Workshop Theme:
Research Methodologies & Translational Research

Research Summit
*Keep it real: how to effect practice change*

School of Nursing & Midwifery
Flinders University

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Introduction to the Theme:

Research Methodologies & Translational Research
Background

Pressure in this era to identify health care interventions, therapies and medications that are:
- Successful (evidence-based)
- Practical & Feasible
- Cost effective

Therefore a need to translate new knowledge to clinical situations whilst testing for these elements – both for treatment and prevention.

Traditionally, many researchers are not educated about the conversion of their research into clinical applications, Research has tended to be independent (removed) from clinical contexts – published results and that was that.
Research-to-Practice Gap

- Pervasive in most health sciences
- Penetration of even the most successful interventions rarely occurs at a quick pace (the ‘pace of translation’ from research into practice)
- Barriers may exist – political atmosphere in the discipline or profession, financing concerns, timing is inappropriate
- The discovery may be out of synch with a provider’s readiness to use it (‘technology push’ not in synch to the ‘practice pull’ or vice versa)
- Publications may not give practical recommendations and discuss implementation considerations
- Clinical practice guidelines have failed overall to alter longstanding (nursing) practice patterns (Jennings, 2004)

A major constraint is if the research has not been implemented in a clinical situation and evaluated not only for effectiveness in the ‘real world’, but also for costs involved, education of clinicians needed, other changes needed to support the implementation, etc.
Research-to-Practice Gap in Australia

Some added factors cited in the literature:

- Due to limited resources, there is a lack of new product development after basic research - further production and testing often done overseas.
- Fragmented ethics approval processes
- Need for improved collaborative links between clinical, research & industry communities
- Need for congruent modern information technology platforms
- Lack of support for careers of those engaged in translation research
Typology of Translational Research

When transporting interventions from research to real-world settings:

- **TYPE I Translation**
  Application of discoveries generated through laboratory and pre-clinical research to the development and testing of treatment and prevention approaches
  (moves basic sciences into the realm of social and personal relevance)

- **TYPE II Translation**
  Enhancing the adoption of effective practices in the community
  (institutionalising evidence-based programs, products and services)
Another Typology

Some writers (e.g. Sussman et al. 2006) talk rather about translational research in regard to 5 phases:

1. Basic research
2. Methods development
3. Efficacy trials
4. Effectiveness trials
5. Dissemination trials

1,2 & 3 = Type I Translational Research
4 & 5 = Type II Translational Research
(with feedback loop to Phase 1 or 2 etc)
The ‘Translational Research Loop’

- Iterative & bidirectional

  Research → Clinical Situations

  Clinical Situations → Research ... and so on

- Includes feedback informational loops between basic and applied research – the user has a more prominent part – influencing research priorities & study designs

- Leads to symbiotic, synergistic and productive R&D for gains in patient care.

- Ideas generated from clinical observations can inform basic research
In the US...

Oct 2006: Clinical & Translational Science Awards (CTSA) Consortium launched to link 60 institutions by 2012:

‘To foster the nascent development and energisation of the discipline of clinical & translational science’ - which is much broader and deeper than the classical and separate domains of translational research and clinical investigation. (i.e. A new discipline or ‘field’)

Includes a focus on mutually beneficial relationships between academia & industry re R&D expertise building, technology licensing, marketing etc
Transdisciplinary Translational Research

- Is the trend

- Some consider this to be a revolution in health research

Note: Some of the US consortium (CTSA) members are implementing new multidisciplinary, patient-orientated research masters degrees and research doctorates, plus researcher mentorship programs across disciplines - that focus heavily on translational research.

What impact may this have on nursing & midwifery researchers into the near future and beyond?
Examples of Australian Initiatives

1 Translational Research Program
Peter MacCallum Institute (Melbourne)

Aim: To foster dialogue & collaboration between research and clinical divisions within the Peter Mac with the ultimate goal of accelerating application of research findings into clinical practice (improving cancer outcomes re novel therapeutics).

Using:
- Basic research
- Clinical trials
- Collaboration with industry
Examples of Australian Initiatives

2  Translational Research Laboratory – Queensland Institute of Medical Research

Focus – Breast cancer & risk factors for survival

Aims:

- To clinically eliminate the human and economic burden of unnecessary treatment when there is not microscopic spread at presentation and hence chemotherapy is not required
- To individualise treatments for women who do have early microscopic spread

The laboratory is not divorced from clinical situations – dialogue, two-way flow of information, research in ‘real’ clinical contexts with contextual factors relevant
Examples of Australian Initiatives

3 Translational Research Institute
Princess Alexandra Hospital (Brisbane)

Will combine some of Queensland’s leading research groups

Aim: To translate science into better patient outcomes for cancer, infection, diabetes and inflammatory diseases.

Features:
- 500 ‘scientists’
- One-stop shop for discoveries, clinical trials and drug manufacture
- Collaboration between 2 universities, a hospital, 2 research institutes and the Queensland Govt.
However:

One factor identified in Australia as a constraint to translational research is:

‘Poor integration of medical, nursing & scientific personnel to create the team approach for translational research’

(DHS, Vic, 2004)
What are the implications for nursing & midwifery research of the push to ‘translational research’?

- Translating nursing & midwifery research results into clinical practice use
- Being part of transdisciplinary research teams (? leading such) aiming for the research results to be translated into clinical practice use
- Being involved with the translation of research results from the research of other disciplines into clinical practice use

- When?
- Where?
- How?
Examples of Translational Research in Nursing & Midwifery

1. **TYPE I** - Analysing implementation issues encountered within a ‘bathing persons with Alzheimer’s Disease at home’ intervention (Mahoney et al. 2006)
   - **Methods:** Simultaneous with an RCT of the intervention – used observation, nurse’s field notes, caregiver journals for data collection, and then did ‘content analysis’ (necessary improvements for intervention delivery were found)

2. **TYPE I** - Fidelity of a 12-week structured medication adherence intervention in people with HIV (Erlen & Sereika 2006)
   - **Methods:** Descriptive correlational study as a sub-study of a larger RCT – used an ‘intervention tracking form’ (there was a lack of fidelity to the intervention protocol and factors why were determined)
Examples of Translational Research in Nursing & Midwifery

3. **TYPE I** – Postpartum depression treatment rates for at-risk women (Horowitz & Cousins 2006)
   - **Methods:** Secondary analysis of data from a wider mother-infant intervention study - re screening for PPD at 2, 3 & 4 months postpartum, plus nurse’s monitoring of symptoms and mental health referral when needed (results – inadequacy of treatment rates & possible reasons why).

4. **TYPE I & TYPE II** – Evaluation of the development and use of health information technologies (Kaufman et al. 2006)
   - **Methods:** Designed an evaluation framework used over 5 studies for evaluation during lab development, field testing and routine use - quant & qual methods, as appropriate for the stage: e.g. multi-site RCTs, clinical logs, observation, ‘screenshots’, ‘think aloud’ (the result was workable, acceptable, useful IT)
5. **TYPE II** – Translating best practice in non-drug post op pain management (Tracy *et al.* 2006)

- **Methods:** ‘Empirically effective’ interventions applied in a ‘Collaborative Research Utilization’ model using tailored patient teaching in one hospital, with various quant instruments used in a survey (results – success of the model but factors identified that need to be considered during implementation). This translational research is to be repeated in other hospitals.
However, implementation researchers are starting to realise globally that they may lack appropriate instruments and methodology to effectively study dissemination and implementation.

New measures and methods may be needed – or new combinations of usual methods.
Workshop Question 1

What research methodologies should ideally be used for Type I Translational Research regarding a primary focus on nursing & midwifery care – and why?

Re:
- Quantitative
- Qualitative
- Mixed methods
Workshop Question 2

What research methodologies should ideally be used for Type II Translational Research regarding a primary focus on nursing & midwifery care – and why?

Re:
- Quantitative
- Qualitative
- Mixed methods
Workshop Question 3

What are the major constraints in Australia for translational research to occur in which nurses and/or midwives can (or should) be involved – and why?
Research Methodologies & Translational Research

Workshop Question 4

What structures, infrastructure and collaboration would be ideal to ensure in Australia that translational research will occur in which nurses and/or midwives can (or should) be involved – and why?