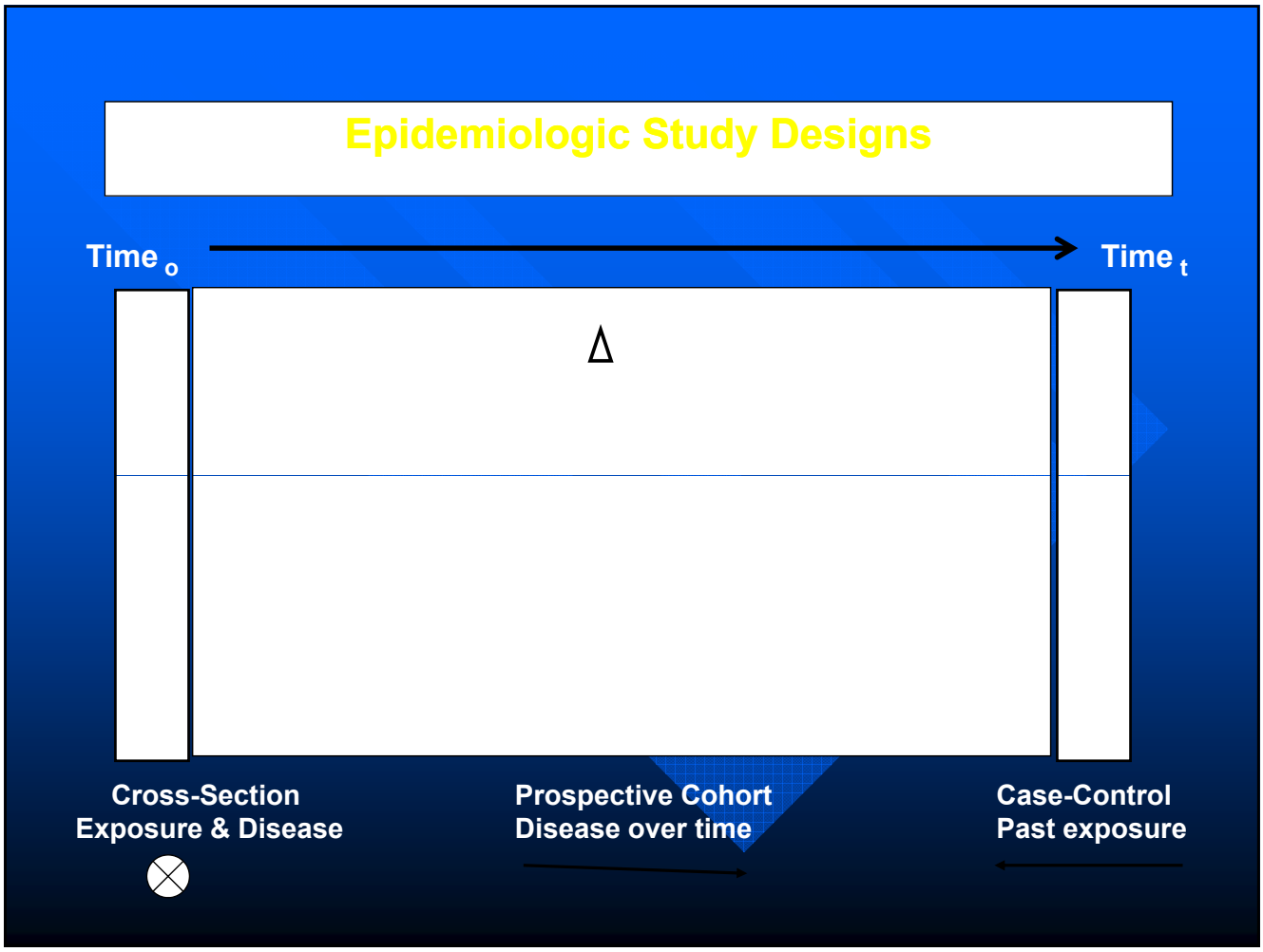
Epidemiological Study Designs

Study Design: Objectives

- Review cross-sectional, ecological, case/ control, & cohort so that the fellow can
  - describe each study design
  - recognize each study design in medical literature
  - state the advantages and disadvantages of each study design


Epidemiologic Study Designs
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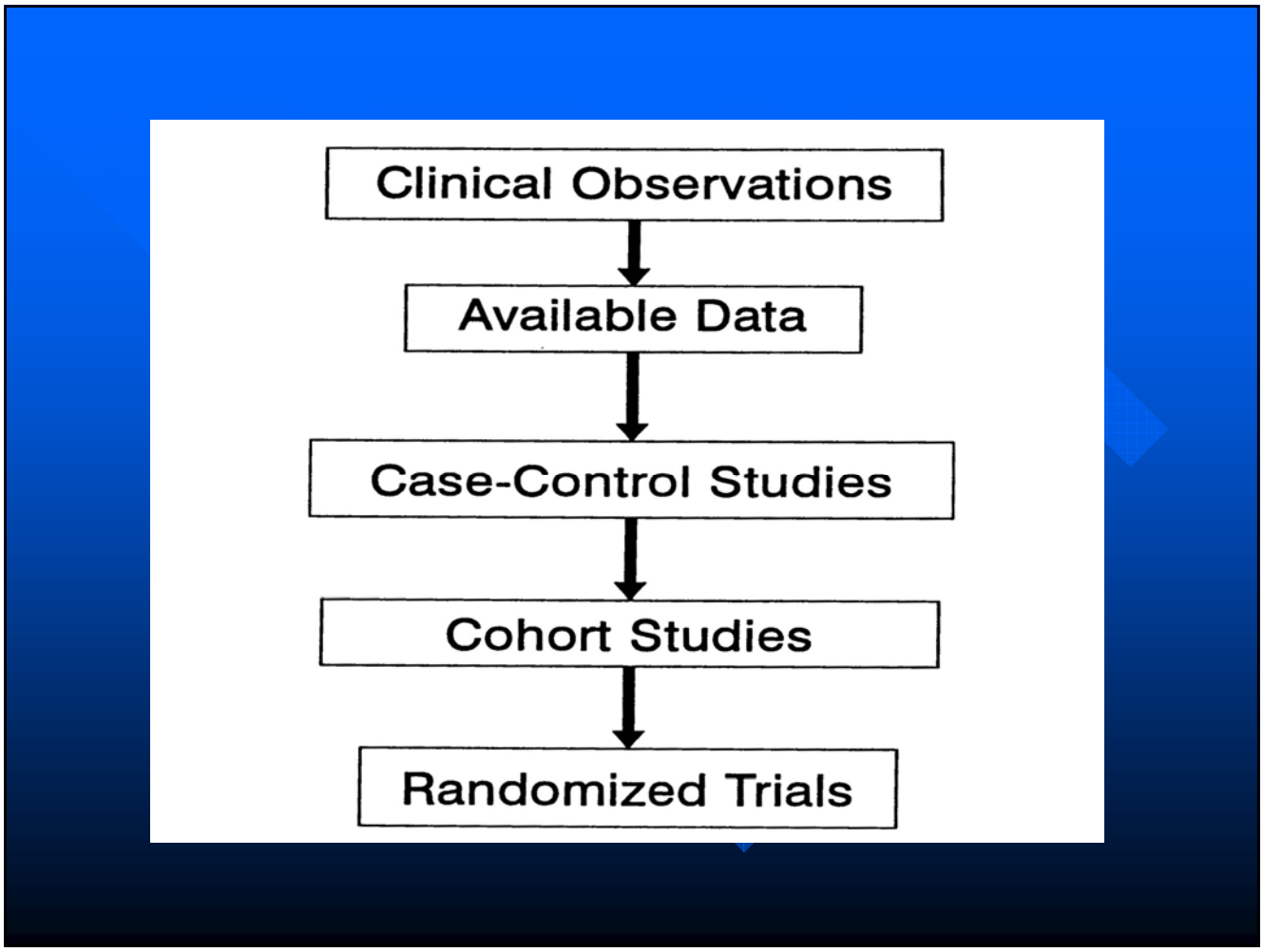
Cross-Section
Exposure & Disease
Prospective Cohort
Disease over time
Case-Control
Past exposure


Clinical Observations
Available Data
Case-Control Studies
Cohort Studies
Randomized Trials

Cross-Sectional Study: Definition

- Conducted at a single point in time or over a short period of time. No Follow-up.
- Exposure status and disease status are measured at one point in time or over a period.
- Prevalence studies. Comparison of prevalence among exposed and non-exp.

Cross-Sectional: Uses

- Very useful for public health planning (number of beds in a hospital).
- Disease etiology. Conduct this by obtaining data on risk factors for a disease.
- Hypothesis generating

Cross-sectional: Diseases/Outcomes

- Diseases of slow on-set and long duration.
- Care not sought for until later advanced stage (e.g. chronic bronchitis or osteoarthritis, mental illness).
- Diseases of short duration.
- Many outcomes can be assessed using cross-sectional studies.

Cross-sectional: Advantages

- Usually use population-based samples, instead of convenient samples. Generalizability.
- Conducted over short period of time
- Relatively inexpensive

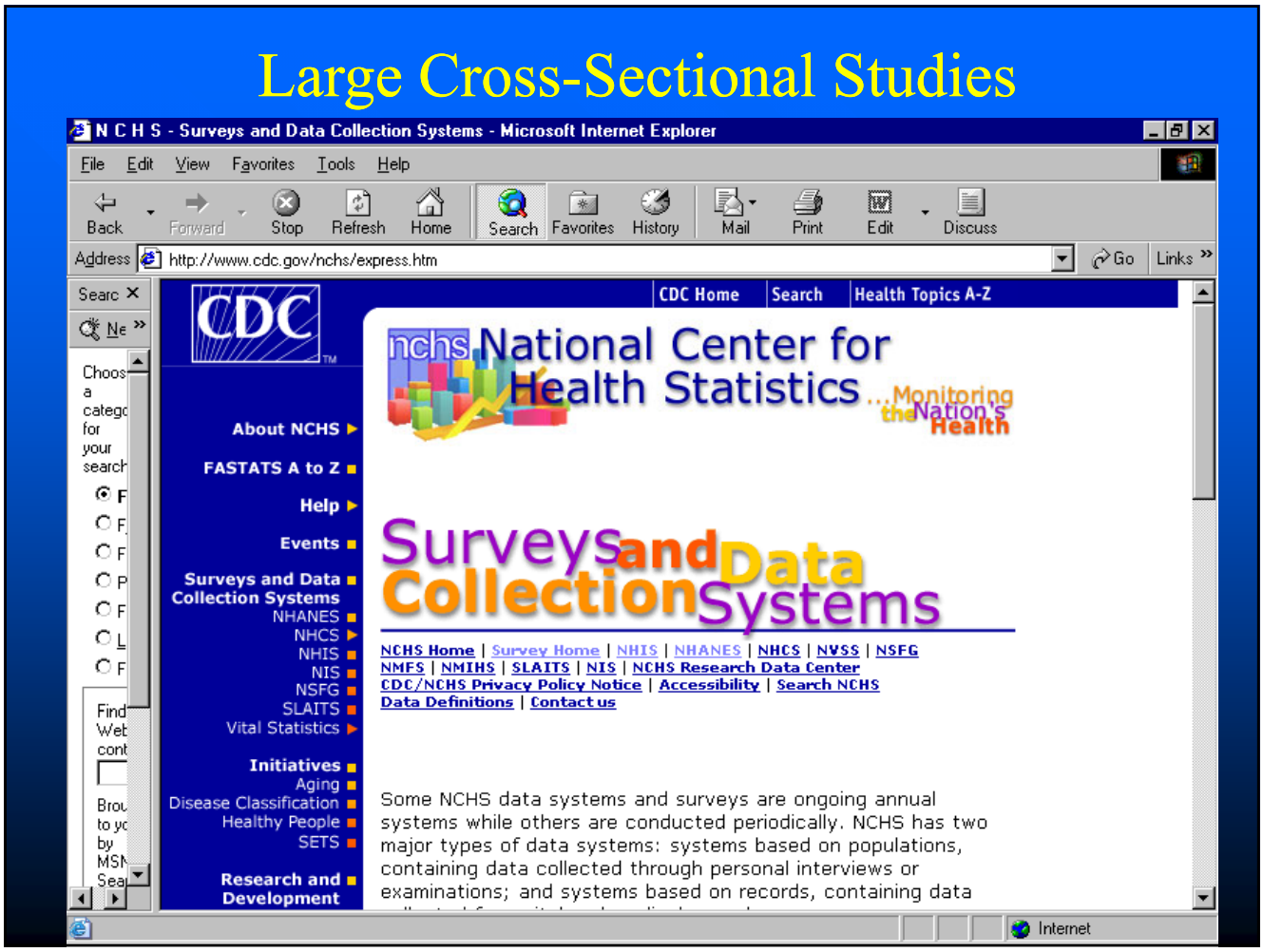
Cross-sectional: Disadvantages

- Difficult to separate cause from effect, because measurement of exposure and disease is conducted at the same time.
- A persons exposure status at the time of the study may have little to do with their exposure status at the time the disease began.
- Neyman Bias. Longer-lasting cases.

Exposure & Disease

- Similar to case/control and cohort studies.
- Various tools: questionnaires, records, lab tests, physical measurements, other procedures.
- Timing. Finding out how long and when
- Changes in exposure over time.
- Disease ascertainment: quest, symptoms

Large Cross-Sectional Studies



Ecologic Studies

- Aggregates of individuals.
- Aggregates often defined by units: geographic region, school, health care facility.
- Does the overall occurrence disease in a population correlate with occurrence of the exposure.
- No individual data

Ecologic Studies: Data collection

- Exposure data and disease data are often collected at different times for different reasons.
- Environmental measures/ Global measures.
- Incidence and mortality data vs working in a factory.
- Ecologic Falacy is an important factor.

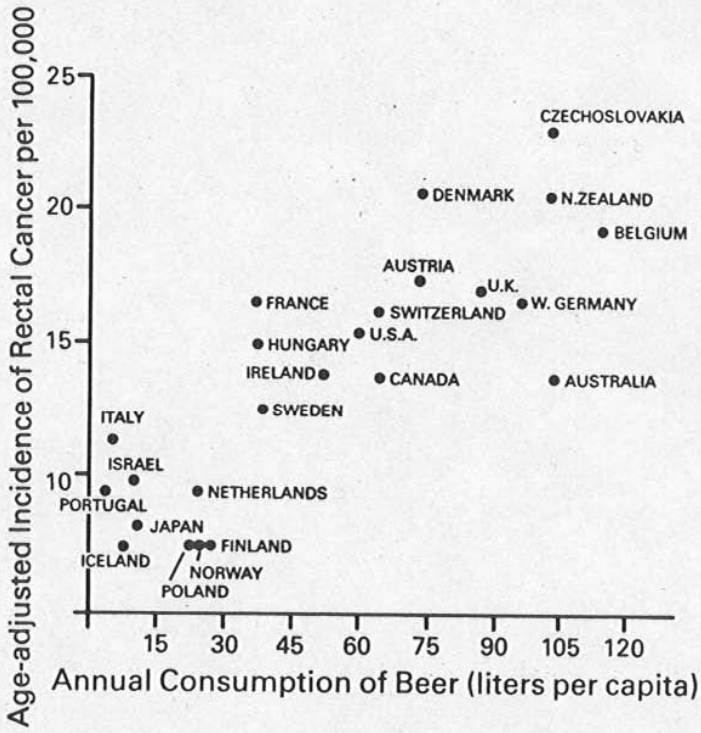


Figure 10–1. Example of data from an ecological study (from Breslow and Enstrom, 1974).

Ecologic Studies: Disadvantages

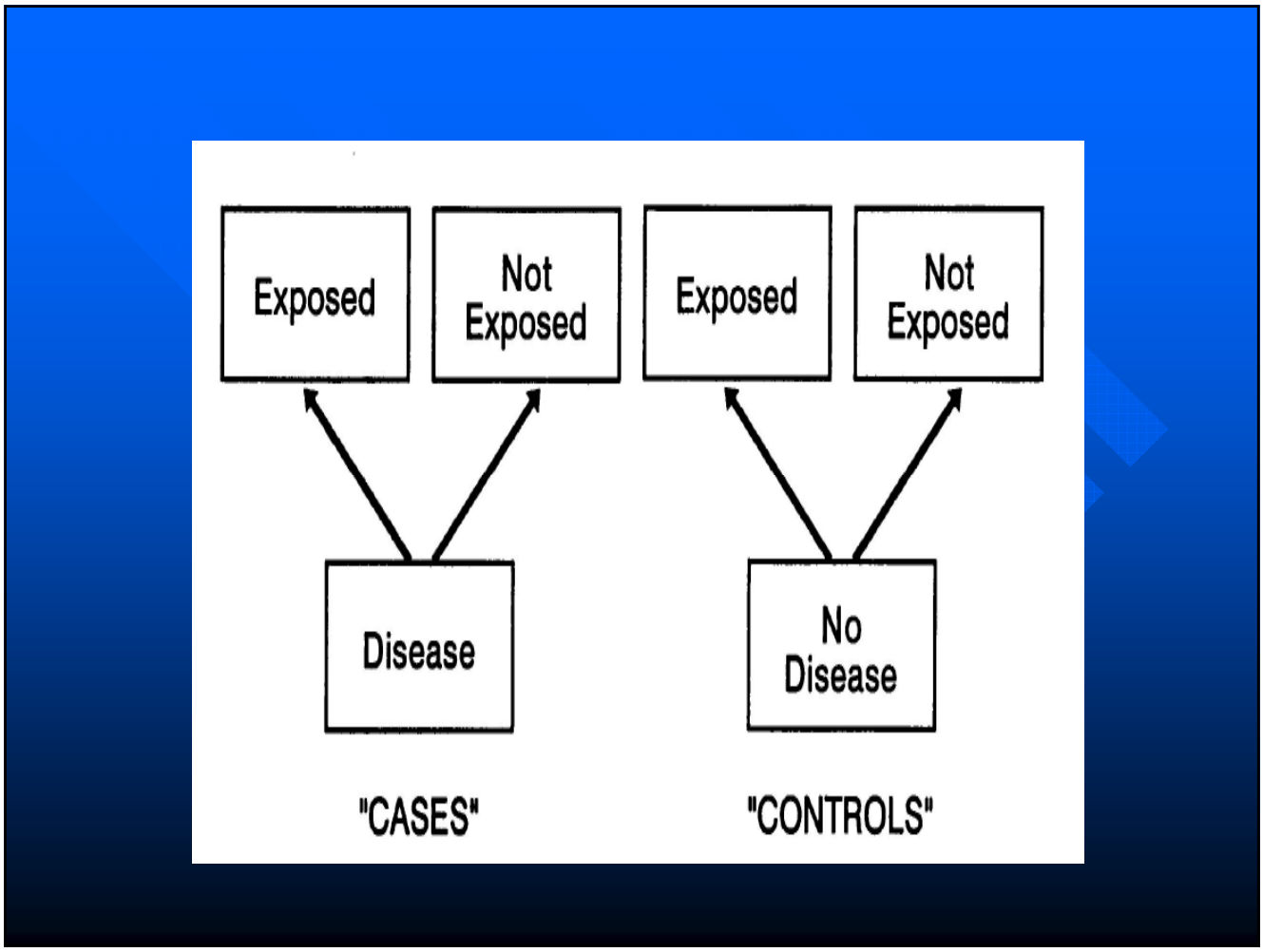
- Ecological Fallacy. Inappropriate conclusions regarding relationships at the individual level based on ecological data/aggregate data.
- Inappropriate conclusions about causation.
- No causal conclusions can be drawn. Temporal ambiguity.
- Lack of adequate data
- Additional studies do and don't support ecological conclusions.

Ecologic Studies: Advantages

- Hypothesis generating.
- Low cost and not time consuming.
- Limited data for individuals (environmental studies).
- Achieves substantial variation.
- If inferences are to be made about groups.
- Useful for social scientists as well as epidemiologists. Evaluation of new policies.

Design of Case-Control Studies

- Cases: persons/group with a given disease
- Controls: persons/group without the given disease
- Ascertain exposure or background of the two groups and compare the proportion
- Best suited for study of diseases where medical care usually sought, (hip fracture, cancer) because this makes it easier to identify cases


Exposed
Not Exposed
Exposed
Not Exposed
Disease
No Disease
"CASES"
"CONTROLS"

Selection of Cases

- Ideally, investigator identifies & enrolls all incident cases in a defined population in a specified time period
- Select cases from registries or hospitals, clinics
- When all incident cases in a population are included, the study is representative; otherwise there is potential for bias (e.g. referral bias)
- Use of prevalent vs incident cases

Selection of controls

- Critical that the exposure in the controls is representative of the exposure in the population
- Ideal controls would have same/similar characteristics as the cases
- Matching cases to controls

Population-Based Controls

- The best control group is a random sample of individuals from same source population (as the cases) who have not developed the disease
- Population-based controls are the best way to ensure that the distribution of exposure among the controls is representative
- Random digit dialing or canvassing households

Hospital Controls

- Hospital controls are the most frequently used source
- Hospital controls may not be representative of exposure rates in the target population (e.g?)
- The use of other ill persons as controls will provide a valid result only if their illness is unrelated to the exposure in question.

Benefits of Using Hospital Controls

- Convenient
- Cheap
- Numerous
- Avoids non-response
- When a population-based case registry is not available, hospital controls better represent the subpopulation from which the cases arose

Other Controls

- Neighborhood controls are somewhat matched on SES & environmental exposures but may “overmatch” & be expensive
- Friends & relatives also cause problems with “overmatching” with habits, environment and occupation & are generally a poor choice for controls

Use of Multiple Controls

- Case to control ratio used is usually 1:1; if large number and cost is the same for both groups
- If a study has a small number of cases, increasing the number of controls increases power of study

Advantages of Case Control Design

- Relatively inexpensive
- Good for diseases with long latency
- Optimal for rare diseases
- Multiple etiologic factors evaluated for single disease
- Shorter time
- Smaller sample

Limitations of Case Control Design

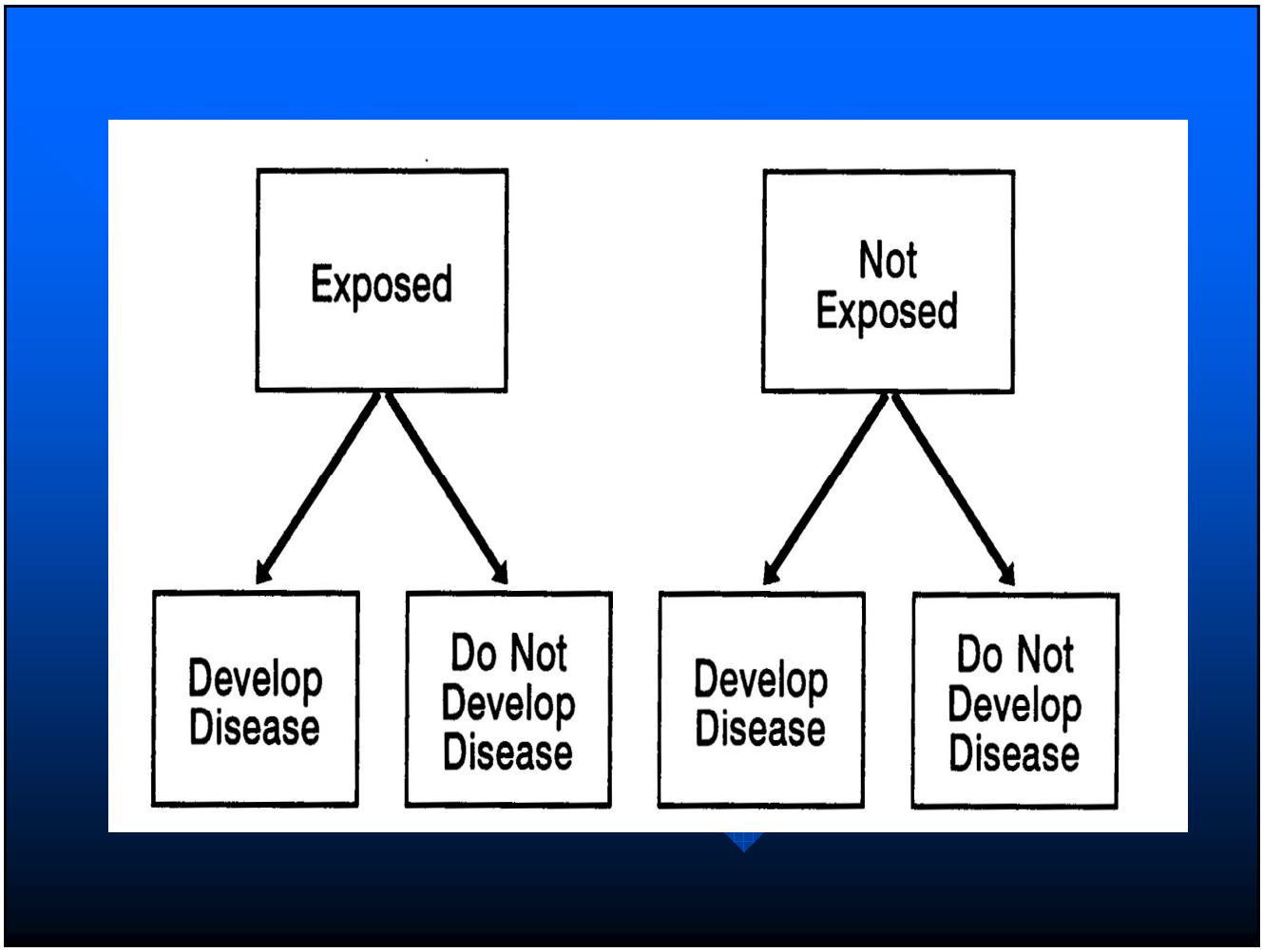
- Identifying controls may be difficult
- Temporal relationship between exposure & disease difficult to establish
- Prone to bias (Recall) compared with other study designs

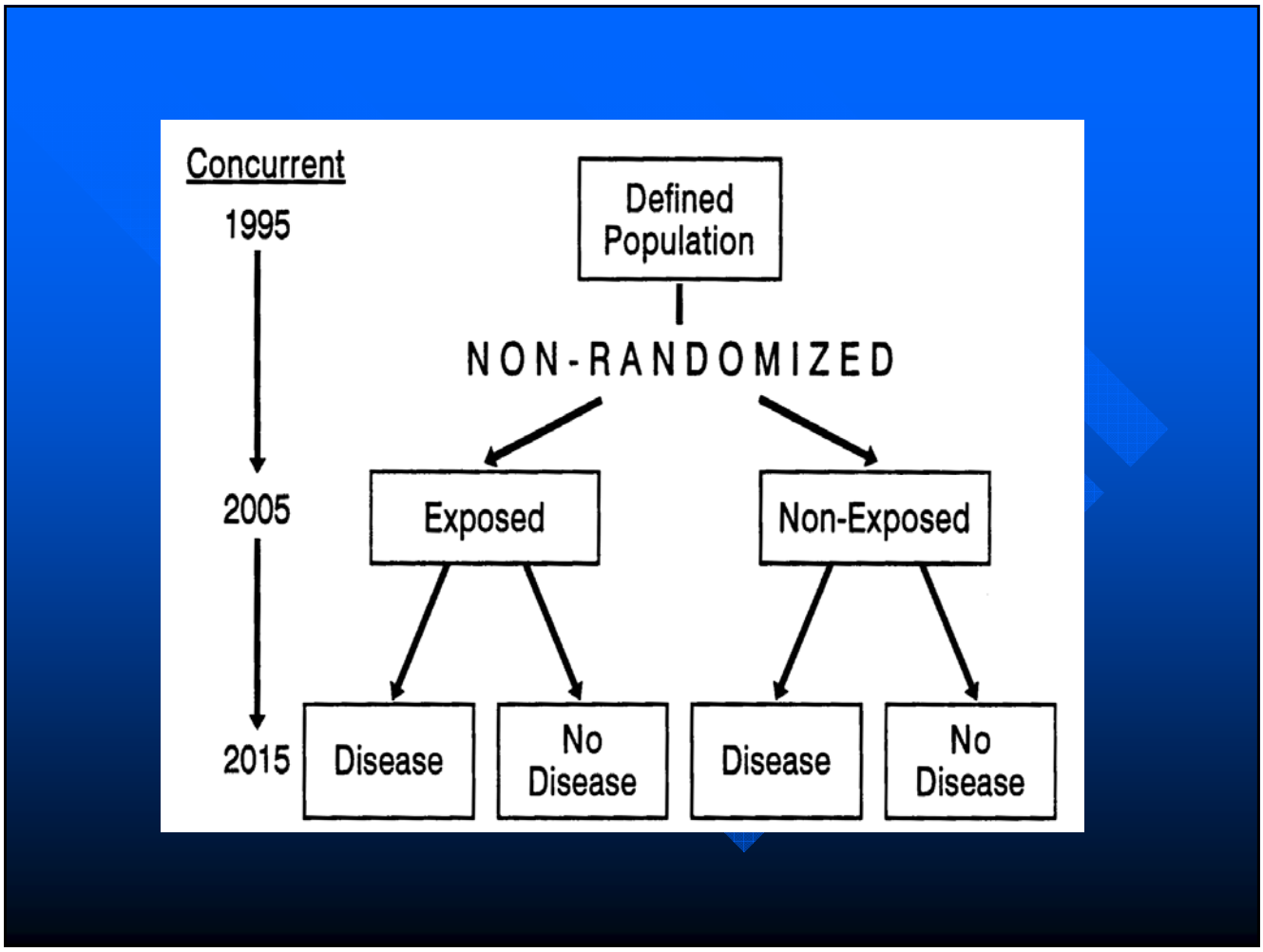
Limitations of Case Control Design Cont'd

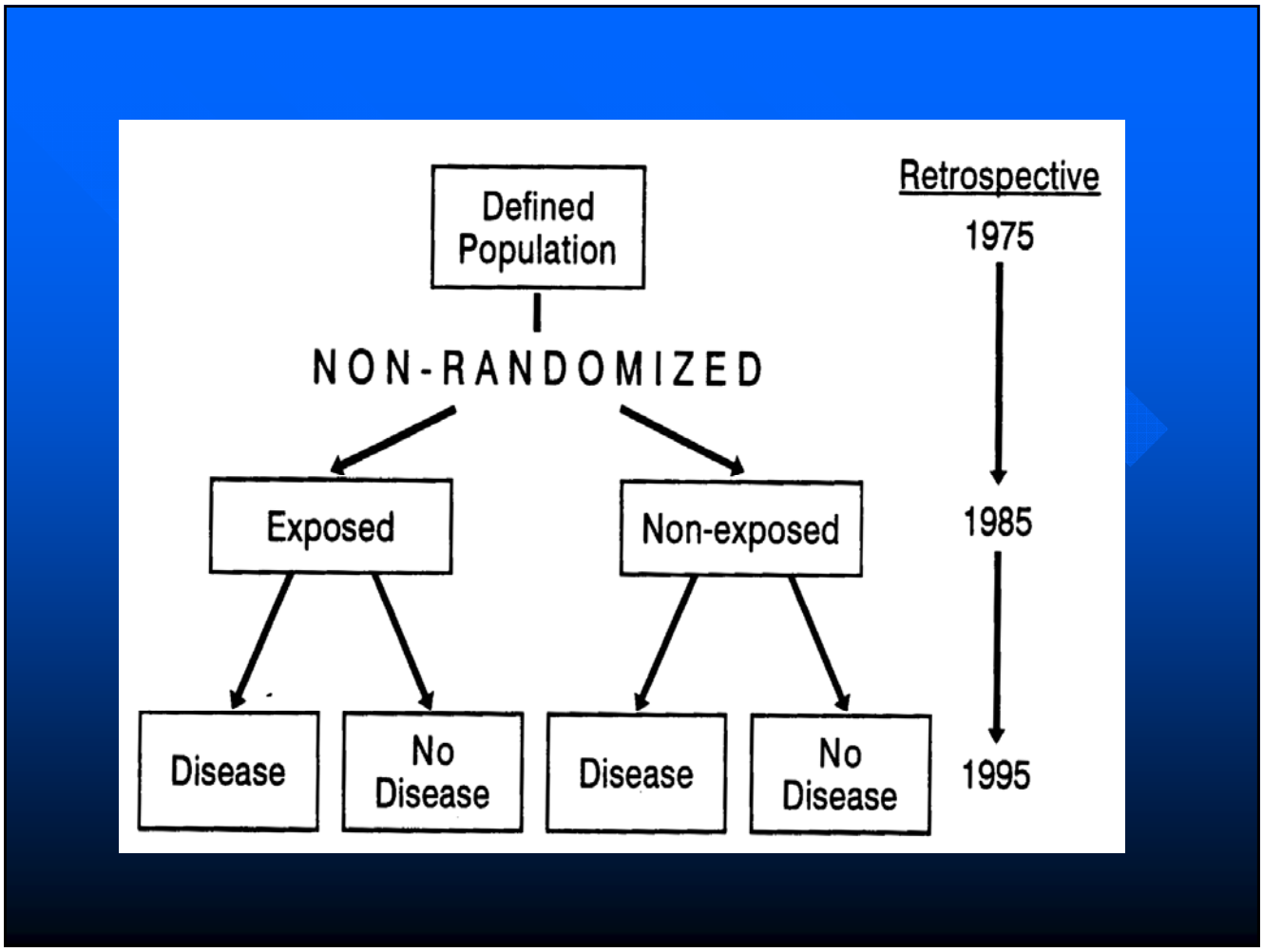
- Difficult to determine representativeness of cases & controls
- Unless study is population based can't measure incidence of disease
- Bad for rare exposures (despite a large number of cases, may still end up with few exposed cases)

Design of Cohort Studies

- Compares (Ie)/(Iue)
- Can either start with group that is exposed or with a defined population and wait for exposure to occur
- Exposure determined prior to DZ
- Framingham Heart Study, NHS
- Prospective vs retrospective cohort


Exposed
Not Exposed
Develop Disease
Do Not Develop Disease
Develop Disease
Do Not Develop Disease


Concurrent
1995
2005
2015
Defined Population
NON-RANDOMIZED
Exposed
Non-Exposed
Disease
No Disease
Disease
No Disease


Defined Population
NON-RANDOMIZED
Exposed
Non-exposed
Disease
No Disease
Disease
No Disease
Retrospective
1975
1985
1995

Advantages of Cohort Studies

- Able to determine time sequence between exposure & disease
- Avoids bias in measuring exposure
- Able to study multiple exposures & multiple outcomes
- Able to calculate incidence of disease in exposed and unexposed
- Good for rare exposures

Disadvantages of Cohort Studies

- Typically requires a long follow up period (although this is shorter with retrospective cohort studies)
- Expensive (again, less so with retrospective)
- May require large sample size
- Potential for loss to follow up
- Inefficient for rare diseases
- Need adequate records of exposure to perform retrospective cohort study

Comparison of Case/Control & Cohort Studies

	Case/Control	Cohort
Rare Exposure	Inefficient	Efficient
Rare Disease	Efficient	Inefficient
Disease with long latency	Efficient	Inefficient
Cost	Cheap	More Expensive
Time	Shorter	Longer
Size	Smaller	Larger
Temporal Relationship	Difficult to assess	Good to determine (RR)