

# ADVERSE EVENTS VS. SIDE EFFECTS

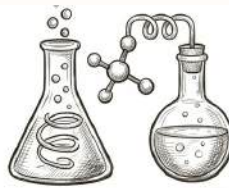


## Adverse Events



“**Adverse events**” (AE) “disliked” events and they may be related, unrelated, or unknown in relation to **vaccine** administration

## Side Effect



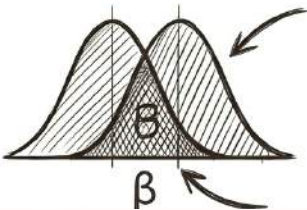
“**Side effect**” is an event that is caused by a vaccine or any medical intervention

## Causality Assessment



To distinguish between **Adverse Event** and **Side Effect** you need a “**causality assessment**” (causality vs. co-incidence): Biological plausibility, timing of events, specificity, clinical studies

## $\beta$ -error



It is **NEVER** possible to exclude causality by observational studies because of the  **$\beta$ -error**, so “safety” can never be proven

## Safety Profile



“**Safety profile**” is the summary of all safety data and established by pre-licensure studies and by post-licensure surveillance

## Concept



**CONCEPT:** Benefit-risk assessment: “worst case scenario” to assess vaccination risk.

## References

Chen WH, Levine MM. Adverse events vs. side effects. Vaccitutor. Published 2010. Updated November 22, 2021. Accessed March 5, 2026.: <https://vaccitutor.com/course/view.php?id=70>

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