

What is translational research? Background, concepts, and a definition

Abstract

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This discussion paper aims to offer an overview and working definition of translational research, appropriate to health. Methods: Using scholarly and applied literature, the paper first identifies key challenges in achieving evidencebased policy and practice. It highlights international policy interest in new approaches to evidence translation and the barriers to achieving sound evidence translation. The paper offers an explicit definition of translational research and explains why it is important to have such a definition. It then elaborates on this definition by identifying and exploring seven distinctive research practices that could be associated with translational research. Findings and conclusions: Translational research is research with a sense of place. Its defining feature is excellence in evidence for a specific context or sphere of action, whether that is health policy for the World Health Organisation or service design for a local non-government organisation. If research is to be translated at all, it needs to be meaningful to many specific contexts, including small and regional contexts. The best promise that translational research offers is of exciting new techniques to achieve rigour and systemacy for such localised 'real world' policy, service and practice contexts.

Keywords: Translational research, policy development, evidence-based practice.

Introduction

'Evidence-based policy' and 'evidence-based practice' are defining terms of our age, not just in health, but many sectors. Research today must meet the needs for integrated 'whole-of-system' policy development as well as 'whole-of-patient' practitioner decision-making.

However, ongoing efforts to develop better healthcare face great obstacles to do with achieving evidence-based decision and action. Many best practice clinical guidelines are still not used in service delivery, and many practitioners lack access to

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practical and conceptual resources for integrating clinical research findings into their daily practice (1). Available information on the performance of healthcare services in Australia and overseas suggests undesirable variations (2,3). The critical studies needed to address these variations remain undone in even developed nations such as the USA where they have been observed for at least a decade (3). The health policy literature offers evidence that too much policy at the micro, meso and macro levels has been shaped without access to sound evidence. Policy decision-making is too often shaped by political or economic imperatives that have little to do with healthy outcomes. It is also often hard for policymakers to use or apply the evidence because the context-particularly in primary and community healthcare—is so dynamic and highly variable itself.

Yet developing countries invest heavily in health research. Much of the world's health evidence base is contributed by The United States of America (USA). About half of web citations of health-related scientific papers are authored in the USA, however, the USA has only 4% of the total global population and a tiny portion of the global disease burden (4). This has important implications for the relevance and usefulness of evidence. Methodologies, evidence bases, and interventions developed in the USA context do not always translate well to other service contexts. For example, rural health practitioners and policy-makers often need to make decisions for small populations in diverse local contexts using a relatively homogenous urbanised evidence base (5). Health programs such as chronic disease self-management programs can require considerable education translation to be useful for remote Australia. However, the Lorig USA-based studies do not prefigure such problems of evidence transfer (6,7).

Health service research comprises a tiny fraction of the growing health research quantum. The USA doubled its biomedical research funding over the 1990s to spend up to 5.6% of total health expenditures on biomedical research by the beginning of the new century (8,9). However, in 2002 just 1.5% of biomedical research funding was spent on health services research (8). From 2000 to 2009 the Australian National Health and Medical Research Council's (NHMRC) research expenditure increased by a factor of four. However, funding increased for health services research only threefold (from 1.4% of total NHMRC funding in 2000 to 4.2% by 2009) (10).

Conceptualizing the key translational challenges

The 2001 America's Institute of Medicine report Crossing the Quality Chasm, observed that despite enormous increases in discovery-oriented basic science and technology, community benefits lagged behind with a healthcare system that too frequently fell short in 'its ability to translate knowledge into practice'(11). This concern-that much research was not being used-became a point of departure for the US National Institutes of Health's emphasis on translational research in its 21st Century research roadmap. Three key kinds of translational hurdles have been identified: between basic science researchers and clinical triallists, between clinical research and clinical practitioners; between clinical practitioners and patients who are the ultimate knowledge translators (1). Such translational hurdles are the subject of an emerging specialised field of enquiry into clinical knowledge translation, reflected in a growing body of literature, journals such as Implementation Science, as well as the operational arrangements of key bodies such as the Canadian Institutes of Health Research which has a division of 'knowledge translation' (1).

In the health policy literature, the translational challenges have also been conceptualised not only in terms of 1)how well research is translated across the disciplines of health, but also in terms of 2)how well research is translated into 'real world' policy, as well as 3)how well policy is translated between policy-makers and their communities of interest.

Increasing recognition of the need for translational research

Here in Australia, the final report of the National Health and Hospitals Reform Commission suggested that evidence-based practice and policy will be critical to delivering the reforms needed if Australia's healthcare system is to improve (12). Other recent Australian policy reports such as the discussion paper *The Healthiest Country by 2020* discussion paper (13) suggested the importance of meeting the three translational challenges just referred to:

- researcher to researcher
- researcher to practitioner and policy-maker
- practitioner or policy-maker to clients or communities of interest.

In *Taking Preventative Action* (14) the Australian government articulates its plan to gather, analyse and disseminate the available evidence and evidencebased programs to prevent disease. Yet there is little indication that there will be funding streams to deliver on these policy reports, including for translational research programs.

Internationally, there is also evidence of an increasing recognition that reform and development of health systems to meet present challenges will require fostering new styles of translational research that go beyond traditional applied or action research methods.

Canada's Health Research Roadmap: Creating innovative research for better health and healthcare (15) offers a strong translational research vision for the Canadian Institutes of Health Research that includes valuing solutions-focussed research and increasing the uptake of research. Research into health systems challenges that deliver innovation in the practitioner-patient interface is recognised as critical, especially in the wake of the global economic recession (15). Work by the Canadian Institutes of Health Research and The University of Toronto has also led to an important book Knowledge Translation in Health Care which offers a collection of papers on wide-ranging issues of knowledge translation. It suggests the sophistication of both theoretical understandings and practices in that country as they relate to translational research and implementation science: the definitions of knowledge translation, strategies for fostering knowledge translation that have relevance to practitioners and policy-makers as well as translational researchers (16).

The UK's Medical Research Council appear to be taking a similar approach in their Medical Research Council's 2009-2014 *Strategic Plan*. This document offers four key strategic aims that include 'Picking research that delivers' including in areas such as 'addressing the complex interplay between genetics, development, and life events or lifestyles'. In particular, aim two 'research to people' states that:

"The MRC will work with researchers in both public and private sectors, regulators, and the breadth of stakeholder communities to ensure that research of the highest quality is translated into tangible benefits for society as a whole. *Objectives:* Translation of research: To bring the health impacts of fundamental research to people more quickly. *Regulation, ethics, governance and working with decisionmakers:* To uphold and guide ethical research practice and the highest standards of research governance; to enhance the regulatory process by providing innovative approaches. *Communication:* To enhance communication with scientists, the public, policy-makers and partners" (17)

New Zealand's Health Research Council's Strategic Plan 2008-13, also contains a strong translational focus. The second of its four goals is to 'Maximise the benefits of health research'. This involves the following 'key activities':

- "Undertake research outcome evaluations
- develop user-friendly research findings database
- Continue to develop and improve web offerings as a key knowledge resource
- Introduce processes that link previous contract performance with future funding
- decisions
- Work with health sector to evolve mechanisms for communication and uptake of
- translational research findings
- Support research champions in policy and service delivery environments
- Grow partnering arrangements"(18)

The World Health Organisation's policy on research for health, contained in its 2007 report *Strengthening Health Systems to Improve Health Outcomes: WHO's Framework for Action* (19) outlines the critical need for research that addresses the needs of health systems and services. It offers a framework with six key features: "service delivery; health workforce; information; medical products, vaccines and technologies; financing; and leadership and governance" (19).

The 'research quality' conundrum: Assessing the real value of research

However, what mechanisms might achieve this translation remains uncertain in many countries. In the Australian health sector such translational research challenges appear relatively less well theorised with reference to what is known about evidence transfer and less well operationalised. This is so even, or perhaps especially, in the light of the NHMRC's recent *Draft National Strategy for Medical Research and Public Health Research*, which places a strong emphasis on translating knowledge through research partnerships, centres for research excellence, collaborative research initiatives and grants for commercial development (20).

Further, what is known about research usefulness too often does not seem to inform frameworks that measure the quality of research and drive the production of ever more research. These quality frameworks are often driven by research establishments that favour impacts in research communities rather than (ostensibly harder to measure) impacts in policy and practice. Current framework trends in Australia quality are demonstrated by the Australian Research Council's 2010 final draft rankings of academic journals: in health disciplines these rankings omit or more lowly rank Australian journals, interdisciplinary journals, journals produced for health practitioners and policymakers, and journals with a health service orientation. Unless greatly revised, this quality framework for Australian research will exclude many forms of research with a high social impact or a practitioner and policy focus. The ERA rankings can to a limited extent address research output, but cannot address research uptake and accessibility and related issues. For example, a focus on published work creates a risk of bias: negative results either remaining unpublished or published in perceived lower quality journals that will in turn affect the potential for the 'whole picture' to be seen and will lead to uptake of incomplete evidence.

The development of Australia's journal rankings for the ERA framework has created a focus on A and Aplus ranked journals in the academic research industry in that country that does not appear to reflect the important thinking, developments, methods and evidence offered by the literature on what is known about evaluating the return for communities of different kinds of investments. For example, a 'social return on investment' analysis of community development work by the Community Development Foundation and the new Economics Framework in the UK (21) suggests how the true return on investments in community development-typically a feature of more applied, community-based, and practitioneroriented research-can be measured. For example, the report suggests that the benefits of research that is oriented to community development ('CD') is much higher than previously acknowledged: 'community development creates £2.16 of social and economic value for every £1 invested' and 'for each £1 a local authority invests in a CD worker, £6 of value is contributed by community members in volunteering time' (21).

In Australia, Community Indicators Victoria (CIV) a collaborative project hosted by the McCaughey Centre at the School of Population Health, University of Melbourne, provides 'a community well-being indicator framework with local level data'. 'Well-being data' can be accessed via 'Well-being reports' based on 'Well-being indicators' that are used in community engagement exercises to develop understandings of goals and priorities leading to better policy development, planning and action planning, supported by better reporting of progress towards these goals. The CIV also offers (trademark) 'Results Based Accountability', a systematic approach to thinking about and taking action in relation to improving the quality of life in different kinds of communities, small and large. 'Results Based Accountability' is also relevant to improvement of the performance of programs, as well as agencies and service systems (http://www.communityindicators. net.au/).

Such approaches to measuring community benefits have application to the task of understanding, measuring, and improving the benefits that research brings to communities. They suggest that research that is more directly focussed on the contexts of real world communities has benefits for society as a whole that should be accounted for in valid notions of research impact and value. The value for the community of narrow notions of research quality need to be challenged through cost-benefits analyses that measure the real return for the community on research investment. Unless that is done, narrow notions of research quality will continue to be supported by faulty, vague and unexamined assumptions of value more suggestive of the academic status quo than the national interest or national health agenda.

Questioning within universities about research practice

The idea that meeting the challenges of evidencebased policy and practice will involve questioning not only narrow notions of research quality, but also the ways in which research is practiced, published and communicated has been gaining ground in health and many other disciplines.(5) In health, the debates around extending classical experimental methods to make them more useful for 'real world' decisionmaking contexts have resulted in new methodological models badged as 'pragmatic clinical trial' designs integrating for example, cost-benefit analyses, as suggested by the work of Tunis and others (22,23). The struggle in social epidemiology to capture neighbourhood complexity is in part a revisionist struggle to engage with causal complexity in a way that is meaningful for 'real world' decision-making (5,24-26). Nursing research has questioned and developed more socially authentic methods for engaging with the interface between practitioners and patients including through innovative languagecentered applications of methods such as hermeneutic analysis and critical discourse theory (27,28). Yet nursing research-even, and perhaps especially, when designed to be fit for purpose-often struggles with perceptions that it is somehow of less importance than that emanating from medically qualified and/or biomedical researchers.

Yet the most vigorous questioning of the social relevance of both traditional quantitative and qualitative research methods has come from outside the health sciences. This has been accompanied by a reworking of those methods (5). The rise of celebrated case-based analysts in the social sciences such as Ragin (29), Rihoux (30), George and Bennett (31) have been part of a sustained re-thinking of the place of traditional research methods. Ragin acknowledged the well-known problems of generalisability that much qualitative and case study research has for highstakes real world decision-making. His book Fuzzy-Set Social Science is widely acknowledged as one of the most sustained and persuasive critiques of the traditional statistical methods in the last few decades. Building on his earlier work What is a Case?(32) Ragin engages with the technical assumptions of classical statistical methods to suggest that these 'variable-driven' methods have often failed the test of social relevance because they fail to engage with the causal complexity of policy and practice contexts (29). The challenge of making research more useful is, according to Ragin, not about translating or reproducing research evidence in different forums and genres, as if policy-makers and practitioners need a watered-down version of this research to help them understand it better. He offers an alternative in his model of quali-quantitative case-based analysis which has been published in over 250 applications across different disciplines (30).

The emerging field of health policy research led by Davies and Nutley (33) in the United Kingdom (UK), and Lavis (34,35) in Canada also provides strong evidence, including from studies of policymakers, that traditional research approaches often have poor transferability to policy-making contexts because they have homogenising and simplifying tendencies. Paradoxically, the technical form of statistical evidence can often take on a seeming complexity or inaccessibility by lay readers even, and perhaps especially, when it is homogenising and simplifying complex causality with what Ragin calls 'correlational thinking' (36).

The health policy research and the wider policy research suggest that Ragin may be right. While there are many barriers to the transfer of research, including its timeliness, there is a disconnect between research methods and what is needed to achieve change in local contexts (37-39). This disconnect is also apparent in the implementation science literature on evidence transfer into clinical practice (1).

Defining translational research

The term 'translational research' has really only become part of the research lexicon in the 21st Century. Almost all of the literature yielded by

searches on variations of this term was published from 2000 onwards.

Translational research has been described as being about the goal of realising the full clinical promise of new basic science or 'laboratory' knowledge in areas such as molecular biology, the genome, neuroscience, immunology and so on, in new therapeutic ways. As such, it focuses on developing bio-medical knowledge for the practical needs of clinical diagnosis, treatment and prevention (4,40). The 'two-way street' of translational research emphasises not only the transfer of research into clinical practice but also the translation of clinical insights into research practice through, for example, the development of hypotheses (40).

However, translational research is a term that has included a broad church of researchers beyond this 'two way street' for clinical research and practice. The term has been used to include many kinds of health services and policy-oriented research as well as a wide range of multidisciplinary research for holistic health interventions, from the treatment of asthma in children to adolescent substance abuse to chronic diseases in older people.

How then should translational research be defined? The best definition of translational research is one that works to promote excellence in research for health policy and practice. Such a definition could be a tool for realising this excellence through new theoretical understandings, strategies and operational arrangements for helping research make a difference. Within university health science departments this definition could become a rallying point for building research capacity, identity and morale, reducing wastage of those many researchers who lie at the margins of narrow and singular 'gold standards' for research quality. This definition could help focus talent on addressing critical gaps, especially in a climate where 'metrics' of research quality and value define 'who' is doing research rather than 'what' knowledge is being used in what ways. Beyond universities, such a definition could work to support the legitimacy of claims policy-makers, practitioners, and patients make that there be a good return on a country's health research investments. Such a definition could also work to strengthen the social contract between universities and their communities, building shared understandings that while quality and usefulness in health research are not the same, they should be related.

Achieving an agreed-on ideal of translational research such as this is clearly a goal that must be worked for over time. However, a preliminary broad working definition of 'translational research' can be developed from the translational research literature and is given in Box 1.

Box 1. A working definition of translational research

Translational is systematic, research transdisciplinary research based on a welldeveloped model of producing or transforming research evidence for the specific local contexts of health and allied health practice and policy. It offers new evidence-based tools and resources for practical application in health prevention, preemption, intervention, and follow-up. It may also offer new health policy frameworks, health service designs and models for services development in those local contexts. Such tools, resources and information may be transformed or developed from a pre-existing or new body of research evidence. Translational research may also include developing new research methods for delivering more useable evidence for practice and policy.

'Transdisciplinary research' in this context is research that, by combining elements of different approaches from different disciplines, offers genuinely new approaches that are more than simply 'multidisciplinary'. That is, transdisciplinary research involves synergising new approaches using elements of methods from different disciplines. The foregoing definition of translational research differs from the operational definition of translational science used by America's National Institutes of Health (NIH) because it goes beyond the idea of a creating a twoway street from laboratory bench to clinical medical bedside and vice versa. It overlaps with the NIH definition because it focuses on 'research aimed at enhancing the adoption of best practices in the community'. Yet it goes beyond this to include a wide group of practitioners in health and allied health areas, as well as policy-makers wanting to adopt 'whole-ofsystems' approaches to complex health challenges. It also shares with the operational NIH definition an emphasis on the idea of 'science' as broadly covering 'the discovery of new knowledge about health and disease prevention, pre-emption, and treatment; as well as methodological research to develop or improve research tools' (41).

From the perspective of translational research, discovery-oriented research is one step in the production of evidence for policy and practice. In translational research, the work of designing policy frameworks or tools for practitioners is seen as also involving an original contribution, albeit in a different kind of science and style of excellence.

A distinctive set of research practices

All research is to some extent translational—although we have been very comfortable with the distinction implied by the terms 'applied research' and 'experimental research' for a long time. Much health research can be located along a continuum in terms of the extent to which it suggests elements of the working definition. However, for the purposes of analysis, seven distinctive research practices of translational research can be identified using the broader evidence transfer literature (42).

translational research First. involves an engagement with policy-makers and practitioners in deciphering the local particulars of the research question (42). A focus on local context has been found to be positively associated with evidence transfer (43). This involves bringing together the local contextual evidence with the national and international evidence. It can involve deciphering the pragmatic dimensions and constraints, possible tradeoffs, uncertainties, and so on, of local policy or practice contexts. It can also involve a focus on implementation issues such as sustainability. One of the useful conceptual models for doing this is presented in a paper by Walker and colleagues, 'Defining uncertainty: A conceptual basis for uncertainty management in model-based decision support' (44). The 2004 National Health Service report Choosing Health: Making Choices Easier offers examples of this focus on local context. It grapples with the policy problems of helping people manage their own health in ways that lead to healthy

choices. It describes very specific constraints in the UK to do with social attitudes, constraints to do with free markets and so on, as well as the contextualised history of policy efforts in areas such as under-age smoking (45). Second, translational research involves new reviewing styles for the inclusion of not just 'gold standard' research understood as randomised clinical trials but also a wide range of possible evidence that falls outside this category (42). A whole body of literature has developed offering techniques for translational reviewing, revitalising traditional reviewing methods. For example, the influential work of Pawson and Tilley in the social sciences and their 'realistic evaluation' methodology challenges many of the tenets and highlights the limitations of the classical experimental model which they say has failed policy-makers across many sectors (46-49). Their focus is upon using diverse sources to understand the underlying mechanisms that make interventions work in specific contexts (48). Government agencies such as the Cabinet Office of the UK Government have become active in developing new guidelines offering alternative models of assessing the quality of, and integrating, different kinds of evidence as part of such translational research practices (50). Over the last decade a host of agencies have been established to meet such translational review challenges: The Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre) in London (http://eppi.ioe.ac. uk); The ESRC UK Centre for Evidence-based Policy and Practice (http://www.esrcsocietytoday.ac.uk/ ESRCInfoCentre/index academic.aspx): The Campbell Collaboration (http://www.campbell collaboration.org/); and in the USA agencies such as the Resource Center for Health Policy at the University of Washington (http://depts.washington. edu/rchpol).

Third, translational research is characterised by innovative transdisciplinary research methods with intelligent designs for policy and practice. These methods reflect a notion of quality that values not only internal research validity but also external or social validity. An engagement with the complex causality at work in specific policy and practice contexts is their defining note (42). Examples include: futures scenario modelling or forecasting methods (51,52) for health policy; street level operations research for hospital performance (53); small-*N* case based methods (29) for comparing health systems.

Fourth, translational research involves a focus consensus-building (consensus-finding on and consensus-making) to achieve change in communities of interest, consistent with best practice in the growing science of community engagement (42). In health the science of participatory research practices is represented in, for example, the book edited by Minkler and Wallerstein Community-based Participatory Research for Health (54). The field of community-based research for health suggests that new science in such techniques as the PANDA (Participatory Appraisal of Needs and Development of Action) designed by White and Taket (55-57) or the Q-methodology for identifying stakeholders and their issues developed by Ellis and colleagues (58). However, despite exhortations for, and studies showing the importance of, participative approaches for evidence-based policy and practice (59), it is known that only a minority of health researchers involve health stakeholders (60).

However, the need for localised, communitybased research of different kinds will persist. In Australia, the creation of local primary care organisations ('medicare locals') and local hospital networks has been accompanied by an idea of quality that is about being responsive to the local and particular. At the Kings Fund in the UK there has been a strong emphasis on the use of action learning cycles and the creation of communities of practice in micro systems at the local level, in ways that include patients and carers. For example, in relation to avoiding hospital admissions, recent work by the Kings Fund suggests that some interventions being used in the NHS do not work very well and that approaches that create micro communities of learning, such as the Wandsworth community virtual wards 'replicating the multidisciplinary approach of the hospital ward in the community' are likely to work better (61).

Fifth, translational research can also include delivering evidence in a form that is persuasive to policy-makers, practitioners and the wider community. The work of Stone (62) and others in the field of policy analysis has demonstrated the critical role of policy argument in delivering evidence to policy-makers and their communities: the art of crafting empirical data into persuasive 'causal stories' (63) and data-driven arguments about for example, interests, rights, equality and efficiency, and trade-offs between these (62). Such work is informed by state-of-the-art knowledge about numeric and language-based sign systems. Some of these approaches have been modelled by Nelson, Hess and Croyle in their 2009 book *Making Data Talk: The Science and Practice of Translating Public Health Research and Surveillance Findings to Policy Makers, the Public, and the Press* (39). A practical example might be the report *Hospital Guide 2008: The Health of our Hospitals Revealed* (64) which has used some of these techniques to make hospital performance a *cause célèbre* in the UK (42).

Sixth, translational research involves the development of models for action that can be operationalised in policy and practice. A range of literature, from policy analysis (65) through to decision-path modelling in evidence-based medicine, suggests ways of developing models for action by policy-makers and practitioners. This involves attention to delivering what is traditionally called the research 'recommendations' in a form that maximises their take-up in specific contexts.

An example might be the stepwise service development framework provided in a recent study from New Zealand *A Review of the Quality, Safety and Management of Maternity Services in the Wellington Region* (42,66).

translational Finally, research is often characterised by an active engagement with the dissemination and implementation of evidence in communities of action. Knowledge about how to achieve this spans a quarter of a century from the founding work of Weiss (67), to the dissemination theory of Rogers (68), to recent notable contributions from health by Nutley, Walter and Davies in their book Using Evidence: How Research can Inform Public Services (33). This suggests that for research transfer to happen something more than knowledge of that research is needed. Translational research is informed by the complexities of taking evidence 'off the shelf'. It is also about creating iterative, strategic processes between the researcher and other knowledge purveyors and communities of action, over time (42,69).

This focus on the more sociological elements of public health, including the science of ensuring better community participation was pioneered largely in the UK, and includes the work of Jennie Popay whose 1994 edited collection *Researching the People's Health* marked a new decade of dissatisfaction with the adequacy of classical statistical methods for complex health reform agendas.

Conclusions

In short, the term 'translational research' lies on the horizon of our understanding of how to make research more useful. It is not simply about 'what is' (an existing body of research methods). It is also about 'what could be' (new and emerging methods across the disciplines). It is research with a sense of place: it is defined by a commitment to excellence in evidence for a specific context or sphere of action, whether that is health policy for the World Health Organisation or service design for a local non government organisation. Perhaps the greatest limitation of existing 'variable-driven', big-N ideas of research quality is that they do not impose an expectation that evidence-making for local and regional settings can be done systematically and to a pitch of excellence. Yet if research is to be translated at all, it also needs to be meaningful to many such small and regional contexts. The best promise that translational research offers is of exciting new techniques to achieve rigour and systemacy for such localised 'real world' policy, service and practice contexts. Some of these new techniques are showcased in this book.

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