

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

Best Practice/Intervention:	Hezode et al. (2009). Telaprevir and Peginterferon with or without Ribavirin for Chronic HCV Infection, <i>N Engl J Med</i> , 360, 1839-1850.			
Date of Review:	March 18, 2011			
Reviewer(s):	Alison Marshall			
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>adults (18-65 years) with hepatitis C, genotype 1</u> Setting: Health care setting/Clinic <input checked="" type="checkbox"/> Home <input type="checkbox"/> Other: _____ Country of Origin: <u>France, Germany, UK, Austria</u> Language: English <input checked="" type="checkbox"/> French <input type="checkbox"/> Other: _____			
Part B				
	YES	NO	N/A	COMMENTS
<i>Is the best practice/intervention a meta-analysis or primary research?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Primary Research
<i>The best practice/intervention has utilized an evidence-based approach to assess:</i>				
<i>Efficacy</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Effectiveness</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>The best practice/intervention has been evaluated in more than one patient setting to assess:</i>				
<i>Efficacy</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	334 persons randomly assigned to one of four treatments, including control group.
<i>Effectiveness</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

	YES	NO	N/A	COMMENTS
<i>The best practice/intervention has been operationalized at a multi-country level:</i>				
<i>There is evidence of capacity building to engage individuals to accept treatment/diagnosis</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<i>There is evidence of outreach models and case studies to improve access and availability</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<i>Do the methodology/results described allow the reviewer(s) to assess the generalizability of the results?</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Are the best practices/methodology/results described applicable in developed countries?</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Study took place in several developed countries. Patients recruited between August 2, 2006, and January 17, 2007.
<i>Are the best practices/methodology/results described applicable in developing countries?</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Access to drugs would present challenges.
<i>Evidence of manpower requirements is indicated in the best practice/intervention</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<i>Juried journal reports of this treatment, intervention, or diagnostic test have occurred</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Study spurred several commentaries in <i>Hepatology</i> and <i>N Eng J Med</i>
<i>International guideline or protocol has been established</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<i>The best practice/intervention is easily accessed/available electronically</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	N Engl J Med . 2009 Apr 30;360(18):1839-50.
<i>Is there evidence of a cost effective analysis? If so, what does the evidence say?</i> Please go to Comments section	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<i>How is the best practice/intervention funded?</i> Please got to Comments section	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vertex Pharmaceuticals.
<i>Other relevant criteria:</i> Notable Findings <hr/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> • Response rate was lowest with regimens that did not include ribavirin. • Rate was significantly higher in the T12PR24 group (69% [56 of 81 patients]) than in the PR48 group (P = 0.004).

				<ul style="list-style-type: none">• Use of telaprevir may improve rate of sustained virologic response.• Larger and longer studies are needed to examine the efficacy and safety of telaprevir for HCV infection.
--	--	--	--	--