Early Phase Telemedicine Requirements Elicitation in Collaboration with Medical Practitioners

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***Abstract*—Ubiquity of Information and Communication Technology enables innovative telemedicine treatment applications for disease management of ambulant patients. Development of new treatment applications must comply with medical protocols and 'way of working' to obtain safety and efficacy evidence before acceptance and use by medical practitioners. Usually, medical researchers design new treatment applications and engineers elicit application requirements in collaboration with these researchers to bridge the knowledge and 'way of working' gaps between them.**

This paper presents an elicitation method for new telemedicine applications in a collaborative setting of time-constraint medical practitioners and requirements engineers if the medical researcher is absent. Engineers compensate this lack of resources through cross-disciplinary studies and use of pathophysiological models in the absence of medical evidence. The paper discusses the application of a mixed elicitation method presented in earlier work in the addressed setting. The method applies a scenario based user needs analysis augmented by domain activity and user-system interaction analysis. The elicitation is conducted in a separation of concerns fashion combined with collaboration handshake protocols to align domain activities and user-system interactions. Later phase elicitation of user-system interaction requirements may apply known methods and is not addressed.

***Index Terms*—Telemedicine requirements elicitation, scenario and model-based elicitation method.**

I. INTRODUCTION

Telemedicine uses ubiquitous availability of Information and Communication Technology (ICT) to enable new ways of ambulant patient treatment. ICT data collection and processing paradigms provide rich technological context for new treatment. For example, remote monitoring of a patient's heart rate (HR) at the point of care enables not only timely monitoring for risk stratification and therapy, but also new HR based outdoor physical training therapies aiming to improve cardiovascular condition of patients with cardiac arrhythmia. This latter aspect may play a crucial role for rehabilitation and return of treated patients to an active lifestyle.

Telemedicine therapeutic treatments may involve adaptation of traditional evidence-based therapies or specification of new ICT-based therapies, which have to comply with medical protocols and the 'way of working' in medicine. Therefore, new treatment must undergo several safety tests and medical efficacy studies before medical practitioners accept this therapy to treat their patients [1]. These studies include medical trials on specific patient categories and aim to collect in several follow up stages the required evidence for medical safety and efficacy of the therapies under study.

Medical evidence is often categorized in levels of evidence, which depend on the way evidence was collected (e.g. type of medical trial) and the statistical power of treatment efficacy.

Medicine adopts the Evidence-Based Medicine (EBM) principle [2], which requires the use of therapies with the best possible evidence. Nevertheless, medical practitioners must consider the therapy suitability for a specific patient. Individual patient characteristics may deviate from the studied patient category and require adaptation of medical guidelines to "local" conditions, often representing the most difficult step for the medical practitioner.

Accordingly, practitioners have a traditional attitude in adopting new therapies without sufficient evidence or by artificially introducing unjustified extrapolations of the results of the clinical trials on which guidelines are based. Due to the dualistic nature of EBM, junior practitioners with less medical experience than their senior colleagues often rely on therapies with clear evidence. This traditional attitude is also reflected in defining new therapies. It is difficult for practitioners to envision a new telemedicine application that supports their patients in an envisioned new therapy. Especially if evidence of underlying components of this envisioned therapy are not available (Section V).

EBM makes development of new telemedicine treatment applications challenging. Practitioners must be aware of ICT capabilities to identify and exploit the enriched context enabling new therapeutic approaches. Moreover, they need to oversee to some extend the new therapy and its contextual consequences, including consequences due to ICT resource performance degradation or even failure.

Medical practitioners often have latent ideas to improve their treatment, but they are constrained in time to elaborate these ideas into new treatment or they are unable to easily prove their ideas are correct due to the lack of appropriate monitoring devices. Usually medical researchers have the responsibility, expertise and time to define new treatment

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based on the practitioner's ideas. Consequently, requirements elicitation of innovative telemedicine applications supporting new treatment requires close collaboration between medical researchers and engineers (i.e. requirements engineers) [3-6].

This paper addresses how to elicit requirements of new telemedicine treatment applications in a multidisciplinary setting in which medical practitioners and engineers closely collaborate, but in the absence of medical researchers. It discusses the early phase of the elicitation process emphasizing on a solution to overcome the absence of the medical researchers. The later phase, which e.g. addresses human-computer interface requirements, may apply known methods, and is beyond the scope of this paper.

Study across disciplinary boundaries is an effective way to bridge the knowledge and 'way of working' gaps in telemedicine application design [4-6]. To overcome the absence of medical researchers, engineers conduct a cross-disciplinary study to enable proposition of initial treatment scenarios, and in collaboration with practitioners abandon unrealistic (i.e. medically uninteresting) scenarios and further iterate the potential ones. To enable effective communication with the practitioners, these scenarios are augmented with the treatment intentions that reflect the ideas of the practitioners and are expressed in terms of patient activities.

Iterated scenarios in sub-sequential designs steps also include aspects of patient-system interactions. Therefore, we adopt from [5, 6] the scenario based requirements elicitation method which separates user (i.e. medical) domain concerns from intended system usage concerns, and apply it in a specific way to fit the medical domain peculiarities, like the EBM principle. This method also adopts the notions originally introduced by Benyon and Macaulay in [7] and is briefly described in Section III. As discussed in [4, 8], we also adapt the requirements elicitation methods and techniques referred previously to better match with our design setting, in particular the absence of the medical researchers. In doing so, we use a pathophysiological model if evidence is not available; this approach not only improves communication between engineers and medical practitioners, but also reduces the risk of technology push in the treatment application design.

This paper is organized as follows. Section II describes briefly the project context of the medical case and the associated collaborative research. Section III covers the applied requirement elicitation methodology. Section IV contains the elicitation techniques used during the methodology application. Section V addresses the evidence levels of envisioned treatments. Section VI summarizes the current state of the work and the future steps. Section VII contains the discussion and conclusion of the work.

II. MOBIGUIDE PROJECT

This paper describes the requirements elicitation process of telemedicine application design being conducted in the European project MobiGuide (MG) [9]. This project aims to develop an intelligent distributed decision-support system for personal therapy guidance of chronic ambulant patients.

Medical practitioners involved in the project are a cardiologist and endocrinologist for the medical cases of atrial fibrillation (AF) cardiac disease and gestational diabetes mellitus (GDM). These medical practitioners have an innovative attitude towards new telemedicine treatment applications. They recognize the potential of the MG system in supporting them and their patients in diseases management in the new telemedicine context.

Besides a decision support system, the MG telemedicine system contains a wearable sub-system to monitor in real time the ambulant patient's vital signs (e.g. HR) and physical activity intensity level. Real-time available and remotely stored data enable the incorporation of new therapies in the patient's current treatment or assists medical practitioners in treatment modifications.

The wearable sub-system contains sensors enabling the MG system to detect deviations from a vital sign's desired behavior (e.g. too high HR) during monitoring and sends a related notification (e.g. "take some rest") to the patient. All occurring events and monitored data are stored in the MG system. Hence, the medical practitioner monitors the patient's condition and studies the treatment effect, and may modify the treatment based on available information.

III. REQUIREMENTS ELICITATION METHODOLOGY

We adopt the requirements elicitation methodology introduced in [5, 6]. These apply a mixed method based on scenario user need analysis [7] that is augmented by user activity and user-system interaction analysis and conducted in a separation of concerns fashion. A collaboration handshake protocol provides the necessary common discourse between collaborating medical researchers and engineers and aligns domain activities and user-system interactions. Following [5, 6], we develop in two stages one scenario for each new treatment instead of a scenario corpus per treatment. The scenario represents the main treatment pathway; other details of the treatment like activity branches will be derived using the user activity analysis in the first stage and user-system interaction analysis in the second stage.

A. iPACT-FICS Scenario-Based Methodology

We define a scenario as a narrative description of a sequence of user activities and user-system interactions that the user engages in performing a specific task [10]. It facilitates the eliciting requirements process in settings where different domains (e.g. ICT and medicine) are collaborating.

In the first stage, the main focus is the specification of medical domain-oriented iPACT scenarios. The notion of PACT originates from Benyon and Macaulay [7] and is adapted for use in telemedicine requirements elicitation in [5, 6]. In those studies the intention of the scenario, in particular the intention of the treatment in [5, 6], has been identified as a significant element. However, in our design setting the treatment intention ("i") is such an important concept that we use the iPACT notion. The significance of treatment intentions in the specification of scenarios is described in the next subsection (Section III.B).

The notion of iPACT stands for ***i**ntention* (i.e. aim of the scenario, e.g. the medical intention of the diagnostic procedure and/or treatment described by the scenario), ***P**eople* (i.e. users involved in the scenario, e.g. a patient or a caregiver), ***A**ctivities* (i.e. relevant domain activities of the people, e.g. treatment activities of a patient), ***C**ontext* (i.e. environment in which activities take place and which may influence the activities) and ***T**echnologies* (i.e. essential technologies required by the domain experts to support the activities, e.g. ICT to support telemedicine activities). As in [5, 6], an iPACT scenario therefore expresses domain activities of users, yet independent of the intended system.

The second stage combines the use of the iPACT notion with the FICS notion [5-7]. FICS stands for ***F**unctions* (i.e. functionality of the intended system which is capable to mediate user activities), ***I**nteractions* (i.e. user-system or system-component interactions realizing user activities), ***C**ontent* (i.e. variables of the interactions) and ***S**ervices* (i.e. types of sets of coherent interactions that are expressed in terms of the technology, e.g. streaming service or reliable messaging service). A scenario expressed in terms of iPACT and FICS is therefore a narrative description of user's domain activities to fulfill a specific domain task, and in the presence of the intended system includes the corresponding user-system interactions that realize the domain activity.

The methodology aligns the user activities and the user-system interactions by a collaborative handshake protocol. In the ideal case (Fig. 1a), medical researchers specify the iPACT scenario. Next, engineers identify every user activity that should be supported by the intended system. In addition, for each identified activity they include the associated context and technology elements, construct the corresponding user-system interactions, including the associated functions, content and services, that they consider to realize the activity, and then integrate these FICS elements in the iPACT-FICS scenario. This second stage scenario needs to be verified by the medical researchers by checking the validity of the FICS elements in realizing the user activities defined in the iPACT scenario, including the prescribed context and technology. This collaborative handshake protocol yields a common discourse expressed in iPACT and FICS terms. In practice, the handshake is not a single proposal-confirmation session but usually consists of several iteration cycles.

B. Absence of Medical Researcher

In this work, the main issue for the requirements elicitation process is the absence of the medical researchers. Ideally, this role has sufficient time and provides medical expertise to specify treatments described in iPACT scenarios (Fig. 1a).

As shown in Fig. 1b, the role of the medical researcher needs to be assigned to a team of medical practitioners with the required medical expertise and ideas for new treatments, and engineers with knowledge of ICT and available time. In this team, engineers take the role of medical assistant. These engineers need to undertake studies across their disciplinary boundary (see Section V.C) to enable effective collaboration with the medical practitioners.

The previously mentioned team has the responsibility to specify the iPACT scenario describing the main thread of activities of the envisioned treatment. Medical practitioners discuss their ideas for new treatments, including patient's categories they expect to benefit from the envisioned treatment. Depending on the state and maturity of the idea, the intention of the new treatment could be derived in team meetings. Engineers, who have studied the medical condition (e.g. AF or GDM), could use the treatment intention to scope their literature study and consequently propose several iPACT scenarios reflecting the envisioned treatment and treatment intention. In this stage, the scenarios focus on the involved people (i.e. patients, including their disease category; the so-called inclusion criteria) and their activities.

Unrealistic scenarios would be abandoned under supervision of medical practitioners; i.e. scenarios that rarely occur in a daily care (e.g. low probability of patients matching the inclusion criteria of the scenarios). On the other hand, potential new telemedicine treatments could be specified and described in a more elaborated iPACT scenario. Proposed iPACT scenarios may provide ideas for new treatment therapies or treatment intention worth to be investigated e.g. in the MG project. Also remarks of medical practitioners, like "… in the long run the optimal should be the other way around …" may trigger engineers, who know the ICT capabilities and (because of their study) better understand the practitioners, to specify new iPACT scenarios. Several iterations are required to achieve an iPACT scenario. Particularly, if medical researchers are not participating in the specification process, additional iterations are needed to synchronize with the practitioner.

If the potential iPACT scenario specification becomes stable, although not necessarily completely detailed, we reuse the collaborative handshake protocol discussed earlier. The engineers may propose FICS elements associated to the addressed activity as explained before (Fig. 1b). However, medical practitioners (not the medical assistant) perform the validation step via this handshake protocol.

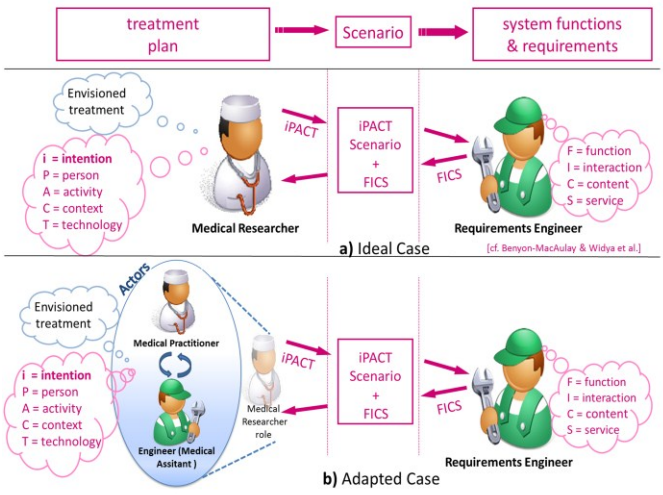

Fig. 1. Requirements elicitation methodology: (a) Ideal case (b) Adapted role assignment case.

IV. TECHNIQUE

Several elicitation techniques are needed in order to apply the previously proposed methodology (Section III) in telemedicine if medical researchers are absent.

A. Cross Disciplinary Study

If medical researchers are involved in telemedicine application design, requirements engineers also need to perform cross-disciplinary study to bridge the knowledge and 'way of working' gaps between them, see also [4-6]. This requires learning medical vocabulary and case terminology via (medical) dictionaries, thesauri, and general literature of the clinical case. Additionally, EBM and medical trial design literature is useful to improve awareness of the medical 'way of working' including the dualistic nature of EBM.

In the MG project (Section II), cross-disciplinary studies have an additional complexity: make engineers capable of taking the role of medical assistants (Fig. 1b) such that they are able to initiate specification of a new therapy. Therefore, engineers need to study parts of medical guidelines and medical literature of the medical case. The selection of guidelines and literature is based on advice of medical practitioners. It provides focus on the information considered relevant for the medical case and relevant for the practitioner's patient categories. Furthermore, engineers also need to search literature using key-words of the clinical case and the treatment intention; e.g. chronic AF, physical exercise training therapy, training target HR.

The previously discussed cross-disciplinary studies are supportive for the collaboration and make engineers better equipped for the following tasks:

- translate to some extent treatment intentions to first versions of iPACT scenarios;
- understand comments and recognize hints or directives of practitioners that are often very subtle. In our experience, this ability could result in new iPACT scenarios, e.g. HR based outdoor physical training (Section V.B);
- gain knowledge on a specific case, its symptoms, and its pathophysiology. Consequently, engineers become able to recognize potential telemedicine treatment activities that could be supported by the intended system;
- get better insight in the requirements (e.g. required treatment data, including availability and quality) and the effect of the treatment procedure in case not all conditions of the requirements are met when treating a patient.

B. Brainstorm and Team Discussion Sessions

Brainstorm sessions are used to determine the medical case and the patient categories that potentially benefit from the new telemedicine application. Teams of medical practitioners and engineers, acting in the medical assistant role, discuss scenario refinements and results of user activity analysis autonomously performed by these engineers. In the later FICS specification stage, teams also discuss results of the user-system interaction analysis.

C. Questionnaires

Engineers made questionnaires for the medical practitioners once the first versions of the iPACT scenarios are sufficiently stable. Specific questions related to the main activities of the envisioned treatment aim to elicit the interrelations, including the effects between therapies and activities within therapies. Additionally, these questionnaires are used to get confirmation of the applied terminology reducing the risk of homonyms.

D. Semi-Structured Interviews

Engineers in the role of medical assistant (interviewer) conduct semi-structured interviews of medical practitioners (interviewees). This interview aims to get details of medical variables (e.g. HR, target HR lower or upper boundaries, blood glucose levels, and patient categories) and the therapy preconditions (i.e. guards) that allow the execution of the therapies. The guards also include certain events (e.g. medical variable change), which might result in the abortion of the executed therapies. Topics covered in these interviews come from scenario sections that are missing or need further detailing.

We use face-to-face meetings, Skype sessions and e-mail exchanges to execute these elicitation techniques.

V. AVAILABILITY AND LEVEL OF EVIDENCE

Section III.B addresses the specification of iPACT scenarios. It describes the main activities thread of the envisioned treatment performed by teams of medical practitioners and engineers, acting in the role of medical researchers.

The complexity of the work of those teams depends on availability and level of evidence of the envisioned treatment elements. We differentiate the following three cases:

A. Evidence Clearly Available

This case does not particularly illustrate the value of the proposed requirements elicitation methodology discussed in Section III. If medical evidence for safety and efficacy is clearly available, for example, if the therapy is addressed in a guideline, the practitioner may apply the relevant parts of the guideline to treat a patient. ICT based applications may be limited to supporting services additional to the treatment activities prescribed in the guideline. For example, generating (electronic) notifications to remind patients to take prescribed medication. As long as those treatment activities are preserved, development of those applications does not need to apply the proposed methodology.

However, guidelines are not always complete or might need certain personalization; in these cases the proposed methodology will be useful.

B. Evidence Partly Available

The proposed methodology has shown its value for cases with evidence of some of the envisioned treatment activities. For example, the exercise training activities discussed by Osbak [11] for chronic Atrial Fibrillation (AF) patients require physiotherapist's supervision during training and have been

accepted by medical practitioners. The differences in context between Osbak's training and the envisioned training treatment for ambulant patients (without supervision) make the latter a different and new treatment; therefore, its development must comply with medical protocols.

Moreover, training instructions of the physiotherapist need to be automated in the envisioned outdoor telemedicine training treatment; i.e. the intended system should guide (via notifications) patient's activity intensity level such that his HR stays within a predetermined target range.

If evidence is partially available, training activities of the envisioned treatment could adopt Osbak's activities. Only the iPACT scenario Context and Technology elements need elaboration.

C. Evidence Not Available

The most challenging requirements elicitation case in the collaboration setting addressed in this paper, is the case of envisioned therapies without evidence. The traditional attitude of medical practitioners and their need to oversee the treatment consequences in case of ICT performance degradation or failure, hamper them to envision a new telemedicine application. Engineers need to be creative in proposing initial iPACT scenario that makes medically sense to start the discussions in the team.

Experience [5] has shown that the use of particular models (e.g. pathophysiological model) of the addressed case known to the practitioners and easy to study by engineers help in the specification of iPACT scenarios that are initiated by engineers.

For example in the case of AF, the normally regular impulses of the sinoatrial (SA) node (i.e. human natural pacemaker) get disturbed and the atria are excited in a chaotic way at very high frequency (>300 beats per minute). As a result, the atrioventricular node (i.e. human backup pacemaker) has to function as a "filter" to avoid excessive beating rate in the ventricle (that would result in life-threatening hemodynamic consequences). Unfortunately the filtering capabilities are not perfect (especially in elder subjects) and this induces irregular and rapid heartbeats, which are not synchronized with the pulses of the SA node, as should be in a normal situations. In such AF episodes, patients may experience symptoms of palpitations or shortness of breath.

An interesting hypothesis is to avoid those symptoms by notifying patients as early as possible at the onset of these AF episodes. These episodes may for example be detected if the patient's monitored HR is higher than the normally expected HR (i.e. a baseline HR measured in a previous consultation) associated to patient's physical activity intensity level.

Ability to measure patient's HR and physical activity intensity level anytime at the point of care may lead to a first version iPACT scenario. The team could elaborate this even in case evidence of the hypothesis mentioned earlier is not yet available.

The use of the AF pathophysiological model as described above is considered useful. Engineers identify the medical variables required to measure and they are aware of the monitoring consequences in case of ICT support degradation of failure. Practitioners can check the hypothesis realism for the medical case and the patient category, and plan a medical pilot study to: i) analyze the correlation between the occurrences of AF episodes and the discrepancies between measured HR and activity intensity levels, and ii) collect evidence.

VI. Current State and Future Work

The elicitation process produced several iPACT scenarios for the AF case, e.g. scenarios to improve patient cardio-vascular condition by physical training, AF symptoms avoidance and abandoned high-altitude patient guidance scenarios. These scenarios were developed in several iterations and therefore were validated regularly by medical practitioners. FICS user-system interactions were partially elaborated using activity analysis, questionnaires and semi-structured interviews. Additionally, an informally specified workflow diagram of scenario activities and partly patient-system interactions is developed.

Moreover, the effects of technology failures or performance degradations on the medical variables (i.e. activity context or interaction content) were analyzed and the treatment consequences (e.g. safe-fail behavior) developed. This results in a Technological Context and Effect ontology specified in Protégé. Future work is the translation of the (refined) workflow diagram into Asbru, which is a semi-formal workflow language suitable for decision support in medicine [9].

VII. Conclusion And Discussion

This paper presents the early phase requirements elicitation of innovative telemedicine applications using a mixed method based on scenarios that are augmented by user activity and user-system interaction analysis. The elicitation process is conducted in a multidisciplinary collaboration setting of medical practitioners and (requirements) engineers. However, medical researchers, with the time and expertise to specify the envisioned treatment are absent. In this paper, we described how a team of medical practitioners and engineers is able to fulfill the role of the absent medical researchers.

The proposed requirements elicitation process complies with the medical way of working by taking the EBM approach into account. The process also separates medical domain concerns from technical support concerns by applying the iPACT-FICS scenario based method. Literature shows that this method is an effective way to specify new telemedicine treatments and fill knowledge gaps. The user domain oriented iPACT scenarios describe the main thread of the envisioned treatment user activities and the iPACT-FICS relation forms the common discourse for both ICT and medicine disciplines.

The EBM principle seems to hamper medical practitioners to envision new telemedicine treatment. Because practitioners are often not fully aware of the capabilities of ICT in creating new context for ambulant patient treatment, they seem to need to oversee treatments consequences in case ICT support degrades or fails. In the addressed collaboration setting a more active role of engineers is necessary. This can be achieved by

converting medical practitioner's treatment ideas to intentions ("i" of iPACT) of envision treatments. Furthermore, engineers with their acquired medical knowledge can propose several initial iPACT scenarios for each intention by studying case related literature. Medical practitioners and these engineers may further refine the initial scenarios.

The use of models, for cases without sufficient evidence makes collaborative specification of a new treatment easier; in particular the use of a pathophysiological model is beneficial. Because medical practitioners better understand the proposed treatment described in the initial iPACT scenario and engineers (acting as medical assistants) could identify the medical variables monitored, they could recognize ICT performance degradation consequences on these variables. Practitioners could then better oversee the treatment consequences. Consequently, this approach balances technological push and domain pull.

However, if medical evidence is (partly) available, study and use of pathophysiological models is not necessary. Elements (e.g. activities) of available evidence-based treatment can be adopted although the treatment has a different context and technological setting. For the envisioned treatment, only Context and Technology of iPACT scenarios need further elaboration in the first stage of the proposed method.

This paper shows the need to identify roles mandatory for the requirement elicitation process; for example, in telemedicine we identified the medical researcher role and the requirements engineer role. If a role is not fulfilled, other stakeholders involved in the elicitation process may act in that role. This paper shows how a team of medical practitioners and engineers takes up the medical researcher role and generates iPACT scenarios.

A disadvantage of the proposed requirement elicitation process in the addressed collaboration setting compared to a setting with medical researchers is the complexity of the process of the previously mentioned team. It requires effort to acquire domain knowledge, several design iterations and access to time-constraint medical practitioners.

Advantages of the proposed approach using the previously mentioned team are: i) a better "see and feel" of the combined ICT and medical problems, the technological context and treatment effect consequences and the solutions, and ii) the team is more open to innovative telemedicine applications than in a traditional way of working situation.

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