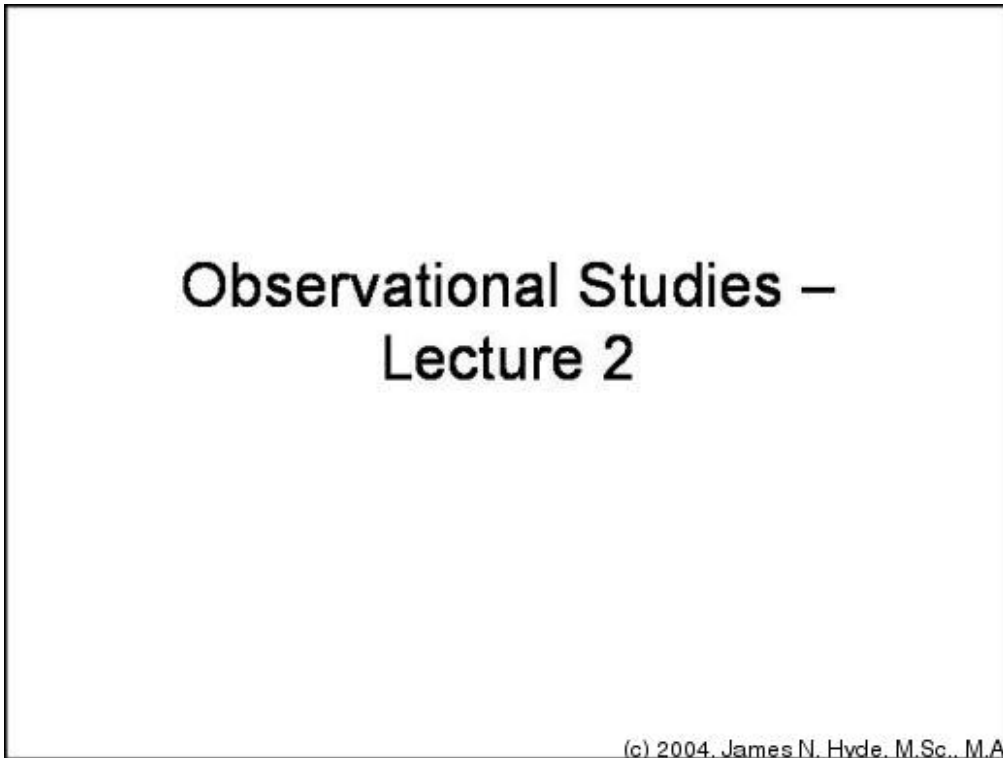
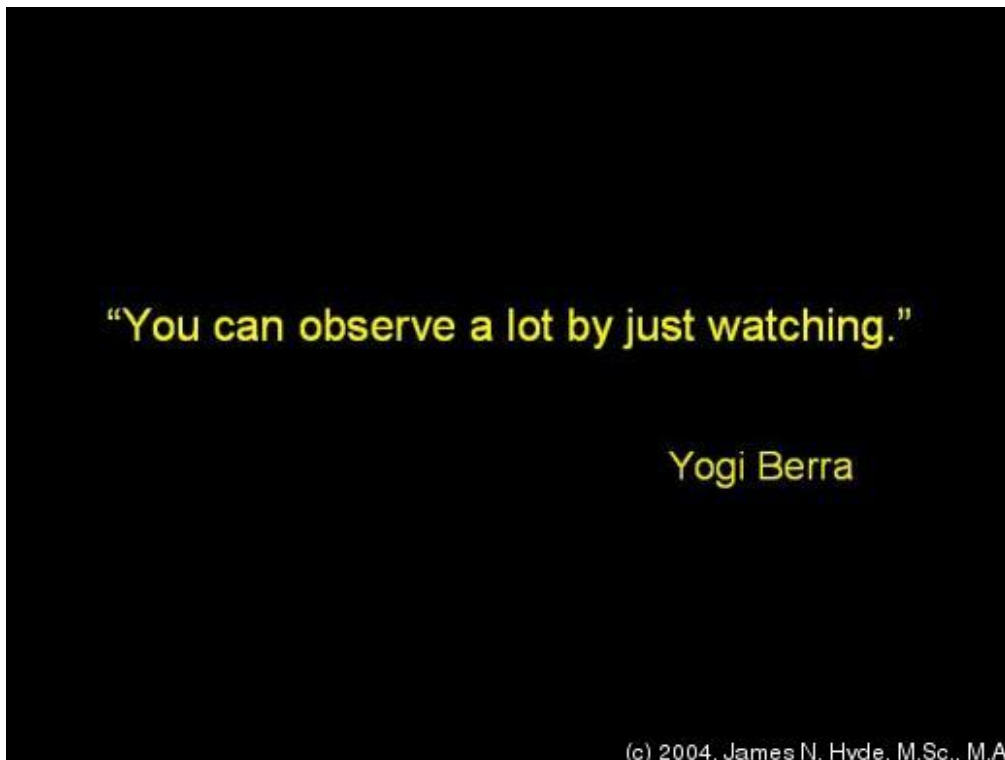


1. Observational Studies Introduction Slide



2. Quote



3. Types of Non-Causal Associations

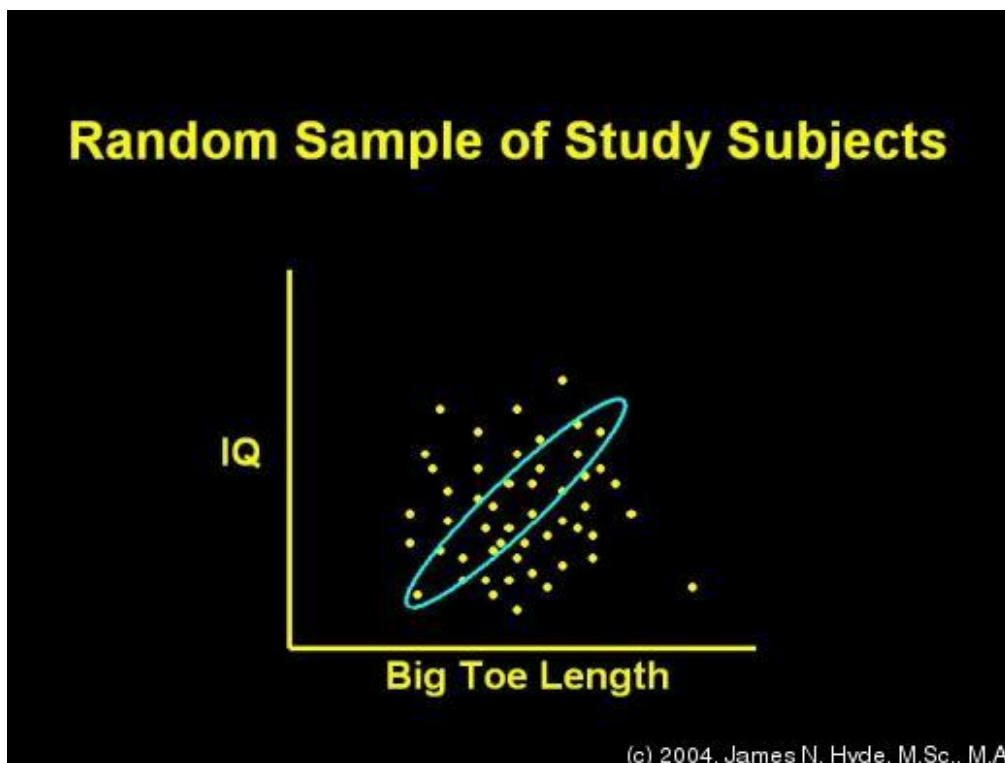
Types of Non-Causal Associations

- Chance Associations
- Artifactual Associations
- Indirect Association

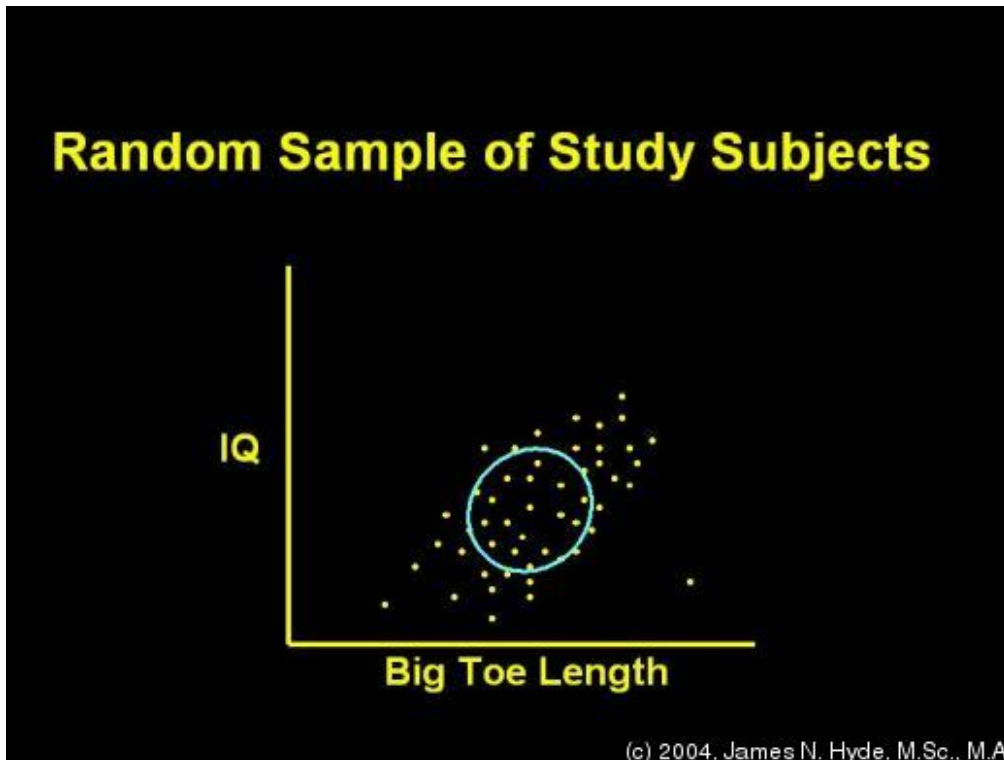
Note: Association does **not** mean causation.

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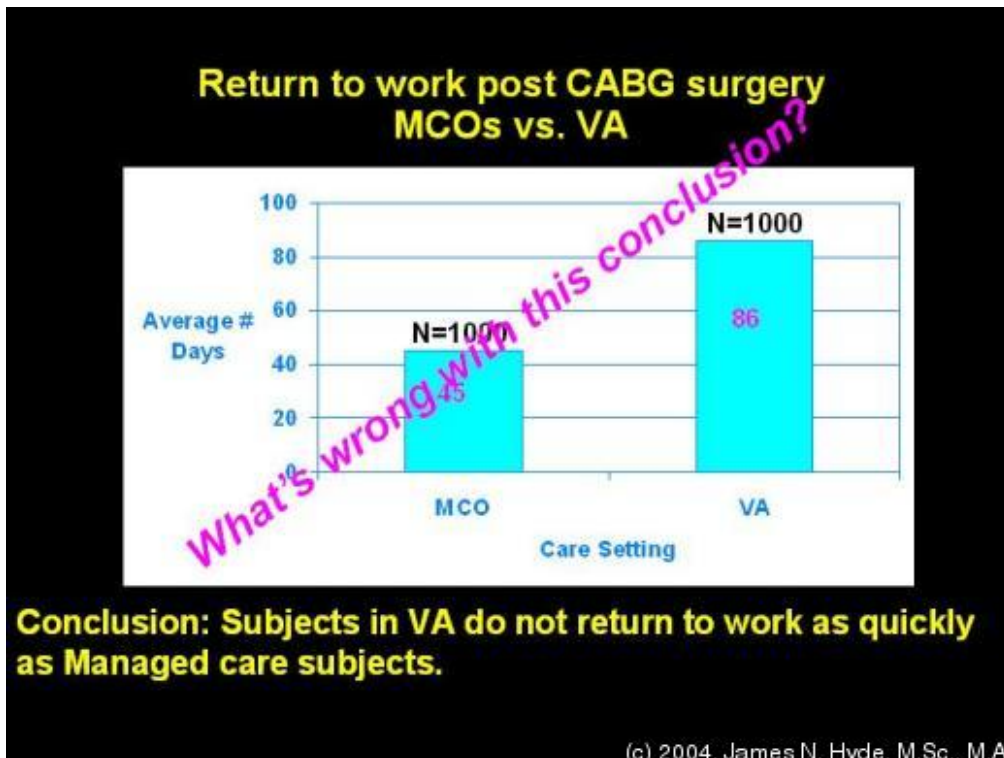
4. Random Sample of Study Subjects



5. Random Sample of Study Subjects, cont.



6. Return to work post CABG surgery MCOs vs. VA



7. Steps in the analytic process...

Steps in the analytic process...

- **R/O Chance (sampling) error**
- **R/O Artifactual (design) errors**
- **R/O Indirect (third factor) errors**

What is left ? The possibility that 'A→B'

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8. Valid Relationship

Per Capita Phones & CHD Deaths for 15 Countries

Per Capita Phones	CHD Mortality
0.1	20
0.2	25
0.3	30
0.4	40
0.5	45
0.6	55
0.7	60
0.8	65
0.9	70
1.0	75
1.2	85
1.3	90
1.4	95
1.5	100
1.6	105
1.7	110

What accounts for this valid relationship?

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9. Criteria for assessing causal associations

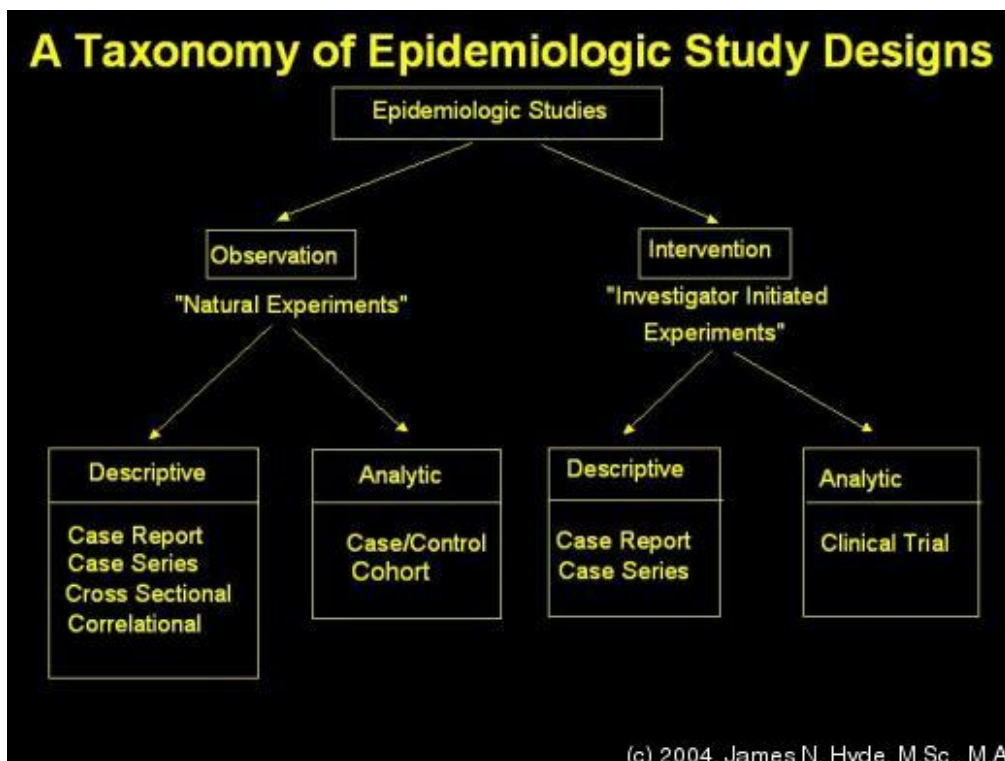
Criteria for assessing causal associations

- Temporality
- Strength
- Dose response Greater import
- Replicability
- Biologic plausibility
- Alternative explanations
- Cessation of exposure Lesser import
- Specificity
- Consistency with other knowledge

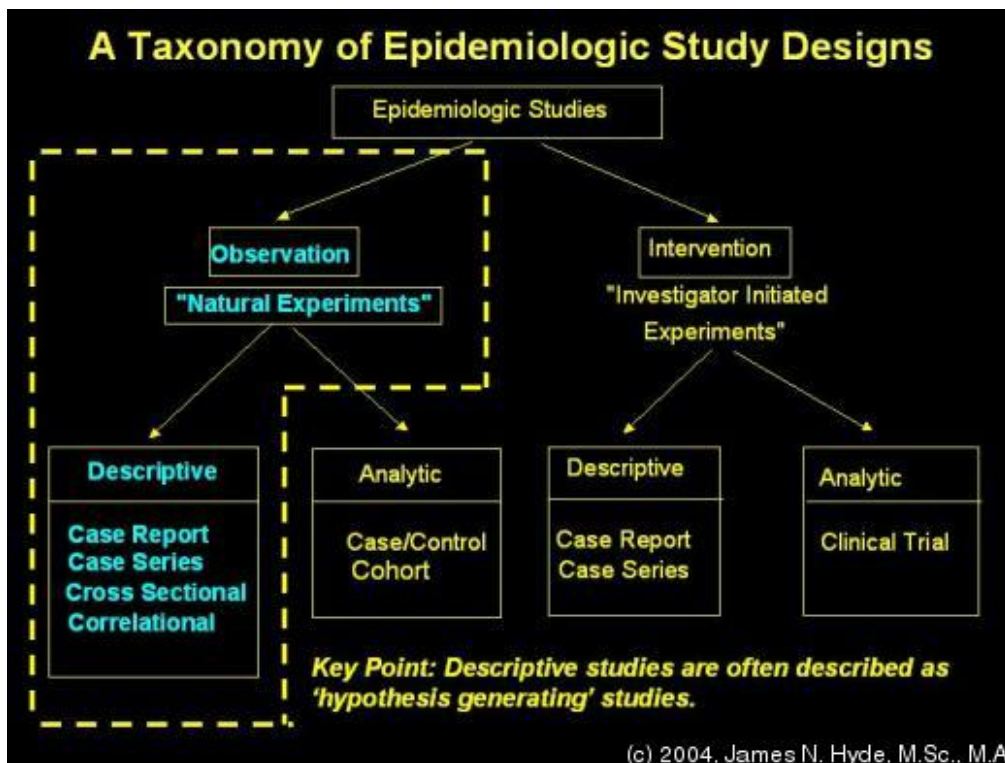
Key Point: *Not all criteria need to be met. The more that are met the more confident we feel in asserting causality*

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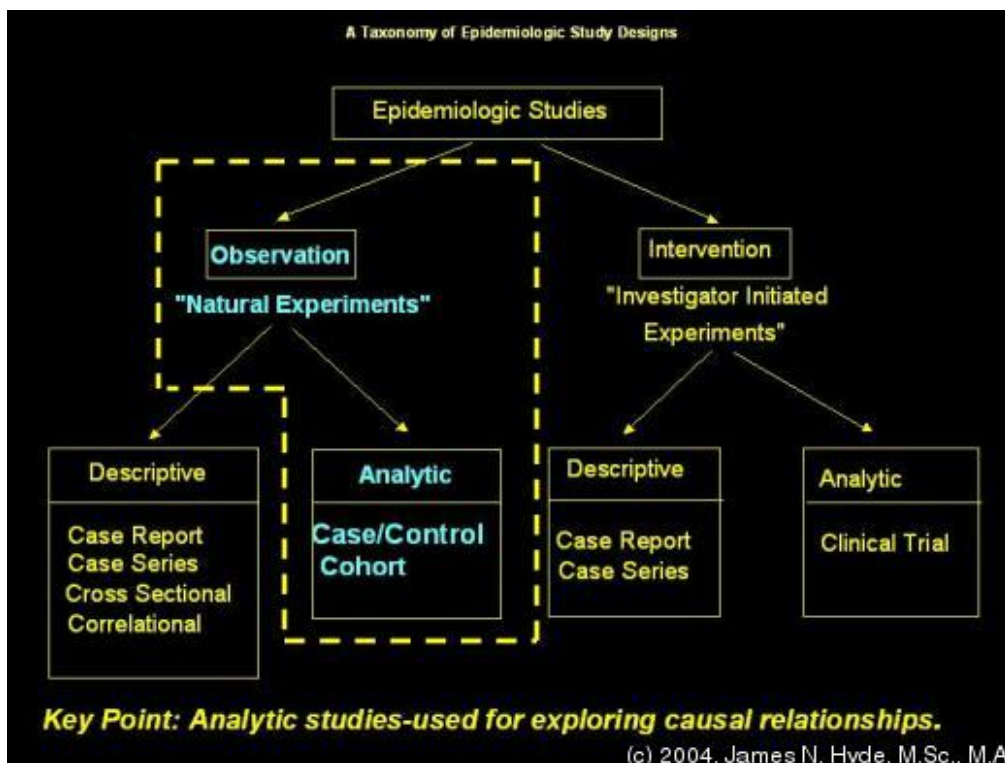
10. A Taxonomy of Epidemiologic Study Designs 1



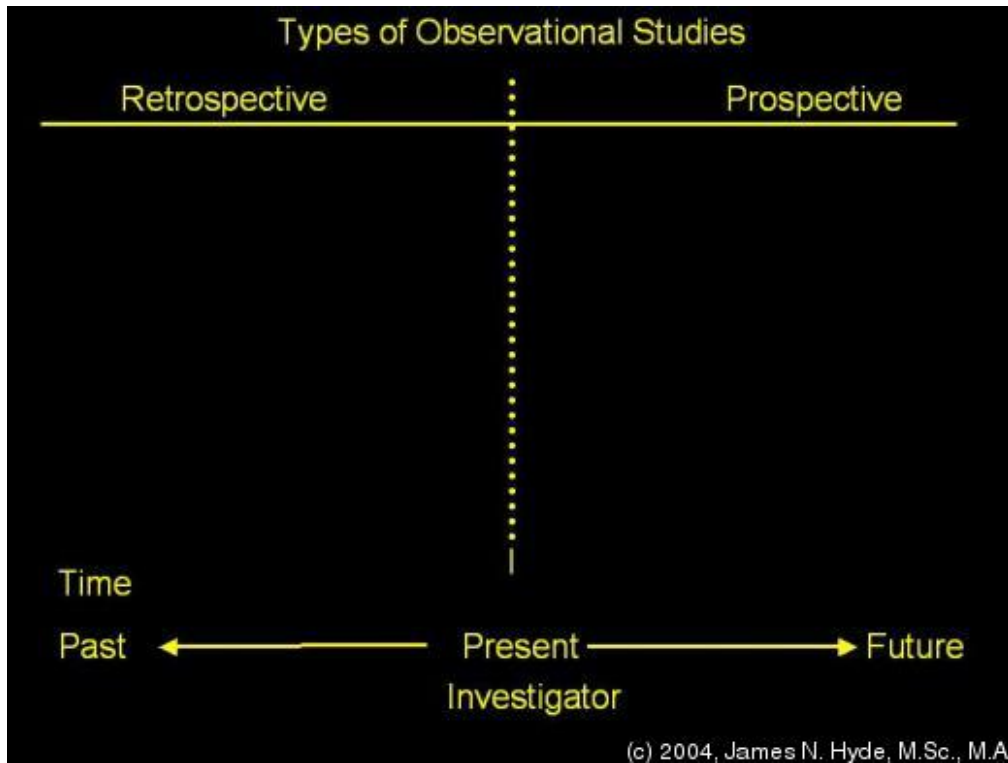
11. A Taxonomy of Epidemiologic Study Designs 2



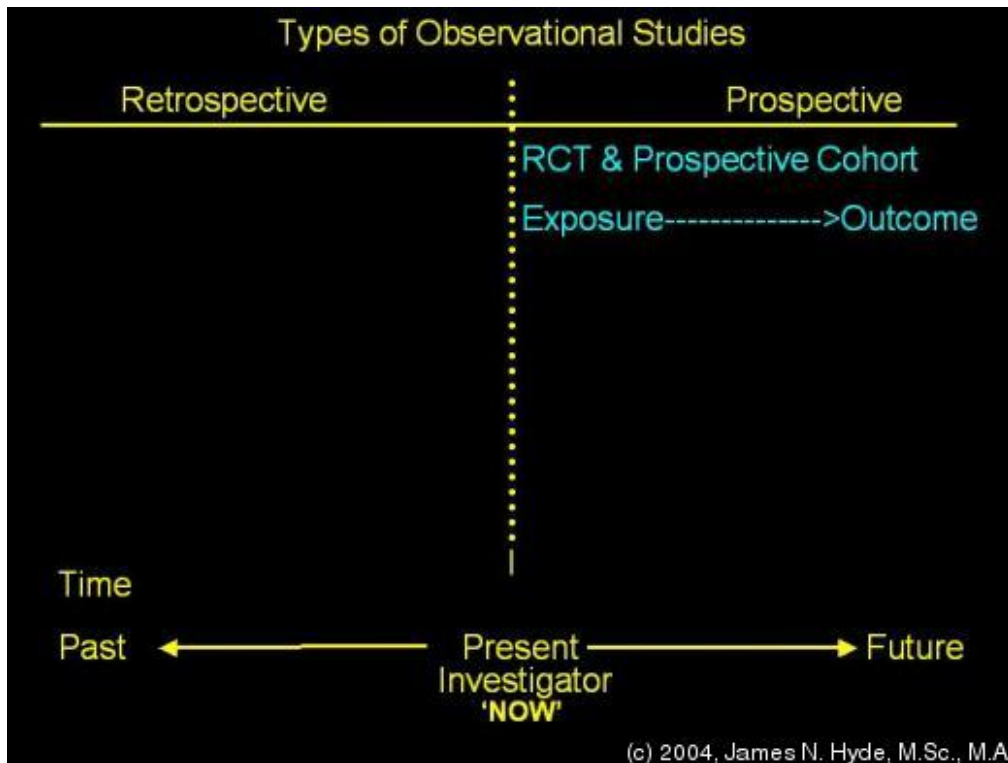
12. A Taxonomy of Epidemiologic Study Designs 3



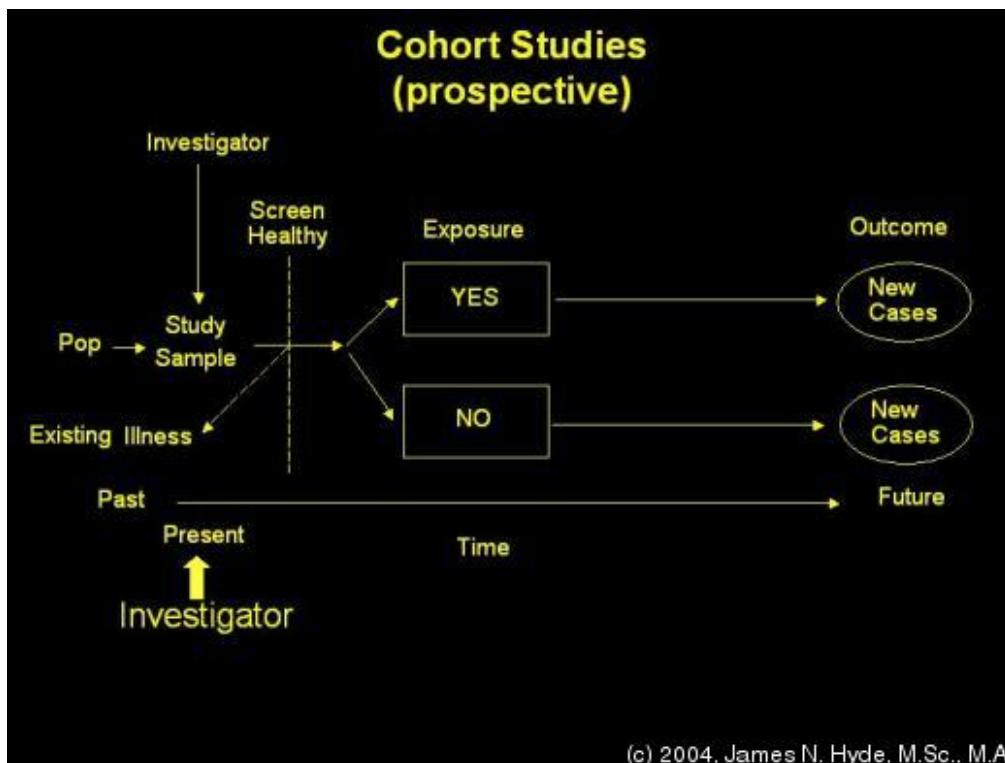
13. Types of Observational Studies 1



14. Types of Observational Studies 2



15. Cohort Studies(prospective)



16. Prospective Cohort Study

Prospective Cohort Study

Example: Concerned about the possible relationship between cell phone use and head and neck cancer a prospective cohort study is undertaken. 10,000 subjects are recruited for study. All are examined and determined to be "cancer-free" at the start of the study. 5,000 are "regular" cell phone users and 5,000 claim never to have used one and promise not to use one until after the study is complete. The investigators follow the subjects for five years.

At the conclusion of the study there are 4 head and neck cancers in the exposed group and 2 in the non-exposed group.

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17. Prospective Cohort Study Key Points

**Prospective Cohort Study
Key Points**

- **Subjects must be “disease-free” at initiation**
- **Assessing exposure**
 - Definition of “exposure”
 - Measuring exposure
- **Comparability of groups**
- **Assessing outcome**
- **Loss to “follow-up”**
- **Analytic methods**

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18. Prospective Cohort Study Strengths and Weaknesses

**Prospective Cohort Study
Strengths and weaknesses**

Strengths:

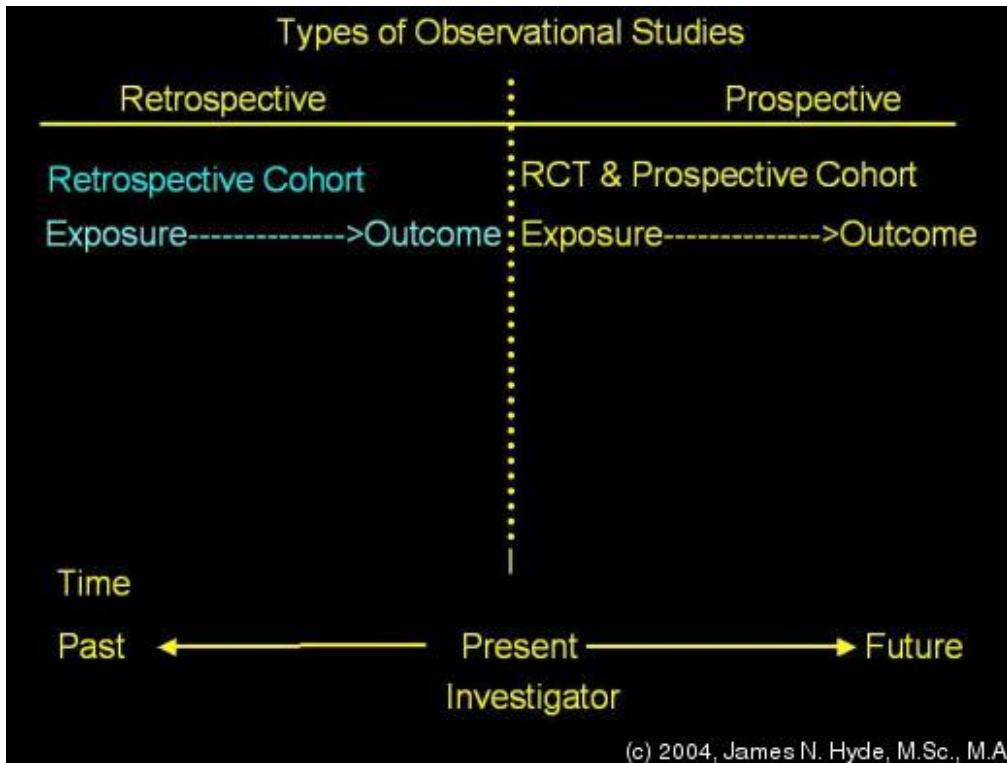
1. Temporal relationship established
2. Multiple outcomes can be studied
3. Good choice for rare exposure situations
4. Investigator defines and applies outcome criteria

Weaknesses:

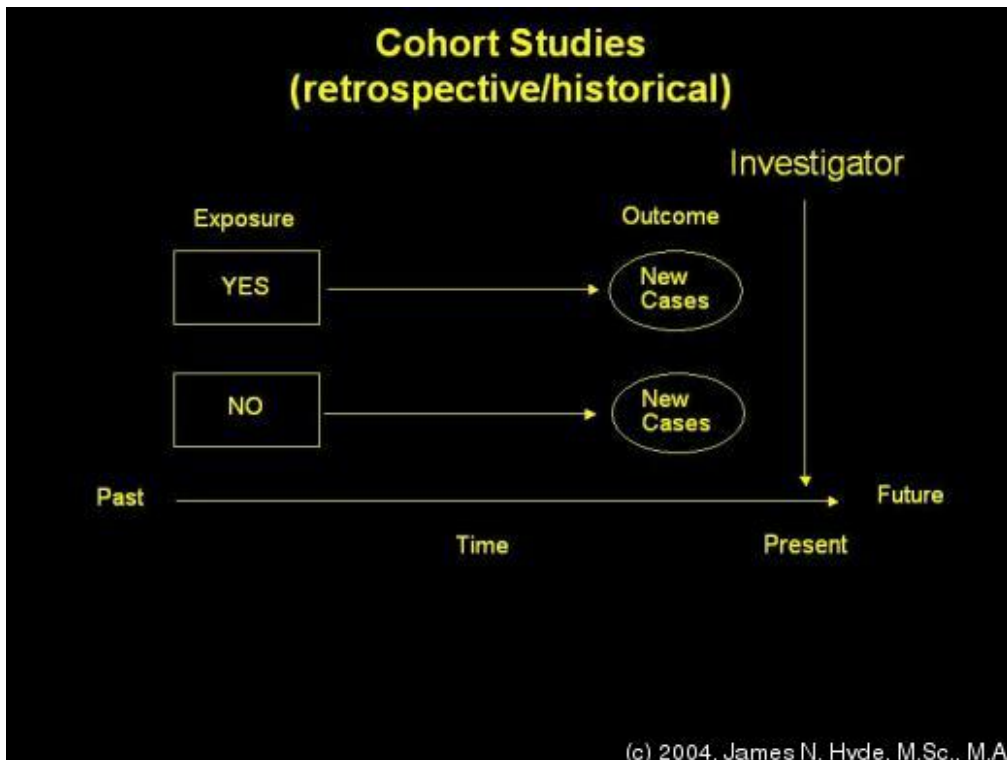
1. Hard to select and maintain a “non-exposed” group
2. Loss to follow-up problem for long induction times
3. Expensive
4. Changes can take place over time in both exposure and outcome assessment.

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19. Types of Observational Studies 3



20. Cohort Studies (retrospective/historical)



21. Retrospective Cohort Study

Retrospective Cohort Study

Example: Concerned about the possible relationship between cell phone use and head and neck cancer a retrospective cohort study is undertaken. 5000 subjects are located through phone company billing records as cell phone owners for at least 5 years. They are matched by age and sex with 5,000 non-cell phone users from the same community.

Subjects are then asked for permission to review their medical records to determine if they have been diagnosed with a head and neck cancers In the past five years. Any subject diagnosed with cancer more than five years earlier is removed from the analysis.

There are 4 head and neck cancers in the exposed group and 2 in the non-exposed group.

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22. Retrospective Cohort Study Strengths and weaknesses

**Retrospective Cohort Study
Strengths and weaknesses**

Strengths:

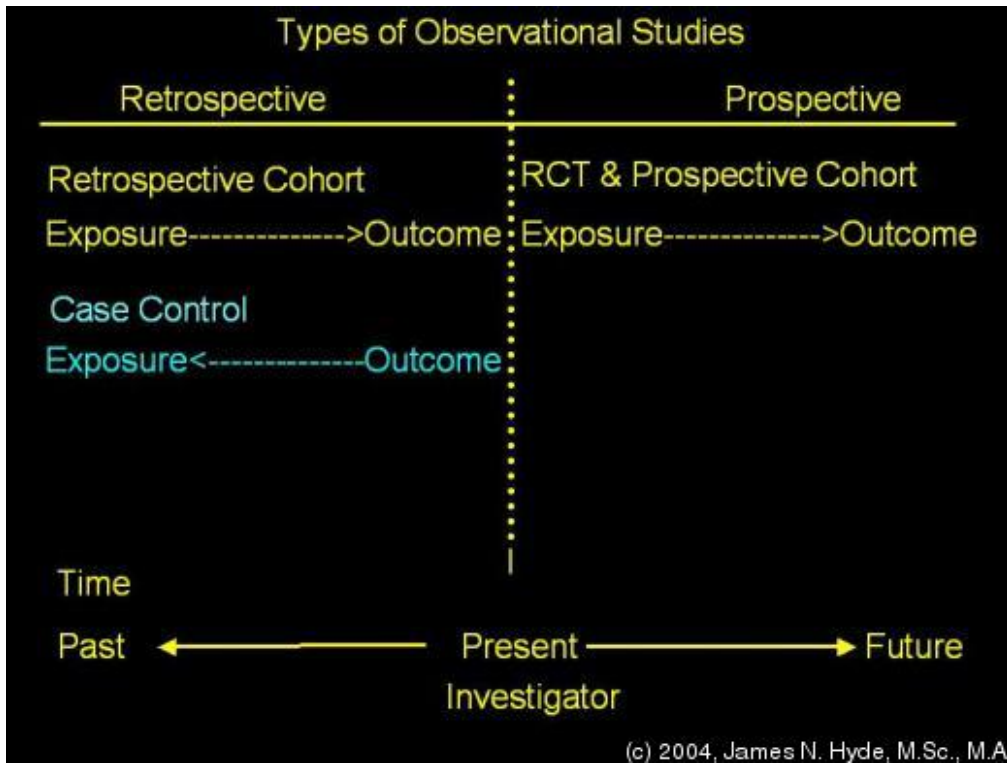
1. Good for studying multiple outcomes
2. Relatively inexpensive (outcome and exposure have already occurred).
3. Quick and relatively inexpensive.

Weaknesses:

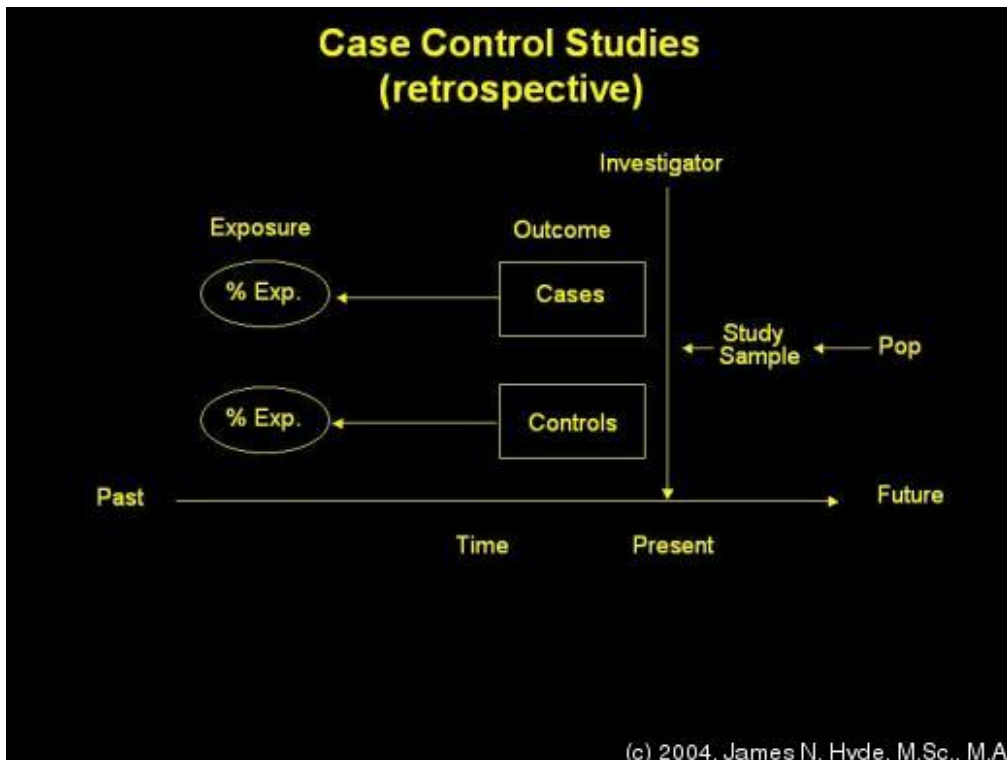
1. Investigator has no control over exposure or outcome assessment. (Reliance on record keeping of others).
2. Temporal relationship often difficult to determine
3. Requires large sample for rare outcomes
4. Comparability between exposed and non-exposed difficult to achieve.

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23. Types of Observational Studies 4



24. Case Control Studies (retrospective)



25.

Case Control Study

Case Control Study

Example: Concerned about the possible relationship between cell phone use and head and neck cancer a case control study is undertaken. 300 cases of head and neck cancer are identified from 6 cancer treatment centers around the US. An additional set of 300 hundred controls are chosen from hospitals associated with the same centers. Controls were selected among those not being treated for cancer. They were matched with cases on age, sex, race and occupational category.

Analysis showed that cases were 20% more likely to report cell phone use than controls.

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26.

Case Control Study Key Points

Case Control Study Key Points

- **Investigator controls outcome definition through case selection**
- **Studies are quick and relatively cheap**
- **Comparability of cases and controls often problematic**
- **Exposure assessment relies heavily on recall or records**
- **Analysis cannot measure risk directly**

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27. Case Control Study Strengths and Weaknesses

**Case Control Study
Strengths and weaknesses**

Strengths:

1. Good for rare diseases
2. Requires relatively little time to conduct
3. Possibility of exploring multiple exposures.
4. Inexpensive

Weaknesses:

1. Reliance on recall and/or historical data on exposure
2. Temporality can be difficult to establish
3. Comparability of cases and controls

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28. Summary

Summary

- **Causation Vs. Association**
- **Criteria for assessing causal associations**
- **Observational studies**
 - ✓ **Take advantage of “natural experiments”**
 - ✓ **Can be great alternative to RCTs**
 - ✓ **Have strengths and weaknesses that must be kept in mind**

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