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First Experiences in Implementing a Software-Based Support for Patient Recruitment at Heidelberg University Hospital

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Abstract. Clinical trials have often got problems in achieving their recruitment target. Making the recruitment process more efficient and timely is tried to achieve in Heidelberg by implementing a software-based system to support patient recruitment. The architecture implemented in Heidelberg was developed in a multi-center research project named 'EHR-based support for patient recruitment'. The architecture is generic as five distinct university hospitals developed it and found it implementable. The same architecture is also implemented at four other university hospitals in Germany. The system was implemented into the existing system architecture and can thus be implemented by the vendor of the system. This makes the system available to all customers of named systems.

Keywords. Patient recruitment, clinical decision support system, EMR, HIS, CIS

Introduction

This work is part of the project 'EHR-based support for patient recruitment' within the partners' five German university hospitals [1].

Clinical trials are important to the development of new procedures and drugs. But currently they often fail to achieve their recruitment objective or need to extend the recruitment period to achieve the recruitment objective [2]. As electronic medical records (EMRs) are spreading [3] and as we found out in earlier studies have all recruitment relevant information electronically and structured, EMRs are likely to support patient recruitment.

At Heidelberg University Hospital the hospital information system (HIS) consists of two mayor parts. The enterprise resource planning (ERP) System based on *SAP ERP* and the EMR based on *SAP IS-H* extended with *Siemens i.s.h.med*. The administration wanted to have a database on clinical trials performed at Heidelberg University Hospital for quality issues. This system was implemented in the ERP System *SAP ERP*, which is already used at Heidelberg University Hospital. It is used as starting point for the implementation support for patient recruitment, as all administrational data (e.g. trial name, trial administrator) is already electronically available. As there was no

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software-based support for patient recruitment in clinical trials yet, we used the synergy effects between one of our departments which was already thinking about implementing such a system and the project 'EHR-based patient recruitment in clinical trials.

One aim of this work is to show that software-based support of patient recruitment using routine data within the EMR can be implemented into existing software products. Another aim is to show the first experiences we made in implementing the features required to support patient recruitment.

1. Methods

First the partners analyzed which functions and modules would be necessary for software-based support patient recruitment by analyzing the systems used for the clinical documentation. Afterwards we analyzed the status quo of the tools already in use within the partners' respective hospitals. Thus we tried to find out which tools can be used or extended to implement the functionality needed for software-based patient recruitment. After finding out that *SAP IS-H* has all the options for an implementation of software-based patient recruitment, the implementation of the functions necessary started. The system for software-based patient recruitment is implemented in the SAP programming language ABAP.

In the analysis of the functions and modules needed and of the status quo the partners in the project 'EHR-based support for patient recruitment' were involved and did the analysis for each of the five university hospitals.

In the implementation of the system at Heidelberg University Hospital four members of the Center for Information Technology and Medical Engineering of Heidelberg University Hospital are involved.

2. Results

The system to support patient recruitment at Heidelberg University Hospital is implemented in the existing ERP *SAP ERP* and in the also existing patient administration system (PAS) and EMR system *SAP IS-H*. The administration of clinical trials for administrational purposes is already implemented as an addition to the database of the *SAP ERP* database.

The medically relevant data for the implementation of clinical trials is implemented in a so-called nursing dialog. In the nursing dialog the following information about the clinical trial has to be entered:

- all inclusion and exclusion criteria,
- the physicians to be notified in case possibly eligible patients are found,
- the time (interval) the search for possibly eligible patients is to be performed.

The information entered into the nursing dialog is used to set up an automatic query for patients possibly eligible for a specific trial.

A trigger starts the database query for possibly eligible patients on the *SAP IS-H* database. Therefore the inclusion and exclusion criteria are translated into a report,

which can be executed on the database. There is a query for each single trial. The query is executed on administrational and medical data found in the *SAP IS-H* database.

For each physician there is a work list in *SAP IS-H* on which the found possibly eligible patients are displayed and have to be reviewed. If they are still eligible after the review, the treating physician talks to them about the trial and asks for the patients consent to participate in the trial. The decision of the patient is then documented in the patient's EMR. The eligibility and participation status of the patients can only be seen by their physicians and study personnel.

3. Discussion

One of the advantages of extending the existing systems is that all mechanisms regarding privacy and security are already implemented and reused in the context of support for patient recruitment.

The implementation shows that it is possible to extend the existing HIS so that software-based patient recruitment is possible.

As the implementation of the functions for the software-based support of patient recruitment was possible using only onboard features of *SAP IS-H*, software-based support of patient recruitment should be included as a feature in the product.

Furthermore all hospitals using *SAP IS-H* and *Siemens i.s.h.med* for adt/billing and as EMR can implement the architecture in the same way we do.

4. Future plans/activities

At Heidelberg University Hospital some clinical trials are going to use the system to support patient recruitment in these trials and to evaluate the system. The study personnel of these trials will have to answer a usability questionnaire and describe the workflow prior to the implementation of the system and after using the system. Thus the effect on recruitment rates is about to be evaluated now that the system is implemented. Publications on the generic architecture and the evaluation are planned and will be published soon.

Legal requirements for the project are discussed for clinical research in general in Germany right now and will thus be published separately.

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