Chapter 5
The State of the Evidence for Integrated Behavioral Health in Primary Care

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Abstract Integrated behavioral health care is a complex, multifaceted healthcare delivery approach that is geared towards addressing mental and behavioral health concerns in primary care. There are a number of different models for integrated behavioral health care, with components that can be conceptualized as structures of care, processes of care, or principles of care. Common models include the IMPACT model (care management for depression), the three-component model (care management, enhanced mental health support, and a prepared practice), and the primary mental health care model of colocated integrated behavioral health care (on-site mental health specialists who collaborate with primary care providers), among others. Meta-analysis has shown that integrated behavioral health care improves health outcomes, although the extant evidence primarily pertains to depression. It is not well known which components of integrated behavioral health care are either necessary or sufficient for improving outcomes. There are many evidence gaps in integrated behavioral health care, including implementation and dissemination and the effects of integrated behavioral health care on disease contexts other than depression, behavioral medicine (e.g., lifestyle change in primary care), diverse populations, and cost and sustainability outcomes. Multiple methodologies should be deployed to address these gaps, including quasi-experimental, mixed methods (quantitative and qualitative), and observational designs.

Introduction

Integrated behavioral health care for mental and behavioral health in primary care settings is a general healthcare delivery concept that encompasses many complex multifaceted systems and practice models. These models are many and varied, but

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generally include the following basic elements: a collaborative team comprised of mental/behavioral health and medical providers; protocols for identifying, triaging, treating, and tracking mental health concerns from within primary care; and supporting information technology infrastructure (Peek, 2011). The primary goal is to improve patient health outcomes (e.g., quality care); additional goals may include reducing costs and increasing efficiency (e.g., high-value care) and enhancing patient and provider satisfaction (e.g., the Triple Aim; Berwick, Nolan, & Whittington, 2008). The status quo in the US healthcare delivery system is that mental and behavioral health concerns are largely addressed by separate and distinct specialty mental health and private care settings (or not addressed at all). Such a system is often described as "fragmented" and difficult for both patients and providers to navigate.

In order to justify wide-scale system changes towards integrated behavioral health care, conclusive and consistent evidence is needed to convince policy and decision makers (including payers) of the value of collaborative care compared to the status quo. Such evidence includes an understanding of the models and their attributes that are feasible, sustainable, affordable, and effective. Such convincing evidence can only be the result of rigorous research and systematic evaluation designed to compare outcomes in integrated versus usual care settings. While the evidence base is fairly well established in some domains (e.g., primary care-based management of depression), in others it is quite sparse. Additionally, much of the research that has been done has been focused on the implementation of specific care protocols that feature aspects of integrated care, often targeted to particular chronic diseases or populations, with few evaluations of efforts to more globally transform the organizational aspects of practices into an integrated model. Mental and behavioral health providers in collaborative care models are positioned not only to aid in the treatment of specific mental disorders, but to enhance self-management of health through behavior change (e.g., motivational interviewing). The scope of the promise of integrated behavioral health care is as yet unrealized, and a key focus of future research should include both mental and behavioral health care.

The purpose of this chapter is therefore to describe the current evidence base (including reviews and meta-analyses), to identify evidence gaps, and to describe a range of research objectives and methodologies needed to fill these gaps. To facilitate interpretation of the evidence and identification of research gaps, the first step is to define integrated behavioral health care, with all of its complexities and variations. There are many terms used to represent this concept, including collaborative care, mental health integration, integrated care, integrated mental health and integrated behavioral health. We follow the standard adopted for this volume and use integrated behavioral health to refer generally to these models; however, when referring to specific projects or reviews, we use the authors' original terms. A number of attempts have been made to distill the concept of integrated care for the purposes of evaluation and comparison of the existing evidence (Blount, 2003; Butler et al., 2008; Collins, Hewson, Munger, & Wade, 2010; Doherty, McDaniel, & Baird, 1996). For instance, Blount (2003) described several key dimensions of the various models of integrated primary care: the relationship between mental health and primary care services

(coordination, colocation, and integration), the populations served (targeted to patients with specific mental health needs vs. non-targeted), and the specificity of treatment modalities (a particular treatment protocol is specified vs. unspecified treatment that is essentially "provider's choice"). In a recent report from the Agency for Healthcare Research and Quality (AHRQ), the key dimensions outlined concerned systematic screening, integrating providers, and integrated care/proactive follow-up (Butler et al., 2008). Level of integration of the care process has been said to consist of ten elements (Butler et al. 2008, 2011), including (1) screening, (2) patient education/self-management, (3) medication, (4) psychotherapy, (5) coordinated care, (6) clinical monitoring, (7) assessment of medication adherence, (8) standardized follow-up, (9) formal stepped care, and (10) supervision. Level of integration of provider roles consists of degree of shared decision making between primary care and mental health providers (consensus, coordinated, or PCP principal responsibility), colocation of primary care and mental health, shared medical records, and communication links (such as e-mail or phone; Butler et al., 2008).

Most recently, Peek (2011) compiled a set of parameters to define a paradigm case for integrated behavioral health care, along with acceptable variations. According to Peek, an integrated behavioral health care practice has "a team with a shared population and mission, using a clinical system supported by an office practice and financial system and continuous quality improvement and effectiveness measurement." While this may represent the ideal or "paradigm" case for integrated behavioral health care, the forthcoming review of the evidence will reveal that little to none of the research conducted to date relates to something truly meeting this definition. Thus, this chapter will describe the variations on the theme of integrated behavioral health care and the evidence (or lack thereof) in support of each. We will then note the many gaps in this literature, especially concerning research on models consistent with the AHRQ report on integrated behavioral health care parameters and acceptable variations, and models consistent with what healthcare organizations are implementing in the real world.

Integrated Behavioral Health Models: Identifying Structural Features and Clinical Processes

As first proposed by Donabedian (1988), it is useful to consider healthcare delivery system models' structure and processes, which then can be examined in terms of their impact on specific outcomes. Integrated behavioral health care can be conceptualized as a set of structural features (clinical, operational, and financial) intended to help address mental health concerns as part of primary care. Research and evaluation can be designed to test the effects (across a range of outcomes) of these features individually, or, more realistically, as part of a comprehensive model. Indeed, it has been argued that integrated care is more than the sum of its parts, and thus we cannot easily evaluate the unique impact of any

given component of an intervention or process change (Miller, Mendenhall, & Malik, 2009). Additionally, integrated care could be conceptualized as a set of processes expected to address a range of populations and health concerns, and targeted to particular outcomes. These processes could be performed under any number of different structural models, some of which may be more feasible or effective for achieving good outcomes in certain contexts. In addition to clinical outcomes, Blount (2003) suggested that attention to a broader array of nonclinical, process-oriented outcomes (e.g., patient and provider satisfaction, adherence to treatment regimens and evidence-based guidelines, and cost-effectiveness/cost-offsets) would facilitate comparison of various models. Access to care, detection, and treatment of mental and behavioral health concerns, practice-level improvement over time, and sustainability are likely all critical outcomes (Miller et al., 2009).

Going beyond Donabedian, a third component of integrated behavioral health care may be the overarching principles or attitudes towards mental health, the need to address it in primary care, and the practice of integrated behavioral health care itself that are embodied by healthcare organizations and their leaders, health care providers, and patients. Research on integrated behavioral health care could be conducted or interpreted based on any of these perspectives.

Structural Features of Integrated Behavioral Health

What happens in an integrated care delivery model? Who delivers care, where, and in what manner? What tools, resources, and infrastructure are needed to support the delivery of care? Table 5.1 represents a conceptual organization of the wide range of structural features of integrated behavioral health care, compiled based on descriptions of both research-based and real-world models of collaborative care, in order to identify gaps in the evidence.

Integrated Behavioral Health Care Processes

The structural features listed above comprise the practice and organizational infrastructure designed to provide mental health care to primary care patients (or vice versa). Ultimately, it may not matter what exactly this infrastructure looks like as long as it enables the provision of certain services. That is, the essential processes (Table 5.2) of an integrated behavioral health care infrastructure for any given setting are those that enhance access to care, detection, and treatment of mental health concerns, facilitate practice-level improvement over time, and are sustainable in terms of resources (Miller et al., 2009). While the structural features are the necessary but not sufficient tools for providing integrated care, these processes define the work done in an integrated behavioral health care setting. At a high level, these

Table 5.1 Structural features of integrated behavioral health care

Structural features	Possible components
Care delivery team	Medical care providers
	Mental/behavioral health providers (e.g., doctoral and masters level therapists, psychiatrists, social workers)
	Supporting nursing staff
	Supervising providers
	Care managers
	Clinical pharmacists
	Patients and families
Physical space	Dedicated space in a practice for mental and behavioral health care providers to interact privately with other providers *or* with patients both individually and in groups
	Practice location (freestanding clinic, part of larger hospital system, etc.)
Information technology	Computers and telephones
	Electronic medical records
	E-mail
	Registries
	Dashboards and portals for tracking outcomes
	Telemedicine (e.g., video conference)
	Mobile health technology
	Triage and clinical decision support
	Data collection and use (e.g., for quality improvement)
Office management policies and protocols	Established leadership (organizational and practice level) who have developed:
	Practice mission and values
	Time and effort protocols (how much time spent consulting with other providers vs. seeing patients)
	Provider access to patient records
	Privacy policies
	Billing and coding policies and protocols
	Incentives and organizational support for collaboration across disciplines
	Data collection and analysis policies and infrastructure (e.g., patient and staff satisfaction, measurement of processes and outcomes)
	Quality improvement models, teams, and procedures (e.g., Plan-Do-Study-Act [PDSA], Six Sigma, Continuous Quality Improvement [CQI])
Clinical care policies and protocols	Screening and population identification protocols
	Risk stratification and algorithms for determining appropriate level of care
	Diagnosis and Assessment Protocols
	Treatment protocols (e.g., use of evidence-based guidelines, stepped care)
	Monitoring and follow-up protocols
	Referral protocols
Education and training	Training programs (e.g., Primary Care Psychology Fellowships)
	Continuing education
	In-services
	Resources for attending conferences
	Informal consultation
	Practice preparation for change
	Team-building exercises

Table 5.2 Integrated behavioral health care processes

Process to enhance or optimize	Services routinely provided to patients and processes designed to enhance quality and value of care
Access	On-site mental/behavioral health
	Lists of local providers
	Helping people sign up for insurance
	Carve-ins versus carve-outs
	Matching with insurance coverage
	Navigation and care coordination services
	Connecting patients to community programs
Detection	Diagnosis and assessment
	Psychological testing
	Systematic mental health screening
	Systematic tracking and follow-up (primary prevention/at risk or at risk of relapse)
Treatment	Care management
	Evidence-based treatment
	Medication
	Psychotherapy and counseling (individual, group, couples, family)
	Shared/collaborative medical visits
	Patient education and skills building
	Counseling and support for patient self-management/behavior change/engagement/activation (e.g., motivational interviewing)
Practice improvement	Quality improvement processes
	Appropriate investment of resources to enhance quality and value of care
	Workforce development
Cost/sustainability	Processes for ensuring appropriate allocation of resources (utilizing community resources, leveraging less expensive personnel such as trainees)
	Securing funding (fund-raising, grant writing, advocacy, and building partnerships with payers to adapt reimbursement strategies and change policy)
	Ensuring receipt of payment for billable services
	Offering services for which patients are willing to pay out of pocket

processes include effective communication within the care delivery team and with patients and families, and monitoring change over time, with respect to the provision of services, appropriate resource allocation, and patient health status.

Principles and Attitudes Towards Integrated Behavioral Health Care

The most successful integrated behavioral health care systems are likely exemplary not only in terms of adequate staffing and resource allocation, but also embody certain attitudes, principles, and policies indicative of organizational value of

integration. This includes principles such as the inseparation of physical and mental health, and the importance of the mind-body connection and caring for the whole person. Attitudes towards other care team members, the value of mental and behavioral health care, and the respective roles of mental and behavioral health versus medical care providers in primary care may also be relevant. If the structural features are the tools and the processes are the work, then the principles and attitudes are the energy compelling the investment of resources and the effort. These principles and attitudes are those held by the providers themselves, by organizational leadership, and by patients and families, and could directly impact the quality of the collaborations, relationships among mental health and primary care providers and patients and families, and ultimately both clinical and financial outcomes. This, however, has not been tested empirically, and most existing work is qualitative.

A number of the structures and processes described above are meant to support the development of positive attitudes and relationships within the care team and with practice management (e.g., education and training). Furthermore, the endorsement of such pro-integrated behavioral health care attitudes may facilitate implementation of practice changes. Positive provider attitudes (e.g., endorsement of the biopsychosocial model) and sensitivity to patient beliefs and preferences, including cultural competence, are said to enhance patient engagement (Beck & Gordon, 2010). At the organizational or administrative level, leadership must recognize the inherent challenges associated with change, and take care to engage practices in and adequately prepare them for the change process. According to Oxman and colleagues (Oxman, Dietrich, Williams, & Kroenke, 2002), a prepared practice is one in which providers have received education on how to follow new practice protocols. Feeling confident in one's abilities to follow new procedures is widely known to facilitate behavior change. Beyond knowledge about guidelines, skills, and communication protocols, however, team-building exercises, including the sharing of training backgrounds, perspectives on care, and strategies for collaboration and shared decision making, would be valuable. Chapter 10 discusses in further detail the relationship factors that are essential for successful collaboration.

Empirical Evidence for Integrated Behavioral Health Care

As mentioned above, much of the early work on integrated behavioral health care focused on depression. This grew directly from the work of Regier and others (Katon & Schulberg, 1992; Regier, Goldberg, & Taube, 1978; Schulberg, 1991) that identified primary care as the source of much mental health care. Subsequent studies examined the quality of care and efforts to improve screening (IMPACT, PRIMeMD, increasing use of the PHQ-9 to screen for depression), leading up to the landmark Agency for Health Care Policy and Research (AHCPR; now the AHRQ) depression guideline (Depression Guideline Panel, 1993). Subsequent work was then focused on trying to improve care once depression was identified. These focused, protocol-driven research projects have been essential for improving the way we attend to mental health in primary care. Increasingly, as our understanding

of depression as a comorbid condition with other chronic diseases has grown, our conceptualization of integrated behavioral health care has transformed into something more broadly concerned with a range of mental health and behavioral health concerns in primary care populations. The systems and tools that have been developed—the use of care managers, integrated information systems, screening tools, protocols, and algorithms for providing the right level of evidence-based treatment, colocated mental/behavioral health providers and training programs—can be adapted to cover this broad range of care. This description of the evidence will start with coverage of the existing systematic reviews and meta-analysis, which are necessarily focused on the more classic models of integrated behavioral health care. A discussion of the classic models (care management for depression) and the contemporary models (integrated behavioral health care systems addressing a range of need) will ensue, including presentation of select research evidence. We will briefly mention how these integrated behavioral health care models have been used to facilitate patient self-management and behavioral health.

Systematic Reviews and Meta-analysis

Previous reviews of the literature support the conclusion that integrated care leads to better clinical outcomes—especially in terms of the treatment of primary care patients with depression. In their 2006 review of collaborative care for depression, Gilbody and colleagues (Gilbody, Bower, Fletcher, Richards, & Sutton, 2006) performed a meta-analysis of both short-term and long-term outcomes of 37 randomized controlled trials for the treatment of depression using a collaborative care approach. They defined collaborative care as "a multifaceted intervention involving combinations of three distinct professionals working collaboratively working within the primary care setting: a case manager, a primary care practitioner, and a mental health specialist." Compared to usual care, collaborative care for depression led to better depression outcomes at six months (standardized mean difference [SMD] = 0.25, 95 % CI: 0.18–0.32) and longer term (1–5 years; SMD range 0.31 at one year to 0.15 at five years post-intervention, all confidence intervals excluded zero). The effect size was related to medication compliance and the professional background and supervision method of case managers, such that effects were larger for case managers with mental health training and regular, planned supervision. While considerable heterogeneity in effects was observed for earlier studies (in the 1980s and 1990s), as of 2006, the post-2000 evidence demonstrated more stable estimates of the effectiveness of collaborative care for managing depression. Of note, the authors concluded that further research would likely not reverse the conclusions that collaborative care for depression is effective.

In a systematic review, Oxman, Dietrich, and Schulberg (2005) described the research on collaborative care models as representing a third generation of research on the treatment of depression in primary care, following a first generation of multifaceted, collaborative care interventions and a second generation

grounded in the principles of the chronic care model and guideline-based care. In this third generation (including the PRISM-E, IMPACT, PROSPECT, and RESPECT-D studies), there was increased emphasis on effectiveness rather than efficacy in the context of translation, dissemination, and sustainability (especially concerning system and practice redesign), and attention to aging populations. An enhancement of "consultation-liaison skills" and better relationships between primary care clinicians and mental health specialists was considered an important advancement in the field. While it was concluded that referral to specialty mental health care would likely lead to better outcomes at an individual level, it was also acknowledged that overall population health would be best improved with the more limited care made available from within primary care because of increased access. In another review, Katon and Seelig (2008) noted that a population-based approach that coordinates the care of depression from within primary care should be particularly effective for reducing overall prevalence of depression. They suggest that three activities well suited to primary care are key to secondary prevention of depression: improved diagnosis (including screening for risk factors and early evidence of minor depression), preventing chronicity, and preventing relapse/recurrence by virtue of more frequent contact and opportunities for tracking and monitoring symptomology.

Recently, the AHRQ published an in-depth report on mental health integration in primary care (Butler et al., 2008). The primary conclusion of this comprehensive review was that while there did not appear to be a relationship between level of integration and effects on clinical outcomes, the purported benefits of integrated care for managing both depression and anxiety were supported by the evidence. Similar methods later applied to the literature on integrated care for depression alone reached the same conclusion—integrated care improves depression outcomes, but level of integration (e.g., degree of shared treatment decision making or extent of colocation) in the care process or in provider roles was not associated with better outcomes (Butler et al., 2011). In both cases, the model with the most support for its effectiveness (in terms of symptom severity but not treatment response or remission rates, which did not differ among the various models) was the IMPACT model. However, it was noted that a continuing limitation in this literature is an inability to separate the effect of specific elements of integrated care on better outcomes from the overall effect of more attention to mental health problems as a result of integration. There are indeed many ways of conceptualizing integrated care, and attempts to quantify a global level of integration rather than distinct elements of the various models that can be independently evaluated have not yielded any increased understanding of how or under what circumstances integrated care is effective. As has been noted in meta-analysis (e.g., Gilbody, Bower, Fletcher, et al., 2006), there is heterogeneity in the effects of integrated care on depression—which therefore suggests that there is *some other variable or set of variables* related to how integrated behavioral health care is implemented (in what context, in what population, using which evidence-based treatments, by whom, with what mindset, in what permutations) that differentially influences outcomes.

Past attempts have been made to determine "active ingredients" of integrated care. In a review from the Canadian Collaborative Mental Health Initiative (CCMHI), Craven and Bland (2006) reached conclusions supporting several elements of integrated care as key factors in improving outcomes, including practice preparation, colocation, collaboration (especially when paired with treatment guidelines), systematic follow-up, patient education, sensitivity to patient preference, and counseling to promote treatment engagement and adherence. In a meta-analysis and meta-regression of specific intervention content, eight aspects of these interventions that varied across 34 studies on collaborative care for depression were tested as predictors of depression outcomes (Bower, Gilbody, Richards, Fletcher, & Sutton, 2006). These variables included setting (USA vs. non-USA), recruitment method, patient population, primary care physician training, case manager background, case management sessions, case manager supervision, and case management content. Of these, four were at least marginally significant predictors of depression symptoms in multivariate analyses—setting (in favor of non-USA studies), recruitment method (in favor of systematic identification through screening rather than referral by clinicians), case manager background (in favor of those with mental health expertise), and case manager supervision (in favor of those receiving regular/planned supervision). Notably, no aspects of intervention content predicted antidepressant use. While the heterogeneity in effect sizes for depression symptoms was reduced when considering these particular aspects of intervention content, as above, it appeared that there were as yet unmeasured intervention features or aspects of study context or setting influencing results. It may be that these unmeasured features are organizational aspects related to the principles and attitudes towards integrated care as described above.

More supporting evidence for these conclusions is emerging. While difficult to separate from other aspects of multifaceted interventions, care management does appear to be an important factor in depression care (Williams et al., 2007). However, care management is a role that functions in different ways across different contexts, and it is therefore not clear which are the most effective components of care management, which background or training is needed for care managers, or whether ongoing supervision of care managers is truly necessary. In a more recent meta-analysis of studies evaluating the effects of interactive communication between primary care clinicians and specialists—defined as "direct, personal interaction with specialists… such as curbside consultations" (Foy et al., 2010, p. 247)—randomized trials involving collaboration between primary care clinicians and psychiatrists on average exhibited a small to medium effect size for mental health outcomes in favor of collaboration. This is consistent with recent findings of a Congressional Budget Office review of Medicare Demonstration Projects, which found that in-person interactions between care managers, providers, and patients were uniquely associated with programs that demonstrated improved outcomes (Nelson, 2012). Continued investigation into the effectiveness of various elements of collaborative care, especially outside the context of depression care, is warranted. Next, we discuss exemplary and prototypical models of integrated behavioral health care, and research and evaluation of instances of these models.

Specific, Exemplar Studies of Integrated Behavioral Health Care Interventions

There are several models of integrated behavioral health care that have been tested using randomized trial designs, still considered to be the gold standard for establishing clinical effectiveness. Many of these models were designed specifically for depression, but the guiding principles and structural features of the care delivery system would presumably apply to other mental illnesses (with some evidence, described below, supporting this supposition). These models share various versions of care/case managers who act as intermediaries or partners with primary and specialty care, with differences in the specific protocols and degree to which care managers and specialty care is embedded within individual primary care clinics. A sampling of the models that have been subject to research and formal evaluation and major conclusions from this work are described here. Others have compiled detailed reviews of the evidence, including a deconstruction of the randomized trials of integrated behavioral health care and/or related interventions for mental health in primary care (Butler et al., 2008; Craven & Bland, 2006; Williams et al., 2007), and thus we will not repeat this work; we will, however, describe the major models of integrated behavioral health care and exemplar research on each.

IMPACT. The IMPACT model of collaborative care was originally conceptualized as a chronic disease management program for older adults with depression (Unutzer et al., 2001, 2002). This model involves a team-based approach to managing depression from within primary care. The care team includes a trained depression care manager, a primary care provider, and a consulting psychiatrist. The team uses a stepped-care approach to managing depression, with a three-step evidence-based treatment algorithm used to guide care advancement. At each step, psychiatric consultation is considered if clinically indicated, and care plans are discussed with the PCP and the consulting psychiatrist. Patients receive routine screening for depression. The acute and maintenance phases of depression are tracked by the care manager, a nurse, or psychologist who provides education, care management, and medication support or psychotherapy, with regular telephone follow-up for a year (weekly at first, and then less frequent as depression lessens). Treatment options include antidepressant medication or brief psychotherapy (Problem-Solving Treatment in Primary Care).

The IMPACT model has very good empirical support (http://impact-uw.org/about/research.html), across a number of health care settings and populations. In the initial grant-supported, multisite randomized trial, those in the intervention group had higher rates of depression treatment (odds ratio [OR] = 2.98 [2.34, 3.79], $p < 0.001$) and experienced significantly greater odds of 50 % reduction in depression symptoms than those in the usual care group (OR = 3.45 [2.71, 4.38], $p < 0.001$; (Unutzer et al., 2002). Usual care patients were also screened for depression and could receive treatment for depression through all existing channels. Evidence also suggested that the intervention led to lower health care costs over a four-year period (Unutzer et al., 2008). More than fifty publications have resulted from research on the IMPACT model (http://impact-uw.org/files/IMPACTPublicationsList.pdf),

with overall favorable results. Having demonstrated the effectiveness of this model, research on IMPACT has shifted towards more complex populations (e.g., patients with comorbid mental health and physical health concerns) and wide-scale implementation and dissemination research, such as the DIAMOND project.

The "Depression Improvement Across Minnesota, Offering a New Direction" (DIAMOND) project is intended to incorporate the IMPACT collaborative care model for depression management in primary care practices throughout the state of Minnesota, using a new payment mechanism agreed upon by participating payers. In contrast to the original IMPACT studies, DIAMOND was designed to evaluate a structure of collaborative care that includes specific elements, rather than a specific care protocol that features collaborative care. An NIH-funded "T3" implementation study was designed to evaluate DIAMOND using a staggered implementation, multiple baseline design based on methods for practical clinical trials (Solberg et al., 2010). There are six components of collaborative care that have been implemented in DIAMOND: depression screening using the PHQ-9, tracking and monitoring with a patient registry, stepped care for depression, relapse prevention planning, care management, and psychiatric consultation and supervision. Within the quasi-experimental evaluation design, implementation of collaborative care and the corresponding changes in reimbursement is staggered in five sequences over 3 years, with 10–20 new clinics implementing the intervention during each sequence (a total of up to 85 clinics in 16 separate healthcare organizations). Patients are identified and data are collected weekly for thirty-seven months in all sites, before and after implementation of the intervention. Sites therefore serve as their own control, with multiple preimplementation scores on key outcomes for each site. Outcomes include use of evidence-based practices for depression (e.g., Institute for Clinical Symptoms Improvement's guidelines for treatment of depression in primary care (Trangle et al., 2012), depression symptoms, health care cost, and work productivity. Using the RE-AIM framework, outcomes related to translation and dissemination will also be evaluated. Among the benefits of this approach are the implications for generalizability to diverse patient populations and practice settings, as well the potential to evaluate questions of reach and organizational context. However, as might be expected in this sort of innovative natural experiment, challenges and tensions between the need to adhere to a study protocol and the practical goals of the overarching initiative have been reported. Results have not yet been reported in the peer-reviewed literature.

Various other integrated care interventions have been based on variations on the theme of care management. The Prevention of Suicide in Primary Care Elderly: Collaborative Trial (PROSPECT) study utilized care managers who used a protocol-based intervention to monitor depression treatment adherence and response and provide guidelines-based recommendations to physicians, the sole decision makers (Bruce et al., 2004). The care managers were nurses, social workers, and psychologists. Patients were offered citalopram as a first course treatment, or interpersonal psychotherapy (IPT) delivered by the care managers if they declined antidepressant medication. PCPs could also recommend other medication or other forms of psychotherapy. Twenty participating practices were randomized at the practice level

to prevent contamination effects. Compared to usual care, the intervention led to increased access to depression care, greater declines in suicidal ideation, earlier treatment response, and higher rates of remission at 4, 8, and 24 months (Alexopoulos et al., 2005, 2009).

Three-component model. Another model is the three-component model (TCM), characterized by care management, enhanced mental health support, and a prepared practice (Oxman et al., 2002). In this model, care management can be either centralized in an organization or localized within a practice, with a spectrum of services such as telephone calls and limited psychotherapy. Important goals of care management include patient education, counseling for self-management and adherence, assessment of treatment response, and communication with other clinicians involved in a patient's care. A psychiatrist is another important component—he or she supervises and provides guidelines for the care manager, provides consultation services to the PCP, and facilitates appropriate use of additional mental health resources. The psychiatrist also plays an important role in preparing a practice to implement the model (primarily providing psychiatric education regarding diagnosis, risk assessment, and care plans) and providing ongoing reinforcement of this education.

The Re-Engineering Systems for Primary Care Treatment of Depression (RESPECT-D) project was a cluster randomized trial of an intervention based on the three-component model (Dietrich et al., 2004). Intervention patients had approximately double the odds of achieving a 50 % reduction in depression symptoms as well as remission at three and six months. The project was supported by training manuals and quality improvement resources, rather than research protocols and grant funding—potentially making this a more sustainable approach (Lee, Dietrich, Oxman, Williams, & Barry, 2007). The implementation and evaluation of RESPECT-D in the military setting (RESPECT-Mil) for the treatment of service members with post-traumatic stress disorder and depression showed that the three-component model was feasible, acceptable, and led to clinically significant improvement in that context (Engel et al., 2008).

Colocated collaborative care. The Strosahl (1998) primary mental health care model of colocated collaborative care is distinguishable from the aforementioned care management models because mental health specialists (e.g., masters and doctoral level psychotherapists, or "primary care psychologists") are located onsite in a primary care clinic and provide services to patients of that clinic, often in collaboration with a primary care clinician. However, as noted by Blount (2003), colocated does not necessarily mean collaborative. While care managers (even those with mental health backgrounds) often provide limited psychotherapy and consultant psychiatrists can provide periodic guidance and advice (often by telephone or e-mail), colocated mental health specialists can provide more traditional psychotherapy regimens (e.g., cognitive behavioral therapy) as well as "curbside" consultation for primary care clinicians from within the primary care clinic. Another key feature of this model is triage, in which level of care is increased depending on patient need, risk, or severity, ranging from behavioral health consultation, to specialty consultation, to fully integrated care. Appropriate training (and retraining of expectations) is also

critical for both mental health and medical care providers. While widely adopted as a collaborative care model, there is limited empirical evidence on this model, with a few exceptions. In the Primary Care Research in Substance Abuse and Mental Health for the Elderly (PRISM-E) study, colocated mental health and primary care for mental health/substance abuse was compared to enhanced referral to specialty mental health care (Levkoff et al., 2004). In PRISM-E, there was evidence demonstrating that integrated care led to increased access to mental health and substance abuse services compared to enhanced referral (Bartels et al., 2004). However, clinical outcomes were generally comparable across the two conditions (Areán et al., 2008; Krahn et al., 2006), although enhanced referral to specialty mental health appeared to be superior for patients with major depression (Krahn et al.).

The US Veterans Health Administration (VA) has embraced integrated behavioral health care, and has implemented a variety of models involving the integration of mental health into primary care, including care management models targeted to depression (Felker et al., 2006) and other mental health conditions (Oslin et al., 2006), and a blended model (colocation plus care management) in a number of their practices across the country (Pomerantz et al., 2010). Nearly 25 years ago, the VA first colocated psychologists and psychiatrists in their primary care clinics. Today, the VA's White River Model incorporates comprehensive mental and behavioral health care into primary care, with colocated behavioral health providers (therapists and psychiatrists) as part of the care team, information technology to support assessment and tracking, care management, and chronic disease management. Screening and triage are also important processes of care. Patients can receive brief or long-term individual psychotherapy or group psychotherapy for a number of mental disorders, including depression, anxiety, stress/anger management, post-traumatic stress disorder, and substance use. Based on "before-after" study designs, this model appears to have led to improvements in access to care, patient and provider satisfaction, and adherence to evidence-based guidelines for depression treatment, and decreased cost of mental health care in the context of this capitated single-payer system (Pomerantz, Cole, Watts, & Weeks, 2008; Watts, Shiner, Pomerantz, Stender, & Weeks, 2007). Furthermore, in a comparison with VA facilities that had VA not implemented this model, facilities with mental health integration showed greater increases in rates of detection of mental health disorders (Zivin et al., 2010). This model has been sustained for over six years. (Further discussion of the approaches to integrated behavioral health care can be found in Chap. 9.)

The 6P framework. The Depression in Primary Care program (supported by the Robert Wood Johnson Foundation) was based on the "6P" conceptual framework incorporating the perspective of six groups of stakeholders—(1) patients/consumers, (2) providers, (3) practice/delivery systems, (4) plans, (5) purchasers, and (6) populations/policies. These programs were designed to promote the use of evidence-based chronic care models for depression (Pincus, Pechura, Keyser, Bachman, & Houtsinger, 2006). A unique focus to this framework is the inclusion of economic considerations and innovative financial incentive arrangements, and the encouragement of collaborations between care providers and payers. Additionally, this

framework explicitly invites the use of clinical information systems to assist in linking stakeholders, enabling clinical decision support, and monitoring and tracking outcomes. While not a model of integrated care per se, the program did define a number of key components as a "blueprint" for treating depression in primary care. These components included a leadership team, decision support to enhance adherence to evidence-based treatment guidelines, delivery system redesign (e.g., use of patient registries), clinical information systems, patient self-management support, and community resources. The program funded a number of demonstration projects in eight states to encourage implementation of a chronic care model for depression in primary care. There was wide variety in how integrated care was implemented across these demonstration projects, consistent with the planned flexibility of the 6P conceptual framework.

As a recipient of one of the Depression in Primary Care grants, Intermountain Health care in Utah developed a model of mental health integration (MHI) that combines evidence-based treatment algorithms (based on degree of patient and family need—low, moderate, high) with innovative informatics tools (e.g., electronic health records, registries, electronic clinical decision support) for tracking patient progress and navigation of the system (Reiss-Brennan, 2006). The goal is to enhance care in three ways: 1) detection, monitoring, and management of mental health conditions, 2) patient and family engagement to support adherence and self-management, and 3) treatment matching and adjustment. In Intermountain's model of risk stratification, progressively more intensive treatment is provided as risk level (severity and nonresponse) increases or persists, with universal screenings for and continued diagnostic assessment of those at risk (Babor et al., 2007). The explicit focus on multiple stakeholder perspectives—including payers and health plans—is intended to promote sustainability. The MHI program at Intermountain was evaluated in terms of patient and provider satisfaction, patient and family health, functioning and productivity, and cost neutrality, using cohort and cost-trend analysis to show changes over time in outcomes in the system (Reiss-Brennan, Briot, Daumit, & Ford, 2006). In a quasi-experimental, retrospective cohort study comparing 73 out of 130 clinics that had implemented the MHI program with those that had not, patients in the treatment cohort had a lower rate of increase in costs than those in usual care—especially for those with depression and at least one other comorbidity (Reiss-Brennan, Briot, Savitz, Cannon, & Staheli, 2010). Intermountain has reported that other analyses from the MHI evaluation showed improvements in satisfaction and depression severity.

In contrast, the University of Michigan's Depression in Primary Care project relied on primary care clinicians to selectively refer patients to care management, in which care managers were remotely based, but assigned to specific clinics (Klinkman et al., 2010). Results showed improved rates of remission in the intervention practice patients at six months (43.4 % vs. 33.3 %, $p=0.11$), 12 months (52.0 % vs. 33.9 %, $p=0.012$), and eighteen months (49.2 % vs. 27.3 %, $p=0.004$).

Reverse integration. Reverse integration models support bringing primary health care to patients with severe mental illness in specialty mental health settings, either

through colocated primary care providers or care coordination. The VA system has also been the context for several reverse integration models (Druss, Rohrbaugh, Levinson, & Rosenheck, 2001; Druss et al., 2010; Saxon et al., 2006). For instance, the Primary Care Access, Referral, and Evaluation (PCARE) study is a randomized trial of primary care management for patients with severe mental illness being cared for in a community mental health center (Druss et al., 2010). In this study, nurse care managers performed two major roles—encouraging patients to seek medical care for their medical conditions through patient education and motivational interviewing, and assisting patients with accessing and navigating the primary care system through advocacy and addressing system-level barriers such as lack of insurance. At the PCARE 12-month follow-up, intervention patients were significantly more likely than usual care patients to have received recommended preventive services (58.7 % vs. 21.8 %), to have experienced greater improvements in mental health status, based on the SF-36 (8 % improvement vs. 1 % decline), and to have lower cardiovascular risk, based on Framingham Cardiovascular Risk scores (Druss et al., 2010).

Telemedicine. Circumstances may exist that prevent on-site mental health services—but innovation in the field of health information technology (HIT), especially mobile HIT, may present new opportunities for integration, especially in rural settings where on-site mental health is not feasible. A number of telemedicine models have been subject to research and evaluation (Rollman et al., 2009; Simon, Ludman & Rutter, 2009). These models include antidepressant consultation with an off-site psychiatrist via video conference (Fortney et al., 2006), telephone-based care management for depression in patients recovering from coronary artery bypass graft (Rollman et al., 2009), telephone care management plus cognitive behavioral psychotherapy for patients taking antidepressant medication (Ludman, Simon, Tutty, & Von Korff, 2007; Simon et al., 2009; Simon, Ludman, Tutty, Operskalski, & Von Korff, 2004). The use of telemedicine for delivering mental health services has been popular in rural Australia in recent decades (Lessing & Blignault, 2001), predominantly for assessment and consultation rather than psychotherapy, with trends over time showing increased access to care.

The TEAM (Telemedicine Enhanced Antidepressant Management) intervention (Fortney et al., 2006) consisted of annual screening for depression using the PHQ-9 and a depression care team that provided a stepped-care model of depression treatment to patients screening positive for depression. This model was essentially a variation on the theme of IMPACT, but with telepsychiatry rather than on-site psychiatry, using interactive video technology. The team was comprised of an on-site primary care physician, a consulting psychiatrist available via teleconference, and off-site nurse depression care managers, clinical pharmacists, and supervising psychiatrists. The stepped-care treatment included (1) watchful waiting or treatment with antidepressant medication (ADM), with symptom monitoring by the care manager; (2) given nonresponse to the initial ADM, the psychiatrist, PCP, and clinical pharmacist consulted (generally via an electronic progress note in the medical record) to make further recommendations; (3) given further nonresponse, a telepsychiatry consultation was recommended; (4) a final step was referral to

specialty mental health at the parent VA medical center. Usual care patients were also screened for depression, had their depression scores entered in to the EMR, and had interactive video equipment available at the point of care for specialty mental health consultation. The results of this randomized trial (randomized at the practice level but analyzed at the patient level due to low intraclass correlations at the practice level) demonstrated no difference in rate of prescription of ADM; however the intervention led to significantly higher odds of experiencing a 50 % improvement in depression severity at six months, and significantly higher odds of remitting at twelve months (Fortney et al., 2007). This rural telemedicine collaborative care intervention was, however, more expensive than its urban, on-site counterparts (Pyne et al., 2010).

Evidence Gaps in Integrated Behavioral Health Care

Despite the number of studies performed on various models and protocols of integrated behavioral health care, there remain many gaps in our knowledge. The existing research covers many of the structural features of integrated behavioral health care, especially members of the care delivery team, screening and treatment protocols, and education and training for practice personnel for specific protocols. The evidence is more limited for other structural features (information technology, training programs, practice management policies, and physical space considerations). Similarly, some processes of care are well covered in the literature, especially access, detection, and treatment of depression. There are increasing reports of cost and sustainability issues, as more research and evaluation concerns real-world implementation of integrated behavioral health care models that are not solely supported by grant funds. More evidence is needed for business models and practice improvement in integrated behavioral health care models, or principles and attitudes towards integrated care, from the perspectives of organizations, providers, and patients. There continues to be a predominant focus on clinical trial methodology, which may not result in knowledge that is easily translatable or sustainable outside well-controlled, resource-rich settings. The more rigorous research tends to be protocol driven and often disease and population specific, rather than focused on care delivery systems in general. The practical barriers to large-scale care delivery systems research are notable, however, and this gap will not be easily filled; such research may never be amenable to the gold-standard randomized trial design. Additionally, despite more recent work done in comorbid conditions such as diabetes and asthma, the broader impacts of multimorbidity and integrated behavioral health care processes and outcomes remain largely unknown. Finally, studies focused on implementation and dissemination remain less common, and results are just beginning to emerge.

Recently, the AHRQ published a research agenda (Miller, Kessler, Peek, & Kallenberg, 2011) for integrated behavioral health care, in which they prioritized the following broad research questions: (1) In what ways (according to what models or adaptations thereof, and for what populations) are real-world practices

implementing collaborative care? (2) Which aspects of these real-world collaborative care models are effective, and for whom? Addressing these broad questions and the others noted above will involve evaluating effectiveness of structures, processes, and attitudes towards integrated behavioral health care in the following contexts, using a variety of complementary methodologies.

Disease Contexts

Empirical research (especially randomized controlled trials) on integrated behavioral health care has typically been conducted in the context of a single disease state (or a specific combination of disease states), such that outcomes are tied directly to the amelioration of these particular conditions (rather than a range of mental health conditions). The main body of evidence is not only disease specific but most often concerns the management of depression, a pervasive and burdensome illness but by no means the only mental health problem confronted in primary care. Limited evidence exists in other mental health domains, such as panic disorder (Roy-Byrne, Katon, Cowley, & Russo, 2001), substance abuse and addiction (Alford et al., 2011; Areán et al., 2008), and bipolar disorder (Kilbourne et al., 2009). In the Netherlands, a collaborative stepped-care RCT for the treatment of panic disorder and generalized anxiety disorder in primary care is currently underway (Muntingh et al., 2009).

Much of the most recent literature on integrated care involves management of multiple psychiatric and/or physical comorbidities. The care delivery system features adopted as part of integrated mental health care (e.g., care management, interdisciplinary collaboration, clinical monitoring and follow-up, stepped care) reflect an instantiation of Wagner's chronic care model and can be used to comanage multiple chronic diseases. It is also thought that treating mental illness may have direct and/or indirect effects on other illnesses, possibly because of physiological, social, cognitive, and/or behavioral factors common to the comorbid conditions (Rustad, Musselman, & Nemeroff, 2011). In a pilot study of a patient-centered depression care management intervention characterized by several elements of integrated care (e.g., education and adherence monitoring), elderly adults with comorbid depression and hypertension were found to have lower depression scores, lower blood pressure, and greater medication adherence at six weeks (Bogner & de Vries, 2008).

Based on the IMPACT model, the Multifaceted Diabetes and Depression Program (MDDP) targets comorbid diabetes and depression in a low-income, predominantly Hispanic population (Ell et al., 2010). MDDP incorporates several IMPACT-like features, with diabetes depression clinical specialists (DDCSs) serving in the care manager capacity, stepped care for depression, supervision by a PCP, and an available consultant psychiatrist. In addition, MDDP involved "sociocultural enhancements" (e.g., addressing social stigma towards mental health), education and counseling in self-management of both depression and diabetes, and patient navigation services. Consistent with the results of other combined depression-and-diabetes collaborative care interventions (Katon et al., 2004) and subgroup analyses of patients with diabetes in the original IMPACT study (Williams et al., 2004), MDDP

resulted in improved depression, functioning, and financial status and reduced symptom burden for both depression and diabetes—but there were no objective effects on diabetes control (e.g., change in HgA1c).

It therefore remains a question as to whether the effective treatment of mental illness (in the context of integrated care) can lead to improved outcomes for comorbid chronic diseases. Longer term follow-up and/or the addition of more intensive chronic disease-specific intervention content may be required to observe an effect on these other outcomes. For instance, the Stepped Care for Affective Disorders and Musculoskeletal Pain (SCAMP) study implemented a 12-week antidepressant therapy intervention in sequence with a six-session pain management intervention (followed by a six-month continuation phase) in patients with comorbid depression and musculoskeletal pain (Kroenke et al., 2009). Not only did patients in the intervention experience significantly greater improvements in depression than those in usual care, they also experienced significantly greater improvements in pain severity and interference. Note that as the intervention involved treatment algorithms coordinated by nurse care managers in primary care settings, who were supervised by a physician depression specialist, SCAMP qualifies as an integrated care investigation, akin to IMPACT.

The results of the TEAMCare intervention, focusing on patients with diabetes or coronary heart disease or hyperlipidemia and depression at Group Health Cooperative, have recently been reported (Lin et al., 2012). The TEAMCare intervention utilized nurse case managers with specialist consultation working with primary care physicians in an attempt to increase adherence to medication and other self-care behaviors for both depression and comorbid physical illnesses (McGregor, Lin, & Katon, 2011). The TEAMCare intervention failed to demonstrate significant effects on medication adherence, but led to significant changes in provider prescribing behavior (Lin et al., 2012).

An early implication of these findings is that treating mental illness may aid in improving coping skills (e.g., emotion coping) and self-regulation/self-management, which have subsequent salutatory effects on stress and pain, which helps to improve functioning and quality of life—even if short-term effects on medical illnesses are not observed. Testing for indirect effects of integrated care interventions on comorbidity outcomes via changes in coping and self-regulatory skills may be a fruitful area of future research.

A broader focus on general mental health across a range of mental health needs, including basic psychosocial needs, health behavior modification, and the myriad mental health conditions presenting in primary care (Ansseau et al., 2004), is much less common in the research literature. When broadly focused models are evaluated, the designs are generally less rigorous, the outcomes are generally more process oriented (rather than clinical), and the conclusions are less generalizable outside the context in which the evaluation took place. The primary exception to this rule is that reverse integration models often seek general medical care (e.g., not just for diabetes) for a range of patients cared for in specialty mental health (e.g., not just patients with schizophrenia). By design, necessity, and/or default, these broad health-focused models are concerned with process and system capacity, such as defining and expanding the roles of health care professionals (e.g., advanced practice nurses; Asarnow & Albright, 2010).

Behavioral Medicine

In practice, the term "behavioral health" (and associated "behavioral health providers") appears to be commonly used to refer globally to mental health (the assessment, diagnosis, and treatment of mental health conditions, representative of psychopathology) as well as a range of other social, environmental, and psychological processes pertaining to human behavior in the domain of health, both clinical and nonclinical. Primary care patients may be in need of assistance with health behavior change (e.g., diet, physical activity, smoking cessation, sleep), stress management, chronic disease coping and self-management, infectious disease prevention behaviors (e.g., vaccination), and enhanced social support and health education, at the individual, family, or group level. Health psychologists, typically trained as masters and doctoral clinical psychologists, are capable of providing psychoeducation and intervention services across this range of what is called "behavioral medicine." Although there is a plethora of research demonstrating the effectiveness of behavioral medicine interventions in primary care settings (e.g., Etz et al., 2008; Pronk, Peek, & Goldstein, 2004) and compelling literature on how to integrate behavioral health into primary care (Martin, 2012), the research on integrated behavioral health care as a care delivery system is largely silent on the structures, processes, and attitudes pertaining to this potentially invaluable role of behavioral health specialists in primary care settings (although see Ray-Sannerud et al., 2012). As psychosocial and behavioral factors are implicated in a rather large proportion of the preventable causes of death in the United States and worldwide (Mokdad, Marks, Stroup, & Gerberding, 2004, 2005), investment in the development of an evidence base on the implementation, dissemination, and sustainability of behavioral medicine structures and processes in primary care is warranted. This may influence policy decisions, as training programs and reimbursement for behavioral medicine services (where it exists at all) fail to recognize the level of training required to effectively deliver behavioral medicine interventions.

Other Specific Populations

There is a good evidence base for older and middle age adults, veterans, and patients cared for HMO settings, although limited to the disease contexts previously noted. Both IMPACT and PROSPECT focused primarily on geriatric populations. In contrast, there is only limited evidence on integrated care for children and adolescents. The Youth Partners-in-Care (YPIC) study was an RCT of the effects of a care management quality improvement intervention compared to enhanced usual care, in youth ages 13–21 with depression (Asarnow et al., 2005). Although generally consistent with standard care management duties, YPIC care managers were masters or doctoral level psychotherapists who delivered cognitive behavioral therapy (CBT) or coordinated delivery of other treatment options and were not supervised by additional mental health specialists. Modest but statistically significant

improvements in depression outcomes and patient satisfaction were observed. Limited evidence exists for integrated behavioral health care for peripartum women (Gjerdingen, Crow, McGovern, Miner, & Center, 2009) and ethnic minorities such as Hispanic and Latino(a) patients (Ell et al., 2009). Other populations that could be targeted include immigrant and refugee populations.

Cost and Sustainability

The sustainability of integrated care models is tenuous at best (Gilbody, Bower, & Whitty, 2006), especially in resource-limited safety net settings (Palinkas, Ell, Hansen, Cabassa, & Wells, 2011). The high cost of these programs, in terms of workforce, information technology, time and space, is an obvious barrier to sustainability. Many of these programs are supported by temporary grant funding and foundation support, or are implemented in resource-rich health maintenance organizations such as the Group Health Cooperative (the origin of the IMPACT model). A significant gap remains in our understanding of how to implement the integrated care interventions in small-to medium-sized, independent primary care practices. There is a need to better understand the circumstances under which integration is cost-effective (what must we pay to yield clinically significant improvements in health at the population level?) and yields cost-offset (does increased investment in care in the short term yield lower costs in the long term?). Many evaluations of financial outcomes have followed reports of clinical outcomes for a range of study designs, from randomized trials to program evaluation, in the context of providing behavioral health services in medical settings (c.f., Blount et al., 2007). Generally speaking, integrated behavioral health care is more acutely expensive than usual care, but yields better outcomes and may offset costs in the long run (Gilbody, Bower, & Whitty, 2006). Business models that enable billing and payment for integrated behavioral health services are needed (Blount et al., 2007). Emerging models of pay for performance and accountable care organizations (ACOs) are dramatically restructuring the incentives for chronic disease care delivery, and may serve as a boon for attempts to implement sustainable integrated behavioral health care programs.

Implementation and Dissemination

The Veteran Health Administration (VHA) Quality Enhancement Research Initiative (QUERI) is a methodology for quality improvement and evaluation of implementation and dissemination of evidence-based practices (Rubenstein, Mittman, Yano, & Mulrow, 2000). It draws upon both quantitative and qualitative methods. The VHA is applying this methodology to the evaluation of their national implementation and dissemination of collaborative care in their Translating Initiatives for Depression into Effective Solutions (TIDES) model of collaborative care for depression

(Luck et al., 2009; Stetler et al., 2006). In this model, the importance of the national leadership, sustainable business models, and clinical feasibility and effectiveness is explicit. There is an emphasis on determining elements of integrated behavioral health care that should be standardized versus customized across the different sites (e.g., the extent to which there should fidelity vs. flexibility in the model). Results of a large-scale evaluation have not been published, although there is evidence that translation of the TIDES model into practice leads to better depression outcomes; they have also seen increased support for the TIDES model at the national policy level (Rubenstein et al., 2010). This and other research on implementation and dissemination of integrated behavioral health care models is a growing area of focus (c.f., Katon, Unutzer, Wells, & Jones, 2010).

Complementary Research Methodologies: Filling the Evidence Gaps

The nature of research on integrated behavioral health care has generally commanded "effectiveness" rather than "efficacy" trials. For instance, there are challenges with respect to randomization and adherence to protocol in "real world" settings, and ethical concerns regarding. Thus, this body of research often reflects the characteristics of pragmatic trials, in which the comparison group is "usual care" or even "enhanced usual care," by which patients and providers are allowed or even encouraged to use any of the standard resources for managing mental illness in their system (e.g., provider or self-referral to specialty mental health).

The traditional bias towards randomized controlled trials (with randomization at the individual patient level) as the gold standard for testing the efficacy of integrated care interventions continues to exist, but may be considered tempered by increased perceptions of value of more pragmatic designs for testing effectiveness in more naturalistic settings. More commonly, we see cluster randomization (randomization at the level of providers or sites, to reduce contamination effects) and stratified or permuted block randomization (randomization within groups of patients with common characteristics). Also, there has been increasing opportunity for the use of quasi-experimental designs, such as interrupted time series or regression discontinuity designs, to evaluate the effects of integrated care interventions that are implemented at a particular point in time or targeted to at-risk populations in a given setting. With an increased emphasis on translational and dissemination research, these rigorous-but-not-randomized designs will be especially useful to consider.

Quasi-experimental Designs

The use of quasi-experimental designs in evaluations of quality improvement or other implementation or dissemination projects can provide strong evidence of

the impact of integrated care. Expert opinion, funding streams, and the realities of today's health care industry dictate designs that deviate from traditional randomized trials (pragmatic trials, quasi-experimental designs, and research otherwise focused on translation) are needed (Kessler & Glasgow, 2011). The DIAMOND project described above represents a quasi-experimental design. These trials are uniquely suited to evaluate packages of care interventions where the individual elements of the package are not being evaluated, rather the overall effectiveness of the package and potential influence of context are of interest (Macpherson, 2004). Pragmatic trials are especially suited to evaluation of complex interventions such as integrated care. The strengths of these designs must be balanced against the need for larger sample sizes and the inability to tease apart components of the intervention. For example, the Robert Wood Johnson-supported Michigan Depression in Primary Care project was run as a pragmatic trial, in that there were both intervention and control practices, but no true randomization protocol. Individual practices had some freedom in how they implemented the process of referring to care managers, and care managers, while they had a general protocol to follow, this was not scripted in the traditional sense of a treatment manual.

Although it is the weakest of the quasi-experimental designs, the pre-post, single group design can still provide some information about changes occurring within an organization following the implementation of an integrated care model. For instance, evaluation of the St. Louis Initiative for Integrated Care Excellence (SLI^{2}CE) (Brawer, Martielli, Pye, Manwaring, & Tierney, 2010) involved such a design. The primary problem with this design is its susceptibility to threats to internal validity, especially history, maturation, and testing threats. Even when no adequate comparison group is available, though, design elements (e.g., multiple baselines and follow-ups) can be incorporated to strengthen the study. An interrupted time series design can yield stronger conclusions—when an abrupt, persistent, and significant change in the trajectory of the outcome occurs at the same moment in time as when the intervention was imposed, it is unlikely that any other factor caused that change.

Qualitative Research

Qualitative methods (semi-structured interviews and focus groups, primarily) have been used to explore a variety of subjective, experiential aspects of integrated behavioral health care, and are often embedded to assist with interpretation of quantitative outcome measures. Most commonly, qualitative designs are used to explore barriers and facilitators to the adoption of integrated behavioral health care models (Gask, 2005; Kilbourne et al., 2008; Nutting et al., 2008; Palinkas, Ell, et al., 2011). Gask (2005) interviewed 45 mental health workers, primary care physicians, and other personnel involved in the interface between mental health and primary care in a group-model HMO, to examine perceived barriers to integration. In her analysis,

grounded in Activity Theory, there were both "overt" and "covert" barriers. Overt barriers included cost, structural barriers to interdisciplinary communication related to patient self-referrals in a carve-out mental health system, and lack of colocation, which prevents easy, informal interaction between primary care and mental health providers. Covert barriers included differences in attitudes and conceptual perspectives on the provision of mental health care. For instance, mental health workers were frustrated by the apparent "learned helplessness" of primary care providers faced with patients with complex mental health issues, while primary care providers were put off by some mental health specialists' tendency to eschew on-the-spot consultation and open access (e.g., the tradition of the "50-minute hour"). There were also concerns about the perceived value of the breadth of the generalist PCP expertise versus the depth of the specialist mental health provider expertise, and differences in perspectives on whose responsibility it is to ensure that patients with mental health needs are seen (the patient's or the health care system's).

A qualitative study involving semi-structured interviews led to the identification of several benefits, barriers, and best practices in the implementation and dissemination of the RESPECT-D care management intervention (Nutting et al., 2008). Thematic analysis (applying a coding scheme to interview transcripts using qualitative analysis software, e.g., ATLAS.ti) was conducted across four waves of interviews with primary care clinicians, care managers, and mental health professionals (varying in their involvement with and enthusiasm for the care management program). Noting widespread endorsement of the value of the care manager for the treatment of depression, tempered by the expected financial and organizational change process barriers, the investigators concluded that "the major barriers to more widespread use of care management in depression are largely economic and related less to attitudes and preferences of primary care clinicians" (p. 35). Additional themes concerned the identification of patients most likely to benefit from care manager contact (e.g., patients undergoing a change in a care plan), the importance of a mental health specialist (e.g., psychiatrist) supervising the care manager, the importance of on-site care management (vs. centralized or located otherwise off-site), and the essential foundation of a good relationship between the primary care clinician and the care manager.

A notable gap in the qualitative literature is consideration of patient and family perspectives (patient satisfaction surveys notwithstanding), including issues pertaining to patient engagement, patient experience, patient preference, and the role of the patient in integrated behavioral health care teams. Qualitative designs also lend themselves well to studying values, principles, and attitudes towards integrated behavioral health care practices and the experiences of interdisciplinary collaboration. For instance, what is the process by which behavioral health providers and medical providers learn to communicate, develop mutual respect for and understanding of each other's skills and conceptual models, and negotiate the balance of power and shared decision making (in concert with the patient/family) on a case-by-case basis? What are the perceived barriers to effective collaboration, and how do these influence the effective implementation and dissemination of integrated behavioral health care systems? Using semi-structured interviews and a grounded theory approach to analysis, Henke, Chou, Chanin, Zides, and Scholle (2008) evaluated

physician perceptions of barriers to depression care, and perceived utility of chronic care model-based interventions for depression in primary care. The providers in this study endorsed care management, mental health integration, and education, but felt that mental health consultation models were less helpful. It was subsequently suggested that attempts to implement models endorsed by providers would be more successful. Such qualitative research may therefore aid in hypothesis generation for future implementation research.

Mixed Method Designs

Mixed method designs interweave quantitative and qualitative design elements, often in an iterative fashion such that the richness of the analysis deepens as the study progresses (Palinkas, Aarons, et al., 2011). Mixed methods can be used in both experimental and observational research and evaluation. A prime example is the CADET project. CADET is a large pragmatic cluster randomized controlled trial of collaborative care for depression in the United Kingdom as part of the National Health Service (Richards et al., 2009). It is a phase III trial following the purportedly successful implementation of phase I and II demonstrations (Richards et al., 2008). The model consists of case management, with a patient management plan and education. To address potential threats to validity stemming from contamination effects, randomization occurred at the practice level. Providers belonging to usual care practices receive no recommendations for altering their typical depression care (e.g., prescriptions of antidepressants and referring to specialty care), except when suicide risk is identified. Both quantitative and qualitative methods are being used to assess a variety of outcomes. Clinical and cost outcome data are primarily quantitative, relying upon validated tools such as the PHQ-9 for depression severity, the SF-36 for quality of life, and the CSQ8 for patient satisfaction, as well as objective administrative data on utilization and costs. Process outcome data are primarily qualitative and are based on interviews concerning mechanisms of change and processes of implementation of the intervention. Results are not yet available.

Observational (Correlational) Designs

The apparent variability in the ways in which different organizations have chosen to implement integrated behavioral health care presents the opportunity to conduct observational comparative effectiveness research (OCER) on integrated behavioral health care in real-world settings. Community-based participatory research approaches, described in Chap. 6, are another way to build on the principles and objectives of integrated behavioral health care. However, a major barrier to conducting this type of research is the lack of well-validated measurement tools or even

agreement on the discrete domains or elements of integration that should be measured. Work on integrated behavioral health care metrics has only just begun (Kessler & Miller, 2011).

Analytic Strategies

Under what circumstances is integrated behavioral health care effective? For whom is it effective? In what contexts and settings is it effective? Questions such as these are appropriately answered by testing for effect modification, or moderation, of the relationship between condition (intervention vs. control) and the study outcomes. For instance, in the PROSPECT study, the presence or absence of a series of comorbid medical conditions was tested as a moderator of the intervention effect on remission rates for depression (Bogner et al., 2005). While two of 16 conditions (atrial fibrillation and chronic pulmonary disease) significantly predicted odds of remission in the usual care condition, no conditions were associated with remission in the intervention condition, and there were no significant interactions after adjusting for multiple comparisons. In another study, although not a moderation analysis, higher scores on measures of anxiety and bipolar disorder at baseline were positively associated with odds of being a nonresponder to a collaborative care program for depression (Angstman, Dejesus, & Rohrer, 2010). It is a well-known phenomenon that detecting significant interaction effects is underpowered, however. Large-scale comparative effectiveness research presents the opportunity to plan for subgroup analysis and testing moderation.

Summary and Conclusions

The state of the evidence for integrated behavioral health care is strong in certain domains (e.g., protocol-driven, depression-focused randomized trials), but still emerging or weak in others (e.g., real-world implementation of non-disease-specific models). Questions of essential elements, effective dissemination and implementation strategies, and the impact of interventions in the context of primary care multimorbidity remain. Meta-analyses show that integrated behavioral health care can lead to better outcomes (e.g., improved rates of remission, reduced symptomology, improved functioning). We now need to focus research efforts on exploring the settings and organizational contexts in which they can be effectively and efficiently implemented, and expanding integrated behavioral health care models to offer care beyond particular mental health conditions.

Furthermore, consensus is needed in order to develop general principles about what constitutes an integrated behavioral health care model, so that the evidence can provide adequate guidance to those organizations seeking to implement such a model. Peek's lexicon (Peek, 2011) is a promising attempt to bring robust

organizing principles to the integrated behavioral health care research domain, and highlights the lack of evidence for what he describes as a paradigm case. More recent research on Strosahl's primary mental health care model and the Depression in Primary Care demonstration projects more closely approximate the paradigm case for collaborative care. As potentially more sustainable healthcare delivery system approaches, these contemporary models are richer and more complex, and address more of the structural features and processes of integrated behavioral health care than did the classic models. The trade-off has been that these models are less amenable to classic randomized trial designs, and the evidence relies upon less rigorous evaluation methods. Indeed, conducting a randomized trial for every possible permutation of integrated behavioral health care would be cost prohibitive. New and innovative methods such as mixed methods (Palinkas, Aarons, et al., 2011), pragmatic trials (Zwarenstein et al., 2008), quality improvement evaluations (Rubenstein et al., 2000), and other emerging research and evaluation methods (Damschroder et al., 2009; Katon et al., 2010; Proctor et al., 2009) appropriate for translation, dissemination, and implementation research—beyond the traditional randomized trial—are needed to fill these evidence gaps.

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