor to monitor the patients bleeding episodes and self-treatment regimen from everywhere at any time. The recorded data could help the doctor to find abnormal bleeding pattern on a regular base. All data are saved and backed up central in server rooms to avoid the risk of loss [8]. Smart electronic algorithms allow early identification of bleeding and treatment problems (alert) or incomplete documentation.

III. “SMART MEDICATION” – ASSISTANCE OF HOME TREATMENT

An electronic diary for the documentation of the haemophilia home treatment named “HaemoassistTM” system was developed by Wyeth-Pharma GmbH. The electronic handheld was tested in the last 5 years with more than 100 patients and the gained experience represent the basis for the development of the new system “smart medication” [6].

A. The System “smart medication”

“Smart medication” was solely developed as a scientific project in collaboration between the Philipps-University in Marburg, Germany, and Haemophilia treaters in Frankfurt and Münster, Germany. The established prototype is now in the process of presentation to industry for funding of the following pilot and outline process. Long term collaboration with insurance companies and federal institutions are in discussion (Figure 1). Google’s operating system Android for smartphones is currently the market leader worldwide and serves as initial basis for the following developments. “Smart medication” consists of the following components:

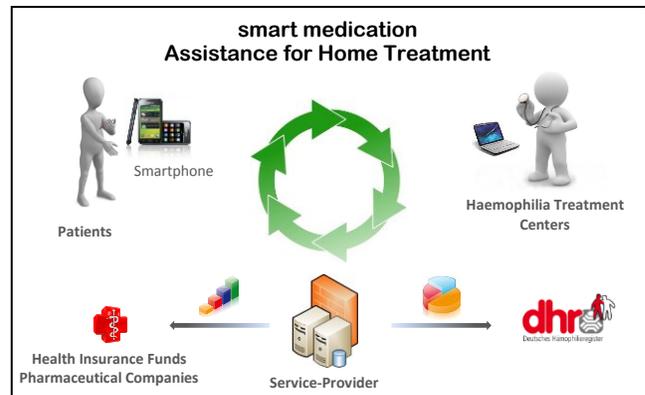


Figure 1. The concept of “smart medication” [10]

- Patients enter all bleeding and treatment data into a mobile device, which are then transmitted to the treatment center. The device can also be used as an emergency tool for direct contact (Phone call), transmission of text (SMS) or even photographs (e.g., swelling of joint) (Figure 3).
- Haemophilia treatment centers document any to a particular patient prescribed and dispensed concentrate batch by a mobile device allowing barcode scanning of the batch. The dispensed concentrate is electronically assigned to the patient stock and by this allows complete backtracking. Patients may find the available concentrate at their storage place but also as virtual storage on their mobile device. Treatment centers can early identify if the patient runs out of stock (low level) or does not document properly (higher than expected home stock). One of the main goals was easy and rapid application by the patient (Figure 2).
- A web-based monitoring tool allows the doctor an online overview of all treatment and bleeding data and simultaneous analysis of all treated patients (Figure 4). Emergency cases are presented as priority message. Defined electronic algorithms (alerts) allow rapid identification of bleeding and treatment problems as well as inappropriate documentation by the patient. Follow-Up data allow early identification of target joints (joints with repeated bleeding and progressive arthrosis).

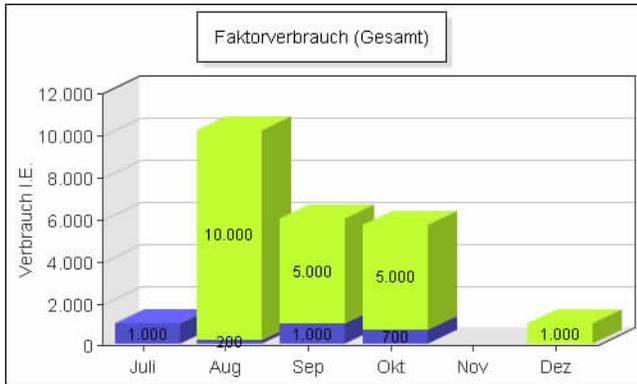


Figure 2. Factor consumption statistics

Analysis of the aggregated data also allow comparison between patient files within one center as well as comparison to pooled data of the other participating centers (benchmarking).

- For the Health Insurance companies, Pharmaceutical Companies and the federal organizations (e.g., German Haemophilia Register) the system could provide anonymized and aggregated analyses and statistics.



Figure 3. Screenshots of the applications.

B. Security

Especially the use of personal patient data requires a high standard of data security. During the development several safety functions were implemented in the system. Some of the most important are:

- A login per PIN/PUK.
- Encoded storage of the password per hash function (SHA-512).
- Encoded data communication per TLS/SSL-protocol
- Centralized data storage.
- A link between the application and the smartphone used.
- Validation of the entries on the phone and on the server.
- Consequent use of the recommendations of the German Federal Office for Information Security (see [11]).

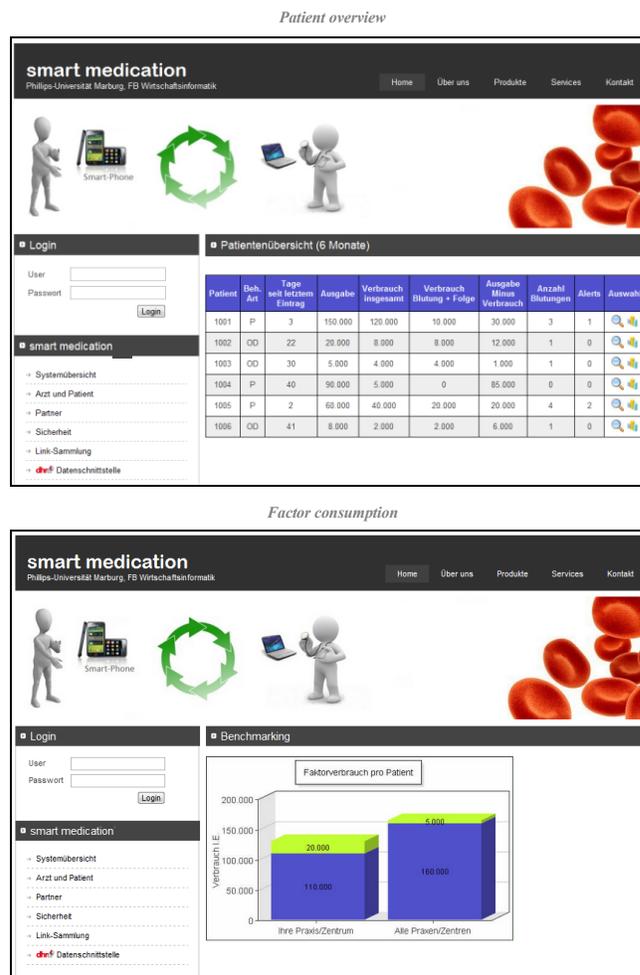


Figure 4. The website [9].

C. Future extensions

For developing these applications we used the experience of the former system “Haemoassist™” and worked together with several medical experts to enhance the benefit for the patient and medical attendance to a maximum. We used as a basis Google’s operating system Android. The next steps will be the adjustment and enhancement of the system by working together with some patients with severe haemophilia as test users, the preparation of the upcoming roll out in Germany and the hosting of the platform. The aim is also to migrate the application from Android to other operating systems like Apple’s iOS or RIM’s BlackBerry OS. Therefore the idea is to use HTML 5 and a cross-platform like PhoneGap (see [12]) or Titanium (see [13]) to gain productivity and lower maintenance costs when implementing on multiple platforms.

Besides the positive effects on the patient’s life and the advantage for the therapy we will analyze the monetary aspects of the employment of this electronic assistant system. We plan to work together with health insurance companies to explore the common costs of a patient with severe haemophilia in detail (e.g., the medicine consumption, the necessity of further treatments, and the need of visiting a haemophilia treatment center). The factor concentrates are some of the most expensive drugs. An unnecessary overuse induces high costs with no improvement for the patients’ health. In contrast a critical shortage can lead to an inability to work and thereby to even higher costs for the society. Therefore an optimized therapy can not only enhance the safety for the patient, but could also reduce the costs for the health care system.

IV. CONCLUSIONS

The genetic disease haemophilia needs life-long medical attendance and treatment. Appropriate use of the required concentrate by self-home treatment improves life expectancy and quality of life dramatically. However, close monitoring of home treatment by the haemophilia center is still mandatory. The still common use of paper based diaries doesn’t allow early identification of bleeding or treatment problems and are difficult to read and time consuming for further analyses. Modern mobile devices offer a simple and sustainable solution and can reduce the time and effort for patients own documentation but also for documentation by haemophilia treatment centers.

The intention of the system “smart medication” is to provide a full managed service platform for the patient and the responsible doctors. It provides an application for the patient to record all necessary information easily, fast, and secure, and offers emergency functions like sending messages and photographs, contacting the doctor directly, and initiating alerts autonomously. The recorded information fulfills the legal requirements in Germany and allows a location-independent monitoring at any time.

Medication management allows a complete trace back of any concentrate given to the patient for self-treatment. Every data is consolidated, saved in an electronic file, and can be monitored online with the web application. By real-time data

processing bleeding and therapy is analyzed at an early stage and may prevent the development of possible target joints in future [7].

In conclusion, the electronic documentation system “smart medication” can improve the quality of bleeding and treatment documentation. Early analysis of treatment problems has a high potential to improve self-home treatment and prevent subsequent health problems such as progressive joint damage and disabling hemorrhage. This may also lead to reduced treatment costs in future [4].

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