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Objectives

1. Learn best practices in conducting a retrospective chart review;
2. Understand quantitative data collection, documentation and coding methods; and
3. Time permitting - Understand accepted approaches for analyzing and reporting data.
What is retrospective chart review research?

- *Research method* utilizing information that was not originally collected for research purposes

- Most common in:
  - Epidemiologic studies
  - Evaluation research
  - Quality Improvement
Why do it?

- **Feasibility**
  - Ethical considerations
  - Cost
  - Avoid lag time in waiting for health outcomes to occur
  - Access to rare cases or occurrences

- **Hypothesis generation**

- **Suitable method based on research goal/question**
RESEARCH ETHICS BOARD
STATUS REPORT 06 January 2011
Total Studies 745
(From 2005 September 01 to Date)
ACTIVE STUDIES =219
PENDING APPROVAL = 28

Type of Ethics Review for ACTIVE Studies

<table>
<thead>
<tr>
<th>Ful Board</th>
<th>Delegated</th>
</tr>
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<tr>
<td>115</td>
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Funding for ACTIVE Studies

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<tr>
<th>Sponsor</th>
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<th>Non-FH Grants</th>
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Active Studies by Department Area

<table>
<thead>
<tr>
<th>Department Area</th>
<th>Number</th>
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<tbody>
<tr>
<td>Acute Programs</td>
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<td>ICU</td>
<td>4</td>
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<tr>
<td>Occupational Therapy</td>
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<td>Psychology</td>
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<td>Cardiology</td>
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<tr>
<td>Infection Control</td>
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<tr>
<td>Oncology</td>
<td>7</td>
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<td>Public Health</td>
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<tr>
<td>Chronic Care</td>
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<tr>
<td>Infectious Diseases</td>
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<tr>
<td>Orthopaedics</td>
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<tr>
<td>Rehabilitation Services</td>
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</tr>
<tr>
<td>Critical Care (ICU)</td>
<td>6</td>
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<tr>
<td>Internal Medicine</td>
<td>1</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>1</td>
</tr>
<tr>
<td>Renal Program</td>
<td>1</td>
</tr>
<tr>
<td>Health Services</td>
<td>1</td>
</tr>
<tr>
<td>Nutrition</td>
<td>2</td>
</tr>
<tr>
<td>Professional Practice</td>
<td>5</td>
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<tr>
<td>Youth and Young Adult</td>
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<tr>
<td>Hospice and Palliative Care</td>
<td>3</td>
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<tr>
<td>Obstetrics</td>
<td>5</td>
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<tr>
<td>Psychiatry</td>
<td>7</td>
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</table>

28% involve retrospective data
Limitations of Retrospective Chart Review Research

- **Internal Validity**
  - Confounding
  - Selection bias
  - History
  - Maturation
  - Regression toward the mean
  - Instrumentation change
  - Differential attrition
  - Researcher bias

- **External Validity**
  - Generalizability of results

“We (the journal) are dubious about the integrity of retrospective chart review studies and therefore cannot accept your manuscript for publication.”
Quick Facts

Pubmed

- Search of terms (18 January 2011)
- “retrospective” = 419358 hits
- “retrospective chart” = 13913 hits
- “retrospective chart methodology” = 9124
  - Limits to title only = 2
  - Review of article = 1 article proposing a methodology for retrospective chart review

Scientific Approach to Retrospective Chart Review

Nine step process (Gearing, 2006)

1. Conception
2. Literature review
3. Proposal development
4. Data Abstraction Instrument Organization
5. Abstraction Protocols and Guidelines
6. Data abstraction
7. Sample size justification
8. Ethics
9. Pilot Study

Comparison of Approaches

Are you ready for a plate of spaghetti?
Comparison of Approaches

Geary et al., 2006

1. Conception
2. Literature review
3. Proposal development
4. Data Abstraction Instrument Organization
5. Abstraction Protocols and Guidelines
6. Data abstraction
7. Sample size justification
8. Ethics
9. Pilot Study

Fraser Health Framework

1. Generate idea
2. Conduct literature review
3. Refine research question
4. Plan research methodology
5. Create research proposal
6. Apply for funding
7. Apply for ethics approval
8. Collect and analyze data
9. Draw conclusions and relate findings

http://research.fraserhealth.ca/media/2010%20research%20process.pdf
1. Generate Research Idea

- Clearly stated research question
- Statement of goal and hypothesis
- Input from peers/experts

- These factors can provide information related to study feasibility
  - Is the information you are seeking available from the medical record and is the chart information likely to be useful in answering your question?
  - This step is often overlooked or not thoroughly undertaken.
1. Generate Research Idea

- Clearly stated research question

<table>
<thead>
<tr>
<th>PICO</th>
</tr>
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<tbody>
<tr>
<td>P = Patient/problem</td>
</tr>
<tr>
<td>I = Intervention</td>
</tr>
<tr>
<td>C = Comparison</td>
</tr>
<tr>
<td>O = Outcome</td>
</tr>
</tbody>
</table>
1. Generate Research Idea

Example: General Clinical Question
What method is best to manage obesity in patients with diabetes?

Example: Applying PICO
P = Adult patients with type II diabetes
I = Lifestyle education and fitness training
C = Weight reducing medication
O = Body Mass Index

In adults with type II diabetes, is weight reducing medication more effective than lifestyle education and fitness training in reducing BMI?
1. Generate Research Idea

Assessing the research goal:

Describe – when little is known about the characteristics of a problem, patient group, health care providers or a health service/system.

Associate – when you want to assess if certain factors might go hand in hand with a well described problem.

Predict – when you want to understand the extent to which certain factors contribute to or cause a problem.

Compare – when you wish assess the impact of an intervention or to determine if there are differences between interventions or characteristics of various groups.
1. Generate Research Idea

Statement of goals/hypothesis – linked to state of knowledge and research question

<table>
<thead>
<tr>
<th>Goal</th>
<th>Types of Questions</th>
<th>Hypothesis</th>
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</thead>
<tbody>
<tr>
<td>Describe</td>
<td>What are the characteristics of x?</td>
<td>No</td>
</tr>
<tr>
<td>Associate</td>
<td>Is there a relationship between x and y?</td>
<td>Yes</td>
</tr>
<tr>
<td>Predict</td>
<td>Do different levels of x predict y?</td>
<td>Yes</td>
</tr>
<tr>
<td>Compare</td>
<td>Is x different from y?</td>
<td>Yes</td>
</tr>
</tbody>
</table>
1. Generate Research Idea

- Input from peers/experts
  - May help in identifying data available/not available in the medical record
  - May identify ways in which to enhance internal validity based on knowledge of contents of the medical record
    - Confounds
    - Instrumentation change
    - Selection of cases – i.e., ICD codes
2. Literature Review

3. Refine Research Question

- Identify available evidence
  - What is already known – what interventions have been studied?
  - How is the patient sample defined?
  - What are the commonly reported outcome measures?
  - What methodologies have been used – what are the limitations?

- Helps to refine research question.
- Conducting literature reviews take time, but this is a very important step in the research process.
- The Fraser Health library can help you with your search.
Make it FINER

**FINER Criteria for a Good Research Question**
(from *Designing Clinical Research*, by Stephen Hulley and Steven Cummings, 1988)

**Feasible** - Adequate number of subjects.
- Adequate technical expertise.
- Affordable in time and money.
- Manageable in scope.

**Interesting** - To the investigators.

**Novel** - Confirms or refutes previous findings.
- Extends previous findings.
- Provides new findings.

**Ethical**

**Relevant** - To scientific knowledge.
- To clinical and health policy.
- To future research directions.

Confirmed through literature search and review
Thank you for not doing research that has already been done.
3. Plan Research Methodology

- Sample and justification
- Data Abstraction Instrument Organization
- Abstraction Protocols and Guidelines
- Data Abstraction
Choosing Your Study Sample

- How many charts do you need to look at?
  - All within a certain time frame?
  - A random sample?
  - TIP: Consult a statistician EARLY!
If you want your results to be statistically valid, your sample size is critical.

If the sample is too small, the random variability will be too large, and the results will be limited in their applicability.

Sample size table for identifying a representative sample from a population.

Consult with epidemiologist if you wish to obtain statistically valid estimates of association, prediction or comparisons/differences.
### Sample Size Table – For Descriptive Research

<table>
<thead>
<tr>
<th>N</th>
<th>95% Confidence</th>
<th>90% Confidence</th>
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<tbody>
<tr>
<td></td>
<td>Margin Of Error</td>
<td>Margin Of Error</td>
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<td></td>
<td>± 3%</td>
<td>± 5%</td>
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<td>500,000</td>
<td>1,110</td>
<td>400</td>
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<tr>
<td>or more</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Random Sampling

**Simple Random Sampling**
- Each unit has an equal probability of being chosen.
- Enumerate list, then choose with random numbers.

**Systematic Random Sampling**
- Selection of the sample using an interval “k” so that every “k” unit in the population is selected
  1. Number the units in the population from 1 to N.
  2. Decide on the n (sample size) that you want or need.
    - k = N/n = the interval size.
  3. Randomly select an integer between 1 and k.
  4. Then take every kth unit.
The nuts and bolts of data quality
3. Plan Research Methodology

- Data Abstraction Instrument Organization
- Abstraction Protocols and Guidelines
- Data abstraction - Validity and Reliability
- Pilot Testing
Validity of chart review data

Pan et al. (2005) Journal of Clinical Epidemiology

- 77.5% to 96.9% accuracy depending on clinical area (lowest in ICU)
- 55.1% to 97.4% accuracy depending on chart section (lowest in diagnosis and surgical)
- 19% errors were missing data
Reducing error in chart review

- Data abstraction
- Coding
- Cleaning
- Validation
- Verification
Data Abstraction Tool (DAT)

Minimum standards

- Design the data abstraction tool (DAT) to collect the data specified by the project protocol.
- Document training of personnel on the protocol, DAT completion instructions and data submission/storage.
Data Abstraction Tool (DAT)

Best practices

- Design the DAT along with the project protocol to assure collection of all data specified in protocol.
- Keep questions, prompts and instructions clear and concise.
- Design the DAT to follow the data flow from the perspective of the person completing it, taking into account the flow and organization of data in a medical record.
- Avoid referential and redundant data points.
- Design the DAT with the primary measures of interest in mind as the main goal of data collection.
- Design the DAT with accompanying data collection instruction book, and library of codes.
DAT Design Considerations

A. Feasible – capable of being completed

B. Acceptable – resulting data is useful

C. Reliable – consistency of information abstracted
A. Feasible

Feasible – capable of being completed

- Logical order
- Match with the order and type of information in the chart
- Abstraction can be done within time limits
## Feasible – Order and Type of Data

### Static
- Snapshot in time
- Demographic
- Medical history

### Evolving
- Information is collected over time
- Repeated measurement
- Vital signs
- Daily Medication orders

### Cumulative
- Collected over time, but not linked to specific points in time
- Medication errors

Single record - single page
Series of single records/pages per time interval
Single page cumulative log linked with time interval
Single page cumulative log

Feasible – capable of being completed
Logical order
Match with the order and type of information in the chart
Abstraction can be done within time limits
Consider ‘modules’ to match chart information (e.g., lab values, pharmacy)

DAT designed to accommodate different chart or report formats (e.g., charting from different sites)

Time to complete
B. Acceptable

Acceptable – resulting data is useful

- Minimization of missing information
- Low data abstraction error rate
- Use of validated or accepted measures
- Reduction of bias
Minimization and management of missing information

- Pre-screen charts for availability of information
  - Missing information may impact sample size precision and feasibility
- Detailed instructions for recording potentially ambiguous information
- Distinguish between missing, not appropriate, not done and 0 values
Acceptable – Error Minimization

- **Error Minimization**
  - Limit manual entry of numbers or text
  - Use boxes/shapes to enter information (standardize formats)
  - Limit use of circled items or checkmarks (use X)
  - Limit use of skip patterns
    - Make skip patterns salient by bolding, highlighting or use of graphics
    - Instruct where to skip to, and not what to skip
  - Easy to read
  - Sufficient space
Minimize Data Abstraction Error

LDL cholesterol value ______

LDL cholesterol value ______mg/dL

LDL cholesterol value ______mg/dL or ______mmol/L

LDL cholesterol value ______ mg/dL □

unit if different ______
Standardize DAT Response Formats

Well designed DATs use cues for different response formats:

Text

Site of injury (e.g. left shoulder)

Numeric

Age [___]

Date

___/____/____

dd mmm yy
Standardize DAT Response Formats

Categorical
Single response
- Yes
- No

Multiple-response
- Diabetes
- Arthritis
- Cancer
- Hypertension

Coded Response
1. Mild
2. Moderate
3. Severe

[ ] 1=Mild; 2=Moderate; 3=Severe
**Immunizations**

**FLU VACCINE (past year)**
- 1 Yes
- 2 No
- 3 Refused

**PNEUMOVAX ever:**
- 1 Yes
- 2 No
- 3 Refused

**Td in past 10 years:**
- 1 Yes
- 2 No
- 3 Refused

**PPD Status:**
- 1 Pos
- 2 Neg
- 3 Refused
- 4 Unknown

If PPD Pos, INH Tx Complete:
- 1 Yes
- 2 No
- 3 Refused
- 4 Unknown

If PPD Neg, Last PPD:
Date: _____/_____/_____
Acceptable – Valid

- **Use of validated or accepted measures**
  - Select measures that are consistent with accepted standards for reporting
  - Consider changes over time in normative data
    - e.g., lab normal ranges
- **Content validity**
  - Does the DAT capture all the relevant information?
- **Concurrent validity**
  - Does the information collected in the DAT correspond with observations?
    - Outcome measures in charts may not correspond with healthcare processes.
Acceptable – Valid

What about the person abstracting data?

- Experience in retrospective research or the content area.
- Blind to the study hypothesis.
C. Reliable

- **Clear and unambiguous**
  - Training of data abstractors
  - Data collection guide
    - Glossary of terms and acceptable alternates
    - Decision rules for ambiguous information
  - Guidance information on the DAT

- **Test-retest reliability**
  - To assess consistency within the same person
    - To assess drift over time
    - To assess errors during learning phase

- **Inter-rater reliability**
  - Do any two data abstractors record the same information?
    - Test data abstractors against each other
    - Test data abstractors against gold standard example
Additional tools: DAT Protocol

- Reference manual
- Clear instructions for how to collect the required information
- Listing of each variable, location in chart, method for transcribing from chart to DAT
- DATs with explicit protocols increase inter-rater reliability
What is a codebook?

- A codebook is a log of your DAT fields and how you will code them for data entry to a spreadsheet.

Why use a codebook?

- A codebook will help everyone understand the coding schemes to ensure that they are on the same page!
- Coded data can be entered into a spreadsheet, which will help when analyzing data.
- Data from DAT should be coded numerically for ease of analysis.
## Codebook Example

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Values</th>
<th>Coding</th>
<th>Missing</th>
</tr>
</thead>
</table>
| age           | age            | 1,2,3,4,5 | 1=10-20 years  
2=21-30 years  
3=31-40 years  
4=41-50 years  
5=51+ years | 97=Incorrect response  
98=No response  
99=Not Applicable |
| sex           | sex            | 1,2     | 1=male, 2=female | 97=Incorrect response  
98=No response  
99=Not Applicable |
| happiness     | happiness at work | 1,2,3 | 1=not happy  
2=somewhat happy  
3=very happy | 97=Incorrect response  
98=No response  
99=Not Applicable |
### Spreadsheet Example

<table>
<thead>
<tr>
<th>ID#</th>
<th>Age</th>
<th>Sex</th>
<th>Happiness</th>
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<tbody>
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</tr>
<tr>
<td>8</td>
<td>88</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
Pilot Testing – for Design

- Consider looking at a few charts
  - See what is documented
    - Will tell you what you can capture
  - Get an idea of what the hurdles are?
    - E.g. details of when antibiotic reached the ward were not available
  - Find out where the information actually is
    - i.e. what section of the chart
    - This helps in planning time to complete the work
Pilot Testing – for Validity

- Once DAT is designed and Codebook is in place – test out the data abstraction and coding process on a few charts:
  - Are key pieces of information missing?
  - Does the information translate easily from chart to DAT?
  - Are there classifications, codes or other information that need refining?
- A formal pilot study to test the feasibility, reliability and validity of the data abstraction process is recommended.
  - Sample size of up to 10 percent of the intended sample
More Spaghetti?
Comparison of Approaches

Geary et al., 2006

1. Conception
2. Literature review
3. Proposal development
4. Data Abstraction Instrument Organization
5. Abstraction Protocols and Guidelines
6. Data abstraction
7. Sample size justification
8. Ethics
9. Pilot Study

Fraser Health Framework

1. Generate idea
2. Conduct literature review
3. Refine research question
4. Plan research methodology
5. Create research proposal
6. Apply for funding
7. Apply for ethics approval
8. Collect and analyze data
9. Draw conclusions and relate findings

See Past and Future Workshops

5. Create research proposal
6. Apply for funding
7. Apply for ethics approval
8. Collect and analyze data
9. Draw conclusions and relate findings

http://research.fraserhealth.ca/education/workshops/presentations/

http://research.fraserhealth.ca/education/calendar/
What to Do with your Data
Fun Things to do with Data

- **Data Cleaning**
  - identify and correct errors made during data entry
    - correcting typos, spelling errors, remove duplicates

- **Data Validation**
  - checking that data is sensible and possible
  - compare data against applicable rules
    - identify inappropriate or out of range values

- **Data Verification**
  - check that data is entered correctly and that there are no transcription errors
    - confirm that missing data is indeed missing
Data Cleaning

- Data cleaning is aimed at identifying and correcting data entry errors.
- Double data entry can help identify data entry errors.
- Comparison of Excel spreadsheets using built-in functions will identify data entry errors.
### Entry 1

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
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<tbody>
<tr>
<td>1</td>
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Note: The formula for Entry 1 – Entry 2 is `=Entry1!A2-Entry2!A2`.
Data Validation with Excel

- **Numbers**
  - Specify if entry is a whole number or a decimal number.
  - Set a minimum or maximum.
  - Exclude a certain number or range.
  - Use a formula to calculate whether a number is valid.

- **Dates and times**
  - Set a minimum or maximum.
  - Exclude certain dates or times.
  - Use a formula to calculate whether a date or time is valid.

- **Length**
  - Limit how many characters can be typed in a cell.
  - Require a minimum number of characters.

- **List of values**
  - Specify choices from a list — e.g., small, medium, large.
Data Validation

Full Tutorial at
http://www.contextures.com/xlDataVal01.html
Data Verification

- Clinical trials research
  - Most rigorous verification methods
  - Compare all abstracted data with source documents
  - Labour intensive and costly
  - Not feasible for most health care-based chart review activities
Verification in the health care setting

- **Goal – 95% accuracy**
  - Verify a sample of DATs with charts
  - Sample based on
    - Experience and training of data abstractors
    - Familiarity of data abstractors with care area
    - Complexity of care
    - Type of information
  - Verify data collected early in the chart audit/review
  - Compute percent accuracy overall and for subsections (demographics, diagnostics, surgical procedures)
  - Identify sections falling below 80% accuracy for full verification
  - Verify all missing information if possible
Activity

- Organize into groups of 3 or 4
- Read/scan the Harry Potter study handout (focus on methods)
- Discuss and complete the Retrospective Chart Review Checklist
- Report back with group ratings
Accepted approaches for analyzing and reporting data.