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# RESEARCH METHODS – INTRODUCTION

## PROF BEVERLEY GLASS

Research Methods as Foundations for Evidence-based  
Practice in Health

What is Ethical Research?

# BACKGROUND

- *“Knowledge is essential to human survival”*
- Acquiring knowledge – best done through research findings using research methods
- Knowledge generates evidence, which can be used in practice
- Two complementary research approaches
  - Qualitative – descriptive methods of data collection (words, diagrams, drawings )
  - Quantitative – quantification in collecting and analyzing data
    - Descriptive and inferential statistical analyses

*“Evidence is information to be used to support and guide practices, programs and policies in health and social care to enhance the health and well being of individuals, families and communities”*

# BACKGROUND

- Evaluating evidence- model of Evidenced-based Practice (EBP) – hierarchical ranking system according to research design
  - Randomized control trial (RCT) and /or systematic review of RCTs
- EBP emerged from a long standing commitment – health practitioners
  - Change in the way research and practice are related ( Research then Practice)
  - In EBP – many of the practice questions resemble the essential parts of research questions
  - Current GAP- EBP and its application to certain population groups
  - Evidence should not be based solely on RCTs - examples
    - Ethnic minorities, indigenous groups, migrants and refugees, LGBTIQ+ and rural communities

# BACKGROUND

- Evidenced-based Medicine (EBM) – patient and scientific perspectives
- Research Designs – Which one?
- Researchers are interested in how individuals within a specific social group perceive health and illness
  - Which design and Why?
- Researchers are interested in finding the causes of a health problem or prevalence e.g. the rate of diabetes in Australia
  - Which design and Why?
- Important to consider the nature of then topic and the individuals being researched

## CASE STUDY

John is a podiatrist who treats athletes for foot injuries. Although he has treated a lot of athletes he does not know the prevalence of these injuries in his area and it seems to be that they are often associated with sporting events in the area. In order to inform his practice and assess the need to provide such services, John needs to have a better grasp of the actual prevalence of these injuries.

John has also noticed that some of the athletes are non-adherent in terms of his advice despite the fact that he follows recommendations, which he gained from systematic review of the literature and he wonders why this is the case. John would like answers to both of these questions

- If you were John how would you go about your research in order to find the evidence you need?

# BACKGROUND

- Ontology and Epistemology are positions underlie - research is undertaken
- What is an Ontological Approach to Research ?
  - Standpoint of objective reality and detachment and ensure a bias-free approach
    - Quantitative approach to the research – reality can be accurately captured
- What is Epistemology?
  - Nature of knowledge and how it is obtained
  - Can the social world be studied according to the same procedures, principles and ethos as the natural sciences?
  - Epistemological paradigms explain the nature of knowledge
    - Two paradigms constructivism and positivism - qualitative and quantitative approaches

# BACKGROUND

- Constructivism – reality is socially constructed
  - Reality is shaped by social factors, researchers are actively involved necessitating use of research methods, which allow people to articulate the meaning of their social realities – qualitative approach
- Positivism – objective reality that can be assessed
  - Reality is viewed as being independent of experiences , striving towards measurability and objectivity and studies undertaken can be duplicated – quantitative approach
  - Traditional research methods – influenced by scientific positivism
- Pragmatism – popular amongst health researchers
  - Reality exists somewhere between natural and physical and psychological and social
    - Employ a combination of methods to best answer research questions

# COMPARING QUALITATIVE AND QUANTITATIVE

- Words
- Participants' points of view
- Meaning
- Contextual understanding
- Rich, deep data
- Unstructured
- Process
- Micro
- Natural settings
- Theory emergent
- Researcher close
- Numbers
- Researcher's point of view
- Behaviour
- Generalization
- Hard, Reliable data
- Structured
- Static
- Macro
- Artificial settings
- Theory testing
- Researcher distant



# MIXED METHODS

- Differences between quantitative and qualitative methods – trade-off between breadth and depth
- To combine depth and breadth – Mixed Methods research
  - Qualitative and Quantitative Methods – focus group and questionnaire
- Different ways to combine methods:
- Triangulation – qualitative research to confirm the findings from quantitative research-vice versa
- Facilitation – one research approach used in order to facilitate research using the other approach
- Complementary – different aspects of an investigation are articulated using the two approaches

# RESEARCH RIGOR

- Research approaches have criteria to evaluate rigor (authenticity/credibility/strength)
- Qualitative Research
  - Trustworthiness – quality of the qualitative enquiry
    - Findings are authentic enough for practitioners to act on with confidence
- Quantitative Research
  - Reliability – stability of the findings
    - Consistence and Trustworthiness
  - Validity (Internal and External) – truthfulness of the findings
    - Integrity
    - Internal ( methods investigates what it purports to investigate) and external (results generalized)

# RESEARCH RIGOR

- Some criteria to judge trustworthiness of this research:
  - Credibility relates to the question “*Are these findings truthful?*”
  - Transferability – *Can these findings be generalized?*
  - Dependability – *Do the research findings fit that data that have been collected?*
  - Confirmability – *Has the researcher allowed his or her values to intrude?*

# SAMPLING METHODS

- Probability Sampling
  - Probability of research participant being selected is known in advance – quantitative research
  - Intent – generalize findings to the population from which sample taken
  - Simple random, systematic random, stratified random and cluster random sampling
- Non-Probability Sampling
  - Likelihood of participants being selected not known in advance
  - Not representative and cannot be generalized to a larger group of people
  - Research not involving large populations and qualitative research projects
    - Interested in not how much or how many by WHAT?

# SAMPLING METHODS

- Purposive sampling (used in Qualitative Research )
  - Deliberate selection of individuals because of the crucial information they can provide not available through other channels
  - Strength of this method of sampling –selecting “information-rich cases”
- Convenience sampling (conveniently available and willing to participate)
  - When to be used – require individuals who meet specific criteria e.g. age, gender, ethnicity or social class

# SAMPLE SIZE

- Qualitative Research
  - Select participants meaningfully and strategically
  - Does the sample provide data that will allow a research question to be answered
  - Flexibility and depth to data saturation
- Quantitative Research
  - Large samples
  - Must consider – degree of confidence required, the homogeneity of the population, the complexity of the analysis, expected strength of the relationships they will measure
  - Sample size can be estimated
    - Existing tables, relevant formulae, statistical power analysis method

**END of Lecture 1**

# WHAT IS ETHICAL RESEARCH?

- Researchers in health rely on members of public accepting invitations to be involved in research
- Need to carry out research in a way that supports this outcome
- QUESTION – how, rules, acting in a moral and ethical way = research ethics
- Terminology:
  - Research participant – person who agrees to take part in a study on equal terms
  - Equality of power in relationship requires freedom that is
    - Autonomy and Will to choose to participate

# WHAT IS ETHICAL RESEARCH?

- Covert or disguised research
  - Does not allowed informed consent
  - Disguise and deception
  - Invasion of privacy – but anonymity assured ( what is the difference with confidentiality )
- Four key ethical principles
  - **Respecting autonomy**- persons making an informed decisions about being involved
  - **Beneficence** – obligation to provide benefits
  - **Non-Maleficence** – avoiding bad intentions
  - **Justice** – benefits, risks and costs equally distributed



# APPLYING ETHICAL PRINCIPLES

- Australia – Medical Council’s Statement on human experimentation was issued in 1966
- National Health and Medical Research Council (NHMRC, established 1992)
- National Statement on Ethical Conduct in Human Research (2007 – updated in 2018)
- Human Research ethics Committee (HREC)
- Carry knowledge and expertise of the merits and standard that apply across paradigms and groups to make fair and just decisions and do so with due process
- NHMRC Guidelines for the makeup of Ethics Committees
  - Researchers
  - Health and social care professional
  - Lawyer ; Lay members
  - Someone with a pastoral role in the community
  - Balance of men and women

# APPLYING ETHICAL PRINCIPLES

- Application to an HREC – submit a research proposal (2008 Helsinki Declaration)
- Article 12 – research must conform to generally accepted scientific principles
- Article 14- design of the research study described in research proposal
- WHY- poorly designed study is by definition unethical
- Research Protocol for Ethics
  - Review of the literature
  - Statement of the study's aims
  - Sample numbers and means of recruitment
  - Research tools being used as well as the approach to analysis
    - Consideration of Ethical Issues

# APPLYING ETHICAL PRINCIPLES

## Case study

A new cancer drug is being tested. The researchers have proposed a double-blind randomized controlled trial

## Question

Is there anything ethically questionable about the above research?

# APPLYING ETHICAL PRINCIPLES

- Thinking about the potential risks in a research project (*Ethics committees will consider the seriousness of the risk the probability of occurrence and the strategies to minimize risk*)
- *HEALTH – Injury to body*
- *PSYCHOLOGICAL – Stress*
- *TO THE COMMUNITY – Disproportionate impacts on marginalized groups or sensitive areas*
- Harm can also be produced by the way in which data is collected, stored and then published
  - Data collected done to protect identities
  - Transcript data de-identified
  - Data stored in locked filing cabinets and on password-protected computers
  - Publication identity of participants even if names are not used

# APPLYING ETHICAL PRINCIPLES

- Some potential benefits accruing from research study
- To knowledge
- To the participant
- To the public good
- AUTONOMY

*A part-time PhD student runs and counselling service and has developed a new method of working with clients – she want to evaluate this new method and has submitted an ethics application. Participants are receiving the treatment free as long as they agree to a questionnaire , battery of health measures every two week and interview at the end. ( cost of 8 sessions \$ 720)*

- *Discuss the ethics of the above scenario*

# APPLYING ETHICAL PRINCIPLES

- Autonomy- important is the understanding of the research in making a decision to participate
- Required to produce a plain language statement that outlines the study in lay language
- INFORMATION SHEET
  - Project's title and aims, investigators , rights of participants , including the right to withdraw from the study, what is expected, the risk and relevant safeguards, benefits of the research, to whom complaints or questions should be addressed
- CONSENT FORMS
  - Statements or tick boxes in which participants say that they have
    - Read the plain language
    - Understand confidentiality and anonymity issues
    - Recognize that they have the right to withdraw from the study
    - Understand that the researcher commits to keeping the data secure

# APPLYING ETHICAL PRINCIPLES

- AUTONOMY – sensitive topics and vulnerable groups
  - Topics which touch deep emotions
  - Areas which are culturally taboo
  - Topic threatening powerful interest
- AUTONOMY – risk and vulnerability
  - Vulnerable people – difficult to understand language and concepts of research
  - In-house ethics procedures
  - Ethics Committees identify level of risk for vulnerable populations
    - E.g. children, indigenous populations etc.
    - Danger – identify the whole group as high risk = paternalism and stereotyping

# SUMMARY

- Framework for Ethical Regulation – a long way since the Helsinki declaration
- <https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/>
- SOME ISSUES
- Extent to which regulation is necessary
- Participants
- Researchers
- DISCUSSION

END of Lecture 2