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An App to Improve Colorectal Carcinoma Follow-Up

Lukas WYSS[a,1] and Martin STIERLIN[b]
[a] *FMH - Swiss Medical Association* [b] *Federal Office of Public Health, University of Berne*

Abstract. Cancer is the second leading cause of death in Switzerland. Patients who have been diagnosed with colorectal carcinoma and received curative surgical R0-Resection frequently relapse or develop metastases in the first 2-3 years postoperatively. With timely detection through appropriate aftercare, some of these patients could potentially be cured. In order to optimize follow-up adherence, we implemented a study environment based on an app, which reminds patients to schedule their follow-up appointments timely with their GP or specialist. In addition, the study environment comprises a central server to collect pseudonomized study data regarding follow-up compliance. The next step will be a study to evaluate the potential impact of such an app. We present the outline of the planned study.

Keywords. Follow-up, mHealth, mobile application, colorectal carcinoma, patient adherence

1. Introduction

In Switzerland, cancer is the second leading cause of death, with particularly high mortality at an advanced age [1]. Demographic developments will continue to accentuate this [2]. The tumors of the lungs, colon, breast and prostate are those with the highest death rates in 2008-2012 [3]. If the cancer is detected early and resected completely, patients can be cured. However, in colorectal cancer, 30-44% of patients with R0-resection (no residual tumor) develop a relapse or metastasis, often in the first 3 years after surgery [4,5,6,7]. Therefore, good follow-up is essential [4,5,6]. For colon cancer a consensus recommendation of the Swiss Society of Gastroenterology (SGG) describes the recommended follow-up for colorectal cancer treated curatively by surgery [8]. There is evidence that IT-based clinical decision support systems (e.g. reminder) have impact on healthcare provider behaviour and in some cases also on patient outcome [9]. Against this background, the idea of an app to impact patient behavior for follow-up of colon cancer was born.

We describe the app which was directly designed in combination with a backend and database to support the evaluation of its impact on the patient and will discuss the planned RCT study design for this mobile application.

[1] Corresponding Author: Lukas Wyss, Berne University of Applied Sciences, Quellgasse 21, CH2502 Biel/Bienne, Switzerland, E-mail: wyslu1@gmail.com

2. Methods

We defined the use case of a patient undergoing colon surgery who may be willing to participate in a study examining the effect of reminder functions on his follow-up. Interviews were conducted with patients, physicians and the Swiss Cancer League to confirm the use case and to develop an appropriate user interface.

We designed a client server application with two different user interfaces, namely the follow-up app on a mobile device for the patient and the so-called GIST interface to support the patient enrolment into the study and the retrieval of study data. A shared normalized relational database model was designed for deployment on the mobile device using the LiteDB library for .net and on the GIST server using Flask-SQLAlchemy. The mobile app has been developed in C# using Xamarin for multi-platform deployment in combination with the Visual Studio IDE. Python 3.6 with the Framework "Flask" was used on top of an Apache 2 webserver for implementation of the server-sided software.

3. Results

The use case starts with the patient Hans, aged 72, who is diagnosed for colon cancer T1N0M0 and goes through hemicolectomy with curative intention. Post-surgery he is visited by a study nurse and asked if he likes to participate in the study. Upon signed consent the study nurse registers his case in the study database using GIST. GIST supports automated blinded randomizing to intervention or control group. It prints an enrolment scheme containing a QR code. The study nurse now assists Hans to install the client app TUNA on his mobile device. She helps him to scan the QR code which initializes the app for communication with the GIST server based on his unique study ID and which loads the appropriate follow-up scheme into the app. TUNA then reminds the patient for follow-up dates and requests confirmation that he made the appointment The following information is transmitted to the study server: completed appointments, deviation from target date of appointment, dropouts, quality of life value (scale of 1-100).

The applications (fig 1) consist of the TUNA mobile app and the GIST GUI running on a dedicated server. The mobile app TUNA (right-hand side) is to some degree independent from the GIST server and may be used as a standalone app by patients who do not want to participate. In those cases, the app can be initialized directly by entering TNM and surgery date and will then select the appropriate follow-up scheme.

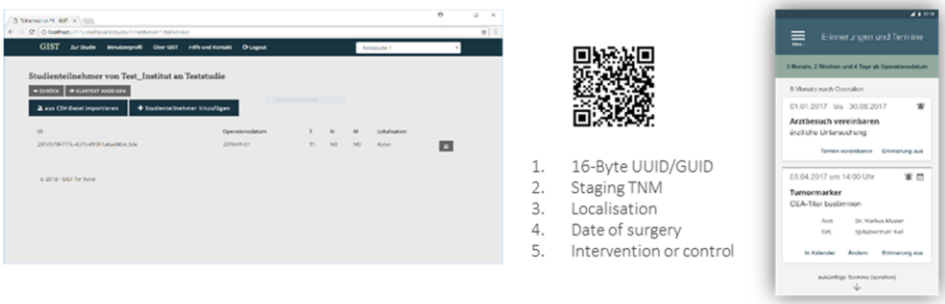

Figure 1. Left GIST server, one study patient opened for enrolment, in the middle printed QR code from enrolment sheet and its content, on the right TUNA mobile app with open reminder for CEA control.

In study mode, the TUNA app communicates patient data based on a unique study ID to the GIST server. This data can be evaluated regarding perceived and missed appointments, deviations from the target appointment date, dropouts and a subjective quality of life indicator.

4. Planned Study

Our goal is to examine the effects of the TUNA reminder app on follow-up adherence in an RCT study. The intervention to be examined is the reminder to the patient to make an appointment with his GP or specialist for the next follow-up. The hypothesis would be, that more follow-ups are made for a longer time period and in a timelier fashion if the patient uses the app. The planned study will be compliant to the «Clinical Protocol template for Investigator initiated trials» of *swissethics*.
Three options for the control group were under discussion:

1. The control group works without the app, they receive a piece of paper with the recommended follow-up scheme.
2. The app displays a PDF with the follow-up scheme on demand.
3. The apps reminder and appointment functions are deactivated.

Within the discussion another fourth option came up and has been implemented within the current design. Randomization is pretty visible to the patient and might influence him in options 1 and 2, whereas option 3 could be a problem for the ethics committee when control group patients have an obvious disadvantage.

Therefore, it is also possible to use the app with the full range of functions in the control group. In that case, however, reminders will be displayed at the very end of the recommended appointment period, i.e. 2 - 4 months after the optimal date, depending on the examination.

5. Discussion

The app and server side have been implemented but cannot yet been considered market ready. Thus, funding must be secured to achieve market readiness and to conduct the planned clinical study. In addition, the study will need a positive votum of an ethics committee.

The knowledge base for the reminders is restricted. The current implementation is limited to colon and rectal cancer. The SGG guideline [8] has concise follow-up recommendations only for the less aggressive tumor states, for complicated cases or patients with an M1 state the follow-up must be defined individually and thus cannot be implemented as a scheme. Other tumor types have been discussed, but, mostly, agreed follow-up schemes are either not existing or unhandy for implementation.

We are aware of the fact that we will need to follow a considerable number of patients over a long period of time (at least 2 years) in order to receive a valid measurement. This is a problem not only in terms of funding but also regarding drop outs, e.g. due to change of the living environment. Furthermore, the app and the GIST server must be maintained continuously for this time period despite potential upgrades e.g. in mobile devices operating systems which may change rapidly. Potentially, we have enabled the environment for multicentric recruiting of patients but intensive testing will be required for this functionality.

We will store sensitive patient data on the GIST server and may have to think about a split between patient identifying data and medical information in order to prevent attacks to the database. The chosen design took some care for this fact by defining the roles "Administrator" and "Registrar" on the GIST database. “Registrar” corresponds to the role of a study nurse and, after initialisation, presents only pseudonomized patient data. Patient identifying data and medical information are stored in different tables. They could also be stored on different servers.

Employing reminder functions has shown positive effects [9], but adverse effects such as alert fatigue and thus non-adherence are also well described [10]. We deal with a very sensitive patient group, patients with a potentially life-threatening disease, which may even get negative feelings when repeatedly reminded of their adverse situation and thus could develop a negative outcome. Therefore, we included a slider for the recording of a subjective quality of life into the app which is displayed every time a reminder pops up. We discussed more comprehensive QoL inventories but decided against it and in favour of a simple user interface and rapid user interaction.

Even if adherence to follow-up will be improved with the app, we cannot prove in the planned study design that this will improve patient outcome. Nevertheless, if such an app really reduces drop outs from patient follow-up, that might well be worth the hassle.

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