

Table 2. Rating System Used to Rate Level of Evidence and Strength of Recommendation

Recommendations are based on scientific evidence and expert opinion. Each recommended statement includes a Roman numeral (I, II, or III) representing the level of the evidence that supports the recommendation and a letter (A, B, or C) representing the strength of the recommendation.

Class	
I	Evidence and/or general agreement that a given diagnostic evaluation, procedure, or treatment is beneficial, useful, and effective.
II	Conflicting evidence and/or a divergence of opinion about the usefulness and efficacy of a diagnostic evaluation, procedure, or treatment.
lla	Weight of evidence and/or opinion is in favor of usefulness and efficacy.
IIb	Usefulness and efficacy are less well established by evidence and/or opinion.
III	Conditions for which there is evidence and/or general agreement that a diagnostic evaluation, procedure, or treatment is not useful and effective or if it in some cases may be harmful.

Level	
Α	Data derived from multiple randomized clinical trials, meta-analyses, or equivalent.
В	Data derived from a single randomized trial, nonrandomized studies, or equivalent.
С	Consensus opinion of experts, case studies, or standard of care.

Adapted from the American College of Cardiology and the American Heart Association Practice Guidelines (AHA, 2011); (Shiffman, 2003).

In some situations, such as for interferon-sparing HCV treatments, randomized clinical trials with an existing standard-ofcare arm cannot ethically or practicably be conducted. The US Food and Drug Administration (FDA) has suggested alternative study designs, including historical controls or immediate versus deferred placebo-controlled trials. For additional examples and definitions see FDA link: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatory Information/Guidances/ UCM225333.pdf. In those instances for which there was a single predetermined, FDA-approved equivalency established, panel members considered the evidence as equivalent to a randomized controlled trial for levels A or B.

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Related References

American College of Cardiology Foundation and American Heart Association, Inc. Methodology manual and policies from the ACCF/AHA task force on practice guidelines, Accessed June 13, 2019.; 2010.





Table 2. Rating System Used to Rate Level of Evidence and Strength of Published on HCV Guidance (https://www.hcvguidelines.org)

Shiffman RN, Shekelle P, Overhage JM, Slutsky J, Grimshaw J, Deshpande AM. <u>Standardized reporting of clinical practice guidelines: a proposal from the Conference on Guideline Standardization</u>. *Ann Intern Med.* 2003;139(6):493-498.