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Electronic health records and clinical trials research in the digital age

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"The next two decades will see the transformation of the patient record from a paper-based document to a full EHR."

Electronic health records (EHRs) have promised to revolutionize and improve the quality of healthcare. Globally, EHRs are making patient information more accessible to health professionals and are helping healthcare administrators with their organizational and population-level healthcare-related decision making. EHRs are electronic repositories of a patient's lifetime health information [1]. EHRs are held by healthcare organizations (i.e., physician offices, clinics, hospitals, regional health authorities and governments) and are used by authorized healthcare providers [1]. Fully implemented EHRs also have the ability to revolutionize and improve research by providing clinical trials researchers with opportunities to:

- Access data that is part of the patient care process;
- Use past patient data to improve the quality and design of future clinical trials;
- Improve recruitment of patients for clinical trials for those that have consented to be contacted;
- Enable better understanding of the use of products in chronically ill subjects;
- Provide opportunities to engage in more effective post-marketing and adverse drug events surveillance [2,3].

Although EHRs are being implemented worldwide by healthcare organizations, many challenges remain. Healthcare organizations are only beginning to move towards implementing all of the components of a full EHR. Clinical trial investigators need to navigate this new hybrid environment as healthcare organizations transition to full EHRs [4,5]. The impact of the move to a full EHR will be significant for clinical trials researchers for decades to come, given current rates of adoption and the current state of implementation of technology.

Research indicates that North American (i.e., Canadian and US) hospitals are in the early stages of EHR adoption. Statistics indicate that 2.4% of Canadian hospitals have implemented between 91 and 100% of the EHR, 29.3% have implemented between 51 and 90% of the EHR, 39% have implemented 11–50% of the EHR, and the remaining 29.3% of hospitals have implemented 0–10% of the EHR [6]. Most (i.e., 97.6%) Canadian hospitals are moving towards implementing full EHRs [1], with 50% of Canadians having at least one component of their patient record in electronic form (e.g., clinical documentation, laboratory results or diagnostic imaging reports) [7]. The situation is much the same in US hospitals. Only 1.5% of US hospitals have indicated that they have a comprehensive EHR on all of their clinical units. A total of 7.6% have a basic EHR system plus clinician notes (consisting of clinical documentation, laboratory results, diagnostic imaging reports, medication lists, physician

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notes and nursing assessments being electronic, with the remainder of the patient record remaining paper based) on at least one hospital unit. A total of 10.9% of US hospitals have a basic EHR (consisting of clinical documentation, laboratory results, diagnostic imaging and radiologic reports and medication lists being electronic, with the remainder of the patient record remaining paper based) on at least one hospital unit. A total of 98.5% of US hospitals are in the process of implementing an EHR [8]. The situation is much the same in other technologically advanced countries (e.g., UK, Denmark and Sweden) as hospitals and regional healthcare organizations are in the process of implementing EHRs and their components [9].

Over the next decade, clinical trial managers will need to adapt to this new healthcare environment. The biggest of these challenges for clinical trial investigators is an understanding of how to effectively work in a hybrid environment, where part of the patient record is electronic and part of it is paper based [4,5]. As healthcare organizations transition from pure paper records to electronic record components with a partial paper record (i.e., hybrid environment), and finally to a full EHR, clinical trial researchers need to understand how to effectively tap into the power of extracting and analyzing data from EHR databases, while at the same time effectively obtaining data from a paper patient record.

The next two decades will see the transformation of the patient record from a paper-based document to a full EHR. From a clinical trial perspective, the impact of this transformation is significant as clinical trial researchers will need to adapt to a hybrid electronic–paper environment in the interim period [4,5]. During this period, the implementation of components of the EHR will be variable internationally [9]. Differing healthcare organizations will implement differing components of the EHR, as there are no standardized sequential approaches to implementing EHR components [4,5,7–9]. Adoption will remain slow in some countries, as EHRs are difficult to implement successfully [10–12]. Current forecasts suggest the next decade will continue to be focused on moving healthcare organizations to full EHRs.

Hybrid electronic–paper records present several challenges for clinical trial researchers:

- Data are spread out across both the paper patient record and the EHR;
- EHR data are more easily extracted from EHR databases, while other patient data requires access to the paper chart;
- Differences between the type of data collected between differing vendor EHRs and local healthcare organization EHR customizations lead to there being data elements represented differently, even between EHRs from the same vendor product and even within the context of a single vendor's EHR (i.e., customization of an EHR to local healthcare site may change the data elements that are collected in the process of care);
- Data quality issues arise from differences between the types of data recorded in the combined hybrid electronic–paper record;
- Some EHR software has the ability to support clinical trials, while other EHRs only support health professionals providing direct patient care. In the upcoming decade, clinical trial researchers will need to understand their local healthcare organization's EHR and learn how data are collected [2–5].

To address this, clinical trial researchers need to understand how the implementation of EHRs and hybrid environments will affect clinical trials and develop interim solutions to these changes as organizations progress from hybrid electronic–paper EHRs to full EHRs. A strategy should include a working knowledge of the current state of your local, regional and national EHR implementation. Find out the planned sequence and timing of your local healthcare organization's EHR component implementations (as many organizations implement EHRs incrementally over a period of several years). Find out the state of EHR implementation in partnering healthcare organizations (e.g., hospitals, clinics or regional health authorities). How many components have been implemented? What vendor system has been implemented? Has the EHR been customized to the local healthcare organization and how? Additionally, determine if the vendor EHR system that has been implemented (or if the local healthcare organization is considering an EHR for purchase) contains features and functions that would support clinical trial research [2,3].

Some EHRs have been only designed to support patient care and may not have a robust clinical trial functionality. Clinical trials research support may include:

- Data warehousing and analysis capabilities;
- Clinical trial registration and visit scheduling functionality;
- Subject accruement support;
- Source documentation about patients;
- Clinical trial relevant ordering and testing;
- Routing of charges to research funding agencies [3].

First, clinical trial investigators need to determine if their local healthcare organization has an EHR that could support clinical trials research. If the local

healthcare organization's EHR does support clinical trial research, the researcher needs to ask about the functionality that it does have. For example, does the local healthcare organization's EHR have the capability to integrate with a data warehouse and are there analysis capabilities? Such information will influence how studies are conducted [3,4]. Obtaining this information is key to understanding how a clinical trial could be conducted and planned within an organization.

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Currently, the state of EHR knowledge allows researchers to identify which components of the EHR are implemented, what data elements are being collected today and into the future, as well as whether the data can be used in supporting clinical trial execution. This will affect clinical trial design, implementation and data collection practices. Such information about EHRs that are implemented in local healthcare organizations can be obtained from the research and information management and information technology departments of the local healthcare organization. Both departments should be consulted. Developing a good understanding of the current and future plans of the local healthcare organization's plans for implementing an EHR, determining which components of the EHR have been implemented and learning about the clinical trials functions of the EHR itself will help researchers to more easily design and conduct clinical trials.

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