An Ontology based Scheme for Formal Care Plan Meta-Description

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Abstract—**Contemporary healthcare delivery is based on state-of-the-art scientific best practices captured in systematically developed formal care plans which include guidelines, clinical protocols, integrated care pathways, etc. Research so far has addressed the computerized execution of formal care plans by developing a number of related representation languages, execution engines and integrated platforms to support real time care plan execution. However, much less effort has been put into organizing available formal care plans. In this paper we propose a conceptual model and an ontology for a meta-description of the formal care plan. The proposed conceptual model and ontology allows semantic tagging and enrichment of clinical protocols so that they can be used and re-used across platforms and also be linked directly to other relevant scientific information, e.g. published works in PubMed or personal health records, and other clinical information systems. It also allows modelling of the provenance and justifications for modifications or alterations to care plans.**

Keywords— **ontology, conceptual model, clinical algorithm, clinical practice guideline, care pathway**

I. Introduction

Contemporary healthcare delivery is based on state-of-the-art scientific best practices on how to approach each clinical situation. This knowledge is captured in systematically developed standardized procedures of a variety of types, which we collectively refer to as formal care plans and include guidelines, clinical protocols, integrated care pathways, etc. Formal care plans were introduced initially around the 70s [1] and progressively gained their way into routine medical decision making [2]. Despite their wide endorsement, early systematic field research identified barriers in their wide implementation [3] which, together with the advent of clinical decision support systems, led to efforts to create computerized forms of formal care plans [4].

Research so far has addressed the computerized execution of formal care plans and this has resulted in a number of related representation languages, execution engines and integrated platforms to support the real time care plan execution [5,6]. However, much less effort has been put into organizing available formal care plans. Mainly, they are maintained in data silos of the respective issuing body without means for straightforward seamless integration and open availability. Additionally, variations and evolution of care plans is an important topic, and would benefit from formal modelling.

In this paper we propose a conceptual model and an ontology for a meta-description of the formal care plan. Rather than addressing the internal algorithmic steps of a care plan (for which considerable work is published) we discuss the care plan as a whole. The proposed conceptual model and ontology allows semantic tagging and enrichment of clinical protocols so that they can be used and re-used across platforms and also be linked directly to other relevant scientific information, e.g. published works in PubMed or personal health records, and other clinical information systems. It also allows modelling of the provenance and justifications for modifications or alterations to care plans.

II. Related work

There are several computer-based frameworks for formal care plans in the literature including representation languages, execution engines and integrated platforms. The representation languages allow the encoding of free text care plans into a computerized form that describes their internal structure. Some examples of these languages are: GLIF [7], EON [8], Asbru [9], GUIDE [10], PROforma [11] and PLAN [12]. Accordingly, the corresponding platforms using the above mentioned languages are: GLEE [13], SAGE [14], DeGeL [15], NewGuide [16] and SpEM [17], with the exception of Tallis [18], ArezzoTM [19] and HeCaSe2 [20,21] that use the PROforma language. An extensive comparison of these platforms is presented in [5]. In short, each platform utilizes a different language syntax which constitutes a drawback in the dissemination of computerized care plans.

All platforms discussed above include repositories for managing care plans with search and retrieval capabilities but only within the internal structure of each system-specific encoded care plan. This issue has been partially addressed by DeGeL [15] and NewGuide [22] that introduce metadata that describes the internal structure of care plans. Additionally, in some platforms (DeGeL, HeCaSe2 and NewGuide) the repository supports versioning of care plans. In contrast, our focus in this work is to define, in a

formal ontology-based way, the platform independent representative metadata and relationships of care plans. This approach aims to be an umbrella over all these systems and provide advantages regarding the management, organization and searching of formal care plans.

III. Formal care plans

Formal care plans may be of a variety of types; the most commonly addressed in literature and in medical practice include clinical guidelines, clinical protocols and care pathways. In practice, one can also find other genres of care plans, such as public health guidelines, social care guidelines, even non-formal, evidence-based authoritative advice plans (e.g. NICE advice [23]). The term 'formal care plans' is used here to encompass all the standardized procedures nowadays used in clinical practice and healthcare delivery. The most basic type includes clinical practice guidelines, which are consensus statements, systematically developed to assist health professionals in clinical practice decision-making; thus they are considered formal general recommendations for prevention, diagnosis, treatment, long-term management of disease or advice and information. [2]. Clinical protocols (or algorithms) are more detailed statements that set out a precise sequence of activities to be adhered to in the management of a specific clinical condition [1]. On the other hand, care pathways are multidisciplinary care plans that outline the optimal sequencing and timing of interventions for patients for integrated care including procedures inside and outside the health care unit [24]. Irrespective of their type, formal care plans share a number of common characteristics that can be used to describe, identify and thus organize, retrieve and in any way manage a collection of care plans. The following paragraphs describe these basic characteristics, common to all care plans, which are then used to derive an ontology for care plans.

Each care plan comes with some general information. This includes a title and a summary description in textual format. Also, there are a number of different categorizations of care plans, according to their genre, intended clinical use, health issue addresses, and, last but not least, according to the quality of evidence and the strength of recommendation.

Based on their primary clinical goal, care plans can have a variety of purposes, including prevention, diagnosis, treatment, long-term management, and patient training or advice. Also, as each care plan addresses a particular symptom, disease or procedure, it is associated with one (or more) related disorder, disease or other health problem.

Formal care plans are issued by authoritative institutions, such as national and international health organizations and other related regulatory bodies. Care plans are developed based on scientific medical evidence based on published literature. The care plan origin is of outmost importance for a number of reasons. The first is provenance: no one could (or should) trust data purporting to represent medical knowledge without the ability to trace it back to its source. Also, in the case of formal care plans, legal and financial issues may arise from their use and deployment, thus the issuing body is a constraint.

Another important aspect of provenance relates to the actual physical source of the protocol, that is, where one can retrieve it. This conventionally is a document produced by the issuing body, but nowadays care plans are increasingly provided in some computerized form. In any case, the link and the specific of the file formats along with any relevant identifier is information needed for the identification and attainment of the actual care plan. All the above relate to overall information on the care plan and its provenance and source data. However, there still is some important information that is important especially for the management of care plan repositories, and for mechanisms that intend to support meaningful search and retrieval. This information relates somehow to the internal structure of the decision tree and includes the entry point, protocol outcomes and required resources.

Care plans constitute formal recommended procedures and decision trees as derived from scientific evidence. Sources of such evidence can range from small in vitro studies or case reports to large elegant randomized clinical trials that have minimized bias to a great extent. Similarly with evidence, recommendations that are based on the evidence can be of different quality. Poor quality evidence can lead to recommendations that are not in patients' best interests; hence it is essential to assess the confidence we have in the recommendations. Several systems and approaches have been proposed for grading clinical practice guidelines. GRADE [25] is the most widely accepted system, which has been adopted by a large number of evidence review bodies and organizations including the World Health Organization (WHO). In GRADE, medical guidelines are graded along two axes: (a) quality of evidence: A = high, B = moderate, C = low, and D = very low, and (b) strength of recommendation: Level 1 = strong ("we recommend"), and Level 2 = weak or discretionary ("we suggest").

While discussing the origin of a formal care plan, one should also add another factor: often formal care plans are subject to changes during their deployment in clinical practice. These deviations may be due to a number of reasons [26]; most common ones include local lack of resources, e.g. diagnostic equipment, a low strength recommendation, specific requirements of a concurrent clinical trial protocol, patient refusal to follow certain steps in the plan (e.g. due to religious or other personal issues), insurance policy re-

quirements (e.g. to firstly perform a lower cost procedure), presenting comorbidities not accounted for in the plan or even health professional's direct disagreement due to new contradicting high level medical evidence. For such justified reasons, formal plans may be adapted to local settings. In this case, one has to record the provenance of the adapted plan, i.e. the initial parent plan. This is also true for the cases where an issuing body officially produces a detailed clinical protocol or a care pathway based for example on another more general formal clinical guideline.

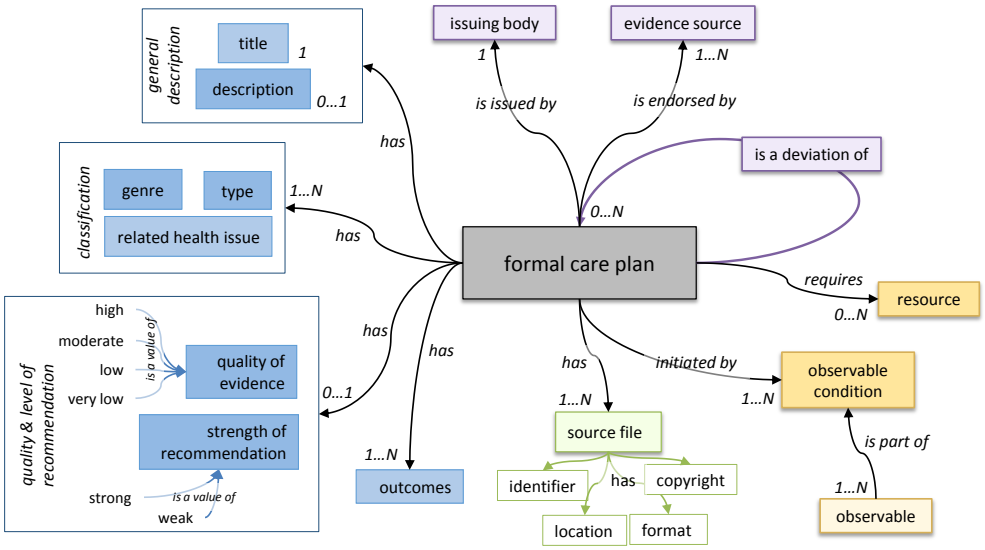

Fig. 1 Conceptual model of formal care plan description.

In order to deploy a care plan for a particular patient and situation, we need to consider both entry and exit points for care plans, as well as necessary resources to execute them. The protocol entry point is generally a condition that has to be met to determine whether a care plan is relevant for a particular situation and patient. This condition is associated with one or more observables, which is most often a physical or mental property of the patient.

To give an example, the KDIGO Clinical Practice Guideline for the Management of Blood Pressure in Chronic Kidney Disease [27] gives recommendations for patients that meet any of the following conditions: (1) chronic kidney disease patients of any stage who are not undergoing dialysis; (2) chronic kidney disease patients of any stage who are not undergoing dialysis, without diabetes mellitus; (3) chronic kidney disease patients of any stage who are not undergoing dialysis, and present diabetes mellitus; (4) kidney transplants patients; (5) children with chronic kidney disease who are not undergoing dialysis; or (6) elderly with chronic kidney disease who are not undergoing dialysis.

Therefore, in order to be able to describe properly the initial condition, or entry point to the care plan, one needs to identify the involved observables (in this example, chronic kidney disease, dialysis, age, diabetes mellitus, etc.) and construct a logical expression around certain conditions that have to be met.

The outcomes of a care plan may include one or more different expected exit points. These refer to variety of actions or states, e.g. medical diagnosis, instructions to the patient, or initialization of another care plan.

Finally, care plans usually require certain resources in order to be executed. These may include special medical equipment (diagnostic or interventional), special drugs or human resources. In certain cases the availability of such resources may constrain the deployment of a care plan or even may dictate plan adaptation or substitution.

IV. Formal Care Plan Model and Ontology

Based on the above analysis, we propose a conceptual model for the overall description of formal care plans. An overview is shown in Figure 1. The conceptual model and ontology assumes the central entity of *Formal Care Plan* which is related to a number of other entities, grouped in several classes. The class of *General Description* contains classes such as title and description, the *Classification* contains all classes related to different care plans taxonomies, e.g. genre, type, and related health issue.

The *Quality and Level of Recommendation* groups all subclasses related to the grading of the formal care plan. The Source File subclass refers to the specifics of the actual care plan data, that is, the location, format, any identifier and information on copyrights of the actual file that constitutes the care plan data.

For the care plan to be initiated for a particular patient, certain circumstances should exist. These are reported via certain *Observables*, that is, variables that can be measured or otherwise ascertained (e.g. biomarkers, biometric variables, biological signals and possibly other non-biological factors e.g. environmental). The circumstances thus are ascertained via an explicit logical expression that involves observables; this logical expression is termed *Observables Condition*.

Formal care plans are determined from clinical studies as reported in evidence based medical literature. Thus each care plan is directly related to one (or more) Evidence Source which is a specific scientific publication. Care plans are issued by an authoritative organization represented by the Issuing Body class, which holds amongst else information on the issuing date and any care plan identifier provided by the issuing body.

Figure 2 shows a view of the proposed eCP ontology, the defined classes and the relationships among them. Finally, key to the model and ontology is the Deviation relationship, which defines the history of the care plans in the case it is derived as an update, an evolution or a deviation from other formal care plans. This includes information on the reason for deriving the new care plan, and a more detailed description of the process.

The proposed model was used to develop the eCP ontology, implemented in the Web Ontology Language (OWL2 [28]) using the Protégé editor [29]. Protégé is a free, open-source tool for building domain models and ontologies. The eCP ontology is available in NCBO BioPortal [30] http://purl.bioontology.org/ontology/ECP.

To ensure that the model and ontology can be seamlessly integrated into existing medical information systems, we adopt commonly used standards and controlled vocabularies. For example, related health conditions and protocol outcomes include an ICD-10 [31] identifier. Observables include a SNOMED-CT [32] identifier, and measurements and units in the observable condition follow the QUDT [33] and UO [34] ontologies. The logical expression for the observable condition that describes the entry point to the care plan is encoded with logical and comparison operators that are derived from OWL Description logic [28]. Furthermore, the observables and the observable condition are mapped with the CARRE Risk Factor Ontology [35]. Evidence sources are described using their DOI and/or their PubMed identifier that are mapped with the Bibliographic Ontology [36], while evidence level and recommendation strength and quality of evidence follows the GRADE system [24]. Issuing bodies are described following the SWRC ontology [37]. Where available UMLS [38] codes are also used. Overall, NCBO BioPortal lists 56 class mappings between the proposed ontology and other ontologies.

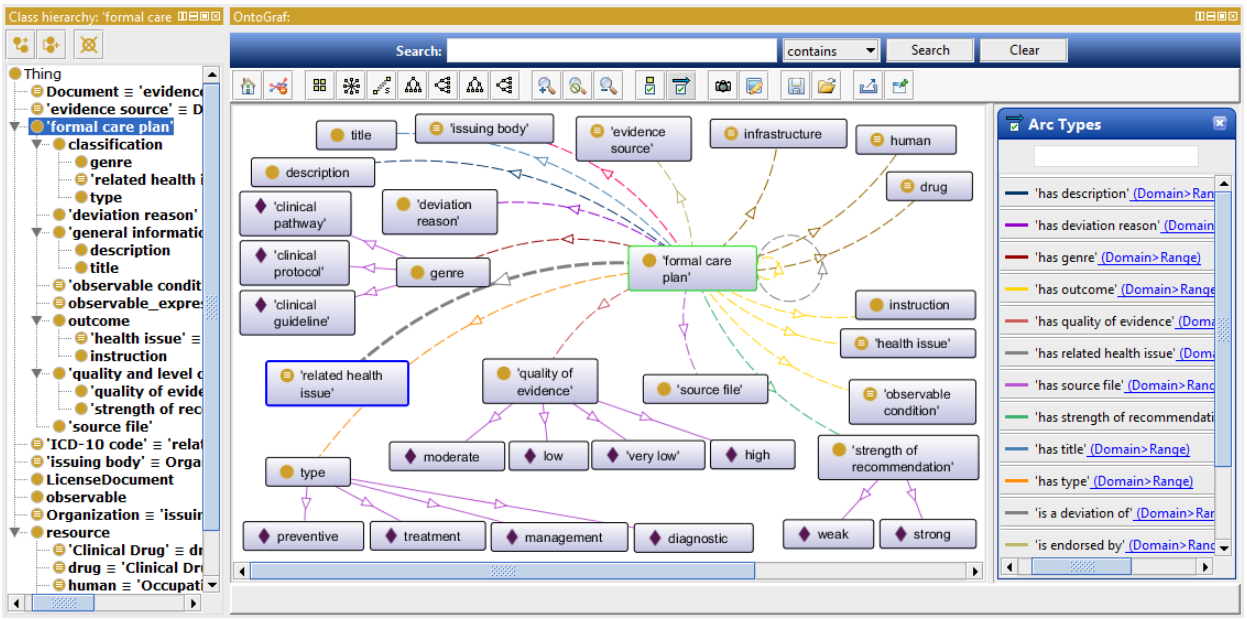

Fig. 2 Snapshot of classes and relationships in the Protégé environment.

The model and ontology were developed based on focus groups with health care professionals (4 medical experts and 4 technology experts). They were tested with 20 protocols and guidelines from the following issuing bodies: National Institute for Health and Care Excellence (NICE), National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI), American Diabetes Association (ADA), Hellenic Society of Nephrology and two Greek National University Hospitals, and with protocols developed in the project "Electronic Clinical Protocols" project (MIS 375876), funded under the Greek National Programme Thales, co-funded by the European Commission. This process of testing and using the proposed model resulted in the following qualitative findings. The medical experts found the model straightforward to use to describe existing guidelines and protocols. The terminology used was found to be familiar and thus easy to understand and apply and also to read descriptions already produced by their colleagues. The only difficulty identified related to expressing accurately and rigorously the initial condition that has to be satisfied in order for a care plan to be deployed. Initially, medical experts were asked to produce this condition in the conventional way this is written in the literature, using natural language – which was a straightforward task. Subsequently, they were asked to reformat this condition using a logical operator expression (so that this expression can be easily translated to computer readable format). This task proved to be more cumbersome and required 1-2 hours training and testing before the medical experts could independently produce correct expressions. To aid this process we have developed a web-based system for the description of care plans which includes a graphical logical expression editor (Fig. 3). The expression builder follows a web component architecture and it is implemented in Javascript and HTML5 using the AngularJS framework.

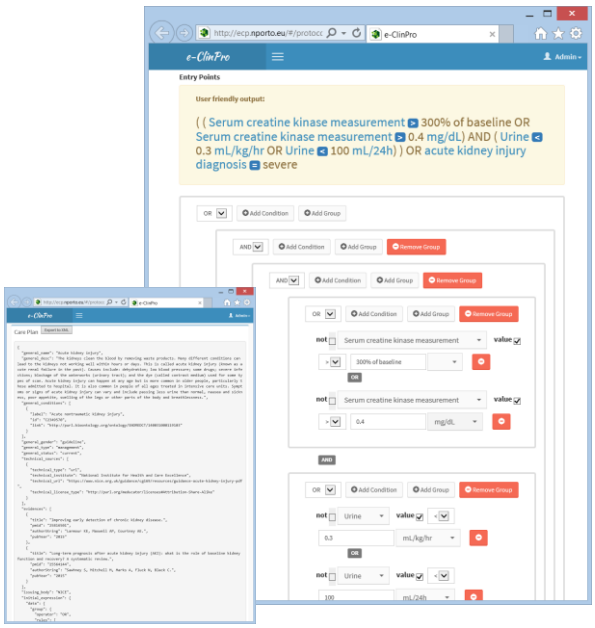

Fig.3 Snapshot of the eCP description environment with the logical expression builder and the export to XML functionality.

V. Conclusions and Discussion

This paper introduces a metadata scheme and ontology for the description of formal care plans. The eCP ontology provides a scheme for care plan meta-description in order to support: (a) care plan management in electronic repositories; (b) organization and classification; (c) universal tracking queries of care plans used by search engines or medical portals; (d) literature of evidence provenance; and (e) institutional provenance.

Work in progress includes development of a web-based editor to allow intuitive generation of metadata for formal care plans, following the proposed ontology. The metadata will be exported as XML and also RDF, the later to allow for care plan descriptions to be integrated into the semantic web and the Linked Open Data cloud.

Our focus in this work is to define in a formal, ontology-based, platform-independent metadata set to describe formal care plans and their relationships of care plans.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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