

## The 2009 Schizophrenia PORT Psychosocial Treatment Recommendations and Summary Statements

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The Schizophrenia Patient Outcomes Research Team (PORT) psychosocial treatment recommendations provide a comprehensive summary of current evidence-based psychosocial treatment interventions for persons with schizophrenia. There have been 2 previous sets of psychosocial treatment recommendations (Lehman AF, Steinwachs DM. Translating research into practice: the Schizophrenia Patient Outcomes Research Team (PORT) treatment recommendations. *Schizophr Bull.* 1998;24:1–10 and Lehman AF, Kreyenbuhl J, Buchanan RW, et al. The Schizophrenia Patient Outcomes Research Team (PORT): updated treatment recommendations 2003. *Schizophr Bull.* 2004;30:193–217). This article reports the third set of PORT recommendations that includes updated reviews in 7 areas as well as adding 5 new areas of review. Members of the psychosocial Evidence Review Group conducted reviews of the literature in each intervention area and drafted the recommendation or summary statement with supporting discussion. A Psychosocial Advisory Committee was consulted in all aspects of the review, and an expert panel commented on draft recommendations and summary statements. Our review process produced 8 treatment recommendations in the following areas: assertive community treatment, supported employment, cognitive behavioral therapy, family-based services, token economy, skills training, psychosocial interventions for alcohol and substance use disorders, and psychosocial interventions for weight management. Reviews of treatments focused on medication adherence, cognitive remediation, psychosocial treatments

for recent onset schizophrenia, and peer support and peer-delivered services indicated that none of these treatment areas yet have enough evidence to merit a treatment recommendation, though each is an emerging area of interest. This update of PORT psychosocial treatment recommendations underscores both the expansion of knowledge regarding psychosocial treatments for persons with schizophrenia at the same time as the limitations in their implementation in clinical practice settings.

*Key words:* schizophrenia/psychosocial/treatment

### Introduction

The Schizophrenia Patient Outcomes Research Team (PORT) psychosocial treatment recommendations provide a comprehensive summary of current evidence-based psychosocial treatment interventions for persons with schizophrenia. There have been 2 previous sets of psychosocial treatment recommendations.<sup>1,2</sup> The publication of the previous recommendations has spawned research suggesting that relatively few patients with schizophrenia have access to the wide array of psychosocial evidence-based programs. These data then led to a number of large-scale state- and system-wide efforts to implement evidence-based practices.<sup>3</sup>

The most recent update of the PORT psychosocial treatment recommendations included 6 recommendations.<sup>2</sup> We undertook this second update for several reasons. First, we aimed to update the existing recommendations with more recent research. Second, we believed that the volume and quality of research in several new intervention areas merited review. These areas include cognitive remediation, peer- and consumer-based programs, first-episode psychosis and treatments for obesity and smoking cessation. Finally, while past PORT efforts have chosen not to review the literature related to treatments for co-occurring substance use disorders (SUDs), the overall importance and clinical impact of these problems and the volume of research caused us to reconsider that decision and to review this treatment area as well. Therefore, this PORT review of psychosocial programs updates reviews in 7 areas as well as adding 5 new areas of review.

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For the current PORT update, we evaluated published studies to determine whether the previous PORT psychosocial treatment recommendations required revision and whether there was sufficient evidence to warrant new treatment recommendations for prespecified interventions and outcomes of interest.

## Methods

Members of the psychosocial Evidence Review Group conducted reviews of the literature in each intervention area and drafted the recommendation or summary statement with supporting discussion. The selection of intervention areas to be reviewed was made in collaboration with the Psychosocial Advisory Committee. For those treatment areas that were previously reviewed, we conducted extensive electronic literature searches (MEDLINE, PsychInfo), using as search terms the names of individual treatments, treatment methods, and schizophrenia. The time period for the search was January 2002 through March 2008. We used snowballing techniques, examining the citation list of selected articles to identify any additional relevant studies. We also consulted our advisory committee and expert panel. We only reviewed articles published prior to January 2002, if they had not been reviewed in one of the previous PORT treatment recommendation publications. Our reviews of intervention areas not previously covered by the PORT extended back as far as necessary to obtain trials that qualified for inclusion. If a relevant article in that area was published after March 2008 (and up until December 2008) and appeared as if it would significantly alter the PORT evaluation of the evidence, then the article was included in the reviewed evidence base. We restricted articles to English language publications. We then reviewed the abstracts. If the study was a randomized controlled trial (RCT), and at least 50% of the participants had a schizophrenia-spectrum disorder diagnosis, ie, schizophrenia, schizoaffective disorder, or schizophreniform disorder, then the article was selected for further extraction and inclusion in the evidence basis for consideration toward a recommendation. The only exception to the requirement that the sample have at least 50% of individuals with a schizophrenia-spectrum diagnosis was in the area of SUD treatment and peer-based services as explained in the text below.

In the case of the extant PORT psychosocial treatment recommendations, the selected articles were reviewed for their potential to modify these recommendations significantly. In the case of new interventions or outcomes, there were 2 possible review results. First, the reviewed evidence could meet criteria for sufficient evidence to merit a treatment recommendation (see Kreyenbuhl et al,<sup>4</sup> this issue, for a description of these criteria). Recommendations included a brief description of the treatment and its key elements, the population for which the

treatment is indicated, and the outcomes produced by the treatment. We required that recommendations be supported by research that could address those fundamental requirements. Further, we required that the success of any recommended psychosocial treatment be replicated by a research group beyond the originators or creators of the intervention.

Alternatively, the evidence could be judged to be not sufficient to merit a treatment recommendation, in which case a summary statement was written that describes the intervention, describes the indication for the intervention, and provides a summary of the evidence and the important gaps in knowledge that preclude treatment recommendation status. Summary statements are structured with a statement of the importance of the problem or treatment area and strengths of the current research base, followed by a synthesis of the ways in which the research falls short of permitting a recommendation. The draft treatment recommendations and summary statements were then reviewed by the expert panel that provided written comments and also feedback at a convened meeting, and their comments were incorporated into revisions, which were rereviewed by the expert panel, and then final versions were produced.

## Treatment Recommendations

There are 8 treatment recommendations. It is important to note that all the psychosocial treatment recommendations are intended as adjunctive to pharmacotherapy for which the treatment recommendations are presented in the companion manuscript (Buchanan et al). Recommendations that were introduced in previous PORT efforts and updated with minor changes are presented first. These are followed by the recommendations that either involved substantial changes from previous versions or that are in new areas. The final section presents summary statements for intervention areas that have not yet met the standard for a recommendation.

### *Assertive Community Treatment*

*Recommendation.* Systems of care serving persons with schizophrenia should include a program of assertive community treatment (ACT). This intervention should be provided to individuals who are at risk for repeated hospitalizations or have recent homelessness. The key elements of ACT include a multidisciplinary team including a medication prescriber, a shared caseload among team members, direct service provision by team members, a high frequency of patient contact, low patient-to-staff ratios, and outreach to patients in the community. ACT has been found to significantly reduce hospitalizations and homelessness among individuals with schizophrenia.

*Evidence Summary.* Persons with disabling schizophrenia who are at risk for discontinuation of treatment or for repeated crises require an array of clinical, rehabilitation, and social services to address their needs. Coordination, integration, and continuity of services among providers over time can be substantially enhanced through ACT. ACT programs emphasize patients' strengths in adapting to community life (vs focusing on psychopathology); provide support and consultation to patients' natural support networks—families, employers, friends and peers, and community agencies; and provide assertive outreach to assure that patients remain in the treatment program. Medication adherence is also emphasized, as well as ready access to a prescriber. Results of RCTs have most consistently found that ACT contributes to lower rates of hospitalization and homelessness relative to standard care.<sup>5–7</sup> Specifically, controlled studies have shown the efficacy of ACT in reducing the number of days hospitalized relative to standard care.<sup>8–18</sup> In turn, individuals assigned to the ACT condition used fewer emergency services and more outpatient services, including financial and housing assistance, relative to individuals in the control conditions.<sup>13,14,16,19,23</sup>

A few studies also found that individuals assigned to the ACT condition reported decreased symptomatology,<sup>17,20,22,24,25</sup> increased medication adherence,<sup>10,17</sup> more contact with the treatment team,<sup>23,26</sup> more days in stable community housing,<sup>7,12,13,17,19,21,25</sup> and greater satisfaction with treatment among patients and their family members relative to the control condition.<sup>9,18–20</sup> However, not all studies have shown these benefits, and the effectiveness of ACT outside of the United States is questionable.<sup>27,28</sup> ACT interventions with higher fidelity to the ACT model have been shown to result in stronger outcomes, with the exception of strict adherence to the low staff-to-patient ratios, which may be a somewhat more flexible criterion.<sup>29,30</sup> ACT interventions also appear to be most successful among populations with high rates of hospitalization.<sup>29</sup>

Since the last Schizophrenia PORT review, investigations examining ACT have continued to support its efficacy in decreasing homelessness and improving housing stability.<sup>7,21</sup> A meta-analysis by Coldwell and Bender<sup>6</sup> including the results of 6 randomized trials found that ACT was associated with a 37% greater reduction in homelessness relative to standard community care. These results are consistent with a review by Nelson *et al*<sup>31</sup> suggesting that involvement in ACT led to greater improvements in housing stability compared with standard care.

Research has also extended ACT to other subpopulations and clinical outcomes, including employment, substance use, and forensic populations. In some cases, this has involved adding a specialized focus to ACT teams, such as supported employment workers and clinicians who are trained to deal with individuals who are diagnosed with co-occurring SUDs. The lack of dismantling

studies prevents us from attributing positive outcomes to ACT specifically. With respect to employment, studies vary in terms of their inclusion of employment specialists, the primary research questions being asked, and the nature of the comparison condition. That considered, studies found that individuals randomized to the ACT condition were significantly more likely to have had paid employment,<sup>32</sup> to be working in competitive employment,<sup>33,34</sup> and to have worked in the previous 6 months relative to those in the standard care condition.<sup>35</sup> Furthermore, individuals in the ACT condition were rated as performing more effectively in their work role<sup>36</sup> and were employed for longer periods of time<sup>33</sup> relative to individuals in the standard care condition. One randomized trial found no benefit of ACT in employment outcomes.<sup>25</sup> Overall, the heterogeneity of research designs and models precludes a specific recommendation for ACT in relation to employment outcomes.

A handful of studies have examined the efficacy of ACT as an integrated treatment for individuals with serious mental illness and SUDs.<sup>21,37,38</sup> Although the study by Drake and colleagues found evidence that individuals involved in ACT reported decreased substance use on some measures relative to individuals in the control condition, 2 recent investigations tested an enhanced form of ACT that included ACT staff with expertise in treating substance use and did not find evidence that these enhancements were associated with superior outcomes for substance abuse.<sup>21,37,38</sup> Specifically, Essock *et al*<sup>38</sup> compared the enhanced ACT condition with an intense clinical case management program that also had dual diagnosis expertise and did not find evidence for differences across groups on substance abuse outcomes. Likewise, Morse *et al*<sup>21</sup> compared ACT with substance abuse expertise (so-called integrated ACT) with ACT alone and with standard care and also failed to find differences in substance use across conditions. However, Morse *et al*<sup>21</sup> found that individuals in both ACT conditions reported more days in stable housing relative to individuals in standard care. Notably, Essock *et al*<sup>38</sup> found that ACT was superior to intensive case management in reducing hospitalization at 1 of 2 sites that had higher rates of institutionalization prior to the study. The specificity of ACT to reduce substance use, even when supplemented by dual diagnosis expertise, is not clear relative to other types of integrated treatments. However, ACT may contribute to other positive outcomes, including improved housing and reduction of hospitalization.

ACT has recently been adapted for forensic populations with the goal of reducing recidivism and promoting engagement in treatment. Modifications to ACT include the addition of a probation officer to the treatment team and, in some cases, the addition of residential housing and addiction treatment services. Evidence for the effectiveness of ACT among individuals with mental illness who also have a criminal background remains mixed,

with limited evidence for reduced arrests and days spent in hospital or jail, as well as reduced rates of substance use.<sup>39,40</sup> Nonetheless, heterogeneity of these ACT adaptations and high levels of study attrition preclude a recommendation for ACT among forensic, mentally ill populations.<sup>41</sup>

### *Supported Employment*

**Recommendation.** Any person with schizophrenia who has the goal of employment should be offered supported employment to assist them in both obtaining and maintaining competitive employment. The key elements of supported employment include individually tailored job development, rapid job search, availability of ongoing job supports, and integration of vocational and mental health services.

**Evidence Summary.** RCTs have consistently demonstrated the effectiveness of supported employment in helping persons with schizophrenia to achieve competitive employment, work more hours, and earn more wages than persons who did not receive supported employment.<sup>32,42–54</sup> In most of these studies, among those who received integrated supported employment and psychiatric services, 50% or more persons obtained competitive employment at some point during the study follow-up period. Outcomes relating to the amount of hours worked and wages earned were also found to be superior among those receiving supported employment in comparison to those receiving traditional vocational services.<sup>32,33,42–45,47,48,50,53</sup>

Studies of supported employment have been carried out in a wide range of socioeconomic and cultural contexts in the United States as well as other countries, eg, Burns et al,<sup>53</sup> Latimer et al,<sup>55</sup> and Kin Wong et al.<sup>56</sup> Because there is no evidence that engagement in supported employment leads to increased stress, exacerbation of symptoms, or other negative clinical outcomes,<sup>33,42,44</sup> supported employment should be offered to any person with schizophrenia who expresses an interest in working.

The major components of supported employment are competitive employment in the community, rapid search for a job rather than prolonged preemployment preparation, integration of employment and mental health services, an emphasis on client preference and choice regarding jobs, and the availability of ongoing job supports. There is clear evidence that employment outcomes are better when there is greater fidelity to the supported employment model (ie, more of these components are in place), eg, Becker et al,<sup>57</sup> Becker et al,<sup>58</sup> Catty et al,<sup>59</sup> and McGrew et al.<sup>60</sup> While greater integration of mental health services and vocational services is associated with better outcomes,<sup>54</sup> the individual effectiveness of the other elements of supported employment has not been demonstrated. Thus, it is recommended that sup-

ported employment programs make every effort to incorporate all aspects of this treatment model.

Despite firm evidence for supported employment as compared with other approaches to vocational rehabilitation, long-term job retention and economic self-sufficiency have not been clearly demonstrated by supported employment.<sup>48,49,54</sup> To address these limitations, there has been increased interest in studying methods for enhancing outcomes by augmenting vocational services with interventions such as cognitive remediation,<sup>61,62</sup> social skills training,<sup>63,64</sup> and cognitive behavioral therapy (CBT).<sup>65,66</sup>

### *Skills Training*

**Recommendation.** Individuals with schizophrenia who have deficits in skills that are needed for everyday activities should be offered skills training in order to improve social interactions, independent living, and other outcomes that have clear relevance to community functioning. Skills training programs vary widely in content but typically include a focus on interpersonal skills and share several key elements, including behaviorally based instruction, role modeling, rehearsal, corrective feedback, and positive reinforcement. Skills training provided in clinic-based settings should be supplemented with strategies for ensuring adequate practice in applying skills in an individual's day-to-day environment.

**Evidence Summary.** Substantial evidence indicates that people with schizophrenia can learn a variety of interpersonal and everyday living skills when provided with structured behavioral training that is focused on clearly defined activities, situations, and problems.<sup>66–69</sup> As indicated in a recent review, social skills training produces significant effects (effect size = 0.52) on proximal measures of skill, ie, as evidenced in role-play tests, as well as more distal measures of community functioning.<sup>69</sup> Evidence is weak or mixed regarding the indirect effects of skills training on relapse or ratings of symptoms and general psychopathology, especially in more rigorous studies. Several studies have reported retention of trained skills over periods up to 1 year<sup>70–73</sup>; however, the number of studies that include follow-up data is too small to draw confident conclusions regarding durability of effects, and further research is needed.<sup>69</sup> Skills training techniques have proven adaptable to a range of content areas including work place interpersonal skills<sup>63,64</sup> and drug refusal skills.<sup>74</sup> More recently, the techniques have been adapted for people of different ethnic and cultural backgrounds with good effect.<sup>75–78</sup>

Investigators continue to search for ways to encourage the generalization of newly learned behavioral skills by people with schizophrenia to their everyday environments. Traditionally, assigned “homework” was used to address this critical goal, but it was often unclear

whether skills training participants completed homework as intended. Programs that directly facilitate the application of trained skills in everyday environments are more likely than traditional homework to support desired generalization.<sup>78,79</sup> Emerging strategies in this regard include incorporating trainer-guided community-based practice into skills training<sup>79</sup> and enlisting and training family members as “generalization agents” to participate in skills training efforts is an emerging strategy in this regard.<sup>75</sup>

Recognizing that the broad disability associated with schizophrenia cannot be addressed with a single focused intervention, skills training is often provided as one component of an integrated intervention, eg, see Petersen *et al.*<sup>81</sup> In addition to pharmacotherapy, several other psychosocial components have been combined with skills training, such as family interventions<sup>75,77</sup> and CBT.<sup>82</sup> Key elements of skills training have also been incorporated into recently developed recovery focused interventions. Useful tools for teaching skills training include trainers’ materials,<sup>83</sup> as well as demonstration videos and workbooks for participants.<sup>84</sup>

### *Cognitive Behavioral Therapy*

*Recommendation.* Persons with schizophrenia who have persistent psychotic symptoms while receiving adequate pharmacotherapy should be offered adjunctive cognitive behaviorally oriented psychotherapy to reduce the severity of symptoms. The therapy may be provided in either a group or an individual format and should be approximately 4–9 months in duration. The key elements of this intervention include the collaborative identification of target problems or symptoms and the development of specific cognitive and behavioral strategies to cope with these problems or symptoms.

*Evidence Summary.* Controlled studies of CBT with individuals with schizophrenia who have persistent psychotic symptoms despite adequate pharmacotherapy have shown benefits in reducing the severity of delusions,<sup>85,86</sup> hallucinations,<sup>87,88</sup> positive symptoms,<sup>88–91</sup> negative symptoms,<sup>88,89,92–97</sup> and overall symptoms<sup>90,92,94,98–102</sup> and in improving social functioning.<sup>89,95,103–105</sup> These conclusions are largely consistent with the results of recent meta-analyses.<sup>106–108</sup> However, some studies have not found CBT to improve patient outcomes in these domains including hallucinations,<sup>105</sup> positive symptoms,<sup>109–112</sup> negative symptoms,<sup>109–112</sup> and social functioning.<sup>98,109,110</sup> The effects of CBT on depression, suicidality, hopelessness, illness insight, relapse, and rehospitalization have not been clearly established with only a small number of studies examining these outcomes.<sup>94,97,101–103,109,110,112–114</sup> The benefits of CBT for patients with recent onset schizophrenia have also not been clearly established.<sup>106,115–118</sup> There is also no

consistent evidence about the benefits of CBT for patients who are not recent onset and who are experiencing an acute exacerbation of psychotic symptoms.<sup>95,112,119</sup>

Methodological issues found in the body of studies of CBT for schizophrenia that may influence study results include whether or not raters are masked to treatment condition.<sup>108</sup> Another issue is the extent to which studies use an active psychotherapy comparison that controls for therapy time and for nonspecific effects.<sup>106,120</sup> Distress about symptoms has been used to select patients for CBT in some studies; this feature may be associated with greater responsiveness to the intervention.<sup>86,87,92</sup> Another issue in the body of CBT studies reviewed here is that the most of these studies were performed outside of the United States, most in the United Kingdom; while there is no evidence that persons with schizophrenia in the United States respond differently to this approach than do patients in other developed countries, more studies are needed of this treatment in US health-care settings.

CBTs include a range of therapeutic approaches that vary in their specific treatment elements. For example, in some CBT psychotherapies, the therapist and the patient determine the psychological precipitants of the patient’s illness and develop a normalizing rationale as a first step in the therapeutic process.<sup>92</sup> Other CBT psychotherapies do not address the psychological origins of the illness but focus exclusively on cognitive and behavioral strategies combined with social skills training.<sup>103</sup> All CBT psychotherapy approaches include a focus on the patient’s view of symptom or problems and the development of more rational or adaptive coping responses. Both individual and group formats have been used to deliver CBT psychotherapy and seem to have similar benefit.<sup>108</sup> The intensity and duration of the therapies that have been studied vary from 6 to more than 50 sessions; weekly or biweekly sessions over a treatment period of 4–9 months is the most typical treatment duration.

### *Token Economy Interventions*

*Recommendation.* Systems of care that deliver long-term inpatient or residential care should provide a behavioral intervention based on social learning principles for patients in these settings in order to improve their personal hygiene, social interactions, and other adaptive behaviors. The key elements of this intervention, often referred to as a token economy, are contingent positive reinforcement for clearly defined target behaviors, an individualized treatment approach, and the avoidance of punishing consequences. The intervention should be delivered in the context of a safe treatment environment that provides patient access to basic amenities, evidence-based pharmacological treatment, and the full range of other recommended psychosocial interventions.

*Evidence Summary.* Based on social learning principles, the token economy constitutes the most extensively researched type of social learning program. A token economy is a comprehensive behavioral program for a group of patients in which immediate positive reinforcement is provided in the form of tokens or points for the performance of specified target behaviors; tokens or points may be exchanged at a later time for individually selected reinforcers.

The results of randomized controlled studies indicate that behavioral token economy programs, based on social learning principles, are effective in increasing the adaptive behaviors of patients with schizophrenia in hospital and residential treatment settings such as personal hygiene, social interactions, and hospital-based work tasks<sup>121–126</sup> though not all trials found a clear benefit of the token economy program.<sup>127,128</sup> The results of controlled studies that were not randomized trials also support the benefits of the token economy intervention.<sup>129–132</sup> A limitation of the research evidence is that with the exception of 2 trials,<sup>126,132</sup> these studies were performed more than 25 years ago when diagnostic practices, treatment conditions, and research methodology differed from current standards. One recent quasi-experimental study was performed in a private hospital inpatient program with persistently ill long-stay schizophrenia patients.<sup>133</sup> In this uncontrolled evaluation study, initiation of contingent reinforcement as part of a point-and-token system in this hospital program was associated with significant changes including a reduction in episodes of seclusion and restraint and an increase in activities of daily living and in treatment compliance. The existing research literature does not establish the extent to which patient gains in a token economy in a hospital or residential setting transfer or generalize when the patient transitions to a less restrictive setting. The existing literature also does not address the extent to which social learning approaches may benefit patients who are receiving other evidence-based psychosocial and pharmacological interventions<sup>134–136</sup> although the study by Silverstein et al<sup>133</sup> is suggestive in this regard. Behavioral interventions based on social learning principles that are developed for specific problem behaviors and that are less comprehensive than the token economy may also be effective; such interventions may also be applied in noninstitutional or in short-stay settings.<sup>137,138</sup>

Implementation of a token economy or related behavioral program should take into account practitioner attitudes and possible misconceptions of the token economy and the principles of social learning on which it is based.<sup>137</sup>

#### *Family-Based Services*

*Recommendation.* Persons with schizophrenia who have ongoing contact with their families, including relatives and significant others, should be offered a family

intervention that lasts at least 6–9 months. Interventions that last 6–9 months have been found to significantly reduce rates of relapse and rehospitalization. Though not as consistently observed, research has found other benefits for patients and families, such as increased medication adherence, reduced psychiatric symptoms, and reduced levels of perceived stress for patients. Family members have also been found to have lower levels of burden and distress and improved family relationships. Key elements of effective family interventions include illness education, crisis intervention, emotional support, and training in how to cope with illness symptoms and related problems. The selection of a family intervention should be guided by collaborative decision making among the patient, family, and clinician. In addition, a family intervention that is shorter than 6 months but that is at least 4 sessions in length should be offered to persons with schizophrenia who have ongoing contact with their families, including relatives and significant others, and for whom a longer intervention is not feasible or acceptable. Characteristics of the briefer interventions include education, training, and support. Possible benefits for patients include reduced psychiatric symptoms, improved treatment adherence, improved functional and vocational status, and greater satisfaction with treatment. Positive family outcomes include reduced family burden and increased satisfaction with family relationships.

*Evidence Summary.* Research demonstrating the effectiveness of family psychoeducation for individuals with schizophrenia dates back to the late 1970s and 1980s and was reflected in the first set of PORT recommendations.<sup>1</sup> Here, we reconsider the issue of the specificity of the value of extended family psychoeducation for specific subgroups, namely, individuals who have no recent hospitalization or exacerbation of illness.

Most investigations focused on family psychoeducation interventions that were 6 months or longer and included individuals who had a recent illness exacerbation. These studies demonstrated lower rates of relapse and rehospitalization among individuals receiving family psychoeducation relative to those in the control condition.<sup>139–147</sup> Meta-analyses support the conclusion that a longer family intervention (ie, an intervention lasting 6–9 months or longer) is necessary to significantly reduce rates of relapse and rehospitalization relative to a control condition.<sup>68,148–150</sup> Family psychoeducation interventions that are 6 months or longer have also been shown to contribute to other positive patient and family outcomes among individuals who have had a recent illness exacerbation. Specifically, individuals who received family psychoeducation reported improved treatment adherence,<sup>151</sup> lower levels of perceived stress,<sup>152</sup> and better vocational outcomes<sup>144</sup> relative to individuals in the control condition. In terms of family member outcomes,

family members of individuals who received family psychoeducation reported lower levels of burden and distress<sup>141,144</sup> and improved family relationships<sup>152</sup> relative to family members in the control condition.

As the effectiveness of family psychoeducation was established, more recent studies began to include patients who did not have a recent illness exacerbation. One set of studies includes only individuals without a recent exacerbation; a second set includes both individuals with a recent exacerbation and those without a recent exacerbation. Valencia *et al*<sup>77</sup> compared psychosocial skills training combined with family therapy to treatment as usual (TAU) among individuals without a recent illness exacerbation and found a reduction in hospitalization and relapse rates in the experimental condition, but it is not possible to attribute the success of the program to family psychoeducation alone. Neither Dyck *et al*<sup>153</sup> nor Magliano *et al*<sup>154</sup> reported differences in rates of relapse and/or rehospitalization between the family intervention and the control group. However, they did report other positive outcomes associated with family psychoeducation including fewer psychiatric symptoms<sup>153</sup>) and improved social and vocational outcomes<sup>154</sup> relative to individuals in standard care. In terms of positive family outcomes, Magliano *et al*<sup>154</sup> found that family members receiving the family psychoeducation intervention reported increased perceptions of professional and social support. Hazel *et al*<sup>155</sup> reported caregiver outcomes from the study conducted by the Dyck *et al*<sup>153</sup> and found that caregivers involved in the multiple family group intervention reported lower levels of distress relative to those involved in standard outpatient treatment.

Several studies included samples of both patients with a recent exacerbation and those without a recent illness exacerbation as well as their family members. Dyck *et al*<sup>156</sup> found that family psychoeducation reduced rates of hospitalization in the following year relative to a control condition. Bradley *et al*<sup>157</sup> found an overall reduction in relapse among individuals receiving a multiple family group intervention relative to those receiving standard case management. Notably, this study also included a substantial group of poorly acculturated recent immigrants from Vietnam to Australia. Ran *et al*<sup>158</sup> compared family psychoeducation plus antipsychotic drug treatment with antipsychotic drug treatment alone and with no intervention and found that individuals who received both family therapy and antipsychotic drugs showed reduced relapse relative to individuals in the other 2 conditions. However, this study was conducted in rural China in which the service context is not comparable to that observed in the United States. Another very large study of a family psychoeducation program conducted in China also included individuals who were characterized as stable, recovered, or remitted and found reduced hospitalization and relapse among individuals involved in family psychoeducation.<sup>159</sup> This study was conducted

in 5 urban areas among patients who were living with a relative. As with the study by Ran *et al*,<sup>158</sup> the generalizability of these findings to the United States is questionable. When considering other positive patient outcomes, relevant studies found that individuals involved in family psychoeducation reported fewer psychiatric symptoms,<sup>157,159</sup> improved treatment adherence,<sup>158,159</sup> and improved social, functional, and vocational outcomes<sup>157,159</sup> relative to individuals in the control condition. In terms of positive outcomes for family members, family members involved in the family psychoeducation condition reported greater knowledge of schizophrenia and improved family relationships compared with those in the control condition.<sup>158</sup>

Overall, the evidence for the effectiveness of a 6- to 9-month family psychoeducation intervention for reduction of relapse and other outcomes among patients who have not had a recent illness exacerbation is not nearly as strong as the evidence for 6- to 9-month family psychoeducation for individuals who have had a recent illness exacerbation. Two relevant studies include only stable patients, though they both found benefits. The studies that include both stable and recently ill patients found benefit, but for several of these studies, their relevance to the US health system is questionable. Nevertheless, given the data and that the stability of patients fluctuates, the weight of evidence supports offering 6- to 9-month family psychoeducation to patients who are stable.

Family psychoeducation interventions that are shorter than 6 months (but at minimum 4 sessions) have been shown to contribute to positive patient and family outcomes among both individuals who are psychiatrically stable and those who have had a recent relapse. Notably, these studies show benefit among a range of outcomes, though no single patient outcome is observed in all or the majority of studies. Also, over half of these interventions are designed for family members only and do not include patients in the treatment sessions.<sup>160-165</sup> However, briefer interventions that include the patient have also been tested.<sup>166-168</sup> The inclusion of family members only permits families to participate in a program during circumstances when the patient is uninterested or unwilling to participate.

In terms of specific outcomes, Posner *et al*<sup>163</sup> conducted a study in which family members were assigned to an 8-week family psychoeducation group or a control group. Family members involved in the family psychoeducation group reported significantly greater knowledge of schizophrenia and satisfaction with medical care relative to those in the control group. Results of a study by Merinder *et al*<sup>167</sup> mirror those of Posner *et al*<sup>163</sup> in that Merinder compared patient and family outcomes between patients and families involved in an 8-session family psychoeducation relative to those in a TAU group ( $N = 46$ ). Patients had schizophrenia-spectrum disorders.<sup>167</sup> Families involved in the family

psychoeducation intervention reported significantly greater increases in knowledge and greater satisfaction with their involvement in their relative's care. Patients involved in family psychoeducation also reported significant increases in knowledge and involvement in their care, as well as significantly fewer psychiatric symptoms and a longer time to relapse. Xiang et al<sup>165</sup> conducted a study comparing a 4-month family psychoeducation combined with a drug treatment to a drug treatment alone condition in rural China. Though the applicability of conditions in rural China is subject to question, among the family psychoeducation and drug treatment group, patients reported higher levels of treatment adherence and higher levels of functioning relative to the drug-only condition. Family members also reported significantly better care of their ill relatives in the family psychoeducation and drug condition relative to the drug-only condition. A study by Spiegel and Wissler<sup>166</sup> compared a family psychoeducation treatment involving a consultation team coming to the family's home for 4–6 weeks after the patient was discharged from the hospital with a control condition. The consultation team provided psychoeducation, problem solving, and crisis intervention to the family and patient. When considering only patients with schizophrenia-spectrum disorders, patients in the family psychoeducation treatment group ( $n = 14$ ) spent fewer days in the hospital, used more outpatient services, and rated their adjustment higher relative to those in the control group ( $n = 22$ ) who did not receive family consultation. Likewise, Pitschel-Walz et al<sup>168</sup> found that individuals involved in an 8-session family psychoeducation intervention (over the course of 4–5 months) had lower rates of rehospitalization and better treatment adherence relative to individuals who received TAU. This study included patients with schizophrenia-spectrum disorders who had been recently hospitalized. A total of 194 patients were randomized with an approximately 20% dropout rate in both conditions. Solomon et al<sup>164</sup> compared individualized family consultation with group family psychoeducation and a third arm that was a waiting list control for relatives of individuals diagnosed with mental disorders with 295 (64%) or 296 (36%) codes (schizophrenia spectrum, major depression, or bipolar disorder). A total of 225 participants were randomized, and 42 dropped out, leaving 183 relatives. Self-efficacy was significantly greater for the persons receiving individual consultation and those in group psychoeducation who had not previously attended a family support group relative to the wait-list control. Results of a meta-analysis by Cuijpers<sup>169</sup> support positive outcomes including reduced burden and distress and improved family relationships among family members receiving the family psychoeducation intervention. It is important to note that some studies did not show benefit of brief family psychoeducation interventions, but the weight of evidence suggests that shorter

interventions can be beneficial, especially for family members.<sup>170</sup>

An additional set of studies led by Pickett-Schenk compared families receiving the Journey of Hope, an 8-week family-led psychoeducation course, with a wait-list control group.<sup>160–162</sup> Families involved in the family-led course reported significantly higher levels of knowledge about schizophrenia, improved information needs, lower levels of depression, improved family relationships, and improved satisfaction in their caregiver role. This program was delivered in the community, so even families in which the patient was not receiving services could participate. Diagnoses of the family members of participants included were collected from the family members themselves, and about 20% had a schizophrenia diagnosis. Given the nature of the mechanism for obtaining diagnoses in this community-based intervention, the relevance of this program is somewhat uncertain. But the findings are consistent with the results of other briefer family-based models.

#### *Psychosocial Interventions for Alcohol and Substance Use Disorders*

*Recommendation.* Persons with schizophrenia and a comorbid alcohol or drug use disorder should be offered substance abuse treatment. The key elements of treatment for alcohol or drug use disorders for persons with schizophrenia include motivational enhancement (ME) and behavioral strategies that focus on engagement in treatment, coping skills training, relapse prevention training, and its delivery in a service model that is integrated with mental health care. The duration of the recommended substance abuse treatment cannot be specified at this time; both brief (1–6 meetings) and more extended (10 or more meetings) interventions have been found to be helpful in reducing substance use and improving psychiatric symptoms and functioning.

*Evidence Summary.* This is the first time that a review of the literature on psychosocial interventions for SUDs in schizophrenia has been included in the PORT. This literature spans the last 30 years; studies examine a wide variety of participants, substances, interventions, and outcomes, and involve a range of designs, methods, measures, and analysis plans. Given this diversity, we were faced with several decisions regarding which studies to include in the review and how the PORT criteria would be applied. First, many studies relevant to the treatment of SUDs in schizophrenia do not have samples with 50% or more persons with schizophrenia or schizoaffective diagnoses. Most studies of SUDs in individuals with schizophrenia are conducted in real-world clinic settings, where there is little or no separation of individuals by diagnosis in terms of providing treatment. Thus, the strict



application of the PORT criteria would result in our excluding many potentially relevant studies that inform our knowledge and understanding of SUD treatment for individuals with schizophrenia. We also reasoned that the validity of diagnoses is somewhat questionable in the setting of active substance abuse.<sup>171–175</sup> To overcome this problem, we have limited the review to RCTs and studies with similarly rigorous methodology but have included (in separate sections) studies with samples of less than 50% schizophrenia-spectrum diagnoses. With respect to specific treatments for SUD, 6 RCT's were available that included more than 50% of individuals with schizophrenia.

Second, this literature is organized around 2 general types of studies: those comparing methods of delivery of SUD treatment (such as comparisons of integrated vs parallel treatment) and studies of specific interventions for treating SUDs. Historically, treatment for SUDs and mental disorders were funded by different agencies and delivered in separate treatment settings. The disconnect between these treatment systems, coupled with the need for both types of treatment in individuals who would have difficulty negotiating 2 separate systems of care, led to the development of integrated treatment strategies. Throughout the 1990s, research focused on the design and delivery of integrated care for mental health and SUDs. Importantly, these studies have operationalized “integrated treatment” in different ways. Some studies compare interventions for substance abuse delivered within mental health care to these same interventions delivered within a separate program that has limited or no connection to mental health treatment. Such studies reflect a true test of integrated vs parallel substance abuse treatment. Other studies adopt more of a services framework and compare integrated substance abuse and mental health treatment to TAU or referral. In these studies, TAU or referral is essentially no treatment, as it would be exceedingly difficult for individuals with severe mental illness (SMI) to access any substance abuse treatment in the real world of nonintegrated care. These studies are “real-world” tests of integrated care but do not permit inferences of the value of integrated care over parallel care when patients can actually access parallel care. Finally, some studies compare different methods of delivering integrated care. This lack of standardization makes it difficult to compare studies and draw conclusions. Moreover, research since 2000 has mostly been focused on examining specific interventions for SUDs in schizophrenia, as integrated treatment has come to be seen as the standard of care for individuals with dual disorders. To accommodate the different parts of this diverse literature, they are reviewed in separate sections here.

*Studies Comparing Methods of Delivery of Treatment for SUDs. RCTs With More Than 50% of Participants With Schizophrenia-Spectrum Diagnoses* Two RCTs

have examined integrated mental health/SUD treatment in schizophrenia with samples comprised of at least 50% of participants with schizophrenia-spectrum diagnoses.<sup>176,177</sup> Hellerstein *et al*<sup>176</sup> randomly assigned 47 participants with schizophrenia and SUDs to either integrated or nonintegrated psychiatric and SUD treatment. The integrated program included a supportive substance abuse treatment group; education about mental illness and medication, alcohol and drug abuse, and the disease model of addiction; weekly urinalysis; linking to self-help groups; monthly medication management or more if needed; and regular communication with clinicians and family members involved in participants' care. The comparison condition provided similar services in a parallel fashion. The groups did not differ on substance use outcomes at follow-up. At 4 months, more participants in the integrated condition remained in treatment than in the nonintegrated group. Lehman *et al*<sup>177</sup> compared 54 participants assigned to either standard care (usual mental health and rehabilitation care; participants could attend substance abuse treatment on their own) vs an experimental integrated care condition (standard care + specialized substance abuse group intervention + case management). There were no differences on psychosocial or substance use outcomes between groups after 1 year.

Three studies have examined the efficacy of ACT as an integrated treatment for individuals with SMI and SUDs.<sup>21,37,38</sup> Drake *et al*<sup>37</sup> compared integrated mental health and SUD treatment within an ACT approach to standard case management for 223 people with dual disorders over 3 years. Teams in the ACT condition included essential features of ACT plus additional components to address SUDs. Standard case management teams delivered services in the community, worked with the client's support system, and addressed co-occurring SUD, but had larger caseloads and more often linked clients with substance abuse treatment providers at other locations. Individuals in the ACT condition reported decreased substance use on some measures relative to the control condition. Two recent investigations tested an enhanced form of ACT that included ACT staff with expertise in treating substance use; neither found these enhancements to be associated with superior substance use outcomes.<sup>21,38</sup> Morse *et al*<sup>21</sup> did find that individuals in both ACT conditions reported more days in stable housing than those in standard care.

*RCTs With Less Than 50% of Participants With Schizophrenia-Spectrum Diagnoses or Percentage Unspecified* - Five RCTs have examined methods of delivery of SUD treatment with samples comprised of less than 50% of participants with schizophrenia-spectrum diagnoses or with the percentage of schizophrenia diagnoses unspecified.<sup>178–182</sup> Herman *et al*<sup>179</sup> randomly assigned participants to an integrated mental health and SUD treatment program or to standard, psychiatric hospital

treatment. The standard program included medical and psychiatric assessment; individual, group, and activity therapy for mental health issues; and 1:8 staff-to-client ratio. The standard program did not emphasize SUD treatment but did include a substance use screen at intake and optional attendance at self-help meetings. The integrated program added more in-depth assessment of SUDs, family- and gender-specific programs geared toward addiction, an addiction-relevant educational curriculum more hours per week of individual and group psychotherapy, and a 1:6 staff-to-client ratio. At discharge, participants in the integrated program indicated more active engagement in treatment and greater awareness of mental health and substance use issues than those who received standard treatment (ST). Participants in the integrated program also saw their treatment as being more effective and had more motivation to stay healthy and sober. In a follow-up article, Herman et al<sup>181</sup> reported that those in the integrated program reduced their rate of alcohol use at 2 months after discharge by 54%. Two other RCTs were conducted in homeless dually diagnosed samples with additional aims around housing provision and stability.<sup>172,180</sup> Given these important differences, results from these studies are less applicable to the study of integrated treatment for the larger population of individuals with dual disorders.

In a partial RCT, Mangrum et al<sup>182</sup> examined 1-year outcomes in 216 individuals with co-occurring SMI and SUDs recruited from 3 treatment programs to receive either integrated or parallel treatment. The integrated condition included dual disorder-focused case management and oversight, treatment planning that included both mental health and SUD issues and goals, along with individual and group treatment tailored for participants with dual disorders. The parallel condition included mental health and SUD treatment by separate treatment centers without coordination. The study design included both random and nonrandom assignment: Random assignment was done at 2 sites; a third site provided treatment in 2 counties, with integrated care in one county and parallel care in the other. Those in integrated treatment ( $n = 123$ ) achieved greater reductions in the incidence of psychiatric hospitalization and arrest than the parallel condition ( $n = 93$ ).

Overall, these results are not definitive but suggest that integrated treatment increases the probability that persons with schizophrenia and co-occurring SUDs will have better treatment participation<sup>177,179</sup> and may have some reductions in substance use,<sup>37,181</sup> more days in stable housing,<sup>21</sup> and greater reductions in psychiatric hospitalization and arrests.<sup>182</sup> In addition, integrated care has been found to have equivalent effectiveness whether delivered via ACT or traditional clinical case management modalities.<sup>38</sup> The specificity of ACT to reduce substance use, even when supplemented by dual diagnosis expertise, is not clear relative to other types of integrated

treatments. Whether truly parallel programs are inferior remains unclear, but this is likely a moot point now because virtually all the trials of specific substance abuse treatments summarized below were conducted within an integrated care structure, rendering integration of care as one of the core ingredients of effective substance abuse treatment.

*Studies of Specific Interventions for Substance Abuse. RCTs With 50% or More Participants With Schizophrenia-Spectrum Diagnoses* There have been 6 RCTs that have examined specific interventions for treating SUDs in samples comprised of at least 50% of participants with schizophrenia-spectrum diagnoses.<sup>183–190</sup> Two studies examined the impact of cognitive behavior therapy for SUDs in schizophrenia.<sup>183,184,187</sup> Barrowclough et al<sup>184</sup> randomly assigned 18 participants with schizophrenia and SUDs and their caregivers to receive either routine care alone or routine care plus motivational interviewing (MI), CBT, and a family/caregiver intervention (29 individual MI/CBT sessions and 10–16 family/caregiver sessions). The experimental group showed better outcomes on several variables tapping symptoms and functioning, including higher Global Assessment of Functioning (GAF) scores and fewer negative symptoms at the post-treatment assessment and higher GAF scores and fewer positive symptoms at the 12-month assessment. The experimental group also showed lower rates of relapse at the 12-month assessment and a greater percentage of days of abstinence from all substances at 3-, 6-, 9-, and 12-month assessments. In a follow-up to this trial, Haddock et al<sup>187</sup> assessed 15 participants from the experimental group and 13 from the comparison group 6 months after treatment completion (18 mo after baseline). Participants in the CBT intervention showed higher GAF scores and fewer negative symptoms than those in the comparison group; the groups showed equivalent rates of relapse at 18 months.

Baker et al<sup>183</sup> randomly assigned participants with psychotic disorders who reported hazardous alcohol, cannabis, and/or amphetamine use during the preceding month ( $n = 130$ , 75% schizophrenia) to either a 10-session experimental intervention (MI + CBT,  $n = 65$ ) or to TAU ( $n = 65$ ). Although individuals in the experimental condition did not show better substance use outcomes, they did report reduced symptoms of depression (from baseline to 6 mo) and improved GAF scores (from baseline to 12 mo).

Three studies examined brief interventions, and all included experimental groups that incorporated motivational or behavioral treatments that were tested in comparison to no treatment or minimal provision of alcohol or drug education.<sup>186,188,190</sup> Graeber et al<sup>186</sup> compared outcomes for 3 sessions of either an ME or an educational treatment (ET) intervention in 30 participants with schizophrenia and alcohol use disorders.

The ME group showed greater rates of abstinence at all follow-ups than the ET group. James *et al*<sup>188</sup> compared a 6-session, manualized, group intervention (ME, coping with high-risk situations, relapse prevention) with a control condition (one-drug education session) in 63 participants with a nonorganic psychotic disorder (57% with schizophrenia diagnosis). The experimental group showed greater improvements in drug-related consequences and reductions in marijuana, alcohol, and polydrug use at follow-up. Martino *et al*<sup>190</sup> randomly assigned 44 participants (77% with schizophrenia diagnoses) to either a 2-session motivational intervention adapted for dually diagnosed patients with psychotic and drug use disorders ( $n = 24$ ) or a 2-session standard psychiatric interview ( $n = 20$ ) with no benefit found.

One study examined the impact of a program that trained case managers to address SUDs in their clients with SMI.<sup>185,189</sup> Johnson *et al*<sup>189</sup> used a cluster-RCT design to assign case managers to dual diagnosis training ( $n = 40$  case managers, 127 clients, 89% schizophrenia) or to wait-list control ( $n = 39$  case managers, 105 clients, 90% schizophrenia). Clients were assessed at 18 months to determine the impact of the case manager training on client alcohol and drug use. Although there were no group differences in substance use at follow up, clients of trained case managers reported reduced psychotic symptoms and symptoms of anxiety and depression and fewer unmet needs for care.<sup>185</sup>

*RCTs With Less Than 50% of Participants With Schizophrenia-Spectrum Diagnoses or Percentage Unspecified* There are 6 RCTs of SMI samples with lower or unspecified numbers of participants with schizophrenia-spectrum diagnoses that examined substance use outcomes.<sup>74,191–195</sup> Baker *et al*<sup>191</sup> randomly assigned 160 inpatients (38% schizophrenia) to receive a motivational interview (MI,  $n = 79$ ) or self-help/brief advice ( $n = 81$ ) and found no benefit for any substance use or psychosocial outcomes. Hulse and Tait<sup>193</sup> randomly assigned psychiatric inpatients ( $n = 120$ , percentage of schizophrenia diagnoses unspecified) to either one ME session ( $n = 62$ ) or an information package ( $n = 58$ ) to reduce alcohol use. At a 6-month assessment, both groups reduced alcohol consumption, but the MI group had a greater reduction in weekly consumption than the information group. Bellack *et al*<sup>74</sup> randomly assigned 129 participants with SMI (40% schizophrenia-spectrum diagnoses) to a behavioral group treatment for SUDs or a manualized supportive treatment comparison group. Both treatments were administered twice a week for 6 months (52 sessions). The behavioral intervention yielded a higher percentage of negative urinalysis test results, longer survival in treatment, and greater session attendance relative to the comparison group. Participants in the behavioral condition showed fewer hospitalizations, more money available for living expenses, and better self-reported quality of life at posttreatment.

The 3 remaining RCTs were done with early-onset patients. Edwards *et al*<sup>192</sup> showed no benefit of a specially designed cannabis-focused intervention on cannabis use in participants with early psychosis. Kemp *et al*<sup>195</sup> compared a brief CBT intervention developed for young adults with psychosis with a TAU and found that while both groups improved across the trial, those exposed to the experimental condition improved significantly on measures of the frequency of cannabis and alcohol abuse. Kavanagh *et al*<sup>194</sup> compared standard care only or with an add-on drug abuse treatment component designed for individuals with early psychosis. Results showed reductions in substance use among completers but not in intent-to-treat analysis.<sup>194</sup>

In a partial RCT, Jerrell and Ridgely<sup>196</sup> compared 3 interventions (12-step recovery, behavioral skills training, and intensive case management) in a sample of 132 dually diagnosed clients (percentage with schizophrenia diagnosis not specified). The sample was recruited in 2 cohorts: (1) 52% of the sample was recruited from 3 sites where participants were being served by existing treatment teams or individual practitioners who chose which of the 3 interventions they wanted to implement at the start of the study. These participants then received whatever intervention their team/practitioner selected; (2) additional participants were randomly assigned to intervention condition. Results showed that the behavioral group yielded lower drug and alcohol use disorder symptom counts at follow-up. Of 10 psychosocial outcomes with a medium effect size, 9 favored the behavioral condition.

There are 2 RCTs of SMI samples with lower or unspecified numbers of participants with schizophrenia-spectrum diagnoses that examined attendance outcomes.<sup>197,198</sup> Baker *et al*<sup>197</sup> randomly assigned 160 psychiatric inpatients (38% schizophrenia) to receive either a MI or no intervention. The primary outcome was engagement in a specialized substance abuse treatment program during the 3-month period following inpatient admission. There were no group differences in attendance at the specialized program. Swanson *et al*<sup>198</sup> randomly assigned 121 psychiatric inpatients (14% with schizophrenia-spectrum diagnoses; 77% with comorbid SUDs) to either ST or ST + MI; outcome was attendance at first outpatient appointment following inpatient discharge. More participants in the ST + MI group attended their first outpatient appointment than those in the ST group. When examined for only the dually diagnosed subgroup, results were similar.

The above review takes a broad approach to the literature on the treatment of SUDs in individuals with schizophrenia. This approach is a sound one for this particular literature, given the emphasis on testing interventions in real-world settings and the research challenges that such a goal presents. Taken together, the studies reviewed here find that motivational and

cognitive-behavioral interventions have yielded improved outcomes in terms of treatment attendance,<sup>198</sup> substance use and relapse,<sup>74,184,186,188,193–195</sup> symptoms,<sup>183,187</sup> and functioning.<sup>74,183,184,187</sup> While not all studies have shown these benefits,<sup>190–192,197</sup> the current state of the literature supports the use of motivational and cognitive-behavioral interventions of varying lengths in people with schizophrenia and SUDs as a way to reduce substance use and improve functioning. These findings are consistent in both RCTs with majority schizophrenia samples<sup>183,184,186–188,190,198</sup> as well as RCTs with lower percentages of individuals with schizophrenia<sup>74,192–195</sup> and a partial RCT.<sup>196</sup> In addition, this review highlights the need for further testing of such interventions in order to maximize their benefits in diverse settings and samples. Interventions that have involved training case managers to identify and address substance abuse in individuals with dual disorders have also shown promise,<sup>185,189</sup> and more use of and research on such approaches will help in the development of broader SUD intervention approaches that are applicable to delivery of services in community settings.

#### *Psychosocial Interventions for Weight Management*

**Recommendation.** Individuals with schizophrenia who are overweight (body mass index [BMI] = 25.0–29.9) or obese (BMI  $\geq$  30.0) should be offered a psychosocial weight loss intervention that is at least 3 months in duration to promote weight loss. The key elements of psychosocial interventions for weight loss include psychoeducation focused on nutritional counseling, caloric expenditure, and portion control; behavioral self-management including ME; goal setting; regular weigh-ins; self-monitoring of daily food and activity levels; and dietary and physical activity modifications.

**Evidence Summary.** Modest weight loss has been associated with health benefits, including improved cardiovascular health among individuals who are overweight or obese as per the National Institutes of Health Clinical Guidelines in the general population.<sup>199</sup> Our review included 7 randomized controlled investigations targeting weight loss among individuals with schizophrenia-spectrum disorders. Participants were randomly assigned to either the psychosocial intervention targeting weight loss or the control condition in 6 of the 7 studies.<sup>200–205</sup> Alternately, in the trial by Wu et al,<sup>206</sup> individuals were randomly assigned to 1 of 4 conditions: placebo alone, metformin alone, metformin plus a psychosocial intervention targeting lifestyle modifications, or the lifestyle modification intervention plus placebo.

All 7 studies found support for greater weight loss (specifically 1–9 lbs; mean weight loss of 5.8 lbs across all 7 studies) among individuals who received the psychosocial intervention relative to those in the control condition.

Three of the 7 studies implemented the intervention in a group format,<sup>198,202,204</sup> while the other 4 implemented the intervention in an individual format.<sup>201,203,205,206</sup> In terms of duration, interventions varied in length from 3<sup>203</sup> to 6 months.<sup>205</sup> Regarding setting, 1 of the trials was completed in an inpatient setting,<sup>205</sup> 5 were completed across a range of outpatient settings,<sup>201–204,206</sup> and 1 trial was completed in both inpatient and outpatient settings.<sup>200</sup>

Six of the 7 studies specified that all study participants were overweight and were also taking first- or second-generation antipsychotic medications; 2 of these studies focused on individuals taking olanzapine who had recently experienced olanzapine-related weight gain,<sup>200–203</sup> 1 focused on individuals with a BMI greater than 27 who were also taking clozapine,<sup>205</sup> 2 included overweight individuals (ie, individuals with BMI  $>$ 25) who were taking a first- or second-generation antipsychotics (ie, clozapine, olanzapine, risperidone, haloperidol, perphenazine, thiothixene, fluphenazine, quetiapine, and ziprasidone),<sup>202–204</sup> and 1 included individuals who had gained 10% of their body weight within 1 year following the initiation of antipsychotic medication, who were also taking clozapine, olanzapine, risperidone, and sulpiride.<sup>206</sup> The investigation by Brown and Chan<sup>201</sup> was the only investigation that did not specify weight or medication inclusion criteria.

Four of the 7 positive weight loss trials explicitly described the use of some variation of a behavioral intervention, including goal setting and self-monitoring of food and physical activity level,<sup>200,202–204</sup> while the investigations by Brown and Chan<sup>201</sup> and Wu et al<sup>206</sup> described use of psychoeducation focusing on diet and exercise as the primary intervention. Finally, the investigation by Wu et al<sup>205</sup> focused on caloric restriction and increased physical activity only.

Moreover, review articles and results of meta-analyses (ie, Alvarez-Jimenez et al,<sup>207</sup> Faulkner and Cohn,<sup>208</sup> Faulkner et al,<sup>209</sup> Faulkner et al,<sup>210</sup> and Loh et al<sup>211</sup>) offer further support for behavioral or psychoeducation-based interventions to promote modest weight loss among individuals with schizophrenia who are overweight or have recently experienced antipsychotic-related weight gain.

Despite the preponderance of positive findings, marked variability regarding intervention techniques, materials, settings, intensity, and duration warrant limited interpretation of the current body of evidence. Additional limitations of the evidence include small sample sizes across most of the studies and difficulties with participant retention. Furthermore, there is limited evidence for sustainability of weight loss. For instance, only the investigation by Jean-Baptiste et al<sup>202</sup> found support for retention of weight loss over a 6-month postintervention period.

While the evidence for interventions for weight loss is strong enough to warrant a recommendation, the current

state of the literature exploring psychosocial interventions for the prevention of weight gain among individuals with schizophrenia is not substantial enough to warrant a formal recommendation at this time. To date, only 3 RCTs targeting the prevention of weight gain among individuals with schizophrenia who had recently begun taking antipsychotic medications have been published.<sup>207,212,213</sup> These 3 studies sought to prevent weight gain using psychosocial interventions comprised of psychoeducation coupled with some level of behavior therapy. All 3 trials showed evidence of a statistically significant difference between the psychosocial intervention group and the control group, with individuals receiving the psychosocial intervention gaining significantly less weight relative to individuals in the control group. Despite these positive findings and the overall strength of the study design of these 3 trials, the limited number of trials addressing the prevention of weight gain, relatively small sample sizes, difficulties with retention, limited duration of intervention, and variability in intervention techniques suggest the need for cautious interpretation. Also, participants in the intervention groups still evidenced modest weight gain, albeit less than the participants in the control conditions.

The investigation by Alvarez-Jimenez *et al.*<sup>214</sup> focused on individuals with a recent diagnosis of a psychotic disorder (ie, first-episode patients), the majority of whom had not previously taken antipsychotic medications. Specifically, patients were randomly assigned to 1 of 3 possible antipsychotic medications (olanzapine, risperidone, or haloperidol) prior to being randomized to an early behavioral intervention or routine care.<sup>214</sup> Individuals assigned to the early behavioral intervention gained significantly less weight over the 13-week period relative to individuals assigned to the routine care condition (ie, 9.0 vs 15.2 lbs, respectively). The investigations by Littrell *et al.*<sup>213</sup> and Evans *et al.*<sup>212</sup> focused on the prevention of weight gain among individuals who had recently begun taking olanzapine. Evans *et al.*<sup>212</sup> included individuals with serious mental illness (the majority of whom had a diagnosis of a schizophrenia-spectrum disorder) and found that individuals who received the psychosocial intervention gained significantly less weight over a 3-month period relative to those assigned to the control condition (ie, 4.4 vs 13.2 lbs, respectively). At 6 months (3 mo after the end of the active intervention), the intervention group continued to show significantly less weight gain than those in the comparison group (ie, 4.4 vs 21.8 lbs, respectively). Littrell *et al.*<sup>213</sup> found that individuals who were diagnosed with a schizophrenia-spectrum disorder who were assigned to the psychosocial intervention also gained significantly less weight over the 4-month period compared with those assigned to the standard care group (ie, 0.81 vs 7.2 lbs, respectively). At 6 months (2 mo after the end of the active intervention), the mean weight change in the intervention group was  $-0.06$  lbs, while

the mean weight change in the standard care group was 9.57 lbs. The intervention by Littrell *et al.*<sup>213</sup> was implemented in a group format with the active intervention lasting 4 months in duration, whereas the interventions by Alvarez-Jimenez *et al.*<sup>214</sup> and Evans *et al.*<sup>212</sup> were implemented in an individual format with the active intervention lasting 3 months. All 3 investigations delivered the intervention in an outpatient setting.

## Summary Statements

Summaries of interventions for which the evidence was judged as not sufficient to merit a treatment recommendation at this time are presented below. For each of these summary statements, a summary of the supporting evidence can be found in the Supplementary Material.

### *Cognitive Remediation*

*Summary Statement.* Cognitive impairment in schizophrenia is common and accounts for significant variation in real-world community outcomes such as work performance. The class of behavioral treatments known as “cognitive remediation” specifically targets memory, attention, reasoning, and similar capacities, with the ultimate aim of enhancing everyday functioning. This is the first detailed review of cognitive remediation by the Schizophrenia PORT. The cognitive remediation literature now spans 40 years, and our review included 33 RCTs and 11 related studies (eg, follow-up to clinical trial). It is encouraging that a substantial number of remediation studies have found improvements with treatment on neuropsychological measures. Fewer studies have investigated cognitive remediation’s impact on psychosocial functioning, and the measurement strategies and results have been less consistent. The PORT considered a wide range of views on the cognitive remediation literature. Our conclusion is that while the literature to date provides a foundation for further research, more work is needed before a concrete recommendation for cognitive remediation can be offered to the field. There are 2 principal considerations underlying this conclusion: (1) that the variation among cognitive remediation models and programs is too great to allow identification of key elements of the intervention and (2) that rigorous clinical trials are still a minority of the studies in the literature and that they offer only mixed support for this intervention at present.

### *Peer Support and Peer-Delivered Services*

*Summary Statement.* The participation of consumers in the planning, delivery, and evaluation of services is increasingly recognized as essential to a recovery-oriented system of care for persons with schizophrenia. Both professional and consumer organizations have participated in efforts to develop and test models of consumers as

providers of different kinds of mental health services. This has entailed a range of approaches including consumers serving as members of regular clinical teams, consumers providing specialty peer-to-peer services, and independent consumer-run agencies. It has been hypothesized that consumers can play a unique role by sharing lived experiences and serving as role models for one another. Employing consumers also can serve to reduce stigma and remove inappropriate hiring barriers faced by people with serious mental illness. An array of studies to date suggest that when trained consumers deliver traditional clinical services, outcomes are not dissimilar to those when such services are delivered by mental health professionals. However, the research literature to date is small; in addition, the body of research is limited by weak experimental designs, the varied peer-delivered services and hypotheses that have been studied, and often a failure to specify how consumers were selected and trained. There is a compelling need for research to determine how consumers may provide unique benefits in the delivery of services to persons with schizophrenia, how such consumers should be selected and trained, and what types of consumer-delivered services are most effective.

#### *Interventions to Increase Adherence to Antipsychotic Medication*

**Summary Statement.** Nonadherence to prescribed antipsychotic medication regimens is a considerable problem among people with schizophrenia and is associated with psychotic relapse, hospitalization, and other adverse outcomes. A variety of strategies that specifically target medication adherence have been tested in RCTs. Research provides only mixed support for educational approaches. Behavioral tailoring approaches have the most promise as demonstrated by small trials on narrowly defined populations. The provision of environmental supports for medication adherence also has promise. However, at this point, there is insufficient evidence to recommend any specific intervention to promote adherence to antipsychotic medications among persons with schizophrenia.

#### *Psychosocial Treatments for Recent Onset Schizophrenia*

**Summary Statement.** Many persons with schizophrenia endure substantial periods of misdiagnosis and delayed treatment after the initial appearance of their symptoms and functional impairments. Such delays may contribute unnecessarily to the long-term morbidity and disability associated with this illness. Recognition of such delays combined with new emphasis on hope and recovery has led to substantial interest in interventions to improve outcomes for persons with recent onset schizophrenia. This field of research is witnessing substantial progress and may be on the cusp of breakthrough approaches. Research has examined application of CBT, family interven-

tions, and supported employment program as well as multimodality intervention “packages.” The current state of the research literature on psychosocial treatments for recent onset schizophrenia does not support any evidence-based treatment recommendations at this time, primarily due to small numbers of studies for any given intervention and some inconsistencies among the findings.

#### **Discussion**

This revision of the Schizophrenia PORT recommendations importantly demonstrates that a number of psychosocial treatments and approaches show ongoing evidence of effectiveness over the 15 years since the first PORT recommendations were published. PORT has consistently included treatment recommendations for supported employment, skills training, and ACT. Recommendations for CBT and the token economy were added in the first PORT update. Other intervention areas such as family psychoeducation have been refined and expanded since the last PORT. The inclusion of briefer family approaches in the family treatment recommendation illustrates the ways in which early research on longer and more complex interventions that were difficult to implement has stimulated the development of and research into strategies that may be easier to implement and disseminate.

This revision also demonstrates the extent to which the evidence for psychosocial interventions in the care of persons with schizophrenia continues to grow. New recommendations in the areas of SUDs and weight management reflect the acquisition of new knowledge in problem areas that formerly may have been minimized or overlooked. The growth of new knowledge is equally important for those treatment areas where no recommendation is yet offered but in which the research base is evolving. The last decade has produced greater understanding of the fundamental importance of cognitive impairment in the outcomes and recovery of persons with schizophrenia. While cognitive remediation does not yet meet our standard for a treatment recommendation, the evidence summary reflects the strong interest in this approach and the progress that has been made in this endeavor. Similarly, peer-based services provide great promise for recovery and have acquired a substantial research base but require more research. In the case of recent onset psychosis, despite consensus about the need to provide treatment earlier to prevent disability, evidence has not yet emerged to fully substantiate any particular psychosocial approach. While excitement about a new approach may not be fully matched by current evidence, we hope that the PORT review provides a stimulus for more research in these areas.

It is important to acknowledge challenges and limitations in the larger field of psychosocial treatments for

people with schizophrenia that impact this PORT review. First, our field has no consistent method to categorize psychosocial treatments. Some psychosocial treatments are organized around the outcome or problem being addressed (eg, alcohol or other drug use, medication adherence). Others are organized around the strategy being used (eg, CBT). Still others are organized around care processes (eg, family psychoeducation, ACT) or phase of illness (early-onset interventions). The lack of a standardized method to organize treatments and approaches can lead to confusion and mask the fact that different interventions and treatments may share common elements. For example, a reader could erroneously conclude that CBT is useful only for those symptoms identified in the CBT recommendation and fail to appreciate that cognitive behavioral strategies are an integral part of other approaches such as family psychoeducation, supported employment, and treatment for substance abuse. Similarly, given the separation of ACT and substance abuse treatment in different sections of the PORT, a reader could erroneously conclude that ACT does not include substance abuse treatment when, in fact, the ACT model routinely includes substance abuse treatment services. In reality, pairings and packages of interventions are being implemented in clinical practice and studied by researchers in the field, a trend that reflects our understanding that people with schizophrenia have many complex treatment needs.

A second consideration regarding the designation of psychosocial treatment recommendations emerged around the threshold for designating an intervention as a treatment recommendation and the criteria by which outcomes qualify as a measure of an intervention's effectiveness. Evaluation of study quality and methods to synthesize the results of different studies are emerging fields. Synthetic efforts such as PORT try to take into account a variety of aspects of study design including the nature of comparison groups, sample and statistical power, outcomes measured, follow-up periods, and treatment fidelity. The challenges of integrating these aspects of study rigor were particularly apparent in our consideration of a recommendation for the treatment of SUDs. The initial conclusion of the PORT review and advisory groups was that the threshold for a recommendation was not achieved. However, after the discussion at our expert panel meeting and reconsideration of additional studies, we viewed that the weight of all the evidence did support a recommendation, a conclusion with which the expert panel concurred in their subsequent rereview of the recommendation.

Similarly, traditional outcomes in the schizophrenia pharmacology literature are focused on symptom reduction and relapse prevention, but these outcomes are often not the primary targets in psychosocial interventions. For example, the goal of supported employment interventions is achieving competitive employment in a nonshel-

tered work setting regardless of the person's ongoing psychiatric symptoms. In evaluating the evidence for cognitive remediation as a treatment recommendation, the PORT expert panel was less certain about the appropriate outcome measures. There was considerable debate about whether proximal outcomes such as improvement on neuropsychological tests should be considered a treatment benefit worthy of a recommendation. While improvement on neuropsychological tests is the most proximal outcome to the intervention, the effect of such improvement on real-world functioning has yet to be consistently demonstrated. By the same token, psychosocial interventions for weight reduction in schizophrenia have shown relatively modest effects on the amount of weight lost, and the long-term health benefits of this weight loss have yet to be demonstrated for the individuals in these studies. The PORT expert panel also debated the issue of an appropriate outcome measure for this intervention. They ultimately decided that the findings were sufficient to warrant a recommendation for a weight reduction intervention because the benefits of even modest weight reduction have been amply demonstrated in the general population.<sup>199,215–218</sup> Our review of peer-based interventions produced even more debate as such programs are often focused on outcomes such as empowerment and hope and important domains for recovery but outcomes that have not been traditionally valued or assessed in standard clinical trials. We attempted to include each intervention's expected outcomes in the structure of each PORT recommendations in order to make these debates more transparent.

Third, there is no accepted standard to measure program fidelity to psychosocial interventions. Unlike a medication, whose purity is evaluated by the US Food and Drug Administration (FDA) and which is either taken or not taken and may sometimes be monitored by blood levels, there is no single accepted standard for measuring adherence to psychosocial interventions. This is an important issue in clinical settings because psychosocial interventions may be implemented or delivered in ways that differ from the ways they were implemented in the research studies upon which a treatment recommendation is based. Issues in implementation and delivery may concern both adherence, providing the agreed upon components of an intervention, as well as competence, providing intervention components in skilled and supportive manner; both are important in order to fully determine the efficacy of an intervention. Fidelity scales were included in toolkits created as part of the National Evidence-Based Practices project which was designed to develop and test strategies to implement evidence-based practices for persons with SMIs. Extensive research has demonstrated the robust correlation of high fidelity with outcomes for supported employment,<sup>57–60,219–221</sup> with a slightly less robust but still positive relationship between fidelity and outcomes for ACT.<sup>8,53,222,223</sup> It is

imperative to thoroughly and systematically consider fidelity in future studies that promote implementation of evidence-based practices.

Fourth, the PORT review highlights the gap between research and clinical services. The many sections of the PORT reflect interventions that have some research base, with some more extensive than others. However, overall there is limited use of these interventions in clinical services. For example, some interventions with well-established efficacy, such as the token economy for persons with severe impairments who are living in residential settings, are rarely used, and others, such as skills training, are often incompletely applied. Others, such as supported employment, are more commonly available but are implemented differently and in many cases without full fidelity to the evidence-based model. The National Evidence-Based Practices project field tested a multi-faceted strategy to disseminate 5 psychosocial evidence-based practices in 53 sites in 8 states and found that supported employment and ACT were the most easily implemented. The implementation of evidence-based practices is a complex process and is dependent on structural aspects of the local public mental system. As noted by Drake et al. (2009)<sup>3</sup> in a review of the implementation of evidence-based practices in schizophrenia, factors that are important to successfully disseminating psychosocial evidence-based practices include the state mental health authority's provision of leadership, funding, and practice standards<sup>224-226</sup> skilled mentoring and training;<sup>227</sup> site level administrative support<sup>224,227-231</sup> and monitoring of fidelity and outcomes.<sup>232,233</sup> Until clinical service settings can administer evidence-based practices as they are developed and studied, the problem of the imperfect and inadequate application of research to clinical practice will persist.

Finally, these treatment recommendations do not provide clear direction about the selection or sequence of psychosocial interventions that are offered to the individual patient or that may be most instrumental in facilitating recovery. They do not address the possible benefits to or erosions of effectiveness as interventions and strategies are combined to address multiple problems. Moreover, we know little about how different psychosocial interventions compare in achieving the same outcomes. For example, how do family psychoeducation and ACT compare in achieving relapse reduction? This review does not offer guidance to consumers or providers in deciding which interventions to implement and in what order for an individual who is experiencing difficulty in multiple areas of functioning. While clinically the problems that are causing the person's greatest short-term difficulties are addressed first, once initial stabilization has been achieved, it is unclear how to order the implementation of subsequent interventions in order to achieve optimal results. Should persistent symptoms be targeted with cognitive behavioral treatment first, or must sub-

stance abuse be addressed first? When should interventions for employment or weight management be provided, and should these be done in conjunction with efforts to enhance medication adherence? While much has been accomplished in terms of treatment outcome research in schizophrenia and is reflected in this PORT review, more work is needed in terms of establishing how to order implementation of services to best support all aspects of recovery.

In spite of the limitations of the PORT methodology for reviewing psychosocial interventions for schizophrenia, the PORT meets an important need in our field to review and synthesize the treatment literature in as objective and rigorous manner as possible. Arguably, the PORT product, a set of treatment recommendations, should be considered a basic package for systems of care that are committed to providing evidence-based practices for persons with schizophrenia.

### Supplementary Material

Supplementary material is available at <http://schizophreniabulletin.oxfordjournals.org>.

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