Terminology for Dissemination and Implementation Research

INTRODUCTION
Dissemination and implementation (D&I) research is increasingly recognized as an important function of academia and is a growing priority for major health-related funding agencies (e.g., the National Institute of Health [NIH], the Centers for Disease Control and Prevention [CDC], the National Institute on Disability and Rehabilitation Research [NIDRR], the Canadian Institutes of Health Research [CIHR] and the World Health Organization [WHO]). One challenging aspect of D&I research is the lack of standardized terminology. As noted by Ciliska and colleagues: “closing the gap from knowledge generation to use in decision-making for practice and policy is conceptually and theoretically hampered by diverse terms and inconsistent definitions of terms.” A survey conducted by Nature Medicine on how their readers define the term “translational research” found substantial variation in interpretation by respondents. Some definitions were consistent with the NIH definition (“the process of applying ideas, insights and discoveries generated through basic scientific inquiry to the treatment or prevention of human disease”), others believed that only research that leads to direct clinical application should be defined as translational research, and only a small group emphasized the bidirectional nature of the process (i.e., bench to bedside and back). This phenomenon can be partly explained by the relatively new appearance of D&I research on the health research agenda and by the great diversity of disciplines that made noteworthy contributions to the understanding of D&I research. Some of the most important contributions originate from the nonhealth fields of agriculture, education, marketing, communication, and management. The primary health-related areas currently contributing to D&I research include health services research, HIV prevention, school health, mental health, nursing, cancer control, violence prevention, and disability and rehabilitation. Further complexity is injected by the variation in terminology and classification of terms across countries. This book uses the term “dissemination and implementation research” to denote the newly emerging field in the United States; however, other countries and international organizations (e.g., the United Kingdom, Canada, the WHO) commonly use the terms “knowledge translation and integration,” “population health intervention research,” or “scaling up” to define this area of research. Furthermore, Graham and colleagues identified 29 distinct terms referring to the some aspect of the D&I (or knowledge translation) process when they looked at the terminology used by 33 applied research funding agencies in nine countries. A more recent review by McKibbon and colleagues identified 100 terms alone just to describe knowledge translation or KT research.

Definitions presented in this chapter reflect the terminology used in the most frequently cited manuscripts, reports, websites, and databases on D&I research in health and in funding announcements of major federal funding agencies (e.g., NIH, CDC, NIDRR, CIHR). To identify terms and definitions, an initial search of the English language literature was conducted to identify peer-reviewed manuscripts and documents from governmental agencies (i.e., gray literature). Further papers and documents were identified from reference lists and expert recommendations using snowball sampling. This chapter builds on a previously published article that used an expert discussion to select definitions to be included from a list of 106 definitions. Additional terms and their definitions were included based on recommendations from the authors and review of
each chapter of this book. For each definition, the most relevant publications and chapters from this book were included so that readers may consult the literature for a more in-depth discussion of the term and its application.

To facilitate the thinking and discussion on D&I research, terms are presented using the three main sections proposed by Padek and colleagues to organize educational competencies for dissemination and implementation research.30 The first section (Definition, Background, and Rational) provides definition for the most commonly used terms in D&I research as well as identifies stages of the research process continuum, their relationship to D&I-related activities, and defines varieties of Type 1 and 2 research. In section 2 (Theories and Approaches) the most commonly used models and frameworks that can inform planning and evaluation activities in D&I research are discussed along with concepts of designing for D&I and sustainability; adaptation and fidelity; D&I strategies; and factors associated with the success, speed, and extent of D&I. Finally, the third section (Design and Analysis) summarizes important concepts of study design and measurement that should be considered when evaluating D&I research. The list of terms and their organization is provided in Table 2.1.

### TABLE 2.1. DISSEMINATION AND IMPLEMENTATION TERMS AND THEIR ORGANIZATION

<table>
<thead>
<tr>
<th>SECTION 1: DEFINITION, BACKGROUND, AND RATIONALE</th>
<th>SECTION 2: THEORIES AND APPROACHES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Innovation</strong></td>
<td><strong>Stage Models</strong></td>
</tr>
<tr>
<td>Evidence-based intervention</td>
<td>Theories and Frameworks</td>
</tr>
<tr>
<td>Empirically supported treatment</td>
<td>Diffusion of innovations</td>
</tr>
<tr>
<td>Evidence-informed practice</td>
<td>RE-AIM framework</td>
</tr>
<tr>
<td>Types of Evidence</td>
<td>Consolidated Framework for Implementation Research</td>
</tr>
<tr>
<td>Type 1 evidence</td>
<td>Designing for Dissemination, Implementation and Sustainability</td>
</tr>
<tr>
<td>Type 2 evidence</td>
<td>Audience Segmentation</td>
</tr>
<tr>
<td>Type 3 evidence</td>
<td>Fidelity and Adaptation</td>
</tr>
<tr>
<td>Processes for D&amp;I</td>
<td>Fidelity</td>
</tr>
<tr>
<td>Diffusion</td>
<td>Adaptation</td>
</tr>
<tr>
<td>Dissemination</td>
<td>Core elements (components)</td>
</tr>
<tr>
<td>Implementation</td>
<td>Adaptome</td>
</tr>
<tr>
<td>Misimplementation</td>
<td>Strategies for D&amp;I</td>
</tr>
<tr>
<td>De-implementation</td>
<td>Dissemination strategy</td>
</tr>
<tr>
<td>Reach</td>
<td>Implementation strategy</td>
</tr>
</tbody>
</table>

### Innovation

The term “innovation” can refer to “an idea, practice, or object that is perceived as new by an individual or other unit of adoption.”19(p. 12) Some authors use this term interchangeably with the term “evidence-based intervention.”

A number of more specific terms denoting the subject of dissemination and implementation activities are commonly used in the context of health research and listed below.

### Evidence-Based Intervention

The subjects of D&I activities are interventions with proven efficacy and effectiveness (i.e., evidence-based). Interventions within D&I research are defined broadly and may include programs, practices, processes, policies, and guidelines.31 More comprehensive definitions of evidence-based interventions are available elsewhere.32-36 In D&I research, we often encounter complex interventions (e.g., multilevel interventions using community-wide education) where the description of core intervention components and their relationships involve multiple
Terminology for Dissemination and Implementation Research

<table>
<thead>
<tr>
<th>TABLE 2.1. CONTINUED</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adoption</strong></td>
</tr>
<tr>
<td><strong>Sustainability/Sustainment</strong></td>
</tr>
<tr>
<td>Maintenance</td>
</tr>
<tr>
<td>Institutionalization</td>
</tr>
<tr>
<td>Capacity building</td>
</tr>
<tr>
<td><strong>Knowledge-for-Action terms</strong></td>
</tr>
<tr>
<td>Knowledge translation</td>
</tr>
<tr>
<td>Knowledge transfer</td>
</tr>
<tr>
<td>Technology transfer</td>
</tr>
<tr>
<td>Knowledge exchange</td>
</tr>
<tr>
<td>Knowledge integration</td>
</tr>
<tr>
<td>Knowledge utilization</td>
</tr>
<tr>
<td>Research utilization</td>
</tr>
<tr>
<td>Knowledge brokering</td>
</tr>
<tr>
<td>Knowledge broker</td>
</tr>
<tr>
<td>Scale up and scaling up</td>
</tr>
<tr>
<td><strong>Evidence Synthesis Approaches</strong></td>
</tr>
<tr>
<td>Scoping review</td>
</tr>
<tr>
<td>Realist review</td>
</tr>
<tr>
<td><strong>Types of Research</strong></td>
</tr>
<tr>
<td><strong>Fundamental (or Basic) research</strong></td>
</tr>
<tr>
<td><strong>Translational research</strong></td>
</tr>
<tr>
<td>T1 research</td>
</tr>
<tr>
<td>Efficacy research</td>
</tr>
<tr>
<td>T2 research</td>
</tr>
<tr>
<td>Effectiveness research</td>
</tr>
<tr>
<td>Dissemination research</td>
</tr>
<tr>
<td>Implementation research</td>
</tr>
<tr>
<td><strong>Mode I and II science</strong></td>
</tr>
<tr>
<td><strong>Science-to-service gap</strong></td>
</tr>
<tr>
<td><strong>Implementation gap</strong></td>
</tr>
<tr>
<td><strong>Assimilation gap</strong></td>
</tr>
<tr>
<td><strong>Population health intervention research</strong></td>
</tr>
<tr>
<td><strong>Comparative Effectiveness Research to Accelerate Translation</strong></td>
</tr>
<tr>
<td><strong>Patient-centered outcomes research</strong></td>
</tr>
<tr>
<td>Quality improvement</td>
</tr>
<tr>
<td>Precision medicine</td>
</tr>
</tbody>
</table>

settings, audiences, and approaches. For a more detailed discussion of complex interventions, refer to Hawe et al.

Empirically Supported Treatments
The term “empirically supported treatment” or EST is commonly used to describe psychological interventions that are proven to be efficacious. EST is different from the evidence-based intervention or treatment terminology in that it requires that interventions are manualized and have at least two, independent, controlled experimental studies showing comparative effectiveness.

Evidence-Informed Practice
The term “evidence-informed practice” expands the traditional evidence-based intervention terminology and intends to emphasize that health
care and population health should always be context sensitive, and use a person- or client-focused (stakeholder) perspective and not be limited to the mere synthesis and application of scientific evidence.\textsuperscript{41} In part, the “evidence-informed” framing seeks to emphasize that health-related decisions are not based only on research (particularly considering political and organizational factors).\textsuperscript{42,43} This perspective highlights the importance of making health decisions using evidence-based methods (information based on the synthesis of scientific evidence) in conjunction with clinician and practitioner expertise and knowledge and information about the values, preferences, and circumstances of the target patient or population. Consequently, real-world experience suggests that the evidence should not be limited to quantitative evidence from highly controlled research trials but should also consider the use of many different levels and types of evidence including qualitative studies, case reports, and expert opinion.\textsuperscript{44} Despite of the initial distinction in meaning between evidence-based and evidence-informed practice, the terms are commonly used interchangeably in the literature.

Additional terms denoting the subject of D&I activities include best practices, evidence-based processes, and evidence-based health care.\textsuperscript{45,46}

**Types of Evidence**

The types of evidence available for decision making in health can be classified as Type 1, Type 2, and Type 3 evidence.\textsuperscript{47} These evidence types differ in their characteristics, scope, and quality.

**Type 1 Evidence**

Type 1 evidence defines to the cause of a particular outcome (e.g., health condition). This type of evidence includes factors such as magnitude and severity of the outcome (i.e., number, incidence, prevalence) and the actionability of the cause (i.e., preventability or changeability) and often leads to the conclusion that “something should be done.”\textsuperscript{34,47}

**Type 2 Evidence**

Type 2 evidence focuses on the relative impact of a specific intervention to address a particular outcome (e.g., health condition). This type of evidence includes information on the effectiveness or cost-effectiveness of a strategy compared to others and point to the conclusion that “specifically, this should be done.”\textsuperscript{34} Type 2 evidence (interventions) can be classified based on the source of the evidence (i.e., study design) as evidence-based, efficacious, promising, and emerging interventions.\textsuperscript{47}

**Type 3 Evidence**

Type 3 evidence is concerned with the type of information that is needed for the adaptation and implementation of an evidence-based intervention.\textsuperscript{32} This type of evidence includes information on how and under which contextual conditions interventions were implemented and how they were received and addresses the issue of “how something should be done.” Type 3 is the type of evidence we have the least of and derives from the context of an intervention, particularly concepts of external validity.\textsuperscript{47}

**Processes for D&I**

**Diffusion**

Diffusion is the passive, untargeted, unplanned, and uncontrolled spread of new interventions. Diffusion is part of the diffusion-dissemination-implementation continuum and it is the least focused and intense approach.\textsuperscript{48,49}

**Dissemination**

Dissemination is an active approach of spreading evidence-based interventions to the target audience via determined channels using planned strategies.\textsuperscript{48,49}

**Implementation**

Implementation is the process of putting to use or integrating evidence-based interventions within a setting.\textsuperscript{50}

**Misimplementation**

Misimplementation involves one or both of two processes: the discontinuation of effective programs and the continuation of ineffective practices in the context of public health.\textsuperscript{51} Misimplementation is a broader term while de-implementation focuses on the discontinuation component of misimplementation.

**De-implementation**

De-implementation is defined as stopping or abandoning practices that have not proved to be effective and are possibly harmful.\textsuperscript{52} In medicine, the term “over use” is sometimes used to identify practices that should be ended. De-implementation gained increasing focus and support in health care and population health in many countries through initiatives like the Choosing Wisely campaign that encourages and supports practitioners to identify and abandon unproven or harmful practices.\textsuperscript{53} De-implementation is believed to be an effective approach for improving patient outcomes and to achieve cost saving. Early evidence indicates that
similar to dissemination and implementation efforts, de-implementation also requires active approaches and local champions for success. Factors associated with successful de-implementation efforts are still being studied, but they are believed to be similar to the factors relevant to determine the speed and extent of implementation and are multilevel and complex in nature.\textsuperscript{54,55} Two main types of de-implementation include substitution (the replacement of the low value practice with a more promising alternative) and disenchantment (abandonment of practice due to information indicating its lack of effectiveness or cost-effectiveness).\textsuperscript{54}

The terminology and strategies for de-implementation are still evolving and include terms such as termination, replacement, reversal, de-adoption, decrease use, disinvesting, and discontinue use.\textsuperscript{55}

Reach
Reach refers to the ability of a program to engage its ultimate target audience, both in terms of quantity (number/percent of participant) and quality (representativeness of participants). The reach of a program can greatly influence the level of public health impact the program can achieve.\textsuperscript{56}

Adoption
Adoption is the decision of an organization or community to commit to and initiate an evidence-based intervention.\textsuperscript{19,57,58}

Sustainability
Sustainability describes the extent to which an evidence-based intervention can deliver its intended benefits over an extended period of time after external support from the donor agency is terminated.\textsuperscript{59} A number of models and instruments are available to conceptualize and measure sustainability.\textsuperscript{60} Most often sustainability is measured through the continued use of intervention components; however, Scheirer and Dearing suggest that measures for sustainability should also include considerations of maintained community- or organizational-level partnerships; maintenance of organizational or community practices, procedures, and policies that were initiated during the implementation of the intervention; sustained organizational or community attention to the issue that the intervention is designed to address; and efforts for program diffusion and replication in other sites.\textsuperscript{61} As discussed in the following, three operational indicators of sustainability are: (1) maintenance of a program’s initial health benefits, (2) institutionalization of the program in a setting or community, and (3) capacity building in the recipient setting or community.\textsuperscript{59}

Maintenance
Maintenance refers to the ability of the recipient setting or community to continuously deliver the health benefits achieved when the intervention was first implemented.\textsuperscript{59}

Institutionalization
Institutionalization assesses the extent to which the evidence-based intervention is integrated within the culture of the recipient setting or community through policies and practice.\textsuperscript{59,59,62} Three stages that determine the extent of institutionalization are: (1) passage (i.e., a single event that involves a significant change in the organization’s structure or procedures such as transition from temporary to permanent funding), (2) cycle or routine (i.e., repetitive reinforcement of the importance of the evidence-based intervention through including it into organizational or community procedures and behaviors, such as the annual budget and evaluation criteria), and (3) niche saturation (the extent to which an evidence-based intervention is integrated into all subsystems of an organization).\textsuperscript{59,63,64} Niche saturation is also referred to as penetration in the literature, as described by Lewis and colleagues in chapter 14.\textsuperscript{65}

Capacity Building
This describes any activities (e.g., training, identification of alternative resources, building internal assets) that build durable resources and enable the recipient setting or community to continue the delivery of an evidence-based intervention after the external support from the donor agency is terminated.\textsuperscript{59,63,66} Leeman and colleagues identified six strategies for capacity building: training, tools, technical assistance, assessment and feedback, peer networking, and incentives.\textsuperscript{67}

Other terms that are commonly used in the literature to refer to program continuation include sustainment, incorporation, integration, local or community ownership, confirmation, durability, stabilization, and sustained use.\textsuperscript{54}

Knowledge-for-Action Terms
The terms knowledge translation, knowledge transfer, knowledge exchange, and knowledge integration are commonly used especially outside of the United States to refer to
the entire or some aspects of the D&I process. This chapter uses definitions coined by the CIHR and KT Canada, Graham and colleagues, Best and colleagues, and McKibbon and colleagues to define these terms. As Best and colleagues suggested, these terms can be classified as linear (knowledge translation and transfer), relationship (knowledge exchange), or systems (knowledge integration) models of D&I.68 Additional terms can be found on the WhatIsKT wiki website: https://whatiskt.wikispaces.com/.

**Knowledge Translation**
Knowledge translation is the term used by the CIHR to denote “a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge.” Knowledge translation occurs within a complex social system of interactions between researchers and knowledge users and with the purpose of improving population health, providing more effective health services and products, and strengthening the health care system.5,27

**Knowledge Transfer**
Knowledge transfer is a commonly used term both within and outside of the health care sector and is defined as the process of getting (research) knowledge from producers to potential users (i.e., stakeholders).27,68 This term is often criticized for its linear (unidirectional) notion and its lack of concern with the implementation of transferred knowledge.27

**Technology Transfer**
Technology transfer is closely related to (some suggests it is a subset of) knowledge transfer and it refers to the process of sharing technological developments with potential users.69,70 While knowledge transfer often refers to individuals as the recipient of the knowledge, technology transfer more often focuses on transfer to larger entities such as organizations, countries, or the public at large.70 The object of technology transfer is often defined broadly as a process, product, know-how, or resource but its focus is still narrower than the focus of the more encompassing knowledge transfer.70

**Knowledge Exchange**
Knowledge exchange is the term used by the Canadian Health Services Research Foundation and describes the interactive and iterative process of imparting meaningful knowledge between knowledge users (i.e., stakeholders) and producers, such that knowledge users (i.e., stakeholders) receive relevant and easily usable information and producers receive information about users’ research needs.27,68 This term was introduced to, in contrast to the terms “knowledge translation” and “knowledge transfer,” highlight the bi- or multidirectional nature of the knowledge transmission process (relationship model).27,68,71

**Knowledge Integration**
The term was introduced by Best and colleagues as the systems model for the knowledge transmission process and is defined as “the effective incorporation of knowledge into the decisions, practices and policies of organizations and systems.”68 The key assumptions around the knowledge integration process are that (1) it is tightly woven within priorities, culture, and context; (2) mediated by complex relationships; (3) needs to be understood from a systems perspective (i.e., in the context of organizational context and strategic processes); and (4) require the integration with the organization(s) and its systems.68

**Knowledge Utilization**
Knowledge utilization refers to the use of broadly defined knowledge including not only research evidence but also scholarly practice and programmatic interventions. It can be regarded as an overarching term that encompasses both research utilization and evidence-based practice.72,73

**Research Utilization**
Research utilization is a form of knowledge utilization; it has long traditions in the nursing literature and refers to “the process by which specific research-based knowledge (science) is implemented in practice.”73,74 Research utilization, similar to knowledge translation and knowledge transfer, follows a linear model and is primarily concerned with moving research knowledge into action.27

**Knowledge Brokering**
Knowledge brokering has emerged from the understanding that there is a belief, value, and practice gap between producers (i.e., researchers) and users (i.e., practitioners, policymakers) of knowledge and it involves the organization of the interactive process between these two groups to facilitate and drive the transfer and
implementation of research evidence. Specific tasks include synthesis and interpretation of relevant knowledge, facilitation of interaction and setting of shared agendas, building of new networks, and capacity building for knowledge use. Knowledge brokering is described as a two-way process that not only aims at facilitating the uptake and use of evidence by practitioners and policymakers, but also focuses on prompting researchers to produce more practice-based evidence.

Knowledge Broker
A knowledge broker is an intermediary (individual or organization) who facilitates and fosters the interactive process between producers (i.e., researchers) and users (i.e., practitioners, policymakers) of knowledge through a broad range of activities (see Knowledge Brokering). More broadly, knowledge brokers assist in the organizational problem-solving process through drawing analogic links between solutions learned from resolving past problems, often in diverse domains, and demands of the current project. Knowledge brokers also help “make the right knowledge available to the right people at the right time.”

A more detailed discussion of knowledge brokering and knowledge brokers is provided by Hargadon.

Scale Up and Scaling Up
The term is commonly used in the international health and development literature and refers to “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 programme development on a lasting basis.” Scaling up most commonly refers to expanding the coverage of successful interventions; however, it can also be concerned with the financial, human, and capital resources necessary for the expansion. It is suggested that sustainable scale up requires a combination of horizontal (e.g., replication and expansion) and vertical (institutional, policy, political, legal) scaling up efforts, which benefit from different D&I strategies (i.e., training, technical assistance hands-on support versus networking, policy dialogue, advocacy). Furthermore, some researchers suggest that scale up has a broader reach and scope than D&I and expands to national and international levels. The National Implementation Research Network uses the term “going to scale” when an evidence-based intervention reaches 60% of the target population that could benefit from it.

Additional terms used to describe some aspect of the D&I process include knowledge cycle, knowledge management, knowledge mobilization, research transfer, research translation, expansion, linkage and exchange.

Evidence Synthesis Approaches
In addition to more traditional evidence synthesis approaches of systematic reviews and meta-analysis, a number of more novel techniques are especially appropriate to use to summarize existing knowledge about D&I research and practice. These methods allow for a more relevant, real-world perspective on studies through a more inclusive, context-sensitive approach. For this chapter, two techniques were selected and are discussed here.

Scoping Review
Scoping reviews aim to map rapidly the key concepts underpinning a research area and the main sources and types of evidence available and can be efficiently used to explore complex areas or areas that have not been reviewed before. The most important differences between a systematic review and a scoping review include level of specificity of the research question it is based on and the types of studies they draw upon. Systematic reviews generally start off with well-defined research questions and are most frequently based on a narrow range of quality-assessed studies. Scoping reviews intend to explore broader topics and include more diverse study designs, and are not concerned with quality assessment of included studies. When undertaken as a standalone activity rather than in preparation of a systematic review, scoping reviews can be used to summarize and disseminate information about interventions to policymakers, practitioners, and consumers.

Realist Review
Realist review is a method for reviewing and synthesizing information about complex, real-world interventions using an explanatory approach and focusing on “what works for whom, in what circumstances, in what respects and how?” Instead of determining if a certain intervention will work, realist reviews provide rich, contextual, and practical information regarding the
mechanisms by which the intervention or program works under certain circumstances. This information can support implementation of programs at different levels. Realist review considers interventions as complex systems that function within systems and will be limited in terms of scope (how much can be looked at), the availability of information (the need for an array of primary sources for information), and the nature of effectiveness information (lack fast truth about effectiveness).88,89

Types of Research
Fundamental (or Basic) Research
Fundamental or basic research develops laboratory-based, etiologic models to provide theoretical explanation for generic or more specific phenomena of interest.57

Translational Research
T1 Research
T1 translational research uses discoveries generated through laboratory and/or preclinical research to develop and test treatment and prevention approaches. In other words, T1 clinical research moves science from “the bench” (fundamental research, methods development) to the patients “bedside” (efficacy research).57,90

Efficacy Research
Efficacy research evaluates the initial impact of an intervention (whether it does more good than harm among the individuals in the target population) when it is delivered under optimal or laboratory conditions (or in an ideal setting). Efficacy trials typically use random allocation of participants and/or units and ensure highly controlled conditions for implementation. This type of study focuses on internal validity or on establishing a causal relationship between exposure to an intervention and an outcome.57,91

T2 Research
T2 translational research focuses on the enhancement of widespread use of efficacious interventions by the target audience. This type of research includes effectiveness research, dissemination research, and implementation research57 and also referred to as “bedside to (clinical) practice (or trench)” translation.90,92

Effectiveness Research
Effectiveness research determines the impact of an intervention with demonstrated efficacy when it is delivered under “real-world” conditions. As a result, effectiveness trials often must use methodological designs that are better suited for large and/or less controlled research environments with a major purpose to obtain more externally valid (generalizable) results.57,91

Dissemination Research
Dissemination research is the systematic study of processes and factors that lead to widespread use of an evidence-based intervention by the target population. Its focus is to identify the best methods that enhance the uptake and utilization of the intervention.57,93

Implementation Research
Implementation research seeks to understand the processes and factors that are associated with successful integration of evidence-based interventions within a particular setting (e.g., a worksite or school).94 Implementation research assesses whether the core components of the original intervention were faithfully transported to the real-world setting (i.e., the degree of fidelity of the disseminated and implemented intervention with the original study) and also is concerned with the adaptation of the implemented intervention to local context.94 Another, often overlooked but essential component of implementation research involves the enhancement of readiness through the creation of effective climate and culture in an organization or community.20,95

Finally, a broader interpretation of implementation research also includes the study of discontinuation of interventions and practices that do not work. See also misimplementation and de-implementation in this chapter.96

More recently it was suggested that rather than two types (T1 and T2), four phases of translational research should be distinguished (T1 through T4).90,97 According to this new classification: (1) T1 translational research is defined as translation of basic research into potential clinical application that leads to theoretical knowledge about a possible intervention; (2) T2 translational research involves efficacy studies and results in efficacy knowledge about interventions that work under optimal conditions; (3) T3 translational research involves effectiveness, dissemination, and implementation research and leads to applied knowledge about interventions that work in real-world settings; and (4) T4 translational research involves outcomes assessment at the population
level and results in public health knowledge at the population level.  

Mode I and II Science
A similar model for the classification of research (knowledge production) established by Gibbons and colleagues was considered by the National Cancer Institute of Canada Working Group on Translational Research and Knowledge Transfer.  

This model suggests the distinction of Mode I and Mode II science. Mode I science refers to traditional investigator-initiated scientific methods designed to produce discipline-based generalizable knowledge and is characterized by clear hypothesis, transparent methods, and replicability. Mode II science is defined as “science in the context of its application” and is described as context-driven, problem-focused research with the production of interdisciplinary knowledge.

Mode II science is concerned with contextual factors such as organizational structure, geography, attitudes, economics, and ethics. Graham Harris introduces the concept of Mode III science that is not only done “in the context of its application but which also influences the context and application through engagement in a contextual and recursive debate.” He further suggests that “to achieve this aspirational goal requires the establishment of a collaborative ‘magic circle,’ a creative collaboration linking the worlds of science, governance, industry, the media and the community.”

Science-to-Service Gap
Science-to-service gap refers to the phenomenon when the interventions that are adopted by individuals and organizations are not the ones that are known to be effective and hence most likely to benefit the target population.

Implementation Gap
Implementation gap refers to the phenomenon when the interventions that are adopted by individuals and organization are not implemented with sufficient fidelity and consistency to produce optimal benefits.

Assimilation Gap
Assimilation gap refers to the population-level (or public health) impact of interventions and describes the phenomenon when interventions that are adopted by individuals or organizations are not deployed widely (e.g., population level) and/or not sustained sufficiently at the individual or organizational level.

Population Health Intervention Research
Population health intervention research (PHIR) emerged from the work of Hawe and colleagues and is supported by the CIHR through their Population Health Intervention Research Initiative for Canada. PHIR uses scientific methods to produce knowledge on interventions operating either within or outside the health sector with potential to impact health at the population level. Population health interventions include programs, policies, and resource-distribution processes and are often aimed at multiple systems, use multiple strategies, and are implemented both within and outside of the health sector into dynamic and complex systems.

PHIR integrates the components of evaluation research and community-based intervention research into traditional intervention research, and is concerned with multiple aspects of an intervention including efficacy and effectiveness, processes by which change is brought about, contextual factors that favor desirable outcomes, reach, differential uptake, dissemination, and sustainability. PHIR considers both controlled and uncontrolled intervention designs and produces practice-relevant knowledge for real-world decision making.

Comparative Effectiveness Research to Accelerate Translation (CER-T)
Comparative Effectiveness Research (CER) is 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. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.” CER-T refers to CER that is concerned with producing results that will disseminate and translate into population-level change.

Patient-Centered Outcomes Research
Patient-centered outcomes research (PCOR) is a form of research that emphasizes the voice of various stakeholders but primarily patients in the process of evaluating health care options. PCOR is achieved through early and ongoing, meaningful engagement of stakeholders in all stages of the
research process including: the identification of priority areas and questions for research, and dissemination and implementation of meaningful interventions. As defined by the Patient-Centered Outcomes Research Institute, "patient-centered outcomes research is the evaluation of questions and outcomes meaningful and important to patients and caregivers." In this sense, PCOR is in line with the concept of designing for D&I and sustainability through the stakeholder-engaged development of interventions and the use of existing dissemination channels for the successful and active spread of effective interventions.

Quality Improvement
Quality improvement (QI) is defined as the concerted and ongoing activities that are undertaken systematically by diverse stakeholders to improve care. In the optimal case, this includes all relevant health care providers, organizational leaders, evaluators, patients, and their caregivers. QI efforts can address improving patient outcomes, health care services and system performance, and/or professional development (i.e., learning health care system) in the context of health care. While QI and D&I science approach health care improvement from different paradigms and use different frameworks and methods, they share the ultimate goal of improving patient health outcomes. The main differences between QI and D&I science involve their scope, starting point, and speed of action. QI is generally initiated at the local level to address a specific issue for a clinic or health care system, while D&I science often starts with an evidence-based intervention or practice and explores how it can be spread and implemented at the health system or clinic level. Usually QI efforts focus on or at least begin with very small "tests," even within a single health care team, using simple measures, often developed by local teams for rapid feedback (i.e., Plan-Do-Study-Act cycle). QI is also, by definition, iterative whereas D&I is usually seen as slower, larger in scope, and more likely to use explicit theoretical or conceptual models and well-validated measures. Recent reviews and thought pieces suggest that if we are to make relevant, significant, and sustainable impact on health outcomes, D&I science should consider adopting some of the methods used by QI such as the iterative, rapid testing and adaptation of interventions and implementation strategies. A proposal for the combination of QI and D&I science methods is described under learning evaluation in Section 3 of this chapter.

Precision Medicine
Precision medicine merges information on genomic, biological, behavioral, environmental, and other data on individuals in order to identify factors that can support individualized treatment. While to date most of the work in precision medicine has focused on the genomic and biological components, there is great need and opportunity in expanding our work to data elements related to the social and behavioral determinants of health, as well as patient values and preferences relevant for shared decision making. These latter factors are especially important when we consider the contextual and pragmatic issues involved in moving precision medicine activities from research into practice and policy. Chambers and colleagues suggested that the key potential of D&I science in precision medicine is to support the integration of various precision medicine interventions into learning health care systems.

SECTION 2: THEORIES AND APPROACHES

Stage Models
Stage models propose that D&I of interventions occurs as a series of successive phases rather than as one event. Although different stage models vary in the number and name of the identified stages, all models suggest that D&I does not stop at the level of initial uptake; further steps are necessary to ensure the long-term utilization of an intervention. This chapter identifies the stages as dissemination, adoption, implementation, and sustainability. Other commonly used models are the innovation-decision process (knowledge, persuasion, decision, implementation, and confirmation) and the stages of the RE-AIM framework (reach, adoption, implementation, maintenance). The different stages of the D&I process can be thought of as process variables or mediating factors (i.e., factors that lie in the causal pathway between an independent
variable [e.g., the exposure to the intervention] and dependent variable [e.g., an outcome such as organizational change] and require different strategies and are influenced by different moderating variables].

Theories and Frameworks
There are a number of theories, theoretical frameworks, and models that shape the way that we think about D&I research and guide our planning and evaluation activities. Tabak and colleagues identified 63 distinct D&I models through their review, which were further expanded with practice-relevant models by Rabin and colleagues to 87 models in their web-based interactive tool (http://dissemination-implementation.org). The most commonly used theories and frameworks include the Diffusion of Innovations theory, theories of organizational change, Social Marketing theory, theories of communication, and organizational decision making. Community Organizing models, the RE-AIM framework, the Consolidated Framework for Implementation Research (CFIR), the Precede-Proceed model, the Interactive Systems Framework for D&I, and the Practical, Robust Implementation and Sustainability model (PRISM) are commonly applied in D&I research. A more comprehensive description of the CFIR framework and related tools are available at: http://cfirguide.org/.

Diffusion of Innovations
The diffusion of innovations theory was proposed by Rogers to explain the processes and factors influencing the spread and adoption of new innovations through certain channels over time. Key components of the diffusion theory are: (1) perceived attributes of the innovation; (2) innovativeness of the adopter; (3) social system; (4) individual adoption process; and (5) diffusion system. Some of these key components are discussed later in this chapter.

RE-AIM Framework
The RE-AIM framework developed by Glasgow and colleagues provides a conceptual model to guide researchers and practitioners in the development of adequate multistage (reach, adoption, implementation, maintenance) and multilevel (individual, setting) indicators when evaluating D&I efforts. A more comprehensive description of the RE-AIM framework and related tools can be found at: http://www.re-aim.org/.

Consolidated Framework for Implementation Research
The CFIR was developed by Damschroeder and colleagues to provide “an overarching typology to promote implementation theory development and verification about what works where and why across multiple contexts.” CFIR is composed of five major domains (i.e., intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation) and each domain includes multiple constructs (e.g., evidence strength and quality, patient needs and resources, culture, evaluate). A more detailed description of CFIR and related terminology and tools are available at: http://cfirguide.org/.

Designing for Dissemination, Implementation, and Sustainability
Designing for Dissemination, Implementation, and Sustainability (D4DIS) refers to a set of processes that are considered and activities that are undertaken throughout the planning, development, and evaluation of an intervention to increase its dissemination and implementation potential.

Some authors refer to the understanding and consideration of the user context (receiver “pull”). Others talk about the need to considering target users’ needs, assets, and timeframes. D4DIS builds on the premises that (1) effective dissemination of interventions requires an active, systematic, planned and controlled approach; (2) planning for D&I and sustainability in the early stage of conceptualization and development of the intervention can increases the success of later D&I and sustainability efforts; (3) early involvement of and partnership with target users in the conceptualization and development process can increase the likelihood of success for later dissemination and implementation efforts; (4) close understanding
of and building on the characteristics, beliefs, norms, and wants of target adopters can positively influence their perception of a new intervention and consequently will increase the likelihood of adoption, implementation, and sustained use of the intervention;\textsuperscript{134} and (5) study designs and measures that generate practice-relevant evidence facilitate and inform later stage D&I and sustainability efforts.\textsuperscript{137} Brownson and colleagues organized strategies for D4DIS into three broad categories of systems changes (e.g., shift in funder priorities and researcher incentives, developing measures, tools, and reporting standards), processes (e.g., early engagement of stakeholders, use of D&E models, identification of appropriate delivery methods) and products (e.g., identify appropriate message, develop user friendly summaries).\textsuperscript{135}

**Audience Segmentation**

Audience segmentation is the process of distinguishing between different subgroups of users and creating targeted marketing and distribution strategies for each subgroup. Dearing and Kreuter suggest that "segmentation of intended audience members on the basis of demographic, psychographic, situational, and behavioral commonalities" allows for the design of products and messages that are perceived more relevant by the intended target audience.\textsuperscript{134} A more detailed discussion about marketing approaches for D&E are described in chapter 12.

**Fidelity and Adaptation**

Understanding the nature and origin of changes made to the evidence-based interventions and implementation strategies during the implementation process and assessing how these modifications might have impacted outcomes, as well as using this information to inform future implementation efforts, is a critical topic for D&E research. This section defines terms related to fidelity, adaptations, and core components.

**Fidelity**

Fidelity measures the degree to which an intervention is implemented as it is prescribed in the original protocol.\textsuperscript{175} Fidelity is commonly measured by comparing the original evidence-based intervention and the disseminated and implemented intervention in terms of: (1) adherence to the program protocol, (2) dose or amount of program delivered, (3) quality of program delivery, and (4) participant reaction and acceptance.\textsuperscript{138}

In the case of complex interventions, the measurement of fidelity focuses more on the function and process of the intervention rather than the individual components.\textsuperscript{27} A more comprehensive discussion of fidelity measurement of complex interventions is found in Hawe et al.\textsuperscript{27}

**Adaptation**

For the success of D&E, interventions in most cases need to be adapted to fit the local context (i.e., needs and realities).\textsuperscript{7} Adaptation is defined as the degree to which an evidence-based intervention is changed or modified by a user during adoption and implementation to suit the needs of the setting or to improve the fit to local conditions.\textsuperscript{79} The need for adaptation and understanding of context has been called Type 3 evidence (i.e., the information needed to adapt and implement an evidence-based intervention in a particular setting or population) (see more on this under Types of Evidence earlier in this chapter).\textsuperscript{32,47} Ideally, adaptation will lead to at least equal intervention effects as shown in the original efficacy or effectiveness trial. Furthermore, while modifications might facilitate implementation and sustainability by improving the fit between the intervention and the population or the facility, program fidelity and outcomes of interest may be affected. To reconcile the tension between fidelity and adaptation, the core components (or essential features) of an intervention (i.e., those responsible for its efficacy/effectiveness) must be identified and preserved during the adaptation process.\textsuperscript{139} Frameworks like the Stirman adaptation and modification framework can support the systematic documentation of adaptations and modifications happening during implementation and can inform future implementation and scale-up efforts.\textsuperscript{140} For a more comprehensive discussion of fidelity and adaptation see chapters 16 and 17 and a number of seminal papers on the topic.\textsuperscript{139,141–144}

Although in this chapter it is defined differently, translation is another term commonly used in the literature to denote the adaptation of relevant research findings to make them useful for a variety of audiences.\textsuperscript{145} Furthermore, “reinvention” is another term that also has been used as a synonym to adaptation.

**Core Elements (or Components)**

The terms core elements or components can refer to the intervention (core intervention elements...
or components) and is defined as the active ingredients of the intervention that are essential to achieving the desired outcomes of the intervention. Some authors differentiate between core intervention elements or components and customizable components, which latter can be modified to local context without harming the effectiveness of the intervention. While understanding of the core elements or components of an intervention or the implementation process can facilitate the adaptation and sustainability of the intervention in a new context (i.e., setting, audience), the identification of these core elements is not always straightforward. Identification can be facilitated by the use of theoretical frameworks during the development of the intervention and detailed description of the elements or components but as Fixsen and colleagues noted, “the eventual specification of the core intervention components for any evidence-based program or practice may depend upon careful research and well-evaluated experiential learning from a number of attempted replications.”

Core elements or components can also refer to the implementation process (core implementation elements or components) and indicate of the drivers of the implementation process that are indispensable for the successful implementation of an intervention.

An extensive discussion of core intervention and implementation components that can be used to successfully implement evidence-based interventions is provided in the report of Fixsen and colleagues.

**Adaptome**

Adaptome was proposed by Chambers and Norton as a common data platform that would allow the systematic capturing and storing of data about adaptations happening during the delivery and implementation of evidence-based interventions across diverse settings and populations. This approach emphasizes the need for ongoing learning about optimal delivery strategies as fit between the intervention and setting and population is maximized. Furthermore, it highlights the need for a paradigm shift from the linear conceptualization of intervention development, testing, and dissemination and implementation to a more iterative, nonlinear approach where the permanence of evidence-base is not assumed.

**Strategies for D&I**

**Dissemination Strategy**

Dissemination strategies describe mechanisms and approaches that are used to communicate and spread information about interventions to targeted users. Dissemination strategies are concerned with the packaging of the information about the intervention and the communication channels that are used to reach potential adopters and target audience. Passive dissemination strategies include mass mailings, publication of information including practice guidelines, and untargeted presentations to heterogeneous groups. Active dissemination strategies include hands-on technical assistance, replication guides, point-of-decision prompts for use, and mass media campaigns. It is consistently stated in the literature that dissemination strategies are necessary but not sufficient to ensure widespread use of an intervention.

**Implementation Strategy**

Implementation strategies refer to the systematic processes or methods, techniques, activities, and resources that support the adoption, integration, and sustainment of evidence-based interventions into usual settings. Fixsen and colleagues refer to implementation strategies as core implementation components or implementation drivers and list staff selection, preservice and in-service training, ongoing consultation and coaching, staff and program evaluation, facilitative administrative support, and systems interventions as components. Powell and colleagues differentiated discrete (i.e., individual implementation actions such as reminders, educational meetings), multifaceted (i.e., combination of two or more discrete strategies such as training with technical assistance), and blended (i.e., protocolized implementation strategies). They used a review and expert consensus approach to create a consolidated compilation of 73 discrete implementation strategies and respective definitions. Chapter 15 discusses these strategies in more detail.

**Factors Associated with the Speed and Extent of D&I**

Several factors (i.e., moderators) influence the extent to which D&I of evidence-based interventions occur in various settings. Moderators are factors that alter the causal effect of an independent variable on a dependent variable. In this...
case, organizational capacity can moderate the effect of an intervention on a desired outcome. These factors can be classified as the characteristics of the intervention, characteristics of the adopter (organizational and individual), and contextual factors. Adoption rate will be influenced by the interaction among the attributes of the innovation, characteristics of the intended adopters, and the given context.\textsuperscript{20}

**Characteristics of the Intervention**

Rogers identifies five perceived attributes of an innovation that are likely to influence the speed and extent of its adoption: (1) relative advantage (effectiveness and cost efficiency relative to alternatives); (2) compatibility (the fit of the innovation to the established ways of accomplishing the same goal); (3) observability (the extent to which the outcomes can be seen); (4) trialability (the extent to which the adopter must commit to full adoption); and (5) complexity (how simple the innovation is to understand).\textsuperscript{19,141} Relative advantage and compatibility are particularly important in influencing adoption rates.\textsuperscript{19}

**Relative Advantage**

Relative advantage refers to the degree to which the evidence-based intervention is perceived by potential adopters as better (e.g., more effective, less costly, takes less time, etc.) than the process or practice it replaces.\textsuperscript{19}

**Compatibility**

Compatibility refers to the perceived fit of the evidence-based intervention with “existing values, past experiences, and needs of potential adopters”\textsuperscript{19,p. 15} as well as practices and processes in place at the adopting organization or setting (e.g., patient flow, community practices).\textsuperscript{19}

**Acceptability**

Acceptability is related to the ideas of complexity and relative advantage; it refers to a specific intervention and describes whether the potential implementers, based on their knowledge of or direct experience with the intervention, perceive it as agreeable, palatable, or satisfactory.\textsuperscript{65}

**Appropriateness**

Appropriateness is related to the idea of compatibility and is defined as the perceived fit and relevance of the intervention for a given context (i.e., setting, user group) and/or its perceived relevance and ability to address a particular issue.

Organizational culture and organizational climate might explain whether an intervention is perceived as appropriate by a potential group of implementers.\textsuperscript{65}

The concepts of acceptability and appropriateness are related terms but not identical. While an intervention might be perceived as a good fit to address an issue in question (i.e., appropriate), it might not be perceived as acceptable due to its characteristics and vice versa.

**Feasibility**

Feasibility is closely related to the concepts of compatibility and trialability and refers to the actual fit, suitability, or practicability of an intervention in a specific setting. Perceived feasibility plays key role in the early adoption process.\textsuperscript{65} A more detailed discussion of this concept is provided in chapter 14.

**Implementation Cost**

Implementation cost (or incremental cost) is defined as the cost impact of an implementation effort and depends on the costs of the particular intervention, the implementation strategy used, and the characteristics of the setting(s) where the intervention is being implemented. Understanding implementation cost can be especially important for comparative effectiveness research.\textsuperscript{65}

A more detailed discussion of the concepts of acceptability, appropriateness, feasibility, and implementation cost is provided in chapter 14.

**Characteristics of the Adopters**

Characteristics of the adopters can be discussed at the individual and organizational/community level. Attributes of the organization/community include its size, formalization, perceived complexity, and readiness for the implementation of the innovation. The characteristics, attitudes, and behaviors of individuals within an adopting organization (e.g., position in the organization, education, individual concerns and motivations) may also determine the uptake and use of an innovation.\textsuperscript{152} Rogers classifies the individual adopters according to their degree of innovativeness into five categories: (1) innovators, (2) early adopters, (3–4) early and late majority, and (5) laggards.\textsuperscript{19,141}

**Opinion Leader**

Opinion leaders are members of a community or organization who have the ability to influence attitudes and behaviors of other members of the
organization or community. Opinion leadership is based on perceived competence, accessibility, and conformity to system norms and is not a function of formal position. Opinion leaders serve as models for other members of the organization or community for innovation decisions, hence they can facilitate or impede the dissemination and adoption process.\(^{19}\)

**Change Agent**

Change agents are representatives of change agencies that are external to an organization or community and their goal is to influence the innovation decisions of members of the organization or community. Change agents often use opinion leaders from an organization or community to facilitate the dissemination and adoption process.\(^{19}\)

**Contextual Factors**

Contextual factors may include the broader political, social, and organizational characteristics as well as the more immediate, local-level features for the implementation of the intervention.\(^{31,153}\) Examples of contextual factors include social support, legislation and regulations, social networks and norms, culture, incentives, and processes. Understanding the delivery context for the intervention is essential for the success of the D&I and closely linked to the concepts of fidelity and adaptation.\(^{154}\) When findings from D&I studies are considered with context taken into account, a greater understanding around the mechanisms leading to said results might emerge more readily.\(^{155}\) Only less than half of the existing D&I theories and frameworks include some aspect of context as a construct.\(^{156}\) Ones that are most useful conceptualize context at multiple levels and from the perspective of multiple stakeholders (e.g., CFIR, PRISM). Furthermore, while it is acknowledged as a critical area of influence for D&I, systematic documentation of context is still rarely reported on.\(^{155}\) Context is best assessed using **mixed methods approaches**, which requires the collection of rich qualitative data in addition to more traditional quantitative data collection efforts (see chapter 20). Glasgow and colleagues propose a template for interviews and observations to collect contextual information that can be applied across settings and topic areas.\(^{155}\) Recent efforts in the organizational change literature discussed context in terms of the inner (organizational) context including structural and cultural features, and system readiness and the outer (interorganizational) context including interorganizational networks and collaborations.\(^{20}\) They also identified several core aspects of context including leadership, infrastructure, and unit variability.\(^{157}\)

A few more common contextual factors (organizational culture, organizational climate, and organizational readiness for change) are defined in this section.

**Organizational Culture**

Organizational culture is defined as the organizational norms and expectations regarding how people behave and how things are done in an organization.\(^{158,159}\) This includes implicit norms, values, shared behavioral expectations, and assumptions that guide the behaviors of members of a work unit.\(^{160}\) Organizational culture refers to the core values of an organization, its services or products as well as how individuals and groups within the organization treat and interact with each other. Schein defined it as “the pattern of shared basic assumptions that was learned by a group as it solved its problems of external adaptation and internal integration, and that has worked well enough to be considered valid and, therefore, to be taught to new members as the correct way to perceive, think, and feel in relation to those problems.”\(^{161}\)

**Organizational Climate**

Organizational climate refers to the employees’ perceptions of and reaction to the characteristics of the work environment.\(^{162–168}\)

**Organizational Readiness for Change**

Organizational readiness for change is defined as the extent to which organizational members are psychologically and behaviorally prepared to implement a new intervention. Organizational readiness is widely regarded as an essential antecedent to successful implementation of change in health care and social service organizations.\(^{169–171}\)

Factors that are associated with organizational readiness for change include (1) change valence (i.e., the employees’ perception of the personal benefit of implemented change), (2) change efficacy (i.e., the perception of their capability of implementing the change); (3) discrepancy (i.e., the employees’ belief in the necessity of change to bridge the gap between the organization’s current and desired state); and (4) principal support (i.e., the employees’ perception of the commitment of the formal organizational leaders and opinion
leaders to support successful implementation of change) and are discussed in more detail in chapter 8.

SECTION 3: DESIGN AND ANALYSIS

Study Designs

Traditional randomized controlled trials (RCTs) are not always desirable or feasible for the evaluation of dissemination and implementation programs. To achieve a greater understanding of external validity, a variety of study designs that take into count contextual factors should be considered for the evaluation of dissemination and implementation efforts, including quasi-experimental designs, interrupted time-series design, before–after designs, adequacy and plausibility designs, cluster (or group) randomized designs, participatory research methods, and pragmatic clinical trials.172,173 This section provides definitions for a number of innovative design options relevant to D&I science. For a more detailed discussion of designs for D&I, see chapter 13 and work by Brown and colleagues.174

Pragmatic (or Practical) Clinical Trial

PCTs are clinical trials that are concerned with producing answers to questions faced by decision makers.175 Tunis and colleagues define PCTs as studies that “(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.”175 PCTs that take into rather than “take out of” (i.e., control for) consideration the large number of mediators and moderators that influence the D&I process are more likely to produce practice-based evidence than their highly controlled counterparts.172

Natural Experiment

Natural experiment is a form of observational study design and is defined as “naturally occurring circumstances in which subsets of the population have different levels of exposure to a supposed causal factor, in a situation resembling an actual experiment where human subjects would be randomly allocated to groups.”120(p. 25)

Plausibility Design

Plausibility design is used to document impact and rule out alternative explanations when an RCT approach is not feasible or acceptable (i.e., complexity of intervention, known efficacy or effectiveness in small scale, ethical concerns). Plausibility studies include comparison groups and also address potential confounders.173

Sequential Multiple Assignment Randomized Trial Design

Sequential, multiple assignment, randomized trials (SMARTs) can be used to develop adaptive interventions and adaptive implementation strategies and involve multiple intervention stages, each indicating a decision point in the development of the adaptive intervention. Adaptive interventions and adaptive implementation strategies allow for using individual (e.g., preference, severity of condition) or setting level (e.g., local processes and resources) variables to adapt an intervention or implementation strategy and individual (e.g., treatment response, adherence) or setting level (e.g., uptake by providers, screening rates at clinic) outcomes to further readapt or refine the intervention or implementation strategy during implementation. These modifications can be important to address changes in circumstances, to reduce burden and cost, and increase success as well as align with the more iterative approach to intervention and implementation strategy development, as suggested in the adaptation and adaptome sections of this chapter.176,177

Stepped-Wedge Design

Stepped-wedge design uses a sequential roll-out of the intervention to target sites or individuals in a manner that all sites or participants will receive the intervention by the end of the trial but the order in which they receive is determined randomly. Data collection happens at the end of each time segment or wedge. Stepped-wedge design is especially favorable to more traditional randomized trial designs when roll out of the intervention is not practical or feasible at once and when the intervention is believed to do more benefit than harm.178 The use of the stepped-wedge design increased over the past decade and is especially suitable for multisite scale-up studies, as it aligns with the realities of real-world settings.179

Hybrid Designs

Hybrid study designs or effectiveness-implementation hybrid designs blend the design characteristics of effectiveness and implementation studies to generate more timely uptake of desirable interventions, more
effective implementation strategies, and more relevant information for future scale up activities. Curran and colleagues identified three types of hybrid designs. Hybrid type 1 includes a primary focus on testing the effectiveness of an intervention while implementation-relevant data is also collected as a secondary outcome. Hybrid type 2 involves the parallel testing of intervention and implementation strategy effectiveness. Hybrid 3 primarily focusing on testing of the effectiveness of an implementation strategy while also gathering information on the intervention impact on relevant outcomes are secondary outcomes.\(^\text{180}\)

**Systems Thinking**

Systems thinking is the process of understanding how things influence one another other within a whole. It is based on the premise that societal problems are complex and that the response to these complex problems is only possible by intervening at multiple levels and with the engagement of stakeholders and settings across the different levels, including the home, school, workplace, community, region, and country.\(^\text{181,182}\) Systems thinking is not only concerned with applying multiple strategies at multiple levels but also focuses on the interrelationships within and across levels and how interventions need to take these relationships into account in their design and implementation.\(^\text{181,182}\) Chapter 9 provides a detailed discussion on the concept of systems thinking for D&I.

System science approaches to study design include system dynamics method, agent-based modeling, social network analysis, system engineering, intelligent data analysis, and decision analysis with microsimulation modeling.

**Learning Health Care Systems**

Learning Healthcare System is defined by the Institute of Medicine as a system in which, "science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience."\(^\text{183}\) As suggested by Chambers, Feero, and Khoury, D&I science has a critical role to play in creating and sustaining Learning Healthcare Systems through providing evidence-based strategies, frameworks, and measures to support ongoing learning and integration of evidence into practice.\(^\text{114}\)

**Rapid, Responsive, Relevant Research**

The concept of rapid, responsive, relevant (R3) research was coined by Riley and colleagues to provide a framework and set of strategies for a rapid learning health research approach and to address limitations of traditional health research. Key criticisms of traditional health research include its slow pace, high cost and resource nature, and most importantly its lack of relevance to stakeholders that use the information for decision making. Proposed strategies to achieve R3 research include greater and more meaningful stakeholder engagement, use of innovative, rapid, and flexible designs, streamlining of the review process, and creation and better use of research infrastructure, rapid learning systems, and other health information technologies.\(^\text{184}\)

**Learning Evaluation**

Learning evaluation is a multiorganization assessment approach that blends principles of quality improvement and D&I science. Balasubramanian and colleagues described the process as follows: "qualitative and quantitative data are collected to conduct real-time assessment of implementation processes while also assessing changes in context, facilitating quality improvement using run charts and audit and feedback, and generating transportable lessons."\(^\text{181}\)

**Measurement Considerations**

In the context of measures of the D&I process, three main components should be considered: moderators (i.e., factors associated with the speed and extent of dissemination and implementation), mediators (i.e., process variables), and outcomes. Moderators and mediators are defined in a previous section of this chapter. The measurement of moderators and mediators can help to identify the factors and processes that lead to the success or failure of an evidence-based intervention to achieve certain outcomes. To reflect the complexity of interventions and diversity in the interest of potential stakeholders (i.e., policymakers, practitioners, clinicians), in D&I research we commonly measure multiple moderators, mediators, and outcomes and assess their relationship.\(^\text{185}\)

**Mixed Methods**

Mixed methods designs involve the collection and analysis of multiple, both quantitative and qualitative data in a single study to answer research questions using a parallel (quantitative
and qualitative data collected and analyzed concurrently), sequential (one type of data informs the collection of the other type), or converted (data is converted—qualitized or quantitized—and reanalyzed) approach. The mixed methods research design can generate rich data from multiple levels and a number of stakeholders and hence is appropriate to answer complex research questions (also see Systems Thinking). 186,187

**Outcome Variables**

Outcome variables, the end results of evidence-based interventions, in D&I research are often different from those in traditional health research and have to be defined broadly, including short-term and long-term outcomes, individual and organizational- or population-level outcomes, impacts on quality of life, adverse consequences, and economic evaluation. 31 Although, individual-level variables can also be important (e.g., behavior change variables such as smoking or physical activity), outcome measures in D&I research are typically measured at organizational, community, or policy level (e.g., organizational change, community readiness for change).

**Implementation Outcomes**

Implementation outcomes are distinct from system outcomes (e.g., organizational-level measures) and individual-level behavior and health outcomes, and are defined as “the effects of deliberate and purposive actions to implement new treatments, practices, and services.” 65(p. 65)

Implementation outcomes are measures of implementation success, proximal indicators of implementation processes, and key intermediate outcomes of effectiveness and quality of care. The main value of implementation outcomes is to distinguish intervention failure (i.e., when an intervention is ineffective in a new context) from implementation failure (i.e., when the incorrect deployment of a good intervention causes lack of previously documented desirable outcomes). 65

Proctor and colleagues proposed the following implementation outcomes: acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration, and sustainability. 65

**Pragmatic Measures**

Pragmatic measures were proposed by Glasgow and Riley as a set of criteria that should apply to instruments used in real-world studies including studies of D&I. In addition to the traditional criteria of validity and reliability, the key characteristics of an ideal pragmatic measure include: (1) measures outcomes important to a diverse set of stakeholders (i.e., practitioners, patients, researchers), (2) imposes a low burden from both data collection and analysis perspective (i.e., brief, user-friendly, low cost), (3) has a broad applicability (i.e., works across populations, settings, languages and cultures), (4) is sensitive to change (i.e., able to track change over time), (5) yields information that enhances patient engagement, (6) is actionable (i.e., based on information realistic action can be taken), (7) has public health relevance, and (8) does no harm (e.g., interferes with relationships, has unintended negative consequences). 188,189

**External Validity**

External validity is the degree to which findings from a study (or set of studies) can be generalizable to and relevant for populations, settings, and times other than those in which the original studies were conducted. 190 Standardized and detailed reporting on factors that influence external validity (such as those recommended in the RE-AIM framework) can contribute to more successful D&I efforts. 56,137,191 In addition, Green and Glasgow have proposed rating criteria for external validity. 137 The concept of external validity is discussed in detail in chapter 18.

**Standards for Reporting Implementation Studies**

The Standards for Reporting Implementation Studies is a checklist compromised of 27 items and provides guidelines for implementation studies on reporting transparently, accurately, and consistently on various aspects of their work. The guidelines were developed using findings from a systematic review, a consensus-building e-Delphi exercise, and input from an international group of experts. 96

**SUMMARY**

In order for a field to prosper and thrive, a common language is essential. As is often the case when many disciplines and numerous organizations converge in the development of a field, D&I research is still characterized by inconsistent terminology.

When compiling this chapter, we encountered a number of challenges. Our research was limited to English language documents, so we may have missed important information from non-English speaking countries. Another challenge was the...
Terminology for Dissemination and Implementation Research

lack of consensus on the overall classification of terms in the literature that may lead to apparent contradictions. For example, this chapter defines the different stages (dissemination, adoption, implementation, and sustainability) of the process under the umbrella term “D&I research.” Other stage models may discuss adoption and sustainability as a distinct stage. Finally, it is important to note that the three-section classification introduced in this chapter was not developed to impose a rigid structure, rather it is used as an organizing framework that allows us to discuss terms in the domain where they are most commonly applied. At the end of this book, the index provides an alphabetized list of terms with respective page numbers to facilitate the search for definitions and the fuller context for each term.

The lack of agreed-upon language for D&I research impedes the systematic analysis and summary of existing evidence in the field and the communication across different stakeholders (i.e., researchers, practitioners, policymakers). The purpose of this chapter is not to advocate or argue the superiority of one term or classification scheme over another, but to facilitate communication by beginning to define commonly used terms in D&I research for researchers, practitioners, policymakers, and funding agencies. A common language should help accelerate the scientific progress in D&I research by facilitating comparison of methods and findings, as well as identifying gaps in dissemination knowledge.

Since the first edition of this chapter, a number of efforts were undertaken to create such ontology (i.e., agreed upon terms, definitions, and their interrelationships) and related data harmonization efforts. A few examples include: work by Padek and colleagues on identifying and organizing D&I research competencies; Powell and colleagues on creating a consolidated compilation of implementation strategies; Larsen and colleagues in suggesting ways to create an ontology for behavior change interventions; Niven and colleagues’ review of terminology for de-adoption; the work described by Colquhoun and colleagues on developing a common terminology and overarching framework for KT interventions and related WhatisKT wiki page; the systematic review and organization of D&I models by Tabak and colleagues and the related Dissemination and Implementation Models (www.dissemination-implementation.org) web-based tool created by Rabin and colleagues; the efforts undertaken by Lewis and colleagues to develop a shared repository of instruments for Implementation Science (https://societyforimplementationresearchcollaboration.org/sirc-instrument-project/); and work by Rabin and colleagues to develop a D&I-focused workspace on NCI’s Grid-enabled Measures Database (https://www.gem-beta.org/public/sooverview.aspx?cat=8&wid=11&aid=0), a crowd-sourcing propelled wiki database of behavior health measures.

While the “state-of-the-art” might still not be advanced enough to resolve all of the existing inconsistencies in terminology, this chapter represents the tremendous amount of development that happened over the past 5 years to create platforms and approaches for a more consistent, agreed upon language for D&I research across topic areas, stakeholder groups, and geographical areas. As the D&I field makes progress toward a shared terminology, we can expect to see higher quality D&I research and greater contribution of D&I science to improving public health and clinical practice.

ACKNOWLEDGEMENTS

The authors are thankful to Ms. Shannon Keating for her assistance with the preparation of the first edition of this chapter. We are also grateful to Melinda Davis, Jonathan Purtle, Shari Rogal, and Nicole Vaughn, who provided valuable input on the organizing structure and approaches used in this chapter, and to Russell Glasgow for reviewing and helping refine some of the definitions.

An earlier version of this chapter was published in the Journal of Public Health Management and Practice in 2008 and was coauthored by Drs. Debra Haire-Joshu, Matthew Kreuter, and Nancy Weaver. We appreciate the contributions from these coauthors.

SUGGESTED READINGS AND WEBSITES

Readings


A monograph that summarizes findings from the review of the research literature on implementation including findings from the domains of agriculture, business, child welfare, engineering, health, juvenile
justice, manufacturing, medicine, mental health, nursing and social services. The authors organize and synthesize critical lessons regarding implementation from these domains and provide definitions for constructs and processes.


A monograph on issues and terminology for knowledge utilization, diffusion, implementation, transfer, and translation. The authors recommend more consideration of background, contextual factors that may influence a policy or program, and how this impacts evaluation efforts.


In this seminal article, Glasgow et al. evaluate public health interventions using the RE-AIM framework. The model's five dimensions (reach, efficacy, adoption, implementation, and maintenance) act together to determine a particular program's public health impact. The article also summarizes the model's strengths and limitations, and suggests that failure to evaluate on all five dimensions can result in wasted resources.


This article describes the Practical, Robust Implementation and Sustainability Model (PRISM), a comprehensive approach to implementation science. The model emphasizes the importance of considering worker perspectives, building partnerships, and providing for program sustainability.


This article reviews the terms used to describe the knowledge to action (KTA) process, and describe a framework for conceiving of this process. The authors stress the importance of relationships to facilitate the knowledge to action process, as well as a common definition of how KTA works.


This paper describes an effort to create harmonized terminology and identify and overarching framework for KT using an expert workgroup approach.


This paper provides a systematic review of the literature on de-adoption, document current terminology and frameworks, map the literature to a proposed framework, identify gaps in our understanding of de-adoption, and identify opportunities for additional research.

Websites and Tools

What is KT wiki?
https://whatiskt.wikispaces.com/

This web-based resource provides an inventory of knowledge translation or KT terms, their definitions, and links to related resources. The What is KT wiki functions as a collaborative environment to define and compare terms and concepts used to describe getting research into practice across a variety of disciplines.

Dissemination and Implementation Models
http://dissemination-implementation.org/

This interactive website was designed to help researchers and practitioners to select the Do-I Model that best fits their research question or practice problem, adapt the model to the study or practice context, fully integrate the model into the research or practice process, and find existing measurement instruments for the model constructs.

REFERENCES


40 DISSEMINATION AND IMPLEMENTATION RESEARCH IN HEALTH

Terminology for Dissemination and Implementation Research


83. Norton WE, Mittman B. Scaling-up health promotion/disease prevention programs in community settings: barriers, facilitators, and initial recommendations. The Patrick and Catherine Weldon Donoghue Medical Research Foundation; 2010.


95. Center for Mental Health in Schools at UCLA. Systemic change and empirically-supported practices: The implementation problem. Los Angeles: Author; 2006.


44 DISSEMINATION AND IMPLEMENTATION RESEARCH IN HEALTH


185. Glasgow RE. What outcomes are the most important in translational research? Paper presented at: In Proceedings of “From clinical science to community: The science of translating diabetes and obesity research” conference 2004; Bethesda, Maryland.


