Document-Driven Care Pathways Using HL7 CDA

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***Abstract*—We describe the use of HL7 CDA documents for representing and driving the execution of care pathways in the open source cityEHR health records system. The method is illustrated using example pathways for electronic pre-operative planning, at the University Hospital of North Norway, and for an osteoporosis treatment, at the Nottingham University Hospitals in the UK. Both have a requirement to involve patients in telehealth consultations prior to attendance at the hospital. Template HL7 CDA documents are created using simple tooling (spreadsheets) to model the care pathway. The template document is then instantiated with data from a specific patient encounter to start the pathway. As the pathway progresses, the document is updated to reflect the current status of tasks and actions; once the pathway is completed the CDA document is stored permanently in the patient record, as the history of the pathway and its execution.**

Keywords - HL7 CDA; care pathway; ontology; clinical document; pre-surgical planning.

I. Introduction

The cityEHR [1] is an open source health records system that uses ontology models to define the structure of the clinical record, following the high-level recommendations of the ISO 13606-1 [2] model and the HL7 Clinical Document Architecture (CDA) [3].

Clinical data are gathered through messaging from external systems, or entered by users as forms or letters. All data are stored as clinical documents in the Extensible Markup Language (XML) [4], using the HL7 CDA standard. This contrasts with EHR systems in which data are stored in a relational database; the rationale for storing as CDA documents is that health records are primarily records systems, incorporating longitudinal data sets and repeated observations of the same data on multiple occasions, rather than normalised data repositories.

Here we describe the modelling of care pathways as clinical documents using CDA, so that they are specified, processed and stored in the patient record in a similar manner to any other clinical document.

Integrated care pathways have been defined as "structured multidisciplinary care plans which detail essential steps in the care of patients with a specific clinical problem" [5]. This definition matches clinical practice, and is a useful basis for the implementation of executable pathways in electronic health records systems.

Closely related to integrated care pathways are clinical guidelines, which seek to recommend best practice in clinical care based on the current evidence, and clinical protocols. Clinical protocols are procedures that define how guidelines, and other best practice, should be implemented at a local level. Many approaches have been proposed and adopted for the representation of pathways, guidelines and protocols, but relatively few have been part of an operational health records system, as concluded in systematic reviews by Gooch & Roudsari [6] and by Loya et. al [18].

The study by Wakamiya and Yamauchi [7] identified seventeen standard features of electronic care pathways, and recommended three features to be considered as the most important: adaptable checklists, measuring variance (of the pathway as performed from the original library version), and recording statistics.

We set out the objectives for our approach to modelling care pathways in Section II and describe the representation of pathways in Section III, including references to the literature on alternative approaches. Section IV describes how a pathway, once expressed as a CDA document, can be progressed in an operational EHR system, from inception through to completion. We then present, in Section V, some examples of out approach for modelling pathways in the context of telehealth and draw our conclusions on the effectiveness of the approach in Section VI.

II. Objectives

Several key drivers led to the consideration of HL7 CDA as the format to represent care pathways. The cityEHR system uses an ontology-driven modelling approach [8] to create a data dictionary which includes data entries, elements (as per the ISO 13606-1 model), and a specification of how entries are combined into sections of compositions. Each composition corresponds to an HL7 CDA clinical document. For the purposes of the cityEHR, these documents can be

 ISBN: 978-1-61208-384-1

messages (from external systems), forms, or letters. In the future, they may also include orders and prescriptions.

Our research question was to determine the feasibility of using HL7 CDA to specify, execute and document integrated care pathways.

The objectives of our approach were therefore to:

- model care pathways as clinical documents;
- use the same HL7 CDA model as all other clinical documents in the system;
- design user interaction with the pathway that was integrated with other actions on clinical documents;
- store completed pathway documents in the record as a history of the actions completed;
- use that historic record to show the variance of any completed pathway from its original library version.

Implementation of the functionality to meet these objectives has been informed by previous studies, methodologies for representing pathways, and guidelines, most notably the Guideline Interchange Format (GLIF) [9], the guideline modelling language PROforma [10], and the ontology-based approach described by Daniyal et al. [11].

III. CARE PATHWAYS AS CLINICAL DOCUMENTS

A Clinical Documents in cityEHR

The cityEHR has a basic architecture for clinical data that includes components from the ISO 13606-1, and HL7 CDA standards. Using this architecture, an information model is created for each specific clinical application. This model defines a data dictionary of entries and elements, together with a specification of how those entries are grouped into sections and compositions. Hence, a form for entering clinical data is represented as a composition that consists of sections (with sub-sections nested to any level), entries within sections, and elements within entries.

The architecture, and the specific information models built from it, are represented as ontologies using the Web Ontology Language (OWL/XML) [12]. The information model is used to generate a runtime configuration for the system, including template CDA documents that are used for forms and letters created by user through a web-based interface. Once completed, the CDA documents are stored in an XML data store as a persistent record for each patient; while in progress, forms and letters can also be stored between user sessions so that they do not need to be completed in a single session, and can be worked on collaboratively by more than one user.

Extensions specific to cityEHR allow for conditional display of sections, entries or elements, calculated element values, default values, and constraints expressed using the standard XPath language [13]. XPath has various built-in functions, and can reference data in entry/element pairs in the historic record, or in the current clinical document.

B Care Pathways as HL7 CDA Clinical Documents

Care pathways, in cityEHR, are modelled as clinical documents, adopting the same approach taken for modelling forms or letters. A pathway is a CDA document, containing sections (nested to any level) and entries, as shown in Figure 1. Sections correspond to tasks in the pathway; entries correspond to individual actions. Hence, the pathway is represented as a hierarchical decomposition of tasks and sub-tasks, with actions forming the leaf nodes of the hierarchy.

The XML structure of a CDA document is ideal for representing the hierarchical decomposition of tasks in a pathway, and the processing of the pathway can take advantage of some general properties of XML as a hierarchy of document nodes, in which parent nodes have child nodes which are an ordered set of siblings.

We have used the term 'action' to denote the atomic unit of activity in the pathway, since this meaning is most widely adopted in the modelling of pathways, and guidelines (for example, in GLIF [9], and PROforma [10]). In more general representations of workflow processes, such as the Business Process Execution Language (BPEL) [14] and the Unified Modelling Language (UML) [15], the term 'activity' is used. In our CDA documents, an action is modelled as an entry which is an HL7 Act, so the terminology is quite consistent.

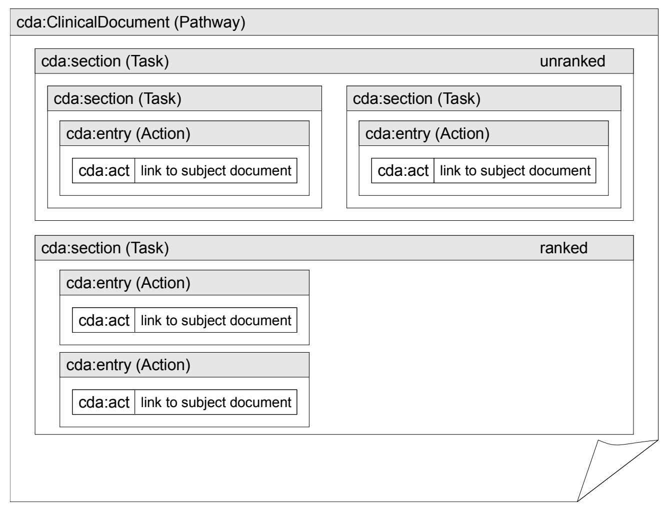

Figure 1. Care pathway as an HL7 CDA document.

Although the importance of hierarchical decomposition of processes is acknowledged in BPEL (as structured activities), and in GLIF, no distinct terminology is used for tasks that can be decomposed into a set of actions. In PROforma, an action is modelled as being a sub-type of task, rather than as having a containment relationship, hence our use of the term 'task' is not consistent with PROforma.

In cityEHR, a task is a section in the document that can contain any combination of sub-sections (tasks), or entries (actions). Sections can be designated as being 'ranked' or 'unranked' (cityEHR extensions to HL7 CDA), which for forms and letters define how the contents of the section should be laid out (vertically or horizontally), but for pathways also define the order in which tasks and actions should be performed (sequentially or concurrently).

An action is performed by a user outside the pathway by completing a form (for clinical data entry and/or review), writing a letter, or completing another pathway. Each of

 ISBN: 978-1-61208-384-1

these three types of actions has an associated clinical document (form, letter, or pathway) as its subject which is completed by one or more users, and then stored in the patient record; when the subject document is completed and stored, its associated action is completed in the pathway.

C Decisions and Looping

Decisions in the pathway (conditional progression of alternative branches) are modelled in cityEHR by attaching conditions to sections, and entries, in exactly the same way as other clinical documents. When used in forms, or letters, these conditions determine whether the section, or entry, is displayed to the user; for pathways they also determine whether the task or action is performed.

To model loops in the pathway (repeated branches of progression), the repeated branch is created as a separate sub-pathway which is performed as the subject of an action in the main pathway, and includes an action which performs the sub-pathway itself. The loop will continue until a condition on that action in the sub-pathway evaluates to 'false'.

IV. PROGRESSING THE CARE PATHWAY

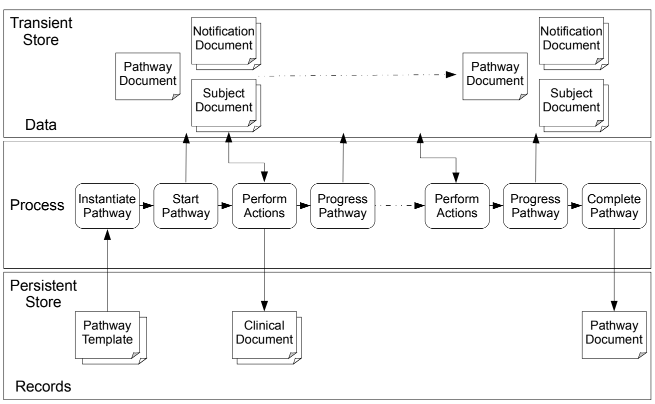

Figure 2. Automatic progression of the care pathway.

A Automatic Progression

Tasks and actions in the pathway have a status that can assume one of four values:

Charted;
Triggered;
In progress;
Completed.

All tasks and actions start in the 'charted' state (equivalent to the dormant state in PROforma) and progress through to the 'completed' state. A pathway is completed when all its top-level tasks are 'completed'; at this point every task, and action, in the pathway also has the status of 'completed'.

A task is 'in progress' when any of its contained tasks or actions are 'in progress', and is 'completed' when all its contained tasks and actions are 'completed'. Each action has an associated subject document, and is 'completed' once that document is completed and stored in the patient record.

The 'triggered' state extends the set of action states in PROforma, and is required because specific processing is needed to move the status of an action from 'triggered' to 'in progress'. The sequence in which tasks and actions are triggered is determined by the document order of the corresponding sections and entries in the pathway. A task or action can only be triggered when its parent task (i.e., the task that contains it) has progressed to 'in progress'.

For an 'unranked' task, all its immediate children in the document hierarchy are triggered as soon as the parent task is 'in progress'. For a 'ranked' task, each child is triggered when it has no preceding siblings (i.e., is the first child), or once its preceding siblings have all been completed.

The progression of the pathway begins when the user selects a new pathway from the templates available in the data dictionary. The template CDA document is loaded, and the CDA header is instantiated with the demographics data for that patient. The user interaction in cityEHR uses the XForms standard [16] which is a useful way to implement web-based forms. In XForms, there is a clear separation of concerns between the model in XML (the CDA document in this instance), the view in XHTML, and the user controls (e.g., controls for data entry, drop-down selection, etc.).

The recursive nature of the triggering of tasks/actions, and the completion of tasks, can be managed by binding of the status attribute on XML elements for cda:section and cda:act. Hence, triggering and completion 'bubble' through the document without the need for recursive function calls.

Once loaded, the user can review the pathway and adapt it to the current clinical context before starting it. On start, each of the triggered actions results in two documents being created in the transient data store for the patient. The first is the HL7 CDA document required as the subject of the action (i.e., a form, letter or pathway to be completed); the second is a notification document (also HL7 CDA) which holds details of the user role designated to perform the action, and the timing of the notification to those users (can be immediate or with a specified time delay). The pathway document itself is also stored in the transient store; the pathway is now 'in progress' and can be accessed by other users. The relationship between the pathway, subject and notification documents is shown in Figure 3.

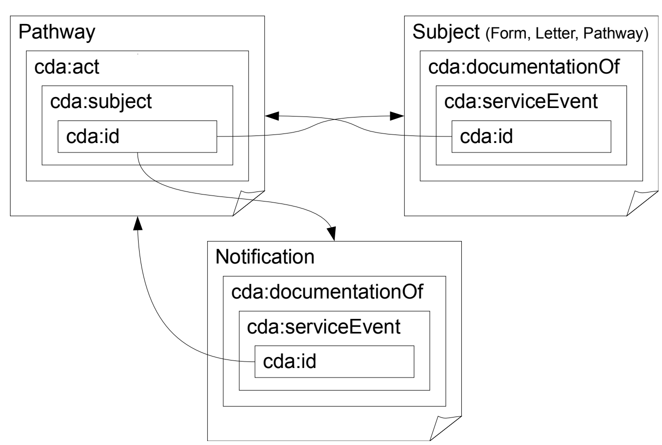

Figure 3. Linking pathway, subject and notification documents

Users perform actions by completing the associated subject document, which can be accessed by several means. Firstly, it can be accessed directly from the pathway by clicking on the action; the subject document will then be loaded in place of the pathway document. Alternatively, the subject document is also shown in the list of 'in progress' documents of that type, whenever any user views the record for that patient; it can then be loaded directly from there.

Finally, subject documents can also be accessed through the user's “In-Tray”. This is a user-centred, cross patient view which shows the list of all notifications that are targeted at the role of the current user. The user can click to view the details of any notification, and can then move directly to the record for that patient, to access the subject document.

When any document is completed, and is stored in the patient record, a check is made to see whether it is the subject of a pathway action. If it is, then that pathway is immediately loaded, causing its automatic progression. On load, all 'in progress' actions are checked to see if their subject document has been completed, which will in turn complete the action. These then bubble through to complete applicable parent tasks and trigger any subsequent actions.

B Manual Progression

A user can adapt a pathway before it starts, or while it is in progress, by setting the start time of actions, changing the role of user performing an action, or forcing tasks or actions to complete.

With the pathway document loaded, the user can make any of these changes, and then commit them to the pathway document, by selecting a manual progression. The status of each task and action is held in a 'session status' attribute for the duration of the user session. On load, the session status attributes of each task/action is set to the status as recorded in the pathway document. The session status can then be changed by the user, with any consequent changes to completed tasks, or triggered tasks/actions, bubbling through the document. The following changes can be made:

- Tasks can be 'completed' from 'charted' or 'in progress' states and can revert from 'completed' back to the committed status;
- Actions can be 'completed' from 'charted', 'triggered' or 'in progress' and revert back to 'charted' or 'in progress'.

This means that a 'completed' task, or action, may gain that status through automatic progression when actions are completed by users, or through manual progression as the pathway is adapted by a user. Hence, the result of a completed task or action is recorded in an attribute which takes one of the following values:

- Completed - the task or action was completed after users had completed the subject documents associated with the charted action(s);
- Skipped - manual progression to ‘completed’ from the ‘charted’ state;
- Aborted - manual progression to 'completed' from the 'in progress' state.

V. EXAMPLES OF DOCUMENT-DRIVEN PATHWAYS

We illustrate our approach to document-driven care pathways using two examples; one for electronic pre-operative planning at the University Hospital of North Norway (UNN), the other for an osteoporosis treatment at Nottingham University Hospital in the UK. Although based on clinical practice, both have been adapted here for the purpose of illustration. Care pathways are often documented as flowcharts and there have been some efforts to formalise this representation using UML Activity diagrams [17]. We have chosen to show the two examples using this familiar visualisation.

In contrast, the cityEHR models pathways as HL7 CDA documents through a multi-stage process that starts by using a spreadsheet to specify the pathway with its constituent tasks, actions, and conditions, as part of the full information model for the application. This model includes the data dictionary of clinical entries and elements, together with the forms, letters, and pathways used in the EHR. The spreadsheet is saved as XML, transformed (using XSLT, the Extensible Stylesheet Language for Transformations) to an OWL/XML ontology, as the base representation, and then further transformed to a set of HL7 CDA XML documents.

A Pre-Surgical Planning

Our first example is a pathway for electronic pre-operative planning at UNN (Figure 4).

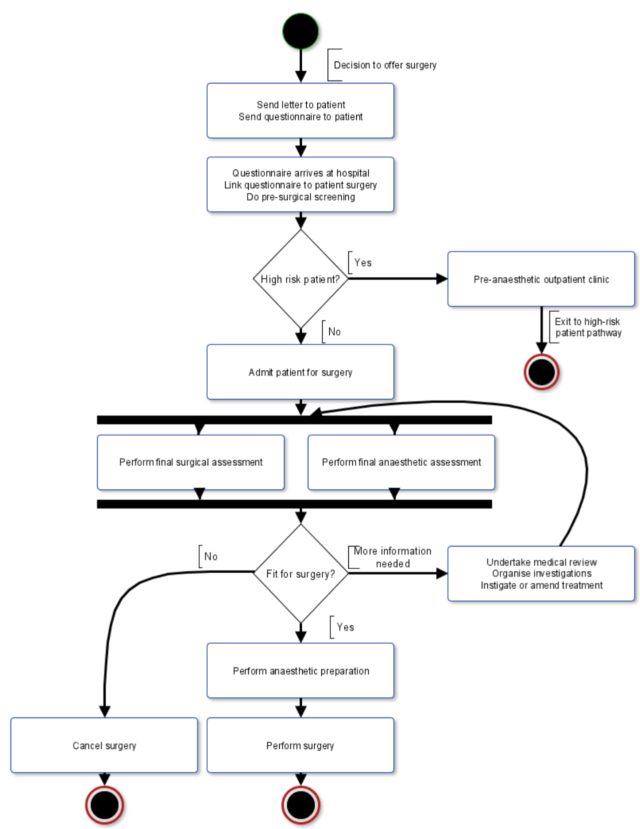

Figure 4. Pre-operative assessment as a UML Activity Diagram

Patients provide information for assessment before attending the hospital, and then undergo separate surgical and anaesthetic assessments. Following these, the surgery may be cancelled, may proceed or the patient may undergo further assessment and/or treatment, before being reassessed for surgery. For modelling, this pathway is interesting, since it includes concurrent progression of two main assessments, and a decision point, with three possible outcomes.

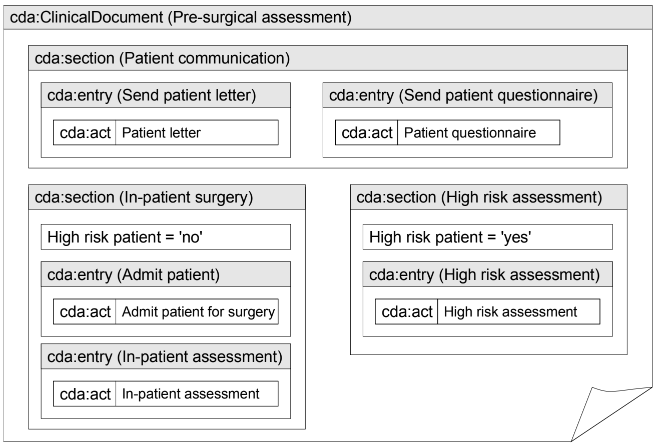

Figure 5. Pre-operative assessment pathway as an HL7 CDA document

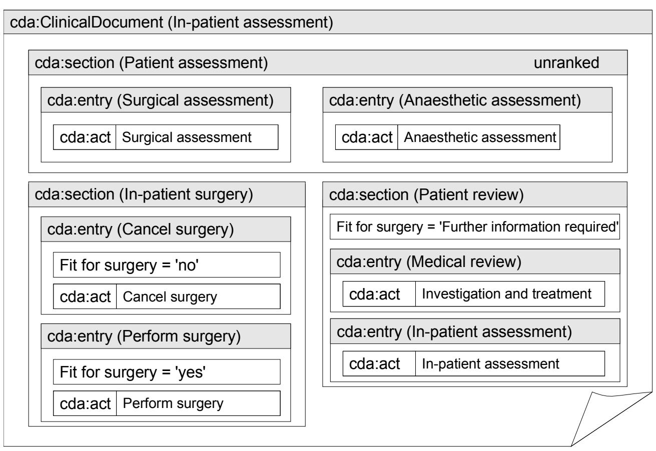

Figure 6. Sub-pathway for In-patient Assessment

When modelled as HL7 CDA, the pathway is split into three documents; one for the overall assessment (Figure 5), one for assessment as an in-patient (Figure 6) and one for further assessment of high risk patients (outside our scope).

B An Osteoporosis Treatment

Our second example is a pathway for an osteoporosis treatment at Nottingham University Hospital in the UK. This forms part of the ORCHID system [8] which is designed to gather data in routine outpatient encounters, both for clinical care and for secondary use in clinical studies, linked to samples in the local biobank. The pathway (Figure 7) covers a bone health assessment with various outcomes, including denosumab treatment, which is the focus of our example.

When modelled as a CDA document (Figure 8), this pathway is split into two, allowing for repetition of the denosumab treatment. Three consecutive decision points, at the start of the pathway, are combined into sets of conditions on the possible branches of progression, and the data required to evaluate those conditions are reviewed on a single form at the start.

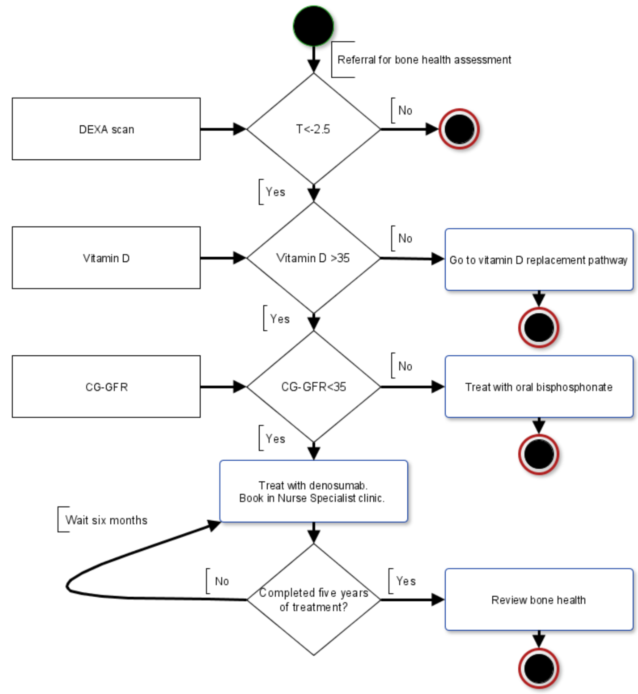

Figure 7. Bone health assessment as a UML Activity Diagram

The data required for the decision (i.e., DEXA scan, Vitamin D, and CG-GFR) are received using HL7 messages from laboratory systems. The pathway can be progressed using the most recently recorded values from the laboratory, but a manual review step is necessary to ensure that the tests were performed within an acceptable timescale; if not, then new tests must be ordered.

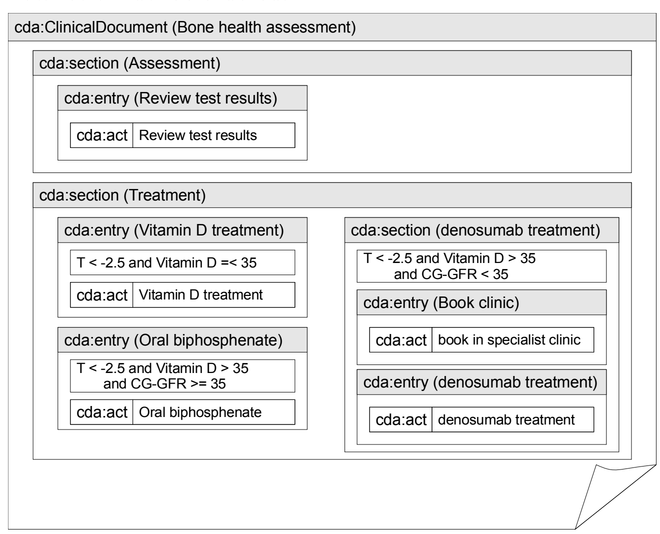

Figure 8. Bone health assessment as a an HL7 CDA Document

 ISBN: 978-1-61208-384-1

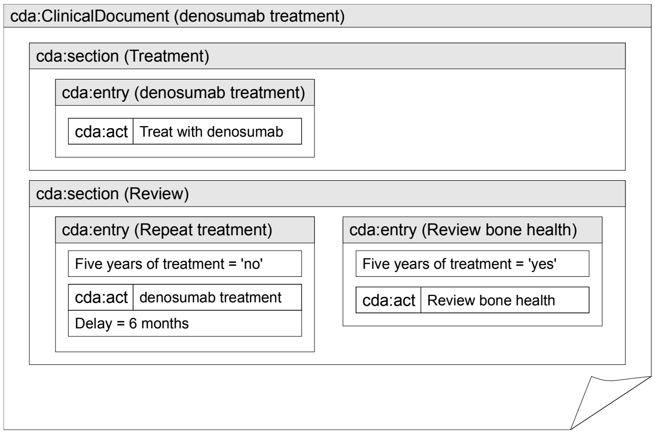

Figure 9. Sub-pathway for denosumab treatment

The sub-pathway for denosumab treatment (Figure 9) is called recursively in an action until five years of treatment have been completed. Note that similar pathways exist for the treatments of vitamin D replacement, and oral bisphosphonate, but are outside the scope of this example.

VI. CONCLUSIONS

We have implemented support for executable, integrated care pathways in the cityEHR health records system, using HL7 CDA documents to model and record the pathway. This approach enables pathways to be handled in much the same way as other clinical documents in the system, and allows them to be stored as a permanent record of the actions taken to fulfil the pathway. Hence, any variance from the original library pathway is captured in the final version of the document stored in the patient record, and statistical analysis of variation can be made by querying the records database.

We have demonstrated that the approach is sufficient to implement typical pathways in different clinical settings, including pathways with conditional branches and repetitive loops. The actions that can be performed in a pathway are currently restricted to clinical data entry/review, clinical letters, or sub-pathways; hence not all the standard features of pathways identified by Wakamiya and Yamauchi [7]. However, the addition of order communications (i.e., computerized physician order entry) to cityEHR would enable support of the full set of standard features.

At present, the transition from a UML Activity diagram as the representation for a pathway, to HL7 CDA document models is not automated. The template pathway CDA is created using the same tooling as for other clinical documents in the system: a spreadsheet is used to define the document, its sections, and entries, saved to XML format, transformed to an ontology representation in OWL/XML, and then transformed again to a CDA document. It would be possible to use UML tooling which enabled the activity diagram to be saved as XML, but whether this could then be transformed into the OWL/XML model remains an open question. However, the reverse transformation is relatively straightforward, whereby a representation as a UML activity diagram is generated from the OWL/XML model.

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