

Table 1. Summary of the Process and Methods for the Guidance Development

Topic	Description
Statement of need	Increased awareness of the rising number of complications of hepatitis C virus (HCV) infection, the recent screening initiatives by the Centers for Disease Control and Prevention (CDC) and US Preventive Services Task Force (USPSTF), and the rapid evolution of highly effective antiviral therapy for HCV infection have driven a need for timely guidance on how new developments change practice for healthcare professionals.
Goal of the guidance	The goal of the guidance is to provide up-to-date recommendations to healthcare practitioners on the optimal screening, management, and treatment for persons with HCV infection in the United States, considering the best available evidence. The guidance is updated regularly as new data, information, and tools and treatments become available.
Panel members	Panel members are chosen based on their expertise in the diagnosis, management, and treatment of HCV infection. Members from the fields of hepatology and infectious diseases are included, as well as HCV community representatives. Members are appointed by the sponsor societies after vetting by an appointed sponsor society committee. The panel chairs are appointed by the society boards, 2 each from the sponsor societies. All panel chairs and members serve as uncompensated volunteers for defined terms (2 to 3 years), which may be renewed based on panel needs.
Conflict of interest management	<p>The panel was established with the goal of having no personal (ie, direct payment to the individual) financial conflicts of interest among its chairs and among fewer than half of its panel members. All potential panel members are asked to disclose any personal relationship(s) with pharmaceutical, biotechnology, medical device, or health-related companies or ventures that may result in financial benefit. Disclosures are obtained prior to the panel member appointments and for 1 year prior to the initiation of their work on the panel. Full transparency of potential financial conflicts is an important goal for the guidance that best ensures the credibility of the process and the recommendations.</p> <p>Individuals are also asked to disclose funding of HCV-related research activities to their institutional division, department, or practice group.</p> <p>Disclosures are reviewed by the HCV guidance chairs, who make assessments based on the conflict-of-interest policies of the sponsoring organizations (AASLD and IDSA). Personal and institutional financial relationships with commercial entities that have products in the field of hepatitis C are assessed.</p> <p>The following relationships are prohibited during membership on the guidance panel and are grounds for exclusion from the panel:</p> <ul style="list-style-type: none"> • Employment with any commercial company with products in the field of hepatitis C • An ownership interest in a commercial entity that produces hepatitis C products • Participation in/payment for promotional or marketing activities sponsored by companies

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	<p>with HCV-related products including non-CME educational activities or speakers bureaus for audiences outside of the company</p> <ul style="list-style-type: none"> • Participation in any single-funder CME activity • Participation on a marketing or medical affairs advisory board <p>The following relationships or activities are reportable but do not merit exclusion:</p> <ul style="list-style-type: none"> • Commercial support of research that is paid to an organization or practice group Due to the rapidly evolving nature of the subject matter, having individuals with expertise in the particular clinical topic is crucial to developing the highest-quality and most-informed recommendations. To that end, research support from commercial entities is not considered grounds for panel exclusion (an unresolvable conflict) if the funding of the research was paid to the institution or practice group, as opposed to the individual. In the instance of someone conducting clinical research in a community practice, research funds to the group practice are acceptable. • Participation on commercial company scientific advisory boards Participation in advisory boards, data safety monitoring boards, or in consultancies sponsored by the research arm of a company (eg, study design or data safety monitoring board) is considered a potential personal conflict that should be reported but is not considered a criterion for exclusion. • CME honorarium earned in excess of \$5000 (total per year, including travel costs) No need to report if total honorarium is less than \$5000. <p>The HCV guidance chairs achieved a majority of panel members with no personal financial interests.</p> <p>Panel members are asked to inform the group of any changes to their disclosure status and are given the opportunity to recuse themselves (or be recused) from the discussion where a perceived conflict of interest that cannot be resolved exists.</p> <p>Financial disclosures for each panel member can be accessed here.</p>
Intended audience	<p>Medical practitioners, especially those who provide care to or manage patients with hepatitis C, are the intended audience of the guidance.</p>
Sponsors, funding, and collaborating partner	<p>AASLD and IDSA are the sponsors of the guidance and provide ongoing financial support.</p> <p>Grant support was sought and obtained from CDC for the initial gathering and review of evidence related to hepatitis C screening and testing recommendations and interventions to implement HCV screening in clinical settings.</p>
Evidence identification and collection	<p>The guidance is developed using an evidence-based review of information that is largely available to healthcare practitioners. Data from the following sources are considered by panel members when making recommendations: research published in the peer-reviewed literature or presented at major national or international scientific conferences; safety warnings from the US Food and Drug Administration (FDA) or other regulatory agencies or from manufacturers; drug interaction data; prescribing information from FDA-approved products; and registration data for</p>

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	<p>new products under FDA review. Press releases, unpublished reports, and personal communications are generally not considered.</p> <p>Literature searches are conducted regularly and before each major revision to ensure that the panel addresses all relevant published data. Medical subject headings and free text terms are combined to maximize retrieval of relevant citations from the PubMed, Scopus, EMBASE, and Web of Science databases. To be considered for inclusion, articles are required to have been published in English from 2010 to the present. Data from abstracts presented at national or international scientific conferences are also considered.</p>
Rating of the evidence and recommendations	<p>The guidance is presented in the form of recommendations. Each recommendation is rated in terms of the level of the evidence and strength of the recommendation using a modification of the scale adapted from the American College of Cardiology and the American Heart Association Practice Guidelines (AHA, 2011); (Shiffman, 2003). A summary of the supporting (and conflicting) evidence follows each recommendation or set of recommendations.</p>
Data review and synthesis and preparation of recommendations and supporting information	<p>Draft recommendations are developed by subgroups of the full panel with interest and expertise in particular sections of the guidance. Following development of supporting text and references, the sections are reviewed by the full panel and chairs. A penultimate draft is submitted to the AASLD and IDSA governing boards for final review and approval before posting online on the website, www.hcvguidelines.org.</p> <p>Subgroups of the panel meet regularly by conference call as needed to update recommendations and supporting evidence. Updates may be prompted by new publications or presentations at major national or international scientific conferences, new drug approvals (or new indications, dosing formulations, or frequency of dosing), new safety warnings, or other information that may have a substantial impact on the clinical care of patients. Updates and changes to the guidance are indicated by a notice of update posted on the home page.</p>
Abbreviations	<p>Commonly used abbreviations in the text are defined in Methods Table 3.</p>
Opportunity for comments	<p>Evidence-based comments may be submitted to the panel by email to stynes@asld.org or by clicking on the “Submit” button on the site contact form. The panel considers evidence-based comments about the recommendations, ratings, and evidence summaries but should not be contacted for individual patient management questions.</p>

Last update: September 21, 2017

Related References

[American Heart Association](#). 2011 .

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

