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Analysis of Pharmacovigilance with Data Mining Techniques – A Survey

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ABSTRACT

All the designed medicines are used to cure or treat the disease, otherwise, to prevent the disease. In last few years the field of pharmacovigilance has evolved significantly. Mining the data or knowledge discovery from the huge amount of data, several algorithms are developed. The application of data mining in the field of pharmacovigilance will give the predictable result in the field of analysis. The making of safety database available in the global, will improve communication for the safety issues on a frequent manner. This paper discusses techniquesof usefulness of data mining techniques in the field of pharmacovigilance, future trends and role of the data mining in pharmacovigilance.

KEY WORDS: Pharmacovigilance, Data Mining, Adverse, Drugs

1. INTRODUCTION

The usage of the medicine is centred to poise between the possible risks and the expected benefits. Therapeutic tools are used for risks assessments of medicines and the benefits of assessments reused by clinical pharmacology. The above mentioned assessments can be done in the two levels. The first level deals with proper drug treatment to a specified patient in daily medical care and the second one is that which uses the benefit of epidemiological tools and policies to get reactions from previous knowledge. People are spending so much money on prescription drugs for the treatment, prevention of diseases or cure. Adverse Drug Reactions (ADR) can clue to patient disease. ADR's are frequently denoted to as "any unintended and undesirable effects of a drug beyond its anticipated therapeutic effects occurring during clinical use" (Mei Liu, Pirmohamed, 1998).

What is data mining?

Data mining has contributed significantly throughout all periods of drug growth, from drug detection to post-marketing investigation (Elisabetta Poluzzi, 2012). Data mining is the procedure of pursuing exciting or valued data within huge data sets (Hand, 2000). The Techniques of the Data mining are used in many areas in the world to retrieve the useful knowledge from the very large amount of data. The applications of the sequence patterns data mining are weblog click streams, DNA sequences, sales analysis, telephone calling patterns, stock markets and etc., (Muthuselvan, 2015).

What is pharmacovigilance?

Pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any drug-related problem" (World Health Organization, 2002).The two stages of Pharmacovigilance are (a) Pre-Marketing surveillance – information regarding ADRs is composed from pre-clinical viewing and phases I to III clinical trials; (b) post-marketing surveillance – data accumulated in the post-approval stage and throughout a drug's market life (Figure 1).Drugs have to compulsory follow a severe and extremely regulated development procedure before they are permissible to be brought to marketplace.

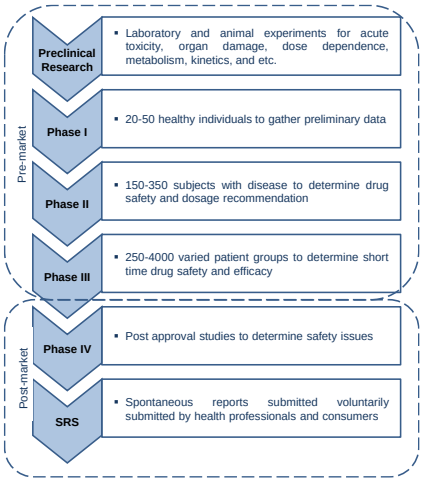

Figure.1.Pharmacovigilance at different stages of drug development

The above figure shows the two stages of pharmacovigilance. The first stage is started with the pre-clinical research. The pre-clinical research is laboratory and animal experiments for acute toxicity organ damage, dose dependence, metabolism, kinetics, etc. The phase I will be the, preliminary data collection from 20 to 50 healthy individuals and phase II, determination of the drug safety and dosage recommendation from 150 to 350 subjects with disease. The last phase in the pre-market stage is to determine the short term drug safety and efficacy from 250 to 4000 different patient groups.

The second stage of pharmacovigilance of drug development is post-market. In this stage, the phase IV is to get the post approval studies to determine safety issues. The final phase of this stage is Spontaneous reports Submission by the health professionals and the consumers.

Role of data mining in pharmacovigilance: Data mining algorithm or methodologies have important role in the pharmacovigilance process. Data mining has to elucidate the numerous composite that can play a role in the development of Adverse Events in a medical setting. Data mining algorithms have the potential to increase pharmacovigilance screening; however, for the majority of drug-event combinations, there was not at all extensive benefit over traditional systems. They should be measured as potential complements to, and not alternatives for, traditional pharmacovigilance policies (Hauben, 2005). The health and safety of the drugs can be retrieved from the wealthy of computerised databases in the particular health care organizations. Using data mining algorithms, the decision support systems can befor matted to the suitable clinical support systems (Manaswini Pradhan, 2014).

Major Uses of Data Mining.

- Identify indirect relations that might happen in huge databases
- Using data mining, the identification of the toxicities potential in the early stages is possible.
- To Identify the multifarious associations not apparent by simple summarization
- Screening the tool to identify prospective associations to undergo clinical/epidemiological follow up

Recent trends in pharmacovigilance: Over the previous few years, relative importance of pharmacovigilance happenings has shifted (Figure 2). The four trends of pharmacovigilance to Observe in 2014 are as follows.

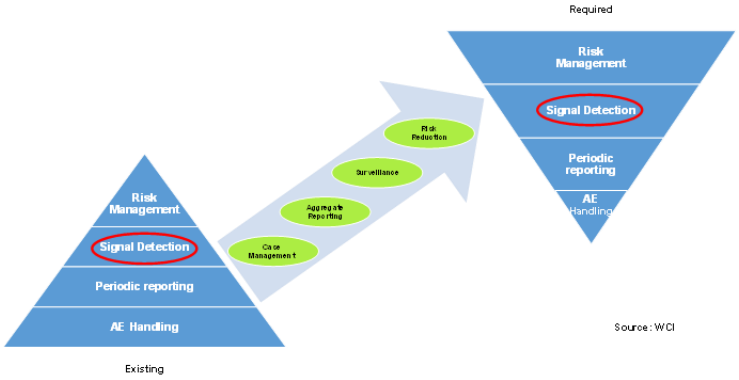

Figure.2. Recent Trends in Pharmacovigilance

- Greater Emphasis on Monitoring
- Increased Costs Associated with Drug Development and Pharmacovigilance
- Enhanced Transparency and Communication Improving Drug Safety
- Proactive Risk Management Gaining Ground

Challenges in the future of pharmacovigilance: The challenges in the future of pharmacovigilance are the need of the data analysis of more real time data. The visual data mining will be more challenging. The relationship with additional data bases can regulate the unfairness. And also, the challenges in the future of pharmacovigilance are, to identify the duplicate data set in the huge amount of the data. Selection of the methods for reducing the false positive and false negative are the another challenge in the future of pharmacovigilance. Now days, the following are the challenges of Pharmacovigilance in businesses (Anutosh Maitraa, 2014).

- Proficient and cost effective running of the process consistently without negotiating on quality.
- Progress of processes and tools to increase business results based on different and shapeless data.
- Continue to build deep skills in identifying the causation relationship, thus migrating Pharmacovigilance from being a reactive to an anticipating process

2. CONCLUSIONS

Data mining algorithms are very effective for retrieving the useful information's from the very huge databases stored in the repositories. With the help of the data mining techniques, the drug safety measurements can be done for the future society. The activities of the pharmacovigilance are to give the report of the individual patient with in the specified time period. At the time of the testing the patient for the new drug, the companies should be

aware about the initial criteria about the safety of the drug usage. Reports from health care professionals and the drug regulators with the help of the drug companies can assist the patients for safe medication, and reduce adverse events.

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