The Role Of Retrospective Chart Reviews In Natural History Studies:

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General Design Types of Natural History Study

- Published medical literature review
- Retrospective chart review
- Prospective cross-sectional
- Prospective longitudinal
Retrospective Chart Review

Challenges

• Often a starting place for a *NH knowledge program*

• Usually not sufficient for all objectives

• Guide to designing a prospective longitudinal study

• Limitations
  – Often because clinical care chart records were for purposes of clinical care, not objectives of NH study
Retrospective Chart Review

– Data often not comprehensive
  • Determined by utility for clinical care at that time
– Variability in what was evaluated and how it was recorded
  • Often varies from site to site
  • May vary within site over time
  • Quality of data may vary
    – Erroneous data not corrected (e.g., lab values)
      – Particularly when not important for clinical care
  • Even if intended to be same aspect of disease
Retrospective Chart Reviews- How to make the most of it

• Realistic expectations- understand the challenges as each situation is unique
• Carefully thought out data elements to extract
• Care when obtaining data eg. lab data(norms)
• Work with experts
• Attention to quality of data (quantity does not always equal quality)
• Need to start early, often before a drug candidate
• Incredibly useful in drug development program
  – Design of end points or in special situation can be used as comparitor group
  – Choose appropriate cohort
3 examples of Retrospective Chart Reviews with varying success