DISSEMINATION AND IMPLEMENTATION RESEARCH IN HEALTH

> TRANSLATING SCIENCE TO PRACTICE

> > SECOND EDITION

EDITED BY ROSS C. BROWNSON GRAHAM A. COLDITZ ENOLA K. PROCTOR

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We dedicate this book to our spouses: Carol Brownson, Pat Cox, and Frank Proctor. We are grateful for their loving support, patience, and good humor.

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FOREWORD

Five years on down the road . . .

Perhaps the most frequently quoted statistic in dissemination and implementation (D&I) research is one that derives from Balas and Boren's seminal article in 2000: "It takes 17 years to turn 14 percent of original research to the benefit of patient care."¹ It is thus interesting to be writing this foreword 17 years after the publication of that article, and contemplating the second edition of this edited volume on D&I just 5 years removed from its inaugural version. By 2000 standards, we should still be some 12 years from the impact of the 2012 edition and yet it has been quite prominent in offering a comprehensive look at D&I research since its publication. And the field continues marching along.

Five years is the typical length of an NIH R01 grant, the standard for completion of a single definitive investigation of a set of research aims, and in the annals of D&I research history, it has been marked by a fair amount of progress made from the previous iteration. It is my intent in this foreword to provide a few reflections of where the field has gone, what D&I investigators have produced, both in terms of quality and quantity, and then to project into the next 5 years.

FIELD PROGRESS

Reflecting on the past few years, there has clearly been an increase in both the quality and quantity of dissemination and implementation research in health. The most recent versions of the trans-NIH program announcements (PARs) on D&I research were released in 2016, with another increase in representation of the components of the Agency, including Institutes, Centers, and Offices, which now number 18. The most recent versions highlight some of the areas in which D&I research is expanding, including greater focus on understanding adaptation of interventions in the context of implementation, sustainability of evidence-based practices (EBPs) over time, and even the de-implementation of ineffective or harmful practices still in use.²⁻⁴ Over the past 5 years, tens of D&I research studies, including small grants, exploratory and developmental studies, and larger R01 grants, have been funded just through the PARs, and a number of additional NIH funding opportunity announcements have made the study of dissemination and implementation a core component of the scientific agenda moving forward.

We have also seen the contribution of other funders support advances in D&I research. The Patient Centered Outcomes Research Institute (PCORI) has identified communication and dissemination research as a key priority and has published several program announcements to stimulate more comparative effectiveness research in this area. The Agency for Healthcare Research and Quality has similarly articulated D&I research priorities for their extramural research program. In addition, the Veterans Administration's Quality Enhancement Research Initiative (QUERI) has continued support for D&I research since its inception in 1998, currently funding a series of centers targeting a variety of health care topics, including personalization of care, clinical care teams, and mobile health. Internationally, we have seen a complementary rise in solicitations of D&I research. The Canadian Institutes for Health Research and Canadian Cancer Society Research Institute, for example, have supported multiple grants in the D&I (or Knowledge Translation) space. The UK's Medical Research Council and the WHO have also supported D&I research (typically referred to as Implementation Science), and multiple foundations have also solicited work in this space.

D&I research has had a prominent role in a range of national conferences. The annual conferences on the science of dissemination and implementation have exceeded 1,100 participants annually, and the Society for Behavioral Medicine, American Society of Preventive Oncology, ASCO Quality Symposium, Society of Prevention Research, among others, have all featured D&I research as plenary sessions in recent years.

Training in Dissemination and Implementation Research has also continued at a frenzied pace. The NIH's Training Institute in Dissemination and Implementation Research in Health recently held trained its sixth cohort, and both MT-DIRC and IRI continue to bring in new investigators focusing on D&I research in cancer and mental health, respectively. Our neighbors to the North have continued the Knowledge Training Canada Summer Training Institutes as well, and additional academic courses, preconference workshops, certificate programs, and online training models have appeared to respond to the increased demand for D&I research knowledge.⁵ In addition, a number of global implementation science training courses have emerged, including several partnerships between the National Institutes of Health, the World Cancer Congress, USAID, and many other international organizations.

More exciting to see has been the increase in the quality of D&I research conducted, much of which is referenced in this volume. The contributions of novel models and frameworks to explain dissemination and implementation processes continue to grow, beyond the previous published reviews⁶⁻⁸ to better reflect the complexity and dynamism in the field. We've seen a number of new priority areas emerge—enhanced focus on sustainability, tailoring of interventions and implementation strategies to local contexts, scaleup across health systems, and the recognition of the need to study de-implementation.

We've seen more work to advance the research designs and available measures in our armamentarium. The former has included an expansion in the use of hybrid effectiveness-implementation designs,⁹ the application of adaptive designs to implementation research questions,¹⁰ as well as the full complement of research designs to apply both rigor and relevance to investigations.^{11,12} The latter has seen much work to operationalize D&I models, including the Society for Implementation Research Collaboration's Instrument Review Project and CFIR's measures database (CFIRguide.org), as well as the NCI's Grid-enabled Measures workspace for D&I research (https://cancercontrol.cancer.gov/brp/ research/gem.html). And as referenced earlier, an increasing number of empirical studies of various approaches to improve adoption, implementation, adaptation, and sustainability of evidence-based health interventions.

SO WHERE IS D&I RESEARCH HEADING NEXT?

Pooling D&I Research Data

We have reached a new era of data sharing. Funding agencies have expanded the expectations for clinical trials, genomic studies, and a whole range of other research areas. As we have made progress in the development and validation of D&I construct measures, we will likely need to up our game in pooling common data elements across D&I studies. Both GEM and the SIRC instrument review projects have increased the democratization of measures, but we need to think about infrastructure needed to accept, compile, and analyze data across studies. This will be particularly important when we consider the potential contribution from analysis at the organization or system level, where any one study may be inadequate to generalize beyond the sample.

Mechanistic D&I Research

The field has not yet taken as much advantage of empirical investigations to capture a mechanistic understanding of what leads to successful D&I of EBPs. Many studies still focus more on answering whether dissemination or implementation strategies were successful rather than seeking to understand how and why these strategies led to differing levels of EBP adoption, implementation, and sustainment; what happened rather than how or why it happened. It is important for the next generation of studies to incorporate tests of hypothesized mechanisms of action so that no matter what the overall impact on D&I may be, we are advancing our understanding of what components of strategies we seek to target, whether they operate as designed, and how different mechanisms may work in concert to affect the overall implementation outcome.

Avoiding Silos Between D&I Research and D&I Practice

As the research community has embraced studies of D&I as a valid form of scientific activity, we have become aware that we may be creating a wedge between those advancing the science with those who work as D&I practitioners. The premise of D&I research was to break down the silos between research and practice, and the next generation of work in this area would be well served not to recreate a new set of barriers in the service of acceptability to biomedical research. We have also seen this to some degree in the ongoing discussions of similarities and differences between D&I research, quality improvement research, improvement science, and other areas of investigation. While some of these distinctions come from slightly different field histories, we should all be concerned that we are erecting even greater silos among investigators and between researchers and other key stakeholders. Chapter 11 in this volume focuses on participatory methods in D&I research, something that perhaps can help to address this issue by bringing all valuable perspectives to the table within specific studies.

Harnessing and Embracing All Evidence

On a related front, with processes of capturing data within front-line practice aided by technological savvy, an opportunity for the field to harness and embrace all available evidence to drive D&I decision-making seems within our reach. The more we increasingly see the health care community and public health systems as challenged by a dynamic world that is moving toward precision medicine, the more that D&I research can help us identify how best way to integrate research evidence, local knowledge, and stakeholder preferences, restoring the concept of evidence-based medicine to its 1995 definition.¹⁴

Return on Investment of D&I Research

Now that we see increased maturity in the D&I research field, we may finally be able to make more progress in being able to calculate the return on investments made to advance our science. We hypothesize that practicing high-value health care through provision of underutilized evidence-based practices may outstrip the benefit of discovering a new practice in an established area,¹⁵ but we should seek to calculate how the results from D&I research contributes to improved value. Systems modeling may be useful in this endeavor, as may be synthesis of

the scientific products from discovery to delivery to see what bang for the buck D&I research generates.

If we are successful in moving these areas forward, I anticipate the fruits of our collective labors will be captured in subsequent editions of this book. The future is bright

David Chambers, DPhil

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PREFACE

Decades of support by governmental and private sources has produced a remarkable foundation of knowledge in all disciplines related to public health, mental health, and health care. The discovery of new knowledge should not occur in large measure to satisfy the curiosity of scientists; rather the goal must be to improve the human condition (lower morbidity and mortality, enhance quality of life). Yet the gap between care that *could be*, were health care informed by scientific knowledge, and the care that is in routine practice has been characterized as a "chasm" by the National Academy of Medicine. The lack of ability to apply research findings has sometimes been equated to a leaky or broken pipeline leading to a lag time of decades between discovery and application.

To understand and begin to fill these leaks, a new science has emerged. It goes by numerous titles, including: translational research, knowledge translation, knowledge exchange, technology transfer, and dissemination and implementation (D&I) research. Although the terminology can be cumbersome and changing existing practices complex, the underlying rationale is simple: too often, discovery of new knowledge begets more discovery (the next study) with little attention on how to apply research advances in real-world public health, social service, and health care settings. With early foundations in the work of Archie Cochrane in the 1970s showing that many medical treatments lacked scientific effectiveness, D&I research focuses on ways to increase the use of evidence-based interventions among practitioners. Research has shown that in efforts to disseminate practice guidelines using passive methods (e.g., publication of consensus statements, mass mailings), adoption has been relatively low, resulting in only small changes in the uptake of a new evidence-based practice. Thus, active approaches to D&I are needed, taking into account a wide array of contextual conditions.

A return on investment of the billions spent on basic and clinical research (discovery research) requires a marked increase in translational research, including the development of its tools and analytic approaches. These efforts have been receiving much greater attention in mainline medical and public health journals. There also is a small set of journals dedicated to D&I research, notably Implementation Science (begun in 2006) and Translational Behavioral Medicine (begun in 2011). Similarly, in multiple countries, federal agencies and foundations are beginning to support D&I research more fully. For example, recent funding announcements from the US National Institutes of Health (NIH) show the higher priority being placed on translational research. While NIH is placing renewed emphasis on T1 research from bench to bedside, we place emphasis on methods and research opportunities for moving from scientific discovery of efficacy to population-wide benefits.

There are tangible examples where the D&I gap has been shortened. This may be best illustrated over the 20th century in the United States where life expectancy rose from 49 years in 1900 to 77 years in 2000. In large part, this increasing longevity was due to the application of discoveries on a population level (e.g., vaccinations, cleaner air and water). Yet for every victory, there is a parallel example of progress yet to be realized. For example, effective treatment for tuberculosis has been available since the 1950s yet globally, tuberculosis still accounts for 2 million annual deaths with 2 billion people infected. In many ways, the chapters in this book draw on successes (e.g., what works in tobacco control) and remaining challenges (e.g., how to address translational research challenges in populations with health disparities).

What needs to happen to shorten the translational research gap?

- First, priorities need to shift. Of the US annual health expenditures, only about 0.1% is spent on health services research (where D&I research is nested). Shifting priorities toward health services research requires political will and a need for social change.
- Second, capacity for finding and implementing evidence-based practice needs to improve among numerous practitioners. For example, many individuals working in public health practice have no formal training in a public health discipline—which suggests the need for more and better on-the-job training. And for those with graduate training, keeping up with current research is a formidable—and sometimes impossible—challenge.
- Third, the science of D&I research needs further development. The range of research needs is vast and covered extensively in this volume.
- Fourth, capacity for conducting D&I research needs to be advanced through training. This training can occur in government agencies, academic institutions, and nongovernmental organizations (such as the World Health Organization).
- Fifth, provider capacity to implement change in health interventions and policies needs to be advanced. We need support for and successful models of training for implementation practice.
- And finally, to build this science and capacity, institutional support and incentives are needed. For example, academic institutions need to shift priorities for faculty to reward time spent in conducting D&I research.

As we began the 2nd edition of our book, we reflected on the significant progress in D&I science since the publication of the 1st edition. This led us to the need for several new or extensively revised chapters in this edition, including those on: ethics in D&I research, models and

frameworks, systems science methods, implementation strategies, adaptation in D&I science, mixed-methods evaluation, worksite D&I, and working in lower resource countries. In the 2nd edition, 10 of 29 chapters are entirely new or extensively revised with mostly new material. In addition, all remaining chapters from the 1st edition have been updated.

We have organized the book in a format that covers the major concepts for D&I researchers and practitioners. It draws on the talents of some of the top D&I scholars in the world-crossing many disciplines, health topics, and intervention settings. Our book has four sections. The first section provides a rationale for the book, highlights core issues needing attention, and begins to develop the terminology for D&I research. In the second section, we highlight the historical development of D&I research and describe several key analytic tools and approaches. Some of the tools are well developed with a rich literature (e.g., economic evaluation, participatory approaches) and others are relatively new, developing fields (e.g., systems thinking). This section also emphasizes the need to better plan interventions for dissemination and think creatively about how lessons from business and marketing can be applied to health. The third section is devoted to design and analysis of D&I studies. It covers core principles of study design, measurement and outcomes, and evaluation. In addition, this section highlights the concepts of fidelity, adaptation, and external validity, which are fundamental to D&I science. The final section of the book focuses on settings and populations. Since D&I research occurs in places where people spend their lives (communities, schools, worksites) or receive care (health care, social service agencies), we devote chapters to specific settings. This section also recognizes the importance of policy influences on health, the science of addressing health disparities, and working in a global context. Our book concludes with a short chapter on future research directions.

The target audience for this text is broad and includes researchers and practitioners across many different disciplines including epidemiology, biostatistics, behavioral science, medicine, social work, psychology, and anthropology. It seeks to inform practitioners in health promotion, public health, health services, and health systems. We anticipate this book will be useful in academic institutions, state and local health agencies, federal agencies, and health care organizations. Although the book is intended primarily for a North American audience, there are authors and examples drawn from various parts of the world and we believe that much of the information covered will be applicable in both developed and developing countries. The challenges of moving research to practice and policy appear to be universal, so future progress calls for collaborative partnership and cross-country research.

Our book documents that in a time of substantial political changes resulting in increasing pressure on scientific and public resources, researchers must continue to meet the implied obligation to the public that the billions of dollars invested in basic science and etiologic research will yield specific and tangible benefits to their health. Taxpayers have paid for many new discoveries yet these are not being translated into better patient care, public policy, and public health programs. We believe that applying the principles in this volume will help to bridge the chasm between discovery and practice.

R. C. B.

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The Promise and Challenges of Dissemination and Implementation Research

GRAHAM A. COLDITZ AND KAREN M. EMMONS

"To him who devotes his life to science, nothing can give more happiness than increasing the number of discoveries, but his cup of joy is full when the results of his studies immediately find practical applications."

-LOUIS PASTEUR

"The ability of science to deliver on its promise of practical and timely solutions to the world's problems does not depend solely on research accomplishments but also on the receptivity of society to the implications of scientific discoveries."

-AGRE AND LESHNER¹

INTRODUCTION

Dissemination and implementation (D&I) of research findings into practice are necessary to achieve a return on investment in our research enterprise and to apply research findings to improve outcomes in the broader community. By not implementing prevention and treatment strategies equitably we incur avoidable morbidity and mortality.² At the level of molecular biology and pathogenesis of disease, the National Institutes of Health (NIH) Director, Francis Collins, seeks more rapid translation from discovery of receptors or pathways to first in-patient studies.3 Whether we are focusing on genomic discovery or evidence that treatment of a condition improves outcomes, moving from scientific discovery to broader application brings society the full return on our collective investment in research. It is estimated that the biomedical research expenditures in the United States in 2012 exceeded \$116 billion on health-related research.⁴ Within this commitment, spending on health services research, models of care, and service innovations, "accounted for between 0.2% and 0.3% of national health expenditures between 2003 and 2011, an approximately 20-fold difference in comparison with total medical research funding,"4(pp. 177-178) Perhaps reflecting the low

priority of research on implementation of scientifically proven approaches to care, in 2001, the Institute of Medicine noted a substantial gap between care that could be delivered if health care was informed by scientific knowledge and the care that is delivered in practice—defining this gap as a chasm.⁵ It is precisely this gap that D&I is designed to address.

Implementation research is active and supports movement of evidence-based effective health care and prevention strategies or programs from the clinical or public health knowledge base into routine use (in some countries, the term "evidence-informed" is used).6 The Centers for Disease Control and Prevention (CDC) has defined implementation research as "the systematic study of how a specific set of activities and designated strategies are used to successfully integrate an evidence-based public health intervention within specific settings" (RFA-CD-07-005).7 The National Cancer Institute (NCI), in a request for proposals (RFP), has defined Implementation research as "the use of strategies to adopt and integrate evidence based health interventions and change practice patterns within specific settings." The Canadian Institutes of Health Research (http://www.cihr-irsc.gc.ca/ e/29418.html) use the following definition for knowledge translation: "a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically-sound application of knowledge to improve the health of Canadians, provide more effective services and products and strengthen the health care system." Despite these definitions, a 2004 survey of readers in *Nature Medicine* showed little agreement and understanding of translational research.⁸ Chapter 2 outlines terminology to help move to common understanding of terms in D&I.

While the translation of evidence-based interventions into practice to improve population health outcomes is a common theme of government agencies, the process for distribution of scientific findings, materials, and associated resources to support interventions is less developed. Dissemination is defined as "the targeted distribution of information and intervention materials to a specific public health or clinical practice audience."9 Rabin et al. are more specific, calling for an active approach of spreading evidence-based interventions to the target audience via determined channels using planned strategies.¹⁰ These definitions are similar to that of Lomas^{11,12} but contrast to some extent with the approach of Curry,¹³ who defines dissemination as a push-pull process. Those who adopt innovations must want them or be receptive (pull), while there is systematic effort to help adopters implement innovations (push). The intent of dissemination research is to spread knowledge and the associated interventions, building understanding of approaches to increased effectiveness of dissemination efforts. In understanding these approaches, numerous studies have shown that dissemination of evidence-based interventions using passive methods (e.g., publication of consensus statements in professional journals, mass mailings) has been ineffective, resulting in only small changes in the uptake of a new practice.¹⁴ The intent of implementation research is to increase understanding of how to increase integration of evidence-based approaches into routine, real-world practices. Therefore, more targeted, active approaches to D&I are needed that take into account many factors, including the characteristics and needs of users, types of evidence needed, and organizational climate and culture. Greater stakeholder engagement across the D&I spectrum and systems approaches can increase the speed of change.15 The definitions and other terms used in the field are described in more detail in chapter 2.

One useful model of translation of discovery to applications that will generate population health benefits comes from a thoughtful review by Bowen and colleagues. Reviewing the application of discovery to prevention of cancer, Bowen and colleagues note, "Our previous 30 years have taught us that dissemination does not just happen if we wait for it. New information is often needed to make it happen."16(p. 483) This call for research to improve understanding of methods for D&I remains true today. The challenges in D&I are broad and apply far beyond health and health care systems. In fact early examples, as we will see, come from other fields of learning. For example, much research in education has addressed the application of new knowledge to improve outcomes in children's learning.¹⁷⁻¹⁹ The rapidly expanding field of D&I research has some common themes and lessons that this book will help bring together, so a more uniform understanding of the principles of D&I research methods and applications may help speed us to achieve the potential to improve population health. First, some key questions arise from the Bowen, et al. review that are applicable to the broader field of D&I research across health, education, and technology.

- How will we gather this information on effective interventions to form the evidence base?
- Will interventions be applicable to our setting?
- What methods should we use to decide what to disseminate or implement?
- Which strategies will give us the greatest impact on population health?
- What outcomes should be tracked to know if we are making progress?
- How long will it take to show progress, or when will it be observed?
- Will implementation be uneven across population subgroups leading to or exacerbating health disparities?

These are but a few of the questions raised by the call to action from Bowen and colleagues.¹⁶ Other authors address specific questions in translation from clinical trials to policy and practice.^{20,21} This book aims to lay out many options to help guide the field as it matures, thus speeding our progress toward improved health for all. This introductory chapter seeks to place D&I research in context, identify the challenges in moving forward,

and the pressure to increase the emphasis on this aspect of knowledge translation and research utilization.

THE CHALLENGE IN TRANSLATING RESEARCH TO PRACTICE

There are a number of issues inherent in moving from discovery to application, which is essential if society is to fully benefit from our collective investment in research. Summarized below are some of the key issues that impact on our ability to translate evidence-based programs into real world practice.

Funding

Over the past 20 years, between 9% and 25% of the \$30 billion NIH budget has been expended on prevention research^{22,23}—that is, the direct and immediate application of effective intervention strategies to benefit the public's health.^{24(p. 93)} Although this indicates a relatively low priority placed on prevention, the funding for D&I research is even lower. Farquhar has estimated that 10% or less of prevention research is focused on dissemination.²² Across all funding sources through 2011-federal and foundationsspending on health services research, models of care, and service innovations, represented only 1/20th of biomedical research funding.⁴ While Moses and colleagues use broad classification categories to assess trends in funding of pharmaceutical research over time (prehuman and preclinical; phase 1-3; phase 4; approval and regulatory; other and unclassified), D&I does not fall into any clear category for this or other analyses.⁴ Rather, D&I research spans all areas from translating discoveries to bedside and broader clinical applications, to health services interventions to implement effective approaches to care. In global health it also spans from innovation in technology for extremely low-cost delivery systems to implementation in field settings.

Representation of D&I Science in the Scientific Literature

Another way to gauge the breadth of D&I research is to examine the types of articles appearing in the peer-reviewed literature. In a content analysis of 1,210 articles from 12 prominent public health journals, 89% of published studies were classified as basic research and development.²⁵ The authors classified another 5% of studies as innovation development, less than 1% as diffusion, and 5% as institutionalization. Similarly, Sallis and colleagues conducted a content analysis of four journals and found that only 2% to 20% of articles fell in a phase defined as "Translate research to practice."26 This is not terribly surprising, given the low level of funding for D&I science. In another review of three health promotion journals, dissemination research was poorly represented despite editorials calling for more D&I research.27 This publication record follows funding priorities. Moreover, onethird of public health researchers themselves rate their dissemination efforts as poor.²⁸ In a crosssectional study of researchers at universities, the NIH, and CDC, only 28% of researchers self-rated their efforts to disseminate research as "excellent/ good" despite the overwhelming majority (87%) agreeing they have an obligation to disseminate their research findings.

Appropriate Outcomes

What are the outcomes for progress in D&I of discoveries? Appropriate outcomes can include more effective health services, better prevention, reduction in health disparities, or in nonhealth settings impact on the underlying root causes of population health-such as social services, better schooling for our children, or employment opportunities. There is growing interest in deimplementation (See NIH PAR-16-238) or reduction of the use of strategies and interventions that are not evidence based.9 While the methods and issues may appear to differ across fields of study, in this book we set forth principles and methods that should be applicable across settings. Like statistics, which has a long history of development in agriculture (the leading industry of the time-Cochran wrote on meta-analysis of results from agriculture trial plots in 1937 and helped define modern approaches²⁹), D&I research also grew from agriculture to guide thinking across many fields.³⁰ The history of D&I science is presented in more detail in chapter 3. With health care expenditures consuming an ever-increasing portion of national and state budgets in the developed world, methods to maximize our societal benefit must be refined and accessible to end usersand will likely be developed and refined most quickly in the context of health and wellness. In fact, data from the Organization for Economic Co-operation and Development (OECD) indicate that the average ratio of health expenditure to GDP has risen from 7.8% in 2000 to 9.0% in 2008, and is at 16.4% for the United States and 10.2% for Canada in 2013.³¹ There is no shortage

of academic research, but how do we sift through studies and draw inference to disseminate and implement effective programs and policies more broadly? A recurring question as we approach D&I research is "Will the evidence and intervention be applicable to the new setting?"

Acceptance of Delays in Adoption

Delay in adoption of scientific discoveries is not a new phenomenon. We can look at Bayesian methods used in statistics in the 1960s to evaluate the authorship of the Federalist papers.32 In the process, described in detail by Fred Mosteller in his autobiography, an empirical test of the Bayesian approach gave new insight to manuscript classification.33 Mosteller also presented on using Bayesian approaches to combine means (Lake Junaluska, North Carolina, 1946-see pages 186-187; also see On pooling data—JASA 1948).34 These statistical methods have only much more recently been adapted to widespread use, with modern computer technology supporting this application. So advances in statistical methods development did not achieve widespread application for decades, perhaps in part due to the technical difficulty of implementing these approaches (lack of technology), but also reluctance on the part of investigators (intrapersonal factors). Both individual and structural barriers impeded implementation, reflecting a complex interplay of barriers to implementation of innovations.

How can the principles and methods we see presented in this book help us move more quickly to build on research findings and apply them to improve health? Do we need new ways of thinking, conducting, and reporting research, or can we take our existing approaches and through consensus apply what is known more rapidly? The challenge of implementation extends along the continuum from discovery of biologic phenomena to clinical application in research settings and the broader application in the population at large. While a range of approaches to describing this continuum has been developed, perhaps more pertinent from the D&I perspective is the perspective summarized by Green and colleagues as a leaky pipeline from research to practice.³⁵ Across these approaches to defining stages of translation and application, some common themes emerge; discovery on its own does not lead to use of knowledge; evidence of impact does not lead to uptake of new strategies; organizations often do not support the culture of evidencebased practice; and maintenance of change is often overlooked, leading to regression of system level changes back to a prior state. The focus of an intervention for implementation, whether at the individual level or up through to system level changes or policies, determines in part the breadth of change toward improved population outcomes. The lag from discovery to application (implementation of effective programs and practices) may vary across disciplines. Examples from public health include the gap from perfecting the Papanicolaou test in 1943 to the establishment of screening programs in all US states in 1995, and the delay from the 1964 Surgeon General's report on smoking to effective statewide tobacco control programs and regulation of tobacco by the FDA in 2009.36 Of course, early applications will typically be in place to varying degrees before full widespread programs are implemented and sustained. As Collins notes, many false starts or failures may be needed before successful translation of discoveries to human applications.3 However, it is important to reduce the time lag from early adoption to comprehensive, widespread adoption, as this lag ultimately represents avoidable morbidity and mortality.

A frequently quoted statement about the total attrition in the funnel and the lapse between research and medical practice indicates that it takes 17 years to turn 14% of original research to the benefit of patient care, and is attributed to Balas & Boren.37 The leakage or loss of medicalclinical research from the pipeline at each stage from completed research through submission, publication, indexing, and systematic reviews that produce guidelines and textbook recommendations for best practices, to the ultimate implementation of those practices in health care settings, all contribute to these estimates. Changing technologies and priorities of publishing, bibliographic data management, and systematic reviews and disseminating evidence-based guidelines will lead to different estimates over time and in different fields. Green and colleagues depict this flow of information as a leaky funnel. In it they identify many leakage points in the scientific process (Figure 1.1).35

Looked at from the other end of the funnel, identifying major advances in engineering that have improved quality of life in the 20th century, the National Academy of Engineering included electricity, electric motors, and imaging—each with a long line of scientific discovery and application before broader social impact was achieved.³⁸ Likewise the lag from



FIGURE 1.1 The funnel depicts loss in the pipeline from research to practice. (From Green et al ³⁵)

original discovery to formal recognition with Nobel prizes grows exponentially.³⁹ A particular challenge in public health is that we are not producing a tangible product or commodity, as in the case with electricity and electric motors, but rather the intangible value of health, which may be even more challenging. That said, the path from scientific discovery to social benefit from broad implementation has common challenges across many scientific disciplines.

CASE STUDIES: FROM BENCH TO BEDSIDE TO POPULATIONS

Several case studies can help in illustrating the real-world challenges and successes in moving from research to practice. Of course, we learn from both successful translation of research to practice and also from failures.

Penicillin

Fleming discovered penicillin in 1928 (though others are attributed with noticing the effect of mold on bacteria in research laboratories). Use of penicillin was not implemented for more than 15 years, when an Australian Rhodes Scholar, Howard Florey, then in the Pathology Department at Oxford, evaluated penicillin in humans and with a team of scientists developed methods for mass production leading to widespread military use for infected soldiers.⁴⁰ Clearly the burden of infection reduced the military capability of the United Kingdom and allied forces in WWII, and increased the priority for effective antibiotics to be available. Only after the War did civilian use become available, first in Australia and then more broadly. The time delay from discovery to clinical application is typical of the lag we still see today. Of course, war has a long history for development of new methods in trauma surgery, arterial limbs, and other areas of clinical medicine, but our focus in this book is broader application of scientific advances. This example not only includes several steps from discovery to clinical application during WWII and then broader community level application for effective health care, but also exemplifies how delays happen and how innovation is motivated by exceptional circumstances (unfortunately, all too often war leads to major innovations in technology for destruction and for sustaining lives). Systems for large-scale production were not available and the market forces did not support commercialization until after WWII.

Insulin

Insulin offers another extreme example we do not see replicated today. Pancreas extract was evaluated in dogs in physiology laboratories in numerous medical centers in the early 1900s. After only 6 or so months of experimentation, Banting and Best moved from their physiology laboratory and animal studies in the Medical Building at the University of Toronto to the delivery to humans at Toronto General Hospital.⁴¹ The clinical condition favored rapid translation to practice, since patients routinely had a steady decline after onset of Type 1 or insulin-dependent diabetes, following standard therapies such as starvation and ultimately dying from metabolic imbalances.42 Rapid physiologic evidence of response to pancreatic extract in terms of blood sugar and urinary ketones led to demand for pancreas extract outstripping supply. Few medical discoveries have had such a huge effect that they move so quickly from bench to bedside and broader application in clinics across North America. In fact, the will of the patients and their providers outpaced the slower development of approaches to large-scale production. Eli Lilly had a major interest from even before the discovery of the extraction methods in Toronto,43 reinforcing the influence of market forces on implementation. More recent experience with HIV and the social forces brought to bear by AIDS activists, along with speeding of the drug approval process, and marketing show faster developments from identification of a new disease condition to effective treatment.44 This time line spans from detection of AIDS cases in California and New York in 1981, to the viral cause identified in 1984, AZT as the first drug for treating AIDS in 1987, a US national education campaign in 1988, and combination antiretroviral therapy that is highly effective against HIV in 1996. Like diabetes, the political will generated by a patient population garnered support for scientific advances at exceptional speed with clear success, making efforts in cancer and other chronic disease management pale in comparison. AIDS research and systems delivery leave open research questions such as optimal scaling up strategies to bring effective prevention and treatment to all.

Smallpox

Smallpox epidemics raged in Boston in 1690 and 1702; inoculation was a folk remedy that was shown to be effective but political leaders forbade the use of inoculation as it was thought to spread the disease rather than prevent it. The 1721 epidemic had a major controversy as Reverend Cotton Mather and the Boston physician William Douglass disagreed as to the utility of inoculation. The Boston physician argued that inoculation spread the disease, while Reverend Mather had inoculated his son and was a vaccine advocate. Church leaders also debated the value of this medical intervention-Mather arguing that inoculation was a gift from God, while those opposed to inoculation claimed the epidemic afflicted people for divine reasons, and so did not want to interfere with the will of God.45 Thus political will alone was not sufficient to implement a potentially major preventive strategy. Despite the development of the Jenner vaccine in 1796, it was not until 1966 that the World Health Organization (WHO) established a goal to interrupt smallpox transmission throughout the world within a decade.⁴⁶ Because of a worldwide campaign to eradicate smallpox, the last known smallpox cases were observed near the 1976 goal—a case in Somalia in October 1977 and two laboratory infections in England in 1978.⁴⁷ The WHO certified that smallpox was eradicated from the world in December 1979. The enormous global public health commitment to achieve this goal of eradication was achieved after more than 150 years of less cohesive public health activity.

These examples of translating discovery to widespread application in varying time frames demonstrate the enormous variation in implementation and some of the social and political factors that may facilitate implementing effective programs and practices. We must balance timely implementation with the caution that pervades the scientific process. Too rapid implementation of ineffective or even harmful technologies will have deleterious consequences for population health. Tempering such caution is evidence from public health, where use of lead in petroleum (gasoline) was opposed by Alice Hamilton as early as 1925 because of the expected adverse health effects, almost 50 years before the US EPA began to restrict the lead content of gasoline in 1975, and 70 years before lead was phased out of gasoline entirely. Tobacco smoking continues to show just how slow we can be to implement effective prevention strategies when commercial interests oppose development of cohesive political will to advance population health. The authors contend, and the chapters in this book illustrate, that stronger methods for D&I research can help reduce this gap and bring us population benefits.

WHAT IS DISSEMINATION AND IMPLEMENTATION RESEARCH AND WHY DOES IT MATTER?

Given these historical examples, how do we conceptualize D&I research and classify it in relation to other systems or types of research? Growing emphasis on the pace of advances in medical systems leads to a number of approaches to classifying the continuum from discovery to delivery and the improvement of the health of the population. Classification of the research continuum from bench to bedside and use of population health metrics is now post hoc and continues to evolve. Briefly, the language to describe these steps and procedures has evolved over the past decade (see chapter 2). Furthermore, the methods research to understand the limitations of research synthesis to gather information on effective interventions and inform next steps continues to provide caution in planning and evaluation of programs.^{20,21} The Institute of Medicine has defined implementation research as an important component of the framework for clinical research, and Zerhouni called for reengineering the clinical research enterprise, but we are more broadly focused including clinical research, health systems, and prevention.48 The NIH roadmap49 defines T1 as moving from basic science to clinical applications (translation to humans); T2 as clinical research (up to phase 3 trials) moving to broader clinical practice (translation to patients); and T3 as D&I research following development of guidelines for practice moving research into health practice through diffusion, dissemination, and delivery research (translation to practice) (Figure 1.2). T4 research has now been added to evaluate real-world outcomes from applying discoveries and bringing them to practice (translation to population). No doubt further subdivisions will be proposed in coming years. Public health approaches may broadly be defined as practice based (though health departments and social marketing strategies for health promotion may be beyond most people's vision for practice-based research).⁵⁰ Accordingly, our methods must be robust and adaptive to the situation that they are applied in. In fact, the development and acceptance of a wide range of scientific methods as necessary for D&I research, beyond the randomized controlled trial, have helped to move the field significantly forward. These methods will be critical as new forms of discovery science proliferate, as some are anticipating with precision medicine. Both the NIH Precision Medicine Initiative and the NCI's Cancer Moonshot Initiative are seeking to accelerate the pace and impact of genetic and genomic research on health. Chambers et al. note the importance of implementation science as a mechanism for ensuring that precision medicine advances become integrated into health care delivery, which will ultimately be critical if the significant investment in these efforts is to be realized.51

A number of proposed models for D&I research are discussed in multiple chapters in this book. Some are "source-based" (i.e., they view D&I from the lens of researchers pushing out science) (see, e.g., chapter 11). Others are community centered, focusing on bringing research



The current National Institutes of Health (NIH) Road map for Medical Research includes 2 major research laboratories (bench and bedside) and 2 translational steps (T1 and T2). Historically, moving new medical discoveries in to clinical practice (T2) has been haphazard, occurring largely through continuing medical education programs, pharmaceutical detailing, and guideline development. Proposed expansion of the NIH Roadmap (blue) includes an additional research laboratory (Practice-based Research) and translational step (T3) to improve incorporation of research discoveries in to day-to-day clinical care. The research roadmap is a continuum, with overlap between sites of research and translational steps. The figure includes examples of the types of research common in each research laboratory and translational step. This map is not exhaustive; other important types of research that might be included are community-based participatory research, public health research, and health policy analysis.

FIGURE 1.2 "Blue Highways" on the NIH Roadmap.

into practice settings. Systems approaches are also proposed to conceptualize the overall framework for D&I.52 Underlying these approaches, the body of scientific evidence must be sufficient to justify moving from individual studies to broader practice (i.e., an evidence-based practice). How this is determined, through systematic synthesis, subgroup analysis, or other approaches continues to be debated. However, to move forward with an intervention one needs a strong scientific evidence base; political will to allocate resources to achieve the goal of implementation; and a social strategy that defines a plan of action to achieve the health goals.53,54 As noted in examples earlier in the chapter, that lack of political will may hinder the uptake of effective public health interventions such as smallpox vaccination.

Scientific Evidence Base

In moving forward with D&I research, we can start with the first of these three dimensions: the scientific evidence base. Here we see confusion in the field over when we have a sufficient scientific evidence base ready for broader implementation.55 In chapter 18, Green and Nasser highlight how the emphasis on internal validity in our research enterprise drives us to restricted populations and narrowly defined interventions. Do these interventions work? Will they work in a different setting? Will results from trials hold up with further evaluation?²¹ The tension of priority on internal validity against external validity and the associated evidence to support broader applications of scientific findings continues within the scientific process.56 Much of the evidence synthesis "industry" focuses on narrowing evidence to specific finite questions. In medicine and public health, this began by meta-analysis even excluding nonrandomized trials from study.57 In an early application of research synthesis and metaanalysis to observational public health data, Berlin and Colditz evaluated quality of exposure measure and used regression methods to predict future health benefits from increases in physical activity.58 Can stronger use of existing approaches to prediction (e.g., metaregression and network meta-analysis) help us understand when interventions will work and how large a benefit we might ultimately see? What range of benefits will fit within the distribution of findings to date?

The scope of synthesis has broadened over time—from consensus and review articles⁵⁹ to rigorous panel (systematic review) methods such as those used by the US and Canadian Preventive Services ⁶⁰ and the CDC community guide. The GRADE system has been developed to more explicitly guide panel decision-making.⁶¹⁻⁶³ Despite these more formal approaches, a review of WHO Guidelines shows that they systematically omit guidance on active implementation strategies.⁶⁴

While reporting standards have focused on the internal validity of clinical trials and observational studies ⁶⁵ new approaches to make features of study design most relevant to effectiveness have been proposed (PRECIS and PRECIS-2).66,67 By making explicit a number of dimensions such as flexibility of the comparison condition and experimental intervention; practitioner expertise; eligibility criteria participant compliance, and so forth, approaches such as metaregression⁶⁸ may be implemented to draw on these contextual factors to better understand if results can be applied in different settings. Furthermore, regression can then be used to predict what level of benefit may be seen in future applications (as has been done in the meta-analysis of BCG vaccine for prevention of tuberculosis).69,70 While one often thinks of meta-analysis as driving for a common single answer to a clinical or public health problem, regression approaches and using meta-analysis to understand sources of heterogeneity highlight the many potentially untapped ways in which data can be synthesized to better inform policy and clinical decision making.⁷¹ Importantly, Implementation Science should study how to translate findings to be contextually relevantand while regression and synthesis offer traditional quantitative approaches, broader system and contextual measures are likely needed to fully capture translation to practice.⁷²

Bero has studied the delay in implementation of clinical practices—guidelines are typically published and sit on a bookshelf.¹⁴ Practice does not change. She reviews effectiveness for a range of approaches that are commonly used. Importantly, while the field of health care has moved substantially to accepting a role for research synthesis over the past quarter century, the study of how to implement the effective approaches to health and public health practice has been far less rigorous. Approaches to synthesis of strategies that work⁷³ could strengthen the field. In addition, Anderson and colleagues adapted some of the Bero factors as they apply to public health settings (Table 1.1).⁷⁴

As in any field, a thorough review of evidence may provide a summary of where the field

TABLE 1.1 FACTORS INFLUENCING DISSEMINATION AMONG HEALTH ADMINISTRATORS, POLICY MAKERS, AND THE GENERAL PUBLIC

Category	Influential Factor
Information	 Sound scientific basis, including knowledge of causality Source (e.g., professional organization, government, mass media, friends)
Clarity of contents	 Formatting and framing Perceived validity Perceived relevance Cost of intervention Strength of the message (i.e., vividness)
Perceived values, preferences, beliefs	 Role of the decision maker Economic background Previous education Personal experience or involvement Political affiliation Willingness to adopt innovations Willingness to accept uncertainty Willingness to accept risk Ethical aspect of the decision
Context	 Culture Politics Timing Media attention Financial, or political constraints

is or identify gaps that require further research.75 Reviewing evidence in service organizations, Greenhalgh and colleagues⁷⁶ provide a model for diffusion of innovations in health service organizations, summarize methodology for review of evidence in this setting, and identify gaps to focus research on. They argue that research on diffusion of innovations should be theory driven; process rather than package oriented; ecological; collaborative; multidisciplinary; detailed; and participatory. They distinguish among "letting it happen," "helping it happen," and "making it happen" as related to diffusion and dissemination. Letting or helping it happen relies on the providers or consumers to work out how to use the science, in contrast with "making it happen," which places accountability for implementation on teams of individuals who may coach, support, or guide the implementation. Minkler et al. describe the value

of participatory research in speeding implementation of research findings (see chapter 11).

Policy and Politics (Political Will)

The framework of Kingdon⁷⁷ is useful in illustrating the policy making process and its impact on D&I research. Kingdon argues that policies move forward when elements of three "streams" come together. The first of these is the definition of the problem (e.g., a high cancer rate, or synthesis of the scientific knowledge base). The second is the development of potential policies to solve that problem (e.g., identification of policy measures to achieve an effective cancer control strategy). Finally, there is the role of politics, political will, and public opinion (e.g., interest groups supporting or opposing the policy). Policy change occurs when a "window of opportunity" opens and the three streams push policy change through.

But how do we summarize the stream of evidence to improve support to get resources allocated for implementation research or knowledge translation? Does the form of the evidence summary interact with the rate of uptake by end users, including policy makers? Lack of consistent approaches may again hinder the allocation of resources to these activities. Academic debate about the appropriateness of data, study populations, and the like, distracts from cohesion and a decision to move forward. The US Preventive Services Task Force separates the level of evidence from the magnitude of expected benefit when synthesizing data. They use a hierarchy of study designs to classify the source of evidence. This approach was expanded by the Institute of Medicine in their reports on vaccines78 and health effects of Agent Orange⁷⁹ (see Mosteller and Colditz for descriptions).75 It was adapted to a range of epidemiologic evidence on causes of cancer to guide risk assessment and prevention strategies.⁸⁰ Brownson and colleagues add to these design levels considerations of the research base contextual variables that inform implementation and adoption: individual, interpersonal, organizational, sociocultural, and political and economic.81 Further research is needed to better understand the interplay of methods for research synthesis, presentation of summary data, and subsequent translation of research findings to policy and practice.

Prevention is lower on the priority list for public health funding at NIH and CDC than the discovery of new therapies, with emphasis on the research priority end of the Green pipeline and limited attention to practitioner needs and applications.82 In contrast with best communication practices that include promotion with repeat messages, CDC rewards new approaches to prevention rather than sustaining effective programs, as exemplified by the contrast between the Australian Sun Smart program running for decades⁸³ and the CDC continuing to fund "novel" approaches to prevention of excess sun exposure. Quantifying improvements in population health contrasts with disease-focused treatment programs where individuals can self-identify demanding services and measurable outcomes. This identifiable benefactor (patient) contrasts with the beneficiaries of public health who are largely unknown.82 Systems innovations to improve delivery of care equity and access to state of the art therapies all receive less support or are valued less by the population than services that are regarded as personal. The time frame for benefits of knowledge translation-D&I research-is in the future and runs counter to public policy and planning, conflicting with pressure to deliver services today.82 In contrast with disease (e.g., breast cancer) and exposure advocacy groups (e.g., those focusing on environmental contaminants; or unions and related occupational exposures), prevention does not have a voice from those who benefit. Despite the apparent priority of tobacco control efforts since the 1964 Surgeon General's report, we have only halved the rate of smoking in the United States. While this reduction in smoking may have prevented more cancer deaths than all adult cancer therapy advances over the same time frame; it leaves us with an enormous lack of accomplishment when the full burden of smoking is summed up. Where are all those who quit smoking or never started and are not suffering or dying prematurely from lung cancer and many other chronic diseases? A lack of voice leads to limited political will and lack of resource allocation to achieve the benefits of translating research to practice. Sometimes governments do step in and do the right thing—as illustrated by the significant progress in tobacco control during the Obama presidency.⁸⁴ Based on the significant foundation of evidence about the health impacts of tobacco and strategies for effective tobacco control, the Obama administration implemented Food and Drug Administration regulation of tobacco (Family Smoking Prevention and Control Act enacted by Congress and signed by President Obama in 2009), improved coverage of tobacco cessation services by health plans via the 2010 Affordable Care Act, funded the first national media campaign designed to highlight the real human costs of smoking, expanded Medicare coverage for older smokers and expanded Medicaid coverage for pregnant smokers, and provided protection from exposure to second-hand tobacco smoke in public housing.

Social Strategy

In launching the first health goals for the nation, Richmond defined social strategy in the context of health-guiding both the landmark Healthy People 1980 and the first nutrition guidelines for the United States.53 He proposed changes to promote health through health care providers, regulations, and community (individual and organizational changes). More recently, Koh and colleagues note the importance of integrating social determinants of health into Healthy People 2020.84 The Healthy People initiative has represented an ambitious yet achievable health promotion and disease prevention agenda for over three decades, but only recently has this effort fully embraced a comprehensive social determinants perspective. Healthy People 2020 includes a new overarching goal to "create social and physical environments that promote good health for all" by accepting shared social responsibility for change.

Now we may expand this concept to incorporate the D&I elements—the innovation; the communication channel; the time; and the social system.¹⁶ Proctor⁸⁵ proposes a model of Implementation research that defines the intervention (from the evidence base) and the implementation strategy (systems environment, organizational, group/learning, supervision, and individual providers/consumers) (Figure 1.3).

Here Proctor specifically defines the levels of change that an intervention is addressing: the larger system or environment, the organization, a group or team, or the individual. This is not unlike Richmond, who focused on policy level changes, provider level changes, and individual and community level changes to promote health.⁵³ One can ask, "Is there a parallel model for dissemination research addressing all these levels"?

WHAT IS MISSING— OUR SOCIAL CONTEXT FOR TRANSLATING RESEARCH INTO PRACTICE

To place the growing emphasis on D&I in the context of current funding, manpower needs,



FIGURE 1.3 Proctor conceptual model of implementation research.85

and academic environments, we summarize a number of opportunities. We note the recent publication of reporting standards for implementation studies (StaRI)⁸⁶ and expect that the adoption of these standards over the coming years will further improve the quality of D&I research. Furthermore, topics such as scaling up and deimplementation are gaining greater attention and are briefly introduced.

Funding—NIH, CDC, AHRQ, and Canadian Priorities

Growing emphasis through funding adds credibility to the area of research implementation and evaluation. RFAs from NIH, CDC, and AHRQ (Agency for Healthcare Research and Quality) attest to the growing commitment of resources in the United States. The Canadian Institutes of Health Research have also increased emphasis on funding of D&I, or knowledge translation. Priority for methods development and application is included in these funding opportunities, and for many institutions provides the building block on which junior faculty members are themselves promoted (holding grants in addition to scientific productivity are often key components of promotion criteria). Many health care organizations are also beginning to recognize the importance of implementing evidence-based practices, which creates opportunities for research partnerships that can help to speed translation.

Education and Training

The need to align D&I training with career stage and goals for workforce development has been reviewed for North America.⁸⁷ Challenges to training identified by this review included core competencies versus specialization,⁸⁸ the rapid pace of the developing field, and sustainability of training programs. Furthermore, for established schools of public health, identifying where this training fits in the methods and content areas covered across epidemiology, biostatistics, environmental health, health services research, and behavioral sciences remains challenging. Expanding shared resources of teaching materials and toolkits (see http://www.pcori.org/research-results/ research-dissemination-and-implementation/ dissemination-and-implementation) will help support these training endeavors. Several NIHfunded initiatives address skills development in specific areas of application including mental health implementation research;89 cancer prevention and control;88 and the training institute for D&I research in health, a collaboration with the Veterans Health Administration.⁹⁰

Academic Rewards

Priority has historically been placed on novel contributions to science-that is, discovery. Even at the Nobel Prize level of recognition, debate was substantial regarding the role of Florey in moving from discovery of penicillin to the refinement of methods for mass production. From the point of view of impact it was clearly the application of methods leading to broad use that saved lives during WWII, not the discovery years earlier that lay dormant in a journal article. So how do we change our academic reward system to acknowledge that application of knowledge or translation to practice is an essential component of effective and affordable health and welfare services? Accountability, given the high levels of government funding for research in the United States and many other countries, does not on its own shift the reward system. In fact, Moses and Martin

call for sweeping changes in the way we conduct research in academic medical centers and reward scientists to more efficiently translate research to practice.91 We need models that are implemented and evaluated within our major academic centers to show that the translation of science to practice is an academic discipline with methods and outcomes that can be evaluated like any other discipline. However if junior investigators do not have options for a career path in these disciplines, then again the growth of this area will be limited. As an example, academic primary care has supported leading researchers at Dartmouth and Case Western to develop strategies for increased use of evidence-based preventive services, testing subsequent widespread implementation⁹²⁻⁹⁵ and recognition at the level of membership in the Institute of Medicine in the National Academy. Broader recognition across health sciences disciplines will support methods development and applications to improve population health.

Innovation versus Replication (Delivery of Effective Programs)

Again, the criteria for funding of grants and the promotion of faculty often hinge on innovation and discovery. Moving a discovery from bench to clinical application or from one health department to a statewide intervention may not appear to be as innovative as a more focused basic science contribution. We might argue it is, however, far more complex and less likely to succeed! Can we refine metrics that will help us estimate lives saved or improvement in quality-adjusted life years to summarize the public health impact of D&I research? How should we quantify the contextual factors that moderate the effectiveness of implementation? As Titler asks,⁹⁶ can we become consistent in approaches to circumstances and setting in which implementation or translation to practice is effective, and define mechanisms for effective interventions?

Scaling Up

When we take evidence-based interventions to scale and deliver them to all population groups equitably, we achieve substantial population health benefits. A common and consistent definition of scaling up is not yet evident in the literature. Why aren't we studying large-scale implementation more routinely? How does scaling up differ from other implementation—if at all? Questions arise such as the strength of the evidence base—the ability to deliver the intervention at low cost, the approaches to monitoring consistency or integrity of the intervention delivery, and outcomes across levels of health system (provider or heath department) and individuals. Will additional technical assistance be needed for broader implementation? How is this developed, delivered, and sustained? How flexible can and must the intervention be?97 What are the measures of organizational success and of overall outcome? One design defined by Curran as effectivenessimplementation hybrid combines a dual focus on both clinical effectiveness and also implementation measures 98 This is described in detail for global mental health care, but could be a framework for other interventions that fall outside the responsive marketing and commercial sectors. How important is the original intervention design for delivery at scale? One guide for scaling up interventions sets out a step-by-step process.99

De-implementation

The need for research on de-implementation is highlighted in the PAR-16-238, which sees this as a means to move more quickly to effective and efficient delivery of evidence-based interventions. The PAR calls for "studies of the de-implementation of clinical and community practices that are not evidence-based, have been prematurely widely adopted, yield sub-optimal benefits for patients, or are harmful or wasteful." De-implementation is critically important because about 30% of all medical spending in the United States is unnecessary and doesn't add value. There has been a clinical focus on this over the last few years, largely as a result of the Choosing Wisely campaigns that targets reduction/elimination of low value care, but there has been relatively limited research emphasis in this area.

There are a wide range of terms that are used to describe de-implementation, including deadoption, exnovation, and de-innovation.100,101 Some authors use the term "misimplementation" to include both practices that are not evidencebased and should be stopped and practices that are evidence-based that should be implemented.¹⁰² Regardless of the terminology, it is important to understand that this area actually represents three different types of problems: De-implementation is basically 3 different problems: (1) ending harmful practices, such as eliminating use of harmful drugs; (2) reducing use of ineffective practices, or those that offer no benefit over less invasive practices; and (3) reducing use of one practice while increasing the use of another.

Niven, et al.¹⁰⁰ recently completed the first knowledge synthesis in the area of deimplementation. They concluded that most de-implementation that occurs is the result of scientific evidence, is focused on market withdrawal of harmful drugs, and results from active interventions. It is also noted that de-implementation studies are largely observational, and little systematic or rigorous work in this area has been conducted.

There are many critical questions to be answered related to de-implementation, including whether the processes are similar across the three different types of de-implementation problems, and whether different people are needed to effectively address these different problems. There is also a real need to consider how to sustain deimplementation over time, especially when considering interventions other than drugs that are not driven by the market or regulatory factors.

There is also a critical need to understand the factors responsible for rapid and unplanned de-implementation, such as reduced use of hormone replacement therapy in the United States. Developing nimble mechanisms to allow for the study of population-level de-implementation as it is occurring may be particularly useful. For example, ongoing changes in practice such as elimination of PAP smears in Australia's national cervical screening program, from January 2017, and replacement with 5-year HPV testing, offer opportunities to consider the perspectives, facilitators, and barriers to de-implementation from the patient, provider, testing laboratory, and insurance perspectives. De-implementation will likely not be the inverse of implementation and dissemination uptakes.¹⁰³ Further, there are likely very different social factors at work in the implementation versus de-implementation context. For example, women have been told for decades that they must have yearly mammograms, and may have many friends who had breast cancer detected via routine mammography. Asking them now to have fewer mammograms, or at older ages to stop completely, may test their confidence in their provider and the health care system, and go against deeply rooted beliefs about taking care of themselves. Where to begin to remove inefficient or unnecessary practices remains an area of study to begin this process, as does identifying the characteristics of the people who will lead or resist deimplementation and how they may differ from those who lead implementation.¹⁰⁴ For example, the Choosing Wisely campaign launched in 2012 in the United States aims to encourage abandoning care that wastes resources or delivers no benefit in specific health areas, such as management of blood sugar and diabetes, and cancer screening. The approach to studying de-implementation mechanisms examines variation among systems, providers, patients, and the actual implementation strategies that may modify the success of the program.¹⁰⁵

Systems to Quantify Benefits of Effective Programs (Outcomes)

How do we sum up the benefits of implementation and effective programs being delivered to broad sectors of the population? Ginexi and Hilton propose that focusing on evidence-based best practices may help bridge the gap from research to practice.¹⁰⁶ They argue that best and worst practice can inform practice improvement. How we quantify program fidelity and implementation remains at the core of the challenge. Proctor and colleagues⁸⁵ now propose a taxonomy of eight conceptually distinct implementation outcomes-acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability-along with their nominal definitions. Further, they propose using a two-pronged agenda for research on implementation outcomes. Conceptualizing and measuring implementation outcomes (or process evaluation measures in the European framework) will advance understanding of implementation processes, enhance efficiency in implementation research, and pave the way for studies of the comparative effectiveness of implementation strategies. As noted in this book, several novel approaches are proposed but coming to agreement on when these measures are most helpful will require further study.

New methods are needed, and consistency across programs will add to the overall advance of the field. The magnitude of benefit, the proportion of the population reached, and the degree to which a program is sustained all impact the long-term population benefit. Proctor defines steps in the model of implementation, noting that conceptualizing and measuring implementation outcomes will advance understanding of implementation processes, enhance efficiency in implementation research, and pave the way for studies of the comparative effectiveness of implementation strategies.⁸⁵ Refinement to better incorporate ethical, legal, and social considerations through stakeholder engagement will further advance this model. The RE-AIM approach to evaluation is also summarized in chapter 19. Other approaches that apply across settings will make for a more robust area of inquiry.

SUMMARY

Given the growing emphasis on D&I as a means to increase the efficiency of the research enterprise, public policy, and the services with which we work, refining methods that will facilitate translation and implementation are imperative. Cultural changes within the academy and in linking researchers and practitioners will be necessary adjuncts to effective progress. Bringing the D&I research community to common understanding of answers to our overarching questions will be a necessary step. Then we can more consistently answer the questions: How will we gather this information on effective interventions to form the evidence base? Will interventions be applicable to our setting? What methods should we use to decide what to disseminate or implement? Which strategies will give us the greatest impact on population health? What outcomes should be tracked to know if we are making progress? How long will it take to show progress, or when will it be observed? The methods outlined in this book will help us in answering these and other important questions.

SUGGESTED READINGS AND WEBSITES

Readings

Glasgow RE, Vinson C, Chambers D, Khoury MJ, Kaplan RM, Hunter C. National Institutes of Health approaches to dissemination and implementation science: current and future directions. *Am J Public Health*. 2012;102:1274–1281.

Addressing the gap between knowledge and practice, this paper reviews core values necessary to advance implementation science. These include rigor and relevance, efficiency, collaboration, improved collaboration, and cumulative knowledge.

Glasziou P, Chalmers I, Altman DG, et al. Taking healthcare interventions from trial to practice. *BMJ*. 2010;341:c3852.

Improved reporting of details of trials will enable use of results in practice. An example of this is illusrated and a call for increased reporting of intervention details to improve replication and use in practice.

Green LW, Ottoson JM, Garcia C, Hiatt RA. Diffusion theory and knowledge dissemination, utilization, and integration in public health. *Annu Rev Public Health.* 2009;30:151–174. Rigrous review of public health implications of diffusion, dissemination, and implementation to improve public health practice and guide design of future research.

Ioannidis JP, Karassa FB. The need to consider the wider agenda in systematic reviews and metaanalyses: breadth, timing, and depth of the evidence. *BMJ*. 2010;341:c4875.

Thoughtful critique of limitations of meta-analysis of clinical interventions, the narrow scope of practice they cover, and the potential to draw misleading conclusions from systemaitc reviews and meta-analysis.

Lobb R, Colditz G. Implementation science and its application to population health. *Ann Rev Public Health* 2013:34:235–253.

Thoughtful review of the role that stakeholder engagement and more rigorous study of barriers to implementation can help identify how systems can implement effective innovations in health care delivery.

Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health.* 2011;38(2):65–76.

Groundbreaking summary of issues in design and evaluation of implementation research, setting out a model that defines steps in the process and discusses a model for quantfying benefits of program implementation.

Woolf SH. The meaning of translational research and why it matters. *JAMA*. 2008;299(2):211–213.

An important contribution defining stages of research and the importance of translation from bench to bedside and from reseach clinic to population wide applications. Also calls for research funding to be directed to inproving population health outcomes.

Selected Websites and Tools

Cancer Control P.L.A.N.E.T. http://cancercontrolplanet.cancer.gov/index.html

Cancer Control P.L.A.N.E.T. acts as a portal to provide access to data and resources for designing, implementing, and evaluating evidence-based cancer control programs. The site provides five steps (with links) for developing a comprehensive cancer control plan or program.

Dissemination and Implementation Research Core at the Institute for Clinical and Translational Science, Washington University in St. Louis, Enola Proctor, Director. http://icts.wustl.edu/ictsresearchers/icts-cores/find-services/by-core-name/ dissemination-implementation-research-core

The Dissemination and Implementation Research Core (DIRC) provides methodological expertise to advance translational (T3 and T4) research to inform and move efficacious health practices from clinical knowledge into routine, real-world use. The DIRC works with scientists to move forward scientific agenda and grant writing related to dissemination and implementation (D&I) of health care discoveries. Furthermore, DIRC develops tools and methods for studying D&I.

Implementation Science exchange (IMPSCIX). https:// impsci.tracs.unc.edu/

A public service of the North Carolina Translational and Clinical Sciences Institute (NC TRACS). UNC Chapel Hill. This free online resource offers help to design, get funded, and execute implementation science research projects.

Task Force on Community Preventive Services. http:// www.thecommunityguide.org

The Community Guide provides a repository of the 200+ systematic reviews conducted by the Task Force, an independent, interdisciplinary group with staff support by the Centers for Disease Control and Prevention. Each review gives attention to the "applicability" of the conclusions beyond the study populations and settings in which the original studies were conducted.

Cochrane Collaboration. http://www.cochrane.org/ The Cochrane Collaboration prepares Cochrane Reviews and aims to update them regularly with the latest scientific evidence. Members of the organization (mostly volunteers) work together to assess evidence to help people make decisions about health care practices and policies. Some people read the health care literature to find reports of randomized controlled trials; others find such reports by searching electronic databases; others prepare and update Cochrane Reviews based on the evidence found in these trials; others work to improve the methods used in Cochrane Reviews; others provide a vitally important consumer perspective.

RE-AIM. http://www.RE-AIM.org

The acronym refers to Reach, Effectiveness, Adoption, Implementation, and Maintenance, all important dimensions in the consideration of D&I research and in the external validity or applicability of research results in original studies for the alternative settings and circumstances in which they might be applied. These were applied in the development of a set of guidelines for assessing and reporting external validity.

D-cubed. http://www.uq.edu.au/ evaluationstedi/Dissemination/?q=dissemination/

A review of dissemination strategies used by projects funded by the Australian Learning and Teaching Council) promotes dissemination strategies that have facilitated effective dissemination. A useful framework for dissemination and guide to use is provided.

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Terminology for Dissemination and Implementation Research

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INTRODUCTION

and Dissemination 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]).1-7 One challenging aspect of D&I research is the lack of standardized terminology.8-13As 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."14 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).¹⁵ 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.¹⁶⁻¹⁸ Some of the most important contributions originate from the nonhealth fields of agriculture, education, marketing, communication, and management.19 The primary health-related areas presently contributing to D&I research include health

services research, HIV prevention, school health, mental health, nursing, cancer control, violence prevention, and disability and rehabilitation.16,20-²⁴ 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.7,25-27 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.²⁷ A more recent review by McKibbon and colleagues identified 100 terms alone just to describe knowledge translation or KT research.28

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.²⁹ 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.

SECTION 1: DEFINITION, BACKGROUND, AND RATIONALE

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

TERMS AND THEIR ORGANIZATION			
SECTION 2: THEORIES AND APPROACHES			
Stage Models			
Theories and Frameworks			
Diffusion of innovations			
RE-AIM framework			
Consolidated Framework for Implementation Research			
Designing for Dissemination, Implementation and Sustainability			
Audience Segmentation			
Fidelity and Adaptation			
Fidelity			
Adaptation			
Core elements (components)			
Adaptome			
Strategies for D&I			
Dissemination strategy			
Implementation strategy			

TABLE 2.1 DISSEMINATION AND IMPLEMENTATION

TABLE 2.1 CONTINUED

Adoption	Factors Associated with the Speed and Extent of D&I
Sustainability/Sustainment	Characteristics of the intervention
<u>Maintenance</u>	<u>Relative advantage</u>
Institutionalization	Compatibility
Capacity building	<u>Acceptability</u>
Knowledge-for-Action terms	Appropriateness
Knowledge translation	<u>Feasibility</u>
Knowledge transfer	Implementation cost
Technology transfer	Characteristics of the adopters
Knowledge exchange	Opinion leaders
Knowledge integration	Change agent
Knowledge utilization	Context
Research utilization	Organizational culture
Knowledge brokering	Organizational climate
Knowledge broker	Readiness (organizational, practice, community)
Scale up and scaling up	
Evidence Synthesis Approaches	SECTION 3: DESIGN AND ANALYSIS
Scoping review	Study Designs
Realist review	Pragmatic or practical clinical trial
Types of Research	Natural experiment
Fundamental (or Basic) research	Plausibility design
Translational research	Sequential, Multiple Assignment, Randomized Trial
<u>T1 research</u>	(SMART) design
<u>Efficacy research</u>	Stepped-wedge design
T2 research	Hybrid designs
Effectiveness research	Systems thinking
Dissemination research	Rapid, responsive, relevant research
Implementation research	Learning health care systems
Mode I and II science	Learning evaluation
	Measurement considerations
Science-to-service gap	Mixed methods
Implementation gap	Outcome variables
Assimilation gap	Implementation outcomes
Population health intervention research	Pragmatic measures
Comparative Effectiveness Research to Accelerate	
Translation	External validity
Patient-centered outcomes research	Standards for Reporting Implementation Studies
Quality improvement	
Precision medicine	

settings, audiences, and approaches.^{20,37} For a more detailed discussion of complex interventions, refer to Hawe et al.³⁷

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.^{38–40}

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.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).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.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.^{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.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."^{34,47}

Type 2 Evidence

Type 2 evidence focuses on the relative impact of a specific intervention to address a particular outcome (e.g., heath 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."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.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.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 one." 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.⁴⁷

Processes for D&I Diffusion

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

Dissemination

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

Implementation

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

Mis-implementation

Mis-implementation involves one or both of two processes: the discontinuation of effective programs and the continuation of ineffective practices in the context of public health.⁵¹ Misimplementation is a broader term while deimplementation focuses on the discontinuation component of mis-implementation.

De-implementation

De-implementation is defined as stopping or abandoning practices that have not proved to be effective and are possibly harmful.⁵² In medicine, the term "over use" is sometimes used to identified 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.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.^{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).⁵⁴

The terminology and strategies for deimplementation are still evolving and include terms such as termination, replacement, reversal, de-adoption, decrease use, disinvesting, and discontinue use.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.⁵⁶

Adoption

Adoption is the decision of an organization or community to commit to and initiate an evidence-based intervention.^{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.⁵⁹ A number of models and instruments are available to conceptualize and measure sustainability.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 communityor 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.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.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.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.58,59,62 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).59,63,64 Niche saturation is also referred to as penetration in the literature, as described by Lewis and colleagues in chapter 14.65

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.^{59,63,66} Leeman and colleagues identified six strategies for capacity building: training, tools, technical assistance, assessment and feedback, peer networking, and incentives.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.⁶⁴

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.^{5,27,28,68} 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.wiki-spaces.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."⁵ 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.^{75–78} 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.^{75,76} 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.⁷⁶

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).^{75,79} 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."^{79(p. 67)}

A more detailed discussion of knowledge brokering and knowledge brokers is provided by Hargadon.⁷⁹

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."6,80,81 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.^{6,82} 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).7 Furthermore, some researchers suggest that scale up has a broader reach and scope than D&I and expands to national and international levels.⁸³ 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.⁸⁴

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.^{5,7}

Evidence Synthesis Approaches

In addition to more traditional evidence synthesis approaches of systematic reviews and metaanalysis, 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, realworld 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"(p. 194) and can be efficiently used to explore complex areas or areas that have not been reviewed before.85 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.86 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.87

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."^{89(p.} ^{S1,21)} 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 **mis-implementation** and **deimplementation** 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 realworld settings; and (4) T4 translational research involves outcomes assessment at the population

level and results in public health knowledge at the population level.^{97,98}

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.68,99 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.68 Mode II science is concerned with contextual factors such as organizational structure, geography, attitudes, economics, and ethics.68 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."100

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.^{84,101}

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.^{84,101}

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 sufficienly at the individual or organizational level.^{56,101,102}

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.¹⁰³ 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.25 Population health interventions include programs, policies, and resourcedsitribution 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.¹⁰³ 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.¹⁰⁴ PHIR considers both controlled and uncontrolled intervention designs and produces practice-relevant knowledge for real-world decision making.¹⁰⁴

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."⁸⁹ CER-T refers to CER that is concerned with producing results that will disseminate and translate into population-level change.¹⁰⁵

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."106(p. 1513) The key premise is that patients have a unique perspective on their condition and through acknowledging this special perspective, PCOR will lead to better quality and stakeholder relevant responses and approaches to disease prevention, diagnosis, and treatment.^{106,107} 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.108-110 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.111 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.¹¹² A proposal for the combination of QI and D&I science methods is described under **learning evaluation** in Section 3 of this chapter.¹¹³

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.114,115 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.¹¹⁴

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.^{17,19,116,117} Although different stage models vary in the number and name of the identified stages,17 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.118 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)¹⁹ and the stages of the RE-AIM framework (reach, adoption, implementation, maintenance).¹¹⁹ 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).¹²⁰

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.12,93 Tabak and colleagues identified 63 distinct D&I models through their review,121 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,19,118 theories of organizational change,122 Social Marketing theory,123 theories of communication,124 individual and organizational decision making,125 Community Organizing models,126 the RE-AIM framework,56 the Consolidated Framework for Implementation Research (CFIR),¹²⁷ the Precede-Proceed model,¹²⁸ the Interactive Systems Framework for D&I,129 and the Practical, Robust Implementation and Sustainability model (PRISM),¹³⁰ the Knowledgeto-Action (KTA) model,27 and the Promoting Action on Research Implementation in Health Services (PARiHS) framework.131,132

This chapter discusses one theory (Diffusion of Innovations), one framework (RE-AIM), and one metamodel (CFIR) that are commonly applied in D&I research in the field of health. More comprehensive discussion of diffusion and D&I theories is available in chapter 3 by Dearing and Kee.

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.¹⁹ 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.⁴³ Some of these key components are discussed later in this chapter.

RE-AIM Framework

The RE-AIM framework developed by Glasgow and colleagues^{56,91,133} 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.¹¹⁹ 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 Damschroder and colleagues to provide "an overarching typology to promote implementation theory development and verification about what works where and why across multiple contexts."^{127(p. 50} 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).¹²⁷ 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").134 Others talk about the need to considering target users' needs, assets, and timeframes.135 D4DIS builds on the premises that (1) effective dissemination of interventions requires an active, systematic, planned and controlled approach;³¹ (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;¹³⁶ (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;¹³⁴ (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;¹³⁴ and (5) study designs and measures that generate practicerelevant evidence facilitate and inform later stage D&I and sustainability efforts.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&I models, identification of appropriate delivery methods) and **products** (e.g., identify appropriate message, develop user friendly summaries).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.¹³⁴ A more detailed discussion about marketing approaches for D&I 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&I 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.^{17,57} 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.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.³⁷ A more comprehensive discussion of fidelity measurement of complex interventions is found in Hawe et al.³⁷

Adaptation

For the success of D&I, interventions in most cases need to be adapted to fit the local context (i.e., needs and realities).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.19 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).^{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.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.¹⁴⁰ For a more comprehensive discussion of fidelity and adaptation see chapters 16 and 17 and a number of seminal papers on the topic.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.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