

KNOWLEDGE BASED DECISION SUPPORT FOR THE MANAGEMENT OF CHRONIC PATIENTS

Sara Colantonio, Massimo Martinelli, Ovidio Salvetti

Institute of Information Science and Technologies, ISTI-CNR, Via G. Moruzzi, 1-56124, Pisa, Italy

Giuseppe De Pietro, Massimo Esposito, Alberto Machì

Institute for High Performance Computing and Networking, ICAR-CNR, Via P. Castellino, 111-80131, Napoli, Italy

Keywords: Decision support, Knowledge formalization, Ontologies.

Abstract: Due to the current socio-economic impact of chronic diseases, a strong effort is being spent in the development of ICT applications able to support a new care paradigm specialized for chronic patients. Such applications are mainly based on patients' telemonitoring for the collection of a number of relevant physiological parameters aimed at identifying and preventing acute events, while maximizing patients' quality of life and reducing clinical costs. The most advanced and challenging features of these ICT applications are intelligent services devoted to the interpretation of monitored patients' data for supporting clinicians in their routine management of chronic patients. In this paper, a Knowledge-based Clinical Decision Support System (KB-CDSS) is presented, which is aimed at aiding clinical professionals in managing chronic patients on a daily basis, by assessing their current status, helping face their worsening conditions, and preventing disease exacerbation events. The CDSS has been developed by encoding the relevant knowledge elicited from clinicians who have a large experience in patients' monitoring. A formalism based on ontologies and rules was selected to build the Knowledge Base according to a scenario-based approach. The system is currently under validation for the management of real clinical cases.

1 INTRODUCTION

Chronic diseases are one of the leading causes of disability and death in most of the industrialized countries, and have a deep impact on today's society, with social health-security systems under constant pressure, both for financial and organizational aspects, especially in many European countries. A chronic disease usually causes major limitations in patient's daily living and are characterized by acute or deterioration events, which can happen more or less frequently and often cannot be totally relieved, causing a worsening of patient's conditions.

Health organizations all over the world are more and more focusing on the development of specific programmes for the management of chronic patients in the long term. These are mainly based on the regular collection of information about patients' status and actions, their compliance to the therapy, the situation around them, and their interactions with

the environment, in a long-stay setting. Tele- or home-monitoring programmes are, hence, being studied and applied for care delivery and management in cases of chronic diseases (Parè et al., 2007). ICT solutions are being developed for this task, and range from (i) "light" applications, based on video or phone consultations of patients for assessing their current conditions (Cleland et al., 2005; Vitacca et al., 2009), to (ii) the continuous or frequent acquisition of patients' vital signs through dedicated sensors, often wearable (e.g., Pentland, 2004), till (iii) complex platforms that merge such a sensor infrastructure with intelligent services for data interpretation (e.g., Chiarugi et al., 2010).

The intelligent components are the most advanced and challenging feature of these telemonitoring platforms. The intelligence can be implemented at different level of complexity: (i) as simple alarming services, which identify variations in patient's vital signs, (ii) as interpretation methods, which recognize exacerbation events, or (iii) as

complex *Clinical Decision Support Systems* (CDSS), which are aimed at supplying to clinicians full assistance in their management of chronic patients.

In this paper, a knowledge-based CDSS is proposed for managing chronic patients by interpreting data acquired through a sensor infrastructure deployed in patients' normal life environment. Such a system combines acquired data with patient's clinical information, issues possible alarms and supplies motivated suggestions. Though the modelling strategy is valid for any chronic disease, two pathologies were considered for initial application, namely Chronic Obstructive Pulmonary Disease (COPD) and Chronic Kidney Disease (CKD). The system was developed within the EU IST Project CHRONIOUS which is aimed at defining a generic platform schema for health status monitoring, addressed to and specialized for people suffering from chronic diseases (Rosso et al., 2011).

In the following sections, the strategy followed is described in more detail, presenting and motivating the CDSS design, the data it handles and the knowledge it utilizes. Particular focus is dedicated to how this knowledge is formalized.

2 THE INTELLIGENT SUPPORT TO CHRONIC DISEASES MANAGEMENT

For being effective and profitable, the management of chronic patients requires monitoring patients in order to follow up their conditions and detect the incoming or the occurring of acute events.

For making this possible, a platform of services was devised to acquire and store data through a sensing infrastructure consisting of (i) a set of wearable sensors for the acquisition of patients' physiological parameters, (ii) a set of environmental sensors for the acquisition of contextual information and (iii) a touch-screen device used for the acquisition of patient's answers to questionnaires. Data collected during patient's clinical visits were, also, gathered by the platform and stored in the internal repository (for a more detailed description of the platform please refer to (Rosso et al., 2011)).

Intelligent services were added into the platform in order to automatically process the collected sensor data, identify worrying patient's conditions and alerting clinicians. In particular, to reach a high level of flexibility and reliability, two levels of sensor data interpretation were conceived: the data acquired by the sensing infrastructure are firstly processed by a

light intelligence deployed on a smart Personal Digital Assistance device (PDA) for detecting possible changes in patient's vital signs by applying simple rules related to the collected parameters. Worrying changes are reported as an alert to clinical personnel and data are passed to a second level of intelligence, i.e., the CDSS, which supplies more accurate suggestions thanks to its ability to process a larger piece of information. Figure 1 summarizes the main components of the monitoring platform. Focus of this paper is on the CDSS described in next sections.

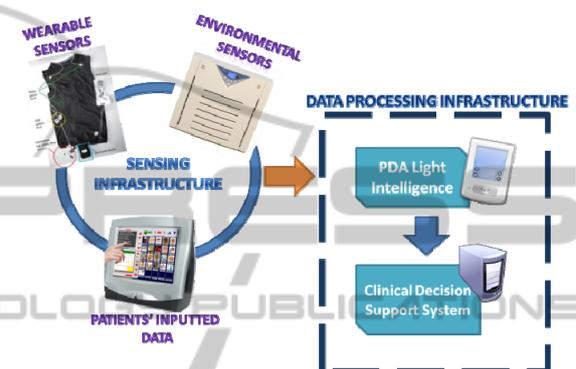


Figure 1: The main components of the patients' monitoring platform: the Sensing infrastructure and the Data Processing infrastructure consisting of two levels of intelligence.

2.1 The Decision Support System

The CDSS was designed to be really effective, efficient and to be perceived really useful by the clinicians it should support. Its main functionalities can be listed as follows:

- analysing the acquired sensor data for identifying worrying conditions;
- alerting clinicians when an acute event happens;
- merging the heterogeneous patient's information for providing pertinent suggestions.

The data are gathered by a sensorized vest that collects parameters pertaining patient's electrocardiographic activity, respiratory activity, arterial oxygen saturation, skin temperature. These data are acquired by the sensors on the vest and, then, collected by a Data Handler, wired to the vest, which sends them to the PDA via a Bluetooth connection. The acquired parameters are the following:

- heart rate;
- respiration rate, inspiration and expiration time;
- inspiration and expiration volume;
- ambient temperature and humidity;
- motion activity and fall;

- cough and snoring.

A touch-screen workstation, the *Home Patient Monitor* (HPM), is employed to collect a number of other physiological and contextual parameters. More in detail, an environmental device, installed in patient's living room and cable-connected with the HPM (USB connection), acquires contextual data related to ambient light, carbon monoxide, volatile organic compound and air particle. Body weight, blood pressure and blood glucose are measured using commercially available devices, which send data to the HPM via a Bluetooth connection. Finally, information pertinent to patient's lifestyle, food and drug intake, and psychological conditions is collected through questionnaires proposed on the touch-screen of the HPM. All these data are gathered, on a regular time basis via a wireless connection, by a PDA assigned to each patient. The PDA performs a first data processing by applying simple range checking rules and detects possible alarming situations, alerting, in this case, the personnel on duty, and requires an in-depth analysis of the situation by the CDSS.

Indeed, the CDSS was designed to be invoked each time new data to be analyzed are available, and this happens in three *scenarios*:

- when the PDA detects a worrying condition and issues an alarm: in this case, the sensor data collected are sent to the CDSS;
- at the end of each day: when the PDA stores all the collected data and sends them to the CDSS for their analysis;
- when a patient undergoes a clinical visit: the newly collected data are sent to the CDSS for interpretation.

In all these cases, the CDSS correlates these data with historical patient's data according to the knowledge modeled into its *Knowledge Base* (KB), and supplies, as a response, a diagnosis about current patient's status, plus suggestions about what to do. The KB is the main component of the system and is modeled for inferential reasoning, through a dedicated inference engine, as described in the next section.

2.2 The Knowledge Base

The clinical knowledge modeled for developing the KB consists of:

- the structure of the domain knowledge, namely the *declarative knowledge*;
- the knowledge about the procedures of the decision making activity, namely the *procedural knowledge*.

In particular, the *declarative knowledge* concerns the domain compositional elements, such as raw and abstract concepts, their properties and inter-relations. On the other hand, *procedural knowledge* captures the behavioral logic and provides more explicit information about which actions/conclusions can be taken/drawn from declarative knowledge. The formalism selected for encoding both these types of knowledge consisted in one *ontology* and a set of *production rules* (i.e. a set of conditional statements expressed in form of "if *antecedents* then *consequent*") built on the top of it.

The main purpose of the ontology and rules is to represent domain-specific knowledge necessary to remotely support clinical operators in the daily home-monitoring of chronic patients. The approach is generally aimed at the chronic disease management, but specific focus was given to the two pathologies chosen for system demonstration, i.e., COPD and CKD.

The way the knowledge is represented for clinical decision support is one of the most key facets for having a successful CDSS, starting from the analysis and design of the CDSS at the very beginning and ending to the implementation of the CDSS at the final stage. Ontologies combined with production rules seemed the most suitable and up-to-date methodology for solving this task since easily understandable by a non-specialized audience, e.g. clinicians. In this way, they could be involved not only in the knowledge elicitation and representation, but also in the process of modification/updating of existing knowledge.

In fact, the eliciting process ran through several meetings with clinicians for systematizing the approach to patients' monitoring. The list of monitored parameters was used as the starting point to formalize all the statements about the different situations and conditions that a patient can go through and that can be identified by these parameters. A great help to this process came from the fact that clinicians were already skilled in patients' telemonitoring and were already trained at interacting with computerized applications for processing of clinical data.

The result of the elicitation was the formalization of evidence-based statements which were used to define the suggestions that should be provided by the CDSS. The clinicians supplied these statements in a rule-like form, written in natural language. These were discussed and extended for creating a set of consistent and complete rules to be processed by an automated rule engine. The ontology was defined to list up all the relevant concepts, selecting a

terminology recognized and agreed by all the clinicians involved in the elicitation process.

The Web Ontology Language, OWL (2009), was chosen as ontology language, in order to grant both formality and expressive power. As regards to the rule representation, *Jena* rule language (Carroll et al., 2004) was identified as the most appropriate language for writing rules that can be combined with OWL ontologies. In particular, such a language enables to build rules starting from the terminological elements defined in the OWL ontology. Thanks to its concise but at the same time very expressive syntax, *Jena* rule language was not only easy to use for writing rules but also extremely simple to read and understand also for non-technical users and, thus, it was very adequate to provide reasoning support that met the CDSS requirements. Moreover, the *Jena* framework includes a Rule Engine used for inference on the base of encoded rules.

2.2.1 The Ontology

The ontology models all the clinical data coming from different possible information sources, such as medical history, patient’s general information, laboratory assays, patient’s monitoring measurements or environmental measurements gathered at the patient’s home, questionnaires about mental problems or symptoms opportunely filled up by the patient at home. Moreover, the ontology also models the results of the inferences generated by the CDSS in terms of suggestions to be reported to the clinicians. Such suggestions are expressed in the form of alerts, i.e. messages with a different severity, varying according to the current patient’s condition, that can require or not the attention of a clinical operator. Each suggestion can also indicate a variation of the patient’s health status with respect to the morbidity he/she is affected by. It includes in natural language the specific clinical guideline applied by CDSS and delineates the action which has to be performed in response to the generated alert.

According to this high-level description, the ontology concepts and properties are defined. Figure 2 shows the concept taxonomy.

As regards the properties, it is worth noting that all the properties defined in the ontology are *datatype* properties according to the definition of OWL language. Figure 3 shows the taxonomy of properties. The use of only *datatype* properties simplifies the writing of rules and their final structure since in the rule antecedents and

consequents it is necessary to indicate only the appropriate *datatype* properties, corresponding to semantically defined terms, opportunely linked to the concepts they are associated to.

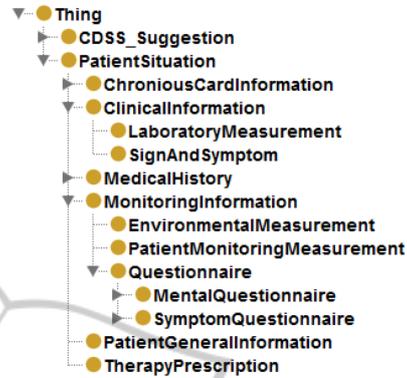


Figure 2: The concept taxonomy.

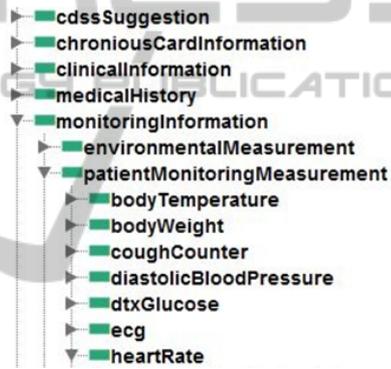


Figure 3: A piece of the property taxonomy.

2.2.2 The Base of Rules

Based on the introduced ontology, production rules were devised for the three scenarios introduced in the previous section, with the final aim of representing the procedural knowledge.

Rules are simple conditional declarations that link a logical combination of antecedent conditions to a consequent, according to the following “*if-then*” structure: *If (antecedents) then consequent*

As a result, the structure of each rule is composed of one or more antecedents, expressed in terms of ontology properties concatenated by logical conjunctive operators, which can be evaluated to be either true or false. Disjunction is not supported. As an example, a rule pertaining to the *HypoVolemia* for CKD disease is reported in natural language as follows:

All individuals with values of systolic blood pressure <110 mmHg, heart rate > 115 beats/min, symptoms of nausea or vomiting determined by means of the

CKD Symptom Questionnaire are classified as being in an abnormal condition due to HypoVolemia. An alert with red severity is contextually sent to the medical doctor to report the situation.

The implementation of this rule in accordance with the Jena rule syntax and in terms of the ontology concepts and *datatype* properties corresponds to a group of rules: one of them has the following form

```
HypoVolemia_Guideline_1_rule_3:
(?p rdf:type
CKD:PatientMonitoringMeasurement),
(?p CKD:systolicBloodPressure_curr ?a),
lessThan(?a,110),
(?p CKD:heartRate_curr ?b),
greaterThan(?b,115),
(?q rdf:type CKD:CKDSymptomQuestionnaire),
(?q CKD:neauseaOrVomiting ?c),
equal(?c,'true'^^xsd:boolean),
(?s rdf:type CKD:CDSS_Suggestion) ->
(?s CKD:inferredPatientCondition
'Suspected Hypovolemia'^^xsd:string)
```

3 SYSTEM DEVELOPMENT & RESULTS

The CDSS was modeled as a resource of a monitoring platform as introduced in the previous section and it is called on demand to analyze new data about patient's situation. This assures the generality and flexibility of this system, which can be easily plugged into any similar platforms.

The implementation of the system was organized in decisional services, which are called when specific events occur. The granularity of these services was decided in accordance to the data flow and the requirements of clinicians about the intervention of the support system. It appeared, then, profitable to make a correspondence between the set of services and the set of identified scenarios introduced in the previous section, which can be named as follows:

- the *Alarm Checking* scenario, which corresponds to an assessment of patient's status after an alarm has been issued by the PDA, for alerting about a possible exacerbation;
- the *Home Monitoring* scenario, which corresponds to a periodic assessment of patient's status, more precisely once a day, even without any alerting exacerbation;
- the *Clinical Assessment* scenario, which corresponds to the evaluation of patient's status after a clinical visits, i.e., when new data comes from the clinical environment.

Several advantages are assured by this approach, since separated and well-focused services are: (i) simpler to integrate; (ii) more flexible; (iii) can be straightforwardly modified; (iv) their complexity can be managed more easily. Moreover, this approach made the implementation strategy of the system straightforward: the decisional services were mapped onto a Service Oriented Architecture approach, and hence implemented as Web Services. This assures the interoperability of the CDSS, whose implementation does not depend on the platform: thanks to the Web Services approach, the system can be integrated in any other general platform without any change to its structure.

The first step in the development of the decisional services regarded the determination of their mapping to the clinical domains, i.e. COPD and CKD. Two services, named *COPD_Decisional_Service* and *CKD_Decisional_Service*, were realized respectively for COPD and CKD diseases. Each service was delineated from a functional perspective in terms of its operations, where each operation is coarse-grained and models how the CDSS works for a whole distinct usage scenario. Coarse-grained services avoid the need to maintain state information between service invocations, reduce the number of network interactions required to implement a given usage scenario, improving, this way, performance and simplifying recovery in the case of failure.

For the development of the KB behind these services, as introduced in the previous section, the ontology was developed using OWL. Currently, it consists of 28 concepts and 860 properties, organized as outlined. The rules were structured in scenarios and divided between the two pathologies: totally the base of rules contains 435 rules for CKD and 273 rules for COPD.

Results provided by the CDSS consist in an advice about the status of the patient and a suggestion about the action to be undertaken for managing the situation. In agreement with clinicians' requirements, the results are shown as a kind of alert/alarm through a Clinician GUI, listing up a number of information. More in detail, the CDSS results report:

- an advice about patient's status diagnosis;
- a suggestion about what to do;
- some additional information, for better presenting such results;
- a colour that indicates the severity of the advice or alarm;
- an explanation of the advice and suggestion produced.

As an example, Figure 4 shows the results inferred

by *CKD_Decisional_Service* in terms of suggestions generated in response to abnormal values firstly identified by the PDA and then passed to the CDSS.

The system has been released to the clinicians and the validation phase has started for testing the system in action.

AlertSeverity	RED
Patient's Condition	Suspected Hypovolemia
Suggested Action	Doublecheck the alarm and alert immediately emergency medical service
	Chronious Guidelines: Monitoring of Chronic Kidney disease.
	Alert data sent by PDA. All individuals with values of systolic
Explanation	blood pressure less than 110 mmHg, heart rate higher than 115 beats/min, symptoms of nausea or vomiting determined by means of the CKD Symptom Questionnaire are classified as being in an abnormal condition due to Hypovolemia.

Figure 4: An example of results inferred by *CKD_Decisional_Service*. The Explanation field states that the suggestion is issued according to the guidelines defined within the project, after an alert sent by PDA (i.e., the scenario) and the natural language form of the guideline.

4 CONCLUSIONS

Due to the socio-economic impact of chronic diseases, a large effort is being spent to develop monitoring platforms able to follow up chronic patients and support clinicians in their management. In this paper, a knowledge based Clinical Decision Support System has been presented which encodes the relevant knowledge elicited from clinicians who have a large experience in patients' monitoring.

A formalism based on ontologies and rules was selected for its expressive power and, at the same time, ease of use and understanding also by non technical users that can be involved in an eventual upgrade process. A scenario-based approach was adopted to implement the system by mapping each scenario on a decisional service. Web Services were, then, used to implement such services, assuring, in this way, interoperability of the system and the possibility to plug it into any monitoring platform of the same kind.

The system was developed within the EU project CHRONIOUS which is, currently, starting the validation phase, during which the system will be deployed to the clinical sites and its functioning precisely tested.

ACKNOWLEDGEMENTS

This work has been partly funded by the EC IST Project FP7-ICT-2007-1-216461 CHRONIOUS: <http://www.chronious.eu>. The authors wish to acknowledge their gratitude and appreciation to all the project partners for the development of the ideas and concepts presented in this paper.

In particular, the authors would like to thank Prof. M. Vitacca from Fondazione Salvatore Maugeri, and Prof. Cusi and his team from the University of Milan. The authors want to thanks all the partners for their support. This paper was written as a joint contribution; authors are listed in alphabetical order and grouped by their affiliations, besides they have equally contributed to this paper.

REFERENCES

Carroll J. J., et al. Jena: Implementing the semantic web recommendations. In *Proceedings of the 13th Int'l World Wide Web conference on Alternate track (WWW Alt.'04)*. ACM, New York, USA, 74-83

Chiarugi F., Colantonio S., Emmanouilidou D., Martinelli M., Moroni D., Salvetti O. Decision support in heart failure through processing of electro- and echocardiograms. In: *Artificial Intelligence in Medicine*, vol. 50 pp. 95 - 104. Elsevier, 2010

Cleland J. G. F., et al. 2005. Noninvasive Home Telemonitoring for Patients with Heart Failure at High Risk of Recurrent Admission and Death: The Trans-European Network-Home-Care Management System (TEN-HMS) study. *Journal of the American College of Cardiology, Volume 45, Issue 10*, 17 May 2005, Pages 1654-1664

OWL 2009. <http://www.w3.org/TR/owl-features/>

Paré G., Jaana M., Sicotte C., 2007. Systematic Review of Home Telemonitoring for Chronic Diseases: The Evidence Base. *J. of the American Medical Informatics Association*, Vol. 14, Issue 3, May-June 2007, Pages 269-277

Pentland, S., 2004. Healthwear: Medical Technology Becomes Wearable. in *IEEE Computer*, 37(5). May 2004. 34-41

Rosso R., Munaro G., Salvetti O., Colantonio S., Ciancitto F., 2010 CHRONIOUS. In: *EMBC 2010 pp. 6850 - 6853. IEEE.*

Vitacca M., Bianchi L., Guerra A., Fracchia C., Spanevello A., Balbi B., Scalvini S., 2009. Tele-assistance in chronic respiratory failure patients: a randomised clinical trial. *Eur Respir J*, 33: 411-418