



Metro North Hospital and Health Service Putting people first

09 February 2021 | Live via Teams

Introduction to Clinical Research Principles

Problem definition: formulating clinical research questions to address knowledge gaps

via Teams

Facilitated by Professor Janet Davies
 MNHHS Office of Research
 MNHHS-Research@health.qld.gov.au



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Sponsors



Faculty of
Medicine



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Agenda

Part 1 Introduction (15 min)

Janet Davies

Part 2 Clinical research examples (10 min each)



Nicholas Green

Bachelor Industrial Design
Masters Engineering (Research)
Senior 3D Medical Modeller,
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Amanda Corley

Bachelor Nursing, Master Adv Practice
Health Care Research
PhD candidate
Research Fellow (Vascular
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Nicole Marsh

Bachelor Nursing, Master Adv
Practice
Director of Research, Nursing
& Midwifery,
Director Clinical Trials,
Adj Assoc Prof Griffith Uni,
QUT

Part 3 Panel Discussion (10 min)

What's next & session close

Please do not mention any confidential details of patients or research.

Teams Virtual session,

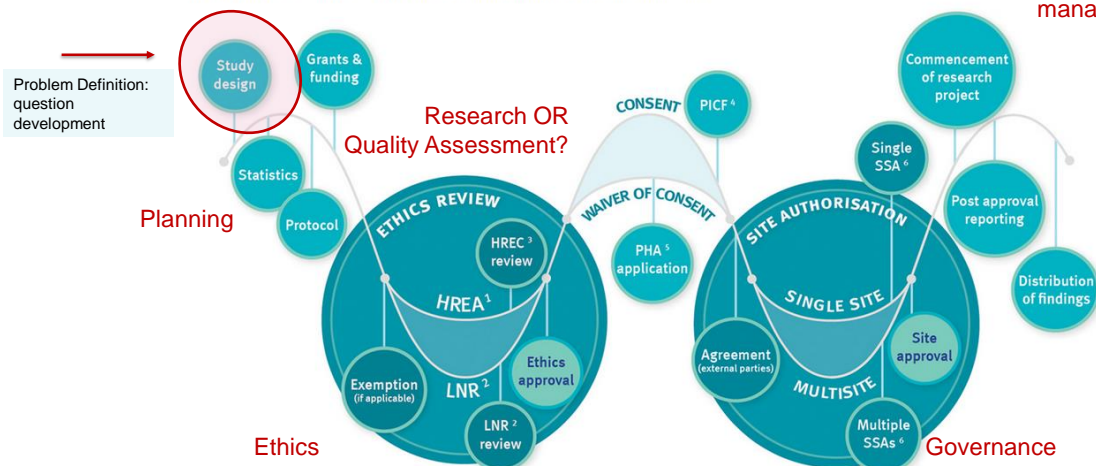
Facilitated by Prof Janet Davies, MNHHS Office of Research MNHHS-Research@health.qld.gov.au

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Research process

Key steps in the research approval process are shown in the diagram below.



Note: the above diagram does not represent proportional time spent in each stage. ¹ Human Research Ethics Application (HREA), ² Low or negligible risk (LNR), ³ Human Research Ethics Committee (HREC), ⁴ Participant Information and Consent Form (PICF) - requires ethics review, ⁵ Public Health Act (PHA), ⁶ Site Specific Assessment (SSA).

<https://metronorth.health.qld.gov.au/research/ethics-and-governance>

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Clinical research education resources and tools


<https://metronorth.health.qld.gov.au/research>

<https://qheps.health.qld.gov.au/metronorth/research/education-resources>

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Metro North Research Education Series

Digital Clinical Research Education Resources



This page has links to short videos of question and answer interviews on introductory topics related to core principles for clinical research.

[View the videos](#)

The MNHHS Research Education Webinar Series is a series of online educational videos focusing on practical educational topics for researchers.

[View the videos](#)

Introduction to Clinical Research Principles

Files with presentation slides from sessions on topics related to basic principles and processes for undertaking clinical research.

[Read more](#)

Advanced Topics in Clinical Research

Files with presentation slides from sessions on advanced topics on understanding and communicating clinical research outcomes and translation of research knowledge into practice.

[Read more](#)

Interactive Research Workshops

Files with presentation slides and template documents from facilitated and peer to peer interactive research workshops aimed at consolidating learning and embedding research principles into clinical settings.

[Read more](#)

Clinical research education videos

Download a question and answer interview on introductory topics related to clinical research.

After watching these videos, please fill out our survey. Your feedback will help us improve the content and how the videos are delivered.

Designing Clinical Research Projects - Professor Patsy Yates

Key to Designing Clinical Research

Patsy's Top Tips for Clinical Research

Planning Biostatistical Analysis - Dr Joel Duthurthy

Planning Statistical Analysis for Research

Joel's Top Tips on Statistics

Reaching significant outcomes

Recommendations for Data Collection

Accessing information from the academic literature - Mr Chris Parker

Searching Academic Literature

Critical appraisal of research evidence - Professor Joan Webster

Defining Knowledge Gaps

Metro North Hospital and Health Service • Clinical Research • Research • Education resources

Introduction to clinical research principles

Files with presentation slides from sessions on topics related to basic principles and processes for undertaking clinical research.

- Designing Effective Questionnaires
- Designing a clinical research project
- Making grant applications appealing to reviewers
- Planning analysis when designing research
- Seeking approvals to undertake clinical research
- Using literature to define knowledge gaps

MNHHS Research Education Webinar Series

The MNHHS Research Education Webinar Series is a series of online educational videos focusing on practical educational topics for researchers.

Convened by the Metro North Office of Research: Dr Joel Duthurthy, Dr Tania Coughlin and Dr Paul Davis, MNHHS.

[Research@hhs.org.au](#)

[More Research events](#)

How to Prepare an SSA Application in ERM - July 2019

Seeking Ethics Approval via ERM - May 2019

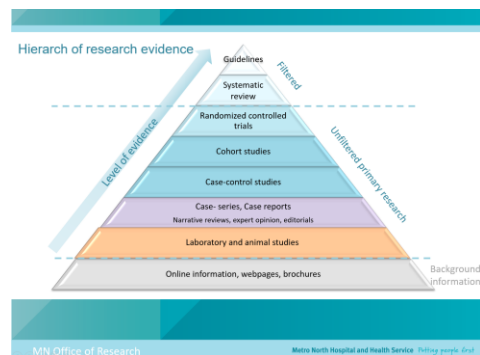
Differences between quality projects and research - 5 March 2019

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Read and review

- Read literature in your field
- Access and utilize library services;
 - UQ on RBWH campus,
 - MNHHS library at TPCH
- Consider a systematic review
 - Lodge protocol PRISMA
 - Publish the systematic review → *track record evidence*
- Work together
 - Multiple separate reviewers of each paper
 - Joint publications, team support and community of practice.
- Evidence of knowledge gaps to inform research direction



Accessing information from the academic literature - Mr Chris Parker

Searching Academic Literature



Video Length: 7min 42sec

[Watch the video](#)

Critical appraisal of research evidence - Professor Joan Webster

Defining Knowledge Gaps



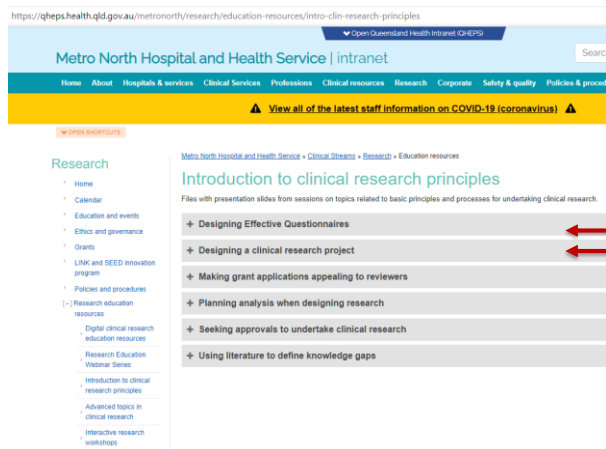
Video Length: 8min

[Watch the video](#)

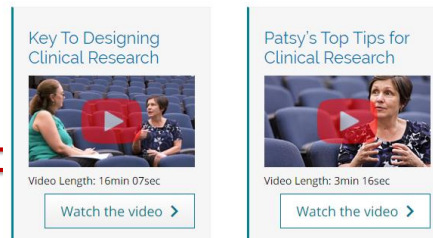
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<https://metronorth.health.qld.gov.au/research>



Designing Clinical Research Projects – Professor Patsy Yates



- Describe frameworks and tools for problem definition
- Deconstruct process with examples

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Stating the purpose and objectives for your research

- What do you want to achieve?
 - **Aims** are general statements of what we are trying to achieve
 - **Objectives** should clearly state what you will do (actions) of your research and be:
 - Specific
 - Measurable
 - Achievable
 - Relevant
 - Timely
 - **Hypotheses** are specific statements of prediction
- What will be the outcome of your research?



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Research design development

Conceptual basis



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Overarching goal

Research question 1.

- Hypothesis 1; anticipated outcome of primary measure
- Objective to specifically address research Question 1.
- Appropriate study design and protocol
- Research output 1

Research question 2.

- Hypothesis 2.
- Objective to specifically address research Question 2.
- Appropriate study design and protocol
- Research output 2

Research question 3.

- Hypothesis 3.
- Objective to specifically address research Question 3.
- Appropriate study design and protocol
- Research output 3

Significant knowledge in field

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Informing Science: the International Journal of an Emerging Transdiscipline Volume 11, 2008

Framework of Problem-Based Research: A Guide for Novice Researchers on the Development of a Research-Worthy Problem

Timothy J. Ellis and Yair Levy
Nova Southeastern University
Graduate School of Computer and Information Sciences
Fort Lauderdale, Florida, USA

ellist@nova.edu, levyy@nova.edu

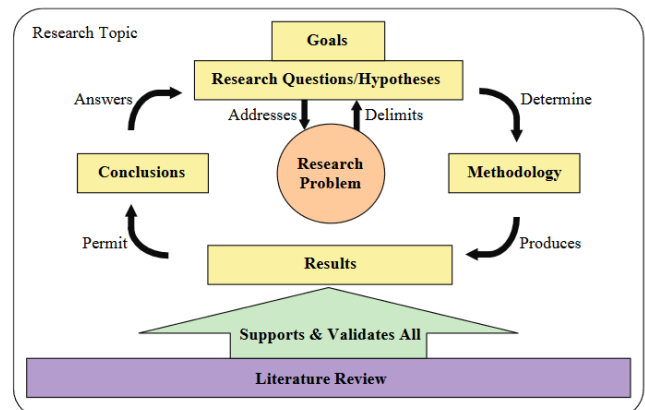


Figure 1: Conceptual Map of the Problem-Based Research Cycle

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Formulating your research question



- **P**atient, population, problem
- **I**ntervention
- **C**omparison
- **O**utcome
- **(T**imeframe)

PICO – An example

Patient or Problem	Intervention	Comparison	Outcomes
In people with cancer who are breathless	Would brief non-pharmacological interventions delivered using self-management techniques	When compared to standard information based interventions	Lead to reduced breathlessness and improved function

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FINER: Judging the research worthiness of a research question

Table 2

Main features of FINER criteria (Feasibility, interest, novelty, ethics, and relevance) to formulate a good research question. Adapted from Cummings *et al* [7]

Component	Criteria
Feasible	<ul style="list-style-type: none"> -Ensures adequacy of research design -Guarantees adequate funding -Recruits target population strategically -Aims an achievable sample size -Prioritises measurable outcomes -Optimises human and technical resources -Accounts for clinicians commitment -Procures high adherence to the treatment and low rate of dropouts -Opts for appropriate and affordable frame time
Interesting	<ul style="list-style-type: none"> -Engages the interest of principal investigators -Attracts the attention of readers -Presents a different perspective of the problem
Novel	<ul style="list-style-type: none"> -Provides different findings -Generates new hypotheses -Improves methodological flaws of existing studies -Resolves a gap in the existing literature
Ethical	<ul style="list-style-type: none"> -Complies with local ethical committees -Safeguards the main principles of ethical research -Guarantees safety and reversibility of side effects
Relevant	<ul style="list-style-type: none"> -Generates new knowledge -Contributes to improve clinical practice -Stimulates further research -Provides an accurate answer to a specific research question

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From ideas to studies: how to get ideas and sharpen them into research questions

This article was published in the following Dove Press journal:
Clinical Epidemiology

Jan P Vandenbroucke¹⁻³
Neil Pearce³

¹Leiden University Medical Center, Leiden, the Netherlands; ²Department of Clinical Epidemiology, Aarhus University, Aarhus, Denmark; ³Department of Medical Statistics and Centre for Global NCDs, London School of Hygiene and Tropical Medicine, London, UK

Abstract: Where do new research questions come from? This is at best only partially taught in courses or textbooks about clinical or epidemiological research. Methods are taught under the assumption that a researcher already knows the research question and knows which methods will fit that question. Similarly, the real complexity of the thought processes that lead to a scientific undertaking is almost never described in published papers. In this paper, we first discuss how to get an idea that is worth researching. We describe sources of new ideas and how to foster a creative attitude by "cultivating your thoughts". Only a few of these ideas will make it into a study. Next, we describe how to sharpen and focus a research question so that a study becomes feasible and a valid test of the underlying idea. To do this, the idea needs to be "pruned". Pruning a research question means cutting away anything that is unnecessary, so that only the essence remains. This includes determining both the latent and the stated objectives, specific pruning questions, and the use of specific schemes to structure reasoning. After this, the following steps include preparation of a brief protocol, conduct of a pilot study and writing a draft of the paper including draft tables. Then you are ready to carry out your research.

Keywords: study design, writing a paper, research questions

- Ideation (brainstorming)
- Cultivation of thoughts
- Focus
- Latent and stated objectives
- Pruning
- Worthiness

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Research-Worthiness?

- Will a known **gap in the body of knowledge** be filled?
- Will previous research be replicated and expanded by investigation of a different category of participants, environment, and/or constructs/variables?
- Will previous research be expanded by more **thoroughly** examining some identifiable aspect?
- Are there **specific, identifiable, and documented problems** with the currently available solutions?

Considerations:

- Is research going to deliver an incremental increase in knowledge or provide a fundamental shift in current thinking?
- Balance between
 - novelty/innovation and risk (may affect feasibility), and
 - risk and reward (flow on effect to benefit/value)
- What is your, or your organisations, or the funding bodies',
 - expectations for originality and innovation, and
 - tolerance for risk and feasibility to achieve outcomes.

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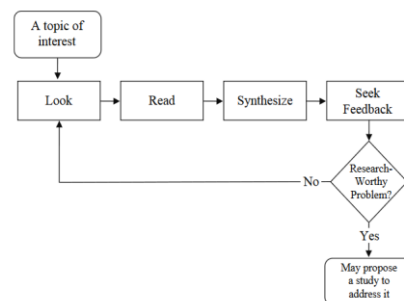
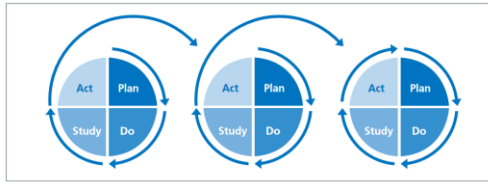


Figure 3: Process of Finding a Research-Worthy Problem

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Plan, Do, Study, Act cycles in the context of clinical research (translation)

Figure 3: Sequential PDSA cycles



Quality, Service Improvement and Redesign Tools:
Plan, Do, Study, Act (PDSA) cycles and the model for improvement

Systematic review of current knowledge →
Problem definition and research question development →
 Observational Study →
 Pilot study to assess feasibility of research design →
 Larger clinical research study →
 Outputs used to design plan to change practice →
 Framework for pragmatic study design / implementation science

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“Academia and researchers have a potential role to play to support appropriate rigour of planning and studying and understanding how to manage emergent learning while engaging diverse stakeholder groups.”

THE PROBLEM WITH... The problem with Plan-Do-Study-Act cycles

Julie E Reed,¹ Alan J Card^{2,3}

INTRODUCTION

Quality improvement (QI) methods have been introduced to healthcare to support the delivery of care that is safe, timely, effective, efficient, equitable and cost effective. Of the many QI tools and methods, the Plan-Do-Study-Act (PDSA) cycle is one of the few that focuses on the craft of change, the translation of ideas and intentions into action. As such, the PDSA cycle and the concept of iterative tests of change are central to many QI approaches, including the model for improvement,¹ lean,² six sigma³ and total quality management.⁴

PDSA provides a structured experimental learning approach to testing changes. Previously, concerns have been raised regarding the fidelity of application of PDSA method, which may undermine learning efforts,⁵ the complexity of its use in practice⁶ and as to the appropriateness of the PDSA method to address the significant challenges of healthcare improvement.

theory can be revised to build on this learning and a subsequent experiment conducted to see if it has resolved the problem, and to identify if any further problems also need to be addressed. In the complex social systems of healthcare, this flexibility and adaptability of PDSA are important features that support the adoption of interventions to work in local settings.

A successful PDSA process does not equal a successful QI project or programme. The intended output of PDSA is learning and informed action. Successful application of the PDSA methodology may enable users to achieve their QI goals more efficiently or to reach QI goals they would otherwise not have achieved. But it is also successful if it saves wasted effort by revealing QI goals that cannot be achieved under realistic constraints or if it identifies new problems to tackle instead of the originally identified issue. A well-conducted PDSA promotes learning. But it does not, and

Healthcare Improvement Research (HICIR) Programme is a joint venture between the University of York and the NHS Yorkshire and the Humber Local Strategic Partnership. It is a registered charity (1140100) and a limited liability company (02050000).

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What is the (primary) purpose of the research ?
 What do you want to achieve through research ?

2. Research Impact indicators			
Knowledge	Health	Economic	Social
Evidence of scientific reach and influence	Engagement	Healthcare cost savings	End-user/public engagement
	Participation in clinical research	IP development	Community health benefit
	Policy leadership	Industry collaboration	Wellbeing of end-user and community
	Clinical guidelines	Start-up company	Reducing inequalities
	Standards	Product to market	
	Development of product/intervention	Employment	

What is the chief complaint?
 What is the intended effect (impact) of findings?

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Writing my Research Question

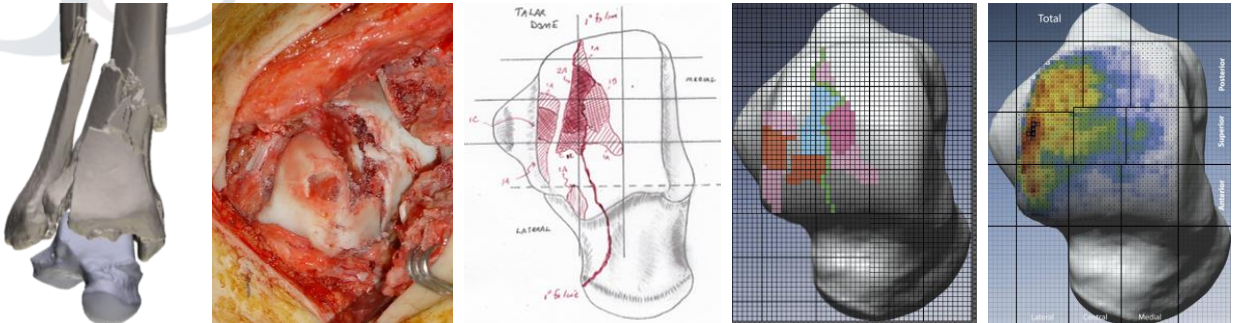
Nicholas Green
Herston Biofabrication Institute

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Topic- Tibial Pilon Fractures



From left to right: a) a 3D model of a tibial pilon fracture; b) an intraoperative photo of a talar fracture; c) map of talar injury drawn by the lead surgeon; d) the digitally transposed injury pattern on a statistical shape model (SSM) of a talar dome e) Heatmap representing the cumulative injuries sustained to the talar dome in association with 55 different distal tibial pilon fractures (AO/OTA 43B/C).

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Problem Definition

Questions from the Surgeon

- What is happening here?
- When do these injuries occur?
- Are there some areas that are worse for the patient than others?

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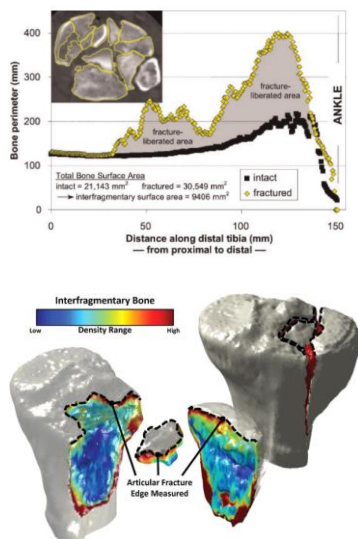
In the study cohort, associated talar dome injuries occurred in 55 out of 104 observed tibial pilon fractures

D. Anderson (2011) found 50% of tibial pilon fractures resulted in osteoarthritis, 30% in the first 1-2 years

Total of 5 reported cases of talar dome fractures occurring with tibial pilon fractures

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International Collaboration- Energy Expenditure



Custom-written software was used to measure surface area of pre-injury cortical and subchondral bone surfaces and post-injury exposed interfracture bone surfaces. The fracture-liberated surface area and the bone densities across that surface were used to calculate fracture energy (Dibbern 2019).

There was a highly significant relationship between contact area-normalized fracture energies and the rates of PTOA (Dibbern 2019). It can be seen the distal tibia is above the curve of PTOA rates.

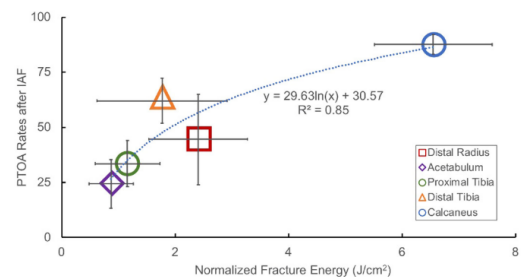


Figure 2. Contact area-normalized fracture energy was highly predictive of PTOA rates across joints

Dibbern, K., McKinley, T. O., Marsh, J. L., & Anderson, D. D. (2019). The influence of acute fracture severity on OA risk following intra-articular fractures. *Osteoarthritis and Cartilage*, 27(2019), S117–S118.

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Thought Process for Research Problem Definition

Ideation	With supervisors and collaborators, colleagues and friends from other disciplines.
Cultivation of thoughts	Taking notes and having to talk about your project in front of other people.
Focus	Remove ideas that distract from the goals and objectives.
Latent and stated objectives	Latent: Understand when these fractures occur Stated: Inform the treatment decision making for surgeons around the world, leading to better patient outcomes.
Worthiness	Research was requested by a senior orthopaedic consultant who wants to understand more about this fracture. No current literature on this phenomenon.

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PICO- Research Question 1

P opulation	I ntervention	C ontrol/ Comparison	O utcome
Patients aged 18-80 who were treated for a tibial Pilon fracture at the RBWH by the orthopaedics department. Patients that were not observed by the lead surgeon will be excluded.	All retrospective fracture CT scans and 3D fracture models will be analysed using the validated 'Fracture Energy Calculation' Matlab code.	Cases will be separated into two groups, patients who had an associated talar dome injury vs those that did not.	Predict talar dome injuries based off energy expenditure. Provide advice for surgeons as to when they should check if there is an associated talar dome injury with a tibial pilon fracture.

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Research Worthiness

Seek Feedback

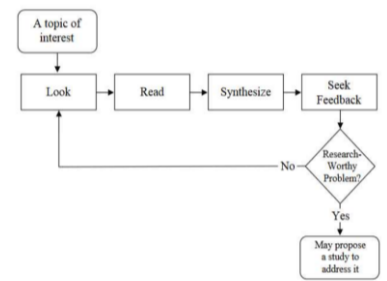
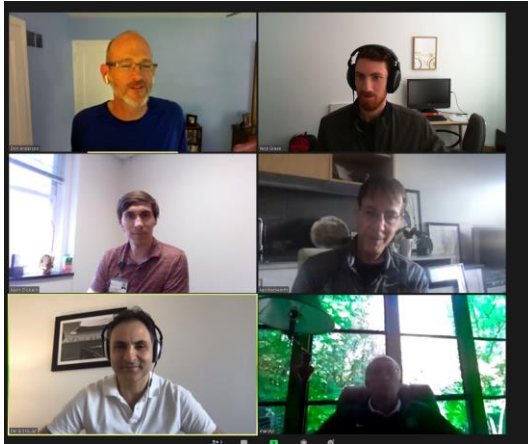


Figure 3: Process of Finding a Research-Worthy Problem

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Writing a Research Question

What causes injuries to the talar dome during a tibial pilon fracture?

The question is too broad- has many different research directions

What impact does fracture energy have on talar dome injuries during tibial pilon fractures?

Fracture energy may only be one aspect of the injury, cannot determine causality

Can the energy expended during a tibial pilon fracture predict associated talar dome injuries?

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Generating evidence in an evidence vacuum

AMANDA CORLEY
RESEARCH FELLOW (VASCULAR ACCESS)
GRIFFITH UNIVERSITY AND RBWH

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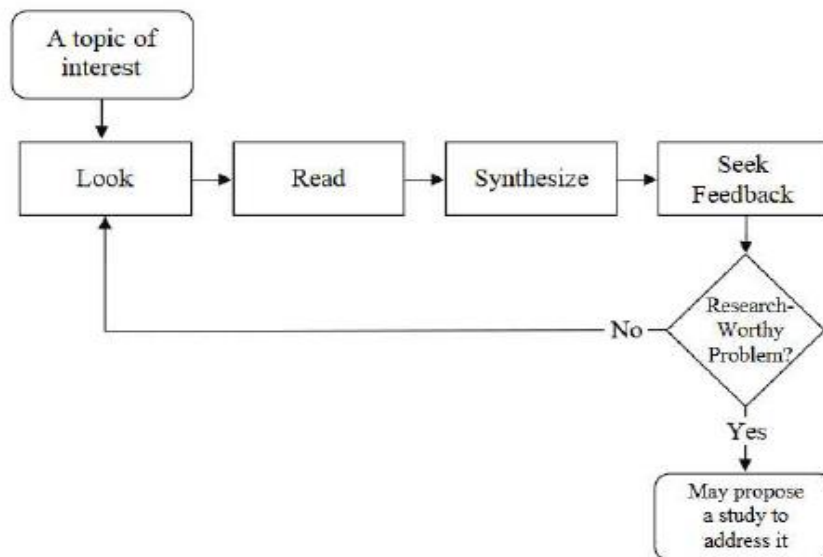
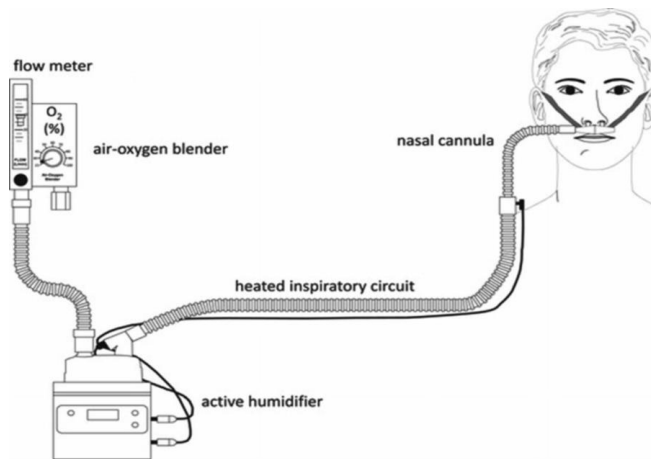


Figure 3: Process of Finding a Research-Worthy Problem

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Topic of interest – High flow nasal oxygen in adults

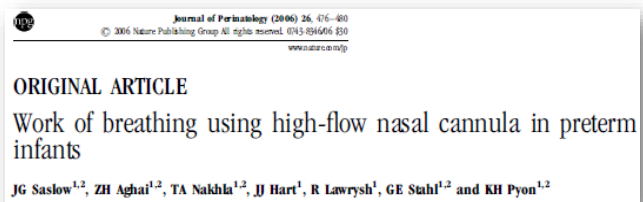


Around 2007, High flow nasal cannula (HFNC) released onto adult market with very little evidence guiding use

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Look and read

Evidence in neonates and paediatrics
but none in adult ICU



EVIDENCE VACUUM despite TGA approval

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Seek feedback

Discussed with ICU colleagues:

Where were the evidence gaps?

What did we need to know?

How will we find out?

IS THIS A RESEARCH WORTHY PROBLEM???

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Problem definition Research question development

THE PROBLEM

We did not know the effects of HFNC use on adults in the ICU requiring respiratory support.

Specifically:

1. Physiological effects
2. Patient-reported effects

THE QUESTION

What are the short term physiological effects of HFNC in adult ICU patients requiring supplementary oxygen?

Do HFNC improve subjective dyspnoea in adult ICU patients?

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Study proposal

PROTOCOL DEVELOPMENT

The team

Study design

Outcomes

Measurement tools

Sample size

CLINICAL TRIALS REGISTRATION

Australia and New Zealand Clinical Trial Registry: ACTRN12609000037202

FUNDING

Fisher & Paykel Healthcare

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THE Study

Observational study of post cardiac surgical patients requiring HFNC post extubation

N=20

Measured lung volume, respiratory rate, airway pressure, oxygenation, subjective dyspnoea (BORG score)

Findings:

- Increased EELV, airway pressure and oxygenation
- Reduced respiratory rate
- Correlation between higher BMIs and lung volume increases
- No adverse events

British Journal of Anaesthesia 107 (6): 998–1004 (2011)
Advance Access publication 9 September 2011 · doi:10.1093/bja/aer265

BJA

Oxygen delivery through high-flow nasal cannulae increase end-expiratory lung volume and reduce respiratory rate in post-cardiac surgical patients

A. Corley^{1*}, L. R. Caruana¹, A. G. Barnett², O. Tronstad¹ and J. F. Fraser¹

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Synthesize

Current to March 2016

Randomised controlled trials only

11 studies (1972 participants)

Meta-analysis performed for some outcomes

Low quality of evidence

Insufficient evidence to recommend HFNC use over standard low flow oxygen for adults in ICU

Further research needed



**Cochrane
Library**

Cochrane Database of Systematic Reviews

High-flow nasal cannulae for respiratory support in adult intensive care patients (Review)

Corley A, Rickard CM, Aitken LM, Johnston A, Barnett A, Fraser JF, Lewis SR, Smith AF

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More synthesis...

REVIEW

Use of high-flow nasal cannula oxygen

Intensive Care Med

<https://doi.org/10.1007/s00134-020-06228-7>



Laurent Papazian
Samir Jaber⁸, S
François Steph

NARRATIVE REVIEW

Use of nasal high flow oxygen during acute respiratory failure



Jean-Damien Ricard^{1,2*}, Oriol Roca^{3,4}, Virginie Lemiale⁵, Amanda Corley^{6,7}, Jens Braunlich^{8,9}, Peter Jones^{10,11}, Byung Ju Kang¹², François Lellouche¹³, Stefano Nava¹⁴, Nuttapol Rittayamai¹⁵, Giulia Spoletini^{16,17}, Samir Jaber¹⁸ and Gonzalo Hernandez¹⁹

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One question invariably leads to another!!

Intensive Care Med (2015) 41:887–894
DOI 10.1007/s00134-015-3765-6

ORIGINAL



Amanda Corley
Taressa Bull
Amy J. Spooner
Adrian G. Barnett
John F. Fraser

Randomized Controlled Trial > Thorax. 2016 Aug;71(8):759–61.

doi: 10.1136/thoraxjnl-2015-207962. Epub 2016 Mar 25.

**Nasal high flow oxygen
COPD reduces respiratory
dioxide while increasing
lung volumes: a random**

John F Fraser¹, Amy J Spooner¹, Kimble R D

Intensive Care Med (2017) 43:465–467
DOI 10.1007/s00134-016-4634-7

LETTER

**High-flow oxygen via tracheostomy
improves oxygenation in patients weaning
from mechanical ventilation: a randomised
crossover study**

Amanda Corley^{1*}, Melannie Edwards¹, Amy J. Spooner¹, Kimble R. Dunster¹, Chris Anstey^{1,2}
and John F. Fraser¹

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Take home points...

1. Choose a question which means something to patients and clinicians
2. Clearly define the evidence gaps prior to embarking on question development
3. Rome wasn't built in a day...Make the question answerable!
4. Seek advice and input from those with experience in planning and conducting research studies...learn from their mistakes!

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From clinical audit to multi-centre randomised controlled trial

Dr Nicole Marsh

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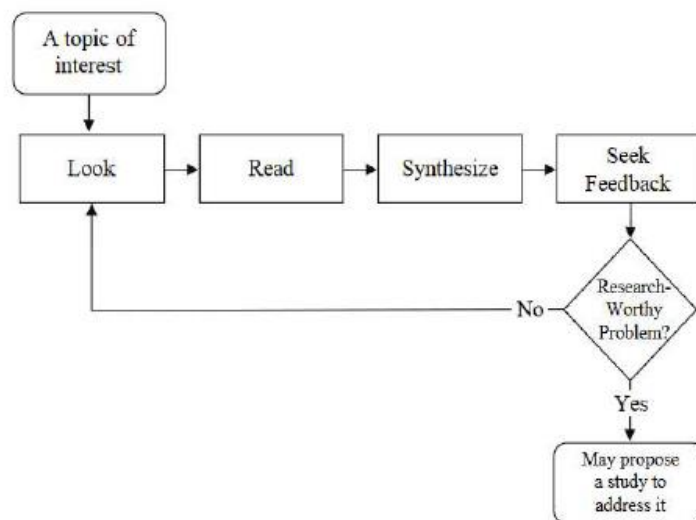


Figure 3: Process of Finding a Research-Worthy Problem

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Topic of interest

Peripheral intravenous catheters



Intravascular device use, management, documentation and complications: a point prevalence survey

Karen A. New^{1,2,4} RN, PhD, Nurse Researcher

Joan Webster^{1,2,3} RN, BA, Nursing Director, Research

Nicole M. Marsh¹⁻³ RN, BN, Project Manager

Barbara Hewer¹ RGON, BN, Clinical Nurse Consultant, Vascular Access Devices

on behalf of the Royal Brisbane and Women's Hospital Intravenous Access Research Council

PIVCs

- 25% medical/surgical patients had **one or more complications** (e.g. redness, pain, tracking, swelling)
- 25% device dressings were **NOT** clean, dry and intact
- Greater than **80%** of PIVCs had non-sterile tape over the insertion site
- **Seven** different primary dressings & securements in use

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Read and synthesize

What is the best way to dress and secure a PIVC?

Devices and dressings to secure peripheral venous catheters to prevent complications (Review)

Marsh N, Webster J, Mihala G, Rickard CM



**THE COCHRANE
COLLABORATION®**

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Read and synthesize

What is the best way to dress and secure a PIVC?

- ✓ 2015
- ✓ 6 randomized controlled trials
- ✓ - 1539 patients studied
- ✓ Risk of bias assessed
- ✓ Meta-analysis

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Read and synthesize

✓ **2015**

✓ 6 randomized controlled trials

✓ - 1539 patients studied

✓ - 10 studies assessed

✓ - meta-analysis

High quality research is needed

•4 Comparisons

1. Transparent PU	Vs	Gauze + Tape	(2 studies)
2. Transparent PU	Vs	Sticking Plaster	(1 study)
3. Bordered Transparent	Vs	Securement Device	(1 study)
4. Bordered Transparent	Vs	Tape	(1 study)

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Seek feedback

**What do we need
from a PIVC
dressing and
securement?**

Be antimicrobial

Breathe

Be comfortable

Be easy to use

Prevent micro-motion

Cover the wound

Prevent / contain ooze

Hold PIV in place

Be transparent

Be affordable



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Seek feedback

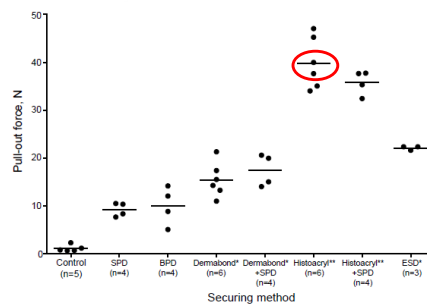
What do we need from a PIVC dressing and securement?

Anaesthesia Intensive Care 2012; 40: 460-466

Cyanoacrylate tissue adhesives – effective securement technique for intravascular catheters: in vitro testing of safety and feasibility

G. SIMONOVA*, C. M. RICKARD†, K. R. DUNSTER‡, D. J. SMYTH§, D. MCMILLAN***, J. F. FRASER††

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Is this a research worthy problem?

Pilot randomised controlled trial

Aim

- To identify clinically and cost-effective methods to prevent PIVC failure.
- To compare usual care dressings (simple transparent) with a novel method (Glue) and two new commercially available technologies – (bordered polyurethane and sutureless securement device)
- To confirm **feasibility** of conducting a larger RCT

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ORIGINAL ARTICLE

Securement methods for peripheral venous catheters to prevent failure: a randomised controlled pilot trial

Nicole Marsh^{1,2}, Joan Webster^{1,3}, Julie Flynn^{1,2}, Gabor Mihala^{2,4}, Barbara Hewer¹, John Fraser^{4,5}, Claire M. Rickard^{1,2,5}

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The SAVE pilot trial



Simple
Transparent
PU

Bordered
Transparent
PU



Adhesive
Securement
Device

Tissue
Adhesive



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The SAVE pilot trial

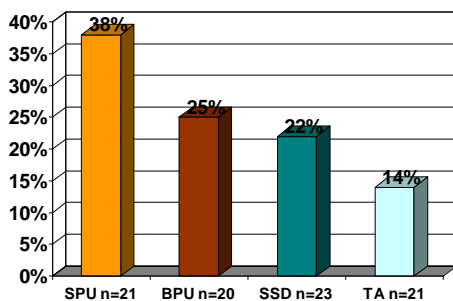


Figure 1: Proportion of failures by device type

Conclusion

- Current SPU dressing did not prevent PIVC failure in many patients
- Alternate products likely to reduce failure rates, but require testing in larger multi-centre studies
- All *priori* established **feasibility criteria met**



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Propose a study

What is the best way to dress and secure and PIVC?

Articles

Dressings and securements for the prevention of peripheral intravenous catheter failure in adults (SAVE): a pragmatic, randomised controlled, superiority trial

Claire M Rickard, Nicole Marsh, Joan Webster, Naomi Runnegar, Emily Larsen, Matthew R McGrail, Fiona Fullerton, Emilie Bettington, Jennifer A Whitty, Md Abu Choudhury, Haitham Taffaha, Amanda Corley, David J McMillan, John F Fraser, Andrea P Marshall, E Geoffrey Playford

- Multi-centre, 4-arm parallel, superiority RCT
- AUD\$1 Million – National Health & Medical Research Council
- Recruitment March 2013-Sept 2014
- 1,709 patients randomized to 4 groups



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The SAVE Trial

Primary outcome: PIVC Failure

	SPU controls N=422	BPU N=423	SSD N=425	TA N=427
PIVC Failure	43%	40%	41%	38%
p value		0.46	0.74	0.21
Per/100 PIVC days	15.1	14.6	14.2	13.3
p value		0.82	0.47	0.25

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The SAVE Trial

Sensitivity analysis PIVC Failure (N=1100)

	SPU controls N=250	BPU N=273	SSD N=296	TA N=281
PIVC Failure	34%	35%	34%	26%
p value		0.93	0.93	0.04
Relative risk (95% CI)		HR 1.10 (0.82–1.48)	HR 0.91 (0.79–1.05)	HR 0.88 (0.79–0.98)
P value		0.52	0.20	0.018

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Questions?

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Next Session: March 2, 2021



Writing your Clinical Research Protocol

Tuesday, 2nd March 2021, 12:30pm – 1:30pm

Introduction to Clinical Research (via Microsoft TEAMS)

Topics covered:

Planning a research protocol that is ethical, feasible, timely and appropriate to address the primary research question. Protocol design will be illustrated with clinical research examples.

This session is designed for early and mid-career clinical researchers, research coordinators, and potential research student who want to develop skills in investigator-led clinical research project design.


 <p>Natasha Roberts Specialist Nurse, CCS Metro North HHS Clinician Research Fellow since 2021</p> <ul style="list-style-type: none"> Prostate Cancer Specialist Nurse at RBWH has a PhD and leads research studies both locally and nationally has worked in both ICU and Medical Oncology Clinical Trials has expertise in qualitative research, mixed methods and clinical trials has received over \$325,000 in grant funding is the first recipient of a MNHHS Clinician Research Fellowship from within the nursing and midwifery stream 	 <p>Assoc Professor Jayesh Dhanani Staff Specialist Metro North HHS Clinician Research Fellow since 2020</p> <ul style="list-style-type: none"> Intensive Care Specialist at RBWH since 2009 research interests cover diverse fields; 'rationalisation of pathology tests in ICU', 'blood sugar in ICU with clinical informatics integrated insulin infusion protocol' has supervised intensive care trainees and medical students toward their college projects has published 28 articles in peer-reviewed journals with RG score 26.1 and h-index 7 has received over \$1 million in grant funding current path breaking research: local pulmonary drug delivery with wide application for diverse patient groups
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- <https://metronorth.health.qld.gov.au/research/webinar-series/evaluation>



Session evaluation form

Name (optional): _____
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 Session name: _____
 Session date: _____

1. Did this course meet your expectations? ☐ Yes ☐ No
 If not, please explain why: _____






2. Please provide a rating for this course (tick the box)

Aspect	Poor	Satisfactory	Good	Excellent
Overall rating for the course	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Course content	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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3. Suggestions for future improvement: _____

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