19 Implementation Science in Health Care

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■ INTRODUCTION

Among the many domains and sectors studied by implementation researchers during the past 30–40 years, the variety of settings and volume of implementation science activity in the domain of health care are arguably among the richest and most diverse. Health care implementation science has contributed valuable theory and empirical evidence and has advanced efforts to identify and address important conceptual and methodological challenges in implementation research. Implementation research in health care has also helped stimulate increased policy and practice interest and has facilitated the field's continuing transformation into a coherent, integrated body of research encompassing multiple disciplines and domains. Yet implementation science in health care continues to confront the full range of challenges facing the field more broadly, including lack of consensus and underdevelopment of concepts and terminology; shortcomings in the availability and application of relevant theory; debates over appropriate research approaches, designs, and methods; and gaps in research attention to key phenomena. This chapter briefly reviews key stages in the evolution and development of implementation science in health care, describes the range of settings and effective practices of interest to implementation researchers—and the implementation strategies and programs developed to facilitate improvements in health care processes and outcomes—and examines key challenges and future directions in the field. A case study of an integrated program of implementation research in schizophrenia illustrates many of the ideas discussed in the chapter.

■ EVIDENCE BASE AND THEORY

The field of implementation science in health care comprises a broad range of studies and literature, much of which developed through separate streams of activity and has only recently begun to coalesce into a more unified whole. Early implementation research within the field of health services research during the 1970s, 1980s, and continuing into the 1990s studied strategies for "changing physician behavior"[1,2] and was conducted primarily by physician researchers and a smaller group of social and behavioral scientists. Driven largely by concerns over excessive resource utilization and costs (e.g., duplicative or nonindicated diagnostic testing), this research assumed that individual physician decisions were the primary driver of most clinical practices and health care resource utilization, and that effective strategies for

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changing physician behavior were key to improving adherence to recommended practices and thus to improving quality and efficiency.

Much of the early research in this period examined the effectiveness of information dissemination and conventional educational strategies such as continuing medical education,[3] based on the implicit assumption that physicians' clinical practices are driven primarily by information, knowledge, and education.[4] Other strategies studied during this period included financial incentives[1] and manual (chart-based) and reminder systems[5,6] intended to incentivize and prompt physicians to follow recommended practices and apply the knowledge they obtained via education and information dissemination strategies. Accumulating evidence showing the lack of effectiveness of these methods helped stimulate a series of articles (beginning in the late 1980s and 1990s) discussing the limitations of passive information dissemination and education and examining the role of professional norms and related factors in influencing physician practices,[7,8] particularly in light of the high levels of uncertainty inherent in clinical decision making.[9] These insights led to the development and testing of strategies such as opinion leader methods,[10] academic detailing,[11] and others based on principles of social influence rather than models of rational, analytical decision making.[12] Positive results from many of these studies, in contrast to the largely negative findings of studies evaluating educational strategies, prompted increased interest and continued research on social influence approaches.[13,14]

In addition to concerns over cost and resource utilization (e.g., excessive test ordering), studies evaluating strategies for changing physician practices were also driven by research documenting significant geographic variations in health care practices and outcomes and a related body of research conceptualizing and measuring the quality of health care. Early research documenting variations in care across health care delivery settings and geographic regions[15] led to further studies producing evidence that many variations reflected inappropriate use of specific medical procedures and services.[16] Research to define and measure "quality of care" began in the 1960s and accelerated in the 1970s and 1980s,[17,18] producing specific measures of quality, such as hospital mortality rates,[19] and the accumulation of additional evidence demonstrating gaps and deficiencies in health care quality and outcomes, including widely cited reports from the Institute of Medicine and other groups in the United States and abroad.[20,21,22,23]

Interest in the development of strategies for addressing quality problems was also strengthened by the introduction of appropriateness criteria,[24] clinical practice guidelines[25,26] and "practice parameters,"[27] and other tools and approaches associated with the emerging field of evidence-based medicine.[28] These tools summarized applicable clinical evidence supplemented by expert consensus to specify the desired clinical practices that proponents of improved clinical practice strove to achieve. They offered detailed clinical recommendations and decision aids that could serve as the focus of behavior change and quality improvement strategies, and provided specific benchmarks for measuring health care quality and progress in its improvement. A significant share of implementation research in health care continues to focus on guideline implementation[29,30,31] targeting guidelines compiled in repositories such as the National Guidelines Clearinghouse and the International Guidelines Database maintained by the Guidelines International Network, as well as

implementation of specific evidence-based programs and practices and evidence syntheses produced by entities such as Cochrane Collaboration review groups, AHRQ Evidence-based Practice Centers, and the UK University of York Center for Reviews and Dissemination. Recent interest in comparative effectiveness research (CER) and the establishment of the Patient-Centered Outcomes Research Institute (PCORI) in the United States will generate additional clinical evidence and evidence-based guidance for health care practice, prompting additional implementation research to guide CER implementation efforts.[32,33] Priorities for CER and support by PCORI are also expected to stimulate expanded research activity in implementation science: the 100 priorities for CER developed by a U.S. Institute of Medicine committee convened to offer guidance for U.S. CER efforts lists numerous implementation-related priorities and highlights the importance of implementation and the need for better guidance and evidence regarding implementation strategies and processes.[34]

Concurrent with the growth of interest in health care quality and evidence-based medicine, the prevailing emphasis on individual clinician practices during the early decades of implementation science in health care was replaced by a focus on the role of organizational structures and policies ("systems") in the 1980s and 1990s, with an accompanying transition away from efforts to change individual physician behavior and toward strategies such as "continuous quality improvement" and "total quality management" employed in the manufacturing and service sectors in the United States and abroad.[35,36] This trend led to replacement of the label "changing physician practices" with the term "quality improvement research" to describe activity now labeled "implementation research." This period also witnessed a significant increase in the volume of policy, practice, and research activity in health care quality improvement and significant growth in quality improvement research funding (e.g., following establishment of the Agency for Health Care Policy and Research in 1989, later renamed the Agency for Healthcare Research and Quality). Several new journals were established in this period as well, including the *American Journal of Medical Quality*, 1986; *International Journal for Quality in Health Care*, 1989; and *Quality in Health Care*, 2000, subsequently retitled *Quality and Safety in Health Care* and later *BMJ Quality and Safety*.

The development and application of theories and conceptual frameworks guiding implementation strategies, and the use of specific techniques for changing behavior, evolved together with changes in emphasis from individual clinicians to organizations. Theories of individual decision making and behavior change were augmented by theories drawn from management research and by conceptual frameworks linked to the dominant quality improvement techniques such as continuous quality improvement and total quality management. Although key theories from the fields of management research and organizational behavior have been harnessed to design and study implementation strategies and processes,[37–42] the volume of activity to catalogue and explore the role and application of organizational theories in implementation lags that devoted to psychological theories,[43–45] which continue to dominate published implementation science literature in health care. Rogers's Diffusion of Innovations theory[46] and extended versions[47] have featured prominently in implementation studies throughout the history of the field, but additional theoretical frameworks have become increasingly prevalent, including

the PARiHS framework[48], as well as broader planning and conceptual frameworks such as PRECEDE-PROCEED[49] and RE-AIM.[50]

The streams of research activity discussed above represent only a portion of the overall body of activity comprising implementation science in health care. Developing largely in parallel with the quality improvement–oriented work in the domain of health care implementation research, additional bodies of implementation research activity in health were underway within related fields such as nursing research, health psychology, and health promotion research, as well as research on substance use disorders, patient safety, health equity and disparities, and others. This research continues to proceed under labels such as "research utilization" (most commonly within nursing research[51,52]), "technology transfer" (substance use disorders research[53]), "operations research"[54] (research in global health and improvement of health systems), and others.[55] Overlapping bodies of research captured by the labels "dissemination and implementation research in health" in the United States, "knowledge translation" (largely in Canada), and related labels in Europe and elsewhere embody theories, research approaches, and empirical studies closely related to work labeled "quality improvement research in health." In the United States, the label "quality improvement research" tends to be more common in studies funded by the Agency for Healthcare Research and Quality and by key foundations supporting quality improvement and patient safety work (e.g., Robert Wood Johnson Foundation, Commonwealth Fund), whereas "dissemination and implementation research" is more commonly seen in studies supported by the National Institutes of Health. The latter body of studies often differs in some respects from quality improvement studies, in their focus on implementation of research evidence and evidence-based practices to overcome the "translational roadblocks" identified by the Institute of Medicine Clinical Research Roundtable[56,57] and serving as a key motivation for the development of the NIH Roadmap Initiative,[58,59] the NIH Clinical and Translational Science Award program, and related initiatives. Despite minor differences in stated policy and practice foundations and goals (e.g., an emphasis on improving quality and reducing quality gaps vs. an emphasis on increasing adoption of research- and evidence-based practices and innovations), each of these subfields of implementation science in health encompasses common theories, research approaches, and methods and pursues common research aims, questions, and hypotheses.

■ DESIGNING DISSEMINATION AND IMPLEMENTATION PROGRAMS AND STRATEGIES

Guidance in selecting and designing implementation strategies in health care is available from a variety of sources. Early work in the field employed an approach representing a form of "empirical treatment" in which single-component, narrowly focused physician behavior change or quality improvement strategies found to be effective in changing clinical practices in earlier studies were selected for use in subsequent studies despite differences between the clinical and quality problems, settings, and other features of the earlier versus subsequent studies. This approach was based on an implicit assumption that specific behavior change strategies were

inherently and broadly effective or ineffective, independent of the implementation problem to be addressed or the features of the setting or other factors. This "magic bullet" approach was eventually replaced by recognition that implementation strategies must be selected on the basis of (1) identified causes of quality and implementation gaps and (2) an assessment of barriers and facilitators to practice change, as well as (3) guided by appropriate behavior change theory and conceptual models and (4) sensitive to features of the context and settings in which the implementation effort will occur. Furthermore, because most implementation or quality gaps have multiple causes and involve multiple barriers to change, implementation programs must generally include multiple components, each designed to address one or more identified causes of poor quality or barriers to adoption of recommended practices, and each guided by relevant theory from the social and behavioral sciences. Recognition and responses to these challenges were gradual, however, with an early transition away from single-component to multicomponent implementation approaches, but only a more gradual recognition of the need for the multicomponent approaches to be guided by theory, careful diagnosis, and identification of the underlying causes of quality and implementation gaps and selected to match specific features of the target settings.

The field's evolution from single-component studies to multicomponent approaches to theory-based and problem-based approaches was relatively slow in part because early studies found multicomponent approaches to be superior to single-component strategies even in the absence of careful selection and matching of components to barriers. In many cases this might have been caused by the simple fact that a multicomponent approach is more likely to successfully address one or more key barriers merely because including more components increases the odds of a fortuitous match to key barriers. Subsequent findings suggesting that multicomponent approaches were not always superior to single-component approaches helped trigger recognition that individual components must be carefully selected. Although only limited evidence is available regarding the benefits of tailoring[60] and directly comparing a randomly selected package of implementation strategies to a package consisting of components explicitly selected to match identified barriers to change, the argument that intentional design of an implementation program based on a thorough diagnosis of observed quality or implementation gaps has considerable face validity and is a feature of key frameworks and published guidance for implementation in health care.[61,62] Increased use of behavioral and social science theory[63–65] and formative and process evaluation in evaluations of implementation programs[66] supports improved selection, application, and tailoring of implementation strategies to underlying implementation gaps and settings.

Researchers and practice leaders interested in selecting and combining individual implementation methods have only limited guidance. The Cochrane Collaboration Effective Practice and Organization of Care (EPOC) review group[67] has published approximately 70 systematic reviews (as of November 2010) of implementation strategies in health care, including strategies incorporating financial incentives, educational programs, organizational policy and structure changes, and others. The EPOC collection includes systematic reviews focused on specific single-component implementation strategies and reviews examining strategies studied in reference

to a specific type of implementation program or care setting. In the United States, the federal Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center program[68] has published several systematic reviews of implementation strategies under the topic "Quality Improvement and Patient Safety," including a multivolume series entitled "Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies." The range of potential strategies and multicomponent (multistrategy) implementation programs (packages of strategies) is limitless, however, and continues to grow as research continues. A useful tool for selecting individual strategies and planning a multicomponent implementation program is the Cochrane EPOC review group's typology of practice change interventions,[69] adapted from a typology employed in a published systematic review.[70]

■ BARRIERS TO DISSEMINATION AND IMPLEMENTATION

Recognition of the importance of identifying and overcoming barriers to implementation in health care is well established: many of the key frameworks for planning and conducting implementation research in health care include specific research phases and activities in which barriers are explicitly assessed and analyzed,[61] and several empirical studies have documented and classified barriers to implementation (e.g., Cabana et al. 1999).[71] Although specific barriers vary across the range of health care delivery settings (e.g., small physician practices, hospitals), most result from a common set of fundamental characteristics of health care, including (1) high levels of uncertainty in diagnostic and treatment decision making and in identifying causal links between treatment activities and outcomes, (2) the resulting dominance of professionals and professional norms and culture in health care delivery, and (3) the diverse range of constraints and influences on health care practices.

Professionals and Professional Norms

The central role of professionals in health care delivery and the implications of professionalism for practice change were recognized at an early point in the development of the field. For implementation efforts targeting individual, autonomous clinicians (e.g., physicians in solo and small practices and working in community hospitals under traditional fee-for-service reimbursement), effective implementation requires changes in professional norms in addition to changes in individual clinicians' knowledge and beliefs, economic incentives, and other factors. Professional norms are typically highly stable and not easily influenced by outsiders. Physician resistance to improvement efforts led by insurers and other outside stakeholders is high: clinical practice guidelines developed by physicians' peers and professional communities (e.g., medical societies) are seen as more credible than those developed by government bodies or insurance companies.[72,73] Traditional norms of professionalism favor individual professional judgment and patient-by-patient decisions over standardized, codified policies and procedures, leading physicians to rely more heavily on their own individual judgment rather than clinical practice guidelines, evidence-based practices documented in systematic reviews, and other

summaries of research and guidance. This led to early organized resistance to clinical practice guidelines by the American Medical Association, which employed the label "practice parameters" rather than "clinical practice guidelines" to convey the belief that guidelines should offer a voluntary, advisory set of parameters for use in clinical decisions rather than a more explicit form of guidance. Although more accepted now than during the 1990s, guidelines and other tools of evidence-based medicine continue to face strong resistance among many physicians and other health care professionals.

Professionalism and professional autonomy represent significant barriers to implementation in large, organized delivery systems as well as individual settings. Conventional approaches to management employed in traditional complex organizations, in which authority increases in relation to higher positions in a traditional, pyramid-shaped organization, are not applicable in health care delivery organizations (and other "professional bureaucracies"[74]) in which frontline workers at the bottom of traditional organizational pyramids are highly educated, professional clinicians whose decisions and practices are more heavily influenced by outside professional communities and peers rather than organizational rules and policies. Although quality improvement strategies such as continuous quality improvement have been adapted successfully to accommodate the unique hierarchical features of health care organizations, the dominance of external professional norms over internal organizational policies remains a significant barrier to implementation efforts within organizations.

Uncertainty

The importance of professional autonomy and individual judgment in professionals' clinical decision making and practices is reinforced by high levels of uncertainty in health care delivery and in cause–effect relationships.[6] High levels of variability in treatment outcomes, combined with the effects of psychological processes such as belief perseverance,[75] contribute to clinical inertia[76] and to considerable stability and resistance to change in clinicians' beliefs regarding clinical practices. Conservatism and resistance to change are reinforced by the prevalence of contradictory findings from clinical research:[77,78] clinicians trained prior to the era of meta-analyses and systematic reviews appropriately downgrade the weight of individual studies, and thus published guidance, and approach clinical practice guidelines and other forms of published guidance with the same inherent skepticism.

Multilevel Influences

Another significant source of challenges to implementation in health care is the multilevel nature of influences and constraints on health care practices. Several authors[79–81] have noted that health care practices are influenced by a broad range of factors operating at the level of the individual patient and patient–clinician dyad; at the level of clinical microsystems, clinics and larger organizations; within professional communities and regions; and at the national policy level. Individual implementation efforts typically involve behavior change strategies aimed at one or two levels (e.g., patients and clinicians); implementation researchers, clinical

leaders, and others attempting to change clinical practices lack sufficient leverage and authority to influence the full range of factors constraining and influencing the target practices. Although the need for multilevel, coordinated approaches to implementation is increasingly recognized and has led to innovative programs such as the Robert Wood Johnson Foundation "Aligning Forces for Quality" initiative,[82] it remains a fundamental challenge and barrier to success.

■ QUALITY IMPROVEMENT CASE STUDY

Frameworks guiding the design and conduct of implementation studies and portfolios of implementation research[61] and texts offering broad overviews of implementation science in health[83,84] describe a series of desirable research activities and study features important for achieving success in identifying, diagnosing, and closing quality and implementation gaps. Table 19–1 summarizes much of this guidance by listing important research activities and selected features of these activities.

Many of the key features of implementation research in health care are illustrated by a rich program of implementation studies targeting quality improvement for schizophrenia. Conducted by Alexander Young and colleagues based at the VA Greater Los Angeles Healthcare System and UCLA, this research encompasses a series of studies documenting and diagnosing gaps in quality and outcomes, and evaluating specific strategies for closing these gaps through implementation of evidence-based practices and other innovations in care delivery.

The origins of this research program include studies documenting significant gaps in the quality of health care received by patients with schizophrenia.[85–87] This evidence, including more recent updated data on quality, implementation, and equity gaps,[88,89] has stimulated and guided a program of research to develop and evaluate quality improvement strategies to improve care, guided by a careful assessment of the key research needs and challenges and a roadmap specifying the research activities to be conducted.[90]

Consistent with frameworks for preimplementation and implementation studies, Young et al. supplemented initial research to identify and quantify quality gaps with studies examining the determinants, and thus potential causes, of these gaps[87] and research to assess key stakeholders' views and recommendations regarding potential approaches for closing these gaps.[91,92] Additional preimplementation and methods development research included studies developing and assessing the validity of key measures of implementation program impacts such as quality of care,[93] clinician competencies,[94] and additional tools, methods, and measures required for implementation studies.[95]

A series of interventional implementation studies launched by Young and colleagues illustrates many of the desirable features of such studies, including extensive formative and process evaluation to examine implementation barriers, facilitators, and processes and thus to supplement and explain analyses of implementation program effectiveness. The research portfolio has included studies examining individual elements of a multicomponent approach to implementation, such as a computerized decision support system,[96] a consumer-led strategy targeting clinicians,[97] and a family targeted intervention.[98] Additional studies (EQUIP-1, EQUIP-2) are evaluating

TABLE 19–1. *Key Features of a Comprehensive Implementation Research Portfolio and Features of Individual Studies*

Research Activity	Desirable Features and Comments
Preimplementation Studies	
Clinical effectiveness research to develop evidence-based, innovative practices	Research design, methods, sampling, and other features should maximize external validity and policy/practice relevance to increase acceptability to target clinicians and leaders.
Development of evidence-based clinical practice guidelines	Guideline development processes should follow published recommendations for appropriate use of evidence, involvement of key stakeholder groups, sponsorship, etc.[72,73]
Development of other innovations	Innovation characteristics should facilitate adoption, incorporating features identified by research on the diffusion of innovations.[47]
Development of methods and measures for implementation studies	Important research tools include validated, casemix-adjusted measures of implementation outcomes (adherence, adoption) and appropriate data sources; study designs for quantitative impact evaluation with adequate external validity; and research approaches and methods for process evaluation.
Documentation of current practices and their determinants	Observational studies to understand current clinical practices and their influences incorporating quantitative and qualitative methods
Measurement and diagnosis of quality or implementation gaps	Observational studies to compare current practices to desired practices and to identify determinants or "root causes" of quality and implementation gaps
Observational Implementation Studies	
Studies of naturally occurring (policy- and practice-led) implementation processes	Observational studies maximize external validity, avoid artificial elements of researcher-led implementation trials, and offer opportunities to develop insights into barriers, facilitators, and key influences on routine implementation processes and success. Strong research designs are needed to achieve adequate internal validity.
Interventional Implementation Studies	
Phase 1 pilot studies of implementation programs	Pilot studies offer opportunities to develop initial evidence regarding the feasibility, acceptability, and potential effectiveness of implementation strategies and to begin to identify key contextual influences and other factors influencing effectiveness. Emphasis on formative evaluation to modify the implementation program based on frequent measurement of impact and operation.
Phase 2 efficacy-oriented, small-scale trials of implementation programs	Trials of implementation programs under idealized (efficacy-oriented) conditions, such as active research team facilitation and support for participating sites and grant funding for added costs, are designed to assess implementation program effectiveness under best-case conditions. Phase 2 studies feature initial formative evaluation to refine implementation programs followed by emphasis on fidelity (with site-level adaptation guided by a predeveloped adaptation protocol).
Phase 3 effectiveness-oriented, large trials of implementation programs	Larger trials of implementation programs under routine conditions (e.g., limited or no research team technical assistance or grant support to participating sites) are designed to assess implementation program effectiveness when deployed under real-world conditions. Phase 3 studies feature site-level adaptation guided by a predeveloped adaptation protocol, and measurement of sustainability, scale-up/spread potential, costs and cost effectiveness, and a broad range of outcomes (implementation outcomes and, where feasible, system-level as well as clinical and patient outcomes , e.g., clinical, functional, quality of life, etc.).
Phase 4 "postmarketing" study of implementation programs	Research-led monitoring and evaluation of policy/practice-led scale-up and spread of an effective implementation program. Phase 4 studies generate feedback to policy/practice leaders to guide their management of an implementation and spread effort.

multicomponent, multilevel implementation programs building on the prior studies of individual components.[99,100] This sequence illustrates the progression from small-scale to larger implementation trials, as well as the value and use of extensive formative and process evaluation and other key features of implementation research portfolios and studies.

■ RESEARCH GAPS AND DIRECTIONS FOR FUTURE RESEARCH

Recent growth in funding, interest, and activity in health care implementation research offers considerable promise for progress in addressing the field's key challenges. Increased attention from researchers trained in a broader range of disciplines and employing a broader range of research approaches and methods will help enrich the methodological toolkit, the range of theoretical perspectives, and the breadth of research epistemologies applied to the field's key questions, while simultaneously helping to increase the volume of empirical evidence and insights and the range of implementation problems and settings studied.

Future activity in the field is likely to help address several identified gaps and advance a number of key debates regarding the future of the field and the need for new ideas and approaches.[101] Important gaps include (1) the limited amount of research attention to barriers and strategies for achieving sustainability and routine scale-up and spread of effective practices following their initial adoption; (2) the need for increased research examining naturally occurring implementation processes (vs. investigator-led implementation); and (3) greater attention to implementation processes and mechanisms via process evaluation and theory-based evaluation, to complement and help understand and interpret the results of impact-oriented research. Key challenges to progress in addressing these research gaps include ongoing debates regarding the role of theory in implementation science and the need for research to inventory, classify, and guide the selection and effective use of theory; debates regarding research approaches and the nature of evidence required to better understand implementation processes and the effectiveness of alternative implementation strategies and programs; and the need for improved methods for observational research on implementation.

Sustainability, Scale-up, and Spread

Interest in barriers and facilitators to sustainability and scale-up and spread has increased recently, based on recognition that successful implementation of effective practices through short-term, research-led efforts targeting a limited number of research sites does not naturally lead to sustained adoption in the participating sites nor broader adoption in additional sites. Interventional implementation studies comparing an intensive, investigator-led multifaceted implementation strategy deployed in a sample of health care organizations against a low-intensity "usual-care" implementation approach in a matched sample of settings can produce significant increases in rates of adoption of the target health care practice. Yet much of this increase might be due to temporary factors such as high levels of researcher

attention, technical assistance and support for participating sites, grant funding for additional staff and resources (e.g., IT support for implementation), and others. Studies measuring long-term sustainability of resulting practice changes after withdrawal of these resources are rare, despite considerable evidence from management theory and related fields suggesting that professional and organizational changes may be temporary. Theory and research on phenomena such as organizational learning[102,103] and institutionalization offer considerable value in explaining and predicting long-term patterns of behavior change, and should be explored as part of a broader program of theory development and empirical research to better understand sustainability phenomena and to guide efforts to design improved implementation strategies to increase the likelihood that short-term successes in changing health care practices will be sustained.

A similar need exists for increased attention to scale-up and spread barriers, processes, and strategies. A range of factors limit the external validity and transferability of the findings from interventional implementation studies assessing effectiveness of an investigator-led implementation program in a small number of sites. Factors limiting sustainability, such as temporary researcher attention and technical assistance and grant-provided funds for staff and IT, serve to limit the spread of effective practices beyond sites participating in time-limited implementation research projects as well: responsibility for deploying effective implementation strategies on a large-scale, including provision of technical assistance and other forms of facilitation and support provided by research teams in grant-funded implementation studies, is often unclear. Other factors contribute to limited spread, including nonrepresentativeness of sites participating in research studies: these sites are often high-resource organizations whose ability to successfully adopt effective practices is likely to be high even in the absence of research support and the use of carefully designed practice change strategies. Research to understand barriers and facilitators to scale-up and spread and to develop effective scale-up strategies will help identify and characterize these and other limitations of current approaches to implementation research and will help develop new guidance for successful scale-up and spread.

Observational Studies

Increased research attention to sustainability and scale-up and spread processes will help stimulate growth in observational research examining naturally occurring spread, as well as phased implementation research programs[61,104] involving progression from small-scale efficacy-oriented implementation trials (involving high levels of researcher technical assistance and support for participating sites) to larger-scale effectiveness-oriented trials and observational studies in which researchers have little or no role in facilitating implementation but serve mainly to evaluate the implementation process. Researcher-led implementation efforts are often highly artificial, addressing quality and implementation gaps viewed as important by researchers but not necessarily by participating sites, and involving a range of practice change strategies led by an external research team rather than internal staff. Insights into barriers and facilitators to practice change from

research-led implementation efforts have limited external validity. Better insights are needed from appropriately designed[105,106] observational studies of large-scale implementation efforts conducted by policy and practice entities, such as CDC and HRSA and Medicare Quality Improvement Organizations in the United States, as well as practice-driven implementation efforts conducted by integrated health care delivery systems such as the VA, Kaiser Permanente, and national health systems outside the United States.

Impact versus Process and Mechanism Focus

Much of the research examining implementation in health care has pursued questions of implementation strategy effectiveness and has employed well-established experimental and quasi-experimental research approaches for assessing the effectiveness of various implementation strategies. Researchers are increasingly recognizing that effectiveness of implementation strategies is often highly dependent on contextual factors and features of the manner in which the implementation strategies are delivered and managed.[107] As a result the main effect of an implementation strategy is often weak and dominated by a large number contextual and delivery factors, limiting the ability of standard evaluation approaches to estimate effectiveness of the core implementation program. Recent interest and efforts to define, conceptualize, and measure contextual factors[108,109] and to develop better analytical methods for examining their effects[110] are addressing the challenge of weak main effects, but the sample size requirements and other barriers to estimating implementation strategy effectiveness when main effects are small and the number of significant contextual factors is large will continue to challenge the field. In extreme (although arguably common) situations in which outcomes of implementation efforts are driven almost entirely by contextual factors and the manner in which implementation strategies are delivered, with essentially no detectable main effect of the implementation strategy, implementation research efforts must focus on developing insights into the processes and mechanisms of action, pursuing questions such as how, when, where, and why an implementation strategy is effective, rather than whether it is effective.[111–113] Research efforts to develop appropriate methods and approaches for these questions, including theory-based evaluation and realistic evaluation, and debates over the role and value of these approaches in quality improvement and implementation research, will help broaden the portfolio of such research and increase the likelihood that valid, useful insights and guidance will emerge and better contribute to ongoing efforts to reduce quality and implementation gaps and enhance the performance and beneficial impacts of health care delivery and health services.

SUGGESTED READINGS

Eccles MP, Armstrong D, Baker R, et al. An implementation research agenda. *Implement Sci.* April 7, 2009;4:18.

Documents results of an expert panel convened to develop an agenda for research in implementation science in the UK.

Estabrooks CA, Derksen L, Winther C, et al. The intellectual structure and substance of the knowledge utilization field: a longitudinal author co-citation analysis, 1945 to 2004. *Implement Sci.* November 13, 2008;3:49.

   Describes the content and evolution of several subfields closely related to, and overlapping with, the field of implementation science. Provides a useful introduction and overview of these fields.

McKibbon KA, Lokker C, Wilczynski NL, et al. A cross-sectional study of the number and frequency of terms used to refer to knowledge translation in a body of health literature in 2006: a Tower of Babel? *Implement Sci.* February 12, 2010;5:16.

   Documents the range of labels employed in published articles within the field of implementation research and its related fields and subfields. Together with the Estabrooks et al. article listed above, it provides a valuable roadmap or inventory of labels, fields, and subfields employed by researchers studying implementation phenomena, facilitating other researchers' access to this literature.

Remme JH, Adam T, Becerra-Posada F, et al. Defining research to improve health systems. *PLoS Med.* November 16, 2010;7(11):e1001000.

   Offers an overview and description of implementation research and related fields of research intended to improve health systems, health care, and public health from a global perspective.

SELECTED WEBSITES AND TOOLS

http://ktclearinghouse.ca/

The KT Clearinghouse is a repository of implementation research (or "knowledge translation") resources and tools. Individual components with in the Clearinghouse include a Knowledge Base listing training resources, research frameworks, a glossary and other items, a KT Tools section listing specific tools for locating and using evidence and evidence-based programs, and links to related resources.

http://www.queri.research.va.gov/clearinghouse/

The VA QUERI Implementation Research Resource Clearinghouse is a repository of implementation research frameworks, annotated bibliographies, listings of key stakeholder organizations and programs (funding programs, research centers, advocacy and partner organizations), and listings of key activities and resources (conferences, training programs, journals, seminar series).

http://conferences.thehillgroup.com/obssr/DI2011/index.html

The Annual NIH Conference on the Science of Dissemination and Implementation (2007, 2009, 2010, 2011, and planned for 2012) represents the largest annual gathering of dissemination and implementation researchers and research activity in the United States and internationally. The website for each year's conference offers copies of the agenda, participant list, presentations, and selected session summaries and videos. Links to prior years' materials are contained on the "Resources" page within the 2011 conference website.

http://www.kusp.ualberta.ca/en/KnowledgeUtilizationColloquia.aspx

The Knowledge Utilization Colloquia Archive provides materials from the annual Knowledge Utilization Colloquium (convened annually from 2001 to 2011 with planned continuation) and the occasional Knowledge Translation Forum. The Colloquium is a relatively small but intensive conference encompassing implementation research and practice in the fields of nursing research and broader domains of health and health care.

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