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Observational research methods—Cohort studies, cross sectional studies, and case–control studies

Méthodes des études d’observation – Etudes de cohorte, études transversales, études cas-témoins

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Abstract Cohort, cross sectional, and case–control studies are collectively referred to as observational studies. Observational studies are often the only practicable method of answering questions of aetiology, the natural history and treatment of rare conditions and instances where a randomised controlled trial might be unethical.

Cohort studies are used to study incidence, causes, and prognosis. Because they measure events in chronological order they can be used to distinguish between cause and effect. Cross sectional studies are used to determine prevalence. They are relatively quick and easy but do not permit distinction between cause and effect. Case controlled studies compare groups retrospectively. They seek to identify possible predictors of outcome and are useful for studying rare diseases or outcomes. They are often used to generate hypotheses that can then be studied via prospective cohort or other studies.

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Abstract Les études de cohorte, transversales et cas-témoins sont toutes désignées par les termes études d'observation. Les études d'observation constituent souvent la seule méthode réalisable pour répondre à des questions relatives à l'étiologie, aux antécédents naturels et au traitement de maladies et cas rares pour lesquels un essai contrôlé randomisé pourrait être contraire à la déontologie. Les études de cohorte sont utilisées afin d'étudier l'incidence, les causes et le pronostic. Ces études, qui mesurent les événements par ordre chronologique, peuvent être utilisées afin de distinguer la cause de l'effet. Les études transversales sont utilisées afin de déterminer la prévalence. Elles sont relativement rapides et simples à réaliser mais ne permettent pas de distinguer la cause de l'effet. Les études cas-témoins comparent des groupes rétrospectivement. Elles visent à identifier les variables explicatives possibles de l'évolution de l'état de santé et sont utiles pour étudier les maladies ou évolutions de l'état de santé rares. Elles sont souvent utilisées afin de générer des hypothèses pouvant ensuite être étudiées au moyen d'études de cohorte prospectives ou autres.

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African relevance

- Observational studies avoid many of the ethical problems of randomised controlled trials.
- Case control studies are particularly simple to organise and establish important risk factors, thus informing disease prevention programmes.
- Cross sectional studies can be done quickly and are the best way to determine prevalence; they are particularly useful for studying infectious diseases.
- Cohort studies allow cause and effect to be distinguished assuming confounding factors have been minimised, e.g., perinatal HIV transmission.

Cohort, cross sectional, and case-control studies are often referred to as observational studies because the investigator simply observes. No interventions are carried out by the investigator. With the recent emphasis on grades of evidence and the apparent supremacy of randomized controlled trials and meta-analyses such studies have been somewhat maligned. However, they remain important because many questions can be efficiently answered by these methods and sometimes they are the only methods available.¹

The objective of most clinical studies is to determine one of the following—prevalence, incidence, cause, prognosis, or effect of treatment; it is therefore useful to remember which type of study is most commonly associated with each objective (Table 1).

While an appropriate choice of study design is vital, it is not sufficient. The hallmark of good research is the rigor with which it is conducted. A checklist of the key points in any study irrespective of the basic design is given in Box 1.

Table 1 Study objectives vs. study design.

Objective	Common design
Prevalence	Cross sectional
Incidence	Cohort
Cause (in order of reliability)	Cohort, case-control, cross sectional
Prognosis	Cohort
Treatment effect	Controlled trial

Every published study should contain sufficient information to allow the reader to analyse the data with reference to these key points.

In this article each of the three important observational research methods will be discussed with emphasis on their strengths and weaknesses. In so doing it should become apparent why a given study used a particular research method and which method might best answer a particular clinical problem.

Box 1.

Study purpose: The aim of the study should be clearly stated.

Sample: The sample should accurately reflect the population from which it is drawn. The source of the sample should be stated. The sampling method should be described and the sample size should be justified.

Entry criteria and exclusions should be stated and justified. The number of patients lost to follow up should be stated and explanations given.

Control group: The control group should be easily identifiable. The source of the controls should be explained—are they from the same population as the sample? Are the controls matched or randomized to minimise bias and confounding.

Quality of measurements and outcomes:

Validity—are the measurements used regarded as valid by other investigators?

Reproducibility—can the results be repeated or is there a reason to suspect they may be a “one off”?

Blinded—were the investigators or subjects aware of their subject/control allocation?

Quality control—has the methodology been rigorously adhered to?

Completeness:

Compliance—did all patients comply with the study? Drop outs—how many failed to complete the study?

Missing data—how much is unavailable and why?

Distorting influences:

Extraneous treatments—other interventions that may have affected some but not all of the subjects.

Confounding factors—are there other variables that might influence the results?

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