User-Centered Design of a National Medical Registry for Tick-Borne Diseases

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Abstract. Tick-borne diseases are increasing in a global perspective, with Lyme disease and tick-borne encephalitis as the most frequent. The Norwegian National Advisory Unit on Tick-borne Diseases is preparing the development of a national medical registry for clinical follow-up of patients with tick-borne diseases based on the best practice guidelines and for research purposes. This paper presents the methodological approach of a user-centered design process applied in the initial phase of the registry development. A user workshop identified user needs, requirements and proposed a service workflow for the registry operation. As the next step, a simulation of the proposed service workflow was performed in a clinical laboratory together with end-user groups. The main contribution of this paper lies on the methodological descriptions of the user-centered design process, and how to facilitate the active contribution of end-users in a technical development process within a health care context.

Keywords: User-centrered Design Medical Registry Simulation Tick-borne Diseases

1 Introduction

Ticks are arachnid organisms that can act as vectors for a broad range of human pathogens, see Figure 1 [1][2]. Tick-borne diseases (TBD) are an increasing health burden in a global perspective [3][4] impacted by climate- and environmental changes and leisure habits, that expose more people to tick-bites [2][5][6]. The most prevalent tick-borne disease in the northern hemisphere is Lyme disease, caused by the Borrelia burgdorferi bacterium [4]. Lyme disease is a multistage and multisystem disorder, with a variety of clinical symptoms that predominantly affect the skin (erythema migrans), but can also manifest in joints, the heart and the nervous system (neuroborreliosis). 7000 persons are treated for erythema migrans and 400 for more disseminated disease, whereof about 300 neuroborreliosis, per year in Norway [7]. Globally, neuroborreliosis is reported in 3-12% of the borrelia patients [4][8]. The Lyme disease diagnosis is guided by clinical examination and analysis of antibodies in blood and cerebrospinal fluid. Antibiotics are the main treatment.

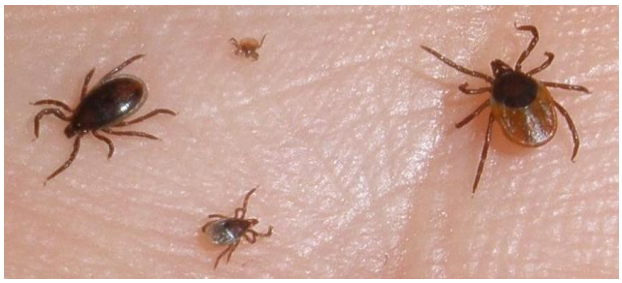

Fig. 1. The castor bean tick, Ixodes ricinus, at different stages of the development (photo: Per Eikeseth Knudsen).

In Norway, disseminated disease has been a nationally notifiable disease since 1995 [9]. The tick-borne infection of the brain, the Tick-borne Encephalitis (TBE) is also increasing. It is caused by a flavivirus that is transmitted by ticks in a geographic area from western Europe to the eastern Japan. TBE can cause acute meningoencephalitis and long-lasting sequelae occur among a third of the patients, with substantial impairment in quality of life and cognitive function. The diagnosis is based on antibodies in blood. There is no existing specific treatment. Vaccination is the main preventive measure for TBE [6][10].

Previous studies have reported that there are constraints related to the diagnosis and clinical management of tick-borne diseases [2][4] and that there is a lack of reliable data on the economic global impact [1][11]. This brings to light challenges with decision support following evidence-based clinical guidelines, particularly for diagnosed patients with remaining symptoms [12].

In this context, The Norwegian National Advisory Unit on Tick-borne Diseases [13] took the initiative to develop a National Medical Registry for Tick-borne Diseases, together with the Centre for eHealth at the University of Agder, the Norwegian Lyme Borreliosis Organization and the industry partner Egde Consulting. The National Medical Registry for Tick-borne Diseases has the aim to provide support in the follow up of patients with a verified tick-borne disease, based on an algorithm developed from international clinical guidelines. In addition, the registry will provide data for research on the prevalence of tick-borne diseases and the management in a long-term perspective.

In the initial project phase, a User-centered Design process was made that consisted of two steps: 1) user workshop with end-users and stakeholders, and 2) simulation of the registry service workflow in a clinical laboratory. This paper presents the methodology of the User-centered Design process in the initial project phase. The research questions (RQs) stated for this study were:

RQ1: *Which methodological procedures facilitate active end-user involvement in technical development projects within a health care context?*

RQ2: *What are the lessons learned that are transferable to other technical development projects within a health care context?*

Following this introduction, the methodology with a research background is presented. In the third and fourth section, the procedures from the User-centered Design process are described, also focusing on the infrastructure for laboratory simulation. The discussion and conclusion reflect on lessons learned and study contributions.

2 Methodology

The communication and information flow in health care services and between organizations are complex by nature, and Health Information Technology (HIT) plays an important role for coordination, information processing and decision support [14] [15]. Development of efficient and user-friendly HIT, such as a National Medical Registry, requires a detailed analysis of the needs and preferences of the end-user groups and stakeholders.

In the system development cycle, the approach of User-centered Design has the aim to actively involve end-users in every step and allowing them to provide suggestions and evaluations regarding design and functionality [16][17][18]. For the National Medical Registry for Tick-borne Diseases development, a User-centered Design approach was chosen to develop technology well-adapted to the clinical work processes of tick-borne disease management, and considered easy to use.

2.1 The Data Collection

Qualitative research methods [19] were used for data collection and analysis of the User-centered Design process that was applied in the National Medical Registry for Tick-borne Diseases development. The data collection was executed from August until November 2017 and included the methods observation and focus group interview in the initial development phase. The User-centered Design process was divided into two parts: 1) the user workshop and 2) the simulation in laboratory, both were audio-visually recorded with a total amount of 6 hours recorded data. In the data analysis, the recordings were viewed and analyzed qualitatively [20]. In addition, the research team made annotations during the different parts of the study, which is also included in the data collection.

2.2 Ethical Considerations

Carrying out evaluations in real clinical environments is not recommended for legal, ethical and privacy reasons [21]. Instead, user-based simulation with evaluation and test of an application can be made in a clinical laboratory, which has the strength of providing a controlled environment for the variables studied [22]. In a simulation, the end-users are asked to perform a role-play and do pre-defined tasks using a system, while being observed and recorded. The goal is to test conceptual ideas and analyze how new technology influences the existing clinical workflow. Measurements can be made on time for task solving and number of errors. The aim is to provide a better understanding of the user interactions and the technology involved in clinical work process [23][24]. Actors are often used, such as in the patient role, to increase the realism [25].

The Norwegian Centre for Research Data approved the study, with project number 55163 [26]. The participation in the study was voluntary and the informants received written information about the project and signed an individual consent form. The authors declare that there are no conflicting interests with any of the participants, organizations or industry.

3 User Workshop

A user workshop with participants from end-user groups and stakeholders was hosted by The Norwegian National Advisory Unit on Tick-borne Diseases and lead by two researchers from the University of Agder, see Table 1 for overview of participants.

Table 1. The Workshop Participants

Profession	N=12
Neurologist hospital	2
Nurse hospital	1
Microbiologist hospital	1
IT department hospital	1
Innovation unit hospital	1…
Research unit hospital	1…
Industry partner	1
Patient representative	2
Researcher University	2

The aim was to understand the context of use of the National Medical Registry for Tick-borne Diseases, and to work out the user requirements and make a conceptual plan for the service workflow of the registry. In addition, the workshop was a source of information and familiarization for people involved in the project.

The workshop lasted 4 hours, including a break, and was divided into two parts. In the first part of the workshop, participants were introduced to the project National Medical Registry for Tick-borne Diseases with a presentation of the most common diseases and how the registry could support the clinical treatment. The conceptual idea for the National Medical Registry was that it should work as a two-way communication platform, connecting the patient with the clinician and provide decision support based on clinical guidelines.

The workshop participants were asked to describe and write down user needs and how they expected the registry to function on colorful post-it notes for 10 minutes. Afterwards, each participant presented their suggestions to the group. The patient representatives described their preferred way of interacting with the registry application in a home setting. A digital versus paper-based consent form was discussed, and the clinicians suggested digital consent to avoid double registrations and increase of the daily workload.

In the second part of the workshop, a white board was used to identify the different user roles involved. A sketch was made to describe the service procedure and the operation of the National Medical Registry, where the case was a patient with a tick-borne disease making registrations for a period of 12 months. The topics discussed were the administration of the consent form, what kind of information a patient would be expected to register, and what kind of feedback should be provided from the health care services or automatically from the system to the patient at home.

4 Laboratory Simulation

The service operation of the National Medical Registry for Tick-borne Diseases was carried out as a realistic clinical situation simulated in a laboratory environment together with end-user groups and stakeholders, see Table 2 for distribution of participants. The scenarios were constructed based on information gathered from the previous workshop, and led by two researchers experienced in simulation of health care services and usability evaluation.

Table 2. The Simulation Participants

Profession	N=11
Neurologist hospital	1
GP/TBDs specialist	1
Nurse hospital	1
Adviser TBDs hospital	1
Industry partner	3
Patient representative	2
Researcher University	2

The simulations were executed in the clinical laboratory of the Centre for eHealth at the University of Agder, Norway. The laboratory consisted of two rooms; the control- and observation room and the test room that simulated an office at the neurological outpatient ward at hospital. The rooms were connected through a one-way mirror with visualization towards the test room, see Figure 2. In the control- and observation room one researcher was in charge of the recordings and the remote control for the fixed camera. The simulation was followed simultaneously on four 55" large monitors and through the one-way mirror.

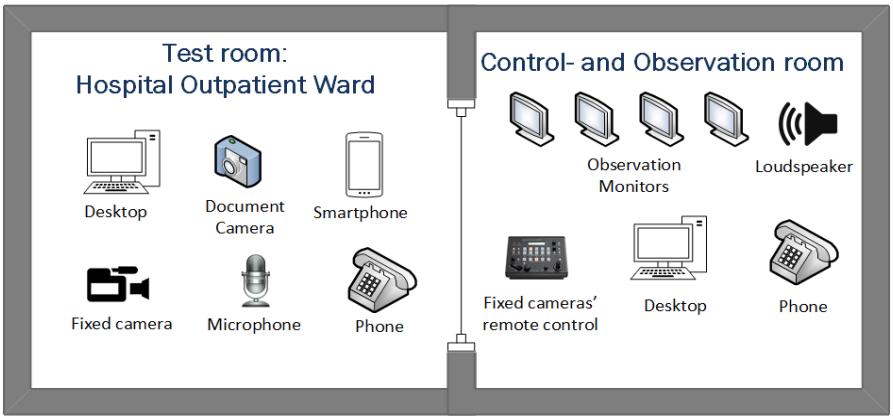

Fig. 2. The physical and technical infrastructure used in the laboratory simulations.

Recordings in the test room were made by the fixed camera and a document camera placed on a stand for the mobile phone. The recordings from the camera sources were merged into one single video file using the software Tricaster, to ease the analysis.

In the test room, the patients' own Samsung smartphone device were used to access the National Medical Registry prototype application, which was developed with the software program proto.io. The smartphone application had a suite of modules that were separated by color coding and designed to support self-management activity, see Figure 3.

Fig. 3. a) Start screen, b) Secure log in, c) The modules, d) Patient's diagnose and last appointment, e) Patient's administration of the clinicians' access, f) Patient's health information input.

Considering the user group, accessibility precautions were important as neuroborreliosis patients can have decreased strength and sensation in fingers, and the design goal was a meaningful presentation with a smooth navigation flow. For the clinician in the test room, a web-based clinical portal was used to access the Medical Registry prototype, see Figure 4.

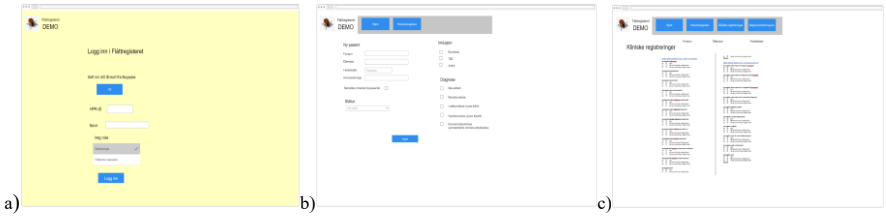

Fig. 4. a) Start screen with log in procedure, b) Registration of a new patient into the registry, c) Registration of clinical symptoms.

Two sessions with simulations were run during one day. In each simulation, there were three different role-based scenarios, each with a description of a situation and tasks to perform. The roles were: a) patient at a first-time consultation the neurological outpatient ward, b) doctor at the neurological outpatient ward, c) nurse at the neurological outpatient ward, d) observer in the observation room following the role-play and technology interactions. The first three roles were assigned to one person at each time. The doctors played the doctor's role, the nurse had the nurse's role and the patient representatives acted the patient's role. The observers were a group of 5-6 per-

sons having the role at the same time. In the test room, a moderator from the research team guided through the scenarios and asked the participants to speak aloud, as a think aloud protocol was used [27][28]. In the control- and observation room, one member from the research team instructed the observers.

In each simulation session the scenario was: 1) a patient with tick-borne disease symptoms having a first-time consultation at the neurological outpatient ward with a doctor, 2) consultation with a nurse for guidance with installing the National Medical Registry application on patient's own smartphone and 3) a second consultation with the doctor for medical results, instructions for treatment and use of the application. The information flow and the interactions with technology across the roles were especially observed and the time for each scenario and potential errors were annotated. A debrief session was organized after each simulation together with the participants. The aim was to use the group dynamics for discussing how the scenarios worked out, how the actions related to existing workflow and improvements were suggested.

5 Discussion

This paper has presented how to involve end-users in technical development, based on the experiences from the National Medical Registry for Tick-borne Disease project. The lessons learned by the research team showed that the User-centered Design process was an efficient way of involving end-users and stakeholders in the initial phase of the development. The research questions (RQs) formulated are answered below based on the results from the study.

About the RQ1, which methodological procedures that facilitate active end-user involvement in technical development projects. The workshop which was organized in an early project phase together with end-user groups and stakeholders, efficiently outlined user needs and the context of use. It was the key to elicit users' requirements of the application and taking on board different user roles and patient groups. In the second part of the workshop, a process model of the workflow was presented as a swimming lane diagram. That provided a good foundation for discussion, showing the participants the details in the service workflow, the user roles and what actions that were suggested. Such visual representations are meaningful in workflow discussions, to show who is supposed to do what and at what time. The outcome of the workshop provided the scenarios for the simulations performed later, where the service workflow and operation of the proposed technology was tested.

The RQ2, lessons learned that are transferable and applicable in similar contexts. It was experienced in the User-centered Design process that the user workshop and simulations were of high importance for the project, providing a deeper understanding on the National Medical Registry's mission and aims. The organization with active end-user involvement in the workshop and laboratory simulation was considered as well structured and can be recommended to other development projects. In the simulation, the role-play and use of real patients as actors to create a realistic scenario was positively evaluated and can be recommended. Regarding the distribution of roles, the role as observer in the control- and observation room was important and allowed the participants to actively follow the information flow and the interactions with technology

in the test room. The observers made notes and contributed at a detailed level to the group debrief after the simulations.

This study had some limitations such as a reduced number of simulations (n=2) to test the service operation of the National Medical Registry prototype. However, a significant number of participants, with a total of 17 people belonging to different user groups and stakeholders, meaningfully represented the end-user groups of the application.

6 Conclusion

This paper was made within the project National Medical Registry for Tick-borne Diseases, in order to share experiences on how end-users can be involved in technical development and how clinical scenarios can be simulated in a laboratory environment. The main contribution lies on the descriptions of how a User-centered Design approach can facilitate the active contribution of the end-user groups in a development process. In addition, the methodological procedures for simulation and the technical descriptions are applicable and transferable to other projects within a health care context. The results presented are congruent with other studies of User-centered Design [16][29], highlighting the importance of involving the end-user groups early in the development. They also showed that simulation with low fidelity software prototypes allows a low-cost test of proposed service workflow and operation [22]. The role-play with real patients as actors in the simulations was useful and informative, and provided realism to the scenarios [24]. The clinical laboratory provided a controlled environment, with audio-video recordings to retrospectively analyze the collected data. In terms of future work, a full development of the National Medical Registry for Tick-borne Diseases is proposed, with an active end-user involvement in all phases.

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References

1. Jongejan, F., Uilenberg, G.: The Global Importance of Ticks. Parasitology. 129(S1), S3--S14 (2004)
2. Dantas-Torres, F., Chomel, B.B., Otranto, D.: Ticks and Tick-Borne Diseases: a One Health Perspective. Trends Parasitol. 28(10), 437--446 (2012)
3. Gray, J.S., Dautel, H., Estrada-Peña, A., Kahl, O., Lindgren, E.: Effects of Climate Change on Ticks and Tick-Borne Diseases in Europe. Interdiscip Perspect Infect Dis. (2009)
4. Koedel, U., Fingerle, V., Pfister, H.W.: Lyme Neuroborreliosis—Epidemiology, Diagnosis and Management. Nat Rev Neurol. 11(8), 446 (2015)
5. Danielová, V., Schwarzová, L., Materna, J., Daniel, M., Metelka, L., Holubová, J., Kříž, B.: Tick-Borne Encephalitis Virus Expansion to Higher Altitudes Correlated with Climate Warming. Int J Med Microbiol. 298, 68--72 (2008)

6. Lindquist, L., Vapalahti, O.: Tick-Borne Encephalitis. Lancet. 371(9627), 1861--1871 (2008)
7. Eliassen, K.E., Berild, D., Reiso, H., Grude, N., Christophersen, K.S., Finckenhagen, C., Lindbæk, M.: Incidence and Antibiotic Treatment of Erythema Migrans in Norway 2005–2009. Ticks Tick Borne Dis. 8(1), 1--8 (2017)
8. Wilking, H., Stark, K.: Trends in Surveillance Data of Human Lyme Borreliosis from six Federal States in Eastern Germany, 2009–2012. Ticks Tick Borne Dis. 5(3), 219--224 (2014)
9. Norwegian Institute of Public Health, Report on Ticks and Tick-borne Diseases in 2015, https://www.fhi.no/globalassets/dokumenterfiler/moba/pdf/flatt-og-flattbarne-sykdommer-pdf2.pdf
10. Lindquist, L.: Tick-Borne Encephalitis. In Handbook of Clinical Neurology. Vol. 123. 531--559, Elsevier (2014)
11. Müller, I., Freitag, M.H., Poggensee, G., Scharnetzky, E., Straube, E., Schoerner, C., Norris, D.E.: Evaluating Frequency, Diagnostic Quality, and Cost of Lyme Borreliosis Testing in Germany: a Retrospective Model Analysis. Clin Dev Immunol. (2012)
12. Lorentzen, Å.R., Forselv, K.J., Helgeland, G., Salvesen, R.E., Sand, G., Flemmen, H.Ø., Bø, M.H., Nordaa, L., Roos, A.K., Jim, M.W., Owe, J.F., Nyquist, K.B., Schüler, S., Eikeland, R., Mygland, Å., Ljøstad, U.: Lyme Neuroborreliosis: Do We Treat According to Guidelines? J Neurol. 264(7), 1506--1510 (2017)
13. The Norwegian National Advisory Unit on Tick-borne Diseases, https://xn--flttsenteret-ucb.no/in-english/
14. Goldzweig, C.L., Towfigh, A., Maglione, M., Shekelle, P.G.: Costs and Benefits of Health Information Technology: New Trends from the Literature. Health Aff. 28(2), w282--w293 (2009)
15. U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, https://www.healthit.gov/patients-families/basics-health-it
16. Vredenburg, K., Mao, J., Smith, P.W., Carey, T.: A Survey of User-Centered Design Practice. In: Conference on Human Factors in Computing Systems (SIGCHI 2002), 471--478 (2002)
17. Lazar, J.: Web Usability- a User-Centered Design Approach. Pearson Education (2006)
18. Nielsen, J.: Usability Engineering. Elsevier (1993)
19. Denzin, N.K., Lincoln, Y.S.: Handbook of Qualitative Research. SAGE Publications, Inc (1994)
20. Kushniruk, A.W., Borycki, E.M.: Development of a Video Coding Scheme for Analyzing the Usability and Usefulness of Health Information Systems. In CSHI. 68--73 (2015)
21. Svanæs, D., Alsos, O.A., Dahl., Y.: Usability Testing of Mobile ICT for Clinical Settings: Methodological and Practical Challenges. Int J Med Inform. 79(4), e24--e34 (2010)
22. Smaradottir, B., Fensli, R.W., Boysen, E.S., Martinez, S.: Infrastructure for Health Care Simulation: Recommendations from the Model for Telecare Alarm Services Project. In: The International Conference on Health Informatics and Medical systems (HIMS'17), 64--69, CSREA Press, Las Vegas (2017)
23. Li, A.C., Kannry, J.L., Kushniruk, A., Chrimes, D., McGinn, T.G., Edonyabo, D., Mann, D.M.: Integrating Usability Testing and Think-Aloud Protocol Analysis with "Near-live" Clinical Simulations in Evaluating Clinical Decision Support. Int J Med Inform. 81(11), 761--772 (2012)
24. Borycki, E., Kushniruk, A.: Identifying and Preventing Technology-Induced Error Using Simulations: Application of Usability Engineering Techniques. Healthc Q. 8(Sp) (2005)

25. Smaradottir, B.F.: The Steps of User-Centered Design in Health Information Technology Development: Recommendations from a PhD Research Study. In: International Conference on Computational Science and Computational Intelligence (CSCI), 116--121 IEEE (2016).
26. The Norwegian Centre for Research Data, http://www.nsd.uib.no/personvern/en/index.html
27. Kushniruk, A.W., Patel, V.L.: Cognitive and Usability Engineering Methods for the Evaluation of Clinical Information Systems. J Biomed Inform. Vol. 37(1), 56--76 (2004)
28. Jaspers, M.A.: Comparison of Usability Methods for Testing Interactive Health Technologies: Methodological Aspects and Empirical Evidence. Int J Med Inform. Vol. 78(5), 340--53 (2009)
29. Ritter, F.E., Baxter, G.D., Churchill, E.F.: Foundations for Designing User-Centered Systems. Springer, London (2014)
30. Regional Research Fund Agder, http://www.regionaleforskningsfond.no/prognett-rff-hovedside/RFF_in_English/1253976860326