Translation Toolkit

A toolkit to facilitate translation planning from the start of a research project

Prepared by: Associate Professor Harriet Hiscock,
Associate Professor Sharon Goldfeld, Ms Sarah Davies
and the Healthcare Innovation Affinity Group at the Murdoch Childrens Research Institute.

What is research translation and translational research?

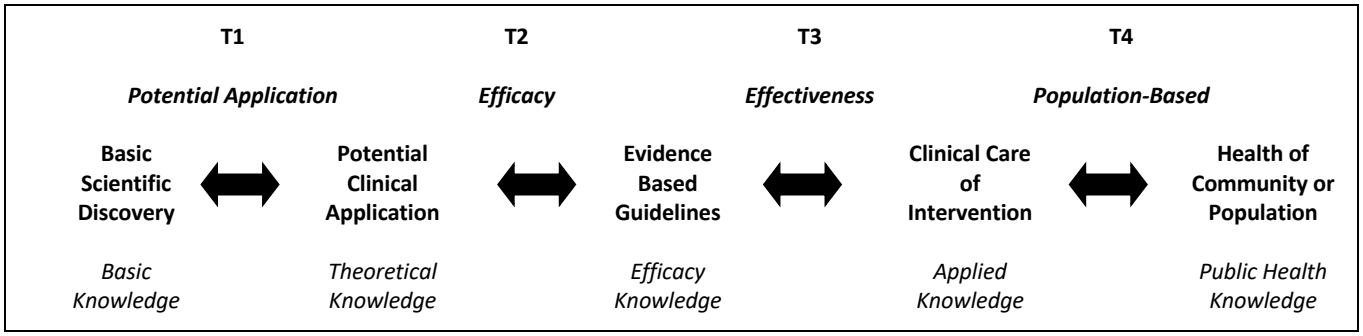
Research translation is the process whereby knowledge is passed anywhere along the translational pathway i.e. research findings are translated into practice, policy or further research (Davidson, 2011).

Translational research is research that looks at how best to translate research into practice and/or policy e.g. research that addresses particular gaps in translation (Davidson, 2011).

The terms 'research translation' and 'translational research' appeared in the literature in the 1990's in response to significant increases in basic or clinical science discoveries with little improvement in the provision of health care and health outcomes (Szilagyi, 2009, Davidson, 2011). These concepts initially tried to address this gap by focusing on moving research from the bench-to-bedside. However, it is generally acknowledged that moving research from the bedside to population-wide health must also be considered (Butler 2008, Szilagyi 2009, Woolf 2011). As such a bidirectional continuum or **translational pathway** has been developed spanning four phases (Szilagyi, 2009, Davidson, 2011):

- T1 refers to the translation of basic research into a potential clinical application.
- T2 refers to efficacy studies, in which new interventions are trialled under optimal conditions.
- T3 refers to effectiveness studies, where promising phase 2 interventions are trialled in 'real world' settings;
- T4 refers impact studies, which examine the impact of a new intervention/guideline at a population level.

Figure 1 Translational pathway



Types of Research	• Phase 1, 2 clinical trials • Pilot studies	• Phase 3 clinical trials • Systematic Reviews • Health services research interventions • Observational studies	• Phase 4 clinical trials • Implementation studies • Communication research • Dissemination studies • Diffusion studies • Systematic reviews	• T3 studies in community • Population /outcome studies • Studies of costs, benefits, policy impact • Studies beyond clinical care that affect health
Example in paediatric asthma	• Phase 1,2 drug trials • Pilot study of asthma intervention	• Phase 3 drug trials • Evidence reviews of asthma intervention	• Practice-based studies of asthma intervention • Practice-based QI studies • Dissemination studies of asthma guidelines	• Population-based outcome studies of impact of asthma interventions • Environmental changes and asthma outcomes
Example in infant sleep	• Pilot study of an infant sleep intervention	• Efficacy trial of infant sleep intervention delivered by 1-2 practices	• Effectiveness trial of sleep intervention delivered by existing workforce (e.g. maternal & child health nurses) in their practice	• State wide training of all nurse with evaluation of change in practice

(Szilagyi, 2009)

The direction of flow along the translational pathway is often two-way. That is, findings from basic research or clinical observations can inform a clinical intervention or development of a product (T1) and then testing of that intervention or product (T2) can feed back to the T1 stage and help improve upon the intervention or product.

As products and novel approaches to disease are developed from basic and clinical research, health technology assessment and service delivery research are used to ascertain how and when best to apply them in practice (Cooksey, 2009).

Lab to Bedside Example

Observations made in the laboratory may lead to better understanding of disease and novel interventions to be used in clinical settings. Equally, clinical research, sometimes involving these novel interventions, will provide insight and information which can feed back into the laboratory and inform future laboratory studies.

For example at MCRI;

- The Surgical Research Group developed a medical device to treat constipation (T1).
- They originally tested a physiotherapy method to provide electrical stimulation across the abdomen to make the bowel push more and to empty stool out (T2).
- They found that existing stimulation devices were hard for patients to set up and use at home. The Surgical Research team patented the method and then applied for funding to support commercial development of a device specifically for constipation (findings in T2 inform T1 improvement of the device).
- An unmet needs analysis showed a large patient group worldwide and a business plan was developed. Key opinion leaders were contacted in the UK and USA to determine if they would use the device. A start-up company was formed and design and regulatory requirements are underway.
- A prototype will be ready for trials in early 2013 (T2 to T3), with sales expected in 2015 (T4).

Bedside to Population example

Often interventions developed and tested in tightly controlled environments can then be translated into a wider population.

For example at MCRI;

- The Community Child Health Group observed that mothers who reported infant sleep problems had double to triple the odds of developing postnatal depression compared with mothers who reported no infant sleep problems.
- They developed a sleep intervention program and trialled it in a small randomised controlled trial with one person delivering the intervention (efficacy trial).
- The intervention was successful so the group then conducted a large, effectiveness trial (T3), with 92 nurses delivering the intervention. The trial also included a health economics evaluation.
- The intervention was effective and cost-effective so the Victorian government chose this intervention for the 8-month maternal & child health well child visit and has funded state-wide training in it for all 1,200 nurses (T4).

Setting up Research Translation

One of the key aspects of good translation is early identification and engagement of stakeholders. This next section suggests a structured way to do this and provides templates to support this process.
Use the following pages for your own project, inserting details into the tables and wherever you see: .

1. About your research

Before identifying and speaking with potential stakeholders, you first need to be clear about your research aims, designs and possible outcomes. You can document these here.

Aims/objectives of research:	
Basic description of research	<<E.G. Design, participant details, research setting>>
Key Outcomes:	
Organisation running this research:	
Sector(s) the research relates to:	

---

2. Stakeholder Identification and Role Tool

The next step is to brainstorm possible stakeholders with a group of investigators. The table below can help you identify stakeholders and their potential role(s).

This tool helps you to identify all key people, groups, or organisations that may impact the success of your project at all stages; setting up, running and translation. It also aims to assess how they may contribute to the project (Friedman and Miles 2006, NHS Institute for Innovation and Improvement 2008).

Stakeholder/s: Is a person, group or organisation who has an interest (something to gain or lose) in the outcomes of a planning process, programme or project (Dialogue by Design 2008) (Markwell 2010).

Stakeholder Identification and Role Tool

Name of Stakeholder	Sector	Value to process/role	Prioritising*	Level of Commitment	Constraints / Limitations
Organisation, group or individual	Government (Local, State, Federal), Health (Primary, Secondary, Tertiary), Not-for-Profit, Community, Education, Research, Professional Bodies e.g. RACP, Business, Media, etc.	Expertise/knowledge Funding/Resources Influence/Leadership Consumer Voice Advocate/Champion Technology Underrepresented	See Power & Impact Matrix. Do you need to Satisfy, Actively Engage, Monitor or Inform?	Support or Oppose the research, to what extent and why?	Need funds to participate, lack of personnel, political or other barriers
Internal Stakeholders MCRI, RCH, Uni Melba					
External Stakeholders					

Add or delete rows as required

*You may not have the time and resources to engage all possible stakeholders. The Power & Impact Matrix may help you prioritise stakeholders (see next page)

Power & Impact Matrix

Working out which stakeholders to engage requires some thought. Below is a "Power & Impact" matrix which may help you in this process.

High power	**Satisfy** Opinion formers/Policy makers. Keep them satisfied with what is happening and review your analysis of their position regularly.	**Actively Engage*** Key stakeholders who should be fully engaged through full communication and consultation.
Low power	**Monitor** This group may be ignored if time and resources are stretched.	**Inform** Recipients of research such as Patients often fall into this category. It may be helpful to take steps to increase their influence by organising them into groups or taking active consultative work.
	Low impact/stake holding	**High impact/stake holding**

*Some high power, high impact stakeholders may oppose your research. There is no simple solution to managing this but you may choose to keep them informed of your research in the hope that they may change their view or at least not 'ambush' you when you release your findings.

Source: Department for Business, Enterprise and Regulatory Reform www.berr.gov.uk, first published August 2007. http://www.bis.gov.uk/files/file40647.pdf

3. Stakeholder Engagement Tool

Now you have identified and prioritised your stakeholders, you need to decided how you want to engage them and at what stage(s) of your project.

This tool will help you do this. It also aims to identify how you will manage relationships between the research team and stakeholders.

Engagement is used as an umbrella term to describe any process that involves contact with the stakeholders, from providing information to running formal consultation processes. (Dialogue by Design 2008)

Name of Stakeholder	**Potential level of Engagement** *The level of engagement is likely to change at the different stages of the project.	**Engagement Method**
Organisation, group or individual	a. Information giving b. Information gathering c. Consultation d. Participation e. Collaboration	a. Newsletters, fact-sheets, website, publications, one-to-one communication via phone or email, education modules etc b. One-to-one interviews, questionnaires, focus group c. Consultation papers, public meetings d. Research Participants, e. Advisory group, Research team, Steering committee
Setting up the project		
Running the project		
Translation of findings		

Definitions:

a. **Information giving**
Purpose: To provide people with information to keep them informed and/or to assist their understanding
Expectation: That information given will be accurate, balanced and updated as necessary.

b. **Information gathering**
Purpose: To collect information about attitudes, opinions and preferences that will assist the research teams' understanding and decision making
Expectation: That information gathered will be treated and used responsibly, and reported honestly.

c. **Consultation**
Purpose: To obtain feedback on specific proposals, activities or policies
Expectation: That feedback will be taken seriously, decisions will be influenced, and people will be informed of the influence they have had.

d. **Participation**
Purpose: To involve people actively at all stages to ensure their concerns are understood and considered, and to give them some influence on and ownership of decisions. Participative processes differ from consultation processes in that they involve the participants more deeply, they tend to involve the same people through several stages, and the results are more transparent
Expectation: That people will be able to shape the process, that it will be transparent throughout, and that they will have some influence over decisions.

e. **Collaboration**
Purpose: To bring people into active partnership and agree sharing of resources and decision-making.
Expectation: That decision making will be shared and some resources will be held in common.

4. Setting up Advisory and Steering groups

Depending on the size and scope of your project, you may want to actively engage some stakeholders in a technical/advisory group and/or a steering committee. Both differ from your research team, which generally consists of Chief Investigators, Associate Investigators, a Project Officer and Research Assistants. The team usually undertakes the day to day running of the research project, develops the materials/methodologies etc and collects, analyses and writes up the data.

Below we define Technical Groups and Steering Committees and give you a template for terms of reference for each.

Definition: Technical / Expert Advisory Group

An advisory group consists of stakeholders with specific expert/technical knowledge. It can offer input and advice on content elements of the research project at predetermined frequencies or can be deferred to for specific issues.

Example template to send to Advisory Group

Background: (insert brief background of the research project)
<<including rational, aims and objectives>>

Purpose

The purpose of the <<insert name>> Advisory Group is to provide advice to the research team on specific elements *<<give examples>>* of the research project.

Terms of Reference

- To provide advice and recommendations **in their area of expertise** at all phases of the project; setting up, running and translation. This may include but is not limited to:
  - project resource content, tools, instruments, interventions, methodologies, processes, systems, analysis etc
  - national and international evidence
  - how best to engage other relevant stakeholders
  - how best to evaluate the success of the resource
  - how best to address potential barriers to success
  - how best to engage current and future modes of dissemination across public and private sectors

- To promote the program to constituents
- To provide input about the project as required

Membership

Membership of the Advisory Group is determined jointly by and extended by invitation for a period of years.

Meetings of the Advisory Group will meet per year (face-to-face and/or teleconference). Funding <<is/is not>>available to support non-government member's participation in the meetings.

The following stakeholder groups will be represented by the membership:

Definition: Steering Committee

A steering committee's function is to provide support, guidance and the executive over sighting of the research at all stages of the project.

Example template to send to the Steering Committee

Background (insert brief background of the research project)
<<including rational, aims and objectives>>

Purpose

The purpose of the <<insert name>>steering committee is to provide advice to the research team on specific elements <<give examples>>of the research project.

Terms of Reference

- to provide a forum for discussion of key issues that are relevant to the achievement of project objectives
- to provide key advice on and help facilitate the development of strategic partnerships
- to provide support, guidance and executive over sighting at all phases of the project; setting up, running and translation. This may include but is not limited to:
  - strategic planning
  - national and international evidence
  - the development of study and intervention processes
  - project resource content to ensure local/national/international relevance
  - how best to engage other relevant stakeholders
  - how best to support the project
  - how best to evaluate the success of the resource
  - how best to engage current and future modes of dissemination across public and private sectors
  - how best to address potential barriers to success
- to keep the project scope under control as emergent issues force changes to be considered
- to promote the program to constituents
- to provide input into key decisions about the project as required

Membership

Membership of the Steering Committee is determined jointly by and extended by invitation for a period of years.

Meetings of the Steering Committee will meet per year (face-to-face and/or teleconference). Funding *<<is/is not>>* available to support non-government member's participation in the meetings.

The following stakeholder groups will be represented by the membership:

Reference: *2008, Project Management Fact Sheet: Steering Committee 'nuts and bolts', Version 1.2, Department of Premier and Cabinet, Tasmania.*

APPENDIX A: References

- Friedman AL, & Miles S. Stakeholders: Theory and Practice. Oxford University Press 2006
- Szilagyi PG: Translational Research and Pediatrics. Academic Pediatrics 2009; 9: 71-80
- Butler D. Crossing the Valley of Death. Translational Research 2008: 840-842
- Woolf SH: The meaning of translational research and why it matters. JAMA 2008; 299:211-3
- Davidson A: Translational Research, What Does it Mean?. Anesthesiology 2011; 115(5)909-11