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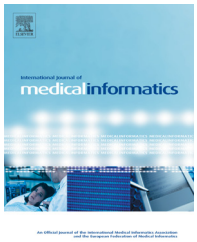

Comparison of Electronic Health Record System Functionalities to support the patient recruitment process in clinical trials

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ABSTRACT

Objectives: Reusing data from electronic health records for clinical and translational research and especially for patient recruitment has been tackled in a broader manner since about a decade. Most projects found in the literature however focus on standalone systems and proprietary implementations at one particular institution often for only one singular trial and no generic evaluation of EHR systems for their applicability to support the patient recruitment process does yet exist. Thus we sought to assess whether the current generation of EHR systems in Germany provides modules/tools, which can readily be applied for IT-supported patient recruitment scenarios.

Methods: We first analysed the EHR portfolio implemented at German University Hospitals and then selected 5 sites with five different EHR implementations covering all major commercial systems applied in German University Hospitals. Further, major functionalities required for patient recruitment support have been defined and the five sample EHRs and their standard tools have been compared to the major functionalities.

Results: In our analysis of the site's hospital information system environments (with four commercial EHR systems and one self-developed system) we found that – even though no dedicated module for patient recruitment has been provided – most EHR products comprise generic tools such as workflow engines, querying capabilities, report generators and direct

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SQL-based database access which can be applied as query modules, screening lists and notification components for patient recruitment support. A major limitation of all current EHR products however is that they provide no dedicated data structures and functionalities for implementing and maintaining a local trial registry.

Conclusions: At the five sites with standard EHR tools the typical functionalities of the patient recruitment process could be mostly implemented. However, no EHR component is yet directly dedicated to support research requirements such as patient recruitment. We recommend for future developments that EHR customers and vendors focus much more on the provision of dedicated patient recruitment modules.

1. Introduction

For many years the focus of Electronic Health Record (EHR) system implementations was on providing patient-centred data input and data presentation as well as communication between clinicians in order to support billing, quality assurance and direct patient care. Output from such systems was typically restricted to predefined but configurable views on the EHR data and a limited set of functionality for creating reports and simple data analysis. Accessing data across sets of patients and making such reports available for research support was rare. Examples, such as the WAMIS systems (with WAREL [1] and ArchiMed [2] in later years as query tools) in Vienna or the ClinQuery system in Boston [3] providing user-friendly query tools which directly allow clinicians to search a hospital's clinical database for research purposes were exceptions and typically limited to few research institutions with IT development teams at site. In Germany first calls to reuse EHR data also for research purposes were published in 2009 by Ohmann and Kuchinke [4] as well as Prokosch and Ganslandt [5]. In the latter publication the integration of EHR systems and clinical trial databases in order to enhance patient recruitment and data capture for clinical trials was declared as one of the major challenges of medical informatics. In the U.S. however, reusing data from EHRs for clinical and translational research has been tackled in a broader manner already since about 2003. Patient recruitment [6,7] and study protocol feasibility [8] were the most important scenarios identified in this context. In a recent review paper Cuggia et al. [9] asked the question "what significant work has been carried out towards automating patient recruitment?" and identified 33 publications (describing 28 distinct systems) addressing this issue. Most of these projects however were based on proprietary research implementations at one particular institution often for only one singular trial. Only few of the authors (e.g. [6,10]) have described that modules and functionalities generally available within EHR systems can be used to integrate clinical trial recruitment support systems closely into the workflow of clinical trial staff and provide system sustainability for more than just one project. To the best of our knowledge, no such publication has focused on an analysis of commercially provided EHR systems. Furthermore, neither the question how good todays EHR systems are already equipped with modules being configurable to support patient recruitment processes, nor the question what particular features and functionalities are currently missing (especially in commercial EHR products) have yet been answered.

This study is embedded in an even more comprehensive and still ongoing research activity funded by the German Federal Ministry of Education and Research (BMBF) aiming at

- the definition of a general architectural approach for hospital information system components interacting with each other in order to provide optimal support for the clinical trials patient recruitment process [11],
- the analysis of EHR contents and data quality in a representative selection of hospital sites in order to satisfy patient identification queries based on eligibility criteria from original clinical trials [12] and
- an analysis and comparison of implementation efforts, usefulness, usability and effectiveness for IT-based patient recruitment interventions at different German hospitals.

2. Objectives

Within the given context the objective of this sub-study is to focus on the market of hospital IT vendors (the research pursued was however restricted to the German market for practical purposes) and EHR implementations within German University Hospitals. We ought to determine the major system vendors and whether the current generation of commercially available EHR systems provides modules/tools which can already be applied for IT-supported patient recruitment scenarios. Subsequently, if missing features would be identified we sought to formulate requirements for the EHR vendors to enhance their systems in future software releases to better satisfy the increasingly arising needs for EHR data reuse support especially in the domain of patient recruitment.

3. Methods

In the following the term HIS (Hospital Information System) is used in the way Van de Velde [13] has defined it as "a medium for communication between the diverse collaborating functional subsystems or units in a hospital. It acts therefore as skeleton to facilitate the integration of various systems operating at subsystem level." In contrast to this an

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