

*This is an example of a completed Translation Toolkit for a
Clinical Research Project*

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:

The primary aim is to determine if, in a broad population of paediatric inpatients, maintenance intravenous fluid containing 140 mmol/L of sodium results in a lower incidence of hyponatraemia compared to maintenance fluid containing 77 mmol/L of sodium.

Basic description of research:

Design

A double blinded, randomised, active controlled superiority trial of a fluid containing 140mmol/L of sodium (Plasmalyte148 with 5% dextrose) compared with a fluid containing 77mmol/L of sodium (0.45% sodium chloride with 5% dextrose).

Participants

Children aged between 3 months and 18 years requiring between 50% and 150% maintenance fluid for at least 6 hours.

This study will include 320 children in each treatment group: a total of 640.

Setting

Royal Children's Hospital, Melbourne – Emergency Department and inpatients

Key Outcomes:

The primary outcome measure is the proportion of subjects in each treatment group that develop hyponatraemia (<135mmol/L having decreased by at least 3mmol/L compared with the baseline measurement).

Secondary outcomes include mean serum sodium, number of IV cannula reinsertions required and the proportion of subjects in each treatment group with episodes of: hypernatraemia (serum sodium >145 with an increase of at least 3mmol/L compared with baseline measurement), hyperchloraemia (serum chloride >110mmol/L), serum bicarbonate >30mmol/L, serum magnesium >1.2mmol/L, over-hydration or dehydration (clinical assessment), seizures, cerebral oedema and serious adverse events.

Organisation running this research: The Royal Children's Hospital, Murdoch Childrens Research Institute

Sector(s) the research relates to: Tertiary health sector

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. RASP, 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					
Clinicians / treating teams (needs breakdown into individual departments)	Tertiary health	Expertise / knowledge Involves their patients Need assistance with logistics Influence / leadership	Actively engage	Generally supportive.	Time limitations Not their priority Difficulty engaging all
CEBU	Research	Expertise/knowledge	Actively engage	Supportive	?Need funds / resource limited
Junior medical staff	Tertiary health	Involves their patients Need assistance with logistics / communication with patients Influence/leadership	Actively engage	Generally supportive	High turnover (approx 3 monthly) so need frequent education. Night staff hard to target
Emergency Department	Tertiary health	Expertise / knowledge Influence / leadership Help with identifying patients and recruitment Use of resources	Actively engage	Supportive	Many research projects – helping them remember or prioritise study Resource limited
Pharmacy Department	Tertiary health	Expertise and advice. Use of resources including storage of	Actively engage	Supportive	Resource limited Time limitations

		fluids and supervision of blinding fluids			
Pre-surgical wards	Tertiary health	Help with identifying patients and recruitment	Actively engage	Generally supportive	Time limitations
Recovery	Tertiary health	Use of resources Assistance with logistics / contacting RAs / communicating with patients	Actively engage	Generally supportive	Time limitations – helping them remember study.
Anaesthetists / surgeons	Tertiary health	Involves their patients Assistance with logistics Influence / leadership	Actively engage	Supportive	High turnover of junior staff – frequent education.
Pathology	Tertiary health	Use of resources	Actively engage	Supportive	Need funding / resource limited
Inpatient wards / nursing staff	Tertiary health	Influence / leadership Assistance with logistics / resources	Actively engage	Supportive	Many, many staff! Frequent education. Night staff hard to target
External Stakeholders					
Patients / families	Community (although only affects those admitted to hospital)	Consumer voice	Monitor / inform		
Clinicians at other hospitals	Secondary / tertiary health	Expertise / knowledge Results may impact this group	Monitor / inform		Very broad group
Journals (e.g. The Lancet)	Research	Expertise May assist with development of protocol Ultimately want to publish	Inform	Supportive – protocol accepted	Could have involved earlier
Fluid manufacturer (Baxter)	Industry	Expertise Assistance with resources Results may impact on this group	Actively involve	Supportive	Conflict between involving industry / having industry too involved or contributing to funding

*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)

Clinical example

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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		
Clinicians / treating teams (needs breakdown into individual departments)	Consultation	Group emails Attendance at meetings One-to-one meetings
CEBU	Collaboration	One-to-one meetings
Junior medical staff	Participation	Email update Attendance at meetings / handover Teaching sessions / education modules
Emergency Department	Collaboration	Group emails Attendance at meetings Education modules One-to-one meetings
Pre-surgical wards	Participation	Email updates Teaching sessions / education modules Attendance at meetings
Recovery	Participation	Email updates Teaching sessions / education modules Attendance at meetings
Pharmacy Department	Collaboration	One-on-one meetings Emails Invite to meetings
Anaesthetists / surgeons	Participation	Teaching sessions / education modules Attendance at meetings

		One-on-one meetings
Pathology	Participation	Email One-on-one meetings
Inpatient wards / nursing staff	Participation	Email updates Teaching sessions / education modules Attendance at meetings
Journals (e.g. The Lancet)	Consultation	Email
Fluid manufacturer (Baxter)	Consultation	Email / phone conference One-on-one meetings
Running the project		
As above		
Translation of findings		
Journals (e.g. The Lancet)	Information giving	Email publication
Paediatrics college	Information giving	Email update
General paediatricians	Information giving	Email Paediatric network update Present at conferences
Patients	Information giving	Post results

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.