

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

Best Practice/Intervention:	Lok et al. (2012). Preliminary Study of Two Antiviral Agents for Hepatitis C Genotype 1. The New England Journal of Medicine, 366, 216-24.			
Date of Review:	January 19, 2012			
Reviewer(s):	Christine Nguyen			
Part A				
Category:	Basic Science <input type="checkbox"/> Clinical Science <input checked="" type="checkbox"/> Public Health/Epidemiology <input type="checkbox"/> Social Science <input type="checkbox"/> Programmatic Review <input type="checkbox"/>			
Best Practice/Intervention:	Focus: Hepatitis C <input checked="" type="checkbox"/> Hepatitis C/HIV <input type="checkbox"/> Other: _____ Level: Group <input checked="" type="checkbox"/> Individual <input type="checkbox"/> Other: _____ Target Population: <u>HCV-Genotype 1a and 2b-infected individuals</u> Setting: Health care setting/Clinic <input checked="" type="checkbox"/> Home <input type="checkbox"/> Other: _____ Country of Origin: <u>United States</u> Language: English <input checked="" type="checkbox"/> French <input type="checkbox"/> Other: _____			
Part B				
	YES	NO	N/A	COMMENTS
Is the best practice/intervention a meta-analysis or primary research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Preliminary study; primary research on the effects of multiple direct-acting antiviral agents on patients with chronic HCV genotype 1 infection who had not had a response to previous therapy.
The best practice/intervention has utilized an evidence-based approach to assess:				
Efficacy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Patients were assigned daclatasvir and asunaprevir to determine the percentage of patients with who responded to the treatment indicated by a reduction in HCV RNA levels response during the clinical trials. Primary efficacy end point: proportion of patients with undetectable HCV RNA (levels of <10 IU per milliliter) 12 weeks after treatment. Secondary efficacy end points: proportions of patients with undetectable HCV RNA at weeks 4, 12, and 24 during the treatment period and at weeks 24 and 48 after the end of the treatment period.

Effectiveness	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	This is a preliminary, open-label, phase 2a study and has not yet been applied outside of a clinical setting.
The best practice/intervention has been evaluated in more than one patient setting to assess:				
Efficacy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21 patients were enrolled at seven centers in the United States during the period from December 2009 through February 2010 in an exploratory cohort to assess safety and antiviral activity.
Effectiveness	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

	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	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
There is evidence of outreach models and case studies to improve access and availability	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Do the methodology/results described allow the reviewer(s) to assess the generalizability of the results?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Methodology is clearly described.
Are the best practices/methodology/results described applicable in developed countries?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Are the best practices/methodology/results described applicable in developing countries?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Evidence of manpower requirements is indicated in the best practice/intervention	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Juried journal reports of this treatment, intervention, or diagnostic test have occurred	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The New England Journal of Medicine
International guideline or protocol has been established	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The study was conducted in compliance with the Declaration of Helsinki, Good Clinical Practice guidelines, and local regulatory requirements.
The best practice/intervention is easily accessed/available electronically	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Downloaded from nejm.org at World Health Organization.
Is there evidence of a cost effective analysis? If so, what does the evidence say? Please go to Comments section	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
How is the best practice/intervention funded? Please got to Comments section	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The study was designed and conducted by the sponsor Bristol-Myers Squibb in collaboration with the principle investigators.
Other relevant criteria: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

