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Editorial

# Pharmacoepidemiology

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Pharmacoepidemiology is the study of the utilization and effects of drugs in large numbers of people; it provides an estimate of the probability of beneficial effects of a drug in a population and the probability of adverse effects. It can be called a bridge science spanning both clinical pharmacology and epidemiology.

Pharmacoepidemiology concentrates on clinical patient outcomes from therapeutics by using methods of clinical epidemiology and applying them to understanding the determinants of beneficial and adverse drug effects, effects of genetic variation on drug effect, duration-response relationships, clinical effects of drug-drug interactions, and the effects of medication non-adherence.Pharmacovigilance is a part of pharmacoepidemiology that involves continual monitoring, in a population, for unwanted effects and other safety concerns arising in drugs that are already on the market. Pharmacoepidemiology sometimes also involves the conduct and evaluation of programmatic efforts to improve medication use on a population basis.

Just as the term implies, pharmacoepidemiology combines clinical pharmacology with epidemiology. Pharmacology is the study of the effects of medications in humans.1(p4) It pertains to using pharmacokinetics and pharmacodynamics of a patient to predict the drug effect on a patient. Epidemiology is the study of the factors that determine the occurrence and distribution of diseases in populations.4(p3) Epidemiologists study how much disease is in a given area, who gets it, and what specific factors put individuals at risk. Epidemiology can often be divided into infectious and chronic disease epidemiology. Chronic disease epidemiology is more dependent on complex sampling and statistical methods; which are often used in pharmacoepidemiology studies to evaluate drug exposure over time.1(p5) By combining the interest of pharmacology and epidemiology, a pharmacoepidemiologist applies epidemiology principles to study the effects of medications in human populations.

Pharmacoepidemiology studies quantify drug use patterns and adverse drug effects.5 For example, they are interested in understanding the patterns of drug prescribing, the appropriateness of use, medication adherence and persistence patterns, and the identification of predictors for medication use.

Pharmacoepidemiologists also conduct safety studies of drug use in large populations. They are interested in common, predictable adverse drug reactions as well as the uncommon and unpredictable ones. It is important to note a few terms that are often used when discussing drug safety (see Chapter 9 for further discussion). An adverse event is any untoward medical occurrence that occurs while a patient is taking a drug but which does not necessarily have a causal relationship with the drug product.6,7 An adverse drug reaction or adverse drug effect refers to an adverse outcome that is harmful or unpleasant that occurs while a patient is taking a drug product and has a causal link with the drug.

Epidemiological studies can be divided into two main types:

- Descriptive epidemiology describes disease and/or exposure and may consist of calculating rates, e.g., incidence and prevalence. Such descriptive studies do not use control groups and can only generate hypotheses, not test them. Studies of drug utilization would generally fall under descriptive studies.
- Analytic epidemiology includes two types of studies: observational studies, such as case-control and cohort studies, and experimental studies which would include clinical trials such as randomised clinical trials. The analytic studies compare an exposed group with a control group and are usually designed as hypothesis testing studies.

Pharmacoepidemiology benefits from the methodology developed in general epidemiology and may further develop them for applications of such methodology unique to pharmacoepidemiology.

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