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A Detailed Study of Pharmacoepidemiology and its Applications

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Perspective

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ABOUT THE STUDY

Pharmacoepidemiology is the study of drug use and side effects of individuals in huge population. Once novel pharmaceuticals have transitioned from limited exposure in controlled therapeutic pre-registration studies to the looser conditions of their use in the community, some Pharmacoepidemiology principles are employed to obtain more insight into the efficacy and notably the safety, of new drugs. Trials conducted in this environment are referred to as observational because the participants in the groups being compared either get the therapy (the subjects being compared) or do not receive the treatment (the subjects being compared are the controls). Comparing these (Phase 4) trials to experimental studies (RCTs), where admission and treatment allocation are rigorously regulated, there is a higher risk of selection bias35 and confounding36. However, when sufficiently big randomized trials are logistically and financially unfeasible, observational studies come into their own.

Results from patients who received a medication are monitored (therapeutic or adverse). This type of research is typically prospective (looking forward). A cohort study allows individuals to be followed "to observe what occurs" without requiring a suspicion of causation (event recording). As prescribing grows more widespread, there is a growing inclination to recognize that most new pharmaceuticals should be monitored in this fashion, as demonstrated by prescription event monitoring (below). The choice of an appropriate control group, the requirement for numerous patients and a lengthy surveillance period are all significant challenges. This type of study is time-consuming for drug development and is inferior scientifically to the experimental cohort study (the RCT).

An observational cohort research including a sizable number of subjects 38 was necessary to investigate the possibility of thromboembolism and the combined oestrogen-progestogen contraceptive pill (the adverse effect is,

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luckily, uncommon). An observational cohort study looking at cancer and the pill would necessitate a 10-15 year period of follow-up. Fortunately, epidemiologists have created a limited substitute: the case-control study.

The identification of causality in pharmacovigilance is one of the most significant and difficult issues. The connection between a given adverse event and a particular medicine is known as causality. Because there aren't enough conclusive or trustworthy facts, determining (or assessing) causality is frequently challenging. Although it is tempting to believe that a favourable temporal relationship "proves" a favourable causal link, this is not necessarily the case. The exception rather than the rule is a "bee sting" adverse event, where the AE can be clearly linked to a particular cause. This is because both the physiology of the human body and the physiology of diseases and disorders are complex. According to this logic, one must first rule out the chance that there were any additional potential causes or contributing factors before determining causality between an adverse event and a drug. If the patient is taking multiple medications, it's possible that the AE is brought on by the mix of these medications rather than any one of them alone. The AE has resulted in a person's death in a number of recent high-profile situations. Despite the fact that none of the numerous medications the patients were taking were overdosed, the combination there appears to be what caused the AE. Therefore, it is crucial to list all medications the patient was taking together with the medicine being reported in your or someone else's AE report.

One would be inclined to blame Drug X, for instance, if a patient started using Drug X and then three days later experienced an adverse event. To find potential risk factors for the AE, it would first be necessary to check the patient's medical history. In other words, did the AE happen as a result of the medicine or because of it? This is due to the possibility that a patient taking a medicine could acquire or be diagnosed with an illness that was not due to the drug.

This is especially true when a patient who has only recently started taking a medication is diagnosed with an illness like cancer, which develops over a long period of time. On the other hand, short-term exposure to some medications might cause some side outcomes, including blood clots (thrombosis). However, identifying risk variables is a critical step in establishing or disproving a connection between an incident and a medicine. The incidence of the incident in a patient population taking the drug is compared to a control group in an observational research, which is frequently the only approach to establish a causal association between an event and a drug. This may be required to evaluate whether the incidence of an occurrence in the general population is lower than in a group receiving medication. A causal association to a medicine may exist if the incidence of an occurrence is statistically significantly greater in the "active" group compared to the placebo group (or other control group), unless other confounding factors may present.