400864 – Research Methods: Quantitative and Qualitative

Week 1 – The Information Supermarket:

Health Practitioners:

- Need to know which treatments
- Know causes and risk factors for health conditions
- Diagnose accurately
- Keep up to date, e.g. with new treatments
- Resolve disagreements about practice and policy
- Base clinical decisions on good evidence
- Need to know about new problems, current knowledge is inadequate
    - Aging population → more chronic, disabling degenerative disorders; fewer acute, quickly curable disorders
    - Role for allied health professionals helping people with chronic disorders; rehabilitation rather than a cure
- **Research: Finding answers to really difficult questions**
- **Evidence-based practice: Putting the answers to work**

Evidence-Based Practice (EBP):

- All reputable health professions are now evidence-based
- Treatments and policy should have prior **empirical basis**
    - **Empirical: Based on experiment, observation and experience**
    - Not just a theory
- Before doing something, what's the evidence for it?
    - Will plain packaging for cigarettes reduce smoking?
    - Will poker-machine pre-commitment reduce gambling?
- **EBP uses existing research rather than doing new research**

Information, Evidence and Research:

- **Information:** Knowledge, data and facts
- **Evidence:** Information used to assist decisions
    - Information about the world – empirical
    - How to apply evidence is just as important as knowing it
- **Research:** Process of finding or collecting information
    - Understand existing knowledge
- To understand evidence:
    - Need to know how that evidence is found
    - Types of research questions and how they are answered
    - How research results are communicated

Limits to Knowledge:

- Differences of opinion
    - Leads to different clinical or policy decisions
    - At least one person could be wrong → bad decisions
- Can't rely on:
    - Hunches – "seems right"
    - Traditional practice – "how it has always been done"

  - Authority – “just following orders”
  - Biased, ambiguous or false information
- ***Aim for reliable knowledge that works***

Understanding the Evidence:

- Need to know how the research is done to better understand it
- Can only evaluate the quality of evidence if:
  - Interpretation is known
  - Common problems, e.g. bias, are known

PICO:

- Population – e.g. post-operative inpatients recovering from total knee replacement surgery
- Intervention – e.g. footstool
- Comparison – e.g. no footstool
- Outcome
- Boolean operators: AND, OR, NOT
- Wildcards: ?, *

Quality of Evidence – NHRMC (2009):

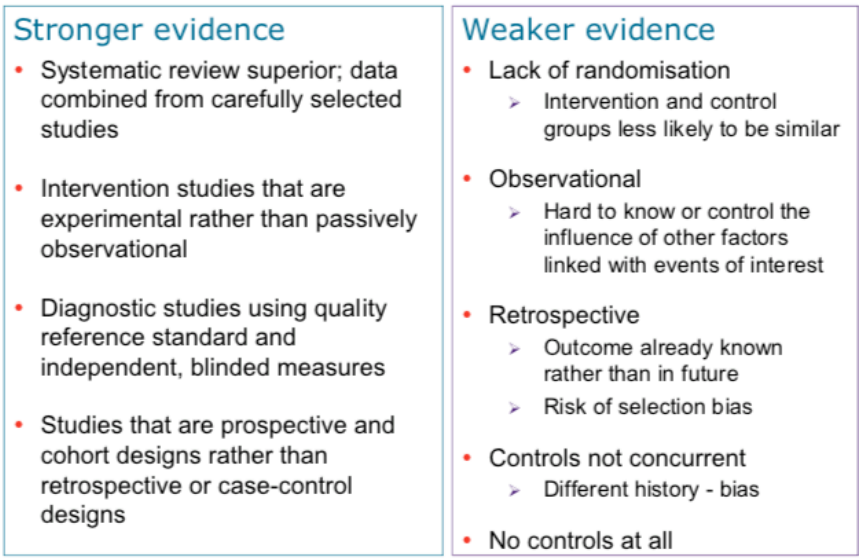
- Five evaluation criteria for developing evidence-based recommendations or guidelines:
  1. Evidence base
  2. Consistency of the evidence
     - Results should agree across a range of studies
     - Differing results mean we are unsure whether results will generalise to clinical setting
  3. Clinical importance
     - Relevance of the evidence to clinical question
     - How long the benefit lasts
     - Cost-effectiveness
     - Risks as well as benefits
  4. Generalisability
     - How well people and setting match up to the target population
     - Better match between study population and target population – representative sampling
  5. Applicability
     - Whether evidence base is applicable to Australian health care system – equipment, cultural factors, characteristics

Grades of Recommendations:

A. Body of evidence can be trusted to guide practice
B. Body of evidence can be trusted to guide practice in most situations
C. Body of evidence provides some support for recommendations, but cause should be taken in its application
D. Body of evidence is weak; recommendation must be applied with caution

Levels of Evidence:

- **Level I: Systematic Reviews**
  - Combine results across at least two eligible studies of similar design and topic
  - Unit of analysis is the individual study – "study of studies"
  - Level I studies, if reviewed, are level II, "as high as studies it contains"
- **Level II: Randomised Control Trials**
  - Treatment and concurrent control groups with subjects randomly assigned
- **Level III-1: Controlled Trials Without Truly Randomised Allocation**
  - Treatment and control groups but using an approximately random method
- **Level III-2: Comparative Study with Concurrent Control Group**
  - Controlled measured concurrently as intervention or cases but without random allocation to groups
- **Level III-3: Comparative Study Without a Concurrent Control Group**
  - Intervention and control conditions could have occurred at different times
- **Level IV: Case Series with No Control Group; Treatment Group Only**



Levels of Evidence and Evidence Quality:

- Higher NHMRC level is better
- Level II are the best for single studies of interventions (treatments), diagnostic accuracy, aetiology or prognosis
- Systematic reviews = Level I if the studies are level II, else at the level of the individual studies reviewed
- Level of evidence is not identical to evidence quality
  - Just because there is a high level of evidence doesn't necessarily make it a good study
  - Poorly conducted randomised controlled trial may be no better than a well conducted comparative study

Need to Evaluate Evidence Quality:

- Quality of measurement – valid and reliable (unbiased)?
- Research design – risk of bias with weaker designs
- Analysis and interpretation
  - Unbiased interpretation, reasonable and logical?
  - Appropriate to research aims and type of data?
- Need to understand measurement, design and analysis so it can be properly evaluated
- Clearly presented and explained – quality reporting

Quality of Evidence:

- NHMRC now using **GRADE** system:
  - **G**rading of **R**ecommendations, **A**ssessment, **D**evelopment and **E**valuation
- Used for developing clinical practice guidelines
  - "Statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options"

GRADE System:

- Clear question – PICO
- Importance of outcomes – how well the study was done
- Study design
- Consideration of treatment context – how, where and with whom treatment was used
- Factors that affect quality of evidence
- Evidence accessible to busy clinicians

Quality of Evidence – GRADE System:

- Study limitations – design and procedures
- Consistency of results – within and between studies
- Directness of evidence:
  - **Direct:** Two treatments compared in the same study
  - **Indirect:** Two treatments each compared with placebo in separate studies – not as good as direct
- Precision of estimates of how well treatment works
- Bias in choice of publications, selective publication
- Size of the effect
- Possible confounding factors confusion the results
- "Dose-response gradient" – how much treatment for a given amount of benefit?

GRADE Quality of Evidence Ratings:

- *About whether further research will change our opinions*
- **Treatment effect = measure of change from treatment**
- High – further research **unlikely** to change confidence in estimate of treatment effect
- Moderate – further research **likely** to importantly change confidence in estimates of effects, may change estimate of effect sizes

- Low – further research **very likely** to importantly change confidence in estimates of effects, may change estimate of effect sizes
- Very low – estimate of treatment effect very uncertain

GRADE Recommendation Ratings:

- *Strength of recommendation*
- **Based on evidence quality and these other factors**
  - Desirable and undesirable effects of treatment
  - Whether we understand patients' values and preferences
  - Whether intervention is cost effective
- Strong – considerable certainty that benefits of intervention do or do not outweigh risks, burdens and costs
  - Most patients would choose recommended management
- Weak (Discretionary) – benefits and risks finely balanced
  - Uncertainty about magnitude of effect sizes (treatment effects)
  - Informed patients may make different choices, based on values

Quality of Research Reporting:

- How well research is reported – different to how well research is done
- **CONSORT** statement – clinical trials
- **STARD** statement – diagnostic accuracy studies
- **PRISMA** statement – systematic reviews

Good Research:

- Builds on earlier work
- Is intellectually honest and ethical
- Results are true and consistent – validity and reliability
- Can be generalised
- Is based on sound reasoning and logic
- Investigates why things happen – not just what happens
- Has a useful outcome
  - Gain in knowledge, new ideas, insight
  - Addressed a practical problem – real world applications
- Can be replicated

Robot Healthcare:

- Mechanical mindset:
  - All action and no thinking
  - Works by habit
  - Ignores new evidence
  - Can't explain why things are done
  - Can't deal with uncertainty
  - Super confident
  - Nothing more to learn
  - Externalises responsibility – can always blame the patient

Reflective Healthcare:

- Action and thought
- Observant and aware

- Knows limits to knowledge
- Confident because knows decisions are informed
- Searches for answers and can evaluate evidence

Relevance:

- Effectiveness of treatments – clinical trials
- Effectiveness of clinical test – diagnostic studies
- What will happen if left untreated? – prognostic studies
- Causes of health disorders – aetiological studies
- Identifying groups at-risk of disease – epidemiological

Quantitative Research:

Intervention studies

- Researcher sets up what happens to subjects — tries to affect outcomes
- Includes *experimental designs*
  - Randomised controlled trials
  - Pseudo or non-randomised controlled trials; sometimes called "quasi-experiments"
  - Subjects in at least two groups receive treatments, placebo or none
  - Outcomes measured *before* and *after* treatments, placebo or none
  - Change in outcome compared for treatments, placebo or none
  - Investigate cause and effect
    - Whether treatment causes expected outcome (effect)
    - Whether drinking caffeinated coffee improves memory more than decaf.

Observational studies

- Researcher doesn't set up what happens — natural, not artificial
- Looks at associations between events or personal characteristics
  - Books at home and children's education (Evans et al., 2010)
- Includes:
  - Epidemiological studies in general
  - Descriptive studies
    - Case reports
    - Surveys, e.g., % who smoke
- Useful when intervention study is impractical or unethical
- Less able to show cause and effect

Systematic reviews

- Studies of studies, combining data

Qualitative Methodologies:

- Qualitative research
  - Range of methodologies
  - Investigates human experience
  - Interprets experience in social and political context
  - Acceptance of subjective reality, rejects "single reality"
  - Others' reality seen "as it is"
  - Rejects scientific method
  - Conclusions specific to time and place: context dependent
- Not "scientific" research

Examples

- Living with a disability that makes you depend on others
- What it's like to lose an ability
- Caring for a sick relative
- How problem gamblers perceive their own addiction
- "Lived experience" of a movie star *or* a homeless person
- What's it's like to drive an ambulance on Friday nights
- What it's like to have an alcoholic parent