Steps towards the Integration of Model Guided Therapy Systems into the Healthcare Environment

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Abstract

Hospital Information Systems (HIS) are the primary source of information in clinical routine. In most clinics and medical centers, an electronic health record (EHR) stores relevant patient information which is passed between sub-systems using the ISO standard Health Level 7 (HL7). In Radiology, the Picture Archiving and Communication System (PACS) is used to store and transfer medical images and other image related patient data and reports.
The paper promotes the development of dedicated patient models based on HIS information. This allows specialized and tailored models for each purpose without the need for a commonly accepted data format.

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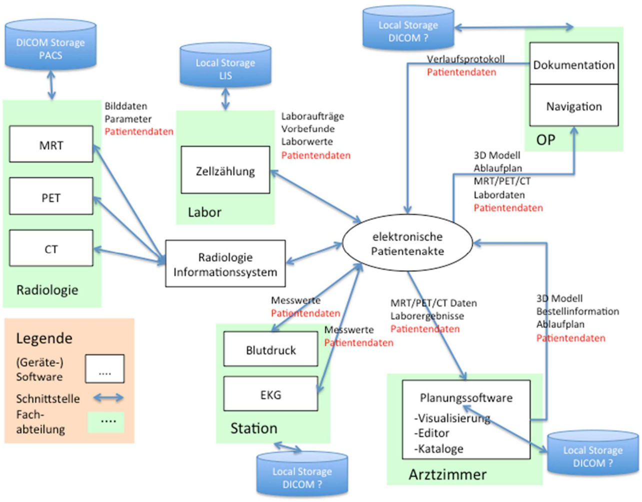

Figure 1: System architecture with EPR as the information hub.

1 Problem Statement – Lack of Integration

Hospital Information Systems (HIS) are the primary source of information in clinical routine. In most clinics and medical centers, an electronic health record (EHR) stores relevant patient information which is passed between sub-systems using the ISO standard Health Level 7 (HL7). In Radiology, the Picture Archiving and Communication System (PACS) is used to store and transfer medical images and other image related patient data and reports. There is a continuous harmonization effort between DICOM and HL7 to facilitate information exchange without loss of information at system boundaries. Unfortunately, the HIS was initially designed to support the hospital administration in the billing process, therefore all patient information is strongly focused on accountability and not on optimally supporting medical decision making or therapy. Usually, medical devices have no or limited access to information stored in the HIS's subsystems.

Model Guided Therapy (MGT) and Personalized Medicine (PM) are gaining more and more importance in clinical routine. Model Guided Therapy can be seen as a successor of Image Guided Therapy (IGT): IGT uses patient images to support medical planning and therapy. MGT uses not only images but additional model parameters like blood pressure, genetic tests, or n-dimensional models of the patient's anatomy. Instant availability of a huge set of patient information combined with increased knowledge on

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individual courses of disease for different groups of patients allows selecting the best treatment for a specific patient based on prior experience and clinical evidence.

Systems supporting MGT, IGT and PM, as well as most medical equipment e.g. in anesthesiology are in most cases stand-alone systems which have no or very limited connection to the HIS. If data has to be transferred between devices, there are manual steps involved (e.g. exporting radiology images, storing them on a USB stick, and opening them in a navigation system), or expensive extensions to the HIS or the underlying communication server have to be implemented. This hinders information flow, it is a potential source of error, time consuming and hinders implementation of modern techniques in clinical care.

The problems described above are intensified by the fact that MGT systems, Medical Devices and HIS components are developed and built by a different community of people and marketed by different companies or sub-organizations in companies.

2 Model Definition, Transfer and Storage for MGT

There have been efforts to build complete models of the human, like the virtual physiological human project, and some authors [QUELLE!] postulate that “the patient is stored in form of a patient model”. It might be feasible to build a model of a patient over time, but for treating a specific disease, it is just not necessary (and way to expensive) to collect all patient information. Furthermore, such a model would require world-wide harmonization of data structures and semantic information which is needed to store all patient information. At the moment, we can’t identify a standard or data format which is fulfilling this requirement, or which could be enhanced with reasonable effort.

A model is always a reduced abstraction of the real world. The model is built for a certain purpose and the level of abstraction must be selected based on the intended use of the model. In medicine, it might be possible that the abstraction is enforced by limited measurement methods, e.g. imaging resolution, lack of understanding, etc.

Based on this generic definition of a “model”, and the lack of a unified modeling data structure in medicine, we propose building one or more dedicated patient models during the treatment course, each model tailored to the needs of the specific therapeutic step. In an optimal case, this would be a just-in-time model generation based on the clinical needs. Those models should be closely linked to the EPR and draw all available information from HIS components. This ensures data consistency and allows for storage of results in the centralized system. In general MGT requires various sources of diagnostic data such as radiological images, laboratory values and physiological data available at the workstations where the treatment is planned. For stand-alone solutions all relevant data and presentation software has to be copied redundantly with the risk of errors and incompleteness. This can be avoided when using integrated viewing solutions based on a central data repository such as provided by the EPR.

3 Standardization Aspects: Rethinking information integration

In the previous chapter we stated that models should be tailored to the specific needs of a therapeutic step. This implies that the data structures used to represent the model internally must be selected based on the

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needs of the application, and not based on the needs of a system integrator. Nonetheless, the MGT system must be capable of receiving (or requesting) the required patient information. This requires a standardized communication with other HIS components.

First of all, the patient, case and order IDs must be harmonized between system components. Since in common installations the HIS serves as the central data pool, it should be considered as the central and above all single source for IDs. Integrating this ID in every patient specific communication allows to track and to associate every bit of information to its diagnostic and therapeutically relevant context. However, today most medical devices are hardly integrated in such an information infrastructure and require manual data entry at each patient contact. This results in the well known problems of lack of data integrity by wrong inputs such as typos and belated data merging. Consequently, integration of various technical devices in modern patient care needs for integrated patient administration.

Medical Standards such as HL7 and DICOM are based on linking diagnostic data with patients, cases and order. However, many device manufacturers beyond radiological applications do not provide standardized interfaces. A common impression among HIS Administrators is a certain restraint of the manufacturers implementing these interfaces in an appropriate form. The expense seems too high because of the large amount of variations of events and message compilations. There are two principal forms of communication:

Lightweight Communication HL7

From a technical point of view the handling of basic HL7 ADT and ORM events could overcome most routine cases and support a better interaction with the EPR in the HIS. In a low-level solution, a HL7 MDM is the most efficient way to transport device specific raw data back to the EPR. If this “raw data” is a link to a web service of the devices control software there is no need to copy the data redundantly. Yet this requires a web based device control software. A further advantage of such a cloud based approach is the availability of medical data at arbitrary sites. This again would be a giant leap towards routine ready telemedicine.

Heavyweight Communication DICOM

If the detached transfer and storage of large amounts of data becomes necessary, the DICOM framework provides a powerful solution. Here, the development of interfaces is more expensive and complex. Additional interaction is required for instance to use a DICOM-worklist. Therefore data integrity is preserved even if information is detached from the data repository. Its processing and extension in an external specialized software for instance as a 3d-mesh based visualization and planning tool does not lead to the loss of patient or case IDs. On the contrary, if this software also supports HL7, current information such as the last laboratory values may be linked instantaneously and automatically to the patient under examination. The processed and extended DICOM data can then be reattached to the storage system with full preservation of data integrity.

Thus HL7 and DICOM are well-established interoperable and systematically evolving standards for medical applications. The strict and reliable procedure for standard extensions has been successfully established over the last three decades. Thus there is always the possibility to define a new robust and reliable extension for the most recent and most specific type of data. Yet these standards require specific and extra implementation of data processing that is not obviously linked to typical device control

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software. The resulting extra expense may be the reason for device manufacturers to avoid full support of these standards.

It is the authors' strong opinion that without considering these integration aspects device manufacturers and developers of integrated MGT software will not have the full impact in their fields of expertise.

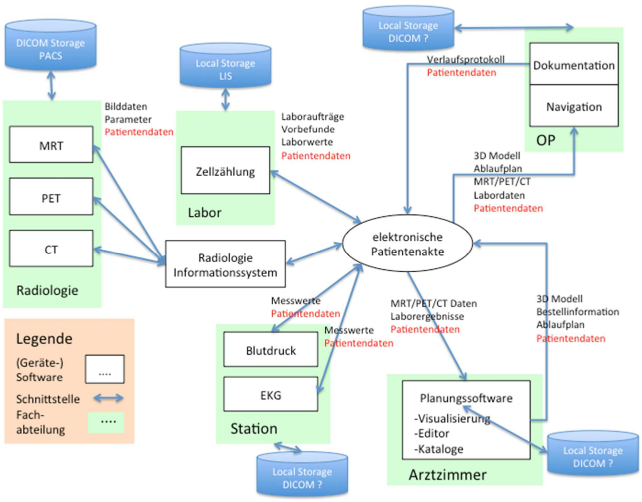

Figure 1: System architecture with EPR as the information hub.

4 System Landscape

Based on the considerations in section 3, the EPR serves as an information hub. The data necessary for MGT is accessible via the EPR GUI. This is sound with the user-experience of medical personnel from their daily work and does not mean a break of the tool chain. Moreover the result of complex planning forms a set of new clinical data, which is also available for broader use within a patients clinical history. A valuable side effect of using the EPR as a hub is the intrinsic handling of access rights which is also provided by the HIS.

Such an approach requires software and devices that are fully interoperable with the EPR administration. There are two classes of data that have to be treated by the system.

1. Classical passing of structured information within the HL7 framework is usefull for small and complex data such as laboratory values or medical findings as text artefacts. This data is stored in a central HIS database. Since the clients of a HIS are usually web-based solutions such as browsers the EPR is accessible throughout the entire facility.

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2. Access to decentralized stored raw data from devices that produce large amounts of values in a specific format such as images, nuclear decay counts in sonograms or ECG measurements. This data needs special software for its display and analysis. Such programs are often heavyweight applications that have to be installed on specific workstations. Yet modern webservices or cloud approaches provide efficient ways to make software available to end-users without involving the IT-staff.

For both classes the respective sub-systems must integrate the communication standards and GUI concepts as introduced in section 3 and 4.

5 Discussion

In this work an integrated approach to MGT is presented which is based on strongly reusing available data by integrating stand-alone devices and planning software into an existing information infrastructure such as a HIS. A specialized component in the clinical care cycle, such as a surgical planning and navigation system, can make use of already available information, build its own tailored patient model and use this model along the component's work-flow. Therefore, it is possible to transfer the model to a sub-network, such as an intra-operative network as proposed by the OR.NET consortium [REF] without allowing a free flow of information (which might be a security and safety risk).

Main Challenges are

1. Avoidance of data inconsistency
2. No unnessecary double examinations
3. Efficient access to medical data via a single GUI framework
4. No redundancy of data storage:
5. Consistent integration of data from several sources
6. Diagnostic and therapeutical relevance
7. Full data access during treatment or surgery

These challenges are met by integrating four concepts in medical informatics which in practical and industrial applications have until now been neglected. Requirements are:

1. Using the EPR as a central storage location
    a. By default available at all workstations in the hospital
    b. Communication infrastrucuture is available

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2. Device manufacturers provide interfaces to patient data communication
   a. Acquired data is linked to the case data via general ids
   b. Device software supports patient individual data management
3. Virtualization of device specific software
   a. Special visualization software for planning is launchable at every workstation
   b. Integration into the EPR allows for a full overview of a patients status
4. Using standard data interfaces
   a. Complex planning by large data that is detached comprehensivly from the central storage.
   b. Standardization organisations ensure broad usability for yet unkown data formats

Realization of such an integrated system requires problem awareness by all affected partners.

1. HIS must be extended to real storage management systems with cloud functionallty which requires new software concepts and fundamental rethinking of HIS SW-Architecures.
2. Device manufacturers must integrate complex medical interfaces such as HL7 to interact with the EPR. This requires the development of new user and system interfaces by the manufacturers.
3. Device manufacturers must provide their data analysis software in a virtualized cloud like architecture to become available at all workstations

Reference

[1] to be added

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