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# Pharmacoepidemiology & Pharmacovigilance: Powerful Emerging Areas to Conquer More

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Pharmacoepidemiology is defined as the study of the utilization and effects of drugs in large numbers of people. To accomplish this study, pharmacoepidemiology borrows from both pharmacology and epidemiology. Part of the task of clinical pharmacology is to provide a risk benefit assessment for the effect of drugs in patients [1]. The core theme of the regulatory bodies like USFDA, Health Canada, EU health agency like EUDRA vigilance system, MHRA etc. are meant to find the safety signals that are associated with the utilization of various medications.

All these agencies will collect adverse drug reports (ADR's) that are reported by the drug manufacturers and perform different statistical evaluations. Resultant will confine the adverse event signal data which are meant to be used for future development of new drug entity in respective therapeutic areas as well improving the efficacy of the existing moieties.

In order to prevent the reoccurrence of the adverse drug experience the manufacturer make changes to his product and report it to the agency. Is that adverse drug reaction prevented by other manufacturers? No, better way to utilize these ADR's is to share them with other manufacturers using a common portal. Agencies suggestion and comments on ADR's can be shared with other manufacturers to avoid these with other drugs. 'Prevention is better than cure' based on these ADR's if the changes are made right at the developmental stage the safety and efficacy of drugs can be improved.

There is variation in the use of the term 'signal' in Pharmacovigilance. One commonly cited definition is from the Council for International Organizations of Medical Sciences (CIOMS), which defines a safety signal as 'information that arises from one or multiple sources (including observations or experiments), which suggests a new, potentially casual association, or a new aspect of a known association between an intervention [e.g., administration of a medicine] and an event or set of related events, either adverse or beneficial, that is judged to be sufficient likelihood to justify verificatory action.

Just to exemplify the new information on an already identified safety signal:

• An oncology drug is associated with characteristic form of cardiomyopathy (aweakening of the heart muscle sometimes seen with certain types of chemotherapy).

• Ongoing surveillance is initiated to gather more information about the association.

Safety signals that warrant further investigation include, but are not limited to:

• New adverse events, not currently documented in the product label, especially if serious and in rare untreated populations.

• An apparent increase in the severity of an adverse event that is already included in the product label.

• Occurrence of serious adverse events known to be extremely rare in general population.

• Previously unrecognized interactions with other medicines, dietary supplements, foods, or medical devices.

• Identification of previously unrecognized at-risk population, such as populations with specific genetic or racial predisposition or coexisting medical conditions.

• Confusion about a product's name, labeling, packaging, or use.

• Concerns arising from the way a product is used (e.g., adverse events seen at doses higher than normally prescribed, or in populations not recommended, in the label).

• Concerns arising from a failure to achieve a risk management goal [2].

## References

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2. http://www.pfizer.com/files/health/medicine_safety/2-4_What_is_a_Safety_Signal.pdf

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