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Dissemination and Implementation Science: Research Models and Methods

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Dissemination and Implementation Science: Research Models and Methods

Abstract

Dissemination and implementation (DI) science has grown exponentially in the past decade. This chapter reviews and discusses the research methodology pertinent to empirical DI inquiry within mental health services research. This chapter (a) reviews models of DI science, (b) presents and discusses design, variables, and measures relevant to DI processes, and (c) offers recommendations for future research.

Keywords

dissemination, implementation, research methods, mental health services research

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Dissemination and Implementation Science: Research Models and Methods

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Abstract and Keywords

Dissemination and implementation (DI) science has grown exponentially in the past decade. This chapter reviews and discusses the research methodology pertinent to empirical DI inquiry within mental health services research. This chapter (a) reviews models of DI science, (b) presents and discusses design, variables, and measures relevant to DI processes, and (c) offers recommendations for future research.

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Introduction

Using the specific criteria for “empirically supported treatments” (Chambless & Hollon, 1998), efficacious psychosocial treatments have been identified for mental health and substance abuse, and national accrediting bodies (e.g., American Psychological Association [APA]) have recommended the use of such treatments, a practice that is often referred to as *evidence-based practice* (EBP; APA, 2005). However, uptake of EBP is a slow process, with some suggesting that the translation of new research findings into clinical practice can take over a decade and a half (Green, Ottoson, Garcia, & Hiatt, 2009). Given the emphasis on dissemination and implementation of research innovation, a number of recent efforts have endeavored to ensure that EBP is disseminated to and implemented within the community (McHugh & Barlow, 2010). For example, the United States Veterans Administration Quality Enhancement Research Initiative and the United

Kingdom's Improving Access to Psychological Therapies are examples of international efforts to enact large-scale systemic change in the provision of EBP.

Part of the impetus for the EBP movement in mental health services in the United States was a 1995 task force report initiated by the Division of Clinical Psychology (Division 12) of the APA (Chambless & Hollon, 1998). The initial report identified empirically supported psychosocial treatments for adults and also highlighted the lack of empirical support for many interventions. Since the initial report, debate with regard to the provision of EBP in clinical practice has ensued, but the movement has gained solid footing. Efforts to expand the use of EBP have encouraged the rethinking of community mental health practice, akin to the movement within evidence-based medicine (Torrey, Finnerty, Evans, & Wyzik, 2003).

Given the different terms used within the area of dissemination and implementation (DI) research (Beidas & Kendall, 2010; Special Issue of the *Journal of Consulting and Clinical Psychology*, Kendall & Chambless, 1998; Rakovshik & Mcmanus, 2010), operational definitions are provided. EBP refers here to the provision of psychosocial treatments supported by the best scientific evidence while also taking into account clinical experience and client preference (APA, 2005). (p. 63) Empirically supported treatments refer here to specific psychological interventions that have been evaluated scientifically (e.g., a randomized controlled trial [RCT]) and independently replicated with a delineated population (Chambless & Hollon, 1998). DI science includes the purposeful distribution of relevant information and materials to therapists (i.e., dissemination) and the adoption and integration of EBP into practice (i.e., implementation; Lomas, 1993). Dissemination and implementation are best initiated together in that both need to occur in order to influence systemic change (Proctor et al., 2009).

This relatively nascent field of study has yet to develop a “gold-standard” set of research methods specific to DI processes. Nevertheless, this chapter reviews relevant research methodology pertinent to research questions within this area. The chapter (a) reviews models of DI science, (b) presents and discusses relevant research methods (i.e., design, variables, and measures), and (c) offers recommendations for future research.

Research Methods

Models

A number of models¹ exist that are specific to DI science (e.g., Consolidated Framework for Implementation Research; Damschroder et al., 2009) or have been applied from other areas (e.g., Diffusion of Innovation; Rogers, 1995) that are salient. When considering models, it is important to consider model typology and the need for multiple models to explain DI processes (Damschroder, 2011). Impact models are explanatory in that they

describe DI hypotheses and assumptions, including causes, effects, and factors (i.e., the “what”), whereas process models emphasize the actual implementation process (i.e., the “how to”; Grol, Bosch, Hulscher, Eccles, & Wensing, 2007). Below, relevant models are described. First, we present heuristic models that can guide study conceptualization, and then we present models that are more specific to various DI questions, including models that emphasize individual practitioners and social and organizational processes. See Table 5.1 for a comparison of DI models and features.

Comprehensive Models

Models included within this section are comprehensive and ecological in nature in that they include individual, organizational, and systemic processes. These models function largely as guiding heuristics when designing DI studies and include Promoting Action on Research Implementation in Health Services (PARiHS; Kitson, Harvey, & McCormack, 1998); Reach, Efficacy, Adoption, Implementation, and Maintenance (RE-AIM; Glasgow, Vogt, & Boles, 1999); Stages of Implementation and Core Implementation Components (Fixsen, Naoom, Blasé, Friedman, & Wallace, 2005); the Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009); the Practical, Robust Implementation, and Sustainability Model (PRISM) (Feldstein & Glasgow, 2008); and a Conceptual Model of Implementation Research (Proctor et al., 2009).

PARiHS

The PARiHS framework has been put forth as a practical heuristic to understand the process of implementation (Kitson et al., 2008). The use of the PARiHS model is twofold, “as a diagnostic and evaluative tool to successfully implement evidence into practice, and by practitioners and researchers to evaluate such activity” (Kitson et al., 2008).

The framework posits three interactive components: evidence (E), context (C), and facilitation (F). E refers to knowledge, C refers to the system within which implementation occurs, and F refers to support of the implementation process. Successful implementation depends on the interrelationship between E, C, and F (Kitson et al., 1998). The PARiHS model emphasizes that (a) evidence is composed of “codified and non-codified source of knowledge,” which includes research, clinical experience, patient preferences, and local information, (b) implementing evidence in practice is a team effort that must balance a dialectic between new and old, (c) certain settings are more conducive to implementation of new evidence than others, such as those that have evaluation and feedback in place, and (d) facilitation is necessary for implementation success (Kitson et al., 2008). Initial support exists around the model (e.g., facilitation; Kauth et al., 2010), although there is the need for prospective study (Helfrich et al., 2010).

RE-AIM

The RE-AIM framework is another model that can aid in the planning and conducting of DI studies. RE-AIM evaluates the public health impact of an intervention as a function of

the following five factors: reach, efficacy, adoption, implementation, and maintenance. This model is consistent with a systems-based social ecological framework (Glasgow et al., 1999). (p. 64)

Table 5.1 A Comparison of Key Features Across Key Dissemination and Implementation (DI) Models

Model	Model Features								
	Comprehensive/ Ecological	Emphasizes Individual Practitioner	Emphasizes Social and Organizational Processes	Emphasizes Feedback Loops	Emphasizes Process of Implementation	Emphasizes Sustainability	Considers Role of Research- Community Partnerships	Emphasizes Key Opinion Leaders	Empirically Evaluated
PARIHS									
RE-AIM									
SI/CIC									
CFIR									
PRISM									
CMIR									
Stetler									

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TPB									
DOI									
ARC									
CID									

Note: PARiHS = Promoting Action on Research Implementation in Health Services (Kitson et al., 1998); RE-AIM = Reach, Efficacy, Adoption, Implementation, and Maintenance (Glasgow et al., 1999); SI/CIC = Stages of Implementation and Core Implementation Components (Fixsen et al., 2005); CFIR = Consolidated Framework for Implementation Research (Damschroder et al., 2009); PRISM = Practical, Robust Implementation, and Sustainability Model (Feldstein & Glasgow, 2008); CMIR = Conceptual Model of Implementation Research (Proctor et al., 2009); Stetler model (Stetler, 2001); TPB = Theory of Planned Behavior (Ajzen, 1988; 1991); DOI = Diffusion of Innovation (Rogers, 1995); ARC = Availability, Responsiveness, and Continuity model (Glisson & Schoenwald, 2005); CID = Clinic/Community Intervention Development Model (Hoagwood et al. 2002).

Feature characterizes model

Reach refers to “the percentage and risk characteristics of persons who receive or are affected by a policy or program,” whereas efficacy refers to positive and negative health outcomes (i.e., biological, behavioral, and patient-centered) following implementation of an intervention (Glasgow et al., 1999, p. 1323). Both reach and efficacy address individual-level variables. Adoption refers to the number of settings that choose to implement a particular intervention, whereas implementation refers to “the extent to which a program is delivered as intended” (Glasgow et al., 1999, p. 1323). Both adoption and implementation are organizational-level variables. Maintenance refers to the extent to which an intervention becomes a routine part of the culture of a context (i.e., sustainability). Maintenance is both an individual- and organizational-level variable. Each of the five factors can be scored from 0 to 100, with the total score representing the public health impact of a particular intervention. Interventions, such as various EBPs, can be scored on each dimension and plotted and compared to one another.

Over 100 studies have been completed using RE-AIM as an organizing heuristic since it was published in 1999, but the authors state that it has not been validated because it is a guiding framework rather than model or theory (http://www.re-aim.org/about_re-aim/FAQ/index.html). No literature reviews of RE-AIM-guided studies exist to our knowledge.

Stages of Implementation and Core Implementation Components

Fixsen and colleagues have provided two key conceptual models for understanding implementation processes (Fixsen, Blase, Naoom, & Wallace, 2009; Fixsen et al., 2005). The recursive and nonlinear stages of implementation include exploration, installation, initial implementation, full implementation, innovation, and sustainability (Fixsen et al., 2005). Fixsen and colleagues (2009) suggest that “the stages of implementation can be thought of as components of a tight circle with two-headed arrows from each to every other component” (Fixsen et al., 2009, p. 534).

Based upon a review of successful programs, a number of core components were proposed within the stages of implementation. These core implementation components include: staff selection, preservice and in-service training, ongoing coaching and consultation, staff evaluation, decision support data systems, facilitative administrative support, and systems interventions (Fixsen et al., 2005). These components are both integrated and compensatory in that they work together and compensate for strengths and weaknesses to result in optimal outcomes. Core implementation components work in tandem with effective programs (Fixsen et al., 2005).

Given the integrated and compensatory nature of the core implementation components, an adjustment of one necessarily influences the others. Importantly, feedback loops must be built into implementation programs that allow for such natural corrections. These core implementation components provide a blueprint for implementation research design (Fixsen et al., 2009). Although this model focuses on clinician behavior as the emphasized

outcome variable, systemic variables and patient outcomes are also included, making it a comprehensive model of implementation processes.

CFIR

The CFIR is a metatheoretical synthesis of the major models emerging from implementation science (Damschroder et al., 2009). CFIR does not specify hypotheses, relationships, or levels but rather distills models and theories into core components, creating an overarching ecological framework that can be applied to various DI research studies. CFIR has five major domains that reflect the structure of other widely cited implementation theories (e.g., Fixsen et al., 2005; Kitson et al., 1998): intervention characteristics, outer setting, inner setting, individual characteristics, and the implementation process.

Intervention characteristics are important in DI, particularly the core (i.e., essential elements) and peripheral (i.e., adaptable elements) components. Other important intervention characteristics include intervention source, stakeholder perception of the evidence for the intervention, stakeholder perception of the advantage of implementing the intervention, adaptability of the intervention for a particular setting, feasibility of implementing a pilot, complexity of the intervention, design quality and packaging, and cost.

The outer setting refers to the “economic, political, and social context within which an organization resides” (Damschroder et al., 2009, p. 57). Specifically, the outer setting concerns patient needs for the intervention, cosmopolitanism (i.e., the social network of the organization), peer pressure to implement the intervention, and external incentives to implement. The inner setting refers to the “structural, political, and cultural contexts through which the implementation process will proceed” (Damschroder et al., 2009, p. 57). These include structural characteristics (e.g., social organization of the agency, age, maturity, size), social networks and communication, culture, and implementation climate. The outer setting can influence implementation and may be mediated through modifications of the inner setting, and the two areas can be overlapping and dynamic (Damschroder et al., 2009).

Individual characteristics refer to stakeholders involved with the process of implementation. This framework views stakeholders as active seekers of innovation rather than passive vessels of information (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004). Constructs within this domain include knowledge and beliefs about the intervention, self-efficacy with regard to use of the intervention, individual stage of change, individual identification with the organization, and other individual attributes. Finally, the implementation process here refers to four activities: planning, engaging, executing, and reflecting and evaluating. Empirical validation for the CFIR model is currently ongoing.

PRISM

The PRISM model (Feldstein & Glasgow, 2008) represents another comprehensive ecological model that integrates across existing DI frameworks (e.g., PARiHS, RE-AIM) to offer a guiding heuristic in DI study design. PRISM is comprehensive in that it “considers how the program or intervention design, the external environment, the implementation and sustainability infrastructure, and the recipients influence program adoption, implementation, and maintenance” (Feldstein & Glasgow, 2008, p. 230).

The first element of the PRISM model considers the perspectives of the organization and consumers with regard to the intervention. Organizational characteristics are investigated at three levels (leadership, management, and front-line staff); the authors (p. 66) recommend considering how the intervention will be perceived by the organization and staff members. For example, readiness for change, program usability, and alignment with organizational mission are a few issues to address. With regard to taking the consumer perspective, PRISM recommends considering how an intervention will be received by consumers, such as burden associated with the intervention and the provision of consumer feedback.

The second element of PRISM focuses on organizational and consumer characteristics. Important organizational characteristics include the financial and structural history of an organization as well as management support. Consumer characteristics to consider include demographics, disease burden, and knowledge and beliefs. Relatedly, the third element considers characteristics of the external environment relevant to DI efforts, which “may be some of the most powerful predictors of success” (Feldstein & Glasgow, 2008, p. 237). The external environment refers to motivating variables such as payer satisfaction, competition, regulatory environment, payment, and community resources.

The fourth element of the PRISM model refers to the infrastructure present to support implementation and sustainability. The authors recommend that for implementation to be successful, plans for sustainability must be integrated into DI efforts from the very beginning. Specific variables to consider within this element include adopter training and support, adaptable protocols and procedures, and facilitation of sharing best practices.

The unique contributions of the PRISM model lie in the integration of various DI models and focus on integrating concepts not included in previous models: (a) perspectives and characteristics of organizational workers at three levels (leadership, management, and staff), (b) partnerships between researchers and those doing the implementation, and (c) planning for sustainability from the beginning. Additionally, the authors provide a useful set of questions to ask at each level of the PRISM model when designing a research project (see Feldstein & Glasgow, 2008).

Conceptual Model of Implementation Research

Proctor and colleagues (2009) proposed a conceptual model of implementation research that integrates across relevant theories and underscores the types of outcomes to consider in DI research. Their model assumes nested levels (policy, organization, group,

individual) that integrate quality improvement, implementation processes, and outcomes. The model posits two required components: evidence-based intervention strategies (i.e., EBP) and evidence-based implementation strategies (i.e., systems environment, organizational, group/learning, supervision, individual providers/consumers). Unique to this model, three interrelated outcomes are specified: implementation (e.g., feasibility, fidelity), service (e.g., effectiveness, safety), and client (e.g., symptoms) outcomes.

Models that Emphasize Individual Practitioners

Moving beyond heuristic models, we describe models that specify various components of DI processes. Models included within this section emphasize individual practitioners and include the Stetler model (Stetler, 2001) and Theory of Planned Behavior (Ajzen, 1988, 1991).

Stetler Model

The Stetler model (Stetler, 2001) emerges from the nursing literature and focuses on how the individual practitioner can use research information in the provision of EBP. The linear model is “a series of critical-thinking steps designed to buffer the potential barriers to objective, appropriate, and effective utilization of research findings” (Stetler, 2001). The unit of emphasis is the individual's appropriate use of research findings.

The Stetler model has been updated and refined a number of times (Stetler, 2001) and comprises five main stages: (a) preparation, (b) validation, (c) comparative evaluation/decision making, (d) translation/application, and (e) evaluation. During preparation, the practitioner identifies a potential high-priority problem, considers the need to form a team or other internal and/or external factors, and seeks systematic reviews and empirical evidence relevant to the problem. During validation, the practitioner rates the quality of evidence and rejects noncredible sources. During comparative evaluation/decision making, the practitioner synthesizes findings across empirical sources, evaluates the feasibility and fit of current practices, and makes a decision about the use of evidence in the problem identified. During translation/application, the evidence is used with care to ensure that application does not go beyond the evidence. Additionally during this stage, a concerted effort to include dissemination and change strategies is necessary. During evaluation, outcomes from the implementation of the evidence are assessed, including both formal and informal evaluation and cost/benefit analyses. Both formative and (p. 67) summative evaluations are to be included (Stetler, 2001).

Theory of Planned Behavior

Theory of Planned Behavior (TPB; Ajzen, 1988; 1991) can be used to understand the behavior of the individual practitioner within DI efforts. From the perspective of TPB, behavior is determined by an individual's intention to perform a given behavior. Intentions are a function of attitudes toward the behavior, subjective norms, and perceived control. This theory has received great attention in other areas of psychology

and is empirically supported (Armitage & Conner, 2001) but has only recently been applied to DI processes.

In one recent study, clinicians were randomly assigned to one of two continuing education workshops: a TPB-informed workshop and a standard continuing-education workshop. Outcomes included clinician intentions and behavior in the usage of an assessment tool. The key manipulation in the TPB-informed workshop was an elicitation exercise to gather participant attitudes, social norms, and perceived control. Findings were supportive in that participants demonstrated both higher intentions and higher implementation rates in the use of the assessment tool (Casper, 2007). This model can be used to guide the design of studies hoping to influence behavior change at the individual practitioner level.

Models that Emphasize Social and Organizational Processes

Models within this section emphasize the social nature of DI and the importance of organizational context and include Diffusion of Innovation (Rogers, 1995), the Availability, Responsiveness, and Continuity model (Glisson & Schoenwald, 2005), and the Clinic/Community Intervention Development Model (Hoagwood, Burns, & Weisz, 2002).

Diffusion of Innovation

The Diffusion of Innovation (DOI) framework (Rogers, 1995) has been widely used and cited within the field of DI science as an integral framework. DOI has been empirically applied across a number of fields, such as agriculture and health sciences (Green et al., 2009). The tenets of DOI are outlined in Rogers' book, *Diffusion of Innovations*, which was revised to its fifth edition before Rogers' death in 2004. Over 5,000 studies have been conducted on DOI, and a new one is published approximately daily (Rogers, 2004).

Rogers defined diffusion as "the process through which an innovation, defined as an idea perceived as new, spreads via certain communication channels over time among the members of a social system" (Rogers, 2004, p. 13). Diffusion can be conceptualized as both a type of communication and of social change that occurs over time (Haider & Kreps, 2004). Adoption of innovation is contingent upon five characteristics: relative advantage, compatibility, complexity, trialability, and observability (Rogers, 1995). Relative advantage refers to whether or not use of an innovation will confer advantage to the individual (e.g., improve job performance, increase compensation). Compatibility is the extent to which an innovation is consistent with the individual's set of values and needs. Complexity refers to how easily an innovation can be learned and used. Trialability is the extent to which an innovation can be tested on a small scale to evaluate efficacy. Observability describes the positive outcomes that are engendered by implementation of an innovation.

Irrespective of innovation characteristics, DOI theory suggests that innovations are adopted according to a five-step temporal process of Innovation-Decision: knowledge, persuasion, decision, implementation, and confirmation. Knowledge refers to an individual learning of an innovation, whereas persuasion refers to attitude formation about an innovation. Decision occurs when a person decides to adopt or reject an

innovation. Implementation refers here to when an individual uses an innovation, whereas confirmation refers to an individual seeking reinforcement about the decision to implement an innovation. Decisions to adopt an innovation are recursive, meaning that an individual can reject an innovation at first while adopting it later (Lovejoy, Demireva, Grayson, & McNamara, 2009). Rogers (2004) describes the diffusion of innovation as following an S-shaped curve where innovation adoption begins at a slow rate (i.e., early adopters; first 16%) but reaches a tipping point when adoption accelerates rapidly (i.e., early and late majority; 68%) and then decreases again (i.e., laggards; last 16%). The tipping point, or threshold of program utilizers, occurs when approximately 25% of the social network become utilizers (Valente & Davis, 1999). A well-known and practical application of DOI includes key opinion leaders, a small group of influential early adopters who make it more likely that innovation will spread within a social network (Valente & Davis, 1999); this theory has been supported in mental health services research (Atkins et al., 2008).

(p. 68) DOI has been influential in DI science. The field has taken into account characteristics of innovations and the innovation-decision process within a social context when designing DI research. DOI has been applied to understanding how to bridge the gap between research and clinical practice within various psychosocial interventions and treatment populations (e.g., autism; Dingfelder & Mandell, 2010).

Availability, Responsiveness, and Continuity Model

The Availability, Responsiveness, and Continuity (ARC) organizational and community model is specific to mental health services research and is based upon three key assumptions: (a) the implementation of EBP is both a social and technical process, (b) mental health services are embedded in layers of context, including practitioner, organization, and community, and (c) effectiveness is related to how well the social context can support the objectives of the EBP (Glisson & Schoenwald, 2005). ARC aims to improve the fit between the social context and EBP through intervening at the organizational and interorganizational domain levels. The organizational level refers to the needs of mental health practitioners, and ARC involves such providers in organizational processes and policies. The emphasis on interorganizational domain level within ARC allows for the formation of partnerships among practitioners, organizational opinion leaders, and community stakeholders with the shared goal of ameliorating identified problems in a community through a particular EBP (Glisson & Schoenwald, 2005).

Within the ARC model, a key component includes an ARC change agent who “works with an interorganizational domain (e.g., juvenile court, school system, law enforcement, business group, churches) at several levels (e.g., community, organization, individual) around a shared concern (e.g., reducing adolescent delinquent behavior)” (Glisson & Schoenwald, 2005, p. 248). This individual works at the community level by helping form a group to support an EBP for a selected population, at the organizational level by providing support in the delivery of EBP, and at the individual level to develop individual partnerships with key opinion leaders. Change agents provide technical information, empirical evidence, evaluation of outcomes, and support during times of conflict. In other words, the role of the change agent is to serve as a bridge between those disseminating and those implementing the EBP (Glisson & Schoenwald, 2005). An especially clear and relevant application of ARC is described in a recent study that improved DI efforts of multisystemic therapy into poor rural communities (Glisson et al., 2010).

Clinic/Community Intervention Development Model

Hoagwood, Burns, and Weisz (2002) proposed the Clinic/Community Intervention Development (CID) model for community deployment efforts of EBP for youth mental health. The CID model allows DI researchers to understand factors associated with sustainable services, including why and how services work in practice settings. The CID model comprises eight steps. Steps 1 through 6 involve efficacy to effectiveness with emphasis on single case applications in practice settings, a limited effectiveness study to pilot the intervention in real-world practice settings, followed by a full effectiveness study. Steps 7 and 8 are specific to DI processes. Step 7 calls for a series of studies to assess goodness of fit with practice settings, whereas Step 8 focuses on going to scale by engaging in dissemination research in multiple organizational settings.

CID is put forth as a model “for speeding up the process of developing scientifically valid and effective services within the crucible of practice settings” (Hoagwood et al., 2002, p. 337). A strength of the model is that it is externally valid given its emphasis on components, adaptations, and moderators and mediators. Additionally, the model calls for innovative thinking as well as new research models to assess goodness of fit and criteria to determine when a program is ready to go to scale.

Summary

As evident from this review, the sheer number of possible DI models to consider when designing a research question can be quite daunting. Each model presented has strengths and limitations, and none of the models offered covers all of the content areas relevant to DI science (see Table 5.1). One clear limitation is that many of these newly derived theoretical models have not yet been subjected to rigorous scientific evaluation. Despite these limitations, we recommend that all DI-related questions be theoretically driven. When designing a research question, first identify a relevant model that can guide the construction of research design in order to provide meaningful contributions to the field. Our bias and recommendation is toward comprehensive ecological models that take into account the contextual aspects of DI processes as the underlying framework. However, when examining certain processes (e.g., attitudes), it can be helpful to select specific models that can lead to testable hypotheses. (p. 69) For example, one might select a heuristic model such as the CFIR (Damschroder et al., 2009) when considering which constructs to focus on in a DI study and then select a more specific model based on the study question (e.g., training and attitudes; TPB, Ajzen, 1988, 1991).

We concur with Damschroder's (2011) suggestions of the following steps when selecting models: consider (a) the nature of the model (i.e., process vs. impact, context, discipline), (b) level of application (e.g., individual, organization), (c) available evidence, and (d) which model has the greatest potential for adding to the literature. Importantly, it is likely that more than one model will be needed when designing complex DI studies. Furthermore, after aggregating results, it is important to consider how the results fit back in with the original model(s) selected with regard to validation of the mode and necessary refinements (Damschroder, 2011).

Research Design

The most relevant research designs for DI studies are provided and discussed. Although all of the research methods addressed within this book may be appropriate in the design of DI studies, given the size and complexity of such studies, we focus on designs that are particularly salient to DI: experimental designs, quasi-experimental designs, and qualitative methodology.

Experimental Designs

Randomized Controlled Trials

A full discussion of randomized controlled trials (RCTs) is beyond the scope of this chapter (see Kendall & Comer, 2011); however, RCT designs are often used in DI studies and merit mention (e.g., Miller, Yahne, Moyers, Martinez, & Pirritano, 2004; Sholomskas et al., 2005). The main strength of RCTs involves the use of random assignment to rule out selection bias, which allows for differences in outcomes between conditions to be explained by the experimental manipulation rather than group differences (Song & Herman, 2010). RCTs are often considered the gold-standard research design.

Much has been written about the use of RCTs in DI research. Some researchers have suggested that limitations exist to RCTs in their application to DI studies (e.g., Atkins, Frazier, & Cappella, 2006; Carroll & Rounsaville, 2003). Such limitations include tightly controlled settings, homogenous participants (although some research suggests this is overstated; see Stirman, DeRubeis, Crits-Cristoph, & Brody, 2003), resource-intensiveness, and delay in application of findings to practice (Atkins et al., 2006; Carroll & Rounsaville, 2003). In addition, DI trials often operate at a larger system level, requiring that the unit of randomization be at the system level (e.g., agencies, schools, classrooms, work settings). Thus, the sample needed to have adequate power to detect differences beyond chance may be beyond the capacity of many DI trials.

Clinical Equipoise

One option for augmenting traditional RCT designs for DI research in a flexible manner comes from clinical equipoise. Freedman (1987) suggested the use of clinical equipoise in RCTs. The criterion for clinical equipoise is met if there is genuine uncertainty within the practice community about a particular intervention. Statistical procedures have been developed that allow for balancing the principle of clinical equipoise with randomization (i.e., equipoise-stratified randomized design; Lavori et al., 2001).

For example, in the case of the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) research trial (Rush, 2001), a patient and a service provider might agree that all treatments possible after a failed trial of citalopram are roughly equivalent (clinical equipoise). Using an equipoise-stratified randomized design allows the clinician and patient to judge what the best treatment option might be based on patient preferences, which can then be statistically controlled by using chosen treatment option as a prerandomization factor (see Lavori et al., 2001, for a detailed description). From a DI perspective, equipoise offers an advance over the constraints typically imposed on participants and settings in RCTs (e.g., West et al., 2008). The concept of equipoise has been integrated into Sequential Multiple Assignment Randomized Trial (SMART) designs, which allow for patient and provider preference while maintaining the use of randomization and the rigor of RCTs (Landsverk, Brown, Rolls Reutz, Palinkas, & Horwitz, 2010) (see also Chapter 4 in this volume). SMART designs make possible experimental investigation of the treatment choices made by patients and providers by using randomization strategies that account for choice.

Standardization

Another way to consider how to augment RCTs for DI research is to determine which components of the intervention require standardization (Hawe, [\(p. 70\)](#) Shiell, & Riley, 2004). A complex intervention refers to an intervention that cannot be simply reduced into component parts to understand the whole (i.e., component analysis; Hawe et al., 2004). However, because an intervention is complex does not mean that an RCT is not appropriate—the question lies in what part of the intervention is standardized. Standardization as it is conceptualized within a traditional RCT suggests that components of the intervention are the same across different sites. Hawe and colleagues (2004) suggest an alternative perspective to standardization: “rather than defining the components of the intervention as standard—for example, the information kit, the counseling intervention, the workshops—what should be defined as standard are the steps in the change process that the elements are purporting to facilitate or the key functions that they are meant to have” (Hawe et al., 2004, p. 1562).

Pragmatically, this means that the form can be adapted while process and function remain standardized. What is varied becomes the form of the intervention in different contexts. For example, to train providers about treatment of anxiety, the traditional way to conduct an RCT would be to standardize training methods across sites. Live group instruction might be compared to computer-guided instruction. In each case, the information provided would be the same and therefore the results would relate to which type of training was superior for the majority of participants. Alternatively, one could standardize the *function* by providing supervisors in an organization with the materials necessary to create training programs that are tailored to the specific setting. In this case, intervention integrity would not relate to typical quality assurance efforts (i.e., did trainer follow specific protocol); rather, it would be related to whether the training developed within each context provided information consistent with the theory or principles underlying the change process. This effort could result in improved effectiveness of DI efforts (Hawe et al., 2004).

Practical Clinical Trials

Practical clinical trials (PCTs; also known as pragmatic clinical trials) have been recommended as an alternative to traditional RCTs (Tunis, Stryer, & Clancy, 2003) and are specifically relevant to effectiveness studies, the mainstay of DI research. PCTs are designed to provide the information necessary to make decisions about best-care practices in routine clinical settings. Tunis and colleagues (2003) describe the distinctive features of PCTs in that “they select clinically relevant interventions to compare, include a diverse population of study participants, recruit participants from a variety of practice settings, and collect data on a broad range of health outcomes” (p. 1626).

March and colleagues (2005) suggested that there are eight defining principles of PCTs: (a) research questions that are of public health interest and clinically relevant, (b) they are performed in usual care settings, (c) power is sufficient to identify small to medium effects, (d) randomization is included, (e) randomization depends on the principle of

uncertainty/clinical equipoise, (f) outcomes are simple and clinically relevant, (g) interventions map onto best clinical practice, and (h) research burden is minimized. PCTs are well suited to answer questions related to intervention effectiveness as well as which treatment works best for which patients depending on their characteristics (March et al., 2005).

PCTs are similar to effectiveness designs in that they aim to provide information to decision makers about whether or not interventions work in routine clinical care settings. Questions best answered by this design include the overall effectiveness of a particular intervention in routine settings and include heterogeneous patient populations necessitating larger sample sizes. Outcomes must include evidence that is relevant to everyday policymakers, such as quality of life and the cost-effectiveness of interventions (Macpherson, 2004).

The main strength of PCTs and their relevance to DI research lies in their emphasis on understanding whether or not interventions can be effective in real-world settings. In other words, these designs are heavy on external validity and ecological evidence and provide evidence for decision makers regarding which interventions to recommend. Such trials have been used effectively in medicine and psychiatry (March et al., 2005). Limitations to PCTs include that they are very costly, need a resource-intensive infrastructure to succeed (March et al., 2005; Tunis et al., 2003), require close collaborations between the research team and practice sites, and may be more reflective of agency priorities than researcher priorities (e.g., symptom reduction may not be the primary outcome measure but rather improved functioning in setting). However, recent advances in electronic health records make it more feasible to realize the potential of such designs in the future (March, 2011).

Adaptive Clinical Trials

Adaptive clinical trials are another alternative to RCTs and are flexible in that they plan for the (p. 71) possibility of reactive changes to study design and/or statistical procedures as the study progresses based upon review of interim data (Chow & Chang, 2008). That is, an adaptive design can be defined as “a design that allows adaptations to trial and/or statistical procedures of the trial after its initiation without undermining the validity and integrity of the trial” (Chow & Chang, 2008). A number of adaptive design strategies exist (see Chow & Chang, 2008, for review). One that stands out as being particularly salient to DI processes includes adaptive treatment switching. This design allows researchers to switch a participant from one group to another based on lack of efficacy. For example, a patient assigned to usual care could be switched to an EBP if usual care is not effective. Bayesian analytic approaches that rely on probability theory are especially appropriate statistical analyses for these designs (Luce et al., 2009).

Although these designs have the advantage of allowing for flexibility to accommodate policy-related questions, they provide challenges to fidelity assessment and there are as

yet no clear guidelines for the appropriate use of adaptive clinical trial designs (Chow & Chang, 2008).

Hybrid Models

Hybrid models have been recommended to capitalize on the best of efficacy and effectiveness methodologies (Atkins et al., 2006; Carroll & Rounsaville, 2003). Carroll and Rounsaville (2003) proposed a hybrid model that retains the methodological rigor of RCTs but adds additional components of traditional effectiveness research. In addition to the typical features of an RCT meant to protect internal validity (e.g., random assignment, blind assessment of outcomes, fidelity monitoring), the authors suggest that the following components be integrated into the design to balance external validity and make RCTs more appropriate for DI research: enhanced diversity in patients and settings, attention to training issues, evaluation of cost effectiveness, and assessment of patient and provider satisfaction. These recommendations have been feasibly integrated into DI RCTs. For example, one study feasibly balanced features of efficacy research (e.g., randomization, rigorous assessment) and effectiveness research (e.g., few exclusion criteria, completed in naturalistic setting; Dimeff et al., 2009). Other important recommendations when considering how to adapt RCT methodology for DI research include understanding organizational context and including a “systematic and iterative approach to study development” (Atkins et al., 2006, p. 107). This allows for flexible research design and “ongoing interaction between researcher- and context-driven information at various information points in a project” (Atkins et al., 2006, p. 107).

Quasi-Experimental Designs

Single-Case Time-Series Intervention

Given the emphasis within the psychological literature on RCTs, single-case time-series designs have fallen somewhat out of favor (Borckardt et al., 2008). Once the mainstay of behavior therapists in the 1970s and early 1980s, single-case designs focus on the experimental analysis of behavior (Hersen & Barlow, 1976). Using single-case interventions may provide the establishment of a model of individualized EBP in which the goal would be less the use of scientifically established treatments and more the scientific use of treatment (Gambrill, 2006), thus returning to the roots of behavior therapy and also bridging the gap between research and practice. The APA Division 12 task force includes the use of systematic single-case intervention as one manner from which to glean scientific evidence (Chambless & Hollon, 1998).

Single-case designs allow for multiple observations before and after treatment to provide evidence of patient change and can be accomplished in both clinical settings and research settings (see Borckardt et al., 2008). Single-case studies have natural appeal to practitioners as they can provide information relevant to each client and allow for the comparison of interventions to determine which works best for this client under specific circumstances (Stewart & Chambless, 2010). Additionally, single-case time-series designs can include important manipulations (e.g., randomization) to help ensure a degree of

methodological rigor from which researchers can generate causal inferences (Kratochwill & Levin, 2010; Lewin, Lall, & Kratochwill, 2011).

Qualitative Methods

Qualitative methods offer a window into the complex processes occurring within DI research studies in a manner that purely quantitative studies are unable to provide. Qualitative research “provides a vivid, dense, and full description in the natural language of the phenomenon under study” (Hill, Thompson, & Williams, 1997, p. 518). Rather than identifying *a priori* hypotheses, relationships between phenomena are identified as part of the process of qualitative research. A qualitative approach allows for the “change over time” investigation of DI efforts (Meyer, 2004).

(p. 72) Qualitative methods can be used to “explore and obtain depth of understanding as to the reasons for success or failure to implement evidence-based practice or to identify strategies for facilitating implementation while quantitative methods are used to test and confirm hypotheses based on an existing conceptual model and obtain breadth of understanding of predictors of successful implementation” (Palinkas et al., 2011, p. 44). In this way, qualitative methodology can be used to augment traditional quantitative methods by providing more nuanced contextual information on barriers and/or facilitators. Numerous examples of exemplary use of qualitative methodology exist within DI literature. For example, one study used an ethnographic approach to understand intentions of community clinicians to use EBP (Palinkas et al., 2008). In this study, participant observation and semistructured interviews were used to understand treatment implementation in an effectiveness trial of EBP for depression, anxiety, and conduct problems in youth. Three patterns emerged with regard to participant intention to use EBP: application of treatment with fidelity, abandonment of treatment, and selective application of treatment. Factors associated with these intentions were also explored.

Qualitative research methods, like all methodologies, are not without limitations. Despite increasing attention to the value of such methods, weaknesses include less scientific rigor than quantitative methods and concerns about reliability and validity, analytic techniques used, and quality of produced knowledge (Fitzpatrick & Bolton, 1996; Mays & Pope, 2000).

Summary of Designs

Each design can be useful when attempting to answer questions relevant to DI processes, and careful consideration of the research question and balancing the strengths and limitations of each design is necessary. A recent review describing elements in studies of EBP implementation in child welfare and mental health settings found RCTs to be the dominant paradigm, with some utilization of mixed methodology. Little use of emerging alternative designs (e.g., PCTs, SMART design) was identified (Landsverk et al., 2010), suggesting that future studies should consider these alternatives.

In a developing area such as DI, researchers might recognize the strengths of established methods but also consider the use of multiple-method research to produce converging results. For example, we agree with Dattilio, Edwards, and Fishman (2010) that each DI study should include (a) an RCT, (b) a qualitative evaluation of the implementation of the study with an emphasis on organizational characteristics, and (c) systematic case studies. Taking a mixed-method approach to DI processes moves the field toward a rapprochement between research and practice (Dattilio et al., 2010). A review of 22 studies utilizing mixed methods in child mental health services research found that mixed methods were used for one of five reasons: (a) to measure intervention and process, (b) to conduct exploratory and confirmatory research, (c) to examine intervention content and context, (d) to understand perspectives of consumers (i.e., practitioners and clients), and (e) to compensate for one set of methods with another (Palinkas et al., 2011). The authors state, “it is the combining of these methods through mixed method designs that is likely to hold the greatest promise for advancing our understanding of why evidence-based practices are not being used, what can be done to get them into routine use, and how to accelerate the improvement of systems of care and practice” (Palinkas et al., 2011).

Outcomes Relevant to Dissemination and Implementation

A number of variables have been examined as both predictors and outcomes within the DI literature and include individual provider (e.g., knowledge, attitudes), organizational (e.g., climate, support), and client variables (e.g., treatment outcome). However, given the present emphasis on DI methods, we focus on reviewing implementation outcomes.

Proctor and colleagues (2011) recommend that DI research focus on implementation outcomes that are conceptually different from service or client outcomes. Specifically, the authors “define implementation outcomes as the effects of deliberate and purposive actions to implement new treatments, practices, and services” (Proctor et al., 2011, p. 65). An emphasis on implementation outcomes is necessary given that such outcomes are indicators of implementation success, are proximal indicators of implementation processes, and are related to service and clinical outcomes (Proctor et al., 2011). Distinguishing between implementation and intervention effectiveness is crucial in DI studies to understand what occurs following implementation (i.e., is failure due to a poorly designed or inappropriate intervention or to an effective practice implemented inadequately). Proctor and colleagues (2011) suggested that there are eight crucial (p. 73) outcomes to understand the effects of DI studies: acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability. We suggest adaptation of intervention as an additional outcome of interest.

Acceptability refers to the belief among stakeholders that a particular EBP is acceptable and up to standards. Proctor and colleagues (2011) distinguish acceptability from satisfaction, stating that acceptability is more specific to a particular set of practices. Additionally, acceptability is fluid in that it changes with experience (e.g., before to after

implementation). Acceptability can be measured at the individual provider, organizational, and client levels. One example of an instrument that measures this construct includes the Evidence-Based Practice Attitude Scale (EBPAS; Aarons, 2004).

Adoption refers here to “the intention, initial decision, or action to try or employ an innovation or EBP” (Proctor et al., 2011). Adoption is measured at the individual or organizational level and refers here to the same construct as delineated in the RE-AIM model. Standardized measures of adoption have yet to be identified, and time criteria have not been specified (i.e., when does adoption become routine practice).

Appropriateness refers to the compatibility of an EBP for a given setting, provider, or consumer. The constructs of appropriateness and acceptability overlap but are also distinct given that an EBP can be appropriate but not acceptable (Proctor et al., 2011). Standardized measures of appropriateness have not been identified.

Feasibility refers to the extent to which an EBP can be used effectively within a service system (Proctor et al., 2011) and can be assessed from an individual and organizational level. Measures of feasibility have not been identified.

Implementation cost refers to the cost of an implementation effort and varies with regard to delivery, complexity of the EBP, and particular service setting. The few studies that have reported on implementation cost have quantified cost by intervention component. However, direct measures of implementation cost are not currently widely used (Proctor et al., 2011). One possible strategy to be used is the English cost calculator, a method used to calculate the cost of core work activities and administrative costs, in order to inform administrators when making implementation decisions (Chamberlain et al., 2011). It is likely that the DI field can benefit from work in health economics to advance this area.

Penetration refers to “the integration of a practice within a service setting and its subsystems” (Proctor et al., 2011)—in other words, how widely used a particular practice is within an organization, conceptually similar to the “reach” component in the RE-AIM framework. Direct measures of penetration have not been identified.

Any successful DI effort should result not only in the EBP being implemented within the community, but also *sustainability* over time if found to be effective. This construct is akin to the “maintenance” component in the RE-AIM model and is directly addressed in the PRISM model.

It is likely that sustained programs are better situated to yield sustained effects. Sustainability is also crucial because outcomes may not realistically be achieved or detected within the timeframe permitted by traditional research studies or the grants that typically support them, particularly if the intervention targets behavioral change or community-level mental health outcomes (Pluye, Potvin, & Denis, 2004). Moreover, the recurrent discontinuation of promising or effective programs can have deleterious

consequences for a community, specifically with regard to willingness to support future projects (Pluye et al., 2004; Shediak-Rizkallah & Bone, 1998).

Sustainability has been operationalized multiple ways, including the continuation of program activities, the maintenance of intended benefits for the target population, and the development of community capacity (Scheirer, 2005; Shediak-Rizkallah & Bone, 1998). Altman (1995, p. 527) has proposed an especially clear definition:

Sustainability is ... defined as the infrastructure that remains in a community after a research project ends. Sustainability includes consideration of *interventions* that are maintained, *organizations* that modify their actions as a result of participating in research, and *individuals* who, through the research process, gain knowledge and skills that are used in other life domains.

This conceptualization highlights the relationship between a program and the setting in which it is implemented and emphasizes that systemic change at multiple levels ought to be a goal of any intervention. Thus, thinking about sustainability ought to reflect enduring change at the community level, as should the ways in which sustainability is planned for and measured.

Too often, DI research is viewed as a linear process, culminating in the sustainability phase. More (p. 74) effective, however, is to view sustainability as a process that unfolds alongside the research effort (Pluye et al., 2004). From this perspective, planning for sustainability becomes part of planning for the DI process more generally (Adelman & Taylor, 2003; Altman, 1995; Pluye et al., 2004), and this planning is best informed by an understanding of factors believed to influence sustainability, among them (a) the presence of a program “champion” or change agent (Adelman & Taylor, 2003; Scheirer, 2005; Shediak-Rizkallah & Bone, 1998), (b) the extent to which the program is compatible with an organization's values or mission (Scheirer, 2005), (c) the extent to which the program is integrated into the structures and routines of an organization or community (Adelman & Taylor, 2003; Shediak-Rizkallah & Bone, 1998), (d) the extent to which community members perceive the program as beneficial and support it (Altman, 1995; Scheirer, 2005), and (e) flexibility to modify the program over time (Scheirer, 2005).

All but the last of these factors can benefit from an ongoing collaboration between researcher and community: “The literature overwhelmingly shows a positive relationship between community participation and sustainability” (Shediak-Rizkallah & Bone, 1998, p. 103). Early involvement of community members in the research process can help researchers appreciate the needs of the community, thereby enabling them to study and develop interventions that better meet those needs (Altman, 1995; Durlak & DuPre, 2008). This, in turn, can increase the willingness among community members and groups to take ownership of the intervention and sustain it beyond the initial funding period (Altman, 1995). To date, measures of sustainability are not available.

Fidelity refers to the implementation of an EBP as specified by treatment developers. Measuring provider adherence and competence/skill has become standard procedure to determine treatment fidelity (Kendall & Comer, 2011; Perpeletchikova & Kazdin, 2005). Adherence refers to the degree to which a clinician follows the procedures of an EBP, whereas competence refers to the level of skill demonstrated by the clinician in the delivery of treatment (Perpeletchikova & Kazdin, 2005). Adherence and competence are typically measured by independent evaluators based on in-session clinician behavior. Illustrative examples of fidelity measures include the Cognitive Therapy Scale (Young & Beck, 1980) and the Motivational Interviewing Treatment Integrity scale (Moyers, Martin, Catley, Harris, & Ahluwalia, 2003). One difficulty with measuring fidelity includes varying fidelity measures across treatment modality.

The emphasis on fidelity has come under criticism. A recent meta-analysis suggests that neither adherence nor competence is significantly related to patient outcomes (Webb, DeRubeis, & Barber, 2010). Possible explanations of this puzzling finding include limited variability on adherence and competence ratings within RCTs included in this meta-analysis (therapists are trained to criterion and monitored, resulting in a limited range) and the possibility of a curvilinear relationship between fidelity and outcomes. However, much is unknown about the causal role of specific treatment interventions on specific outcomes (Morgenstern & McKay, 2007), and more dismantling studies are needed to understand the relative contribution of various therapeutic procedures on outcomes. Given the current literature, it is premature to conclude that fidelity to EBP is unimportant in DI efforts, but further empirical study is necessary.

The question of *adaptation* of treatments to particular settings has been raised with regard to fidelity. Adaptation has been defined as intentional or unintentional additions, deletions, or modifications of a program (Center for Substance Abuse Prevention, 2002). The term “re-invention” has been used (Rogers, 1995), often interchangeably. Most researchers agree that adaptation is not inherently negative; it is often beneficial to make certain changes to better address the needs, culture, and context of the local environment (Bauman, Stein & Ireys, 1991; Castro, Barrera, & Martinez, 2004; Center for Substance Abuse Prevention, 2002; Ozer, Wanis & Bazell, 2010; Rogers, 1995). In fact, there is evidence to suggest that adaptation can serve to increase both the effectiveness of an intervention (e.g., McGraw, Sellers, Stone & Bebhuk, 1996) and the likelihood that an intervention is sustained over time (e.g., Scheirer, 2005), which may be a consequence of increasing the relevance of the intervention for the target population (Castro et al., 2004; Ozer et al., 2010).

When we shift our attention to the process by which individuals and organizations implement EBP, a key issue that arises is the extent to which the programs or practices being used in fact resemble those upon which the evidence was based. Despite findings from a recent meta-analysis (Webb et al., 2010), a number of studies have demonstrated that a high level of fidelity to an intervention's design has been linked to improved outcomes (Battistich, (p. 75) Schaps, Watson, & Solomon, 1996; Blakely et al., 1987; Botvin, Baker, Dusenbury, Tortu, & Botvin, 1990; Durlak & DuPre, 2008; Rohrbach,

Graham, & Hansen, 1993), and there are those who insist that absolute fidelity must be maintained (O'Connor, Small, & Cooney, 2007). Many researchers acknowledge that what matters most is fidelity to an intervention's core components or causal mechanism(s). In other words, testing interventions in real-world settings requires a balancing act, of sorts, between preserving an intervention's core components and making needed adaptations given the local context (i.e., flexibility within fidelity; Bauman et al., 1991; Center for Substance Abuse Prevention, 2002; Green & Glasgow, 2006; Kendall & Beidas, 2007; Kendall, Gosch, Furr, & Sood, 2008).

Rogers (1995) noted that some amount of re-invention is inevitable among adopters of innovations; for example, several studies report that adaptations are the norm when implementing school-based interventions (Datnow & Castellano, 2000; Dusenbury, Brannigan, Hansen, Walsh, & Falco, 2005; Larsen & Samdal, 2007; Ozer et al., 2010; Ringwalt, Ennett, Vincus, & Simons-Rudolph, 2004). That said, the true prevalence of adaptations is unknown because they are not reported consistently. Durlak and DuPre (2008) found that only 3 of 59 studies assessing the impact of implementation on intervention outcomes reported on adaptation, whereas 37 reported on fidelity.

In light of this, those involved in DI research must take care to document the adaptation process. According to the Center for Substance Abuse Prevention (2002), the following steps have been proposed to guide the process of adapting programs to new settings: (a) identify the theory of change underlying the program, (b) identify the components that are essential to the program (i.e., its “core” components), (c) identify appropriate adaptations given the local circumstances, (d) consult with the program developer regarding the previous steps, (e) consult with local stakeholders, and (f) develop a plan for implementation, including a plan for assessing the fidelity/adaptation balance.

The task is not without challenges. First, few interventions adequately delineate which components are *core* (Durlak & DuPre, 2008), making it difficult to determine whether a proposed adaptation may threaten the very mechanism that makes the intervention work. Those involved in DI research are urged to work in tandem with program developers, requesting, if necessary, that they conduct some manner of core component analysis. Ideally, program developers would not only identify those elements central to the program's theory of change that must remain intact, but also articulate the range of acceptable adaptations (Green & Glasgow, 2006). Second, the definition provided earlier—which encompasses additions, deletions, and modifications to the program model—may lead to some confusion regarding what actually *counts* as an adaptation. For instance, how should we distinguish between an *addition* to a program's model and a separate but related practice taking place alongside the program, within the same organization?

These challenges demand a thoughtful and deliberate implementation process, in which researchers work closely with local stakeholders to plan for the implementation of EBPs. During this process, consideration should be given to both the local conditions that make adaptations appropriate in practice, as well as the extent to which they may be

permissible by the theory underlying the intervention (Green & Glasgow, 2006). Finally, descriptions and rationales for adaptations must be documented so that implementation can be more meaningfully evaluated and outcomes can be interpreted more accurately.

Measures

Variables of interest in DI research vary from those in other related areas. Accordingly, measures explicit to DI research have emerged and made it possible to measure constructs from an ecological perspective including provider, client, and organizational variables (Table 5.2). Measures specific to DI processes (as in Proctor et al., 2011) also exist. For further discussion of DI measures, see Lewis, Comtois, and Krimer (2011).²

Measures at the Provider Level

Provider Attitudes

Measure of Disseminability (MOD; Trent, Buchanan, & Young, 2010), a 32-item self-report measure, assesses therapists' attitudes toward the adoption of a particular EBP on a scale from 1 (not at all) to 7 (very much). The MOD is based upon a three-factor model (treatment evaluation, level of comfort, and negative expectations) that has been studied using exploratory and confirmatory factor analysis (Trent et al., 2010). Psychometric properties include strong retest reliability (.93) and internal consistency (.73 to .83; Trent et al., 2010).

Evidence-Based Practice Attitude Scale (EBPAS; Aarons, 2004), a 15-item self-report measure, assesses therapists' attitudes toward the adoption and implementation of EBP on a scale from 0 (not at all) (p. 76) (p. 77) to 4 (to a great extent). The EBPAS maps onto four subscales: appeal, requirements, openness, and divergence (Aarons, 2004). Appeal refers to the extent to which a therapist would adopt a new practice if it is intuitively appealing. Requirements refers to the extent to which a therapist would adopt a new practice if required by his or her organization or legally mandated. Openness is the extent to which a therapist is generally receptive to using new interventions. Divergence is the extent to which a therapist perceives research-based treatments as not useful clinically (Aarons, 2004). The EBPAS demonstrates good internal consistency (Aarons, 2004), subscale alphas range from .59 to .90 (Aarons & Sawitzky, 2006), and its validity is supported by its relationship with both therapist-level attributes and organizational characteristics (Aarons, 2004). Recently, a 50-item version of the EBPAS (EBPAS-50) has been developed and includes an additional eight factors: limitations, fit, monitoring, balance, burden, job security, organizational support, and feedback. Exploratory analyses demonstrated high internal consistency among factors (.77 to .92; Aarons, Cafri, Lugo, & Sawitzky, 2010).

Table 5.2 A Comparison of DI Measures

Measure	Measure Features									
	Provider Level	Provider Attitudes	Provider Knowledge	Provider Fidelity	Organizational Level	Implementation Process	Client Level	Psychometrically Investigated	Freely Available	Website
MOD										
EBPAS										
MPAS										
ASA										
TX-CHAT										

Dissemination and Implementation Science: Research Models and Methods

KEBSQ										http://www.childfirst.ucla.edu/resources.html
CBT-KQ										
TPOCS-S										
ORC										http://www.ibr.tcu.edu/evidence/evi-orc.html
OSC										

Dissemination and Implementation Science: Research Models and Methods

ORCA										http://www.implementationscience.com/content/4/1/38
AII										
SHAY										
TCAT										http://www.ibr.tcu.edu/pubs/datacoll/commtrt.html

Dissemination and Implementation Science: Research Models and Methods

OS										http://www.mh.state.oh.us/what-we-do/protect-and-monitor/consumer-outcomes/instruments/index.shtml
CIS										http://www.dhs.state.il.us/page.aspx?item=32589

Dissemination and Implementation Science: Research Models and Methods

PROMIS										http://www.nih.promis.org/
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Note: MOD = Measure of Disseminability (Trent, Buchanan, & Young, 2010); EBPAS = Evidence Based Practice Attitude Scale (Aarons, 2004); MPAS = Modified Practitioner Attitude Scale (Chorpita et al., 2004); ASA = Attitudes Toward Standardized Assessment Scales (Jensen-Doss & Hawley, 2010); TX-CHAT = Texas Survey of Provider Characteristics and Attitudes (Jensen-Doss, Hawley, Lopez, & Osterberg, 2009); KEBSQ = Knowledge of Evidence Based Services Questionnaire (Stumpf et al., 2009); CBT-KQ = Cognitive-Behavioral Therapy Knowledge Quiz (Latham, Myles, & Ricketts, 2003; Myles, Latham, & Ricketts, 2003); TPOCS-S = Therapy Process Observational Coding System for Child Psychotherapy Strategies Scale (McLeod, 2001); ORC = Organizational Readiness for Change (Institute for Behavioral Research, 2002); OSC = Organizational Social Context (Glisson et al., 2008); ORCA = Organizational Readiness to Change Assessment (Helfrich, Li, Sharp, & Sales, 2009); AII= Adopting Innovation Instrument (Moore & Benbasat, 1991); SHAY= State Health Authority Yardstick (Finnerty et al., 2009); TCAT = Treatment Cost Analysis Tool (Flynn et al., 2009); OS = Ohio Scales (Ogles, Lunnen, Gillespie, & Trout, 1996); CIS = Columbia Impairment Scale (Hurt, Arnold & Aman, 2003); PROMIS = Patient-Reported Outcomes Measurement Information System (Cella et al., 2010).

Feature characterizes model

Modified Practitioner Attitude Scale (MPAS; Chorpita et al., unpublished measure, 2004) is an eight-item measure created for administration to direct service providers to understand therapists' attitudes toward EBP. Items are measured on a scale from 0 (not at all) to 4 (to a great extent). Items on the MPAS are similar to items on the EBPAS but are specifically worded to avoid references to treatment manuals (e.g., referring to treatments rather than treatment manuals). Psychometric properties for the MPAS suggest adequate internal consistency (.80) and moderate relationship with the EBPAS ($r = .36$). The wording in the MPAS (i.e., not referring to treatment manuals but referring to EBP) may result in differential results in reported provider attitudes (Borntrager, Chorpita, Higa-McMillan, & Weisz, 2009).

Attitudes Toward Standardized Assessment Scales (ASA; Jensen-Doss & Hawley, 2010) is a 22-item measure created for administration to direct service providers to understand therapists' attitude towards standardized assessment measures often utilized in EBP. Items are measured on a scale from 1 (strongly agree) to 5 (strongly disagree). Items address three factors: benefit over clinical judgment, psychometric quality, and practicality. Benefit over clinical judgment refers to items assessing the extent to which standardized measures provide extra information above and beyond clinical judgment by itself. Psychometric quality refers to clinicians' beliefs about the reliability and validity of standardized measures. Practicality refers to clinicians' belief about the feasibility of using standardized measure in clinical practice. In an initial psychometric evaluation, internal consistency ranged from .72 to .75, and scale structure was corroborated by a confirmatory factor analysis suggesting adequate model fit (RMSEA = .045, CFI = .935). The measure was also found to be predictive of intentions to use evidence-based assessment (Jensen-Doss & Hawley, 2010).

Texas Survey of Provider Characteristics and Attitudes (TX-CHAT; Jensen-Doss, Hawley, Lopez, & Osterberg, 2009) is a 27-item measure created for administration to direct service providers to understand therapists' attitudes toward EBPs that they are currently using in their clinical practice. Items are measured on a scale from 1 (not at all true for me) to 5 (very true for me). Items map onto five subscales: provider's attitudes toward evidence-based treatments, colleagues' attitudes toward evidence-based treatments, agency support for implementation, barriers to implementation, and quality of training. The measure has held up to initial psychometric investigation with adequate alpha's at .69 or above (Jensen-Doss et al., 2009; Lopez, Osterberg, Jensen-Doss, & Rae, 2011).

Provider Knowledge

Knowledge of Evidence Based Services Questionnaire (KEBSQ; Stumpf, Higa-McMillan, & Chorpita, 2009) is a 40-item self-report measure administered to direct service providers to measure their knowledge of EBP. Items on the KEBSQ include practice elements of EBP and non-EBP used in the treatment of four childhood difficulties: (a) anxious/avoidant, (b) depressed/withdrawn, (c) disruptive behavior, and (d) attention/hyperactivity. In this measure, 40 practice elements are listed and practitioners are to classify if a particular practice element (e.g., relaxation) is used in EBP for each of the four difficulties. Each item is scored on a scale from 0 to 4 with a total possible score of 160; higher scores indicate more knowledge of EBP. The measure has acceptable temporal stability (.56), sensitivity to training, and discriminative validity (Stumpf et al., 2009). Overall internal consistency is low (.46; Okamura, Nakamura, McMillan, Mueller, & Hayashi, 2010), but the original authors caution against measuring internal consistency given that each item represents a unique and independent technique that is not necessarily related to other items (Stumpf et al., 2009).

(p. 78) *Cognitive-Behavioral Therapy Knowledge Quiz* (CBT-KQ; Latham, Myles, & Ricketts, 2003; Myles, Latham, & Ricketts, 2003) is a 26-item self-report multiple-choice measure administered to direct service providers to measure knowledge of CBT in adult patients. Items on the CBT-KQ map onto the following categories: (a) general CBT issues, (b) underpinnings of behavioral approaches, (c) underpinnings of cognitive approaches, (d) practice of behavioral psychotherapy, and (e) practice of cognitive therapy. Each item is scored as correct or incorrect with a total possible score of 26; higher scores indicate more knowledge of CBT. Psychometrics are not yet available.

Provider Intervention Fidelity

Several instruments exist to measure fidelity to specific treatment modalities. For example, for motivational interviewing, one can use the Motivational Interviewing Skill Coding (MISC; Moyers et al., 2003) whereas for cognitive therapy, one can use the Cognitive Therapy Scale (CTS; Young & Beck, 1980), the Cognitive Therapy Scale-Revised (CTS-R; James, Blackburn, & Reichelt, 2001), or the Collaborative Study Psychotherapy Ratings Scale (CSPRS; Hollon et al., 1988). Often, investigators create intervention-specific fidelity measures for the specific EBP they are researching and disseminating (Beidas & Kendall, 2010). Recommendations have been made for using standardized fidelity measures across EBPs; however, there is currently no measure that can be used across EBPs, and as can be seen, often multiple measures exist for the same treatment modality. However, one observational coding system that cuts across modalities for child psychotherapy strategies has been psychometrically explored and is described below.

Therapy Process Observational Coding System for Child Psychotherapy Strategies Scale (TPOCS-S; McLeod, 2001) is a 31-item coding measure intended to allow for description of provision of mental health treatment in practice settings. TPOCS-S subscales differentiate between intervention strategies and include cognitive, behavioral, psychodynamic, family, and client-centered techniques. The TPOCS-S scoring involves

“extensiveness ratings of therapeutic interventions designed to measure the degree to which therapists use specific therapeutic interventions during a therapy session” (McLeod & Weisz, 2010, p. 438). Coders observe sessions and indicate the degree to which a therapist engages in each strategy during the whole session from 1 (not at all) to 7 (extensively). Extensiveness ratings include thoroughness and frequency. Thoroughness refers to depth of provision of intervention; frequency refers to how often a therapist provides the intervention during a session. The TPOCS-S has been psychometrically investigated. The measure has shown good interrater reliability (.66 to .95), internally consistent subscales (.74 to .86), and adequate construct validity (McLeod & Weisz, 2010). The TPOCS-S has been used successfully in studies characterizing usual care (Garland et al., 2010).

Measures at the Organizational Level

Organizational Readiness for Change (ORC; Institute for Behavioral Research, 2002) is a 129-item instrument that measures organizational characteristics and is gathered through administration to various individuals in an organization. Responses are provided based on a 5-point Likert rating scale ranging from 1 (strongly disagree) to 5 (strongly agree). The 18 scales represent three major domains: motivation, resources, and organizational factors. Motivational factors include program needs, training needs, and pressure for change. Resources include office facilities, staffing, training, equipment, and availability of Internet. Organizational factors include staff attributes and organizational climate. Staff attributes include growth, efficacy, influence, and adaptability; organizational climate includes mission, cohesion, autonomy, communication, stress, and flexibility for change.

Psychometrically speaking, the instrument has shown moderate to high coefficient alphas (range: .56 to .92), and support for the factors has been gleaned from principal component analysis (Lehmen, Greener, & Simpson, 2002). This measure has multiple forms to be administered to various individuals within an organization, such as front-line staff and supervisors. Additionally, the measure has been modified for use in settings other than community mental health centers (e.g., criminal justice). Score profiles can be mapped onto norms, allowing for direct comparisons to other national organizations. Ideally, the measure is administered to at least five individuals in an organization (TCU IBR, 2002).

Organizational Social Context (OSC; Glisson et al., 2008) is a measurement system that quantitatively evaluates the social context of mental health and social services organizations through administration to direct service providers. Specifically, the OSC measures both individual-level (work attitudes, work behavior) and organizational-level (culture) variables, as well as individual and shared (p. 79) perceptions (climate). Assessing the social context of an organization makes it possible to capture features that may influence service and treatment, clinician morale, and adoption and implementation of EBP.

The OSC has 105 items that form 16 first-order scales and 7 second-order scales. Factors are grouped by structure, culture, psychological and organizational climate, and work attitudes. Culture refers to the norms and values of an organization; climate refers to the impact of a work context on an individual. Work attitudes refer to morale of an individual worker. The measurement of these factors together allows for an understanding of an organization's context and can be compared with norms of national service settings. Confirmatory factor analysis supported these factors; alpha coefficients for scales range from .71 to .94 (Glisson et al., 2008). It is preferable that four or more individuals from an organization complete this assessment for adequate measurement of organizational climate (P. Green, personal communication).

Measures Specific to DI Processes

The instruments below measure specific constructs relevant to DI processes and either map onto relevant DI models (e.g., PARIHS, DOI) or provide information specific to Proctor and colleagues' (2011) suggested implementation outcomes.

Organizational Readiness to Change Assessment (ORCA; Helfrich, Li, Sharp, & Sales, 2009) operationalizes the core constructs of the PARIHS framework. The ORCA is a 77-item measure that is administered to staff involved in quality improvement initiatives; responses range from 1 (very weak) to 5 (very strong). Items map onto three scales that make up the core elements of the PARIHS framework: (a) strength and extent of evidence, (b) organizational climate, and (c) capacity for internal facilitation of QI program. A three-factor solution was identified via exploratory factor analysis, and reliability (.74 to .95) was acceptable, but further validation is necessary (Helfrich et al., 2009). A follow-up study found the preimplementation ORCA scores to be predictive of low and high implementation rates across sites (Hagedorn & Heideman, 2010).

Adopting Innovation Instrument (Moore & Benbasat, 1991) is a 38-item self-report measure that assesses perceptions a provider may have toward adopting an innovation. In the rigorous development of this instrument, the authors specifically aimed to measure the constructs that Rogers (2004) proposed. Specifically, this instrument contains eight factors: relative advantage, compatibility, ease of use, result demonstrability, image, visibility, trialability, and voluntariness. Psychometrics are adequate with regard to reliability (.71 to .95) and validity, with a principal component analysis identifying seven factors (Moore & Benbasat, 1991).

State Health Authority Yardstick (SHAY; Finnerty et al., 2009) is a 15-item agency-specific behaviorally anchored instrument that assesses systems-level considerations that are relevant to the implementation of EBP. Specifically, the SHAY assesses seven domains: planning, financing, training, leadership, policies and regulations, quality improvement, and stakeholders. Items are rated from 1 (little or no implementation) to 5 (full implementation). The SHAY is intended to be administered by two independent raters who interview multiple informants in an organization. The two raters make independent ratings and then create consensus ratings. Initial evidence partially supports construct

and criterion validity of the instrument in assessing state-level facilitators of and/or barriers to EBP implementation (Finnerty et al., 2009).

Treatment Cost Analysis Tool (TCAT; Flynn et al., 2009) is a measure created to assist in cost analysis of outpatient substance abuse treatment programs. To generate cost analysis, the TCAT includes information about client volume, counseling, total program costs, overhead costs, and personnel data. The measure is easy to use and is available through an Excel spreadsheet. This measure provides information on cost effectiveness as suggested by Proctor and colleagues (2011).

Measures at the Client Level

Given the complexity of DI studies, client measures to address client characteristics and client outcomes should be easy to implement and score, freely available so that their use may be sustained following the research project, and specific to the research question. Several large systems have adopted outcome measures that would be appropriate in DI research studies.

For example, Illinois requires the Ohio Scales (Ogles, Lunnen, Gillespie, & Trout, 1996) and Columbia Impairment Scale (Hurt, Arnold & Aman, 2003) for all children funded by Medicaid. The Ohio Scales (Ogles et al., 1996) focus on efficient administration, scoring, and interpretation. There are three parallel forms of the Ohio Scales that can be completed by the youth, caregiver, and service provider. All forms include questions relating to problem severity, functioning, satisfaction, and hopefulness. These scales were developed not (p. 80) to diagnose youth but to provide an efficient means of tracking outcomes in community agencies. Psychometric properties are solid with adequate test-retest reliability (.65 to .97) and preliminary validity (Ogles et al., 1996). The Columbia Impairment Scale (CIS; Hurt et al., 2003) focuses on impairment of functioning and assesses how well an individual carries out age-appropriate daily activities. The items are scored on a 4-point scale, with a greater score indicating greater impairment. The CIS can be filled out by either a clinician or a caregiver and demonstrates good internal consistency, test-retest reliability, and validity (Hurt et al., 2003).

An exciting initiative sponsored by the National Institutes of Health also has produced efficient and easily accessible outcome measures that can be utilized in DI studies: the Patient-Reported Outcomes Measurement Information System (PROMIS). The goal of this project is “to develop and evaluate, for the clinical research community, a set of publicly available, efficient, and flexible measurements of patient-reported outcomes, including health-related quality of life” (Cella et al., 2010, p. 1180). Content areas for items include physical health (e.g., fatigue), mental health (e.g., anxiety), and social health (e.g., social function). These items are available as paper-and-pencil measures and computer adaptive tests. Large-scale testing of PROMIS items suggests good reliability and validity. A larger discussion of PROMIS is beyond the scope of this chapter, but these tools may be particularly well suited for DI studies given their brevity, ability to be tailored to particular populations, and ease of use. For example, if one is interested in studying the

DI of CBT for youth anxiety disorders, one could use the pediatric PROMIS anxiety and depressive symptoms scales to measure outcomes (Irwin et al., 2010).

Conclusion and Future Directions

DI science is a relatively new area of inquiry within mental health services research that strives to understand the key mechanisms and processes needed to expand the utilization of EBP in community mental health settings. DI research aims to bridge the research-to-practice gap that prevents knowledge and practices of effective treatments from reaching many people in need (Weisz, Donenberg, Han, & Kauneckis, 1995). Researchers focus on the need to systematically study the process of DI to increase the use of best practices in community mental health settings (Schoenwald & Hoagwood, 2001; Schoenwald, Hoagwood, Atkins, Evans, & Ringeisen, 2010).

Several models relevant to DI research were described. Comprehensive models (e.g., CFIR; Damschroder et al., 2009) provide heuristics as to areas and levels of study, while more specific models (e.g., TPB; Ajzen, 1988, 1991) describe specific targets that might be vital to understand DI mechanisms. The comprehensive models underscore the importance of considering multiple levels of change and organization, leading to the need for complex studies that address not only *whether* an implemented intervention has the desired effect, but also *how* the context affects the changes (or lack thereof) that may be a result of the intervention. This necessitates the careful and thoughtful assessment of fidelity and a thorough understanding of the issues that are inherent in fidelity measurement (e.g., What are the core elements of the intervention? Is ongoing quality assessment incorporated into the DI process? Can interventions be adapted with fidelity?). With regard to adaptation, empirical questions to tackle include: What adaptations, for whom, result in improved client outcomes? Do adaptations result in higher rates of implementation or sustainability of EBP? When does flexibility in implementation of an EBP become infidelity (Kendall & Beidas, 2007; Kendall et al., 2008)?

The specific models reviewed suggest possible targets of intervention to optimize DI efforts. For example, models emphasizing the organizational context of DI efforts (e.g., ARC; Glisson & Schoenwald, 2005) suggest that key components of the organizational context such as norms and expectations within the setting may influence DI outcomes. An organizational perspective includes how to influence and support an organization in the adoption and implementation of EBP. Traditionally, this perspective has included an understanding of the structures needed to support new models and learning and infrastructures that can support new models of mental health services. For example, providing facilitation to an organization in the creation of the structures and infrastructures needed to support a new intervention model increased the likelihood that

a particular intervention was adopted and more clients improved following implementation (Glisson et al., 2010).

Other important organizational considerations include the role of social networks within DI efforts. Given that adoption of EBP may be a slow process, program response needs to be understood as unfolding over time, requiring longitudinal studies that account for the differential adoption of interventions. In addition, if programs are not adopted (p. 81) throughout a social system such as an agency or school, this may suggest that the program is not seen by a sufficient number of members as appropriate to their needs. This could lead to a series of questions as to how to adapt programs or how to activate key opinion leaders to influence mental health program use to inform DI efforts throughout a social system (Atkins et al., 2008). Key questions with regard to how organizational context may influence DI outcomes include: How do organizational constructs (e.g., organizational support) operate to facilitate or impede DI? How can knowledge of barriers/facilitators be used to coordinate and augment DI of EBP in community mental health settings? How can organizational interventions effectively improve DI efforts? How can social networks be used to augment DI?

A fundamental issue that arises when taking an organizational perspective is the natural tension between the adaptability of a services setting and the adaptability of a new intervention. There is often an implicit assumption that a service setting is ready to adopt a new intervention. However, if one takes an ecological perspective, there is an active transactional interplay between an organization and a new intervention, with the organization influencing the intervention and the intervention influencing the organization. For example, the organization is likely to be constrained by the structure of the agency, staffing, and budget issues, whereas intervention delivery may be constrained by the common elements that are required to effect change. How and what changes at each level is an empirical question that can enhance the understanding of DI processes and mechanisms. Research that addresses and resolves this tension is paramount.

As stated earlier, the added complexity of including multiple levels of change (i.e., individual, organizational) within a study calls for research methods and design that may stray from the traditional models or “gold standard” of RCTs. Although it remains important to assess and evaluate client outcomes, there are several methods to augment traditional RCT designs, as well as alternative designs (e.g., PCTs). Research on the development of DI-specific methods is sorely needed. Choosing a specific research design requires consideration of the most effective method and design to answer the specific research questions, the strengths and weaknesses of each design, the context of the research, and the available resources. Relying on mixed-method designs may be optimal given that different levels of inquiry may address various questions within the same research study. Finally, there are both proximal and distal outcomes that are relevant for DI research. For example, measuring organizational change or therapist attitude change is a proximal outcome, whereas improved client outcome is the distal outcome.

Despite the many challenges, DI research has an important place in the field of mental health services research. The primary goal of DI research is to identify key processes and mechanisms for change while spreading EBP into community mental health settings (i.e., dissemination), resulting in uptake and adoption of such new technologies (i.e., implementation) that is sustainable (i.e., is maintained). The public policy implications of such empirical inquiry are substantial, given the unmet mental health needs within the U.S. population. One study found that only 21% of in-need children received mental health services within a year and that uninsured youth were especially vulnerable (Kataoka, Zhang, & Wells, 2002).

The public policy implications of DI research suggest that policymakers can, and will, play a key role in shaping the future of DI efforts. Recently, policymakers have been moving from passive users of technology to active participants in a process of DI. For example, Illinois policymakers are insisting that mental health providers implement EBP (e.g., Illinois requires that agencies receiving grants to implement school-based mental health services utilize EBP). This results in the formation of a critical relationship between policy and DI efforts and also provides an opportunity for research and policy to inform one another. Future research can include key questions with regard to public policy such as: How can researchers engage and capitalize on the push policymakers are currently making for the use of EBP? How can researchers partner with policymakers to ensure that efforts are indeed effective and sustainable?

New knowledge is a key feature of all research. DI research can contribute new knowledge both through an understanding of the support and monitoring structures that are needed to support DI of effective practices and the natural processes that support DI, such as social networks and key opinion leaders. Mental health service settings can be transformed with potentially enormous impact on the public health of the general population.

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Notes:

(1.) The term “model” encompasses theories, models, and frameworks in this chapter.

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