Recent Advances in Pharmacovigilance and Pharmacoepidimiology

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Abstract

Pharmacovigilance is become more effective with help of pharmacoepidemiolgy and drug safety become easier due to drug utilization monitoring on large and special population. So the 20-70% of patient becomes safe because of pharmacoepidemiolgy application and Pharmacovigilance become more proactive and drug monitoring will be easy for large population.

KEYWORDS : Pharmacovigilance, Pharmacoepidimiology, beneficial effect, adverse drug effect, utilization of drugs, co-morbids, large populations, special populations, black box, demography

Introduction

Pharmacovigilance is become more advance with Pharmacoepidimiology because research has gone more towards special populations and large populations to observe the drug track record for post marketing surveillance. The Pharmacovigilance has now broad spectrum in work for demography clinical specialties Pharmacoepidimiology and pharmacy, epidemiology biostatics studies. The pre marketing information's are not sufficient for drug safety as clinical trial I to III phases has only single drug trail and minimum population of single disease and not trail done over special population so large population trail is needed to make drug safe.

The phase IV are post marketing trails are essential for co-morbids patients and special population of deferent places and of different ages with different races are needed for the studies on utilization of drugs for adverse and beneficial effect in real life conditions

Pharmacoepidimiology and Pharmacovigilance are joint studies are needed for drug safety to withdraw and black box warning to avoid post marketing risk care and regulatory problems.

Methodology

Pharmacovigilance, have many methodology like spontaneous ADR reporting Randomized controlled trails, observational studies, these are very common in post marketing data analysis by regulatory bodies confirmed by meta analysis of all tools to work on ADR and drugs efficacy.

The 20-70% of ADR may be preventable in future by use of Pharmacoepidimiology Methods prevention to ADR in drug utilization population are certain condition necessary to evaluate the drugs and adversity.

From other Pharmacoepidimiology tools are like

- Real life condition like poverty, old age, multi drug, multi diseases, co-marbidity, special population like pregnancy, lactational, paediatrics and geriatrics etc.
- Internal validity like is age, sex, co-marbidity pharmacogenetic functional state residence and frailty and accurate information on potential are also critical to ensure
- External validity which is known as generalizability to orther population biological age and choronological are useful tools in Pharmacoepidimiology.
- Risk assessment tools
- Assessment of effectiveness

Discussion

Pharmacovigilance is complicated science to prevent the drug Hazard in public health. Pharmacoepidimiology includes pharmacodyanamic, pharmacokinetics to know about the drug inside the body its action and reaction achieved in large population, To make the policy decision risk factors in disease and targets for major application with logistic approaches and methodology to support Pharmacovigilance activity needed. The clinicians are interested in drug and cost and they are not very much conscious about the risk factor and advers effect of drugs. The pharmaceuticals industries and acadmia must be aware about clinicalpharmocology and Pharmacovigilance – Pharmacoepidimiology pharmacogenitcs and risk management with spontaneous reporting to regulatory bodies. The teaching and training must be given to undergraduate, postgraduate, post post graduate, of medical practice and health care provider like nursing staff and chemist.

Result

The net 20 to 70% of adverse effect can be prevented by application of Pharmacoepidimiology and Clinical Pharmacology and Pharmacovigilance

Conclusion and Direction

The approval of new drugs should be only five years with re evalution of next licensing the cumulative information on safety and efficacy will be more if phase III and post marketing are helped by Pharmacoepidimiological study and pharmacogentic on large population based data is used for proactive Pharmacovigilance study.

Future challenges

Pharmacovigilance is assisted by Pharmacoepidimiological study and pharmacogentic is essential for drug safety and drug efficacy in large population, drug utilization safety to avoid drug hazard and make world safe from drug terror

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