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Abstract

Clinical practice guidelines are knowledge uptake instrument that support decision making by the physicians. They are often implemented as computer-interpreted guidelines that are embedded in a hospital information system. We argue that computer-interpreted guidelines should be considered as regular information system, thus their development should follow all the steps of system analysis and design, starting with exploration and definition of user requirements. In this paper we propose the ActCPG conceptual framework to establish basic user requirements for implementing computer-interpreted guidelines. This framework relies on the Activity Theory to structure and decompose information coming from a clinical practice guideline and associated narrative so UML use cases can be developed. We illustrate operation of the ActCPG framework with an example of a practice guideline for a management of clinically obese children enrolled in some obesity program.

Keywords: Clinical Practice Guidelines, Computer-Interpreted Guideline, Activity Theory, ActAD, User Requirements.

1   Introduction

It is widely acknowledged that evidence based patient management has a positive impact on a patient's outcomes and improves the quality of care (McCabe et al., 2009). One of the most common methods for implementing evidence-based practice are clinical practice guidelines (CPGs) (Rosenfeld and Shiffman, 2009). A CPG is a disease-specific description of patient management process created on the basis of experts' consensus and medical evidence extracted from document repositories (Hayward et al., 1995). It reflects best practices in collecting patient data, drawing conclusions from this data with regards to possible diagnoses and prescribing the most effective therapeutic plan. CPGs in textual narrative form are used for developing Computer-Interpreted Guidelines (CIGs) that become an active support medium for guiding physicians throughout the patient management process. According to such an interpretation, the CIG plays the role of an Information System (IS) that guides and supports a disease-specific process, and therefore CIG should be regarded as a regular IS.

There is a significant body of literature concerning the positive impact of CIGs on patient outcomes (Goud et al., 2010). Several formal frameworks and tools were developed in order to facilitate the creation of CIGs. For example, a collaborative project involving biomedical informatics groups from Harvard, Columbia, and Stanford universities produced the Guide Line Interchange Format (GLIF) that can serve as a common representation format for CIGs (Peleg et al., 2002, Boxwala et al., 2004). One of the major contributions of GLIF is transforming a textual CPG into a flowchart and establishing the specifications for this process (Boxwala et al., 2004). There are many other formal representations of the CIGs (see Peleg et al. (2003) for a review), however, there are no uniformly adopted standards of these representations (Mulyar et al., 2007). This lack of standardization is discussed in Latoszek-Berendsen et al. (2010).

Regardless of the framework used, developing a CIG should be similar to developing any information system (IS). Learning about user requirements is a first and essential part of effective IS design – a step of particular importance when developing healthcare IS (Rozenblum et al., 2011). This implies that a definition of user requirements needs to constitute the first step in CIG design. Considering that a CPG presented in a narrative format is a blueprint for CIG, it is plausible to assume that user requirements should be derived from this blueprint. The objective of this research is to create a conceptual framework to formalize extraction of user requirements from a CPG and configuring them into a structured format that can be used for developing a CIG. Because we rely on concepts from the Activity Theory when developing the proposed framework we call this framework the ActCPG.

The paper is organized as follows: the next section describes the research design, including an overview of activity theory and its use in IS research. The ActCPG framework is also introduced and explained in this section. Section 3 illustrates how the ActCPG framework can be used to extract and structure user preferences using an example CPG for the management of clinically obese children. The paper concludes with a discussion of the implications of this research.

2   Research Design

The purpose of the proposed methodological framework is to complement, not substitute existing methods of transforming a CPG into a CIG by helping to get better understanding of the information requirements of the CIG users (physicians, nurses, allied health professionals). We claim that analysis of these requirements through the lenses of the Activity Theory (AT) and Activity Analyses and Development (ActAD) framework will help with development of the specifications for the CIG.

In the next subsections we describe the essence of the AT, its use in the IS research, adaptation of the ActAD framework for the analysis of CPGs, and finally how we derived at the ActCPG conceptual framework.

2.1 Activity Theory overview

Activity is an integral component of any CPG. Example activities include collecting patient data through physical examination and through a variety of tests, and reasoning on the basis of this data in order to derive at differential diagnoses and associated therapeutic plans. In that sense, an activity can be viewed as an object-directed process motivated to transform an object (i.e. a patient with some health condition) into an output (i.e. healthy patient). Purposeful transformation of an object is essential for an activity to exist. AT can be understood as a methodology that facilitates understanding of an activity, its change over time, and its interaction with other activities. The AT originated from the German philosophy of Kant and Hegel that was further interpreted by the Soviet psychologists Vygotsky, Leontjev and Luria (Leontjev, 1978, Vygotsky, 1978). Much of the recent AT research has come from Engeström. According to Engeström (1987), a subject (obesity team: physician, nurse, etc) understood as an social actor performing the activity, exists within a community, which shares the same object. The community has a set of different rules for the subject to follow. Rules cover both explicit and implicit norms and conventions, and social relations within a community. Division of labour refers to the explicit and implicit organization of the community. Essentially AT is a multi-activity paradigm that considers interactions between activities (Engeström, 1999). Individual activities are often modelled graphically as illustrated on Figure 1.
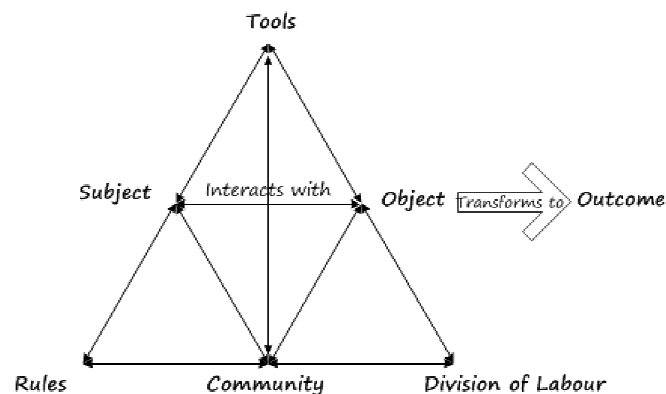

Figure 1. Activity theory

While an "activity" is the basic unit of analysis, AT encompasses participating social actors, the technological and non-technological tools they employ, the rules and norms of the social or socio-technical context, and the roles and responsibilities of participating actors. Usually the AT components and mediators are interpreted through the lenses of such questions as: *who* (subject) interacts with *what* (object) and *why* (motivation that leads to an outcome); *by what means* the subject interacts with the object (tools); *who else* is involved in this interaction (community); *how* the subject interacts with the object and community (rules); and *who does what* in this activity (division of labour/roles – vertical and horizontal). A graphical representation in the form of a "triangle" encapsulates relationships and dependencies among mediators (represented as the vertices).

Vygotsky (1978), Leontjev (1978), and later Engestrom (1999) stressed that activity should be considered as being social/collective. The collective activity is driven by the motivation. The distinction between individual goal-oriented action and collective/team object oriented and motive-driven activity has critical importance in the AT research (Engeström, 1999b). A collective activity is oriented to the modification of the object, which is seen as raw material that should be processed to the final product, outcome of the activity. This transformation is driven by shared motive that represents a common ideology of the collective members. However, to accomplish the collective activity, object transformation should be decomposed into specific goals that might be achieved by individual actions. The individual goal-driven actions consist of automatic operations, which are driven by conditions. Hierarchical nature of activity corresponds to the ability of a number of operations to make up one

action and several actions to make up one activity. However, the different set of actions can make up the same activity as well as an action can be involved in different activities.

2.2   AT in IS research

AT has been applied in IS research for the last two decades. First, Kuutti (1991) proposed to consider an IS as an "activity system". This sparked an interest in using AT as a potential methodological framework in different fields of IS research, including Computer-Supported Cooperative Work (CSCW), Human-Computer Interaction (HCI), Health Informatics, Computer System Design, Information Science (Kuutti, 1996, Martins and Daltrini, 1999b, Martins and Daltrini, 1999a, Daisy, 2001, Mwanza, 2001, Guy, 2004, Korpela et al., 2004, Toivanen et al., 2004, Bardram and Doryab, 2011).

However, despite initial high expectations associated with use of the AT in IS research (Kuutti, 1996), the theory has not been widely accepted. One of the main reasons was a difficulty in direct application of the AT in the analysis of an IS. This issue triggered research in developing AT-based methods that could be applied in a more direct manner. Quek and Shah (2004) reviewed five AT-based methods for IS research: ActAD method (Korpela et al., 2002, Korpela et al., 2004, Mursu et al., 2006), the Activity Checklist (Kaptelinin et al., 1999), the AODM method (Mwanza, 2001, Mwanza, 2002), the Jonassen & Rohrer-Murphy framework (Jonassen and Rohrer-Murphy, 1999), and the Martins & Daltrini framework (Martins and Daltrini, 1999a, Martins and Daltrini, 1999b). Although there are no well-defined AT-based methods for the user requirements elicitation, ActAD and the Martins & Daltrini framework allow revealing functional and non-functional requirements that make them suitable for the analysis of user requirements. Martins and Daltrini (1999a) proposed a framework for requirements elicitation using the following three stages: identification of activities, identification of activities' elements, and activity decomposition.

The ActAD method has its origin in Engeström (1987) research. However it expands it by incorporating collective activity and individual actions intertwined in the same model. Korpela et al. (2004) proposed to use ActAD as an exploratory requirements analysis method composed of the following three stages:
1. Exploration of the activity in the network of inter/intra-organizational activities. This step includes gathering, structuring, and describing the information needs. The results of the first step are presented in the form of the ActAD diagram.
2. Transformation of an object into outcome in terms of actions and actors. The diagrams combining elements of ActAD diagram together with elements of UML activity and case diagrams are used for this purpose. The IS architecture and the first draft of the software architecture are defined in this stage.
3. Adoption of software requirements specifications identified in the pervious stage for software engineers. UML component, activity, and case (including scenarios) diagrams are developed.

This framework has never been completely implemented and Korpela et al. (2004) argued that derivation of the UML diagrams from the ActAD diagrams needed to be better specified.

2.3   The ActCPG conceptual framework

Our research does not aim to develop the formalized AT-based method since as Fitzgerald (1996) stated, such method should be presented as "a recommended series of steps and procedures to be followed in the course of developing an IS". Instead we propose to adopt the existing methods (AT, ActAD, and Martins & Daltrini framework) into a unified and cohesive ActCPG framework geared towards the elicitation of user requirements from CPGs as a first step in developing the CIGs. The ActCPG conceptual framework, while introducing some structure to the analysis of the CPGs, still requires specification in terms of the precise checklist for extraction of all required actions to be considered in the formalized AT-based method as per Fitzgerald's recommendation.

We assume that the ActCPG framework is applied to a CPG that is presented in some structured format (i.e. a flowchart or activity graph) accompanied by a narrative explaining individual steps, logical sequence of these steps, and their clinical meaning. It is specially useful when care is delivered by a multidisciplinary healthcare team, with each team member having specific and well-defined role in a care process. Clearly, not all the CPGs can be presented in such a way, especially if they involve complex actions that need to be described as lower level sub-guidelines. Thus, a key purpose of the ActCPG framework is to identify all actions that are relevant for a given activity and associate these actions with the team members who play role of the subjects according to the AT nomenclature, objects (patient, data repository, etc), means and community (other team members) can be identified and present it in a structured manner. This provides enough specifications to determine inputs and outputs that are necessary to execute a CIG so it meets generally understood users' requirements. Based on earlier research (e.g., Jonassen and Rohrer-Murphy, 1999, Martins and Daltrini, 1999a, Korpela et al., 2002, Korpela et al., 2004) and using supporting methodologies for user requirements elicitation (e.g., Maguire and Bevan, 2002) we are proposing the ActCPG conceptual framework composed of the following six stages:

1. *Activity discovering*. The semi-structured CPG together with the narrative is used to define the work activity. Considering that all information for the user requirements' elicitation is by definition embedded in the CPG and narrative, traditional methods for obtaining user requirements such as interviews are not necessary.
2. *Activity structuring and describing.* The identified work activity is structured according to the ActAD method including defining the related activities. If activity structure is not fully endorsed by the end-user, Activity Discovering stage needs to be revisited.
3. *Activity decomposing.* This stage is concerned with better understanding how transformation produces an outcome. All actions and decisions together with the information captured in the ActAD diagrams are considered as candidates for the UML case diagram. This stage terminates with a set of the action diagram
4. *User requirements identification*. User needs are identified from the action diagrams and UML case diagrams developed in the Activity Decomposing stage. All actions being subject of the use cases should be explained in the narrative form in order to identify user needs and common patterns.
5. *User requirements evaluation.* At this stage a variety of user requirements presentation methods can be implemented. This is also when rapid prototyping can be considered for the first time in developing the CIG. This is an important stage and depending on its outcome, a repetition of User Requirements Identification stage might be required.
6. *User requirements specification.* At this stage depending on the CIG scope, user and/or organizational requirements should be enunciated and documented. This document should include task/function mapping, requirements categorization, prioritization, and criteria settings.

3   Proof of concept

We illustrate the use of the ActCPG conceptual framework for the identification of user requirements for developing a CIG for managing clinically obese children. In light of space limitations we decided to focus on the first three stages of the ActCPG framework, as these stages are key for the success of the entire user requirements elicitation process.

Activity discovering. Clinically obese children are those who are considered to have a Body Mass Index and waist circumference measure that puts them in top 5th percentile for their age group and gender. Such children are referred to the obesity clinic where a range of treatments (from pharmacological, through psychological, to life style changes) are evaluated and prescribed. Depending on the obesity program in place, these children are offered to participate in an intensive therapy or to follow less rigorous regimen. We have obtained the CPG for management of clinically obese children that is in place at the Children's Hospital of Eastern Ontario (CHEO) in Ottawa, Canada. The CPG contains narrative describing patient evaluation, therapy, and education. With the

help of collaborating physicians we have structured the action parts of the CPG and represented them as a flowchart shown in

Figure 2. The flowchart allowed us to better understand the work activity "obesity management" and how it is composed of the individual actions.
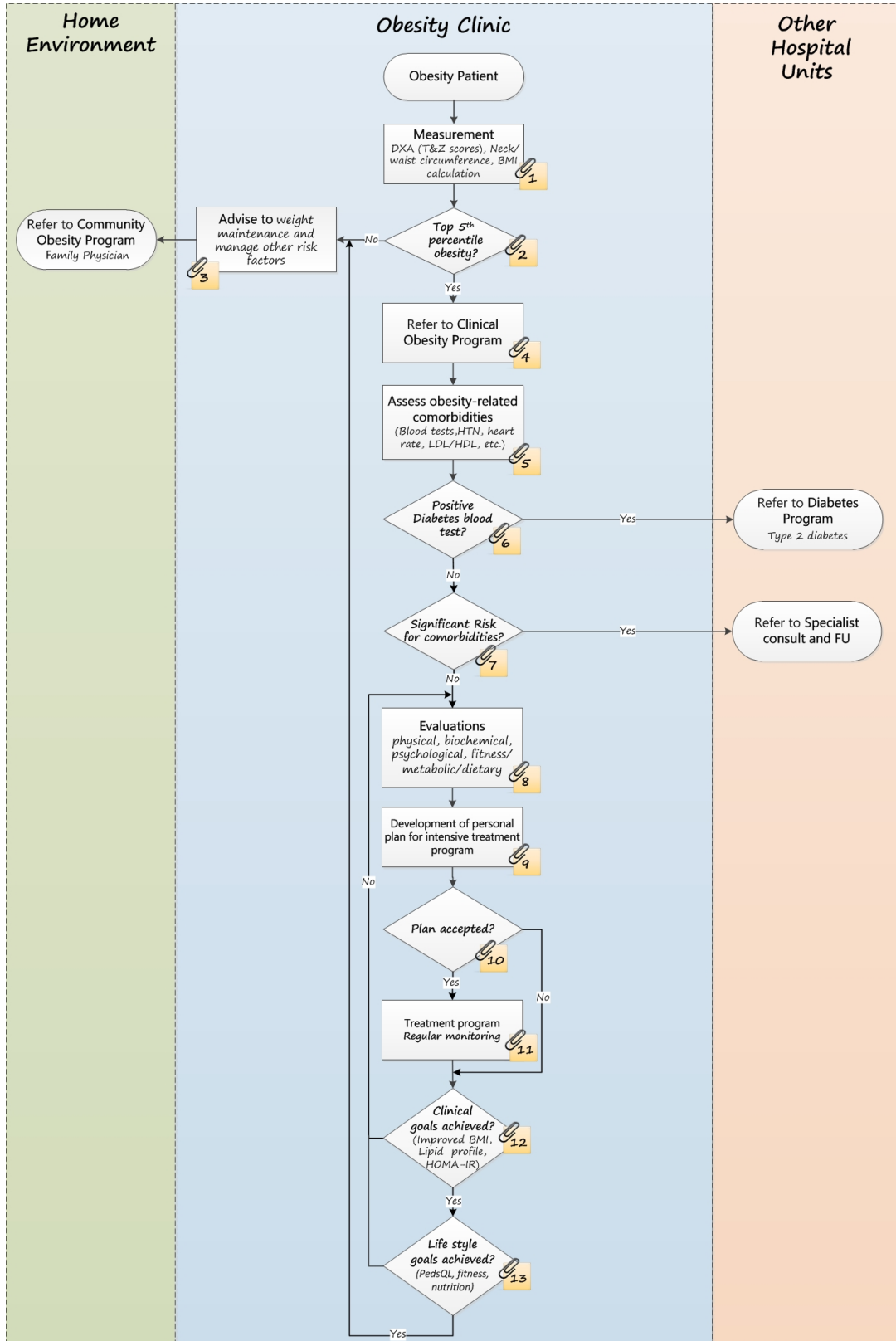
Figure 2. Flowchart representing actions for clinical obesity management

According to this flowchart an obese child is first evaluated for a clinical obesity using set of standard measurements. Assuming that inclusion criterion is met, a second set of the assessments involves evaluation for serious comorbid condition and type 2 Diabetes. Children diagnosed with any of these conditions do not follow the obesity program and are referred to appropriate specialist consult. Once in the obesity program, a child undergoes a variety of assessments including physical, psychological, and life style. After these assessments a customized obesity management program is designed and a child either follows this program in an intense manner with support, or unsupported. At some point (usually after 6 months) progress of the treatment is assessed and next steps are identified.

All these steps are recorded in detail in the on Figure 2. In this rectangles indicate action items while diamonds indicate decision steps. Actions that are external to the program are indicated with the ovals.

Activity structuring and describing. Further analysis of the processes described on Figures 1 and 2 and accompanying narrative allowed us to establish a set of related activities including management of diabetes, management of comorbidities, and management of obesity in home environment. In the AT terms, the object of the work activity is an obese child and a desired outcome is to decrease the obesity level so a child is no longer considered to be clinically obese. The collective subject of the work activity is the multidisciplinary healthcare team that includes: physician (MD), Registered Nurse (RN), Psychologist (Psych), Councillor (Counc), Physiotherapist (Physio), and Dietician (Diet). Using the ActAD method we identified such means as patient record (PR), measurement tools (e.g., tape, scale, medical knowledge), means of coordination and communication (e.g. face to face, telephone, charting), and means of networking between the activities (such as PR).

Activity decomposing. *Decomposing the work activity was conducted by means of analysing actions and decisions identified in the patient management (*

Figure 2). Some of the actions were combined due to the same functionality producing 10 use-cases. The narrative was consulted to define who specific actors are among multidisciplinary obesity management team members. The UML diagram was composed with the following use-cases: obesity stage assessment, patient education and discharge, patient enrolment in obesity program, diabetes assessment, comorbidities assessment, evaluation, treatment plan, treatment, clinic health status assessment, and life style assessment. These are presented on Figure 3 as the UML case diagram.

From the obtained information and the constructed diagrams we were able to identify a set of 19 actions where each actions was represented as the AT action triangle. Some of the actions (e.g. treatment) were presented as one action for the sake of simplicity.

Using information coming from the UML case diagram it is possible to focus on individual actions in a greater detail. Here, we illustrate ActCPG framework using two actions: measurement patient and updating PR. We selected describe these two actions related to the one first function in UML case diagram because of the page limitations. The AT triangles for the measurement action for obesity stage assessment, and updating PR action are presented in Figures 4 and 5 (derived from the original AT representation illustrated in Figure 1).
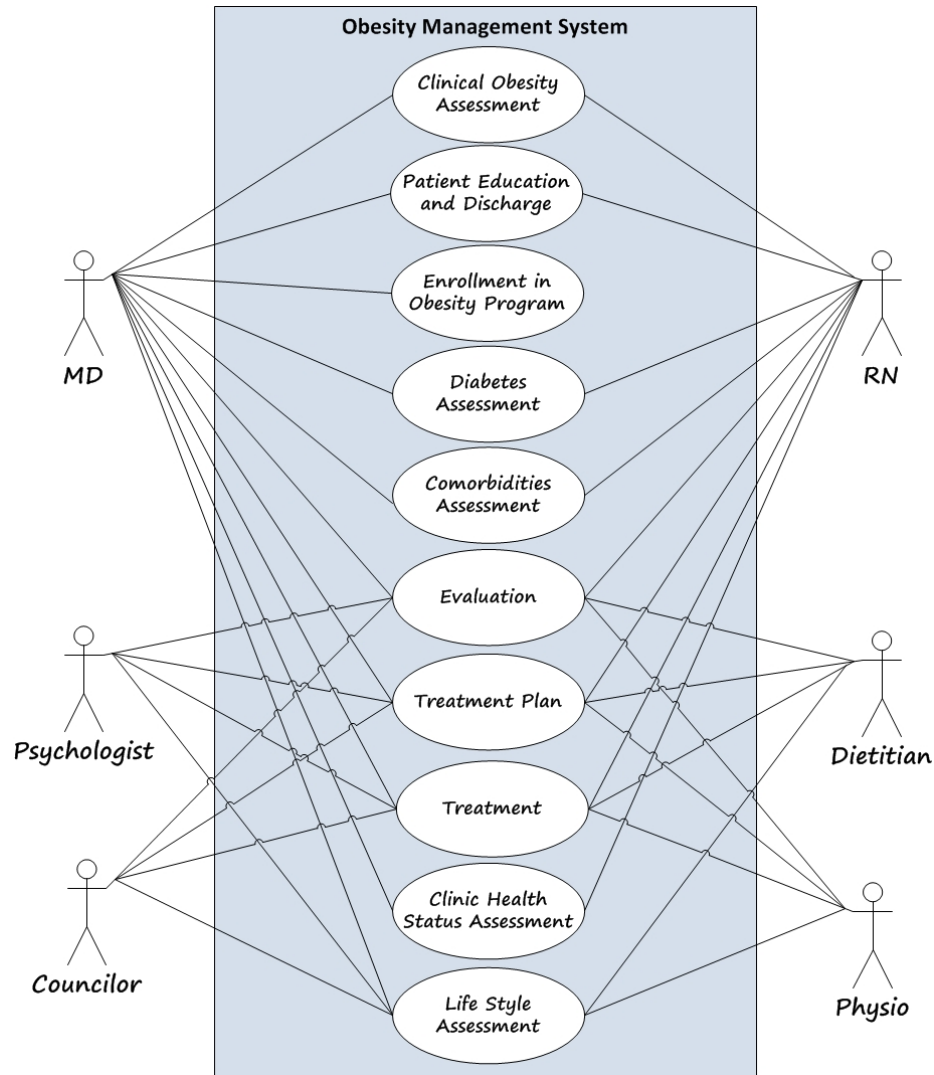
Figure 3. UML Case diagram for clinical management of children obesity

In Figure 4, the MD (subject) executes the measurement action on the patient (object). The goal of this action is to update the PR with the result of the measurement. To complete this action the MD employs a variety of measurement tools (such as measurement tape, scale, patient history, etc). For the measurement action the specific facility is required making this action a location-dependant. Although the subject of the action is the MD, the RN is also involved as part of the community for a measurement action. S/he assists the MD with the measurement and updates the PR. The measurement action can be further decomposed into the series of operations like taking a tape, measuring circumference, input the data, etc. but such decomposition is beyond scope of the paper.
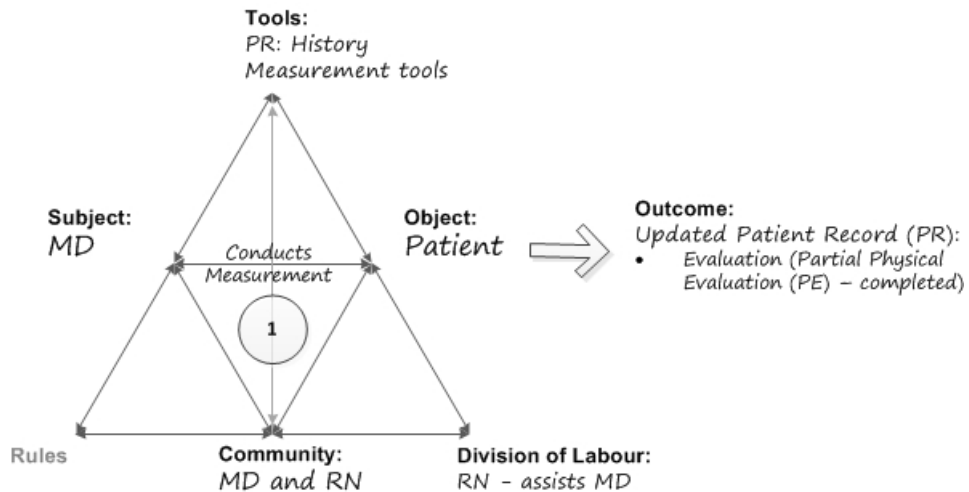
Figure 4. Measurement action of obesity stage assessment

The clinical obesity assessment (Figure 5) involves a decision-making process based on the measurement from the previous action. While MD is still a subject of this action, the PR is an object (because this action directly transforms PR by updating information that is recorded). This is a solitary action with no community and with no dependence of a location. MD uses a set of the tools to execute the action and as a result the PR is updated with patient's obesity assessment.
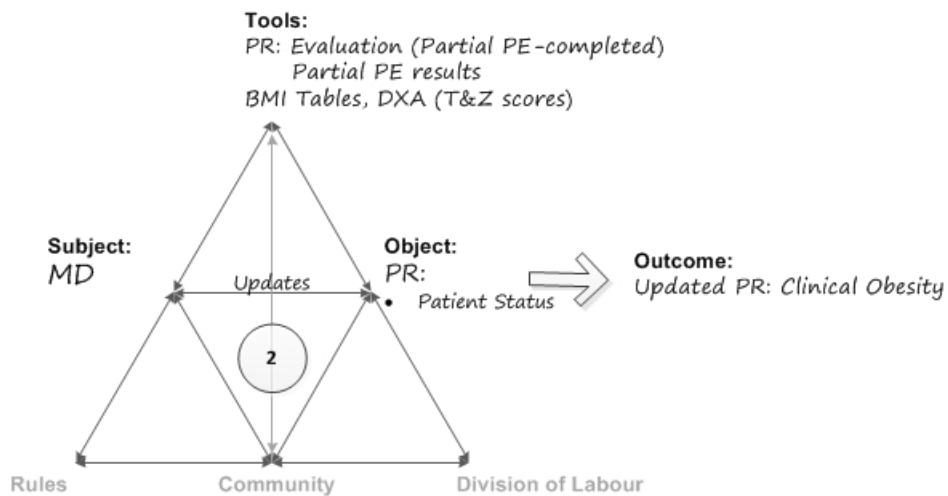

Figure 5. PR update action of clinical obesity assessment

At the end of this stage of the ActCPG conceptual framework, we have information on the functional requirements for the computerization of the CPG. Every UML use case (Figure 3) represents a functional requirement of the system, identification of which is an essential stage in defining user requirements since it clarifies all functions that a CIG system should accomplish. The analysis of all actions in AT triangle form (e.g Figure 4 and Figure 5) enables us to reveal all non-functional requirements of system. Clarification of both functional requirements (e.g. obesity stage assessment) and non-functional requirements (e.g. PR must available, the outcome of one action is the a tool of the following action) are necessary for identification, evaluation, and specification of user requirements in the next stages of the ActCPG conceptual framework.

4   Discussion and Conclusions

Evidence-based medicine aims at providing the best possible care to patients using diagnostic and therapeutic knowledge that is supported by scientific evidence obtained from a series of randomized clinical trials. To improve knowledge uptake by the physicians it is often represented in a semi-structured format as a disease-specific CPG. As stated earlier in the paper, presentation of evidence to physicians at point of care may impact how it is used and applied in clinical practice. In order to facilitate uptake of CPGs, there is a significant effort to provide physicians with CPG encoded as a CIG. These CIGs are developed from structured representations and upon development are encoded as components of larger healthcare IS such as, for example a Computerized Physician Order Entry System (CPOE). Development of the CIG usually follows a format of rapid prototyping where user requirements are identified in an ad hoc manner depending on the habits and practices of the systems' analyst. In this paper we put forward an argument that the development of a CIG should follow all the steps of system development life cycle because CIG need to be considered as another – albeit integrated – hospital IS. In that context proper development of a CIG calls for a rigorous user requirements' elicitation stage.

A typical CPG constitutes an activity-based guide that supports a physician (and other team members in a situation when it is used by the multidisciplinary healthcare team) through a series of steps, each of them with a purpose of acquiring information about a patient's state or making diagnostic and/or therapeutic decisions. To this end, AT is considered to be a useful framework for decomposing and analysing activities, actions that form them, and the relationships among them. Building on AT research and its translation into AT-based methods, we proposed the ActCPG conceptual framework for identification and structuring of user requirements encapsulated in the CPG document and associated narratives. The ActCPG framework is composed of six stages that include activity discovery, structuring, and decomposing together with user requirements' identification, evaluation, and specification. At the core of the ActCPG is use of the ActAD method to structure the activities for development of the UML case diagram. The actions identified in this diagram are subsequently represented as the AT triangles for better definition of the inputs and outputs and relationships among them that define user requirements. We consider the ActCPG framework to be our main contribution to a body of health IS research.

We have illustrated the implementation of ActCPG framework using a CPG for management of clinically obese children by a multidisciplinary healthcare team. Using structured representation of the patient management process, we were able to associate each action with the appropriate team member, identify most relevant means necessary for conducting the action, and finally to identify how execution of each action impacts other team members and contributes to the overall patient management process. In other words, the ActCPG framework helped us to identify the most relevant process components that we used to define inputs and outputs that team members require from the CIG. Another contribution of our research is that much of the existing work on CIGs has focused on individual providers and actions. The ActCPG framework enables CIG design to support multidisciplinary healthcare team, which is becoming a more common approach for healthcare delivery.

The ActCPG framework has some limitations. Firstly, its application necessitates access to a document repository that supplements structured CPG with a narrative describing how CPG is utilized. Secondly, application of the AT-based tools such as the ActCPG framework is more an "art" than "science" and requires substantial experience, as discussed and demonstrated in multiple studies referenced in the paper. Third, more than one analyst should conduct activity structuring and describing. This way objective view of a problematic situation can be developed. Finally, the ActCPG framework relies on a mapping between the activity-based stages and user requirements. Currently this mapping is heavily influenced by the level of experience of an analyst that may have a detrimental effect on the granularity of discovered inputs and outputs. In order to address all these limitations, we

are currently working on formalizing the ActCPG framework in a form of a computer tool that guides the analyst through the six stages of user requirements' elicitation process.

Acknowledgements

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