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Part II
Organizational Models and Information Systems

A telematic based approach towards the normalization of clinical praxis

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Abstract. The provision of comprehensive support for traceability and control is a raising demand in some environments such as the eHealth domain where processes can be of critical importance. This paper provides a detailed and thoughtful description of a holistic platform for the characterization and control of processes in the frame of the HACCP context. Traceability features are fully integrated in the model along with support for services concerned with information for the platform users. These features are provided using already tested technologies (RESTful models, QR Codes) and low cost devices (regular smartphones).

Keywords: traceability, eHealth, software platform, mobile environments

1 Introduction

The healthcare environment is an area in which the quality and safety of clinical procedures and practices is particularly relevant. The arise of situations and risks not properly tackled may put at stake the life of patients [1]. For example, in case a patient requires to be provided with intravenous nutrition, it is especially critical to ensure the quality of the nutrient mixture supplied and the attention given [2].

Due to the sensitivity of the area, it is common the definition, by experts in the domain, of clinical practice guide and policy recommendations [3]. Upon its implementation, the control and verification of adherence to the procedures defined therein must be enforced.

In this line, one of the control methodologies with greater acceptance in environments where health hazards can arise is the HACCP (Hazard Analysis and Critical Control Points) [4]. HACCP is a system aimed to establish a preventive, systematic and organized control of risks. The core of this system is the identification of moments or places where monitoring specific variables within procedures in order to control potential hazards. HACCP is applied mainly in the field of nutrition. However, it is becoming more common its use in the pharmaceutical and healthcare environment [5], 6].

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The recording of events facilitates the assembling of evidences of the actions carried out and the results obtained. These records enable the application traceability mechanisms. This feature, traceability, must be understood as the ability to track the history, actual usage and current status of entities [7]. Traceability allows health authorities to respond quickly and appropriately to the eventual detection of risks for quality and safety. Therefore, in environments of risk for health, traceability is often enforced at the legislative level (e.g., in EU [8]). Nevertheless, it is common that health practitioners initially record data on paper and then they transfer it to information technology based systems [9]. In addition, these information systems are often ad-hoc telematics solutions, designed to cover only specific tasks (e.g., prescription and adherence to treatment). Thus, monitoring management tends to be error prone and expensive. Furthermore, many existing systems are not open and interoperable and its architecture is too rigid and monolithic.

Based on this lack, the authors of this work, a group of researchers from different institutions and experts with extensive experience in the healthcare and technology field, have collaborated under the support of projects mentioned in the acknowledgments to address a solution to this problem. Finally, a telematic based solution to support the standardization of control and traceability procedures in any health field was developed. The objective was to create a tool to carry out the implementation of controls (in systems such as HACCP) and to record the values obtained efficiently and in a cost-effective manner. To do this, the system must provide with tools to control the entire life cycle of procedures and entities (e.g., medication). Furthermore, it should allow to check and automatically analysis the recorded information in real time.

The applicability of the proposed system is verified in the field of parenteral nutrition (PN). This scenario was chosen due to the previous experience of the authors [10]. The PN is considered as a "high alert medication" and should be controlled throughout its life cycle [11]. Therefore, this is an ideal context that illustrates the application and associated outcomes of our system.

This document provides with a detailed description of the proposed model in its context and a deployment guideline. Therefore, the following section provides a high-level description of the context and characteristics of the system. Then, in Section 3, it is presented an overview of the architecture and functionality of the system. Later on, on section 4, the application of the proposal in the frame of PN is exemplified. Finally, in Section 5, a set of conclusions is laid.

2 General Description of the System

This proposal, as already mentioned, is based on the HACCP model. Under this model, moments or places where it is necessary to monitor one or more variables must be identified. These monitoring moments or places are known as Control Points (CPs) [12]. In our system, CPs are intended to record the monitored variables and elements under control into traceable records, hereinafter, traces.

In some cases, CP can be carried out without human intervention by automated agents (e.g., an embedded system that periodically records an operating temperature).

However, interaction with human users is usually required to monitor complex variables and the collaboration of a number of agents is required. This includes actors such as patients themselves and their families.

The proper implementation of the proposed system should allow to meet different objectives: monitoring adherence to procedures, risk control, traceability of entities and even behavioral analysis for continuous optimization and decision making procedures. To achieve these goals, it is required to monitor all types of entities involved. Actually, the solution must include mechanisms for the management of physical entities or conceptual ones (e.g., a treatment, a particular event, etc.).

One of the key requirements for traceability is the unique identification of entities [13]. Actually, this identification is usually done using labels on the entity itself or, in the case of logical entities, labeling a related area (e.g., the table where it is performed the control). Our system supports several types of labels, including wireless labels (such as NFC tags) and optical ones (such as 2D QR and DataMatrix codes). In this paper, we encode information using QR tags [14]. These tags can be easily read using devices such as smartphones with cameras, quite common nowadays to access to Web pages and services. In our proposal, labels are encoded as an HTTP URI. This URI will be generated by the system and will uniquely identify one single entity.

Users can retrieve from the Web, at runtime, the information and the operations associated with an entity simply by reading its label. These operations can be of two types, control or information. Control operations can carry out a particular CP. Specifically, a control operation defines variables that the user (automated agent or human) must monitor. Conversely, information operations are intended to retrieve relevant resources for the human user associated with the entity (e.g., video tutorials, manuals, brochures, etc.), a paramount feature nowadays [15].

The in-depth analysis of such contexts leads us to point out a number of characteristics that drive the modeling of the system and its behavior. The main conditions are:

- **Non intrusive**: platform should not collide with the established procedures.
- **Universal use**: no especial technological skills should be required.
- **Suitable devices for the context**: devices in use must allow features such as mobility and others required by the practitioners.
- **Security constraints:** the system must ensure that this information will not be accessed without proper authorization.
- **Robustness:** the platform must ensure its proper working and the traces collection even in adverse contexts (i.e., little or no connectivity).

3 System Architecture

The system fits on a client-server model. Actually, main features implemented are offered using REST APIs [16]. These APIs enable customers: to recover data stored about different elements of the domain under different formats (e.g., HTML or RDF); to retrieve the list of custom operations or the description of each operation; to invoke an operation with particular values; or to manage the historical of traces. The client software will be able to access the server functions via secure connections (i.e.,

HTTPS protocol). Agents are provided with a graphic layer for user interaction. In addition, the device on which it runs must support the required functional capabilities, such as reading labels, Internet access, and so on. Current mobile devices (e.g., tablets and smartphones) cover these needs. Indeed, there are a number of past experiences that proves their application in this environment (e.g., [17]).

In our system, two types of client agents were developed: a Web client and an Android application. The Web client allows access to the basic features of control through a common Web browser. Meanwhile, the Android application is a generic client agent capable of providing a functional service to any user in any application scenario. Among its main features is the ability to dynamically generate user interfaces based on the responses from the server. It is also provided with caching mechanisms that allow the system to continue operating even when the server is temporarily not available.

Regarding the control process procedures, the general scheme of interaction between the client and the server follows the steps shown on Fig. 1. This scheme starts when a label is read. Based on the URI contained on that label, the client queries the server agent about the accessible operations referenced by that address. The server parses the query and gathers (and returns) the available operations. These operations are shown to the user in a list. Depending on the user's choice, the client agent requires the system description of the operation. These operations are represented as resources in the REST server interface. In line with this, WADL [18] is used for the description of the operations. This language allows a comprehensive description of interfaces based on HTTP (e.g., input and output parameters, invocation mechanisms, response formats, etc.). The client agent processes this description to dynamically adapt to the appropriate invocation needs. In the case of a control operation, the monitor variables (represented as input parameters) that can not automatically be inferred (e.g., the product status) are requested to the user by means of forms. These forms are generated at runtime. Once the user enters the values, the client software uses the description information from the WADL file to invoke the method on the interface associated with the operation.

Finally, in the system, an auditable record of the monitoring process carried out is generated. For the formal modeling of this information, semantic-based technologies have been used. Semantic technologies enable to model and characterize the behavior of entire framework in a machine interpretable fashion. Thus, these technologies allow the application of advanced mechanisms for analysis and automatic extraction of new knowledge from the existing records (e.g., using inference engines). They also allow implementing mechanisms based on SPARQL query language to conduct complex and structured searches.

In the presented system, a data model for the abstract characterization of the application context was designed (check Fig. 2). In this model, concepts (e.g., users, CP, etc.), properties (e.g., name, description, etc.) and relationships (e.g., between a CP and the parameters to be monitored) are included. As far as possible, during the modeling phase, widely recognized semantic vocabularies (e.g., FOAF or Dublin Core) were used. Of course, it is possible to explicit concepts and characteristics of individuals in narrower environments.

These technologies allow the development of high-level functionality. The aim is to facilitate the efficient management of knowledge generated each context. In this

sense, the system enables the generation of audit reports and real-time filtering of historical traces. It also allows the generation of human-friendly reports (e.g., graphics) with the extracted information. Based on this, managers can perform better analysis and, thus, optimize effort and resources.

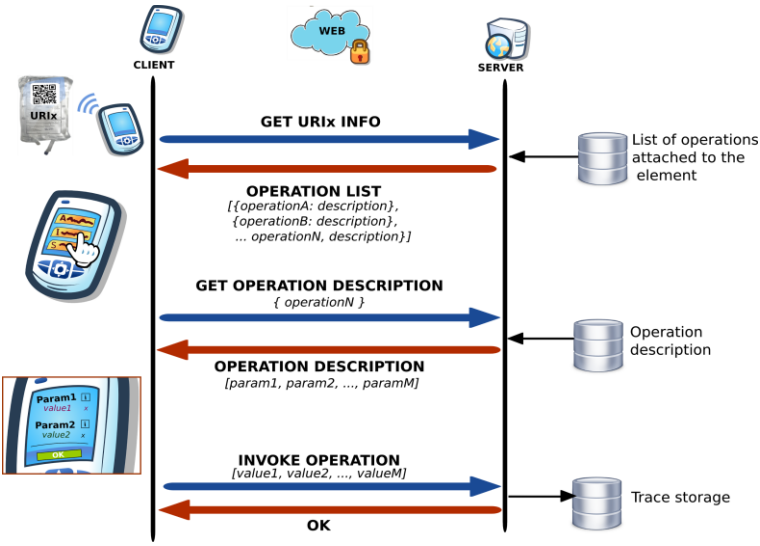

Fig. 1. Client-server interaction for the invocation of a control operation.

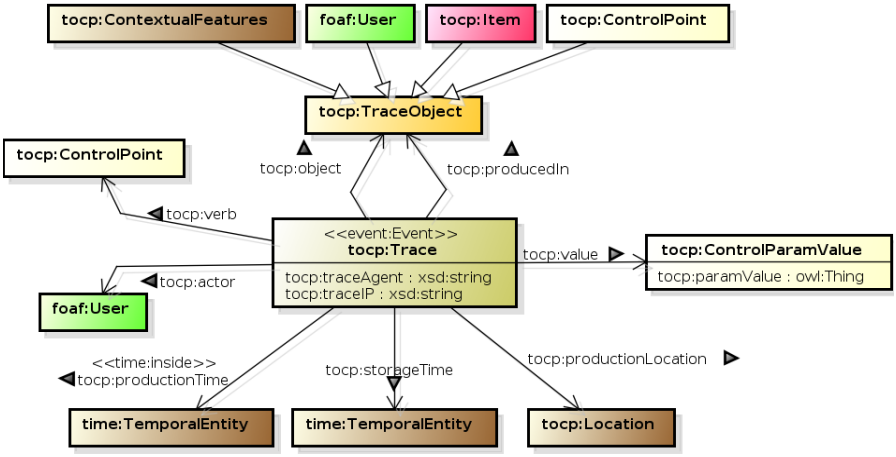

Fig. 2. Semantic model focused on the characterization of traces.

In order to achieve greater effectiveness in this type of analysis, the more comprehensive and the more detailed the information, the better. In this case, the use

of semantic technologies facilitates the implementation of enriching techniques for population of data using external information shared publicly on the Web (e.g., adding information about a drug component using data extracted from Wikipedia/DBPedia). Interested readers can check the performance of these techniques in previous works of authors [19].

4 Validation

PN mixtures are intended to provide basic nutrients intravenously, mainly, for patients whose gastrointestinal tract is not functioning. The PN mixtures can contain more than 50 components with a high potential for chemical and physical-chemical interactions.

All these conditions lead us to think that this is an ideal environment for setting up a control and traceability plan. In order to achieve this goal, the standardized procedures throughout the life cycle of PNs are used as the starting point. As a general rule, in due course of this normalization process, a set of documentation is generated, including textual descriptions of the various actions and behavioral recommendations. This documentation is known as Standard Operating Procedures (SOP) [20]. SOPs often introduced flow diagrams in order to facilitate the understanding of certain parts of the procedures.

Afterwards, a panel of experts discuss possible risks that may arise in the addressed processes. Finally, CPs are identified along identified processes and certain variables are targeted for monitoring. Regretfully, the implementation of a CP is often a costly procedure. Therefore, the HACCP system advocates only for implementing CP that are critical, also referred to as CCP (Critical Control Points). However, the application of the proposed platform reduces the cost per CP. Thus, it is possible to increase the number of CP and enhance the information available for control and traceability.

As an example scenario, in Fig. 3 it is shown a flowchart showing a standardized procedure excerpt. In particular, it is shown the immediately following events after the elaboration of a PN mixture, i.e., the bag labeling, quality control and storage.

Applying the HACCP model, on the diagram four CPs have identified for monitoring: CP1) the results of controls applied to the PN; CP2) identification of discarded PN; CP3) the type of protocol applied to each PN mixture for conservation; and CP4) the temperature of the refrigerator in which each PN is stored. The enactment of the first two CPs is the responsibility of the pharmacist; the nurse in charge of the third one; and the fourth one is on an electrical device provided with a temperature sensor.

In this scenario, human users will be provided with a smartphone with camera and Internet connection. In such devices, it has been installed the client application agent of our platform. In addition, entities of interest in the scene have been uniquely identified using labels with QR codes beforehand. These entities of interest include: each PN bag, the required tools to perform checks on the mixing, storage coolers, the waste container, CPs themselves, etc.

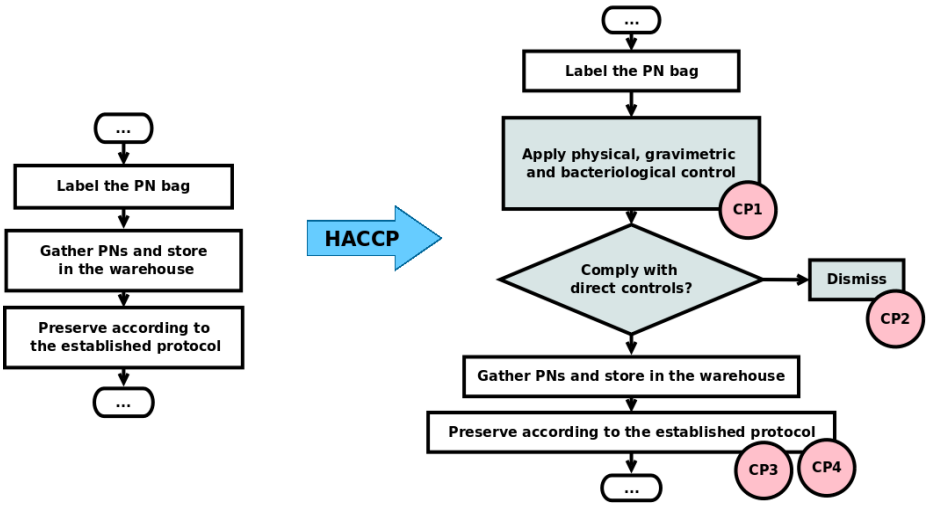

Fig. 3. Flowchart of a standardized treatment for PN and the result.

Using the proposed setup, it turns out feasible and convenient to implement the proposed technological system. Specifically, the common usage of the system takes place when users responsible for carrying out the procedure meet a CP. At that point, the user through the mobile client can use the agent to retrieve and invoke the associated operations.

Given the scenario above presented, the CP1 will be described in the frame of the application. In this CP, the pharmacist must check the quality of the mixture made according to its physical and biological properties (e.g., color changes, visible particles, weight, etc.). In this case, the pharmacist will use the application to read the label on the bag of the PN. In this way, he/she will receive a list of available operations on the mobile (check Fig. 4a). These operations will be conditioned by the status of pharmacist and the mixture PN itself. In case the label would be read by a nurse (or any other user), the list of retrieved operations would be different.

The pharmacist will be able to navigate among the different operations to select the desired one, i.e., the one designed to control the physical properties of the PN. Afterwards, on the screen of the device a form is generated (check Fig. 4b). In this form, it is requested to introduce mandatory data and optional information regarding the corresponding operation. These variables include: select from a list, the color of the mixing; mark whether or not precipitates can be seen with the naked eye; actual weight of the PN; read the label of the measuring equipment used (e.g., scales.); personal comments; etc. In addition, each requested field in the form has a description to guide the user. Once the appropriate values are introduced, the user submits the form for validation and registration.

According to this usage model, users can record the control actions performed. These traces can be checked online by the staff in charge in real time by means of a Web client. Using this tool, a paginated list of traces can be accessed. Moreover, this list can be filtered according to different criteria: the absence or presence of particular values in the parameters, the date and location where the trace were generated, the

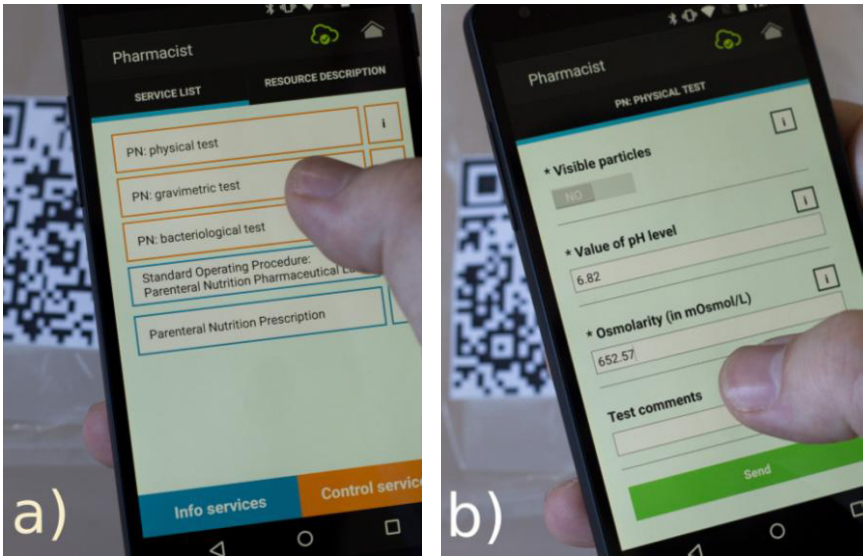

Fig. 4. Android client interfaces for: a) choosing a operation after reading a label; b) the form of a control operation with parameters to be monitored.

user responsible, the operation involved, the label read to invoke the operation, etc. These features allow managers to search in a agile and convenient fashion through all traces within the system and to get timely information to act with diligence as required. For example, if it is detected that the scales used in the CP1 is unbalanced, it would be feasible to identify immediately the PN mixtures involved and their last known location (check Fig. 5a).

Additionally, the log of traces also provides detailed information on any procedure. This information can be used to get a better understand of the operations and their context to optimize procedures. In this sense, the Web client provides access to statistics and plots about different features: number of traces by user, operation, or day; number of times each operation is invoked by each user; weekly and monthly average of traces (check Figure 5b) averages; etc. Also, the platform can export the gathered information as traces on standardized XES [21] formats to carried out further analysis. Therefore, it is possible to take full advantage of process mining tools as ProM[1].

5 Conclusions

A telematic-based platform to offer support for the implementation of plans for control and traceability in a health domain is presented. Its application has been

[1] http://www.processmining.org/prom/start

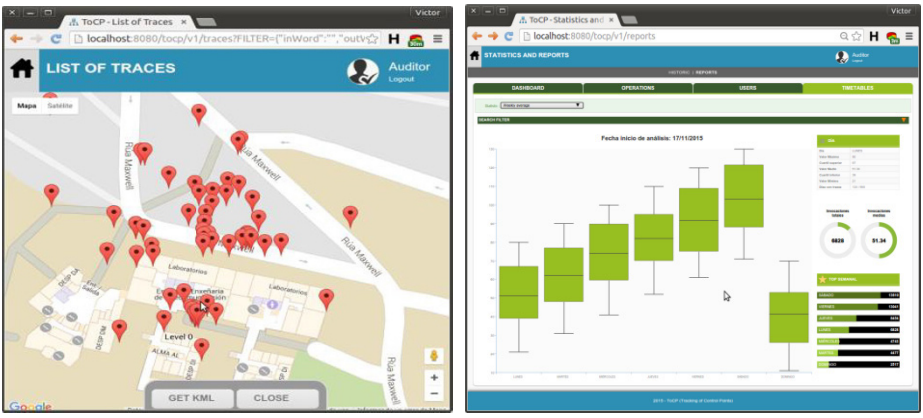

Fig. 5. Screenshots of the Web client for: a) trace location on a map; b) graph for the average generation of traces per week.

described and tested as a use case in the context of PN mixtures. Nevertheless, the selected scenario and the advantages of the platform identified can be easily applied to any other health care environment.

The system allows a simple and quick evaluation and analysis of trace generated during its application. This allows users to reduce their efforts in both, the implementation of quality policies, and the execution of actions in the event of a health risks.

The proposed platform is based on control systems widely tested and broadly adopted in the community. The CPs application allows to minimize deviations in the standard processes. Additionally, the use of regular mobile devices guarantees the availability and familiarity of use for human users on client agents. This way, and using the proposed scheme, the recovery services for dynamic interaction can be achieved in a straightforward manner taking into account each user at each moment and context in which he/she is located.

In addition to this, the system also provides a flexible mean to access relevant information according to the specific needs of each user. This feature may strengthen the knowledge of professionals involved. At the same time, it offers patients and their relatives support to get information about their background and situation.

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