



# An Introduction to Translational Research

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# Overview

**This resource has been designed to introduce health professionals, including clinicians, practitioners, managers and policy makers, to translational research.**

It will help you understand:

- The NSW Health view of translational research
- The unique contribution translational research can make to improving health
- The different types of translational research and the translational research continuum
- Where a research project might fit on the translational research continuum
- How to turn an interesting idea into a translational research project
- How NSW Health promotes, funds and prioritises translational research
- The key considerations when designing your translational research project – tailored for each phase along the translational research continuum
- When and where to seek further information or advice




This resource is introductory and, on its own, won't equip you to plan, design and implement a translational research project. Rather, it will help you think critically about the things you'll need to consider and suggests where you can get additional support.



# What is translational research?

Translational research builds understanding about whether and how innovations can work in the real world and on a large scale. It aims to **accelerate how quickly health and medical research findings can improve the healthcare system, patient outcomes and population health**. Translational research involves the strategic integration of different types of health and medical research to make research findings usable and applicable to patients and populations.

NSW Health views the **key characteristics of translational research** as:

<b>Innovation</b> 	Involving novel interventions and/or contexts rather than repeating previous evaluations of already-proven interventions in similar circumstances.
<b>Partnership</b> 	Bringing practitioners, consumers and health administrators together with people who specialise in research methods in order to rigorously test innovations. For larger scale research projects where there may be broader system-level implications, more senior managers, executives and/or policy makers may also need to be involved.
<b>Progression</b> 	Tailoring the research to enhance the existing level of available evidence by applying different methodologies to answer different questions across a research continuum. This continuum moves from the development and testing of a truly innovative health service, program or policy; to adapting innovations that have worked in different contexts; through to the system-wide application of well-tested innovations

Translational research is one of several related but different processes that support evidence-based practice. Although there is much overlap across these processes, this resource focuses specifically on introducing how translational research is defined and approached within NSW Health.

Other processes that support evidence-based practice include:

- Implementation Science
- Evaluation
- Knowledge translation
- Quality assurance or monitoring
- Quality improvement

## Further information:

[Translational Research Framework](#) (The Sax Institute; 2016)

[Translational Research Framework: Source Book](#) (The Sax Institute; 2016)

[Translational Research Framework: Introductory video](#) (Professor Don Nutbeam, The Sax Institute; 2017)

[Successful partnerships in research: video](#) (Dr Andrew Milat, NSW Ministry of Health; 2017)

# What makes translational research particularly valuable?

This progressive, innovation-focussed, partnership approach **delivers practical research questions that can be answered confidently and really make a difference**, increasing the chance of achieving timely and meaningful improvements to health outcomes.

The best translational research incorporates all the key principles of **knowledge translation**, which is the process of applying strategies to increase the use of research findings in policy and practice. Strategies that support knowledge translation include:

- Establishing genuine partnerships between relevant stakeholders (including researchers, practitioners, potential consumers and policy networks), especially partnering with local champions of the innovation
- Considering future **scalability** when first considering an innovation
- Planning how the research findings will be disseminated to all the key audiences
- Advocating for changes in policy
- Developing practical resources, or selecting implementation strategies, that facilitate practitioners or patients to make the relevant changes
- Replicating and **scaling up** proven innovations

Without translational research:

- Potentially-brilliant innovations may never be implemented on a large scale – the “missed opportunities”
- Ineffective innovations may be rushed into large-scale implementation due to panic or unfounded over-enthusiasm – the “seemed-like good ideas”
- Researchers could explore innovations that would be impractical for health services to deliver – the “not-policy-relevant ideas”
- Health professionals could poorly answer great research questions – the “inconclusive ideas”

Further information:

[Eight Strategies for Research to Practice](#) (FHI 360; 2012)

# The translational research continuum

The continuum starts with idea generation and ends with monitoring, but it is the five phases between these that make up translational research:



- **Feasibility** studies test the practicality and acceptability of an innovation (e.g. Is nicotine replacement therapy (NRT) safe and acceptable for pregnant women?)
- **Efficacy** studies test whether an innovation is successful under ideal conditions (e.g. Can NRT help pregnant women quit smoking?)
- **Replicability and Adaptability** studies test an innovation's success under some other conditions (e.g. Can NRT help other high-risk patient groups, such as mental health patients, quit smoking?)
- **Effectiveness** studies test whether an innovation is successful under real-life conditions (e.g. Is routinely offering free NRT at hospital admission an efficient way of reducing smoking rates, across all patient sub-groups?)
- **Scalability** studies test how well an innovation can be integrated into the overall health system (e.g. How consistently can offering free NRT be integrated into hospital admission processes across a local health district (LHD)?)

# Working out where your innovation fits on the translational research continuum

The translational research continuum is linear and its phases should be done in order for any given innovation. However, some innovations may not need all of the phases, while others may explore multiple phases simultaneously ... and you **don't have to do all the phases yourself!**

To understand where a project fits along the continuum, first consider any existing evidence about the innovation you're interested in, then think about the next logical research question that needs answering in working towards widespread implementation.

Nature of the existing evidence	Next logical questions	Relevant translational research phase
There is little or no evidence about the innovation	▶ Is this innovation practical, safe, feasible and acceptable?	<b>Feasibility</b>
There is some evidence of the innovation's feasibility (from local experience or published research) - BUT not whether it makes a difference to the outcomes of interest	▶ Can this innovation make a difference to health and/or service outcomes under the best possible conditions?	<b>Efficacy</b>
There is some evidence the innovation can make a difference (from local experience or published research) - BUT the evidence is from a different context and/or a different population of interest	▶ Can this innovation still make a difference to health and/or service outcomes under different conditions? ▶ Which innovation elements are most important for achieving the health and/or service outcomes?	<b>Replicability and Adaptability</b>
There is evidence of the innovation making a difference under a variety of conditions and/or with a variety of population sub-groups (usually published research) - BUT always under fairly tightly-controlled conditions	▶ Can this innovation still make a difference to health and/or service outcomes under real-life conditions?	<b>Effectiveness</b>
There is evidence that the innovation is efficient and can make a difference under real-life conditions (usually published research) - BUT it hasn't yet been implemented anywhere on a larger scale	▶ How can this innovation be most effectively implemented on a large scale across the LHD, state or nationally? ▶ Which patient, practitioner, site, innovation or other contextual factors are associated with improved reach or outcomes?	<b>Scalability</b>

# Getting from an “interesting idea” to a translational research project

Most research starts with an interesting idea. There are **four key things to think about** in trying to progress that idea into a meaningful research project:

**1** Having a clear and specific **research question** – usually involving three components, which also each need to be well-defined:

Component	Poorly-defined	Well-defined
<b>Your innovation</b> – what you’re going to do	Animal visitors	Daily visits from a companion dog
<b>Your target population</b> – who you hope to affect	Elderly patients	People aged 75 years or older admitted to hospital
<b>Your primary outcome of interest</b> – what you hope will change	Recovery	Length of stay in hospital
<b>Your research question</b>	Do animal visitors improve elderly patients’ recovery?	Can daily companion dog visits reduce the length of stay for hospital inpatients aged 75 or older?

**2** **Specifying why and how** you expect your innovation to make a difference to the outcomes of interest, based on existing literature and/or your past experience. Make sure you have examined the problem comprehensively to be confident your innovation is a potential solution, and that you have reviewed how it will fit alongside or replace other interventions that may already be in place.

**3** Using a **study design** and **research methods** that are most suited to answering your research question.

**4** Having an adequate **sample size** to answer your research question.

With translational research, you also need to:

- Ask a research question that **builds on the existing evidence**
- Target a **local or state health priority**
- Have an innovation with **potential for scaling up in an efficient way**
- Make sure you have the **right partners** on board including those who are essential for your innovation to be implemented as you expect. These may include, for example, Primary Health Networks, relevant policy branches, consumers and/or other internal or external organisations.
- Collect **comprehensive cost data** – to help with assessing the feasibility of delivering the innovation on a larger scale and to create a business case for health system implementation

## Further information:

[NSW Government priorities in health](#) (NSW Health)  
[Study Design for Evaluating Population Health and Health Service Interventions: A Guide](#) (NSW Health)  
[Increasing the scale of population health interventions: A Guide](#) (NSW Ministry of Health; 2014)

[Commissioning economic evaluations: A Guide](#) (NSW Ministry of Health; 2017)  
[Health Consumers NSW: website](#)  
[Patient Experience and Consumer Engagement: A Framework for Action](#) (NSW Agency for Clinical Innovation; 2015)  
[Primary Health Networks: website](#)  
[Successful partnerships in research: video](#) (Dr Andrew Milat, NSW Ministry of Health; 2017)



# Choosing the right study design

Study design refers to the set of methods and procedures used in collecting and analysing data to answer a research question.

Different study designs will be appropriate for different phases of the translational research continuum. Your study design should be as rigorous as possible while meeting the pragmatic needs of your research context.

The figure provides an overview of different study designs. To learn more about the study designs, hover your cursor over each of the study design types.



Further information:

[Study Design for Evaluating Population Health and Health Service Interventions: A Guide](#) (NSW Health)

# Getting translational research projects funded

In 2015, NSW Health launched its Translational Research Grants Scheme (TRGS), which offers grants annually to stimulate high impact research that will translate into better patient outcomes, health service delivery, and population health and wellbeing – while also building research capability within NSW Health. This funding is available to all staff within NSW local health districts, specialty health networks, the Ambulance Service of NSW and NSW Health Pathology and has supported a wide range of projects – including these examples:

A state-wide strain typing network for rapid detection of outbreaks of healthcare associated infection

An integrated care intervention to reduce breathlessness in patients with chronic obstructive pulmonary disease

Building capacity for child and adolescent community-based eating disorders service provision across a diverse health service

Detecting child abuse and neglect in the emergency department: Streamlining access to care and assessment for vulnerable children

Implementation and evaluation of take-home naloxone for opioid overdose prevention

An overview of projects funded through TRGS is available on the [TRGS website](#).

TRGS **funds research about innovations that are “ripe” for translation**, which are those that:

- Target local or state strategic health priorities and could complement or integrate with existing initiatives
- Are novel (or add value to a similar existing intervention) and address gaps or inadequacies in the current health system
- Have a good likelihood of making a difference to their intended outcomes (based on experience or existing literature)
- Are conducted in partnership with the various **stakeholders** needed to implement the innovation, or influence the desired system changes
- Would be potentially feasible to implement on a large scale, across whole LHDs/specialty health networks (SHNs) or across the state

## Further information:

[Translational Research Grants Scheme \(TRGS\) website](#)

[Translational Research Framework: Introductory video](#) (Professor Don Nutbeam, The Sax Institute; 2017)

[NSW Government priorities in health](#) (NSW Health)

# Feasibility study considerations

Feasibility studies are the first step in practicality-testing any innovation and many 'good ideas' won't get past this stage of testing. You may need to do multiple rounds of feasibility testing before you feel confident to move on to more formal testing. The key considerations here are:

- **Are there any potential ethical concerns?** The main ethical concerns to consider in feasibility studies are how the innovation might affect your participants' safety and privacy. For example, changes to service delivery arrangements might result in patients missing out on treatment or being over treated. Early advice from a [NSW Human Research Ethics Committee \(HREC\)](#) can be very useful as this will have implications for your research design, methods and timing. NSW Health and the National Health and Medical Research Council (NHMRC) offer guides to help you [identify potential ethical risks](#) and the [triggers for seeking formal ethical review](#), as well as flagging [special ethical considerations and HRECs](#) relevant if your research involves routinely collected data, Aboriginal people and/or communities, or staff and/or prisoners within the NSW correctional system.
- **What sample size will I need?** This depends on the innovation being tested. While the sample size can be small for feasibility studies, it is important to include a broad range of views (including consumers, service providers and managers), and have enough participants to identify any potential safety issues.

- **What data do I need to collect?** You will need to take a [mixed methods](#) approach, which includes both [quantitative data](#) (e.g. countable information from surveys or administrative records) and [qualitative data](#) (e.g. themed information from interviews, observations, focus groups, meeting minutes). The data collected will need to cover a range of issues:
  - **Implementation** - Was the innovation delivered as planned? What were the main variations from the planned approach and why did they occur? Could the innovation be made simpler to deliver?
  - **Acceptability** - What was staff and patients' experience of the innovation?
  - **Resource implications** - What did the innovation cost to deliver (e.g. expenses, staff time)?
  - **Impact** - Although unlikely to have enough participants for statistical testing, feasibility studies should still include some measures of whether and how the innovation made a difference to the outcomes of interest to help with assessing unintended effects.

## Further information:

Bowen et al. [How we design feasibility studies](#). *Am J Prev Med*. 2009;36(5):452-457

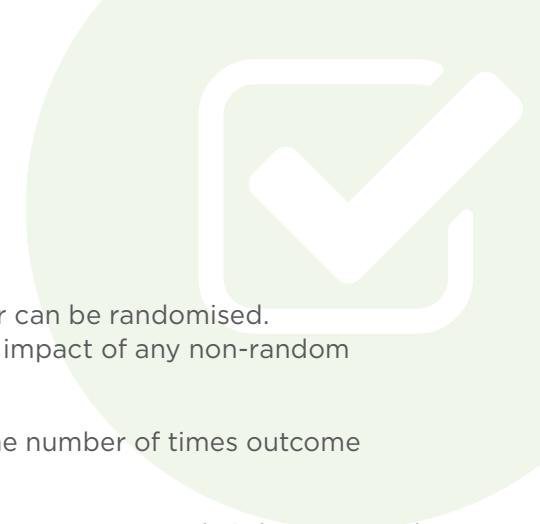
## Example projects – TRGS:

- [Counselling and Nicotine \(CAN\) QUIT in Pregnancy Rewards Plus](#) – exploring the feasibility, acceptability and uptake of effective tobacco cessation strategies among women attending substance use in pregnancy services in Newcastle and Sydney, a population that has extremely low tobacco cessation rates (Hunter New England LHD)

## Example projects – published:

- Denney-Wilson E et al. [Development and feasibility of a child obesity prevention intervention in general practice: The Healthy 4 Life pilot study](#). *J Paediatr Child Health*. 2014;50(11):890-4. (Centre for Primary Health Care and Equity, University of New South Wales)
- Achhra AC et al. [Moving away from Ritonavir, Abacavir, Tenofovir, and Efavirenz \(RATE\)-agents that concern prescribers and patients: a feasibility study and call for a trial](#). *PLoS One*. 2014;9(6):e99530. (The Kirby Institute, University of New South Wales)

# Efficacy study considerations



Efficacy studies explore whether an innovation **can** improve your intended outcomes by giving it the best possible chance to do so. This usually involves testing it under tightly-controlled conditions with a specific sub-group of willing participants. While still considering any ethical issues and collecting similar data to feasibility studies, efficacy studies also need to be designed in a way that enables a good chance of delivering meaningful results by more thoroughly addressing the following methodological considerations:

- **Having a control group** – to help you understand whether any observed improvement exceeds what would have happened with ‘usual care’ or ‘doing nothing’. Ideally participants would be randomised between the control and innovation groups and then kept very separate, but this can’t always be achieved in the real world of translational research. Although there is now a much broader range of experimental study designs available that can be used in efficacy studies, the most rigorous designs remain randomised controlled trials and cluster randomised controlled trials.
- **Choosing the best experimental study design**, within the constraints of your research context, to increase your confidence that any observed improvements are truly a result of your innovation, and not some other factors, or even just chance.

Factors to consider in choosing a study design include:

- Whether it’s possible to stagger the delivery of the innovation so different groups receive it at different times. This could help with spreading resources over time or may be practical if sites aren’t all ready to implement at the same time.

- Whether the innovation delivery order can be randomised. This is the best way of minimising the impact of any non-random differences between groups.
- How many groups are involved and the number of times outcome data can be measured.
- **Having an adequate sample size** to make sure your study is large enough to answer your research question. This means that there are enough participants to be able to use common statistical tests to determine whether or not your innovation has an observable, significant effect.

Exactly how to calculate your required sample size will vary, depending on your study design and the nature of your primary outcome (**numerical** or **categorical**). However, the calculation is always based on knowing three things:

- How confident you want to be that a significant result is actually true – your **significance level**, which is usually set at 95%, or  $p < 0.05$ , meaning you have only a 5% chance of a false positive result (**Type I error**)
- How confident you want to be that a non-significant result is actually true – your **power**, which is usually set at 80%, meaning you have a 20% chance of a false negative result (**Type II error**)
- How much change you expect to see in your primary outcome and from what baseline level (e.g. a 10% increase in breast cancer screening from a baseline of 70%) – your **effect size**, which can usually be estimated from previous research results and an understanding of what level of change would be clinically-meaningful.



Once you know these three figures, there are many free website or software calculators you can use to do the sample size calculations (e.g. [UCSF website](#), Minitab, PS, GPower). However, you may need to adjust the sample size upwards to allow for factors like your expected response rate (to allow for drop-outs), if you have multiple hypotheses being tested ([Bonferroni adjustments](#)), or if your primary outcome participants are clustered into groups (like wards, hospitals or schools).

#### Further information:

McCrum-Gardner E. [Sample size and power calculations made simple](#). *Int J Ther Rehab*. 2010; 17(1):10-14

- **Knowing if the innovation was delivered as intended** to make sure you draw the right conclusions about whether or not it was effective. This is called “fidelity” and requires careful monitoring of what was actually done, who participated and whether they received the whole innovation. Assessment of fidelity is one aspect of [process evaluation](#) and usually involves patient and service delivery information being routinely collected as the innovation is delivered.

#### Further information:

Craig P et al. [Developing and evaluating complex interventions: the new Medical Research Council guidance](#). *BMJ*. 2008;337:979-983  
[Study Design for Evaluating Population Health and Health Service Interventions: A Guide](#) (NSW Health)

## Example projects – TRGS:

- [Implementation of the INCOG guidelines for cognitive rehabilitation within the Liverpool Brain Injury Rehabilitation Unit](#) – exploring the efficacy of a recognised 4-step Knowledge Implementation Model for managing post traumatic amnesia within acute hospital and inpatient rehabilitation wards, and of external aids for people with severe memory impairment post-TBI in outpatient community settings (South Western Sydney LHD)
- [Building capacity for child and adolescent community-based eating disorders service provision across a diverse health service](#) – exploring the efficacy of Family Based Therapy treatment by community-based Child and Adolescent Mental Health teams for young people with eating disorders (Hunter New England LHD)

## Example projects – published:

- Delaney T et al. [Cluster randomized controlled trial of a consumer behavior intervention to improve healthy food purchases from online canteens](#). *Am J Clin Nutr*. 2017 Nov;106(5):1311-20. (Hunter New England Population Health, Hunter Medical Research Institute and Priority Research Centre for Health Behaviour, University of Newcastle)
- Metse AP et al. [Efficacy of a universal smoking cessation intervention initiated in inpatient psychiatry and continued post-discharge: A randomised controlled trial](#). *Aust N Z J Psychiatry*. 2017;51(4):366-81. (Hunter New England Population Health, Hunter Medical Research Institute and University of Newcastle)
- Butler L et al. [Effects of a pedometer-based intervention on physical activity levels after cardiac rehabilitation: a randomized controlled trial](#). *J Cardiopulm Rehabil Prev*. 2009 Mar-Apr;29(2):105-14. (Illawarra Shoalhaven LHD)

# Replicability and Adaptability study considerations

Replicability and adaptability studies explore a previously-proven innovation's success across a wider range of circumstances. For example:

- Testing an innovation in a similar hospital, where clinicians may be less experienced
- Exploring whether an innovation can be adapted to different circumstances or contexts, perhaps in rural hospitals, or with harder to reach populations

Replicability and adaptability studies are not always necessary but they are recommended for innovations that are expensive, need extensive modification in new circumstances, or are heavily dependent on local conditions.

Again, all the ethical and methodological considerations mentioned earlier (i.e. ethical issues, control groups, study design, sample size, implementation data) remain relevant here, but some warrant more thorough investigation in replication and adaptation studies:

- **Pre-specifying the potential key elements of the innovation** so they can be measured to help identify any that are more critical to the innovation's success and how much they can vary without compromising its success. Key elements could include contextual variables (e.g. local support and the expertise or discipline of those delivering the innovation) as well as specific components of the innovation itself (e.g. resourcing and the order in which components are delivered).
- **Getting a detailed understanding about innovation delivery** – which again will require collecting comprehensive information to help you understand whether, how and why the innovation was delivered differently than in the efficacy study.
- **Quantifying the resource implications** to help understand the potential costs of delivering the innovation on a larger scale. This should include detailed breakdowns of the costs of the staffing, consumables and infrastructure required to deliver the innovation.

One way that replication and adaptation studies can vary from efficacy studies is in the nature of their control groups – depending on the extent of the variations in their contexts and innovation. If the context and innovation are very different, you may still need a separate control group, as outlined for efficacy studies. However, if your context and innovation are very similar to the efficacy study, then you could also use a “**benchmarking**” approach, where you simply assess whether your participants achieved similar outcome improvements to those in the efficacy study or studies.

## Example projects – TRGS:

- [SMS SOS: Using SMS text messages to prevent self-harm](#) – exploring the adaptability of a proactive, follow-up messaging strategy (from mailed postcards to SMS text messages) for reducing re-presentations among young people after an initial self-harm hospital presentation (Western Sydney LHD)

## Example projects – published:

- Neubeck L et al. [Choice of Health Options in Prevention of Cardiovascular Events \(CHOICE\) Replication Study](#). *Heart Lung Circ.* 2018;27(12):1406-14. (Prevention Research Collaboration, University of Sydney)
- Sangster J et al. [Effects of a pedometer-based telephone coaching intervention on physical activity among people with cardiac disease in urban, rural and semi-rural settings: a replication study](#). *Heart Lung Circ.* 2017;26(4):354-61. (Illawarra Shoalhaven LHD)

# Effectiveness study considerations

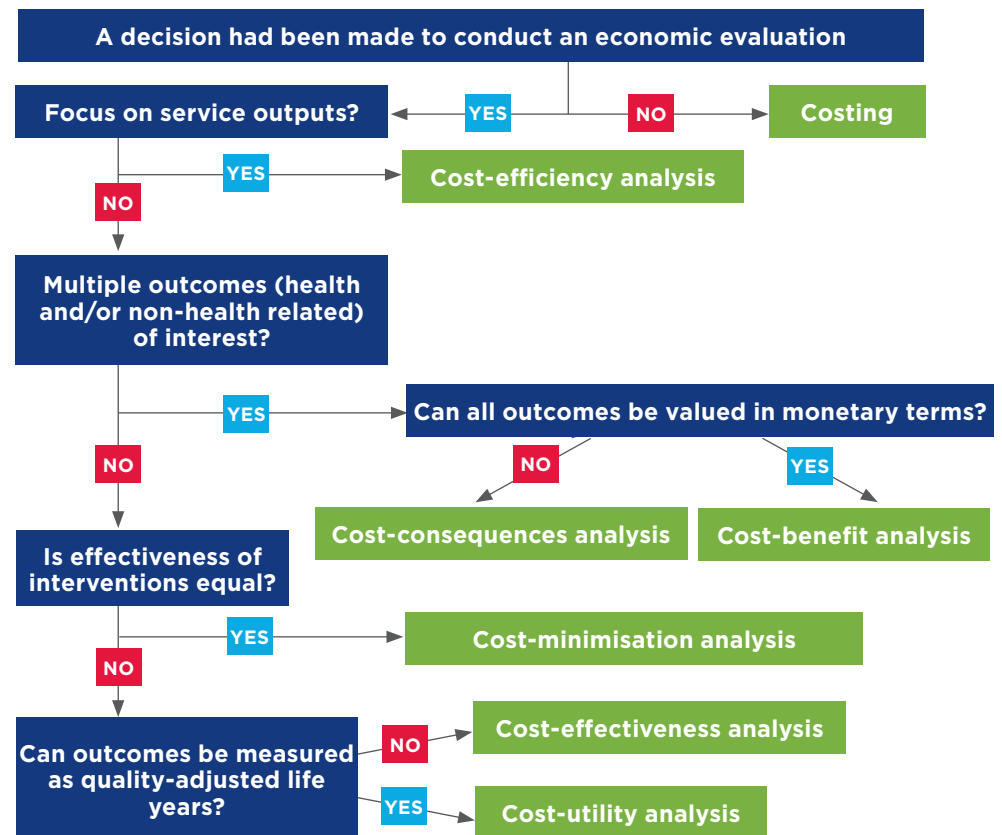


Effectiveness studies explore the extent to which a widely-proven innovation is successful under normal operating conditions or real-life circumstances. Again, all the ethical and methodological considerations mentioned earlier (i.e. ethical issues, control groups, study design, sample size, implementation data, resource implications) remain relevant here, but those warranting more thorough investigation for effectiveness studies include:

- **Ensuring you have a representative sample** so your findings are generalisable to your whole intended target group. This means making sure all potential participants have an equal chance of being sampled. For example, you might randomly select participants from a list of all hospitals or relevant specialist clinics in the region, or you might sample every patient attending for care within a certain timeframe. You will need to document your approach and keep careful records of the reasons for any non-participation. The differences between those who took part and those who did not should be documented.
- **Collecting quality site and participant characteristics, and participant feedback (process data)** to help inform a detailed understanding about innovation delivery. This should include the nature and extent of any differences in delivery, uptake and/or acceptability between sites or participant sub-groups.
- **Gathering comprehensive cost data.** This becomes more critical in effectiveness studies as it helps with understanding the resource implications of scaling up and implementing an innovation. Detailed cost data show where and how resources are used within a program and provide the foundation for conducting economic analyses (even if you don't do them yourself). Economic analyses explore the relationship between the costs and benefits associated with an innovation, which helps health services identify "best buy" innovations for scaling up and enables them to maximise health and/or service outcomes within the resources they have available. There are many forms of economic evaluation and this decision tree highlights some

of the key factors to consider in choosing the one that's right for you:

- Whether the evaluation is focussed on service outputs or participant outcomes
- The number of outcomes of interest
- Whether the outcomes can be valued in monetary terms or measured in quality-adjusted life years



**Source:** Centre for Epidemiology and Evidence. Commissioning Economic Evaluations: A Guide. Evidence and Evaluation Guidance Series, Population and Public Health Division. Sydney: NSW Ministry of Health, 2017.



Wherever possible, NSW Treasury recommends **cost-benefit analysis** as the preferred approach because it captures social and environmental impacts, as well as economic impacts.

#### Further information:

[Commissioning economic evaluations: A Guide](#) (NSW Ministry of Health; 2017)  
[Issues in the Costing of Large Projects in Health and Healthcare](#) (NSW Ministry of Health; 2008)

[NSW Government Guide to Cost-Benefit Analysis](#) (NSW Treasury; 2017)  
[How to Compare the Costs and Benefits: Evaluation of the Economic Evidence](#) (NHMRC; 2009)

Eccles M et al. [Research designs for studies evaluating the effectiveness of change and improvement strategies](#). *Qual Saf Health Care*. 2003;12:47-52.

## Example projects – TRGS:

- [Implementation and evaluation of take-home naloxone for opioid overdose prevention](#) – exploring the effectiveness of a brief intervention for enhancing Drug and Alcohol workers' knowledge and skills at preventing and responding to opioid overdoses (South Eastern Sydney LHD)
- [Implementation of an Aboriginal Transfer of Care model: Impact on unplanned readmissions and ED presentations](#) – exploring the effectiveness of a structured, multidisciplinary planning process for Aboriginal patients being discharged from hospital at reducing rates of unplanned hospital readmissions, emergency department presentations, and rates of discharge against medical advice (South Western Sydney LHD)

## Example projects – published:

- Plant N et al. [Implementation and effectiveness of 'care navigation', coordinated management for people with complex chronic illness: rationale and methods of a randomised controlled trial](#). *BMC Health Serv Res*. 2013;13:164. (Menzies Centre for Health Policy, University of Sydney and others)
- Carrington MJ et al. [Impact of nurse-mediated management on achieving blood pressure goal levels in primary care: Insights from the Valsartan Intensified Primary care Reduction of Blood Pressure Study](#). *Eur J Cardiovasc Nurs*. 2016 Oct;15(6):409-16. (Centre for Primary Health Care and Equity, University of New South Wales)
- Sutherland RL et al. [The Physical Activity 4 Everyone cluster randomized trial: 2-year outcomes of a school physical activity intervention among adolescents](#). *Am J Prev Med*. 2016 Aug;51(2):195-205. (Hunter New England Population Health, Early Start Research Institute)

# Scalability study considerations

Scalability studies are the final step of [exploring how to maximise an effective innovation's service improvement and/or health outcomes](#). This step involves [scaling up](#) an innovation, or implementing it as widely as possible, to see if it can retain its proven effectiveness while reaching a greater proportion of the eligible population.

Not all innovations are suitable for scaling up, depending on their strategic significance, level of effectiveness, likely reach and uptake rates, the costs of operating at scale, and local contextual factors. It is always worth doing a scalability assessment first – see [Increasing the Scale of Population Health Interventions: A Guide](#) for more information.

The key considerations when designing scalability studies are:

- **Gathering comprehensive “reach” data.** This is critical in scalability studies to help with understanding the extent to which the innovation was successfully implemented. You will need to clearly define the relevant target group for your innovation to understand the size of the eligible population (e.g. clients aged over 50 years or young adults with type 2 diabetes). This forms a denominator from which you can calculate the proportion actually reached.
- **Getting a detailed understanding about innovation delivery.** As in replicability studies, you will need comprehensive [fidelity](#) data to help understand whether the innovation was implemented as intended. It is also important to understand what workforce, technical and organisational factors influenced [adoption](#) in order to understand the need for the innovation to be adapted. For example, the fidelity study could assess: factors that influence reach and adoption; the capacity of the system/organisation to implement the innovation (including capacity of workforce, information systems and training); and compatibility with other interventions, policies and practice environments.

- **Gathering comprehensive process data** to help with understanding participant and site characteristics associated with improved implementation, reach, participation and/or acceptability – the barriers and enablers of larger-scale implementation of the innovation.
- **Using a mixed methods approach** including both quantitative (with a focus on data routinely collected by the health system) and qualitative data (primarily from the perspective of service providers and managers, although consumers could also be included, where relevant).
- **Making your sample as representative as possible** to enhance the generalisability of your findings.
- **Achieving an adequate sample size** to make sure your study is large enough (or has enough [power](#)) to answer your research question.
- **Conducting some form of economic analysis** to enable health services to prioritise which programs to implement in order to maximise health and/or service outcomes within the resources they have available.

Scalability studies can measure innovation effectiveness, but this is not always necessary, especially where there is already strong evidence of effectiveness.

## Further information:

- [Increasing the scale of population health interventions: A Guide](#) (NSW Ministry of Health; 2014)
- [NSW Government Guide to Cost-Benefit Analysis](#) (NSW Treasury; 2017)

## Example projects – TRGS:

- [The Far West Palliative Approach Framework](#) – exploring the scalability of an end-of-life framework and model of care across five new rural and remote generalist healthcare sites, examining the impact on patient care and identifying the key educational elements, processes and factors important for implementation and translation into different locations, settings, and contexts (Far West LHD)

## Example projects – published:

- Lonsdale C et al. [Scaling-up an efficacious school-based physical activity intervention: Study protocol for the ‘Internet-based Professional Learning to help teachers support Activity in Youth’ \(iPLAY\) cluster randomized controlled trial and scale-up implementation evaluation](#). *BMC Public Health*. 2016 Aug 24;16(1):873. (Early Start Research Institute, University of Wollongong and others)
- Middleton S et al. [From QASC to QASCIP: successful Australian translational scale-up and spread of a proven intervention in acute stroke using a prospective pre-test/post-test study design](#). *BMJ Open*. 2016;6:e011568. (Nursing Research Institute, St Vincents Health Australia (Sydney) and others)
- Welsby D et al. [Process evaluation of an up-scaled community based child obesity treatment program: NSW Go4Fun®](#). *BMC Public Health*. 2014 Feb 10;14:140. (Physical Activity Nutrition Obesity Research Group, University of Sydney)



## Where to get help

- **Social scientists** can help with designing your research question and research project, especially if you will be using qualitative data. You can find them at universities, through Primary Health Networks and at some LHD-based research institutes and/or Population Health units.
- **Statisticians** can help with research design, calculating sample sizes and analysing quantitative data. You can find them at universities, in LHD-based Planning or Population Health units, and research institutes.
- **Health economists** can help with measuring costs, understanding resource implications and economic analyses. You can find them at universities, in LHD-based Planning or Population Health units, and research institutes.
- **Ethics officers** can help with considering the ethical implications of your research project. You can find them at universities, in LHD-based research offices, in research institutes, and through your local [Human Research Ethics Committee](#).



# Resource list

Topic	Resource
Translational Research Grants Scheme	<a href="#">Translational Research Grants Scheme (TRGS) website</a> <a href="#">Translational Research Grants Scheme: Introductory video</a> (Ms Christine Whittall, NSW Ministry of Health; 2017) <a href="#">Translational Research Framework</a> (The Sax Institute; 2016) <a href="#">Translational Research Framework: Source Book</a> (The Sax Institute; 2016) <a href="#">Translational Research Framework: Introductory video</a> (Professor Don Nutbeam, The Sax Institute; 2017) <a href="#">Successful partnerships in research: video</a> (Dr Andrew Milat, NSW Ministry of Health; 2017)
NSW health priorities	<a href="#">NSW Government priorities in health</a> (NSW Health)
Partnerships	<a href="#">Successful partnerships in research: video</a> (Dr Andrew Milat, NSW Ministry of Health; 2017) <a href="#">Primary Health Networks: website</a>
Consumer engagement	<a href="#">Health Consumers NSW: website</a> <a href="#">Patient Experience and Consumer Engagement: A Framework for Action</a> (NSW Agency for Clinical Innovation; 2015)
Ethics	<a href="#">NSW Human Research Ethics Committees (HRECs) Ethical Considerations in Quality Assurance and Evaluation Activities</a> (NHMRC; 2014) <a href="#">Human Research Ethics Committees - Quality Improvement &amp; Ethical Review: A Practice Guide for NSW</a> (NSW Health; 2007) <a href="#">Research - Ethical &amp; Scientific Review of Human Research in NSW public health organisations</a> (NSW Health; 2010) <a href="#">Commissioning Evaluation Services: A Guide</a> (NSW Ministry of Health; 2017)
Study design	<a href="#">Study Design for Evaluating Population Health and Health Service Interventions: A Guide</a> (NSW Health)

Topic	Resource
Sample size	<a href="#">McCrum-Gardner E. Sample size and power calculations made simple. <i>Int J Ther Rehab.</i> 2010; 17(1):10-14</a> <a href="#">UCSF Sample Size Calculators</a>
Economic analysis	<a href="#">Commissioning economic evaluations: A Guide</a> (NSW Ministry of Health; 2017) <a href="#">Issues in the Costing of Large Projects in Health and Healthcare</a> (NSW Ministry of Health; 2008) <a href="#">NSW Government Guide to Cost-Benefit Analysis</a> (NSW Treasury; 2017) <a href="#">How to Compare the Costs and Benefits: Evaluation of the Economic Evidence</a> (NHMRC; 2009) <a href="#">Eccles M et al. Research designs for studies evaluating the effectiveness of change and improvement strategies. <i>Qual Saf Health Care</i> 2003;12:47-52.</a>
Feasibility	<a href="#">Bowen et al. How we design feasibility studies. <i>Am J Prev Med.</i> 2009;36(5):452-457</a>
Efficacy	<a href="#">Craig P et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. <i>BMJ.</i> 2008;337:979-983</a>
Effectiveness	<a href="#">Eccles M et al. Research designs for studies evaluating the effectiveness of change and improvement strategies. <i>Qual Saf Health Care</i> 2003;12:47-52</a>
Scalability	<a href="#">Increasing the scale of population health interventions: A Guide</a> (NSW Ministry of Health; 2014)
Other	<a href="#">Eight Strategies for Research to Practice (FHI 360; 2012)</a>

# Appendix: Glossary of Key Terms

**Acceptability:** the degree of support for the intervention among stakeholders.

**Adaptability:** the degree to which the innovation can be changed while still maintaining effectiveness.

**Adoption:** the proportion of intended target settings, practices or organisations (e.g. schools, workplaces) that adopt an innovation.

**Benchmarking:** assessing whether your research participants achieve similar outcome improvements to those achieved in previous studies.

**Bonferroni adjustment:** a method used to adjust the desired significance level for projects involving multiple comparisons, to reduce the risk of Type I errors.

**Categorical data:** data that can be grouped into categories (e.g. gender, marital status).

**Compatibility:** how well the innovation fits with the systems, services and practices of the new environment or setting.

**Control group:** the group in a research study that does not receive the experimental intervention.

**Cost-effectiveness:** refers to the benefit or outcome received relative to the cost.

**Cost effectiveness analysis (CEA):** looks at possible consequences of the innovation measured in terms of a single uni-dimensional unit considered to capture the relevant outcomes.

**Cost efficiency analysis:** modification of the CEA where the benefits of interest are service outputs rather than health outcomes.

**Cost-benefit analysis:** where both the consequences and the costs of the innovation are measured in monetary units.

**Cost consequence analysis (CCA):** presents the full array of outcomes rather than summarising innovation consequences into a single measure to enable the user to form their own judgements.

**Cost minimisation analysis (CMA):** used when the consequences of two or more health programs are judged to be equivalent.

**Cost utility analysis (CUA):** a specialised form of CEA where the consequences of the innovation are measured in terms of an outcome that combines survival and quality of life.

**Effectiveness:** the extent to which an innovation is successful in 'real life' conditions in achieving the outcomes that were predicted in the planning of the program.

**Effect size:** a measure of the strength of effect. It can be used to extrapolate the effect of an intervention to larger groups or populations.

**Efficacy:** the extent to which an innovation is successful under controlled or 'best possible' conditions.

**Feasibility:** the viability, practicability, or workability of the study, program or innovation.

**Fidelity:** the extent to which delivery of an innovation adheres to the protocol or program model originally developed.

**Generalisability:** the extent to which findings from the study are likely to be reproduced in other groups or in the whole population.

**Innovation:** a novel intervention intended to bring about change or produce outcomes.

# Appendix: Glossary of Key Terms

**Knowledge translation:** the application of research findings to policy and practice, supported by evidence-based strategies to increase research uptake.

**Mixed methods:** research that involves both qualitative and quantitative methods.

**Numerical data:** data that can be counted and where each number has a meaning (e.g. age, blood pressure, waiting times, 0-10 satisfaction ratings).

**Power:** the probability that a statistical analysis will correctly reject a false null hypothesis.

**Process evaluation:** a set of activities designed to assess the success of program implementation. Process evaluation describes and explains what happens once the program has actually started, and the extent to which the program is implemented and delivered as planned, the program's reach, and participants' feedback about the program.

**Qualitative data:** themed information from interviews, observations, focus groups, meeting minutes, etc.

**Quantitative data:** countable information from surveys, administrative records, etc.

**Reach:** the level of contact with or individual participation of an intended target population in an intervention.

**Replicability:** the degree to which the results of the innovation can be repeated in a different setting, or different population or sub-group.

**Representative sample:** a research sample that accurately reflects the larger population (sampling frame) from which it is drawn, usually achieved by all potential participants having an equal chance of being selected.

**Sample:** a group of individuals selected from a population for study, or to be the subjects for an innovation.

**Sample size:** the number of people needed for a research study to accurately answer its research question(s). To calculate this, you'll need to specify the quantitative change expected (e.g. a 10% increase in breast cancer screening from 70% to 80% following the innovation), the power and the significance level.

**Scalability:** the ability of an innovation shown to have been efficacious on a small scale and/or under controlled conditions to be expanded under real world conditions to reach a much greater proportion of the eligible population, while retaining effectiveness.

**Scaling up:** deliberate efforts to expand successfully tested health interventions so as to benefit more people and to foster policy and program development on a lasting basis.

**Stakeholder:** an individual or an organisation that can influence, will be affected by, or may have an interest in the intervention.

**Statistical significance:** a measure of the extent to which the relationship between variables, or observed results, from a study might have occurred by chance. Statistical significance is assessed after the application of appropriate statistical tests.

**Study design:** the set of methods and procedures used in collecting and analysing data to answer a research question.

**Type I error:** concluding your innovation made a significant difference when it actually didn't.

**Type II error:** concluding your innovation did not make a significant difference when it actually did.

NSW Ministry of Health  
Locked Mail Bag 961  
NORTH SYDNEY NSW 2059  
Tel. (02) 9391 9000  
Fax. (02) 9391 9101  
TTY. (02) 9391 9900  
[www.health.nsw.gov.au](http://www.health.nsw.gov.au)

Produced by: NSW Ministry of Health

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SHPN (CEE) 190241  
ISBN 978-1-76081-130-3

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August 2019

