

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

<b>Best Practice/Intervention:</b>	Kwo et al. (2010). Efficacy of boceprevir, an NS3 protease inhibitor, in combination with peginterferon alfa-2b and ribavirin in treatment-naïve patients with genotype 1 hepatitis C infection (SPRINT-1): an open-label, randomized, multicentre phase 2 trial. <i>Lancet</i> , 376, 705-16.			
<b>Date of Review:</b>	February 10, 2012			
<b>Reviewer(s):</b>	Christine Nguyen			
<b>Part A</b>				
<b>Category:</b>	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"/>			
<b>Best Practice/Intervention:</b>	<b>Focus:</b> Hepatitis C <input checked="" type="checkbox"/> Hepatitis C/HIV <input type="checkbox"/> Other: _____ <b>Level:</b> Group <input checked="" type="checkbox"/> Individual <input type="checkbox"/> Other: _____ <b>Target Population:</b> <u>treatment-naïve patients with genotype 1 HCV infection</u> <b>Setting:</b> Health care setting/Clinic <input checked="" type="checkbox"/> Home <input type="checkbox"/> Other: _____ <b>Country of Origin:</b> <u>multicentre study across the USA, Canada, and Europe</u> <b>Language:</b> English <input type="checkbox"/> French <input type="checkbox"/> Other: _____			
<b>Part B</b>				
	<b>YES</b>	<b>NO</b>	<b>N/A</b>	<b>COMMENTS</b>
<i>Is the best practice/intervention a meta-analysis or primary research?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Primary research: a SPRINT-1 (Serine Protease Inhibitor Therapy-1) HCV study was designed to establish the safety and efficacy of boceprevir when added to peginterferon and ribavirin.
<i>The best practice/intervention has utilized an evidence-based approach to assess:</i>				
<i>Efficacy</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> <li>• An open-label, randomized, multicentre phase 2 clinical trial was conducted to assess the efficacy of boceprevir based on evidence such as:               <ul style="list-style-type: none"> <li>○ Primary endpoint: the sustained virological response (SVR) 24 weeks after treatment, which was defined as the proportion of patients with undetectable HCV RNA.                   <ul style="list-style-type: none"> <li>▪ This was measured using the Roche Cobas TaqMan.</li> </ul> </li> <li>○ Viral breakthrough: defined as a 2log<sub>10</sub> increase of HCV RNA</li> </ul> </li> </ul>

				<ul style="list-style-type: none"> <li>○ Mutations: assessed by population sequencing of the NS3 domain.</li> <li>○ Intention-to-treat analysis</li> <li>● To determine whether the efficacy of ribavirin could be maintained while reducing anemia, weight-based low-dose versus standard-dose ribavirin was assessed in Part 2 of the study.</li> </ul>
<i>Effectiveness</i>	<input type="checkbox"/>	<input checked="" 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"/>	This is a multicentre study that included 67 different patient settings in the USA, Canada, and Europe.
<i>Effectiveness</i>	<input type="checkbox"/>	<input checked="" 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"/>	SVR was summarized for important subpopulations of patients on the basis of prespecified baseline demographic and disease characteristics, such as: race, age, weight, HCV genotype, baseline HCV RNA, and cirrhosis. In particular, the results are generalizable to specific ethnic groups: black and non-black. Each group achieved different SVR rates, specifically, black people and those with cirrhosis had a lower SVR than did participants of non-black race and with no cirrhosis.
<i>Are the best practices/methodology/results described applicable in developed countries?</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Are the best practices/methodology/results described applicable in developing countries?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Need data, human resources, and technology.
<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"/>	This study has been published in the <i>Lancet</i> .
<i>International guideline or protocol has been established</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> <li>The study was taken in accordance with provisions of the Declaration of Helsinki and Good Clinical Practice guidelines.</li> </ul>
<i>The best practice/intervention is easily accessed/available electronically</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Downloaded from <a href="http://www.onlinelibrary.wiley.com">www.onlinelibrary.wiley.com</a>
<i>Is there evidence of a cost effective analysis? If so, what does the evidence say?</i> <b>Please go to Comments section</b>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<i>How is the best practice/intervention funded?</i> <b>Please go to Comments section</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	This study was funded by Merck.
<i>Other relevant criteria:</i> _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	