Single Source Information Systems to Connect Patient Care and Clinical Research

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Abstract. Currently documentation processes for routine patient care and clinical research are kept separate (dual source). Due to overlaps between routine and research documentation, a single source approach provides opportunities to improve efficiency of medical documentation given the large workload of physicians related to documentation. Organisational, technical and regulatory conditions need to be considered for the design of single source systems. We present a single source architecture for clinical studies and provide results from pilot implementations.

Keywords. single source, hospital information system, clinical study, patient recruitment, routine data

1. Introduction

Data management in hospital information systems (HIS) and clinical research is currently based on separate systems, i.e., a dual source concept (Figure 1). Documentation for routine patient care is provided within the HIS with its various software components, such as patient administration system, clinical information system (CIS), laboratory information management systems (LIMS) or radiologic information systems (RIS). Data for clinical research are collected separately on case report forms (CRFs) and stored in dedicated research databases, even if these data items are available in HIS. In this context, clinical research refers to different types of clinical studies such as observational studies and controlled clinical trials.

This dual source approach has various reasons, such as legal regulations, in particular need for data validation in clinical trials, as well as data modelling and terminology issues. However, the dual source approach increases documentation burden for physicians and nurses massively. A recent study [1] – concordant with results from a previous German study [2] – showed that a physician is spending about a quarter of his daily working time for documentation tasks. Any effort for research documentation is added on top of this massive documentation workload.

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Single source information systems provide integrated documentation for patient care and research. They are intended to make data collection more efficient and to support the workflow of clinical studies, for instance patient recruitment or scheduling.

2. Methods

In a single source setting (Figure 2), data for patient care and clinical research are both collected in the HIS. Redundant data entry for research and patient care is reduced. Typical examples for redundant data items are patient demographics, laboratory results, medical history and diagnosis codes. There are quality assurance procedures for clinical studies (e.g., data monitoring) and in routine patient care (e.g., medical quality management). In a single source setting both routine care and clinical research benefit from these different quality assurance activities, because they refer to the same data source.

It must be pointed out that in Figure 2 clinical research data are exported from HIS to a separate research database. This concept enables to model different roles and responsibilities in clinical trials: The sponsor of a trial (e.g., a pharmaceutical company) is responsible for the clinical trial database while each hospital is responsible for its own HIS.

Specific data export functions are needed to transfer study data from HIS to the research database. For instance, patients need to be pseudonymized. Data entry modules of HIS need to be expanded to enable collection of study data and need to provide audit trails. Research data are subject to monitoring to provide high quality data. In a single source context, queries regarding incomplete or inconsistent data need to be processed by physicians in the HIS, because they do not have direct access to the research database. Those monitoring activities are initiated by the study data management team, which can access the research database. When data queries are completed, data export functions provide a synchronisation mechanism between HIS and research database.
3. Results

3.1. A Pilot System for a Monocentric Prostate Cancer Study

We implemented a pilot system in the context of a monocentric, observational study on prostate cancer [3]. HIS access was approved by the responsible data protection officer. Primarily, this prototype aims to support clinical documentation of prostate biopsies and facilitates the workflow between urology and pathology departments. We designed electronic forms for histological prostate biopsies in our HIS. These forms are sent electronically from urologists to the pathology department. Pathologists enter their findings into the system and send results in electronic form back to the urology department. In a study with 173 patients this electronic workflow improved time from biopsy to final report on average by more than one day per patient.

From a clinical research perspective, our pilot system in urology provides highly structured clinical data, for example prostate volume, size and location of biopsies, Gleason score, prostate specific antigen (PSA) and international prostate symptom score (IPSS). Using reporting capabilities of our HIS, incomplete or implausible data sets were identified. These reports were applied as monitoring tools for an observational study on prostate cancer. In addition, data items for this study were exported from the HIS database for statistical analysis.

With respect to the architecture of a single source system in Figure 2, this pilot system enables input of research and clinical data within the HIS, it provides simple monitoring functions and data export capabilities. However, research data are stored in flat files and not in a research database, therefore data export and monitoring are
performed manually. In addition, we addressed an observational study and not a controlled clinical trial which requires validation of documentation procedures.

3.2. Support for Patient Recruitment from HIS Data

Documentation tasks in clinical research go beyond data capture of medical findings for an individual patient. For instance, the patient recruitment process needs to be documented according to each study protocol. In a single source system, HIS data can be accessed to support identification of suitable study patients.

With approval by the responsible data protection officer a system to support patient recruitment for leukemia trials in Münster based on HIS data was implemented [4]. An automated HIS report exports data elements relevant for patient recruitment. Physicians are notified automatically by email about potential trial subjects and verify eligibility. During a test period of 50 days 41 patients were identified by this prototype system. Thirteen patients could be included as new trial patients, seven were already included during earlier visits. According to review of paper records, no trial patient was missed by the system.

4. Discussion

In general, concepts to improve efficiency of medical documentation are highly relevant for routine patient care and clinical research, because the documentation workload for physicians is huge – about a quarter of daily working time [1, 2].

There is evidence for a relevant overlap of routine and research oriented documentation. Williams [5] replicated four randomized controlled trials (RCT) using routine data in place of the data already collected. He reports that generally two-thirds of the research questions addressed through RCTs could be answered using routinely collected data. The validity of routine data in clinical medicine is a matter of discussion. However, there is evidence that primary electronic data capture integrated in routine patient care can be faster and more precise than paper-based procedures. This was demonstrated for computer-based scores on intensive care units [6].

Computerized data become more and more the primary data source in medicine. For instance, laboratory and medical imaging data are stored and validated in dedicated information systems. The general topic to use the electronic medical record for research receives more and more attention [7].

It seems straightforward to use HIS data for clinical research. However, there are quite a few challenges: From a legal perspective, the sponsor of a clinical trial is in charge of the trial database and all participating hospitals are responsible for their own HIS. Data protection issues need to be observed strictly. Many trials are multicentric and take place in different countries, therefore different HIS platforms are involved. To address this one-to-many relationship between study and HIS, a separate common research database for each study is necessary. Data in clinical research are subject to quality control and validation, therefore mechanisms to support monitoring and repeated data export (synchronisation) between HIS and research database need to be provided for single source information systems.

In 2007 a first proof-of-concept study for a single source system in the context of a cardiology trial was published [8]. This approach to connect routine patient care and
clinical research is especially relevant for physicians at university hospitals, because they are involved in both types of activities.

We implemented a pilot system for a monocentric, observational study. Future work will address controlled clinical trials and multicentric studies. From an informatics perspective, different terminologies and standards pose a challenge for single source systems: Major HIS standards are HL7 and CDA; for clinical trials CDISC plays a key role [9]. There's a need to develop and standardise medical data models that are suitable both for routine patient care and clinical research. In addition, during implementation of our pilot systems we discovered that HIS data structures are mainly case oriented (e.g., for billing purposes) while research data are primarily patient oriented (e.g., select patients with first diagnosis), which increases complexity of data transfer mechanisms between HIS and research database.

5. Conclusions

Single source information systems to connect patient care and clinical research have a great potential to increase efficiency of medical documentation processes, but more research is needed to address challenges such as common terminology standards as well as data quality and validation.

References