

*Southern Network of Specialized
Care*

*Introduction to Research
Methods
July 22, 2011*

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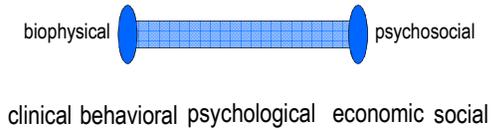
Plan for the Next Hour

- *Research and Evidence-Based Practice*
- *Developing Research Questions*
- *Quantitative Research Designs*
- *Qualitative Research Designs*
- *Appraising Study Outcomes*
- *Changing Practice*

**Identify an issue, question, or
problem....**

- Research is about addressing an issue or asking and answering a question or solving a problem.
- Basic and applied research distinction

Topic: what are you researching?



Case Study: CBT and Dual Diagnosis

- In the United Kingdom, the National Institute for Health and Clinical Excellence recommends Cognitive Behavioural Therapy (CBT) as the treatment of choice for a number of mental health difficulties, including post-traumatic stress disorder, OCD, bulimia nervosa, and clinical depression.
- Historically people with intellectual disabilities have not been offered or received cognitive behavioural interventions...for mental health and emotional problems.

- Hatton (2002): Although evidence to support the efficacy of these approaches is severely limited,...these treatments, appropriately modified, may be a feasible intervention option for people with mild intellectual disabilities....
- The Royal College of Psychiatrists (2004): The lack of good quality research evidence to support the use of psychological therapies with this population is, in part, due to intellectual disability having been used routinely as an exclusion criterion from efficacy research.

• Sturmev (2005): ...concluded that the evidence is not available to support the use of psychotherapy, including CBT, with people with intellectual disabilities.

• Taylor (2007): ...there is limited evidence for the effectiveness of psychotherapeutic approaches. ... (BUT)... CBT, with these clients is promising. A reasonable number of case studies and case series reports indicate that these approaches show promise in the effective treatment of mental health problems experienced by people in this population.

• Psychotherapist and professor Andrew Samuels, CBT ...this constitutes "a coup, a power play by a community that has suddenly found itself on the brink of corralling an enormous amount of money. Science isn't the appropriate perspective from which to look at emotional difficulties. Everyone has been seduced by CBT's apparent cheapness."^[68]

• As more research focuses on CBT, more studies are published on CBT. This reinforces the logical error that CBT is superior and this has a direct negative effect on other forms of therapy, which are well documented but have smaller bodies of research.

• People who get therapy improve substantially, regardless of the type of therapy they get. When therapies are compared to one another, they usually appear to be equally effective.

• Excessive spending on CBT while discouraging other forms of therapy hurts the public.

Evidence-Based Practice (EBP)

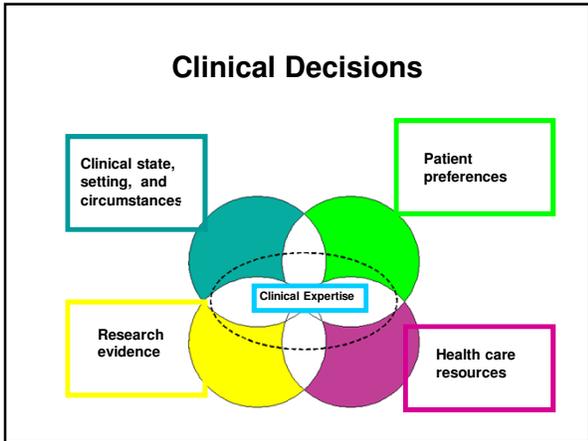
“The integration of best research evidence with clinical expertise and patient values to facilitate clinical decision making”

(Sackett et al, 2000)

Evidence-Based Care

- Incorporating evidence from research, clinical practice and patient preferences into our decisions about the health care for our patients (treatment, prevention, prognosis).
- Critical appraisal of the research helps us to identify systematically the strengths and weaknesses of the research to enable providers to apply the information correctly to their practices.





- ### Dual Diagnosis Best Practice:
- Dagnan (2007) "Psychosocial Interventions for People with Intellectual Disabilities and Mental Ill-Health"
 - Allen and Davies (2007) "Challenging Behaviour and Psychiatric Disorder in Intellectual Disability"
 - Lunskey et al (2006) "The Clinical Profile and Service Needs of Hospitalized Adults with Mental Retardation and a Psychiatric Diagnosis"
 - Torr and Davis (2007) "Ageing and Mental Health Problems in People with Intellectual Disability" 2

- ### Guidelines -
- Practice Guidelines for the Assessment and Diagnosis of Mental Health Problems in Adults with Intellectual Disabilities
 - Consensus Guidelines for Primary Health Care of Adults with Developmental Disabilities
 - International Guidelines to Prescribing Psychotropic Medications for Management of Problem Behaviors in Adults with Intellectual Disabilities
 - Guidelines for Managing the Client with Intellectual Disabilities in the ED.

Critical Appraisal of Studies

You need to ask yourself:

- ◆ *Are the results valid? (Internal Validity)*
- ◆ *What are the results? Stats and Relevance*
- ◆ *Are the results applicable (and useful) to my patient care population?*

Steps of EBP

1. Formulate an answerable question
2. Conduct an efficient literature search
3. Critically appraise the evidence
4. Apply the results in health care decisions
5. Evaluate the outcome

EBP is a 5-Stage Process

1. Clinical uncertainty from practice is converted into focused, structured questions. (based on a knowledge gap, uncertainty, a problem or clinical topic of interest).
2. Focused questions are the basis for an efficient literature search to identify relevant evidence from research (a systematic retrieval of the best evidence available)

3. Critically appraise the evidence for validity and applicability
4. Apply the evidence alongside clinical expertise, patient preferences and available resources to plan care. (make health care decisions, develop policies, programs, etc.)
5. Evaluate the outcomes

6 Levels for the Organization of Evidence-Based Information⁴

⁴ Adapted from Haynes, 2007

Hierarchy of Pre-Processed Evidence – Haynes 2007



The Hierarchy of Evidence

- Systematic reviews and meta-analyses (RCTs)
- Cohort Studies
- Case control studies
- Cross sectional surveys
- Case reports

Clinical Practice Guidelines

- systematically developed statements to assist practitioners and patients with decisions about appropriate health care for specific clinical circumstances
- an attempt to distill a large body of knowledge into a convenient readily usable format

http://www.guideline.gov/

Clinical Practice Guidelines

The screenshot shows the National Guideline Clearinghouse website. At the top, there is a navigation bar with links for 'What's New', 'Contact', 'About', 'Site Map', and 'RSS'. Below this is a search bar with a 'Search' button and a '20 Results' indicator. To the left of the search bar is a sidebar with 'Resources' and 'Browse' sections. The 'Resources' section includes links for 'Approach', 'Biometrics', 'Discussion List', 'EPC Reports', 'FAQ', 'Guideline Archive', 'Guideline Index', 'NLM Links', 'Patient Resources', 'PDA/Palm', and 'SARS'. The 'Browse' section includes 'Disease / Condition'. The main content area features a 'Welcome!' message, a search instruction, and 'NGC News' with several news items.

Hierarchy of Evidence: Supporting Guideline Recommendations

Example (Canadian Task Force on Preventive Health Care):

- I: Evidence from at least 1 well-designed RCT (2 groups)
- II-1: Evidence from controlled trials without randomization (2 groups)
- II-2: Evidence from cohort or case-control studies (2 groups)
- II-3: Evidence from comparisons between times or places with or without the intervention
- III: Expert opinion

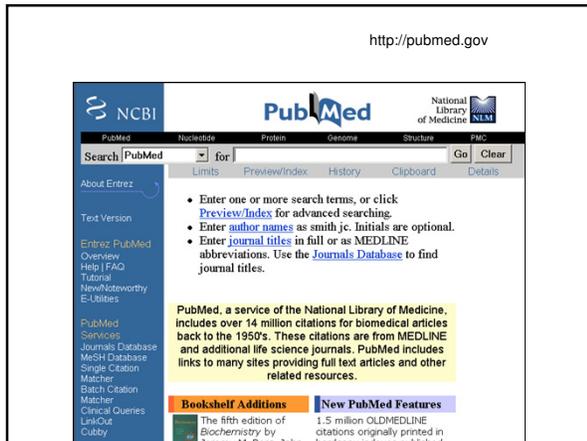
Systematic reviews

- A **systematic review** is a literature review focused on a research question that tries to identify, appraise, select and synthesize all high quality research evidence relevant to that question. Systematic reviews of high-quality randomized controlled trials are crucial to evidence-based medicine.

Systematic Reviews (Syntheses)

- comprehensive identification of studies
- review of study relevance
- evaluation of methodological quality
- extraction of data
- analysis of data
- drawing conclusions

Single Studies:
CINAHL and Pub Med/Medline



Asking searchable, answerable clinical questions:

- ◆ Your question will determine the kind of evidence needed to answer it.
- ◆ And , a well formulated question will help you find the answer efficiently! (Search)

Formulating Research Questions
Use the P.I.C.O.T Model

P.I.C.O.T Model

- ♦ P= Population
- ♦ I = Intervention
- ♦ C = Comparison or counter-intervention
- ♦ O = Outcome
- ♦ T = Time Frame (1 hour, 24 hours, 48 hours, in 6 months)

This model is appropriate for formulating *quantitative* questions

Question

Population	People with back pain
Intervention	Exercise
Comparison	Bed rest
Outcome	Reduced pain

Example:

Is exercise more effective than rest for relieving chronic back pain?

P.I.C.O.

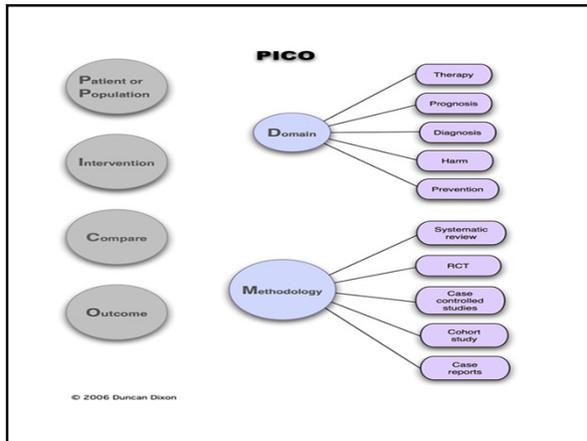
P opulation: newborn infants
I ntervention: water
C ounter intervention: alcohol
O utcome: umbilical infections

Question

Is water as effective as alcohol in preventing umbilical cord infections in newborn infants?

Question – Causation or Harm

P opulation: High school students
E xposure: Soft drinks in vending machines
C ounter exposure: No soft drinks
O utcome: Obesity



Writing Qualitative Questions

- ♦ P = Population/patient
- ♦ S = Situation

This model is appropriate for formulating *qualitative* questions

Question

Population - People with HIV/AIDS

Situation - Disclosing their status to their health care providers

Example:

How do people with HIV/AIDS living in a rural community feel about disclosing their status to their health care provider?

P.S.

P opulation: informal caregivers

S ituation: placing a spouse with Alzheimer's Disease in a nursing home

Question

How do caregivers (spouse, family or friends) feel about placing a spouse/relative with Alzheimer's Disease in a nursing home?

Two Broad Types of Research

1. Quantitative Methods – are best to address questions of treatment effectiveness, diagnostic effectiveness, causation, prognosis, prevention

- Characterized by objective scientific experimental designs or observations (use numbers/statistics, RCT, cohort studies, case control studies).

...continued

2. Qualitative Methods – are best to address questions about patient experiences in treatment, feelings, how patients adapt and cope, or impressions of nurses working in palliative care, or of patients who are dying,

-characterized by interviews, focus groups, observation)

Major Classes of Research

Quantitative

- Experimental (involves intervention, tests relationships)
- Non- Experimental (no intervention is introduced by researcher).

Qualitative

- Grounded Theory
- Phenomenology
- Ethnography

Quantitative:

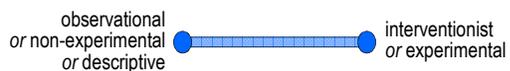
Descriptive studies - Correlational studies

- Cross-sectional surveys
- Case reports
- Case series

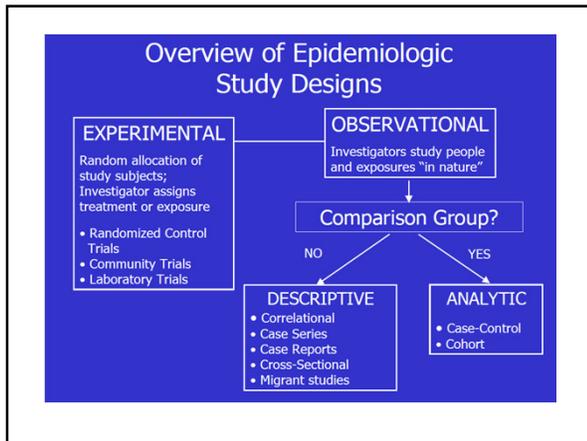
Analytic studies

- Observational studies
 - Case-control studies
 - Prospective cohort studies – historical and longitudinal
- Intervention studies
 - Clinical or community trials

Design: observational or interventionist?



- In an observational study...the aim is to gather data or information about the world as it is. (prevalence, association).
- In an interventionist study...you do something to the world and see what happens.



Ethics in Research

- ### Ethical Principles to Guide Research Involving Humans
- ◆ Respect for human dignity
 - ◆ Respect for free and informed consent
 - ◆ Respect for vulnerable persons
 - ◆ Respect for privacy and confidentiality
 - ◆ Respect for justice and inclusiveness
 - ◆ Balancing harms and benefits
 - ◆ Minimizing harm
 - ◆ Maximizing benefit
- *From the Tri-Council Policy Statement (1998)

Quantitative Study Designs...

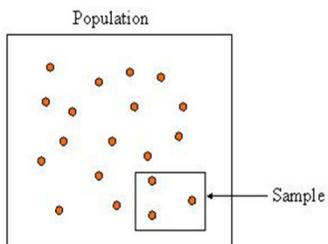
- Most appropriate for answering...
Treatment/Prevention/Diagnostic,
Causation/Risk, Prognosis, ...
- Types:
 - RCT
 - Cohort
 - Case Control

Hypothesis Testing

- Quantitative research uses statistical measures to understand differences between groups...
- Process begins with a *null hypothesis*
- The null hypothesis typically states that there is no difference in outcomes between the interventions and groups

Population vs Sample

A sample is a subset of the population



Two Different Sampling Techniques

- Probability sampling
- Non-probability

Quantitative: Probability Sampling

- **Simple random sampling**
- **Stratified random sampling**
- **Systematic sampling**
- **Sample Size – Power and the Type II Error**

Qualitative – Non probability Sampling

- **Convenience Sampling**
- **Snowball Sampling**
- **Purposive Sampling**
- **Theoretical Sampling**

Sampling Bias

•Systematic over-representation or under-representation of some segment of the population in a sample in terms of a characteristic relevant to the research question/outcome...

•Sampling bias occurs usually as a result of a systemic flaw in the research process...inadvertently overlooked...(e.g., education level, income)

Cross Sectional Studies:

-Studies the characteristics of the group of interest (e.g., disease, behavior, age, etc.) in the population?

-What are the distributions of these factors of interest (age, blood pressure, vital capacity, etc.) in the study population?

Case Reports and Case Series

To make observations about patients with defined clinical characteristics (e.g., patients with a certain disease or cluster of symptoms)

Design: Simple description of clinical data without comparison groups...the data derived from a well-defined group of individuals

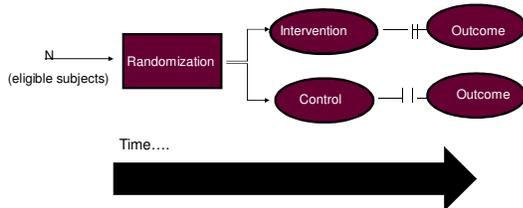
RCT – Randomized Controlled Trial

- Investigators randomly allocate participants to control & treatment groups. (hopefully concealed)
- Random allocation to groups makes them similar (equal chance of belonging to either group).
- Follow them forward in time...Do they experience the outcome of interest?
- The dependent variable is the outcome ! e.g., hospital admissions, pain relief, death, weight, physical activity, smoking cessation, etc.

Randomized Controlled Trial (RCT)

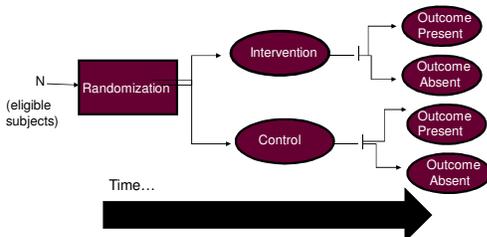
(continuous vs discrete outcome)

...a outcome measure is weight, BP, cholesterol



Randomized Controlled Trial (RCT)

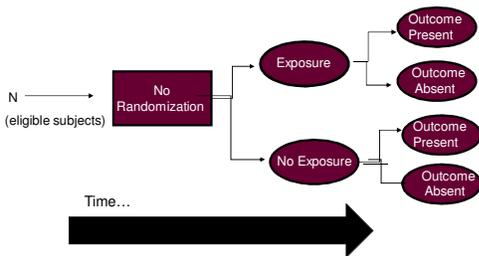
(discrete outcome)



RCT Example

- Qn: Among young women who are moderate smokers, does nicotine replacement therapy increase the probability of smoking cessation?
- Design: RCT, participants allocated to patch with NRT or patch with placebo

Cohort Analytic Study



Cohort Study

- Investigators identify similar patients with and w/- exposure of interest
- Follow them forward in time (prospectively)
- Do they experience the outcome of interest?
Systematic follow-up of the incidence of lung cancer, death, heart disease
- E.g., Occurrence of lung cancer in smokers vs. non smokers

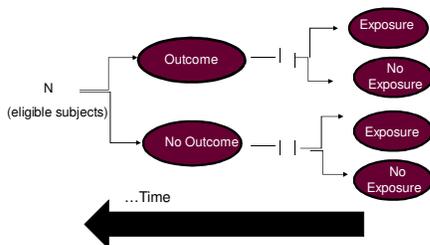
Cohort Example

- Among middle aged men, does smoking lead to a higher incidence of lung cancer?
- Design: Cohort; investigators identify middle-aged male smokers & middle-aged male non-smokers, follow them over time, monitor occurrence of lung cancer in each group

Case-Control Study

- Investigators identify patients w and w/- the outcome of interest –
- WE BEGIN WITH THE OUTCOME!
- Look back in time (retrospectively)
- Were patients exposed (to the potentially harmful agent) of interest?

Case-Control Study

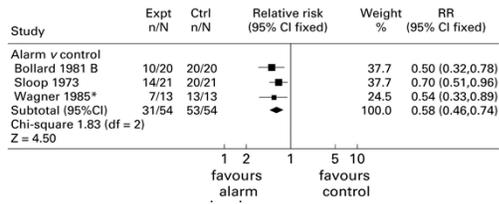


What is Meta-analysis?

- Meta-analysis is systematic review where there is statistical analysis of data from the trials.
- The data from each study is combined to arrive at an overall statistic and treatment effect.

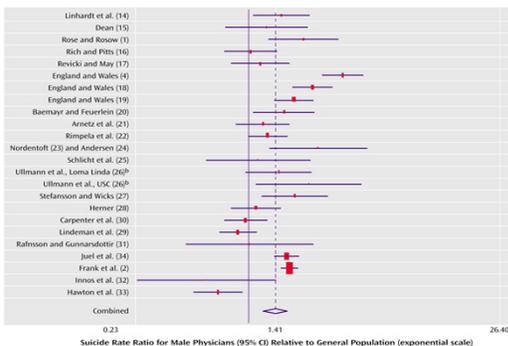
Graphical display of results of meta-analysis.

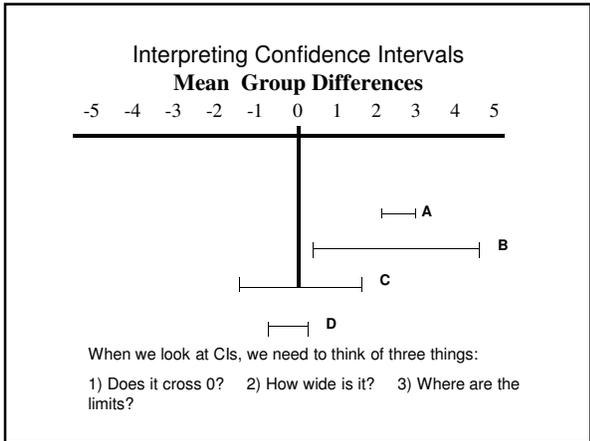
Review: alarm interventions for nocturnal enuresis in children
 Comparison: ALARM v CONTROL
 Outcome: numbers not achieving 14 dry nights or relapsing



Ciliska, D. et al. Evid Based Nurs 2001;4:100-104

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Qualitative Approaches

- Phenomenology
- Grounded Theory
- Ethnography

Phenomenology

- Phenomenology focuses on describing what all study participants have in common as they experience a phenomenon (e.g. grief). What is the “lived experience”...
- The basic purpose of phenomenology is to reduce individual experiences with a phenomenon to a description of it’s universal essence – what and how participants experienced this phenomenon
(Creswell, 2007)

Grounded Theory

- A qualitative research design in which the researcher generates a general explanation (a theory) of a process, action or interaction, as expressed in the views of a large number of participants.
- The intent is to move beyond description to develop a theory that is grounded in data, especially the actions, interactions and social processes of the people studied.

(Creswell, 2007)

Ethnography

- Ethnography is a qualitative design in which the researcher describes and interprets the shared and learned values, behaviors, beliefs and language of a cultural group
- Study participants are likely to be living in the same place or interacting so frequently that they develop shared patterns of behavior and understandings;
- focus is on beliefs, attitudes, practices, shared knowledge and understanding

(Creswell, 2007)

Assessing Qualitative Studies

Credibility (truth value): Has the researcher established confidence in the truth of the findings

Transferability (fittingness or applicability): Can the findings be applied to other contexts settings or groups?

Dependability (consistency): Are the findings consistent if the research is replicated with the same subjects and context?

Confirmability (neutrality): Is the research free from bias in the research procedures and results?

2 x 2 Table

- To compute measures of association, based on Discrete Outcomes, we are basically counting bodies in different categories.How many had this, and how many had that...
- We look at these variables in terms of proportions:

	Present	Absent
Present	a	b
Absent	c	d

Presentation of findings: The 2 X 2 table

Characteristic/ Exposure	Presence of Disease		Total
	Number with Disease	Number without Disease	
Present	a	b	a + b
Absent	c	d	c + d
Total	a + c	b + d	N

A familiar measure of association is **relative risk**, which is risk in exposed $[a/(a+b)]$ divided by risk in unexposed $[c/(c+d)]$:

$$\text{Relative Risk} = \frac{a/(a+b)}{c/(c+d)}$$

If the disease to be studied is rare, the odds ratio may be written:

$$\text{Odds Ratio} = \frac{a/(\sim b)}{c/(\sim d)} = \frac{ad}{bc}$$

The p Value – and Type I Error

- The alpha level is denoted with a p valueA typical value would be $p < .05$
- “the probability that the difference occurred by chance or randomly, is only 5%”
- “we are 95% sure the difference is a true difference”
- $p < .01$ “there is a 1 in 100 chance”

A Knowledge Transfer Story

....circa 1747 (Source: Maureen Dobbins)

**Time Elapsed from Lancaster to Adoption:
264 years**

1497	1601	1747	1795	1865
Vasco da Gama rounds Cape of Good Hope to find sea route to India. Of the 160 crew, 100 die of scurvy	Captain Lancaster sails with 4 ships; Crew #1 given 3tsp lemon juice daily	Dr. James Lind conducts random trials of six treatments for scorbatic sailors	British Navy orders citrus fruit in diet for sailors	British Board of Trade orders citrus on merchant marine vessels
