Quantitative Designs for Research and Evaluation

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2012 Seed Grant Competition

2012 Seed Grant Guidelines are now available online. Take advantage of this opportunity for NEW Researchers to get an award of $5000 to spend on research.

Read More

HIGHLIGHTS

Research News - October 2012

Download the latest newsletter.
Objectives

- To describe the key concepts and elements of quantitative research
- To understand the main principles of quantitative research designs/methods
- To understand the relationship between the research question and the quantitative design
Workshop Outline

9:00 – 9:20 Definitions and Key Concepts

9:20 – 10:40 Measurement

10:40 – 10:55 Break

10:55 – 12:30 Quantitative Research Methods
Definitions and Key Concepts
Quantitative Research Definition

Research based on traditional scientific methods, which generates numerical data and usually seeks to establish causal relationships between two or more variables, using statistical methods to test the strength and significance of the relationships.

<table>
<thead>
<tr>
<th>Qualitative</th>
<th>Quantitative</th>
</tr>
</thead>
<tbody>
<tr>
<td>The aim is a complete, detailed description.</td>
<td>The aim is to classify features, count them, and construct</td>
</tr>
<tr>
<td></td>
<td>statistical models in an attempt to explain what is observed.</td>
</tr>
<tr>
<td>Researcher may only know roughly in advance what</td>
<td>Researcher knows clearly in advance what he/she is looking</td>
</tr>
<tr>
<td>he/she is looking for.</td>
<td>for.</td>
</tr>
<tr>
<td>Recommended during earlier phases of research</td>
<td>Recommended during latter phases of research projects.</td>
</tr>
<tr>
<td>projects.</td>
<td></td>
</tr>
<tr>
<td>The design emerges as the study unfolds.</td>
<td>All aspects of the study are carefully designed before data</td>
</tr>
<tr>
<td></td>
<td>is collected.</td>
</tr>
<tr>
<td>Researcher is the data gathering instrument.</td>
<td>Researcher uses tools, such as questionnaires or equipment to</td>
</tr>
<tr>
<td></td>
<td>collect numerical data.</td>
</tr>
<tr>
<td>Data is in the form of words, pictures or</td>
<td>Data is in the form of numbers and statistics.</td>
</tr>
<tr>
<td>objects.</td>
<td></td>
</tr>
<tr>
<td>Subjective - Individuals’ interpretation of</td>
<td>Objective - seeks precise measurement &amp; analysis of target</td>
</tr>
<tr>
<td>events is important, e.g., uses participant</td>
<td>concepts, e.g., uses surveys, questionnaires etc.</td>
</tr>
<tr>
<td>observation, in-depth interviews etc.</td>
<td></td>
</tr>
<tr>
<td>Qualitative data is more ‘rich’, time consuming,</td>
<td>Quantitative data is more efficient, able to test hypotheses,</td>
</tr>
<tr>
<td>and less able to be generalized.</td>
<td>but may miss contextual detail.</td>
</tr>
<tr>
<td>Researcher tends to become subjectively immersed</td>
<td>Researcher tends to remain objectively separated from the</td>
</tr>
<tr>
<td>in the subject matter.</td>
<td>subject matter.</td>
</tr>
</tbody>
</table>
Key Characteristics

Process is deductive
  - To test ideas or hypotheses

Data are numeric
  - To enable statistical analysis

Pre-specified methods are used
  - To ensure scientific rigour
Key Objectives

To **describe:**
- Magnitude of issue being studied

To **evaluate**
- Association between variables

To **predict**
- Identify variables that predict outcomes

To **compare**
- Identify differences between groups
Framework for Quantitative Research

Conduct literature review
Develop rationale

Formulate research question

Generate objective(s) and/or hypothesis

Apply methods and conduct the study

Why do want to do this research?
What do others say?
What are knowledge gaps?

PICO Method
P = population / patient
I = intervention
C = comparison
O = outcome

Objective
“Action” statement

Measurement
Study Design
Analysis
Example: Statins and AMI in RA
1. Conduct literature review: Develop rationale

### Table 1.3 Human Studies Evaluation Potential Roles of Statins in Rheumatoid Arthritis

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Type*</th>
<th>Study</th>
<th>Statin</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STATINS IN PREVENTION OF RA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jick</td>
<td>2008</td>
<td>M</td>
<td>Nested case-control (N=313 RA, 1,252 controls)</td>
<td>All statins</td>
<td>↓ odds ratio for RA (99)</td>
</tr>
<tr>
<td>Holmqvist</td>
<td>2009</td>
<td>A</td>
<td>Case-control (N=1,973 RA, 2,230 controls)</td>
<td>All statins</td>
<td>No association with RA or activity at RA onset (100)</td>
</tr>
<tr>
<td>Amittal</td>
<td>2009</td>
<td>A</td>
<td>Retrospective cohort (N=211,527 statin users)</td>
<td>All statins</td>
<td>↓ hazard ratio for RA (101)</td>
</tr>
<tr>
<td>Hippisley-Cox</td>
<td>2010</td>
<td>M</td>
<td>Prospective cohort (N=225,922 statin users)</td>
<td>All statins</td>
<td>No association with RA (102)</td>
</tr>
<tr>
<td><strong>STATINS IN MANAGEMENT OF RA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ANTIRHEUMATIC ROLE in RA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kanda</td>
<td>2002</td>
<td>L</td>
<td>Open-label case-series (N=8)</td>
<td>Simvastatin</td>
<td>↓ tender joints; ↓ ESR; ↓ CRP (89)</td>
</tr>
<tr>
<td>Abud-Mendoza</td>
<td>2003</td>
<td>M</td>
<td>Open-label case-series (N=5)</td>
<td>Atorvastatin</td>
<td>Clinical improvement on ACR20 clinical response (72)</td>
</tr>
<tr>
<td>Abud-Mendoza</td>
<td>2003</td>
<td>M</td>
<td>Short-time open clinical trial (N=15)</td>
<td>Simvastatin</td>
<td>ACR50 or better response; ↓ CRP (72)</td>
</tr>
<tr>
<td>Hochman</td>
<td>2004</td>
<td>A</td>
<td>Cross-sectional (N=6,265; 968 statin users)</td>
<td>All statins</td>
<td>↑ function on Health Assessment Questionnaire (88)</td>
</tr>
<tr>
<td>McCarey</td>
<td>2004</td>
<td>M</td>
<td>Double-blind, randomised placebo-controlled (N=116)</td>
<td>Atorvastatin</td>
<td>↓ RA disease activity, ↓ ESR; ↓ CRP (91)</td>
</tr>
<tr>
<td>Okamoto</td>
<td>2007</td>
<td>M</td>
<td>Cross-sectional (N=7,512; 4,152 statin users)</td>
<td>All statins</td>
<td>↓ swollen joint counts; ↓ CRP (93)</td>
</tr>
<tr>
<td>Maki-Petaja</td>
<td>2007</td>
<td>M</td>
<td>Double-blind randomised crossover with etoziimbe (N=20)</td>
<td>Simvastatin</td>
<td>↓ disease activity; ↓ CRP (94)</td>
</tr>
<tr>
<td>Charles-Shoarmen</td>
<td>2007</td>
<td>M</td>
<td>Double-blind randomised placebo-controlled (N=20)</td>
<td>Atorvastatin</td>
<td>↓ high-sensitivity CRP (96)</td>
</tr>
<tr>
<td>Kanda</td>
<td>2007</td>
<td>M</td>
<td>Open-label case-series (N=24)</td>
<td>Simvastatin</td>
<td>↓ CRP; clinical improvement (87, 97)</td>
</tr>
<tr>
<td>Shirinsky</td>
<td>2009</td>
<td>M</td>
<td>Open-label case-series (N=33)</td>
<td>Simvastatin</td>
<td>Clinical improvement on EULAR response (98)</td>
</tr>
<tr>
<td><strong>CARDIOPROTECTIVE ROLE in RA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VanDoornum</td>
<td>2004</td>
<td>M</td>
<td>Open-label case-series (N=29)</td>
<td>Atorvastatin</td>
<td>↓ arterial stiffness (92)</td>
</tr>
<tr>
<td>Hermann</td>
<td>2005</td>
<td>L</td>
<td>Double-blind, randomised placebo-controlled (N=20)</td>
<td>Simvastatin</td>
<td>↑ endothelial function (90)</td>
</tr>
<tr>
<td>Tikiz</td>
<td>2007</td>
<td>M</td>
<td>Randomised, placebo-controlled (N=45)</td>
<td>Simvastatin</td>
<td>↑ endothelial function; ↓ CRP (95)</td>
</tr>
</tbody>
</table>

*Type of publication: M-published manuscript; A-abstract in conference proceedings; L-letter to editor reporting study results*
PICO

- Taxonomy used in evidence-based medicine to help formulate questions
- Translate clinical problem into a structured question and identify key concepts
- Elements
  - **Patient**: Who are you studying?
  - **Intervention**: What intervention are you studying?
  - **Comparison**: What will the intervention be compared to?
  - **Outcome**: What outcome(s) are you interested in?
In patients with RA \( P \), does the administration of statin therapy \( I \), compared with placebo \( C \), reduce the risk of acute myocardial infarction \( O \)?
Objective (Action statement)

- To evaluate the association between statin use and AMI in patients with rheumatoid arthritis

Hypothesis (Testable statement)

- RA patients who take statins have a lower risk of AMI compared with RA patients who take the placebo
Measurement
Measurement: Thinking in Numbers

The assignment of numbers to constructs using rules:

▪ Express observations numerically
  ▪ Quantify / assign value(s) to factors studied
  ▪ Example: height, depression score

▪ Categorize / classify
  ▪ Example: 1=mild pain, 2=moderate pain, 3=severe pain
  ▪ Example: 1=have disease, 0=do not have disease
“Thinking in Numbers”

<table>
<thead>
<tr>
<th>ID</th>
<th>Gender</th>
<th>Age</th>
<th>Disease Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>59</td>
<td>Y</td>
</tr>
<tr>
<td>2</td>
<td>Female</td>
<td>52</td>
<td>Y</td>
</tr>
<tr>
<td>3</td>
<td>Male</td>
<td>53</td>
<td>N</td>
</tr>
<tr>
<td>4</td>
<td>Female</td>
<td>60</td>
<td>N</td>
</tr>
</tbody>
</table>

From this

<table>
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</tr>
<tr>
<td>3</td>
<td>1</td>
<td>53</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>60</td>
<td>0</td>
</tr>
</tbody>
</table>
Variables

- In quantitative research, the phenomenon that can be measured or classified is called a variable.

- A variable is a property or characteristic of things and people that varies in quality or quantity.
Consideration with Variables

1. Independent and Dependent

2. Level of data/measurement

3. Psychometric properties: Reliability and Validity

4. Operational Definition
Independent & Dependent Variables

Independent variable (IV)
- Influences some other variable
- Usually represents study factors (predictors)
- Active IV: manipulated/assigned by researcher
  - Example: treatment assignment
- Attribute IV: pre-existing characteristic, not under control of researcher
  - Example: sex, age, education level, comorbidities

Dependent variable (DV) is influenced by the IV(s)
- Usually represents outcome studied
Level of Measurement
Level of Measurement

a. Nominal

- Data is categorized into mutually exclusive groups
- Categories cannot be arranged in any particular order
- Can assign number codes but calculations would be meaningless
- Example: food types, gender, eye colour, ethnicity
Level of Measurement

b. Ordinal

- Data classified/categorized with implied order
- Distance between data not always equal
- Can't measure the magnitude or quantify the difference between data: how much lower is middle from higher income?

Examples:
- SES level: low, middle and high income
- Pain severity: mild, moderate, severe
Level of Measurement

c. **Interval:** attributes measured on interval scales
   - Equal distance between each interval
   - Distance between scale numbers has meaning
   - Arbitrary zero point (e.g., temperature)

d. **Ratio:** similar to interval scale
   - Has true zero point
     - Clear definition of 0: There is none of the variable
     - Example: weight, salary ($0=$0).
   - Can make assumptions about the ratio of two measurements – 6 grams is twice as much as 3 grams
### Level of Measurement & Acceptable Statistical Operations

<table>
<thead>
<tr>
<th></th>
<th>Nominal</th>
<th>Ordinal</th>
<th>Interval</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency distribution</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Mode</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Median &amp; percentile</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Mean &amp; standard deviation</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Group Exercise 1
Group Exercise 1

For each question:
- What is the dependent variable in this study?
- What is the independent variable?
- What is the level of measurement?
Group Exercise 1

1) **Researcher Purple** examine if consumption of calcium is related to large foot size. Calcium is measured in mg, and foot size is measured in cm. Researcher Purple hypothesizes that calcium affects foot size.

2) **Researcher Orange** if a man’s consumption of orange juice is related to an increase in male pattern baldness. Consumption of orange juice is measured in ml, and male pattern baldness is measured on a scale of 1-3 (1=totally bald, 2=some balding, 3=no balding). Researcher Orange hypothesizes that orange juice affects male pattern baldness.

3) **Researcher Green** if pet type is associated with happiness. Pet type is classified on a coding scheme of 1-5 (1=cat, 2=dog, 3=bird, 4=fish, 5=other). Happiness is measured on a scale of 1-3 (1=not happy, 2=somewhat happy, 3=very happy). Researcher Green hypothesizes that pet type will affect level of happiness.
Group Exercise 1 (solution)

<table>
<thead>
<tr>
<th></th>
<th>Dependent Variable</th>
<th>Independent Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Foot size</td>
<td>Calcium</td>
</tr>
<tr>
<td></td>
<td>Interval</td>
<td>Ratio</td>
</tr>
<tr>
<td>2</td>
<td>Male baldness</td>
<td>Orange juice</td>
</tr>
<tr>
<td></td>
<td>Ordinal</td>
<td>Ratio</td>
</tr>
<tr>
<td>3</td>
<td>Happiness</td>
<td>Pet type</td>
</tr>
<tr>
<td></td>
<td>Ordinal</td>
<td>Nominal</td>
</tr>
</tbody>
</table>
Measurement Considerations

- **Direct measurement**
  - Height, blood pressure
- **Indirect measurement**
  - Anxiety, satisfaction → use questionnaires
  - May use several both methods for measuring a particular phenomenon (e.g., BMI)

Goal is precision of measurement and reduction of bias
Psychometric Properties
Psychometric Properties: Reliability

- “Consistency in measurement”
- Answers the question: Will the experiment/test yield the same results on repeated trials?
- Pertains to stability of scores over time
Reliability

- Sources of threats to reliability
  - Subject: factors related to research subjects (mood; fatigue)
  - Observer or raters: abilities, experience, opinions
  - Measurement environment: changes in environment from one measurement to another
    - e.g. time of the day, distraction in the room, lighting
  - Measurement device calibration
Determining Reliability

Types of reliabilities

- **Test-retest reliability** – measurements over time yield similar values

- **Inter-rater reliability** – similar values are obtained by multiple individuals measuring the same phenomenon
Psychometric Properties Validity

- “Truth in measurement”
- Answers the question: Did you measure what you intended to measure?
- Errors in measurements that are systematic
Threats to Validity

- If measuring device cannot make fine distinctions
- If measuring device cannot capture people/things that differ
- When attempting to measure something irrelevant or unknown to subject
- Can measuring device really capture the phenomenon?
Relationship between reliability and validity

- A measure can be reliable and not valid but there cannot be validity without reliability.
- Example: a measuring scale could be reliable because it gives you consistent reading, however, the scale may not have been calibrated correctly.
Operational Definition
Operational Definition

- Is a detailed and precise definition of variables (measures) and how they are measured in a certain context
- Provides a set of rules or procedures for measuring a variable
- Specifies a measurement procedure in detail in order to determine the presence or quantity of a variable
- Applied to both direct and indirect variables
"Our troubles are over, coach. I found us a 7-footer ..."
Operational Definition: Steps

1. Identify the characteristic of interest
   - Name the variable to be defined

2. Describe the measuring instrument
   - Physical piece of measuring equipment (e.g., scale)
   - A classification system, rating scale or checklist

3. Describe how observations will be made
   - Actual procedure used for taking the measurement
   - Consider who will be measured, who will collect information, how and when this will be completed
Operational Definition: Steps

4. Describe what will be observed
   - What information will be collected and what is the level of the measurement? What criteria for classifications will be used?

5. Describe what is recorded
   - Specify the information that may be recorded
   - The information may be a quantity or classification
   - Describe any calculations
Group Exercise 2
Group Exercise 2

Your research group is interested in studying factor ______________ in your research:

1. Describe the factors that might influence the validity of the measurement
2. Describe the factors that might influence the reliability of the measurement
3. Create an operational definition for this factor
<table>
<thead>
<tr>
<th>Group</th>
<th>Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Height</td>
</tr>
<tr>
<td>2</td>
<td>Physical activity in the last month</td>
</tr>
<tr>
<td>3</td>
<td>Vitamin intake in the last week</td>
</tr>
<tr>
<td>4</td>
<td>Blood pressure</td>
</tr>
<tr>
<td>5</td>
<td>Satisfaction with clinic visit</td>
</tr>
</tbody>
</table>
Quantitative Research Methods
Considerations

Status of existing knowledge

Question and purpose
- Describe, associate, predict, compare

Study design
- Experiment, observe

Independent variable
- Considerations of data type, measurement
Research Question ➔ Purpose

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

Associate
- do certain factors might go hand in hand with a well described problem

Predict
- do certain factors contribute to or cause a problem

Compare
- assess the impact of an intervention
- determine if there are differences between interventions or characteristics of various groups (e.g., differences between patients or health services)
<table>
<thead>
<tr>
<th>State of Knowledge</th>
<th>Type of Research Question</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem is new or characteristics of problem not well defined</td>
<td>Describe</td>
<td>What are the characteristics? To what extent is this observed? What are the experiences?</td>
</tr>
<tr>
<td>Possible linkages between problem and other relevant factors</td>
<td>Associate</td>
<td>Is there an association? What are the correlates?</td>
</tr>
<tr>
<td>Determine the extent to which other characteristics influences the problem</td>
<td>Predict</td>
<td>What are the predictors? What are possible causes?</td>
</tr>
<tr>
<td>Identify differences between groups Determine effects of interventions</td>
<td>Compare</td>
<td>Do differences exist? Is the treatment effective? Does the condition change over time?</td>
</tr>
</tbody>
</table>
Study Designs

**Experimental studies**
- Apply treatment to experimental unit
- Measures effect (change) in other variables
- Condition: clinical intervention, drug

**Observational studies**
- Researcher observes and measures subjects in their natural setting
- Intervention beyond control of researcher
Study Designs

**Experimental studies**
- Random allocation: Yes
  - Randomised controlled trial
    - Used to explain causation
    - Compare treatments
  - Non-randomised controlled trial

**Observational studies**
- Random allocation: No
  - Analytical study
    - Tests a hypothesis: Relationship between exposure & outcome
  - Descriptive study
    - No hypothesis
    - Describes how things are
Selecting a Study Design

“The function of a research design is to ensure that the evidence obtained enables us to answer the initial question as unambiguously as possible.”

(David de Vaus: Research Design in Social Research, 2001)

Research question(s) inform(s) the study design
Other Study Design Considerations

- **Researcher**
  - Skills, beliefs, and values

- **Resources**
  - Availability of data, time, funds

- **Ethics**
1. Describe

- Describes a phenomenon not used to test hypothesis
- Know that a problem exists, but little is known of about the problem
- The bases for more rigorous studies
- Five “W” questions*:
  - **Who** has the disease in question? Consider age, race, sex
  - **What** is the condition or disease being studied?
  - **Why** did the condition or disease occur?
  - **Where** does or does not the disease or condition occur?
  - **When** is the condition common or rare?

---

1. Describe

Cross-sectional
- Assess both exposure & outcome status at one point in time

Case report
- Detailed description of individuals with unique conditions
- Can help in the identification of new trends or diseases

Case series
- Extension of case report
- Describes characteristics of a small group of individuals with same condition/symptoms

Ecological studies
- Unit of observation is the population or community
- Populations may be defined in various ways
- E.g., The association between chlorinated water and cancer among 30 municipalities
1. Describe

- Data collection methods
  - Review of available records
    - Chart reviews
  - Surveys
    - Canadian Community Health Survey
1. Describe

**Objectives/Hypothesis:** Cochlear implantation (CI) is effective in the treatment of childhood sensorineural hearing loss and is associated with minimal surgical complications. We investigated the incidence of anesthetic complications in young patients undergoing general anesthesia for CI.

**Study Design:** Retrospective chart review.

**Methods:** A retrospective chart review of 123 patients younger than 18 years, who underwent CI between 2007 and 2008, was conducted for identification of intra- and postoperative anesthesia-related complications. The relation of collected variable to the complication events was analyzed using logistic regression.

**Results:** Of the 123 CI procedures, eight patients had nine anesthesia-related complications, yielding a complication rate of 6.5% and included the following: postoperative wheezing/stridor (5 cases), laryngospasm (3 cases), and emesis during inhalational induction (1 case). Divided by age group, 12 patients were <12 months with one complication (8%), 18 patients were between 1 and 2 years with one complication (5.6%), 35 patients were between 2 and 5 years with one complication (3%), 39 patients were between 5 and 12 years with five complications (13%), and 19 patients were older than 12 years with no complication (0%). Logistic regression failed to identify a significant association of any collected variable(s) with the observed complications. The incidence of complications is similar to that previously reported in elderly patients (4.3%) (Pearson $\chi^2$, $P = .523$).

**Conclusions:** General anesthesia is well tolerated by pediatric patients undergoing CI, even under 1 year of age. Significant perioperative complications are primarily respiratory, are usually free of long-term sequelae, and occur with an incidence similar to other reported age groups.

**Key Words:** Children, general anesthesia, cochlear implantation, anesthetic complications.

**Level of Evidence:** 4.

*Laryngoscope, 121:2240–2244, 2011*
2. Associate

- Association: presence and strength of relationship between two variables
  - Example: depression and anxiety
  - Required to establish causation

- Cannot infer causation – not used to prove that one variable is causing change in another variable

- Exposure and outcome variables from the same subject are assessed for association
  - at the same point in time (cross-sectional)
  - at different points in time (case-control, cohort)
Case-Control Study

- Observational, analytic study
- Starting point is outcome/disease
  - compare people with a specific outcome of interest (cases) to people from the same population without that disease or outcome (control)
- Assesses relationship between the outcome and prior exposure to particular risk factors
Cohort Study

- Observational, analytic study
- A defined group of people is followed over time
- Starting point is exposure
- Compare outcomes of those exposed or not exposed (e.g., to drug, intervention) to disease/study outcome
- Designed as retrospective or prospective studies
2. Associate

**Purpose**
Regular physical activity reduces the risk of developing colon cancer, however, its influence on patients with established disease is unknown.

**Patients and Methods**
We conducted a prospective observational study of 832 patients with stage III colon cancer enrolled in a randomized adjuvant chemotherapy trial. Patients reported on various recreational physical activities approximately 6 months after completion of therapy and were observed for recurrence or death. To minimize bias by occult recurrence, we excluded patients who experienced recurrence or died within 90 days of their physical activity assessment.

**Results**
Compared with patients engaged in less than three metabolic equivalent task (MET) hours per week of physical activity, the adjusted hazard ratio for disease-free survival was 0.51 (95% CI, 0.26 to 0.97) for 18 to 26.9 MET-hours per week and 0.55 (95% CI, 0.33 to 0.91) for 27 or more MET-hours per week. The adjusted $P$ for trend was .01. Postdiagnosis activity was associated with similar improvements in recurrence-free survival ($P$ for trend = .03) and overall survival ($P$ for trend = .01). The benefit associated with physical activity was not significantly modified by sex, body mass index, number of positive lymph nodes, age, baseline performance status, or chemotherapy received. Moreover, the benefit remained unchanged even after excluding participants who developed cancer recurrence or died within 6 months of activity assessment.

**Conclusion**
Beyond surgical resection and postoperative adjuvant chemotherapy for stage III colon cancer, for patients who survive and are recurrence free approximately 6 months after adjuvant chemotherapy, physical activity appears to reduce the risk of cancer recurrence and mortality.

*J Clin Oncol* 24:3535-3541. © 2006 by American Society of Clinical Oncology
2. Associate

- Data collection methods
  - Available records
    - Administrative health databases (e.g. BC MoH)
  - Surveys
    - Canadian Community Health Survey
  - Interviews
    - Cohort studies: Assess baseline exposure status
    - Case control studies: Assess previous exposure status
- Analysis
  - Correlation coefficients: Pearson, Spearman
  - Measures of association: odds ratio (case control, cohort) relative risk (cohort)
2. Predict

- Intent is to determine if one variable caused a change in another variable
- Independent (predictor) and dependent (outcome) variables are identified
  - There may be more than one independent variable
- There is a temporal order
  - Independent (predictor) variable occurs before the dependent (outcome) variable (cohort study)
- Does not assess causation
2. Predict

- Data collection methods
  - Available records
    - Administrative health databases (e.g. BC MoH)
  - Surveys
    - Canadian Community Health Survey
  - Interviews
    - Cohort studies: Assess baseline exposure status

- Analysis
  - Mathematical equation that can be used to predict values
    - Regression
2. Predict

Prediction of Coronary Heart Disease Using Risk Factor Categories

Peter W.F. Wilson, MD; Ralph B. D’Agostino, PhD; Daniel Levy, MD; Albert M. Belanger, BS; Halit Silbershatz, PhD; William B. Kannel, MD

Background—The objective of this study was to examine the association of Joint National Committee (JNC-V) blood pressure and National Cholesterol Education Program (NCEP) cholesterol categories with coronary heart disease (CHD) risk, to incorporate them into coronary prediction algorithms, and to compare the discrimination properties of this approach with other noncategorical prediction functions.

Methods and Results—This work was designed as a prospective, single-center study in the setting of a community-based cohort. The patients were 2489 men and 2856 women 30 to 74 years old at baseline with 12 years of follow-up. During the 12 years of follow-up, a total of 383 men and 227 women developed CHD, which was significantly associated with categories of blood pressure, total cholesterol, LDL cholesterol, and HDL cholesterol (all \( P < .001 \)). Sex-specific prediction equations were formulated to predict CHD risk according to age, diabetes, smoking, JNC-V blood pressure categories, and NCEP total cholesterol and LDL cholesterol categories. The accuracy of this categorical approach was found to be comparable to CHD prediction when the continuous variables themselves were used. After adjustment for other factors, \( \approx 28\% \) of CHD events in men and 29% in women were attributable to blood pressure levels that exceeded high normal (\( \geq 130/85 \)). The corresponding multivariable-adjusted attributable risk percent associated with elevated total cholesterol (\( \geq 200 \text{ mg/dL} \) was 27% in men and 34% in women.

Conclusions—Recommended guidelines of blood pressure, total cholesterol, and LDL cholesterol effectively predict CHD risk in a middle-aged white population sample. A simple coronary disease prediction algorithm was developed using categorical variables, which allows physicians to predict multivariate CHD risk in patients without overt CHD. (Circulation. 1998;97:1837-1847.)
3. Compare: Experimental

- Establish cause-effect *(causal)* relationship between dependent and independent variables
- Independent variable is under the control of the researcher *(active independent)*
  - Drug, intervention, program
- Researcher control of study conditions
  - Random assignment of participants to the groups or conditions that constitute the independent variable
3. Compare: Experimental

- Randomization
  - Each participant has the same chance of being assigned to either intervention or control
  - Eliminates selection bias
  - Balances treatment arms with respect to prognostic variables (known and unknown)
- Types of Randomization
  - Simple – coin toss; random numbers table
  - Blocked – equal treatment numbers at certain equally spaced points in the sequence of subject assignments
  - Stratified – randomization occurs within specified strata (e.g., sex, age groups, disease stage)
3. Compare: Experimental

- Randomized controlled trial (RCT)
  - Two or more groups assigned by randomization
  - Take baseline measure on all groups
  - Give study treatment (independent variable)
  - Measure outcome

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3. Compare: Experimental

- Post-test Only Control Group Design
  - Two or more groups assigned by randomization
  - Give study treatment (independent variable)
  - Measure outcome (dependent variable)

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3. Compare: Experimental

- Analysis
  - T-test, Mann-Whitney
  - Chi square
  - Relative risk
  - Regression
MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20 536 high-risk individuals: a randomised placebo-controlled trial

Heart Protection Study Collaborative Group*

Summary

Background Throughout the usual LDL cholesterol range in Western populations, lower blood concentrations are associated with lower cardiovascular disease risk. In such populations, therefore, reducing LDL cholesterol may reduce the development of vascular disease, largely irrespective of initial cholesterol concentrations.

Methods 20 536 UK adults (aged 40–80 years) with coronary disease, other occlusive arterial disease, or diabetes were randomly allocated to receive 40 mg simvastatin daily (average compliance: 85%) or matching placebo (average non-study statin use: 17%). Analyses are of the first occurrence of particular events, and compare all simvastatin-allocated versus all placebo-allocated participants. These “intention-to-treat” comparisons assess the effects of about two-thirds (85% minus 17%) taking a statin during the scheduled 5-year treatment period, which yielded an average difference in LDL cholesterol of 1.0 mmol/L (about two-thirds of the effect of actual use of 40 mg simvastatin daily). Primary outcomes were mortality (for overall analyses) and fatal or non-fatal vascular events (for subcategory analyses), with subsidiary assessments of cancer and of other major morbidity.

Findings All-cause mortality was significantly reduced (1328 [12-96%] deaths among 10 269 allocated simvastatin versus 1507 [14.7%] among 10 267 allocated placebo; p=0-0003), due to a highly significant 18% (SE 5) proportional reduction in the coronary death rate (587 [5.7%] vs 707 [6.9%]; p=0-0005), a marginally significant reduction in other participant studied, including those without diagnosed coronary disease who had cerebrovascular disease, or had peripheral artery disease, or had diabetes; men and, separately, women; those aged either under or over 70 years at entry; and—most notably—even those who presented with LDL cholesterol below 3.0 mmol/L (116 mg/dL), or total cholesterol below 5.0 mmol/L (193 mg/dL). The benefits of simvastatin were additional to those of other cardioprotective treatments. The annual excess risk of myopathy with this regimen was about 0.01%. There were no significant adverse effects on cancer incidence or on hospitalisation for any other non-vascular cause.

Interpretation Adding simvastatin to existing treatments safely produces substantial additional benefits for a wide range of high-risk patients, irrespective of their initial cholesterol concentrations. Allocation to 40 mg simvastatin daily reduced the rates of myocardial infarction, of stroke, and of revascularisation by about one-quarter. After making allowance for non-compliance, actual use of this regimen would probably reduce these rates by about one-third. Hence, among the many types of high-risk individual studied, 5 years of simvastatin would prevent about 70–100 people per 1000 from suffering at least one of these major vascular events (and longer treatment should produce further benefit). The size of the 5-year benefit depends chiefly on such individuals’ overall risk of major vascular events, rather than on their blood lipid concentrations alone.

Lancet 2002; 360: 7–22
See Commentary page 2
3. Compare: Quasi Experimental

- Quasi = Almost

- Lacks random assignment to study treatment
  - Independent variable is only partially under the control of the researcher

- Can examine cause and effect by ruling out plausible alternative explanations
3. Compare: Quasi Experimental

- Pre-test Post-test Non-Equivalent Group
  - Both a control group and an experimental group are compared
  - Groups are formed out of convenience (rather than randomization)

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3. Compare: Quasi Experimental

The effects of integrated care on quality of work in nursing homes: A quasi-experiment

**Background:** In nursing homes there is a gradual move from traditional care to integrated care. Integrated care means a demand-oriented, small-scale, co-operated and coordinated provision of services by different caregivers. This integration has direct effect on the work of these separate disciplines. With the introduction of integrated care the quality of work of these caregivers should be assured or even be improved.

**Objectives:** The purpose of this study was to examine the implementation of integrated care in the nursing home sector and its effects on the quality of work of the caregivers (work content, communication and co-operation and worker’s outcomes).

**Design:** A non-equivalent pre-test/post-test control group design was used in this study.

**Settings and participants:** Two nursing homes in the Netherlands participated in the study. One nursing home provided the five experimental nursing wards and the other nursing home provided four control wards.

**Method:** Data were selected by means of written questionnaires.

**Results:** The results showed that the intervention appeared to be only successful on the somatic wards. The caregivers of these wards were more able to create a home-like environment for their residents, to use a demand-oriented working method and to integrate the provision of care and services. Regarding the effects of the intervention on quality of work factors, the results included an increase of social support by the supervisor, an increase of the degree of collaboration and a decrease in job demands. No changes were found for the worker’s outcomes such as job satisfaction.

**Conclusions:** The intervention on the psycho-somatic wards was unsuccessful. Although the introduction of integrated care on the somatic wards was successful, the effects on quality of work were limited. Next to quantitative research, more qualitative in-depth research is needed to examine models of integrated care and their effects on the work of
Group Exercise 3
Group Exercise 3

- You are building a program of research concerning Type II Diabetes and weight
- For each of the following research questions, identify an appropriate research design that will answer the question and specify the independent and dependent variables

  - What is the level of physical activity of patients with Type II Diabetes?
  - Is Type II Diabetes associated with obesity?
  - Is childhood weight status related to adult onset diabetes?
  - What obesity reduction interventions are most effective in controlling Type II Diabetes?
Helpful Links

Block Randomization:
https://www.sealedenvelope.com/simple-randomiser/v1/lists

National Collaborating Centre for Methods & tools:
http://www.nccmt.ca/
Thank you