ENSURE - Educating students for developing high quality research skills

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Cohort design

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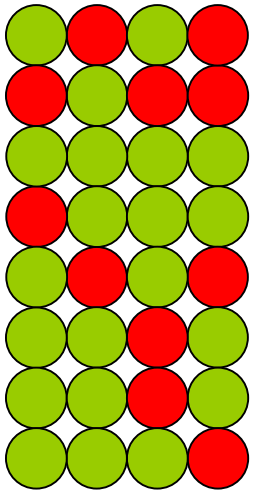
Cohort study

Disease-free general population



Exposure

Yes

No

Disease

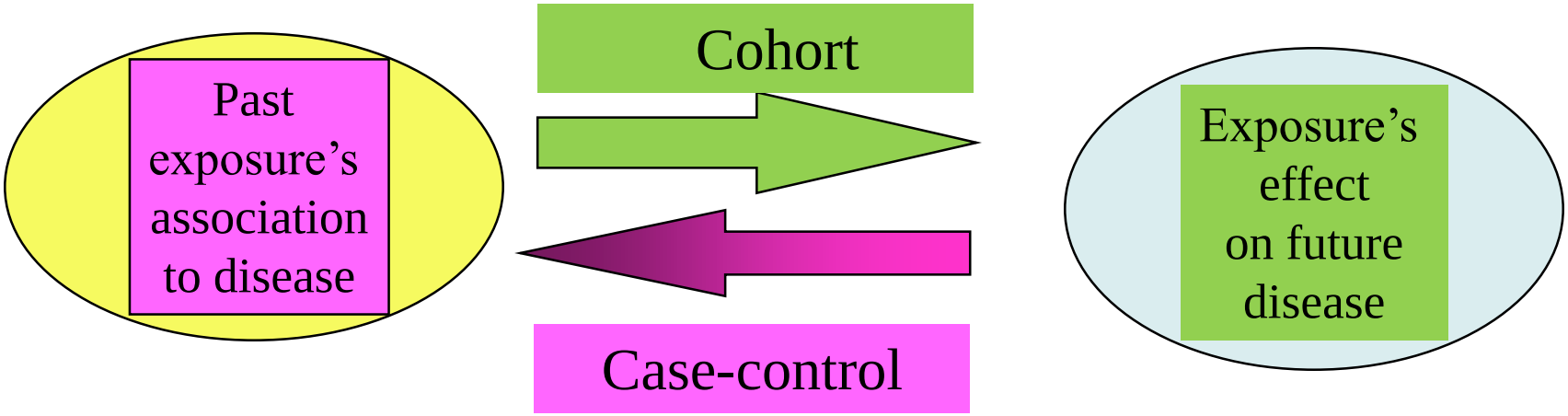
Yes

No

Yes

No

Cohort vs. case-control design



Selection of study population

- General population
- Repetetive populationbased studies
  - *The Tromsø study (7 repetions with biobanks), HUNT* (another populationbased study in Norway)
- Work-related databases
- By residence*
- Other groups
  - Etnic groups, religious groups
  - Professional databases
    - Nurses' Health Study
- Public/private insurance databases
- Military/veteran databases

Measuring exposure

T0-baseline – change in exposure from baseline

Exposure measured for each individual at the beginning of the study and assessed at intervals during the period of follow-up.

T0-baseline – change in confounders (co-morbidity)

Many cohort studies do only have exposure at baseline

Measuring outcome

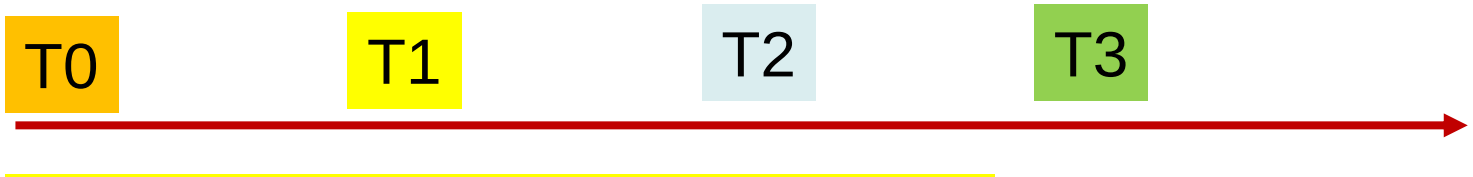
Sources for outcome:

- ❖ Medical records
- ❖ Registry data
  - Cancer registry
  - Disease specific quality registers
  - Death certificates
- ❖ **Direct from the participants**

Validation of outcome

Method used to ascertain outcome must be identical for both exposed and unexposed participants

Follow-up



Passive follow-up through:

- ❖ Medical records
- ❖ Registry data
  - Cancer registry
  - Disease specific quality registers
  - Death certificates

Active follow-up by visits at interval

- ❖ **Direct from the participants**

- Feasible
- Little costs/merging files

- Time-consuming
- Costly

Potential sources of bias in cohort studies

- Lost-to-follow-up (< 5% very good, > 20% not acceptable)
- Attrition rate (> 95% very good, < 80% not acceptable

Inverse

- Misclassification of **exposure**
  - Differential misclassification (unexposed are exposed; underestimation of the real effect)
- Misclassification of **outcome** (over-under-estimation of effect)
- Missed outcomes (lost-to-follow-up)
- Healthy worker effect (occupation) – stay healthy – continued participation

Outcome measures – incidence/relative risk

Smoking and risk for MI

	MI +	Person-yrs	Incidencerate/ 1000 person-yrs
Smoke +	84	2700	31,1
Smoke -	87	5000	17,4

Relative risk (RR)	**Incidence exposed**	**31.1**	**1.8**
	Incidence unexposed	**17.4**	

OR ≈ RR when:

- The disease is rare
- The cases are representative of exposure to the diseased in the background population
- The controls are representative of exposure to those without disease in the background population

Number needed to treat:

- Prospective studies measure insidence differences
- Provide information for assessing how many persons who need to be treated to prevent one case from the «outcome»

NNT – number needed to treat

= 1/absolute decrease in risk

NNH – number needed to harm

= 1/absolute increase in risk

When treating atrial flutter with warfarin, the incidence of cerebral infarction are reduced from 5.1% to 1.8%. In order to prevent one cse of cerbral infarction you need to treat…

NNT= 1/(0.051-0.018)=1/(0.033)=33.3

Weaknesses of cohort studies

- Costly and time consuming – sample size – long follow-up time.
- Prone to bias due to loss to follow-up.
- Prone to confounding.
- Participants may move between one exposure category – multiple f-up
- Knowledge of exposure status may bias classification of the outcome
- Being in the study may alter participant's behaviour.
- Classification of individuals (exposure or outcome status) can be affected by changes in diagnostic procedures
- Poor choice for the study of a **rare disease**

Strengths of cohort studies

- Can measure incidence and prevalence
- Exposure is measured before the onset of disease (in prospective cohort studies, measurement of exposure is unrelated to disease)
- Demonstrate direction of causality
- Multiple outcomes can be measured for any one exposure
- Good for measuring **rare exposures**, for example among different occupations