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PHARMACOVIGILANCE FROM ELECTRONIC MEDICAL RECORDS TO REPORT ADVERSE EVENTS

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ABSTRACT

Electronic medical records form a major source of information regarding a patient's health history. Governments in the present take necessary steps to gather the patient's health history to carry out research and be prepared for any disease outbreaks at large to the citizens. Research has shown that the disease outbreaks are due to the lifestyle, the living conditions and the treatment undergone during the past. Medical literature states that many drugs whose complete safety profile unknown have been approved. Some drugs have shown serious adverse events (SAE), and subsequently withdrawn. There may be some drugs which still show adverse effects on the patients. This work makes an attempt to extract details regarding the drug administration from the electronic medical records (EMR) and employ the Bayesian classifier to find any SAE. It also analyses the various data mining techniques to find adverse events. The main advantage in using EMR is that they can be enhanced with powerful classification algorithms that can deal with images also.

Keywords: Pharmacovigilance, Bayesian Classifier, Data mining, Adverse Events

INTRODUCTION

In the present medical scenario medical records are being digitized and maintained as Electronic Medical Records (EMR). The abundance of these records can be used for research on finding useful patterns relating to adverse effects, drug efficiency and related information. These reports can also give a view of the treatment process like any surgeries undergone and report any adverse events after the process.

Drug use could lead to better outcome' is undoubtly accepted by all but there are some side effects also in the present days. These side effects are sometimes equally dangerous and may be fatal. These effects are being identified by the present system and a study on the medication process is being carried out. A known tragedy was way back in 1960s with Thalidomide and then origin of international drug monitoring activities in 1968 making it mandate for manufacturers, stakeholders, regulators, drug authorities and healthcare professionals to vigilantly monitor drug use. No wonder "Pills for ill" concept adopted as "Pills make ill". Regulations for drugs are proposed by authorities but execution delay interrupted the whole network Pharmacovigilance network is well sustained in developed countries but still on its way to progress in developing countries. With increased number of new chemical entities (NCE), pharmacovigilance has become mandatory requirement for pharmaceutical companies. It also insists manufacturers to update safety information in product leaflet or summary of product characteristics (SPC) within stipulated time period.

Regulatory authorities are concerned about drug safety and implementing risk minimization plan to improve patient outcome, prevent drug associated injury or hazard, minimize healthcare associated cost especially cost attributed to Adverse Drug Reactions (ADR), create awareness among consumers, healthcare professionals, stakeholders, third party payers and managed care organizations (MCOs), frame prevention strategies for highly vulnerable population, plan management strategies for effective care, disseminate safety information via communication network, develop guidelines for effective management of drug safety issues and execution and implementation of well framed guidelines based on recent information and ongoing safety review.

Good reporting practices (GRP) could improve the quality of ADR reports and also minimize the subsequent occurrence of ADRs. Adverse drug reactions once notified should be subjected to analysis to establish causality. For analysis of ADR, standard scales are used to assess causality, severity and preventability aspects. Clinical interpretation of ADRs is of clinical importance to attribute the causality link between drug and reaction. In many clinical situations causality link is difficult to establish due to contradictory information or lack of proper data. Certain parameters which must be included for analysis are previous history, demographics, date of onset of reaction, onset time, time temporal relationship, suspected drug, description of the reaction, dechallenge, rechallenge, management and outcome of the reaction.

Pharmacovigilance in India: In order to improve the patient outcome, constant efforts are required to build up a strong pharmacovigilance network. In India, we do not have robust structure which could in turn compromise the safety and lead to adverse outcome. We still remember the Rofecoxib story of devastation. Drugs are meant to treat not to harm but practically speaking drugs could alter the normal physiology of patients despite targeting the affected organ which in turn could lead to adverse effects. Adverse effects could be avoided by vigilant monitoring and reporting.

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In developing countries like India, the pharmacovigilance programme was initiated by Central Drugs Standard Control Organization (CDSCO) in Nov 2004 under the aegis of ministry of health and family welfare based on the recommendations made in the WHO document entitled "Safety monitoring of medicinal products-guidelines for setting up and running a pharmacovigilance centre" with the objective to monitor ADRs and report through hierarchy of pharmacovigilance network and disseminate the information with global healthcare community through WHO-Uppsala Monitoring Centre.

In india the main drawback is the lack of data. Only in the present scenario are the hospitals digitizing the data. There is a severe resistance to adopt the new technology. Due to lack of sufficient information and under reporting, the programme has been modified as Pharmacovigilance Programme of India (PvPI) and reinitiated in June 2010 with the aim to expand the existing structure and proactively report ADRs. The purpose of PvPI is to collect, collate and analyze data to recommend regulatory interventions and communicating risks to healthcare professionals and consumers.

Electronic Medical Record: An electronic medical record (EMR) is a systematic collection of electronic health information about an individual patient or population. It is a record in digital format that is theoretically capable of being shared across different health care settings. In some cases this sharing can occur by way of network-connected, enterprise-wide information systems and other information networks or exchanges. EHRs may include a range of data, including demographics, medical history, medication and allergies, immunization status, laboratory test results, radiology images, vital signs, personal statistics like age and weight, and billing information. The system is designed to represent data that accurately captures the state of the patient at all times. It allows for an entire patient history to be viewed without the need to track down the patient's previous medical record volume and assists in ensuring data is accurate, appropriate and legible. It reduces the chances of data replication as there is only one modifiable file, which means the file is constantly up to date when viewed at a later date and eliminates the issue of lost forms or paperwork. Due to all the information being in a single file, it makes it much more effective when extracting medical data for the examination of possible trends and long term changes in the patient. The main content of the EMR is the discharge summary. The discharge summary has the important information that can be used for the pharmacovigilance process. Contents of the discharge summary are described below. In the present work the main focus is on the discharge summary of the EMR from which the data is being extracted.

Extracting Information from the Discharge Summary: In the present work the prime focus was on extracting the information from the discharge summary. The summary shows the treatment process which gives the details of the medication process and the period which would form the main source of information.

1. Reason for hospitalization shows the present illness.
2. The findings suggest the primary diagnosis.
3. The Procedures and treatment provided give the details of the medication process.
4. The Patient's discharge condition states the condition after the treatment which is the prime information for the analysis.
5. Patient and family instructions (as appropriate) states the discharge medications and/or activity orders and/or therapy orders and/or dietary instructions and/or plans for medical followup.
6. Attending physician's signature to authorize the treatment process.

Adverse Event Reporting through Pharmacovigilance:

Pharmacovigilance (abbreviated PV or PhV), also known as Drug Safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. Pharmacovigilance heavily focuses on adverse drug reactions, or ADRs, which are defined as any response to a drug which is noxious and unintended, including lack of efficacy. Medication errors such as overdose, and misuse and abuse of a drug as well as drug exposure during pregnancy and breastfeeding, are also of interest (even without adverse event itself), because they may result in an ADR.

Information received from patients and healthcare providers via pharmacovigilance agreements (PVAs), as well as other sources such as the medical literature, plays a critical role in providing the data necessary for pharmacovigilance to take place. In fact, in order to market or to test a pharmaceutical product in most countries, adverse event data received by the license holder (usually a pharmaceutical company) must be submitted to the local drug regulatory authority. Ultimately, pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients.

Algorithms for Pharmacovigilance: The main process involved in pharmacovigilance is the signal detection. This is finding any adverse events associated with a drug. Statistical tools support the identification of the patterns

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associated with this issue. Signal identification methods under each analysis domain also tend to utilize any or all of these two data analysis strategies:

Safety database querying: A systematic process whereby clinical safety databases are searched or queried for potential association between a product and adverse event that may be of regulatory or epidemiological interest.

Safety database mining: A systematic process whereby large databases are searched for associations among two or more variables (say, drug product and adverse event, drug-drug interactions, etc.) that occur at a higher than expected frequency. Given an observed pattern, other signaling methods can be utilized to support and assess the strength of this signal.

Many statistical tools are used for finding patterns related to the medicines and their effects. The main advantage in employing the EMR is the long term analysis of a drug.

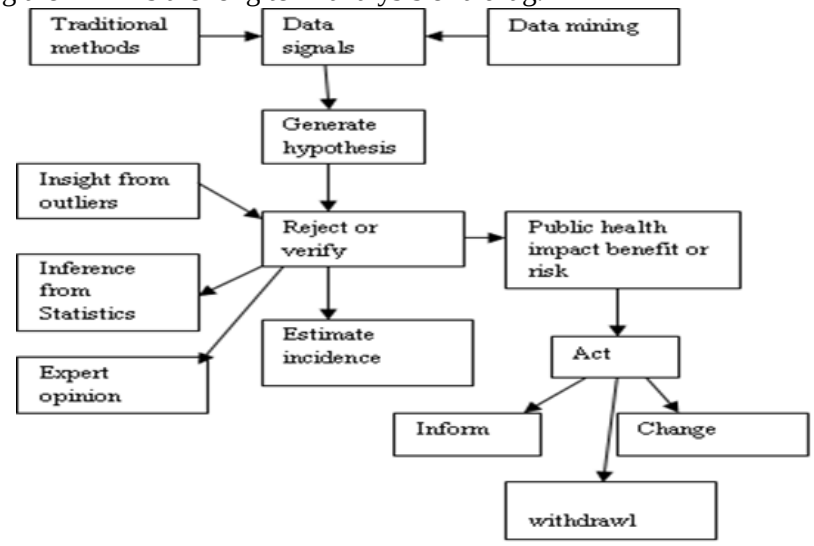

Fig.1.The Pharmacovigilance Process

Proposed Method: The method involved in collecting the EMR of patients from a hospital database. From the EMR key words search was performed. For example words such as "Cardiac Arrest", stroke, fracture and the related terms and also the related treatment along with the drug prescribed will be fetched. Fig.1. There are two main phase in the model. First is the extraction of the information from the EMR. Second is the classifier to find adverse events. Fig.2.

The proposed approach relies on a semantic lexicon and extraction rules as a two-phase strategy: first, drug names are recognized and, then, the context of these names is explored to extract drug-related information (mode,dosage,etc) according to rules capturing the document structure and the syntax of each kind of information. Different configurations are tested to improve this baseline system along several dimensions, particularly drug name recognition, and this step being a determining factor to extract drug-related information. Changes were tested at the level of the lexicons and of the extraction rules. Fig.2. From the extracted information a Bayesian classification is performed. This aims at signal detection from the extracted information. The algorithm counts the instances of a drug for a patient , the dosage, time and any adverse reaction as mentioned in the EMR discharge summary associated with the drug. In the traditional method an expert opinion by way of observation signal detection was carried out. But in the new millennium due to the accumulation of voluminous data it became difficult by personal observation. It would be efficient only with an automated process using efficient algorithms.

Bayesian algorithm for signal detection: In the algorithm a search for the associatiations between a drug and any adverse event is analysed.

Pr (RID)/Pr (R) = Pr (R,D)/Pr(R)*Pr(D)

Where Pr(R/D) is the posterior probability of obtaining a specific adverse event R given that a specific drug D is the suspect drug.Pr(R) AND Pr (D) are prior probabilities of a observing R and D in the entire database Pr (R,D) is joint probability that both R and D where observed within same data base coincidently .

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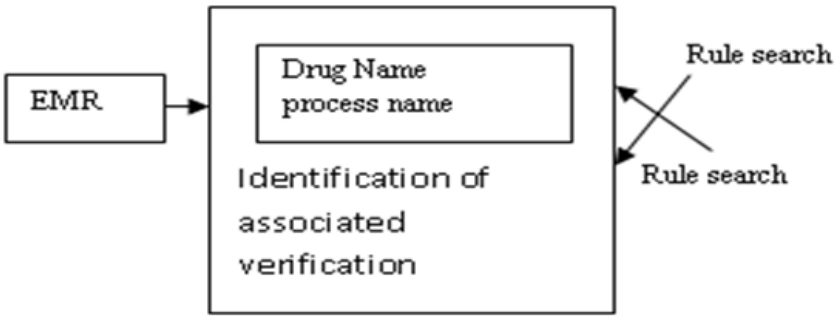

Fig.2.Pharmacovigilance from EMR

CONCLUSION

This study demonstrates the usage of the EMR for performing pharmacovigilance. A few discharge summaries from the EMR were analyzed and the drugs related information was classified using the Bayesian classifier. It was found that a simple rule-based system can achieve good performance on the medication extraction task. Once the hospitals digitize their data efficient algorithms can be employed to extract important information.

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