THE SCIENCE OF TRANSLATIONAL RESEARCH:
WHAT WE KNOW (AND WHAT WE NEED TO KNOW)
FOR CLOSING EVIDENCE – PRACTICE GAPS

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**Summary**

An academic field of translational studies is beginning to coalesce in the United States. This new field is applied in nature, with interdependent knowledge bases in translational research, with the aspirations of a becoming a generalizable science, and translational practice, through the art of customizing solutions to problems in real-time in practice settings.

As is often the case with new fields of study, the field of translational studies is fomenting and forming without much strategic direction. Haphazard development can be seen in the mutually exclusive efforts being made in advocating for and conducting research about translation in the disparate fields of business and management, communication, international development, policy analysis, and education. This lack of foresight, if continued, will slow theoretical codification of how to achieve translation. No where is the potential gain from a well-considered research and practice agenda for translational studies more critical than in health and health care.

After mapping the parameters of this new field and presenting a rationale for why a field of translational studies is important, concentration is given over to the research portion of translational studies. In contrast to the efficacy and effectiveness study objective of establishing the internal validity of interventions, the defining characteristic of translational research is an objective of establishing external validity and diffusion. The latter must be established with efficiency. Without the achievement of efficiency in translational intervention, evidence – practice gaps are likely to worsen.

Two types of translational research are identified: (1) external validity studies, and (2) diffusion of innovation studies. The former are characterized by emphasis on identifying the factors related to the replication of desired effects across sites. The latter are characterized by emphasis on breadth of adoption and implementation. The report concludes with a call for merging the study of the external validity and diffusion of evidence-based practice, programs, and policies.
I once asked a worker at a crematorium, who had a curiously contented look on his face, what he found so satisfying about his work. He replied that what fascinated him was the way in which so much went in and so little came out.

- A. L. Cochrane (1972, p. 12)\(^1\)

*Effectiveness and Efficiency*

Being innovative is a cherished American value. The independence associated with being first, being different, and being creative is all constitutive of our long celebration of individualism. Doing things differently is also a value that suffuses our national health services system. In clinical decision making and patient treatment, in health services research, in proposal and manuscript scoring criteria, in each and every facet of the health services system, we reward innovation. The result is that innovations – the novel practices, programs, and policies that we test and try – enter the health services system from all directions and sources.

We are acculturated early to share in this pro-innovation bias. In college, the student who wishes to learn how to design and test new health programs has hundreds of academic units from which to choose, from schools of public health to departments of psychology to health sciences units. Yet what of the student who wishes to learn how to replicate effective programs? She is alone. Not one American academic unit has translation, diffusion, or dissemination of effective programs as its forte. Not one. While some health services analysts may prefer to think of our innovative health services system as percolating with potential, a sober analysis based in the realities of imperfect communication, information overload, and bounded rationality is more suggestive of the American health services system as a place where innovations go to die. Much goes in, but little comes out.

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Ironically, Archie Cochrane contributed to this structural imbalance with publication of his influential monograph. His was an eloquent and timely call for better evidence of intervention effect to improve the British National Health Service, an objective interpreted by his many followers to require rigorous study of intervention efficacy. The subsequent focus on establishing the effects of new treatments, protocols, and programs meant that questions of how to spread the relatively few effective health services interventions were not the object of much study.

Questions of how to spread effective practices, programs, and policies must assume an important and central position in the future of health care and health promotion research if we are to improve our systems of health care and health promotion. While disparate cases of heightened effectiveness, efficiency, and equity can be identified in America’s clinics, hospitals, HMOs, worksites, and settings such as nursing homes and health clubs, quality improvement at the systems level as called for in texts such as Crossing the Quality Chasm, Continuous Quality Improvement in Health Care, Evaluating the Healthcare System, and The Healthcare Quality Book\(^2\) will only be achieved if effective innovations spread across organizations, across networks, and from state to state.

The purposive spread of evidence-based policies, programs, and practices by expanding them or multiplying them has been identified as the single most valuable contribution that private foundations and federal agencies can make to society.\(^3\) Such a position reflects a pro-*diffusion* bias in which efficiency is the central focus, not the prevalent pro-innovation bias with its focus on intervention efficacy and effectiveness. Achieving Healthy People 2010 objectives will require the use of efficient strategies for spreading effective interventions. This is the purpose of translational research.

**Defining Translational Research**


The birth of a new science – especially a social science – does not often occur. The most recent major discipline-level innovation in American higher education social sciences was the field of communication study founded in the 1950s, an institutionalization driven by the arrival of new communication technologies, the interests of philanthropies and the needs of federal agencies, and applied problems that were inadequately addressed by the dominant paradigms in education, psychology, sociology, and political science. Now, a science of translational research is emerging, driven by some of the same factors that gave rise to communication study.

Research about translation is a response to a general acknowledgment that successful, effective practices, programs and policies resulting from clinical and community trials, demonstration projects, and community-based research as conducted by academicians very often do not affect the services that clinical staff, community service providers, and other practitioners fashion and provide to residents, clients, patients, and populations at risk. In any one societal sector (constituted, for example, by program coordinators of after-school programs) the state of the science (what researchers collectively know) and the state of the art (what practitioners collectively do) co-exist more or less autonomously, each realm of activity having little effect on the other. Concerning medical care, this situation has been referred to as a “quality chasm” by the U.S. Institute of Medicine. Concerning workplace safety, the National Institute for Occupational Safety and Health identifies this as a problem of “research-to-practice”. Concerning the lack of healthy choices in school cafeterias, the National Cancer Institute identifies a “problem of translation.” Education policy makers lament the challenges of “going to scale” with proven programs. The National Science Foundation has an active and expanding funding agenda not just in dissemination, but in “dissemination research.” The Robert Wood Johnson Foundation attends to efforts in “rapid replication.” The Environmental Protection Agency labels this a challenge of “diffusing innovations.” These concerns and initiatives are synonyms for the process and objectives of translation when one is not only observing or documenting a change process, but intervening to affect it.

The forthcoming field of translational studies will consist of research about translation (consisting of studies of external validity and of diffusion) as well as instruction in the practice of translation (how to evaluate and select evidence-based innovations, how to select and identify target populations, and how to

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adapt and improve innovations for practice settings). Here, the focus is on the research portion of this new field, with emphasis on achieving the efficient spread of effective innovations. This means affecting many health care and health promotion settings of a common type, concomitantly.

**Translational research** is the study of how evidence-based practices, programs, and policies can best be communicated for adaptation and improvement by practitioners for the benefit of their constituents. A **practitioner** is an organizational representative who makes decisions about which programs and practices will be implemented to provide information, advice, support, and services to constituents. The organizations that employ practitioners exist in societal sectors, defined as collections of focal organizations operating in the same domain without respect to proximity, as identified by the similarity of their services, products or functions, together with those organizations that critically influence the performance of the focal organizations. Conceptualizing and then figuring out how to learn about and communicate with a societal sector of practitioners who often work in complex organizations is a key to the efficient spread of evidence-based innovations.

The level of analysis of the societal sector means that broad spread is the research objective. Translational research draws heavily on the diffusion of innovations paradigm, particularly in exploring strategies to mimic “natural” diffusion processes that either do not or seemingly do not have a centralized diffusion source at the root of intervention effort. Yet translational research goes beyond the typical diffusion study since translation (1) only considers evidence-based (especially worthy) innovations, (2) is predictive and interventionist, (3) targets practitioners who are service delivery intermediaries, (4) relies on much formative feedback from representative members of the societal sector in question as in marketing, (5) offers choice and encourages context-specific adaptation and improvement, and (6) draws on other literatures such as cognitive psychology and interactive website design to encourage spread.

So translational research is a form of process intervention research in which the domain of action concerns how previously validated interventions can be spread.

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among practitioners of a type, such as chiropractors or exercise physiologists. When practitioners know one another, meet, and talk, the societal sector is tied together through an informal communication network. Targeting a societal sector in which the members are tied together in a communication network offers strategic advantages for the diffusion of evidence-based practices since the relational structure of the network can be studied and its relationally most important members recruited to assist in the diffusion effort. To affect a societal sector that is not interconnected through communication, diffusion effort must build on some commonly perceived or actual similarity among sector members, such as professional membership, training, occupation, co-location, or preference or behavior, as in marketing research.

Why are practitioners, not the end-users or people who directly experience a problem, the objects of translational change? In organizations such as social service agencies, community-based nonprofits, schools, hospitals, and clinics, practitioners interact directly with constituents by counseling them or instructing them. For this reason, practitioner organizations are often referred to as intermediaries: They mediate and potentially add value to the flow of resources from government and other funding sources to populations of people who need services. The attitudes and behavior of practitioners in intermediary organizations in response to the diffusion of innovations is key to eventual constituent outcomes (such as a reduction in the percentage of low-income women of childbearing age who smoke) and societal impacts (such as cancer incidence among low-income women decreasing). Intervening “upstream” is an efficient diffusion approach as long as the inductions are sufficiently strong to change the services that are provided to end-users.

The orientation to translational research presented here has implications for how researchers may study translation in the coming years:

- Researchers will not design and study their own practices, programs, and policies. Rather, translational researchers will select evidence-based innovations developed and tested by others, and then design and test strategies for spreading those innovations into broader use.
- Efficiency will become a more important variable than effectiveness in translational research. Broad impact at low cost will be the gold standard for the assessment of translation, in sharp contrast to the gold standard of randomized controlled trials for the assessment of internal validity in efficacy studies.
Translational strategies will be informed by the history of social influence research, which documents that non-purposive, “natural” diffusion is more the result of imitation and influence than it is information and education.

Why Translational Research, and Why Now?

It is not hyperbole to claim that a crisis characterizes the ways that government agencies, private foundations, and the vast majority of their grantees address social problems. We reward the new at the expense of the proven; we award primacy to local solutions rather than good ideas from afar; we recognize as evidence of effect the measurement of internal validity without serious attention to the measurement of external validity; and we spend a wildly disproportionate share of public resources on invention, with precious little for subsequent diffusion.

There have been recent calls for change, and increasing if modest federal support for studying the translation of research evidence into practice use. Still, unlike in the American commercial sector where every dollar invested in R&D is tripled in the work of marketing, distribution, and product support to enhance the probability of widespread sales, federal agencies and foundations that support research emphasize the generation and testing of innovations without equivalent rigorous thought or ample resources devoted to subsequent diffusion.

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Inquiry into these problems is being driven by stakeholders outside of academe, in government, philanthropy, nongovernmental organizations, and multinational business. Yet commonalities proliferate across these diverse practice contexts. If common problems, processes, and solutions can be codified, academic departments of translational studies could populate American higher education by 2015, awarding degrees in translational studies. First, however, sense has to be made of this evolving hybrid field of study.

While the traditional approach to diffusion scholarship popularized by Katz and Lazarsfeld\textsuperscript{10} and Rogers\textsuperscript{11} and since tested and explicated by them and others has applicable concepts and clear implications for advancing translational research, it is deficient in certain respects, too.

**Difficulties of Translation**

Translational research concerns the purposive spread of innovations that have been derived from empirical research and are repackaged for practitioners, for the benefit of the people served by those practitioners. Translation is challenging because the knowledge in question must traverse a heterogenous divide, from the intellectual and social world of researchers on one side to the intellectual and social world of practitioners on the other. We know from many studies of failed technology transfer, failed knowledge dissemination, and failed research-to-practice that translation cannot be assumed. Researchers and practitioners often exhibit heterogeneity in education, occupation, interests, and value systems. Practitioners tend to see themselves as members of client systems in which they attempt to gain entree and intervene on local cultural terms. Practitioners often live and work within the same communities that they try to affect. Researchers tend to be outside such systems even when they spend long periods studying them, and are often identified more with change agencies, government departments, and universities. Effective practitioners are considered insiders by the people they try to help; researchers – even effective ones – rarely achieve such status. And while some types of information about effective practices can be communicated effectively and efficiently between heterogenous groups, other types of information resists easy or rapid translation. People retain some knowledge tacitly, not even knowing what it is that they themselves know and

\begin{itemize}
  
  \item \textsuperscript{11}Rogers EM. *Diffusion of Innovations*. Glencoe, IL: Free Press, 1962.
\end{itemize}
thus what it is that others too need to know. Tacit knowledge is sticky knowledge; it likes to stay where it is.\textsuperscript{12}

While these reasons for the common failure to share effective programs and practices between researchers and practitioners are understandable, conditions are actually worse. The perceptual basis of heterogeneity requires far less to manifest. Effective practices have been shown to require years to diffuse across departments \textit{even within the same organization and even among similarly trained employees}.\textsuperscript{13} While a sense of competition can lead people in the same positions but in different organizations to adopt innovations,\textsuperscript{14} it can also function within the firm as a disincentive on sharing and helping.

A focus on research-to-practice translation has been of long concern and empirical study in health services, particularly in efforts to embed effective medical and clinical treatments in practice guidelines and then communicate them to health care providers.\textsuperscript{15} For scholars in other fields, translational research is quite novel. For a behavioral scientist in forestry, for example, studying how the posting of markers along hiking trails may reduce degradation of forests would not be uncommon. But studying how proven practices in trail signage can be spread among forestry managers – a translational research topic – would be uncommon. To water conservation specialists, studies of novel approaches to water reclamation have been common. But studies of failed city to city adoption of evidence-based water reclamation projects – translation – are uncommon. Even among disease prevention researchers, studies of hypodermic needle exchange programs for the reduction of HIV have proliferated, but translational studies of how to best encourage city health departments to adopt effective needle exchange programs have been rare.

\begin{itemize}
  \item \textsuperscript{12} Szulanski G. Exploring the internal stickiness: Impediments to the transfer of best practice within the firm. \textit{Strategic Management Journal}; 1996; 17; 27-43.
  \item \textsuperscript{13} O’Dell C, & Grayson CJ. If only we knew what we know: Identification and transfer of internal best practices. \textit{California Management Review}; 1998; 40(3); 154-174.
  \item \textsuperscript{14} Burt RS. Social origins of good ideas. Unpublished manuscript. Chicago: Graduate School of Business, University of Chicago; 2003.
\end{itemize}
Where are problems of translation vested? Who is responsible in the many cases when translation fails? Since research evidence in topical domains such as patient care and classroom learning is constantly produced and communicated, a lack of uptake by practitioners such as nurses and teachers is most often conceptualized as their problem; that is, a practitioner problem. The solution in typical dissemination terms is to communicate more, more often, in more ways. The highly publicized disparities in health care have been conceptualized and redressed in this way. If use of the most effective medical care options lag in the American south, medical staff there are blamed for not counseling patients to select those options. Translation is a problem of practitioners, and as a consequence it is their constituents who lose out.

The problem with this typical view of translation responsibility is twofold: First, solutions to this assignment of blame have not produced more uptake by practitioners. Doctors are blamed for not using a new effective procedure, so content about the procedure is added to continuing medical education modules in addition to emailed office alerts, messages to patient support groups for them to ask their doctors about the procedure, and professional conference presentations. Unfortunately, more communication, more often, in more ways does not predictably lead to more adoption and implementation of evidence-based practices. We know that practitioners are skilled at ignoring and disavowing the relevance of research to their problems of practice. We know that evidence of effectiveness is not a strong predictor of adoption and use. The diffusion literature is replete with ineffective innovations that broadly diffused, and of innovations that rapidly spread without any evidence of their effectiveness. The majority of studies of clinical practice guidelines, which recommend proven practices and procedures for patient conditions, document


the difficulty of affecting the decisions of health care providers, and should give pause to anyone with a more-information-is-better view of translation.

Second, researchers can be poor or unconcerned communicators; researchers can develop research-based interventions without consideration of practitioner needs or wants; and researchers can mistakenly perceive practitioners as homogeneous sets of professionals (“clinical endocrinologists”) who do not have or experience personal, professional, workplace, and client-based variations that would logically lead to diverse practitioner preferences, too. In short, there is much to blame researchers for if part of the objective of the research in question is to make a difference among non-researchers. In an attempt to sensitize researchers to some of these issues, an increasing number of scholars and funders of research have begun suggesting that “if we want more research-based practice, we need more practice-based research.”

**Achieving Efficiency: Societal Sectors as Learning Systems**

With externally validated health care and health promotion interventions, efficiencies in dissemination must be achieved to have a reasonable chance at closing evidence – practice gaps on a large scale. One means for doing this is to conceptualize and then operationalize societal sector-level strategies.

Societal sectors are collections of similar organizations together with their suppliers and collaborators that constitute systems of service provision. Members of the National Council on the Aging constitute a societal sector, as do competing and collaborating health maintenance organizations, as do members of the International Fitness Professionals Association. The inter-organizational networks and common channels of information that tie together organizations in societal sectors are becoming the locus of idea production and decision making –

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21 Greer, Goodwin, Freeman, & Wu, 2002.

even governance – through standards setting. Sectors can be real or imagined; employees of member organizations can recognize as real the existence of a particular sector because of their interactions with employees of other like organizations, or researchers and others can simply conceptualize a societal sector on the basis of observed commonalities of its focal organizations.

Societal sectors and the complex organizations that comprise them are a logical locus for change because they can be transformed from the status quo at time 1 to other, more desirable states at time 2 (such as from the use of ineffective physical activity programs to a state of practice where evidence-based programs are understood and appropriately adapted and improved). Sector change is a learning process, one that is indicative of the active translation of research into practice and sometimes back again. When information about effective practices, programs, or policies is framed in ways meaningful to potential adopters, packaged and presented back to them as informational products, and then targeted first to influential organizational members of a sector and met with a positive opinion leader response, knowledge is translated from science to art, from research to practice. The state of the sector does not just change due to communication; it improves. Thus, translation, when it occurs, is a learning process.

But learning is not the normative state for social systems. Usually, learning is resisted effectively at the systems level. Rejection of innovation is a means of system preservation. Being conservative is being safe. This is the case in social systems (superorganisms) of animals and insects just as it is among humans. When systems level change occurs, it often occurs rapidly. This is so because of two reasons. First, consequential individual decision making that cascades into system level learning is not a linear process. It begins slow, accelerates, and then slows. Acceleration is due to individuals modeling their attitudes and behaviors


on their perceptions of others.\(^{26}\) Modeling occurs with reference to influential individuals,\(^{27}\) one's real or imagined group,\(^{28}\) and to what is currently favored within the larger social system.\(^{29}\) Modeling occurs through perceptions of others' beliefs and behaviors. When those perceptions of system norms culminate to a critical mass of acceptance, the system suddenly converts or "tips" via social contagion just as infectious diseases do in epidemiologic contagion.\(^{30}\) In the spread of innovations this is what Rogers (2003) referred to as "the diffusion effect".

So the small scale, uncoordinated beliefs and actions of individuals are subject to social communication, verbal and otherwise. Individuals who have not yet adopted an innovation feel increasing social pressure to do so. Through watching, listening, reading, questioning, and talk, they come to believe that they are in a decreasing minority. Then, they too adopt. The cognitively simple heuristics of imitation used by most humans in social systems just as by animals in groups and by insects in swarms culminate into system level learning effects that appear collectively wise since at that level they do represent a sophisticated social response.\(^{31}\)

The second reason why system level change can proceed rapidly is that group members simultaneously search for and advocate alternatives, thus speeding the


time to decision. Simultaneous-option decision making can occur nearly
instantaneously in heuristic fashion as individuals perceive acceptance or
rejection by others.\textsuperscript{32}

Recognizing and using these social determinants of human behavior is precisely
what so many unsuccessful information dissemination campaigns do not do.\textsuperscript{33}
There is no larger lesson to be drawn from the dismal record of consensus
statement and practice guideline dissemination research.\textsuperscript{34} More or better
information alone is not the answer.\textsuperscript{35} Strategies to pair social influence with
information dissemination are needed, and they underlie the perspective on
translational research here.

A societal sector is not defined by geography, though a translational effort may
of course be focused on a geographic portion of a societal sector (public K-6
schools in the mountain states, for example). A radiating hub and spokes
network of relations that an organization such as Los Angeles General Hospital
has with its board of directors, funders, outreach units, collaborating service
providers and community groups, and patients (termed an organizational field) is
a good choice for deciding whom to target and involve in a localized change
effort when adoption of a given innovation is needed by a variety of local actors
all of which are stakeholders of the same focal organization. Combining focal
organizations of a type as in a societal sector, with key stakeholders in a
geographic area as in an organizational field, produces an ecological community,
a hybrid approach to system identification named for its holistic, complex, local
composition.\textsuperscript{36}

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Using the Extant Structure of Societal Sectors

Societal sectors have two types of lead user organizations.

Innovative organizations are risk-taking; they adopt more innovations and do so earlier than other organizations of the same type. They are often poorly integrated into networks of other like-organizations, with extensive links outside the sector, and thus not much bound by sector norms. For the majority of potential adopting organizations, the actions of innovative organizations often serve as examples of what not to do.

Opinion leading organizations are visible and admired organizations that serve as models for others in the sector. These norm-setting organizations determine through their own example which innovations will receive attention and be widely tried. Representatives of opinion leading organizations actively monitor the oftentimes inefficient trial and error of innovations by innovative organizations, selecting for adaptation and implementation those that best suit the needs of their organization and of the sector. These early adopting organizations engage in a rationale decision process since they base their adoption decisions on the extent of the match that is achievable between the innovation and their organization.

Opinion leading organizations, because of their potential in determining the reactions to innovations by the majority of organizations within a societal sector, link together the behavior of focal organizations. Follower organizations eventually fall in line, depending on their degree of organizational innovativeness, less out of desire for efficiency than a desire to not be left out. Whereas lead users adopt for performance after extensive information search, many later adopter organizations with less information and higher uncertainty adopt because opinion leading organizations have adopted. Stated differently,


38 Rogers, 2003.

position in a social network affects not only the time at which that unit adopts an innovation, but also why it adopts when it does.\textsuperscript{40} Very often, convincing data is not available about the effectiveness of the innovation in question, but in the absence of performance data, sometimes even prior to the availability of performance data,\textsuperscript{41} innovations spread as fashions or fads – social contagion – throughout societal sectors.\textsuperscript{42}

Because of the somewhat conservative orientation of opinion leading organizations – they have reputation to lose as a result of acting too innovative – innovations that are perceived to be high risk are better seeded with innovative organizations, where risk taking is normative, and whose actions are often monitored by those in opinion leading organizations. Moderate and low risk innovations can be directly seeded with opinion leading organizations. Delineating which early adopting organizations are innovative and which organizations are opinion leading can be done through multiple means, though sociometric analysis of questionnaire or archival data about information seeking and advice seeking is most valid when practical.

**External Validity Study as a Type of Translational Research**

While the emphasis in this report is on the spread of evidence-based innovations into many practice settings in societal sectors, there is another type of translational research that is crucial for building the knowledge base about how we achieve translation and with what quality. This type of study emphasizes the measurement and achievement of *external validity*, the ability of a program to achieve positive effects across different sites. The purpose of external validity studies is to assess how well internally valid interventions fare when tested under real-world field conditions. In the medical fields, this is the distinction between efficacy and effectiveness trials, of moving from bench to bedside. In public


health and community health fields, this is the distinction between a first fielding of an intervention at an initial site and its subsequent replication at other sites. Scholars in other fields have long referred to this distinction as a difference between basic and applied research.\textsuperscript{43}

The extent to which internal validity claims generalize across variations in settings, populations, times, and variations in implementation is the key question in external validity studies. The ultimate objective of such work is to be able to predict which interventions are most likely robust in their effects.

Serious attention to issues of external validity is long overdue. The evaluation of interventions is based in the widespread belief that \textit{“internal validity is the sine qua non”} of evaluative activity.\textsuperscript{44} Internal validity is an assessment of the extent to which changes in the level of some dependent variable \((Y)\) is the result of a program or intervention \((X)\). Questions of the sort, “Does patient implementation of a balance and flexibility routine persist as a result of daily peer support?” and “What are the outcomes of the intervention?” and “Which treatment produced the highest benefit/cost ratio?” are questions of the internal validity of a practice, program, or policy. The operative issue for nearly all such evaluative endeavors is the extent to which the program produced its designers’ intended effect. The commonplace existence of differences in epistemology, method, and utility has led to a belief among contemporary researchers that intervention studies are well-characterized by pluralism; that the many types of evaluations conducted represent a broad diversity of possible research approaches.\textsuperscript{45}

In fact, however, pluralism resides in only one domain of intervention evaluation: The establishment of internal validity. Nearly ignored are the domains of (1) external validity and (2) broad-scale diffusion of effective programs. While tests of external validity and diffusion are inappropriate foci for the study of unproven health services innovations, external validity and diffusion tests are precisely the domain of interest for studying evidence-based practices, programs, and policies.

\textsuperscript{43} Rowe AP. From scientific idea to practical use. \textit{Minerva}, 1964; II(3): 303-319.

\textsuperscript{44} Campbell DT, Stanley JC. Experimental and quasi-experimental designs for research on teaching. In Gage NL (ed.), \textit{Handbook of Research on Teaching}. Chicago: Rand McNally, 1963; 175, italics in the original.

Though the term was first introduced by Donald T. Campbell, the first methodologist to explicate the factors associated with external validity was Lee J. Cronbach. In his large-scale studies of federal education programs, Cronbach came to believe that internal validity was a poor measure of a program’s ability to perform under diverse environmental and organizational conditions. The more an intervention that was demonstrated and validated in one site could still achieve positive effects when translated for other places, other populations, other times, even other topics, the more externally valid the intervention. In Guala’s (2003) words, “...it [the program] is externally valid if A causes B not only in E, but also in a set of other circumstances of interest F, G, H, etc.”

In his 1982 book, Cronbach’s schema concerning external validity focused on program replication. He was not referring to statistical generalizability, the extent to which the results from a sample are representative of an untested population. Nor was Cronbach so much focused on “scaling up” a program from a decontextualized experimental setting into a full-scale field test as are some analysts. Cronbach’s focus in this aspect of his voluminous career was on theorizing about the process for translating a full-scale field test into altered or unaltered replications to achieve sector-wide social improvement through systematic investigation and comparison of the units (frequently individuals) studied and unstudied, the treatments they receive, how observations of effects are made, and differences between settings. This process he labeled extrapolation.


Lately, measurement and research design theorists have begun to refine Cronbach’s ideas, arguing that the likely external validity of specific programs can be assessed through causal generalization via five variables:

- **surface similarity**, the extent to which the prototypical characteristics of a model program are like those in second-order sites;
- **ruling out irrelevancies**, in which one clarifies which differences between the original demonstration and the subsequent second-order tests are superfluous;
- **making discriminations**, by identifying those conditions under which the causal processes of a program do not operate;
- **interpolation and extrapolation**, by generalizing both within a range of observed scores and beyond it; and
- **causal explanation**, such that one can explain which parts of a treatment affect which parts of an outcome through which mediating processes.\(^{51}\)

Other scholars have termed similar external validity emphases ecological validity for the purpose of encouraging more studies that include larger proportions of groups that are typically underrepresented in psychological research.\(^{52}\)

In health services research, a great deal of attention has been paid to limited scale replication of health care and health promotion interventions. In these studies and in the journals that report them, such studies comprise the field of translational research, moving from research to practice, in the form of a science-based intervention that is tested in an uncontrolled setting such as a dentist’s office, or a prevention program demonstrated to be effective in dentist’s office that is tested anew at multiple offices, or consensus guidelines and the use of their suggestions by dentists. Unfortunately, the purpose of most of these studies has not been to contribute to theory about external validity.


Literature about evidence-based medicine, in particular, is replete with the assumption of a research progression or “pipeline” from efficacy tests to effectiveness trials. This assumption is often represented in different but synonymous language, as from basic to applied research, and from the establishment of internal validity to the establishment of external validity. The key to this assumption is the belief that there is a positive relationship between a program working well and its subsequent effectiveness in other settings, for other populations, at other times. But is there a positive relationship between internal validity and external validity? Is it only the internally valid program that can prove externally valid? There is reason to doubt the veracity of this assumption.

Moderating variables that differ from site to site can interact to differentially affect program performance across sites. A program implemented in precisely the same ways in multiple sites can, due to site moderating variation, show different results. There is no logical reason why the factors that account for program success in one site will be similarly associated with program adoption, implementation, persistence, and success in subsequent sites unless sites are selected to be very homogenous. And homogeneity of sites is not the point of external validity tests. Indeed, Glasgow, Lichtenstein, and Marcus (2003) posit that “it is highly unlikely that interventions that are successful in efficacy studies will do well in effectiveness studies, or in real-world applications.”

External validity (the replication of intervention effects across sites) is one of Cronbach’s means for achieving generalization. Another is construct validity, an understanding of the theoretical reasons why an intervention achieves its effects. All attempts at generalization involve abstraction; construct validity is particularly important because a theoretical model that explains observed intervention effects at site 1 can be applied in the creation of context-specific, adapted interventions at subsequent sites. Some analysts argue that an abstract notion is all that can be translated when the innovation is a social program. Studies of research utilization and policy decision makers have shown that instrumental use


54 Glasgow, Lichtenstein, & Marcus, 2003; 1262.


(specific results about specific studied interventions) is often overshadowed by the use of conceptual knowledge,\textsuperscript{57} which bears a relationship to construct validity.

Generalizing on the basis of external validity concerns the fidelity with which a specific intervention is implemented in subsequent sites. Generalizing on the basis of construct validity concerns theoretic fidelity; the extent to which the same causal variables are responsible for observed effects. Many various implementations of an original program can be true to the theoretical basis for an original observed effect. Thus even with adaptations in practice, construct validity can be high.

External validity concepts have been most explicitly emphasized and operationalized by Russell Glasgow and his colleagues. In a series of studies and in the development of a tool created for practitioners and researchers to use in formative and summative evaluations of intervention external and internal validity, they draw attention to participation rates and representativeness of participants, internal validity and unintended negative consequences of interventions, organizational adoption rates, implementation fidelity, and individual maintenance and institutional sustainability.\textsuperscript{58} The web-based interactive tool allows intervention designers or evaluators to assess each of these aspects of intervention reach, efficacy or effectiveness, adoption, implementation, and maintenance.\textsuperscript{59} A number of investigators have now begun or completed studies using this framework for assessing external validity and the extent to which the interventions studied can be likely applied to other settings.\textsuperscript{60}


\textsuperscript{59} www.re-aim.org.

\textsuperscript{60} For example, Gordon JS. Tobacco cessation via public health dental clinics. Oregon Research Institute. Award Number 1R01CA107442-01A2. Bethesda, MD: National Cancer Institute.
Variables predictive of external validity need to be tested summatively and applied formatively to improve future programming. These are new research directions for the fields of program evaluation and health services that promise a direct means of improving the design of interventions on the basis of what affects program implementation and maintenance in field settings. The result will be effective practice-based research.61

**Diffusion Study as a Type of Translational Research**

Albert Bandura suggested that there is “the need to examine the efficacy of alternative modes of diffusion with the same care and rigor as is devoted to the development of the models being diffused”62 This suggestion is echoed here from a system transformation perspective63 that recognizes the existence and, thus, intervention utility of interpersonal networks that tie together organizations of a common type within societal sectors.

After decades during which diffusion processes were studied descriptively and through the post-hoc investigation of why innovations spread, a validated understanding of the individual and organizational level explanations for diffusion exists.64 In the 1960s, researchers began to use principles from this paradigm to spread reproductive health and agricultural innovations.65 Rogers (1973) presented a strategy for accelerating diffusion based on empirical studies of contraceptive adoption.66 Scholars successfully used diffusion concepts in a

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variety of field studies, including those with improved public health as an objective, and those with the objectives of improving the lives of farmers domestically and internationally with cooperative extension services as innovation distribution channels.

Beginning with the results of Bryce Ryan and Neil Gross, diffusion – the over-time spread of new ideas – has been understood to be a social process. While knowledge is often gained through the largely one-way transmission of information especially with the increased information search capabilities of new communication technologies, persuasion occurs most effectively through the two-way communication of social influence in the form of local informal local opinion leaders who are already in place and who already influence the decisions of others.

When people decide to adopt an innovation, they do so in part because of what they think about the innovation, what they think others think about the

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innovation, how they judge the innovation comparatively to alternatives, and timing.

- **Innovation attributes** are the perceived characteristics of an innovation; attributes most positively related to adoption decisions are lower cost, effectiveness, compatibility, simplicity, observability, and trialability.
- **Opinion leaders** are perceived as trustworthy and expert by followers and looked to for example, information, and advice. For consequential innovations, opinion leaders form passive or active judgments about innovations that affect the rate and extent of diffusion.
- **Clustering** is the grouping of a small set of innovations for the purposes of increasing the likelihood that potential adopters will find a best fit between an innovation and their organizational and programming context, and make an adoption decision.
- **Timing** is the estimation of when to introduce an innovation so that potential adopters are already primed to appreciate the problem that the solution addresses.

These four variables can be designed into the information and influence strategies that form the basis of a diffusion effort and that, importantly, are of low cost so that efficiency in reach can be achieved.

Opinion leadership is not created in a diffusion effort; it is a trait identified to exist with a small proportion of societal sector members. Opinion leaders are perceived to be influential, credible, popular, a near-peer friend, and

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accessible.\textsuperscript{77} Opinion leadership tends to be stable across time,\textsuperscript{78} operates consistently across social systems such as hospitals, schools, and towns,\textsuperscript{79} as well as national level policy networks,\textsuperscript{80} and operates negatively as well as positively.\textsuperscript{81} In intervention research, opinion leaders are especially effective when they are not asked to do too much. Asking opinion leaders to advocate, persuade, promote, or educate in ways they normally would not with their colleagues is asking them to risk their status within the system in question by formalizing what is an informal role.\textsuperscript{82}

The use of diffusion principles such as innovation attributes, opinion leadership, and clustering can be done via a centralized diffusion source that still

\textsuperscript{74} Lam SSK, & Schaubroeck J. A field experiment testing frontline opinion leaders as change agents. \textit{Journal of Applied Psychology}, 2000; 85(6): 987-995.

\textsuperscript{75} Kelly et al., 1991.


\textsuperscript{78} O’Brien DJ, Raedeke A, & Hassinger EW. The social networks of leaders in more or less viable communities six years later: A research note. \textit{Rural Sociology}, 1998; 63(1): 109-127.


\textsuperscript{81} Leonard-Barton D. Experts as negative opinion leaders in the diffusion of a technological innovation. \textit{Journal of Consumer Research}, 1985; 914-926.

acknowledges and is at least partly embedded in the realities of practice settings. Practitioners who adopt innovations do not do so passively. Practitioners talk with other practitioners and exchange information and advice.

Practitioners also actively shape innovations by reinventing, combining, and customizing them so that the parameters of practice are best served by the innovation. Because every practitioner is unique and modification is the norm with health care and health promotion innovations, invention at the local level needs to be encouraged. This can be done in responsible ways. Rather than being seen as a threat to implementation fidelity, local invention that is facilitated and guided through tools that enhance construct validity and external validity will produce greater satisfaction and attention to implementation. The most effective translational strategies will encourage choice and creativity through efficient means, and be designed to require learning by researchers of implementation in practice settings for researcher enlightenment.

While this orientation to diffusion increases the participation of adopters in the diffusion process, the overall effort implied is only modestly decentralized. Centralization of resources is a key to efficiency of effort. This approach to decentralized diffusion is one that seeks to marry the advantages of centralized resources and the efficiency of diffusion effects, with good options for individuation at the level of practitioner-adopters.

Care is warranted in the early stages of planning for diffusion, just as thoughtful planning is key to many types of intervention. The primary tools in this endeavor are social network analysis, media content monitoring for the estimation of timing, and marketing-based techniques of formative evaluation that operationalize innovation attributes.

Perception, for all of its frequent irrationality, drives diffusion in ways that the quality of an innovation often does not. Literature about diffusion is replete with cases of faster, better, or cheaper policies and practices that do not achieve widespread use, even after many years, and even when campaigns are conducted

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to publicize them. This is so even for evidence-based policies and practices that have demonstrated advantages compared to alternative ways of achieving the same ends. And the paradigm has its share of policies and programs that do not work but that diffuse readily.

Evidence, in the history of diffusion studies as well as in the history of policy studies and knowledge utilization, is not necessary for diffusion to occur. In our mediated and interpersonal information environments, evidence has considerable competition.\(^{85}\)

Is the common lack of a relationship between innovation quality (which may well correlate with external validity) and the rate of diffusion an indication that evidence does not matter? No. For certain audiences, evidence is very important, especially in confirming the prior beliefs of potential adopters. Evidence of effectiveness and efficiency is important because it can be combined with other sorts of information to collectively affect perceptions. But the perceptions of intended target audience members can be measured in advance of introducing an innovation for the purpose of improving its chances of diffusion.

**Aligning External Validity and Diffusion Studies**

The translational research agenda deriving from an alignment of external validity studies and diffusion studies is very rich with possibility. This possibility goes well beyond the suggestion that more research should be conducted to understand the facilitators and barriers involved in the process of intervention adoption and implementation.\(^{86}\) The point here is not that such an understanding would be without merit or insight; it is that the answer to such questions does not focus on tests of efficient strategies for affecting behavior, where efficiency means reaching many in as cost-effective a way as is possible.

For example, marketing principles can be used to tie together the external validity emphasis on assessing intervention effects and the diffusion emphasis on

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efficiency of reach.\textsuperscript{87} For while the external validity objective is replication of effect and the diffusion objective is broad spread of the practice, program, or policy, study designs exist to measure the achievement of both objectives. Again, part of the answer may be in making sure that information-based interventions have an influence strategy component. This can make the difference between intervention effects achieved via workshops at a cost of $269-470 per practitioner versus intervention effects achieved via opinion leader engagement at a cost of $38 per client.\textsuperscript{88}

The primary advantage for combining external validity and diffusion study is that their objectives are consonant with translating research into practice, and what we learn from each type of study is non-redundant and important. While both types of studies concern themselves with the variables of reach, compatibility, effectiveness, adoption, implementation, and maintenance, they do so in different ways. External validity study tells us about the likelihood or extent to which the effects of an intervention are achieved at one or multiple sites. Diffusion study tells us the extent to which an intervention spreads to many sites. This could be a marriage of the maximization of reach and careful attention to effectiveness.

Both outcomes are important in translational research in concluding which strategies achieve efficiency.

The brightest possibility of bringing together these two traditions of translational research is that both offer actionable tools and strategies for improving health services. And both traditions begin with evidence-based interventions.

Translational studies in health services can be usefully informed by several literatures other than external validity studies and diffusion studies. For example, studies of how policies spread from country to country, across the American states, and among organizations such as hospitals are conducted by political scientists and scholars of public administration.\textsuperscript{89} Policy diffusion differs from the

\textsuperscript{87} Maibach EW, Van Duyn MA, & Bloodgood B. A marketing perspective on disseminating evidence-based approaches to disease prevention and health promotion. \textit{Preventing Chronic Disease}, 2006; 3(3): 1-11.


\textsuperscript{89} Roberts NC, King PJ. \textit{Transforming Public Policy: Dynamics of Policy Entrepreneurship and Innovation}. San Francisco: Jossey-Bass, 1996; Mintrom M. \textit{Policy Entrepreneurs and School
more general literature about diffusion because once adopted, implementation of and adherence to an innovative policy is often compulsory rather than voluntary. As evidence-based practices become more integrated into reimbursement systems, compulsory adoption begins to better characterize many health care provider decisions.

Studies about the framing and spread of public issues, termed agenda-setting, also could be combined with translational studies to provide contextual understanding and provide novel measures of social and informational environments and their influence on reach, effectiveness or diffusion, adoption, implementation, and maintenance. The agenda-setting process is an ongoing competition among issue proponents to gain the attention of media professionals, the public, and policy elites. Agenda-setting offers an explanation of why information about certain issues, and not other issues, is available to the public; how public opinion is shaped; and why certain issues are addressed through policy actions while other issues are not. Agenda-setting is about salience, the importance of an issue. But agenda-setting effects have been shown to extend to framing, too, meaning how an issue is understood and with which other issues or events it will be associated.90

Translational studies will not only concern themselves with estimating the external validity and diffusion of evidence-based practices and programs. Ideas, positions on issues, technologies, and policies all will prove interesting in translational study, too, for they are all relevant to the lessening of evidence-practice gaps.

Conclusion

The forthcoming field of translational studies will consist of research about translation as shown in studies of external validity and of diffusion, as well as instruction in the practice of translation that will focus on how to evaluate and select evidence-based innovations, how to select and identify target populations, and how to adapt and improve innovations for practice settings. The focus in this report has been on the research portion of this new field, with emphasis on achieving the efficient spread of effective innovations by combining the study of

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external validity with the study of diffusion. Health services research, in particular, can benefit from this applied research combination.