

CDI Questionnaire (Pediatric)

General Instructions

The CDI questionnaire is a research tool designed to measure the depressive symptoms through a series of questions that determine how the patient has felt in the past two weeks. The CDI will be administered to patients that are 7-17 years of age during the course of the trial. If younger than 7, the parent is to complete the form. If the patient turns 18 during the course of the trial, complete the CES-D.

The questionnaire is completed at the screening visit and baseline visit. Patients randomized to the treatment group complete this questionnaire at weeks 12, 24, 36, 48, 60, 84, and 96. Patients randomized to the control group complete this questionnaire at weeks 48 and 96. Results of the CDI should be used in conjunction with clinical judgment.

Per the study protocol, a score of >19 could result in a referral to a mental health provider.

This version of the CDI is available in English only.

The questionnaire is self-explanatory and the patient should be asked to complete it without additional instructions or assistance. The clinical coordinator should not attempt to interpret, elaborate upon, or rephrase questions. If the patient asks for assistance from the clinical coordinator, the coordinator should encourage the patient to do his/her best to complete the form on his/her own, stating that "there are no right or wrong answers".

The questionnaire is designed to be completed on-line via the HBRN web-based system. If completed on-line, the coordinator will initialize the session for the patient. The patient will complete the battery of questionnaires and then turn the session over to the coordinator. The coordinator will have the opportunity to review incomplete items with the patient before exiting the session. If the questionnaire is completed on paper, the coordinator should review the questionnaire for completeness while the patient is still present.

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Specific Instructions

Patient ID: Record the Patient ID in the top right hand corner.

Date of Evaluation: Record the date (month/day/year) that the patient completed the questionnaire.

Protocol visit: Record the protocol timepoint that corresponds to the visit.

Form completed by: If the patient is unable to understand the questions because of educational,

cultural or language difficulties help may be provided by a trained translator or the patient's next of kin or friend. In these situations the person helping the patient can read the questions to the patient and record the answers, or supply

the answers to the best of his/her knowledge.

Check all that apply to indicate who completed the form (patient, coordinator,

interpreter, parent/caregiver, family member/friend or other).

CDI Each statement refers to which statement best describes the patient in the *past*

two weeks. A response should be recorded for each question.



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The data system will generate the CDI score once all responses are entered. The data system will not generate the CDI score when one or more responses are missing.

The CDI score can be calculated by summing the values associated with the responses. Remember that questions 2, 5, 7, 8, 10, 11, 13, 15, 16, 18, 21, 24 and 25 are reverse scored. For these four questions a response of 0 should be counted as a 2, a response of 1 should be counted as a 1, and a response of 2 should be counted as a 0.

The scores for each item are as follows, e.g. item 1:
 0 □ I am sad once in a while. 1 □ I am sad many times. 2 □ I am sad all the time.
Reverse scored items, e.g. item 2:
2 Nothing will ever work out for me.
1 ☐ I am not sure if things will work out for me.
0 ☐ Things will work out for me O.K.