IEEE Journal of Translational Engineering in Health and Medicine

Received 31 January 2015; revised 4 May 2015; accepted 2 July 2015. Date of publication 21 July 2015; date of current version 12 August 2015.

Digital Object Identifier 10.1109/JTEHM.2015.2458870

An Ontology for Telemedicine Systems Resiliency to Technological Context Variations in Pervasive Healthcare

NEKANE LARBURU, RICHARD G. A. BULTS, MARTEN J. VAN SINDEREN, (Member, IEEE), ING WIDYA, AND HERMIE J. HERMENS

(Selected Conference Paper)

University of Twente, Enschede 7522 NB, The Netherlands

CORRESPONDING AUTHOR: N. LARBURU (n.larbururubio@utwente.nl)

This work was supported by the European Union's Seventh Framework Programme for the research, technological development, and demonstration under Grant 287811.

ABSTRACT Clinical data are crucial for any medical case to study and understand a patient's condition and to give the patient the best possible treatment. Pervasive healthcare systems apply information and communication technology to enable the usage of ubiquitous clinical data by authorized medical persons. However, quality of clinical data in these applications is, to a large extent, determined by the technological context of the patient. A technological context is characterized by potential technological disruptions that affect optimal functioning of technological resources. The clinical data based on input from these technological resources can therefore have quality degradations. If these degradations are not noticed, the use of this clinical data can lead to wrong treatment decisions, which potentially puts the patient's safety at risk. This paper presents an ontology that specifies the relation among technological context, quality of clinical data, and patient treatment. The presented ontology provides a formal way to represent the knowledge to specify the effect of technological context variations in the clinical data quality and the impact of the clinical data quality on a patient's treatment. Accordingly, this ontology is the foundation for a quality of data framework that enables the development of telemedicine systems that are capable of adapting the treatment when the quality of the clinical data degrades, and thus guaranteeing patients' safety even when technological context varies.

INDEX TERMS Context, ontology, telemedicine, quality of data.

I. INTRODUCTION

Data, clinical data in particular, is essential to create clinically relevant information in healthcare for treatment's diagnosis and prognosis besides other concerns, such as the information of potential conflicting treatments or contraindication drugs. As technology advances, new ways of acquiring and processing clinical data are emerging to better enable patient care. Pervasive healthcare, for example, uses Information and Communication Technology (ICT), to obtain clinical data from remotely monitored ambulatory patients and it often employs automated Clinical Decision Support Systems (CDSS) to process the data at the point of care. This way the patient is more 'closely' treated, while financial and human resource requirements are lowered.

However, the CDSS needs to deal with uncertainties in order to provide safe and efficient care to the patient. The sources of uncertainty are diverse: from patients who cannot describe their situation to laboratories that report erroneous clinical data [1]. The quality of the clinical data (QoD) contributes to the decisions uncertainty. In case the clinical data quality is unknown, the clinical decisions can be done based on the assumption that the clinical data fulfils the medical requirements, resulting in a certain but erroneous decision. In the traditional medical practice, in intramural settings (such as a hospital), medical domain experts usually trust the clinical data used for their decision making process since they study and evaluate the data before using it in their decision making process. In case they determine that the data is suspicious (e.g. erroneous, noisy or out of date), they perform additional measurements or make use of complementary data. Nevertheless, in some cases the medical domain experts store erroneous or incomplete data in medical registries

or laboratory report results may contain errors [1], [2]. Furthermore, performance issues regarding ICT-based technological resources (e.g. weak internet signal or low device battery) might cause QoD degradation [3], [4]. QoD-unawareness can thus lead to risky treatment guidance, particularly in extramural settings where the ambulant outpatient is guided by an automated CDSS, and where the CDSS makes use of ICT-based clinical data. Moreover, in the extramural settings, there are no quality controls from hospitals or medical domain experts. Accordingly, nobody supervises the data at the point of care, which further increases the possibility of unnoticed quality problems. This paper, therefore, addresses the problem of QoD degradation in extramural settings for pervasive healthcare.

In order to develop a telemedicine system resilient to technological disruptions we need to build a QoD-framework that defines the relation between clinical treatments and technological context characterized by the performance of ICT-based technological resources. This work proposes an ontology to describe this relation. This ontological characterization of the clinical and technological relation provides a formal way to represent the knowledge, which is to be used by the QoD-aware telemedicine system. The developed ontology is the output of a refined requirements elicitation (RE) method supported with a layering technique [4].

The following section summarizes the RE method and layering technique to build a QoD-framework for telemedicine systems. Section III presents the hierarchical ontology that contributes to the QoD-framework development. Section IV presents the application of the QoD-framework in a telemedicine study and its results. Finally, Section V discusses the potential impact of the presented methodology for telemedicine systems and future work directions.

II. METHODS AND PROCEDURES

Quality of Data (QoD) is addressed in several healthcare studies [2], [5]–[10]. There are several ways of addressing QoD in healthcare. Some studies cope with uncertainties in the knowledge representation and inference schemes for CDSS [11]. The QoD is one of the uncertainties that healthcare must study in order to provide best treatment to the patients. GRADE [12] considers the necessity to involve quality of evidence (QoE) and strength of recommendation (SoR) in clinical guidelines in order to guarantee best evidence-based care to patients. Other studies focus on how to determine the quality of data stored in medical databases, such as for electronic health records, and its impact on healthcare [2], [5]. Additionally, the impact of the performance of technological resources on clinical data quality or in the treatment is studied in [8], [13], and [14].

Telemedicine systems often aim to provide treatment guidance to ambulatory outpatients in extramural settings for pervasive healthcare. These systems are data-driven and their guidance at the point of care is mainly based on the monitored clinical data by using body area networks (BAN), which consist of sensors, actuators, communication and processing facilities that are connected via a wireless network [15], and personal medical devices, such as Blood Pressure (BP) monitors or Heart Rate (HR) sensors. We refer to all these ICT-based components and facilities as technological resources. Telemedicine systems highly depend on the clinical data used to guide patients remotely. Therefore, the quality of this data also has a significant effect on the guidance and its degradation may negatively affect the treatment, putting the patient's safety at risk. In order to prevent such a treatment risk increment by erroneous treatment guidance, we present a method to build a QoD-framework for these telemedicine systems to make them QoD-aware.

There are several factors that can influence the quality of clinical data. Some of the factors are related to the performance of the technology used to obtain the data (i.e. internal factors), and other factors are related to the usage of the technological resources by the user (i.e. external factors).

Firstly, we study performance properties, i.e. quality of service (QoS) of technological resources. In this paper, QoS of technological resources is described by a set of Resource Qualifying Parameters (RQP). Since the quality of the data that is provided by a technological resource will depend on the QoS of this resource, RPQs are used to compute QoD. For example, the mobile internet coverage, the robustness against noise, or the battery capacity of a specific technological resource may influence the clinical data quality used for the treatment. Furthermore, other factors, such as environmental circumstances also contribute to the technological resources' performance and they are modeled as RQPs. For example, the temperature of the place where the measurement is done may influence the performance of a device, or a rainy weather can alter the internet connectivity to transmit the data causing data transmission delays or data loss, which characterize the quality of the clinical data. Therefore, we propose a QoD computation model which is based on RPQs.

Secondly, we also study the usage of technological resources (by the user) since its usage has an influence on the quality of the clinical data. Accordingly, user characteristics are modeled as RQPs used to compute QoD. Patient education is one of these characteristics that influence the proper usage of a device. For example, BP must be measured sitting and in a relaxed condition to provide an accurate BP measurement. If the patient is not educated to make the measurement correctly and stands up, the QoD of BP degrades and the BP value may not be clinically valid. Patient trustworthiness is another user characteristic that influences the QoD. Some patients for example, perform measurements at their convenience in order to obtain the clinical data values that they are content with. Besides, when the data is input manually, potential typing errors might occur. Therefore, the trustworthiness value (used to compute QoD) for manual input is set *Medium* whereas for automatic device input it is set to *High*. Additionally, the system checks if the value is within range given by the BP monitor manufacturer to

IEEE Journal of Translational Engineering in Health and Medicine

prevent accidental typing errors (e.g. 1000 instead of 100) and determine the final QoD. Therefore, in the ontology presented in Section III, we model these user characteristics as RQPs of, for example, manual input device, which can be categorized under a sensing or a processing component.

All these characteristics or RQPs comprise what we call technological context, defined as technical information provided by a collection of technological resources that characterizes patient's treatment [3], [16]. We focus on the impact of technological context on the QoD and the impact of QoD on the treatment in order to build a QoD-aware telemedicine system. To achieve such a system, we develop an ontology that represents the relation between clinical data at the technological level and clinical data at the clinical decision making level. This ontology is the result of applying a refined RE method and the layering technique from [4], which is summarized here.

A. RE METHOD FOR QoD AWARENESS

To acquire requirements of the envisioned QoD-aware telemedicine system we adopt the role of requirement engineers and apply the iPACT-FICS RE method [3], [4], [17]. This method has been applied in several healthcare projects, since it was easily understood by medical domain experts and produced successful results.

Here, we summarize the iPACT-FICS RE method as follows. iPACT describes the *intention* of the envisioned system's usage (e.g. supporting out-patients' treatment guidance) by *People* who directly interact with this system (e.g. patient) and their treatment related *Activities* (e.g. walking physical exercise) in a particular *Context* (e.g. outdoors exercise activity) supported by *Technology,* which is the envisioned system (e.g. a mobile patient guidance system). This iPACT analysis is used to build a medical scenario from a user perspective; i.e., the thread of main activities for the patient treatment prescribed by the medical practitioner using the envisioned system. Next, we focus on the FICS analysis. FICS stands for *Functionality* of the intended telemedicine system, user-system *Interactions*, *Content* of these interactions, and the intended system's *Services* which are constituted by the interactions [17]. The FICS analysis is concluded with an augmented iPACT scenario, which describes the people-envisioned system interactions. The iPACT-FICS scenario is finalized after approval from medical domain experts.

In order to study the influence of the technological context on the treatment and incorporate adaptation mechanisms in the system, this RE method is applied as follows. In the first iPACT-FICS iteration the envisioned technology is a telemedicine system assumed to perform without disruptions (i.e. *Ideal Case*) and the context has no influence on the system performance. In the second iteration we focus on the technological resources' disruptions (i.e. *Non-Ideal Case*), which leads to a new technological ***C***ontext (iPA***C***T), and their impact on patient treatment. Now we introduce a telemedicine system, which is QoD-aware as the selected technology (iPAC***T***). Additionally, we make medical domain experts aware about the potential technological disruptions that can occur. Next, these medical domain experts determine how to adapt patient treatment activities (iP***A***CT), by taking precautionary actions to ensure patients' safety and system efficacy. Therefore, this results in a new iPACT'-FICS', where the intention of the envisioned system and the people involved in the scenario remain the same. Medical practitioners considered the requirements presented in this new iPACT'-FICS' scenario as a guarantee of patient safety. Therefore, these requirements must be implemented into the system.

In the *Ideal Case*, the context corresponds to the treatment activities and the patient where no possible technological disruptions occur. Accordingly, the envisioned system and the treatment activities are not affected. However, in the *Non-Ideal Case*, the context also involves the technological context variations. Consequently, this new (technological) context leads to a new technology which needs to be QoD-aware and further leads to new treatment activities that must guarantee patients safety.

For example, for both cases, the *intention* (**i**PACT) can be to support out-patient's physical exercise treatment guidance and the *people* (i**P**ACT) can be a cardiac out-patient. In the *Ideal Case*, the *activity* is to perform physical exercise in an outdoors *context* with the support of the envisioned telemedicine system *technology*. In contrast, in the *Non-Ideal Case*, the *context* is an outdoors exercise with degraded quality of the data caused by data communication disruptions. Consequently, the envisioned system is a QoD-aware telemedicine system *technology*, which provides treatment adaptation mechanisms, so that the physical exercise *activity* is modified by informing the patient to slow down or stop the physical exercise treatment.

As presented in [4], the RE method refinement to design technological context and QoD-aware telemedicine systems focuses on the detailed specification of the iPA**C**T *Context* analysis. This makes the technological context an explicit part of the medical activities context that triggers an additional RE cycle, i.e., iPACT'-FICS'. As a result, the intended telemedicine system is QoD-aware, set for technological disruptions.

B. LAYERING TECHNIQUE

The layering technique, described in [4], defines the functional (i.e. conceptual) relation and non-functional (i.e. qualitative) relation between clinical layer and technological layer of a telemedicine system. We summarize the concepts of the functional and non-functional aspects.

1) FUNCTIONAL RELATION

The functional relation refers to the direct dependency between the data being used in the clinical layer and technological layer. As presented in [4], the clinical layer comprises *clinical abstractions*, which are high-level medical concepts (events) obtained typically from temporal patterns of elementary clinical variables. The elementary

clinical variables (e.g. BP, HR) are the concepts of clinical data that require additional patient and treatment context information to become a meaningful clinical information, i.e. clinical abstractions. The clinical abstractions are used by the clinical decision making agents (e.g. medical practitioners or CDSS) to treat patients. Hence, the clinical abstraction is the data in the clinical layer that can trigger clinical recommendation from the CDSS for the treatment guidance. An example of a clinical abstraction is the over-exertion of a patient during physical exercise, defined as the event when monitored heart rate (HR) is above the recommended target HR range for more than 30 seconds. As a result the decision making agent, such as the CDSS, may send a clinical recommendation to the patient to slow down.

The technological layer comprises *technological variables*, which are 'unprocessed' raw data handled by technological resources that do not apply or require any clinical interpretation. Technological resources measure data at point of monitoring, (pre)process and transfer these technological variables. For example, a sensor monitors the electrode signal technological variable, which is processed and transported by other technological resources. At the point of decision, where the CDSS is executed, technological variables are interpreted as clinical variables, usually represented by patient's vital signs, like the HR.

2) NON-FUNCTIONAL RELATION

Complementary to the functional relation is the non-functional relation between QoD of clinical abstraction, clinical variables and technological variables.

Being QoD vulnerable to technological disruptions, as seen in [4], the technological context plays a significant role in this non-functional relation. In the first phase of this non-functional relation of the data, the technological context is compliant with the medical requirements (i.e. *Ideal Case*). This means that the QoS of the technological resources fulfil the requirements to provide *high* quality data. Thus, the QoS of the relevant technological resources is specified in this phase, so that the QoD of technological variables, and as a consequence the QoD of clinical variables and clinical abstractions, fulfil the clinical quality requirements.

In the second phase (i.e. *Non-Ideal Case*), the potential technological disruptions that alter the technological context and their effects on the QoD are studied. Thus, the QoS of the technological resources affects the QoD of the technological variables in the technical layer. This has an effect on the QoD of clinical variables and ultimately on the QoD of clinical abstractions used for the treatment in the clinical layer. In order to ensure the patient's safety and maintain treatment's efficacy, treatment adaptation mechanisms are developed by applying the RE method described in Section II. A.

III. RESULTS: THE QoD-FRAMEWORK ONTOLOGY

The applied RE method refinement and the layering technique results in an ontology, which we refer to as the QoD-Framework ontology. This ontology captures the necessary knowledge for QoD-aware telemedicine systems that aim at preventing the risk of treatment increment when the technological context varies. As described by Paganelli and Giuli [18], ontologies may help in: 1) specifying contextual knowledge in terms of classes of objects, relationships, and constraints on their properties; 2) describing contexts semantically in a way which is independent of programming languages, underlying operating systems, or middleware; 3) enabling formal analysis of domain knowledge, i.e. context reasoning using first-order logic, or temporal logic; 4) deriving fresh knowledge and facts through reasoning on context data by using inference engines; and 5) enabling knowledge reuse, as ontologies of different domains can be composed and extended with new concepts in order to produce new ontologies without starting from scratch.

There are existing ontologies that represent the context for smart home applications [19] and healthcare [18]. In [18], Paganelli and Giuli presents a personal context ontology for a specific home care application that supports patients in 'alert' situations where patients might require assistance. The context entities include persons (e.g. patient, medical practitioner) and locations (e.g. patient's home and care center); and the related context items include information on the patient's biomedical parameters (e.g. vital signs) and home living environment (e.g. temperature). The 'alert' situations are attributed to the patient's clinical status (e.g. heart rate out of range) or external environmental situations (e.g. temperature out of range). Other studies address QoD related ontologies, which describe the QoD dimensions [20] that represent different aspects of QoD. Moreover, in recent years ontologies have been often used to represent clinical guidelines [21], [22]. The usage of clinical guidelines in information systems, such as CDSS, has contributed to this ontology application. The formalization of the guideline in an ontology supports the implementation of a computer interpretable guideline (CIG), applied in guideline-based CDSS (Section IV. B).

We target an ontology that captures the relations between the following three concepts – technological context, quality of clinical data, and patient treatment – in order to represent the knowledge for a QoD-aware telemedicine system. However, most of the studied ontologies address either clinical guidelines, quality of data, or personal (user) context. Therefore, the QoD-Framework ontology presented here (Fig. 1) covers these three concepts and differs from the currently existing ontologies. Fig. 1 illustrates the overview of the QoD-Framework ontology.

The QoD-Framework ontology has been specified with the Web Ontology Language (OWL) [23]. In Fig. 1, the OWL ontology is represented by means of Unified Modeling Language (UML) class diagrams. UML classes represent OWL classes, UML class attributes represent OWL datatype properties, and UML associations among classes are used for representing OWL object properties.

IEEE Journal of Translational Engineering in Health and Medicine

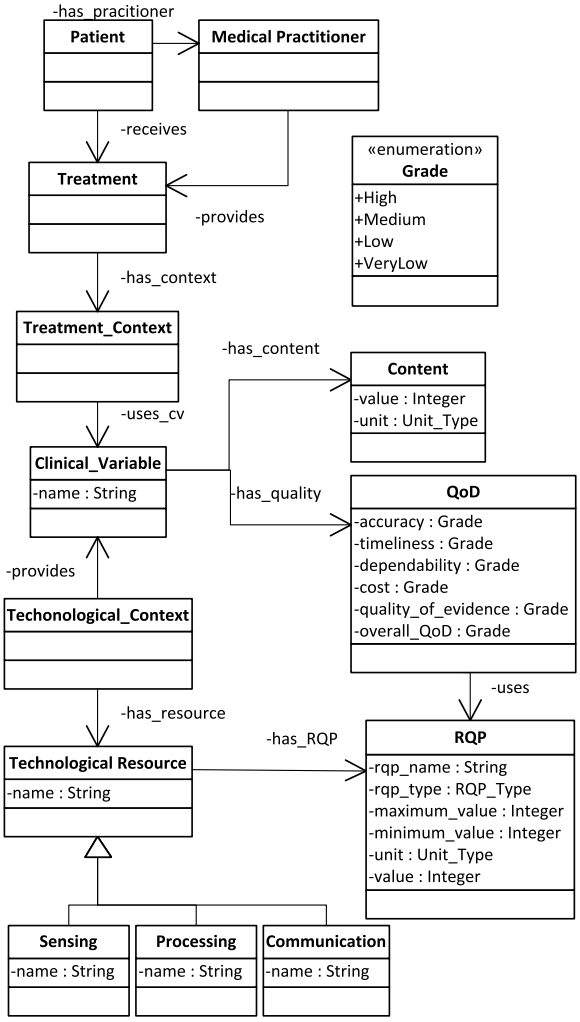

FIGURE 1. **QoD-framework ontology overview.**

The QoD-Framework ontology is designed to formalize the relation between the technological context and the clinical context and support the delivery of specific guidance based on the technological context. Additionally, the QoD-Framework ontology was validated and used by medical practitioners to understand and formalize these relations. The QoD-framework is based on the layering technique and it consists of two parts: A) the technical domain ontology, which captures the knowledge on the technological layer, including the relation between the technological context and the QoD relevant to clinical variables; and B) the clinical domain ontology, which captures the knowledge on the clinical layer, including the relation between the QoD relevant to clinical variables and the patient treatment.

A. TECHNICAL DOMAIN ONTOLOGY

The technical domain ontology is illustrated in the lower part of Fig. 1. As described before, the ICT-based technological resources make it possible to obtain clinical data from remotely monitored ambulatory patients. On the other hand, the technological context is characterized by the performance of ICT-based technological resources. Additionally, the technological context, which comprises technological resources, provides clinical variables with QoD related information.

The performance of each technological resource, determined by resource qualifying parameters (RQP), corresponds to the quality of service (QoS) of each technological resource. Each technological resource can have one or more RQPs. As discussed in [3], the RQPs are either static or dynamic. The static RQPs are usually given by the technological resource manufacturer and represent the constant properties of the device. For example, the BioHarness sensor manufacturer provides the specification of the sensor [26], such as the sample frequency of the general log data (e.g. 1Hz). The dynamic RQPs are obtained during system execution time and can vary. For example, the battery level of the BioHarness sensor at a particular moment in time. The RQPs have a name, type (static or dynamic), a maximum and minimum value (usually for static RQPs), a unit and a value (see Fig. 1 and Table 2).

The RPQs of the technological resources, which are given in a specific technological context, are associated with one or more QoD dimensions of the provided clinical variables [3], [4]. Accordingly, Fig. 1 shows that the QoD of the clinical variable uses RQPs for its QoD dimensions computation. To select the required QoD dimensions, we first did a literature survey [12], [20], [24], [25], where we came up with potential relevant quality dimensions for the applied study. Secondly, we conducted discussions with the medical practitioners of the MobiGuide project to ascertain the QoD dimensions that needed consideration. Medical practitioners request limited QoD dimensions that can cover their necessities. As a result, it was agreed to adopt the following five QoD dimensions: Accuracy, Timeliness, Dependability, Cost, and Quality of Evidence. These QoD dimensions also cover other similar quality dimensions (e.g. delay under timeliness), which may be applicable in other studies and do not overwhelm the system or medical practitioners with additional QoD information.

By using the RQPs in the computational models presented in [3], we calculate the scalar value of each QoD dimension. The output is a scalar value, which is assigned a quality grade – *High*, *Medium*, *Low*, or *Very Low* – by using the stratification model described in [3]. These grades, commonly used in the medical practice and identified by GRADE healthcare working group [12], were also easily understood and validated by the medical practitioners involved in the study. The stratification model is treatment context specific, and therefore, the medical practitioner is the one in charge of determining the scalar value ranges that correspond to each quality grade. For example, the scalar value (e.g. 85%) of a computed dependability QoD dimension is based, among others, on the HR sensor battery level (e.g. 50%), which might have different interpretations depending on the treatment context. In a treatment context that consists of an outdoors 1 hour duration physical exercise,

where the mobile HR sensor needs to have a battery level higher than 49%, this dependability QoD dimension scalar value of 85% is mapped to *High* quality grade. In contrast, in a 24 hours monitoring treatment, the dependability of 85% corresponds to *Medium* quality grade since the mobile HR sensor needs to have a higher battery level to provide the HR data for the 24 hour monitoring treatment. The overall QoD is based on the five QoD dimensions and it is used to obtain an easier QoD interpretation.

The technological context can vary not only due to the performance variation of the technological resources, but also due to the specific technological resources used. In certain scenarios, it is possible to choose between alternative technological resources in the complete technological resource configuration chain. These alternative resources (e.g. Wi-Fi or 4G connection for data communication) have the same functionalities, but different RQP characteristics. Therefore, depending on the chosen technological resource, the RQPs (e.g. subscription cost, transmission delay, and trustworthiness) will differ and consequently, we will have a different technological context that provides the same data but potentially with QoD grade variations. These technological resource configuration chains are often used to optimize the output data quality [25].

We address ICT-based technological resources that influence QoD from the technological context point of view, since the focus of the paper is the impact of technological context on QoD. Hence, we exclude other technological resources that may deal with other issues, such as technological resources integration and security. Accordingly, this study classifies the technological resources into three high-level categories: sensing components, processing components and communication components.

Sensing components comprise of a comprehensive set of sensors and data acquisition devices, which provide all relevant 'raw' physiological measurements of the patient (e.g. electrocardiogram signals). These are located at the point of monitoring. An instance (individual) of a sensing component can be the BioHarness 3 sensor device [26] which provides RQPs, such as the battery level and noise related information (see Table 2).

Processing components comprise of algorithms or processes that can analyze and interpret the sensed ''raw'' data. Usually the output consists of clinical variables or higher level clinical data abstractions. For example, the BioHarness (BH) processor is a processing component. First, it acquires an electrocardiogram signal and detects, for example, the R peaks of the electrocardiogram, which are higher level clinical data abstractions. The accurate R peak detection is essential in signal processing for HR measurement. Hence, it applies signal processing functions to determine the HR. This BH processor can have RQPs, such as robustness against noise, determined by sensitivity and specificity.

Communication components are composed of wire and wireless components that enable data transmission between the set of sensing and processing components from the point of monitoring to the point of decision. The wireless communication involves, for instance, Bluetooth, Wi-Fi and 4G, and wire communication involves fiber-optic communication among others. RQPs that may characterize the performance of the communication components are the data transmission cost, bandwidth and availability.

TABLE 1. Example of the technological context.

CLASS		Individual
Technological Context		Resource perform failure type 2
Technological Resource		
Subclass	Sensing	BH sensor
	Processing	BH processor
	Communication	Bluetooth

TABLE 2. Example of individuals of technological resources.

Class	Individuals
RQP (BH sensor)	- rqp_name: BH_sensor_battery, rqp_type:dynamic, max:100, min:0, unit:%, value: 5 - rqp_name: BH_sensor_SNR, rqp_type:dynamic, max:30, min:-30, unit:dB, value: 0
RQP (BH processor)	- rqp_name: BH_processor_battery, rqp_type:dynamic, max:100, min:0, unit:%, value: 86
RQP (Bluetooth)	- rqp_name: Bluetooth_range, rqp_type:static, max:10, min:0, unit: meter, value: - - rqp_name: Bluetooth_range_value, rqp_type:static, max:10, min:0, unit: meter, value: 5

TABLE 3. Example of the QoD of the clinical variable.

Class	Datatype	Individual
Clinical Variable	Name	heart_rate
Content	value	85
	unit	bpm
QoD	accuracy	Low
	timeliness	High
	dependability	Very Low
	cost	Low
	qoEvidence	High
	overallQoD	Low

TABLE 4. Example of the treatment adaptation.

CLASS	Individual
Treatment	THRmax = 0.6 × HRmax THRmin = 0.5 × HRmax Treatment delay: 1 hour

In the following tables (Table 1, Table 2, Table 3 and Table 4), we present a simplified example of a use case study used in the QoD-aware system development. Table 1 presents an example of a technological context, which

IEEE Journal of Translational Engineering in Health and Medicine

comprises three technological resources, Table 2 provides the RQPs of each of these technological resources and Table 3 lists the provided clinical variable and its associated QoD.

Table 2 contains the RQP individuals of each technological resource presented in Table 1, which characterize the performance of the technological resources, and consequently the technological context. The RQP individuals of Table 2 are specified by the RPQ datatype properties (name, type, a maximum and minimum value, a unit and the value). These RQP individuals are used to compute the five QoD dimensions' grade (Fig. 1), and based on these five QoD dimensions, the overall QoD. Table 3 presents the heart rate clinical variable and its associated QoD grades of the five QoD dimensions and the overall QoD.

B. CLINICAL DOMAIN ONTOLOGY

In the upper part of Fig. 1, we present the clinical domain ontology, which corresponds to the treatment adaptation knowledge acquired during the RE method (Section II. A). Fig. 1 illustrates the main classes of this domain. The clinical domain ontology shows that a patient receives a treatment, and has one medical practitioner, who provides the treatment. The treatment class has a context, i.e. treatment context, which makes use of clinical variables to conduct the treatment. The QoD of the clinical variables characterize the treatment context, and consequently it has an impact on the treatment activities, which are adapted based on the medical requirements (see Section II).

Adding to the previous example, on the one hand, the clinical variable has certain quality grades (Table 3), which are based on a specific technological context. On the other hand, the treatment (e.g. a physical exercise treatment) is provided by a medical practitioner (e.g. Peter the cardiologist) to a patient (e.g. cardiac patient John). In a treatment context that consists of an unsupervised outdoor physical exercise with degraded QoD of the HR clinical variable (Table 3), the telemedicine system that supports John needs to adapt the treatment according to this clinical variable QoD degradation. Therefore, the clinical domain ontology, which is the clinical knowledge used by the system, specifies the treatment adaptation mechanisms caused by degraded QoD defined during the RE method.

Table 4 presents some of the potential treatment adaptations that are described in the ontology, which are triggered when the treatment context uses the HR clinical data with QoD grades of Table 3 in an unsupervised outdoors physical exercise treatment. For example, target heart rate parameters (THRmax, THRmin), which are the clinical abstractions used to determine the intensity level of the prescribed physical exercise treatment based on a measured patient maximum HR (HRmax), are lowered (Table 4). Consequently, the QoD-aware system ensures that the patient will not be recommended to perform a strenuous exercise due to the unreliable HR measurement. Besides, due to a *Very Low* grade of dependability QoD dimension, the treatment is being request to be delayed for 1 hour (Table 4).

IV. QoD-FRAMEWORK ONTOLOGY APPLICATION IN MOBIGUIDE

This work has been implemented in the MobiGuide (MG) European project [27]. MG aims to develop QoD and context-aware evidence-based CDSS for guiding mobile patients during their treatments ubiquitously. Hence, one of the challenges addressed in this paper is to develop a QoD and context-aware telemedicine system to adapt the treatment according the patients' technological context.

As discussed before, the technological context characterizes the quality of the clinical data used by the system to guide the patient during his/her treatment activities. In order to design and develop a QoD-aware telemedicine system we require two main components: (1) QoS Broker, which is a component that translates the technological context information into QoD, and (2) CDSS, which is a component that uses potentially relevant information, such as the clinical data and its quality, to guide patients during their treatment (Fig. 2). The QoD-Framework ontology represents the knowledge required by the QoD Broker schemas and CDSS schemas in order to provide the 'correct' service. Based on inputs from practitioners, we validated the QoD-Framework ontology iteratively during the implementation phase. We made extensions or modification to the ontology whenever inconsistencies between the current ontology and information from the medical practitioners were found. Additionally, this

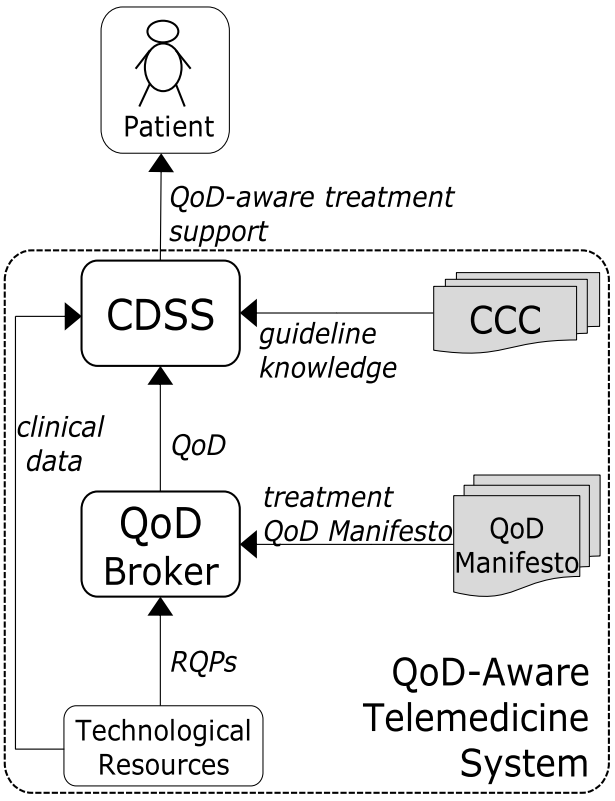

FIGURE 2. High level design of the QoD-aware telemedicine system with QoD-Framework knowledge ontology formalized in the CCC and QoD Manifesto.

ontology was used in the MG prototype, resulting in several instances of the QoD-Framework ontology.

The presented ontology in Section III represents the QoD Broker knowledge schema and the CDSS knowledge schema (Fig. 2).

1) QoD BROKER – QoD MANIFESTO

QoD Broker, which is the MG telemedicine system component in charge of translating technological context information into QoD, computes the QoD of clinical variables based on the acquired technological resources' specific performance information (i.e., RQPs), and by applying computational models described in [3]. The knowledge used by QoD Broker is specified in a so-called generic QoD Manifesto, XLM file, which contains the Technical Domain Ontology described in Section III, A. Depending on the treatment, QoD Broker will run the specific treatment QoD Manifesto, so that the computation of QoD corresponds to the specific treatment requirements. The computed QoD information is sent to the MG CDSS, so that the CDSS can process the QoD together with the clinical data in order to provide QoD-aware treatment support (Fig. 2).

2) CDSS – CONTEXT CUSTOMIZED CLINICAL GUIDELINE

The MG CDSS uses evidence based clinical guidelines to provide the best treatment guidance to the patient. As described by Peleg *et al.* [28], these guideline-based CDSS need to create a computer interpretable representation of the clinical knowledge contained in the guidelines, i.e. a computer interpretable guideline (CIG). The presented Clinical Domain Ontology (Section III.B) is merged with the original guideline, therefore augmenting the CIG with *technological context*. This results in a Context Customized CIG (CCC) [27], which has been developed in Asbru CIG modeling language [21].

As a result, the CDSS will receive the guideline knowledge that corresponds to each treatment (Fig. 2), and the output of the CDSSs will be a safe QoD-aware treatment guidance induced by the technological context in terms of the QoD and the clinical data. The guidance (usually implemented in terms of clinical recommendations) will be adapted when necessary to the QoD to ensure patient's treatment safety (see Table 4).

V. CONCLUSION

This paper describes the effects that technological resources disruptions have on the clinical data quality (QoD) and the potential impact of this QoD degradation on patient treatment. As discussed in the paper, pervasive healthcare often deals with uncertainties, namely the quality of the clinical data used to treat patients. This paper shows how to cope with this QoD uncertainty in order to provide 'best' quality care to patients, even when QoD does not fulfil the medical requirements due to undesirable technical disruptions that modify the technological context. In telemedicine systems that support ubiquitous (unsupervised) patients' guidance, the QoD has a major role. The clinical data is the core to guide the patients with a telemedicine system. Therefore, an unreliable (i.e. low QoD) clinical data can lead to an erroneous treatment guidance, potentially putting the patient at risk.

To formalize this knowledge and develop a QoD-aware telemedicine system resilient to technological disruptions, we present a QoD-Framework ontology. This ontology is the result of applying a RE method together with the layering technique described in Section II. QoD-Framework ontology covers both the technological domain knowledge to translate technological context into QoD and the clinical domain knowledge to interpret the QoD into a treatment. This knowledge is provided in a separation of concerns fashion. This separation of concerns is necessary since medical practitioners are not used to specific technical information and clinical guideline should not be 'polluted' with technological information.

Besides, the chosen approach makes it possible to discuss technological context issues in terms of QoD with medical practitioners, who understand this quality concept. As a result, the ontology has been validated in a participatory design fashion involving the medical practitioners of the MG project. The medical practitioners defined the adaptation mechanisms needed to guarantee patient's safety for all instances addressed in the applied ontology. This was conducted via semi-structured interviews carried out by requirement engineers with medical practitioners, who systematically derived the requirements in an iterative process for completeness and requirements confirmation. Consequently, the presented ontology has been partially validated. Additionally, this study will be further validated through independent trials in order to obtain empirical evidence.

Furthermore, the QoD-Framework ontology locates the clinical domain ontology in the CDSS knowledge based – CCC – and the technical domain ontology in the QoD Broker knowledge based – QoD Manifesto, avoiding the clinical guideline being polluted. Both domains are linked by the clinical data and their QoD (Fig. 1). We present a simple use case where a particular technological context characterized by the performance of technological resources leads to a clinical variable quality that affects the treatment (Section III). This use case shows that the approach performs as we expected. The use case also illustrates how the technical domain ontology can be stored in a software agent that outputs QoD and also shows how the clinical domain ontology can be stored in a different software agent that uses QoD and other relevant clinical information (e.g. clinical data) to provide patient treatment guidance (Section IV). This separation of concern makes it possible to include, on the one hand, additional technological resources information into the QoD Manifesto without the necessity of modifying the CCC and, on the other hand, augment the CCC without modifying the QoD Manifesto.

In this paper we do not address the clinical data quality optimization. Nevertheless, in future works, we plan to extend this ontology with QoD optimization mechanisms, such as

IEEE Journal of Translational Engineering in Health and Medicine

the method provided by Widya et al. [25] or with simpler strategies (e.g. send technological recommendations to the patient in order to improve the performance of the system, and hence, the QoD). Furthermore, the overall QoD computation and potential QoD management requirements will be detailed in future work.

We have shown that the proposed QoD-Framework ontology for developing a QoD-aware telemedicine system is feasible and validated by domain experts. Our vision of the future is a whole QoD-aware healthcare system, where medical experts and telemedicine systems not only make use of the clinical data, but also its associated QoD, since quality of the clinical data may have a major effect on patient treatment. Therefore, our QoD-Framework ontology represents knowledge of a QoD-aware telemedicine system that can be used to support development of future pervasive healthcare applications that are resilient to technological resources disruptions.

ACKNOWLEDGMENT

The authors would like to give special thanks to Dr. Carlo Napolitano for his time and collaboration.

REFERENCES

[1] P. Szolovits, "Uncertainty and decisions in medical informatics," *Methods Inf. Med.*, vol. 34, nos. 1–2, pp. 111–121, Mar. 1995.
[2] S. Hasan and R. Padman, "Analyzing the effect of data quality on the accuracy of clinical decision support systems: A computer simulation approach," in *Proc. AMIA Annu. Symp.*, 2006, pp. 324–328.
[3] N. Larburu, R. G. A. Bults, I. Widya, and H. J. Hermens, "Quality of data computational models and telemedicine treatment effects," in *Proc. IEEE 16th Int. Conf. e-Health Netw., Appl. Services (Healthcom)*, Oct. 2014, pp. 364–369.
[4] N. Larburu, I. Widya, R. G. A. Bults, and H. J. Hermens, "Making medical treatments resilient to technological disruptions in telemedicine systems," in *Proc. IEEE-EMBS Int. Conf. Biomed. Health Informat. (BHI)*, Jun. 2014, pp. 285–288.
[5] N. G. Weiskopf and C. Weng, "Methods and dimensions of electronic health record data quality assessment: Enabling reuse for clinical research," *J. Amer. Med. Informat. Assoc.*, vol. 20, no. 1, pp. 144–151, Jan./Feb. 2013.
[6] J. L. Brożek *et al.*, "Grading quality of evidence and strength of recommendations in clinical practice guidelines: Part 2 of 3. The GRADE approach to grading quality of evidence about diagnostic tests and strategies," *Allergy*, vol. 64, no. 8, pp. 1109–1116, Aug. 2009.
[7] D. G. T. Arts, N. F. de Keizer, and G.-J. Scheffer, "Defining and improving data quality in medical registries: A literature review, case study, and generic framework," *J. Amer. Med. Informat. Assoc.*, vol. 9, no. 6, pp. 600–611, 2002.
[8] S. Vavilis, N. Zannone, and M. Petkovic, "Data reliability in home healthcare services," in *Proc. IEEE 26th Int. Symp. Comput.-Based Med. Syst. (CBMS)*, Jun. 2013, pp. 377–380.
[9] J. L. McCormack and J. S. Ash, "Clinician perspectives on the quality of patient data used for clinical decision support: A qualitative study," in *Proc. AMIA Annu. Symp.*, 2012, pp. 1302–1309.
[10] E. S. Berner, R. K. Kasiraman, F. Yu, M. N. Ray, and T. K. Houston, "Data quality in the outpatient setting: Impact on clinical decision support systems," in *Proc. AMIA Annu. Symp.*, 2005, pp. 41–45.
[11] G. Kong, D.-L. Xu, and J.-B. Yang, "Clinical decision support systems: A review on knowledge representation and inference under uncertainties," *Int. J. Comput. Intell. Syst.*, vol. 1, no. 2, pp. 159–167, May 2008.
[12] G. H. Guyatt *et al.*, "Going from evidence to recommendations," *Brit. Med. J.*, vol. 336, pp. 1049–1051, May 2008.
[13] S. Vavilis, M. Petković, and N. Zannone, "Impact of ICT on home healthcare," in *ICT Critical Infrastructures and Society*. Berlin, Germany: Springer-Verlag, 2012, pp. 111–122.
[14] M. Shin, "Secure remote health monitoring with unreliable mobile devices," *J. Biomed. Biotechnol.*, 2012.
[15] A. van Halteren *et al.*, "Mobile patient monitoring: The mobihealth system," in *Proc. Int. Congr. Med. Care Compunetics (NCC)*, Jun. 2004, pp. 25–32.
[16] A. K. Dey, "Understanding and using context," *Pers. Ubiquitous Comput.*, vol. 5, no. 1, pp. 4–7, Feb. 2001.
[17] N. Larburu, I. Widya, R. G. A. Bults, H. J. Hermens, and C. Napolitano, "Early phase telemedicine requirements elicitation in collaboration with medical practitioners," in *Proc. 21st IEEE Int. Requirements Eng. Conf. (RE)*, Jul. 2013, pp. 273–278.
[18] F. Paganelli and D. Giuli, "An ontology-based system for context-aware and configurable services to support home-based continuous care," *IEEE Trans. Inf. Technol. Biomed.*, vol. 15, no. 2, pp. 324–333, Mar. 2011.
[19] X. H. Wang, Z. Da Qing, T. Gu, and H. K. Pung, "Ontology based context modeling and reasoning using OWL," in *Proc. 2nd IEEE Annu. Conf. Pervasive Comput. Commun. Workshops*, Mar. 2004, pp. 18–22.
[20] Y. Wand and R. Y. Wang, "Anchoring data quality dimensions in ontological foundations," *Commun. ACM*, vol. 39, no. 11, pp. 86–95, Nov. 1996.
[21] Y. Shahar *et al.*, "A framework for a distributed, hybrid, multiple-ontology clinical-guideline library, and automated guideline-support tools," *J. Biomed. Informat.*, vol. 37, no. 5, pp. 325–344, Oct. 2004.
[22] M. Peleg and S. Tu, "Decision support, knowledge representation and management in medicine," *Yearb Med. Inf.*, vol. 45, pp. 72–80, 2006.
[23] D. L. McGuinness and F. Van Harmelen, "OWL Web ontology language overview," *W3C Recommendation*, vol. 10, p. 2004, 2004.
[24] R. Y. Wang, M. P. Reddy, and H. B. Kon, "Toward quality data: An attribute-based approach," *Decision Support Syst.*, vol. 13, nos. 3–4, pp. 349–372, Mar. 1995.
[25] I. Widya, B.-J. van Beijnum, and A. Salden, "QoC-based optimization of end-to-end M-health data delivery services," in *Proc. 14th IEEE Int. Workshop Quality Service (IWQoS)*, Jun. 2006, pp. 252–260.
[26] *Zephyr BioHarness 3. BioHarness 3 Medical Data Sheet*. [Online]. Available: http://www.zephyranywhere.com/products/bioharness-3/
[27] *MobiGuide*. Online]. Available: http://www.mobiguide-project.eu/
[28] M. Peleg *et al.*, "Comparing computer-interpretable guideline models: A case-study approach," *J. Amer. Med. Informat. Assoc.*, vol. 10, no. 1, pp. 52–68, 2003.

NEKANE LARBURU was born in Basque Country, Spain, in 1986. She received the M.Sc. degree in telecommunication engineering from the Public University of Navarre, Spain, in 2011.

She completed her master's thesis with imec, The Netherlands, where she worked on signal processing for atrial fibrillation detection. She is currently pursuing the Ph.D. degree in telemedicine with the University of Twente, The Netherlands. Her research interests include design methods and architectures for quality of service and quality of data (QoD) computation, the impact of the QoD on healthcare systems, telemedicine systems development, smart IT application, and pervasive healthcare.

RICHARD G. A. BULTS received the B.Sc. degree in technical computer science and the M.Sc. (*cum laude*) degree in telematics. He is an Experienced Researcher (15 years) with the Telemedicine Group of the Bio Signals and Systems Chair, University of Twente, The Netherlands. He has co-authored 45 reviewed telemedicine publications. His research interests are requirements elicitation methods and techniques for telemedicine systems design, and quality of clinical data effects on clinical guidelines for teletreatment.

MARTEN J. VAN SINDEREN (M'04) received the M.Sc. degree in electrical engineering and the Ph.D. degree in computer science from the University of Twente (UT), Enschede, The Netherlands, in 1982 and 1995, respectively. He was a Senior Researcher and Research Area Coordinator of service architectures and health applications with the Centre for Telematics and Information Technology, UT. He is currently an Associate Professor of Services, Cybersecurity, and Safety with UT. He managed and participated in several national and international research projects, and has co-authored over 100 research papers. His major research interests are design methods and architectures for networked information systems, in particular, in the area of next-generation collaborative enterprises and smart IT applications. He was the Chair of the Steering Committee of the IEEE EDOC Conference on Enterprise Computing from 2010 to 2014. He is a member of the Editorial Board of the *Enterprise Information Systems* (Taylor & Francis) journal. He is also a member of the Managerial Board of the IFIP Working Group 5.8 on Enterprise Interoperability.

ING WIDYA has retired. However, in part time, he is still involved in some research activities. His Ph.D. is involved in stochastic signal processing. He has work experience in application oriented Internet protocols and telemedicine systems. His current focus is on requirements elicitation in telemedicine that aligns with the evidence-based way of doing medicine, and partly on quality of data (QoD) of monitored clinical variables and their clinical abstractions, including the impact of QoD on clinical interventions.

HERMIE J. HERMENS received the master's degree in biomedical engineering from the University of Twente, and the Ph.D. degree in surface EMG simulation, processing, and clinical applications. Since 2008, he has been the Head of the Telemedicine Research Group, embedded in both the Mira and the CTIT research institutes. He is currently a Professor of Neuromuscular Control and the Cluster Manager in the area of monitoring and diagnostics with Roessingh Research and Development. He has co-authored over 160 peer-reviewed scientific journal papers. His work was cited 460 times in 2010 (an h-index of 30). His current research is focused on combining biomedical engineering with ICT to create new end-to-end telemedicine applications for people with chronic disorders.