PHARM.D • YEAR 5

Pharmacoepidemiology & Pharmacoeconomics

CHAPTER 1.2

Measurement of Outcomes in Pharmacoepidemiology



PPT CHAPTER COVER

DOCTOR OF PHARMACY

Clinical and Safety Outcomes

An outcome is a defined health event or condition measured during follow-up after an exposure.

Therapeutic outcomes include symptom relief, disease control or remission.



Safety outcomes include toxicity, hospitalization, mortality and suspected adverse drug reactions.

Example: blood-pressure reduction measures benefit, while gastrointestinal bleeding after NSAID use measures a safety event.

A recorded event after exposure requires investigation before attributing it to the medicine.

Surrogate and Patient-Reported Outcomes

Surrogate outcomes

Surrogate outcomes are indirect markers, such as LDL cholesterol, used to represent a clinical outcome.

Their validity depends on evidence linking marker changes to meaningful patient benefit.



Link to clinical outcome (needs validation)

Patient-reported outcomes



Patient-reported outcomes record pain, functioning or quality of life directly from patients.

Validated questionnaires improve consistency.

Economic outcomes



Economic outcomes describe resource use and treatment costs.

Together these measures help evaluate real-world benefit, harm and the patient experience.

Outcome Measures and Comparisons

Risk

Risk describes the probability of an event over a specified period.

Incidence rate

Incidence rate uses person-time to describe event frequency.



NNT = 1 / absolute risk reduction.

NNT requires risks expressed as proportions and a stated follow-up period.

Prevalence

Prevalence describes existing cases.

Relative risk

Relative risk compares risks.

Odds ratio compares odds and commonly appears in case-control studies.

Hazard ratio

Hazard ratio compares instantaneous event rates among people still at risk.

Outcome Data and Measurement Errors

Sources and Errors

Outcome data can come from medical records, claims, disease registries, patient reports and prescription-linked databases.

Misclassification occurs when an event receives the wrong category or code.

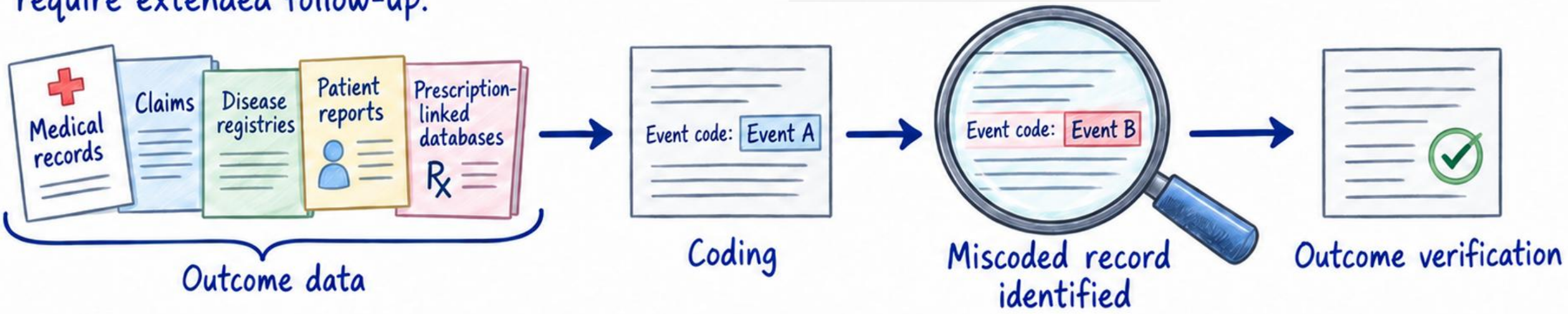
Missing and under-reported events can distort estimates.

Some effects have a long latency period and require extended follow-up.

Defining and Measuring Outcomes

Researchers specify an outcome definition, ascertainment method and time window before analysis.

Consistent definitions improve comparisons between exposure groups.



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