RESEARCH
Monograph

What Is Translational Research? Concepts and Applications in Nutrition and Dietetics

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ABSTRACT
This monograph is tenth in a series of articles focused on research design and analysis, and provides an overview of translational research concepts. Specifically, this article presents models and processes describing translational research, defines key terms, discusses methodological considerations for speeding the translation of nutrition research into practice, illustrates application of translational research concepts for nutrition practitioners and researchers, and provides examples of translational research resources and training opportunities. To promote the efficiency and translation of evidence-based nutrition guidelines into routine clinical-, community-, and policy-based practice, the dissemination and implementation phases of translational research are highlighted and illustrated in this monograph.
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THIS MONOGRAPH IS TENTH IN A SERIES EXPLORING the importance of research design, statistical analysis, and epidemiologic methods as applied in nutrition and dietetics research. The purpose of this series is to help registered dietitian nutritionists (RDNs) and aspiring researchers apply and interpret analytic and scientific principles consistent with high-quality nutrition research in their own work. This monograph focuses on translational research, emphasizing the dissemination and implementation phases. Numerous definitions and models of translational research exist, which can trigger diverse meanings of this concept across disciplines, yet underscores the importance of translational research across nearly all health professionals.[1-3] In brief, translational research is the process of applying laboratory research to human studies and enhancing the adoption of evidence-based practices in real-world settings to reach broad populations. Translational research provides the data underlying evidence-based clinical practice and population-based health promotion efforts, thereby offering direct relevance for RDNs. To effectively communicate within a multidisciplinary health care and/or research team, RDNs should become familiar with prominent translational research models, concepts, methods, resources, and training opportunities.

It takes an estimated 17 years to translate 14% of research discoveries into day-to-day practice.[4] Labeled as the 17-year odyssey, this alarming statistic is attributed to a number of factors along the research pipeline, ranging from the number of years it takes to transfer knowledge from the completed research stage to submission and acceptance for publication, to indexing through bibliographic databases, to inclusion in systematic reviews, to the development of evidence-based guidelines, and to the dissemination and implementation of evidence-based guidelines.[4-6] Other estimates suggest this process takes closer to 24 years.[7] Regardless, this lag time is considered excessive, and a more rapid implementation of conclusive findings to provide public health benefit endorses the principles of translational research. For example, while the 20-year National Cholesterol Education Program produced three Adult Treatment Panel Guidelines as well as Population Based Guidelines and the first ever Pediatric Panel Guidelines for prevention and treatment of cardiovascular disease, none of these reports were derived from the type of systematic reviews that are currently required for the 2010 Dietary Guidelines for Americans and the American Heart Association/American College of Cardiology guidelines published in 2013.[8-12] These systematic reviews now encompass the quality, quantity, and ranking of the research available that form the basis for the recommended guidelines. The growing emphasis on translational research has further supported a better defined and more rapid turnaround than what was previously more often based on expert opinion and therefore lacked efforts and evidence for broad-scale dissemination and implementation.

Efficiency and productivity in converting conclusive research into practice are now high priorities for RDNs, including both practitioners and researchers. This monograph describes prominent models and fundamental processes of translational research, defines key terms and discusses critical methodological considerations for speeding the translation of nutrition research into practice, illustrates how translational research concepts can be applied, and

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provides examples of key translational research resources and training opportunities. For purposes of advancing the field of nutrition and dietetics research and because of the paucity of peer-reviewed publications in the dissemination and implementation phases of translation research, this monograph specifically focuses on these dissemination and implementation phases.[13,14] Because RDNs serve key roles within health care, community, and research systems, they have important responsibilities related to the translation of evidenced-based nutrition research into clinical practice and population-based health efforts.

MODELS OF TRANSLATIONAL RESEARCH

To adequately comprehend the related research concepts, methods, and measurement issues presented in this review, familiarity with prominent translational research models is helpful. The goal here is to highlight some commonalities and critiques among several current models, leaving the investigator free to choose the best approach.

Simply stated, translational research represents the transition between basic laboratory research and evidence-based practice, described by Sung and colleagues[15] as Translation 1 and Translation 2. Translation 1 is the translation of basic biomedical science to applied studies, including initial clinical testing in humans; and Translation 2 is defined as the translation of clinical science and knowledge into clinical practice and health decision making. Some have argued, however, that a two-phase model of translational research is too narrowly defined,[3] resulting in the development of several other multiphase (eg, three-[16,17] and four-phase[18]) models. For example, Westfall and colleagues[16] expand on Sung and colleagues' model to include a Translation 3 (Translation 3). The Translation 1 of Sung and colleagues' and Westfall and colleagues' model is similar; both focus on the translation from basic science to human studies. However, Westfall and colleagues' model further divides Sung and colleagues' Translation 2 into two distinct phases. Specifically, Westfall and colleagues' Translation 2 phase depicts research moving from early clinical trials (eg, small clinical trials testing treatments with healthy study participants) into later clinical trials (eg, randomized controlled multicenter trials with large and more diverse patient groups), and successively to guideline development, meta-analysis, and systematic reviews. The Translation 3 phase moves research from controlled clinical trials into more practical and more broadly generalizable practice-based research, as well as dissemination and implementation research. Dissemination and implementation research involves an active research approach of spreading evidence-based interventions to targeted audiences, and includes the process of integrating evidence-based practices and interventions into real-world settings.

Westfall and colleagues clearly denote translational steps that have historically been missing from medical and nutrition research, such as the translation of scientific discoveries from laboratory/research settings to patients receiving care in real-world amublatory care settings.[16] These steps provide a critical connection from academic scientific discoveries to improving individual patient care and to subsequently advancing public health.

Several other models are also frequently noted in the translational research literature. In the "3 T's roadmap model," Dougherty and colleagues define Translation 1 as activities to test what care works, Translation 2 as activities to test who benefits from promising care, and Translation 3 as activities to test how to deliver high-quality care reliably and in all settings.[17] Alternatively, Khoury and colleagues'[18] model defines translational research as Translation 1 from gene discovery to health application, Translation 2 from health application to evidence-based guideline, Translation 3 from guideline to health practice, and Translation 4 from practice to health impact. Across each of these models, there are distinctions in the number of phases and associated terminology, yet the underlying key features and research progressions are remarkably similar. Nonetheless, Trochim and colleagues[6] critique the literature on translational research models by noting that the conflicting numbers and definitions across the translational research phases have the potential to complicate communication and confuse interpretations. A thorough synthesis of the underlying differences and commonalities among these models can be found elsewhere.[6]

Although each of these models incorporates the concept of bi-directionality, another critique of translational research models is the conventional linear approach. As a result, new conceptual models continue to emerge, including those that highlight the dissemination and implementation phases of translational research, such as the "evidence integration triangle" proposed by Glasgow and colleagues.[19] Within a multilevel context, evidence and stakeholders are central in the "evidence integration triangle"; surrounded by interactions among three main components, including intervention program/policy, implementation processes, and practice progress measures. Regardless of the specific model of translational research, each provides guidance in understanding the process of moving from basic, to clinical, to broad population health research.

METHODOLOGICAL CONSIDERATIONS IN TRANSLATIONAL RESEARCH

Key Concepts and Methods in Translational Research

Figure 1 details key concepts in translational research and thus the confidence that any individual study informs the translational message/guidance for a body of research. First, a key translational research concept is the distinction between a study's internal and external validity.[25] Internal validity can be defined as the degree to which study bias is minimized so that a study produces valid estimates of a causal relationship within the study sample.[20] External validity can be defined as the degree to which findings based on a study sample can be generalized to other populations and settings.[20] Both types of validity are critical, yet study designs often face a tradeoff between internal and external validity such that strengthening the features of one type of validity compromises the other. In designing and executing research studies, the threats to internal and external validity should be dually considered. Historically, emphasis in research has been placed on protecting internal validity.[26] However, to increase the likelihood that evidence-based guidelines and programs fit within local circumstances and real-world settings, more attention to conducting research with high external validity is needed.

Second, it is important to understand the types of trials conducted across the phases of translational research.[27] The early phase of research (Translation 1) is generally regarded as basic research and includes pre-intervention studies, such as preclinical and animal research. This research can identify disease mechanisms and promising interventions or treatments—those for which there is reason to believe there will be positive effects if applied more broadly, including to humans. The Translation 2 research is commonly referred to as early human clinical studies and efficacy type trials. These trials test whether the treatment or intervention works for humans under optimal conditions. In both Translation 1 and 2 studies, the priority is to minimize threats to internal validity by isolating variables and intervention effects. The later phases of research (Translation 3) are typically referred to as effectiveness trials, dissemination trials, implementation trials, and scale-up or spread trials. This research translates scientific findings from earlier study samples examined in controlled clinical research settings to broader populations and real-world settings. In these trials, the emphasis shifts to minimizing threats to external validity and optimizing design factors that promote generalizability of findings. While dissemination trials and implementation trials can be distinctly described, dissemination is an inherent part of implementation. Although these research phases are often illustrated separately, hybrid-type trial designs should also be considered.[28] Hybrid trials have an a priori focus of simultaneously assessing effectiveness and implementation outcomes. Hybrid trials help balance internal and external validity factors and can stimulate the efficiency and speed of translating the research findings. An illustration of a hybrid-type trial can be found in case study 1 of the Applications in Nutrition and Dietetics Practice and Research section, as this study example concurrently assesses effectiveness and implementation outcomes. Finally, it is important to recognize that population-based observational studies and surveys typically fit into the Translation 2 phase of translation.

Distinguishing between explanatory and practical or pragmatic trials is another important translational research concept.[1,22-24,29] Explanatory trials are designed to maximize the opportunity for discovering some biological or clinical effect of a new treatment. The primary focus of explanatory trials is on internal validity, with emphasis on randomization and highly controlled conditions. In pragmatic and practical clinical trials, by contrast, the hypothesis and study design are formulated based on information needed to make a decision. Practical clinical trials compare a given intervention to other clinically relevant interventions (as opposed to a no-treatment or placebo control condition), include diverse participants from a variety of practice settings, and measure a broad range of health outcomes, including those most relevant to organizational decision makers. The overall goal of a practical clinical trial is to evaluate whether a program works under usual conditions, with emphasis on external validity. Several tools are available to assist in application of research concepts related to practical clinical trials, including the extended Consolidated Standards of Reporting Trials (CONSORT) checklist, which adds eight items to the original checklist to guide the conduct and reporting of practical clinical trials[29] (the original CONSORT consists of a 22-item checklist to help improve the reporting of a randomized controlled trial[30]); and the Pragmatic-Explanatory Continuum Indicator Summary, which provides 10 dimensions to identify the extent to which a trial is pragmatic vs explanatory.

Similar to practical clinical trials, there is advocacy for more comparative effectiveness research,[1] defined as "the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat, and monitor health conditions in real-world settings."[31] Comparative effectiveness research involves multiple stakeholders, such as patients, caregiver, clinicians, and policymakers, in shared decision making along all stages of the research process. Many key elements of comparative effectiveness research are similar to those of practical clinical trials, such as assessing multiple outcomes using mixed methods, applying flexible research designs to fit the research questions, and transparent reporting. Some scholars specifically distinguish comparative effectiveness research from practical clinical trials in that they evaluate participation and representativeness, and collect cost and economic data.[14] Nonetheless, comparative effectiveness research and practical clinical trials are similar and share the goal of producing actionable evidence that is relevant to real-world situations, as opposed to the traditional research paradigm that decontextualizes and simplifies evidence in an effort to preserve internal validity.

Models for Dissemination and Implementation Research

To effectively speed the translation of nutrition and dietetics research, familiarity with models intended to guide dissemination and implementation research is important.[13] Dissemination and implementation models are comparable to the application of health behavior theories to guide nutrition program planning and evaluation, and should be used in a similar capacity. For ease of description, dissemination and implementation theories and frameworks are mutually referred to as models in this monograph. Ideally, a dissemination and implementation model should be applied across all research phases to inform the study's hypothesis, design, methodology, measures, execution, and evaluation. Tabak and colleagues recently synthesized 61 dissemination and implementation models and categorized them based on three criteria, including a 5-point scale of construct flexibility (ie, 1=broad, 5=operational), the spectrum of focus along the dissemination to implementation continuum (ie, D-only, D>I, D=I, I<D, I-only), and the socioecologic level targeted by the dissemination and implementation model (ie, individual, organization, community, system, policy).[32] The overview tables and case studies presented by Tabak and colleagues in this comprehensive review serve as a guide for RDNs in the selection and/or adaptation of a dissemination and implementation model. For descriptive purposes, three models are previewed here, including the Diffusions of Innovations Theory, the RE-AIM framework,[2,26] and the Consolidated Framework for Implementation Research[33] (see Figure 2).

Diffusions of Innovations Theory

The Diffusions of Innovations Theory focuses on dissemination only. As described by Rogers,[34] diffusion of innovations is

Term	Definition
Internal validity[20]	The degree to which study bias is minimized and a causal relationship of the treatment/clinical intervention within a study sample can be estimated. *Example:* Can effect sizes from a randomized-controlled weight loss study (eg, magnitude of weight change between a treatment group and control group) be determined, while minimizing confounding variable?
External validity[20]	The degree to which research findings from a study can be generalized to other populations and settings. *Example:* Can the effects from a weight-loss study be generalized to real-world practice settings (eg, health care clinic, community center), and diverse participants (eg, minorities, low health literate)?
Pre-intervention research	Research that is done in a controlled laboratory setting, typically using nonhuman subjects. The focus is on understanding cellular and molecular mechanisms that underlie a disease or disease process. *Example:* Is there an observed relationship between variables? (T1[a])
Efficacy research	Highly controlled clinical research that is primarily concerned with internal validity. Threats to causal inference are typically reduced by using homogeneous samples/settings and controlling intervention parameters. The primary outcome measures target individuals and are usually symptom specific. *Example:* Does the treatment work under optimal conditions? (T2[b])
Effectiveness research	Clinical or community research that is primarily concerned with external validity. Threats to generalizability are typically reduced by using heterogeneous samples in "real-world" and diverse study locations. The main outcomes can be broad, ranging from clinical to other individual and organizational level outcomes (eg, quality of life, costs). *Example:* Does the treatment work under real-world conditions? (T3[c])
Dissemination research[14]	An active research approach of spreading evidence-based interventions to a targeted audience via determined channels using planned strategies and examining the success of this dissemination. The main outcomes may target individuals and/or organizations, such as awareness, receipt, acceptance, and use of information. *Example:* Can the treatment be diffused to and engage the targeted users? (T3)
Implementation research[14]	The process of putting to use or integrating evidence-based interventions within a setting and examining whether the interventions are put into place as designed. Implementation research is focused on the adoption or uptake of clinical interventions by providers and/or systems of care, with primary outcomes such as levels and rates of adoption, fidelity, implementation costs, and sustainability. *Example:* Can the treatment be adopted by providers and systems? (T3)
Scale-up and spread research[14,21]	"Deliberate efforts to increase the impact of health service innovations successfully tested in pilot or experimental projects so as to benefit more people and to foster policy and program development on a lasting basis." The main outcomes are similar to dissemination and implementation outcomes, but typically at national and international levels. *Example:* Can the treatment be adopted and maintained by a practice-based reach network, for long-term, lasting impact? (T3)
Hybrid type trial[14]	A study design that takes an a priori focus in the dual assessment of clinical effectiveness and implementation. Hybrid designs can typically take 1 of 3 approaches: 1) testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation; 2) dual testing of clinical and implementation interventions/strategies; 3) testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

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Figure 1. Key concepts, methods, and trial types in translational research.

Term	Definition
Pragmatic or practical clinical trials (PCTs)[14,22,23]	Clinical trials for which the hypothesis and study design are developed specifically to answer the questions faced by decision makers are called pragmatic or PCTs. The characteristic features of PCTs include: 1) select clinically relevant alternative interventions to compare, 2) include a diverse population of study participants, 3) recruit participants from heterogeneous practice settings, and 4) collect data on a broad range of health outcomes.
Comparative effectiveness research[14,24]	The conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat, and monitor health conditions in real-world settings.
[a]T1=Translation 1.	
[b]T2=Translation 2.	
[c]T3=Translation 3.	

Figure 1. *(continued)* Key concepts, methods, and trial types in translational research.

"the process in which an innovation is communicated through certain channels over time among the members of a social system." Several concepts central to this theory include the innovation, communication channel, the social system, and time (see Figure 2). Rogers also describes a number of factors that can influence the rate of adoption of an intervention, including the intervention's relative advantage, compatibility, complexity, trialability, and observability. Finally, individuals adopt innovations at different rates, described as innovators (ie, the first people to use the innovation), early adopters, early majority adopters, late majority adopters, and laggards (ie, the last people to adopt the innovation).[34] Understanding the diffusion process can aid in the successful dissemination of evidence-based programs.

This theory is useful at the individual, organization, and community levels and has broad construct flexibility, implying more loosely defined constructs.[32] This allows researchers to have greater flexibility in application of the model, yet also demands from researchers more responsibility for operationalizing and implementing the model. The Diffusion of Innovations Theory, and its adaptations, has been applied across several health- and nutrition-related studies.[35,36]

RE-AIM Framework

With a focus on both dissemination and implementation, the RE-AIM framework was primarily developed in response to a need for better understanding and improved reporting on implementation and external validity of health research.[2,26] As developed and defined by Glasgow and colleagues,[2] the five dimensions of RE-AIM include reach, efficacy/effectiveness, adoption, implementation, and maintenance (see Figure 2). Although specific components and criteria used to explain each dimension has evolved over the years, the fundamental definitions have remained consistent. Reach, effectiveness, and maintenance are assessed at the individual level, and adoption, implementation, and maintenance are assessed at the organizational level.[2]

The RE-AIM framework is useful at the individual, organization, and community levels, and is described as having a higher level of operationalization across the constructs or dimensions.[32] This implies the RE-AIM framework might be less flexible, but its more detailed definitions can help researchers conceptualize the study design and measurement for the dissemination and implementation research process. The RE-AIM framework has been widely applied in the obesity and disease management literature,[37] and has high relevance in the field of nutrition and dietetics. Recommended adjustments to the RE-AIM framework for environmental-level[38] and policy-level[39] approaches to addressing public health can also provide guidance to RDNs.

Consolidated Framework for Implementation Research

The Consolidated Framework for Implementation Research focuses on implementation only.[33] As conceptualized by Damschroder and colleagues,[33] and described as a pragmatic meta-theoretical framework, the Consolidated Framework for Implementation Research is comprised of five major domains including intervention characteristics, outer settings, inner settings, characteristics of the individuals involved, and process of implementation (see Figure 2). The Consolidated Framework for Implementation Research is intended to help researchers and practitioners organize, understand, and synthesize the dynamic nature of implementation within specific contexts.[33]

The Consolidated Framework for Implementation Research framework is useful at the organization and community levels and also has a high level of operationalization across constructs or dimensions.[32] Similar to the RE-AIM, this indicates defined actions for the dissemination and implementation research process, yet less flexibility across the constructs. The MOVE! Program, a weight-management program designed, implemented, and evaluated by the Veteran Affairs National Center for Health Promotion of Disease Prevention, is one of the first and most widely published trials applying the Consolidated Framework for Implementation Research.[37,40,41]

Selecting an appropriate dissemination and implementation model should be done in conjunction with defining the research question and selecting the study design.

Central concepts, attributes, dimensions, or domain	Definition
The Diffusions of Innovations Theory[34]	
The innovation	An idea, object, or practice that is thought to be new by an individual, organization, or community
Communication channel	The means of transmitting the new idea from one person to another
Social system	A group of individuals who together adopt the innovation
Time	Length of time to adopt the innovation
Relative advantage	Degree to which an innovation is better than the previous idea, practice, object
Compatibility	Degree to which an innovation is perceived as being consistent with current values, experiences, needs
Complexity	Degree to which an innovation is perceived as difficult to understand and use
Trialability	Degree to which an innovation can be tested on a limited basis
Observability	Degree to which the results of an innovation are visible to others or can be easily communicated
RE-AIM Framework[2,26]	
Reach	The number, proportion, and representativeness of individuals who participate in a program
Efficacy/effectiveness	The impact of the program on outcomes, including quality of life and any negative effects
Adoption	The number, proportion, and representativeness of intervention agents and settings who are willing to participate in a program
Implementation	The intervention agents' fidelity to a program's protocol, including duration and frequency, as well as cost of the program
Maintenance	The program's effects on individual level outcomes at least 6 months after the last program contact, as well as the degree to which the program is institutionalized within an organization
Consolidated Framework for Implementation Research[33]	
Intervention characteristics	Intervention source, evidence strength and quality, relative advantage, adaptability, trialability, complexity, design quality and packaging, and cost
Outer settings	Patient needs and resources, cosmopolitanism, peer pressure, external policies, and incentives
Inner settings	Structural characteristics, network and communications, culture, and implementation climate which also includes nine subcategories
Characteristics of the individuals involved	Knowledge and beliefs about the intervention, self-efficacy, individual stage of change, individual identification with organization, and other personal attributes
Process of implementation	Planning, engaging, executing, reflecting, and evaluating

Figure 2. Examples of relevant models for dissemination and implementation (D&I) research.

Highlighting the Diffusions of Innovations Theory, the RE-AIM framework, and the Consolidated Framework for Implementation Research framework does not inclusively depict all elements of existing dissemination and implementation models; however, these models help illustrate the available range, differences, and commonalities in model constructs. Within the burgeoning dissemination and implementation research field, there have been some recent criticisms in the practical application of dissemination and implementation models. For example, critiques include the degree to which dissemination and implementation models are fully utilized, including the selection and/or report on only a subset of the key elements of the models. For example, Kessler and colleagues[42] reviewed 42 dissemination and implementation National Institutes of Health grant applications that stated use of the RE-AIM framework and found that

<10% thoroughly used each of the five key dimensions in their evaluation plan. Consequently, Kessler and colleagues argue for a more comprehensive application of RE-AIM framework.[42] Alternatively, Estabrooks and Allen[43] have discussed the importance of differentiating how the RE-AIM framework can be applied across different trial types (eg, efficacy trial vs dissemination and implementation trial) and recognized the need for flexibility in defining full employment of the framework. The tradeoff between fidelity and flexibility when applying conceptual models is not exclusive to the dissemination and implementation field, as it is also relevant for the application of behavioral change theories. However, as the availability and demand for more systematic reviews of dissemination and implementation literature become available,[37] it is important to recognize inconsistencies in model application and reporting across key elements. Another broad criticism of the application of dissemination and implementation models in the existing literature—highlighted further below—is the lack of standardized measures to support model constructs.

Study Designs in Translational Research and Dissemination and Implementation Research

Researchers must take many methodological considerations into account when conducting translational research. This begins with the research question and the type of evidence available and is followed by selecting a specific study design. The "strength of evidence pyramid" is often used when evaluating the evidence for specific research questions. For example, both the Cochrane Collaboration and the Academy of Nutrition and Dietetics use an evidence pyramid approach when conducting evidence-based analysis reviews and summary statements.[44,45] In this hierarchy, meta-analysis and randomized controlled trials are at the peak, followed by nonrandomized trials, cohort studies, case-control studies, cross-sectional studies, case studies, and finally, case reports and expert opinion. In the earlier phases of translational research when internal validity factors are most critical, the important role of randomized controlled trials is clear and seldom disputed in the scientific community. However, when considering the later dissemination and implementation phases of translational research, many have challenged the notion that randomized controlled trials are the optimal or preferred study design and have pointed out their limitations.[46,47]

Figure 3 illustrates the diversity of research designs that have emerged with dissemination and implementation focused efforts, but is not intended to provide an exhaustive list of dissemination and implementation designs. Although a detailed explanation of the key strengths and limitations of the designs described in Figure 3 is beyond the scope of this monograph, this information can be found elsewhere.[49] In brief, these designs highlight that rigorous quasi-experimental studies can be conducted, regardless of randomization. Because observational study designs (ie, prospective, cross-sectional, and case-control studies) and experimental study designs (ie, cross-over randomized trial and randomized blinded trial) have been previously addressed in the part one publishing nutrition research monograph,[51] these designs will not be repeated here.

Even among the research designs commonly associated with dissemination and implementation research, including those highlighted in Figure 3, the efficacy/effectiveness outcomes may seem the most inherently emphasized. Yet dissemination and implementation models require going beyond efficacy/effectiveness outcomes and acquiring evidence for other key implementation processes and program adoption and maintenance outcomes. Using a mixed-methods research design,[52] one that combines the strengths of both quantitative and qualitative[53] design elements, is often recommended. Furthermore, there are numerous other study designs that can also be considered (eg, systems dynamics modeling, network analysis, cost-effectiveness); these designs are beyond the scope of this monograph.

Measures for Dissemination and Implementation Research

To fully advance dissemination and implementation research, some commonality in measurement and reporting is essential. Despite the availability of dissemination and implementation models and conceptual overlap among numerous model constructs,[32] few metrics are consistently applied across studies. The lack of standardized measures is attributed to a number of different factors. First, the dissemination and implementation field is still relatively new and the terminology is still evolving. The lack of consistent measures and subsequent lack of operationalization of dissemination and implementation outcomes is reflected, in part, by the lack of standardized terminology. Second, the multilevel context in which dissemination and implementation research occurs complicates measurement and evaluation. Full utilization of dissemination and implementation models often requires outcomes to be assessed across numerous levels, such as individual participants, program delivery agent teams, units, clinics, medical centers, communities, counties, and regions. This demands close attention to multilevel measurement, unit of analysis, and appropriate analytic techniques. Third, due to the highly contextual nature of dissemination and implementation research, many primary research questions of Translation 3 research naturally lend themselves to qualitative data collection and analysis; which also contributes to lack of measurement standardization. Finally, although the overall scope of Translation 3 research is often large, the actual sample size at higher levels can be relatively small, adding difficulties to the already laborious process of measurement development. For example, although Translation 1 and Translation 2 phases of research are often statistically powered and tested on several hundred subjects, the sample size of dissemination and implementation studies (eg, number of settings, number of delivery agent staff) is often much smaller. The example research questions across the phases of translational research in Figure 4 help illustrate several of these points.

Although dissemination and implementation measurement issues have somewhat slowed the progression of the field,[14] there are several ongoing initiatives to promote standardization and evaluation of dissemination and implementation measures. One example is the interactive Grid-Enabled Measures website developed by the National Cancer Institute,[54] which is designed to encourage the use of common measures. Users are allowed to search across numerous content areas, as well as search by measures

Study design	Design features
Randomized designs	
Stepped-wedged design[48]	The intervention is rolled out sequentially to the participants over several time periods. Individuals are randomized to the order in which they receive the intervention. By the end of the study, all individuals will have received the intervention. Data collection points are incorporated each time period where a new group (step) gets the intervention. Intervention effects are assessed by comparing data points of participants in the control section of the wedge with participants in the intervention section. This design can also be applied to clusters of individuals.
Randomized encouragement trial[49]	This design encourages study participants randomized to the intervention condition to participate in the intervention or to choose among specifically defined intervention components from a menu of options. Control participants are not offered the intervention nor encouraged to participate. This design can include randomization at individual level or higher, and is often used to mimic the delivery of preventive services in real-world settings.
Quasi-experimental designs or nonrandomized design with or without controls	
Pre-post[20,49]	Measures variables at a single point before the intervention begins and at a single point after the intervention. In this design, there may or may not be a control or comparison group.
Interrupted time series[20,48,49]	Consecutive observations are measured and interrupted at a specific point in which the intervention, service or policy will occur. These consecutive observations are made before, during, and after implementation of the intervention. Effects are assessed by examining fluctuations in the slope or level of the series following the intervention implementation.
Multiple Baseline[49,50]	This design is a form of an interrupted time series design. Numerous intervention components can be initiated at the onset of the study, and then components are selectively removed to understand which ones are most effective. Alternatively, components can be consecutively added until the intervention achieved the desired effect. This design provides the ability to study different components of the intervention, in contrast to designs that only allow evaluation of a whole intervention package.
Regression discontinuity design[21,49]	Rather than random assignment, this design involves assigning individuals to the intervention and comparison conditions based on cut-point scores for the targeted variable. This design can be applied to groups, and can also include two or more intervention conditions. Intervention effects are assessed by studying the regression line, and examining whether the intervention groups' regression line is discontinuous from the comparison group.
Natural experiments[20,49]	
	Natural experiments typically involve situations where an intervention cannot be manipulated by the researcher. This can involve the study of existing or newly developing programs or policies in naturally occurring situations. Nonexperimental and quasi-experimental designs can both be used to study natural experiments.

Figure 3. Examples of research study designs for the dissemination and implementation (D&I) phases of translational research.

and theoretical constructs. This unique and free resource contains scientific measures organized by construct, including many dissemination and implementation model constructs, as well as other behavior and psychosocial constructs. Another example of efforts to promote organization of dissemination and implementation measures is the ongoing systematic review of dissemination and implementation science instruments by the Seattle Implementation Research Collaborative.[55] Focused exclusively on dissemination and implementation instruments, the goal of this project is to create a library of dissemination and implementation measures and apply a rating system to reflect the psychometric properties of the measures. The underlying impetus for this project is to identify dissemination and implementation measure redundancy, identify dissemination and implementation constructs for which there is no existing measure, and rate the quality and usability of existing measures. This team currently has >450 dissemination and implementation instruments indexed in its comprehensive library.

Research phase	Definition	Example type of research	Example research question
T1	Identification of disease mechanisms and health problem	Basic research, animal research, preclinical, and pre-intervention studies	What is the mechanistic action of dietary fiber sources on serum lipids?
T2	Discovery of application to human health and clinical settings	Human clinical studies, efficacy studies, controlled observational studies	Among patients with cardiovascular disease, what is the effect on serum lipids from dietary fiber from whole foods as compared to dietary supplements?
T3	Health application to evidence-based practice guidelines, practice guidelines to health practices, and practice to population health impact	Effectiveness research, dissemination research, implementation research, scale-up, and spread research	What is the degree to which registered dietitian nutritionists in community health clinics can adopt, implement, and maintain an evidence-based nutrition program to improve cardiovascular risk factors?

Figure 4. Translational research phases, definitions, and examples for registered dietitian nutritionists.

RDNs are urged to consult existing dissemination and implementation models and literature, and available measurement resources to help operationalize study outcomes. Most importantly, the measures and evaluation plan should match the research question and study design. Although assessing more traditional efficacy/effectiveness-type outcomes (eg, diet quality, anthropometric measures, biological measures) may be one aim of the study, there are many other important dissemination and implementation aims and outcomes to consider (eg, representativeness of study population, characteristic of adoption agents and organization, implementation processes). Undoubtedly, efforts to maximize scientific rigor of study design and measurement, while balancing feasibility, can be extremely challenging. This leads to a discussion on the practical application of translational and dissemination and implementation research in nutrition and dietetics practice and research.

APPLICATIONS IN NUTRITION AND DIETETICS PRACTICE AND RESEARCH

Dissemination and implementation research concepts were applied to two nutrition-related case studies and illustrated in Figures 5 and 6, including the situational background, evidence-based program background, dissemination and implementation model, study design, research aims and key indicators, and best practices. In case study 1, a researcher conducts a comparative effectiveness study based on the RE-AIM framework in order to evaluate the implementation of two evidence-based school nutrition programs. Because evidence already exists that each program can have positive effects on student health outcomes under the right circumstances, the researcher focuses primarily on the adoption (A) and implementation (I) aspects of the RE-AIM framework, and secondarily on the other aspects. Consider the scenario where these programs have similar effects on student health outcomes, but the researcher finds that one program has higher potential for adoption among teachers/schools, higher implementation fidelity, lower implementation costs, and higher potential for program maintenance by the teachers/schools. These research data would provide actionable evidence about which program has greater promise for successful implementation and more far-reaching effectiveness, evidence that is relevant to the school administrators, teachers, and students. Under a different scenario, the researcher might find that one program shows greater potential for adoption and high-quality implementation under certain circumstances, but the other program shows greater potential under different circumstances. For example, one program might be adopted more readily in rural schools but less readily in city schools.

In case study 2, a researcher uses the Consolidated Framework for Implementation Research framework to study the implementation of an established adult diabetes-prevention program in satellite clinics. This research is motivated by concerns about the extent to which a diabetes-prevention program, for which there is evidence of success, may not be implemented broadly when put into practice, perhaps because the relevant staff are not adequately prepared to implement it. For this example, consider the scenario where several key program characteristics are identified that can easily be adapted and that a contextually relevant professional training is developed and implemented. The researcher uses a two-phase mixed-methods design. In the first phase, the researcher examines features of the intervention and characteristics of participating clinics that promote or discourage update of the program. In the second phase, the researcher examines the process of implementation and key characteristics of individuals targeted by the training measured before and after the training. Suppose that the researcher finds that the training has positive influence on the patient-care staff (eg, RDNs, physicians, and nurses), resulting in increased uptake of the diabetes-prevention program at satellite clinics. These outcomes would provide relevant, actionable evidence for decision making among clinic-level administrators, patient-care staff, and patients.

Situational background. A registered dietitian nutritionist (RDN) employed at a State Department of Health Office is working in collaboration with the State Department of Education, and on an established state-wide School Wellness Task Force. As a result of a comprehensive needs assessment, the task force has decided to evaluate and compare the implementation of two different evidence-based school nutrition programs across the state.

Evidence-based program background. After thoroughly appraising the available literature, the task force has decided to compare Planet Health with the Physical Activity and Teenage Health Program (PATH)—two programs that have been designed to be implemented in classrooms. Although both programs have established evidence for improving student health outcomes (eg, diet quality, physical activity, weight), they vary in their pragmatic appeal and potential ease of adoption by schools/teachers (eg, number/length of lessons, duration of program, complexity of program components, integration within school curriculum, cost).

Guiding D&I[a] framework. RE-AIM (reach, effectiveness, adoption, implementation, maintenance).

Study design. This comparative effectiveness research will compare the two programs using a clustered randomized controlled trial. Twenty schools have agreed to participate, each with approximately 15 teachers/classes for the targeted grades, and approximately 20 students/class. Ten schools are randomized to implement Planet Health and 10 schools to implement the PATH Program.

Primary research aims. To compare and determine the:

- Degree to which teachers within each school will **adopt** the assigned program. Key indicators: number, proportion, and representativeness of teachers/staff who deliver the program.
- Quality of program **implementation** of the assigned program. Key indicators: implementation fidelity and implementation cost.

Secondary research aims. To compare and determine the:

- **Reach** within the targeted student population. Key indicators: proportion and representativeness of students participating in each program.
- **Effectiveness** of student outcomes. Key indicators: changes in student health outcomes (eg, diet quality, physical activity, weight), quality of life, and potential negative effects.
- **Maintenance** of each program. Key indicators: extent to which the teachers will sustain the program over time, and the degree to which student outcomes are sustained over time.

Best practices.

1. Through involvement in the task force, the RDN has a strong professional network and established relationships with diverse stakeholders, including school administration leaders.
2. The RE-AIM framework is a good conceptual fit and helps guide the research aims. The aims are aligned with the study design and key indicators/measures.
3. The RDN is utilizing programs that have already demonstrated effects at improving student health outcomes, allowing this research to primarily focus on efforts to evaluate the adoption and implementation processes and outcomes.

[a]D&I=dissemination and implementation.

Figure 5. Case study 1: Implementation of two evidence-based school nutrition programs.

Both case studies exemplify the complexity and multilevel context that is characteristic of dissemination and implementation research. Rather than investing resource-intensive efforts into developing new programs and only focusing on effectiveness testing, RDNs could start with established evidence-based programs and focus research efforts on evaluating dissemination and implementation processes and outcomes. In this type of dissemination and implementation research, organizational-level programs adopters (eg, RDNs, physicians, nurses, administrators, teachers) are often the primary subject for process and outcome data. Although testing effects within the targeted populations (eg, health outcomes of students, clinical indicators among prediabetic patients) may be one desired research aim, it is usually not the sole or primary outcome driving the research. In addition, although randomization can certainly be one element of a Translation 3 study design, such as in case study 1, randomization may not always be feasible or practical, such as in case study 2. Importantly, these examples also highlight the focus on external validity. Ensuring the fit of evidence-based programs within real-world settings and within local circumstances is key for speeding the translational of nutrition-related research into practice.

KEY RESOURCES IN TRANSLATIONAL RESEARCH AND A CALL TO ACTION

The emerging emphasis in translational and dissemination and implementation research provides numerous

Situational background. A registered dietitian nutritionist (RDN) employed at a large, health maintenance organization (HMO)—affiliated urban clinic leads a multidisciplinary, evidence-based adult diabetes prevention program. He is also affiliated with a regional practice-based research network. As prioritized by a recent HMO-commissioned health care report, regional satellite clinics are not consistently implementing established components of the diabetes program.

Evidence-based program background. The urban clinics' program is based on the evidence-based Diabetes Prevention Program (DPP). Electronic medical records show significant improvements in pre-diabetes clinical markers of DPP participants from this urban clinic.

Guiding D&I[a] framework. Consolidated Framework for Implementation Research (CFIR).

Study design. Using a systems based approach, this research will involve professional development training aimed at increasing uptake of the adapted DPP and will target both patient-care staff (eg, RDNs, physicians, nurses) and organizational administrators. This study will include a mixed-methods and pre-post design to assess the degree of DPP implementation. Fifteen HMO-affiliated satellite clinics have been requested to participate in this research.

Phase 1 research aims.

- To determine current **intervention characteristics** of the DPP that promote/discourage uptake by each of the satellite clinics. Key indicators: relative advantage, adaptability, trialability, complexity, design quality and packaging, cost.
- To understand **inner setting characteristics** that promote/discourage uptake of the DPP by each of the satellite clinics. Key indicators: structural characteristics, network and communications, culture, and implementation climate.

Phase 2 research aims.

- To evaluate the **process of implementing** the professional trainings aimed at increasing uptake of the DPP. Key indicators: planning, engaging, executing, reflecting, and evaluating.
- To evaluate changes in the **characteristics of the individuals** before and after implementation of the trainings. Key indicators: knowledge and beliefs about the DPP, self-efficacy, individual stage of change, and individual identification with organization.

Best practices.

1. The RDN is well-positioned within the urban clinic and research network and can use this research as an opportunity to further establish relationships with patient-care staff and administrators at the satellite clinics.
2. The CFIR framework is a good conceptual fit for the research aims. The mixed-methods approach including the analysis of both qualitative and quantitative data, which allow data instruments to be standardized, yet the findings contextualized across each satellite clinic.
3. Using a program that has established evidence for clinical outcomes, allows the RDN to focus resources and efforts on the development and implementation of professional trainings to increase the uptake of the evidence-based diabetes program.

[a]D&I=dissemination and implementation.

Figure 6. Case study 2: Implementation of an evidence-based diabetes prevention program to satellite clinics.

opportunities for RDNs to integrate these efforts into their current scope of work. First, RDNs should use what works. In other words, they should use evidence-based programs, policies, and guidelines as the foundation when applying the dissemination and implementation concepts illustrated in this monograph. Figure 7 illustrates a number of comprehensive repositories of resources that detail evidence-based programs and guidelines.[44,45,56,57] To avoid repeating the lengthy steps along the research pipeline and transition more rapidly into the implementation of evidence-based guidelines and programs, RDNs can take full advantage of existing evidence-based resources. Using what works is a necessary and efficient approach at speeding the translation of nutrition research.

Second, translational research demands collaboration among health care professionals from multiple disciplines and with diverse stakeholders. As argued by Glasgow and colleagues, stakeholder involvement is at the center of, or key for, translational research.[19] Therefore, RDNs must seek to develop professional networks both within and outside their organization. Specific to dissemination and implementation efforts, a number of recommendations emerge from the literature including involvement in Practice-Based Research Networks, participation in community-based participatory research efforts, and connections to systems-based science networks.[14,62]

Finally, because this type of research is increasingly in demand, RDNs should seek additional resources and training opportunities in translational research in order to be competitive in proposing new studies. An extensive list of advanced translational and dissemination and implementation research topics is beyond the scope of this monograph. To stay abreast on late-breaking advances and current research topics, busy professionals may find it

Source	Description
Repositories of evidence-based resources	
Research-tested Intervention Programs (RTIPS)[56]	This is a searchable database of interventions and program materials that have been research-tested, and provides health care practitioners with easy access to materials. Of the approximate 147 intervention programs currently in RTIPS, 39 interventions are specifically matched to the diet/nutrition criteria. Across these interventions, the majority focus on behavior modification, yet the targeted populations are diverse (eg, adults, school children, employees, faith-based groups, medically underserved).
Academy of Nutrition and Dietetics' Evidence Analysis Library (EAL)[45]	An online user-friendly website that synthesizes relevant research on dietetics practice questions. The EAL uses an objective methodology to assess food and nutrition-related science. The website provides a wealth of evidence-based dietetics practice resources, including 41 evidence analysis project topics and 17 evidence-based nutrition practice guidelines.
Guide to Community Preventive Services[57]	An online resource to assist health care practitioners and researchers choose programs and policies to improve community health and prevent disease. Systematic reviews are used to answer questions about the effectiveness, appropriateness, and cost of health program and policy interventions, including nutrition-related program and polices.
Cochrane Reviews[44]	Cochrane Reviews are one of the highest standards in evidence-based health care and comprise systematic reviews of research in human health care and health policy. These systematic reviews investigate the effects of prevention, treatment, and rehabilitation interventions and are published in The Cochrane Library.
Textbook	
Dissemination and Implementation (D&I) Research in Health[14]	This textbook provides a comprehensive review on the background, theory, and approaches, design and analysis, and setting- and population-specific D&I, as well as countless applied examples and lists of key resources. Illustrating the fundamental tenets of D&I research, this book is a roadmap with broad practical relevance to both researchers and practitioners.
Online Resources to Centers and Initiatives	
National Institutes of Health's (NIH) Institutes and Centers is The National Center for Advancing Translational Sciences (NCATS)[58]	NCATS is the newest of 27 Institutes and Centers at NIH. The goal of NCATS is to transform the translational science process so that new treatments and cures for disease can be delivered to patients faster. This center supports the Clinical and Translational Science Awards program that provides an established consortium of >60 medical centers and offers multiple opportunities for networking and participating in translational research efforts. The website provides up-to-date news and events, as well as research and funding opportunities in translational science.
NIH's National Cancer Institute's (NCI) Implementation Science[59]	The key priorities of NCI's Implementation Science program is to build and advance the field of implementation science, develop ongoing training networks, and establish partnerships. The website houses a comprehensive list of training and education opportunities, as well as tools for D&I research. Free subscription to a listserv is available.
The Center for Excellence for Training and Research Translation (TRT)[60]	Center for TRT is based at the University of North Carolina at Chapel Hill, one of the Prevention Research Centers supported by the Centers for Disease Control and Prevention. Center for TRT bridges the gap between research and practice and supports the efforts of public health practitioners working in nutrition, physical activity, and obesity prevention. The website provides practical information on training, interventions, evaluation, sustainability, and health equity in translational science and the dissemination and implementation of evidence-based programs and policies.
Veterans Affairs (VA) Healthcare System Quality Enhancement Research Initiative (QUERI)[61]	The mission of the QUERI is to enhance the quality and outcomes of VA health care by systematically implementing clinical research findings and evidence-based recommendations into routine clinical practice. In evaluating quality of care, the QUERI process focuses on structure, process, and outcomes. Example of website downloads include an implementation guide and a quality-improvement toolkit.

Figure 7. Key resources in translational and dissemination and implementation (D&I) research.

helpful to seek additional resources illustrated in Figure 7[14,58-61] and to participate in listserves, advanced training, and conference opportunities. These resources will promote heightened attention to language and vocabulary, as the lack of standardized terminology can adversely influence clear communication among multidisciplinary health care professionals and stakeholders. Lastly, to ensure RDNs are positioned as nutrition leaders in the rapidly expanding translation and dissemination and implementation research agenda, swift efforts are needed to integrate translational research concepts (eg, models, trial types, study designs, measures) into current standards of dietetics education, training, and practice.

SUMMARY

This monograph illustrates numerous opportunities for applying translational research concepts to the field of nutrition and dietetics. The lack of standardized terminology complicates attempts to convey translational and dissemination and implementation research concepts in this monograph.[14] Nonetheless, this article offers a nutrition-specific overview of key translational research concepts and encourages interested RDNs to acquire new proficiencies, as well as apply and interpret translational and dissemination and implementation research in their own areas of work. Translational research is both bidirectional and multidisciplinary. RDNs already serve as key members on multidisciplinary teams and are highly integrated into health care, community, and research systems. They play a vital role in speeding the translation of nutrition research into evidence-based clinical practice and population-based health efforts. Furthermore, RDNs recognize the metrics required to assess, address, and document these new methods. Although there are clear opportunities across all phases of the translational research spectrum, attention to the dissemination and implementation of established, evidence-based nutrition guidelines into routine clinical-, community-, and policy-based practice represents a highly relevant target for RDNs. Attention to scientific principles consistent with high-quality dissemination and implementation research, gives RDNs the potential to make timely differences in real-world settings. Finally, because translation research demands the perspectives and support of multiple individuals, including consumers, public health, and advocacy groups, these stakeholders also need to collaboratively engage in translation research opportunities with RDNs.

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