



The Possibility of Using Electronic Medical Records for Clinical Observation

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Abstract

Today, the health care system accumulates and concentrates colossal material on the information of patients who are at the doctor's office, collected and accumulated from electronic medical records (EMR). The possibilities of EHR are not only enormous in clinical practice, but also have great potential for clinical research.

EHRs are a unique database from which information for large research projects can be obtained using various methods and methods.

One of the major application challenges for collaborative research in expanding the use of EMC are issues of semantic interoperability, privacy, and security.

Currently, consensus and standards of international associations involved in the development of protocols for the use of EHR have been formed, which can provide the semantics of clinical information and semantic compatibility between different systems.

When using EMR in clinical trials, a basic rule should apply. EHR can combine data from clinical trials from different centers according to the study protocol to allow identification of different study methods and different patient populations.

International standards for the interoperability of information structures published in recent years have made it possible to create such management systems that have the ability to record and exchange data between different groups of patients and clinics.

With the help of the created systems, it becomes possible to eliminate complications when using various clinical languages and styles of documentation, as well as unfinished routine records.

Keywords: Electronic Health Record; Unified Structure of Electronic Health Record; Numerous Studies; Compatibility

Recent decades of progress in healthcare information technology have changed the way we provide care and the way we document medical data.

Currently, healthcare practice generates data exchange and stores a huge amount of patient-specific information [1,2] in electronic medical records (EMC) and auxiliary databases, in particu-

lar in genetic databases, or huge amounts of information obtained from studies of digital images.

Clinical and observational clinical and prophylactic research centers are increasingly paying attention to repeated visits with the corresponding secondary use of clinically recorded data to optimize and effectiveness of disease prevention and treatment strategies [3].

In the ongoing studies, a comprehensive analysis of the clinic, concomitant diseases, stratification of patient risk, as well as the interaction of drugs from various clinical databases is carried out.

A serious factor for the successful use of available data in ongoing research is the access, management and analysis of integrated patient data both within and between different functional areas.

For example, most clinical and basic research data is currently stored in disparate and separate systems, and it is often difficult for clinicians and researchers to access and share these data. Very often, much clinical and basic research data resides in disparate and separate systems that are often difficult for clinicians and researchers to access and share. In addition, ineffective workflow management in clinics and research laboratories creates many barriers to decision making and evaluating results [4].

In this case, in search of rational grain and truth in these sets of information, various innovative methods are used [5].

There are various methods for obtaining data when conducting research projects.

For example, integrated EMC has some unique capabilities.

It is essential today to remove barriers to semantic interoperability, privacy, and security in order to expand the use of EMC.

In 2011-2016 the largest project in this area was carried out EHR4CR (electronic medical record 4 clinical research) in which 35 academic and 10 pharmaceutical companies, 11 hospitals in France, Germany, Poland, Switzerland and the UK participated with a budget of 16 million euros, sponsored by the European Commission as part of the Initiative on innovative drugs [6].

The EHR4CR project has created a robust and ever-changing platform in which the EMC systems in full analogy with moral, setting standards, in full compliance with the ethical, regulatory and protective requirements of each participating country.

The platform was securely connected to EMC hospital systems and clinical data repositories throughout Europe.

One of the key aspects was that patient data never left the database of connected hospitals.

EHR4CR showed that such a platform can significantly increase the efficiency of developing and conducting clinical trials, reduce time and costs, and most importantly, optimize assessment of protocol implementation, speed up patient recruitment, make research more efficient, and increase research revenue.

What is a clinical trial?

There are many different types of research projects that are combined with the term "clinical research". In particular, for example, controlled clinical trials.

This type of research is very important because thanks to them, there are opportunities for obtaining an evidence-based and effective database.

Often, research projects are not related to therapy, but study, for example, the natural course of diseases, diagnostic criteria, or study the role of genes in the development of diseases and their relationship with the influence of various drugs. Some clinical studies relate to the health system with an analysis of the effectiveness of various organizational structures, including the provision of medical care and medical expenses.

Such studies require clinical records, as well as data that can be stored in various administrative databases for patient care or for reimbursing facilities.

Such clinical trials use structured and descriptive medical records from EMC, as well as from special laboratory databases, image databases, genetic analysis databases, as they are in most cases stored in separate systems. Therefore, the creation of a new federal EMC paradigm will be an important tool for conducting interagency clinical research.

Some of the main sources of medical information that can be used for scientific research.

- Electronic medical record in one institution. Advantages. Simple management. Simple management. Full clinical content of structured and unstructured data. Semantics are the same for everyone. Disadvantages. Too few cases to conduct serious research. Sometimes there are no universal research methods.
- Specific disease registries at regional or national level (often referred to as quality registers). Advantages. Data is collect-

ed from several institutions. Comparison of results and large samples is allowed. Well defined parameters data variables. Disadvantages. A limited and fixed dataset that is rarely defined. In addition to the collected data, other data are not analyzed. Sophisticated rights management. However, in some cases it is possible to transmit data from the EMC. Often double registration: in the EMC and in the quality register.

- A specific research database system for a specific project (for example, a regulated clinical trial). Advantages. Very well-controlled data, including functions to provide support for the project process and its competent support. Disadvantages. Expensively set up for one project. High probability of additional work for medical personnel, because data cannot be extracted from EMC, as well as data transfer from a screen or paper to a research electronic system
- Federal or integrated system of electronic medical records (IEMC) and special tools for research projects. Advantages. It is possible to include a large number of patients, especially with the participation of government agencies for conducting international studies. Disadvantages. Semantic compatibility and agreement are difficult to manage.

What is now most often called EMC was created back in the 1960s. It is interesting to note that many of the enthusiasts already understood the possibilities and importance of the transition from paper to electronic recording systems.

Despite this, future progress of clinical information systems was mainly focused on center for improvement of administrative processes, for example, taking into account the use of expenses, although recently the direct provision of clinical care. Unfortunately, early attempts to structure data entry were replaced by free text narration (letters, reports, and progress notes), mainly dictated by the doctor, sometimes using speech text support.

The transition to EMC was far from uniform in different parts of the world and did not reflect general developments in the field of information technology.

For example, in Scandinavia and the UK, electronic systems were first introduced in primary care clinics, while in other countries, the foundation was laid by university clinics based in large hospitals.

Although many countries and the world are still a long way off to stop using paper documents, but in recent years there have been revolutionary changes in digitalization that today in many countries almost 90% of all medical documents are digital. For example, a sharp increase in the use of EMC in the United States was mainly due to government financial incentives. An early analysis of doctors' reports by Desroches CM. et al. on the adoption and ease of use of EMC, showed that "43.5% of doctors reported that they had a basic EMC, but 9.8% met the criteria for "significant use", i.e. few doctors could meet significant criteria for use, and as a result, the use of computerized systems was difficult" [7].

Despite the current EHR systems that support the needs of established research today do not provide a sound basis for clinical research.

The effective use of EMC systems for clinical research requires a number of functions, which, unfortunately, are often missing. In addition, the collection of structured data requires functions to ensure the correctness, completeness and accuracy of data in EHR systems [8,9].

Equally important is the provision of safety systems in the EMC, with confidentiality, integrity and overall reliability, to meet the needs for high-quality scientific data [10-12] including regulated clinical trials, where recognized ethical and scientific quality requirements for research [13]. Mechanisms are now needed that will not only ensure quality, but will also ensure that these EHR systems meet certain quality characteristics.

Therefore, the certification of EMC is important to ensure its quality. High level of data refers to completeness, correctness, correctness, consistency, reliability and relevance [9,14].

Given the poor quality of many legacy EMC systems, it is not surprising that their use in clinical trials is limited. But, some countries invest heavily in such registries. For example, Swedish research by Porter SC. et al. in which "quality registers" are observed, they collect high-quality data, the analysis of which allows preparing international publications that significantly affect the development of medical science and practice" [15], which was demonstrated in the Swedish Heart Failure Register.

EMC used for research usually always have a number of problems. First, EMC systems have markedly different repositories (server-storage), and secondly, the methods by which clinical information is entered into the database are radically different.

The use of EMR in clinical trials always implies the possibility of compatibility of input information in accordance with the acceptance criteria of the protocol, clinical trial data elements, EMS data for one purpose only, to ensure the identification of patient groups.

In the last years of this millennium, all the developments carried out in the field of health informatics have been concentrated on developing approaches to combining heterogeneous electronic medical records with one single goal - the possibility of semantic interpretation [16].

The combined efforts of a variety of international associations that develop standards have led to the creation of standards for both the structure and semantics of clinical information, which could ensure semantic compatibility between different systems. At present, three main areas dominate at the international level.

Firstly, the recently approved standard ISO EN 13606, which is a common and comprehensive representation for the exchange of information on EMC between heterogeneous systems. The standard is intentionally very simple in order to minimize the burden on doctors, especially if it is associated with a display in or out of an intermediate view. It is ideal for extracting, transmitting and/or displaying EMC data, including fine-grained parts of EMC [17].

Secondly, the open-EHR Foundation standard, which supports a specific model that meets the widest range of different patient-level data usage options. Ideal for implementing an integrated EMC system as a persistence model. This standard can be seen as an extension of the formal standard ISO 13606 [18].

Thirdly, the HL7 Reference Information Model (RIM) and the HL7 Clinical Document Architecture (CDA HL7), which are designed to “transmit a single clinical document as a message and are therefore ideally suited for a messaging environment in which version 3 of HL7 is already used and for other purposes where a message is required for one document at a time (for example, a summary of an extract)” [19].

All of these standards use a “semantic multi-level” approach to presenting the meaning of the clinical information they contain [20,21]:

- General reference information models that can represent the general characteristics of any clinical information, such as authorship and responsibilities, dates and times of observations, version control, access policies and digital signatures. It is important to note that these models require a related, reliable data type model, such as that defined in ISO 21090;
- More detailed clinical information structures (13606/open EHR archetypes and CDA HL7 templates) that reflect the documentation of specific details in EMC, such as breathing difficulties, heart sounds, echocardiogram, differential diagnosis or prescribing; [22] and
- Clinical terminology systems, such as the International Classification of Diseases (ICD) or SNOMED-CT, which provide a range of possible values for each element in the information structure.
- The current Clinical Data Exchange Standards Consortium (CDISC) has created platform-independent standards that support the collection, exchange, submission to regulatory authorities, and subsequent archiving of clinical trial data.

For example, the published Protocol Presentation Model (PRM) and Study Design Model (SDM), which can assist in providing institutions with accurate, machine-readable, interchangeable descriptions of their clinical trial plans [23].

Conclusion

EMCs have tremendous potential to support clinical research. However, to achieve this, there are a number of problems, and perhaps soon regularly collected data in the EMC will be able to replace the traditional clinical trial workflows. Nevertheless, modern EMCs combined with a platform that supports semantic compatibility can be used in clinical trials that go beyond a single institution. The European research initiative EHR4CR plays an important role in developing innovations to support federal clinical research based on the semantic integration of various EMC products between organizations. Consequently, advanced integrated EMCs can provide innovative solutions to advance medical care and revolutionize clinical research.

Authors' Contributions

All authors meet the ICMJE criteria for authorship, participated in the preparation of the article, the collection of material and its processing.

Conflict of Interest

The author declares no conflict of interest.

Bibliography

1. Kimberly A., *et al.* "Current use and costs of electronic health records for clinical trial research: a descriptive study". *CMAJ Open* 7.1 (2019): E23-E32.
2. Beck T., *et al.* "Knowledge engineering for health: a new discipline required to bridge the "ICT gap" between research and healthcare". *Human Mutation Variation, Informatics and Disease* 33.5 (2012): 797-802.
3. Laszlo Vasko., *et al.* "Smart Program Design Through a Common Information Model". *Therapeutic Innovation and Regulatory Science* 49.1 (2015): 116-125.
4. Geissbuhler A., *et al.* "Trustworthy reuse of health data: a transnational perspective". *International Journal of Medical Informatics* 82.1 (2013): 1-9.
5. Jensen PB., *et al.* "Mining electronic health records: towards better research applications and clinical care". *Nature Reviews Genetics* 13.6 (2012): 395-405.
6. Innovative Medicines Initiative (IMI). Electronic Health Record Systems for Clinical Research (EHR4CR).
7. Desroches CM., *et al.* "Meeting meaningful use criteria and managing patient populations: a national survey of practicing physicians". *Annals of Internal Medicine* 158.11 (2013): 791-799.
8. Hayrinen K., *et al.* "Definition, structure, content, use and impacts of electronic health records: a review of the research literature". *International Journal of Medical Informatics* 77.5 (2008): 291-304.
9. Weiskopf NG and Weng C. "Methods and dimensions of electronic health record data quality assessment: enabling reuse for clinical research". *JAMA* 20.1 (2013): 144-151.
10. De Moor G., *et al.* "Policy brief on the current status of certification of electronic Health Records in the US and Europe". *Studies in Health Technology and Informatics* 170 (2011): 83-106.
11. Hoerbst A and Ammenwerth E. "Electronic health records. A systematic review on quality requirements". *Methods of Information in Medicine* 49.4 (2010): 320-336.
12. Hoerbst A and Ammenwerth E. "Quality and Certification of Electronic Health Records: an overview of current approaches from the US and Europe". *Applied Clinical Informatics* 1.2 (2010): 149-164.
13. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP) (2002).
14. McCormack JL and Ash JS. "Clinician perspectives on the quality of patient data used for clinical decision support: a qualitative study". *AMIA Annual Symposium Proceedings 2012* (2012): 1302-1309.
15. Kimberly A., *et al.* "Using electronic health records for clinical trials: Where do we stand and where can we go?" *CMAJ* 191.5 (2019): E128-E133.
16. Black AD., *et al.* "The impact of eHealth on the quality and safety of health care: a systematic overview". *PLoS Medicine* 8.1 (2011): e1000387.
17. Weng C., *et al.* "Using EHRs to integrate research with patient care: promises and challenges". *JAMIA* 19.5 (2012): 684-687.
18. Botsis T., *et al.* "Secondary use of EHR: data quality issues and informatics opportunities". *Summit on Translational Bioinformatics 2010* (2010): 1-5.
19. Kopcke F., *et al.* "Evaluation of data completeness in the electronic health record for the purpose of patient recruitment into clinical trials: a retrospective analysis of element presence". *BMC Medical Informatics and Decision Making* 13 (2013): 37.
20. Kahn MG., *et al.* "A pragmatic framework for single-site and multisite data quality assessment in electronic health record-based clinical research". *Medical Care* 5 (2012): S21-29.

21. Ovretveit J, *et al.* "Continuous innovation: developing and using a clinical database with new technology for patient-centred care-the case of the Swedish quality register for arthritis". *International Journal for Quality in Health Care* 25.2 (2013): 118-124.
22. Coorevits P, *et al.* "Electronic health records: new opportunities for clinical research". *Journal of Internal Medicine* 274.6 (2013): 547-560.
23. Health informatics - Electronic health record communication - Part 1: Reference model (ISO 13606-1:2019). Irish Standard I.S. EN ISO 13606-1 (2019).