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Five-year experience with setup and implementation of an integrated database system for clinical documentation and research

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ABSTRACT

In radiation oncology, where treatment concepts are elaborated in interdisciplinary collaborations, handling distributed, large heterogeneous amounts of data efficiently is very important, yet challenging, for an optimal treatment of the patient as well as for research itself. This becomes a strong focus, as we step into the era of modern personalized medicine, relying on various quantitative data information, thus involving the active contribution of multiple medical specialties. Hence, combining patient data from all involved information systems is inevitable for analyses. Therefore, we introduced a documentation and data management system integrated in the clinical environment for electronic data capture. We discuss our concept and five-year experience of a precise electronic documentation system, with special focus on the challenges we encountered. We specify how such a system can be designed and implemented to plan, tailor and conduct (multicenter) clinical trials, ultimately reaching the best clinical performance, and enhancing interdisciplinary and clinical research.

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1. Introduction

In the age of intelligent information systems, data sharing in a medical environment remains a challenging objective [1]. The aim lies in ensuring that system architecture, communication protocols and usable procedures facilitate the interaction of data for any use, regardless of the point of origin of the information. This communication refers to the reuse of data by other systems in the same department, or healthcare networks (e.g. for telemedicine consultations and clinical referral), or collaborative research projects.

In the past, data from various information systems, which included both paperless and paper-based documentation, were used parallel within the clinical setting. Recently, information availability has become more elaborate and wide spread, and treatment decisions are based on a multitude of factors including imaging, molecular or pathological markers,

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surgical results and/or patient's preference. To avoid double documentation, loss or mix-up of data, and to provide a fast and reliable basis to collect all relevant data, interconnected information systems are developed. Relying on various quantitative data information becomes a strong focus, as disease management steps into the era of modern personalized medicine [2], thus involving the active contribution of multiple medical specialties. Gathering relevant data is therefore critical for reaching the best clinical performance, and enhancing interdisciplinary and clinical research – ultimately leading to optimizing treatment concepts, adjusting them, and developing new ones.

The achievement of building a new system uniting all these specifications is a challenging task from both a technical and non-technical point of view. Certainly, protecting patient privacy on all levels is of key importance and security mechanisms are required. Further, significant technical and architectural focus must lie on a vendor independent [3] and IHE (Integrating the Healthcare Enterprise) [4] complying concept with innovative methods and tools, thus, providing increasing flexibility and performance for the future.

Conducting clinical evaluations especially with large groups of patients is rather difficult in radiation oncology. Heterogeneous, distributed, voluminous amounts of data arise. This creates high complexity and involves considerable time and effort for analysis. As a result, it requires a precise methodical design to address these aspects in particular. The proposed method using an analysis system has the main goal to reduce time and effort for future clinical evaluations, ensuring high-quality data at the same time. Clinical experience during treatment will be transferred efficiently with the goal to improve therapy concepts. With advanced methods and tools complex problems can be processed in an understandable, transparent and reproducible way.

This interdisciplinary work contains two key aspects: a highly IT-focused setting and the application within an in-depth medical context. First task is designing a detailed concept, which includes the implementation of an analysis system. This system must be realized and gradually integrated into the clinical routine. Further steps are the set-up of an adaptable analysis workflow to electronically assess clinical research questions. Eventually, several tools for analyzing radiotherapy treatments are connected. The validation of the concept of the analysis and documentation system is performed by conducting multiple clinical evaluations. Using the analysis system, it will be possible to get sophisticated evaluations faster and with less effort. New intelligent infrastructures and analysis procedures in medical diagnostics and therapy will be enabled by integrating the analysis system into the clinical routine. The resulting adjustment and optimization of therapy concepts will improve clinical practice and patient care and, ultimately, shape modern medicine.

2. Background

The intention of clinical trials is to test new and promising diagnostic and therapeutic methods with the objective to improve existing standard treatments and diagnostics. Scientific relevant evaluations are conducted retrospectively or with prospective clinical trials. With focus on current guidelines these new treatment concepts can identify prognostic and outcome-relevant parameters. Particularly in oncology, where treatment concepts are elaborated in interdisciplinary collaborations, handling large heterogeneous amounts of data efficiently is essential for an optimal treatment of the patient as well as for research itself – as Reboussin et al. [5] stated "good science requires good data".

The last decades showed enormous technical advances in radiation oncology, for instance introducing particle therapy with protons and carbon ions into clinical routine [6,7]. Especially radiation oncology is a highly image intensive medical specialty. Diagnostic and therapeutic data acquisitions are acquired throughout the course of treatment and during follow-up. Hence, not only heterogeneous and large amounts of data must be evaluated, it is also spread across various information systems within several involved departments in a large variety of documentation styles [8,9]. Involved systems are the Hospital-, Laboratory- and Oncology Information System (HIS, LIS, OIS), Picture Archiving and Communication System (PACS) and Record & Verify System. Researchers need assistance in reusing the terabytes of invaluable information collected routinely in all separate information systems. They hold treasures that are hidden in the deep [10].

Therefore, to date, retrospective clinical analyses, especially with large groups of patients, involve an immense time effort [11–13]. However, these evaluations provide important information about the efficacy of therapy, side-effect profiles or data for clinical quality assurance. Accordingly, these analyses are highly relevant [14].

Combining patient data from all involved systems is essential to prepare unstructured data for the analysis of retrospective and also prospective clinical trials. This demands special coordination in data management [11,15]. Such centralized repositories are non-existent in the medical enterprise [16,17]. Thus a documentation and data management system integrated in the clinical environment for electronic data capture needs to be introduced. This approach is a challenging task, but with researchers willingness for improvement, it offers many advantages regarding data collection, monitoring as well as analyzing and validation [11,18–20]. Key goal of the approach is to add an additional, built-in possibility to use the documentation system for immediate analysis of the collected data [21]. To establish such a documentation and analysis system, necessary workflows must be characterized and technical as well as clinical requirements regarding the subsystems must be defined.

The combination of medical image data with all other relevant documentation parameters or trial documentation, as well as the integrated analysis possibilities distinguishes the presented approach from other documentation systems and allows an improved outcome analysis for the future. The solution differs from other systems, which either only manage and organize patient treatment within a single department or other numerous strategies only focused on electronically documenting a single clinical trial (see Table 1). Our approach combines both: On the one hand, a common platform was created, that allows the coordination of clinical trials in radiation oncology even across departments and country borders. On the other hand, the system was linked