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Perspicacity in Pharmacovigilance

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Commentary

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ABSTRACT

Current day's pharmacovigilance have been fast evolving sector in the fields of medicine and software technologies. Present insight focuses on major trends of pharmacovigilance in various countries, its importance, use in different drug strategies, future advances. Pharmacovigilance advancing into the major factor of drug safety portions of the drug introduction into market has gained huge response. It has generated into key fields in the Pharmacy profession providing well sophisticated opportunities to Pharmacy professionals around the globe.

Introduction

Pharmacovigilance (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 includes safe drug clinical trials with various measures to obtain a efficacious quality product such as Clinical trials in artemether lumefantrine in pregnant women [1] etc.

Outlook

Various examples are taken into account regarding the massive clinical trials administered for safe Drug analysis which covers the broad scope the recent laws of pharmacovigilance in European and US [2], Pharmacovigilance teaching strategies in the major countries [3,4], Biosimilars in Pharmacovigilance [5], Pharmacogenetics Therapies development [6], SAR Studies [7], ADR studies [8-10], Alcohol Medication Interactions [11,12].

Safety signal initiative by WHO regarding Pharmacovigilance has developed as a system [13,14]. Patient Safety have evolved at rate in all the Countries on the primary focus of drug safety in clinical perspectives [15,16], the trends, scope ,future initiatives, Modern developing technologies have wide scope for the enhancement of Pharmacovigilance career [17-21].

Pharmacovigilance Vs Adverse Drug Interactions

The safety of drug is peculiar when in the case of adverse drug interaction appears such as clinical pharmacists major role and the correct quality dosage, the various reports illustrated are [22-29], the

adverse drug interactions being the main obstacle for the Pharmacovigilance, thus including several steps.

Recent Pharmacovigilance studies use the reliable software of SAS (Statistical Analysis System) for the early and fast retrieval of large clinical data in number of Individuals participating. Even the Pharmacovigilance have evolved in the economic field rapidly with global advancements and approaches [30-33].

Adverse reactions effect lead to serious consequences which result in drug- drug interaction, drug to foreign substance interaction, etc.

Hence a clear study with safety measures in use with well developed and highly professional individual's presence is required. Careful review on the adverse drug reactions must be clear as adverse drug reactions are undesirable impacts on the drug which badly affect the drug influence in treatment.

Special Technologies are used for drug safety with upcoming development in technology such as use of Apple's Research Kit a recent innovation for medical research data collection, where retrieval of absolute details in less time is possible.

Several Excipients used in drug development are carefully scrutinized for its further non interaction with drug main active ingredients.

Physician's views and concerns regarding several cases they handle may give us the idea regarding the adverse drug reactions and hence the knowledge of Pharmacovigilance at present can be noticed.

Recently Pharmacovigilance for Novel Oral Anticoagulants have been studied which show that physicians should be precise regarding the pharmacology of NOACs, dose adjustments, contra-indications, drug-drug interactions.

They should have a complete record of patients with the Anticoagulants treated with adverse reactions reported if any.

Safety and efficacy assessment is prime importance in Pharmacovigilance. Clinical trials are framed as such maintaining a set of regulations and procedures that determine the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use.

Special regulations are followed in Pharmacovigilance which are mentioned by Food & Drug Administration organisation, where every clinical trial is followed with utmost care and importance towards studies of Adverse Drug Interactions are studied and well defined terms are illustrated for the improvement of clinical trials in each and every stage starting from Clinical Trial-I to Clinical Trial-III, and Clinical Trial IV after releasing into market with the effective and strong documented suggestions by persons excelled in Pharmacovigilance.

Pharmacovigilance hence developed into a major research interest today in pharmacy professional with more employment opportunities in Multinational organizations as the the field is related to scientific arena of science and technology requiring developing of knowledge in the fields of software development tools coupled with scientific knowledge.

Drug safety is hence a very crucial factor as the drug starting from its formulation, quality checks, approval by FDA in preliminary stages, Quality Assurance, clinical trials and then into the market all at last gives or based on result of Drug Safety.

If Safety province of Drug is not maintained it may lead to vain of all works done starting from formulation to release in market, which results in heavy money loss and financial crisis.

CONCLUSION

Recent trends in the development of Pharmacovigilance provide enormous employment opportunities for the vast pharmacy professionals especially and the fast growing era show a major path in the economics field, with careful studies absconding the Adverse drug reaction problems [34-41].

REFERENCES

1. Stephen Rulisa. 2nd International Conference and Exhibition on Pharmacovigilance & Clinical Trials, Hilton San Antonio Airport, TX, USA. 2013.

2. Montanari-Vergallo G. Recent Developments in EU and US Pharmacovigilance Legislation. J Pharmacovigilance 2013; 1: 105.
3. Mishra H and Kumar V. Pharmacovigilance: Current Scenario in a Tertiary Care Teaching Medical College in North India. J Pharmacovigilance 2013; 1: 108.
4. Elkalmi RM, Ahmad Hassali MA, et al. The Teaching of Subjects Related to Pharmacovigilance in Malaysian Pharmacy Undergraduate Programs. J Pharmacovigilance 2013; 1: 106.
5. Chablani L. Pharmacovigilance of Biosimilars. J Pharmacovigilance 2013; 1: 107.
6. Mishra H and Kumar V. Pharmacovigilance: Current Scenario in a Tertiary Care Teaching Medical College in North India. J Pharmacovigilance 2013; 1: 109.
7. Agrawal P. Structure-Based Drug Design. J Pharmacovigilance 2013; 1: 111.
8. Yamamoto M. The Role of a Pharmacist and Undergraduate Pharmacy Education with Special Reference to the Adverse Drug Reaction Reporting System in Japan. J Pharmacovigilance 2013; 1: 113.
9. Prasad A, Datta PP, et al. Pattern of Adverse Drug Reactions Due to Cancer Chemotherapy in a Tertiary Care Teaching Hospital in Eastern India. J Pharmacovigilance 2013; 1: 107.
10. Kaur I, Jindal S, et al. Cutaneous Adverse Drug Reaction with Ofloxacin. J Pharmacovigilance 2014; 2: 144.
11. Borja-Oliveira CR. Alcohol-Medication Interactions: The Acetaldehyde Syndrome. J Pharmacovigilance 2014; 2: 145.
12. Itoi N, Abe H, et al. Breath Alcohol Concentration in Japanese Breast Cancer Patients Following Alcohol-Containing Chemotherapeutic Agent Infusion. J Pharmacovigilance 2014; 2: 138.
13. Garlapati S, Priyanka S. Cradles of Signals for Pharmacovigilance Process. J Pharmacovigil 2015; 3: 126.
14. Shinde S. Treprostinil: Safety Signal Detection Based on Adverse Event Reporting System Database. J Pharmacovigilance 2014; 2: 140.
15. Elhassan GO. Pharmacovigilance: Clinical Perspectives towards Patient Safety. J Pharmacovigil 2015; 3: 129.
16. Hamad F and Elnour A. The Role of Clinical Pharmacist in Pharmacovigilance . J Pharmacovigilance 2014; 2: 121.
17. Preda A. Pharmacovigilance and Beyond. J Pharmacovigilance 2013; 1: 114.
18. Dave VS. Current Trends in Pharmacovigilance. J Pharmacovigilance 2013; 1: 104.
19. Vijay Kumar. Challenges and Future Consideration for Pharmacovigilance. J Pharmacovigilance 2013; 1: 102.
20. Mohammad Arif Khan, Krishna Pandey,et al. Pharmacovigilance in India: A Need Indeed. J Pharmacovigilance 2014; 2: 126.
21. Naik P. The Future of Pharmacovigilance. J Pharmacovigilance. 2015; 3:159.
22. Zimmermann A. Reporting Adverse Drug Reactions in Poland â€“ The Legal Situation. J Pharmacovigilance. 2014; 2: 117.
23. Srba J and Vlcek J. Position and Processing of Adverse Drug Reactions Directly Submitted by Patients to National Regulatory Authorities in Europe. J Pharmacovigilance 2014; 2: 122.
24. Yongyang X, Danhui Y, et al. Quantitative Pharmacovigilance Modeling for TCM Injections Adverse Event Reporting. J Pharmacovigilance 2014; 2: 124.
25. Khoda DA, Ganachari MS, et al. Clinical Pharmacist Driven Impact towards Intensive Monitoring and Reporting of Adverse Drug Events in Psychiatric Patients. J Pharmacovigilance 2014; 2: 128.
26. Elkalmi RM, Al-lela OQ, et al. Motivations and Obstacles for Adverse Drug Reactions Reporting among Healthcare Professionals from the Perspective of Lewinâ€™s Force Field Analysis Theory: Analytic Approach. J Pharmacovigilance 2014; 2: 130.

27. Jaiswal P. A Review on Adverse Drug Events to Create Awareness. J Pharmacovigilance 2014; 2: 1.
28. Necho W and Worku A. Assessment of Knowledge, Attitude and Practice of Health Professionals towards Adverse Drug Reaction Reporting and Factors Associated with Reporting. J Pharmacovigilance 2014; 2: 135.
29. Alves GMR, Varallo FR, et al. Role of the Clinical Pharmacist in Detection of Drug Therapy Problems in Critically Inpatients: Experience Report. J Pharmacovigilance. 2014; 2: 139.
30. Wertheimer AI. The Importance of Pharmacoeconomics. J Pharmacovigilance. 2014; 2: 115.
31. Salmon JW. Global Health Systems. J Pharmacovigilance. 2014; 2: 134.
32. Persaud-Sharma V and Zhou SF. Incorporation of New Technologies into Global Pharmacovigilance. J Pharmacovigilance. 2013; 1: 102.
33. Preda A. Pharmacovigilance in the New Millennium: Challenges, Opportunities and New Directions. J Pharmacovigilance. 2013; 1: 106.
34. Wertheimer AI. The Curious Path of Pharmacovigilance. J Pharmacovigilance. 2013; 1: 109.
35. Maria Allauddin, Farooque Azam, et al. A Survey of Quality Assurance Frameworks for Service Oriented Systems 2011; 2: 188-198.
36. Cáceres MC, Moyano P, et al. Trends in Antihypertensive Drug Use in Spanish Primary Health Care (1990-2012). Adv Pharmacoepidemiol Drug Saf. 2015; 3: 172.
37. Jhansi K. Review on Adverse Drug Reactions. Adv Pharmacoepidem Drug Safety. 2015; 4: 05-R.
38. Yiannakopoulou ECh. Pharmacovigilance for Novel Oral Anticoagulants: Why is It So Crucial?. J Pharmacovigilance 2015; 3: 135.
39. Turiel M, Galaverna S, et al. Practical Guide to the New Oral Anticoagulants. J Gen Pract 2015; 3: 194.
40. Lee A, Rajaratnam R. Tailoring the Novel Anticoagulants to the Stroke Patient – One Size Does Not Fit All Novel Anticoagulants in Stroke. J Neurol Neurophysiol 2015; 5: 248.
41. Kamali F. Are Novel Oral Anticoagulants (Noacs) as Safe as they are Said to Be? Adv Pharmacoepidemiol Drug Saf 2014; 3: 126.