# User Evaluation of a Smartphone Application for Anticoagulation Therapy

Berglind SMARADOTTIR[a,1], Santiago MARTINEZ[a], Elizabeth BORYCKI[b], Gareth LOUDON[c], Andre KUSHNIRUK[b], Jarle JORTVEIT[d] and Rune FENSLI[a]
[a] *Centre for eHealth, University of Agder, Norway*
[b] *School of Health Information Science, University of Victoria, Canada*
[c] *Cardiff School of Art and Design, United Kingdom*
[d] *Department of Cardiology, Sørlandet Hospital Arendal, Norway*

**Abstract.** Anticoagulation therapy with Warfarin is used for specific cardiovascular diseases to control the ability of blood clotting. Traditional ways of self-management therapy are based on paper forms and procedures. This paper presents an evaluation of the smartphone application Warfarin Guide, a computer-assisted decision-support system used to help patients in their management of anticoagulation therapy related to International Normalized Ratio (INR) values. The evaluation consisted of a usability test with 4 participants and a field test with 14 participants who used the application at home during four months. A mixed methods research approach included quantitative and qualitative analysis of the test results. The results showed that participants evaluated the Warfarin Guide as 'useful' for self-management of anticoagulation therapy, reporting key issues for further improvement.

**Keywords.** International Normalized Ratio, Computer-Assisted Therapy, Usability Evaluation, Medical Informatics

## 1. Introduction

Patients with specific cardiovascular diseases, e.g., mechanical heart valves, venous thromboembolic disorders and selected high risk patients with atrial fibrillation, are prescribed life-long anticoagulation therapy with Warfarin to prevent thromboembolic complications. The intensity of the anticoagulant therapy is monitored by measurements of the International Normalized Ratio (INR) value [1]. A high value of INR indicates an increased risk of bleeding and a low value indicates a risk of increased blood clotting. The latter can lead to life-threatening conditions such as pulmonary embolism or cerebral infarction. Food intake with vitamin K-rich vegetables, alcohol consumption, physical exercise, illness and stress may also influence the INR values. Patients treated with Warfarin may, in some cases, self-monitor the INR values by a portable coagulometer device that samples whole blood obtained by a fingerprick. Previous studies have reported fluctuations outside the therapeutic INR range [2], which brings to light challenges, particularly for recently diagnosed patients, regarding regular checks of their INR values and decision-making about dose adjustments based on the measured values.

[1] Corresponding author, Department of Information and Communication Technology, Faculty of Engineering and Science, University of Agder, Jon Lilletuns vei 9, N-4879 Grimstad, Norway, E-mail: berglind.smaradottir@uia.no.

In this context, the project *Smartphone Warfarin Guide* aims to develop an easy-to-use application for computer-assisted anticoagulation therapy, based on an algorithm developed from the Norwegian national clinical guidelines for Warfarin therapy [3]. The project was divided into three phases: 1) user-centred design process [4], 2) usability tests during iterative development and 3) a randomised control trial. This work presents the results of the second phase. The research questions (RQs) stated for this study were:

RQ1: *How can a smartphone application support the self-management of anticoagulation therapy with Warfarin?*

RQ2: *What are the benefits and constraints of using a smartphone application for decision-making in an anticoagulation therapy with Warfarin?*

## 2. Methodology

A mixed methods research approach [5][6] was used in the evaluation of the smartphone application. The evaluation was conducted in two phases: 1) usability tests in a controlled environment (laboratory) and 2) a field test where participants continuously used the smartphone application during four months at home.

In phase 1, the usability evaluation was made in the Usability Laboratory of the University of Agder, Norway, with 4 participants using the anticoagulation therapy. Two test sessions were undertaken in October and two in November of 2016. In between, there was an iteration in the smartphone application development. The test participants were recruited from the local hospital, where they had taken a course in self-management of INR-measurements and dosage of Warfarin. The recommended INR range for all the participants was 2.5 to 3.5 and they used 2 to 4 Warfarin pills daily. They were aged from 34 to 63 (with a mean of 53 years) and were three males and one female. Participants had used anticoagulation therapy for 1.5 to 6.5 years (average of 4.3 years) and measured INR at home 1 to 4 times each month, with the average of 2.3 times each month. All were smartphone users: one iPhone user and three Android users. Participants had several ways of self-managing INR measurement and dosage. One participant had a traditional paper form manually filled-in, another participant used a table with data printed out before appointment, another participant used the notes function in the smartphone and other did not write or register any data, but stated that the last measurements would be visible in the INR measurement device.

The usability evaluations started with a pre-test interview that had an average duration of 9 minutes, to collect demographic information and participants were informed about the test procedure. The test sessions were led by the same moderator, and had an average duration of 48 minutes. The goal of the test sessions was to solve differentiated tasks and explore the user interface of the smartphone application in a Samsung smartphone device. A concurrent Think aloud protocol was employed [7][8].

The Usability Laboratory consisted of two rooms; one test room and one control- and observation room, connected through a one-way mirror with visualisation towards the test room, more details were presented previously [9]. Two cameras recorded the test sessions, one remotely controlled fixed on the wall and one document camera focusing on the smartphone's user interface on a stand. The research group, with a multi-disciplinary background within health informatics, usability engineering and medicine, followed the evaluation in real-time through four monitors in the control and observation

room and made annotations. In addition, one of the developers was present during the usability evaluations to assist in case of technical errors.

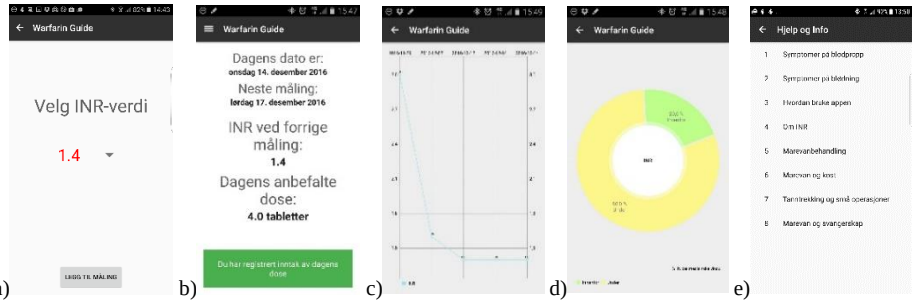
In phase 2, the field test was run with 14 anticoagulation therapy patients recruited from a local hospital. Participants used the smartphone application at home during four months, starting in February 2017. After month two, they filled in two questionnaires, the System Usability Scale (SUS) questionnaire [10] on user experience and another questionnaire on design and functionality of the system. After month four, there was a user meeting organized at the local hospital, where patients gave feedback about their user experience with the smartphone application. The smartphone application was used in conjunction with the paper-based clinical guidelines, to identify discrepancies.

The data collection consisted of audio-visual recordings from the usability evaluation and interviews in the laboratory, questionnaire data and annotations from the tests and feedback sessions. The Norwegian Centre for Research Data approved the study, with project number 50277 [11]. The participation in the study was voluntary and the informants received written information about the project and signed a consent form.

## 3. Results

### *3.1. Phase 1: Usability Evaluation*

The participants needed minor assistance to install the application from the file hosting service Dropbox to the smartphone. The test started with the input of the result from the last INR measurement in a scroll down menu (Fig. 1a). The application provided then a recommendation of dosage for the next days and date for a new INR measurement (Fig. 1b). Manual changes of dosage were allowed. One of the participants expressed that his/her INR routines were stable during normal daily conditions, but during travelling or in the case of sickness, there were more irregular results of the INR measurements. Consequently, the participant reported the flexibility to change the dose and frequency of measurements as desired. The participants explored the functions available; settings for reminder of daily dosage and weekly INR measurement, historical line diagram (Fig. 1c), circle diagram for time in therapeutic range (Fig. 1d) and the Help and information function (Fig 1e). The participants were asked to activate an alarm at the same time, daily, for reminder of pills and weekly measurement. In the historical diagram (Fig. 1c), the view had limited information since the app was just installed, but one participant stated




a) b) c) d) e)

**Figure 1.** a) Input of INR value, b) Start screen with last INR measurement and recommended dose of Warfarin, c) Historic diagram with overview of INR results, d) time in therapeutic range, e) Help and Information view.

that that was the best part of the application, compared to the paper based registration form. The circle diagram for time in therapeutic range (Fig. 1d), shows a historic presentation of time below, over and in the therapeutic range visualized by a green, yellow or red area, which was evaluated as a useful and clear presentation. The help and information function (Fig 1e) had 8 choices for information on how to use the application, symptoms and recommendations. The medical information was taken from the national clinical guidelines, to which participants were acquainted. One participant stated that it would be practical to always have access to the guidelines through the mobile device instead on written on papers. In the first two evaluations, participants stated that a 'note' function would be useful for creating own notes about food, newly added medication, etc. The notes function was implemented in an iteration and tested in the last two evaluations with positive response, but one of the participants suggested that the date should be registered automatically in a note.

The participants were asked about storage and data privacy. They explained that they would rely on the hospital to take care of security in an adequate way and found it useful that the hospital could access measurements, but they did not expect direct feedback on measurements. They expected the stored results to be used in outpatient ward consultations, without the need of bringing paper-based information in the future.

Overall, the participants found the application useful for self-management of INR measurement and calculation of dosage. They agreed to test the application for a longer period of time at home. Only one of the participants found the application use complex, leading to some extra actions. Another participant stressed the importance of quick and easy daily interactions with the application, to strengthen the patient adherence to the application. A few errors occurred during the evaluations. There were server connectivity problems which were solved with manual work arounds. Participants closed several times the application by mistake, looking for a back function. That functionality was implemented in the iteration.

### *3.2. Phase 2: Field Test*

Two questionnaires were sent by post mail to 14 anticoagulation therapy patients and out of them 13 responses were received, i.e., 93% response rate. The results of the System Usability Scale [10] were calculated and evaluated based on recommendations in Bangor et al. [12] where values in the range 70-100 indicates acceptable result (green colour), 50-70 marginal (yellow) and below 50 is not acceptable (red), see Table 1. The mean of the scores is 85.0, which is placed in the middle of the acceptable result range.

**Table 1.** Results of System Usability Scale Questionnaire

| P1 | P2 | P3 | P4 | P5 | P6 | P7 | P8 | P9 | P10 | P11 | P12 | P13 | **Mean** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 100 | 100 | 80 | 97,5 | 100 | 57,5 | 77,5 | 72,5 | 100 | 65 | 72,5 | 100 | 82,5 | 85,0 |

P= participant.

The design suggestions in the other questionnaire referred to adaption for all smartphones and a missing function for manual change of a measurement's day, as by default, the day for application installation was chosen. Also, export of data to a personal computer was suggested for redundancy, in case of a lost phone. Two discrepancies were found in the recommended week dose compared to the paper-based clinical guidelines.

## 4. Discussion

This paper has presented an evaluation of the Smartphone Warfarin Guide application, developed with a user-centred design approach. Regarding RQ1, the results showed that a smartphone application may support self-management of an anticoagulation therapy, even though there was room for improvements. Regarding benefits and constraints (RQ2), the application strengthens the patient empowerment by providing flexibility and decision-support, but the application needs to be further tested and validated according to regulations for medical software. Participants expressed that they *hoped to able to use the system after the trial*.

This study has some limitations, such as including a reduced number of test participants. Nevertheless, the study had participants that were patients using anticoagulation therapy and with a background that meaningfully represented the user group and other studies have showed that a low number of participant can identify major usability issues [13]. Future work would include implementation of Bluetooth transmission from the measurements' device to the smartphone application to reduce errors in manual input of INR measurement results. Further, a randomised controlled trial (RCT) is proposed, with a comparison of using the smartphone application and the standardised paper-based decision support system.

## References


[1] S.E. Kimmel, Z. Chen, M. Price, C.S. Parker, J.P. Metlay, J. D. Christie, R. Gross, The influence of patient adherence on anticoagulation control with warfarin: results from the International Normalized Ratio Adherence and Genetics (IN-RANGE) Study, *Arch Intern Med* **167**:3 (2007), 229-235.

[2] J.M. Hasenkam, et al., Self management of oral anticoagulant therapy after heart valve replacement, *Eur J Cardiothorac Surg* **11:**5 (1997, 935-942.

[3] Norsk kvalitetsforbedring av laboratorievirksomhet utenfor sykehus (NOKLUS). Opplæring i egenkontroll av antikoagulasjonsbehandling med Marevan og egenmåling av PT-INR. [cited 2017 November 3]. Available from: https://www.noklus.no/Portals/2/Egenm%E5ling/Bakgrunnsdokument%20om%20NOKLUS%20oppl%E6ring%20i%20egenkontroll.pdf

[4] M. Gerdes, S. Martinez, B. Smaradottir, R. Fensli, J. Jortveit, Warfarin Guide: Co-design of a Mobile Computer-Assisted Anticoagulant Therapy, *Stud Health Technol Inform* **245** (2017), 1222.

[5] C. Teddlie, A. Tashakkori, Mixed methods research. Denzin,Norman; Lincoln, Yvonna (eds.), *The Sage handbook of qualitative research* **4** (2011), 285-300.

[6] J.W. Creswell, V.L.P. Clark, *Designing and conducting mixed methods research*. SAGE Publications Inc, 2007.

[7] M.W. Jaspers, A comparison of usability methods for testing interactive health technologies: methodological aspects and empirical evidence, *Int J Med Inform* **78**:5 (2009), 340-353.

[8] A. Kushniruk, V.L. Patel. Cognitive and usability engineering methods for the evaluation of clinical information systems. *J Biomed Inform* **37**:1 (2004), 56-76.

[9] M. Gerdes, B. Smaradottir, R. Fensli, End-to-end infrastructure for usability evaluation of ehealth applications and services. *Proceedings of Scandinavian Conference on Health Informatics 2014*, Linköping University Electronic Press, p. 53-59. ISSN(print): 1650-3686, ISSN(online): 1650-3740, ISBN: 978-91-7519-241-3, 2014.

[10] J. Brooke, SUS-A quick and dirty usability scale, *Usability evaluation in industry*, 189(194), 4-7, 1996.

[11] The Norwegian Centre for Research Data. [cited 2017 November 3]. Available from: http://www.nsd.uib.no/nsd/english/index.html

[12] A. Bangor, P. Kortum, J. Miller, Determining what individual SUS scores mean: Adding an adjective rating scale. *J Usability Stud* **4**:3 (2009), 114-123.

[13] J. Nielsen, T.K. Landauer, A mathematical model of the finding of usability problems, *Proceedings of ACM INTERCHI Conference* (1993), 206-13.