Electronic Health Records in Clinical Research

Background
The first reference to the creation and usefulness of a patient electronic medical record may have been the visionary writing of Robert Ledley and Lee Lusted in 1959, *The Use of Electronic Computers to Aid Medical Diagnosis*. The authors speculated about the use of computers to “record and recall desired aspects of a particular patient’s total medical record” (Ledley & Lusted, 1959). Interestingly enough, the concerns of the authors around the validity of input information, the standardisation of coding procedures, and privacy and confidentiality are the same issues that challenge the healthcare community more than 50 years later.

Between 1959 and 2000, speculation and research into the usefulness of electronic health records continued to grow. By 2005, scientists from around the world were debating over the impact of the electronic storage, dissemination, use, and security of information in medicine and laying out the roadmap for its implementation (The 2020 Science Group, 2005). Despite the many concerns around the practical application of electronic health records (EHR) in a variety of settings, it is agreed that if used correctly, they will revolutionise clinical research as well as patient care (Powell & Buchanan, 2005). In particular, utilising EHRs in clinical research can simplify retrospective and prospective studies, reduce medical errors, improve protocol/study feasibility, and aid in subject identification/patient recruitment.

Access to qualified EHR data allows researchers
- Access to historical data that may impact study eligibility
- To locate AE data directly from EHR
- To identify safety concerns or exclusionary criteria prior to patient enrolment
- Protocol Feasibility EHRs give researchers access to large cohorts of patients to

EHR Usage – United States
It was not until 2009 with the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act that entities in the US began to respond and take action toward implementing systems that would allow them to use EHRs effectively. HITECH allocated $2 billion to the National Coordinator for:

- Infrastructure to allow for the electronic exchange and use of health information for each individual in the United States;
- Updating the Department of Health & Human Services’ technologies to allow for the electronic flow of information;
- Integrating health IT education into the training of healthcare professionals; and,
- Promoting interoperable clinical data repositories.

In addition, the HITECH Act directed the Office of the National Coordinator for Health Information Technology (ONC) to promote the adoption and meaningful use of EHRs. As a result, the ONC adopted an initial set of HIT standards, created an incentive programme for meaningful users of EHR certified technology; developed a policy framework for the development and adoption of a nationwide health information infrastructure, including standards for the exchange of patient medical information; and developed standards, implementation specifications, and certification criteria for the electronic exchange and use of health information.

In the last five years
- Hospital adoption of at least a Basic EHR system more than tripled since 2009, increasing from 12% to 44% (Figure 1).
- The percentage of hospitals possessing a certified EHR technology increased by 18% between 2011 and 2012, rising from 72% to 85%.

Adoption of EHR systems by non-federal acute care hospitals has steadily increased since HITECH. In 2012, 44% of non-federal acute care hospitals had adopted at least a Basic EHR system with clinician notes. This represents a 61% increase from the previous year and a more than threefold increase in EHR adoption since 2009. In addition, a vast majority of acute care hospitals (85%) possessed EHR technology certified as meeting federal requirements for Meaningful Use objectives (Charles, King, Patel & Furukawa, 2013). This growth sets the groundwork for the use of EHRs to aid in the recruitment of clinical trial participants.

As the use of EHRs grows every year, clinical data, previously available only from paper charts, will become exchangeable, databases will store volumes of medical data never even imagined before and unprecedented opportunities for clinical research will be created. Today, healthcare practice generates a huge volume of patient-specific data in EHRs and ancillary databases, including digital images and genome sequence data.
However, there is still a great deal of work to be done before EHR data can be successfully used on a wide-scale basis for clinical research purposes in the United States. To do so, many features are required:

- Structured data capture
- Processes to ensure the correctness, completeness and accuracy of the data within the EHR system
- Security systems to protect confidentiality and data integrity so they meet the standards required for good clinical practice

Unfortunately, most EHR systems in the United States do not have these features (Coorevits et al., 2013). On the upside though, with the significant uptake in EHR adoption rates, experts still expect 90 per cent of physicians in the US to adopt an EHR system by 2019 (Hanrahan, 2013).

EHRs in Europe

In 2004, the European Federation of Pharmaceutical Industry and Associations (EFPIA) led a consortium of industry, government and public sector organisations in an effort to accelerate the development of new, safe, and more effective medicine in Europe. This movement was in response to the increasingly high public sector investment in drug development in the US compared to Europe. The goal of the consortium was the identification of the main barriers to European innovation in biomedical research and the development of a European Technology Platform to overcome those barriers and reverse the decline in pharmaceutical R&D investment in Europe.

Several research projects and initiatives focusing on the use of EHRs grew from the work of the consortium. The Electronic Health Records for Clinical Research (EHR4CR) project is one such project. The four-year programme was launched in 2011 and involves 35 academic and private entities, including 10 pharmaceutical companies and 11 hospital systems. The goal of EHR4CR, with a 16 million Euro budget, is to demonstrate how EHR data can be reused to improve the clinical research process across international borders while still protecting privacy (Coorevits et al., 2013). This goal will be achieved by the creation of a technical platform to re-use EHR data to:

- Transform clinical research models to bring innovative medicines to market faster and at a lower cost
- Enhance efficiency and success rate of clinical research – i.e. speed it up and make it more efficient
- Create a uniform system of research and information exchange by reusing existing longitudinal patient-level data available in electronic health records (EHRs) (Kalra, Schmidt, Dupont, Sundgren & De Moor, 2013).

To date, the EHR4CR has made significant progress toward its goal. A protocol feasibility pilot programme was launched in 11 hospitals across five countries (Germany, France, US, Switzerland, and Poland) to evaluate 12 clinical studies in different therapeutic areas. The pilot programme was
successful on 80% of defined criteria: the successful retrieval of information from hospital EHR4CR-compliant data warehouses; timely response; patient counts validation (EHR chart review to validate ongoing precision); and transnational platform across systems, hospital, and legal frameworks. The pilot programme succeeded in overcoming issues of interoperability as clinical data was successfully used from five million people (Duga & Cuggage, 2014) using 446 million data points.

EHRs for Patient Recruitment

EHRs are already being used on a limited scale to recruit patients for specific clinical research studies. In some health systems, data searches are launched using select terms relevant to the condition being studied, such as disease, sex, age, and/or medication, to identify individuals who meet certain I/E criteria and may be qualified for study participation. The individual’s physician receives an alert via the EHR indicating that the patient may be qualified. The physician has the option, at that time, to inform the patient of their potential eligibility. The alerts contain links with additional study information and details on how to contact an investigator.

In the US, several ‘early adopters’ have successfully leveraged EHR systems to recruit clinical trial participants:

- The Mayo Clinic may very well be the pioneer in utilising EHR data for patient recruitment. Using natural language processing (NLP), the investigators at Mayo have successfully leveraged access to EHR data to locate and enroll patients for various CV trials.
- Another early adopter is Penn Medicine, part of the University of Pennsylvania Health System. The clinical trial application Penn Research Trial Advisory, which took several months to develop, delivered promising results in 2011 by increasing physician referrals to an ob-gyn study by 87% (McGee, 2011).
- Geisinger Health Plan also proved that EHRs helped to recruit and enroll clinical trials patients quickly and effectively. As one of 600 medical centres participating in a study of a new drug which is aimed at lowering the risk of heart attacks and strokes in those with coronary heart disease, Geisinger used queries of the health system’s EHR data to identify over 5000 patients who matched at least 20 criteria for the study. Eventually over 100 patients recruited using this method were successfully enrolled (Simmons, 2011).

There are many more examples, just as limited in nature as those noted above, of medical centres, healthcare systems, and researchers successfully utilising EHR data to recruit clinical trial patients. The problem is, though, that each case is limited to within the confines of a healthcare system. There are far fewer examples of cross-healthcare system recruitment – if any exist at all. However, patient recruitment is, more often than not, the first or second benefit that researchers list when discussing the future use of EHR for clinical research (Safran et al., 2007).

The Future Possibilities

According to the Office of the National Coordinator for Health Information Technology (ONC), more than 50% of office-based physicians were using some kind of EHR in 2012, up from 17% in 2008 (U.S. Department of Health and Human Services, 2013). While major challenges of interoperability and privacy remain, EHR systems have the potential to provide a communication platform across institutions, connecting the data of millions of individuals with researchers and public health officials.

Researchers, policy-makers, and any number of government agencies predict a wealth of opportunities to apply patient data contained in EHRs to advance scientific discovery and accelerate the drug to market timelines (Prokosch & Ganslandt, 2009). Realising these opportunities and the potential of EHR data requires an understanding of what EHRs can realistically contribute, as well as the limitations of obtaining and utilising the data. In the perfect world, the use of EHRs would enable patient data to be collected just once across all providers; that data could be repurposed for a wide variety of applications; the flow of data between healthcare providers of all kinds would be seamless and streamlined; and the burden on data providers and collectors would be reduced (Friedman, Parrish & Ross, 2013).

There are presently several projects or initiatives underway that paint a picture of what the future holds for clinical research. One of the most progressive and forward-thinking might be the Patient-Centered Outcomes Research Institute’s National Patient-Centered Clinical Research Network Program. The goal of the programme is to improve the nation’s ability to conduct clinical research by creating a large, highly representative electronic data infrastructure for conducting clinical research that includes broader participation of patients, researchers, health systems, and payers (Patient-Centered Outcomes Research Institute, 2013).

The proposed National Patient-Centered Clinical Research Network would be overseen by the PCORI and a scientific advisory board with special experts brought on-board as needed. A coordinating centre would provide project-management support, technical resources, meeting support, and programme evaluation. The core components of this network will be clinical data research networks (CDRNs) which are healthcare delivery system-based networks that have the potential to become an ideal electronic network, without structural impediments, and patient-powered research clinical data research networks (PPRNs) which are groups of patients interested in forming a research network and in participating in research.

The PCORI is making $72 million in funding available to help make this vision of the future a reality (Patient-Centered Outcomes Research Institute, 2013). The network components will be responsible for creating and maintaining synergies and efficiencies that partner patients with researchers. This will only be possible if EHRs are vastly improved and their use implemented across a vast majority of healthcare institutions in the US.
After a long period of inaction, much progress has been made towards effectively utilising EHRs for clinical research purposes, specifically for patient identification and recruitment. However, as noted throughout this paper, even more significant action is required for wide-scale use of EHRs for these purposes. With the increasing cost of patient recruitment and increasing demands by the FDA for larger trials, what can be done today to facilitate the process?

Just as the clinical data generated from a clinical trial needs to be analysed across different source systems, the disparate data collected from a multitude of proprietary and in-house EHR systems needs to be mined so that potentially eligible trial participants can be identified. Waiting for thousands of electronic systems to adopt a common data set is not feasible, not to mention that those healthcare systems and countries are only now migrating from paper-based records. This wide variety of patient data can be viewed and queried against eligibility criteria while maintaining its present structure and security using a system similar to a clinical data analytical system.

Virtual, on-demand data warehouse analytic-based systems are capable, today, of analysing huge disparate data sets and providing sponsors with clinical data solutions that cross-correlate data from multiple source systems so mission-critical decisions can be made using real-time analytics. So it is with EHR systems and data. This new technological approach does not focus on the problem of incompatible systems and disparate data, but on understanding and correlating the data – on finding connections and meaning – determining how the data from various EHR systems work together. All of the combined data can be analysed in one place; source systems remain untouched, with minimal impact on the source systems. Source system data is initially loaded into the cloud and only when new data is introduced, that data is read into the system. Critical queries can be designed to run against updated patient data as often as necessary depending upon the needs of the sponsor or CRO. Furthermore, as source EHR systems are updated to comply with HITECH’s meaningful use requirements, the system constantly analyses the connections between the source data and the combined data set to validate the quality and accuracy of the data.

A robust and long-term solution is required so that EHR data can be used to its fullest extent to improve the quality, safety, and efficiency of healthcare for not only Americans but also people around the world. As we move towards that future, revolutionary SaaS-based analytic solutions built on a virtual, on-demand data warehouse provide sponsors and CROs with the ability to analyse and utilise disparate clinical and EHR data creating a single source of truth – a solution of
the future, TODAY.

Next Steps

The future of EHRs as a clinical trial patient recruitment tool is clear. To deal with the increasing complexity of trials and associated costs, a new way to source eligible and willing participants is necessary. EHRs are one of several tools that can help to accomplish this providing:

- EHR data is at the level of accuracy and completeness required for valid research
- Patient privacy concerns are addressed and mitigated
- Healthcare system business managers understand that using EHR data for clinical research recruitment aligns with the primary role of the institution – healthcare delivery
- The bridge between clinical information system (CIS) and clinical research environment (CRE) - functionality

Success will depend on wide-scale efforts to bridge patient and researcher priorities and concerns and to create technologies to develop interoperable EHRs that safeguard patient data but make it available for eligibility queries nationwide.

References


Ben McGraw is the vice president of marketing at Comprehend. Prior to joining Comprehend, McGraw served as a director of life science industry solutions at TIBCO Software, Inc. McGraw holds a B.S. in business computer systems from Pepperdine University and the University of Southern California.

Email: bmcgraw@comprehend.com