

Translational Research Framework

Testing innovation in policy, programs and service delivery

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Introduction

This guide has been developed for health professionals applying for the Translational Research Grants Scheme (TRGS) who may have limited research experience, but may also be useful for more experienced researchers as a structured reminder of the range of issues that will be taken into account in the screening and assessment of proposals.

This guide provides a number of prompts to help identify the steps you need to take to:

- demonstrate that a health service, program or policy innovation works
- understand the conditions under which it was successful (or unsuccessful)
- where appropriate, identify how to scale up an innovation for greatest impact.

The guide will assist you in refining research questions, and identifying feasible research methods to answer these questions. An application is more likely to be successful if the expected outcomes are clearly defined, those outcomes are being measured accurately and the research design fits the research questions.

At times it will be essential to seek further advice, and we have tried to indicate where this may be the case. This guide is not intended to be prescriptive, and there is no one-size-fits-all approach. Rather, it can be used as a tool to help you critically think about where projects may fit on the translational research continuum, and with this in mind, how best to refine your research question and methods.

The Framework: an overview

Figures 1 and 2 describe different steps in translational research as a prompt to help you identify your research question and the kinds of methods that might be suitable. There are many ways to categorise research and different people will think about this in different ways. We have found these ways of thinking useful in our work and the Framework should be seen as a summary of this experience, rather than as a set of fixed rules that will apply in every circumstance.

The Framework describes a series of research steps moving from the development and testing of a truly innovative health service, program or policy; to testing the application of novel interventions that have worked in different circumstances or settings; through to system wide application of innovations – reflecting the flow from innovation to system wide testing.

Although Figure 1 shows a linear progression, it will often not be necessary or possible to undertake every step in the sequence. Figure 2 provides some advice about the kinds of information that you might want to have before you initiate research at each step.

The continuum in figure 1 begins with the idea generation; we recognise that the idea or innovation might come from your own experience or ideas, from published research or from seeing examples in Australia or elsewhere. We haven't described idea generation in the guide as this is not relevant for TRGS. The continuum ends with monitoring; while there can be research questions associated with monitoring, it is not usually included as translational research. Rather we anticipate that monitoring may stimulate new ideas to improve the innovation or its implementation and therefore stimulate a new round of translational research questions.

For the purposes of this Framework, the term **innovation** has been used to refer to new or modified programs, policies, service delivery models or other structured approaches designed to improve health outcomes. 'Intervention' is another term often used to describe this same concept.

Outcomes will vary depending on the step, the innovation, and the research question. For example, outcomes might be health status (e.g. diabetes control), health behaviours (e.g. diet),

clinical behaviours (e.g. frequency of checking blood glucose control) or systems factors (e.g. numbers of diabetes nurses). We recommend that you carefully consider the relevant outcomes for your particular study; it can be useful to develop a program logic that will help you make explicit what you expect the innovation to change. If you are not familiar with program logics, information can be found in a guide developed by the Centre for Epidemiology and Evidence, entitled [Commissioning Evaluation Services: A Guide](#) (Evidence and Evaluation Guidance series, Population and Public Health Division. Sydney: NSW Ministry of Health 2015).

Most research will require **Ethics Committee Approval**; you might want to talk to your Research Office and read the references below.

Notes for each step have been provided along with some case studies and additional reading to assist in guiding you through the Framework.

The **Source Book** is an important companion for this Framework. It includes definitions and additional information about designs, economic evaluation and a decision tree for selecting between designs. Translational research often includes difficult design challenges and we recommend that you seek advice from an evaluation expert if your innovation or circumstances are not straightforward.

Additional reading:

Bauman AE, Nutbeam D. *Evaluation in a Nutshell: A practical guide to the evaluation of health promotion programs*. 2nd edition. 2014, North Ryde: McGraw-Hill.

Craig P, et al. [Developing and evaluating complex interventions: new guidance](#). *BMJ*. 2008;337:979-983.

The National Health and Medical Research Council. [Ethical considerations in quality assurance and evaluation activities](#). 2014, Canberra: Commonwealth of Australia.

NSW Health. *Research ethics and governance*. 2016, June 17. Retrieved from <http://www.health.nsw.gov.au/ethics/pages/default.aspx>

Figure 1. Translational Research Framework: testing policy, program and service innovation

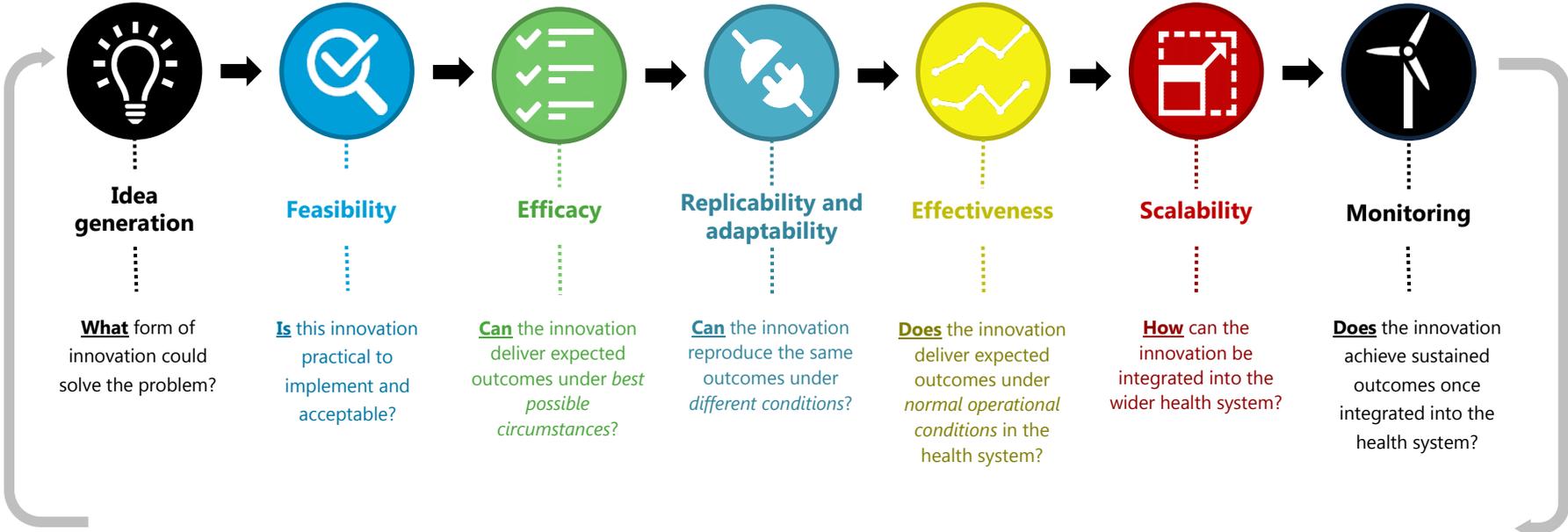


Figure 2. Translational Research Framework: research design matrix for testing policy, program and service innovation

If your question is...	What matters?	You may need advice about...
Idea generation*		
<p>1. Feasibility</p> 	<p>I want to know whether an innovation is <u>practical, feasible and acceptable</u> before further testing.</p> <p>Usually, the innovation has not been previously tested in a comparable environment.</p>	<p>Example research questions: Is the innovation safe, acceptable, feasible? Were there unanticipated effects? Did people participate as expected?</p> <p>Design and controls: Usually qualitative and quantitative measures. Controls not usually required.</p> <p>Participants: May be both patients/consumers and service providers and should be selected to reflect a broad range of views and experience; the number of participants will depend on the questions of interest.</p> <p>Resource implications: Should include broad assessment of resource implications.</p> <p>How to manage potential ethical concerns from an ethics officer.</p> <p>Recording, analysing and interpreting qualitative and/or direct observation data from a social scientist.</p> <p>How to measure costs from those with finance or accounting expertise.</p> <p>Additional reading: Bowen et al. How we design feasibility studies. Am J Prev Med. 2009;36(5):452–457.</p> <p>The National Health and Medical Research Council. National statement on ethical conduct in human research (updated May 2015). 2015, Canberra: Commonwealth of Australia.</p>

	If your question is...	What matters?	You may need advice about....
<p>2. Efficacy</p> 	<p>I want to find out whether a policy, program or service innovation <u>can</u> make a difference to the health or service outcomes of interest under <u>best possible circumstances</u>.</p> <p>Usually there will already be evidence from your own or other local experience, or from published research that the innovation is feasible.</p>	<p>Example research question: Did the innovation improve the outcomes of interest relative to observed change in a non-intervention control?</p> <p>Innovation factors: Must be able to demonstrate that the innovation was delivered as planned.</p> <p>Design and controls: Controls are required to ensure that any changes in the health or service outcomes did not occur as a result of factors other than the innovation. See Source Book for advice about selecting appropriate controls.</p> <p>Participants: Does not need to be representative of the whole population. There should be enough participants to ensure that the impact of the innovation can be accurately assessed and sample size will need to be carefully calculated.</p> <p>Resource implications: The costs and resource implications of the innovation should be assessed.</p>	<p>How to select appropriate designs and controls from an evaluation expert.</p> <p>How to demonstrate that the innovation was delivered as planned from an evaluation expert.</p> <p>Sample size advice from a statistician.</p>

	If your question is...	What matters?	You may need advice about....
<p data-bbox="185 244 365 336">3. Replicability and adaptability</p> 	<p data-bbox="405 244 719 368">I want to find out if this innovation <u>can</u> work under <u>different conditions</u> before testing more widely.</p> <p data-bbox="405 392 768 608">Usually, there will be some evidence from your own or other local experience or from published research that the innovation can have an impact on the health or service outcomes in different operating conditions.</p>	<p data-bbox="790 244 1574 400">Example research questions: Can the innovation improve the outcomes of interest relative to a non-intervention control <i>under these new conditions</i>? In these different operating conditions can the innovation achieve the same benchmark levels as demonstrated in previous studies and experiences?</p> <p data-bbox="790 424 1536 549">Innovation factors: Must be able to describe whether and how the innovation may have been modified from previous studies. Should be able to indicate whether differences in implementing the innovation made it difficult to compare with previous findings.</p> <p data-bbox="790 572 1559 697">Design and controls: Usually similar approaches to design and controls are used to those outlined for efficacy studies. Sometimes replicability and adaptability studies use a 'benchmark' approach rather than a control group.</p> <p data-bbox="790 721 1514 804">Participants: Does not need to be representative of the whole population. There should be enough participants to ensure that the impact of the innovation can be accurately assessed.</p> <p data-bbox="790 828 1514 884">Resource implications: Should include assessment of the costs and resource implications of the innovation in this new environment.</p>	<p data-bbox="1597 244 1962 336">How to select appropriate designs and controls from an evaluation expert.</p> <p data-bbox="1597 360 1917 416">Sample sizes and power calculations from a statistician.</p> <p data-bbox="1597 440 1962 564">How to describe and define the variation in innovation delivery required in the new setting, from a social scientist.</p>

	If your question is...	What matters?	You may need advice about....
<p>4. Effectiveness</p> 	<p>I want to find out whether an innovation <u>does</u> work when it is tested under <u>normal or real life conditions</u>.</p> <p>Usually, there will already be evidence from your own or other local experience or from published research in similar settings that the innovation can have an impact on the health or service outcomes in a variety of circumstances.</p>	<p>Example research questions: Does the innovation improve the health or service outcomes of interest when it is tested in a representative sample of people or organisations under real life conditions?</p> <p>Innovation factors: Must be able to record accurately whether the innovation was delivered as planned and any significant differences in delivery, participation or acceptability at different sites or among different kinds of participants.</p> <p>Design and controls: Many different experimental designs are possible; cluster randomised trials are considered the best approach when feasible, but alternatives are acceptable where this is impractical. Wherever possible, participants should be randomly allocated to control and innovation conditions.</p> <p>Participants: Sites and participants must be selected to be representative of the total population of interest. Because of likely variation in delivery, it is likely that larger numbers of participants will be required for effectiveness studies.</p> <p>Resource implications: Assessment of costs relative to benefits is highly desirable.</p>	<p>How to select appropriate designs and controls from an evaluation expert.</p> <p>Sample sizes and power calculations from a statistician.</p> <p>How to describe and define the variation in innovation factors between sites or participants, from a social scientist.</p> <p>How to measure costs and assess benefits from an economist.</p> <p>Additional reading: Eccles M, et al. Research designs for studies evaluating the effectiveness of change and improvement strategies. Qual Saf Health Care 2003;12:47-52</p> <p>The National Health and Medical Research Council. How to compare the costs and benefits: evaluation of the economic evidence. 2001, Canberra: Commonwealth of Australia.</p>

	If your question is...	What matters?	You may need advice about....
<p>5. Scalability</p> 	<p>I want to know <u>how</u> the innovation can be <u>effectively rolled out</u> across the LHD, state or nationally.</p> <p>Usually there will already be evidence that the innovation is effective and that resource implications are appropriate.</p>	<p>Example research questions: What approaches to dissemination achieve the highest uptake of the innovation? What system attributes (resourcing, training) support the adoption and maintenance of the innovation?</p> <p>Innovation factors: Should examine the factors affecting the differences in delivery, participation or acceptability at different sites, and may also examine different responses among different kinds of participants.</p> <p>Design and controls: Usually qualitative and quantitative measures of uptake and implementation. Controls will depend upon the research question; it might be possible to use randomised controls but more usually comparisons will be pre or post-test or with another state or LHD where the program is not provided. Use of routinely available measures of health or service outcomes where feasible.</p> <p>Participants: Focus on innovation/service providers and managers who should be selected to reflect a broad range of views and experience; may also include patients or consumers. The number of participants will depend on the questions of interest</p> <p>Resource implications: This is critical, close assessment of delivery costs, marginal costs and cost benefits should occur.</p>	<p>Time series analysis, from a statistician or evaluation expert.</p> <p>How to describe and define the variation in innovation factors between sites or participants, from a social scientist.</p> <p>How to measure costs from those with finance or accounting expertise.</p> <p>Additional reading: Milat AJ et al. Increasing the scale of population health interventions: a guide. Evidence and Evaluation Guidance Series, Population and Public Health Division. Sydney: NSW Ministry of Health, 2014</p> <p>Milat A, et al. A guide to scaling up population health interventions. Public Health Res Pract. 2016 28;26(1):e2611604</p>

Monitoring*

* Information for "Idea generation" and "Monitoring" has not been provided in the table as these components are outside the scope of the TRGS

Notes for each step

Feasibility

Is this innovation safe, practical and acceptable?

Before testing whether an innovation makes a difference, it is usually advisable to have evidence of safety, feasibility and acceptability. Many 'good ideas' will not progress beyond this stage of testing! There may be a need for several rounds of feasibility testing to refine your ideas and methods before you are confident to proceed to more formal testing.

From the outset, a careful consideration of ethical issues should be made; unintended outcomes that may affect staff and/or consumers and patients are common. Early discussion with an Ethics Committee can be very useful.

The components of feasibility testing will be different depending upon the nature of your innovation. The number of participants can be small but will depend upon the innovation being tested; however, sufficient numbers should be included in the study to ensure that a range of different perspectives are sampled. A useful checklist might include the components below but you should think this through for your innovation.

Safety: *Case study 1* below describes a study that tests the safety of a nurse led hepatitis B clinic – making sure that this is safe and there are no unintended side effects are important. There may be safety issues with many other types of innovations – changes to service delivery arrangements, for example, might result in patients missing out on treatment or being over treated. You will need to make sure that you have enough patients to identify any potential problems with safety.

Acceptability to staff and patients: If the intended beneficiaries of an innovation do not find it acceptable, then it is unlikely that it will be adopted. Assessment of acceptability can include surveys, and interviews with participants will help you to understand their experience. *Case study 1* gathered feedback from clients on attitudes towards a community based clinic.

Participation: Measures of participation can be thought of as a proxy measure of acceptability – if the innovation is not acceptable, people will not take part. This should be carefully assessed.

Delivery of the innovation: Questions here might include: was the innovation delivered as planned?; what were the main variations from the protocol and why did they occur?; could the innovation be made simpler to deliver?

A range of measurement techniques might be used including observation, surveys and interviews. Advice from a social scientist can be useful.

Outcomes or impact assessment: In general, when testing the feasibility of an innovation you are unlikely to have sufficient participants or adequate controls for outcome or impact assessment to be meaningful. Whenever possible, feasibility assessment should include some measures of impact and outcome for the purposes of assessing unintended effects.

Resources: It is important to take account of the resources used in testing feasibility; if it appears that the innovation is going to require very intensive resourcing you need to be confident that it would produce exceptional improvements in service or outcomes.

CASE STUDY 1

Feasibility, acceptability and safety of a nurse led hepatitis B clinic based in the community.

The study examined the **feasibility, acceptability and safety** of a community based hepatitis B (HBV) nurse clinic in improving access to best practice chronic hepatitis B care in the Sydney Local Health District. A weekly clinic was trialled in the inner west for 18 months. Information on patient demographics, clinical findings, triage decisions and sources of referral were analysed, and the study also included a self-administered survey for patients that gathered feedback on attitudes towards the clinic and opinions on barriers to accessing treatment and care. The study provided evidence of the feasibility, acceptability and safety of the model. Participant numbers were small, and the need for further research in relation to efficacy and implementation was identified (for example, exploring how to increase engagement with GPs and people living with chronic hepatitis B).

Pritchard-Jones J, Stevens C, McCaughan G, Strasser S. *Collegian*. 2015;22:233-240.

Efficacy



Can the innovation deliver expected outcomes under the best possible circumstances?

Some issues to consider:

Controls: Efficacy studies require a control because they are examining whether an innovation improves the outcomes compared to 'doing nothing' or 'usual care'.

In the real world of translational research, it can be difficult to establish an ideal control. You may, for example, be testing an innovation that requires change in a whole hospital or whole community or it may not be possible to randomise participants to receive or not receive the innovation.

Over the past decades, considerable effort has been invested in understanding the kinds of controls that might be used in these conditions. Although randomised control groups are recognised as the best approach, there are other designs that may be sufficient for the circumstances of implementation that you face. More information can be found in the Source Book, and from the guidelines developed by the Medical Research Council entitled [Developing and evaluating complex interventions: new guidance](#) (Craig P, et al. BMJ. 2008;337:979-983). The Source Book also includes a decision tree to help you think about the kinds of controls that

might be possible in your situation. *Case study 2* shows an example of a pre-post design with non-randomised controls.

We recommend that you consider seeking advice from a social scientist that specialises in research design if you are unsure about how best to establish controls.

Sample and power: You will need to be sure at the outset that your study is large enough to answer your question of interest. This means that there are enough participants (or units of analysis) to be able to use common statistical tests to determine whether or not your innovation has an observable, significant effect. We recommend that you seek the advice of a statistician in considering the size (power) of your study; calculation of statistical power in experimental research designs can be complex.

Was the innovation delivered as intended: If your innovation was not delivered as you intended, then you might draw the wrong conclusions about whether or not it was effective. Careful assessment of what was actually done, who participated and whether the full 'course' of the innovation was followed will help you know whether or not the innovation was delivered as planned. Sometimes this kind of assessment is called 'fidelity assessment' and it can be part of a set of measures that can be used to reassure you that the innovation was implemented as intended.

CASE STUDY 2

Rates of in-hospital arrests, deaths and intensive care admissions: the effect of a medical emergency team.

This study examined the efficacy of a medical emergency team (MET) in reducing the rates of selected adverse events in public hospitals. The MET is called by staff from anywhere in the hospital if a patient appears to be deteriorating on the ward. It was not possible to randomly allocate individual patients to receive or not receive the MET and therefore the study compared adverse events in one hospital where the MET was operating with two other hospitals providing usual care (conventional cardiac arrest teams). The main outcomes were rates of cardiac arrest, unanticipated admission to intensive care unit (ICU) and death; case mix-adjusted rates were used to reduce bias from differences between hospitals.

Bristow PJ, Hillman KM, Chey T, Daffurn K, Jacques TC, Norman SL, Bishop GF, Simmons EG. *Med J Aust.* 2000;173:236-240.

Replicability and adaptability



Can the same outcomes from the innovation be achieved in different circumstances?

Replicability testing can be considered as an intermediate step between testing efficacy and testing effectiveness.

In efficacy testing, the innovation is tested in the best possible circumstances. For example, the clinicians might be enthusiastic or particularly skilled, the hospital may be exceptionally supportive and/or patients might be motivated volunteers. Often the innovation is developed and tested by the same people.

Replicability testing is the first step towards demonstrating the potential of an innovation for widespread adoption in a variety of conditions. It can include testing the innovation in another similar hospital where the clinicians may be less experienced or motivated; it might also include exploring whether the innovation can be adapted to different circumstances or contexts, perhaps in rural hospitals, or with harder to reach populations.

Replicability and adaptability studies might not be necessary – sometimes researchers move directly from efficacy to effectiveness. However, a replicability or adaptability study is recommended if the innovation is expensive, needs extensive modification for testing in new circumstances, or is heavily dependent on local conditions. *Case study 4* provides an example where a replicability study was needed given the different context.

Some issues to consider:

Details of the innovation and tolerance

variation: You will need to describe and measure the critical elements of the innovation. These might include contextual variables (e.g. local support and expertise) as well as the specific elements of the program implementation that you have found to be essential for success of the program. You will need to decide how much variability in the delivery of the innovation is acceptable to you.

For example:

- what level of expertise is important for innovation delivery?
- what is the appropriate level of resourcing?
- does it matter if the components of the innovation occur in a different order?

These should be defined in advance of the research; expert advice from a social scientist might be valuable.

Controls: The kind of control that you need will depend upon the extent to which the contexts and innovation are different from the previous efficacy studies. If they are very different, you may wish to establish full controls as outlined for efficacy studies. However, if the context and innovation are very similar to the efficacy study, then it is appropriate to consider a 'benchmark' approach; that is, your question might be whether the same level of symptom reduction as was observed in the efficacy study can also be achieved. This approach will not always be appropriate and if in doubt consulting an expert in research design is advisable. *Case studies 3 and 4* used different controls to assess outcomes: a pre/post control was used when testing an innovation with a different target group in *case study 3*; and a randomised controlled trial (RCT) was used when testing an innovation in a different international context.

Innovation delivery and resource implication:

As with efficacy studies, the measurement of innovation delivery is critical in replication and adaptation studies. Measures should be developed to understand whether program delivery differed from that in the efficacy study, how it differed and why. As replication and adaptability studies are often precursors to an effectiveness study or routine adoption, it will also be critical to understand the resource implications. This might include measures of costs, expertise requirements and impact on facilities.

CASE STUDY 3

Accessible weight loss: adapting a lifestyle intervention for adults with impaired mobility.

This study looked at whether a weight-loss program that had been shown to work in the general population can work with adults with impaired mobility.

A pre-post-design was used and mean weight loss and BMI scores were measured over the course of the program (20 weeks). The study examined the number of participants, level of participation in the 20-week program, and exposure to specific components of the innovation (e.g. conference calls that encourage reducing calorie and fat intake and increasing exercise through self-monitoring and problem solving). Satisfaction, retention, and engagement (proportion of conference calls attended and compliance with self-monitoring through the course of the program) were also measured.

Betts AC, Froehlich-Grobe K. *Disabil Health J.* 2016;S1936-6574(16)30092-9.

CASE STUDY 4

German adaptation of the Resources for Enhancing Alzheimer's Caregiver Health II: study protocol of a single-centred, randomised controlled trial.

A program called Resources for Enhancing Alzheimer's Caregiver Health II (REACH II) was developed in the United States and previous research demonstrated that it can result in a reduction of the stress and burdens faced by informal caregivers at home.

This paper describes the adaptation, application and evaluation of this intervention for use in a German-speaking area for the first time (the intervention was called Deutsche Adaption der Resources for Enhancing Alzheimer's Caregiver Health or DeREACH). The adaptations made to DeREACH were clearly articulated in the study design. As the context for DeREACH was very different to REACH, a randomised control trial was used to examine the impact of DeREACH in comparison to standard care. The outcome of primary interest was the effect on the burden of care-giving, and a validated tool for measuring the caregiver's perceived burden was utilised. A range of secondary outcomes were also measured (e.g. depression, health-related quality of life and social support of the family caregivers).

Heinrich S, Berwig M, Simon A, Jänichen J, Hallensleben N, Nickel W, Hinz A, Brähler E, Gertz HJ. *BMC Geriatr.* 2014;14:21.

Effectiveness



Does the innovation deliver expected outcomes under normal circumstances?

Effectiveness testing explores the impact of the innovation under normal operating conditions or real-life circumstances.

Some issues to consider:

Controls and samples: As with replicability and adaptability testing, effectiveness testing can either include controls or take a 'benchmarking' approach.

The sample must be representative of the population for which the innovation is intended. In effectiveness testing, you must invite participants in a representative way; for example, you might select participants from a list of all hospitals in the region, a list of all specialist clinics relevant to the project, or all patients attending for care. You will need to document your approach and keep careful records of the reasons for non-participation. You will want to be able to document any differences between those who took part and those who didn't. In *case study 5* participants were randomly selected in order to achieve a representative sample for the study.

You will also need to consider the number of participants, and advice from a statistician will

help make sure that you have sufficient numbers to answer your research question.

Innovation delivery and who did it work for?:

As with replicability and adaptability testing, good measures of how the innovation was delivered in practice will be important. As the number of participants is likely to be large in effectiveness studies, it may also be valuable to collect some information about the circumstances and conditions under which the innovation worked well and where it didn't. For example, you might want to analyse participation rates at different sites (or different kinds of sites) or examine the acceptability of the program to different kinds of participants.

Resourcing: As effectiveness testing is examining the impact in real life, a more accurate estimate of the resource implications is possible. These should be carefully assessed and an examination of the relationship between costs and benefits should be considered because it may be important in decision-making about adoption in routine practice. Further advice about economic analysis is in the Source Book but we recommend you consult an economist about the best approaches. In some cases the primary measure when assessing resource implications is cost of delivery.

CASE STUDY 5

The Medical Emergency Team System and not-for-resuscitation orders: results from the MERIT study.

Previous efficacy studies by the team have shown that the Medical Emergency Team (MET) can improve patient outcomes. The **effectiveness** study (the MERIT study) used a cluster randomised controlled trial to examine the effect of introducing a MET system in 23 hospitals. It compared the proportion and rate of Not For Resuscitation (NFR) orders issued in relation to "adverse events" and "adverse event-free emergency team calls" in hospitals with or without a MET system. Impact of treatment allocation in relation to proportion and rate of NFR orders issued at time of event were compared between MET and control hospitals. Compared to control, MET hospitals issued a greater number of NFR orders for both "adverse events" and "adverse event-free emergency team calls".

Chen J, Flabouris A, Bellomo R, Hillman K, Finfer S, MERIT Study Investigators for the Simpson Centre and the ANZICS Clinical Trials Group. Resuscitation. 2008;79:391-397.



Scalability

How can the innovation be integrated into the wider health system?

This stage will assess how an innovation that has been shown to be efficacious and/or effective can be expanded to reach a greater proportion of the eligible population, while retaining effectiveness.

Outcomes: Reach among the 'eligible population' is critical when assessing adoption. The eligible population needs to be clearly defined, and will vary depending on the type of innovation. For example, it could refer to a broad population group (clients over 45 years), or a small segment of the population (young adults with type 2 diabetes). What is important is that the research measures the number of those eligible to receive the innovation who participate, and understands who does or does not participate and why.

Some adoption studies measure the effectiveness of the innovation, but this is not essential, and in most cases the focus moves from outcomes of the innovation to the system for implementation. For example, if the evidence of the effectiveness of an innovation is strong, and the main question for researchers is how the innovation can be implemented in routine care, the study would focus on adoption rates, reach of the innovation, and factors that influence adoption (barriers and enablers).

Innovation delivery and who did it work for?:

This type of research should help us to understand whether the innovation is implemented as intended (fidelity), and what workforce, technical and organisational factors influence adoption (in order to understand the need for the innovation to be adapted). For example, the evaluation could assess: factors that influence reach and adoption; capacity of the system/organisation to implement the innovation (including capacity of workforce, information systems and training); compatibility with other interventions, policies and practice environments.

These studies can answer questions like: how does the innovation fit with existing systems?; what is the impact of this innovation on the organisations running it?

Samples: This type of research will usually draw upon qualitative and quantitative research methods. In both, the sample must be as representative of the 'eligible population' as feasible. If you are using quantitative research, you will need to consider the number of participants, and advice from a statistician will help make sure that you have sufficient numbers to answer your research question.

Costs and resourcing: Measurement of the costs should be considered; we recommend seeking advice from those with finance or accounting expertise.

CASE STUDY 6

A national evaluation of a dissemination and implementation initiative to enhance primary care practice capacity and improve cardiovascular disease care: the ESCALATES study protocol.

The EvidenceNOW Initiative (developed by the Agency for Healthcare Research and Quality) was designed to rapidly disseminate and implement evidence based cardiovascular disease preventive care in smaller primary care practices. Regional Cooperatives covering 12 states in the USA have been funded to create a health practice extension infrastructure for smaller primary care practices, to facilitate the implementation of interventions aimed at decreasing cardiovascular risk for their patient populations.

A protocol for a prospective observational study is described, with aims to evaluate the dissemination and implementation effort through EvidenceNOW with the goal of understanding *if the* innovation worked and *how* it worked. The study is a well-developed evaluation framework. A broad range of outcome measures will be collected in 1500 small primary care practices, measuring the extent to which practices meet performance targets in delivering evidence-based cardiovascular disease preventive care and the practice, organisational and associated contextual factors. The national evaluation included qualitative and quantitative data. Qualitative data included: online implementation diaries; observation and interviews at Cooperatives and practices; and systematic assessment of context from the perspective of Cooperative team members. Quantitative data included: practice-level performance on clinical quality measures; practice manager and member surveys; and systematic tracking of intervention delivery.

Cohen DJ, Balasubramanian BA, Gordon L, Marino M, Ono S, Solberg LI, Crabtree BF, Stange KC, Davis M, Miller WL, Damschroder LJ, McConnell KJ, Creswell J. *Implement Sci.* 2016;11:86

CASE STUDY 7

Evaluation of the national Cleanyourhands campaign to reduce *Staphylococcus aureus* bacteraemia and *Clostridium difficile* infection in hospitals in England and Wales by improved hand hygiene: four year, prospective, ecological, interrupted time series study.

This **scalability** study evaluated the impact of the Cleanyourhands campaign on rates of hospital procurement of alcohol hand rub and soap, reported trends in selected healthcare associated infections, and investigated the association between infections and procurement. It used a prospective interrupted time series design to assess changes over four years in 187 acute trusts in England and Wales. The innovation included installation of bedside alcohol hand rub, materials promoting hand hygiene and institutional engagement, regular hand hygiene audits, rolled out nationally from the beginning of the four year period. Time series designs need many regular measurements; this study assessed quarterly (that is, every three months) rates for each trust of hospital procurement of alcohol hand rub and liquid soap; *Staphylococcus aureus* bacteraemia (meticillin resistant (MRSA) and meticillin sensitive (MSSA)) and *Clostridium difficile* infection for each trust. Associations between procurement and infection rates were assessed by mixed effect Poisson regression model (which also accounted for effect of bed occupancy, hospital type, and timing of other national interventions targeting these infections).

Stone SP, Fuller C, Savage J, Cookson B, Hayward A, Cooper B, Duckworth G, Michie S, Murray M, Jeanes A, Roberts J, Teare L, Charlett A. *BMJ*. 2012;344:e3005.