Requirements Elicitation in a Telemedicine Pain-treatment Trial[1]

I. Widya[1], R.G.A. Bults[1], B.J.F. van Beijnum[1], L. Sandsjö[2], L. Schaake[3],
M.H.A. Huis in't Veld[3], V. Jones[1], H.J. Hermens[1]

[1]*Remote Monitoring & Treatment group, University of Twente, the Netherlands,*
[2]*Occupational and Environmental Medicine, the Sahlgrenska Academy*
at University of Gothenburg, Sweden
[3]*Roessingh Research and Development, the Netherlands*

Abstract

This paper presents the early phase requirements elicitation for a work-related neck-shoulder pain teletreatment trial and the assessment of those requirements in respect of their importance to the trial and the feasibility of the needed software adaptations of the telemedicine system within the constraints of the project organizing the trial. The elicitation adopts specific solutions and constraints that are typical for working practices in medicine. In particular, the contribution of this paper is its holistic approach in addressing the intertwining of the requirements elicitation and the trial design. Trial design defines the trial settings and the treatment protocols in a standardized way such that treatment efficacy can be evaluated based on evidence. A cyclic approach which applies a set of elicitation techniques and informal specification styles (e.g. tables and mock-ups) is adopted in order to converge on a set of requirements understood and agreed upon also by the trial designers, who are medical professionals, often unaware of formal methods, and who co-shape the telemedicine system.

1. Introduction

In medicine, diagnostic and treatment procedures are investigated and approved in several stages [1]. Such investigation includes clinical trials on humans to collect the necessary medical evidence. In the design of a trial (trial design), the trial settings are defined and the treatment protocol is developed in a standardized way such that treatment efficacy can be evaluated whilst avoiding sources of bias and preserving patient safety. If the trial result is accepted, the treatment protocol can be adapted in an evidence based way to match to the patient's treatment case [2].

In telemedicine, a treatment protocol typically applies an Information and Communication Technology (ICT) based telemedicine system, which brings clinical data to the points of diagnostic analysis and treatment decisions, for example to the care professional who works remotely from the patient.

The early design or update phase of a system, such as the requirements elicitation phase aimed at defining the intended system, is considered crucial to successful development. This paper discusses how to elicit requirements in the domain of telemedicine. It presents the early phase requirements elicitation in a teletreatment trial and the assessment of the requirements in respect of their importance to the trial and the feasibility of the corresponding software adaptations of the supporting telemedicine system within the constraints of the project organizing the trial.

Requirements elicitation in the domain of healthcare is for example described in [3]. It classifies healthcare workflows (e.g. treatment protocols), including their goals, and it discusses how to check completeness and feasibility of workflows and how to formalize healthcare guidelines. A task analysis approach to requirements elicitation for a web-based Health Information System case study is applied in [4]. Especially interesting is the work of Cysneiros [5], who points out some pitfalls in requirements engineering in the healthcare domain and ways of dealing with them; our findings are often in accordance with these.

In this paper, we present a medicine specific way to elicit requirements that using a holistic approach which utilizes the intertwining of requirements elicitation and trial design. We consider requirements elicitation as a separate concern in the design or the adaptation of a telemedicine system but which is nevertheless strongly connected to the design of the trial to be supported. A cyclic approach that applies a set of elicitation techniques and informal specification styles is adopted in order to converge on a set of requirements

---

understood and agreed upon by trial designers, who are medical professionals, often unaware of formal techniques, and who co-shape the telemedicine system. Our experience shows that this approach manages expectations of trial designers better, which is crucial for the collaboration between the medical professionals and the telemedicine system engineers during the execution of the trial as well as for innovation uptake.

The requirements elicitation process applied a scenario based approach. Treatment tasks and their objectives were identified from both the scenario and the trial design and then analyzed. The approach is therefore goal-oriented (cf. [6] and [7]), which aligns well with working practices in medicine.

The tasks analysis further identifies the actors responsible and their activities and interactions, which have to be mediated by the telemedicine system to be. We mainly discuss activities of these actors and less the details of the interactions mediated by the system; i.e. we address the early phase requirements elicitation.

This paper is organized as follows. Next, we briefly describe the trial and the needed telemedicine system. Section 3 describes the requirements elicitation process and Section 4 describes the assessment of the elicited requirements. Section 5 contains a discussion of the work and thereafter we present our conclusions.

2. Neck-shoulder pain teletreatment trial

This paper describes the requirements elicitation process in the European eTEN project MyoTel [8], which investigates the feasibility of a myofeedback based teletreatment service which enables patients with work-related neck-shoulder complaints to receive personalized remotely supervised treatment during daily activities. The project validates the teletreatment service in four European countries.

The MyoTel service uses clinical data, in particular surface-ElectroMyoGraphy (s-EMG) that represents trapezius muscle activity. Measures of muscle activity are fed back to the patient and also presented to a remote myofeedback therapist. This service provides three feedback loops to enable control of patient's muscle relaxation patterns (Figure 1). A micro-loop provides local tactile feedback in the form of vibration from a body-worn device which indicates insufficient muscle relaxation averaged over a moving time window. A meso-loop provides visual feedback on a PDA screen to indicate near real time muscle activity performance of the left and right trapezius muscles. A macro-loop enables supervised feedback from a remote therapist during planned consultation sessions.

The MyoTel telemedicine system consists of a Body Area Network (BAN) consisting of body-worn s-EMG sensors and vibrating actuator communicating with a PDA with wireless public network access; an m-Health

Portal; a professional Terminal; and a hybrid communication infrastructure consisting of public and private wireless networks, the internet and optionally an intranet.
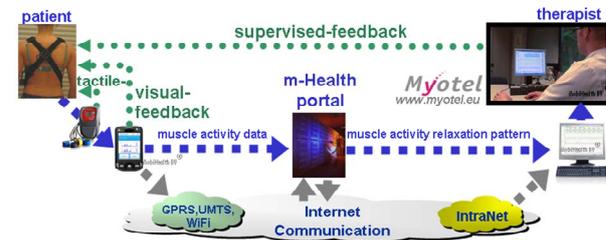

Figure 1. MyoTel monitoring & treatment system.

3. Requirements elicitation

Our requirements elicitation approach and techniques are designed to conform to the evidence based approach in medicine. The elicitation approach uses a set of inputs, namely:
- a scenario defined and owned by the trial designers;
- the objectives (i.e. goals) underlying the activities or tasks described in the scenario;
- components of the trial design and their (derived) objectives, e.g. the treatment protocol.

In the MyoTel project, myofeedback experts design the trial and develop a scenario narrating the activities during treatment of a patient and a treating therapist. Based on feedback received from system designers, these trial designers refine the scenario by including interactions which have to be supported by the system.

An analysis of the (derived) objectives of the trial design provides additional system constraints and requirements, often complementing the requirements elicited from the scenario, because scenarios are inherently incomplete.

In medicine moreover, the trial design has to be approved by a medical ethical committee, who may impose additional constraints. Requirements elicitation in medicine therefore involves stakeholders who are not necessarily the users of the intended system.

3.1. Techniques

We apply a set of techniques to elicit requirements holistically. System engineers with ICT background investigate the literature on pain treatment (e.g. [9]) and they study the trial design to acquire the necessary background knowledge on the trial, for example, the objectives of the trial, the treatment protocol, inclusion and exclusion criteria, clinical data and its processing.

The major benefits of studying the medical case and the trial design for system engineers are for example:
- to understand the medicine domain vocabulary, necessary for the system engineers with ICT

background to shape the system in a collaboration with the trial designers (cf. [5]);
- to gain knowledge of the clinical case so as to be able to identify alternative solutions (cf. [5]);
- to get better insight into the required quality of the clinical data in order to estimate the required Quality of Service (QoS) of the data transport channels.

In contrast with the scenario development, the elicitation process is led by the system engineers; they carry out the requirements elicitation using a cyclic approach in which trial designers provide feedback.

These system engineers conduct several semi-structured interviews and e-mail exchanges with the trial designers to elicit and update requirements. Group discussions conducted during plenary project meetings, are also used for feedback of the identified (and prioritized) requirements.

To aid meaningful multidisciplinary collaboration, elicitation means to specify the requirements include tables, textual descriptions and screen mock-ups. Analyzed and prioritized requirements from each iteration cycle are checked by the trial designers to validate the telemedicine system functionality with respect to their expectations.

During these interviews and group discussions the requirements are validated by these participating experts. In medicine, moreover, a working practice is to train the users, for example the therapists, before the trial execution. These training sessions use simulations (e.g. mock-ups of screens displaying muscle relaxation patterns) and an early prototype of the telemedicine system. These sessions provide additional evaluation feedback from the professional users.

3.2. Approach

In line with working practices in medicine, we adopt a basically top-down and task-oriented analysis approach. We identify and analyze the necessary trial tasks (including the functional support required) from the scenario and the trial design. Thereafter, we identify the actors that will be responsible for these tasks in conformance with the scenario and treatment protocol. Then we elaborate the activities that belong to these tasks, including the remote interactions between the actors that have to be mediated by the intended system or the interactions of an actor with the system, for example to securely access stored data.

Besides task analysis, we also analyze the objectives of the tasks. This makes our approach goal-oriented. Analyzing objectives moreover provide system alternatives and improves completeness of the elicitation process.

The system engineers who elaborate the elicitation process validate the (intermediate) results by interviews with individual trial designers, who may however have biased opinions. To overcome such difficulties, the engineers apply different, not necessarily coherent, starting points of the elicitation process as discussed earlier, namely scenarios, trial design components and evidence collected during the preliminary studies. If the collected information seems to be contradictory or inconsistent, the elicitation will be reiterated. With this approach we discovered in an early stage a mismatch in the data specifications of multiplexed s-EMGs in the consulted sources; this caused a rescheduling of the project plan and a postponement of the start of the trial.

3.2.1. Trial objectives and functions.
The trial objectives provide the context for the pain treatment application functionality. They therefore scope the elicitation and assessment processes. A close inspection of the scenario and trial design yields the objectives:
- pain treatment based on strictly supervised training: an objective is to treat patients by training them to relax their trapezius muscles at their place of work;
- assessment of diary-based remote treatment: an objective which originates from the trial design is to assess remote monitoring of muscle activation and relaxation patterns of patients, including the ICT technology, and to assess the training process which uses activity data from patient's diaries.

This trial involves a therapy training programme. In educational science, training is a learning workform which has specific didactical settings and structure of plan, do and check phases. Accordingly, the pain treatment has to contain the following elements:
- training: training material are Root Mean Squares (RMS) and Relative Rest Time (RRT) [10] of the left and right shoulder's s-EMGs, visual feedback and also tactile feedback in case those measures exceed a specified threshold. A therapist supervises training strictly, meaning that the therapist needs to check training compliance regularly and at arbitrary but convenient moments for the therapist. This moreover ensures that measured data collected in amounts and at quality needed for data analysis.
- planned consultations: a therapist has to prepare the consultation material by analyzing and optionally annotating the stored RMS or RRT data, in correlation with activity data from patient diary. Future development is to incorporate synchronous use of the telemedicine system during consultations.

Strict supervision of training was not originally described in the trial design, but was identified as a requirement during an interview. This influences the data transfer mode of the intended system significantly.

3.2.2. Stakeholders.
A stakeholder is an organizational entity or a group of individuals involved in the trial.

Addressed stakeholders therefore scope the context of the elicitation process in respect of the business model. Identified stakeholders from the scenario are:

- MyoTel trial programme owner: this stakeholder is a Centre of Excellence (CoE) in a participating country that offers the MyoTel pain treatment trial;
- Users: this stakeholder is represented by the patient and therapist users of the pain treatment service;
- Telemedicine system provider: this stakeholder provides the intended telemedicine system;
- Communication service provider: this stakeholder provides the wireless access to the internet.

Additional stakeholders identified from the trial design are:

- Employer: this stakeholder facilitates internet access and provides the equipment, such as PC or laptop, to access the internet during office hours;
- Medical Ethical Committee: this stakeholder grants permission to run the trial and typically imposes constraints on the trial, e.g. relating to security and privacy aspects of the clinical data collected.

A special stakeholder relevant for the requirements assessment, not mentioned in the trial design or the scenario, is the European eTEN Programme Commission (Section 2) who sponsors the trial. This stakeholder constrains the system software adaptation, because the programme only grants minor software adaptation. Consequently, this stakeholder influences the requirements that are feasible for implementations not only from a cost/benefit perspective but also from a software development effort perspective.

Due to the scope of the trial design, the identified stakeholders are the relevant ones for preparation and running the trials. Other stakeholders, for example, those relevant for large scale roll out of the neck-shoulder pain treatment service using the proposed telemedicine system are not considered in this paper.

3.2.3. Actors and their responsibility. Actors are defined here as the telemedicine system users, who have specific responsibility and represent a stakeholder. Actors that have been identified from the scenario and the trial design are:

- patient: the subject participating in the trial. A patient is responsible for complying with the training to relax his/her neck-shoulder muscles;
- therapist: the professional who is responsible for the treatment, including supervision of consultations;
- trial programme system administrator: the actor who represents the CoE trial programme owner in the participating country and who has the responsibility to organize the trial and in particular to manage the logistics of the trial;
- telemedicine system administrator: the actor who represents the telemedicine system provider stakeholder and who has the responsibility of

initializing system settings, such as registrations of trial programme system administrators of the participating countries, set-up of the MyoTel mHealth portal (Figure 1) and registration and distribution of mobile devices to trial sites.

Especially, the identification of the administrator actors and their responsibilities demonstrates the influence of the trial design on the requirements elicitation since they were identified from the trial design rather than the provided scenario.

3.2.4. Actors, assigned tasks and activities. Based on the responsibilities derived from the scenario or treatment protocol or refined from the task analysis, actors can be assigned to tasks. A task typically contains ordered activities (i.e. workflow) that are operationally needed to realize the task. An actor who performs the activities of his assigned tasks in the correct order will therefore realize the objectives of the tasks, and consequently fulfill his responsibilities.

Example: a therapist who supervises the training of a patient strictly (i.e. a task), needs amongst others to check the patient's training discipline. The latter is a subtask of the therapist with the objective of supervising the patient's training compliance. The therapist is also responsible for the preparation of the consultation material; this is thus another subtask of the therapist and it embeds the training compliance subtask. Since patient data needs to be protected and kept private (a constraint typically imposed by the Medical Ethical Committee regulation stakeholder), another subtask of the therapist is to undergo an authentication, a subtask to assure authorized access.

On the other hand, the trial programme system administrator of a trial site has to administer the mobile BAN devices received from the telemedicine system administrator, to register the therapists and to enroll patients. This actor is therefore responsible for the configuration of the role based login mechanisms. This configuration set-up task is therefore a consequence of the need for authorized data access.

4. Requirements assessment

After elicitation, the requirements are further assessed on their importance to the trial and on the feasibility of the software adaptations needed to modify the supporting telemedicine system within the project constraints as imposed by the EU Commission stakeholder mentioned earlier. Assessed requirements attributed with their priority and feasibility are input for the next requirement engineering phase, where requirements are further refined, for example, to detail the GUI window screens on the PDA of the patient and the display of the therapist, the controls or the down sampled RMS and RRT graphs.

4.1. Requirements priority and feasibility

In the MyoTel project, one partner provides a telemedicine system for remote monitoring of clinical data. However, this pre-MyoTel system had to be adapted to support the trial. Nevertheless, this system complies with some of the elicited requirements.

On the other hand, the short duration of the MyoTel project constrained the implementation of requirements to those deemed essential for trial safety and efficacy and those necessary for collection of clinical evidence. Other requirements considered less important from the trial design perspective can only be reconsidered for implementation if they can be piggy backed with the implementation of the essential ones or are easy to implement. Elicited requirements are therefore categorized as "need to have" and "nice to have".

Furthermore, the software development constraint of the sponsoring stakeholder discussed earlier determines the feasibility of the requirement for implementation. Figure 2 shows the categorization of the requirements:

- *compliant* requirements: refer to requirements supported by the pre-MyoTel telemedicine system;
- *implementable* requirements: refer to requirements not supported by the pre-MyoTel system but considered feasible for an upcoming system release;
- *ignorable* requirements: refer to "nice to have" requirements that are not supported and the corresponding system adaptations are considered not feasible within the constraints of the project sponsor stakeholder;
- *undecided* requirements: refer to "need to have" requirements that are not supported and the corresponding system adaptations are considered not feasible within the project constraints.
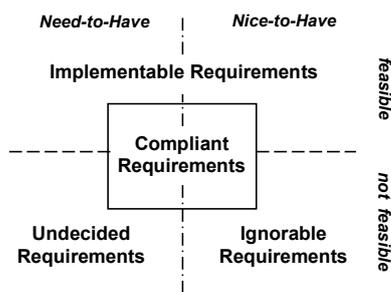

Figure 2 Requirements priority and feasibility

Requirements classed as *undecided* are essential risks for trials, they have to be discussed further and they may imply a trial design update. In one of our iteration cycle, we identified an *undecided* requirement. After a group discussion with trial designers and project management it was decided to upgrade this requirement to *implementable* via some manpower rescheduling.

4.2. Telemedicine services needed for the trial

Finally, we observed that the task and activity assessment using the earlier mentioned tables identifies the services of the telemedicine system that are needed to support the work-related neck-shoulder pain treatment. These services are the following:

- monitoring services: for monitoring RMS and RRT signals. In a strictly supervised training, monitoring needs to be continuous to enable therapists to check at any time the training compliance of patients via the measured data stored on the portal;
- diary services: to enable patients to submit a diary reporting their activities and to enable correlation between measured muscle activity and relaxation patterns and patient's activities;
- feedback services: to provide visual RMS and RRT feedback on the PDA and tactile feedback;
- consultation services: to prepare consultation material for supervised treatment feedback;
- registration services: for conformance to stakeholder's constraints on security and privacy guaranteeing controlled access to clinical data.

From an ICT perspective, the previously listed services can be realized by web-based services for registration, password protected data access, diary submission and other consultation logistics settings; data rendering services for viewing, zooming, comparing RRT/RMS data and synchronizing with diary data and therapist annotations; remote monitoring services for transport of data from sensing devices via patient PDA to the portal; security related services for authorized data access; and performance measurement services to enable the assessment of ICT based teletreatment cases.

5. Observations and discussion

The need for medical practice to be evidence based raises challenges for requirements elicitation. An approach which balances a holistic with a detailed in depth way of working is needed. Intensive multidisciplinary collaboration between trial designers and system engineers that makes topics of discussions explicit and mutually understandable is required. In such collaborations, cross disciplinary literature study is essential for in depth discussions to uncover needs. In our requirements elicitation case, the collaborators apply a handshake protocol in which requirements elicitation acts as the common universe of discourse. The system engineers lead and manage the collaboration, opposed to the design of the scenario where the trial designers take the lead. This mode of collaboration preserves intentions or goals of actors' activities and their interactions with the intended system at the appropriate levels.

In evidence based medicine, it is also problematic to propose alternative requirements which imply the use of new technologies that has not (yet) been indicated by clinical evidence, unless the use of these technologies itself is a subject of assessment.

On the other hand, the staged-approval in medicine implies that trial designers are usually researchers and hence accustomed to systematic reasoning and use of methodolgies, this makes collaboration with system engineers easier.

To some extent we apply a participatory design approach, but complement it with other methods. We use a scenario as a commonly understood subject of discourse, whilst recognizing that scenarios are inherently incomplete. Additionally, relevant stakeholders have been analyzed to elicit requirements holistically, because it is not the way of working of regulatory or sponsoring stakeholders to be involved in participatory design. Identification of stakeholders from scenarios or trial design is however not sufficient. In our case, the sponsoring stakeholder who imposes software development constraints would have been missed if we had not augmented the approach by taking a business administration perspective. On the other hand, task and task objective analysis yielded in depth results, e.g. by viewing training as an educational workform with a known and a well defined structure (plan, do and check phases, intentions, roles and tasks).

Despite our efforts to address requirements elicitation completely and thoroughly in a multidisciplinary setting, we identify a limitation. Not all trial design rationales may have been exposed to the system engineers. In our case, a further study on myofeedback strategies after the elicitation process provides new insights. The meso-loop visual feedback (called Knowledge of Performance) is in certain cases considered better than the micro tactile feedback (called Knowledge of Result). With this knowledge, a new requirement might be elicited to explicitly exclude solutions that do not make sense, in which the ICT support for tactile feedback is more complex (therefore more sensitive to resource failures) than the support for visual feedback. Our solution happens to be correct, but this was not enforced by an elicited requirement. Requirements elicitation in medicine is a conscious activity and has to be addressed holistically.

6. Conclusions

This paper presents an early phase requirements elicitation and assessment procedure for telemedicine that basically applies a task- and goal-oriented approach. The approach makes use of a scenario and the trial design; augmented with a stakeholders analysis. This mix is believed typical for telemedicine and considered necessary to achieve a holistic solution.

The elicitation process is moreover carried out by means of multidisciplinary collaboration between trial designers, who are in charge of scenario design, and system engineers, who are in charge of requirements elicitation. For effective collaboration, cross disciplinary literature or domain study is essential.

The teletreatment case addressed is relatively simple because it only involves one treatment professional, i.e. the therapist. The overview of the elicitation process is easily maintained without the need for engineering tools. Interesting future work is requirements elicitation in multi-professionals treatment settings such as the disease management in Chronic Obstructive Pulmonary Disease (COPD). In such cases, we will take on new challenges, e.g. to assess the additional use of formal elicitation techniques and software engineering tools.

7. References

[1] Chow, S-C., and Liu, J-P., *Design and Analysis of Clinical Trials: Concepts and Methodologies*, Wiley-Interscience, 2004;

[2] Sackett, D.L., and Rosenberg, W.M.C., "The need for evidence-based medicine", *Journal of the Royal Society of Medicine*, 88, pp. 620-624, 1995;

[3] Song, X-P. et al., "Understanding Requirements for Computer-Aided Healthcare Workflows: Experiences and Challenges", ICSE06, pp. 930-933, Shanghai, China, May 2006;

[4] Teixeira, L., Ferreira, C. and Santos, B.S., "Using Task Analysis to Improve the Requirements Elicitation in Health Information System", in *Proc. of the 29th Annual Int. Conf. of the IEEE EMBS*, pp. 3669 – 3672, Lyon, France, Aug. 2007;

[5] Cysneiros, L.M., "Requirements Engineering in the Health Care Domain", in *Proc. of the IEEE Joint Int. Conf. on Requirements Engineering (RE'02)*, 2002;

[6] Letier, E. and Lamsweerde, A. van, "Reasoning about Partial Goal Satisfaction for Requirements and Design Engineering", SIGSOFT'04/FSE-12, Newport Beach, CA, Oct. 31 – Nov. 6, 2004;

[7] Mylopoulos, J., Chung, L. and Yu, E., "From Object-Oriented to Goal-Oriented Requirements Analysis", *Comm. of the ACM,* 42(1), pp. 31-37, Jan. 1991;

[8] MyoTel, "MYOfeedback based TELetreatment Service", EU/eTEN prg. 046230, http://www.myotel.eu;

[9] Huis in 't Veld et al., "A staged approach evaluation of remotely supervised myofeedback treatment in women with neck-shoulder pain related to computer work", *Telemedicine and E-health*, 2007;

[10] Hermens, H.J. and Vollenbroek-Hutten, M.M.R., "Effects of electrode dislocation on electromyographic activity and relative rest time: effectiveness of compensation by normalisation procedure", *Medical and Biological Engineering and Computing* 42(4), July 2004, pp. 502 – 508, Springer, Berlin.