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The Promise and Challenges of Dissemination and Implementation Research

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“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 Leshner

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. 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. 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. 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.”

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. 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). 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). 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. 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.” These definitions are similar to that of Lomas but contrast to some extent with the approach of Curry, 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. 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. 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.” 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. 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. Other authors address specific questions in translation from clinical trials to policy and practice. 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\textsuperscript{22,23}—that is, the direct and immediate application of effective intervention strategies to benefit the public’s health.\textsuperscript{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.\textsuperscript{25} Across all funding sources through 2011—federal and foundations—spending on health services research, models of care, and service innovations, represented only 1/20th of biomedical research funding.\textsuperscript{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.\textsuperscript{3} 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.\textsuperscript{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.”\textsuperscript{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.\textsuperscript{27} This publication record follows funding priorities. Moreover, one-third of public health researchers themselves rate their dissemination efforts as poor.\textsuperscript{28} In a cross-sectional 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 dissemination (See NIH PAR-16-238) or reduction of the use of strategies and interventions that are not evidence based.\textsuperscript{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 approaches\textsuperscript{29}), D&I research also grew from agriculture to guide thinking across many fields.\textsuperscript{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 users—and 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.\textsuperscript{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. 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. 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. The leakage or loss of medical-clinical 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).

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. Likewise the lag from
original discovery to formal recognition with Nobel prizes grows exponentially. 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. 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. 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. 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, 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. 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. Thus political will alone was not sufficient to implement a potentially major preventive strategy. Despite the development of the Jenner vaccine in 1796, it wasn’t until 1966 that the World Health Organization (WHO) established a goal to interrupt smallpox transmission throughout the world within a decade. 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. 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.
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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. 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. The NIH roadmap 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). 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.

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

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FIGURE 1.2 "Blue Highways" on the NIH Roadmap.

The current National Institutes of Health (NIH) Roadmap 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 into daily practice. 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.
into practice settings. Systems approaches are also proposed to conceptualize the overall framework for D&I. 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. 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. 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? 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. 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. In an early application of research synthesis and meta-analysis 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. 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 articles to rigorous panel (systematic review) methods such as those used by the US and Canadian Preventive Services and the CDC community guide. The GRADE system has been developed to more explicitly guide panel decision-making. Despite these more formal approaches, a review of WHO Guidelines shows that they systematically omit guidance on active implementation strategies.

While reporting standards have focused on the internal validity of clinical trials and observational studies new approaches to make features of study design most relevant to effectiveness have been proposed (PRECIS and PRECIS-2). 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 metaregression 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). 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. Importantly, Implementation Science should study how to translate findings to be contextually relevant—and while regression and synthesis offer traditional quantitative approaches, broader system and contextual measures are likely needed to fully capture translation to practice.

Bero has studied the delay in implementation of clinical practices—guidelines are typically published and sit on a bookshelf. 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 work 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). As in any field, a thorough review of evidence may provide a summary of where the field
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Reviewing evidence in service organizations, Greenhalgh and colleagues 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 Kingdon 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 vaccines and health effects of Agent Orange (see Mosteller and Colditz for descriptions). It was adapted to a range of epidemiologic evidence on causes of cancer to guide risk assessment and prevention strategies. 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. 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

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limited attention to practitioner needs and applications. 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 decades 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. 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. 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. 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. 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. 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. Proctor 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. 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,
and academic environments, we summarize a number of opportunities. We note the recent publication of reporting standards for implementation studies (StaRI)\(^8\) 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 de-implementation 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.\(^7\) Challenges to training identified by this review included core competencies versus specialization,\(^\) 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 NIH-funded initiatives address skills development in specific areas of application including mental health implementation research;\(^9\) cancer prevention and control;\(^\) and the training institute for D&I research in health, a collaboration with the Veterans Health Administration.\(^\)  

**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

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**Figure 1.3** Proctor conceptual model of implementation research.
call for sweeping changes in the way we conduct research in academic medical centers and reward scientists to more efficiently translate research to practice.\textsuperscript{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 implementation\textsuperscript{92-95} 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.

\textbf{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,\textsuperscript{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?

\textbf{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 health 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?\textsuperscript{97} What are the measures of organizational success and of overall outcome? One design defined by Curran as effectiveness-implementation hybrid combines a dual focus on both clinical effectiveness and also implementation measures.\textsuperscript{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.\textsuperscript{99}

\textbf{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 de-adoption, exnovation, and de-innovation.\textsuperscript{100,101} Some authors use the term “misimplementation” to include both practices that are not evidence-based and should be stopped and practices that are evidence-based that should be implemented.\textsuperscript{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. recently completed the first knowledge synthesis in the area of de-implementation. 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 de-implementation 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. 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 healthcare 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 de-implementation and how they may differ from those who lead implementation. 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.

**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. 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 colleagues 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. 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 will when it be observed? The methods outlined in this book will help us in answering these and other important questions.

SUGGESTED READINGS AND WEBSITES
Readings
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.
Improved reporting of details of trials will enable use of results in practice. An example of this is illustrated and a call for increased reporting of intervention details to improve replication and use in practice.
Rigorous 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 meta-analyses: 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 systematic reviews and meta-analysis.
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.
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 quantifying benefits of program implementation.
An important contribution defining stages of research and the importance of translation from bench to bedside and from research clinic to population wide applications. Also calls for research funding to be directed to improving population health outcomes.

Selected Websites and Tools
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/icts-researchers/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
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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.
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.
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 in reference 29 following.
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.

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


DISSEMINATION AND IMPLEMENTATION RESEARCH IN HEALTH


