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Review Article

The need for Electronic Health Records (EHR) based Clinical Decision Support (CDS) in developing countries like India

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Abstract

Electronic health records (EHRs), an integrated approach is gaining importance not only within healthcare organizations and with their related stakeholders but also with the clinical research studies. EHR-based clinical decision support (CDS) systems in clinical studies have been proven successful in many clinical studies. The World Health Organization has emphasised the necessity to revolutionise the healthcare system in all levels, from primary health care and community service to health care research and this started with the implementation of EHR services extensively in various health care systems. Further, American and European healthcare systems are keen in improving EHR-based measurements to enable interoperability for future integrations of multiple data sources, which in turn would prove beneficial in the global platform for not only to the provider, patient, and other healthcare stakeholders but also for clinical research studies. This paper discusses the EHR in clinical research, the challenges in the EHR, and the need for developing nations to adopt and develop EHR.

Keywords: Clinical Research; Clinical decision support (CDS); Electronic health records (EHR); Electronic Medical Records (EMR); Algorithms

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1. Introduction

Electronic health record's (EHR's) rapid advancement in healthcare has a considerable significance in clinical research. According to Komathi Stem, MSE, founder and CEO of monARC Bionetworks (1):

"The sheer tsunami of healthcare data available from medical records and the growing use of mobile and digital sensor technologies to collect health data, combined with rising online patient engagement in health care and research, present an unprecedented opportunity to modernize clinical trials through greater collaboration with patients and their clinical care systems."

Vast requirements and procedures in the healthcare limit the usefulness of this information for the improvement of healthcare research studies. Therefore, in 2008, the Innovative Medicine Initiative project developed adaptable, reusable, and scalable solutions for reusing data from EHR systems for clinical research

purposes. (2) Similarly, In 2010, American Recovery and Reinvestment Act (ARRA) (3) has taken measures to ensure precise quality and reporting through EHR-based measurement for all healthcare stakeholders, such as payers, providers, patients, pharma industry, policymakers, and regulatory bodies. This paper focuses on the importance of EHR- based clinical research and emphasises the need for EHR in developing nations.

EHRs are extensive data that are compiled along with several phases of the standard healthcare process. EHRs support to understand demographic information, comorbidities, and associated medications of the healthcare process. Further, the magnitude of an EHR application varies in each type of research studies, such as observational studies, safety surveillance, clinical research, and regulatory purposes. (4) When focused on its application in clinical research, the EHR-based clinical decision support (CDS) though has several limitations has significant contribution in accelerating Clinical Research studies.

2. EHRs in Clinical Research

EHRs-based clinical research has remodeled, enhanced and reduced the cost, which in turn assured increased the efficiency of clinical trials. The impact of EHR based clinical research on disorders like Chronic Kidney Disease, Diabetes, Rheumatoid Arthritis, and Gastrointestinal Complications are discussed below.

Chronic Kidney Disease: Studies has proved that automated clinical alert based on EHR for Chronic kidney disease (CKD) patients has improved earlier detection and referral to nephrologist. (5) Alberta Kidney Disease Network, in Canada, and the Center for Disease Control and Prevention, in the United States of America, have identified CKD patients from the data of various studies, clinical trials, laboratory, and institution, and collated and upgraded the health records across countries.

Diabetes: EHR-based clinical decision support (CDS) systems have contributed significantly to ameliorate diabetes care. In 2007, in order to identify and combat clinical inertia in the management of blood pressure, glucose, and lipids in adults with type 2 diabetes a CDS system called "Diabetes Wizard" was randomly implemented in six clinics and high-level successful outcome was reported by primary care providers (PCPs). (6,7) "Diabetes Wizard" is a user interface used by PCPs and nurses for better diabetic patient care. Further, the printed reports were shared with patients by PCP, which helped in educating and motivating patients. And engaging patients in developing EHR is substantially beneficial than ingress to Health records.

Rheumatoid Arthritis: Carroll et al. (2011) (8) in their study, used high-performance machine learning techniques, Support Vector Machines (SVMs), to detect RA cases. SVMs was applied to both naïve and expert-defined collections of EHR to identify Rheumatoid Arthritis cases and focused on billing codes, medication exposures, and natural language processing-derived concepts. Though SVMs operating on naïve sets of attributes performed better than the defined collection of EHR, both performed better than the previously used algorithms.

Gastrointestinal Complications: Gill et al. (2011) (9) with EHR conducted the randomised controlled trial in a national network of primary care centers and aimed at the patients taking nonsteroidal anti-inflammatory drugs (NSAIDs) and factors associated with high-risk gastrointestinal complications. And the study showed that EHR-based clinical decision support for high-risk patients on NSAIDs in primary care offices had only a small impact. This study helps in further studies in defining the complication of EHR-based CDS.

3. Challenges in EHR

EHR has a significant role in supporting clinical research studies. They support in clinical trials, testing, understanding population of study, analyzing clinical issues, conducting surveillance, and accessing treatment and further, understanding demographic information, comorbidities, and associated medications. As per Jeff Wendel, President of Advarra (1):

"The ability to mine information in EHRs will allow us to identify potential patients, expose them to the opportunity of participating in research, and then connect them with physicians they may be familiar with, including their own physician."

EHRs can help identify, reach, and serve a broader patient population, to benefit the patient and further research. Hence, it plays a significant role in clinical research usefulness and meaningful data requisites.

Due to the enormous workload and limited timeline the EHR process faces many challenges. EHR-based data information process should neither increase administrative work nor impose higher financial costs to healthcare providers, healthcare organizations, or patients. To improve the process, firstly, one consistent standard protocol should be followed by all the stakeholders to avoid inconsistency and implement it in an efficient way. Secondly, integrating and collaborating with multiple data source with efficient accurate approaches, i.e., high-level algorithms, to matching individuals in multiple data sources would be a critical step, it would eliminate redundant data for research. However, while integration there is more possibilities of missing data or incomplete data that would hinder the research and protection of data privacy is also a big challenge. Finally, as the integration of multiple data proceeds in long time a longitudinal methodologies would be required for causal inference and prediction.

EHR adoption around the World

Although effective utilization of EHR is creating a tectonic shift in health care, EHR system has several challenges; developing healthcare information has been a major project around the world. Manpower and financial funds are the major limitations in adopting EHRs in large scale. However, most of the developed countries such as Canada, France, Norway, Sweden, USA, and the U.K., have made huge investment in developing EHR system as they understand the importance of adoption of EHR system for healthcare systems. But the developing nation like India faces many challenges in adopting EHR.

EHR in developing countries (India)

Compared to the other sectors, such as Banking, Transport, etc., Information Technology in Healthcare Services in India is substantially limited. But, India is luring patients from different parts of the world as they provide quality healthcare of worldwide standards at a relatively low cost. In April 2013, Government of India had set guidelines for EHR standards in India based on the EMR standards committee, which was constituted by order of Ministry of Health and Family Welfare (10) and was revised in 2016. But, in India because of the hugely diverse population adopting and developing EHR system is a challenging task.

Public and Private Healthcare Systems in India

There are public and private healthcare systems in India. Many people in India prefer private hospitals for the better facilities provided by them. EMR and EHR are adopted in some of these private and corporate

hospitals, such as Sankara Nethralaya has implemented EHR/EMR in their clinics and hospitals and Corporate hospitals like Max Health, Apollo have implemented and attained Stage 6 level from HIMSS of the EMR Adoption Model (Table .1). (11,12) However, there are

many healthcare providers where maintaining EHR is lacking. Being a huge populated country with diverged practices much remains to be done.

Table 1 The 8-Stage model for electronic medical record adoption from HIMSS (11,12)

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Stages	Electronic Medical Record Adoption Model Requirements
Stage 7	Complete EMR; External HIE; Data Analytics, Governance, Disaster Recovery, Privacy And
	Security
Stage 6	Technology Enabled Medication, Blood Products, And Human Milk Administration; Risk
	Reporting; Full CDS
Stage 5	Physician Documentation Using Structured Templates; Intrusion/Device Protection
Stage 4	CPOE With CDS; Nursing And Allied Health Documentation; Basic Business Continuity
Stage 3	Nursing and Allied Health Documentation; EMAR; Role-Based Security
Stage 2	CDR; Internal Interoperability; Basic Security
Stage 1	Ancillaries - Laboratory, Pharmacy, And Radiology/Cardiology Information Systems; PACS;
	Digital Non-DICOM Image Management
Stage 0	The organization has not installed all of the three key ancillary department systems
	(laboratory, pharmacy, and radiology).

4. Developing Infrastructure

Developing a strong infrastructure for health care system is vital, and measures have been taken for the development of Health IT, interoperability of EHR, privacy and protection, and provide awareness and training for the professional.

Healthcare IT: Health IT developing EHRs were more focused for insurance claims and for hospital references for private hospitals. And, even these systems do not prefer to invest in developing the EHR process as leasing from the third party is cost effective. The Awareness of EHR is changing the scenario and paving a way to create Electronic Health Record Architecture to handle huge data. However, high investments are required to create and manage huge voluminous data. Free and opensource software, mobile devices, and the cloud computing environment usage could be beneficial in creating and obtaining huge database. Further, the evolving data science, machine learning and artificial intelligence field are going to facilitate in integrating these huge data.

Interoperability of EHR: Interoperability of EHR is crucial for the global development of healthcare information. This could be accomplished only when EHR are shared among different sectors of health care. But often provider due to several reasons unable to share the information, as many policies are made in the interest of patients.

Protection of Privacy: Individuals health information are useful in many surveys, public health policymaking and in clinical research. With necessary anonymity measures these information are shared by the providers. But with growing EHRs preserving privacy protection and the financial viability to invest in such a project still summons to contest, as the confidentiality of patients health data should not be compromised.

Awareness and Training Program: A patient's past clinical information, family history, and genetics do add value during that patient's treatment. However, it should not overload the current process of physicians and other

staff. Hence, awareness and training program should be made to accommodate the EHR in the current process. In addition, Jeremiah Scholl (2011) (13) study on Indian hospital reflect light on the process of systems that are reluctant to change the traditional way as there are many skeptical users, but eventually adopted EMR with the addition of user-friendly features that could be used by skeptical users as well. Similarly, more adaptive methodologies need to be introduced so that developing countries could benefit from EHR-based patient care program.

5. Conclusion

In this age of globalization, EHR-base CDS has caused a tectonic shift in health care studies. Besides, integrating healthcare around would elevate clinical research platform to a greater extent. However, a collaborative approach and better machine learning techniques are required to cross the current barrier of the EHR. EHRs and EMR scopes need to be maximised to ameliorate the overall health information system. And developing countries should develop methodologies to fill the gaps by educating about the importance of health information, and creating scopes to improve the healthcare system.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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