BOLD MEDICINE:

Clinical Global Impression (CGI) Scales
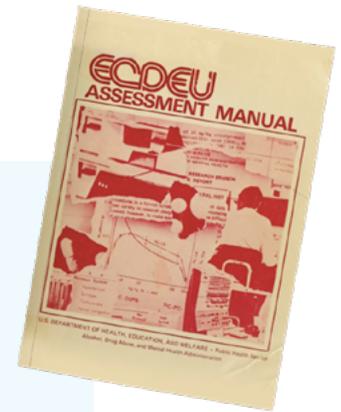
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Clinically Assessing an Individual's Global Functioning

Since the 1970s, Clinical Global Impressions (CGI) scales have been used in clinical studies to provide objective clinical impressions of a single individual that transcend mere symptom checklists.

The scales track clinical progress across time, taking into account all available information:

- *Patient's history*
- *Caregiver input*
- *Psychosocial circumstances*
- *Symptoms*
- *Behavior*
- *Impact of the symptoms on the patient's ability to function*

CGI scales have been shown to correlate with other, longer rating clinical measurement tools across a wide range of neurologic and psychiatric diagnoses. It has been used to support drug regulatory approvals for schizophrenia, bipolar disorder and ADHD treatments.

Tracking Improvement Over Time with the Two CGI Scales

The methodology includes two companion one-item measures evaluating the following:

CGI-SEVERITY (CGI-S)

An objective measure of condition severity at the start of the trial, establishes a baseline for each patient

Clinicians ask: "Considering your total clinical experience with this particular population, how ill is the patient at this time?"

Answers fall on the following seven-point scale:

1 — — — — **7**

Normal, not at all impaired

The most severely impaired

CGI-IMPROVEMENT (CGI-I)

An objective measure of a single patient's change (improvement or worsening) compared to baseline

Clinicians ask: "Compared to the patient's condition at baseline, this patient's [average] condition has...?"

Answers fall on the following seven-point scale:

1 — — — — **7**

Very much improved

Very much worse

What CGI Scores Mean

The two CGI scales help track changes that are relevant to each individual patient.

±.05 For the CGI-I scale specifically, **a change of 0.5 indicates a clinical impact of significance** that will influence a physician's treatment decisions.

While the CGI-I score generally tracks with the CGI-S—in that improvement in one follows improvement in the other—the two CGI scores can occasionally be dissociated. A clinician may notice changes in the CGI-I relative to baseline, despite no recent change in the overall CGI-S score, or vice versa.

A Brief Guide to Administering CGI Scales

The general administration guidelines for CGI scales have evolved over the years, but some of the more commonly used research conventions include:

The Administrator

In clinical research, the CGI is administered by an experienced clinician who is familiar with the disease under study and the likely progression of treatment—who can make an expert clinical global judgment about illness severity across time and within the context of that clinical experience.

The Assessment

The clinician makes a judgment about the total picture of the patient at each visit: the illness severity, the patient's level of distress and other aspects of impairment, and the impact of the illness on functioning. The CGI is rated without regard to the clinician's belief that any clinical changes are or are not due to medication and without consideration of the etiology of the symptoms.

The Timeframe

The CGI is usually rated relative to the past seven days (including the day of the visit up to and through the visit). In this respect, the CGI is a state-dependent measure summarizing one week rather than a lifetime of symptoms and behavior.

The Sources of Information

Make use of all information available—a clinical patient interview should be combined with any other information available for the time period under study, from such sources as chart notes, family members, caseworkers, unit nurses, schoolteachers for children, or significant others.

The Questions to Ask

Establish the presence of relevant symptoms, the frequency of their occurrence over the seven-day rating timeframe, the intensity or severity of the symptoms, and the effect of the symptoms on functioning in major areas of the patient's life: work, home, school, and relationships.