

**Stat2001**  
**Readings & Exercises**  
**Fall 2024**

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**Stat2001 Readings & Exercises**  
**Fall 2024 - continued**

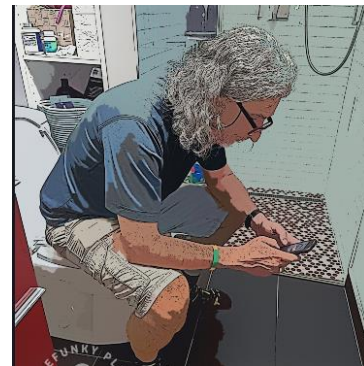
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## Foundations (Theoretical and Practical)

**Background:** We are living in turbulent times. Despite the many improvements science has brought to us, large segments of populations in many countries distrust scientific evidence for climate change, the effectiveness and safety of vaccines, safe injection sites, access to dangerous substances like drugs, guns and mobile apps and other complex phenomena. Many individuals question our understanding of what knowledge and truth are, and trust in current institutions seem to be eroding. While these are big and important issues with strong connections to research and health sciences, we will not tackle them directly in this course. We will investigate science as a (not the) way of knowing and get more familiar with methods (thinking tools) used by scientists to make sense of the world around us and to manage situations where variability and uncertainty make decisions difficult.

**Research** is rooted in human curiosity, in wanting to know how things work, and in the desire to control the environment within which we live. Many people do research informally, (e.g. *they just google it* 😊 or use trial and error).

To do research formally means that that you are doing so within a community of researchers and experts using methods developed over generations or proposing new methods. A researcher who publishes and shares their results has opened themselves up to scrutiny from a wider community of researchers who act as checks and balances to make sure that any published findings are valid (i.e. true based on current knowledge). This is why we occasionally hear about amazing breakthroughs in medical or other research, but have to wait months (or even years) to find out whether those findings have been accepted by experts in the field.



Doing 'my own research' on vaccines.

The Canadian Institutes of Health Research describes 4 pillars of research in health sciences:

**Pillar 1:** Biomedical research (in a lab with microscopes),

**Pillar 2:** Clinical research (testing treatments on volunteer human participants),

**Pillar 3:** Health Services Research (about health care systems: organization, support & delivery)

**Pillar 4:** Social, cultural, and population health research (epidemiology and more)

Check out <https://cihr-irsc.gc.ca/e/53146.html> for more information

This course focuses on the **theory and practice** of health sciences research (Pillars 2 & 4) through 3 activities:

1. Think about research as a way of knowing and building knowledge.
2. Design and conduct mini-research study.
3. Read and evaluate research articles.

## Science as a way of knowing

**Phenomena and classification:** A phenomenon is something that appears to our senses. Key to an event or object appearing is that we notice it and give it a name. Once humans give it a name (e.g. fish, or poisson, or рыба, 魚, سمكة, 魚, iasc, मछली – nope not Wanda 😊) it stops being an individual and becomes a phenomenon, belonging to a class – we classify it and bring it under a metaphorical umbrella. By classifying objects we aim to build knowledge about them without studying each individually (sorta like stereotyping).

**Randomness:** We recognize a phenomenon as random when we cannot distinguish a pattern to its behaviour or appearance. (*Some random guy walked up to me....*) Are the shapes of a bonfire's dancing flames truly random (i.e. there is no pattern), or do we need more information, better technology or better thinking tools in order to predict their dance? Discoveries from biomedical research help build understanding of the mechanisms that control our health - the emerging study of nutri-epigenetics aims to explain seemingly random occurrences of some cancers. Mathematicians create probabilistic models as thinking tools to help scientists make sense of random events.

**Scientific research methods:** The scientific method is a (not the) way of learning about the world. The methods and thinking tools you will learn in this course are a small part of a system that has yielded remarkable technologies and thinking tools (e.g. *cartesian coordinates, heart rates, randomized control experiment, normal distribution*) that help us make sense of the world around us and see patterns not visible without them. As we learn more and develop stronger and more sophisticated thinking tools and technologies, our understanding of the world evolves.

**Reasoning vs thinking vs making decisions:** These are three behaviours that separate us out from rocks, grass, tables and other beings. Many beings (*those closer to us on the evolutionary tree*) make decisions and think, some can only make decisions about simple things like 'Is that food?', while others make more complex decisions like 'Where should I build a nest?' and in that way are similar to humans in that they are thinking. Reasoning is a more complex form of thinking that involves the ability to think and communicate about our thinking (metacognition), and to provide reasons for our thinking and decision making.

**Informal vs formal reasoning:** Humans reason about the wider world informally all the time – this is often called intuition, common sense based on experience. Stereotypes about groups of people based on partial information come from that kind of informal, and often faulty, thinking, as do predictions about the future based on past events. Formal reasoning comes from intentionally slowing down our thinking in a systematic way to provide evidence for our intuitions, or to change them if there is no good reasons to have them. (e.g. learn about recognition of wild mushrooms rather than fearing that they will all kill you.)

In Health Sciences research the formal reasoning involves a specific research process based on evidence that comes from data. Inferential reasoning (making generalizations) is rooted in statistical methods grounded in probabilistic mathematics.

## Scientific thinking and worldview

A person who thinks scientifically tends to see reality as physical or material. Scientists view the universe as made up of objects which interact in ways that can be described through the laws of physics, chemistry, and biology described by mathematics. In contrast, most religious worldviews see the universe as well as objects as real but also see immaterial spirits, moods, energies; gods (or a single God) as real.

Though scientific thinking is often *contrasted with mythological thinking*, scientific thinking emerged from mythological and religious thinking, which have their own formal systems of reasoning. Scientific thinking claims to explain everyday phenomena (*like solar eclipses, sun halos and sun dogs*) and treat illnesses more successfully and rejects the notion of magic, or control by an external force. People get sick for explainable reasons (drinking dirty water) not because a god was unhappy or because stars were not aligned properly. And there is no such thing as fate or luck for scientists unless they find physical, chemical, biological and/or mathematical explanations for them.

The findings of scientists - the answers to formal scientific research questions - go through a process of peer review to ensure **validity**. Every scientific research discipline (e.g. psychology, medicine, pharmacology, physics, and biology) has its own flavour of establishing validity, but there are some universal aspects to them.

To be **valid** scientific findings must:

1. pass a sceptical **peer review** process and be published in a relevant journal
2. be **replicated** (i.e. repeated in a variety of settings at a variety of times)
3. have been conducted **ethically** – a formal Research Ethics Board (REB) application process is needed
4. be **universally** true for a defined population

**Note on causation and proof:** the goal is find an ‘A’ that causes ‘B’, and to prove that this is true without a doubt. Establishing causation only comes after many individual research studies reach the same conclusion (replication). Typically the process starts with pilot studies which are descriptive in nature, these lead to studies that show a strong relationship (predictive but not causal) between variables which then lead to studies – experiments - that test a causal relationship. It is very difficult to establish cause, just as proof is difficult to establish in a court of law. Use the word ‘cause’ and ‘proof’ sparingly, and be wary when others use it.

## Which comes first objects or subjects?

All research conducted formally starts from a theoretical perspective – theoretical perspectives act as a lens through which researchers study the world around them. Objectivity and subjectivity are foundations for many of the lenses (the theoretical perspectives) that are used by scientists today.

**In the beginning there were objects** without anyone or anything to know that the objects existed.

From the interaction of these objects (chemical/physical) emerged other objects including minds (thinking machines?), which were able to think and perceive and make sense of other objects around them and communicate this understanding with other ‘minds’.

This is a simplified summary of the objectivist perspective. Researchers with an objectivist perspective seek objective truths about phenomena that can be reduced to discussions about fundamental elements that are observable and measurable/countable.

The typical quantitative scientist is *objectivist in orientation*, i.e. he/she believes that it is possible to study phenomena by observing them as an interaction of objects, gathering data and looking for patterns - i.e. reality is objective and it exists ‘out there’. (This objectivism is not to be confused with Ayn Rand’s objectivism - a philosophy of pseudo-rational ego-centric living.) For the objectivist, whether we study human behaviour or the interaction of chemicals we are studying the interactions of objects ‘out there’.

**In the beginning there were subjects** who through the wonderful act of thought/imagination and perception created the world within which they lived. Subjectivists study the act of perception and ‘creation’ (social creation of reality?) without attempting to reduce them to mechanistic processes.

The act of perception/experience and thought/consciousness is what is fundamental to a subjectivist, and that is what needs to be studied in and of itself, not as an object.

In contrast to objectivism, the *subjectivist perspective* starts with the idea that the subject (i.e. the mind) is primary because (put simply) in perceiving/experiencing the world ‘out there’ the mind is constructing reality. Descartes, a mathematician/philosopher came up with a clever argument for subjectivity which culminated in the famous conception of human consciousness “Cogito ergo sum” – “I think therefore I am.”

The researcher is a subject (a mind) engaged in perceiving the world is also constructing and interpreting reality, thus the researcher cannot ignore the fact that the mind is involved in perception.

The methods of research using the subjectivist perspective – (political science, education and to some extent health care), tends to be less understood by the general public.

## Unit 2: The Research Process: Design research

In this chapter I will introduce you to each element of the research process through practice – you need to spend time with each of the exercises in class – then try them at home too in order to get comfortable and competent with this process.

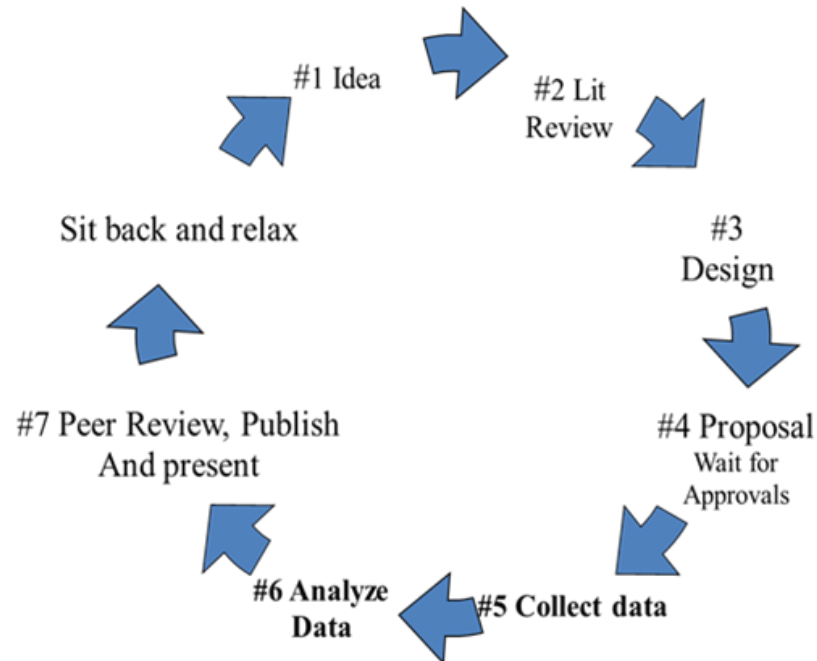


Figure 1: visualization of the research process

Details on next page

**Compare(#in brackets) the research process to the 5 steps of the scientific method.**

Observe(#1) → Gather Background Information(#2) → Frame a Hypothesis(#3) →  
Test Hypothesis through experiment (#5) → Analyse Data (#6) → Conclusion(#7)

## Research process: 7 steps.

*(Our focus will be on quantitative research, but the process is similar for qualitative research.)*

1. Refine research idea into a research question: Ideas are easy - they are products of curiosity, the harder part is giving them life and framing them for research.
2. The Review of Literature provides a foundation for your research idea & involves summarizing prior knowledge and learning from others who have pursued research in the area you are interested in.
3. A good structure is crucial to the success of the project and includes the following elements:
  - research question(s)
  - well defined variable(s)
  - formally structured sampling and recruitment design. How will you choose who to approach as a potential participant (sampling) and how will you ask them to become a participant (recruitment)?
  - formally structured data collection design
  - a blank template of the data set
  - a plan for data analysis (oriented around structure of data types)
4. Write a proposal for funding (one for \$\$ and one for ethics approval).
5. Collect the data: If the design is good then this is simply a matter of implementing the plan.
6. The analysis of data involves **data preparation, exploration**, then **calculations of practical/statistical** significance). It starts after data has been collected.
7. Write up a report and disseminate results helps validate ones' findings (formally called knowledge dissemination). Other experts in the research community review the design and results and sceptically critique the study by asking whether the results are a valid, important and novel contribution to research in the particular area of research. If the results are considered valid, and novel, then the results will be published or presented at a conference. If not then a re-evaluation of the idea or methodology would be the next step.

## Classify Research:

There are various ways of classifying research. The 4 pillars outlined by CIHR (page 3) are a great start. Recall that our course focuses on methods used in pillars 2 (clinical) and 4 (population).

Study types (except by time) that you will encounter in this course are visualized in figure 3.

We will use in stat2001use the following 3 markers:

1. Purpose/Goal;
2. Data Collection Method;
3. Data analysis method;

## Quantitative vs Qualitative:

**Quantitative research** typically has an objectivist perspective (evidence comes from counting the # of objects in a group or measuring objects or behaviours of objects), and aims to justify making inferences from sample to population through hypothesis testing and confidence intervals. Examples of Quantitative research questions:

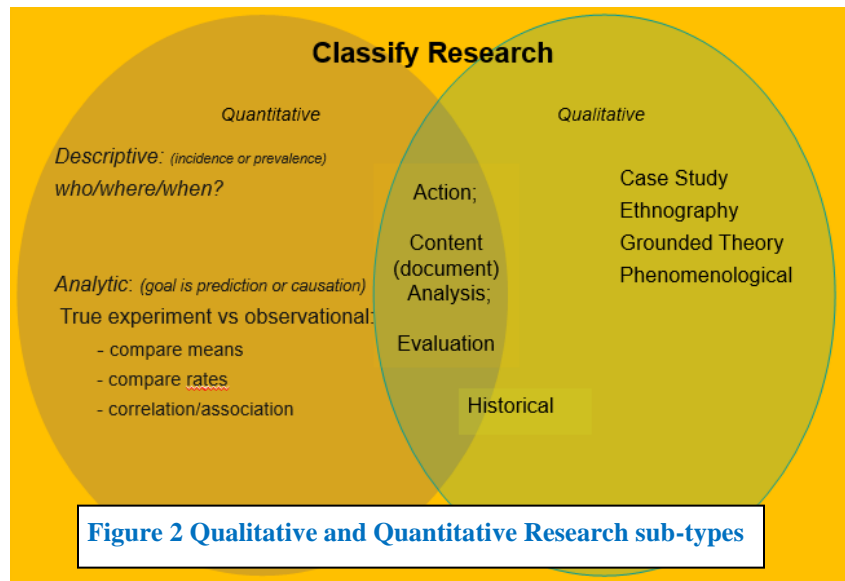
- ‘Will homeless people move to a shelter if one is provided for them?’
- ‘Is clinical depression a factor prevalent in those that are homeless?’

Sub-types are related to research goals (descriptive vs analytic) and within analytic on the structure of data collection.

**Qualitative research** emerged from what were seen as philosophical and practical limitations of quantitative research, and a questioning of the objective perspective. Qualitative researchers aim to understand their subjects holistically and naturalistically and not strictly as objects. Qualitative research aims to develop hypotheses about phenomena that are poorly understood and accepts a wide variety of methods (flexible) all related to the researcher taking a subjectivist perspective.

Example of Qualitative research question: What is it like to be homeless?

Sub-types (Action, Case Study, Ethnography, Grounded Theory, and Phenomenology) are quite different from each other and highlight the wide focus of qualitative research. See unit 6 for details.



**Quantitative research:** Having a systematic approach for recognizing the distinct types will help. First decision: Is it Descriptive? If no, then it must be Analytic. If Analytic, is it a true experiment? If not, it must be 'observational' (which could be cohort or correlation, or case control, but we won't worry about cohort or case control until epidemiology course).

**Descriptive:** The purpose or goal is description without searching for reasons: Questions posed are **who, where, when** is getting a disease, or getting richer, or smarter in mathematics? Examples: What percentage of HIM professionals are female?

Comparisons of rates, means etc, and changes over time can be part of the discussion, but the intent is to describe, not to explain or to show effects.

**Analytic Research:** The purpose or goal is to explain... why or how is disease happening in the populations where it is taking place? (search for determinants of disease)

**Experiment:** The gold standard of quantitative research, the experimental approach helps isolate a causal path from exposure to outcome. Key to recognition is that the intervention is administered by the researcher. The key to a proper design is to isolate the treatment group (those that receive treatment) from the control group (who do not) so that one can be sure that the treatment (exposure to xxx) is the only thing leading to a specific change in outcome. Results from one experiment do not establish a causal relation, but it sure helps. (detailed description on next page)

**Observational:** Variations on the experimental approach which act as a first step towards experimental research or when experiments are impossible. Once researchers establish the strength and direction of the relationship between independent and dependent variables predictions can be made about individuals based on known characteristics even without understanding of the causal path. (competence before comprehension 😊)

**Classify by Time:** Key to distinguishing between these is to focus on when the data collection started.

**Cross-Sectional** studies take a slice or snapshot of a particular time.

**Longitudinal** studies take place over a long period of time are subdivided as follows: **prospective** (data collection starts now, and will continue to track events that will take place in future) or **retrospective** (data collection starts now, but reaches back into events that took place in the past).

Experiments have to be prospective in nature, the others can be any of the above.

## Quantitative design foundation - the 'true' experiment.

The gold standard of research is the true experimental method pictured in figure 4 below. The true experiment needs to have an intervention (treatment) being applied to the participants. In the example below the intervention is elimination of caffeine.

**Example:** Does elimination of caffeine lead to a higher total sleep time (measured in minutes per night) in those who drink more than 3 cups of coffee a day?

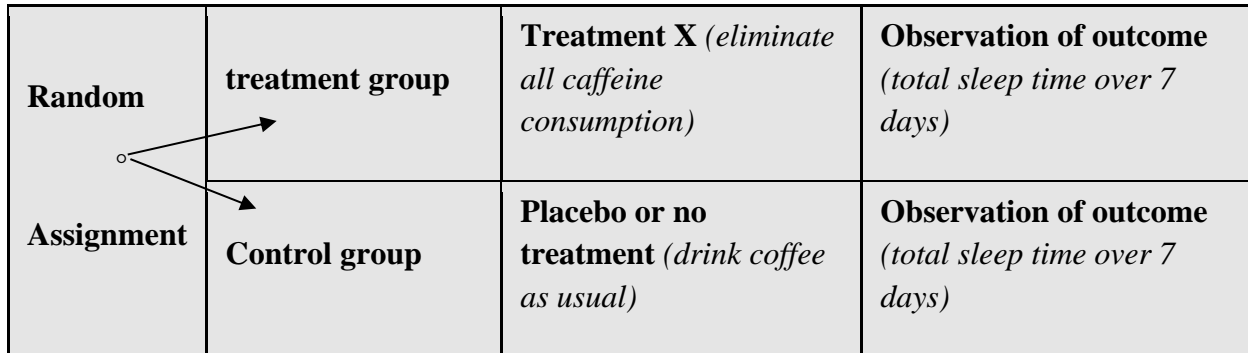


Figure 3 True Experiment flowchart with example

### Terminology

**Variable** – any characteristic of an object being studied (*coffee drinkers*) that has two or more possibilities. *e.g Do you drink more than 3 cups of coffee a day?*

**Independent variable** – the treatment (*eliminate caffeine from diet*) that may (or may not) be responsible for changes in the dependent variable. Also known as exposure. Typically categorical, and often with 2 categories (treatment vs control). *e.g. (eliminate coffee or not)*

**Dependent variable** – the characteristic (*total sleep time over 7-day period*) that may or may not be affected by the independent variable. Also known as the **outcome**. The dependent variable can be categorical (*Did you sleep well*) or measurement (*total sleep time over 7 days*).

**Randomization (random assignment)**– Key element of the experimental method. Individuals get assigned to one of the groups randomly. One of the groups (**treatment**) gets a dose of the independent variable, while the other (**control**) gets nothing or a placebo.

**Control** – Having 2 similar groups in a study (one getting exposed to treatment and the other – control group - not) ensures that researchers can assess the effect of the treatment. The control group getting no treatment makes sure that the researcher can recognize when the independent variable is responsible for any changes in the dependent variable.

**Confounding variable** – a variable that was not measured yet is found (or suspected) to have an effect on the dependent variable. This is the variable that researchers try to eliminate by randomization.

## Exercise 1: Classify Quantitative Research

A. Classify the research scenarios/research questions as **descriptive**, **experimental**, or **observational**. and justify your choice

(i) What is the rate of new cases of Covid per 100,000 population in each province?

(ii) The Prevalence of ADHD in American Society: Is it related to access to smartphones and social media?

(iii) *Is heading a football bad for your health? (BBC News, 17 July 2018)*: London researchers will study the physical and cognitive skills of former football (soccer) players by comparing the incidence of degenerative neuro-cognitive disease in ex-professional footballers to that in the normal population.

(iv) Individuals with the highest levels of optimism have twice the odds of being in ideal cardiovascular health compared to their more pessimistic counterparts,” said Rosalba Hernandez, the lead author of the study and social work professor at the University of Illinois.

(v) Understanding the Relationship Between Education and Longevity.

Findings: Among white Americans without a high school diploma, especially women, life expectancy has decreased since the 1990s, whereas it has increased for others. The average age at time of death is increasing among the most educated Americans, accompanied by steady or decreasing average age of death among the least educated.

## Exercise 1: Classify Quantitative Research (continued)

**B.** read over the 3 scenarios/Research Questions below and decide whether the researchers used comparison of means, comparison of rates or correlation for data analysis methods. Make sure to justify your choice

**(i)** *Is heading a football bad for your health?* (BBC News, 17 July 2018): London researchers will study the physical and cognitive skills of former football (soccer) players by comparing the incidence of degenerative neuro-cognitive disease in ex-professional footballers to that in the normal population.

**(ii)** Understanding the Relationship Between Education and Longevity.

Findings: Among white Americans without a high school diploma, especially women, life expectancy has decreased since the 1990s, whereas it has increased for others. The average age at time of death is increasing among the most educated Americans, accompanied by steady or decreasing average age of death among the least educated.

**(iii)** The Prevalence of ADHD in American Society: Is it related to access to smartphones and social media?

**C.** Classify the research scenario as **prospective** or **retrospective**. Provide explanations.

**(i)** Alcohol-related deaths in Canada increasing faster for women than men: Researchers who followed 5,000 Canadians over a 10 year period found that the death rate of women (per 100,000 population) from causes linked directly to alcohol jumped a whopping 26 per cent. For men during that same period, the death rate from alcohol increased roughly 5 per cent.

## Exercise 2: (Step 1 of research process) Refine research idea(s) into research question(s).

In quantitative research design, this is the first challenge for a researcher – the clearer the question at the start the easier will be all other steps of the research process. As you refine the research idea into a research question, you will need to consider all elements of the research design.

**Instructions:** Transform 2 research ideas below into good research questions (RQs). Start by thinking about the object being studied (who or what?) and the characteristic(s) of interest. The characteristics will become the variables once they are well defined (i.e. it becomes clear how data about the characteristic of the participants can be collected). This is a skill that is best developed through practice.

a. GBC HIM students hear from graduates that it is hard to find work after graduation.

Who/what is the object to be studied (unit of analysis)? Who are the potential participants?	
What variable(s) is the researcher planning to collect? Variable name(s) and data types.	
Variable 1:	Data type:
Variable 2(if needed):	Data type:
Research Question (RQ):	

b. A nurse notices that patients who drink more coffee tend to have shorter hospital stays.

Who/what is the object to be studied (unit of analysis)? Who are the potential participants?	
What variable(s) is the researcher planning to collect? Variable name(s) and data types.	
Variable 1:	Data type:
Variable 2(if needed):	Data type:
Research Question (RQ):	

**Step 2 - Literature Review concepts:** Conducting and producing a literature review helps researchers get a sense of what other researchers have been doing in the field. Literature reviews are both processes and products.

***Literature review as a process and product***

Literature Review **as a process**. Every research study (whether qualitative or quantitative) requires the researcher to search out and read through pertinent literature on the topic.

Literature Review **as a product**: Refers to a report on the findings after the review is complete. Either as part of a proposal for funding, or as a separate published, and peer reviewed, report.

***Purpose of Literature Review (the process)***

1. To help establish whether your topic is important and unique, i.e. to avoid unnecessary duplication of research and look for gaps (needs for further research). Has a need for this research been identified? Has other research been done in that general (or specific) topic?
2. To identify variables that may have an effect on the outcome (dependent) variable.
3. To identify promising procedures and validated instruments.
4. To limit the problem.
5. To trace the development of research on the topic in general.

***Purpose of Literature Review (the product):*** can be short mini-summaries or long (20+ page reports)

1. Helps convince others that there is a need for research.
2. Helps validate a proposed method of data collection and analysis and assesses feasibility.
3. A published literature review helps researchers know what research has already been done.

***Elements of a successful literature review (the process)***

1. A topic statement that is clear and feasible; with meaningful search words
2. Organize your notes as you go: These will help you establish patterns and refer them to the articles you have been reading, and will help you figure out when you need to stop.
3. Find tools that will organize your readings and find good resources:
  - access to journals (many journals are paid – GBC has a license to some but not others)
  - organizational schema/charts – e.g. bibliography and log charts to keep track of articles read.
  - There are electronic tools to help with that: dropbox is good and Mendeley is better.
4. Primary sources (research articles published in journals): read as widely as possible in research related to your topic. If you can't get the full text of an article, make sure to get the abstract. You do not need to read every single word of every research article that comes up.
5. Secondary Sources (Books and more general articles on background to your topic): get to know the topic you will be researching.

### Exercise 3: (Step 2 of research process) preparing for a literature review

A few years ago, I read a newspaper article which described the use of honey in treating postoperative infections that had developed in women who had C-sections. We will try to track down information on any research that was done on this and look into research on the usefulness of honey in general, as I would like to submit a proposal for a grant to study the effectiveness of honey as an anti-biotic.

Google Scholar (*scholar.google.ca*) filters out all the junk and newspaper articles so that you can focus your reading on scientifically sound research. Note that for medical research PubMed and ProQuest are also used, but I find more success with google scholar. You can also use the GBC library to search for academic articles.

Below are a few suggestions on phrases to search on the efficacy of honey. Starting too broad gets you too many articles, too narrow and you have the opposite.

phrase 1: honey in medicine #hits = \_\_\_\_\_

phrase 2: honey as anti-biotic #hits = \_\_\_\_\_

phrase 3: honey\_\_\_\_\_ #hits = \_\_\_\_\_

The idea is that each phrase will generate fewer, and more focused results. It requires some playing around, but helps prepare for the search on Pub – MED if needed.

The links could lead to an Abstract or Full Text – or a pay per view article. Even if the article is paid you can get links to related articles, other studies by same authors etc.

**The summary** What did you find out about honey as an anti-biotic? Do you know more about honey as a possible treatment? Does there seem to be scientific evidence to back it up? Which studies are the ‘good ones’? Where does more research need to be done? Is your topic important and unique?

**Notes:**

### Step 3: Design (creating structure for the proposal)

**The process:** To design a research project means to create a plan for the structure that holds the object together, making sure all elements work to achieve the goal.

**The product:** a plan, usually in the form of a proposal for research. This proposal needs to be approved by those who are funding the research, and by Research Ethics Board(s) before any formal research takes place.

Make sure to think about and be able to describe the following elements down to the details (think of it as a set of instructions for a robot). This will mean making a lot of decisions and slow thinking along the way.

Elements of research design – all need thoughtful consideration.

1. Who, or what objects will you be studying? What do you want to know about the individuals you will be studying?
2. Who is your target population? Where will you be choosing your participants from? Be able to describe this target population precisely.
3. Sampling: How will you be choosing individuals, whom you will approach as part of recruitment process... i.e. from the target population. Step by step instructions needed.
4. Recruitment: How will you convince the individuals that you ‘sampled’ to take part in your study, and do so ethically (remember the TCPS2)? (this element is not necessary in studies where the population is being observed from a distance in a public place) Step by step instructions needed.
5. Data Collection and Analysis: How will you collect the data? Step by step instructions needed. What analysis tools will you use? Do they help answer the research question?

## Elements of design 1: participants, their characteristics and the Research Question

There are two fundamental elements to all quantitative research: participants (the objects being studied) and the characteristics (variables) of the participants of interest to the researcher. Both are fundamental to a well-defined research question

**Participant:** an individual object (the ‘who’ or ‘what’) being studied and analysed. Other terms used may be *case*, *respondent* or *unit of analysis*. Participants must come from a population of individuals. Most Health Sciences and Health Information Management research has to do with patients with a common illness or ailment, but the unit of analysis could also be hospitals, wards, mice, or any other object that is of interest to researchers.

Example 1: A researcher is interested in head circumference of Ontario infants in rural vs urban settings. The participants would have to be recruited from the population of infants in Ontario. It would be important that this population (this set ☺) be well defined so that the recruiter would know which babies were infants (e.g. under 3 months of age).

Example 2: Researcher is interested in comparing hospitals with respect to Length of Stay (LOS) for mothers after birth. Though on the surface it is hospitals that are the objects of study, the raw data that would be collected would come from individual patients’ records. Thus the participants (who would not be ‘participating’ in any meaningful way) would be the individual mothers.

Example 3: Researcher is interested in comparing teaching vs non-teaching hospitals with respect to bed occupancy (the % of a set of available beds with patients in them). Here the participant/unit of analysis (the object being studied) would be hospitals,

**Characteristics as Variables:** in algebra, a variable is an abstract object (letter or symbol) that represents a quantity that can vary. In research a variable represents a *characteristic of an object (a participant) in a population that can take on more than one value*. Once collected from the participant variables get packaged into a data set. Data is the information that has been collected for one or more variables representing characteristics of a group of individuals.

Example 1 continued: There are two variables (characteristics) of interest. One is the circumference of the head (measured in cms?) and collected by observation, and the other is the residence type (rural vs urban) which would likely be identified through postal code.

Example 2 continued: The characteristics of interest – LOS (#of days) and ‘name of hospital’ (categorical) where baby was born.

Example 3 continued: the characteristics of interest - bed occupancy (measured as a rate) and type of hospital (categorical) would both come from hospital records.

**Research Question (RQ):** Research questions must incorporate the characteristics of interest, but will not always spell out the population explicitly; see samples below.

Example 1 continued: Do rural infants have larger head circumferences than urban infants?

Example 2 continued: Is maternal LOS higher in teaching hospitals?

Example 3 continued: Which hospitals have the highest Bed Occupancy?

## Elements of design 2 and 3: population and sampling

**Target Population:** This is the set of all potential participants (cases, respondents). For example: in Exercise 2a (topic: Is it hard for GBC-HIM graduates to find work?) the population that first comes to mind is all GBC-HIM graduates.

Populations are often to be too large or difficult to collect data from, a reframing may be needed. For example, instead of all GBC-HIM graduates (remember some could be well past retirement) it may make more sense to target graduates from the last 5 years, especially when the characteristic of interest is the likelihood of getting a job. The result is a **population frame** or **target population**.

**Sampling** is the act of selecting a subset of the population being studied producing a set of potential participants called ‘the sample’. A valid sample is one which yields a subset of the target population that is a good representative of the population.

Sampling is only used if researchers cannot study all the individuals in the population – i.e. cannot conduct a *census*. When attempting to do research on GBC HIM grads a census is impossible as there is no list of GBC-HIM grads, and it will take too long to find them all. The only option is to conduct reframe the target population (graduates from the last 5 years – there will be about 300 of them) then try to get about 10-20 from each year.

**Random Sampling:** is the gold standard of sampling methods and almost impossible to achieve.

What does random sampling mean? The key is that you have to organize your sampling in such a way as to have “*blind chance determine the outcomes of the selection process to as great a degree as possible*”

- Every member of the population being studied has an equal chance of being chosen.
- Each individual is chosen independently.
- All combinations – even the weirdest ones are possible.

How do I conduct a random sample in a perfect world?

- 1) define the target population/population frame
- 2) number the population
- 3) generate numbers randomly using table/computer program

Why do random sampling?

The mathematical foundations of the Central Limit Theorem (see unit 4) provide a scientific justification for inferential statistics. If ‘every member of the population has an equal chance of being chosen’ then I can be pretty sure that the characteristics of my random sample will be close to those of the target population, and I can account for the likelihood of getting the ‘weird sample’ (e.g. with 95% confidence). A well-designed sample will likely be **representative** of the population leading to a stronger **external validity**.

Is random sampling a must?

Theoretically and mathematically yes, but practically it is very difficult to get lists of members of populations and contact information due to privacy and other practical concerns. The sampling design would have to be clever – as close to random as possible and practically feasible to carry out.

## Elements of design 3: sampling continued

**Sampling design:** a set of instructions for choosing potential participants from a defined target population.

**Example** – Use the 3 steps of random sampling to design a sample for the following RQ: What is the rate of cell phone ownership in grade 7 students in the Toronto District School Board?

*Target population:* grade 7 students in the Toronto District School Board.

*Sampling instructions:*

- 1) Get a list of all TDSB schools (since list of students not available) and
- 2) number the schools from 1 to xxx
- 3) Take a random sample of 12 schools using random.org or excel or other tool.
- 4) all grade 7 students at each of the 12 chosen schools are potential participants

### Sample size: What is an appropriate sample size?

The best answer is that the sample size should be as big as is affordable (time and/or \$\$). A balance needs to be established between precision and costs. Precision costs money and thus a large sample size (and the extra work in recruitment and data collection) needs to be justified to the funder. Some hypothesis tests also have requirements for sample sizes. This is tied to the concept of statistical power which we will not explore in this course (it is a mathematical algorithm).

Below you will find a table of formal sampling methods that are used by researchers.

Population Characteristic	Suitable population (example)	Sampling method structures
Population list and contact information available and ethically appropriate	College of nursing members who have consented to share personal contact information for research.	<b>Simple Random Sampling</b> – use mechanical means to select sample randomly.
Population contains definite strata that are accessible.	A high school with access to lists of grade 9, 10, 11, 12 students.	<b>Stratified random sampling</b> - random sample of individuals from each strata.
Population consists of discrete clusters with similar characteristics.	Toronto public high school students are clustered into schools that are more or less similar.	<b>Cluster sampling</b> – choose one or more clusters of individuals – capturing all individuals from that cluster. These few clusters are to represent all clusters.
Population with clear boundary, but no list available.	Residents of city of Toronto	<b>Purposeful sampling:</b> design a strategy that captures a sample that possibly represents the population (e.g. stand on street corners in a variety of neighbourhoods)

## Elements of design 4: Recruitment

After taking a sample using the instructions in the sampling design, the researcher will have what is called a sample, or a pool of potential participants. Before data collection those potential participants must be invited (convinced😊) to participate in the research. This process of converting ‘potential participants’ into ‘actual participants’ is called **recruitment**. The goal of recruitment is to get all potential participants to participate in the research.

Recruitment must be done as a formal invitation - all individuals who choose to participate must give their **informed consent**. Research Ethics Boards require that each participant give informed consent and are unlikely to approve studies in which there is any hint of coercion to participate. In many studies the process of recruitment is quite challenging as potential participants are often reluctant to give their informed consent. In some cases gifts or honorariums are given to thank participants for participation – but they can’t be coercive.

Balancing ethical principles and achieving a high participation rate is challenging.

**Recruitment design:** The product of recruitment design is a set of instructions that the recruiter will follow when trying to convince a potential participant to participate. Often this will also include a script detailing the words the recruiter must use in recruiting. Key issues: will information participants provide be confidentiality or will they remain anonymous, what exactly are the researchers asking them to do. There must be a physical or virtual record of consent given to the release of specific data or to be observed in specific situations.

**Response rate:** It is important to keep track of the number of potential participants who said yes and no generating a participation/response rate. This rate can often be as low as 25%, which means that the actual participants may not be a good representation of the target population – i.e. poor external validity.

**Example of Recruitment design:** from a study of JUMP math at GBC (shortened for space)

- Research assistant (RA) walks into class and reads the following: *“The goal of study is to compare the effectiveness of a teaching approach in foundations mathematics. The teaching approach used in your class would have likely been used anyway even if it were not for the study. Participation is strictly voluntary, and all information collected (i.e. demographics and individual scores) will be confidential, and be known only to the researchers, not your teachers.”*
- RA distributes envelopes containing information/consent document plus pre-tests to whole class. Each envelope will have the name of a student on it (written on a yellow sticky). It will also have a personalized code written directly on the envelope.
- Once an envelope is handed out potential participants remove the sticky and deposit into trash, then complete the documents.
- RA collects the envelopes once students have indicated that they have finished.

## Elements of design 5: Data collection and analysis

**Data collection** is the act of collecting data from participants (those that gave informed consent).

Factors to consider in preparation for planning data collection

- 1 a. Clarify the variables of interest and their type.
  - b. What type of research is it? (look back at classifying research in this unit)
  - c. What is/are the research question(s)? How precise a measure needs to be taken to answer the question?
2. Decide on data collection method: There are two possibilities: survey and observation, with many potential instruments for each.

**Survey**/interviews: instruments can be on-line, handouts, phone or face to face; (interviews can be structured, as in quantitative research, or semi-structured, unstructured; face to face interviews can be one on one, or focus group....and more) see example of a semi-structured interview design with open ended questions in appendix 1.

questionnaires: paper or electronic; Many answer types are possible: most surveys are set up as likert scales (very satisfied, satisfied etc), fewer are set up with fill in the blank, or open ended questions. Often questionnaires are used to come up to create a summary score.

Data quality – depends on honesty of respondents, expertise and honesty of interviewers, response rates, and ethics (informed consent and confidentiality)

**Observation**: Choices: Structured observation, participant observation, mechanical observation (where a machine collects data e.g. blood pressure, or internet use, video/audio recordings), could be ‘blinded’ or ‘overt’.

Data quality - measurement instruments must be reliable and valid. Most researchers consider the validity of observation data to be higher than survey data because it is less reliant on human subjectivity – it is more objective.

If your data collection design is weak (i.e. weak data quality and internal validity), then there is very little any statistician can do in the data analysis phase to clean up your study and make it valid. There is a famous phrase – ‘garbage in means garbage out’ – make sure to spend time on designing data collection.

**Data Analysis**: Which tools will be needed: inferential or non-inferential? Compare means? Compare Rates? Correlation? Does your plan fit with the variables you defined in element #1? Creating a template (a blank data set in preparation – and before collecting data is a really important thing to do.

## Parts of a formal research proposal

1. Statement of problem/question/hypothesis  
Focus on a researchable topic, which is stated in such a way that all elements are ‘well defined sets’.
2. Background and significance  
Focus on importance and uniqueness of the study
3. Research Method and design: including a detailed description of proposed sampling, recruitment, data collection and data analysis methods,  
This is where the bulk of the content is located – details are very important here. Step by step processes etc.
4. Limitations  
If there are any methods that include compromises these need to be acknowledged up front.
5. Timeline/budget.  
Very important for the organization who is being asked to fund the project.
6. Review of literature  
This is usually conducted early on in the process, but it may not be completed until the proposal is being written – it helps with establishing #1, #2, and #3.

### **Parts of a proposal for the research project in this course:** (see assignment outline for details)

1. Research question
2. Targe population, Sampling and recruitment designs
3. Data collection design with timeline
4. Proposed data analysis
5. Blank SPSS template for data entry

*See an example of a real proposal for health sciences research in appendix 2*

## Exercise 4: (step 3 of research process) practice with research design.

Instructions:

You will receive one strip of paper with a rough research idea on it. Think about how it can be worded to make a well-defined research question.

Step 1 - Individually: Start of design process: Answer the following to the best of your abilities.

Write down you're the research idea you were given:	
Who/what is the object to be studied (unit of analysis)? Who are the potential participants?	
What variable(s) is the researcher planning to collect? Variable name(s) and data types.	
Variable 1:	Data type
Variable 2(if needed):	Data type:
Research Question (RQ):	

Review the readings booklet pages 18-24 on sampling, recruitment, and data collection.

Step 2. Find your team members by the research idea # you were given.

task 1: share your versions of the well-defined research question and come to a consensus on the best wording.

task 2: work together to create a rough sketch for each of the elements of design listed below. Post your groups design to OneNote/Collaboration in the appropriate page (note that you can always go back to improve your research question if you find that the design requires it.

### Exercise 4: (continued)

The full structured design will include the following:

Group responses

Write down you're the research idea you were given:	
Who/what is the object to be studied (unit of analysis)? Who are the potential participants?	
What variable(s) is the researcher planning to collect? Variable name(s) and data types.	
Variable 1:	Data type
Variable 2(if needed):	Data type:
Research Question (RQ):	
Type of research	
Target population	
Sampling design as a set of instructions	
Recruitment design	
Data collection design (provide instructions and include surveys etc)	
Data analysis approach (compare means, compare rates or correlation)	



## Unit 3: Read research abstracts

Reading research and learning from it is not an easy task. It is much more difficult than reading a newspaper article or a detective novel. The only way to get good at it is to dive right in and start reading... while remembering that you now have a series of thinking tools at your disposal to help make sense of what you are reading.

Thinking tools for reading research:

Research question  
Classification system (goal, time)  
Design (elements)  
Data types and data analysis type



Each of these thinking tools appears in the template on the next page. The template is designed to force you to find each one in the abstracts that you will read.

### **Competence before comprehension.**

Daniel Dennet a philosopher who thinks a lot about thinking claims that before one can truly understand a concept one has to get good at using it and playing around with it. Don't worry if you don't 'get it' i.e. understand the article when you read it. Take it apart piece by piece using the thinking tools, and practice getting good at that. Comprehension will come later.

## Reading quantitative research template: Questions to answer when reading Research Abstracts

1. Write out reference (citation) in proper APA format – an example is given below.  
Peckover, S., & Winterburn, S. (2003). Teaching research to undergraduate community nursing students: reflections upon curriculum design. *Nurse Education in practice*, 3, 104-111.
2. Write out the Research Question (RQ): don't just copy the title of the paper – though at times this may be appropriate
3. Describe the target population. Make this into a well-defined set by using precise language; e.g. females 18-24 whose mother is named Mary.
4. Describe the sampling and recruitment design. Did the researchers explain how the sampling was done? (many times sampling and recruitment won't be described in the abstract.) What is the sample size? What is the participation rate – i.e. what % of those who were sampled actually participated?
5. How was the data collected? Give as many details as were explained in the abstract.
6. What data was collected? How many variables? Specify exposure (independent) and outcome (dependent) variables.
7. What type of quantitative study is it? Think about the goal and use process of elimination starting with experimental.
8. Describe the major conclusions/findings. (What was the answer to the RQ and what evidence was provided?)
9. What data analysis tools were used? (If the tools were not specified speculate on the most likely tool – e.g. correlation, comparison of means etc.)

## Exercise 5a: Practice reading research summaries/abstracts.

There are five research summaries reproduced here. Read them carefully and use the 'Reading quantitative research template' (page 26) questions to help understand the article. Make sure to answer all questions fully. The first article on prostate cancer screening will be taken up in class for practice.

### Randomised prostate cancer screening trial: 20 year follow-up

Gabriel Sandblom, associate professor, Eberhard Varenhorst, professor<sup>2</sup>, Johan Rosell, statistician<sup>3</sup>, Owe Löfman, professor<sup>4</sup>, Per Carlsson, professor<sup>5</sup>  
Accepted 24 December 2010 British Medical Journal

#### ABSTRACT

**Objective:** To assess whether screening for prostate cancer reduces prostate cancer specific mortality.

**Design:** Population based randomised controlled trial.

**Setting&Participants:** All men aged 50-69 in the city of Norrköping, Sweden, identified in 1987 in the National Population Register (n=9026).

**Intervention:** From the study population, 1494 men were randomly allocated to be screened by including every sixth man from a list of dates of birth. These men were invited to be screened every third year from 1987 to 1996. On the first two occasions screening was done by digital rectal examination only. From 1993, this was combined with prostate specific antigen testing, with 4 µg/L as cut off.

**Main outcome measures:** Data on tumour stage, grade, and treatment from the South East Region Prostate Cancer Register. Prostate cancer specific mortality up to 31 December 2008.

**Results:** 85 cases (5.7%) of prostate cancer were diagnosed in the screened group and 292 (3.9%) in the control group. The risk ratio for death from prostate cancer in the screening group was 1.16 (95% confidence interval 0.78 to 1.73,  $p=0.45$ ).

**Conclusions:** After 20 years of follow-up the rate of death from prostate cancer did not differ significantly between men in the screening group and those in the control group.

You may also choose to look at the raw data and analyse it yourself.

Data set '*prostate screening*' available in your OneNote notebook

## Exercise 5b: Practice reading research summaries/abstracts.

### *The Influence of Race and Gender on Time to Initial Electrocardiogram for Patients with Chest Pain*

Kevin M. Takakuwa, MD, Frances S. Shofer, PhD, Judd E. Hollander, MD

#### Abstract

**Objectives:** To determine whether race or gender affected time to initial electrocardiogram (ECG) for patients who presented to an emergency department with chest pain.

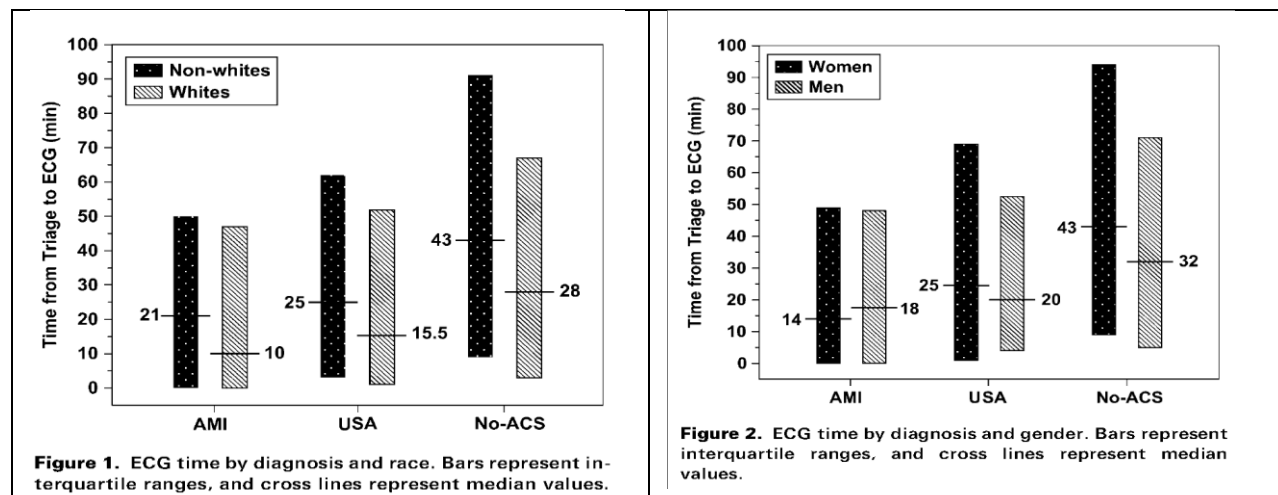
**Methods:** This was a prospective cohort study of patients with chest pain. Patients were divided into three groups based on final diagnosis of acute myocardial infarction or unstable angina and all others with non cardiac chest pain. Data were analyzed using ranks in a two-way analysis of covariance adjusted for age.

**Results:** A total of 4,358 patients were studied; 58.6% were women and 41.4% men, and 70.3% were African American, 26.0% white, and 3.6% other. Overall, non white patients had longer times to initial ECG compared with white patients. These effects were consistent regardless of ultimate diagnosis. Overall, women had longer times to initial ECG than men. However, ECG time differed by final diagnosis. There were no differences in time to ECG for women compared with men with acute myocardial infarction or unstable angina, but women received an ECG significantly slower than men for non cardiac chest pain.

**Conclusions:** The first screening test for acute coronary syndrome, the ECG, took longer to obtain for non white patients, regardless of final diagnosis. This was unfortunately consistent with the literature that shows racial disparities in all aspects of emergent cardiac care. For women, the overall delay in ECG time can be explained by delays for those women with non cardiac chest pain.

ACADEMIC EMERGENCY MEDICINE 2006; 13:867–872 © 2006 by the Society for Academic Emergency Medicine

**Keywords:** electrocardiogram, time, gender, race, chest pain, acute coronary syndrome



## Exercise 5c: Practice reading research summaries/abstracts.

The relationship between cell phone use, academic performance, anxiety, and Satisfaction with Life in college students.

Andrew Lepp; Jacob E. Barkley; Aryn C. Karpinski;

### Abstract

While functional differences between today's cell phones and traditional computers are becoming less clear, one difference remains plain – cell phones are almost always on-hand and allow users to connect with an array of services and networks at almost any time and any place. The Pew Center's Internet and American Life Project suggests that college students are the most rapid adopters of cell phone technology and research is emerging which suggests high frequency cell phone use may be influencing their health and behavior. Thus, we investigated the relationships between total cell phone use ( $N = 496$ ) and texting ( $N = 490$ ) on Satisfaction with Life (SWL) in a large sample of college students. It was hypothesized that the relationship would be mediated by Academic Performance (GPA) and anxiety. Two separate path models indicated that the cell phone use and texting models had good overall fit. Cell phone use/texting was negatively related to GPA and positively related to anxiety (see tables 2 and 3); in turn, GPA was positively related to SWL while anxiety was negatively related to SWL. These findings add to the debate about student cell phone use, and how increased use may negatively impact academic performance, mental health, and subjective well-being or happiness.

{I have included the evidence these researchers had so that you can make your own decisions about the significance of the findings.}

<p>RQ1: <i>CPUse</i> will have a negative relationship with GPA and a positive relationship with anxiety. GPA will be positively related to SWL and anxiety will be negatively related to SWL.</p>	<p><b>Table 2</b> Pearson correlations between the variables for research question 1 (<math>N = 496</math>).</p> <table border="1"> <thead> <tr> <th>Variable</th> <th>1</th> <th>2</th> <th>3</th> <th>4</th> </tr> </thead> <tbody> <tr> <td>1. CPUse</td> <td>-</td> <td>-.203***</td> <td>.096*</td> <td>.012</td> </tr> <tr> <td>2. GPA</td> <td></td> <td>-</td> <td>.004</td> <td>.207***</td> </tr> <tr> <td>3. Anxiety</td> <td></td> <td></td> <td>-</td> <td>-.221***</td> </tr> <tr> <td>4. SWL</td> <td></td> <td></td> <td></td> <td>-</td> </tr> </tbody> </table> <p>Note. CPUse = cell phone minutes per day, GPA = Grade Point Average, Anxiety = Total Beck Anxiety Inventory (BAI) score, SWL = Total Satisfaction with Life Scale score. * <math>p &lt; .05</math>. *** <math>p &lt; .001</math>.</p>	Variable	1	2	3	4	1. CPUse	-	-.203***	.096*	.012	2. GPA		-	.004	.207***	3. Anxiety			-	-.221***	4. SWL				-
Variable	1	2	3	4																						
1. CPUse	-	-.203***	.096*	.012																						
2. GPA		-	.004	.207***																						
3. Anxiety			-	-.221***																						
4. SWL				-																						
<p>RQ2: <i>Texting</i> will have a negative relationship with GPA and a positive relationship with anxiety. GPA will be positively related to SWL and anxiety will be negatively related to SWL.</p>	<p><b>Table 3</b> Pearson correlations between the variables for research question 2 (<math>N = 490</math>).</p> <table border="1"> <thead> <tr> <th>Variable</th> <th>1</th> <th>2</th> <th>3</th> <th>4</th> </tr> </thead> <tbody> <tr> <td>1. Texting</td> <td>-</td> <td>-.098*</td> <td>.093*</td> <td>-.010</td> </tr> <tr> <td>2. GPA</td> <td></td> <td>-</td> <td>-.007</td> <td>.209***</td> </tr> <tr> <td>3. Anxiety</td> <td></td> <td></td> <td>-</td> <td>-.207***</td> </tr> <tr> <td>4. SWL</td> <td></td> <td></td> <td></td> <td>-</td> </tr> </tbody> </table> <p>Note. Texting = texts sent per day, GPA = Grade Point Average, Anxiety = Total Beck Anxiety Inventory (BAI) score, SWL = Total Satisfaction with Life Scale score. * <math>p &lt; .05</math>. *** <math>p &lt; .001</math>.</p>	Variable	1	2	3	4	1. Texting	-	-.098*	.093*	-.010	2. GPA		-	-.007	.209***	3. Anxiety			-	-.207***	4. SWL				-
Variable	1	2	3	4																						
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2. GPA		-	-.007	.209***																						
3. Anxiety			-	-.207***																						
4. SWL				-																						

## Exercise 5d: Practice reading research summaries/abstracts.

### *Physiological Effects of a Conducted Electrical Weapon {Taser} on Human Subjects*

Gary M. Vilke, MD; Christian M. Sloane, MD; Katie D. Bouton, BS; Fred W. Kolkhorst, PhD; Saul D. Levine, MD; Tom S. Neuman, MD; Edward M. Castillo, PhD, MPH; Theodore C. Chan, MD. © 2007 American College of Emergency Physicians. Annual meeting, May 2007, Chicago, IL.

#### **Study Objective:**

Sudden death after a conducted electrical weapon exposure has not been well studied. We examine the effects of a single Taser exposure on markers of physiologic stress in healthy humans.

**Methods:** This is a prospective trial investigating the effects of a single Taser exposure. As part of their police training, 32 healthy law enforcement officers received a 5-second Taser electrical discharge. Measures before and for 60 minutes after an exposure included minute ventilation; tidal volume; respiratory rate (RR); end-tidal PCO<sub>2</sub>; oxygen saturation, pulse rate; blood pressure (systolic blood pressure/diastolic blood pressure); arterialized blood for pH, PO<sub>2</sub>, PCO<sub>2</sub>, and lactate; and venous blood for bicarbonate and electrolytes. Troponin I was measured at 6 hours. Data were analyzed using a repeated-measures ANOVA and paired *t* tests.

**Results:** At 1 minute postexposure, minute ventilation increased from a mean of 16 to 29 L/minute, tidal volume increased from 0.9 to 1.4 L, and RR increased from 19 to 23 breaths/min, all returning to baseline at 10 min. Pulse rate of 102 beats/min and systolic blood pressure of 139 mm Hg were higher before Taser exposure than at anytime afterward. Blood lactate increased from 1.4 mmol/L at baseline to 2.8 mmol/L at 1 minute, returning to baseline at 30 minutes. pH and bicarbonate decreased, respectively, by 0.03 and 1.2 mEq/L at 1 minute, returning to baseline at 30 minutes. All troponin I values were normal and there were no EKG changes. Ventilation was not interrupted, and there was no hypoxemia or hypercarbia.

**Conclusion:** A 5-second exposure of a Taser X26 to healthy law enforcement personnel does not result in clinically significant changes of physiologic stress.

- GMV, MD; CMS, MD; SDL, MD; TSN, MD; EMC, PhD, MPH; and TCC, MD are from the Department of Emergency Medicine, University of California, San Diego Medical Center, CA.
- KDB, BS FWK, PhD are from the Department of Exercise and Nutritional Sciences, San Diego State University, San Diego, CA.

**Author contributions:** GMV and TCC conceived the project, were coprincipal investigators, and worked on protocol formulation. CMS, FWK, SDL, and TSN assisted with protocol refinement. KDB assisted with analysis. GMV, CMS, FWK, SDL, TSN, EMC, and TCC assisted with article preparation. EMC assisted with data management and statistical analysis. GMV, CMS, KDB, FWK, SDL, TSN, and TCC worked on data collection. GMV takes responsibility for the paper as a whole.

**Funding and support:** By *Annals* policy, all authors are required to disclose any and all commercial, financial, and other relationships in any way related to the subject of this article, that might create any potential conflict of interest. See the Manuscript Submission Agreement in this issue for examples of specific conflicts covered by this statement. This study was funded by the National Institute of Justice (2005-IJ-CX-K051).

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reserved. <http://www.charlydmiller.com/LIB11/2007NovTaserVilkeEtAl.html>

## Exercise 5e: Practice reading research summaries/abstracts.

The Efficacy of Duct Tape vs Cryotherapy in the Treatment of Verruca Vulgaris (the Common Wart)

Dean R. Focht III, MD; Carole Spicer, RN; Mary P. Fairchok, MD

*Arch Pediatr Adolesc Med.* 2002;156(10):971-974. doi:10.1001/archpedi.156.10.971

### Abstract

**Objective** To determine if application of duct tape is as effective as cryotherapy in the treatment of common warts.

**Design** A prospective, randomized controlled trial with 2 treatment arms for warts in children.

**Setting** The general pediatric and adolescent clinics at a military medical center.

**Patients** A total of 61 patients (age range, 3-22 years) were enrolled in the study from October 31, 2000, to July 25, 2001; 51 patients completed the study and were available for analysis.

**Intervention** Patients were randomized using computer-generated codes to receive either cryotherapy (liquid nitrogen applied to each wart for 10 seconds every 2-3 weeks) for a maximum of 6 treatments or duct tape occlusion (applied directly to the wart) for a maximum of 2 months. Patients had their warts measured at baseline and with return visits.

**Main Outcome Measure** Complete resolution of the wart being studied.

**Results** Of the 51 patients completing the study, 26 (51%) were treated with duct tape, and 25 (49%) were treated with cryotherapy. Twenty-two patients (85%) in the duct tape arm vs 15 patients (60%) enrolled in the cryotherapy arm had complete resolution of their warts ( $P = .05$  by  $\chi^2$  analysis). The majority of warts that responded to either therapy did so within the first month of treatment.

**Conclusion** Duct tape occlusion therapy was significantly more effective than cryotherapy for treatment of the common wart.

Data set available in your OneNote notebook : *duct tape vs. warts*

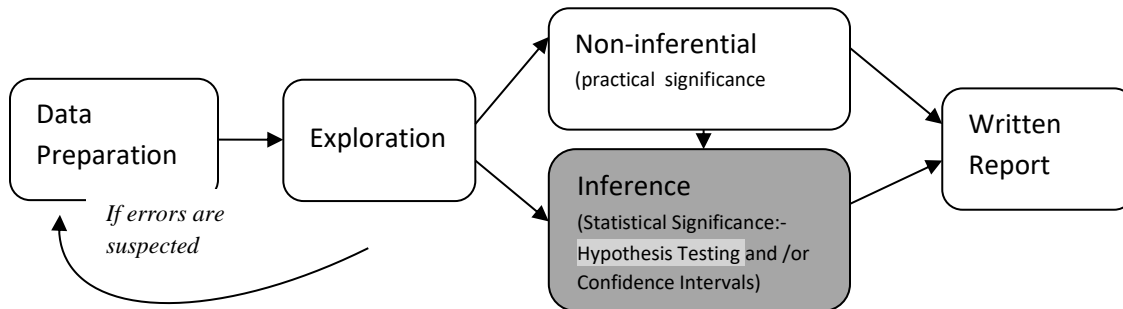


## **Unit 4: Inferential Statistics**

The elements of data analysis were first presented in the Stat1013 class. You worked with all the elements except for hypothesis testing part of inference and the written report. The first part of this unit is a review the non-inferential work you did last semester. One of the keys to competence with data analysis comes from using data types as a thinking tool.

**Quantitative Data analysis (elements):** The product of quantitative research study is a data set, which needs to be analysed. The process and product of analysis for each of the elements from Fi Key elements:

- ✓ practical significance calculations for each combination of data types.
- ✓ normal distribution, z-score calculations, & areas under the standardized normal curve.
- ✓ formal inferential statistics tools



**Figure 4:** visual representation of elements of data analysis

Figure 2 on previous page is described below.

### Data Preparation

**the process:** after data collection, the data set needs to be complete, properly formatted and valid. Activities include entering data into electronic format (in our case SPSS), searching for and cleaning up data entry errors, and establishing what missing data (and/or outliers) may mean. If data collection and design aren't done carefully, or if data is messy then preparation of data can take up a significant portion of the data analysis process.

**the product:** a nice clean data set that can be used to help answer the research question(s).

### Exploration

**the process:** depends on the data type scenario (see table 1 on page 36). In each scenario exploration involves numerical calculations, and visualization of the distribution of the data for the variable of interest. Luckily, we have SPSS to do the detailed work for us – the process involved giving SPSS the correct instructions to produce what we need.

**the product:** Numerical summary statistics, tables and visualizations through appropriate graphs. In some cases you may already be able to sense what the answer the research question will be.

### Practical significance – for scenarios with 2 variables only

**the process:** calculate appropriate measures of practical significance using the data set available (calculations depend on data types)

**the product:** A measure of the strength of association/relation between 2 variables, and an answer to the research question for the collected data. Practical significance is called **clinical significance** in medical research, and is also referred to as a measure of effect.

## **Inference (Statistical significance)**

*the process:* calculations of confidence intervals and/or hypothesis testing for measures of practical significance using SPSS (you will gain competence in through the next few weeks.)

*the product:* a decision (based on probabilities) suggesting whether the findings from practical significance can be generalized to a population from which the sample data (i.e. from study participants) came. Can your findings (this drug helps relieve pain!) be true for everyone in the target population?

In some research journals ‘statistical significance’ is incorrectly considered primary to ‘practical significance’, but that is changing.

## Terminology-4 Types of Data - review of stat1013

Data (and variables) can be classified as categorical or measurement. Some textbooks and online resources may label categorical data as 'qualitative' and measurement as 'quantitative'.

**Categorical data:** comes from variables that classify individual participants as belonging to one of 2 or more categories. Categorical data is further broken down into nominal or ordinal. In **nominal data** categories are named, and have no particular order. (e.g. gender, colour of eyes, favourite musical genre, country of birth). In **ordinal data** categories form a natural order, but no real sense of space or distance between the levels. (e.g.: first, second, third in a race: difference may be 0.1 seconds or 5 seconds but that doesn't matter with order; letter grades, birth order, likert scale on a survey)

**Exploration/description:** examine frequency (number of participants, or % of participants) in each category numerically using frequency tables, and visually using bar graphs, pie charts.

**note1:** in some disciplines, notably psychology, ordinal data can be treated as measurement data

**note2:** SPSS does not have a designation called categorical data, but it does allow you to label data as nominal or ordinal.

**Measurement data:** • comes from a variable that measures a characteristic of individuals of a population. e.g. earnings per hour, shoe size, height of one month old tomato seedlings are all measurement variables. Measurements can be imprecise (He is 2 metres tall), or very precise (He is 1.892345 metres tall.)

**Exploration/description:** is much more rich and complex than data analysis with categorical variables. Key interest is to describe the distribution of the data numerically and visually. Of interest is the shape, centre and spread of the distribution. In some cases researchers are also interested in relating an individual score to the population – measures of position.

**Numerically :**

- Measures of shape capture symmetry/skewness and kurtosis of distribution.
- Measures of central tendency that are calculated: mean, median, mode. Remember that means are very sensitive to outliers and other extreme values
- Measures of spread(dispersion) include: range, variance, and standard deviation.
- Measures of position (percentiles and z-score) help you relate individual scores to the group.

To the right is the formula for z-score

$$Z = \frac{X - \mu}{\sigma}$$

**Visually:** plot a histogram or boxplot to visualize centre, spread and shape. Measurement data can be distributed in various ways: e.g. skewed left/right, uniform, bimodal and normal.

**note:** In mathematical statistics all data is classified as either **discrete** or **continuous**. All nominal and ordinal data, and most measurement data is discrete. Some measurement data is continuous. Continuous data is that which can take on all possible values between two other values. In our day to day lives most measurements are not continuous in practice because our instruments are not infinitely precise. The distinction between discrete and continuous is important for mathematicians, but not important for us in this course.

Chart of data types and analysis approaches. Many of the nuances within the analysis are not included.

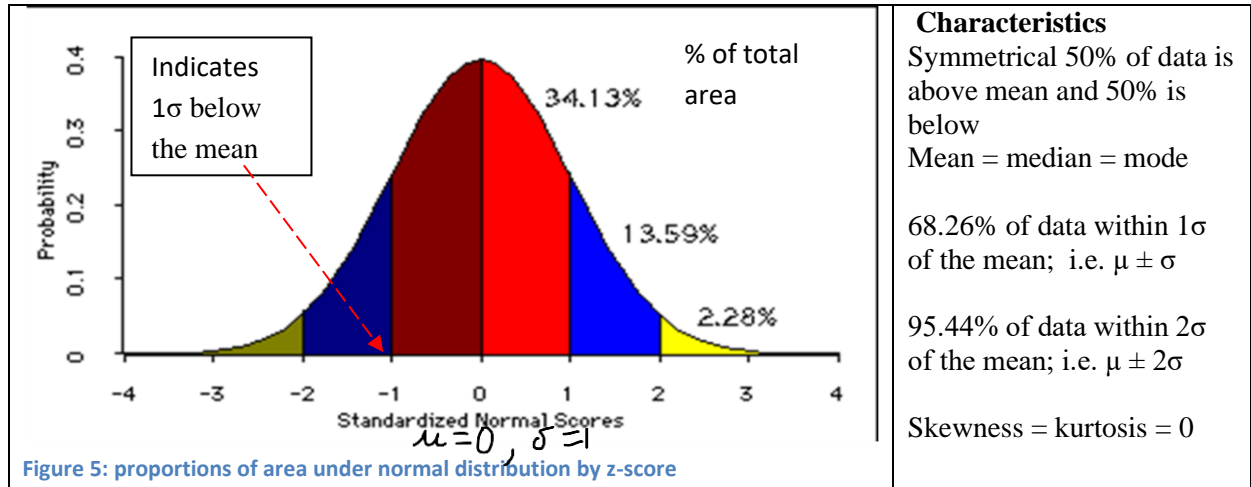
Data Type(s)	Explore Visually	Explore Numerically	Practical significance	Inference (statistical significance)
one measurement	dot plot; histogram box plot <i>(shape, centre, spread outliers?)</i>	mean, median/mode; std. dev./ and more <i>(if normal distribution z-scores &amp; percentiles)</i>	N/A	Confidence Interval for mean ( $\mu$ ) hypothesis test single mean (t-test) $H_0: \mu = \mu_{\text{predicted}}$
one categorical	bar; pie	rate/frequency table	N/A	Confidence interval for proportion ( $\pi$ ) hypothesis test 2 options $\chi^2$ - goodness of fit (or (z-test) $H_0: \pi = \pi_{\text{predicted}}$ )
Two Measurement (correlation)	scatter plot <i>(look for tightly packed points along a line)</i>	Correlation/regression Pearson's 'r'; regression equation	Pearson's r & $r^2$  <i>Strength &amp; Direction</i>	Confidence interval for 'r' Hypothesis test of pearson's r; $H_0: r = 0$
Two categorical (compare rates)	paneled pie	Compare rates or %/probabilities through Contingency table	RR = Ratio of rates or Relative Risk RD = Risk Difference	C.I. for RR (if 2 by 2 contingency table) $\chi^2$ - independence (hypothesis test) $H_0$ : no association between 2 variables <i>(IF 2 by 2 can use z-test test of 2 proportions - not on SPSS)</i>
One categorical & one Measurement (compare means)	comparison box plot  paneled histogram <i>(compare shape, centre, spread &amp; outliers?)</i>	Compare means, medians, std. deviations, min/max etc	-Raw difference between means, -% difference means - Cohen's d	C.I. for difference between 2 means $H_0: \mu_{\text{group1}} = \mu_{\text{group2}} = \mu_{\text{group3}} = \dots$ (use ANOVA) + post Hoc  (Is there more variation within groups or between groups?) <i>or Independent means test(if 2 categories/groups ),</i>

Table 1 chart of appropriate analysis by data type(s)

## Review of normal distribution

When exploring the distributions of various data sets, early statisticians found patterns they could use to understand what had seemed chaotic (mathematicians love finding patterns). One pattern took on the name 'normal distribution' just over 100 years ago. The normal distribution is a mathematical construct (model) that happens to work very well in describing the distribution of many biological characteristics (measurements) in human and other populations. For example, head circumference, shoe size etc.

A standardized normal distribution is mathematically beautiful, and has many applications.



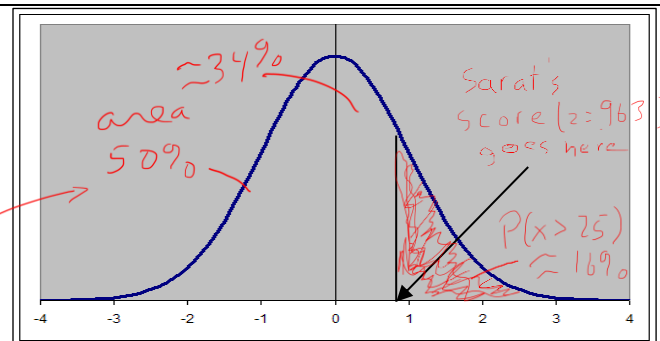
**What is the normal distribution used for?** Very useful in relating individual scores to a group – once it is established that the characteristic of the group is normally distributed and we know  $\mu$  and  $\sigma$ , we can know a lot about the variable and possibly make inferences.

**Measures of position (percentiles)** relate the individual score to the population (the group) – the z-score is what helps us do that when know that the distribution is normal. The z-score tells us how many standard deviations a particular point is above or below the mean in a normal distribution.

**Example:** The distribution of HIM time spent studying in semester 1 (hrs/week) had  $\mu = 17.2$  and  $\sigma = 8.1$ . Sarat studied 25 hours per week. Use the z-score to relate Sarat's time spent studying to his peers.

- $z = \frac{25 - 17.2}{8.1} = \frac{7.8}{8.1} = 0.963$ . This means that Sarat's time studying was 0.963 standard deviations above than the mean. This does not tell us much, unless we use the fact that time spent studying is normally distributed and visualize it on a normal curve (see below) to calculate probabilities (or percentiles).

- Given that time spent studying is normally distributed plot Sarat on the normal distribution and see where he sits compared to his classmates using the z-table appendix 2. Since Sarat's z-score(0.963) is close to +1 we can estimate that  $P(x > 25) = P(z > 1) \approx 100 - 84\% \approx 16\%$



- Using areas under the normal curve (z-tables) to represent actual students we can get the exact proportion of students who studied more than Sarat's 25 hours or less than 25 hours.

$$P(x > 25) = 16.85\%$$

$$P(x < 25) = 83.15\% \text{ \{make sure to Remind yourself of the mechanics\}}$$

## Exercise 6a: review of normal distribution and z-score:

In stat1013 we worked with a data set which represented the time spent studying of first year HIM students at GBC.

Time spent studying is normally distributed with  $\mu = 17.2$  hours per week and  $\sigma = 8.1$ .

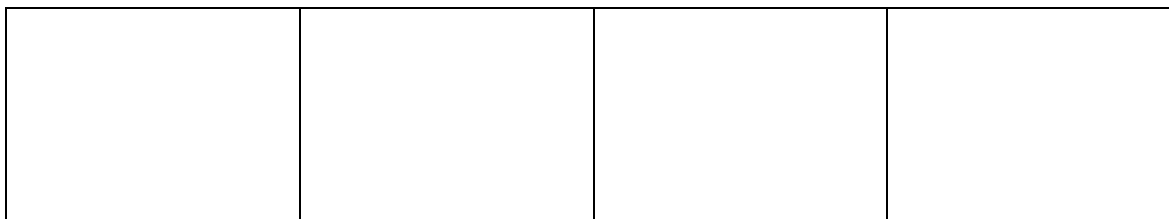
1. Sketch a normal curve for each and shade in the given area for  $x$  - timestudying

a.  $x > 25$

b.  $17 < x < 25$

c.  $12 < x < 17$

d.  $x < 12$



2. Draw a standardized normal curve

3. Calculate z-scores for the following (remember  $\mu = 17.2$  hours per week and  $\sigma = 8.1$ ):

a.  $x = 12$ ;

b.  $x = 17$ ;

c.  $x = 25$ ;

$z =$

$z =$

$z =$

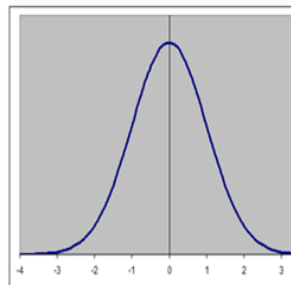
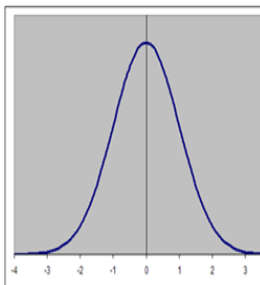
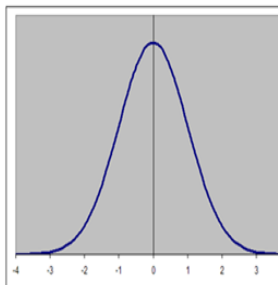
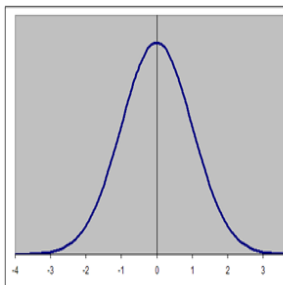
4. Shade each of the regions defined below on the given standardized normal curves.

a.  $x > 25$

b.  $17 < x < 25$

c.  $12 < x < 17$

d.  $x < 12$



5. Use z-tables to find a.  $P(x > 25)$ , b.  $P(17 < x < 25)$  c.  $P(12 < x < 17)$  d.  $P(x < 12)$

## Exercise 6b: review of normal distribution and z-score:

**Instructions:** Answer each of the questions in order as best you can. If you need support, review notes from stat1013 or the ppt on normality look for them in the OneNote notebook under class notes. If there is anything unclear please ask Taras.

N.B. **Please** do this exercise individually and using your imaginative powers of prediction only.

**Part I: Hypothesizing:** In this section you will come up with a hypothesis (prediction) for stat1013 marks for first semester HIM students at GBC.

1. *Predict* the following measures of marks (as a mark out of 100) for first year HIM students without looking at the data set.

$\mu$  \_\_\_\_\_ Median \_\_\_\_\_ Range \_\_\_\_\_  $\sigma$  \_\_\_\_\_

2. *Draw a mini-sketch* of what you think the distribution will look like. Do you think that the data will be distributed normally? Explain why or why not?

3. Prediction: How unusual do you think a mark of 80 is? What percent of first semester HIM students do you think achieved a mark greater than 80?

4. Prediction: How unusual do you think a mark below 50 is? What percent of first semester HIM students do you think achieved a mark below 50?

### ***Exercise 6c: working with the data – from z-scores to probabilities:***

We will be working with a data set of Stat1013 final marks from 2006 –2013 (I removed ‘outliers’ defined as those students who achieved 30% or lower in the course).

Open up the *stat1013 marks no outliers* data set from OneNote notebook and explore the *mark\_final* variable numerically and visually, then answer the following questions:

1. How many students took the stat1013 course over those years?  $N =$  \_\_\_\_\_
  
2. Are marks distributed normally? Is there another distribution that could better model the distribution of marks? Give evidence to support your decision.
  
3. Get SPSS to produce summary statistics for marks achieved by the students in the data set.  
 $\mu =$  \_\_\_\_\_ median = \_\_\_\_\_ range = \_\_\_\_\_ &  $\sigma =$  \_\_\_\_\_.
4. Use the values in #3, (and assuming that the data is close to normally distributed) calculate the following:
  - a. Z-score for  $\text{mark\_final} = 80$ ;
  
  - b.  $P(\text{mark\_final} > 80) =$
  
  - c.  $P(\text{mark\_final} < 80) =$
  
  - d. Explain what you have found in c.
  
  - e.  $P(\text{mark\_final} > 50) =$
  
  - f.  $P(\text{mark\_final} < 50) =$
  
  - g. Draw a sketch of the normal distribution shading the area you defined in f.

**Sketch of Inference process (one variable):** Figure 6 represents the process of sampling from a population and using a sample mean (or proportion) to build an estimate for the true population mean (or proportion). This is work that you did in stat1013.

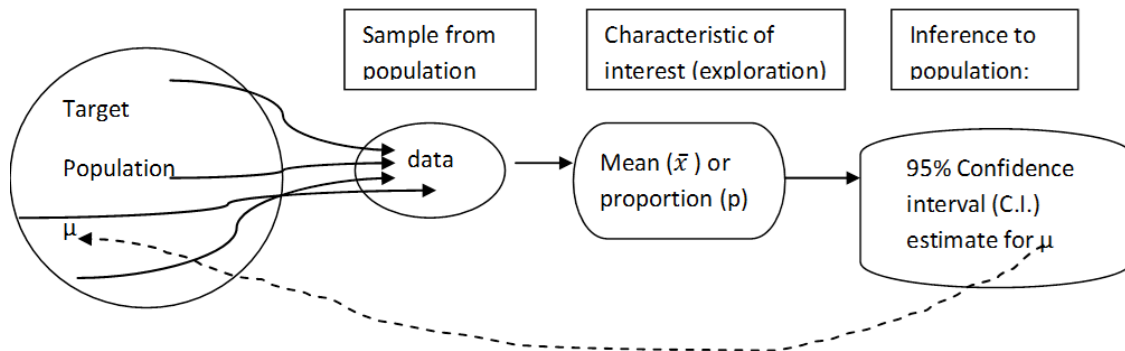


Figure 6 : making an inference about a single characteristic (one variable), from sample to population.

**Sketch of Inference process (two categorical variables):**

Figure 7 represents the process of sampling from a population and data collection and analysis when conducting a basic experiment on individuals sampled from a population and where the outcome is categorical. (visualize a contingency table with exposure in rows and outcome in columns). Data analysis involves a comparison of rates and calculation of practical significance. For two categorical variables that means calculating relative risk (RR).

**Confidence Intervals** for RR can be calculated, and that is one way of making a careful inferential statement about the RR in the population. **Hypothesis Testing** is conceptually more complex, and often misunderstood.

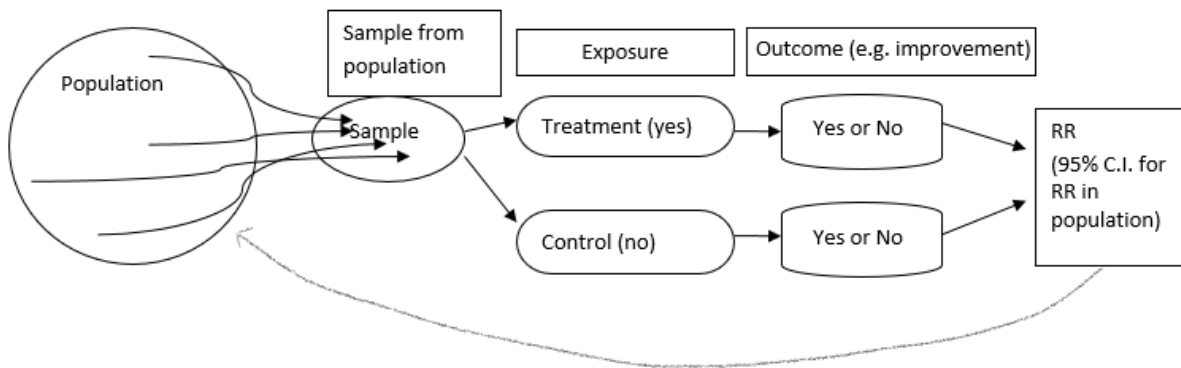


Figure 7 Flow Chart of process (data collection and analysis) in a true experiment where outcome is categorical.

## Inference concepts: a review

To make an inference with statistics is to use information from a sample to make predictions (generalizations) about the population from which the sample was chosen.

With apologies for repetition

**Target population:** a subset of the population that presents a realistic, and well-defined target for the particular study. For example: we start with a design in which we are interested in testing a treatment for a population of all type 2 diabetes patients in Canada, and gradually realize that with the limited resources (time, money and logistics) targeting Toronto type 2 diabetes patients is much more realistic. Thus, our target population becomes type 2 diabetes patients living in Toronto.

**Sampling frame:** the physical representation of the target population from which the sample is chosen. (list of names is easiest, but could be a description of boundary)

**Parameter:** the characteristic of interest *in the population*. The characteristic could be population mean ‘ $\mu$ ’, population standard deviation ‘ $\sigma$ ’, population proportion ‘ $\pi$ ’, RR, Pearson’s R, etc.

**Statistic:** the characteristic of interest *in the sample*. For mean use the symbol  $\bar{x}$ , for sample proportion use ‘p’, while for the others there is no differentiated symbol for parameter vs. statistic.

**p-value:** the probability of getting a more extreme value than the one you are testing in a random draw of a sample from a given population. If the p-value is very low, then either you have a ‘weird’ sample, or your test value is not what you have hypothesized it is.

**Four Fundamental concepts of statistics- Central limit theorem for means:** review from stat1013, from Caldwell(2010); Chapter 5

1. The vast majority of studies **base their conclusions on samples from a population**. It is best to conduct a **random sample**; random sampling is hard to do properly.
2. Samples are subsets of the population. No sample is a perfect representation of the population from which it is taken; **each sample contains error. Sampling error is natural**; every sample – even the weirdest one – is possible even when taking a random or other type of sample.
3. We can keep taking samples (of size  $n=??$ ). Each sample will have a sample mean  $\bar{x}_i$  where  $i$  represents the numbered order of the sample. As we keep taking samples, calculate  $\bar{x}_i$  and plot the individual sample means  $\{ \bar{x}_1, \bar{x}_2, \bar{x}_3 \dots \bar{x}_N \}$  as points onto a histogram, we create a **distribution of sample means**.
4. Given a large number of samples ‘N’ (up to  $N = \infty$  infinity), the distribution of sample means ( $\bar{x}_i$ ) will be normally distributed with mean =  $\mu$  (the true population mean), and standard deviation (called standard error) =  $\frac{\sigma}{\sqrt{n}}$  where  $n$  is the sample size. The larger the sample size ( $n$ ), the smaller the standard error.

**Confidence intervals for single mean and proportion: calculation.** Confidence intervals are constructed when taking a sample from a population and estimating the true population mean (or proportion) based on the sample mean (or proportion).

**Example (proportions):** We want to know whether a group of coders is keeping their success rate above the 97% target. What we need to do is to compare their codes to the original charts. It would be impossible to check every single chart that each coder has coded. Instead check a random sample of 200 charts and get – for example –  $p = 73\%$ . Because we are taking a sample from the population of charts that have been coded, we know that there is a probability that the resulting proportion of errors ‘p’ from the sample is not an perfect representation of the true population proportion  $\pi$  of errors. In order to get an estimate we build a 95% confidence interval for the proportion (see the right column of table 2 below).

**Example (means):** We would like to know the average number of charts coders code per hour. The goal is 14. Instead of looking through each coders charts over a very long time period, the researcher can randomly choos 5 one hour blocks for 40 coders, giving us a sample size of 200. The sample mean  $\bar{x} = 13.2$ , while the standard deviation was 2.12. Now we simply build a 95% confidence interval for using the data we have collected. Details + the formula used can be found to the left of table 2.

Table 2: 95% confidence intervals example and practice

<p>Confidence intervals for means (t-tables)  <math>\mu</math> – the ‘true’ population mean we are trying to capture.  <math>\bar{x}</math> – the mean from the sample  <math>s</math> – the standard deviation of the sample  <math>n</math> – the sample size  <math>t</math> – the t-score which is dependent on the degrees of freedom (<math>n - 1</math>) and the level of significance (<math>\alpha=0.05</math>)</p>	<p>Confidence intervals for proportions (z-tables)  <math>\pi</math> – the ‘true’ population proportion we are trying to capture.  <math>p</math>– the proportion from the sample  <math>n</math> – the sample size  <math>z</math> – will typically be 1.96 since we are using 95% confidence intervals in this course. This comes from the area (<math>0.475 \times 2 = 0.95</math>) on either side of the mean in the normal distribution.</p>
$\mu = \bar{x} \pm t \left( \frac{s}{\sqrt{n}} \right)$ <p style="text-align: right;">remember the excel Confidence Interval calculator</p>	$\pi = p \pm z \sqrt{\frac{p(1-p)}{n}}$
<p>From example above: <math>\bar{x} = 13.2, s = 2.12;</math>  <math>\mu = 13.2 \pm 0.29561; 12.9 \leq \mu \leq 13.5</math>  Based on this sample we are 95% sure that the coders are coding fewer than 14 charts per hour.</p>	<p>From example above: <math>p = 0.73, n = 200.</math>  <math>\pi = 0.73 \pm 0.06153; 0.6685 \leq \pi \leq 0.7915</math>  Based on this sample we are 95% sure that the coders accuracy is well below 97%.</p>
<p>Practice: Find the 95% confidence interval for the mean number of charts in the following:  What happens as the sample size changes?</p> <ol style="list-style-type: none"> <li>Sample size = 16; <math>\bar{x} = 13.2, s = 2.12.</math></li> <li>Sample size = 73; <math>\bar{x} = 13.2, s = 2.12</math></li> <li>Sample size = 100; <math>\bar{x} = 13.2, s = 2.12</math></li> </ol>	<p>Practice: Find the 95% confidence interval for the proportions of errors in the following.  What happens as sample size increases?</p> <ol style="list-style-type: none"> <li>Sample size = 12; <math>p = .73</math></li> <li>Sample size = 500; <math>p = .73</math></li> <li>Sample size = 2000; <math>p = .73</math></li> </ol>

**Exercise 7a: Random Rectangles – a review of inferential statistics and confidence intervals**

Below you have 100 rectangles subdivided into bunches of squares of equal size. We will use random sampling to estimate (make an inference about) the mean area (i.e. number of squares) of all 100 rectangles, without having to calculate all 100 areas.

**Random Rectangles**

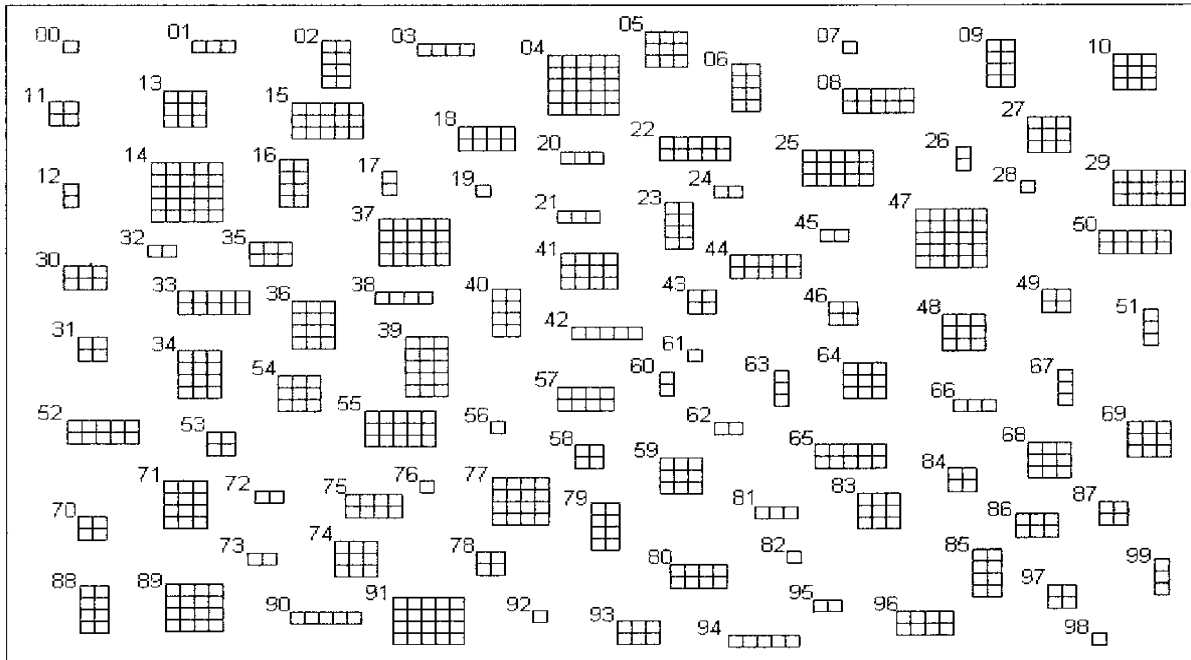


Figure 8; 100 Random Rectangle area exercise (sourced from <http://www.socr.ucla.edu/>)

**Instructions:**

1. Fill in the table below: note that the area of each rectangle = the number of squares in it.

Unit of analysis:	Variable name:	Variable type:	N =
-------------------	----------------	----------------	-----

2. Choose a random sample of 10 rectangles by using one the following: The pencil method described by Taras, or go to Random.org and generate 10 numbers from 0 to 99.

Write out 10 corresponding areas(#of squares) from your sample: \_\_\_\_\_

3. Use SPSS or excel to calculate the mean and std. dev. of your sample areas:  $\bar{x}_{area} = \underline{\hspace{1cm}}$ ;  $S_{area} = \underline{\hspace{1cm}}$

4. Predict the mean area of the population ( $\mu_{area}$ ) by finding the 95% confidence interval for  $\mu_{area}$

$$\leq \mu_{area} \leq \quad LB = \underline{\hspace{1cm}} \quad UB = \underline{\hspace{1cm}}$$

5. Open up the ‘random rectangles’ data set. Calculate the actual value for  $\mu_{area} = \underline{\hspace{1cm}}$

Does your C.I. capture the true mean between the LB and the UB? \_\_\_\_\_

### Exercise 7b: Review of random sampling with SPSS and the distribution of sample means

Open up the *numdrinks* data set. This is data for 131, 061 Canadians surveyed by Stats Canada over 2007. We will treat this data set as a population. Take a random sample of 2000 to see if random sampling is useful for capturing means. This data set will be referred to as the ‘original distribution’.

1. Explore the variable in the original distribution numerically and visually (don’t forget to check for normality)
2. Take a random sample of 2000 (make sure to set the random number seed using instructions in your SPSS instructions booklet. If needed Taras can go over this with you.  
Calculate the following:  $\bar{x} = \underline{\hspace{2cm}}$ ;  $s = \underline{\hspace{2cm}}$   
and the 95% C.I for the mean:  $\underline{\hspace{10cm}}$
3. Taras will collect the values of your sample mean and each sample mean generated by your classmates on the white board.
4. A volunteer will enter these sample means into a new data set: ‘sample means no. of drinks’ and post to pbworks
5. Open up the ‘sample means no. of drinks’ data set and explore the variable therein.
6. Fill in the blanks below:

	Original Distribution “numdrinks “	Distribution of sample means “sample means no. of drinks”
Visual Description of distribution	Draw a rough sketch	Draw a rough sketch
Numeric description of the distribution	$\mu =$ $\sigma =$ median =                  Range = mode =                      min = N =                              max =	mean =                  std. dev. =                  N = median =                  min =                  max = 95% C.I. for mean
Discuss to what extent sampling was an effective way of estimating the average # of drinks?		

## Formal Hypothesis testing – concept and logic

**Informal vs Formal Hypothesis testing:** Everyday decisions (e.g. to take studying seriously, as then I will learn something meaningful/important and be rewarded with a good grade) are based on informal (and often hidden) hypotheses (e.g. teacher will be fair, what schools are teaching is meaningful/important) that have been tested informally usually, through experiential feedback loops.

Other hypotheses need to be tested formally (e.g. effectiveness and safety of covid vaccine). Formal hypothesis testing (much like a confidence interval) is important if we want to make claims about the future, or about populations of individuals, based on a sample from a population? It is a system of measuring the degree of certainty of our claims.

**The Basic Logic:** Start with a hypothesis (with expected test value). SPSS will calculate the probability that the sample data set (i.e. the sample statistic: sample mean or risk ratio or Pearson's  $r$ ... etc) you have, came from a population with "test value = true". If the probability (the  $p$ -value) is very low (usually  $<5\%$  is the rejection zone) this means that it is highly unlikely that the sample comes from a population with the hypothesized test value and we can safely reject the original hypothesis. **Note:** the concept of null hypothesis will be introduced in a few pages. For now simply thinking about the null hypothesis as a type of expected test value is sufficient.

**Hypothesis testing answers the following question:** Does the sample data I am analysing come from a population with the hypothesized test value = true? If the  $p$ -value is low, then the answer is no, and we can reject the original hypothesis.

**Simple example: One Measurement variable.** Do HIM graduates make an average of \$40k after CHIM certification? Imagine that in our collected data from 87 graduates, we calculate the mean starting income over the past 5 years in HIM graduates to be  $\bar{x} = \$43,000$ . Well, it looks like the average income is higher. But, we may have got a weird sample, and the true mean is actually \$40k. After hypothesis testing, if we get a  $p$ -value  $<0.05$  then we know that the likelihood that the sample comes from a population in which  $\mu = \$40k$  is  $<5\%$ , and that would be enough to reject the hypothesis that  $\mu = \$40k$ . Given that the sample mean was higher, we could then make the statement that we are quite sure that the average HIM graduate makes more than \$40k after CHIM certification. With Confidence intervals we would get a more complex story.

**Many versions of the hypothesis test:** The flavour of hypothesis test that is used depends on the number and type of variables being analysed. For example: is the mean difference more than 0? Is the Relative Risk more than 1? Is the correlation more than Pearson's  $R = 0$ ? Each of this requires a different kind of hypothesis test, since the data collected is different.

## The null hypothesis ( $H_0$ ) ... I want to be rejected

When we think of a hypothesis we usually think of a hypothesis (a prediction) like the following: men are taller than women. This can be framed in hypothesis testing as such:  $\mu_{\text{heightmen}} > \mu_{\text{heightwomen}}$ .

In statistical hypothesis testing a different kind of hypothesis a unique logic are used! Even though we think men are taller than women we start off by stating a **null hypothesis** ( $H_0$ ) in which our test value will be 0.

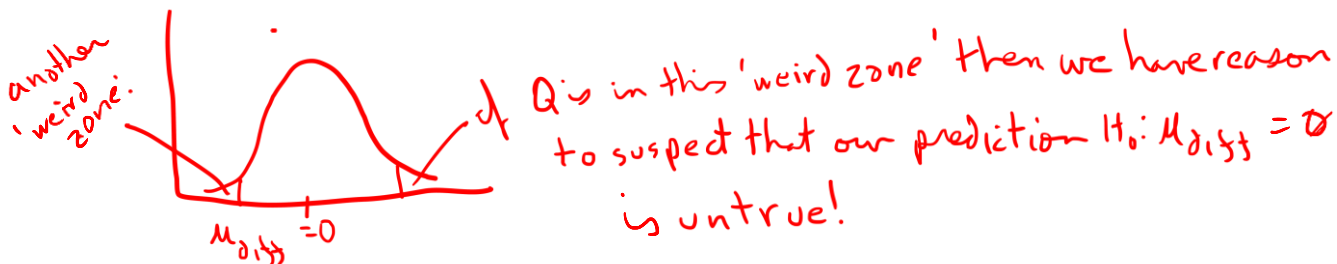
$$H_0: \mu_{\text{heightmen}} = \mu_{\text{heightwomen}}; \quad \text{or} \quad H_0: \mu_{\text{heightmen}} - \mu_{\text{heightwomen}} = 0 \quad \text{or} \quad H_0: \mu_{\text{diff}} = 0$$

After data is collected from a sample of men and women (2 variables: gender and height), we use SPSS to compare sample means for each calculate the raw difference:

$$\bar{x}_{\text{heightmen}} - \bar{x}_{\text{heightwomen}} = \bar{x}_{\text{difference}}; \text{ which we will call } Q$$

Let  $Q = 7\text{cm}$  (i.e. the average man in our sample is 7cm taller than the average woman).

$Q$  ( $\bar{x}_{\text{difference}}$ ) is only one score from a distribution of sample 'differences of means' which I have sketched below. If  $Q=7$  is in the weird zone then we can reject the null hypothesis  $H_0: \mu_{\text{diff}} = 0$ . SPSS will help us place it.



SPSS will generate a **p-value** along with a lot of other statistics we won't use. The **p-value** (a number between 0 and 1) is the probability of getting a sample mean difference  $Q_i > Q=7$  assuming that our null hypothesis is true i.e. that  $H_0: \mu_{\text{diff}} = 0$ .

**If** the *p-value* is  $< 0.05$  **then**  $Q=7$  is **statistically significant** (i.e. in the weird zone) and  $H_0: \mu_{\text{diff}} = 0$  is rejected. This means that  $\mu_{\text{diff}} \neq 0$  and that  $\mu_{\text{diff}} > 0$  or  $\mu_{\text{diff}} < 0$ .

Given that  $Q=7$ , we have evidence that  $\mu_{\text{diff}} > 0$  and thus  $\mu_{\text{heightmen}} > \mu_{\text{heightwomen}}$  (population mean height of men is greater than mean height of women).

**Note:** A *p-value* of 0.03 (for example) tells us that the chances of getting a weirder sample is 3%. Thus it is expected that we will reject a true hypothesis 3 out of 100 times (called a **Type I error**).

## Inference/Hypothesis Testing process – 4- step template

Before conducting a hypothesis test you need to make sure of the variables and the data types that you will be analysing. If you don't know the variables then you won't be able to set up the correct  $H_0$ : and won't know which Hypothesis test to run on SPSS.

Don't forget that hypothesis testing is only one element of the data analysis process.

### The 4 step template for hypothesis testing.

This 4 step process will be used for every hypothesis test that you will do after exploration and practical significance. Follow the steps carefully – at first they may not seem natural to you, so make sure to work slowly and methodically. With practice and you will develop an understanding of this topic. Practice is key – you need to get good at the mechanics in order to develop an understanding of the concepts!

1. Set up a null hypothesis  $H_0$
  
2. a. Calculate the *p-value* using the appropriate hypothesis test (use SPSS instructions for the appropriate hypothesis test).  
  
b. Calculate the confidence interval for the appropriate value (single mean, proportion or measure of practical significance)
  
3. Make a statement about your decision in rejecting the  $H_0$  or not
  
4. Write a nice final statement that summarizes your decision and provides evidence for the decision about statistical significance (*p-value and confidence intervals*) only. The statement should contribute to the final report by indicating whether result can be generalized to the previously defined target population.

## Data Analysis with Inference FAQ (frequently asked questions)

*What is expected in a solution to data analysis problems?*

In short each of the elements as visualized in figure 3 (see page 6)

- A. Prepare the data (e.g. remove any errors)
- B. Explore the variable(s) using skills you learned in stat1013
- C. Choose the correct measures of practical significance (stat1013) and inference (using information from the chart on page 36)
- D. Write up (see tips below)

*What does a proper write up look like?*

Every scenario will be different and that there is no ‘one size fits all’ solution, but there are elements that help.

- Make sure that you keep your focus on answering the research question (RQ). Your ultimate goal is to use the information from the data to answer the question. If the information gives you a clear picture then that is your story, if the information provides a muddy or cloudy answer then that should be part of your story.
- Structure the solution using the various elements of data analysis separately. i.e. exploration, practical significance and inference

*Is there a ‘right answer’?*

That depends on the scenario. It is more accurate to say that there are better and worse answers, and that 2 excellent answer may look quite different.

*How do I know I am on the right track?*

I know that you are not experienced in data analysis and thus the right track is to follow the path that I have laid out – i.e. steps A, B, C, and D above. Each one has nuances, and in each there are decisions you will have to make, but if you follow the steps thoughtfully you are likely on the right track. Experience/practice is actually the thing that will help you build confidence and competence in this field.

Make all your mistakes in class and at home practicing!

## Inference with one measurement variable (sample solution)

Hypothesis test of single mean; Confidence interval for single mean

A sample has been taken from a population your job is to test whether a reported/estimated/ or previously calculated value of the mean  $\mu$  (the predicted value:  $\mu_{\text{predicted}}$ ) is likely to be true.

e.g. do 500ml bottles of water really contain 500ml?

Steps:

1. **set up a null hypothesis** and an alternative hypothesis with respect to  $\mu$ .

$H_0: \mu = \mu_{\text{predicted}}$  (the predicted value);

$$H_0: \mu = 500 \text{ ml}$$

2. a. *find the p-value using SPSS.* Go to the SPSS instructions booklet and look for inferential statistics for one measurement variable to run single means test.

$$p = 0.000$$

- b. *Confidence Interval using SPSS:* Go to the SPSS instructions booklet and look for inferential statistics for one measurement variable to produce the lower and upper bounds for the 95% confidence interval.

$$LB = 524.35 \quad UB = 526.05$$

3. **Decision:** If the *p-value* is  $\leq 0.05$  then there is enough evidence to reject the null hypothesis, if not then we 'fail to reject the null hypothesis' and thus we can't expect that any observed difference between the sample mean and the hypothesized mean can be generalized to the population.

Reject  $H_0: \mu = 500$ . It looks like  $H_a: \mu > 500$  is correct!

4. **Concluding Statement:** 2 thoughtful and clear statements are a minimum. The first simply rejecting/failing to reject  $H_0$  (with evidence) and the second mentioning what you think the 'true' mean will be – this is where a statement of the Confidence interval can really help.

We reject  $H_0$  ( $p = 0.000$ ) and thus are very confident that the bottles do not contain 500ml as stated.

We are 95% confident that the bottles contain more than 500ml of water. The 95% C.I. is  $524.35 \leq \mu \leq 526.05$ .

## Inference with one categorical variable: option 1 - 2 categories (sample solution)

Hypothesis test of single mean; Confidence interval for single mean

### Notation for proportions:

$\pi$  – population proportion;  $p$  – sample proportion (not the  $p$ -value);  $n$  – sample size

A sample has been taken from a population and your job is to test a reported/estimated/ or previously calculated value of the proportion  $\pi$  (the test value:  $\pi_{\text{predicted}}$ ) is likely to be true.

e.g. is the rate of repetitive strain injury in Canada really 7%?  
exploration found that  $p = 0.107$  (the proportion) – based on sample!

### Steps:

1. **set up a null hypothesis** and an alternative hypothesis with respect to  $\mu$ .

$H_0: \pi = \pi_{\text{predicted}}$  (the predicted value);

$$H_0: \pi = 0.07$$

2. a. Calculate the  $p$ -value using SPSS Go to the SPSS instructions booklet and look for inferential statistics for one categorical variable to run single proportions (binomial) test.

$$p\text{-value} = 0.000$$

- b. Confidence Interval: you will need to use the excel confidence interval calculator available on [www.stataras.com](http://www.stataras.com) to produce the lower and upper bounds for the 95% confidence interval for  $\pi$ .

$$LB = 0.093 \quad UB = 0.121 \quad \text{this is the estimate for } \pi \text{ (i.e. in the population)}$$

3. **Decision:** If the  $p$ -value is  $\leq 0.05$  then there is enough evidence to reject the null hypothesis, if not then we ‘fail to reject the null hypothesis’ and thus we can’t expect that any observed difference between the sample proportion ( $p$ ) and the hypothesized proportion ( $\pi_{\text{predicted}}$ ) can be generalized to the population.

$$\text{reject } H_0 \text{ (since } p\text{-value} = 0.000 \text{ which is } < 0.05)$$

4. **Concluding Statement:** 2 thoughtful and clear statements are a minimum. The first simply rejecting/failing to reject  $H_0$  (with evidence) and the second mentioning what you think the ‘true’ proportion will be – this is where a statement of the Confidence interval can really help.

The predicted rate of RSI (7%) does not seem to hold up & we are extremely confident that the actual rate is  $> 0.07$  ( $p$ -value = 0.000). We are also 95% confident that the actual rate of RSI is between 9.3% & 12.1%.

## Inference with one categorical variable: $\geq 2$ categories (sample solution)

$\chi^2$  – goodness of fit test

A sample has been taken from a population and your job is to test whether a reported/estimated/ or previously calculated *set of proportions* are true. Instead of testing one proportion ' $\pi$ ' the  $\chi^2$ - *goodness of fit test* tests multiple categories (proportions) i.e. does the observed frequency in each category fit with expected frequency in each category. (is the distribution of cases as expected)

*eg. When rolling 6 dice 600 times we expect to get 100 of each # (1-6). If we get 200 ones, 200 sixes, 50 twos, 50 threes, 50 fours & 50 fives then we may suspect that the dice is not fair.*

### There are two possibilities for null hypothesis based on expected frequencies.

Expectation of an equal number of 'cases' (i.e. equal frequency) in each category as the example of rolling one 'balanced' die 600 times, which yields a uniform distribution i.e. close to 100 of each # or 16.667% (100/600) for each category. **Research Question:** Is the die fair?

Expectation of unequal frequencies (adding up to 100% of course). For example asking 600 people the political party preference – e.g. Conservatives 180/600 = 30%, Greens 66/600 = 11%, Liberals 162/600 = 27%, NDP 132/600 = 22%, Rhinoceros 12/600 = 2%, undecided 48/600 = 8%

### Steps:

#### 1. set up a null hypothesis

$H_0$ : here one needs to specify expected frequencies (all equal or not) as outlined above.

*eg.  $H_0$ : each category (# on the die) will appear equally.*

#### 2. a. Calculate the p-value using SPSS. Go to the SPSS instructions booklet and look for inferential statistics for one categorical with more than 2 categories to run the $\chi^2$ – goodness of fit test.

*p-value for the example described at the top of the page (200 ones, 200 sixes etc.)  
data set 'dice rolls 600 weird' can be found on [www.statcrash.com](http://www.statcrash.com).  
p-value = 0.000 after running the goodness of fit test.*

b. Confidence Interval – not possible without manipulating the data and only to be used if you wanted to study one of the categories (proportions) vs. the rest.

1. **3. Decision:** If the *p-value* is  $\leq 0.05$  then there is enough evidence to reject the null hypothesis, if not then we 'fail to reject the null hypothesis' and thus we can't expect that any observed difference between the sample proportion ( $p$ ) and the hypothesized proportion can be generalized to the population.

*Reject  $H_0$  (since p-value = 0.000 which is  $< 0.05$ )*

2. **Concluding Statement:** 2 thoughtful and clear statements answering the RQ are a minimum. The first simply rejecting/failing to reject  $H_0$  (with evidence) and the second addressing the research question more directly – when there are more than 2 categories the Confidence interval will typically not be useful.

*It is clear that the result is not close to expectations. ( $p = 0.000$ )  
and thus it is hard to believe that the die is fair.*

## Goodness of fit and tests of independence – null hypothesis testing without a parameter

The normal distribution is a great model for many phenomena and thus for hypothesis testing and confidence intervals. It is not appropriate in scenarios where categorical variables with more than 2 categories are studied and a normal approximation is impossible. (e.g. testing a whether a single die is ‘fair’- see example of this below). For these types of scenarios mathematicians in the 1920’s developed another mathematical model called the  $\chi^2$  distribution (called Chi-square). The associated hypothesis tests are called goodness of fit tests- for one variable, and  $\chi^2$  tests of independence for 2 variables. Goodness of fit tests and  $\chi^2$  tests of independence are similar in structure, and start off with a null hypothesis, but there are differences as outlined below.



The basis of a  $\chi^2$  hypothesis tests is a comparison of sampled (observed) frequency in each category vs. hypothesized (expected) frequency in each category. The hypothesized (expected) values are generated from the  $H_0$ . The  $H_0$  is typically a statement of association. e.g.  $H_0$ : When rolling a single die 600 times the % frequency for each category/number should be equal (i.e. each number should come up 100 times or 16.6667% of the time), {2 variable scenario example:  $H_0$ : there is no association between gender and marital status. }

**Step 1:** Start with a null hypothesis like the one above.

**Step 2:** SPSS will use the  $H_0$  you provide to calculate *expected frequencies* ( $E_i$ ) for each cell of the contingency table (or each category if there is only one variable).

Note: In order for the  $\chi^2$ -test to work well  $E_i \geq 5$  for each category/cell.

$$\chi^2 = \sum_{i=1}^n \frac{(E_i - O_i)^2}{E_i}$$

Figure 9: formula for the  $\chi^2$  distribution

Collect data and enter the *observed values* ( $O_i$ ) into a data set.

SPSS will calculate the expected values ( $E_i$ ) and calculate  $\chi^2$  using the formula in figure 9, as part of the hypothesis test. Then using  $\chi^2_{\text{calculated}}$  SPSS will use a  $\chi^2$  – table (similar to t-tables – there is one for every sample size) to produce a *p-value* showing the probability that there is a sample in which observed between expected and observed came from the hypothesized distribution (set of  $E_i$ ).

**Step 3:** Decision time. The *p-value* is generated by SPSS as follows: If observed values ( $O_i$ ) are unusually higher (or lower) than expected ( $E_i$ ) then  $\chi^2_{\text{calculated}}$  will be very high and generate a *p-value*  $< 0.05$  (i.e. in the weird zone) based on a  $\chi^2$  –table (see sketch above) similar to the t-tables (there is one for distribution for each sample size). If the *p-value* is  $< 0.05$  then the values are not randomly distributed into the cells of the contingency table and the null hypothesis can be rejected with 95% confidence. This tells you nothing about RR or any other statistic, it just tells you that the null hypothesis is highly unlikely to be true.

Despite conceptual differences, the process of the  $\chi^2$  hypothesis tests are very similar to those based on the normal distribution. You will use the same template – described on next page.

## Exercise 8a Analysing a scenario with a single measurement variable –

**Research Question:** Do 500ml water bottles really have 500ml of water in them as claimed?

Wei Zhou decided to find out. He collected a sample of 30 bottles and conducted a full analysis in order to help settle the question.

The data set ‘*water weizhou*’ can be found in your OneNote notebook. Your task is to answer the research question using a full data analysis.

Note that with a single measurement variable there is no calculation of practical significance.

A: results of exploration (numerical and visual) – summarize what you have found.

B: There is no ‘calculation’ of practical significance, but you can get a sense of whether it looks like there will be an answer to the question, by comparing your results of the exploration to the 500ml claim.

C: Inference:

1. Set up  $H_0$ :  $\mu = \underline{\hspace{2cm}}$
2. a. Use SPSS to find the *p-value*  $p = \underline{\hspace{2cm}}$   
b. Confidence Interval: LB =  $\underline{\hspace{1cm}}$       UB =  $\underline{\hspace{1cm}}$     or     $\underline{\hspace{1cm}} < \mu < \underline{\hspace{1cm}}$
3. Make decision: reject null hypothesis or not?
4. Final Statement: 2 statements

D. write up

## Exercise 8b Analysing a scenario with a single categorical variable – 2 categories

**Research Question:** Is the rate of RSI (Repetitive Strain Injury) in Canada 7% per year as claimed by the RSI industry?

We can test the claim using information collected by Statistics Canada as part of the Canadian Community Health Survey.

The data set ‘*repstrain*’ can be found in your OneNote notebook. Your task is to answer the research question using a full data analysis.

Note that with a single categorical variable there is no calculation of practical significance.

A: results of exploration (numerical and visual) – summarize what you have found.

B: There is no ‘calculation’ of practical significance, but you can get a sense of whether it looks like there will be an answer to the question, by comparing your results of the exploration to the 7% claim.

C: Inference:

1. Set up  $H_0$ :  $\pi = \underline{\hspace{2cm}}$
2. a. Use SPSS to find the *p-value*  $p = \underline{\hspace{2cm}}$   
b. Confidence Interval: LB =  $\underline{\hspace{1cm}}$       UB =  $\underline{\hspace{1cm}}$     or     $\underline{\hspace{1cm}} < \pi < \underline{\hspace{1cm}}$
3. Make decision: reject null hypothesis or not?
4. Final Statement: 2 statements.

D. write up

## Exercise 8c Analysing a scenario with a single categorical variable -> 2 categories

**Research Question:** Are there an equal number of smarties of each colour produced in boxes of smarties?

We can test the claim using information from one sample pack of 55 smarties that was purchased at a randomly selected store in Toronto.

The data set '*smarties*' can be found in your OneNote notebook. Your task is to conduct a full analysis of this data.

Note that there is no calculation of practical significance with one categorical variable.

A: results of exploration (numerical and visual) – summarize what you have found.

B: There is no 'calculation' of practical significance, but you can get a sense of whether it looks like there will be an answer to the question, by comparing your results of the expectation of an equal number of every colour (category).

C: Inference: set up the null hypothesis as an expectation – i.e. I expect there to be an equal number of each colour – or I expect there to be 25% red 10% blue etc.

1. Set up  $H_0$ :

2.  $\alpha = 0.05$  Use SPSS to find the *p-value*;  $p = \underline{\hspace{2cm}}$

b. Confidence Interval – is not appropriate here.

3. Make decision: reject null hypothesis or not?

4. Final Statement: answer the research question using all of the analysis that you conducted.

D. write up

### Exercise 8d Analysing scenarios with a single variable – you decide which to use

You will have to decide whether the scenario is based on a single measurement or categorical variable, and if categorical, whether the variable has 2 or >2 categories before choosing the appropriate hypothesis test. Make sure to use exercise 4a-c as models for your solutions.

**Q1:** In this scenario we will use the ‘*largemouth vass*’ data set available in your OneNote notebook.  
**Research Question:** Is the mercury level in the fish low enough that they are safe for consumption. (i.e. below 1ppm)

- a. Name of variable: \_\_\_\_\_ Type: \_\_\_\_\_
- b. Name of hypothesis test: \_\_\_\_\_
- c. Conduct a full analysis and write up your findings.
- d. Describe how the 95% C.I. tells the same story as the hypothesis test?

**Q2:** 2000 Canadians were asked whether they had ever had a flu shot. The data set is the ‘*flu shot*’ available in your OneNote notebook. The government claims that more than 50% of Canadians have received the flu shot.

**Research Question:** Did at least 50% of Canadians receive the flu shot?

- a. Name of variable: \_\_\_\_\_ Type: \_\_\_\_\_
- b. Appropriate hypothesis test: \_\_\_\_\_
- c. Conduct a full analysis and write up your findings.

**Q3:** A random sample of 6 Ontario lakes that had been stocked with Lake Trout 4 years previously were chosen and all the Lake Trout in them were tagged and counted. The results are presented in the table below. There is no data set available.

**Research Question:** Is the average Ontario lake healthy or not? Lakes are considered ‘healthy’ if they have at least 700 fish in them.

		Frequency	
lake1	574	lake4	699
lake2	591	lake5	664
lake3	660	lake6	689

- a. Name of variable: \_\_\_\_\_ Type: \_\_\_\_\_
- b. Appropriate hypothesis test: \_\_\_\_\_
- c. what is the unit of analysis in this study?
- d. Conduct a full analysis and write up your findings.



## Inference with 2 measurement variables (sample solution)

### Hypothesis Testing

Setup: A sample has been taken from a population and 2 measurement variables are collected for each individual. Your job, after having explored the relation through a scatter plot and calculating Pearson's  $r$  is to test whether the observed value of  $r$  is statistically significant. i.e. is  $r$  likely non-zero in the population from which the sample was taken.

**Correlation** analysis (and regression) are useful when looking for the strength and direction of the relation between 2 measurement variables, but don't tell me whether the results can be generalized to the target population.

Hypothesis testing will do that. Conditions for valid hypothesis testing: both variables must be measurement in nature, no evidence for non-linear (curved) relation and no crazy outliers (if so repeat results with and without outlier)!

**Example. Research Question:** Is the second medical terminology course a good preparation for coding? Do students who do better in medical terminology 2 also do better in coding?

#### Steps:

##### 1. set up a null hypothesis

$H_0: r = 0$  ( the null hypothesis will always be the same – we start off by hypothesizing that there is no relation between medical terminology and coding marks)

2. a. when you get SPSS to calculate Pearson's  $r$ , it automatically generates a *p-value* (called 'sig')  $r = 0.705$ ; ( $r^2 = 0.497$ );  $p = 0.000$
- b. Confidence Interval for Pearson's  $r$  – Use the excel confidence interval calculator for Pearson's  $r$  found on [www.stataras.com](http://www.stataras.com). *95% Confidence interval for  $r$  is  $0.581 < r < 0.797$*
- c. *see note below about regression*

##### 3. Decision:

If the *p-value* is  $< 0.05$ , then we are in the weird zone, i.e. there is enough evidence to reject the null hypothesis, if not then we 'fail to reject the null hypothesis' and thus we can't expect that there is any relation between the two variables in the population.

*Reject the null hypothesis ( $p$ -value = 0.000);  $r$  is definitely  $> 0$ .*

##### 4. Final statement:

*The relation between medical terminology 2 marks and coding marks is positive and strong. I am 95% confident that pearson's  $r$  is between 0.581 and 0.797.*

*A higher mark in medical terminology is a good predictor of higher marks in coding.*

**Note:** in this example I have not produced a regression equation, which would normally be included as part of any solution. In exercise 9 make sure to practice with regression as well as hypothesis testing.

## Exercise 9a. Analysing scenarios with two measurement variables -

**Research Question:** Is an HIM students mark in medical terminology 2 a good predictor of how well they do in coding.

The data set '*med terminology vs coding marks*' can be found in your OneNote notebook. Your task is to conduct a full analysis using the 2<sup>nd</sup> mark in medical terminology as the predictor and the coding mark as the outcome. Data was collected over a 2 year period.

A: results of exploration (numerical and visual) – summarize what you have found.

B: Use the values for  $r$  and  $r^2$ , and take a look at the regression equation to get a sense of the strength and direction of relation.

C: Hypothesis test:

1. Set up  $H_0: r = 0$
2. a.  $\alpha = 0.05$  Use SPSS to find the p-value  $p = \underline{\hspace{2cm}}$   
b. Confidence Interval: LB =  $\underline{\hspace{1cm}}$  UB =  $\underline{\hspace{1cm}}$  or  $\underline{\hspace{1cm}} < r < \underline{\hspace{1cm}}$
3. Make decision: reject null hypothesis or not?
4. Final Statement: answer the research question using all of the analysis that you conducted.

## Exercise 9b Analysis with 2 measurement variables

**Q1.** Governments everywhere in Canada are trying to reduce their health care costs by reducing the *number of consultations with family doctor*. It was thought that BMI (*body mass index*) would be a good predictor of number of consultations. These variables were collected for 2000 Canadians and are available in the *cchs condensed 24 variables* data set.

**Research Question:** Do Canadians with higher BMIs consult with their family doctors more than those with lower BMIs?

Conduct a full data analysis to answer the research question.

**Q2.** Governments are also interested in reducing alcohol consumption and are looking at understanding good predictors of high consumption. Using the *cchs condensed* data set (variables: *no of drinks past week*, and *Total usual hrs worked per week*) answer the RQ.

**Research Question:** Do Canadians who work more hours per week consume more ‘drinks’?

Conduct a full data analysis to answer the research question.

**Q3.** ‘Annual Income’ and ‘Systolic Blood Pressure’ in 20 randomly selected resident in Toronto, were ascertained as part of research to test to what whether annual income was a good predictor for elevated blood pressure.

**Research Question:** Do individuals with higher annual incomes also have higher systolic blood pressure? Data collected is available: ‘*income vs. various*’.

- Analyse the data (don’t forget regression) to gauge the strength and direction of any relation between the two variables.
- The researchers believed that with an increase in annual income would come an increase in blood pressure. Using your results (from 3a) what would your response be? Make sure to justify your answer with numerical and visual data.
- Is there any other variable that could be responsible for the increase in blood pressure?

**Q4.** Take a look at the data set *Detroit homicides*. It is a set of data collected over 12 years in Detroit USA. Your job is to investigate the data using your skills with data analysis techniques appropriate with 2 measurement variables.

**Research Question:** Which variable in the set is most likely to be the dependent (outcome) variable? Which is the strongest predictor? Fill in the table below with the top six candidates to help you answer the question.

Predictor variable	r	r <sup>2</sup>	95% C.I. for r (LB, UB)	p-value

## Inference with 2 measurement variables – special case - related (paired) means (pre-post testing) - What is special about these types of scenarios.

A sample has been taken from a population in which getting a particular person (or score) means that you get his a related person (or score) as well (e.g. pre-post testing in education). The data collected consists of two measurement variables. Correlation analysis could be done to see if students with higher pre-test scores also score higher in post-tests, (or if father's who had higher scores had sons with higher scores), but instead we want to know whether there is an improvement after a treatment (teaching or diet).

**The mechanics.** The focus is on the difference between scores (usually improvement) for each individual case (pair of scores). The case could be one person or a pair that are related in some way. Are fathers different than their sons (individual father compared to son)? Are student post-test scores an improvement over pre-test scores? Create a new variable –the difference between individual cases in the sample:

$D_1 = X_{1post} - X_{1pre}$ , (or difference between father and son's scores)

$D_2 = X_{2post} - X_{2pre}$  .... etc. until

$D_n = X_{npost} - X_{npre}$  - then calculate the mean of the differences  $\bar{D}$ . (for  $D_1, D_2, D_3 \dots D_n$ , where  $n$  is the number of cases in the sample.)  $\bar{D}$  is the sample mean and  $\mu_{\bar{D}}$  the population mean. The variable  $D_i$  is a measurement variable and we can analyse it just like we would any other single measurement variable ( $H_0: \mu_{\bar{D}} = 0$ ; and single means t-test).

e.g. Research Question: Do fathers have higher cholesterol levels than their eldest sons? take a look at *father son ldl* data set.

**Hypothesis test steps:**

### 1. set up a null hypothesis

$H_0: \mu_{\bar{D}} = 0$  (the null hypothesis will always be the same)

### 2. Conduct the hypothesis test.

a. Follow SPSS instructions one measurement variable to get a *p-value*  $p = 0.847$

b. Confidence Interval for difference LB = -17.382 UB = 14.582

### 3. Decision:

If the *p-value*  $< 0.05$  then that means the improvement is not 0 – but we really need the confidence interval to indicate which of the alternate hypotheses is correct. **Fail to reject**

### 4. Final statement:

There is no evidence that there is a difference between Father and son LDL level ( $p = 0.847$ ).

The 95% confidence interval is  $-17.4 < \mu_{\bar{D}} < 14.582$ . The large range for the interval indicates that a study with a larger sample size may be necessary.

**Exercise 9c** .An investigation into the effect that a treatment had on weight gain in 17 teenagers with anorexia nervosa i.e. weighed before treatment and after treatment yielded the following data set *bef.after.annorexia*.

**Research Question:** Did patients gain weight after treatment? Is there evidence that the treatment is effective?

a. Use data analysis techniques that you have studied in order to answer that question.

b. Propose another variable you think may influence the weight gain of these teenagers.

**Exercise 10a Introduction to the  $\chi^2$ - test of independence:** Comparing observed to expected results

**Conceptual Experiment: part 1:** Adapted from Rosen and Jerdee(1974) sex role study

48 bank supervisors were eligible for a promotion and submitted their paperwork. 24 were male and 24 were female. There were 35 openings – i.e. 13 would not get the promotion.

1. Set up a contingency table assuming that:

a) There is discrimination against females for sure

		Hired		
		Yes	No	Total
Applicant	Male			
	Female			
	Total			

b) There is no discrimination at all

		Hired		
		Yes	No	Total
Applicant	Male			
	Female			
	Total			

2. Get together with at least 3 neighbours and compare tables then write out best tables on one side of a whiteboard.

If the jobs are distributed fairly (as would be expected given equally qualified applicants) then the expectation is that the contingency table will look like table b). Another way of saying this is that the 2 variables (gender and getting hired) are not associated, not related at all. Hiring (yes) rates will be the same for males as for females.

3. The actual results can be retrieved from a data set in your OneNote notebook; the data set is called *promotions experiment* write out the actual results in the table below.

**Research Question:** Did males get preferential hiring treatment over females?

a) Enter Actual hiring results from 1974 below

		Hired		
		Yes	No	Total
Applicant	Male			
	Female			
	Total			

b) Calculate the RR of being hired for males  
RR =

c) Use the confidence interval calculator on [www.stataras.com](http://www.stataras.com) to calculate the 95% Confidence interval for RR of getting hired for males.  
Males were \_\_\_\_\_ times more likely to be hired than females in a bank in 1974  
(95% C.I. LB = \_\_\_\_, UB = \_\_\_\_)

*It looks like a yes, but the actual results are not 100% clear. The reason is that the actual result 3a) is somewhere in between contingency table 1a) and 1b). The researcher needs to make a decision – and in the next few pages you will learn how hypothesis testing helps us make that decision. But before we do that let’s see what randomly distributed hiring might look like.*

**Exercise 10a-cont'd Conceptual experiment part 2 – Random world:** where everything happens by chance – or at least the kind the kind of chance that exists in the world of cards.

4. What if the executives made the hiring decision not based on gender, but using playing cards to simulate randomness, especially given that all applicants were fairly equally qualified.

Instructions: you will be in groups of about 4. Each group will have a deck of cards and a whiteboard/marker.

- Remove any jokers and 2 black and 2 red cards to leave your deck with 48 cards 24 red and 24 black). Shuffle the cards very well.
- You will deal the cards out into two piles: pile 1 represents those that were hired (n=35), pile 2 represents those that did not get a job (n = 13).
- Black cards are male, red cards are female. Count the number of black and red cards among the hired and not hired and enter them into the contingency table d) below and onto the white board

a) Results of ‘random hiring by cards’

		Hired		
		Yes	No	Total
Applicant	Male			
	Female			
	Total			

b) Calculate the RR of being hired for males using table d) and enter it onto the whiteboard: RR =

c) Use the confidence interval calculator on [www.stataras.com](http://www.stataras.com) to calculate the 95% Confidence interval for RR of getting hired for males in your random hiring by cards. Males are \_\_\_\_\_ times more likely to be hired than females in my random experiment

(95% C.I. LB = \_\_\_\_, UB = \_\_\_\_)

Q1. Was your ‘random’ hiring fair?

Q2. Your ‘random hiring’ was in effect a random sample of all hirings. Use that fact to explain why results not consistent for the whole class?

Q3. Does the Confidence interval help? How can hypothesis testing help us answer the research question?

## Inference with 2 categorical variables. (sample solution)

As usual start up with data preparation and exploration. (key element is setting up contingency tables calculating practical significance (ratio of rates –RR, and difference between rates – Drift there are only 2 categories in each variable), the  $\chi^2$  test of independence and/or confidence interval for RR will help establish whether one can generalize results to the population the sample was taken from. Make sure to review the notes on  $\chi^2$  tests on page 55. Just as with the goodness of fit test (for one categorical variable) the test assesses whether what was observed ‘fits’ with expectations as stated in the  $H_0$ .

### Hypothesis test:

1.  $H_0$ : There is no association between the two variables (they are independent). You will have to craft the wording to make it relate directly to the variables at hand – this can be tricky when you have more than 2 categories in each variable.

*Example: Are Immigrants to Canada as likely to live in a home owned by a member of their household as non-immigrant Canadians?*

### 2. Conduct the hypothesis test.

a. Follow SPSS instructions for inference with 2 categorical variables to generate the *p-value*  $p=0.262$

b. Confidence Interval for RR only when both variables have 2 categories, there is an excel calculator for RR on [www.stataras.com](http://www.stataras.com).

*Non immigrants are 1.05 times more likely to live in a home owned by a member of their household (which essentially means that there is very little difference. RR = 1.0478 LB = 0.96 UB = 1.14*

### 3. Decision:

If *p-value* < 0.05 then your observed results do not ‘fit’ with the expected - *However in this case the p-value (0.262) is >0.05. We fail to reject the null hypothesis – there is no evidence to support the idea that immigrants in Canada are more or less likely to live in a home owned by a member of their household than non-immigrants.*

### 4. Final statement:

If there are only 2 categories in each variable then use the calculations of practical significance (RR and RD) and the final statement is easy.

*There is no evidence that immigrants are more (or less) likely to live in a home owned by a member of their household ( $p=0.262$ ; 95% C.I. 0.96, 1.14)*

If there are more than 2 categories in each variable then it gets tricky. Go back to your exploration (crosstabs with %, clustered bar chart etc.) and poke around for any patterns, this is much easier if one or both variables are ordinal.

Often, data analysts look at the residuals (difference between Observed and Expected). When they are ‘large’ as a percentage of the expected value then you have a practically significant difference too.

## Exercise 10b Analysing scenarios with two categorical variables – (both 2 categories)

**Research Question:** Are Immigrants to Canada as likely to live in a home owned by a member of their household as non-immigrant Canadians?

The data set ‘*immstatvsdwelling*’ can be found in your OneNote notebook. Your task is to conduct a full analysis of this data.

A: results of exploration (numerical and visual) – summarize what you have found.

B: Calculate RR and RD in order to get a sense of the difference between rates of ownership between immigrants and non-immigrants.

C: Hypothesis test: SPSS does not have a function for comparing 2 proportions ( $H_0: \pi_1 = \pi_2$ ), which is commonly used, but the  $\chi^2$  test of independence works just as well. Set up the null hypothesis as an statement of no association. No association is equivalent to the statement that proportions are equal.

1. Set up  $H_0$ :

2.  $\alpha = 0.05$  Use SPSS to find the *p-value*  $p =$  \_\_\_\_\_

b. Confidence Interval using the Excel C.I. calculator for RR:

$$LB = \underline{\quad} \quad UB = \underline{\quad} \quad \text{or} \quad \underline{\quad} < RR < \underline{\quad}$$

3. Make decision: reject null hypothesis or not?

4. Final Statement: answer the research question using all of the analysis that you conducted.

## Exercise 10c Analysing scenarios with a two categorical variables – (both > 2 categories)

In class exercise

**Research Question:** Do Canadians with higher levels of activity for a usual day, say that they are more satisfied with life?

The data set 'satlifevsphysact' can be found in your OneNote notebook. Your task is to conduct a full analysis of this data.

A: results of exploration (numerical and visual) – summarize what you have found.

B: Calculate % by rows, in order to get a sense of the difference between rates of satisfaction by level of activity – it won't be easy to see anything though.

C: Hypothesis test: because we have variables with >2 categories each, you need to set up the null hypothesis as an statement of association.

1. Set up  $H_0$ :

2.  $\alpha = 0.05$  Use SPSS to find the *p-value*  $p = \underline{\hspace{2cm}}$

b. Confidence Interval cannot be found here without manipulating the data set.

3. Make decision: reject null hypothesis or not?

4. Final Statement: answer the research question using all of the analysis that you conducted.

## Exercise 10d Analysis with 2 categorical variables

**Q1. Research Question:** Does treatment lead to the desired outcome?

Of 83 individuals 59 were randomly assigned to the treatment group, and 24 to the placebo group (no treatment). The data set is called *exposure\_outcome*.

Use appropriate data analysis techniques to help answer the question including a discussion of practical and statistical significance.

**Q2. Research Question:** Does aspirin lower the risk of getting heart attacks in people with previous history of heart disease. A random sample of 250 people with a previous history of heart disease, were tracked for a full year. Some were given Aspirin to take daily, and some were given a placebo (that looked exactly like Aspirin). The data set is called *aspirin*.

a. Use data analysis techniques to help answer the question including a discussion of practical and statistical significance.

b. Propose another variable that could affect the ‘risk’ of getting a heart attack?

**Q3.** A researcher involved in marriage counseling wanted to know if *marital status* was related to *satisfaction with life in general*. She contacted you, and luckily you had access to the *cchs condensed* data set.

**Research Question:** Is there any evidence to suggest that there is a relation between one’s marital status and one’s *satisfaction with life in general* in general.

a. Conduct a full analysis to help answer the following question.

b. Propose another variable that you think could affect *satisfaction with life in general*?

**Q4.** 120 Albertans and 120 Ontarians were asked the following 2 questions:

- Do you support having a more privatised health care system in Canada?
- Are you a resident of Alberta or Ontario?

The researchers hypothesized that more Albertans are comfortable with the idea of a privatised health care system, and therefore a higher proportion of Albertans would respond that they are ‘for’ privatised health care than Ontarians.

Exploratory analysis showed that 78 Albertans and 52 Ontarians expressed support for privatised health care. The data is saved under *attitude to private health*.

**Research Question:** Do a higher proportion of Albertans support private health care than Ontarians? Your task is to use your skills in data analysis to answer this question, and convince the reader that you are correct.

**Q5. Research Question:** Are Canadians who had never even smoked one cigarette in their lives more likely than those who had smoked to be employed over the last year?

Use the *cchs condensed* data set and the variables *Worked at job&. Ever Smoked whole cigarette*. Conduct a full analysis to help answer the question.

## Inference with one categorical {2 categories} vs. one measurement variable

### (partial solution to 11A)

A survey was carried out by HIM students in their stat1013 course. The students sampled their friends in a non-random way and data was gathered into a data set called *survey stat1013*.

Research Question: given that the birth rate in Canada is very low, Do students in stat1013 and their friends and family born in Canada have fewer siblings than those born elsewhere? Two variables are of interest: *born in Canada* and *number of siblings*. We can get SPSS to divide the sample into 2 groups for comparison of means – e.g. comparing those born in Canada to those who were not. Don't forget about the calculations of practical significance (raw difference, % difference and Cohen's d – those are not shown here) .

#### Steps:

##### 1. set up a null hypothesis

$H_0: \mu_{\text{group1}} = \mu_{\text{group2}}$  or  $H_0: \mu_1 - \mu_2 = 0$ . (the null hypothesis will always be in the same format, only the names of the groups will change – could be male/female, treatment/control etc.)

$H_0: \mu_{\text{born in Canada}} = \mu_{\text{not born in Canada}}$  where  $\mu$  is the mean number of siblings

##### 2. Conduct the hypothesis test.

a. Follow SPSS instructions for independent means (one categorical and one measurement variable) - it automatically generates *p-value*

$p = 0.000$  (you will generate the sample means for each group as part of exploration)

b. Confidence Interval – use the excel calculator available on [www.stataras.com](http://www.stataras.com) to generate a 95% confidence interval for the raw difference.

*The 95% confidence interval for the raw difference indicates that those not born in Canada have between LB = 0.22 and UB = 0.70 more siblings than those born in Canada*

##### 3. Decision:

If the *p-value* is  $< 0.05$ , then there is enough evidence to reject the null hypothesis, Don't forget that you need to assess practical (clinical) significance before hypothesis testing.

*Reject the null hypothesis – it looks like the observed difference (in this case 0.465) can be generalized to the population.*

##### 4. Final statement:

*If our sample is representative of the Canadian population (it is not as it is a convenience sample) then we can say that those born in Canada have fewer siblings than those not born in Canada and that the difference is statistically significant ( $p = 0.000$ ).*

*I am 95% confident that the mean number of siblings for those born outside Canada is between 0.22 and 0.70 higher than the mean number of siblings of those born in Canada.*

## Inference with one categorical { $\geq 2$ categories} vs. one measurement variable (partial solution to 11B)

### ANOVA

#### Note on hypothesis testing:

A sample has been taken from a population, and since one of the variables is categorical with  $\geq 2$  categories we cannot simply compare means of 2 independent samples (groups). Instead the analysis examines whether the ratio of variation between the groups to the variation within the groups. If there is ‘significantly’ more variation between the groups then that indicates that we can reject the null hypothesis. We will not go into the details of the calculations or the distribution (F distribution); comparison boxplots help us visualize this approach.

*Do youth who have a busier educational status spend more on junk food?*

#### Steps:

##### 1. set up a null hypothesis

$H_0: \mu_{\text{group1}} = \mu_{\text{group2}} = \mu_{\text{group3}} = \dots$  (the null hypothesis will always be the same except for the names of the groups – could be different colleges, level of education etc.)

$H_0: \mu_{\text{full-time}} = \mu_{\text{part-time}} = \mu_{\text{non-student}}$

##### 2. Conduct the hypothesis test.

a. Follow SPSS instructions for ANOVA - it automatically generates a *p-value*

$p = 0.003$

b. Confidence Interval – will not be calculated, though practical significance (comparing each pair is possible. Instead ‘Tukey’s post-hoc’ helps identify pairs of means in which the differences are statistically significant.

##### 3. Decision:

If the *p-value* is  $< 0.05$ , then reject the null hypothesis.

Reject ( $p = 0.003$ )

#### Post Hoc analysis

If you failed to reject  $H_0$ , then there is no evidence for any differences between ‘groups’. However, if you have rejected  $H_0$ , you know that at least one pair of means is significantly different. Using SPSS, choose Tukey’s HSD in order to identify the specific pairs that are significantly different.

*Full time students spend significantly more than non-students – other differences were not considered statistically significant.*

##### 4. Final statement:

*If the sample is representative of the population, then we have evidence that the population of youth in Toronto spending on junk food is related to education status ( $p=0.003$ )*

- *Based on post hoc analysis I can see that Full time students spend significantly more money on Junk food than non-students ( $p=0.002$ ).*
- *Using practical significance (raw score difference) I can see that full-time students spend a mean of \$17.14 per week more.*

## Exercise 11a Analysing scenarios with one categorical (2 categories) and one measurement variable

**Research Question:** Do Canadians not born in Canada have more siblings than those born in Canada?

We can test the claim using information collected by HIM students as an exercise in stat1013.

The data set 'survey stat1013' can be found in your OneNote notebook. Your task is to conduct a full analysis of this data.

A: results of exploration (numerical and visual) – summarize what you have found.

B: There are a few possible calculations of practical significance; you will have to do them by hand.

C: Hypothesis test:

1. Set up  $H_0$ :  $H_0: \mu_{\text{---}} = \mu_{\text{---}}$  (2 independent means test)

2. a. Use SPSS to find the *p-value*  $p = \text{---}$

b. Confidence Interval for raw difference – use excel calculator:

LB =  $\text{---}$     UB =  $\text{---}$     or     $\text{---} < \mu_1 - \mu_2 < \text{---}$

3. Make decision: reject null hypothesis or not?

4. Final Statement: answer the research question using all of the analysis that you conducted.

## Exercise 11b Analysing scenarios with one categorical (>2 categories) and one measurement variable

**Research Question:** Do students who have a busier educational status spend more on junk food?

We can test the claim using information collected by an HIM student in previous years.

The data set '*fastfood spending vs ed*' can be found in your OneNote notebook. Your task is to conduct a full analysis of this data.

A: results of exploration (numerical and visual) – summarize what you have found.

B: There are a few possible calculations of practical significance, but you have to do them by hand.

C: Hypothesis test:

1. Set up  $H_0$ :  $\mu_{\text{---}} = \mu_{\text{---}} = \mu_{\text{---}} = \mu_{\text{---}}$

2. Use SPSS to find the *p-value*  $p = \text{---}$

b. Confidence Interval: (or post – hoc )

3. Make decision: reject null hypothesis or not?

4. Final Statement: answer the research question using all of the analysis that you conducted.

## Exercise 11c Analysis: one categorical vs. one measurement variable

Assume that all data comes from random samples of the populations in question. Answer the questions using all aspects of data analysis including practical and statistical significance.

**Q1. Research Question:** Does the group taking the treatment have a better memory than the placebo group?

To determine the effectiveness of an herbal supplement to increase memory, nurses working with a healthy elderly population conducted a study in which they hypothesized that elderly clients taking the herbal supplement would have a better memory than a group of elderly clients taking a placebo. The sample contained 20 elderly clients (10 in each group). The data is available in *memtest\_herb* data set.

**Q2. Research Question:** Do Canadians who think they should do something to improve health have a higher BMI than those who do not?

Use the *cchs condensed* data set to help answer the question.

**Q3. Research Question:** Are male GBC students taller than female GBC students?

9 men and 7 women were randomly sampled from the George Brown College population to test whether GBC men were taller than GBC women. Their heights were recorded as follows; (in cm.).

Note you will have enter data for two variables: Sex and height

men: 188, 167, 162, 142, 189, 200, 174, 166, 185

women: 154, 168, 160, 171, 155, 151, 153

**Q4: Research Question:** Is the LOS at Sunnybrook lower than other hospitals in the city of Toronto?

The *LOS in Toronto* data set is from a study in which LOS for appendicitis is compared in a group of 4 hospitals in the city of Toronto. (St. Joseph's, Mount Sinai, Toronto General, and Sunnybrook). It was thought that the LOS at Sunnybrook was significantly lower than the others. Propose another variable that could have influence LOS?

**Q5.** A Social psychologist has been studying the relationship between group composition and level of cooperation on the part of preschool children in a task completion exercise. Each group is observed, and the number of cooperative acts exhibited by each member of the group is recorded. Three types of groups are under study: all male, all female, and mixed (M and F). Results are laid out in the table below (the higher the number the higher the level of cooperation):

All Male	All Female	Mixed
4, 4, 3, 1, 3, 4	6, 9, 8, 4, 8, 8	3, 5, 6, 4, 7, 6

**Research Question:** Does the mixed group (M and F) perform more cooperative acts than the others?

Propose another variable that could affect the levels of cooperation.

**Exercise 12: Data analysis boot camp** – you choose the appropriate approach based on the data types of the scenario and the goals of the research. Make sure to conduct all parts of data analysis, using all elements of data analysis (figure 3) and previous examples as a guide.

**Q1.** The Irongate Foundry, Ltd., has kept records of on-the-job accidents for many years. Accidents are reported according to which hour of an 8-hour shift they happen.

**Research Question:** Is there any evidence that would lead one to believe that there is a higher number of accidents later in the shift (since the workers are getting tired etc.)? Once you open up the ‘*irongate*’ data set from your OneNote notebook and explore it you will see that it seems that more accidents happen in the later hours of the shift.

**Q2.** The *maternal stress* data set is from a study in which Maternal stress is compared in a group of mothers of low birth-weight infants in the experimental group(LBWE) – they received daily massage treatments, mothers of low birth weight infants in the control group(LBWC) – who received no massage treatments, and mothers of full-term infants (FT) coded as follows: LBWE= 1, LBWC = 2; FT = 3.

**Research Question:** Is there some evidence that massages are an effective treatment for maternal stress?

Propose another variable that could influence maternal stress.

**Q3.** In 2006 the rate of obesity among boys aged 7-12 in Hamilton was 15%. A new research study found that out of 243 boys 7-12 yrs of age in Hamilton, 46 were overweight or obese. See *obesity hamilton boys* data set

**Research Question:** Has the rate of obesity in 7-12 yr old boys in Hamilton changed? If so, what is the new rate?

**Q4.** The rates of posttraumatic stress disorder (PTSD) in mothers and fathers was examined in Sudbury. Parents were interviewed 5 to 6 weeks after an accident or a new diagnosis of cancer or Type 1 diabetes in their child. 28 of the 175 fathers and 43 of the 180 mothers met the criteria for current PTSD. Data is saved under the name *ptsd*.

**Research Question:** Is there sufficient evidence for us to conclude that fathers are less likely to develop PTSD than mothers after a traumatic accident, cancer diagnosis or diabetes diagnosis for their child?

a. Use a complete analysis to answer this question.

b. Propose another variable that could influence the development of PTSD?

**Q5.** Research engineers were hired to help standardize brick production in 143 brick factories in Egypt. After 3 years data was collected on the number of bricks produced and gas consumption ( $m^3$ ). Use data from the ‘*brick factory data*’ to answer the research question below.

**Research Question:** Is there evidence to suggest that brick production has been standardized?

**Q6** 9026 men were divided into two groups for a 20 year cohort study. 1409 were screened for prostate cancer and the rest were not. After 20 years the rates of death from cancer in both groups were compared. See data set *prostate screening* for results.

**Research Question:** Is screening an effective way of preventing death from prostate cancer?

## Unit 5: ethics and validity

In this chapter you will investigate the last step of the research process by learning how researchers evaluate each other's work for scientific validity, and ethical principles. Most of the work in understanding ethics was done in your TCPS2 certification, but we will look at some philosophical foundations in this section.

**Validity in quantitative research:** (Validity in qualitative research will not be discussed.)

Assessing the validity of research can be tricky because a lot of research involves the exploration of unexplained phenomena - there is no outside expert or god like figure who knows 'the answer' to the research question, and to whom researchers can go to verify that what was found in the research is actually true. Thus, establishing validity is dependent on honest and competent peers who take the time to evaluate others' work in progress.

Before results of a research study are considered valid, the methods used to collect and analyse data and the written report must be accepted as valid by other researchers in the field of study (**peer review**). To be worthy of publication the findings of a research study must also address a gap in knowledge or open a new avenue of inquiry in the field of study within which the research has taken place. Finally, it is best if the findings are **replicated** by other researchers in similar studies. Research in which the goal is beyond simple description, where the goal is prediction or causation, must also demonstrate that the relation (think practical significance) is strong and clear – i.e. there is nothing else that can explain the phenomenon in question.

Researchers try to convince peers (and the public at large if needed) that the findings are valid, by demonstrating that all the methods used were valid, and by using formal inferential reasoning through statistical tools to help provide evidence that supports their conclusions. The methods used must be described in detail, in order to be validated. The evidence needed depends on the context within which the study takes place (for example: the field of study, the consequences of being wrong, the scepticism of one's peers).

When this process goes wrong the consequences can be profound. A recent example of this is a study published in the Lancet purporting to establish a causal link between early childhood vaccinations and autism – though the study has been retracted many people still believe that the findings are valid (see page 84).

## Evaluating research: Threats to validity

*Threats to validity* can be **internal** or external

**Internal validity** is- the degree to which claims made about participants reflect the characteristics of the participants

**External validity** (also known as generalizability) is the degree to which the participants are representative of the target population, or the degree to which results from the study can be extended to the general population.

### An Internal and external validity checklist

<p><b>Internal validity</b> is the degree to which claims made about participants are true. Can also be called data quality</p>	<p><b>External validity:</b> Degree to which the participants are representative of the target population or the degree to which results from the study can be extended to the general population.</p>
<p><b>Components:</b></p> <p>Information bias</p> <ol style="list-style-type: none"> <li>a. Recall/compliance bias</li> <li>b. interview/observer bias</li> <li>c. measurement error</li> <li>d. data analysis error</li> </ol> <p>Selection bias</p> <ol style="list-style-type: none"> <li>a. control selection bias (experiments or other research in which there is a treatment and control group)</li> <li>b. non-response bias</li> </ol> <p>Confounding</p> <p>are there variables not in the research that may have an impact on the outcome (or even on the exposure)</p>	<p><b>Components:</b></p> <p>Elements of a good sample</p> <ol style="list-style-type: none"> <li>a. Is target population well-defined? too narrow? too wide?</li> <li>b. Sampling method likely to produce a sample representative of the target population? Is anyone missed?</li> </ol> <p>Indications of a weak sampling method</p> <ol style="list-style-type: none"> <li>a. self-selection</li> <li>b. inappropriate inclusion/exclusion criteria</li> <li>c. non-response</li> </ol>

### Threats to Internal validity (*Bias and Confounding*)

**Bias** captures the wider notion that the study is poorly designed, has flawed or inappropriate sampling or recruitment strategies (selection bias), inappropriate data collection instruments (observation bias), or doesn't take into account how individuals may answer question e.g. people with a disease recall their past behaviours differently than those without the disease (recall bias).

**Confounding** is often referred to as a type of bias: When looking for the effect of an exposure on an outcome the observed changes may be due to a factor that the researchers did not consider. (see Hawthorne Experiments article below).

## Threats to validity continued

### Threats to External validity

In most studies the researchers work with a sample of individuals taken from a population. If the results in the sample are practically significant (e.g. a drug show that it can prolong the life of cancer patients in the sample), then the researchers would typically like to make a claim that the results would hold for a larger population. Poor population definition, poor sampling design, loss to follow-up, poor participation rates and inappropriate sample sizes can limit the claims that can be made, and pose threats to external validity (generalizability). Hypothesis testing (statistical significance or the p-value) and/or confidence intervals help establish the extent to which the results of the sample are generalizable to the general population.

External validity is usually the most challenging part of the research process to establish. There are many potential threats that can render a very well-constructed study weak with respect to external validity.

### Confounding – an example

The Hawthorne Experiments.

Adapted from <http://ocmed.oxfordjournals.org/cgi/content/full/56/3/217>

Confounding was clearly at play in the first of many experiments performed at the Hawthorne works of the Western Electric Company in Chicago from November 1924 onwards. The original aim was to test claims that brighter lighting would increase productivity in a controlled experiment. To the surprise of the investigators, productivity rose equally in both the control (old lighting) and treatment (new lighting) groups.

In the next experiment, lighting was reduced progressively for the test group until, at 1.4 foot-candles, they protested that they could not see what they were doing. Until then the productivity of both groups had once again risen in parallel. The investigators next changed the light bulbs daily in the sight of the workers, telling them that the new bulbs were brighter. The women commented favourably on the change and increased their work rate, even though the new bulbs were identical to those that had been removed. This and other manoeuvres showed beyond doubt that productivity related to what the subjects believed, and not to objective changes in their circumstances.

What do you think was the confounding variable that affected productivity?

\_\_\_\_\_ (Best answer at bottom of the page.)

Answer: Being watched by the researchers (and bosses) made the workers work more productively.

## Exercise 13: using the Internal and External validity checklist

Given the research question below you will describe a study which has weak external and internal validity and one which is very strong. Use the checklist from page 80.

Research Question: Does 15 minutes of vigorous exercise a day help university and students reduce their level of stress over one semester?

Task 1. Design a sampling method with poor external validity.

Task 2. Design a data collection method with poor internal validity. Make sure to name the variables you will be collecting – and a timeline in which they will be collected.

Task 3. Evaluate the design using the components in the above chart.

Task 4. Design Sampling with strong external validity.

Task 5. Design data collection with strong internal validity. Make sure to name the variables you will be collecting – and a timeline in which they will be collected.

Task 6. Suggest possible confounding variables.

## Ethics in Research: notes

Ethical conduct is important in all fields of human endeavor, and humans have been trying to establish a balance between freedom and controlling 'bad' actions for millennia. In many societies external forces acted were seen as all powerful beings (gods/demons weather) who would punish 'bad' behaviour. Plato was the first to question this divine 'goodness' as a philosopher by posing the following question over 2000 years ago:

*When gods say that something is good do they do so because it is good, or because the gods just feel like saying it is good?*

The way he puts it there seem only 2 options: 1. Goodness exists before 'godness', or gods can (and maybe do) just go around making stuff up. Plato chose the former and thus discussions about the nature of goodness, moral behaviour along with ethics began.

Three of the major schools of ethics that have emerged over the past centuries in the western world include the categorical imperative, utilitarianism and relativism. These will be discussed in class. It is not crucial that you learn them as facts, but it is important that you have a sense of the evolution of thinking about ethics in the western world.

The principles of ethics in scientific research come from the ashes of WWII and the abuses of some Nazi and other doctors, who felt that some humans could be experimented on as their lives or their pain was not worth considering. Many were subsequently punished as part of the Nuremberg trials. The research that took place under the Nazis was but an extreme form of the kind of research that took place in other parts of the world including Canada. Some humans were seen as 'weaker' and thus 'less than human' and could be subjected to all sorts of indignities in the name of science. After Nuremberg this would be no more.

Today, all legitimate and valid research must go through a review process. Every institution that is involved in research must have a Research Ethics Board (REB) and in Canada these must subscribe to the Tri-Council Policy on Research (TCPS2). The main pillars of ethical conduct in research can be summarized in the following

**5 principles** that are key to thinking about ethics in research.

1. Protection from harm
2. Informed Consent
3. Right to Privacy
4. Honesty with Professional Colleagues
5. Treating all subjects equally

## Exercise 14: using ethical principles to think about research

Instructions: Read through the 5 'Bad Ethics' Cases below. For each one, choose which of the 5 principles outlined on page 83 are being violated and provide an explanation to support your decision. There may be more than one principle violated per scenario.

CASE #1: the CYRIL BURT Affair - Cyril Burt was a famous British criminologist in the early 20th century who wanted to prove Lombroso and Goddard right that there were "born criminals" and that they were feeble-minded or had low intelligence. You'll sometimes find him mentioned in criminology textbooks as the "father of twin studies." After it was discovered that Goddard faked his photographs to make the eye sockets of Irish immigrants look more deeply recessed, it was also discovered that Burt faked his data and published phony tables of numbers showing such people had low IQs. The affair is memorable as a lasting tribute to the "publish or perish" environment in academics, where professors, like Burt, need to get promoted by rushing into print with research results.

CASE #2: *TEAROOM TRADE* -- was the name of a book published by a sociologist named Laud Humphreys in 1970 who posed as a "watch queen" in public restrooms to observe homosexual behavior. After every liaison where an old man would seduce some "chicken hawk" with money for an oral sex experience, Humphreys would jot down the license plate number of each old man's vehicle. Then, he had a friend in the police department trace the addresses. He would then visit the old men at home and pressure them into giving him an interview.

CASE #3: Milgram -- was the name of a book by psychologist Stanley Milgram in 1974 who wanted to see how far people would be willing to turn up the dial, if ordered to do so, on a machine that pretended to give electrical shocks to people in the next room. You'd be surprised how many people were willing to go all the way, even though some broke down in tears after hearing fake screams coming from the other room.

CASE #4: the TUSKEGEE SYPHILIS STUDY -- was conducted from 1932 to 1974 and involved the withholding of penicillin from Black male sharecroppers so the government could find out the long term effects of syphilis. Similar experiments went on with the U.S. military involving nerve gas and nuclear radiation. The CIA also performed bizarre mind control experiments involving LSD, ESP, hypnosis, and surgery.

## **Exercise 14: Practice with analyzing Ethics in Research – cont'd**

CASE #5: ZIMBARDO'S PRISON SIMULATION - was a study by psychologist Philip Zimbardo in 1972 that took Stanford University undergrads and made some of them guards and some of them prisoners in a mock underground dungeon for a planned two week stay. The experiment had to be cancelled after six days because by then, the student-guards became quite sadistic, really getting into their roles. The prisoners were also becoming quite mental.

There are many, many more examples, but these are the most famous ones. The only other one that deserves mention is the 1954 Wichita Jury Study which involved criminal justice researchers using a wiretap, or "bugging", a jury room to find out what goes on when juries deliberate. Although a lot of significant knowledge was gained by this study, it led to a wiretap law in 1956 that prohibited jury "bugging" even if jurors consent.

## Autism-vaccine study retracted

*Last Updated: Tuesday, February 2, 2010 | 6:11 PM ET* [Comments47](#)[Recommend222](#)

### [CBC News](#)

*Britain's General Medical Council ruled that Dr. Andrew Wakefield acted unethically in doing his research. (Luke MacGregor/Reuters)*

A medical journal in Britain has retracted a controversial study it published in 1998 that linked the use of a vaccine in children to autism.

The study retracted on Tuesday looked at 12 children suffering from colitis, a gastrointestinal disease.

British surgeon and medical researcher Andrew Wakefield concluded a component of the measles, mumps and rubella, or MMR, vaccine caused the colitis, which in turn led to development problems that are part of autism spectrum disorder.

"It has become clear that several elements of the 1998 paper by Wakefield ... are incorrect," The Lancet said in a statement.

Since the controversial paper was published, British parents abandoned the vaccine, leading to a resurgence of measles in the U.K. and elsewhere in Europe.

Subsequent studies have found no proof that the vaccine is connected to autism, though some parents are still wary of the shot. In March 2004, the majority of co-authors on the paper retracted their support for the claims of a possible link between the vaccine and colitis or autism.

### **'Callous disregard'**

A disciplinary panel of Britain's General Medical Council ruled last week that Wakefield had presented his research in an "irresponsible and dishonest" way and shown a "callous disregard" for the suffering of the children he studied.

It also ruled he had brought the medical profession "into disrepute."

Wakefield and the two colleagues who have not renounced the study face being stripped of their right to practise medicine in Britain.

For the study, Wakefield took blood samples from children at his son's birthday party, paying them five pounds each (\$8) for their contributions and later joking about the incident.

Meanwhile, fallout from the publication of the study continues.

## **Autism-vaccine study retracted – (continued)**

"It was out there for a very long time. So it's good The Lancet has retracted it. It helps in a small way. But the truth of the matter is the damage has been done," in terms of changes in belief and perception, said Dr. Allison McGeer, an infectious diseases expert at Toronto's Mount Sinai Hospital.

### **Costs of retraction delay**

The retraction is important, but the time it has taken to get to this point dulls its impact, said Dr. Evdokia Anagnostou, a clinician scientist at Bloorview Research Institute in Toronto.

"There is room to study the link between the immune system and autism," she added. "Still, I don't think we have clarified that issue, and I would hope that the money goes towards that route and not again on the MMR hypothesis."

It took a lot of time and effort to debunk the hypothesis, agreed Dr. Bonnie Henry, chair of the Canadian Coalition of Immunization Awareness and Promotion.

"If the amount of money and time and effort had been put into understanding autism, they might have made a lot more gains," in understanding the mechanisms behind the disorder, how to prevent it, and better integrate children with autism into society, Henry said from Ottawa.

### **Mumps outbreaks**

The medical publishing industry has made strides to ensure trials are registered properly, people are reviewed appropriately and that conflicts of interest are prominent so people can make up their own minds in controversial areas, Henry added.

Concerns about the MMR vaccine spread to Europe and North America.

In 2007, a large outbreak of mumps was set off in the Maritimes after the virus was imported from the United Kingdom, said Dr. Noni MacDonald, a pediatric infectious diseases expert at Dalhousie University in Halifax.

More than 1,000 cases were recorded over a period of months as that outbreak spread across the country.

Wakefield remains outspoken and said last week that the panel's findings were "unjust and unfounded." His supporters believe he has been the subject of a conspiracy to discredit him.

*With files from The Associated Press and The Canadian Press*

Read more: <http://www.cbc.ca/health/story/2010/02/02/autism-mmr-lancet-wakefield.html#ixzz0eR7XJe3x>

## South Korean stem-cell scientist faces charges

Last Updated Fri, 12 May 2006 09:04:44 EDT [CBC News](#)

A South Korean scientist, who was disgraced after it was revealed that he faked human stem cell research, has been indicted on a series of charges that include fraud, embezzlement and bioethics violations. [INDEPTH: Genetics: Reproduction](#)

Hwang Woo-suk was hailed around the world as a medical pioneer after he announced that his team had managed to clone a human embryo and extract stem cells from it.

Later investigations showed that he and his team had fabricated key data.

In announcing the fraud charges, South Korea prosecution official Lee In-kyu said Hwang had accepted private donations amounting to \$2.2 million Cdn after claiming to have made the breakthrough.

Lee also said Hwang was being charged with embezzling nearly \$1 million in research funds.

Five members of his research team face lesser charges.

Hwang's work had given hope for breakthrough treatments in such diseases as Alzheimer's.

After his research was discredited, he lost his position as a professor at Seoul National University.

Hwang publicly apologized in January, saying he was deceived by two junior researchers but would still take full responsibility for his fraudulent claims.

"I ask for your forgiveness," he told a nationally televised news conference in Seoul. "I feel so miserable that it's difficult even to say sorry."

In 2004, Hwang received international attention for producing the world's first dog clone.

The scientific panel that revealed the human stem cell fraud validated that Snuppy the Afghan hound was indeed a true clone. The dog's name was a short form for Seoul National University puppy.

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## Journal Faulted in Publishing Korean's Claims

By [NICHOLAS WADE](#) Published: November 29, 2006 New York Times

Fraudulent stem cell reports that shook the scientific world could have been prevented by extra review procedures, according to a panel appointed by Science, the journal that published the claims.

Donald Kennedy, the editor of Science, said the journal would accept the panel's major findings.

The South Korean researcher [Dr. Hwang](#) Woo-suk reported in Science in 2004 that he had generated embryonic stem cells from an adult human cell, the necessary first step in proposed schemes for growing replacement tissues from a patient's own cells. In a second report, in 2005, he claimed he could perform this step routinely and efficiently, using very few human eggs.

Both reports proved to be fabrications, and the journal formally retracted the papers in January. The fraud came to light not through any of the formal checking procedures in the scientific process, but because a whistle-blower in Dr. Hwang's lab spoke to the South Korean television station MBC.

Like other scientific journals, Science has long taken the position that its reviewing procedures work well but cannot be expected to detect deliberate fraud, and therefore no change is necessary. But the spectacular nature of the fraud prompted deeper than usual soul-searching on the part of leading journals.

After reviewing the paper record of how the Hwang reports were handled, a panel led by John I. Brauman, a chemist at [Stanford University](#), yesterday recommended four changes in Science's procedures.

A risk-assessment method should be developed to flag high-visibility papers for further review, the panel said. Also, authors should specify their individual contributions to a paper, a reform aimed at Dr. Hwang's stratagem of allowing another researcher, Gerald Schatten of the [University of Pittsburgh](#), to be lead author of one of the reports even though Dr. Schatten had done none of the experiments.

The panel advised online publication of more of the raw data on which a scientific report is based. It also suggested that Science, Nature and other leading journals establish common standards for reviewing papers to prevent authors bent on deceit from favoring journals with laxer standards.

The panel states in its report that these measures "would have detected" Dr. Hwang's fraud.

But in a news conference, Dr. Brauman retreated from that statement, saying only that they "might have" uncovered it.



## Unit 6: Qualitative research

Up to now we have been focused on testing quantitative hypotheses using a rigid logical system, which can yield compelling results. We depart from that approach into another in which our goal is to create a hypothesis, to learn about something that we do not yet know much about. Qualitative research primarily uses Inductive reasoning and many other thinking tools to delve into phenomena that are yet poorly understood, and gives us fresh perspectives and open new avenues for research on phenomena that we may think quantitative researchers have figured out.

In this chapter you will simply be introduced to some of the principles of qualitative research and challenged to read and classify qualitative research abstracts by their type. Make sure to put in the time and effort to read and familiarize yourself with this type of research.

## Introduction to types of qualitative research

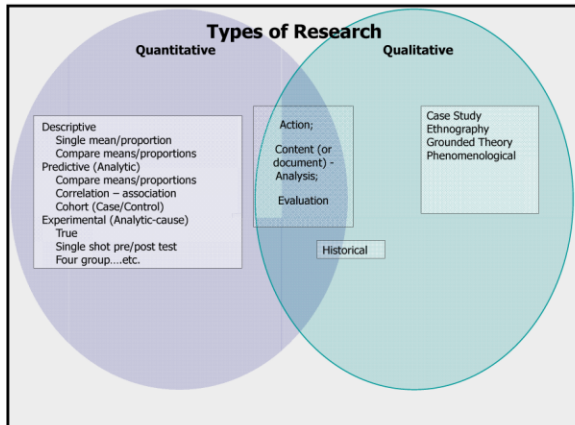
### Qualitative Research

is rooted in the understanding of the  
subjectivist theoretical perspective

### Qualitative Research characteristics

from page 4

- Flexible – adapts to nature of subject being studied
- Inductive rather than deductive
- Holistic – aims to capture the totality of the subject being studied
- Naturalistic setting – does not aim to isolate the subject nor control for confounding variables



### Identifying Qualitative Research

- **Goal:** to describe a process or group on its own terms (natural setting); to develop a theory/generate a hypothesis(inductive); capture all aspects of the topic (holistic); use a variety of methods (flexible).
- **Data collection:** observation and surveys/interview; but all are as open ended as possible; unit of analysis could be the subject or actions, documents of the subjects
- **Data analysis:** all based in non-mathematical search for patterns and themes – though at times quantitative methods are utilized

### Identifying Qualitative Research types from abstracts

- Focus on goal and data collection method for the most part.
- Use process of elimination – start off by trying to eliminate action research then document (content) analysis, etc.

### Types of Qualitative research

Note: There is no definitive agreement on how to classify research. Some authors do not even use the classifications qualitative and quantitative.

They remain very useful tools.

## Introduction to qualitative research powerpoint-2

### Action Research

Purpose (goal): to improve a program or service

data collection: participation of all people involved, including decision makers, workers and those using the program/service.

Question, plan, act, observe, reflect, plan, act, observe, etc.

May use quantitative methods including experiments.

data analysis: through negotiation with all parties involved decisions get made/implemented, and the process keeps going.

### Case Study

purpose(goal): particular individual, program or event is studied in depth on its own turf and described from various points of view

data collection: participant or other observations, interviews, records.

data analysis: categories and patterns must emerge from data; synthesis is particularly tricky – danger of oversimplification.

- best if two different data collection methods come to same conclusion.

### Case Study examples

- Plagiarism by Adult Learners Online: A case study in detection and remediation
- Linux helps medical research: a case study: we needed to acquire digital patient records and make them available. We focused, initially on mammography.

### Documentary (Content) Analysis

purpose(goal) – to study characteristics of a collection of materials (i.e. unit of analysis is not people)

data collection – sample or census of archive or other collection, eg. minutes of meetings, letters and diaries, reports, recycling boxes, computer hard drives, etc.

analysis – coding/tabulation based on predetermined characteristics. Possible use of descriptive or inferential statistics

### Smart quotation re content analysis

- As stated by one of the pioneers of content analysis:
  - To arrive at the facts of the condition of a people through the discourse of individuals, is a hopeless enterprise. The plain truth is - it is beginning at the wrong end. The grand secret of wise inquiry... is to begin with the study of THINGS

Martineau, 1995, p.73

### Content analysis examples

- Newspaper coverage of asylum seekers.
- A content analysis of the letters of Pierre Eliot Trudeau – what was he really like?
- How has the depiction of robots changed over more than a century's worth of writing?

## Introduction to qualitative research power point – 3

### Ethnography

purpose(goal):- the understanding of a particular group with common culture through description; search for values, attitudes and beliefs;

data collection - from inside of group, as a participant observer – 'going native' – or get story from members of group (audio/video, notes, diary)

data analysis – describe aspects of group attitudes/behaviour e.g. typical day; categories and patterns emerge from data to form a coherent 'story' telling us about the nature of the group.

### Ethnography examples

- What are doctors like when not working?
- Dating and Interpreting Rock Art in British Columbia
- Mortuary Beliefs and Practices of the Northern and Southwestern Athapaskans

### Grounded Theory

purpose(goal) – search for a theory about a social process or structure. i.e. go beyond description to investigate factors involved in the process

data collection – mostly interviews involving a continual 'back checking' and analysis as one collects more data; can have a formalized coding process

data analysis – continuous, and very specific, involving testing various theories as they emerge

### Grounded Theory examples

- Breaking Out: The Emergence of Autonomous Selfhood in Women Through Psychotherapy & the Women's Movement
- The Stages of Friendship Formation
- Deciphering Chronic Pain

### Phenomenological Research

Purpose (goal) – search for meaning of 'lived experience' as described from person's point of view. What is it like to experience a particular event/phenomenon ?

data collection – through participant observation, lengthy (semi-structured) interview process, previous research

data analysis – finding patterns called 'meaning units'

### Phenomenological research examples

- What is it like to live through an aerial bombing?
- Survival in a totalitarian state?
- 'On the team.' An analysis of the high school experience of teenagers who participate in team sports.

## Exercise 15 Reading qualitative research abstracts

### **Qual1: Releasing From the Oppression: Caregiving for the Elderly Parents of Japanese Working Women**

YumiHashizume University of Tsukuba, Japan, hashizume.yumi.gu@u.tsukuba.ac.jp

#### **Abstract**

Caregiving in Japan is defined as predominately a woman's responsibility. However, caregiving has been largely understudied as a lived experience or within a cultural frame of reference. In an estimated 50% of Japanese households, women are currently caregivers of one or more family members. However, the relative absence of information on their experiences has held back the development of programs and services to support their caregiving. In this article, I present results of a grounded-theory study that explored the experiences of Japanese working women caregivers as they cared for the elderly family member in their home. I interviewed 11 women caregivers including 6 daughters and 5 daughters-in-law. I generated a substantive grounded theory, resulting in the identification of the core concept of "releasing self," which included three dimensions: laughing away, self-belief, and losing enthusiasm for the elderly and elderly care.

### **Qual2: Breast Cancer Messaging for Younger Women: Gender, Femininity, and Risk**

Rebecca J. Haines University of British Columbia, Vancouver, British Columbia, Canada,  
Joan L. Bottorff, Stephanie Barclay McKeown, Erin Ptolemy, Joanne Carey, Kelli Sullivan,  
UBC Okanagan, Kelowna, British Columbia, Canada

#### **Abstract**

Evidence linking both active smoking and secondhand smoke exposure to premenopausal breast cancer makes the development of health messages specific to younger women a pressing priority. To determine how to communicate information about this modifiable breast cancer risk to young women, we analyzed a selection of 32 recent English-language breast cancer messages and campaigns that targeted young women. In addition, we obtained young women's responses to three breast cancer campaign images during focus group discussions. A visual analysis of messages points to an explicitly gendered discourse within contemporary campaigns, one that entails conflicting messages regarding breast cancer, health, feminine beauty, and risk. Although the intent might be to educate and empower young women to "fight" against breast cancer, paradoxically, the messages employ imagery that sexually objectifies young women's breasts and bodies. Recommendations are made for messaging about tobacco and breast cancer risk to avoid reproducing one-dimensional or stereotypical presentations of gender and femininity.

## **Exercise 15 Reading qualitative research abstracts - continued**

### **Qual3: Getting on With Life: Positive Experiences of Living With a Spinal Cord Injury**

Eleanor Weitzner, Susan Surca, Sarah Wiese, Andrea Dion, Zoe Roussos, Rebecca Renwick, Karen Yoshida, University of Toronto, Toronto, Ontario, Canada

#### **Abstract**

Currently, the dominant cultural beliefs toward disability are negative, and the existing literature is limited with respect to examining how people are using and/or viewing their disabilities positively. The purpose of this study was to identify how individuals living with a spinal cord injury (SCI) viewed and/or used their disability positively, and what contextual influences facilitated this positive approach. This study was a secondary analysis of qualitative data from a larger study. The findings revealed three levels at which disability was viewed and/or used positively by people with SCI: self, peers, and disability community. In addition, several aspects of the participants' situations were found to facilitate this positive view and/or use of disability: personality, spirituality, support systems, and acceptance of one's disability. The findings reveal that individuals with SCI are viewing and/or using their disabilities positively in many different ways. This study has significant implications for the direction of future research and for health care professionals who need to increase their advocacy and facilitating roles.

### **Qual4: Suicide Notes Among Native Americans, Hispanics, and Anglos**

Lenora M. Olson, University of Utah; Stéphanie Wahab, Portland State University, Cheryl W. Thompson MD Informatics, Salt Lake City, Utah, USA Lynne Durrant, University of Utah

#### **Abstract**

Suicide is a significant health problem, yet many questions regarding suicide remain unanswered. One of the most frequently asked questions is related to motive: "Why did that person complete suicide?" We explored motivations for completing suicide, especially with regard to cultural differences, by analyzing suicide notes written by Native Americans, Hispanics, and Anglos in New Mexico. Five categories emerged describing motivation: feelings of (a) alienation, (b) failure or inadequacy, (c) being psychologically overwhelmed; (d) the desire to leave problems behind, and (e) reunification in an afterlife. The largest difference to emerge between ethnic groups was in the alienation category, which included more Hispanics and Native Americans than Anglos. The overall lack of differences in motivation among the ethnic groups suggests that commonalities in suicidal behavior outweigh the differences. Practical implications for research and practice are discussed, along with strengths and limitations of the study.

## Exercise 15 Reading qualitative research abstracts cont'd

### Qual5: Always Single And Single Again Women: A Qualitative Study

Karen Gail Lewis<sup>1</sup>, Sidney Moon<sup>2</sup>

What is it like to be a single woman today? Are the experiences of women who have always been single different from those who find themselves single again after having been married? How can family therapists promote the development of single women both individually and relationally? The purpose of this study was to investigate perceptions of being single among heterosexual single women between the ages of 30 and 65. Nine focus group interviews and a semistructured, mailed questionnaire were used to collect the data. Constant comparative analyses were used to develop the findings. The findings were organized around the most salient theme that emerged from the analyses: single women have unresolved or unrecognized ambivalences about being single. This overarching theme was supported by three subassertions: (a) single women are aware of both the advantages and the drawbacks of being single; (b) single women are ambivalent about the reasons for their singleness; (c) although content with being single, many women simultaneously experience feelings of loss and grief.

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**Qual6: What is case management and what do case managers do?** (setting is an agency designed to provide case management for homeless people with mental illness.)

data collection:- collection of field notes over 5 month period through daily on-site observation (staff-meetings, shadowing team members in and out of office etc.), and unstructured interviews with 10 informants.

data analysis:- interviews and other data transcribed and coded using a computer program for text analysis.

conclusion:- the external environment (misallocation of resources, provincial and federal contests for power, bureaucratic regulations and politics of social systems) can make the most desperately needed, well planned, and adequately funded program go awry.

\*no reference

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**Qual7: What role do friends and peer groups play in the lives and psychological development of teenagers?**

data collection:- 41 volunteers (m&f teenagers) all meeting the criteria for 'high risk youth' were interviewed twice (1.5-2 hours each) In all cases, full clinical case histories were available for review.

Interview 1: open ended questions based on themes of adolescence, relationships, social competencies, coping strategies, experiences of power and control and mental health.

Interview 2: themes developed based on analysis of interview 1 and case histories. At this interview participants were also asked to comment on any emerging theoretical statements.

data analysis:- ongoing trial of theoretical statements grounded in data

conclusion:- recognition of three developmental stages of power and identity as adolescents.

- 1) being stuck with an identity (usually given by adults: parents, teachers, police, etc.)
- 2) trying on new identities within peer groups as coping strategy
- 3) the construction of a self-definition (i.e. of their own choosing) which were accepted and reinforced by peers. "This is who I am, accept me.

\* no reference

## Exercise 15 Reading qualitative research abstracts cont.

### ***Qual8:- Development of nature tourism in the Windward Islands***

Franklin, Beth (1998)

In 1991, an action research process was initiated to explore how nature tourism could be instituted on each of the four Windward Islands in the Caribbean - St. Lucia, Grenada, Dominica, and St. Vincent. The government took the lead, for environmental conservation, community-based development, and national economic development purposes. Realizing that the consultation process had to involve many stakeholders, including representatives of several government ministries, environmental and heritage groups, community organizations, women's and youth groups, farmers' cooperatives, and private business, an action research approach was seen as appropriate.

Two action researchers from York University in Toronto, with prior experience in the region, were hired to implement the project, with a majority of the funding coming from the Canadian International Development Agency. Multi-stakeholder national advisory councils were formed, and national project coordinators selected as local project liaisons. Their first main task was to organize a search conference on each island.

The search conferences took place, the outcome of which was a set of recommendations and/or action plans for the carrying out of a number of nature tourism-oriented sub-projects at the local community level. At this point, extended advisory groups were formed on several of the islands, and national awareness activities and community sub-projects were implemented in some cases.

To maintain the process, regional project meetings were held, where project coordinators and key advisory members shared experiences, conducted self-evaluations and developed plans for maintaining the process (e.g., fundraising). One of the more valuable tools for building a sense of community was the use of a video camera to create a documentary video of a local project.

The outcomes varied.<sup>[xiii]</sup> In St. Vincent the research project was highly successful, with several viable local developments instituted. Grenada and St. Lucia showed mixed outcomes, and Dominica was the least successful, the process curtailed by the government soon after the search conference took place. The main difference in the outcomes, it was felt, was in the willingness of the key government personnel to "let go" and allow the process to be jointly controlled by all participants. There is always a risk that this kind of research will empower stakeholders, and change existing power relations, the threat of which is too much for some decision-makers, but if given the opportunity, there are many things that a collaborative group of citizens can accomplish that might not be possible otherwise.

## Exercise 15 Reading qualitative research abstracts cont.

### Qual9: Health and Physical Activity Messages Marketed to African American Children During After-School Television Programming

Corliss Wilson Outley, PhD; AbdissaTaddese

*Arch PediatrAdolesc Med.* 2006;160:432-435.

**Objective** To examine the number of food advertisements African American children are exposed to during children's television programming aired on predominantly African American and general television stations.

**Design** A content analysis was conducted to identify and analyze the health-related content (HRC) and physical activity-related content (PARC) of food advertisements shown during children's television programming.

**Setting** Three sets of television advertisements from 3stations (Black Entertainment Television, The WB [Warner Bros], and Disney Channel) served as the sample during a 1-week period in July 2005 (July 11-15), from 3 PM to 9 PM.

**Results** In total, 1098 advertisements were recorded, with256 food and beverage commercials used for this study. Results indicate that 36.3% of all commercials were based on fast food restaurants, 31.3% were for drinks, 16.8% were for candy, 13.7%were for cereals, and 2.0% were for snacks (percentages do not total 100 because of rounding). Compared with The WB and Disney Channel, Black Entertainment Television had significantly ( $P=.001$ ) more food and beverage advertisements. Few HRC or PARC advertisements were shown. Of 256 food and beverage commercials, only 8.2%contained HRC and 9.4% had PARC. Also, the HRC and PARC scenes contained messages that were implied vs. explicitly talking about the health or physical benefits of the product.

**Conclusions** African American children are overexposed to numerous types of food and beverage advertisements. These advertisements do not provide an adequate level of positive HRC and PARC messages. Consequently, the messages that are portrayed may undermine efforts to teach African American children about the importance of healthy living and physical activity.

**Author Affiliation:** School of Kinesiology, University of Minnesota, Minneapolis.

## Exercise 15 Reading qualitative research abstracts cont.

### **Qual10: Evidence based guidelines or collectively constructed "mindlines?" Ethnographic study of knowledge management in primary care**

**John Gabbay**, *professor of public health*<sup>1</sup>, **Andrée le May**, *reader in nursing*<sup>2</sup>

<sup>1</sup>Wessex Institute for Health Research and Development, Community Clinical Sciences, University of Southampton, Southampton SO16 7PX, <sup>2</sup> School of Nursing and Midwifery, University of Southampton

Correspondence to: J Gabbay [j.gabbay@soton.ac.uk](mailto:j.gabbay@soton.ac.uk)

**Objective** To explore in depth how primary care clinicians (general practitioners and practice nurses) derive their individual and collective healthcare decisions.

**Design** Ethnographic study using standard methods (non-participant observation, semistructured interviews, and documentary review) over two years to collect data, which were analysed thematically.

**Setting** Two general practices, one in the south of England and the other in the north of England.

**Participants** Nine doctors, three nurses, one phlebotomist, and associated medical staff in one practice provided the initial data; the emerging model was checked for transferability with general practitioners in the second practice.

**Results** Clinicians rarely accessed and used explicit evidence from research or other sources directly, but relied on "mind lines"—collectively reinforced, internalized, tacit guidelines. These were informed by brief reading but mainly by their own and their colleagues' experience, their interactions with each other and with opinion leaders, patients, and pharmaceutical representatives, and other sources of largely tacit knowledge. Mediated by organizational demands and constraints, mindlines were iteratively negotiated with a variety of key actors, often through a range of informal interactions in fluid "communities of practice," resulting in socially constructed "knowledge in practice."

**Conclusions** These findings highlight the potential advantage of exploiting existing formal and informal networking as a key to conveying evidence to clinicians.

## Exercise 15 Reading qualitative research abstracts cont.

### Qual11: Appropriateness of use of medicines in elderly inpatients: qualitative study

Anne Spinewine<sup>1\*</sup>, Christian Swine<sup>2</sup>, SorayaDhillon<sup>3</sup>, Bryony Dean Franklin<sup>4</sup>, Paul M Tulkens<sup>1</sup>, Léon Wilmotte<sup>5</sup>, Vincent Lorant<sup>6</sup>

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**Objectives** To explore the processes leading to inappropriate use of medicines for elderly patients admitted for acute care.

**Design** Qualitative study with semistructured interviews with doctors, nurses, and pharmacists; focus groups with inpatients; and observation on the ward by clinical pharmacists for one month.

**Setting** Five acute wards for care of the elderly in Belgium.

**Participants** 5 doctors, 4 nurses, and 3 pharmacists from five acute wards for the interviews; all professionals and patients on two acute wards for the observation and 17 patients (from the same two wards) for the focus groups.

**Results** Several factors contributed to inappropriate prescribing, counselling, and transfer of information on medicines to primary care. Firstly, review of treatment was driven by acute considerations, the transfer of information on medicines from primary to secondary care was limited, and prescribing was often not tailored to elderly patients. Secondly, some doctors had a passive attitude towards learning: they thought it would take too long to find the information they needed about medicines and lacked self directed learning. Finally, a paternalistic doctor-patient relationship and difficulties in sharing decisions about treatment between prescribers led to inappropriate use of medicines. Several factors, such as the input of geriatricians and good communication between members of the multidisciplinary geriatric team, led to better use of medicines.

**Conclusions** In this setting, improvements targeted at the abilities of individuals, better doctor-patient and doctor-doctor relationships, and systems or transferring information between care settings will increase the appropriate use of medicines in elderly people.

## Exercise 15 Reading qualitative research abstracts cont.

### **Qual 12: What do patients receiving palliative care for cancer and their families want to be told? A Canadian and Australian qualitative study**

**Peter Kirk**, *clinical professor (family medicine and palliative care)*<sup>1</sup>, **Ingrid Kirk**, *educator and hospice volunteer*<sup>2</sup>, **Linda J Kristjanson**, *professor*<sup>3</sup>

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**Objective** To obtain feedback from patients receiving palliative care and their relatives from various ethnic backgrounds about their experiences of the disclosure process and their satisfaction with information sharing during the illness.

**Design** A qualitative study with semistructured single interviews.

**Setting** Perth, Western Australia, and Winnipeg, Manitoba, Canada.

**Participants** 72 participants registered with palliative care: 21 patient-family dyads in Perth and 14 dyads and 2 patients in Winnipeg.

**Results** Participants described their experiences in great detail. The analysis indicates that in information sharing the process is as important as the content. The timing, management, and delivery of information and perceived attitude of practitioners were critical to the process. This applied to information interactions at all stages of the illness. Main content areas mentioned related to prognosis and hope. Hope can be conveyed in different ways. Secondary information from various sources is accessed and synthesized with the primary information. All patients, regardless of origin, wanted information about their illness and wanted it fully shared with relatives. Almost all patients requested prognostic information, and all family members respected their wishes. Information was perceived as important for patient-family communication. Information needs of patient and family changed and diverged as illness progressed, and communication between them became less verbally explicit.

**Conclusions** Information delivery for patients needs to be individualized with particular attention to process at all stages of illness. Patients and families use secondary sources of information to complement and verify information given by health careers.

## Exercise 15 Reading qualitative research abstracts cont.

### Qual 13: Why do general practitioners prescribe antibiotics for sore throat? Grounded theory interview study

Satinder Kumar, *senior research fellow*, <sup>a</sup>Paul Little, *professor of health services research*, <sup>a</sup>Nicky Britten, *director*. <sup>b</sup>

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**Objectives:** To understand why general practitioners prescribe antibiotics for some cases of sore throat and to explore the factors that influence their prescribing.

**Design:** Grounded theory interview study.

**Setting:** General practice.

**Participants:** 40 general practitioners: 25 in the maximum variety sample and 15 in the theoretical sample.

**Results:** General practitioners are uncertain which patients will benefit from antibiotics but prescribe for sicker patients and for patients from socioeconomically deprived backgrounds because of concerns about complications. They are also more likely to prescribe in pressured clinical contexts. Doctors are mostly comfortable with their prescribing decisions and are not prescribing to maintain the doctor-patient relationship.

**Conclusions:** General practitioners have reduced prescribing for sore throat in response to research and policy initiatives. Further interventions to reduce prescribing would need to improve identification of patients at risk of complications and be workable in busy clinical situations.

#### What is already known on this topic

Prescribing of antibiotics for sore throat has fallen in the past 10 years

General practitioners overestimate patients' expectations for antibiotics

#### What this study adds

General practitioners are uncertain who benefits most from antibiotics for sore throat and are particularly concerned about complications

Maintaining the doctor-patient relationship was not the primary reason for prescribing antibiotics

Doctors are mostly comfortable with their antibiotic prescribing for sore throat

## Exercise 15 Reading qualitative research abstracts cont.

### Qual 14: Keeping close: Mothering with serious mental illness.

*Journal of Advanced Nursing* 54, 1, 20-28.

Montgomery, P., Tompkins, C., Forchuk, C., & French, S. (2006).

- **Aim.** The aim of this paper is to describe the experiences of mothers with serious mental illness from their perspectives and how they attempted to manage their mothering circumstances.
- **Background.** The desire to mother in women with serious mental illness is increasingly acknowledged by healthcare professionals. For these women, mothering is often framed as a pathological problem needing professional intervention. Yet little is known about mothering and illness from the perspectives of the mothers themselves.
- **Method.** Using Glaser's grounded theory approach and both purposive and theoretical sampling, interviews were conducted with 20 mothers who were receiving treatment for mental health problems. The data were collected in 2002.
- **Findings.** We found the core category of "Keeping close" described mothers' efforts to have meaningful relationships with their children in the context of illness and suffering.
- To this end, mothers chose strategies that would hide illness for the sake of protecting their roles and their children. These strategies – masking, censoring speech, doing mother work and seeking help – served to imitate ideal perceptions of mothering while making illness invisible to their children. Mothering in illness, however, became a vortex of contradictions, resulting in mothers 'hitting bottom', a point in time when they realized they could not keep close via pretences. To return to the valued place of mother, they sought treatment, hoping to learn how to be with their children authentically.
- **Conclusion.** To assist mothers with serious mental illness, healthcare professionals must be sensitive to the social and cultural context in which they mother in order to create healthier possibilities for nurturing their children.

## Exercise 15 Reading qualitative research abstracts cont.

### Qual 15: Ginger compress therapy for adults with osteoarthritis.

Therkleson, T. (2010) *Journal of Advanced Nursing* 66(10), 2225–2233.

**Keywords:** ginger compress therapy; Giorgi's method; nursing; osteoarthritis; phenomenology

#### Abstract

**Aim.** This paper is a report of a study to explicate the phenomenon of ginger compresses for people with osteoarthritis.

**Background.** Osteoarthritis is claimed to be the leading cause of musculoskeletal pain and disability in Western society. Management ideally combines non-pharmacological strategies, including complementary therapies and pain-relieving medication. Ginger has been applied externally for over a thousand years in China to manage arthritis symptoms.

**Method.** Husserlian phenomenological methodology was used and the data were collected in 2007. Ten purposively selected adults who had suffered osteoarthritis for at least a year kept daily diaries and made drawings, and follow-up interviews and telephone conversations were conducted.

**Findings.** Seven themes were identified in the data: (1) Meditative-like stillness and relaxation of thoughts; (2) Constant penetrating warmth throughout the body; (3) Positive change in outlook; (4) Increased energy and interest in the world; (5) Deeply relaxed state that progressed to a gradual shift in pain and increased interest in others; (6) Increased suppleness within the body and (7) More comfortable, flexible joint mobility. The essential experience of ginger compresses exposed the unique qualities of heat, stimulation, anti-inflammation and analgesia.

**Conclusion.** Nurses could consider this therapy as part of a holistic treatment for people with osteoarthritis symptoms. Controlled research is needed with larger numbers of older people to explore further the effects of the ginger compress therapy.

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*Sample Proposal*

**XX for patients with positive surgical margins following surgical excision of basal cell carcinoma or squamous cell carcinoma in-situ of the skin**

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## Sample Proposal - continued

### 1. Schema

Basal cell carcinoma or squamous cell carcinoma in-situ of the skin with positive surgical margin(s)



XX topical cream 5x/wk for 6 weeks



Post-treatment biopsy at 6-8 weeks after protocol treatment



Clinical evaluation q 3 months for any recurrence at the treated site over 24 months

Primary endpoint: Recurrence rate at the treated site over 24 months

Secondary endpoints: Patients' ability to complete the 6-week protocol treatment,  
Incidence of residual malignancy in the post-treatment biopsy,  
Cosmetic assessment

### 2. Objective

To assess the effectiveness of XX topical cream for the prevention of recurrence of nonmelanoma skin cancer in patients with positive resection margin(s) after surgical excision of basal cell carcinoma (BCC) or squamous cell carcinoma-in-situ (SCCis) of the skin.

### 3. Background

XX is a topical immune response modifier, recently approved for the management of external anogenital warts. Its major mechanism of action is the induction of interferon alfa (IFN- $\alpha$ ) and a broad array of cytokines by its cellular targets. It activates innate immunity including antigen-presenting cells such as monocytes, dendritic cells, and epidermal Langerhans cells<sup>1-3</sup>, and alters their cytokine profile, particularly interleukin-12 (IL-12) production increase. Thus, it can affect the quality of acquired immune responses, favoring T<sub>H</sub>1 lymphocyte (IFN- $\gamma$ -producing)-mediated immune response against foreign antigens and inhibiting the T<sub>H</sub>2-lymphocyte (IL-4-producing) subset.<sup>4</sup> Because of these immunopharmacologic properties, XX has proven efficiency for the treatment of external genital and perianal warts and was approved by the Food and Drug Administration (FDA) for this indication in 1998.<sup>5-6</sup>

Because of the induction of cytokines and activation of innate immunity including antigen-presenting cells, XX exhibits therapeutic efficacy in animal models of antitumor immunity.<sup>7-9</sup> These animal model data translate well in the clinical use of XX for skin cancer. Several preliminary reports indicate favorable therapeutic activity of XX cream in the treatment of skin cancers including basal cell carcinoma<sup>10-11</sup>, squamous cell carcinoma in-situ<sup>12-13</sup>, lentigo maligna<sup>14</sup>, and cutaneous melanoma metastases.<sup>15</sup> The initial study of XX cream for basal cell carcinoma was a vehicle-controlled, 16-week, dose-ranging study.<sup>10</sup> In this study, the overall response rate (tumor clearance by the end of treatment) was 83% in XX-treated group. Efficacy was stringently assessed by using histologic criteria for residual tumor in the excised skin after XX treatment. Post-treatment excision, while providing precise information about residual tumor at the treatment site, did not allow assessment of post-treatment recurrences over time.

## Sample Proposal - continued

In the presence of increasing evidence for the anti-tumor activity of XX, it is worthwhile to explore its potential role in various clinical situations. One such area is a clinical setting of positive resection margin(s) following surgical excision of nonmelanoma skin cancer (i.e. basal cell and squamous cell carcinoma). In this clinical situation, management options are diverse and include close surveillance alone, wider local excision, and post-operative adjuvant radiotherapy. Reported recurrence rates for incompletely excised basal cell carcinoma vary widely, from 30 to 67 %. For squamous cell carcinoma, the risk of recurrence is considered higher in view of its more aggressive nature. Liu reported in the retrospective review of 187 patients with incompletely excised basal cell carcinomas of skin that the 5-year probability of remaining relapse-free in the group immediately treated for positive resection margin was 91%, compared with 61% for the group managed expectantly.<sup>16</sup> For those patients opting to have further therapeutic intervention for positive resection margin, topical treatment using XX is an attractive alternative to wider local excision or post-operative adjuvant radiotherapy, since it does not entail more surgery or a protracted course of daily radiotherapy. It can be administered as an outpatient treatment and may be associated with less long-term morbidity, including better cosmetic outcome. Even if XX fails to prevent tumor recurrence, a patient can still have surgery or radiotherapy as salvage treatment. There has been, to date, no study evaluating the efficacy of XX for the prevention of recurrence in patients with positive resection margins after surgical excision of basal cell carcinoma or squamous cell carcinoma-in-situ of the skin. In this pilot study, we attempt to evaluate a potential role of XX cream in the aforementioned clinical setting.

### 4. Study Design

Prospective, single-arm, study

### 5. Inclusion and Exclusion

#### 5.1 Eligibility Criteria

There will be NO EXCEPTIONS to eligibility requirements at the time of study enrolment. Questions about eligibility criteria should be addressed prior to study enrolment.

The eligibility criteria for this study have been carefully considered to assure that patients who enter this study are medically appropriate candidates for the study intervention. It is important that no exceptions be made to these criteria for admission to the study in order to ensure that the results of this study can be useful for making treatment decisions regarding other patients with similar diseases.

Patients must fulfill all of the following criteria to be eligible for admission to the study:

- ◆ Histologically confirmed BCC or SCCis of the skin.
- ◆ Recent surgical excision within 4 months of study enrollment
- ◆ Pathologically positive resection margin(s)
- ◆ No clinical evidence of gross residual tumor
- ◆ No clinical evidence of nodal metastasis
- ◆ No previous radiotherapy to the target area where imiquimod is to be applied
- ◆ Life expectancy > 2 years
- ◆ Patient consent must be obtained according to local Institutional and/or University Human Experimentation Committee requirements.
- ◆ Patients must be accessible for treatment and follow-up. Investigators must assure themselves the patients enrolled in this trial will be available for complete documentation of the treatment and follow-up visits
- ◆ Protocol treatment is to begin within 2 weeks of study enrolment

## Sample Proposal - continued

### 5.2 Ineligibility Criteria

Patients with any one of the following criteria are not eligible for admission to the study:

- ◆ Invasive squamous cell carcinoma of the skin
- ◆ History of other malignancy within the last 5 years, other than treated BCC or SCCis of the skin or superficial bladder cancer
- ◆ No concurrent chemotherapy

## 6. Evaluation

### 6.1 Pre-treatment evaluation

Investigations		Timing
History and Physical Exam including:	Performance Status, Photo of the target area	Within 2 weeks before enrolment
Pathology review of the resected specimen*		Within 3 weeks after enrolment

\*Pathology review is mandatory and should be completed within 3 weeks after study enrolment. However, a patient can be enrolled into the study before the completion of pathology review, as long as the outside pathology reports BCC or SCCis of the skin and positive resection margin(s).

### 6.2 Evaluation DURING and AFTER protocol treatment

Investigations		During Treatment (6 weeks)	After Treatment (24 months)	
History and Physical Exam including:	Performance status, Photo of the target area	Week 3 and 6	Week 12-14	Week 16 and then q 3 months
Post-treatment biopsy of the treated area		N/A	Week 6-8	At any f/u visit (q 3 months) ONLY if clinically suspicious of recurrence

## 7. Therapeutic Intervention

### 7.1 XXcream

XX cream is to be applied to the site of recent surgery with positive resection margin(s), 5 times a week (Monday to Friday; no treatment on Saturday and Sunday) for 6 weeks. Rest periods up to 7 days and/or a step-down to 3 times a week frequency are allowed if a patient is not able to comply with the dosing regimen because of application site reactions or other adverse events.

## Sample Proposal - continued

### 7.2. Post-treatment biopsy

Post-treatment biopsy is performed at 6-8 weeks after the completion of protocol treatment. The number of biopsy to be taken depends on the size of initial surgical bed and the extent of positive resection margin. But, the minimum number of biopsies required is 2. The location of biopsy site is at the discretion of attending physician, but should be guided by the site(s) of positive resection margin(s) described in the initial pathology report.

If post-treatment biopsy is positive, further treatment is at the discretion of attending physician. Management options include surveillance alone, surgical excision, and radiotherapy. When additional intervention is considered due to positive post-treatment biopsy, wide local excision is preferable as it allows thorough examination of the resected specimen for any residual cancer and its extent. Even if post-treatment biopsy is positive, one can opt for close surveillance alone when there is no clinically visible residual or recurrent cancer.

If post-treatment biopsy is negative, further biopsies will not be performed unless there is a clinical suspicion of recurrence at any of the follow-up visits (q 3 month until month 24).

## 8. Endpoints

The primary endpoint is the rate of tumor recurrence at 24 months at the site of initial surgical excision, which had positive resection margin(s). Tumor recurrence is first evaluated histologically at 6-8 weeks post-treatment, and then clinically every 3 months at follow-up visits. If there is any clinical suspicion, biopsy is to be performed at that visit. Patients undergoing further surgery because of positive post-treatment biopsy, will be scored as recurrence only when the resected specimen demonstrates residual malignancy.

The secondary outcomes are:

1. patient's ability to complete the 6-week course of treatment
2. the incidence of positive biopsy after the completion of protocol treatment
3. cosmetic assessment

## 9. Sample Size and Statistical Considerations

If recurrence rate after imiquimod treatment is 30% or greater at 24 months, it will be of no clinical significance. Conversely, if the recurrence rate is 10% or less at 24 months, then further study is indicated.

The sample size of this study is 40 patients. Assuming  $\alpha=0.05$  (two-sided),  $P_0=0.30$  (recurrence rate for null hypothesis), and  $P_1=0.10$  (recurrence rate for alternative hypothesis), the sample size of 40 patients will have the power of 90%. This means that if the 'true' recurrence rate is 10% at 24 months, there is 90% power for this study to demonstrate this treatment effect against the null hypothesis of recurrence rate being 30%. The exact 95% confidence interval for 10% recurrence rate with a sample size of 40 patients is 2.8% to 23.7%.

**Appendix 3 - Qualitative Data collection example: Interview Guide for *Health Information Management learning outcomes: preparing for changes in the profession; what the stakeholders say***

**Demographic Information**

City/town/province of residence

Type of setting/employment

- a. regional hospital (only hospital in region)
- b. multi-site hospital
- c. long term care facility
- d. other hospital
- e. government
- f. research within hospital or not
- g. private clinic
- h. other clinic
- i. other (if other please specify)

If government what ministry?

How many health Information management professionals are employed in your department?

How many HIM professionals are employed in the organization overall?

Position/title within organization

Is your position a traditional HIM position?

Year of HIM certification:

Where did you study Health Information Management?

How many years of HIM or Health records experience did you have before certification?

Years in current position

How many additional qualifications/upgrading courses have you taken – post certification - in order to keep current?

**Appendix 3 - Interview Guide (continued) for: *Health Information Management learning outcomes: preparing for changes in the profession; what the stakeholders say***

**Open ended questions**

Describe your role within the department you work in.

How many different positions have you had in your HIM career?

How well prepared were you for your first job in HIM?

Identify any areas in which you felt stronger and weaker at that time.

Do you feel there are gaps in the knowledge you need to do your current job?

What do you see as the major issues confronting HIM professionals currently or within the foreseeable future?

What opportunities /new career areas do you see for HIM professionals within the foreseeable future?

Do you feel prepared for the changes you have identified? (if no ask about needs)

What barriers do you see that would prevent HIM professionals from taking advantage of any opportunities or from moving into these new areas?

Describe some of the specific changes you foresee in the health care system within the next 5 years.

How will these changes affect the HIM profession?

What kind of knowledge do you see HIM students needing for entry to practice?

What professional development would like to see for yourself?

What professional development do you feel would be advantageous/ necessary for others in the HIM profession?

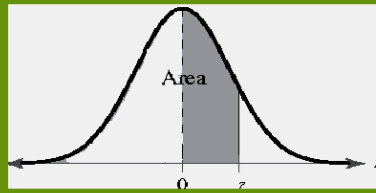
If you had an opportunity to give a few words of advice to new graduates from an HIM program, what would you say?

**Appendix 4 - Evaluating research** – We will get into evaluating research more in the epidemiology class coming up next semester. The checklist below is mostly self-explanatory and will help you organize your thinking towards this task.

<p>Internal validity is the degree to which claims made about participants are true:</p>	<p>External validity: Degree to which the participants are representative of the target population</p>
<p>Components:</p> <p>Information bias</p> <ul style="list-style-type: none"> <li>a. Recall/compliance bias</li> <li>b. interview/observer bias</li> <li>c. measurement error</li> <li>d. data analysis error</li> </ul> <p>Selection bias</p> <ul style="list-style-type: none"> <li>c. control selection bias (experiments or other research in which there is a treatment and control group)</li> <li>d. non-response bias</li> </ul> <p>Confounding</p> <ul style="list-style-type: none"> <li>a. are there variables not in the research that may have an impact on the outcome (or even on the exposure)</li> <li>b. loss to follow up</li> </ul>	<p>Components:</p> <p>Description</p> <ul style="list-style-type: none"> <li>c. Is target population well-defined? too narrow? too wide?</li> <li>d. Sampling method likely to produce a sample representative of the target population? Is anyone missed?</li> </ul> <p>Selection Bias</p> <ul style="list-style-type: none"> <li>d. self-selection</li> <li>e. restriction: inappropriate inclusion/exclusion criteria</li> <li>f. non-response</li> </ul>

## Appendix 5 – z-table

Z table Area between mean and z-score.  
 For example  $z = 1.24$  corresponds to area = 0.3925  
 (or 39.25% of total area).



<b>Z</b>	<b>0</b>	<b>0.01</b>	<b>0.02</b>	<b>0.03</b>	<b>0.04</b>	<b>0.05</b>	<b>0.06</b>	<b>0.07</b>	<b>0.08</b>	<b>0.09</b>
<b>0</b>	0.0000	0.0040	0.0080	0.0120	0.0160	0.0199	0.0239	0.0279	0.0319	0.0359
<b>0.1</b>	0.0398	0.0438	0.0478	0.0517	0.0557	0.0596	0.0636	0.0675	0.0714	0.0753
<b>0.2</b>	0.0793	0.0832	0.0871	0.0910	0.0948	0.0987	0.1026	0.1064	0.1103	0.1141
<b>0.3</b>	0.1179	0.1217	0.1255	0.1293	0.1331	0.1368	0.1406	0.1443	0.1480	0.1517
<b>0.4</b>	0.1554	0.1591	0.1628	0.1664	0.1700	0.1736	0.1772	0.1808	0.1844	0.1879
<b>0.5</b>	0.1915	0.1950	0.1985	0.2019	0.2054	0.2088	0.2123	0.2157	0.2190	0.2224
<b>0.6</b>	0.2257	0.2291	0.2324	0.2357	0.2389	0.2422	0.2454	0.2486	0.2517	0.2549
<b>0.7</b>	0.2580	0.2611	0.2642	0.2673	0.2704	0.2734	0.2764	0.2794	0.2823	0.2852
<b>0.8</b>	0.2881	0.2910	0.2939	0.2967	0.2995	0.3023	0.3051	0.3078	0.3106	0.3133
<b>0.9</b>	0.3159	0.3186	0.3212	0.3238	0.3264	0.3289	0.3315	0.3340	0.3365	0.3389
<b>1</b>	0.3413	0.3438	0.3461	0.3485	0.3508	0.3531	0.3554	0.3577	0.3599	0.3621
<b>1.1</b>	0.3643	0.3665	0.3686	0.3708	0.3729	0.3749	0.3770	0.3790	0.3810	0.3830
<b>1.2</b>	0.3849	0.3869	0.3888	0.3907	0.3925	0.3944	0.3962	0.3980	0.3997	0.4015
<b>1.3</b>	0.4032	0.4049	0.4066	0.4082	0.4099	0.4115	0.4131	0.4147	0.4162	0.4177
<b>1.4</b>	0.4192	0.4207	0.4222	0.4236	0.4251	0.4265	0.4279	0.4292	0.4306	0.4319
<b>1.5</b>	0.4332	0.4345	0.4357	0.4370	0.4382	0.4394	0.4406	0.4418	0.4429	0.4441
<b>1.6</b>	0.4452	0.4463	0.4474	0.4484	0.4495	0.4505	0.4515	0.4525	0.4535	0.4545
<b>1.7</b>	0.4554	0.4564	0.4573	0.4582	0.4591	0.4599	0.4608	0.4616	0.4625	0.4633
<b>1.8</b>	0.4641	0.4649	0.4656	0.4664	0.4671	0.4678	0.4686	0.4693	0.4699	0.4706
<b>1.9</b>	0.4713	0.4719	0.4726	0.4732	0.4738	0.4744	0.4750	0.4756	0.4761	0.4767
<b>2</b>	0.4772	0.4778	0.4783	0.4788	0.4793	0.4798	0.4803	0.4808	0.4812	0.4817
<b>2.1</b>	0.4821	0.4826	0.4830	0.4834	0.4838	0.4842	0.4846	0.4850	0.4854	0.4857
<b>2.2</b>	0.4861	0.4864	0.4868	0.4871	0.4875	0.4878	0.4881	0.4884	0.4887	0.4890
<b>2.3</b>	0.4893	0.4896	0.4898	0.4901	0.4904	0.4906	0.4909	0.4911	0.4913	0.4916
<b>2.4</b>	0.4918	0.4920	0.4922	0.4925	0.4927	0.4929	0.4931	0.4932	0.4934	0.4936
<b>2.5</b>	0.4938	0.4940	0.4941	0.4943	0.4945	0.4946	0.4948	0.4949	0.4951	0.4952
<b>2.6</b>	0.4953	0.4955	0.4956	0.4957	0.4959	0.4960	0.4961	0.4962	0.4963	0.4964
<b>2.7</b>	0.4965	0.4966	0.4967	0.4968	0.4969	0.4970	0.4971	0.4972	0.4973	0.4974
<b>2.8</b>	0.4974	0.4975	0.4976	0.4977	0.4977	0.4978	0.4979	0.4979	0.4980	0.4981
<b>2.9</b>	0.4981	0.4982	0.4982	0.4983	0.4984	0.4984	0.4985	0.4985	0.4986	0.4986
<b>3</b>	0.4987	0.4987	0.4987	0.4988	0.4988	0.4989	0.4989	0.4989	0.4990	0.4990
<b>3.1</b>	0.4990	0.4991	0.4991	0.4991	0.4992	0.4992	0.4992	0.4992	0.4993	0.4993
<b>3.2</b>	0.4993	0.4993	0.4994	0.4994	0.4994	0.4994	0.4994	0.4995	0.4995	0.4995