

# **Epidemiological designs for vaccine safety assessment: methods and pitfalls**

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Vaccine safety concerns post licensure may arise from a number of sources, including pharmacovigilance, ad-hoc reports, ecological associations and events associated with other vaccines. Whilst it may be possible to address some concerns based on an initial assessment, such as calculating observed/expected ratios using incidence data, others will require well designed epidemiological studies. The three designs most commonly employed for vaccine safety assessment are cohort, case-control and self controlled case series methods. These methods as well as the types of data-source they are used with will be presented and compared using examples. The methodological pitfalls that apply to all methods as well as those that apply to individual methods will be discussed. These include identifying the population of interest, sample size, case-definition and ascertainment, ascertainment of vaccine history, control selection, confounding, dealing with events that are contra-indications to vaccination, combining data across countries and calculating attributable risks.