American Association for the Study of Liver Diseases
American Gastroenterological Association Institute
American Medical Association (AMA)-convened Physician Consortium for Performance Improvement® (PCPI®)

Hepatitis C
Performance Measurement Set

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* Introductory content is listed as originally drafted in 2013 and may not be up to date

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Work Group Members

Hepatitis C

Work Group Members

John W. Ward, MD (Co-chair) (internal medicine)
John B. Wong, MD (Co-chair) (gastroenterology, hepatology, methodology)

Joel V. Brill, MD, AGAF, CHCQM (gastroenterology)
Roger Chou, MD (internal medicine, guideline experience)
Richard H. Davis, Jr., PA-C (physician assistant)
Yngve Falck-Ytter, MD, AGAF (gastroenterology/liver/hepatology)
Troy Fiesinger, MD, FAAFP (family medicine)

Marc G. Ghany, MD, MHSc (guideline experience/hepatology)
Marwan Haddad MD, MPH, AAHIVS (HIV/HCV, community health center)
Arthur Yu-shin Kim, MD (Infectious Diseases, HIV/HCV co-infection)
Pritha Kuchaculla (American Liver Foundation, patient advocacy)
Daniel B. Raymond (consumer/patient advocacy group)
Paola Ricci, MD (hepatology/gastroenterology)
Martha Shea, BSN, RN (American Liver Foundation, patient advocacy)
Jessica A. Shepherd, MD, MBA (OB/GYN)
Margaret C. Shuhart, MD, MS (hepatology/gastroenterology)
Amy Hirsch Shumaker, PharmD, BCPS (pharmacy, hepatology, infectious diseases)
Aynsley D. Smith, CNP, MPH (hepatology nurse practitioner)
Chris Taylor (patient advocacy/public health)

Glenn Treisman, MD, PhD (HIV and HCV psychiatrist)

Weifeng Weng, PhD (health services researcher/ABIM PIM development)
John Yao, MD, MPH, MBA, MPA, FACP (health plan representative)

Work Group Staff

American Association for the Study of Liver Diseases
Sherrie H. Cathcart
Audrey Davis-Owino
Erika Miller

American Gastroenterological Association Institute
Wendy Cohen, MPH
Deborah P. Robin, MSN, CHCQM
Anushree Vichare, MBBS, MPH

American Board of Internal Medicine
Rebecca A. Baranowski

American Medical Association
Mark Antman, DDS, MBA
Katherine Ast, MSW, LCSW
Kathleen Blake, MD
Keri Christensen, MS
Jodie Dvorkin, MD, MPH
Anu Gupta, JD
Kendra Hanley, MS
Karen Kmetik, PhD
Samantha Tierney, MPH
Greg Wozniak, PhD

Purpose of the Measurement Set:

The American Association for the Study of Liver Diseases, American Gastroenterological Association Institute, and American Medical Association (AMA)-convened Physician Consortium for Performance Improvement® (PCPI®) formed a Hepatitis C Work Group to identify and define quality measures toward improving outcomes for adult patients with hepatitis C in ambulatory settings (see diagram at the end of this section). The Work Group aimed to develop a comprehensive set of measures that support the efficient delivery of high quality health care in each of the Institute of Medicine's (IOM) six aims for quality improvement (safe, effective, patient-centered, timely, efficient, and equitable).

In 2006, the PCPI developed a set of measures for adult patients with hepatitis C. Nine of these measures received endorsement from the National Quality Forum (NQF) and are in current use in the Centers for Medicare and Medicaid Service (CMS)'s Physician Quality Reporting System (PQRS). This work represents the formal periodic review and maintenance of an existing measurement set. The PCPI stipulates a regular review of measures every 3 years or when there is a major change in scientific evidence, results from testing or other issues noted that materially affect the integrity of the measure.

The current measure development project aimed to review and update these existing Hepatitis C measures to ensure that they reflect the latest guideline recommendations, address areas most in need of performance improvement, and incorporate results from testing projects, where existent. The Work Group also looked to the development of new measures with particular attention to exploring the development of outcome and composite or bundled measures. The Work Group composition is balanced and reflects different medical specialties and non-physician professionals. The team includes Work Group members from the fields of infectious diseases, gastroenterology, methodology, hepatology, HIV/HCV co-infection, family medicine, internal medicine, OB/GYN, physician assistant, public health, nursing, pharmacy, community health, psychiatry, health services research, health plan representation, and patient/consumer advocacy.

Importance of Topic

Prevalence and Incidence:

- The hepatitis C virus (HCV) is a major public health problem and a leading cause of chronic liver disease.[1]
- An estimated 180 million people are infected worldwide.[2]
- In the United States, the prevalence of HCV infection between the years 1999 and 2002 was 1.6%, equating to about 4.1 million persons positive for antibody to hepatitis C (anti-HCV), 80% of whom are estimated to be viremic.[3]
- In a population-based study, 1.8% of a large household-based sample was positive for anti-HCV antibody (2.3% in adults 20 years or older), which translates into an estimated 3.9 million infected persons in the United States. Of this population, 74% had viremia, which indicated chronic infection, or an estimated 2.7 million.[4]
- According to the Centers for Disease Control and Prevention (CDC)[5], of every 100 HCV-infected individuals, approximately:
    - 75–85 will develop chronic infection
    - 60–70 will develop chronic liver disease
    - 5–20 will develop cirrhosis over a period of 20–30 years
    - 1–5 will die from the consequences of chronic infection (liver cancer or cirrhosis)

Morbidity and Mortality:

- Hepatitis C is the principal cause of death from liver disease and the leading indication for liver transplantation in the U.S.[6]
- According to the CDC's Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965[7]:
    - Hepatocellular carcinoma (HCC) and cirrhosis have been increasing among persons infected with HCV,[8,9] and these outcomes are projected to increase substantially in the coming decade.[10,11]
    - HCC is the fastest growing cause of cancer-related mortality, and infection with HCV accounts for approximately 50% of incident HCC.[12]
    - A CDC review of death certificate data found that the hepatitis C mortality rate increased substantially during 1999–2007 (annual mortality rate change: +0.18 deaths per 100,000 population per year); in 2007, HCV caused 15,106 deaths.[13] Of the HCV-related deaths, 73.4% occurred among persons aged 45–64 years, with a median age of death of 57 years (approximately 20 years less than the average lifespan of persons living in the United States).[13]
    - On the basis of data from prospective and retrospective cohorts, an estimated 20% of infected persons will progress to cirrhosis 20 years after infection, and up to 5% will die from HCV-related liver disease.[14]
    - Modeling studies forecast substantial increases in morbidity and mortality among persons with chronic hepatitis C as they age into their third, fourth, and fifth decades living with the disease.[15,16] These models project that during the next 40–50 years, 1.76 million persons with untreated HCV infection will develop cirrhosis, with a peak prevalence of 1 million cases occurring from the mid-2020s through the mid-2030s[11]; approximately 400,000 will develop HCC.[11] Of persons with hepatitis C who do not receive needed care and treatment, approximately one million will die from HCV-related complications.[11,17]

Disparities:

- Although the continued prevalence of HCV is problematic in communities across America, inequalities in disease prevalence, treatment, and outcomes make it a particularly important minority health issue.[18]
- First, there are disparities in the prevalence of HCV infection, with African Americans being twice as likely to have ever been infected with HCV, and having a higher prevalence of chronic HCV infection compared with non-Hispanic white Americans.[19]
- Additionally, there are significant disparities in access to HCV care for racial and ethnic minorities.[20]
- Finally, African American and Hispanic patients with HCV infection, even once properly diagnosed, have less desirable treatment outcomes compared to white patients.[21]
- Race/ethnicity has been shown to be an important predictor of sustained virological response (SVR) in clinical trials, where only 19–28% of African Americans with genotype 1 and 57% of those with genotype 2 or 3 had SVR.[22,23,24]
- These trends are indicative of a growing healthcare crisis with regards to HCV that threatens minority communities for decades to come.[18]

Special Populations:

- HCV is prevalent in unselected alcoholic populations (14-36%) and in alcoholic individuals with liver disease (< or =51%).[25]
- Hepatitis C virus-infected individuals with high alcohol intake have more severe fibrosis, more rapid disease progression, and a higher rate of cirrhosis and hepatocellular cancer.[25, 26]

Opportunity for Improvement

- A 2010 retrospective cohort study using a nationwide U.S. health insurance company research database of 10,385 patients with HCV looked at quality of HCV care received by patients, as measured by 7 explicit quality indicators included in Medicare's 2009 Physician Quality Reporting Initiative (PQRI).[27]
    - ✓ Proportions of patients meeting quality indicators varied, ranging from 21.5% for vaccination to 79% for the HCV genotype testing indicator.[27]
    - ✓ Overall, only 18.5% of patients received all recommended care.[27]
    - ✓ Older age and presence of comorbid conditions were associated with lower quality, whereas elevated liver enzyme levels, cirrhosis, and HIV infection were associated with higher quality.[27]
        - ✓ Patients who saw both generalists and specialists received the best care.[27]

- Although effective treatments are available to clear HCV infection from the body, most persons with HCV do not know they are infected, do not receive needed care (eg, education, counseling, and medical monitoring), and are not evaluated for treatment.[7]
- Antiviral treatment for hepatitis C virus (HCV) has high efficacy rates for achieving sustained viral response (SVR) in randomized controlled trials (RCTs) (40–80%); however, it can be lower in community-based practice settings.[28] Using the nationwide Veterans Administration (VA) HCV Clinical Case Registry (CCR), researchers examined a cohort of veterans who had HCV viremia between 2000 and 2005 and identified patients who received pegylated-interferon (PEG-INF) and ribavirin. Of 99,166 patients identified with HCV viremia:
    - ✓ 11.6% received PEG-INF with ribavirin and 6.4% completed treatment.
    - ✓ Contraindications were present in 57.2% of the patients that did not receive treatment.
    - ✓ SVR was documented in 39.9% and 58.3% of patients who completed treatment; 23.6% and 50.6% of patients who initiated treatment; and 3.9% and 11.2% of the entire HCV cohort for genotype 1 or 4 and 2 or 3, respectively. Overall, only 3.5% of the entire HCV viremic cohort had a documented SVR.[28]
    - ✓ Researchers concluded that treatment effectiveness for HCV is low. In addition to fixed factors, such as race and virus genotype, the drop in effectiveness is due to low rates of antiviral treatment initiation and treatment completion.[28]

Clinical Evidence Base

Evidence-based clinical practice guidelines are available for hepatitis C. This measurement set is based on guidelines from:

- American Association for the Study of Liver Diseases (AASLD)
- European Association for the Study of the Liver (EASL)
- Centers for Disease Control and Prevention (CDC)
- U.S. Preventive Services Task Force (USPSTF)

These guidelines meet all of the required elements and many, if not all, of the preferred elements outlined in a recent PCPI position statement establishing a framework for consistent and objective selection of clinical practice guidelines from which PCPI Work Groups may derive clinical performance measures. Clinical practice guidelines serve as the foundation for the development of performance measures. Performance measures, however, are not clinical practice guidelines and cannot capture the full spectrum of appropriate care for all patients with hepatitis C. The guideline principles with the strongest recommendations and often highest level of evidence (well-designed randomized-controlled trials) served as the basis for measures in this set.

Hepatitis C Outcomes

Ideally, a set of measures for patients with hepatitis C will include both measures of outcomes as well as measures of processes that are known to positively influence desirable outcomes. Desired outcomes for hepatitis C include:

1. Achieve sustained virological response (SVR) "cure"
2. Decrease hepatitis C virus (HCV)-related mortality
3. Decrease HCV-related morbidity
4. Reduce HCV transmission
5. Decrease futile treatment (based on treatment response)
6. Improve quality and quantity of life
7. Improve functional status
8. Reduce delays in hepatitis C treatment
9. Promote shared decision making between patient, family, and clinician
10. Improve clinician communication and increase patient/family knowledge and satisfaction

Intended Audience, Care Setting, and Patient Population

The PCPI encourages use of these measures by physicians, other health care professionals, and healthcare systems, where appropriate, to manage the care for patients aged 18 years and older with a diagnosis of hepatitis C. These measures are meant to be used to calculate performance and/or reporting at the practitioner level. Performance measurement serves as an important component in a quality improvement strategy but performance measurement alone will not achieve the desired goal of improving patient care. Measures can have their greatest effect when they are used judiciously and linked directly to operational steps that clinicians, patients, and health plans can apply in practice to improve care. The Work Group attempted to develop measures that would be applicable in ambulatory settings.

Hepatitis C Work Group Recommendations

This measurement set includes measures that focus on appropriate evaluation and management of hepatitis C and associated symptoms, increasing patient awareness and participation in treatment decisions, care coordination, and promoting and enhancing patient safety. These measures can help guide treatment, decrease potentially preventable harmful events, lead to higher levels of personal functioning, and ease patient and caregiver burden through referrals to additional sources for support.

The Hepatitis C Work Group focused on current quality gaps in care in order to identify processes that could potentially improve patient outcomes for patients with hepatitis C. The Links to Outcomes diagram illustrates how each measure is linked to a process, which may eventually lead to an improved outcome.

These clinical performance measures are designed primarily for practitioner level quality improvement to achieve better outcomes for patients with hepatitis C. These measures are appropriate for accountability if the appropriate methodological, statistical, and implementation rules are achieved.

The measures listed below may be used for quality improvement and accountability.

Measures focusing on desired outcomes

Measure #10: (QI only) Sustained Virological Response (SVR)
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measures focusing on underuse of effective services

Measure #1: Confirmation of Hepatitis C Viremia
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #5: Hepatitis A Vaccination
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #6: Hepatitis B Vaccination
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #7: Counseling Regarding Risk of Alcohol Consumption
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measures focusing on effective and efficient services

Measure #2: Hepatitis C RNA Testing Before Initiating Treatment
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #3: HCV Genotype Testing Prior to Treatment
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #4: HCV RNA Testing Between 4-12 Weeks After Initiation of Treatment
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #9: Discontinuation of Antiviral Therapy for Inadequate Viral Response
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #12: Screening for HCC in patients with Hepatitis C Cirrhosis
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measures focusing on patient-centered care

Measure #11: Discussion and Shared Decision Making Surrounding Treatment Options
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measures focusing on timely care

Measure #8a: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk

Measure #8b: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users

Measure #8c: Appropriate Screening Follow-up for Patients Identified with Hepatitis C Virus (HCV) Infection

These measures also support the efficient delivery of high quality health care in many of the Institute of Medicine's (IOM) six aims for quality improvement as described in the following table:

IOM Domains of Health Care Quality		Safe	Effective		Patient-centered	Timely	Efficient	Equitable
			Underuse	Overuse				
	Measures							
1	Confirmation of Hepatitis C Viremia *This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.*	√		√		√		√
2	Hepatitis C RNA Testing Before Initiating Treatment (Paired Measure) *This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.*	√	√	√		√		√
3	HCV Genotype Testing Prior to Treatment (Paired) *This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.*	√	√	√		√	√	√
4	HCV RNA Testing Between 4-12 Weeks After Initiation of Treatment *This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.*	√		√		√	√	√
5	Hepatitis A Vaccination (Paired Measure) *This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.*		√			√		√
6	Hepatitis B Vaccination (Paired Measure) *This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.*		√			√		√

7	Counseling Regarding Risk of Alcohol Consumption *This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.*		√		√	√		√
8a	Screening for Hepatitis C Virus (HCV) for Patients at High Risk		√			√		√
8b	Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users		√			√		√
8c	Appropriate Screening Follow-up for Patients Identified with HCV Infection		√			√		√
9	Discontinuation of Antiviral Therapy for Inadequate Viral Response *This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.*	√		√		√	√	√
10	<u>QI only</u>: Sustained Virological Response (SVR) *This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.*							√
11	Discussion and Shared Decision Making Surrounding Treatment Options *This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.*		√	√	√	√		√
12	Screening for HCC in patients with Hepatitis C Cirrhosis *This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.*		√			√		√

Retired Measures

A number of circumstances might warrant the retirement of a measure from a measurement set including, but not limited to:

- The measure no longer remains clinically relevant/appropriate as determined by current guidelines and scientific evidence
- To avoid excessive clinician burden, other performance measures, such as outcome measures, may take precedence
- High clinician performance, implying that the measure no longer represents an opportunity for quality improvement
- Testing results demonstrating poor feasibility of data collection or weak correlation with improved health outcomes
- Identification of significant unintended consequences of measurement.

Three measures were retired as a part of review and maintenance of this measures set: Counseling Regarding the Use of Contraception Prior to Antiviral Treatment, HCV RNA Testing at Week 24 of Treatment, and Antiviral Treatment Prescribed.

In light of the changing landscape of treatment for patients with Hepatitis C and the development of additional directly acting anti-HCV agents, the Work Group ultimately decided against moving forward with a measure addressing antiviral treatment. The Work Group recognized that a significant opportunity for improvement remains related to the underutilization of evidence-based therapy, even after accounting for those patients with contraindications to currently approved treatments. However, they also acknowledged that treatment decisions within the rapidly evolving evidence surrounding treatment options need a careful evaluation and patient discussion of the risks and benefits individualized to the particular needs of the patient. Therefore, the Work Group felt it would be premature to move forward with an antiviral treatment measure at this time. With measure #11, the Work Group developed a measure that could promote this individualized, patient-centered approach to treatment that will be a mainstay of appropriate management.
In addition, the Work Group decided to replace the Counseling Regarding Risk of Alcohol Consumption measure with the Preventive Care & Screening: Unhealthy Alcohol Use: Screening & Brief Counseling measure. Consistent with USPSTF guidelines, the Preventive Care and Screening measure aims to include a broad patient population (ie, all patients aged 18 years and older) and is therefore applicable to all adult patients with a diagnosis of hepatitis C. To promote a comprehensive approach to performance improvement, the Hepatitis C measurement set is intended for use in its entirety when measuring clinical quality in the care of eligible patients. Full implementation of this measurement set for patients with a diagnosis of hepatitis C should always include the Preventive Care & Screening: Unhealthy Alcohol Use: Screening & Brief Counseling measure. The PCPI Preventive Care & Screening measurement set may be accessed on the PCPI web site at: www.physicianconsortium.org.

Other Potential Measures

The Work Group considered several other potential measures, though ultimately determined that they were not appropriate for inclusion in the measure set.

- Screening patients for co-morbidities or severity factors
- Rates of liver disease, cancer or mortality; rates of changes in liver cirrhosis and liver transplantation

The Work Group discussed developing a performance measure on screening patients for co-morbidities or severity factors. However, it was noted that some of the non-invasive severity tests cited in clinical guidelines are only available in Europe; additionally, there was concern about the rates of false positives and false negatives that may occur. Ultimately, it was decided that the degree of variation in practice for these particular recommendations made a performance measure not very reliable or valuable at this time.

Potential measures on clinical outcomes for hepatitis C were also discussed. Work Group members agreed that it would be desirable to measure rates of liver disease, cancer or mortality; or rates of changes in liver cirrhosis and liver transplantation. However, there were many concerns about the variability of disease presentation and time of referral. Work Group members considered the difficulty of comparing outcomes for those with mild and advanced disease. Measuring clinical outcomes was deemed critically important but developing a risk adjustment methodology in order to judge the performance of all clinicians with vastly different patient populations proved too complicated. In addition, the Work Group feared the possible unintended consequences of patient selection and wanted to see more data gathered prior to developing a long-term outcome measure.

To this end, one short-term outcome measure is included in the Hepatitis C measurement set (Sustained Virological Response [SVR]) in the hopes of gathering the data needed to develop long-term outcome measures in the future. The Work Group did not feel that this measure was ready for use as an accountability measure; rather it is being developed for quality improvement only until the data can be collected to develop a risk adjustment methodology for use in an accountability measure. In addition, the group recommended that certain variables be collected for stratification purposes, including race, hepatitis C genotype, timing of the infection (ie, acute or chronic), timing of referral for treatment, type of treatment received, bridging fibrosis or cirrhosis or not, HIV-infected or not, and viral load.

Measure Harmonization

When existing hospital-level or plan-level measures are available for the same measurement topics, the PCPI attempts to harmonize the measures to the extent feasible. When developing our measures for the Hepatitis C measurement set, harmonization was not deemed applicable for any measures.

Technical Specifications: Introduction

There are several data sources available for collecting performance measures; generally different data sources require different sets of measure specifications, due to the structure of the systems storing the data.

Quality measure technical specifications for administrative data sources are developed with administrative code sets – ICD-9-CM, ICD-10-CM, CPT, for example. A measure intended for administrative data source use or reporting may have significant differences in the specifications due to the nature of the various data sources. In administrative data sources, administrative or billing codes are typically used to identify eligible populations and reported immediately following the provision of care.

Quality measure technical specifications for electronic data sources are developed in alignment with national standards for clinical quality measures. Based on a measure's intended data sources, coding terminology recommendations and tools are used to create specifications to allow for clinical quality measure reporting. In electronic clinical data sources,

data can be aggregated over a specific time period and also allow for greater ability to express certain types of data through use of the recommended terminologies for electronic sources.

The Centers for Medicare and Medicaid Services (CMS) developed *A Blueprint for the Measures Management System*, which provides guidance related to the development, implementation, and maintenance of clinical quality measures. Specific to eCQMs, this resource includes the recommended vocabularies used to develop the value sets used in the measures. The Blueprint can be found at the following webpage: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html

When expressing clinical concepts found within a measure, specifically for those electronically specified, the Value Set Authority Center (VSAC) is used as a repository for the value sets. The VSAC serves as a repository for value sets in various stages of development, from draft to published, and allows for maintenance of value sets as updates are made to terminologies. It also allows measure developers to search for value sets currently in the VSAC and stewarded by another organization which could potentially be reused in a measure, as an effort towards harmonization with existing value sets so as not to duplicate value sets already in use with the same or similar clinical concepts. The VSAC can be accessed at the following webpage: https://vsac.nlm.nih.gov/

The Quality Data Model (QDM) is a framework used to categorize clinical concepts used in quality measures, as well as the relationships among them for electronic specification. The QDM allows for an Health Quality Measures Format (HQMF) rendering of logic using the Measure Authoring Tool (MAT) to express complex measure logic, and subsequently export measures in several formats, currently including a human-readable document, which can be viewed in a web browser, and the XML.
Links to these tools are found below:
QDM: https://ecqi.healthit.gov/qdm
MAT: https://www.emeasuretool.cms.gov/

CMS and the Office of the National Coordinator for Health IT (ONC) host a website, the Electronic Clinical Quality Information Resource Center (eCQI Resource Center), which is designed to serve as a one-stop shop for all resources related to eCQM development.
The eCQI Resource Center can be accessed at: https://ecqi.healthit.gov/ecqm

Measure Exclusions and Exceptions

Measure Exclusions
The PCPI distinguishes between measure exceptions and measure exclusions. Exclusions arise when the intervention required by the numerator is not appropriate for a group of patients who are otherwise included in the initial patient or eligible population of a measure (ie, the denominator). Exclusions are absolute and are to be removed from the denominator of a measure and therefore clinical judgment does not enter the decision.

Measure Exceptions
Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences.

For ***process measures***, the PCPI provides two categories of reasons for which a patient may be excluded from the denominator of an individual measure:

- **Medical reasons**
  Include:
  - Contraindicated in patient (potential allergy due to previous reported allergic history, potential adverse drug interaction, other)
  - Already received/performed
  - Intolerant (therapy was tried and the patient was intolerant)
  - Other medical reason(s)

- **Patient or Non-medical reason(s)**
  Include:
  - Patient refused/declined
  - Access issues or insurance coverage/payor-related limitations (patient not covered for treatment)
  - Patient preference: Social reason(s) (eg, family or support system not supportive of intervention/treatment); Religious reason(s) (eg, religious beliefs regarding blood transfusion)
  - Other patient or non-medical reason(s)

These measure exception categories are not available uniformly across all measures; for each measure, there must be a clear rationale to permit an exception for a medical or patient/non-medical reason. For some measures, examples have been provided in the measure exception language of instances that would constitute an exception. Examples are intended to guide clinicians and are not all-inclusive lists of all possible reasons why a patient could be excluded from a measure. There are different approaches for reporting measure exceptions, depending on whether the measure is being reported from an electronic clinical data source or an administrative data source.

Electronic Clinical Data Sources:
Value sets are included in the electronic clinical data source specifications for Medical Reason and Patient Reason. These have been specified in SNOMED-CT and include a broad list of reasons that pertain to each type of exception and cover various situations. The contents of these value sets are broad, and facilitate re-use of the Medical and Patient Reason value sets across measurement sets.

Administrative Data Sources
Exceptions reported from administrative data sources can be reported using a Quality Data Code (QDC), which may be a CPT Category II code or a G-code.

Where CPT Category II codes are used, the exception of a patient may be reported by appending the appropriate modifier to the CPT Category II code designated for the measure:

- **Medical reasons**: modifier 1P
- **Patient reasons**: modifier 2P

Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the *specific* reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each

physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception.

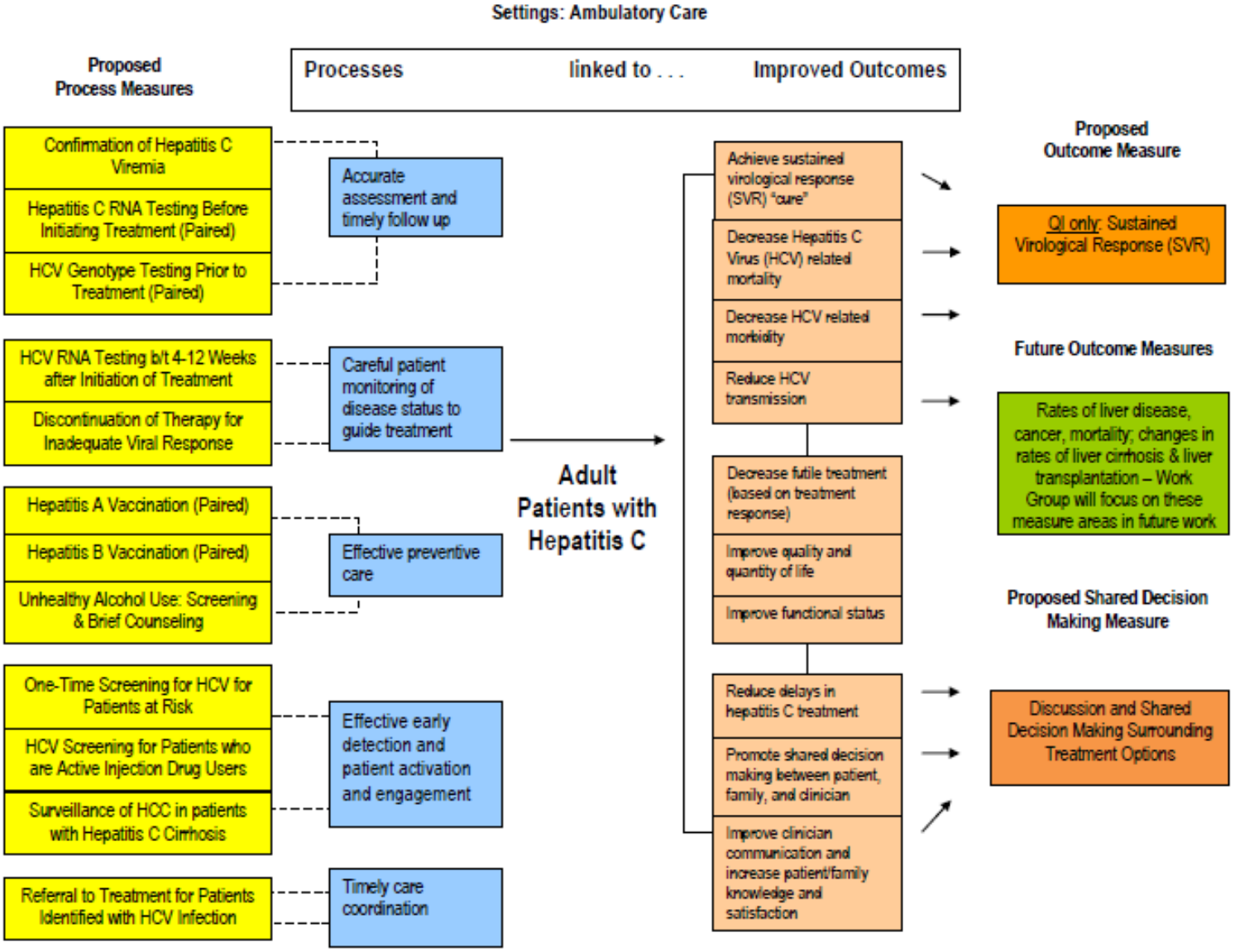
Please refer to documentation for each individual measure for information on the acceptable exception categories and the codes and modifiers to be used for reporting.

Testing of the Measurement Set

The measures in the set are being made available without any prior testing. The PCPI recognizes the importance of testing all of its measures and encourages testing of the One-Time Screening for HCV for Patients At Risk, Annual HCV Screening for Patients who are Active Injection Drug Users, and Appropriate Screening Follow-up for Patients Identified with Hepatitis C Virus (HCV) Infection measures for feasibility and reliability by organizations or individuals positioned to do so. The Measure Testing Protocol for PCPI Measures was approved by the PCPI in 2007 and is available on the PCPI web site (see Position Papers at www.physicianconsortium.org); interested parties are encouraged to review this document and to contact PCPI staff. The PCPI will welcome the opportunity to promote the initial testing of these measures and to ensure that any results available from testing are used to refine the measures before implementation.

Link to Outcomes:

The Hepatitis C measures focus on appropriate evaluation and management of hepatitis C and associated symptoms, increasing patient awareness and participation in treatment decisions, care coordination, and promoting and enhancing patient safety. These measures can help guide treatment, decrease potentially preventable harmful events, lead to higher levels of personal functioning, and ease patient and caregiver burden through referrals to additional sources for support.



Measures #1-#7 have been removed from this document

Measure #1: Confirmation of Hepatitis C Viremia
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #2: Hepatitis C RNA Testing Before Initiating Treatment (Paired Measure)
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #3: HCV Genotype Testing Prior to Treatment (Paired Measure)
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #4: HCV RNA Testing Between 4-12 Weeks After Initiation of Treatment
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #5: Hepatitis A Vaccination (Paired Measure)
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #6: Hepatitis B Vaccination (Paired Measure)
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #7: Counseling Regarding Risk of Alcohol Consumption
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measures Transitioned to the American Gastroenterological Association (AGA)

The Hepatitis C measures transitioned to AGA are available at: http://www.gastro.org/practice-management/quality/performance-measures

All AGA inquiries may be sent to: measures@gastro.org

Measure #8a: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk

Hepatitis C

Measure Description

Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945–1965 who received one-time screening for hepatitis C virus (HCV) infection

Measure Components

Numerator Statement	Patients who received one-time screening for HCV infection* *Screening for HCV Infection includes current or prior receipt of: HCV antibody test, HCV RNA test, or Recombinant immunoblot assay (RIBA) test (if performed at any time in the past)
Denominator Statement	All patients aged 18 years and older who were seen twice for any visit or who had at least one preventive visit within the 12 month reporting period with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945–1965
Denominator Exclusions	Patients with a diagnosis of chronic hepatitis C
Denominator Exceptions	Documentation of medical reason(s) for not receiving one-time screening for HCV infection (eg, decompensated cirrhosis indicating advanced disease [ie, ascites, esophageal variceal bleeding, hepatic encephalopathy], hepatocellular carcinoma, waitlist for organ transplant, limited life expectancy, other medical reasons) Documentation of patient reason(s) for not receiving one-time screening for HCV infection (eg, patient declined, other patient reasons)
Supporting Guidelines	In addition to testing adults of all ages at risk for HCV infection, CDC[7] recommends that: • Adults born during 1945–1965 should receive one-time testing for HCV without prior ascertainment of HCV risk (Strong Recommendation, Moderate Quality of Evidence), and • All persons identified with HCV infection should receive a brief alcohol screening and intervention as clinically indicated, followed by referral to appropriate care and treatment services for HCV infection and related conditions (Strong Recommendation, Moderate Quality of Evidence). Providers and patients can discuss HCV testing as part of an individual's preventive health care. For persons identified with HCV infection, CDC recommends that they receive appropriate care, including HCV-directed clinical preventive services (e.g., screening for alcohol use, hepatitis A and hepatitis B vaccination as appropriate, and medical monitoring of disease). Recommendations are available to guide treatment decisions. Treatment decisions should be made by the patient and provider after several

factors are considered, including stage of disease, hepatitis C genotype, comorbidities, therapy-related adverse events, and benefits of treatment. (CDC, 2012)[7]

The USPSTF recommends screening for hepatitis C virus (HCV) infection in persons at high risk for infection. The USPSTF also recommends offering 1-time screening for HCV infection to adults born between 1945 and 1965. (Grade B recommendation) (USPSTF, 2013)[29]

Assessment of Risk
The most important risk factor for HCV infection is past or current injection drug use. Another established risk factor for HCV infection is receipt of a blood transfusion before 1992. Because of the implementation of screening programs for donated blood, blood transfusions are no longer an important source of HCV infection. In contrast, 60% of new HCV infections occur in persons who report
injection drug use within the past 6 months (1). Additional risk factors include long-term hemodialysis, being born to an HCV-infected mother, incarceration, intranasal drug use, getting an unregulated tattoo, and other percutaneous exposures (such as in health care workers or from having surgery before the implementation of universal precautions). Evidence on tattoos and other percutaneous exposures as risk factors for HCV infection is limited.
The relative importance of these additional risk factors may differ on the basis of geographic location and other factors. (USPSTF, 2013)[29]

Verbatim from AASLD and IDSA Recommendations for Testing, Managing, and Treating Hepatitis C, February 2016[30]:

One-time HCV testing is recommended for persons born between 1945 and 1965* without prior ascertainment of risk.. (Rating: Class I, Level B) (AASLD/IDSA, 2016)[30]

Other persons should be screened for risk factors for HCV infection, and one-time testing should be performed for all persons with behaviors, exposures, and conditions associated with an increased risk of HCV infection.

1. Risk behaviors
   a. Injection drug use (current or ever, including those who injected once)
   b. Intranasal illicit drug use

2. Risk exposures
   a. Long-term hemodialysis (ever)
   b. Getting a tattoo in an unregulated setting
   c. Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-infected blood
   d. Children born to HCV-infected women
   e. Prior recipients of transfusions or organ transplants, including persons who:
      i. Were notified that they received blood from a donor who later tested positive for HCV infection
      ii. Received a transfusion of blood or blood components, or underwent an

	organ transplant before July 1992 iii. Received clotting factor concentrates produced before 1987 f. Persons who were ever incarcerated 3. Other a. HIV infection b. Unexplained chronic liver disease and/or chronic hepatitis including elevated alanine aminotransferase levels c. Solid organ donors (deceased and living) *Regardless of country of birth (Rating: Class I, Level B) (AASLD/IDSA, 2016)[30]

Measure Importance

Relationship to desired outcome	In the United States, an estimated 2.7–3.9 million persons (1.0%–1.5%) are living with hepatitis C virus (HCV) infection,[31] and an estimated 17,000 persons were newly infected in 2010, the most recent year that data are available.[32] With an HCV antibody prevalence of 3.25%, persons born during 1945–1965 account for approximately three fourths of all chronic HCV infections among adults in the United States.[33] Although effective treatments are available to clear HCV infection from the body, most persons with HCV do not know they are infected,[34],[35],[36],[37] do not receive needed care (eg, education, counseling, and medical monitoring), and are not evaluated for treatment.[7] HCV causes acute infection, which can be characterized by mild to severe illness but is usually asymptomatic. In approximately 75%–85% of persons, HCV persists as a chronic infection, placing infected persons at risk for liver cirrhosis, hepatocellular carcinoma (HCC), and extrahepatic complications that develop over the decades following onset of infection[32].**Error! Bookmark not defined.** HCV testing is the first step toward improving health outcomes for persons infected with HCV.	
Opportunity for Improvement	In a recent analysis of data from a national health survey, 55% of persons ever infected with HCV reported an exposure risk (eg, injection-drug use or blood transfusion before July 1992), and the remaining 45% reported no known exposure risk (CDC, unpublished data, 2012). Current risk-based testing strategies have had limited success, as evidenced by the substantial number of HCV-infected persons who remain unaware of their infection.[38] Of the estimated 2.7–3.9 million persons living with HCV infection in the United States, 45%–85% are unaware of their infection status[34],[35],[36],[37]; this proportion varies by setting, risk level in the population, and site-specific testing practices. Studies indicate that even among high-risk populations for whom routine HCV testing is recommended, prevalence of testing for HCV seromarkers varies from 17%–87%[34],[35]; according to one study, 72% of persons with a history of injection-drug use who are infected with HCV remain unaware of their infection status.[39] Barriers to testing include inadequate health insurance coverage and limited access to regular health care[37]; however, risk-based testing practices have not been successful in identifying most HCV-infected persons, even those covered by health insurance.[36]	
IOM Domains of Health Care Quality Addressed	• Effective	• Timely • Equitable

Exclusion Justification	Exclusions arise when patients who are included in the initial patient or eligible population for a measure do not meet the denominator criteria specific to the intervention required by the numerator. Exclusions are absolute and apply to all patients and therefore are not part of clinical judgment within a measure. Patients with a diagnosis of chronic hepatitis C do not need one-time screening for HCV infection and should be excluded from the denominator.
Exception Justification	Exceptions are used to remove patients from the denominator of a performance measure when a patient does not receive a therapy or service AND that therapy or service would not be appropriate due to specific reasons for which the patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment and individual patient characteristics. A medical reason exception has been included so that clinicians can exclude patients for whom receiving one-time screening for HCV infection may not be appropriate (eg, decompensated cirrhosis indicating advanced disease [ie, ascites, esophageal variceal bleeding, hepatic encephalopathy], hepatocellular carcinoma, waitlist for organ transplant, limited life expectancy, other medical reasons). A patient reason exception has been included so that clinicians can exclude patients for whom receiving one-time screening for HCV infection may not be appropriate (eg, patient declined, other patient reasons).
Harmonization with Existing Measures	The PCPI attempts to harmonize measures with other existing measures to the extent feasible. Harmonization was not deemed applicable for this measure.

Measure Designation

Measure purpose	• Quality improvement • Accountability
Type of measure	• Process
Level of Measurement	• Individual practitioner
Care setting	• Ambulatory Care
Data source	• Electronic Health Record (EHR) data • Prospective Claims-Based Reporting

Measure #8b: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users

Hepatitis C

Measure Description

Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12 month reporting period

Measure Components

Numerator Statement	Patients who received screening for HCV infection* within the 12 month reporting period **Numerator Definition:** **Screening for HCV infection-** includes HCV antibody test or HCV RNA test
Denominator Statement	All patients, regardless of age, who are seen twice for any visit or who had at least one preventive visit within the 12 month reporting period who are activeinjection drug users* Denominator Definition: *Active injection drug users are those who have injected any drug(s) within the past 12 months
Denominator Exclusions	Patients with a diagnosis of chronic hepatitis C
Denominator Exceptions	Documentation of medical reason(s) for not receiving annual screening for HCV infection (eg, decompensated cirrhosis indicating advanced disease [ie, ascites, esophageal variceal bleeding, hepatic encephalopathy], hepatocellular carcinoma, waitlist for organ transplant, limited life expectancy, other medical reasons) Documentation of patient reason(s) for not receiving annual screening for HCV infection (eg, patient declined, other patient reasons)
Supporting Guidelines	Verbatim from AASLD and IDSA Recommendations for Testing, Managing, and Treating Hepatitis C, February 2016[30]: Annual HCV testing is recommended for persons who inject drugs and for HIV-seropositive men who have unprotected sex with men. Periodic testing should be offered to other persons with ongoing risk factors for exposure to HCV. Rating: Class IIA, Level C (AASLD/IDSA, 2016)[30] The USPSTF recommends screening for hepatitis C virus (HCV) infection in persons at high risk for infection. The USPSTF also recommends offering 1-time screening for HCV infection to adults born between 1945 and 1965. (Grade B recommendation) (USPSTF, 2013)[29]

	Assessment of Risk The most important risk factor for HCV infection is past or current injection drug use. Another established risk factor for HCV infection is receipt of a blood transfusion before 1992. Because of the implementation of screening programs for donated blood, blood transfusions are no longer an important source of HCV infection. In contrast, 60% of new HCV infections occur in persons who report injection drug use within the past 6 months. Additional risk factors include long-term hemodialysis, being born to an HCV-infected mother, incarceration, intranasal drug use, getting an unregulated tattoo, and other percutaneous exposures (such as in health care workers or from having surgery before the implementation of universal precautions). Evidence on tattoos and other percutaneous exposures as risk factors for HCV infection is limited. The relative importance of these additional risk factors may differ on the basis of geographic location and other factors. (USPSTF, 2013)[29]

Measure Importance

Relationship to desired outcome	In the United States, an estimated 2.7–3.9 million persons (1.0%–1.5%) are living with hepatitis C virus (HCV) infection,[31] and an estimated 17,000 persons were newly infected in 2010, the most recent year that data are available.[32] With an HCV antibody prevalence of 3.25%, persons born during 1945–1965 account for approximately three fourths of all chronic HCV infections among adults in the United States.[33] Although effective treatments are available to clear HCV infection from the body, most persons with HCV do not know they are infected[34],[35],[36],[37], do not receive needed care (e.g., education, counseling, and medical monitoring), and are not evaluated for treatment.[7] Since 1998, routine HCV testing has been recommended by CDC for persons most likely to be infected with HCV.[40] These recommendations were made on the basis of a known epidemiologic association between a risk factor and acquiring HCV infection. HCV testing is the first step toward improving health outcomes for persons infected with HCV.	
Opportunity for Improvement	In a recent analysis of data from a national health survey, 55% of persons ever infected with HCV reported an exposure risk (e.g., injection-drug use or blood transfusion before July 1992), and the remaining 45% reported no known exposure risk (CDC, unpublished data, 2012). Current risk-based testing strategies have had limited success, as evidenced by the substantial number of HCV-infected persons who remain unaware of their infection.[38] Of the estimated 2.7–3.9 million persons living with HCV infection in the United States, 45%–85% are unaware of their infection status[34],[35],[36],[37]; this proportion varies by setting, risk level in the population, and site-specific testing practices. Studies indicate that even among high-risk populations for whom routine HCV testing is recommended, prevalence of testing for HCV seromarkers varies from 17%–87%[34],[35]; according to one study, 72% of persons with a history of injection-drug use who are infected with HCV remain unaware of their infection status.[39]	
IOM Domains of Health Care Quality Addressed	• Effective	• Timely • Equitable

Exclusion Justification	Exclusions arise when patients who are included in the initial patient or eligible population for a measure do not meet the denominator criteria specific to the intervention required by the numerator. Exclusions are absolute and apply to all patients and therefore are not part of clinical judgment within a measure. Patients with a diagnosis of chronic hepatitis C do not need screening for HCV infection and should be excluded from the denominator.
Exception Justification	Exceptions are used to remove patients from the denominator of a performance measure when a patient does not receive a therapy or service AND that therapy or service would not be appropriate due to specific reasons for which the patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment and individual patient characteristics. A medical reason exception has been included so that clinicians can exclude patients for whom screening for HCV infection may not be appropriate (eg, decompensated cirrhosis indicating advanced disease [ie, ascites, esophageal variceal bleeding, hepatic encephalopathy], hepatocellular carcinoma, waitlist for organ transplant, limited life expectancy, other medical reasons) . A patient reason exception has been included so that clinicians can exclude patients for whom screening for HCV infection may not be appropriate (eg, patient declined, other patient reasons).
Harmonization with Existing Measures	The PCPI attempts to harmonize measures with other existing measures to the extent feasible. Harmonization was not deemed applicable for this measure.

Measure Designation

Measure purpose	• Quality improvement • Accountability
Type of measure	• Process
Level of Measurement	• Individual practitioner
Care setting	• Ambulatory Care
Data source	• Electronic Health Record (EHR) data • Prospective Claims-Based Reporting

Measure #8c: Appropriate Screening Follow-up for Patients Identified with Hepatitis C Virus (HCV) Infection

Hepatitis C

Measure Description

Percentage of patients aged 18 years and older with either (1) a positive HCV antibody test result and a positive HCV RNA test result or (2) a positive HCV antibody test result and an absent HCV RNA test result who are prescribed treatment or are referred to evaluation or treatment services

Measure Components

Numerator Statement	Patients who are prescribed treatment or are referred to evaluation or treatment services *Numerator Note: To meet the numerator for this measure, patients with an absent HCV RNA test result must be referred to evaluation or treatment services within 90 days following a positive HCV antibody test result, while patients with a positive HCV RNA test result must be either prescribed treatment or referred to evaluation or treatment services within 90 days following a positive HCV RNA test result
Denominator Statement	All patients aged 18 years and older who are seen twice for any visit or who had at least one preventive visit with either (1) a positive HCV antibody test result and a positive HCV RNA test result or (2) a positive HCV antibody test result and an absent HCV RNA test result
Denominator Exclusions	Patients with a negative HCV RNA result, patients with a diagnosis of chronic hepatitis C
Denominator Exceptions	Documentation of medical reason(s) for not prescribing treatment or being referred to evaluation or treatment services (eg, participation in a clinical trial, decompensated cirrhosis indicating advanced disease [ie, ascites, esophageal variceal bleeding, hepatic encephalopathy], hepatocellular carcinoma, waitlist for organ transplant, limited life expectancy, other medical reasons) Documentation of patient reason(s) for not prescribing treatment or being referred to evaluation or treatment services (eg, patient declined, other patient reasons)
Supporting Guidelines	In addition to testing adults of all ages at risk for HCV infection, CDC[7] recommends that: • Adults born during 1945–1965 should receive one-time testing for HCV without prior ascertainment of HCV risk (Strong Recommendation, Moderate Quality of Evidence), and • All persons identified with HCV infection should receive a brief alcohol screening and intervention as clinically indicated, followed by referral to appropriate care and treatment services for HCV infection and related conditions (Strong Recommendation, Moderate Quality of Evidence). Providers and patients can discuss HCV testing as part of an individual's preventive health care. For persons identified with HCV infection, CDC recommends that they

	receive appropriate care, including HCV-directed clinical preventive services (e.g., screening for alcohol use, hepatitis A and hepatitis B vaccination as appropriate, and medical monitoring of disease). Recommendations are available to guide treatment decisions. Treatment decisions should be made by the patient and provider after several factors are considered, including stage of disease, hepatitis C genotype, comorbidities, therapy-related adverse events, and benefits of treatment. (CDC, 2012)[7]

Measure Importance

Relationship to desired outcome	Clinical preventive services, regular medical monitoring, and behavioral changes can improve health outcomes for persons with HCV infection. HCV care and treatment recommendations have been issued by AASLD and endorsed by the Infectious Disease Society of America and the American Gastroenterological Association[30]. Routine testing of persons born during 1945–1965 is expected to lead to more HCV-infected persons being identified earlier in the course of disease. To improve health outcomes, persons testing positive for HCV must be provided with appropriate treatment. Linking patients to care and treatment is a critical component of the strategy to reduce the burden of disease.[7] Attaining treatment-related SVR among persons with HCV is associated with a reduction in the relative risk for hepatocellular carcinoma (HCC).[41] A systematic review published in 2013 summarized the evidence from 30 observational studies examining the risk for HCC among HCV-infected persons who have been treated and either achieved an SVR or did not respond to therapy. Findings showed a protective effect of treatment-related SVR on the development of HCC among HCV-infected persons at all stages of fibrosis and among those with advanced liver disease.[41] With the availability of newer and more effective therapies, SVR rates can be increased and HCC incidence rates can be reduced in HCV-infected persons.[41] The association between SVR and HCC should be considered when weighing the benefits and harms of identifying and treating HCV-infected persons.	
Opportunity for Improvement	Many persons identified as HCV-infected do not receive recommended medical evaluation and care after the diagnosis of HCV infection;[42] this gap in linkage to care can be attributed to several factors, including being uninsured or underinsured, failure of providers to provide a referral, failure of patients to follow up on a referral, drug or alcohol use, and other barriers.[7] The lack of such care, or substantial delays before care is received, negatively impacts the health outcomes of infected persons.[7]	
IOM Domains of Health Care Quality Addressed	• Effective	• Timely • Equitable
Exception Justification	Exceptions are used to remove patients from the denominator of a performance measure when a patient does not receive a therapy or service AND that therapy or service would not be appropriate due to specific reasons for which the patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment and individual patient characteristics. A medical reason exception has been included so that clinicians can exclude patients for whom prescribing treatment or being referred to evaluation or treatment services may not be appropriate (eg, participation in a clinical trial, decompensated cirrhosis indicating	

	advanced disease [ie, ascites, esophageal variceal bleeding, hepatic encephalopathy], hepatocellular carcinoma, waitlist for organ transplant, limited life expectancy, other medical reasons). A patient reason exception has been included so that clinicians can exclude patients for whom prescribing treatment or being referred to evaluation or treatment services may not be appropriate (eg, patient declined, other patient reasons).
Harmonization with Existing Measures	The PCPI attempts to harmonize measures with other existing measures to the extent feasible. Harmonization was not deemed applicable for this measure.

Measure Designation

Measure purpose	• Quality improvement • Accountability
Type of measure	• Process
Level of Measurement	• Individual practitioner
Care setting	• Ambulatory Care
Data source	• Electronic Health Record (EHR) data • Prospective Claims-Based Reporting

Measures #9-#12 have been removed from this document

Measure #9: Discontinuation of Antiviral Therapy for Inadequate Viral Response
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #10: Sustained Virological Response (SVR) (Quality Improvement Only)
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #11: Discussion and Shared Decision Making Surrounding Treatment Options
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measure #12: Screening for Hepatocellular Carcinoma (HCC) in Patients with Hepatitis C Cirrhosis
This measure is stewarded by the American Gastroenterological Association. It has been removed from this document.

Measures Transitioned to the American Gastroenterological Association (AGA)

The Hepatitis C measures transitioned to AGA are available at: http://www.gastro.org/practice-management/quality/performance-measures

All AGA inquiries may be sent to: measures@gastro.org

EVIDENCE CLASSIFICATION/RATING SCHEMES

AASLD and IDSA Recommendations for Testing, Managing, and Treating Hepatitis C, February 2016[30]

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

Level of Evidence Description:
Level A Data derived from multiple randomized clinical trials or meta-analyses.
Level B Data derived from a single randomized trial, or nonrandomized studies.
Level C Only consensus opinion of experts, case studies, or standard-of-care.

NOTE: To more fully characterize the quality of evidence supporting recommendations, the Practice Guidelines Committee of the AASLD requires a Class (reflecting benefit versus risk) and Level (assessing strength or certainty) of Evidence to be assigned and reported with each recommendation (Table 1, adapted from the American College of Cardiology and the American Heart association Practice Guidelines).

Centers for Disease Control and Prevention (CDC) Recommendations & Ratings[7]
These recommendations were developed using GRADE methodology, which has been adopted by approximately 60 organizations, including CDC federal advisory committees (i.e., the Advisory Committee on Immunization Practices and the Healthcare Infection Control Practices Advisory Committee), the World Health Organization, IDSA, AGA, and the Cochrane Collaboration (www.gradeworkinggroup.org). GRADE provides guidance and tools to define research questions, develop an analytic framework, conduct systematic reviews, assess the overall quality of the evidence, and determine the direction and strength of the recommendations.
The following four factors are considered when determining the relevance and strength of a GRADE-based recommendation:
1) quality of evidence, 2) balance between benefits and harms, 3) values and preferences, and 4) resource implications. During the consultation, the Work Group considered each of these factors in light of the evidence presented. A statement based on the direction and strength of the recommendation was developed using the GRADE criteria; statements were either "for" or "against" an intervention and were either strong (designated by a "should" statement) or conditional (designated by a "may consider" statement).

U.S. Preventive Services Task Force (USPSTF) Recommendations & Ratings[29]
The Task Force grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):
A. The USPSTF strongly recommends that clinicians routinely provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

B. The USPSTF recommends that clinicians routinely provide [the service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.
C. The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.
D. The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.
I. The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

Non-Material Interest Disclosures

Hepatitis C

Summary of Non-Material Interest Disclosures

None of the members of the Hepatitis C Work Group had any disqualifying material interests under the PCPI Conflict of Interest Policy. The following is a summary of non-disqualifying interests disclosed on Work Group members' Material Interest Disclosure Statements (not including information concerning family member interests). Completed Material Interest Disclosure Statements are available upon request.

Work Group Member	**Disclosures**
Joel V. Brill, MD	Service on a Quality Committee: American Gastroenterological Association Editorial Board of a Peer-Reviewed Journal
Roger Chou, MD	Research or Grant Support: AHRQ – Review on HCV Screening & Treatment
Richard H. Davis, Jr., PA-C	Receipt of Speaking Honoraria: Series of talks for the American Academy of Physician Assistants (AAPA) on HCV for primary care, funded by unrestricted (and without editorial access) educational grant from Schering-Merck
Marc G. Ghany, MD, MHSc	Receipt of Speaking Honoraria: Talk for the University of Chicago
Arthur Yu-shin Kim, MD	Receipt of Speaking Honoraria: Educational talks for non-profit organization (New England AIDS education and treatment center) Payment for Consulting Services: for Vertex (one time) on role of Infectious Disease physicians in viral hepatitis care
Daniel B. Raymond	Research or Grant Support: Unrestricted educational grant to my employer from Vertex and Genentech
Paola Ricci, MD	Employed at VA Medical Center
John B. Wong, MD	Research or Grant support: University of New Mexico—Cost Effectiveness of Project ECHO (telemedicine), Dept. of Veteran Affairs—Cost Modeling Royalties and/or other intellectual property rights: UpToDate, Learning Clinical Reasoning Book Royalties Payment for Consulting Services: statistical editor, Annals of Internal Medicine

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American Association for the Study of Liver Diseases
American Gastroenterological Association Institute
American Medical Association (AMA)-convened
Physician Consortium for Performance Improvement® (PCPI®)

APPENDIX A

Hepatitis C Performance Measurement Specifications

Coding Reviewed and Updated: June, 2016

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Hepatitis C

Measure #8a: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk

A. Specifications for Administrative Data Sources

Denominator (Eligible Population)	All patients aged 18 years and older who were seen twice for any visit or who had at least one preventive visit within the 12 month reporting period with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945–1965 Age >= 18 years **AND** **At least one preventive visit during the reporting period (CPT or HCPCS):** 99385, 99386, 99387, 99395, 99396, 99397, G0438, G0439 **OR** **At least two visits during the reporting period (CPT):** 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350 **AND** **Patients who were born in the years 1945 to 1965**: G9448 **OR** **History of receiving blood transfusions prior to 1992:** G9449 **OR** **Receiving maintenance hemodialysis (CPT):** 90951, 90952, 90953, 90954, 90955, 90956, 90957, 90958, 90959, 90960, 90961, 90962, 90963, 90964, 90965, 90966, 90967, 90968, 90969, 90970, 99512 **OR** **History of injection drug use:** G9450
Denominator Exclusions	Diagnosis for Chronic Hepatitis C (ICD-9-CM) [for use 1/1/2015-9/30/2015]: 070.44, 070.54 Diagnosis for Chronic Hepatitis C (ICD-10-CM) [for use 10/01/2015-and beyond]: B18.2
Numerator	Patients who received one-time screening for HCV infection* *Screening for HCV Infection includes current or prior receipt of: HCV antibody test, HCV RNA test, or Recombinant immunoblot assay (RIBA) test (if performed at any time in the past) **Report quality data code:** G9451: Patient received one-time screening for HCV infection

Denominator Exceptions	**To report a medical or patient reason exception, report quality data code**: G9452: Documentation of medical reason(s) for not receiving one-time screening for HCV infection (eg, decompensated cirrhosis indicating advanced disease [ie, ascites, esophageal variceal bleeding, hepatic encephalopathy], hepatocellular carcinoma, waitlist for organ transplant, limited life expectancy, other medical reasons) G9453: Documentation of patient reason(s) for not receiving one-time screening for HCV infection (eg, patient declined, other patient reasons)

B. Specifications for Electronic Clinical Data Sources

PCPI has developed a health quality measures format (HQMF) electronic clinical quality measure (eCQM). As of the date of the posting of this document, this measure is not included in a national program utilizing electronic clinical data sources or electronic health record data sources. If you are interested in receiving the HQMF eCQM, please contact cpe@ama-assn.org for more information.

Hepatitis C

Measure #8b: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users

A. Specifications for Administrative Data Sources

Denominator (Eligible Population)	All patients, regardless of age, who are seen twice for any visit or who had at least one preventive visit within the 12 month reporting period who are active injection drug users* Denominator Definition: *Active injection drug users are those who have injected any drug(s) within the past 12 months Age >= 18 years **AND** **At least one preventive visit during the reporting period (CPT or HCPCS):** 99381, 99382, 99383, 99384, 99385, 99386, 99387, 99391, 99392, 99393, 99394, 99395, 99396, 99397, G0438, G0439 **OR** **At least two visits during the reporting period (CPT):** 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350 **AND** **Documentation of active injection drug use:** G9518
Denominator Exclusions	Diagnosis for Chronic Hepatitis C (ICD-9-CM) [for use 1/1/2015-9/30/2015]: 070.44, 070.54 Diagnosis for Chronic Hepatitis C (ICD-10-CM) [for use 10/01/2015-and beyond]: B18.2
Numerator	Patients who received screening for HCV infection* within the 12 month reporting period Numerator Definition: Screening for HCV infection - includes HCV antibody test or HCV RNA test **Report quality data code:** G9383: Patient received screening for HCV infection within the 12 month reporting period
Denominator Exceptions	**To report a medical or patient reason exception, report quality data code**: G9384: Documentation of medical reason(s) for not receiving annual screening for HCV infection (eg, decompensated cirrhosis indicating advanced disease [ie, ascites, esophageal variceal bleeding, hepatic encephalopathy], hepatocellular carcinoma, waitlist for organ transplant, limited life expectancy, other medical

	reasons) G9385: Documentation of patient reason(s) for not receiving annual screening for HCV infection (eg, patient declined, other patient reasons)

B. Specifications for Electronic Clinical Data Sources

PCPI has developed a health quality measures format (HQMF) electronic clinical quality measure (eCQM). As of the date of the posting of this document, this measure is not included in a national program utilizing electronic clinical data sources or electronic health record data sources.
If you are interested in receiving the HQMF eCQM, please contact cpe@ama-assn.org for more information.

Hepatitis C

Measure #8C: Appropriate Screening Follow-up for Patients Identified with Hepatitis C Virus (HCV) Infection

A. Specifications for Administrative Data Sources

PCPI does not recommend this measure for use with administrative or claims based data sources.
If you have any questions, please contact cpe@ama-assn.org for more information.

B. Specifications for Electronic Clinical Data Sources

PCPI has developed a health quality measures format (HQMF) electronic clinical quality measure (eCQM). As of the date of the posting of this document, this measure is not included in a national program utilizing electronic clinical data sources or electronic health record data sources.
If you are interested in receiving the HQMF eCQM, please contact cpe@ama-assn.org for more information.