CLINICAL PROCESS MANAGEMENT IN THE FUTURE - STANDARD OPERATION PROCEDURES ON MOBILE DEVICES

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Abstract

Clinical Pathways (CPs) and Standard Operation Procedures (SOP) have evolved as important tools in the fields of clinical process management and quality management documentation. However, building CPs & SOPs is a very time-consuming and costly task, where different stakeholders such as physicians, nurses and management employees have to be involved. In the current situation, update needs usually lead to an inconsistent documentation. In this paper we present a modeling tool for mobile devices, which allows a comprehensive and simple design and update of clinical process models. It facilitates the work on process diagrams of the SOPs and CPs without any in-depth knowledge about CASE-Tools. Thus, the creation and update of clinical processes like SOPs and CPs is no longer a task, which can be conduced solely by consultants. The integration of process modeling on mobile devices enables a flexible and accessible solution for clinical process management.

Keywords

Clinical Processes, Clinical Pathways, Standard Operation Procedures, Conceptual Modeling

Background

Clinical Pathways (CPs) and Standard Operation Procedures (SOP) have evolved as important tools of clinical process management and quality management documentation [1], [2]. CPs are built individually by hospitals with the main focus on process efficiency and are driven by cost savings [3]. Beside the global view of treatment process, single steps of CPs can be described in detail by SOPs. They describe repeatedly performed operational procedures an organization has to abide by. Building CPs & SOPs is a very time-consuming and costly task, where different stakeholders such as physicians, nurses and management employees have to be involved [4]. Thus it is usually a collaborative activity conducted in expert boards. In the current situation, update needs usually lead to an inconsistent documentation. Additionally, the process models can hardly be accessed due to the mostly paper-based storage (e.g. within quality management manuals). This paper therefore contributes by presenting a modeling tool for mobile devices, which allows a comprehensive and simple design and update of clinical process models, providing an instrument for ad-hoc clinical process within workshops.

Status-Quo & Prior Research

Up to now, process modeling in the health care sector is widely performed by physicians themselves or supported by quality manager. Usually, they are triggered by the need for certification, or by strategic decisions of the clinical management. Currently, there are two main routes of using modeling tools. Firstly, utilities from the area of standard office applications such as MS Power Point or MS Visio are used for creating process diagrams. Secondly, products of consulting firms are used with their specific modeling language [5]. In both cases, the model usage is very paper-driven (printed quality management manuals) while process models are shared in portable document format through the intranet. The creation of process models is a time consuming process, where different stakeholders iteratively elaborate the common processes. This also comprises that the results of process workshops are currently stored in prose or drawn graphics first and transformed into a model afterwards. Mobile device tools for building process models are very uncommon. As a proof we analyzed the current situation regarding available modeling tools in the Apple app store. This analysis revealed three main types of tools. Firstly, “drawing tools” like *Instaviz* provide a set of different node types without a

semantic definition. Secondly, there are tools that implement one specific general-purpose language, such as BPMN (*Process Note, ProcessCraft*), flowchart (*Process Modeller*) or UML class diagram *(Astah* UML pad*). The third group consists of tools that support a range of different modeling languages (*Cubetto*). However, the analysis also reveals that in the field of modeling clinical process there are no tools available on the market that provide specific modeling languages for the medical domain. Domain Specific Modeling Languages (DSML) contain domain-specific language concepts within their abstract concept definition (abstract syntax) as well their graphical notation (concrete syntax) [6], [7]. By providing a modeling language, which is derived on the basis of the typical domain concepts, a DSML fosters a comprehensible model usage in terms of creation, understanding and maintenance.

Objectives

We aim to build an easy accessible and intuitional tool, which allows the comprehensive and simple design and maintenance of clinical process models. It should be possible to work on the process diagrams of the SOPs and CPs without any expertise in CASE-Tools (Computer Aided Software Engineering). Otherwise, there should be the possibility of a wide utilization and application in different scenarios like quality management, education and verification. The implemented modeling language should be slight understandable for domain experts by using a common language set and domain-specific language concepts. The application should implement a gesture control concept to ensure an intuitive modeling process.

With the implementation of a specific modeling tool called Cubetto Medical[1], the result of our research is an IT artifact. Therefore, we use a Design Science Research approach, which systematically guides the creation of IT artifacts. The phases of a usual design science process are the definition of the design objectives, its operationalization by requirements, the evaluation of the current state of research and common practice as well as the creation, evaluation and dissemination of an IT artifact [8].

Conceptual Considerations

The result of our preliminary conceptual considerations consists of a set of requirements that provide the foundation for design and implementation of our artifact. These requirements were derived from the basic goal and its gradual decomposition.

[1] http://cubetto.semture.de

General Aspects

A first non-functional requirement is the need for a comfortable user handling mostly equivalent to the usual handling of the basis system. An intuitive handling decreases entry thresholds as it increases the user acceptance. This effect is additionally supported, if users can focus on the actual medical content of their SOP model rather than dealing with layouting shapes and handling complex and multiple diagrams. This is gaining additional relevance against the background of collective SOP-development during meetings or patient-individual procedure discussions in a medical board. The limited screen size of mobile devices on the one hand and high demands of user-optimized modeling lead to the requirements of an automated layouting, an adequate navigation through complex models as well as assistance for creating graphical connections between model shapes.

In terms of quality management aspects, all developed SOPs within an organization should be retained in a central repository providing a knowledge base. This can be used solely as information provider offering graphical SOP representations (e. g. images or PDFs) to support their reuse, but also for continuous SOP improvement offering standardized, machine-readable formats of the model data (e. g. XML). It is therefore essential to provide functionality for model data exchange between different mobile devices as well a centralized cloud-like SOP repository.

To attain a wide user spectrum and prospectively engage international collaboration in SOP development, the tool should be multilingual, meaning the user interface, as well as the actual modeling content.

Domain Specific Aspects

Considering an SOP modeling tool from the content point of view, it should particularly provide a process modeling language that is terminologically aligned to the medical domain. This means providing a set of adequate modeling concepts on the one hand, but also providing graphical representations, that correspond to the concepts they represent and therefore originate from the medical domain on the other hand. The use of intuitionally medic-interpretable icons will further facilitate the modeling process and foster the clarity of complex SOP models. Such graphic items should be based on usual medical types of activities (e.g. therapeutic, diagnostic), documents (e. g. lab result, anamnesis questionnaire) and organizational units (e.g. surgeon, anesthetist, nurse) that are explicitly integrated in the structural modeling language definition (meta-model).

Another crucial structural facet of the modeling language is the handling of the level of evidence of a modeled recommendation. The development of CPs and hereafter SOPs is strongly influenced by evidence-

based knowledge of clinical practice guidelines (CPG). In terms of traceability and continuous improvement the origin of the modeled knowledge within an SOP should be indicated. This means at least the possibility of annotating the class of evidence of a recommendation given by a specific model element. The actual linkage of the CPG document and navigation into the relevant paragraph, where a specific part of the SOP originates would top this off.

Results & Demonstration

Results

In order to realize the requirement set, we decide to use a platform, which allows specifying a DSML by configuring a basis system. We decide to use the platform of Cubetto Mobile, which is a native implementation for iOS- and Android-devices, which can be complemented with additional language set. Therefore, a meta-model including the modeling concepts, their relations and icons has to be specified. The benefit using this basis is distinguished by the following bullets:

- **Native implementation**, which means that the typical user interface of the basis system is implemented. The look and feel is identical to the entire system, making the tool slightly accessible and applicable.
- In order to enhance the modeling process and to optimize the use of the limited screen size, an **auto layout mechanism** is implemented.
- The platform provides an **open XML interchange format** for models, which allows a flexible exchange of the models between different users, and different platforms. Thus, the process model can be recorded during a process workshop using the mobile application and can be refined afterwards using **Cubetto Medical[2] on a Mac OS workstation**.
- Cubetto Mobile supports **numerous of export formats**, structured formats like XML as well as binary formats like PDF or JPEG.
- Implementing **Cloud Services** like *iCloud* or *Dropbox* facilitates the collaboration within a project group.

Beside these general functionalities of the basis

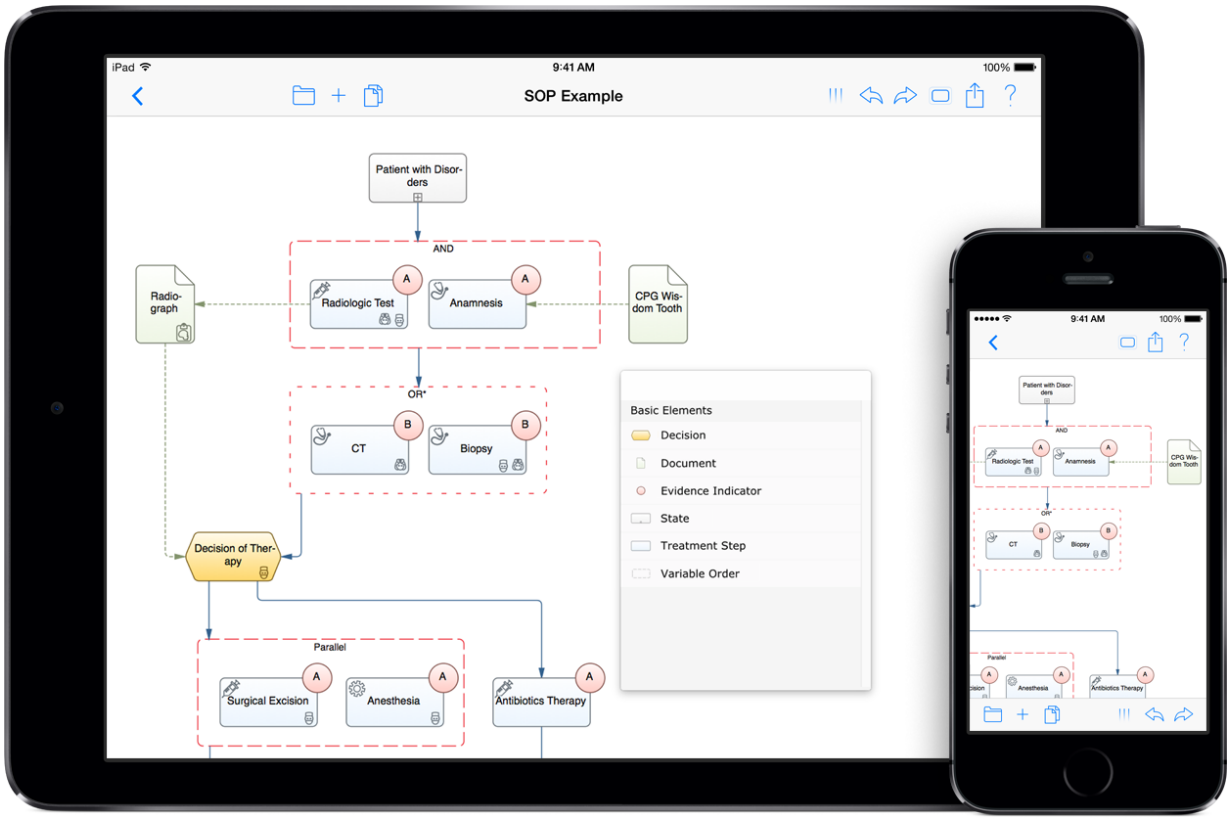

Fig. 1: Screenshot of Cubetto Medical on iPad and iPhone with the basic modeling elements of an SOP model.

[2] http://cubetto.semture.de

system, the modeling language itself should be perfectly aligned to the clinical domain. Thus, we adopted the DSML of Burwitz et al. (2013) [9], who analyzed the state of the art in the field of modeling clinical processes and extended the typical flowchart language with additional concepts and predefined concept types. We also attempt to achieve a layout of the process model similar to the process documentation in quality management manuals. Thus, we added a box at the footer, containing the SOP's meta-information of the model such as author, date of creation, state and version.

Demonstration

To illustrate the utilization of Cubetto Medical, we applied the app in the scenario of wisdom tooth treatment (fig. 1). Algorithms of clinical practice guidelines are used as primary source for this modeling task. At the beginning, a state is modeled including criteria for inclusion and exclusion. These criteria describe the patient types being relevant for the defined process. The + at the bottom indicates the existence of several criteria, while the state can be expanded for a detailed visualization. The treatment starts with the actions of anamnesis and radiographic test. Since the order of these steps is not explicitly determined, while both steps are obligatory, we can use an AND-region as their container. The radiograph created is necessary for the later decision of therapy, which is expressed by the information flow. Computer tomography and biopsy are additional but optional explorations expressed by an OR*-region. All these actions are of diagnostic type, which is illustrated by the corresponding icon. Since the dentist decides for a surgical excision, this action has to be supported concurrently by an anesthesia and is therefore modeled using a parallel region. Evidence indicators are attached to each action, decision and information object, expressing the evidence level [10]. For example, the radiographic test and the anamnesis are highly approved by the current medical science, which is why we used the A-level classification.

Conclusion

The presented paper addresses the lack of modeling instruments on mobile devices that allow a flexible model creation and maintenance of process descriptions in the clinical domain. Therefore, we present the implementation *Cubetto Medical* as mobile modeling tool, that fits for the clinical context [9]. The tool combines the flexibility of mobile applications one the one hand and the strength of a professional modeling tool on the other hand by providing an export mechanism for XML-based model exchange.

In summary, the creation and maintenance of clinical processes like SOPs and CPs is no longer a task, which can be conducted only by consultants. The integration of process modeling on mobile devices enables a flexible and accessible solution for clinical process management.

Additional Information

http://cubetto.semture.de

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