

REVISIT-C

RATER TRAINING MEMORANDUM No.1

Positive and Negative Syndrome Scale (PANSS), Clinical Global Impression Scales for Aggression (CGI-A), and MacArthur Community Violence Interview (MCVI)

The purpose of this Rater Training Memorandum is to provide raters with important reminders about the Positive and Negative Syndrome Scale (PANSS), MacArthur Community Violence Interview (MCVI), and CGI-Severity and CGI-Improvement scales for aggressive behaviors in schizophrenia as administered in the REVISIT-C study. To ensure standardization of scale administration and scoring across sites and raters, the following important information should be carefully reviewed and adhered to by raters continuing to administer the PANSS, MCVI and CGI scales in the study.

Considerations for PANSS

Delusions: It is important to keep in mind that if a patient endorses a symptom during the interview, all PANSS items where that symptom is applicable should be scored accordingly. For example, the patient reports delusions, then delusions are scored on all items where this symptom is applicable, not just scored for Item P1 Delusions.

Items	Relationship to delusions
P3 Hallucinatory Behavior	Beginning at a response of 5 or above, the patient may have a delusional interpretation of their hallucinatory experiences, therefore if Item P3 is scored 5 or above, Item P1 Delusions should be scored at least a 3 or above
P5 Grandiosity	Item P5 Grandiosity is an exaggerated self-opinion and unrealistic convictions of superiority, including delusions. If the patient receives a score of 4 or higher on Item P5 Grandiosity, Item P1 Delusions should also be scored 3 or higher
P6 Suspiciousness and Persecution	Item P6 Suspiciousness and Persecution are unrealistic or exaggerated ideas of persecution, as reflected in guardedness, and distrustful attitude, suspicious hypervigilance or frank delusions that others mean harm. Therefore, if Item P6 Suspiciousness and Persecution is scored 3 or higher, item P1 Delusions should also be scored 4 or higher
G1 Somatic Concern	There is delusional conviction related to physical complaints once the patient scores 5 or higher on G1 Somatic Concern. If the patient scores 5 or higher on G1 Somatic

	Concern, then Item P1 Delusions should also be scored 3 or higher
G3 Guilt Feelings	Guilt feelings refer to a sense of remorse or self-blame for real or imagined misdeeds in the past and may have a delusional basis. If G3 Guilt Feelings is scored 5 or higher then Item P1 Delusions may be scored 3 or higher if it is evident the feelings of guilt have a delusional basis
G6 Depression	For the highest score of 7 on G6 Depression, a patient report experiencing depressive or nihilistic delusions. In this case, Item P1 Delusions may be scored 3 or higher if it is evident that there are depressive or nihilistic delusions
G9 Unusual Thought Content	G9 Unusual Thought Content looks at the presence of strange, fantastic, or bizarre ideas. For a score of 2 to 4 on Item G9 Unusual Thought Content, there may be a lack delusional content. However, for the score for 5 and higher, the patient may exhibit a delusional ideation with bizarre content, therefore Item P1 Delusions should be scored at least 3 or higher
G12 Lack of Judgment and Insight	Item G12 Lack of Judgement and Insight may include a delusional basis at a score of 4 or higher, therefore P1 Delusions cannot be Absent (i.e., a score of 1)
G16 Active Social Avoidance	Item G16 Active Social Avoidance includes diminished social involvement associated with unwarranted fear, hostility, or distrust which may have a persecutory delusion basis at a score of 7. If G16 is scored 7, then Item P1 Delusions and Item P6 Suspiciousness and Persecution cannot be scored 1 or Absent and should have a score of at 3 or higher

Anxiety: When scoring anxiety, keep in mind the following important reminders for scoring anchors. Generally, the item scores should not exceed a difference in scoring of more than 1 point.

Items	Relationships to anxiety
G2 Anxiety and G4 Tension	A score of 3 on Anxiety confirms there was no physical evidence of worry, and a score of 5 on Tension indicates that there was physical evidence of tension that may be similar to symptoms seen in anxiety. If Item G2 Anxiety is scored 3, then Item G4

	<p>Tension cannot be scored 5</p> <p>The definition of G4 Tension includes anxiety, therefore if Tension is scored 3 or higher, then Anxiety should be scored 2 or higher</p>
G1 Somatic Concern	<p>Higher scores on item G1 Somatic Concern, i.e., scores of 4 to 7, indicate increasing concern regarding the patient's physical well-being therefore he patient can also experience some level of anxiety and item G2 Anxiety should be scored 2 or higher if there is evidence of anxiety related to somatic concerns</p>
G16 Active Social Avoidance	<p>A score of 4 on G16 Active Social Avoidance may include premature termination from all or most social activities as a result of anxiety. Therefore, if scoring Item G16 Active Social Avoidance as a score of 4 as a result of the patient's anxiety, then Item G2 Anxiety should be scored 3 or higher</p>

Lack of Spontaneity and Flow of Conversation: Lack of spontaneity and flow of conversation refers to a reduction in the normal flow of communication associated with apathy, avolition, defensiveness or cognitive deficit. This item is related to other constructs measured on the PANSS

Items	Relationships to spontaneity and conversations observed throughout the interview
G7 Motor Retardation	<p>G7 Motor Retardation includes both physical movements and speech. A score of 5 on G7 Motor Retardation refers to a marked reduction in motor activity which renders communication highly unproductive or limits functioning in social and occupational situations. Therefore, a score of 5 or higher on Motor Retardation is related to marked lack of spontaneity and openness in conversation and Item N6 Lack of Spontaneity and Flow of Conversation should be scored at least a 5</p>
N3 Poor Rapport	<p>Poor Rapport refers to a lack of interpersonal empathy, openness in conversation and sense of closeness, interest, or involvement with the interviewer. Therefore, if N6 Lack of Spontaneity and Flow of Conversation is scored 3 or higher, then N3 Poor Rapport should also be scored 3 or higher</p>

Hostility: Verbal and nonverbal expressions of anger and resentment, including sarcasm, passive-aggressive behavior, verbal abuse and assaultiveness. This item is related to other constructs measured on the PANSS.

Items	Relationships to hostility
G14 Poor Impulse Control	<p>At a score of 3 or higher on Item P7 Hostility, there is some indication of anger, hostile expressions, and irritability, therefore Item G14 Poor Impulse Control which assesses disordered regulation and control of actions cannot be scored as Absent (i.e., score of 1)</p> <p>If Item P7 Hostility is scored 5 or higher indicating that the patient is highly irritable and occasionally verbally abusive or threatening, G14 Poor Impulse Control should be scored at least 3 or higher</p>
G8 Uncooperativeness	<p>The definition of Item G8 Uncooperativeness includes non-compliant behavior that may be associated with distrust, defensiveness, stubbornness, negativism, rejection of authority, hostility, or belligerence. Therefore, Item P7 Hostility and Item G8 Uncooperativeness should be scored in alignment with each other and should not exceed 2 or more points between scores</p>

Considerations for CGI-Improvement (CGI-I)

It is important to keep in mind that when scoring the CGI-I, ONLY the change in the patient's severity **since baseline** (i.e., since the initiation of treatment) should be considered.

CGI-I: Consider change from baseline

Response Options for CGI-I

Each scoring anchor for the CGI-I is based on three important aspects:

1. The patient's **change in clinical status**: either improvement, worsening, or no change
2. If a change is observed, note the perceived **clinical meaningfulness of the change**
3. The patient's **change in functioning** (e.g., social roles, occupational roles, daily activities)

CGI-I Scoring

When scoring the CGI-I, please keep in mind the following important reminders for scoring anchors that can be difficult to differentiate between. For example,

- **Much Worse** indicates that the patient has a significant increase in their symptoms of aggression and loss of functioning in several areas
 - If the patient has stopped work, school or activities of daily living due to their symptoms, stays at home and does not attend scheduled activities, does not

interact with any of their friends, and only interacts with one or two family members, the patient would score **Much Worse**. The patient would **NOT** score **Very Much Worse** since they are still able to participate in some functional roles

- **Minimally Worse** on the CGI-I indicates that the patient presents with slightly worse symptoms but no clinically meaningful change in their clinical presentation or overall functional capacity

Considerations for CGI-Severity (CGI-S)

It is important to keep in mind that when scoring the CGI-S, ONLY the patient’s severity within the **past week or 7 days** should be considered.

CGI-S: Consider severity in the past 7 days

Response Options for CGI-S

Each scoring anchor for the CGI-S is based on three important aspects:

1. **Symptom presentation:** Symptoms reported or observed within the past 7 days
2. **Intensity of the symptom** within the past 7 days
3. **Degree of impairment:** Effect of the symptom on functioning within the past 7 days

CGI-S Scoring

When scoring the CGI-S, please keep in mind the following important scoring reminders for scoring anchors that can be difficult to differentiate between:

- **Extremely Affected** on the CGI-S indicates that the patient cannot function on their own and is completely incapacitated
 - If the patient has stopped work or school or all activities and adjusted their schedule due to their aggression symptoms but is still unable to function in **most** areas of daily activities, this is considered **Severely Affected** and **NOT Extremely Affected** as the patient can still function in some areas. If the patient cannot function in **all** areas of daily living, then the patient would be considered **Extremely Affected**
- **Severely Affected** on the CGI-S indicates that the patient presents with very marked aggressive symptoms, and is unable to function in **most** areas of daily activities
 - If the patient has stopped work or school or other activities because of their aggressive behaviors, and may have stopped certain activities such as attending group sessions or attending scheduled appointments, this is affecting **most** areas of daily activities
- **Moderately Affected** on the CGI-S indicates that the patient presents with some prominent symptoms of aggression with **some** interference in the level of daily functioning

Association between PANSS, MCVI and CGI-A Scales

The PANSS Excitement Component (PANSS-EC), MCVI and CGI-A all measure some level of aggressive and violent behavior. Scores on these items can be interrelated. Here are some reminders when scoring the PANSS-EC, MCVI and CGI-A scales:

- For the MCVI completed at Screening, the Rater considers all violent acts within the **past 6 months**. For the PANSS regardless of the visit, the scores are based on behaviors within the **past 7 days**
- If a violent act is endorsed on the MCVI and the act was noted to have occurred within the past 7 days, then P7 Hostility, G14 Poor Impulse Control, and P4 Excitement CANNOT be scored as 1 (Absent) and the CGI-Aggression CANNOT be scored as 1 (Normal, no aggression)
- Following completion of scoring for each scale, review the scales as a whole and confirm that the results across all three (3) assessments are consistent and equivalent for the timeframe under consideration

We hope these reminders have been helpful. If you have any questions, feel free to contact Jean Pierre Lindenmayer (jeanpierre.lindenmayer@nki.rfmh.org), Anzalee Khan (Anzalee.khan@nki.rfmh.org) or Valis Bioscience at REVISITC@valisbioscience.com