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Ontology Design for the Development of Semantically Interpretable Clinical Practice Guidelines

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Abstract

Clinical practice guidelines (CPG) are becoming an essential help tool in medical care. Despite their continuous evolution and dissemination, their application in the context of the new Information and Communication Technologies is not sufficiently developed. A fair amount of work still remains to be achieved in the area of CPG execution, and as a consequence, it is difficult to find even medium sized repositories of formalized and executable CPG. In this context, we present an initiative for modeling and executing clinical guidelines, named SCPG, where a new, ontology based approach is proposed to fill this gap. The proposed model aims to be a novel contribution to the representation and organization of knowledge in this area. In this paper we provide new model to represent CPG focused in sharable and reusable elements, derived from the application of CPG among several healthcare institutions in Spain.

Keywords:

Practice Guidelines, medical practice management, Clinical Decision Support Systems, integrated health care systems, semantics

Introduction

Major efforts are being undertaken in the health domain today towards the standardization of healthcare processes, which have undergone a considerable development in the last few decades, in terms of both magnitude and complexity . Such complexity is due to the universalization of medical care among the population, at all the levels of the health organization. The collaboration between the different agents involved in the health system is a key problem in order to provide a high-quality care. This cooperation must be made possible by some degree of ubiquity in processes and organizations. From the point of view of business organization, the need for personalization and standardization is becoming increasingly clear. This is so because medical care tends to be individualized and homogeneous at any point of the system. Individualized in the sense that each patient has their own attention process but based on common resources for all the patients in the health system. We said homogeneous in the sense that all patients are over the same clinical environment. The existence of an integral clinical information and process management system in hospitals has a positive impact on the quality of assistance and the efficiency of the health personnel . Achieving this successfully saves institutions from dedicating an excessive part of their human resources, included doctors themselves, to documentary and bureaucratic routines. Furthermore, a more efficient information management can be achieved, better supporting the work of doctors, who are thus not constrained to do without relevant information about her/his patients because retrieving it at the right time is not feasible. To achieve this combination of goals it is essential to rely on suitable organizational means, such as Business Process Management (BPM) methodologies , and appropriate Information and Communication Technology (ICT) infrastructures for knowledge management in health structures. For this reason, enterprise management techniques need to be implemented in healthcare organizations, along with normalization standards, e.g. driven by symptomatology, techniques, or diagnosis. In this sense, the standardization of patient care through clinical practice guidelines (CPG) provides significant benefits, since:

- Procedures are normalized, as guidelines establish the standard to guide the doctor's action.
- Clinical evidences are systematized, allowing a fast knowledge transfer between organizations sustained by contrasted clinical evidences.
- Guidelines establish the relevant information domain for a process, simplifying the access and management of this information.
- Patient care is personalized. Guidelines define the specific care system activity for a particular patient, rather than all possible patients. Assistance can be proactive and planned instead of reactive and spontaneous.
- Guidelines help the fast dissemination of new work practices, and help structure all the knowledge of a healthcare organization. When a new evidence or technique suggests the modification of guidelines, these are modified and transmitted to all the personnel in a homogeneous and immediate way.

CPG are a helpful tool for the administration of medical care. They should not be just a set of rigid regulations. They should be characterized by their flexibility, clinical applicability, clarity, documentation and elaboration after a suitably planned revision. A large number of CPG are cur-

rently available that have been developed by different public and private organizations. The application of CPG in the context of the new ICTs is still fairly scarce today , , . Much work remains to be done in the scope of the automation of CPG execution, and despite important initiatives on repositories of formalized guidelines, there is a lack of a wide public repository of interpretable CPG. The overall goal of our work is to provide support for the execution of guidelines in heterogeneous and distributed health systems. Our research, by the date, is focused on the validation of our ontology for the representation of CPG, which is described next.

Some reasons to adopt ontology as a representational model to CPG

It is a need, in the actual scenario of health, to share, reuse, distribute and understand the enormous amount of information daily generated in any health institution, laboratory, research centre, etc. in a similar way. The representation and dissemination without ambiguities of the complex medical concepts described is a foremost question in order to achieve this objective. By means of clinical domain ontologies it is possible to solve this need . However, in the context of CPG, there is a lack of a normalized, semantically representative and generally adopted definition of what does a clinical guide means. Ontologies, as formal representation tools, are natural solutions to fill this lack.

In the design or redesign of CPG modeling phases, the use of ontologies lets the users a high flexibility and easy reutilization of elements. Some individual elements of a guide like, for example, the way by means a clinical analysis must be done or the monitoring of a treatment in a concrete patient, could be easily reused in other guide or adapted to cover the special needs of a new guide. This is a natural reuse of elements of the ontology, which facilitate the design of new guides with common elements from other previous CPG. By the reutilization of information shared between CPG, unique and commonly accepted, it is possible a quick and efficient deploying of innovative information not only within the organization which adopts the guide, but also between different organizations. As an example of the reutilization of concepts we have the action *degree of tabaquism* is modeled in different processes like *Cholesterol* and *Tabaquism*. The reutilization of elements of huge clinical guide repositories could lead to an enormous and very difficult work. This is the reason to define explicit relations between all the elements sharing the same elements or being specializations of some more general ones of the ontological models. This guideline conception enables the reutilization of elements in a different way to those used in GLIF guidelines, as we show in figure 1.

All the previous reasons are something enough to adopt ontologies as representation formalism for the definition and interoperability of CPG. In addition and based on the aspects that characterize a CPG definition formalism identified in , SCPG addresses further areas not covered by prior proposals, concerning the organization of plans and the representation of goals.

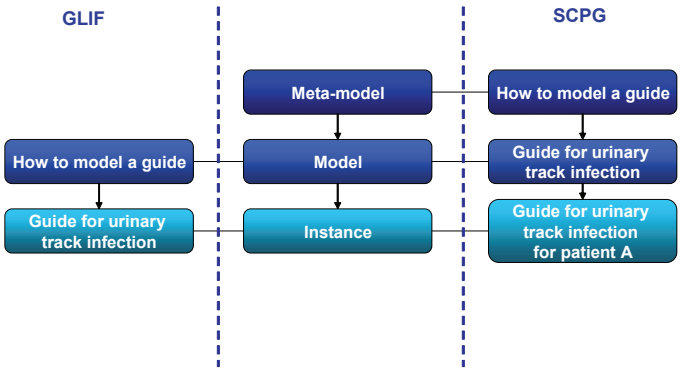

Figure 1 – Differences on SCPG conceptual model

In the remaining aspects, namely, action models, decision models, expression languages, interpretation of data and abstractions, medical concept models, and patient information models, a similar functionality is covered, but based on ontologies. Furthermore, SCPG incorporates the notion of roles, typically not included in this type of representations to date.

Concrete new proposals for our model

In SCPG we are introducing a kind of new concepts in order to enrich the descriptions of the clinical process to be modeled. The foremost ones are described in advance.

In the area of plan organization, SCPG introduces the concept of encounter, which represents the interaction between the patient and the medical staff in a certain space and time. The encounter represents the context in which a set of clinical activities take place. With SCPG there are different ways to represent a clinical attention process. For example, in the clinical guideline for VIH, here is a first encounter which is followed by an undetermined number of encounters for the continuous patient supervision. But in contraposition to this model, the guideline on *Cholesterol* has up to eleven different encounters. The encounter labeled *Middle Risk with LDL<130* has a total of eight actions, but when the LDL Cholesterol is over 160, the related encounter has a total of eleven actions. The difference between the two encounters is based on actions that analyze hormones (like TSH) or enzymes (like CPK, ALT or AST). Figures 2 and 3 (both in Spanish) shows the Protégé ontology model for the first encounter *Cholesterol* and a partial fragment of the actions involved in that

encounter. With this modeling freedom, SCPG is not restricted to a linear conception of medical care.

The representation and exploitation of clinical goals has been only addressed to a limited extent in the available literature on clinical guidelines representation formalisms. This is addressed in SCPG for two fundamental reasons: a) in the clinical domain, it is particularly true that there is a difference between performing an action, and the action having the desired effect; and b) the goals can be extremely useful to exploit the formal representation, enabling a better evaluation of the care processes, the recommendation of clinical guidelines, goal based planning, etc. This way, each action, encounter, and process in SCPG can have a set of associated valuable goals, which describe the guideline in terms of what is the intended purpose, rather than what has to be done.

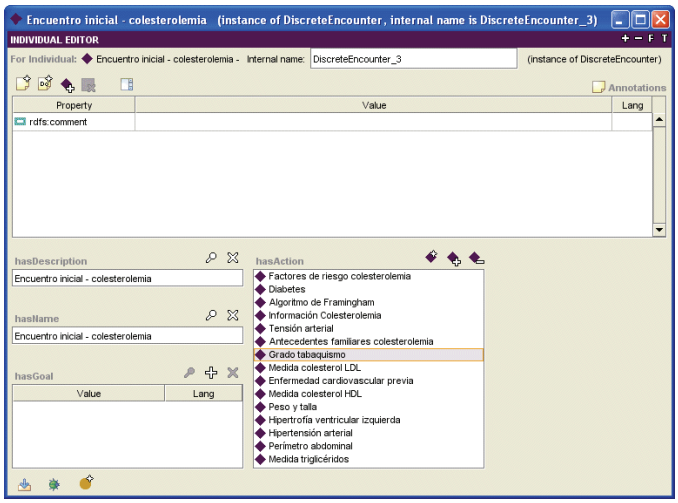

Figure 2 – Protégé definition for the first Cholesterol encounter

Regarding roles, they represent the skills of the medical personnel in charge of actually carrying out the actions prescribed by the guideline. Whilst such information might seem of rather institutional than clinical nature, this is not quite exact. Roles have a strong clinical component, insofar as they represent a set of clinical skills required from the personnel assigned to peform a certain action.

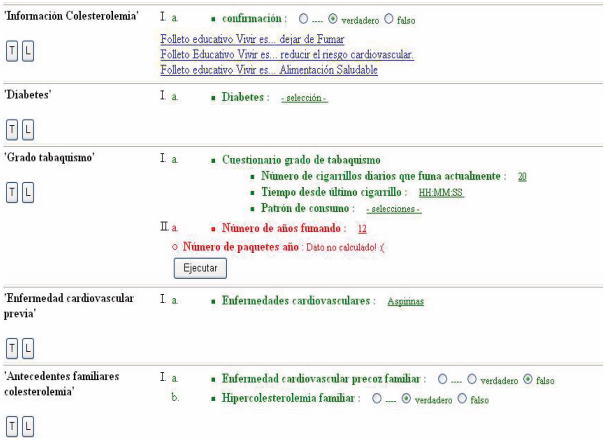

Figure 3 - Partial fragment of the actions involved in a Cholesterol encounter

In addition to the direct advantages of the proposed model in the area of executable CPG representation, the SCPG ontology enables further potential added value in areas such as interoperability, reuse and inference. As mentioned earlier, in realistic settings, CPG need to be executed in heterogeneous and distributed environments, and, in addition, act as transmissions for medical knowledge. Therefore, a high degree of interoperability is required, both syntactic and semantic, between the different involved systems. This problem is addressed in the Semantic Web field by means of the definition of ontologies. Since SCPG is based exclusively on such ontological descriptions, it has the potential to benefit from any progress achieved in the area of interoperability by Semantic Web technologies.

With regards to the problem of the scarce availability of formalized and executable clinical guidelines, the ontology based approach in SCPG allows the definition of a set of classes that represent a complete guideline. Such classes are easily reusable and can be restricted, versioned and manipulated by sub classification, inheritance, and the definition of constraints, in order to produce new guidelines. Thus, SCPG greatly facilitates the formalization of medical knowledge.

Finally, the guidelines represented in SCPG have a much more powerful logic component than other formalizations achieved to date. With our model, represented in OWL, reasoners can be employed to validate the logic correction of guidelines, avoiding potential inconsistencies in the model which, otherwise, would be difficult to detect except by an exhaustive set of system tests, without a completely guaranteed proof of correctness. On the next section we are going to present our proposal for modeling CPG.

Modeling CPG by means of SCPG

SCPG is an ontology for the representation of executable CPG which was conceived in order to apply the Semantic Web vision to the fields of Healthcare and process representation. The ontology has been defined in OWL, using the Protégé environment as an editing tool. SCPG comprise a set of clinical domain related ontologies. Their complete description of classes and relations can be found in [15].

In a common process between a patient and his family doctor, they both have different encounters in the same place but in different times. This concurrency is modeled in SPCG by means of the encounter concept. During an encounter some activities described as actions are carried on. For example, to ask for the patient weight and height, to compute her BMI (Body Mass Index) or to give a diet are example of actions. These actions provide some data about the patient, which are represented in SCPG as data items. In addition to these actions there is an objective associated with the diet: to lose about 5 to 10 kg. In SCPG this is modeled by means of objectives. One of the differences between actions and objectives is that with objectives there is an intention, but there are no guarantees for the consecution. Suppose that 3 months latter there is a new encounter. With the previous data and related with the objective consecution, the doctor has to take a decision: to continue with the diet (previous action), to give some drugs (new action) or to recommend surgery (new action). Therefore, a clinical guide provides the following aspects modeled by means of the set of ontological components:

- The formal representation of the guide, which represents the flow of the attention supplied to the patient. Clinical guides are organized into processes and this has encounters. A formal description of the described process (the order of the encounters carried on in the example), in this formal description, the patient doctor encounters are chained in the basis of the process itself, the patient state, the clinical staff decisions and, finally, due to temporal restrictions. Each encounter is made of a set of actions that must be carried on by the staff. With this model SCPG it is no restricted to a lineal conception of the clinical attention in opposite to other languages proposed to date.
- The clinical actions, which represents the different activities carried out during the attention process by the clinical staff (for example to ask for the patient weight and height; to give a diet, to give some drugs against obesity). An action could represent from a sophisticated surgical activity over a patient, to the supply of a drug or the acquisition of a concrete data from the patient. One can guess that the set of clinical actions it is too large, with lot of possibilities. Therefore it is a need to represent all the actions and their possibilities in a flexible way. With SCPG it is possible to link each action with a clinical objective in order to justify the reasons for that action and to harness such a kind of information also. There is also a link between actions and clinical roles. Each action could be taken off by a specific clinical staff, and this thing is possible to be modeled also.
- The patient data, which has the entire data patient related, previously acquired or acquired during the attention (weight, height and BMI). It is necessary to take into account the amount of data derived from the application of any monitored process to a patient. These data could be modified also in a period of time, so it is desirable to increase the relevance of a good data model.
- Clinical roles, which define the skills of the clinical staff giving attention. They are commonly used in the business management description context. In the previous example, the doctor must have some endocrinology knowledge to give some diet or some drugs.
- Clinical objectives, which represents the set of desirable objectives as a result of the supplied attention.

Integrating vocabularies

Finally it is significant to remark that all the factors included are by means of ontology descriptions, in order to achieve the objectives pointed at the beginning of the 2nd heading. As we mentioned above, in order to use and to annotate elements of a clinical guide to reach a general common understanding, we need to get domain ontologies. And this is a very important question. How we can do this?

As is well known and generally accepted, nowadays there is a set of clinical vocabularies like (ICD ; LOINC ; SNOMEDCT ; UMLS ; etc.) which represents different clinical knowledge. UMLS try to assemble a set of these languages, extracting and integrating the semantic associated from each one in order to get a common representation. However, there are some semantic defects mainly derived from polysemic words. The UMLS creators admit these defects that could be palliated by means of semantic analysis techniques as in ONIONS . In ONIONS it is described a methodology for the semantic analysis and integration of clinical vocabularies. This methodology is a part of a big project called GALEN whose objective is to supply with a common ontology and a language to represent vocabularies to allow the definition of terminologies that could be integrated in a common ontology . In our ontology we are integrating vocabularies by means of a specific class in the model. This class allows

us to refer to different actions in an encounter by means of the concept they are defined with. For example, an action that has to order a laboratory test for the enzyme CPK, could be defined as an instance of that class, which is an entry of the UMLS vocabulary also.

Conclusions and future work

The proposed approach to the formalization of clinical processes aims to bring novel contributions in several aspects. First, SCPG introduces new concepts in this area, such as the definition of patient encounters, and the explicit consideration of clinical goals. On the other hand, techniques imported from other areas, such as the Semantic Web, are brought to meet recently identified needs, such as the execution of guidelines in distributed and heterogeneous environments.

The value of the SCPG model is such insofar as it is possible to exploit the model to automate and improve the quality of medical assistance. In this respect, we are pursuing further investigation in diverse areas, such as the semiautomatic recommendation of guidelines, the semiautomatic generation of guidelines for a given symptomatology, and the optimization by aggregation of parallel guidelines over a single patient. Currently, we are completing the development of the SCPG guideline representation model, and implementing care assistance prototypes in several county level healthcare institutions (servicing above 150.000 patients). It is our goal to achieve, along the present year, the first executable clinical guidelines on SCPG, using the BMPS-e3 process management engine developed by BET Value.

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