

Assessing Person-Centered Health Outcomes in Patients with Hepatitis C Virus (HCV)

These recommendations are offered as a starting point for consideration. They are not necessarily the best choices for every application and do not substitute for a comprehensive literature review.

Key Domains to Consider in patients with Hepatitis C Virus (HCV)

HCV can have a significant impact on an individual's **global health** and can be associated with symptoms of **fatigue, depression, cognitive impairment, sleep disturbance, liver pain, muscle and joint aches, and perceived stigma**. The treatment for HCV can cause fatigue, nausea, and headache. Patient-reported outcome (PRO) assessments can be used as an important part of the process in both clinical care and clinical research for diagnosing, monitoring, and characterizing patients and their illnesses. They can also be used in treatment comparison to evaluate the impact that differing regimens have on patient experiences and well-being.

Suggested HealthMeasures for Primary Domains in HCV

Global Health

Global health refers to the general domains of health and functioning including overall physical health, mental health, social health, pain, fatigue, and overall perceived quality of life. The PROMIS® Global Health 10-item scale assesses each of these facets for individuals with HCV and provides summary scores for physical and mental health.

Fatigue

Fatigue is one of the most common symptoms individuals with chronic HCV report and is a common side effect of current HCV treatments. The PROMIS Fatigue (FACIT-Fatigue) measure assesses a person's level of fatigue and the effect of that fatigue on daily activities. The measure is available as a 13-item short form or via computerized adaptive testing (CAT).

Depression

Perceived and actualized stigma, health anxiety, and prolonged fatigue may lead to depression for individuals with HCV. The PROMIS Depression 8-item short form or CAT version is used to assess negative mood (sadness, guilt), views of self (self-criticism, worthlessness), and social cognition (loneliness, interpersonal alienation), as well as decreased positive affect and engagement (loss of interest, meaning, and purpose).

Summary

- Recommended primary domains for Hepatitis C Virus research or care include global health, fatigue, and depression.
- Recommended secondary domains for HCV include Anxiety, Anger, Cognitive function, Sleep Disturbance, Belly pain, Pain intensity and Pain Interference (for muscle and joint aches and pains), and Stigma (when available).
- HealthMeasures offers brief, psychometrically sound measures for these domains.
- Recommended assessment times include those scheduled to capture baseline symptoms, the effects of treatment, and longer-term outcomes.

Suggested HealthMeasures for Secondary Domains in HCV

HCV may impact many aspects of a person's physical, emotional, and social functioning, which means that other health status and quality of life domains can also be significantly impacted and represent secondary domains worth assessing:

Secondary HealthMeasures	Description
PROMIS Anxiety 8-item short form or CAT	Assesses fear, worry, dread, tension, nervousness, restlessness, and somatic symptoms associated with arousal (racing heart, dizziness).
PROMIS Anger 5-item short form or CAT	Assesses irritability, frustration, negative social cognitions (interpersonal sensitivity, envy, disagreeableness), and efforts to control anger.
PROMIS Cognitive Function 8-item short form or CAT	Concerns and perceived disturbances in mental acuity, concentration, verbal and nonverbal memory, and verbal fluency; NIH Toolbox: Assessment of Executive Function, Attention, Episodic Memory, Language, Processing Speed and Working Memory
PROMIS Sleep Disturbance 8-item short form or CAT	Perceptions of sleep quality, sleep depth, and restoration associated with sleep.
PROMIS Pain Intensity 3-item short form	Assesses the severity of a person's pain.
PROMIS Pain Interference 6-item short form or CAT	Assesses how much a person's pain interferes with their normal daily activities.
PROMIS Gastrointestinal – Belly Pain 5a short form	Assesses frequency, severity, bothersomeness and interference of belly pain

*Stigma is also an important domain and a PROMIS measure for this domain is currently being validated.

Assessment Times

Ideally, patient-report measures included in the set of primary domains (and secondary domains if patient burden is not too great) would be used at a variety of assessment time points including pre- and post- treatment / intervention both in clinical care and clinical trials.

Additional Information

The www.HealthMeasures.net website includes more information about measurement selection, data collection tools, scoring, and interpretation. Its [Search and View Measures](#) tool includes access to all HealthMeasures described here. A Forum allows for questions and responses from the HealthMeasures community. The HealthMeasures team is also available for collaboration or consultation via help@healthmeasures.net.

Primary HealthMeasures for HCV Patients

- PROMIS Global Health 10-item scale
- PROMIS Fatigue (FACIT-Fatigue) 13-item short form or CAT
- PROMIS Depression 8-item short form or CAT

Learn More!

You can read about CATs and watch a video tutorial at the HealthMeasures.net website [here!](#)