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Archetype based patient data modeling to support treatment of pituitary adenomas

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Abstract

The treatment of patients with pituitary adenoma requires the assessment of various patient data by the clinician. Because of their heterogeneity, they are stored in different sub-information systems, limiting a fast and easy access. The objective of this paper is to apply and test the tools provided by the openEHR Foundation to model the patient data relevant for diagnosis and treatment of the disease with the future intention to implement a centralised standard-based information platform. This platform should support the clinician in the treatment of the disease and improve the information exchange with other healthcare institutions. Some results of the domain modeling, so far obtained, are presented, and the advantages of openEHR emphasized. The free tools and the large database of existing structured and standard archetypes facilitated the modeling task. The separation of the domain modeling from the application development will support the next step of development of the information platform.

Keywords:
Patient data modeling, pituitary adenoma, archetypes, openEHR.

Introduction

A Pituitary adenoma is a kind of tumor that is located in the sella region of the brain. Usually, the tumor is benign, but it can affect the normal production of hormones, such as the sexual or growth hormone. These dysfunctions are responsible for example for infertility, erectile problems or enlargements of the extremities (hands, nose, ears) and of the internal organs (heart, kidneys) causing premature death. Because of the proximity of the pituitary gland with the optic chiasm, which is the region where the optic nerves cross, large pituitary tumors can moreover affect the vision of patients.

The diagnosis of the presence of a pituitary tumor is primarily performed based on MR imaging (figure 1). The position of the tumor in the pituitary gland and its size are estimated based on the image data. However, additive examinations, especially eye examinations, and blood tests which measure the quantity of hormones, provide complementary information about the kind of tumor. All these features strongly influence the choice of therapy [1].

Figure 1 – MR data of patient revealing a large adenoma (white arrow) in the pituitary gland.

More generally, the treatment of diseases requires nowadays the acquisition and interpretation of a large amount of patient data of various formats, including image data, results of laboratory tests, findings or medical reports and letters. At hospitals, these patient data are digitalized in so-called electronic health records (EHR) and stored within a centralized database called hospital information systems (HIS) [2]. The history and all data of patients are therefore available at anytime for all clinicians within the hospital. However, the main drawbacks of these systems for the every-day use by clinicians are their heterogeneity and ,therefore ,their complexity of use.

Since patient data occurs in various data formats, different sub information systems constitute usually the HIS. Image data acquired within the hospital are stored in a Picture Archiving and Communication System (PACS) and are visualized and interpreted by the clinicians through a computer interface, a DICOM-viewer. Results of laboratory tests are also commonly managed within the specific software, specially designed for such particular data. External medical letters and findings are scanned and stored in specific databases accessible through their unique user interfaces. It becomes clear that it can be very complex for clinicians to find the relevant patient information among the available patient data distributed in the different software components of the HIS. The access to the patient data can moreover be very slow. Finally, the management and maintenance of such systems is very complex.

To overcome this situation we intend to implement a centralized and standard-based information platform dedicated to the treatment of patients with pituitary tumor according to the point of view of neurosurgeons. Domain modeling is a key step in such development [3]. It consists in representing and storing the involved patient data in a suitable way. This paper focuses therefore on the modeling of the relevant patient data required for the treatment of the disease. The requirements associated with the domain modeling are presented. They form the basis to justify the choice of openEHR and associated tools. Finally, first results and experiences with the modeling are presented. In the future, the developed information platform should facilitate the diagnosis, therapy choice, treatment and monitoring of the disease by:

- Improving the access to patient data;
- Facilitating the interpretation of patient data;
- Increasing the exchange and re-use of patient data.

Materials and Methods

Selection of relevant patient data

The first step in the patient data modeling was the description of the clinical workflow for the treatment of patients with pituitary adenoma and the selection of relevant associated data. This was performed based on interviews with neurosurgeons.

Requirements for the patient data modeling

The second step consisted in representing the selected patient data according to models - to store and represent the information in the platform. This important task had to fulfill different requirements described in the following.

Definition of requirements. Content or fields of patient data models have to be determined. For example, the administrative data has to include personal information of patients, such as name, sex, birthday, address, identifier number and entry date.

Standard representation. The patient data has to be represented in a way so that it is understable to all actors. For example dates and time points need to be uniquely represented since they are differently recorded according to continents and countries [4].

Structured representation. In the context of the treatment of pituitary adenomas, a neurosurgeon makes the decision for the treatment based on images, laboratory data or information from the clinical reports provided by other clinical specialties. An unexperimented neurosurgeon is little familiar with these patient data. Structuring the information by enhancing important facts or conclusions facilitates the interpretation [5].

Interoperability. The use of existing norms and standards for modeling is a key point to improve the exchange of patient data between healthcare institutions [6].

Support for the implementation of the information platform. Patient data modeling forms the basis for the implementation of an information platform and most widely support and facilitate it [3].

openEHR

The openEHR Foundation is described on its web site (http://www.openehr.org/) as follows: "OpenEHR is a virtual community working on interoperability and computability in e-health. Its main focus is electronic patient records (EHRs) and systems." [7, 8]. Different applications were already developed based on openEHR [9, 10], for example in the field of neonatology [11] and epidemiological studies [12]. The tools provided by openEHR have important advantages for the development of our application.

Free availability. The philosophy of openEHR is to share the knowledge in the field of patient data modeling. Several tools are available to all for free. Users are encouraged to reuse these archetypes for their applications. These archetypes are good templates for the development of new archetypes. The database is totally free available so that each one can contribute on its enlargement. A discussion forum enables support and collaboration.

Standard-based archetype database. Patient data models are called archetypes in openEHR. A large database of existing archetypes is available. They were developed based on rules and structures, now recognized as standard. For example, a large set of archetypes represents the results or findings of a medical examination. A main component of these archetypes are conclusions of the examination -that are crucial for the diagnosis of the disease. However, further information about the requester of the examination, the name of the healthcare institutions where the examination was performed as well as the data and time are also important and included in the templates in general. Moreover, it is possible to link the archetypes with existing terminologies, for example, to code some text like the modality of image data.

Archetype Editor tool. This editor aims at supplementing existing archetypes for a specific applications, at building new archetypes and at assembling archetypes for the development of an application.

Separation of domain modeling and application development. The idea of openEHR is to separate the domain modeling from the application development. Therefore, the modeling of patient data can be performed by physicians or noncomputer scientists. The tools proposed by openEHR, like the *Archetype Editor*, are intended to be easy to use. A second software tool, the *Template Designer*, was developed to join all archetypes relevant for one application. The existing archetypes include a large number of information fields -that are not all relevant for a given application. With the *Template Designer,* it is possible to define constraints on the archetypes, for example the occurrence of an archetype. Some information fields can be prohibited. An XML-document is then generated from the domain modeling, on which the computer development of the information platform is based.

We tested and applied the tools provided by openEHR for the domain modeling of the treatment of pituitary adenomas.

Results

Clinical workflow and patient data set

The clinical workflow of treatment of patients with pituitary adenoma includes mainly three phases: firstly diagnosis of the disease, secondly therapy choice and treatment, and thirdly control of treatment and monitoring of the disease (figure 2).

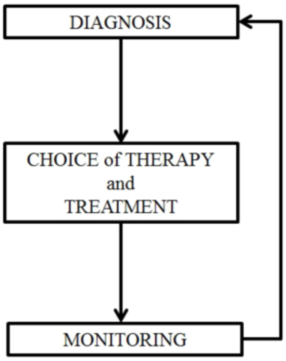

Figure 2 – Clinical workflow of the treatment of pituitary adenomas.

Diagnosis phase. During the first visit of the patient at the hospital, the administrative data of the patient are recorded. Diagnosis of the disease is primarily performed based on MR data which reveals the possible presence of a tumor and, if it is positive, provides an estimation of its size and position. Moreover, results of laboratory tests, eye examinations (more specifically the measurement of visual acuity and visual field) and clinical symptoms expressed by patients strongly influence the choice of therapy. The most common options are pharmacotherapy, surgery, observation of the disease development and combinations of them.

Treatment phase. In our application, the patient data are collected only in the pre-, intra- and postoperative phase of the surgical therapy. At the University Hospital of Leipzig transsphenoidal endoscopic operations is performed. An Endoscope and surgical instruments are inserted through the nose and the sphenoid bone till the sphenoidal sinus cavity - - to remove the tumor. The operation is assisted using a navigation system that indicates at anytime the position of the surgical instruments on CT and MR image data acquired one day before. Bone structures are well revealed on the CT image to guide the surgeon on the way to the tumor, while the MR data enhance the soft tissue, like the pituitary adenoma, in the brain area. During the operation planning, the surgeon can semi-automatically segment the tumor, especially when it is badly visible in the images. In the operating room, endoscopic video images are generated and stored for operation documentation. Postoperatively, a CT or MR image is generated in order to reveal possible bleeding or to detect possible remnants of tumor. Finally, the surgeon draws up the operation progress on a medical report.

Monitoring phase. Patient data involved in the monitoring of the treatment and of the disease are the same than those used for the diagnosis.

In conclusion, Table 1 lists patient data involved in the different clinical phases and the relevant information they provide to the neurosurgeon.

Table 1 – Patient data involved in the diagnosis, surgical treatment and monitoring of pituitary adenomas

Phase	Patient data	Relevant information
1	Master data	PID / Sex / Age
	MR data of the head	Tumor size and location
	Clinical symptoms	List of symptoms
	Laboratory tests	Hormone concentration in blood above or under normal values
	Eye examination	Measurements of the visual acuity and visual field
2	Preop. MR data	Tumor size and position (segmentation) for surgery planning
	Preop. CT data	Bone structures (visualization) for surgery planning
	Intraop. endoscopic video	Selected images for documentation
	Operation report	Documentation
	Postop. CT or MR	Presence of bleeding / Detection of remnants of tumor
3	Identical than in phase 1	

preop.: preoperative
intraop.: intraoperative
postop.: postoperative

Clinicians pointed out that four kinds of information must be attached to each archetype:

- Original text or image data
- Healthcare institution which performed the medical examination
- Date and time of the examination
- Comments of the neurosurgeon

Domain modeling with openEHR

The patient data listed in Table 1 were modeled using seven archetypes from the openEHR database and five self-implemented archetypes (Table 2). Since imaging examination are required for the three phases of patient treatment, its modeling is described in more detail in the following.

Table 2 – List of archetypes used for pituitary adenoma domain modeling

Patient data	Archetype name	Open-EHR	New
Master data	*Research study*		x
Image data	*Imaging examination results*	x	
Radiological findings	*Organisation*	x	
	Pituitary adenoma classification		x
Clinical symptoms	*Pituitary adenoma clinical symptoms*		x
Laboratory tests	*Pituitary hormones*		x
Eye examination	*Visual acuity*	x	
	Visual field measurement	x	
Choice of therapy	*Procedure request*	x	
Intraoperative image data Operation report	*Procedure undertaken*	x	
Histological findings	*Histopathology*	x	
	Pituitary adenoma histology		x

Example: imaging examination modeling

Image data and radiological findings

The existing archetype *imaging examination result* from the openEHR database, models image data with the corresponding radiological finding. The finding is structured in different sub-parts including the examination name, the examined anatomical site, the date, time and status of the given result, the radiological diagnosis and possible conclusion or comment. A link to the original text data can be specified. Moreover, the imaging examination can be documented: who requested and performed the image acquisition, when was the acquisition performed, what was the patient position. A reference image of a current view can be attached.

Usually, only selected fields are required according to the medical application. In agreement with the neurosurgeon the following fields were kept:

- "Imaging modality": possible choices were coded;
- "Conclusion": in this field can the neurosurgeon add his comments;
- "Examination result representation" includes the link to the original radiological report;
- "Name of organisation" which performed the imaging examination;
- "Image details" includes the date and time of image acquisition as well as a reference image, possibly with the tumor segmentation.

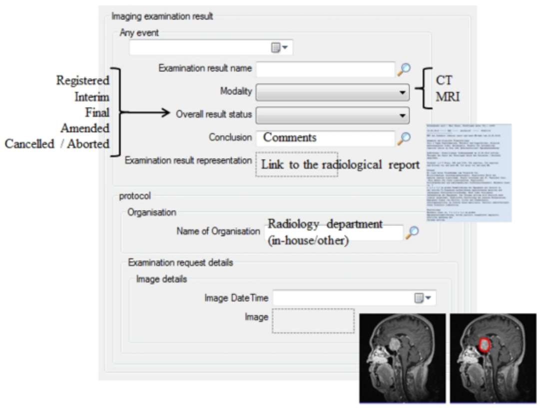

Figure 3 – Preview performed with the tool "TemplateDesigner" of the selected fields of the existing archetype "Imaging examination result".

The archetype was improved using the tool *Archetype Editor*. The choices for the field "Imaging modality" were coded using an internal code because only CT or MR data is involved. The field "Name of organisation" was linked to the existing archetype *Organisation*, which reports details of an organisation or agency.

In the tool *Template Designer*, the other fields not required for our application were set as prohibited so that they will not appear in the information platform. Moreover, the fields "Examination result name" and "Overall result status" are mandatory by definition in the archetype. A preview of the mask corresponding to the modified archetype can be generated and is shown in figure 3.

Pituitary adenoma classification

Based on the observation of the image data and on the reading of the radiological findings, the neurosurgeon infers a classification of the pituitary according to its size and location (Table 3). Since this classification is specific to our application, we developed ourself the corresponding archetype.

Table 3 – Description of the new archetype "pituitary adenoma classification"

Fields	Description	Modeling
Number of tumors	Between 1 and 4	Number
Maximum size	Maximum tumor size estimated in the three radiological directions	Quantity
Macroadenoma	Tumor size ≥ 10 mm	Boolean
Microadenoma	Tumor size ≤ 10 mm	Boolean
Localization	Tumor localization and link with adjacent structures	Boolean
Symmetrical growth	Performed in the coronal view	Boolean
Hardy classification	Classification based on tumor size and localization: Grade 0 to Grade IV	Coded text

The new archetype was developed using the tool *Archetype Editor*. Different kinds of data can be included into the archetype like text, numbers or boolean values. The unit can be attached to a data "quantity", like it is the case for the tumor size given in millimeter. It is possible to specify the range of value which are entered by the user. For example, the number of tumors was limited to four, the values for maximum tumor size must be positive. The Hardy classification [13] was coded using an internal code from Grade 0 until Grade IV. A preview of the archetype is shown in figure 4.

Discussion and conclusion

Patient data modeling is a crucial step towards the development of information systems in health care domain. The openEHR Foundation proposes free software that is well adapted to support this task. The domain modeling is totally separated from the application development. This enables a medical expert with limited experience in computer development to implement the respective domain knowledge. The large database of archetypes provided by openEHR was developed according to standards. The tool *Archetype Editor* enables to complement existing archetypes, to implement new archetypes and to specify constraints on the archetypes. Then, they are put together in the tool *Template Designer*. A preview of the web mask corresponding to the domain modeling can be generated. The model can be exported as an XML file which forms the basis for the development of the web mask. The standardisation of the models of patient data should encourage the exchange between healthcare organisations. In general, the use of the openEHR tools require experience since a documentation is available only to a limited extend or difficult to find. This can be a limitation for clinicians.

So far we implemented a prototype of the information platform based on a couple of patient data. This proof of concept project showed us the feasibility of developing an information system based on openEHR. The future objective of this work is the development of therapeutic assistance system to support clinicians in decision making for the treatment of patients with pituitary adenomas. This requires the extraction of semantic information from patient data, whose representation in archetypes is supported by openEHR. For example adverse events concerning the patient or occurring during the treatment can strongly influence therapeutic decisions. Specific new text mining and image processing tools have to be developed in research environment and included within our information platform [14, 15].

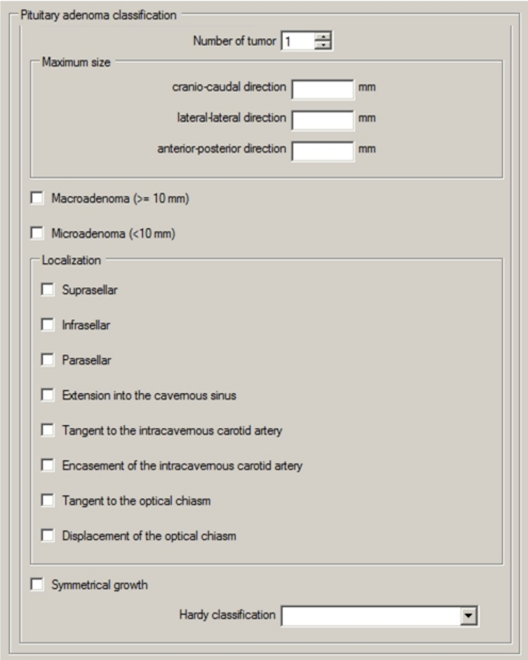

Figure 4 – Preview of the new archetype "Pituitary adenoma classification" recording the tumor classification performed based on image patient data (mask generated by the "Template Designer").

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