Making Medical Treatments Resilient to Technological Disruptions in Telemedicine Systems

Nekane Larburu, Ing Widya, Richard G.A. Bults and Hermie J. Hermens

Abstract— **Telemedicine depends on Information and Communication Technology (ICT) to support remote treatment of patients. This dependency requires the telemedicine system design to be resilient for ICT performance degradation or sub-system failures. Nevertheless, using telemedicine systems create a dependency between medical and technological concerns. We propose a layering technique that links medical and technological concerns by using a two-staged scenario based requirements elicitation method. This layering technique provides functional relations between technological variables (e.g. raw ECG signal) and their technological context (e.g. measurements conditions), clinical variables (e.g. heart rate), and clinical abstractions (e.g. physical exercise target heart rate) and the non-functional quality of data relations between the layers. We use a hierarchical ontology to specify these functional and non- functional relations, which enables the development of technological context and quality-aware telemedicine systems that are able to cope with technological disruptions whilst preserving patient safety.**

I. Introduction

Information and Communication Technology (ICT), including physiological sensors, supports the creation of telemedicine systems that enable unsupervised remote treatment of patients. However, the ICT infrastructure might be prone to technological disruptions during remote patient treatment. These disruptions can potentially have a negative impact on the quality of patient's data at points of clinical decision with an undesirable effect on the treatment. The challenge is to make telemedicine systems technological context- and quality- aware [1, 2], i.e. awareness of performance fluctuations in the applied technology that might affect data quality and the treatment. In this way, the intended telemedicine systems could be designed to respond appropriately to technological disruptions by following treatment protocols refined by medical practitioners to maintain treatment efficacy and to assure patients safety in those situations.

In this paper, we apply a scenario based requirement elicitation (RE) method [3, 4] and refine it with a layering technique to enable the development of intended technological context- and quality-aware telemedicine systems.

The adopted RE method develops scenarios in two stages (Fig. 1). The first stage focusses on user (e.g. patient) activities specified from a medical perspective, and the second stage focusses on the user-system interactions which would be mediated by the intended telemedicine system that implements the aforementioned user activities.

The layering technique proposed in this paper to refine the RE method establishes the functional (i.e. conceptual) and non-functional (i.e. qualitative) relations between the distinguished medical and technological concerns (Fig. 2). We introduce a hierarchical ontology which specifies the relations between the clinical concepts of telemedicine treatments and concepts of the supporting technology explicit. In particular, the ontology specifies the relations between patient data at technological level and abstractions of patient data at clinical decision making level, with clinical variables as intermediate elements. This ontology plays a significant role in the design of a technological context- and quality- aware telemedicine systems that could adapt to contextual changes to fulfill the medical requirements. Besides, it plays also a role in triggering medical practitioners to refine the treatment protocol.

Several studies address methods for designing context-aware healthcare systems [5]. However, those studies did not define the technological context effect on a telemedicine treatment. Other studies [6, 7] are focused on the impact of technology and other parameters on clinical data quality. This paper studies both the effects of technological disruptions on clinical variable quality and its further effects on the treatment.

This work has been implemented in the MobiGuide (MG) European project [8]. MG aims to develop an evidence based context-aware patient guidance system (PGS). Hence, one of the challenges is to develop a context-aware telemedicine system that includes technological, medical, personal and environmental context, to adapt patient treatment to context. This paper focuses on technological changing context and quality awareness.

The following section briefly discusses the adapted RE method. Section III describes the layering technique applied for the RE method refinement and Section IV closes with a brief discussion and conclusion of the obtained result.

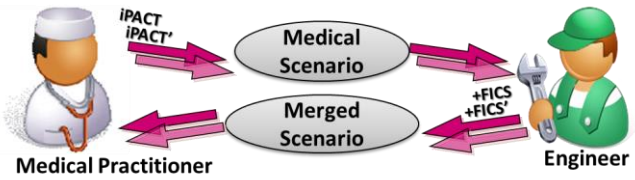

Figure 1. iPACT-FICS requirements elicitation method

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All authors are with University of Twente, Enschede, Netherlands (corresponding author Nekane Larburu: 0031 53 4-892-692; fax: 0031 534-892-287; e-mail: n.larbururubio@utwente.nl).

II. Requirements Elicitation Method

The applied Requirements Elicitation (RE) method is based on [3] and adapted in earlier work [4, 9]. It is a scenario user need analysis method which develops scenarios in two stages, a clinical oriented user activities stage, followed by a technological support oriented user-system interactions stage. These stages contain several cycles and finalized by a handshake mechanism which links the results of the two stages (Fig. 1).

A. First Stage – User Activities

In the first stage medical practitioners develop an iPACT [3, 4, 9] scenario from a clinical perspective focusing on patient activities. The notion of iPACT stands for *Intention* of the intended treatment represented by the scenario (e.g. therapy to improve cardio-vascular condition of Atrial Fibrillation (AF) patients), *People* involved in the scenario (e.g. patients), *Activities* of the treatment protocol (e.g. walking physical exercise), *Context* of the activities (e.g. HR controlled unsupervised exercise activity; see patient data abstraction context details in Section III) and *Technologies* required to support the activities (e.g. wearable lead-1 ECG).

In the adopted methodology, medical practitioners describe an iPACT scenario in an "ideal" situation by inherently assuming that the applied technology performs adequately and the quality of the measured and processed clinical variables fulfils the treatment requirements.

B. Second Stage – User-System Interactions

In the second stage we focus on user-system interactions and extend the scenario with FICS elements. FICS stands for: *Functionality* of the intended system to support the iPACT scenario (e.g. system monitoring and control functions), *Interactions* between user-system or system-component (e.g. patient physical exercise guidance, ECG monitoring system), *Content* of these interactions (e.g. to slow down based on monitored HR (mHR) derived from ICT resources ; see detailed content examples in Section III) and the intended system's *Services* of the interactions (e.g. atomic request-response service elements).

Requirements engineers propose FICS elements that are feasible to implement by technology and are considered able to realize the iPACT activities. Medical practitioners confirm the iPACT-FICS match by the handshake protocol (Fig. 1).

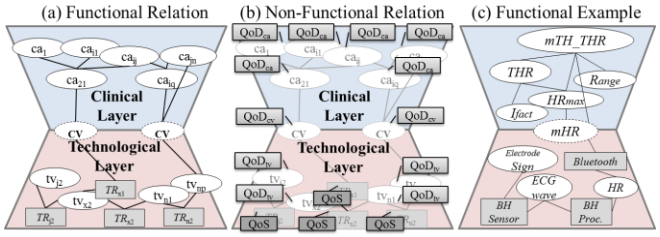

Figure 2. Layering technique representation: (a) Functional relation of clinical abstractions (ca), clinical variables (cv) and technological variables (tv) with technological resources (TR); (b) Non-functional relation of QoD and QoS relation; (c) Example.

III. Layering Technique

A layering technique refines the presented RE method (Section II) by explicitly defining the functional (Section III.A) and non-functional relation (Section III.B) between clinical abstractions in a medical layer and technological variables in a technological layer (Fig. 2). The technological disruptions effects in the treatment are further studied (Section III.C).

A. Functional Relation

In this paper we use the term *functional* relation to refer to the direct relation or dependency that exists between clinical abstractions at points of decision and technological variables at points of monitoring by using clinical variables as an intermediate element.

1) Clinical abstraction

A clinical abstraction is a high-level context dependent clinical interpretation of lower level abstractions and of a set of coherent elementary clinical variables, such as HR and Blood Pressure (BP) [10, 11]. Besides hierarchically structured, a clinical abstraction is typically represented as a temporal pattern. Due to its context sensitivity, a clinical abstraction contains context information that influences the interpretation of the abstraction. An example of such a context is the information about the medical protocol applied or guideline associated to the clinical abstraction.

Example: In MG, a physical exercise (e.g. walking) treatment to improve the cardiovascular condition of an Atrial Fibrillation (AF) patient applies a clinical abstraction for a safe and effective physical training. This clinical abstraction represents a temporal pattern in which mHR of a patient fluctuates within a predetermined Range (e.g. 10%) of the Target HR (THR) (Fig. 3). This THR is the clinical abstraction of the maximum HR value (HR_{max}) of a patient reduced by an Intensity factor (I_{fact}) of the particular patient. During a supervised stress test (e.g. the treadmill Bruce test [12]) the medical practitioner determines HR_{max} and I_{fact} in order to keep the telemedicine treatment safe and effective in an unsupervised extramural physical exercise environment. Hence, the clinical abstraction is mHR_THR:= mHR $\in$ [(THR-Range), THR] (Fig. 3) with THR := $HR_{max} \times I_{fact}$. If during physical exercise the clinical abstraction mHR_THR is not observed for a certain specified time (e.g. T = 2 min), the treatment decision support system infers an over or an under exertion and generate a message to the training patient to slow down or to speed up respectively (Fig. 3). This example shows a hierarchically structured clinical abstraction, including the context (e.g. Bruce treadmill protocol).

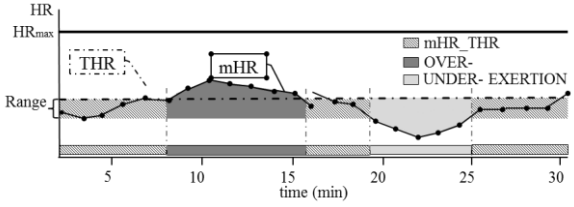

Figure 3. Clinical Abstraction mHR_THR of AF physical exercise treatment

2) Clinical Variables

Clinical variables are elementary variables which represent patient's vital signs and some commonly used trend signs known in medicine (e.g. BP, HR). On the one hand, these clinical variables form the leaf elements of a hierarchically structured clinical abstraction which typically is a higher level abstraction discussed earlier (Fig. 3). On the other hand, these clinical variables need to be captured, transported and processed by ICT resources like sensors, and processing and communication resources. Therefore, clinical variables act as an intermediate between high level clinical data concepts(i.e. clinical abstraction) and data variables at technological level (i.e. technological variables), visually shown in Fig. 2a.

3) Technological variables

Technological variables represent the acquired, processed and communicated data of ICT technological resources. Technological resources measure, (pre)process and transport technological variables in order to derive treatment specific clinical abstractions at points of decision making.

Example: In the AF physical exercise treatment technological resources provide technological at point of monitoring. The BioHarness (BH) sensor [13], shown in Fig. 2c, measure the electrode signal and outputs electrocardiogram (ECG) wave. An internal processor (BH proc.) of the BH system derives the HR technological variable from the R-R peaks of the measured ECG wave (Fig. 2c). This HR trend sign is wirelessly transmitted providing at point of clinical decision, genuine remote mHR clinical variable.

The developed hierarchical ontology is modeled as an hourglass (Fig. 2) by the fact that a large set of clinical abstractions could be associated to a small set of clinical variables and moreover a small set of clinical variables could be associated to a large set of technological variables. We formalized this functional relation, outcome of the RE method refinement, in a hierarchical ontology (Fig. 2a). As shown, the RE method refinement focuses on the specification of the FI**C**S *Content* of the interaction, making the clinical variables the solely intermediate element to link medical and technological layers.

B. Non- Functional Relation

Complementary to the functional relation is the *non-functional* relation between Quality of Data (QoD) of clinical abstraction, clinical variables and technological variables.

In the literature we found five main quality dimensions for clinical variables quality indication [14, 15]: Accuracy, Dependability, Timeliness, Cost and Quality of Evidence. These quality dimensions may contain data sub-qualifiers. For example, Sensitivity (Se) and Specificity (Sp) are sub-qualifiers of Accuracy. These five quality dimensions are evaluated with high, medium, low, and very low, in line with the medical practitioners way of working [15]. QoD of technological variables is influenced by the Quality of Service (QoS) of mediating ICT technological resources. The QoS is also expressed in terms of these five quality dimension. In this case, QoS quality dimension represents the extent to which the technological variable's QoD is preserved by the service of the resources. In this paper, QoS of technological resources is described by a set of Resource Qualifying Parameters (RQP), e.g. Signal to Noise Ratio (SNR). RQPs are the basic elements we use to compute QoS following algebraic computational models of [16].

In the adopted RE method (Section II) the QoD and QoS requirements of the clinical data and technological resources respectively are not made explicit. The layering technique supports the specification of the non-functional relation between medical and technological layers (Fig. 2a transforms into Fig. 2b). Firstly, we present the *Ideal Case* on which the quality requirements are fulfilled, secondly the *Non-Ideal Case,* where some technological disruptions occur affecting the quality requirements, and we finalize with the *Treatment Adaptation* sub-section.

1) Ideal Case: Medical to Technological Layer

In the first RE cycle, the quality requirements of clinical abstractions, clinical variables and technological variables are inherently assumed to be fulfilled. However, these quality requirements need to be made explicit. Hence, in the ideal case, the quality requirements are elaborated top-down, from *medical to technological layer*.

Firstly, medical practitioners specify the quality requirements of clinical abstractions and their underlying clinical variables in order to perform the medical activity defined in the scenario. Based on these quality requirements and using the functional relation, engineers specify QoD requirements for the technological variables and QoS requirements for the technological resources involved. Hence, the technological context quality is compliant with the "ideal" case.

Example: In an ideal case the physical exercise activity is led by a THR, with $I_{fact,\ ideal} := 70\%$, and requires mHR clinical variable and ECG technological variable with Accuracy:= High and Timeliness:=High to assure patient's safety. This is translated by engineers to the technological requirements by specifying that BH sensor and processor have to guarantee a SNR higher than 5dB and Sensitivity (Se) higher than 90% respectively (Table 1, *Ideal* case).

TABLE I. FUNCTIONAL & NON-FUNCTIONAL RELATION FOR AF EXERCISE TRAINING THERAPY

Functional Relation	**Non-Functional Relation**	**Example**		
		Functional	***Non-Functional***	
			Ideal	***Non-Ideal***
Clinical Abstraction	CA (QoD)	THR **:=** $HR_{max} \times I_{fact}$	$I_{fact,\ ideal} :=$ 70%	$I_{fact,\ non\text{-}ideal}$ = 60%
Clinical Variable	CV QoD	mHR	Acc.[c]**:=** H[e] Tim.[d]**:=** H	Acc. **:=** L[f] Tim. **:=** H
Tech.[a] Variable	TV QoD	ECG wave	Acc.**:=** H Tim.**:=** H	Acc. **:=** L Tim. **:=** H
Tech. Resources	QoS (RQP)	BH sensor	SNR > 5dB	SNR=0dB
		BH proc.[b]	Se > 90%	Se = 90%

a. Technological; b. Processor; c. Accuracy; d. Timeliness; e. High; f. Low

2) Non-Ideal Case: Technological to Medical Layer

As described previously, ICT technological disruptions can occur unexpectedly and alter the technological context. As a result, the QoD of technological variables first and thereafter QoD of clinical variables and clinical abstractions at point of decision may degrade. Hence, the "non-ideal" case study is performed bottom-up, from *technological to medical layer*. First, engineers study the potential technological disruptions that could arise. Thus, when a certain resource fails or underperforms, one or more RQPs, which represents QoS and affects QoD and the quality of the technological context, will vary.

Example: In the physical exercise treatment, the BH sensor's SNR might provide a value of 0 dB, which does not fulfill the "ideal" case quality requirements. As a result, mHR clinical variable's quality degrades (i.e. Accuracy:=Low). In this new situation, medical practitioners determine that the intensity factor that defines THR must be lowered to I_{fact}:=60% in order to preserve patient's safety (Table 1, *Non-Ideal* case).

This non-functional relation of QoS represented by RQPs, and QoD of technological variables, clinical variables and clinical abstractions are coupled and also formalized in the hierarchical ontology.

C. Treatment Adaptation

Medical practitioners have to face potential new technological context, where the clinical variable quality does not fulfil the requirement, and determine how to adapt or modify the clinical abstractions in order to ensure the patient's safety and maintain treatment's efficacy. This means that the new technological context triggered by the Non-Functional Relation (Section III.B) requires a new Functional Relation (Section III.A) specification. Hence, the RE method refinement focuses on the detailed specification of the iPA**C**T *Context* analysis, making the technological context an explicit part of the medical activities context, that triggers an additional RE cycle, iPACT'-FICS' (Fig. 1). As a result, the intended telemedicine system is context- and quality-aware and set for technological disruptions.

IV. Discussion And Conclusion

In this paper we present a layering technique that refines a RE method to successfully confront problems caused by technological disruptions. This layering technique defines the functional relations between medical and technological concerns by using the clinical variable as an intermediate element. Additionally, we make explicit the non-functional relations between the two layers, characterized by the quality of technological context. Therefore, when the quality of the technological context varies undesirably clinical variables quality may degrade, affecting potentially the treatment. We argue that both the technological context of medical activities and the content (i.e. clinical variables) used in the user-system interaction are focal points in the RE refinement. This refinement links medical and technological concerns and avoids mixing both concerns. This has two major advantages. Firstly, during our RE study [9] we understood that medical practitioners should not deal with specific technological information. Moreover, the clinical decisions, which might be based on medical guidelines, should not be "polluted" with technological information. Hence, the ontology resulting from the layering technique must define medical and technological concerns separately. Thereby, in MG, the technological specific information is translated to clinical variables and their QoD, and their clinical effects are addressed separately.

The scope of this paper is in the effect that technological context has on clinical data quality. This paper does not address the effect of certain other features (e.g. patient education) on the QoD. For future work, we will describe the algebraic computational models to calculate QoD of the clinical variables defined in the ontology from QoS of technological resources and how these QoD are mapped to quality grades and trigger the treatment adaptation.

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