

OUTPATIENT EDUCATION AND MEDICATION ADHERENCE

By

Veronica Sherwood

A Project Submitted in Partial Fulfillment of the Requirements

for the Degree of

MASTER OF SCIENCE

in

Nursing

University of Alaska Anchorage

February, 2018

APPROVED:

Colleen Kelley, PhD, Committee Chair

Tina Traber, PhD, Committee Member

Marianne Murray, DNP, Director

*Department of Nursing*

Andre Rosay, PhD, Associate Dean

*College of Health*

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### Outpatient Education and Medication Adherence

Mental illness can contribute to major functional impairment that can be detrimental to a person. Ustun and Kennedy (2013) report that mental illness can make a person unable to function within “social and occupational spheres of life” (p. 83). Ustun and Kennedy (2013) state that in the DSM-5, the definition of functional impairment is left open to the judgment of the clinician. While the DSM-5 does not define functional impairment, the Social Security Administration (2017) has a very complex system to define and rate the levels of functional impairment relating to mental health disorders (see Appendix A). Levels of impairment range from no limitation to extreme limitation. Functional impairment related to mental illness may contribute to non-adherence to medication management (Haddad, Brian, & Scott, 2014).

Mental illness is prevalent in the United States. When surveying adults in 2013, the Substance Abuse and Mental Health Services Administration’s (SAMHSA) found that approximately one out of every five Americans or 18.5% of the total population had a mental illness, such as schizophrenia and bipolar disorder. The National Alliance on Mental Illness (2015) found that in the United States, there are approximately 2.4 million adults diagnosed with schizophrenia and 6.1 million adults diagnosed with bipolar disorder. Schizophrenia and bipolar disorder, left untreated, can be very debilitating illnesses and affect a person’s ability to carry out day to day activities (National Alliance on Mental Illness, 2015). Novick et al. (2009) found that patients with schizophrenia who were non-adherent with medication management were at a higher risk of relapse, readmission, suicide attempts, increased patient costs, and experienced poorer long-term outcomes.

### **Background and Significance**

Patient medication adherence or lack of adherence is not a new concept to nursing nor is it a new concept within the specialty of psychiatric care. The World Health Organization (WHO) published a report in 2003 recommending a call to action to find ways to improve medication and treatment adherence, including psychiatric medications, and thereby improving the effectiveness of our healthcare system. WHO (2003) reported that approximately 50% of patients with chronic illnesses did not adhere to the treatment recommendations of their practitioner. Adherence is defined by WHO (2003) as “the extent to which a person’s behavior, such as taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider” (p. 18). Mert, Turgut, Kelleci, and Semiz (2015) reported patients who were non-compliant attributed such non-compliance to being unaware of resources, having lack of knowledge regarding their illness or their prescribed medication. In addition, participants did not adhere to practitioner recommendations as they did not accept their diagnoses or believe a need for their medication, or they experienced undesirable side effects from prescribed medications.

### **Clinical Question**

There are many ways that health care providers can guide patients to improve their medication adherence. The National Institute for Health and Care Excellence (2009) recommend several ways to increase the likelihood of adherence such as including patients in decisions about their medication regimen, providing resources to increase knowledge about their disease process, and clarifying what the patient’s goals of treatment are. We, as providers, should strive to improve the patient’s attitudes, perceptions and expectations of both their disease and the

treatment process. The question remains, what is best practice in providing outpatient education to patients with mental health disorders, specifically schizophrenia and bipolar disorder, that improves medication adherence?

### **Literature Search, Data Evaluation, and Analysis Plan**

In order to answer this question, a review of the literature was completed with an unbiased evaluation of peer-reviewed evidence. The following databases were searched: CINAHL Plus, PubMed Health, PsycARTICLES, and PsycINFO. The search consisted of keywords: mental health, schizophrenia, bipolar disorder, medication adherence, medication compliance, outpatient education, and education. The inclusion criteria consisted studies that were: (a) qualitative, quantitative, mixed methods, or meta-analysis studies; (b) published in English; (c) published between 2007 and 2017, with a few exceptions; (d) contents must be relevant to mental health; (e) only full-length articles; (f) peer reviewed; (g) adult (aged 18 and over) participants and (h) study used validated tools. Articles were excluded on the following basis: (a) written in any other language than English; (b) undergraduate research; (c) narrative reviews, editorials, or research opinion pieces; (d) partially published or abstract only; or (e) or published in non-scientific journal.

After selecting articles from the literature search, a Melayk's & Fineout-Overholt's (2011) rapid critical appraisal was utilized (See Appendix B). The purpose of the rapid critical appraisal was to evaluate whether the article was appropriate for the clinical question being asked. The rapid critical appraisal that was used to evaluate the article was dependent upon the level of evidence reported by the authors. The level and quality of the evidence were graded using Dearholt and Dang's (2012) quality guide evidence table and pyramid (see Appendix C). Study validity, credibility, reliability and applicability were examined. If there were more than

three to five answers to the questions on the rapid appraisal that were answered no, the article was excluded. Data collected from the literature search and articles that passed the rapid critical appraisal were summarized and interpreted into categories presented later on in this review. The integrative review was written using objective writing in order to keep the review bias free.

### **Data Evaluation and Critical Appraisal Results**

#### **PsycINFO**

A search was conducted in PsycINFO using the search terms *schizophrenia* or *bipolar disorder*, and *medication adherence* or *medication compliance*, and *education*. Thirty-six articles were produced with these search terms. After applying inclusion criteria, 11 articles remained. After applying the critical appraisal appropriate for each study, there were five useable articles left.

#### **PubMed**

A search was conducted in PubMed using the search terms, *schizophrenia* or *bipolar disorder*, and *medication adherence* or *medication compliance*, and *education*. Those terms produced 177 articles; after the inclusion criteria were applied, there were 16 usable articles. After taking out duplicate articles that were found on previous databases, and applying the critical appraisal appropriate for each study, four articles remained.

#### **CINAHL**

A search was conducted in CINAHL using the terms *schizophrenia* or *bipolar disorder*, and *medication adherence* or *medication compliance*, and *education*. Those terms produced 46 articles; after inclusion criteria were applied, there were three usable articles. No useable articles remained after checking for duplicates and applying the critical appraisal to each article.

#### **PsycARTICLES**

A search was conducted in PsycARTICLES using the search terms *schizophrenia* or *bipolar disorder*, and *medication adherence* or *medication compliance*, and *education*. This search produced 629 articles. After the inclusion criteria were applied, seven articles remained. After taking out duplicate articles found in previous database searches, no articles were used from the PsycARTICLES database.

### **Data Display**

There were nine articles that met inclusion criteria and quality assessment that were used to create evaluation tables (Appendix D). These evaluation tables contain important information from each study in regards to the clinical question being asked, including: citation, design method, characteristics and setting, variables, measurement, data analysis, findings, and worth to practice (Melnik & Fineout-Overholt, 2015). This table provides a clear visual tool for readers to identify what the pertinent information is from each study in relation to the clinical question being asked.

### **Data Synthesis**

The purpose of the data synthesis table is to provide a visual aid with the characteristics of the studies that are common and to show what themes have become apparent (Melnik & Fineout-Overholt, 2015). More specifically, the synthesis process is described as “combining, contrasting, and interpreting a body of evidence to reach a conclusion about what is known and what should be done with that knowledge to improve healthcare outcomes” (Melnik & Fineout-Overholt, 2015, p. 134).

### **Limitations**

Three out of the nine articles used had small sample sizes, which may affect the outcome of the studies (Bond & Anderson, 2015; Bauml et al., 2016; Pasadas & Manso, 2016). Six of the



nine articles used self-reporting tools which can affect the bias that presents in the results (Chein, Mui, Gray & Cheung, 2016; Novick et al., 2015; Pasadas & Manso, 2016; Ran, Chan, Guo, & Xiang, 2015; Staring et al., 2010; Velligan et al., 2007). Participants from several studies were higher functioning patients. This may affect the generalization of the study as patients that are lower functioning will not be taken into consideration in the study. One of the studies included patients who had already been diagnosed for 10 years, leading the authors to hypothesize that if education had taken place earlier in the disease process, better outcomes may have been seen (Velligan et al., 2007). Inclusion criteria required by many of the studies may have omitted the population of people that had multiple readmissions to the hospital and were less adherent to medication and treatment regimens. This may have influenced the results of the studies for the better.

### **Strengths**

Seven out of the nine were rated level 1 evidence and had either A or B quality (Bond & Anderson, 2015; Bauml et al., 2016; Chein et al., 2016; Ran et al., 2015; Staring et al, 2010; Velligan et al, 2007). Articles with level 1 evidence, according to Dearholt and Dang (2012) are consistent, generalizable, and are more recommended to be used in practice (see Appendix C for definitions of levels and quality definitions). Two studies were rated level 3 evidence, however still had an A or B quality (Aziz et al., 2016; Pasadas & Manso, 2016). These studies, according to Dearholt and Dang (2012) have consistent and generalizable results, and are still recommended to be used in practice (see Appendix C for definitions of levels and quality definitions). All nine studies had positive results and were rated recommended to be used in practice. Using Melnyk and Fineout-Overholt's (2015) Rapid Critical Appraisal tool, all nine articles were determined to be valid, reliable, and applicable.

### **Compare and Contrast**

While the main goal of this literature review was to find the best education method in the outpatient setting to improve medication compliance in patients diagnosed with schizophrenia or bipolar disorder, no two studies used the exact same educational method or materials. Education was provided in many styles, including individual therapy, group settings, and multiple sessions. The similarity of the studies shows that education created with intention of improving insight into the disease process creates improvement in medication adherence and in overall functional outcome. All tools used to measure insight and functioning are listed in appendix D. When compared to the control groups, many studies showed decreased hospitalizations or decreased manic and depressive episodes in the groups receiving education (Bond & Anderson, 2015; Bauml et al, 2016; Chein et al., 2016; Ran et al., 2015; Staring et al., 2010). Two studies showed that when education is tailored to fit the individual educational needs of the patient, participation in the sessions is improved (Staring et al., 2010; Velligan et al, 2007). One study showed the importance of integrating cultural beliefs when planning patient education (Aziz et al., 2016). One study found that if patients used a faith healer, there is greater chance of medication non-adherence (Aziz et al., 2016). Two studies showed that education can improve long-term adherence and overall functioning (Pasadas et al., 2016, Velligan et al., 2007). One study showed evidence that multiple sessions that took place over a longer period of time and thorough educational material were more beneficial (Bond & Anderson., 2015).

### **Commonalities**

Eight of the nine studies used self-reporting measurement questionnaires, improving knowledge about diagnoses and treatment by education, and improving insight into their illness (Aziz et al., 2016; Bauml et al., 2016; Chein et al., 2016; Novick et al., 2015; Pasadas et al.,

2016; Ran et al., 2015; Staring et al, 2010; Velligan et al, 2007). All therapy or education was client centered and one particular study examined the effect when family members were included in the education (Ran et al., 2015). All nine studies reported increased medication compliance, increased insight, or increased overall functioning. Five of nine studies were randomized controlled studies and compared the differences between groups receiving education and groups receiving standard psychiatric care (Bauml et al., 2016; Chein et al., 2016; Pasadas et al., 2016; Ran et al., 2015; Velligan et al, 2007). All nine studies included patients diagnosed with schizophrenia or bipolar disorder. Two of the studies included a portion of patients that were diagnosed with bipolar disorder and a portion of patients that were diagnosed with schizophrenia (Bond et al., 2015; Novick et al., 2015).

## **Discussion**

### **Implications**

The literature reviewed in this document consistently showed that education improves patient insight, medication adherence, patient satisfaction, work abilities, and overall functioning. Education is shown to decrease the amount of hospitalizations, the amount of time spent in the hospital if hospitalization is necessary, and to decrease manic and depressive episodes by improving medication adherence. While none of the studies used the same education method, the authors indicate that education geared toward improving patient insight into their disease improves satisfaction and participation (Chein et al., 2016; Novick et al., 2015; Pasadas et al., 2016). All nine articles show that any form of education is more effective at improving medication adherence when compared to patients receiving the general instructions about medication.

**Recommendations**

Based on all nine articles included in this integrative review, it is appropriate to recommend providing education based therapy (with topics of prescribed medication, medical diagnosis, with insight and coping education) for psychiatric patients diagnosed with schizophrenia or bipolar disorder to improve patient outcomes. It does not appear to matter if the education is primarily medication based, diagnosis based, or about lifestyle skills. Any education provided was found to contribute to increased medication adherence as was the original intent of this integrative review, the patient's ability to maintain employment, self-reported higher satisfaction scores related to what was reported prior to the education received, and overall improved quality of life. By improving quality of life for patients diagnosed with mental illness, it may also contribute to money savings for communities due to less citizens diagnosed with mental illness living on the streets, decreased hospitalizations and relapses. The common theme shown in the current literature recommend that education be patient-centered, more thorough and multiple sessions take place over an extended period of time as being key to improving medication adherence. It is imperative to note the importance of a positive patient-provider relationship helps improve medication adherence and patient outcomes. Further research is needed to study the effect of combining detailed patient-centered educational methods and improved patient-provider relationships to patients diagnosed with schizophrenia and bipolar disorder.

**Conclusion**

The research included in this integrative and exhaustive review indicates the importance of providing patients diagnosed with schizophrenia and bipolar disorder outpatient education to improve their insight. This in turn will contribute to improving medication adherence along with

other patient outcomes. Educational methods used need to integrate the patient's culture and specific individualized needs. In conclusion, traditional education provided today is inadequate in helping patients reach optimal insight and follow recommended medication treatment by practitioners. There is sufficient evidence to support the implementation of a multi-session, patient-centered education with the intention to improve patient insight to help increase medication adherence rates.

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**Appendix A****Social Security - Disability Evaluation**

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12.00-Mental Disorders-Adult

**Social Security**

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**Medical/Professional Relations**

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**Disability Evaluation Under Social Security****12.00 Mental Disorders - Adult****Section****12.01**

Category of Impairments, Mental

**12.02**

Neurocognitive disorders

**12.03**

Schizophrenia spectrum and other psychotic disorders

**12.04**

Depressive, bipolar and related disorders

**12.05**

Intellectual disorder

**12.06**

Anxiety and obsessive-compulsive disorders

**12.07**

Somatic symptom and related disorders

**12.08**

Personality and impulse-control disorders

**12.09**

[Reserved]

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**12.10**

Autism spectrum disorder

**12.11**

Neurodevelopmental disorders

**12.12**

[Reserved]

**12.13**

Eating disorders

**12.15**

Trauma- and stressor-related disorders

**12.00 Mental Disorders****A. How are the listings for mental disorders arranged, and what do they require?**

1. The listings for mental disorders are arranged in 11 categories: neurocognitive disorders (12.02); schizophrenia spectrum and other psychotic disorders (12.03); depressive, bipolar and related disorders (12.04); intellectual disorder (12.05); anxiety and obsessive-compulsive disorders (12.06); somatic symptom and related disorders (12.07); personality and impulse-control disorders (12.08); autism spectrum disorder (12.10); neurodevelopmental disorders (12.11); eating disorders (12.13); and trauma- and stressor-related disorders (12.15).
2. Listings 12.07, 12.08, 12.10, 12.11, and 12.13 have two paragraphs, designated A and B; your mental disorder must satisfy the requirements of both paragraphs A and B. Listings 12.02, 12.03, 12.04, 12.06, and 12.15 have three paragraphs, designated A, B, and C; your mental disorder must satisfy the requirements of both paragraphs A and B, or the requirements of both paragraphs A and C. Listing 12.05 has two paragraphs that are unique to that listing (see 12.00A3); your mental disorder must satisfy the requirements of either paragraph A or paragraph B.
  - a. Paragraph A of each listing (except 12.05) includes the medical criteria that must be present in your medical evidence.
  - b. Paragraph B of each listing (except 12.05) provides the functional criteria we assess, in conjunction with a rating scale (see 12.00E and 12.00F), to evaluate how your mental disorder limits your functioning. These criteria represent the areas of mental functioning a person uses in a work setting. They are: understand, remember, or apply information; interact with others; concentrate, persist, or maintain pace; and adapt or manage oneself. We will determine the degree to which your medically determinable mental impairment affects the four areas of mental functioning and your ability to function independently.

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appropriately, effectively, and on a sustained basis (see 404.1520a(c)(2) and 416.920a(c)(2) of this chapter). To satisfy the paragraph B criteria, your mental disorder must result in "extreme" limitation of one, or "marked" limitation of two, of the four areas of mental functioning. (When we refer to "paragraph B criteria" or "area[s] of mental functioning" in the introductory text of this body system, we mean the criteria in paragraph B of every listing except 12.05.)

- c. Paragraph C of listings 12.02, 12.03, 12.04, 12.06, and 12.15 provides the criteria we use to evaluate "serious and persistent mental disorders." To satisfy the paragraph C criteria, your mental disorder must be "serious and persistent"; that is, there must be a medically documented history of the existence of the disorder over a period of at least 2 years, and evidence that satisfies the criteria in both C1 and C2 (see 12.00G). (When we refer to "paragraph C" or "the paragraph C criteria" in the introductory text of this body system, we mean the criteria in paragraph C of listings 12.02, 12.03, 12.04, 12.06, and 12.15.)
- 3. Listing 12.05 has two paragraphs, designated A and B, that apply to only intellectual disorder. Each paragraph requires that you have significantly subaverage general intellectual functioning; significant deficits in current adaptive functioning; and evidence that demonstrates or supports (is consistent with) the conclusion that your disorder began prior to age 22.

## **B. Which mental disorders do we evaluate under each listing category?**

### **1. *Neurocognitive disorders (12.02).***

- a. These disorders are characterized by a clinically significant decline in cognitive functioning. Symptoms and signs may include, but are not limited to, disturbances in memory, executive functioning (that is, higher-level cognitive processes; for example, regulating attention, planning, inhibiting responses, decision-making), visual-spatial functioning, language and speech, perception, insight, judgment, and insensitivity to social standards.
- b. Examples of disorders that we evaluate in this category include major neurocognitive disorder; dementia of the Alzheimer type; vascular dementia; dementia due to a medical condition such as a metabolic disease (for example, late-onset Tay-Sachs disease), human immunodeficiency virus infection, vascular malformation, progressive brain tumor, neurological disease (for example, multiple sclerosis, Parkinsonian syndrome, Huntington disease), or traumatic brain injury; or substance-induced cognitive disorder associated with drugs of abuse, medications, or toxins. (We evaluate neurological disorders under that body system (see 11.00). We evaluate cognitive impairments that result from neurological disorders under 12.02 if they do not satisfy the requirements in 11.00 (see 11.00G).)
- c. This category does not include the mental disorders that we evaluate under intellectual disorder (12.05), autism spectrum disorder (12.10), and neurodevelopmental disorders (12.11).

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2. *Schizophrenia spectrum and other psychotic disorders (12.03).*

- a. These disorders are characterized by delusions, hallucinations, disorganized speech, or grossly disorganized or catatonic behavior, causing a clinically significant decline in functioning. Symptoms and signs may include, but are not limited to, inability to initiate and persist in goal-directed activities, social withdrawal, flat or inappropriate affect, poverty of thought and speech, loss of interest or pleasure, disturbances of mood, odd beliefs and mannerisms, and paranoia.
- b. Examples of disorders that we evaluate in this category include schizophrenia, schizoaffective disorder, delusional disorder, and psychotic disorder due to another medical condition.

3. *Depressive, bipolar and related disorders (12.04).*

- a. These disorders are characterized by an irritable, depressed, elevated, or expansive mood, or by a loss of interest or pleasure in all or almost all activities, causing a clinically significant decline in functioning. Symptoms and signs may include, but are not limited to, feelings of hopelessness or guilt, suicidal ideation, a clinically significant change in body weight or appetite, sleep disturbances, an increase or decrease in energy, psychomotor abnormalities, disturbed concentration, pressured speech, grandiosity, reduced impulse control, sadness, euphoria, and social withdrawal.
- b. Examples of disorders that we evaluate in this category include bipolar disorders (I or II), cyclothymic disorder, major depressive disorder, persistent depressive disorder (dysthymia), and bipolar or depressive disorder due to another medical condition.

4. *Intellectual disorder (12.05).*

- a. This disorder is characterized by significantly subaverage general intellectual functioning, significant deficits in current adaptive functioning, and manifestation of the disorder before age 22. Signs may include, but are not limited to, poor conceptual, social, or practical skills evident in your adaptive functioning.
- b. The disorder that we evaluate in this category may be described in the evidence as intellectual disability, intellectual developmental disorder, or historically used terms such as "mental retardation."
- c. This category does not include the mental disorders that we evaluate under neurocognitive disorders (12.02), autism spectrum disorder (12.10), or neurodevelopmental disorders (12.11).

5. *Anxiety and obsessive-compulsive disorders (12.06).*

- a. These disorders are characterized by excessive anxiety, worry, apprehension, and fear, or by avoidance of feelings, thoughts, activities, objects, places, or people. Symptoms and signs may include, but are not limited to, restlessness, difficulty concentrating, hypervigilance, muscle tension, sleep disturbance, fatigue, panic attacks, obsessions and compulsions, constant thoughts and fears about safety, and frequent physical complaints.
- b. Examples of disorders that we evaluate in this category include social anxiety disorder,

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panic disorder, generalized anxiety disorder, agoraphobia, and obsessive-compulsive disorder.

- c. This category does not include the mental disorders that we evaluate under trauma- and stressor-related disorders (12.15).

6. *Somatic symptom and related disorders (12.07).*

- a. These disorders are characterized by physical symptoms or deficits that are not intentionally produced or feigned, and that, following clinical investigation, cannot be fully explained by a general medical condition, another mental disorder, the direct effects of a substance, or a culturally sanctioned behavior or experience. These disorders may also be characterized by a preoccupation with having or acquiring a serious medical condition that has not been identified or diagnosed. Symptoms and signs may include, but are not limited to, pain and other abnormalities of sensation, gastrointestinal symptoms, fatigue, a high level of anxiety about personal health status, abnormal motor movement, pseudoseizures, and pseudoneurological symptoms, such as blindness or deafness.
- b. Examples of disorders that we evaluate in this category include somatic symptom disorder, illness anxiety disorder, and conversion disorder.

7. *Personality and impulse-control disorders (12.08).*

- a. These disorders are characterized by enduring, inflexible, maladaptive, and pervasive patterns of behavior. Onset typically occurs in adolescence or young adulthood. Symptoms and signs may include, but are not limited to, patterns of distrust, suspiciousness, and odd beliefs; social detachment, discomfort, or avoidance; hypersensitivity to negative evaluation; an excessive need to be taken care of; difficulty making independent decisions; a preoccupation with orderliness, perfectionism, and control; and inappropriate, intense, impulsive anger and behavioral expression grossly out of proportion to any external provocation or psychosocial stressors.
- b. Examples of disorders that we evaluate in this category include paranoid, schizoid, schizotypal, borderline, avoidant, dependent, obsessive-compulsive personality disorders, and intermittent explosive disorder.

8. *Autism spectrum disorder (12.10).*

- a. These disorders are characterized by qualitative deficits in the development of reciprocal social interaction, verbal and nonverbal communication skills, and symbolic or imaginative activity; restricted repetitive and stereotyped patterns of behavior, interests, and activities; and stagnation of development or loss of acquired skills early in life. Symptoms and signs may include, but are not limited to, abnormalities and unevenness in the development of cognitive skills; unusual responses to sensory stimuli; and behavioral difficulties, including hyperactivity, short attention span, impulsivity, aggressiveness, or self-injurious actions.
- b. Examples of disorders that we evaluate in this category include autism spectrum disorder with or without accompanying intellectual impairment, and autism spectrum disorder

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with or without accompanying language impairment.

- c. This category does not include the mental disorders that we evaluate under neurocognitive disorders (12.02), intellectual disorder (12.05), and neurodevelopmental disorders (12.11).

9. *Neurodevelopmental disorders (12.11).*

- a. These disorders are characterized by onset during the developmental period, that is, during childhood or adolescence, although sometimes they are not diagnosed until adulthood. Symptoms and signs may include, but are not limited to, underlying abnormalities in cognitive processing (for example, deficits in learning and applying verbal or nonverbal information, visual perception, memory, or a combination of these); deficits in attention or impulse control; low frustration tolerance; excessive or poorly planned motor activity; difficulty with organizing (time, space, materials, or tasks); repeated accidental injury; and deficits in social skills. Symptoms and signs specific to tic disorders include sudden, rapid, recurrent, non-rhythmic, motor movement or vocalization.
- b. Examples of disorders that we evaluate in this category include specific learning disorder, borderline intellectual functioning, and tic disorders (such as Tourette syndrome).
- c. This category does not include the mental disorders that we evaluate under neurocognitive disorders (12.02), autism spectrum disorder (12.10), or personality and impulse-control disorders (12.08).

10. *Eating disorders (12.13).*

- a. These disorders are characterized by disturbances in eating behavior and preoccupation with, and excessive self-evaluation of, body weight and shape. Symptoms and signs may include, but are not limited to, restriction of energy consumption when compared with individual requirements; recurrent episodes of binge eating or behavior intended to prevent weight gain, such as self-induced vomiting, excessive exercise, or misuse of laxatives; mood disturbances, social withdrawal, or irritability; amenorrhea; dental problems; abnormal laboratory findings; and cardiac abnormalities.
- b. Examples of disorders that we evaluate in this category include anorexia nervosa, bulimia nervosa, binge-eating disorder, and avoidant/restrictive food disorder.

11. *Trauma- and stressor-related disorders (12.15).*

- a. These disorders are characterized by experiencing or witnessing a traumatic or stressful event, or learning of a traumatic event occurring to a close family member or close friend, and the psychological aftermath of clinically significant effects on functioning. Symptoms and signs may include, but are not limited to, distressing memories, dreams, and flashbacks related to the trauma or stressor; avoidant behavior; diminished interest or participation in significant activities; persistent negative emotional states (for example, fear, anger) or persistent inability to experience positive emotions (for example, satisfaction, affection); anxiety; irritability; aggression; exaggerated startle response; difficulty concentrating; and sleep disturbance.

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- b. Examples of disorders that we evaluate in this category include posttraumatic stress disorder and other specified trauma- and stressor-related disorders (such as adjustment-like disorders with prolonged duration without prolonged duration of stressor).
- c. This category does not include the mental disorders that we evaluate under anxiety and obsessive-compulsive disorders (12.06), and cognitive impairments that result from neurological disorders, such as a traumatic brain injury, which we evaluate under neurocognitive disorders (12.02).

### **C. What evidence do we need to evaluate your mental disorder?**

1. *General.* We need objective medical evidence from an acceptable medical source to establish that you have a medically determinable mental disorder. We also need evidence to assess the severity of your mental disorder and its effects on your ability to function in a work setting. We will determine the extent and kinds of evidence we need from medical and nonmedical sources based on the individual facts about your disorder. For additional evidence requirements for intellectual disorder (12.05), see 12.00H. For our basic rules on evidence, see 404.1512, 404.1513, 404.1520b, 416.912, 416.913, and 416.920b of this chapter. For our rules on evaluating medical opinions, see 404.1520c, 404.1527, 416.920c, and 416.927 of this chapter. For our rules on evidence about your symptoms, see 404.1529 and 416.929 of this chapter.
2. *Evidence from medical sources.* We will consider all relevant medical evidence about your disorder from your physician, psychologist, and other medical sources, which include health care providers such as physician assistants, psychiatric nurse practitioners, licensed clinical social workers, and clinical mental health counselors. Evidence from your medical sources may include:
  - a. Your reported symptoms.
  - b. Your medical, psychiatric, and psychological history.
  - c. The results of physical or mental status examinations, structured clinical interviews, psychiatric or psychological rating scales, measures of adaptive functioning, or other clinical findings.
  - d. Psychological testing, imaging results, or other laboratory findings.
  - e. Your diagnosis.
  - f. The type, dosage, and beneficial effects of medications you take.
  - g. The type, frequency, duration, and beneficial effects of therapy you receive.
  - h. Side effects of medication or other treatment that limit your ability to function.
  - i. Your clinical course, including changes in your medication, therapy, or other treatment, and the time required for therapeutic effectiveness.
  - j. Observations and descriptions of how you function during examinations or therapy.
  - k. Information about sensory, motor, or speech abnormalities, or about your cultural background (for example, language or customs) that may affect an evaluation of your mental disorder.

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- I. The expected duration of your symptoms and signs and their effects on your functioning, both currently and in the future.
3. *Evidence from you and people who know you.* We will consider all relevant evidence about your mental disorder and your daily functioning that we receive from you and from people who know you. We will ask about your symptoms, your daily functioning, and your medical treatment. We will ask for information from third parties who can tell us about your mental disorder, but you must give us permission to do so. This evidence may include information from your family, caregivers, friends, neighbors, clergy, case managers, social workers, shelter staff, or other community support and outreach workers. We will consider whether your statements and the statements from third parties are consistent with the medical and other evidence we have.
4. *Evidence from school, vocational training, work, and work-related programs.*
  - a. *School.* You may have recently attended or may still be attending school, and you may have received or may still be receiving special education services. If so, we will try to obtain information from your school sources when we need it to assess how your mental disorder affects your ability to function. Examples of this information include your Individualized Education Programs (IEPs), your Section 504 plans, comprehensive evaluation reports, school-related therapy progress notes, information from your teachers about how you function in a classroom setting, and information about any special services or accommodations you receive at school.
  - b. *Vocational training, work, and work-related programs.* You may have recently participated in or may still be participating in vocational training, work-related programs, or work activity. If so, we will try to obtain information from your training program or your employer when we need it to assess how your mental disorder affects your ability to function. Examples of this information include training or work evaluations, modifications to your work duties or work schedule, and any special supports or accommodations you have required or now require in order to work. If you have worked or are working through a community mental health program, sheltered or supported work program, rehabilitation program, or transitional employment program, we will consider the type and degree of support you have received or are receiving in order to work (see 12.00D).
5. *Need for longitudinal evidence.*
  - a. *General.* Longitudinal medical evidence can help us learn how you function over time, and help us evaluate any variations in the level of your functioning. We will request longitudinal evidence of your mental disorder when your medical providers have records concerning you and your mental disorder over a period of months or perhaps years (see 404.1512(d) and 416.912(d) of this chapter).
  - b. *Non-medical sources of longitudinal evidence.* Certain situations, such as chronic homelessness, may make it difficult for you to provide longitudinal medical evidence. If you have a severe mental disorder, you will probably have evidence of its effects on your functioning over time, even if you have not had an ongoing relationship with the



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medical community or are not currently receiving treatment. For example, family members, friends, neighbors, former employers, social workers, case managers, community support staff, outreach workers, or government agencies may be familiar

with your mental health history. We will ask for information from third parties who can tell us about your mental disorder, but you must give us permission to do so.

- c. *Absence of longitudinal evidence.* In the absence of longitudinal evidence, we will use current objective medical evidence and all other relevant evidence available to us in your case record to evaluate your mental disorder. If we purchase a consultative examination to document your disorder, the record will include the results of that examination (see 404.1514 and 416.914 of this chapter). We will take into consideration your medical history, symptoms, clinical and laboratory findings, and medical source opinions. If you do not have longitudinal evidence, the current evidence alone may not be sufficient or appropriate to show that you have a disorder that meets the criteria of one of the mental disorders listings. In that case, we will follow the rules in 12.00J.

6. *Evidence of functioning in unfamiliar situations or supportive situations.*

- a. *Unfamiliar situations.* We recognize that evidence about your functioning in unfamiliar situations does not necessarily show how you would function on a sustained basis in a work setting. In one-time, time-limited, or other unfamiliar situations, you may function differently than you do in familiar situations. In unfamiliar situations, you may appear more, or less, limited than you do on a daily basis and over time.
- b. *Supportive situations.* Your ability to complete tasks in settings that are highly structured, or that are less demanding or more supportive than typical work settings does not necessarily demonstrate your ability to complete tasks in the context of regular employment during a normal workday or work week.
- c. *Our assessment.* We must assess your ability to complete tasks by evaluating all the evidence, such as reports about your functioning from you and third parties who are familiar with you, with an emphasis on how independently, appropriately, and effectively you are able to complete tasks on a sustained basis.

**D. How do we consider psychosocial supports, structured settings, living arrangements, and treatment?**

- 1. *General.* Psychosocial supports, structured settings, and living arrangements, including assistance from your family or others, may help you by reducing the demands made on you. In addition, treatment you receive may reduce your symptoms and signs and possibly improve your functioning, or may have side effects that limit your functioning. Therefore, when we evaluate the effects of your mental disorder and rate the limitation of your areas of mental functioning, we will consider the kind and extent of supports you receive, the characteristics of any structured setting in which you spend your time, and the effects of any treatment. This evidence may come from reports about your functioning from you or third parties who are

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familiar with you, and other third-party statements or information. Following are some examples of the supports you may receive:

- a. You receive help from family members or other people who monitor your daily activities and help you to function. For example, family members administer your medications, remind you to eat, shop for you and pay your bills, or change their work hours so you are never home alone.
  - b. You participate in a special education or vocational training program, or a psychosocial rehabilitation day treatment or community support program, where you receive training in daily living and entry-level work skills.
  - c. You participate in a sheltered, supported, or transitional work program, or in a competitive employment setting with the help of a job coach or supervisor.
  - d. You receive comprehensive “24/7 wrap-around” mental health services while living in a group home or transitional housing, while participating in a semi-independent living program, or while living in individual housing (for example, your own home or apartment).
  - e. You live in a hospital or other institution with 24-hour care.
  - f. You receive assistance from a crisis response team, social workers, or community mental health workers who help you meet your physical needs, and who may also represent you in dealings with government or community social services.
  - g. You live alone and do not receive any psychosocial support(s); however, you have created a highly structured environment by eliminating all but minimally necessary contact with the world outside your living space.
2. *How we consider different levels of support and structure in psychosocial rehabilitation programs.*
- a. Psychosocial rehabilitation programs are based on your specific needs. Therefore, we cannot make any assumptions about your mental disorder based solely on the fact that you are associated with such a program. We must know the details of the program(s) in which you are involved and the pattern(s) of your involvement over time.
  - b. The kinds and levels of supports and structures in psychosocial rehabilitation programs typically occur on a scale of “most restrictive” to “least restrictive.” Participation in a psychosocial rehabilitation program at the most restrictive level would suggest greater limitation of your areas of mental functioning than would participation at a less restrictive level. The length of time you spend at different levels in a program also provides information about your functioning. For example, you could begin participation at the most restrictive crisis intervention level but gradually improve to the point of readiness for a lesser level of support and structure and possibly some form of employment.
3. *How we consider the help or support you receive.*

- a. We will consider the complete picture of your daily functioning, including the kinds, extent, and frequency of help and support you receive, when we evaluate your mental

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disorder and determine whether you are able to use the four areas of mental functioning in a work setting. The fact that you have done, or currently do, some routine activities without help or support does not necessarily mean that you do not have a mental disorder or that you are not disabled. For example, you may be able to take care of your

personal needs, cook, shop, pay your bills, live by yourself, and drive a car. You may demonstrate both strengths and deficits in your daily functioning.

- b. You may receive various kinds of help and support from others that enable you to do many things that, because of your mental disorder, you might not be able to do independently. Your daily functioning may depend on the special contexts in which you function. For example, you may spend your time among only familiar people or surroundings, in a simple and steady routine or an unchanging environment, or in a highly structured setting. However, this does not necessarily show how you would function in a work setting on a sustained basis, throughout a normal workday and workweek. (See 12.00H for further discussion of these issues regarding significant deficits in adaptive functioning for the purpose of 12.05.)

4. *How we consider treatment.* We will consider the effect of any treatment on your functioning when we evaluate your mental disorder. Treatment may include medication(s), psychotherapy, or other forms of intervention, which you receive in a doctor's office, during a hospitalization, or in a day program at a hospital or outpatient treatment program. With treatment, you may not only have your symptoms and signs reduced, but may also be able to function in a work setting. However, treatment may not resolve all of the limitations that result from your mental disorder, and the medications you take or other treatment you receive for your disorder may cause side effects that limit your mental or physical functioning. For example, you may experience drowsiness, blunted affect, memory loss, or abnormal involuntary movements.

#### **E. What are the paragraph B criteria?**

1. *Understand, remember, or apply information (paragraph B1).* This area of mental functioning refers to the abilities to learn, recall, and use information to perform work activities. Examples include: understanding and learning terms, instructions, procedures; following one- or two-step oral instructions to carry out a task; describing work activity to someone else; asking and answering questions and providing explanations; recognizing a mistake and correcting it; identifying and solving problems; sequencing multi-step activities; and using reason and judgment to make work-related decisions. These examples illustrate the nature of this area of mental functioning. We do not require documentation of all of the examples.
2. *Interact with others (paragraph B2).* This area of mental functioning refers to the abilities to relate to and work with supervisors, co-workers, and the public. Examples include: cooperating with others; asking for help when needed; handling conflicts with others; stating own point of view; initiating or sustaining conversation; understanding and responding to social cues (physical, verbal, emotional); responding to requests, suggestions, criticism, correction, and challenges; and keeping social interactions free of excessive irritability, sensitivity,

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argumentativeness, or suspiciousness. These examples illustrate the nature of this area of mental functioning. We do not require documentation of all of the examples.

3. *Concentrate, persist, or maintain pace (paragraph B3)*. This area of mental functioning refers to the abilities to focus attention on work activities and stay on task at a sustained rate. Examples include: initiating and performing a task that you understand and know how to do; working at an appropriate and consistent pace; completing tasks in a timely manner; ignoring or avoiding distractions while working; changing activities or work settings without being disruptive; working close to or with others without interrupting or distracting them; sustaining an ordinary routine and regular attendance at work; and working a full day without needing more than the allotted number or length of rest periods during the day. These examples illustrate the nature of this area of mental functioning. We do not require documentation of all of the examples.
4. *Adapt or manage oneself (paragraph B4)*. This area of mental functioning refers to the abilities to regulate emotions, control behavior, and maintain well-being in a work setting. Examples include: responding to demands; adapting to changes; managing your psychologically based symptoms; distinguishing between acceptable and unacceptable work performance; setting realistic goals; making plans for yourself independently of others; maintaining personal hygiene and attire appropriate to a work setting; and being aware of normal hazards and taking appropriate precautions. These examples illustrate the nature of this area of mental functioning. We do not require documentation of all of the examples.

#### **F. How do we use the paragraph B criteria to evaluate your mental disorder?**

1. *General*. We use the paragraph B criteria, in conjunction with a rating scale (see 12.00F2), to rate the degree of your limitations. We consider only the limitations that result from your mental disorder(s). We will determine whether you are able to use each of the paragraph B areas of mental functioning in a work setting. We will consider, for example, the kind, degree, and frequency of difficulty you would have; whether you could function without extra help, structure, or supervision; and whether you would require special conditions with regard to activities or other people (see 12.00D).
2. *The five-point rating scale*. We evaluate the effects of your mental disorder on each of the four areas of mental functioning based on a five-point rating scale consisting of none, mild, moderate, marked, and extreme limitation. To satisfy the paragraph B criteria, your mental disorder must result in extreme limitation of one, or marked limitation of two, paragraph B areas of mental functioning. Under these listings, the five rating points are defined as follows:
  - a. *No limitation (or none)*. You are able to function in this area independently, appropriately, effectively, and on a sustained basis.
  - b. *Mild limitation*. Your functioning in this area independently, appropriately, effectively, and on a sustained basis is slightly limited.
  - c. *Moderate limitation*. Your functioning in this area independently, appropriately, effectively, and on a sustained basis is fair.

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- d. *Marked limitation.* Your functioning in this area independently, appropriately, effectively, and on a sustained basis is seriously limited.
  - e. *Extreme limitation.* You are not able to function in this area independently, appropriately, effectively, and on a sustained basis.
3. *Rating the limitations of your areas of mental functioning.*
- a. *General.* We use all of the relevant medical and non-medical evidence in your case record to evaluate your mental disorder: the symptoms and signs of your disorder, the reported limitations in your activities, and any help and support you receive that is necessary for you to function. The medical evidence may include descriptors regarding the diagnostic stage or level of your disorder, such as "mild" or "moderate." Clinicians may use these terms to characterize your medical condition. However, these terms will not always be the same as the degree of your limitation in a paragraph B area of mental functioning.
  - b. *Areas of mental functioning in daily activities.* You use the same four areas of mental functioning in daily activities at home and in the community that you would use to function at work. With respect to a particular task or activity, you may have trouble using one or more of the areas. For example, you may have difficulty understanding and remembering what to do; or concentrating and staying on task long enough to do it; or engaging in the task or activity with other people; or trying to do the task without becoming frustrated and losing self-control. Information about your daily functioning can help us understand whether your mental disorder limits one or more of these areas; and, if so, whether it also affects your ability to function in a work setting.
  - c. *Areas of mental functioning in work settings.* If you have difficulty using an area of mental functioning from day-to-day at home or in your community, you may also have difficulty using that area to function in a work setting. On the other hand, if you are able to use an area of mental functioning at home or in your community, we will not necessarily assume that you would also be able to use that area to function in a work setting where the demands and stressors differ from those at home. We will consider all evidence about your mental disorder and daily functioning before we reach a conclusion about your ability to work.
  - d. *Overall effect of limitations.* Limitation of an area of mental functioning reflects the overall degree to which your mental disorder interferes with that area. The degree of limitation is how we document our assessment of your limitation when using the area of mental functioning independently, appropriately, effectively, and on a sustained basis. It does not necessarily reflect a specific type or number of activities, including activities of daily living, that you have difficulty doing. In addition, no single piece of information (including test results) can establish the degree of limitation of an area of mental functioning.
  - e. *Effects of support, supervision, structure on functioning.* The degree of limitation of an area of mental functioning also reflects the kind and extent of supports or supervision

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you receive and the characteristics of any structured setting where you spend your time, which enable you to function. The more extensive the support you need from others or the more structured the setting you need in order to function, the more limited we will find you to be (see 12.00D).

f. *Specific instructions for paragraphs B1, B3, and B4.* For paragraphs B1, B3, and B4, the greatest degree of limitation of any part of the area of mental functioning directs the rating of limitation of that whole area of mental functioning.

- i. To do a work-related task, you must be able to understand and remember and apply information required by the task. Similarly, you must be able to concentrate and persist and maintain pace in order to complete the task, and adapt and manage yourself in the workplace. Limitation in any one of these parts (understand or remember or apply; concentrate or persist or maintain pace; adapt or manage oneself) may prevent you from completing a work-related task.
- ii. We will document the rating of limitation of the whole area of mental functioning, not each individual part. We will not add ratings of the parts together. For example, with respect to paragraph B3, if you have marked limitation in maintaining pace, and mild or moderate limitations in concentrating and persisting, we will find that you have marked limitation in the whole paragraph B3 area of mental functioning.
- iii. Marked limitation in more than one part of the same paragraph B area of mental functioning does not satisfy the requirement to have marked limitation in two paragraph B areas of mental functioning.

4. *How we evaluate mental disorders involving exacerbations and remissions.*

- a. When we evaluate the effects of your mental disorder, we will consider how often you have exacerbations and remissions, how long they last, what causes your mental disorder to worsen or improve, and any other relevant information. We will assess any limitation of the affected paragraph B area(s) of mental functioning using the rating scale for the paragraph B criteria. We will consider whether you can use the area of mental functioning on a regular and continuing basis (8 hours a day, 5 days a week, or an equivalent work schedule). We will not find that you are able to work solely because you have a period(s) of improvement (remission), or that you are disabled solely because you have a period of worsening (exacerbation), of your mental disorder.
- b. If you have a mental disorder involving exacerbations and remissions, you may be able to use the four areas of mental functioning to work for a few weeks or months. Recurrence or worsening of symptoms and signs, however, can interfere enough to render you unable to sustain the work.

**G. What are the paragraph C criteria, and how do we use them to evaluate your mental disorder?**

1. *General.* The paragraph C criteria are an alternative to the paragraph B criteria under listings

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12.02, 12.03, 12.04, 12.06, and 12.15. We use the paragraph C criteria to evaluate mental disorders that are “serious and persistent.” In the paragraph C criteria, we recognize that mental health interventions may control the more obvious symptoms and signs of your mental disorder.

**2. Paragraph C criteria.**

- a. We find a mental disorder to be “serious and persistent” when there is a medically documented history of the existence of the mental disorder in the listing category over a period of at least 2 years, and evidence shows that your disorder satisfies both C1 and C2.
- b. The criterion in C1 is satisfied when the evidence shows that you rely, on an ongoing basis, upon medical treatment, mental health therapy, psychosocial support(s), or a highly structured setting(s), to diminish the symptoms and signs of your mental disorder (see 12.00D). We consider that you receive ongoing medical treatment when the medical evidence establishes that you obtain medical treatment with a frequency consistent with accepted medical practice for the type of treatment or evaluation required for your medical condition. We will consider periods of inconsistent treatment or lack of compliance with treatment that may result from your mental disorder. If the evidence indicates that the inconsistent treatment or lack of compliance is a feature of your mental disorder, and it has led to an exacerbation of your symptoms and signs, we will not use it as evidence to support a finding that you have not received ongoing medical treatment as required by this paragraph.
- c. The criterion in C2 is satisfied when the evidence shows that, despite your diminished symptoms and signs, you have achieved only marginal adjustment. “Marginal adjustment” means that your adaptation to the requirements of daily life is fragile; that is, you have minimal capacity to adapt to changes in your environment or to demands that are not already part of your daily life. We will consider that you have achieved only marginal adjustment when the evidence shows that changes or increased demands have led to exacerbation of your symptoms and signs and to deterioration in your functioning; for example, you have become unable to function outside of your home or a more restrictive setting, without substantial psychosocial supports (see 12.00D). Such deterioration may have necessitated a significant change in medication or other treatment. Similarly, because of the nature of your mental disorder, evidence may document episodes of deterioration that have required you to be hospitalized or absent from work, making it difficult for you to sustain work activity over time.

**H. How do we document and evaluate intellectual disorder under 12.05?**

1. *General.* Listing 12.05 is based on the three elements that characterize intellectual disorder: significantly subaverage general intellectual functioning; significant deficits in current adaptive functioning; and the disorder manifested before age 22.
2. *Establishing significantly subaverage general intellectual functioning.*

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- a. *Definition.* Intellectual functioning refers to the general mental capacity to learn, reason, plan, solve problems, and perform other cognitive functions. Under 12.05A, we identify significantly subaverage general intellectual functioning by the cognitive inability to function at a level required to participate in standardized intelligence testing. Our findings under 12.05A are based on evidence from an acceptable medical source. Under 12.05B, we identify significantly subaverage general intellectual functioning by an IQ score(s) on an individually administered standardized test of general intelligence that meets program requirements and has a mean of 100 and a standard deviation of 15. A qualified specialist (see 12.00H2c) must administer the standardized intelligence testing.
  - b. *Psychometric standards.* We will find standardized intelligence test results usable for the purposes of 12.05B1 when the measure employed meets contemporary psychometric standards for validity, reliability, normative data, and scope of measurement; and a qualified specialist has individually administered the test according to all pre-requisite testing conditions.
  - c. *Qualified specialist.* A "qualified specialist" is currently licensed or certified at the independent level of practice in the State where the test was performed, and has the training and experience to administer, score, and interpret intelligence tests. If a psychological assistant or paraprofessional administered the test, a supervisory qualified specialist must interpret the test findings and co-sign the examination report.
  - d. *Responsibility for conclusions based on testing.* We generally presume that your obtained IQ score(s) is an accurate reflection of your general intellectual functioning, unless evidence in the record suggests otherwise. Examples of this evidence include: a statement from the test administrator indicating that your obtained score is not an accurate reflection of your general intellectual functioning, prior or internally inconsistent IQ scores, or information about your daily functioning. Only qualified specialists, Federal and State agency medical and psychological consultants, and other contracted medical and psychological experts may conclude that your obtained IQ score(s) is not an accurate reflection of your general intellectual functioning. This conclusion must be well supported by appropriate clinical and laboratory diagnostic techniques and must be based on relevant evidence in the case record, such as:
    - i. The data obtained in testing;
    - ii. Your developmental history, including when your signs and symptoms began;
    - iii. Information about how you function on a daily basis in a variety of settings; and
    - iv. Clinical observations made during the testing period, such as your ability to sustain attention, concentration, and effort; to relate appropriately to the examiner; and to perform tasks independently without prompts or reminders.
3. Establishing significant deficits in adaptive functioning.
- a. *Definition.* Adaptive functioning refers to how you learn and use conceptual, social, and practical skills in dealing with common life demands. It is your typical functioning at home and in the community, alone or among others. Under 12.05A, we identify



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significant deficits in adaptive functioning based on your dependence on others to care for your personal needs, such as eating and bathing. We will base our conclusions about your adaptive functioning on evidence from a variety of sources (see 12.00H3b) and not on your statements alone. Under 12.05B2, we identify significant deficits in adaptive

functioning based on whether there is extreme limitation of one, or marked limitation of two, of the paragraph B criteria (see 12.00E; 12.00F).

- b. Evidence. Evidence about your adaptive functioning may come from:
  - i. Medical sources, including their clinical observations;
  - ii. Standardized tests of adaptive functioning (see 12.00H3c);
  - iii. Third party information, such as a report of your functioning from a family member or friend;
  - iv. School records, if you were in school recently;
  - v. Reports from employers or supervisors; and
  - vi. Your own statements about how you handle all of your daily activities.
- c. Standardized tests of adaptive functioning. We do not require the results of an individually administered standardized test of adaptive functioning. If your case record includes these test results, we will consider the results along with all other relevant evidence; however, we will use the guidelines in 12.00E and F to evaluate and determine the degree of your deficits in adaptive functioning, as required under 12.05B2.
- d. *How we consider common everyday activities.*
  - i. The fact that you engage in common everyday activities, such as caring for your personal needs, preparing simple meals, or driving a car, will not always mean that you do not have deficits in adaptive functioning as required by 12.05B2. You may demonstrate both strengths and deficits in your adaptive functioning. However, a lack of deficits in one area does not negate the presence of deficits in another area. When we assess your adaptive functioning, we will consider all of your activities and your performance of them.
  - ii. Our conclusions about your adaptive functioning rest on whether you do your daily activities independently, appropriately, effectively, and on a sustained basis. If you receive help in performing your activities, we need to know the kind, extent, and frequency of help you receive in order to perform them. We will not assume that your ability to do some common everyday activities, or to do some things without help or support, demonstrates that your mental disorder does not meet the requirements of 12.05B2. (See 12.00D regarding the factors we consider when we evaluate your functioning, including how we consider any help or support you receive.)
- e. How we consider work activity. The fact that you have engaged in work activity, or that you work intermittently or steadily in a job commensurate with your abilities, will not always mean that you do not have deficits in adaptive functioning as required by 12.05B2. When you have engaged in work activity, we need complete information about

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the work, and about your functioning in the work activity and work setting, before we reach any conclusions about your adaptive functioning. We will consider all factors involved in your work history before concluding whether your impairment satisfies the criteria for intellectual disorder under 12.05B. We will consider your prior and current

work history, if any, and various other factors influencing how you function. For example, we consider whether the work was in a supported setting, whether you required more supervision than other employees, how your job duties compared to others in the same job, how much time it took you to learn the job duties, and the reason the work ended, if applicable.

4. Establishing that the disorder began before age 22. We require evidence that demonstrates or supports (is consistent with) the conclusion that your mental disorder began prior to age 22. We do not require evidence that your impairment met all of the requirements of 12.05A or 12.05B prior to age 22. Also, we do not require you to have met our statutory definition of disability prior to age 22. When we do not have evidence that was recorded before you attained age 22, we need evidence about your current intellectual and adaptive functioning and the history of your disorder that supports the conclusion that the disorder began before you attained age 22. Examples of evidence that can demonstrate or support this conclusion include:

- a. Tests of intelligence or adaptive functioning;
- b. School records indicating a history of special education services based on your intellectual functioning;
- c. An Individualized Education Program (IEP), including your transition plan;
- d. Reports of your academic performance and functioning at school;
- e. Medical treatment records;
- f. Interviews or reports from employers;
- g. Statements from a supervisor in a group home or a sheltered workshop; and
- h. Statements from people who have known you and can tell us about your functioning in the past and currently.

**I. How do we evaluate substance use disorders?** If we find that you are disabled and there is medical evidence in your case record establishing that you have a substance use disorder, we will determine whether your substance use disorder is a contributing factor material to the determination of disability (see §§ 404.1535 and 416.935 of this chapter).

**J. How do we evaluate mental disorders that do not meet one of the mental disorders listings?**

1. These listings include only examples of mental disorders that we consider serious enough to prevent you from doing any gainful activity. If your severe mental disorder does not meet the criteria of any of these listings, we will consider whether you have an impairment(s) that meets the criteria of a listing in another body system. You may have another impairment(s) that is

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secondary to your mental disorder. For example, if you have an eating disorder and develop a cardiovascular impairment because of it, we will evaluate your cardiovascular impairment under the listings for the cardiovascular body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing (see 404.1526 and 416.926 of this chapter).
3. If your impairment(s) does not meet or medically equal a listing, we will assess your residual functional capacity for engaging in substantial gainful activity (see 404.1545 and 416.945 of this chapter). When we assess your residual functional capacity, we consider all of your impairment-related mental and physical limitations. For example, the side effects of some medications may reduce your general alertness, concentration, or physical stamina, affecting your residual functional capacity for non-exertional or exertional work activities. Once we have determined your residual functional capacity, we proceed to the fourth, and if necessary, the fifth steps of the sequential evaluation process in 404.1520 and 416.920 of this chapter. We use the rules in 404.1594 and 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

### **12.01 Category of Impairments, Mental Disorders**

#### **12.02 Neurocognitive disorders (see 12.00B1), satisfied by A and B, or A and C:**

- A. Medical documentation of a significant cognitive decline from a prior level of functioning in one or more of the cognitive areas:
  1. Complex attention;
  2. Executive function;
  3. Learning and memory;
  4. Language;
  5. Perceptual-motor; or
  6. Social cognition.

AND

- B. Extreme limitation of one, or marked limitation of two, of the following areas of mental functioning (see 12.00F):
  1. Understand, remember, or apply information (see 12.00E1).
  2. Interact with others (see 12.00E2).
  3. Concentrate, persist, or maintain pace (see 12.00E3).
  4. Adapt or manage oneself (see 12.00E4).

OR

- C. Your mental disorder in this listing category is "serious and persistent" that is, you have a

<https://www.ssa.gov/disability/professionals/bluebook/12.00-MentalDisorders-Adult.htm>

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1. Your mental disorder in this listing category is "serious and persistent," that is, you have a medically documented history of the existence of the disorder over a period of at least 2 years, and there is evidence of both:

1. Medical treatment, mental health therapy, psychosocial support(s), or a highly structured setting(s) that is ongoing and that diminishes the symptoms and signs of your mental disorder (see 12.00G2b); and
2. Marginal adjustment, that is, you have minimal capacity to adapt to changes in your environment or to demands that are not already part of your daily life (see 12.00G2c).

**12.03 Schizophrenia spectrum and other psychotic disorders (see 12.00B2), satisfied by A and B, or A and C:**

A. Medical documentation of one or more of the following:

1. Delusions or hallucinations;
2. Disorganized thinking (speech); or
3. Grossly disorganized behavior or catatonia.

AND

B. Extreme limitation of one, or marked limitation of two, of the following areas of mental functioning (see 12.00F):

1. Understand, remember, or apply information (see 12.00E1).
2. Interact with others (see 12.00E2).
3. Concentrate, persist, or maintain pace (see 12.00E3).
4. Adapt or manage oneself (see 12.00E4).

OR

C. Your mental disorder in this listing category is "serious and persistent;" that is, you have a medically documented history of the existence of the disorder over a period of at least 2 years, and there is evidence of both:

1. Medical treatment, mental health therapy, psychosocial support(s), or a highly structured setting(s) that is ongoing and that diminishes the symptoms and signs of your mental disorder (see 12.00G2b); and
2. Marginal adjustment, that is, you have minimal capacity to adapt to changes in your environment or to demands that are not already part of your daily life (see 12.00G2c).

**12.04 Depressive, bipolar and related disorders (see 12.00B3), satisfied by A and B, or A and C:**

A. Medical documentation of the requirements of paragraph 1 or 2:

1. Depressive disorder, characterized by five or more of the following:
  - a. Depressed mood;
  - b. Diminished interest in almost all activities;

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- c. Appetite disturbance with change in weight;
  - d. Sleep disturbance;
  - e. Observable psychomotor agitation or retardation;
  - f. Decreased energy;
  - g. Feelings of guilt or worthlessness;
  - h. Difficulty concentrating or thinking; or
  - i. Thoughts of death or suicide.
2. Bipolar disorder, characterized by three or more of the following:
- a. Pressured speech;
  - b. Flight of ideas;
  - c. Inflated self-esteem;
  - d. Decreased need for sleep;
  - e. Distractibility;
  - f. Involvement in activities that have a high probability of painful consequences that are not recognized; or
  - g. Increase in goal-directed activity or psychomotor agitation.

AND

- B. Extreme limitation of one, or marked limitation of two, of the following areas of mental functioning (see 12.00F):
- 1. Understand, remember, or apply information (see 12.00E1).
  - 2. Interact with others (see 12.00E2).
  - 3. Concentrate, persist, or maintain pace (see 12.00E3).
  - 4. Adapt or manage oneself (see 12.00E4).

OR

- C. Your mental disorder in this listing category is "serious and persistent;" that is, you have a medically documented history of the existence of the disorder over a period of at least 2 years, and there is evidence of both:
- 1. Medical treatment, mental health therapy, psychosocial support(s), or a highly structured setting(s) that is ongoing and that diminishes the symptoms and signs of your mental disorder (see 12.00G2b); and
  - 2. Marginal adjustment, that is, you have minimal capacity to adapt to changes in your environment or to demands that are not already part of your daily life (see 12.00G2c).

**12.05 Intellectual disorder (see 12.00B4), satisfied by A or B:**

- A. Satisfied by 1, 2, and 3 (see 12.00H):
- 1. Significantly subaverage general intellectual functioning evident in your cognitive inability to function at a level required to participate in standardized testing of

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- intellectual functioning; and
- 2. Significant deficits in adaptive functioning currently manifested by your dependence upon others for personal needs (for example, toileting, eating, dressing, or bathing); and
- 3. The evidence about your current intellectual and adaptive functioning and about the history of your disorder demonstrates or supports the conclusion that the disorder began prior to your attainment of age 22.

OR

B. Satisfied by 1, 2, and 3 (see 12.00H):

- 1. Significantly subaverage general intellectual functioning evidenced by a or b:
  - a. A full scale (or comparable) IQ score of 70 or below on an individually administered standardized test of general intelligence; or
  - b. A full scale (or comparable) IQ score of 71-75 accompanied by a verbal or performance IQ score (or comparable part score) of 70 or below on an individually administered standardized test of general intelligence; and
- 2. Significant deficits in adaptive functioning currently manifested by extreme limitation of one, or marked limitation of two, of the following areas of mental functioning:
  - a. Understand, remember, or apply information (see 12.00E1); or
  - b. Interact with others (see 12.00E2); or
  - c. Concentrate, persist, or maintain pace (see 12.00E3); or
  - d. Adapt or manage oneself (see 12.00E4); and
- 3. The evidence about your current intellectual and adaptive functioning and about the history of your disorder demonstrates or supports the conclusion that the disorder began prior to your attainment of age 22.

**12.06 Anxiety and obsessive-compulsive disorders (see 12.00B5), satisfied by A and B, or A and C:**

A. Medical documentation of the requirements of paragraph 1, 2, or 3:

- 1. Anxiety disorder, characterized by three or more of the following:
  - a. Restlessness;
  - b. Easily fatigued;
  - c. Difficulty concentrating;
  - d. Irritability;
  - e. Muscle tension; or
  - f. Sleep disturbance.
- 2. Panic disorder or agoraphobia, characterized by one or both:
  - a. Panic attacks followed by a persistent concern or worry about additional panic attacks or their consequences; or
  - b. Disproportionate fear or anxiety about at least two different situations (for

<https://www.ssa.gov/disability/professionals/bluebook/12.00-MentalDisorders-Adult.htm>

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- or disproportionate fear or anxiety about at least two different situations (for example, using public transportation, being in a crowd, being in a line, being outside of your home, being in open spaces).
- 3. Obsessive-compulsive disorder, characterized by one or both:
  - a. Involuntary, time-consuming preoccupation with intrusive, unwanted thoughts; or
  - b. Repetitive behaviors aimed at reducing anxiety.

AND

- B. Extreme limitation of one, or marked limitation of two, of the following areas of mental functioning (see 12.00F):
  - 1. Understand, remember, or apply information (see 12.00E1).
  - 2. Interact with others (see 12.00E2).
  - 3. Concentrate, persist, or maintain pace (see 12.00E3).
  - 4. Adapt or manage oneself (see 12.00E4).

OR

- C. Your mental disorder in this listing category is "serious and persistent;" that is, you have a medically documented history of the existence of the disorder over a period of at least 2 years, and there is evidence of both:
  - 1. Medical treatment, mental health therapy, psychosocial support(s), or a highly structured setting(s) that is ongoing and that diminishes the symptoms and signs of your mental disorder (see 12.00G2b); and
  - 2. Marginal adjustment, that is, you have minimal capacity to adapt to changes in your environment or to demands that are not already part of your daily life (see 12.00G2c).

**12.07 Somatic symptom and related disorders (see 12.00B6), satisfied by A and B:**

- A. Medical documentation of one or more of the following:
  - 1. Symptoms of altered voluntary motor or sensory function that are not better explained by another medical or mental disorder;
  - 2. One or more somatic symptoms that are distressing, with excessive thoughts, feelings, or behaviors related to the symptoms; or
  - 3. Preoccupation with having or acquiring a serious illness without significant symptoms present.

AND

- B. Extreme limitation of one, or marked limitation of two, of the following areas of mental functioning (see 12.00F):
  - 1. Understand, remember, or apply information (see 12.00E1).
  - 2. Interact with others (see 12.00E2).
  - 3. Concentrate, persist, or maintain pace (see 12.00E3).

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4. Adapt or manage oneself (see 12.00E4).

**12.08 Personality and impulse-control disorders (see 12.00B7), satisfied by A and B:**

A. Medical documentation of a pervasive pattern of one or more of the following:

1. Distrust and suspiciousness of others;
2. Detachment from social relationships;
3. Disregard for and violation of the rights of others;
4. Instability of interpersonal relationships;
5. Excessive emotionality and attention seeking;
6. Feelings of inadequacy;
7. Excessive need to be taken care of;
8. Preoccupation with perfectionism and orderliness; or
9. Recurrent, impulsive, aggressive behavioral outbursts.

AND

B. Extreme limitation of one, or marked limitation of two, of the following areas of mental functioning (see 12.00F):

1. Understand, remember, or apply information (see 12.00E1).
2. Interact with others (see 12.00E2).
3. Concentrate, persist, or maintain pace (see 12.00E3).
4. Adapt or manage oneself (see 12.00E4).

**12.09 [Reserved]****12.10 Autism spectrum disorder (see 12.00B8), satisfied by A and B:**

A. Medical documentation of both of the following:

1. Qualitative deficits in verbal communication, nonverbal communication, and social interaction; and
2. Significantly restricted, repetitive patterns of behavior, interests, or activities.

AND

B. Extreme limitation of one, or marked limitation of two, of the following areas of mental functioning (see 12.00F):

1. Understand, remember, or apply information (see 12.00E1).
2. Interact with others (see 12.00E2).
3. Concentrate, persist, or maintain pace (see 12.00E3).
4. Adapt or manage oneself (see 12.00E4).

**12.11 Neurodevelopmental disorders (see 12.00B9), satisfied by A and B:**



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A. Medical documentation of the requirements of paragraph 1, 2, or 3:

1. One or both of the following:

a. Frequent distractibility, difficulty sustaining attention, and difficulty organizing tasks; or

b. Hyperactive and impulsive behavior (for example, difficulty remaining seated, talking excessively, difficulty waiting, appearing restless, or behaving as if being "driven by a motor").

2. Significant difficulties learning and using academic skills; or

3. Recurrent motor movement or vocalization.

AND

B. Extreme limitation of one, or marked limitation of two, of the following areas of mental functioning (see 12.00F):

1. Understand, remember, or apply information (see 12.00E1).

2. Interact with others (see 12.00E2).

3. Concentrate, persist, or maintain pace (see 12.00E3).

4. Adapt or manage oneself (see 12.00E4).

#### **12.12 [Reserved]**

#### **12.13 Eating disorders (see 12.00B10), satisfied by A and B:**

A. Medical documentation of a persistent alteration in eating or eating-related behavior that results in a change in consumption or absorption of food and that significantly impairs physical or psychological health.

AND

B. Extreme limitation of one, or marked limitation of two, of the following areas of mental functioning (see 12.00F):

1. Understand, remember, or apply information (see 12.00E1).

2. Interact with others (see 12.00E2).

3. Concentrate, persist, or maintain pace (see 12.00E3).

4. Adapt or manage oneself (see 12.00E4).

#### **12.15 Trauma- and stressor-related disorders (see 12.00B11), satisfied by A and B, or A and C:**

A. Medical documentation of all of the following:

1. Exposure to actual or threatened death, serious injury, or violence;

2. Subsequent involuntary re-experiencing of the traumatic event (for example, intrusive memories, dreams, or flashbacks);

3. Avoidance of external reminders of the event;

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4. Disturbance in mood and behavior; and
5. Increases in arousal and reactivity (for example, exaggerated startle response, sleep disturbance).

AND

B. Extreme limitation of one, or marked limitation of two, of the following areas of mental functioning (see 12.00F):

1. Understand, remember, or apply information (see 12.00E1).
2. Interact with others (see 12.00E2).
3. Concentrate, persist, or maintain pace (see 12.00E3).
4. Adapt or manage oneself (see 12.00E4).

OR

C. Your mental disorder in this listing category is "serious and persistent;" that is, you have a medically documented history of the existence of the disorder over a period of at least 2 years, and there is evidence of both:

1. Medical treatment, mental health therapy, psychosocial support(s), or a highly structured setting(s) that is ongoing and that diminishes the symptoms and signs of your mental disorder (see 12.00G2b); and
2. Marginal adjustment, that is, you have minimal capacity to adapt to changes in your environment or to demands that are not already part of your daily life (see 12.00G2c).

## Appendix B - Rapid Critical Appraisal Tools

### RAPID CRITICAL APPRAISAL OF QUALITATIVE EVIDENCE

1. Are the results of the study valid (trustworthy and credible)?
  - a. How were the participants chosen?
  - b. How were accuracy and completeness of data assured?
  - c. How plausible/believable are the results?
    - i. Are implications of the research stated?
 

Yes	No	Unknown
-----	----	---------

      1. May new insights increase sensitivity to others needs?
 

Yes	No	Unknown
-----	----	---------
      2. May understandings enhance situational competence?
 

Yes	No	Unknown
-----	----	---------
    - ii. What is the effect on the reader?
      1. Are results plausible and believable?
 

Yes	No	Unknown
-----	----	---------
      2. Is the reader imaginatively drawn into the experience?
 

Yes	No	Unknown
-----	----	---------
2. What are the results?
  - a. Does the research approach fit the purpose of the study?
 

Yes	No	Unknown
-----	----	---------

    - i. Does the researcher identify the study approach?
 

Yes	No	Unknown
-----	----	---------

      1. Are language and concepts consistent with the approach?
 

Yes	No	Unknown
-----	----	---------
      2. Are data collection and analysis techniques appropriate?
 

Yes	No	Unknown
-----	----	---------
    - ii. Is the significance/importance of the study explicit?
 

Yes	No	Unknown
-----	----	---------

      1. Does review of the literature support a need for the study?
 

Yes	No	Unknown
-----	----	---------
      2. Do sample composition and size reflect study needs?
 

Yes	No	Unknown
-----	----	---------
    - iii. Is the sampling strategy clear and guided by study needs?
 

Yes	No	Unknown
-----	----	---------

      1. Does the research control selection of the sample?
 

Yes	No	Unknown
-----	----	---------
      2. Do sample composition and size reflect study needs?
 

Yes	No	Unknown
-----	----	---------
  - b. Is the phenomenon (human experience) clearly identified?
 

Yes	No	Unknown
-----	----	---------

    - i. Are the data collection procedures clear?
 

Yes	No	Unknown
-----	----	---------

      1. Are sources and means of verifying data explicit?
 

Yes	No	Unknown
-----	----	---------
      2. Are researcher roles and activities explained?
 

Yes	No	Unknown
-----	----	---------
    - ii. Are data analysis procedures described?
 

Yes	No	Unknown
-----	----	---------

      1. Does analysis guide direction of sampling and when it ends?
 

Yes	No	Unknown
-----	----	---------
      2. Are data management processes described?
 

Yes	No	Unknown
-----	----	---------
  - c. What are the reported results (description or interpretation)?
    - i. How are specific findings presented?
      1. Is presentation logical, consistent, and easy to follow?
 

Yes	No	Unknown
-----	----	---------
      2. Do quotes fit the findings they are intended to illustrate?
 

Yes	No	Unknown
-----	----	---------
    - ii. How are the overall results presented?
      1. Are meanings derived from data described in context?
 

Yes	No	Unknown
-----	----	---------
      2. Does the writing effectively promote understanding?
 

Yes	No	Unknown
-----	----	---------
3. Will the results help me in caring for my patients?
  - a. Are the results relevant to persons in similar situations?
 

Yes	No	Unknown
-----	----	---------
  - b. Are the results relevant to patient values and/or circumstances?
 

Yes	No	Unknown
-----	----	---------
  - c. How may the results be applied in clinical practice?
 

Yes	No	Unknown
-----	----	---------

# RAPID CRITICAL APPRAISAL QUESTIONS FOR COHORT STUDIES

## 1. Are the results of the study valid?

- |  |     |    |         |
|--|-----|----|---------|
| a. Was there a representative and well defined sample of patients at a similar point in the course of the disease? | Yes | No | Unknown |
| b. Was follow-up sufficiently long and complete?   | Yes | No | Unknown |
| c. Were objective and unbiased outcome criteria used?  | Yes | No | Unknown |
| d. Did the analysis adjust for important prognostic risk factors and confounding variables?                        | Yes | No | Unknown |

## 2. What are the results?

- |   |     |    |         |
|---|-----|----|---------|
| a. What is the magnitude of the relationship between predictors (i.e. prognostic indicators) and target outcomes? | Yes | No | Unknown |
| b. How likely is the outcome event(s) in a specified period of time?  | Yes | No | Unknown |
| c. How precise are the study estimates?   | Yes | No | Unknown |

## 3. Will the results help me in caring for my patients?

- |   |     |    |         |
|---|-----|----|---------|
| a. Were the study patients similar to my own?                       | Yes | No | Unknown |
| b. Will the results lead directly to selecting or avoiding therapy? | Yes | No | Unknown |
| c. Are the results useful for reassuring or counseling patients?    | Yes | No | Unknown |

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- |   |     |    |         |
|---|-----|----|---------|
| groups?   | Yes | No | Unknown |
| b. Was random assignment concealed from the individuals who were first enrolling subjects into the study? | Yes | No | Unknown |
| c. Were the subjects and providers blind to the study group?  | Yes | No | Unknown |
| d. Were reasons given to explain why subjects did not complete the study?                                 | Yes | No | Unknown |
| e. Were the follow-up assessments conducted long enough to fully study the effects of the intervention?   | Yes | No | Unknown |
| f. Were the subjects analyzed in the group to which they were randomly assigned?                          | Yes | No | Unknown |
| g. Was the control group appropriate?   | Yes | No | Unknown |
| h. Were the instruments used to measure the outcomes valid and reliable?                                  | Yes | No | Unknown |
| i. Were the subjects in each of the groups similar on demographic and baseline clinical variables?        | Yes | No | Unknown |

## 2. What are the results?

- |  |  |
|--|--|
| a. How large is the intervention or treatment effect (effect size, level of significance)? |  |
| b. How precise is the intervention or treatment?   |  |

## 3. Will the results help me in caring for my patients?

- |  |     |    |         |
|--|-----|----|---------|
| a. Were all clinically important outcomes measured?  | Yes | No | Unknown |
| b. What are the risks and benefits of the treatment?   |     |    |         |
| c. Is the treatment feasible in my clinical setting?   | Yes | No | Unknown |
| d. What are my patient's values/family's values and expectations for the outcome that trying to be prevented and the treatment itself? |     |    |         |

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### RAPID CRITICAL APPRAISAL OF SYSTEMATIC REVIEWS OF CLINICAL INTERVENTIONS/TREATMENTS

- |   |     |    |         |
|---|-----|----|---------|
| <b>1. Are the results of the review valid?</b>  |     |    |         |
| a. Are the studies contained in the review randomized controlled trials?  | Yes | No | Unknown |
| b. Does the review include a detailed description of the search strategy to find all relevant studies?  | Yes | No | Unknown |
| c. Does the review describe how validity of the individual studies was assessed (e.g. methodological quality, including the use of random assignment to study groups and complete follow-up of the subjects)? | Yes | No | Unknown |
| d. Were the results consistent across studies?  | Yes | No | Unknown |
| e. Were individual patient data or aggregate data used in the analysis?   | Yes | No | Unknown |
| <b>2. What were the results?</b>  |     |    |         |
| a. How large is the intervention or treatment effect (odds ratio, effect size, level of significance)?  |     |    | <hr/>   |
| b. How precise is the intervention or treatment?  |     |    | <hr/>   |
| <b>3. Will the results assist me in caring for my patients?</b>   |     |    |         |
| a. Are my patients similar to the ones included in the review?  | Yes | No | Unknown |
| b. Is it feasible to implement the findings in my practice setting?   | Yes | No | Unknown |
| c. Were all clinically important outcomes considered, including risks and benefits of treatment?  | Yes | No | Unknown |
| d. What is my clinical assessment of the patient and are there any contraindications or circumstances that would inhibit me from implementing the treatment?  | Yes | No | Unknown |
| e. What are my patient's and his/her family's preferences and values about the treatment that is under consideration?   |     |    | <hr/>   |

### RAPID CRITICAL APPRAISAL OF EVIDENCE-BASED PRACTICE IMPLEMENTATION OR QUALITY IMPROVEMENT (QI) PROJECTS

Indicate the extent to which the item is met in the published report of the EBP or the QI project.

Validity of Evidence Synthesis (i.e., good methodology)	1	2	3	4	5
	No	A little	Somewhat	Quite A Bit	Very Much
1. The title of the publication identifies the report/project as an EBP implementation or QI project					
2. The project report provides a structured summary that includes, as applicable: data to establish the existent and background of the clinical issue, inclusion and exclusion criteria, and sources of evidence, evidence synthesis, objectives and setting of the EBP or QI project, project limitations, results/outcomes, recommendations and implications for policy					
3. Report includes existing internal evidence to adequately describe the clinical issue					
4. Describes multiple information sources (e.g., databases contact with study authors to identify additional studies, or any other additional search strategies) included in the search strategy and date					
5. States the process for title, abstract, and article screening for selecting studies					
6. Describes the method of data extraction (e.g. independently or process for validating data from multiple reviewers)					
7. Includes conceptual and operational definitions for all variables for which data were abstracted (e.g., define blood pressure as systolic blood pressure, diastolic blood pressure, ambulatory blood pressure, automatic cuff blood pressure, or arterial blood pressure)					

8. Describes methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level)
9. States the principal summary measures (e.g., risk ratio, difference in means)
10. Describes the method of combining results of studies including quality, quantity, and consistency of evidence
11. Specifies assessment of risk and bias that may affect the cumulative evidence (e.g. publication bias, selective reporting within studies)
12. Describes appraisal procedure and conflict resolution
13. Provides number of studies screened, assessed for eligibility, and included in the review, with reasons for exclusion at each stage, ideally with a flow diagram
14. For each study, presents characteristics for which data were extracted (e.g. study size, design, method, follow-up period) and provides citations
15. Presents data on risk of bias of each study and, if available, any outcome-level assessment
16. For all outcomes considered (benefit or harms) includes a table with summary data for each intervention group, effect estimates, and confidence intervals, ideally with a forest plot
17. Summarizes the main findings including the strength of evidence for each main outcome, considering their reference to key groups (i.e., healthcare providers, users, and policy makers)
18. Discusses limitations at study and outcome levels (e.g. risk of bias) at review level (e.g. incomplete retrieval of identified research, reporting bias)
19. Provides a general interpretation of the results in the context of other evidence and implications for

**Validity of Implementation (i.e., well-done project)**

1. Purpose of project flows from evidence synthesis
2. Stakeholders (active and passive) are identified and communication with them is described
3. Implementation protocol is congruent with evidence synthesis (fidelity of the intervention)
4. Implementation protocol is sufficiently detailed to provide replication among project participants
5. Education of project participants and other stakeholders is clearly described
6. Outcomes are measured and measures supported in the evidence synthesis

**Reliability of Implementation Project (i.e., I can learn from or implement project results)**

1. Data are collected with sufficient rigor to be reliable for like groups to those participants of the project
2. Results of evidence implementation are clinically meaningful (statistics are interpreted as such)

**Application of Implementation ( i.e. this project is useful for my patients)**

1. How feasible is the project protocol?
2. Have the project managers considered/included all outcomes that are important to my work?
3. Is implementing the project safe (i.e., low risk of harm)?

Summary Score \_\_\_\_\_

<b>Recommendations with consideration of this type of level IV intervention evidence:</b>
32-64 Consider evidence with extreme caution
65-128 Consider evidence with caution
128-160 Consider evidence with confidence
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## Appendix C

### Quality Guide Evidence Table and Evidence Level

# Quality Guide Evidence

#### Levels I, II, & III (Includes Experimental, Quasi-Experimental & Non-Experimental Research Studies)

- **A High Quality:** Consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence
- **B Good Quality:** Reasonably consistent results; sufficient sample size for the study design; some control, fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence
- **C Low Quality or Major Flaws:** Little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn

#### Level IV (Includes Clinical Practice Guidelines & Position Statements)

- **A High Quality:** Material officially sponsored by a professional, public, private organization, or government agency; documentation of a systematic literature search strategy; consistent results with sufficient numbers of well-designed studies; criteria-based evaluation of overall scientific strength and quality of included studies and definitive conclusions; national expertise is clearly evident; developed or revised within the last 5 years
- **B Good Quality:** Material officially sponsored by a professional, public, private organization, or government agency; reasonably thorough and appropriate systematic literature search strategy; reasonably consistent results, sufficient numbers of well-designed studies; evaluation of strengths and limitations of included studies with fairly definitive conclusions; national expertise is clearly evident; developed or revised within the last 5 years
- **C Low Quality or Major Flaws:** Material not sponsored by an official organization or agency; undefined, poorly defined, or limited literature search strategy; no evaluation of strengths and limitations of included studies, insufficient evidence with inconsistent results, conclusions cannot be drawn; not revised within the last 5 years Evidence

#### Level V (Includes Literature Reviews, Expert Opinion, Quality Improvement, Financial/Program Evaluation) Organizational Experience:

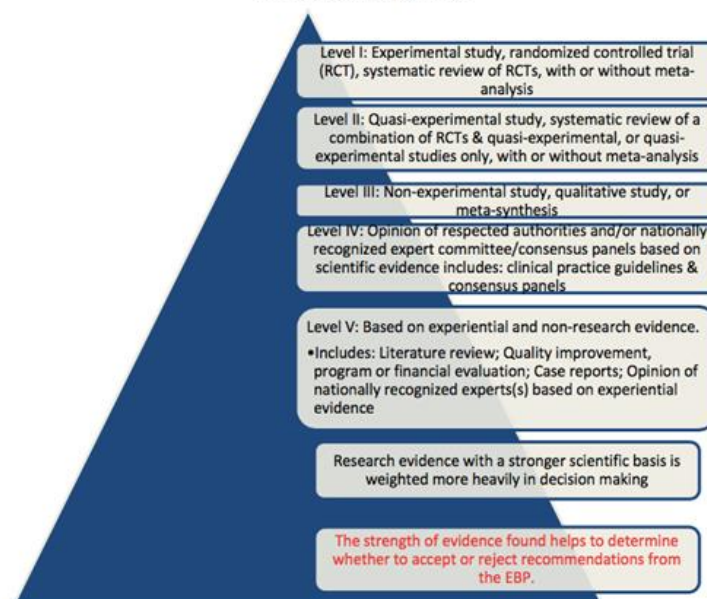
- **A High Quality:** Clear aims and objectives; consistent results across multiple settings; formal quality improvement; financial or program evaluation methods used; definitive conclusions consistent recommendations with thorough reference to scientific evidence
- **B Good Quality:** Clear aims and objectives; consistent results in a single setting; formal quality improvement or financial or program evaluation methods used; reasonably consistent recommendations with some reference to scientific evidence
- **C Low Quality or Major Flaws:** Unclear or missing aims and objectives; inconsistent results; poorly defined quality improvement, financial or program evaluation methods; recommendations cannot be made

#### Literature Review, Expert Opinion, Case Report, Community Standard, Clinician Experience, Consumer Preference:

- **A High Quality:** Expertise is clearly evident; draws definitive conclusions; provides scientific rationale; thought leader(s) in the field
  - **B Good Quality:** Expertise appears to be credible; draws fairly definitive conclusions; provides logical argument for opinions
  - **C Low Quality or Major Flaws:** Expertise is not discernible or is dubious; conclusions cannot be drawn
- Dearholt & Dang, 2012

## Evidence Level

Dearholt & Dang, 2012



**Appendix D - Evaluation Table**

Citation	Design and Method	Characteristics and Setting	Variables	Measurement	Data Analysis	Findings	Level and Quality of Evidence
Chein, W., Mui, J., Gray, R., Cheung, E. (2016). Adherence therapy versus routine psychiatric care....	Single blind randomized controlled trial - 1 group received a 6-session adherence therapy over 12 weeks, 1 group received standard psychiatric care	134 outpatients with schizophrenia spectrum disorders in Hong Kong. All subjects were assessed by a psychiatrist and followed for up to 18 months.	IV: 6 session adherence therapy, standard psychiatric care DV: Outcome measurements (symptom severity, medication adherence, hospitalization rates, insight, and functioning)	Adherence Rating Scale (ARS), Positive and negative syndrome scale (PANSS), Insight and treatment attitudes questionnaire (ITAQ), Specific level of functioning (SLOF)- measured at recruitment, 2 weeks, 6 months, and 18 months	Intention to treat basis using IBM SPSS, Goodness of fit chi-square (categorical data) and an independent-sample t-test (for interval/ratio data)	Adherence therapy group showed improvements into insight of illness/treatment, functioning levels, and reductions of severity of symptoms and hospitalization rates.	Level: 1 Quality: A Limitations: Over 60 of original patients (3000) were found not to be eligible. Patients that agreed = higher functioning. Outcome measurements = all self-reported Strengths/findings: Implemented Self-control for patients, systematic, multifaceted, and client centered therapy/education
Velligan, D., Diamond, P., Mintz, J., et al. (2007). The use of individually tailored environmental supports to improve.....	Single blind randomized controlled trial - 1 group received full cognitive adaption training (CAT), 1 group received pharmacologic CAT, and 1 group received standard psychiatric care.	95 outpatients with schizophrenia who were being seen at a community mental health center, treatment lasted for 9 months and then patients were followed for an additional 6 months.	IV: Full CAT. Pharm CAT, standard psychiatric care DV: Medication Adherence and functional impairment	Brief Psychiatric Rating Scale (BPRS), Unannounced pill counts, Pharmacy Records, Social and Occupational Functioning Scale (SOFAS)	Mixed effects regression with repeated measures (SAS PROC MIXED). Time lapse - proportional hazard regression model with DISCRETE.	Both the Full Cat group and the Pharm Cat group had high medication adherence rates and improved functional outcome then the standard care group,	Level: 1 Quality: A Limitations: ↓ number of recruits participate in study, participants had been ill for over 10 years, observer bias may have interfered with randomized pill counts. ** What is important to note for practice with this study is that while only 19% of the patients in the standard care group made it through the study with no hospitalizations - 65% of the CAT groups had no hospitalizations.

**Evaluation Table – Continued**

Aziz. K., Elamin, M., El-Saadouni, N., et al. (2016). Schizophrenia : Impact of psychopathology, faith healers, and psycho-education on adherence to medications	Non-experimental study to find correlations between psychopharmacology, faith healers, and individual components of patient's psychopathology and how those affected medication adherence rates as outpatients	121 outpatients followed from inpatient status to post 6 weeks outpatient status located in the United Arab Emirates	IV: Independent components of psychopathology, Faith Healers involvement, psychopharmacology DV: Medication Adherence	Comprehensive medical and psychiatric history taking, pill counts, medication diaries, and collateral information collected from family members	Regression analysis between full adherences, partial adherence, no adherence. Data Analysis done via SPSS. Chi-square - symptoms, Multiple Logistic regression - predictors of nonadherence	Faith healers were a predictor of noncompliance as well as persecutory delusions. Psychoeducation was a strong predictor for adherence and increased insight.	Level: 3 Quality: B Limitations: 1 person was involved in both evaluation during admission and post-discharge evaluation, results between adherence and symptoms should be considered as exploratory, a complete history concerning illicit drug use was not able to be obtained due to patients declining to answer. Implications: Involvement with community psychiatric team and psychoeducation ↑ medication adherence, important to note patients' beliefs and culture also.
Pasadas, C., Manso, F. (2016). Psychoeducation: A strategy for preventing relapse in patients with schizophrenia	Descriptive Study to evaluate if an 8 week psychoeducational program improved insight to improve health gains	10 outpatients diagnosed with schizophrenia participated in an 8 week psychoeducational program designed to increase patient's knowledge about their disease process and promote overall better functioning	IV: 8 week psychoeducational program DV: Overall Functioning	Sociodemographic characteristic questionnaire, knowledge assessment questionnaire, medication adherence scale (MARS)	Comparison of pre and posttests.	Implementation of an intervention program promotes increased overall functioning and adaptation of the disease, also increases the stabilization of the disease	Level: 3 Quality: C Limitation: existence of an open group, extremely small sample, no control group, difficulties in getting some responses, no follow up *** Some notable things to consider for future research - By including education to teach patients coping skills, they reduced overall reported stress - also by implementing education to increase patient's knowledge about their disease - medication adherence, participation in continuing groups, and reported satisfaction scores were increased at the end of the study.

**Evaluation Table – Continued**

Novick, D., Montgomery, W., Treuer, T., Aguado, J., Kraemer, S., Haro, J. (2015). Relationship of insight with medication adherence and the impact on outcomes....	Prospective, Observational (non-interventional), naturalistic, multicenter, multicounty study	903 patients diagnosed with schizophrenia or bipolar from outpatient and inpatient settings, taking place from April 2007 to May 2009	IV/DV: None - Observational Study	Clinical severity - Clinical Global Impression (CGI) for Bipolar or Schizophrenia, Global Assessment of Functioning, Medication Adherence Rating Scale, Scale to assess unawareness of mental disorder	Patient characteristics - Chi-square test for categorical variables, Kruskal-Wallis test for continuous variables, Spearman Correlation Coefficients for associations between baseline and endpoint	612 patients - schizophrenia, 291 - bipolar Important for practice- study found patients with ↑ insight had ↑ medication adherence scores, milder clinical severity, after 1 year - found that an improvement in patient awareness was related to an increased medication compliance	Level: 3 Quality: A Limitations: data was drawn from an observational study, assessment of factors were done by the same evaluation, some tools used are self-reported - subject to bias, only one evaluation done at follow up Finding/Discussion - interventions to enhance medication adherence are particularly helpful for patients with low insight
Bond, K., Anderson, I. (2015). Psychoeducation for relapse prevention in bipolar disorder.....	Systemic review of randomized controlled trials	16 studies were included that involved a direct psychological intervention and self-management of the patient's disease	Systemic Review	Data was extracted using standardized preforms by both authors	Risk of bias - Cochrane Collaboration risk of bias tool, Efficacy of psychoeducation - analyzed quantitatively by pooled odds ration	30% of control group had no relapse/45% of patients that received education, 54% of control group had no manic episode/69% who received education, 57% of control group had no depressive episode/66% who received education - Reasonable evidence that education ↑ medication compliance	Level: 1 Quality: 5 Limitations: analysis was limited to group psychoeducation, which reduced study heterogeneity for any relapse, increased the size of effects. Small amount of studies used, small number of participates, For Practice: greatest efficacy was found in group education which had a longer follow up and more hours of therapy

**Evaluation Table – Continued**

Staring, A., Van der Gaag, M., Koopmans, G., Selten, J., Van Beveren, J., Hengeveld, M., Loonen, A., Mulder, C. (2010) Treatment adherence therapy in people....	Randomized Controlled Study of Treatment Adherence Therapy and medication compliance	109 out patients were included that participated in a varied amount of therapy and sessions	IV: Therapy, varied depending on the problems presented by the patient DV: service engagement and medication compliance	Logistical Regression analysis, Intention to treat multivariate analysis, significant effects were reported in effect size (Cohen's d)	Medication Adherence Rating Scale, Medication Adherence Questionnaire, Drug Attitude Inventory, Compliance Rating Scale, Service Engagement Scale	Treatment Adherence Therapy improved service engagement scores, medication adherence scores, and lowered involuntary admissions to the psychiatric hospital	Level: 1 Quality: B Limitations: small sample size, inclusion of many outcome variables may have increased the chances of finding a significant result, distributed attention unevenly between the groups which may have produced a bias, self-reported tools were used For Practice: treatment protocol was based on an empirical-theoretical model that were tailored to individual's causes for no adherence which showed promise to tailoring education to individuals' own situation and levels of service engagement
Ran. M., Chan. C., Guo, L., Xiang. M. (2015). The effectiveness of psychoeducational family intervention for patients with schizophrenia in a 14 year follow up	Cluster Randomized Control Trial Study of psychoeducational family interventions in a 14 year follow up	326 outpatients from rural areas in China randomly assigned to three groups (family intervention group, medication group, control group)	IV: Adherence Therapy, No Therapy DV: Treatment adherence	ANOVA to compare differences in continuous factors, Chi-Squared test for categorical data, Cox Hazard regression analysis for the differences in death rate	Patient follow-up scale, Positive and Negative Syndrome Scale (PANSS), Global Assessment of Functioning (GAF)	Psychoeducation group - ↑ short term and long term medication adherence, work abilities, and ↓ relapse and hospitalization rates	Level: 1 Quality: A Limitations: possible recall bias, dead or homeless patients were excluded which may have influenced the results, difficult to control outside factors on the patients Important for practice: psychosocial and psychoeducation interventions are more efficient in early stages, Family beliefs and attitudes appear to affect a person's adherence rate

**Evaluation Table – Continued**

Bauml, J., Pitschel-Walz, G., Vols, A., Lucsher, S., Rentrop, M., Kissling, W., Jahn, T. (2016). Psychoeducation improves compliance and outcome in schizophrenia	Randomized PIP Study at 3 different areas around psychiatric hospitals in Munich with a 7 year follow up	41 outpatients randomly assigned to a group receiving psychoeducation or a control group	IV: Psychoeducation DV: Medication adherence and outcome factors	Fisher's exact test was used for all comparisons, Chi-square was used for all categorical variables	Compliance - rated on a 4 step ordinal scale by psychiatrists, Blood samples to measure drug levels	Psychoeducation group - ↓ re-hospitalization rates, lower days in the hospital when readmitted, improved medication adherence	Level: 1 Quality: B Limitations: Sample size was small, Medication was not documented except at the beginning and at 6 months before the end of the study Important for Practice: Psychoeducation shows an improvement for adherence which can decrease hospitalizations and treatment costs and improve overall functioning and better quality of life for patients
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### Appendix E - Synthesis Table

Citation	Design, Level/Quality	Sample	Intervention	Outcomes
Chein, W., Mui, J., Gray, R., Cheung, E. (2016). Adherence therapy versus routine psychiatric care....	Single Blind Randomized Controlled Study Level 1, Quality A	134 outpatients with schizophrenia spectrum disorders in Hong Kong.	6 session adherence therapy over the course of 12 weeks, or standard psychiatric care. Patients were followed for up to 18 months	Adherence therapy group = ↑ insight, ↑ functioning levels, ↓ severity of symptoms, ↓ hospitalization rates, likely due to ↑ medication adherence
Velligan, D., Diamond, P., Mintz, J., et al. (2007). The use of individually tailored environmental supports to improve.....	Blind Randomized Controlled Trial with 3 different groups that took place over 15 months Level 1, Quality A	95 Outpatients with schizophrenia	Full Cognitive Adherence Therapy, Pharmacological Adherence Therapy, or Standard Psychiatric Care	Full CAT & Pharm Cat groups = ↑ medication adherence rates, ↑ functional outcome, 46% ↓ hospitalization rates
Aziz, K., Elamin, M., El-Saadouni, N., et al. (2016). Schizophrenia: Impact of psychopathology, faith healers, and psycho-education on adherence to medications	Non-experimental study Level 3, Quality B	121 patients followed from inpatient status to post 6 weeks outpatient status located in the United Arab Emirates	No direct Intervention, psychiatric history taken, pill counts, medication diaries, and collateral information collected from family members	Psychoeducation that was received prior to study = ↑ medication adherence, ↑ Insight. *** Study recommends taking patient's culture into consideration when planning the care plan
Pasadas, C., Manso, F. (2016). Psychoeducation: A strategy for preventing relapse in patients with schizophrenia	Descriptive Study, Level 3, Quality C	10 outpatients diagnosed with schizophrenia	8 week psychoeducational program designed to increase patient's knowledge about their disease process and promote overall better functioning	Implementing an education program = ↑ functioning and adaptation of the disease, ↑ stabilization of the disease, likely due to ↑ medication adherence
Novick, D., Montgomery, W., Treuer, T., Aguado, J., Kraemer, S., Haro, J. (2015). Relationship of insight with medication adherence and the impact on outcomes....	Prospective, Observational Study, Level 3, Quality A	903 patients diagnosed with schizophrenia or bipolar from outpatient and inpatient settings, taking place from April 2007 to May 2009	There was no intervention, just data collection using several different scales	Patients who had ↑ insight at the onset of the disease had ↑ medication adherence and milder clinical severity of their symptoms
Bond, K., Anderson, I. (2015). Psychoeducation for relapse prevention in bipolar disorder.....	Systemic Review, Level 1, Quality B	16 randomized controlled studies were reviewed	Direct psychological intervention and patient self-management of the disease	Intervention Group= ↓ Relapse ↓ Occurrence of Manic Episodes ↓ Occurrence of Depressive Episodes Evidence Shows Education ↑ Medication Compliance

**Synthesis Table - Continued**

Citation	Design, Level/Quality	Sample	Intervention	Outcomes
Staring, A., Van der Gaag, M., Koopmans, G., Selten, J., Van Beveren, J., Hengeveld, M., Loonen, A., Mulder, C. (2010) Treatment adherence therapy in people....	Randomized Controlled Study Level 1, Quality B	109 outpatients	Therapy sessions varied depending on the specific problems presented by the patient	Patients in the Treatment Adherence Therapy groups showed ↑ engagement scores, ↑ medication adherence scores, ↓ involuntary admissions to the hospital
Ran. M., Chan. C., Guo, L., Xiang. M. (2015). The effectiveness of psychoeducational family intervention for patients with schizophrenia in a 14 year follow up	Cluster Randomized Control Trial Level 1, Quality A	326 outpatients from rural areas in China followed for 14 years	Three groups - family intervention group, medication group, control group	Both Psychoeducation groups = ↑ short term and long term medication adherence, ↑ work abilities, ↓ relapse and ↓ hospitalization rates
Bauml, J., Pitschel-Walz, G., Vols, A., Lucsher, S., Rentrop, M., Kissling, W., Jahn, T. (2016). Psychoeducation improves compliance and outcome in schizophrenia	Randomized PIP study Level 1, Quality B	41 outpatients around 3 different psychiatric hospitals in Munich were followed for 7 years	Psychoeducation or standard psychiatric care	Psychoeducational group = ↓ hospitalization rates, ↓ days spent in the hospital when admitted, ↑ medication adherence