Medical Guidelines for the Patient: Introducing the Life Assistance Protocols

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Abstract. This paper introduces our preliminary results in the modeling of Life Assistance Protocols, a new vision of medical guidelines and protocols through the lenses of p-Health. In this context the patients role in the process is emphasized, the actions to be performed less defined and not only clinical situations considered, but also healthier lifestyle promotion processes accounted for, where the persons preferences and motivations play a key role.

We propose a complete framework, balancing on classical clinical guideline models and covering both the theoretical and the practical aspects of the problem, describing it from conceptualization to the execution environment.

1 Introduction

One of the common issues that has become popular in recent years, in the domain of the e-Health technologies for citizen centered health systems, is the way to integrate disease prevention, control and treatment, into the person’s daily life in a personalized and non-invasive way. This is one of the seeds that has led to the creation of a new concept: the Personal Health or p-Health.

The Life Assistance Protocol (LAP) model is defined within this context, and it is going to be the kernel of the framework described in this paper. A LAP is a set of guidelines, recommendations and prescriptions (actions) for a concrete need of the user, including not only health care actions but also healthier lifestyle related activities. In this setting users needs may be pathologies (i.e. diabetes, heart failure), special conditions (i.e. pregnancy, elderliness), main heath concerns (i.e. quitting smoking) or simply following a healthy lifestyle. The LAP defines, then, a set of actions in order to solve user needs. These actions represent the cycle (workflow) of the life of a person, in which each stage takes into consideration all the person dimensions: motivation, clinical status, personal context, etc. These dimensions are continuously re-evaluated to trigger moves forward and backward in the stages of the LAP.

Being presented in this paper is the creation of a complete framework that covers the LAP definition and representation, along with the final execution of the protocols actions via ICT systems.

The paper is organized as follows: in Section 2 we present the rationale that led us to the definition of the LAP model as an extension of existing clinical guidelines frameworks; in Section 3 we define the LAP Conceptual Model in details and illustrate, through a hypothetical example, how the elements fit together. Section 4 introduces the other components of the proposed framework, namely the Workflow and Execution Models. In Section 5 we discuss our plans for the implementation and evaluation of the framework, while in Section 6 we present our conclusions.

2 Rationale

Clinical guidelines (or Care Plans) are a powerful method for standardization and uniform improvement of the quality of medical care. Clinical guidelines are a set of schematic plans, at varying levels of abstraction and detail, for management of patients who have a particular clinical condition (e.g., insulin-dependent diabetes).

The application of clinical guidelines by care providers typically involves collecting and interpreting considerable amounts of data over time, applying standard therapeutic or diagnostic plans in an episodic fashion, and revising those plans when necessary [12]. Clinical Pathways differ from practice guidelines, protocols and algorithms as they are employed by a multidisciplinary team and have a focus on the quality and co-ordination of care [9].

However, in both cases the intervention of the patient in the execution of the protocols is very limited, and the protocols themselves do not include all the variability that patient daily life presents, which, at the end of the day, is one of the main causes of the non-compliance with the treatments when put into practice. LAP doesn’t differ from the former definitions, in philosophy, but tries to empower those two dimensions, the patient and his environment, as active actors of the care plan outside hospitalized environment (not clinical) and the inclusion of the patient’s daily activities and choices. LAP is, then, concerned on how the medical procedures are applied to meet the patient particular needs within the patient preference context. At the same time, as it has been mentioned, the LAP targets both those patients that suffer from chronic diseases but are in a stable status at home and do not need strong clinical interventions, and citizens at risk or wanting to carry out a healthier lifestyle (public health interventions).

In our vision, a solution that focuses on supporting the patients in such environments must take into account the following elements:

- The patient must be considered the main active actor in the care process, instead of the passive receiver of the actions performed by the caregivers;
- For the above reason, motivational aspects and possible non compliance must be accounted for in the core of the model, instead of being considered just as undesirable deviations from the normal path;
In such a context, the recommendations and guidelines (actions) are usually less strict, in some cases even given without direct mediation of a health professional;

On the other hand, the level of variability is greater and the need of adaptation to the patient’s life (preference and context) much higher;

The framework we are proposing tries to address directly these needs and the peculiarities that such processes may present, and we believe that the management of such variability via ICT solutions is not only possible but also advisable, in order to improve patient’s compliance and to give to all the involved actors the possibility to better adjust the guidelines to their needs, therefore increasing their efficacy.

## 3 LAP Conceptual Model Definition

The LAP Conceptual Model can be defined as follows:

**LAP:** is a set of guidelines, recommendations and prescriptions for a concrete need of the user. It is defined by a general objective and it is composed of a set of nodes grouped into stages.

**NODE:** contains a set of actions\(^5\), which are mutually independent, transactionally simultaneous and that will be executed over or by one or several determined actors. Each node will be defined by a description, a set of actions, indicators and reactions. A node could possibly include an explicit enumeration of user relevant data out of a predefined set (e.g. clinical record)\(^6\). A node is active if at least one action is in execution, otherwise it is inactive.

**STAGE:** is the set of active nodes in a concrete moment of time, and may have an associated label. There are two special types of stages to be defined here, initial stages (usually one per LAP) and objective stages, that can be more than one. The latter will be reached whether the general objective of the LAP has been achieved or the patient is in a stage in which the LAP is not able to continue (i.e. the person needs to go urgently to a hospital). However, these stages do not explicitly represent the status of the patient.

**INDICATOR:** is a function of time\(^7\) and a (possibly empty) subset of the static or dynamic actors features to a discrete set of values (indicator labels).

**ACTION:** is defined by an activity, an actor which executes the activity (executor) and one or more actors that benefit from the execution of the activity (addressee). The executor and the addressee can be the same actor.

**ACTOR:** is considered to be any user of the system or the system itself, and it is defined by a set of static or dynamic features, that might be retrieved from the person’s clinical record, or even other sources containing non-clinical information, such as preferences, beliefs, habits, etc...

**REACTION:** models the transition between nodes, and it is defined as a function of one or more nodes and one ore more indicators labels to one or more nodes.

**OBJECTIVE:** is the desired outcome of the overall execution of the LAP. It is formally represented by a subset of the final nodes. When one of these nodes are reached by the patient it indicates that the LAP’s objective has been achieved successfully.

In order to make the discussion as concrete as possible, we are now going to illustrate how this definition applies to a hypothetical example. The setting we consider is the following: a patient who recently discovered to suffer of diabetes, let’s call him John, has finally managed to get used to his drug therapy. Now that he’s able to control his glycemic level (GL) with drugs, his doctor wants him to go a step further and reduces the drugs. To achieve these results, motivate and educate the patient to follow a diet, the doctor activates the LAP graphically presented in Figure 1.

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\(^5\) All those actions related to a specific circumstance, like treating an edema.

\(^6\) These might become inputs for actions or just be collected for human interpretation.

\(^7\) Time is being considered to model timeout events that can trigger a reaction.
The idea is that we have two main concurrent activities: trying to follow a diet and keeping the glycemic level controlled. For the former, when we detect a non compliance we keep on with the same activities but we add motivational support, which ends as soon as the person becomes compliant again. For the latter, we just increase the dosage of insulin and follow a more accurate monitoring process if hyperglycemia is detected.

This example is not realistic from a clinical point of view, for instance it lacks proper reactions if the user keeps being non-compliant or in hyperglycemia, notification to the doctor at LAP completion, etc. However, it is simple and yet meaningful enough to let us illustrate all the elements involved.

With respect to the definition above, this LAP is composed of six nodes \((n_0, n_1, \ldots, n_5)\). The possible activities that can be executed are things like measuring the weight, motivating the user providing him supporting information, filling a 24h recall questionnaire\(^8\), etc. Notice that some of them will be actions where the executor and the addressee is the same (John, i.e. measuring the weight), while for others the executor and the addressee are different (the System and John, i.e. motivating).

We have two main indicators: a simple one related to the GL (HyperGlycemia if GL > 250) and a more complex one related to the compliance in following the diet and filling the 24h recall (Compliant if he reaches the target weight or continues to loose weight and he keeps on filling the 24h recall with results close to his diet caloric target). Moreover, we have timeouts that model the frequency at which actions have to be carried out in the different nodes.

The reactions can be derived directly from the graph but notice, for instance, when a non compliance is detected in \(n_1\) both \(n_1\) and \(n_2\) are concurrently activated.

Finally, having six nodes, potentially there exist \(2^6\) stages but due to the topology of the graph there exist only six possible stages:

\[
q_0 = \{n_0\},\ q_1 = \{n_1, n_3\},\ q_2 = \{n_1, n_2, n_3\},\ q_3 = \{n_1, n_3, n_4\},\ q_4 = \{n_1, n_2, n_3, n_4\}\text{ and }q_5 = \{n_5\} \text{ will be our objective stage.}
\]

Even with this very simple example it can be seen how this type of model helps in dealing with the multi-faceted dimensions defining a person health condition and how they correlate with each other. Through the separation of concerns, in our example the glycemic level and the diet compliance, we simplify the process definition but at the same time, through the power offered by stages, we are still able to capture those complex interactions.

## 4 LAP Framework

The classical approaches that can be found in literature related to the specification, representation and execution of medical guidelines are based on different models. They could be sorted as logic-based (PROforma), rule-based (Arden Syntax), Network-based (Prodigy), and Workflows as Petri Nets (Guide) [8]. The aim of these models is creating computer-interpretable guidelines that facilitate decision support, covering both computable data and clinical knowledge. There are also other models focused on the knowledge representation by using XML guideline document models, such as GEM [13] or HGML [5], which in some cases can be also computable.

Most of the written guidelines implicitly define a workflow process, therefore by using a language definition based on workflows, and working in adapting the medical guidelines to it, they can be expressed in the mentioned language, and be decomposed in smaller tasks which can be easily executed under the figure of a coordinator.

\(^8\) A tool designed to elicit from the patient the amount of calories eaten in a day.

This model is basically focused on the workflow of the medical acts; where the actions to be performed are not taken into account at the beginning, and only the workflows nodes are important. The evaluation of the indicators resulting from the execution of the actions in the nodes, will be used to obtain the jumping conditions from one node to another of the workflow.

All this drives us to create a complete framework, which must cover both the theoretical and the practical aspects of the problem. The framework will include the following set of models and tools:

- A Conceptual model;
- A Workflow model;
- An Execution model;
- A LAPs specification language (workflow-oriented);
- A set of software tools, such as a CASE and verification application based on graphical symbols to define workflows, a compiler to generate workflow LAP templates and a tool to adapt and personalize LAP templates with patient specific parameters (possibly taken from clinical records) in order to make a computable instance of the LAP;

The conceptual model was presented in the previous section and creates a theoretical base upon which all the framework stands. All the concepts in the model will be used in order to create templates, which will be filled by the domain experts through a graphical tool and instantiated by the system for a concrete person. This instance needs to be internally represented in a formal language that will be executed by the model discussed in the following sections. These layers are represented in Figure 2.

![Figure 2. LAP layers from abstract to concrete](image-url)
In the following sections we introduce the workflow model specification, and, briefly, the execution model.

4.1 LAP Workflow Model

As it has been mentioned in the previous section, the LAP framework includes a workflow model. The theoretical model that is going to be used for the LAP workflow is taken from the preliminary studies on Timed Parallel finite Automata (TPA) [3] which are based on Parallel Finite Automata (PFA). PFA are an improvement of Determinist Finite Automata (DFA) and model automata with capability to execute parallel activities.

A parallel automaton implies that more than one node is active at the same time -like in Petri Nets- but they also are supported by the concept of states, that approximates the PFA to the DFA by joining the parallel active nodes into a different state, and finally this, based on states concept model, is an abstraction that maps the PFA to a DFA which is a well controlled framework. TPA is a formal framework that appends timers to the PFA by adding the concept of Clocks to the PFAs definition and also using Clocks timers as indicators.

In [3] it is also explained how the TPA model covers a series of classical data workflow patterns, like the parallel split pattern, the synchronization pattern, the discriminate ending pattern, the milestone pattern etc. The TPA formal model is defined taking all these concepts into consideration.

By using the timed parallel automata notation, we are now formalizing the LAP conceptual model. This formalization, as we will see later in this section, ensures that the execution model is going to be finite and deterministic.

Definition 1 A Life Assistance Protocol is a tuple \( \text{LAP} = \{A, \Delta, \Sigma, \Psi, N, Q, q_0, O, \gamma, \sigma\} \), where:

- \( R \) is a finite set of typed features;
- \( A \subseteq R^* \) is a finite set of actors, where each actor is characterized by zero or more features;
- \( P \) is a finite set of activities;
- \( \Delta \subseteq A \times P \times A^+ \) is the set of actions, which are activities performed by one actor and received by one or more actors;
- \( C \) is a finite set of Clocks;
- \( T \) is a finite set of time labels that can be generated by the Clock set \( C \);
- \( \Phi \) is a finite set of symbols;
- \( \Sigma \subseteq T \cup \Phi^+ \cup T \times \Phi^+ \cup \{\lambda\} \) is the finite input alphabet;
- \( \Psi \mid \Phi_0 : \Sigma \times R^* \rightarrow \Sigma \) is the set of all possible indicators, where an indicator is a function of time (indicated by clocks) and actors features to the input alphabet ;
- \( N \subseteq \Delta^* \times \Psi^* \) is a finite set of nodes, where each node contains zero or more actions and zero or more indicators;
- \( Q \subseteq N^+ \) is a finite set of stages;
- \( q_0 \in Q \) is the initial stage;
- \( O \subseteq Q \) is the set of objective stages;
- \( \gamma : N^+ \times \Sigma \rightarrow N^+ \) is the transition function between nodes;
- \( \sigma : Q \rightarrow Q \) is the transition function between stages.

It is clear that there are differences between LAPS and TPAs but they can be summarized saying that:

- The LAP model explicitly defines the actors involved in the modeled workflow, along with their characteristic features;
- In LAPS we refer to stages instead of states, because in our vision they better incorporate the kind of complexities that can be found while trying to model the health condition of a person;
- The finite set of indicators used in the LAPS definition produces elements of the finite input alphabet used in the TPAs definition.
- In the LAPS definition we assume that the Clocks used in the TPA, and their temporized labels, may be directly used as indicators;
- The set of actions of a LAP is equivalent to the TPAs set of processes, \( \delta_{\text{TPA}} \equiv \Delta_{\text{LAP}} \), but adding to the TPAs processes an executor and addressers. Thus, along with the previous point, let us conclude that \( N_{\text{TPA}} \equiv N_{\text{LAP}} \).
- At this point we want to stress that, despite the fact that both models do not include the same concepts, the input alphabet remains regular, and the transition functions are still compatible, therefore we ensure that the execution model is going to be based on a finite and deterministic formalism.

4.2 LAPS Representation

As it was mentioned before, the LAP’s definition language will be dependent on the execution model implemented. It should express the workflow process identified by the experts by using sections that allow them to write the nodes, stages, transitions and the actions executed by the nodes. The possible actions that they can select are expressed as services and the entire workflow can be understood as the execution of those services. Our model is focused on the process and the way it should be executed by carrying out actions and evaluating their results, it has also a kind of "supervisor" which are checking the decisions, the results and the possible interactions of them.

Comparing this approach, which is basically oriented to the guidance of the execution of the actions, to already existing guideline representation models, the Arden Syntax and GLIF approaches are more focused on the guidelines standardization, while PROforma on execution aspects [1], but oriented to facts declaration. Finally, Asbru defines a guideline representation language that has a very rich set of temporal constructs, however an execution engine, which is able to handle the complexity of Asbru plans, is very complicated due to the powerful features of Asbru, although there exists some execution engines based on relaxed versions of Asbru, like Asbru Light or Asbru Light+ [4].

Another difference, and the most important one is the possibility of inferring the LAP model from examples, since the LAP complexity is bounded to regular grammars, as is demonstrated in [3].

4.3 LAP Execution Model

In addition to the workflow model specification, the execution model appears. It must support multiple LAP instances and their tasks concurrently executed, but support also autonomy, flexibility and interaction with the users. In order to support these features, we have selected a Multi-Agents System (MAS) approach, which is also being considered a viable solution by other authors, like Moreno and Is-ern [6]. The MAS is used to divide and distribute correctly the tasks and processes of each running LAP instance by using the features and knowledge of the agents present in the system. As we said previously, the final instance of the LAP has a workflow inside that can be easily extracted in order to compose the different nodes present in the workflow, and as a less complex process, it can be easily computed.

In the system there is a type of agent, the node agent, that represents a workflow node from the LAP and computes its list of actions. There is also a type of agent, the coordinator agent, whose tasks are the verification of the indicators, the possible jumps, the follow-up of the execution flow, and the activation of the nodes in each stage.
reached. This type of agent is the one who controls the workflow execution and the transition between nodes.

Finally, in the system there are also specialized agents who receive requests from the agent node. The specialized agents provide solutions, perform actions, make suggestions and also check the patient’s signals and health care parameters. The node agents inspect the actions to perform, and since these were fully specified from the beginning when the templates were defined, by using ontologies they know that at least one specialized agent exists which is able to perform those actions and is able to dynamically invoke them.

In the MAS, other types of agents play an important role, such as the GUI agents, but in this paper we are not going into that level of detail in the execution model, since we have focused it on the conceptual and the workflow models.

5 Implementation and Evaluation Plans

The proposed model is currently being used and tested in the context of the PIPS Project (Personalised Information Platform for Health and Life Services, [2]), an e-Health Integrated Project funded by the European Commission under the Sixth Programme Framework call, that aims at creating novel healthcare delivery models by building an holistic environment for Health and Knowledge Services Support.

This environment integrates different technologies in order to enable healthcare professionals to get access to relevant, updated medical knowledge, and European citizens to choose healthier lifestyles. The project aims to bring together healthcare suppliers, citizens, public organizations, food/drug industry and services, researchers, and health related policy makers in order to create a dynamic knowledge environment. This dynamic environment builds on traditional health related policy makers in order to create a dynamic knowledge environment and disparate knowledge sources from health/nutrition domains.

In the PIPS project, major attention is dedicated to the issue of promoting compliance to the medical advices. The PIPS philosophy, in accordance with recent research in health promotion, is that the patient/citizen has to have control of his own behavior, in order for the advice to be completely understood and put into practice.

Such a context perfectly marries the LAP philosophy and the LAP framework will be employed in the next months to model several clinical and lifestyle related scenarios, from supporting people suffering from heart failure in their everyday chores to motivating overweight people in following a personalized nutritional plan. The first results of this experimentation should be available by the end of the current year and a thorough validation and evaluation process will be completed to understand advantages and limitations of the proposed approach.

Once the LAPS are described for the selected use cases, a twofold validation will be carried out. On the first place and before the execution model is created, a set of experts will be elicited for the validation of the LAP model and the first LAP templates. Those experts will be selected so that to have both a medical background and expertise in e-health and process management, in order that the model can be analyzed in detail in personal interviews. On the second place, after the templates are implemented in an execution solution, the instantiated LAP will be validated by controlled pilot studies, including real actors and real health care organizations, to assess its applicability and evaluate if those experiences show a tendency to the desired impact. As a result of these phases, a refinement of the templates and the model will be performed, setting the basis for the dissemination of them in wider forums.

6 Conclusions

In this paper we introduced the Life Assistant Protocol model, a concept coming from the classical medical guidelines but, now, framed in the new p-Health paradigm. This approach has been presented in a framework, including the Conceptual Model and the Workflow Model, which are the theoretical base of the LAP, and the Execution Model, that will allow us to put in practice the LAP concept. The PIPS Project represents our development environment, in which we will be able to validate and evaluate the complete framework, also receiving feedback from real users in real situations. The project will be deployed in San Raffaele Hospital (Milan, Italy) in the next months and in La Fe Hospital (Valencia, Spain) at the end of the project, giving us the opportunity to evaluate the effectiveness of our approach.

ACKNOWLEDGEMENTS

We would like to thank the European Commission for funding the PIPS Project (Contract 507019), where all this work is being carried out, as well as to the other partners who are helping in the project development.

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