Criteria Grid
Best Practices and Interventions for the Diagnosis and Treatment of Hepatitis C

Best Practice/Intervention:	Jacobson et al. (2011). Telaprevir for Previously Untreated Chronic Hepatitis C Virus Infection. *The New England Journal of Medicine.* 364: 2405-16.
Date of Review:	February 13, 2012
Reviewer(s):	Christine Nguyen

Part A

Category:	**Basic Science** ☐ **Clinical Science** ☒ **Public Health/Epidemiology** ☐ **Social Science** ☐ **Programmatic Review** ☐
Best Practice/Intervention:	**Focus:** **Hepatitis C** ☒ **Hepatitis C/HIV** ☐ **Other:** _____ **Level:** **Group** ☒ **Individual** ☐ **Other:** _____ **Target Population:** Previously untreated chronic HCV-infected patients **Setting:** **Health care setting/Clinic** ☒ **Home** ☐ **Other:** _____ **Country of Origin:** 123 international sites **Language:** **English** ☒ **French** ☐ **Other:** _____

Part B

	YES	NO	N/A	COMMENTS
Is the best practice/intervention a meta-analysis or primary research?	☐	☐	☐	Primary research: the study was designed to assess the efficacy of telaprevir and its potential to shorten the duration of treatment for previously untreated HCV-infected patients. Two regimens of telaprevir of different durations of time (8 weeks or 12 weeks) were evaluated: telaprevir combined with peginterferon alfa-2a and ribavirin versus peginterferon alfa-21 and ribavirin alone.
The best practice/intervention has utilized an evidence-based approach to assess:				
Efficacy	☒	☐	☐	This study was a phase 3, randomized, double-blind trial, placebo-controlled for telaprevir. Efficacy was assessed based on evidence such as the HCV RNA level at the primary end point: • HCV RNA levels greater than 1000 IU per milliliter at week 4 led to discontinuation of telaprevir. • HCV RNA levels less than a $2\log_{10}$ decrease from baseline at week 12

				led to discontinuation of treatment. • HCV RNA levels with a lower limit of detection of 10 IU per milliliter, measured with the use of the COBAS TaqMan HCV RNA assay, determined extended rapid virological response.
Effectiveness	☐	☒	☐	
The best practice/intervention has been evaluated in more than one patient setting to assess:				
Efficacy	☒	☐	☐	In conducting this international, phase 3, randomized, double –blind, placebo-controlled trial, 1088 patients were enrolled at 123 international sites.
Effectiveness	☐	☒	☐	

	YES	NO	N/A	COMMENTS
The best practice/intervention has been operationalized at a multi-country level:				
There is evidence of capacity building to engage individuals to accept treatment/diagnosis	☐	☒	☐	
There is evidence of outreach models and case studies to improve access and availability	☐	☒	☐	
Do the methodology/results described allow the reviewer(s) to assess the generalizability of the results?	☒	☐	☐	Methodology can be replicated. Results are generalizable to specific subgroups. The primary end point was evaluated by an analysis of the consistency of the treatment effect in prespecified subgroups according to 10 baseline variables: • Age • Body-mass index • Male sex • Race • Ethnic group • Alanine aminotransferase level • Total bilirubin • Serum albumin level • Platelet count • HCV subtype
Are the best practices/methodology/results described applicable in developed countries?	☒	☐	☐	

Are the best practices/methodology/results described applicable in developing countries?	☐	☐	☐	Need data, human resources and technology
Evidence of manpower requirements is indicated in the best practice/intervention	☐	☒	☐	
Juried journal reports of this treatment, intervention, or diagnostic test have occurred	☒	☐	☐	This study has been published in *The New England Journal of Medicine.*
International guideline or protocol has been established	☒	☐	☐	
The best practice/intervention is easily accessed/available electronically	☒	☐	☐	Downloaded from www.nejm.org
Is there evidence of a cost effective analysis? If so, what does the evidence say? ***Please go to Comments section***	☐	☒	☐	
How is the best practice/intervention funded? ***Please got to Comments section***	☐	☐	☐	Funded by Vertex Pharmaceuticals and Tibotec
Other relevant criteria: _____	☐	☐	☐	