Early Phase Requirements Assessment of a Teletreatment Trial

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ABSTRACT
This paper presents the early phase requirements elicitation of a teletreatment trial and the assessment of the requirements in respect of their importance to the trial and the feasibility of the corresponding adaptations of the telemedicine system within the trial project constraints. The elicitation approach and techniques adopt the particulars of the telemedicine working practices. The proposed approach not only uses the treatment description and scenario, it also utilizes the trial design. A trial design defines the settings of a trial and develops the treatment protocols such that treatment efficacy can be evaluated based on evidence. Such a design has to be a priori approved by a medical ethical committee, which may impose additional constraints that influence the elicited requirements. The approach therefore involves stakeholders who are not necessarily the users of the system to be. In line with the telemedicine working practices, the approach is moreover based on the identification and analysis of the tasks and task objectives associated to the responsibilities of the involved stakeholders. Furthermore, the elicitation is cyclic and applies a collection of known techniques and informal specification styles (e.g. tables and mock-ups). Results of the cycles converge to a set of requirements understood and agreed upon by the trial designers, who are medical professionals, typically unaware of the methods and techniques applied by engineers, but who co-shape the telemedicine system to be. This way of working manages expectations better, necessary in a telemedicine collaboration.

Categories and Subject Descriptors
D.2.1 [**Software Engineering**]: Requirements/Specifications – *elicitation methods, methodologies.*

General Terms
Design.

Keywords
Goal-oriented requirements elicitation, telemedicine, trial design.

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1. INTRODUCTION
In medicine, diagnostic and treatment procedures are investigated and approved in several stages [1]. Such investigation includes in the later stages clinical trials on humans and the design of these trials. Trial design defines the trial settings and develops the treatment protocol in a standardized way such that the trial, purified from sources of bias, is safe and the treatment efficacy can be evaluated based on evidence. In telemedicine moreover, a treatment protocol typically involves the use of an ICT based telemedicine system, which brings clinical data to the points of diagnostic analysis and treatment decisions, for example at the location of the care professional who resides remotely from the patient or from the care centre accommodating the data.

This paper addresses the adaptation of a telemedicine system to support the teletreatment trial, with a focus on the early redesign phase. In particular, this paper discusses how to elicit requirements in the domain of telemedicine and presents the assessment of the requirements in respect of their importance to the trial and the feasibility of the corresponding adaptations within the trial project constraints. We present a telemedicine specific way to elicit the requirements holistically by utilizing the trial design besides the use of the treatment description and scenario.

2. REQUIREMENTS ELICITATION
This paper describes the requirements elicitation in the European eTEN project MyoTel[1], which investigates a myofeedback based teletreatment service that enables mobile patients with neck-shoulder complaints to receive remotely supervised and personalized treatment during their daily activities. The service uses surface-ElectroMyoGraphy (s-EMG), which is a measure of the trapezius muscle activity, as local muscle relaxation feedback to patients and treatment sign to supervising therapists (Figure 1).

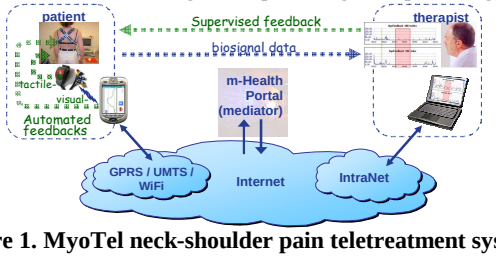

Figure 1. MyoTel neck-shoulder pain teletreatment system.

[1] This work has been sponsored by the EU under the eTEN programme in project MyoTel – 046230.

2.1 Elicitation Techniques

We apply a collection of known techniques to elicit requirements holistically. We, the engineers, have conducted e-mail exchanges and interviews with the trial designers. Group discussions during plenary project meetings have been used for validation feedback. Therapist pretrial training sessions, which use emulations of muscle activities presented on screen mock-ups, have provided validation feedback from professional users. These sessions are a common practice in medicine and used here to get early feedback.

2.2 Elicitation Approach

The elicitation approach uses a set of inputs, namely:

- a scenario provided by the trial designers;
- the trial design and the literature on pain treatment;
- results of the interviews, discussions and feedback sessions discussed in the previous section.

We have studied the trial design and the literature on pain treatment to acquire insight on the objectives of the trial, the treatment protocol, the trial enrollment inclusion-exclusion criteria and the clinical data. The major benefits of the studies are:

- understanding the telemedicine vocabulary (cf. [3]); this is relevant for the collaboration between the engineers and the trial designers, who typically are medical professionals and who co-shape the telemedicine system to be;
- having a better background to identify alternative solutions;
- having a better insight in the required quality of the data; this is for example needed to estimate the transport channel capacity.

In line with the working practices in telemedicine, we adopt a basically top-down task-oriented analysis approach. We identify and analyze the necessary tasks (including the objectives and the functional support required) from the scenario and the trial design. We then identify the stakeholders involved in the trial and the actors that represent them and who are responsible for executing the tasks using the system to be. Furthermore, actor-actor and actor-system activities that embody the tasks are identified and analyzed to get the requirements. Objectives (i.e. goals) play an important role in our analysis because it provides alternative choices (e.g. password protected data access or data encryption to ensure data privacy) and right solutions (e.g. continuous on-line monitoring and data transfer to ensure anytime data inspection). Our approach is therefore goal-oriented (cf. [4]).

2.3 Elicitation Results

The trial objectives provide the context of the requirements and scope the elicitation process. A close inspection of the trial design and also the scenario yields the following MyoTel trial objectives:

- treatment based on strictly supervised training: the trial objective to train patients to relax their neck-shoulder muscle under strict supervision, meaning that therapists inspect the training compliance anytime and frequently. This trial objective for instance requires a continuous on-line monitoring system.
- assessment of the diary based teletreatment: this trial objective originates from the trial design; it includes the assessment of the supporting ICT technology. Performance checkpoints are for instance required to address this objective.

Training as a didactical learning approach typically involves a training task and a task to plan and to conduct training feedback consultations. These tasks involve the actors: patient and therapist, and comprise activities that have to be supported by the telemedicine system (e.g. s-EMG monitoring, data transfer, data analysis, diary submission and reporting). Thus tasks lead to requirements, which we specify by tables that record activities, associated actors, quality of support, and assessment attributes.

Another interesting stakeholder is the medical ethical committee who typically imposes constraints on privacy aspects of patient clinical data. Our elicitation results in an explicit need for a role-based data access and processing mechanism and introduces system administrator actors at the trial sites and for the system provider, who ensure the imposed constraint of this stakeholder.

3. REQUIREMENTS ASSESSMENTS

The studies, interviews and discussions provide the degree of importance of the activities for the trial. The following values are used to attribute the activities:

- *need to have*: this refers to an essential activity needed for achieving the treatment objectives of the trial;
- *nice to have*: this refers to an activity that is considered not essential but it may improve the efficiency of the treatment.

As in Conway [2], requirements have been categorized into:

- *compliant* requirements: requirements fulfilled by the system;
- *non-compliant amended* requirements: unfulfilled by the current system, but considered implementable for a next update;
- *non-compliant no-action* requirements: unfulfilled requirements from *nice to have* activities that will not be implemented;
- *non-compliant undecided* requirements: these are unfulfilled requirements from *need to have* activities that are considered not feasible for implementation within the project.

Some of the elicited requirements were categorized as *non-compliant undecided*. Negotiation with trial designers and the project management were needed to upgrade these requirements to *non-compliant amended* via manpower rescheduling.

4. CONCLUSIONS

Several requirements identified from the trial design complement the requirements identified from the scenario, which in this respect is inherently incomplete. The role of the trial design in the requirements elicitation is therefore considered essential for collecting multi-stakeholder and coherent requirements in the domain of telemedicine. We also propose the use of a cyclic and informal approach to enable collaboration with trial designers who typically are not accustomed to formal methods but who co-shape the telemedicine system. In addition, a formal method may also be applied, because its analytical capability may improve the justification of choices to convince trial designers even better.

5. REFERENCES

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