Research Education Seminar Series

Lecture 1

Alex Stephens, PhD, Director of Research

Basic outline

1. *Research Overview*

- Overarching aims of the research office
- Why do we engage in research?
- Simplified research framework
- Research translation framework
- Evidence-based practice pyramid

2. *Robust study design*

- Epidemiological methods – study designs
- Key elements of study validity and critical appraisal
- Measures of association
- Determining sample size – power analysis

3. *Analysis*

- Basic biostatistical methods and analysis

4. *Writing for research*

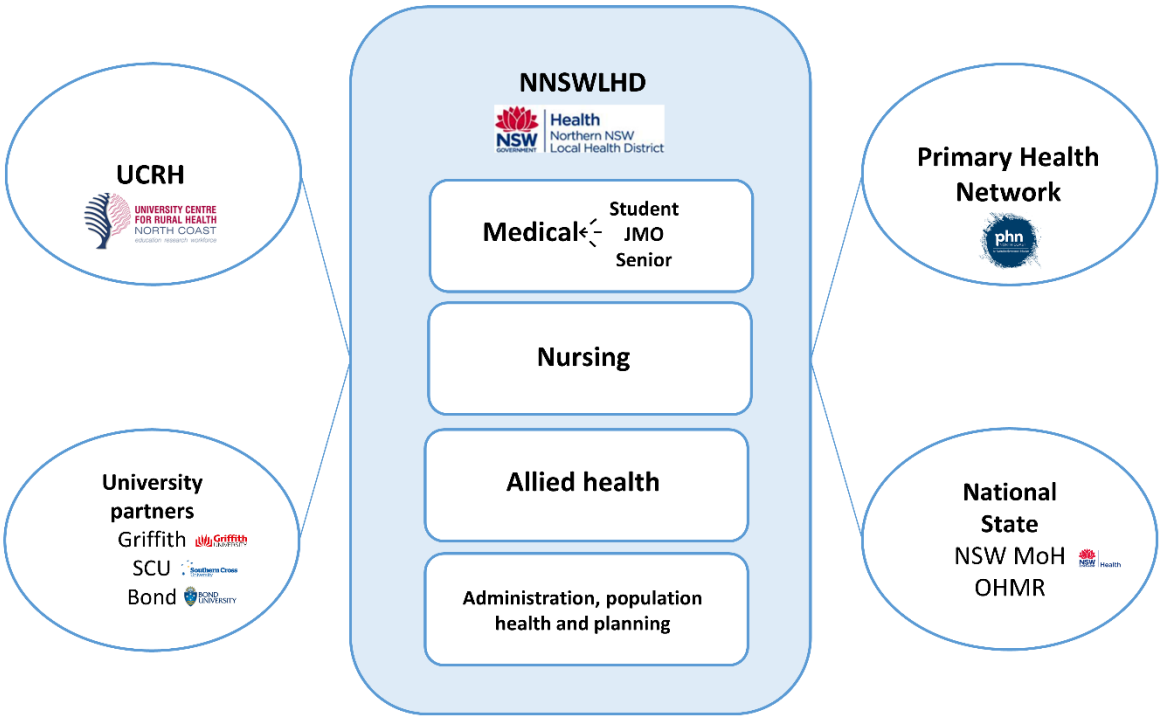
- Writing grants, papers and scientific presentations

5. *Ethics, governance and software*

- Research ethics and governance
- Research software

Aims of the research office

First, let's consider our structure – simplified version



Facilitating and empowering research

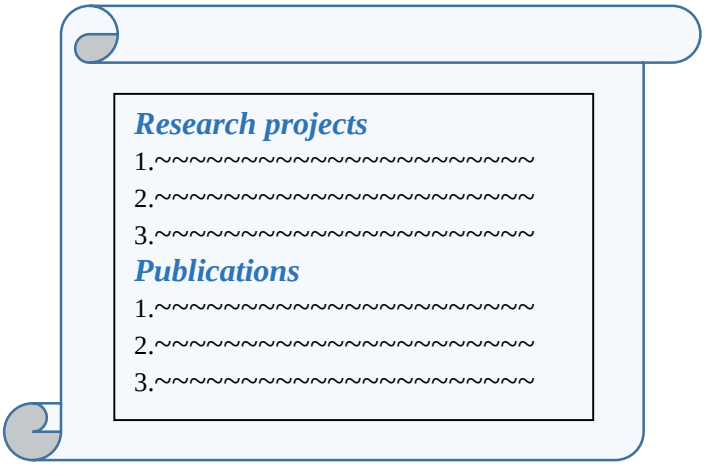
- Foster an environment and culture that supports research and is backed by executive/senior management (establish steering committee, strategic plan)

RESEARCH STRATEGIC PLAN

- LHD investigator led research
- Health services research
- Population health research
- Health services and models of care in rural settings

- Address research barriers (e.g. lack of time, funding, support) → research survey, research register

RESEARCH RESGISTER



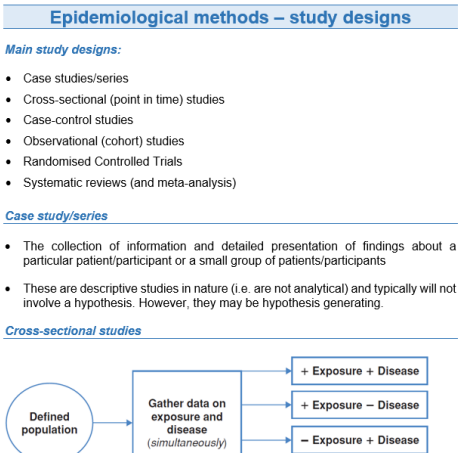
- Celebrate and recognise high quality research → research day

RESEARCH SYMPOSIUM

A day where we can come together with our University and Research partners to celebrate our research achievements and see some great presentations from local researchers

- Training and resources (e.g. basic research/scientific method, study design/power analysis, data collection and management, biostatistical analysis)

RESEARCH TRAINING AND RESOURCES



Epidemiological methods – study designs

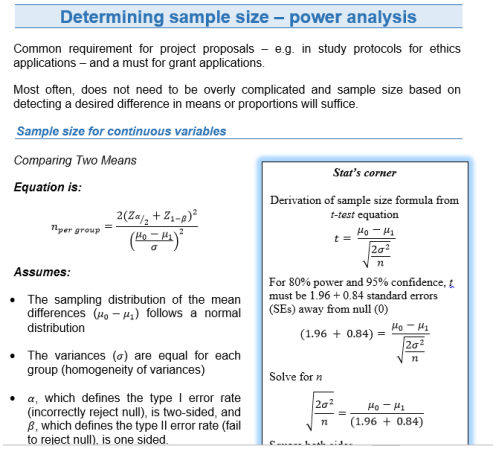
Main study designs:

- Case studies/series
- Cross-sectional (point in time) studies
- Case-control studies
- Observational (cohort) studies
- Randomised Controlled Trials
- Systematic reviews (and meta-analysis)

Case study/series

- The collection of information and detailed presentation of findings about a particular patient/participant or a small group of patients/participants
- These are descriptive studies in nature (i.e. are not analytical) and typically will not involve a hypothesis. However, they may be hypothesis generating.

Cross-sectional studies



Determining sample size – power analysis

Common requirement for project proposals – e.g. in study protocols for ethics applications – and a must for grant applications.

Most often, does not need to be overly complicated and sample size based on detecting a desired difference in means or proportions will suffice.

Sample size for continuous variables

Comparing Two Means

Equation is:

$$n_{per\ group} = \frac{2(Z_{\alpha/2} + Z_{1-\beta})^2}{\left(\frac{\mu_0 - \mu_1}{\sigma}\right)^2}$$

Assumes:

- The sampling distribution of the mean differences $(\mu_0 - \mu_1)$ follows a normal distribution
- The variances (σ) are equal for each group (homogeneity of variances)
- α, which defines the type I error rate (incorrectly reject null), is two-sided, and β, which defines the type II error rate (fail to reject null), is one sided.

Stat's corner

Derivation of sample size formula from *t-test* equation

$$t = \frac{\mu_0 - \mu_1}{\sqrt{\frac{2\sigma^2}{n}}}$$

For 80% power and 95% confidence, t must be 1.96 + 0.84 standard errors (SEs) away from null (0)

$$(1.96 + 0.84) = \frac{\mu_0 - \mu_1}{\sqrt{\frac{2\sigma^2}{n}}}$$

Solve for n

$$\sqrt{\frac{2\sigma^2}{n}} = \frac{\mu_0 - \mu_1}{(1.96 + 0.84)}$$

- Engage with our University and research partners including the University Centre for Rural Health (UCRH), Southern Cross University, Griffith University and Bond University → link to researcher profiles; share LHD register of research

RESEARCH PARTNERS

University Centre for Rural Health North Coast – education research workforce

Southern Cross University

Griffith University

Bond University

NSW Government Health – Northern NSW Local Health District

NSW Government Health

cancer institute NSW

Clinical Excellence Commission

ACI NSW Agency for Clinical Innovation

Why should we engage in research?

There is a clear directive in Australia to promote and embed high quality research in health services as evidenced by:

- The recommendations of the "Strategic Review of Health and Medical Research in Australia – Better Health" – otherwise known as the McKeon Strategic Review
- The National Health and Medical Research Council's (NHMRC) recognition of Advanced Health Research & Translation Centres (AHRTC) and Centres for Innovation in Regional Health (CIRH) – academic science super centres of high calibre research capacity and translation (potential)

These centres, among which a number are recognised in NSW, have comprehensively demonstrated their capability to develop, lead, conduct and translate health and medical research into policy and practice as part of their applications to be recognised by the NHMRC. Therefore, these centres probably have amongst the highest levels of research capability and capacity throughout the country.

The Sydney Partnership for Health, Education, Research & Enterprise | Maridulu Budyari Gumal

SPHERE → major partners include UNSW, SESLHD, SWSLHD, UTS & UWS

Sydney HealthPartners

Sydney Health partners → major partners include The University of Sydney, SLHD, NSLHD and WSLHD

NSW REGIONAL HEALTH PARTNERS
CENTRE FOR INNOVATION IN REGIONAL HEALTH

NSW Regional Health Partners → major partners include The University of Newcastle, HNELHD, MNCLHD and CCLHD

Research as a pathway for continual improvement

We also engage in research to challenge the ways in which we do things and ask questions such as: is this the best way to do this? And can we improve on current practice and models of care? → research facilitates engagement in the science of improvement and constructive change

Benefits of embedding research in health services

It is widely accepted that embedding research in health systems has many benefits,[1–5] including:

- Advancing knowledge of health and disease
- Identifying novel treatments and models of care
- Improving patient health outcomes and reducing mortality
- Building a culture of quality and excellence
- Reducing low-value care (waste) and adverse events
- Promoting more rapid uptake of new evidence and therapies
- Driving a culture of evidence-informed practice
- Providing a sense of contribution to improved care for other/future patients by clinicians and patients

1. McKeon, S. *et al.* Strategic Review of Health and Medical Research. (2013).
2. Boaz, A., Hanney, S., Jones, T. & Soper, B. Does the engagement of clinicians and organisations in research improve healthcare performance: a three-stage review. *BMJ Open* **5,** (2015).
3. Krzyzanowska, M. K., Kaplan, R. & Sullivan, R. How may clinical research improve healthcare outcomes? *Ann. Oncol. Off. J. Eur. Soc. Med. Oncol.* **22 Suppl 7,** vii10-vii15 (2011).
4. Ozdemir, B. A. *et al.* Research activity and the association with mortality. *PloS One* **10,** e0118253 (2015).
5. Downing, A. *et al.* High hospital research participation and improved colorectal cancer survival outcomes: a population-based study. *Gut* **66,** 89–96 (2017).

Simplified research framework – the scientific method

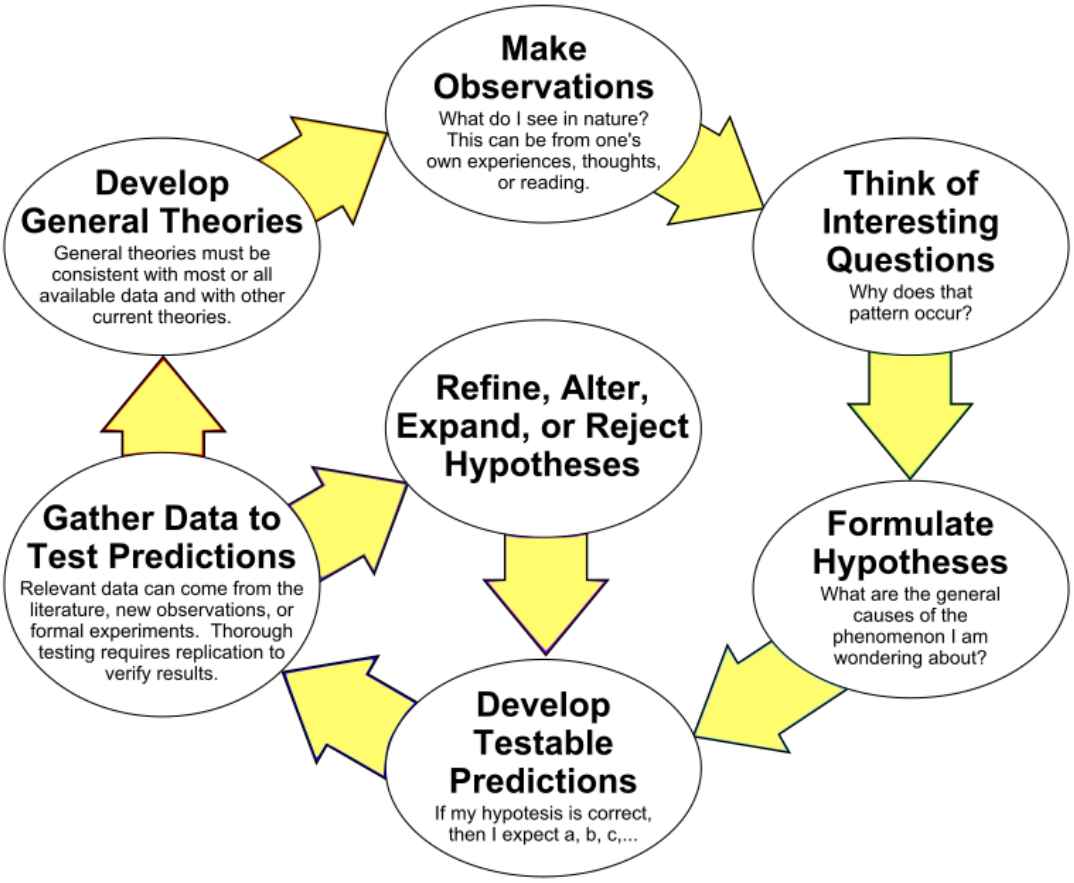
What is research? And how do we go about doing it? – Research is a formalised process of discovery or knowledge creation underpinned by the scientific method

Research idea	**Hypothesis development**	**Research method (study design)**
What is the prevalence of sexual dysfunction in women attending an oncology outpatient clinic for cancer therapy?	There is a high prevalence of sexual dysfunction in women receiving cancer treatment	Survey of women receiving cancer treatment
Data collection	**Analysis**	**Interpretation & write up**
Conduct surveys in oncology clinic	Descriptive analyses of the prevalence of sexual dysfunction by important variables (e.g. type of cancer, stage, age, treatment)	Does the prevalence and type of dysfunction inform future policy/health care to address problem?

Sits at the core of every good research project and is the first step in developing a research project

Take 5 min to consider a potential project and see whether you can write to each of the components

The Scientific Method as an Ongoing Process



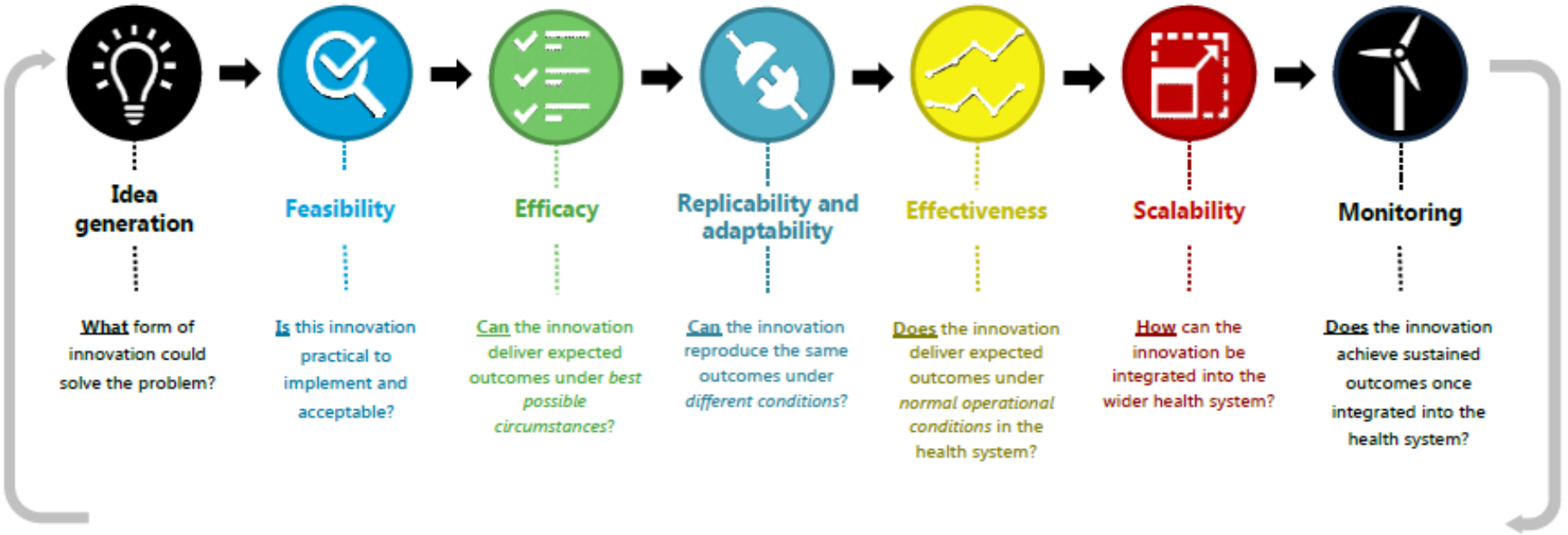
Source: Wikipedia (https://en.wikipedia.org/wiki/Scientific_method)

A more detailed example from a highly reliable source!

Defining the scientific method (Nature Methods Editorial 2009) – suggests that the emergence of mass data – omics on various platforms and big data e.g. hospital data – has changed researchers' approach to conducting studies, and now does not necessarily rely on developing hypotheses. Research can be large scale, descriptive studies on patterns and correlations which are, themselves, hypothesis generating.

Research Translation Framework

In the current environment, where there is a major focus state wide and nationally to drive and embed high quality research in health services, research takes on a central role → it is now, more than ever, recognised that investment in research (e.g. in-kind, financial) must lead to better returns on investment (e.g. more efficient services, improved health outcomes) and embedding research in health services has been judged as the way to achieve this. Having a framework that directs research to a translatable outcome helps increase the return on investment by increasing the likelihood of the research being used for a tangible purpose.



Source: *Translational Research Framework* (Sax Institute)

Most commonly, research has been conducted in the first 3 parts of this framework

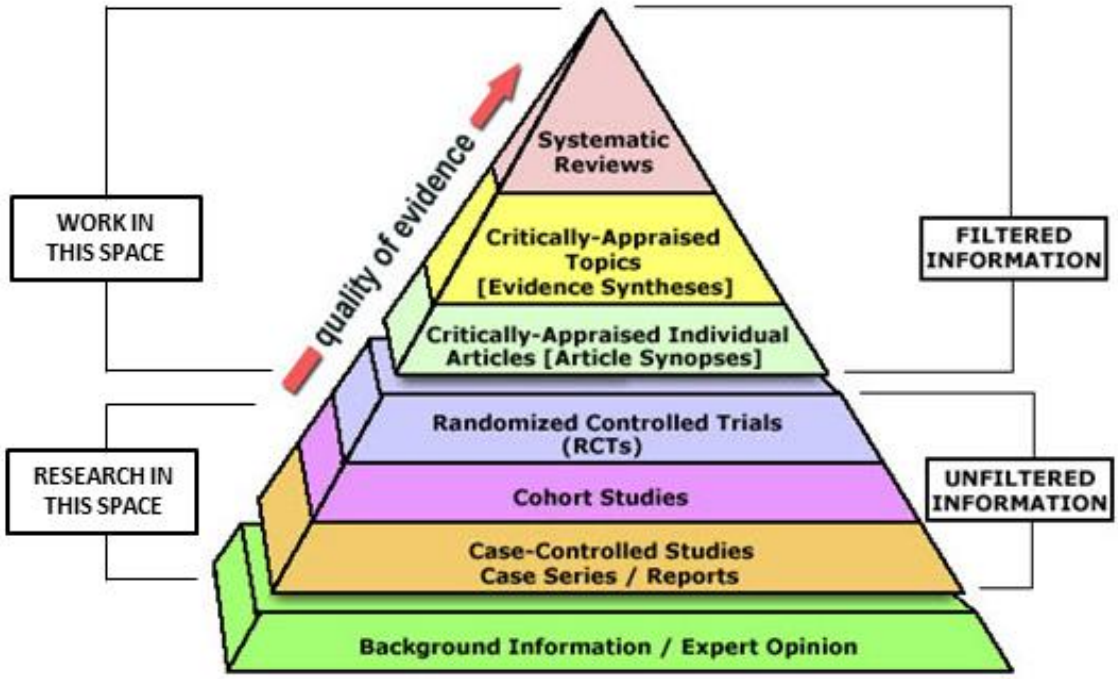
- idea generated to address a problem or improve current practice → Idea
- test the idea by conducting a study and collecting data → Feasibility
- analyse the data to determine if the idea (intervention) worked → Efficacy

At this point, a paper is written and eventually published, and everyone is happy (academic career model?)

However, at both national (e.g. NHMRC) and state (e.g. Office for Health and Medical Research) levels, there is now a strong emphasis on continuing through the research translation pipeline.

For example, the NHMRC have now recognised a number of **Advanced Health Research and Translation Centres** (AHRTCs) (e.g. Sydney Health Partners, Sphere), which are large collaborative teams consisting of multiple LHDs, Universities and Medical Research institutes. Larger sums of funding will soon start flowing to these AHRTCs from the Commonwealth government via the **Medical Research Future Fund** (MRFF), and will hopefully fund high quality, priority research projects with a focus on translation.

Evidence-based practice: Levels of the Evidence Pyramid



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Filtered information

- Also called secondary evidence or appraised evidence, and is evidence collected and summarised from a number of primary studies
- For systematic reviews, often the aim is to include all relevant studies on a particular topic that meet the inclusion criteria
- The Cochrane library and health and medical databases including MEDLINE and PubMed are excellent sources for finding this level of evidence

Unfiltered information

- Also called primary evidence, and is obtained from original research studies including controlled trials, cohort studies, cross-sectional (descriptive studies), case-control studies, and case series/reports
- Primary information can be found in health and medical journal databases (e.g. PubMed, MEDLINE), The Cochrane Library (particularly the Central Register of Controlled Trials), the NIH National Library of Medicine Clinical Trials Database, and the Australian New Zealand Clinical Trials Registry (ANZCTR)