NATIONAL QUALITY FORUM

Stage 1 Concept Submission and Evaluation Worksheet 1.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's concept evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 0635 NQF Project: GI and GU Project

Date Submitted: Jul 16, 2012

CONCEPT SPECIFICATIONS

De.1 Concept Title: Chronic Liver Disease - Hepatitis A Vaccination

Co.1.1 Concept Steward: ActiveHealth Management

De.2 Brief Description of Concept: The percentage of adult patients with chronic liver disease who have received a hepatitis A vaccine

2a1.1 Numerator Statement: Patients with chronic liver disease who have received a hepatitis A vaccine or who have been tested for immunity in the past. Keeping in consideration that providers who test for Hepatitis A immunity most likely intend to take action on the test results and that hepatitis A testing is usually communicated in the form of LOINC codes which do not indicate immunity confirmed , immunity testing is considered sufficient for completion of the numerator for this measure.

2a1.4 Denominator Statement: All patients, ages 18 and older, diagnosed with chronic liver disease

2a1.8 Denominator Exclusions: Patients with a previous history of viral hepatitis A. General exclusions: 1. Evidence of metastatic disease or active treatment of malignancy (chemotherapy or radiation therapy) in the last 6 months; 2. Patients who have been in a skilled nursing facility in the last 3 months (this exclusion is included to avoid holding physicians who care for patients during a transitional period, e.g. temporary SNF placement, for their ongoing care; hence, the time limitation of 3 months).

1.1 Concept Type: Process
2a1. 25-26 Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy, Healthcare Provider Survey, Patient Reported Data/Survey
2a1.33 Level of Analysis: Population : National, Population : Regional

1.2-1.4 Is this concept paired with another measure? No

2a1.1 Numerator Statement *(Brief, narrative description of the concept focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
Patients with chronic liver disease who have received a hepatitis A vaccine or who have been tested for immunity in the past. Keeping in consideration that providers who test for Hepatitis A immunity most likely intend to take action on the test results and that hepatitis A testing is usually communicated in the form of LOINC codes which do not indicate immunity confirmed , immunity testing is considered sufficient for completion of the numerator for this measure.

2a1.3 Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, timeframe, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*
For new concepts, describe how you plan to identify and calculate the numerator.
One of the following:
1. At least 1 fill of Hepatitis A vaccine from claims or HIE anytime in the past
2. At least 1 Hepatitis A vaccine procedure from claims or HIE anytime in the past
3. At least 1 Hepatitis A antibody procedure from claims or HIE anytime in the past

4. At least 1 Hepatitis A Lab result from claims or HIE anytime in the past
5. Patient-reported data indicating that they received a Hepatitis A vaccine anytime in the past

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
All patients, ages 18 and older, diagnosed with chronic liver disease

2a1.5 Target Population Category *(Check all the populations for which the concept is specified and tested if any)*: Adult/Elderly Care, Populations at Risk

2a1.7 Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, timeframe, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*
For new concepts, describe how you plan to identify and calculate the denominator.
All of the following:
1. Age >/= 18 years
2. One of the following
a. One of the following
i. At least 2 diagnosis codes from claims or 1 diagnosis code from HIE for Chronic Hepatitis B in the past 24 months
ii. Patient self-reported data, via PHR or telephonic nurse assessment in our disease management program, confirming a diagnosis of Chronic Hepatitis B anytime in the past
iii. At least 2 hepatitis B surface or E antigen or DNA Labs Result Value > 1 in the past 12 months from claims
iv. At least 2 diagnosis codes from claims for Chronic Hepatitis B anytime in the past with one of the following
A. At least 1 current fill of a Hepatitis B medication from HIE
B. At least 2 fills of a Hepatitis B medication from claims in the past 24 months
C. At least 2 procedure codes for Interferon therapy in the past 24 months from claims
b. One of the following
i. At least 2 diagnosis codes from claims or 1 diagnosis code from HIE for Chronic Hepatitis C in the past 24 months
ii. Patient self-reported data, via PHR or telephonic nurse assessment in our disease management program, confirming a diagnosis of Chronic Hepatitis C anytime in the past
iii. At least 1 hepatitis C antibody or RNA Labs Result Value > 1 in the past 12 months
iv. Patient self-reported data, via PHR or telephonic nurse assessment in our disease management program, confirming a diagnosis of Chronic Hepatitis C anytime in the past
v. At least 2 diagnosis codes from claims for Chronic Hepatitis C anytime in the past with one of the following
A. At least 2 fills of a Hepatitis C medication from HIE
B. At least 2 fills of a Hepatitis C medication from claims in the past 24 months
C. At least 2 procedure codes for Hepatitis C treatment in the past 24 months from claims
D. At least 2 diagnosis codes from claims for chronic liver disease (excluding Hepatitis A) in the past 12 months

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Patients with a previous history of viral hepatitis A. General exclusions: 1. Evidence of metastatic disease or active treatment of malignancy (chemotherapy or radiation therapy) in the last 6 months; 2. Patients who have been in a skilled nursing facility in the last 3 months (this exclusion is included to avoid holding physicians who care for patients during a transitional period, e.g. temporary SNF placement, for their ongoing care; hence, the time limitation of 3 months).

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*
For new concepts, describe how you plan to identify and calculate the exclusions.
One of the following:
1. At least 1 diagnosis code for Hepatitis A infection from claims or HIE anytime in the past
2. Patient self-reported data,via PHR or telephonic nurse assessment in our disease management program, indicating that they are allergic to the Hepatitis A vaccine anytime in the past

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*
For new concepts, if you plan to stratify the measure results, describe the plans for stratification.
None

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in measure testing in the stage 2 measure submission)*
For new concepts, if an outcome, describe how you plan to adjust for differences in case mix/risk across measured entities.
No risk adjustment necessary

2a1.25 Data Source *(Check all the sources for which the concept is specified and tested*). If other, please describe:
Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy, Healthcare Provider Survey, Patient Reported Data/Survey

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): Claims ingested via ActiveHealth Management´s rules engine, CareEngine. Electronic clinical data source for pharmacy, lab, and EHR data is ActiveCareTeam (clinical workflow tool and dashboard) and MyActiveHealth (PHR). Healthcare provider survey and pati

2a1.33 Level of Analysis (*Check the levels of analysis for which the concept is specified and tested)*: Population : National, Population : Regional

2a1.34 Care Setting *(Check all the settings for which the concept is specified and tested)*: Ambulatory Care : Clinician Office/Clinic, Home Health

IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is the criterion that must be met in order to recommend a concept for approval. All three subcriteria must be met to pass this criterion. See guidance on evidence.

1a. High Impact: H☐ M☐ L☐ I ☐
(*The concept directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

De.4 Subject/Topic Areas *(Check all the areas that apply)*: Gastrointestinal (GI), Prevention
De.5 Cross Cutting Areas (*Check all the areas that apply)*: Population Health, Prevention : Immunization

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers; Severity of illness

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data)*:
According to the WHO, there are 1.4 million cases of hepatitis A every year globally, with 70% of infected adults and older children develop jaundice.According to the Center for Disease Control and Prevention (CDC), chronic liver disease and cirrhosis is the 12th leading cause of death [1]. Acute hepatitis A in patient with chronic liver disease (CLD) may result in more severe clinical infection with an associated higher rate of fulminant hepatic failure and mortality [2-6]. Studies have been conducted to confirm the safety and immunogenicity of hepatitis A vaccines in patient with chronic liver disease [7-8]. The CDC recommends vaccination in individuals with chronic liver disease. In addition, the American Association for the Study of Liver Disease recommends patients with chronic hepatitis B and C (with or without CLD) for vaccination against hepatitis A [9-11]. There has been a dramatic decline in the incidence of hepatitis A in US since the introduction of vaccine in 1995 (from an estimated 120,000 acute cases in 1980 to approximately 10,000 in 2010).

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1. Minino, AM, Murphy SL, Xu J, Kochanek, KD. Death: final data for

2008. Natl Vital Stat Rep 2011;59:10
2. Kumar M, Herrera JL. Importance of hepatitis vaccination in patients with chronic liver disease. South Med J. 2010 Dec;103(12):1223-31
3. Keeffe E. Hepatitis A in patients with chronic liver disease – severity of illness and prevention with vaccination. J Viral Hepat. 2000 May;7 Suppl 1: 15-7
4. Cooksley WG. What did we learn from the Shanghai hepatitis A epidemic? J Viral Hepat 2000;7 Suppl 1:1-3
5. Keeffe EB. Is hepatitis A more severe in patients with chronic hepatitis B and other chronic liver diseases? Am J Gastroenterol 1995;90:201-205
6. Fukumoto Y, Okita K, Konishi T, el al. Hepatitis infection in chronic carriers of hepatitis B virus, in Sung J-L, Chen D-S (eds): Viral hepatitis and hepatocellular carcinoma. Amsterdam, Excerpta Medica, 1990, pp43-48
7. Keeffe EB, Iwarson S, McMahon BJ, et al. Safety and immunogenicity of hepatitis A vaccine in patients with chronic liver disease. Hepatology 1998;27:881-886
8. Lee SD, Chan SY, Yu MI, et al. Safety and immunogenicity of hepatitis A vaccine in patients with chronic liver disease. J Med Virol 1997;52:215-218
9. MMWR Recommended Adult Immunization Schedule – United States, 2012
10. Lok ASF. AASLD Practice Guidelines Update: Chronic Hepatitis B: Update 2009. Hepatology. 2009 Sep;50(3):661-2
11. Ghany MG, Strader DB, Thomas DL, Seeff LB; AASLD. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology. 2009 Apr;49(4):1335-74

1b. Opportunity for Improvement: H☐ M☐ L☐ I ☐
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this concept:
This measure is aimed at identifying and optimizing the care of chronic liver disease patients who require hepatitis A vaccination and potentially prevent severe complications that follow acute viral hepatitis. This measure was developed with the goal to help increase the overall immunity to hepatitis A amongst patients with chronic liver disease and thus, decrease the overall public health burden.

1b.2 Provide data demonstrating performance gap/opportunity for improvement *(Variation or overall less than optimal performance across providers).* List citations in 1b.3.
For endorsement maintenance, provide performance data on the measure as specified *(mean, std dev, distribution of scores by decile, min, max).* Describe who was included in the performance data in 1b.3.Hepatitis A vaccination in patients with chronic liver disease has increased during the past few years; however the implementation rate remains low. In a 2011 NHANES study of 24,871 participants, the rate of hepatitis A vaccination among chronic liver disease patients increased from 13.3% (1999-2004) to 23.4% (2005-2008) [1]. Similarly, a low implementation rate was observed in the VA HCV Clinical Case Registry. Among 88,456 patients with chronic hepatitis C, only 20.7% of patients received hepatitis A vaccination [2]. Additionally, only a suboptimal 45.5% of the patients in this registry were tested for hepatitis A immunity or received hepatitis A vaccination.
From a test of this measure done on a sample population of 2.46 million, we found 5907 patients with chronic liver disease. Of these patients, 2129 received hepatitis A vaccination or were tested for hepatitis A during the measurement year. This translates to a performance gap of 64% [3] across the entire test population.

1b.3 Citations for Data on Performance Gap provided in 1b.2.
For endorsement maintenance, describe who was included in the performance results reported in lb.2 *(number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include)*
2.46 million lives were included in the sample population, representing a cross-sectional nationwide sample from our client population, 49% male, 51% female,with an average age of 37 years. Test was performed in 2012. From a test of this measure done on a sample population of 2.46 million, we found 5907 patients with chronic liver disease. Of these patients, 2129 received hepatitis A vaccination or were tested for hepatitis A during the measurement year. This translates to a performance gap of 64% [3] across the entire test population, which consists of data from a large, nationwide healthplan,private employer group, and a state employer.
1. ActiveHealth Management, Inc., testing done from June 3rd, 2009 to June 3rd, 2010, includes both commercial and Medicare population.

1b.4 Provide data on disparities by population group. List citations in 1b.5.
For endorsement maintenance, provide performance data by population group on the measure as specified *(e.g., mean, std*

dev). Describe who was included in the performance data in 1b.5.
There are no demographic or socioeconomic factors that are consistently associated with disparities of data from the reviewed literature [1].
We will be able to supply additional disparities data from the measures as implemented in Stage 2.

1b.5 Citations for Data on Disparities Cited in 1b.4:
1. Younossi ZM, Stepanova, M. Changes in hepatitis A and B vaccination rates in adult patients with chronic liver diseases and diabetes in the U.S. population. Hepatology 2011 Oct;54(4):1167-78

1c. Evidence (*Concept focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the concept focus a health outcome? Yes☐ No☐ If not a health outcome, rate the body of evidence.

Quantity: H☐ M☐ L☐ I☐ Quality: H☐ M☐ L☐ I☐ Consistency: H☐ M☐ L☐ I☐

Quantity	Quality	Consistency	Does the concept pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise No☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the concept pass subcriterion1c? Yes☐ IF rationale supports relationship

Please see the attached Evidence Submission Worksheet for evidence specifications.

Was the concept approval criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*) Yes☐ No☐
Provide rationale based on specific subcriteria:

3. USABILITY

4.1 Current and Planned Use
Performance results from NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement (in addition to use for performance improvement).
(Check only the current and planned uses; for any current uses that are checked, provide a URL for the specific program)
Current Use:
Planned Use: Public Reporting, Quality Improvement (Internal to the specific organization)

5. COMPARISON TO RELATED AND COMPETING CONCEPTS & MEASURES

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:
0399 : Paired Measure: Hepatitis C: Hepatitis A Vaccination (paired with 0400)

5a.1 If this concept has EITHER the same focus OR the same target population as NQF-endorsed measure(s): Are the specifications completely harmonized?
No

5a.2 If the specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability

and data collection burden:
While our measure includes adults with chronic liver disease in the denominator, measure 0399 includes only those with hepatitis C.

5b.1 If this concept has both the same focus and the same target population as NQF-endorsed measure(s):
Describe why this concept is superior to competing measures *(e.g., a more valid or efficient way to measure quality);* OR provide a rationale for the additive value of endorsing an additional measure. *(Provide analyses when possible)*:
While our measure includes adults with chronic liver disease in the denominator, measure 0399 includes only those with hepatitis C. We feel that our measure is more encompassing of and brings attention to all of those individuals who should receive a hepatitis A vaccine. We have not yet discussed with the developers of measure 0399 to see if the endorsed measures can be combined and expanded.

CONTACT INFORMATION

Co.1 Concept Steward (Intellectual Property Owner): ActiveHealth Management, 1333 Broadway | New York | New York | 10018

Co.2 Point of Contact: Bani | Vir, MD | bvir@activehealth.net | 212-651-8200-

Co.3 Concept Developer if different from Concept Steward: ActiveHealth Management | 1333 Broadway | New York | New York, 10018

Co.4 Point of Contact: Bani | Vir, MD | bvir@activehealth.net | 212-651-8200-

Co.5 Submitter: Bani | Vir, MD | bvir@activehealth.net | 212-651-8200- | ActiveHealth Management

Co.6 Additional organizations that sponsored/participated in concept development:

Co.7 Public Contact: Bani | Vir, MD | bvir@activehealth.net | 212-651-8200- | ActiveHealth Management

ADDITIONAL INFORMATION

Concept Developer/Steward Updates and Ongoing Maintenance
Ad.3 Year the concept was first released:
Ad.4 Month and Year of most recent revision:
Ad.5 What is your frequency for review/update of this measure?
Ad.6 When is the next scheduled review/update for this measure?

Ad.7 Copyright statement: This information, including any attachments hereto, is the sole, exclusive, proprietary and confidential property of ActiveHealth Management, Inc., and is for the exclusive use of The National Quality Forum. Any use, copying, disclosure, dissemination or distribution by anyone other than the National Quality Forum is strictly prohibited.

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:

Date of Submission (*MM/DD/YY*): Jul 16, 2012

NATIONAL QUALITY FORUM—Evidence (1c) Pilot Submission Form

Measure Title: Chronic Liver Disease - Hepatitis A Vaccination
Date of Submission: 6/25/2012

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages incudes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the evidence criterion (1c) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- See NQF guidance on evaluating evidence. Contact NQF staff for examples, resources, or questions.

STRUCTURE-PROCESS-OUTCOME RELATIONSHIP
1c.1.This is a measure of:
Outcome
☐ Health outcome: 2T
☐ Intermediate clinical outcome: 2T
☒ Process: Vaccinating high-risk individuals with hepatitis A vaccination
☐ Structure: 2T
☐ Other: 2T

HEALTH OUTCOME MEASURE *If not a health outcome, skip to 1c.3*
If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.
1c.2. Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

1c.2.1. **State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service**.

Receiving vaccination---> immunity to Hepatitis A -----> preventing Hepatitis A & associated complications

Note: For health outcome measures, no further information is required

STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE
If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).
1c.3. Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. *(Do not summarize the evidence here.)*

receiving vaccination---> immunity to Hepatitis A -----> preventing Hepatitis A & associated complications

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes☒ No☐
If no, skip to #1c.6

If yes, *answer 1c.4.1-1c.5.*

1c.4.1. **Guideline citation** (*including date*):

1. *Recommended Adult Immunization Schedule – United States, 2012*
   Morbidity and Mortality Weekly Report, February 3, 2012

2. *AASLD Practice Guideline Update – Chronic Hepatitis B: Update 2009*
   Hepatology, September 2009

3. *AASLD Practice Guidelines – Diagnosis, Management, and Treatment of Hepatitis C: An Update*
   Hepatology, April 2009

1c.4.2. **URL** (*if available online*):

1. http://www.cdc.gov/vaccines/schedules/downloads/adult/mmwr-adult-schedule.pdf
2. http://www.aasld.org/practiceguidelines/documents/bookmarked%20practice%20guidelines/chronic_hep_b_update_2009%208_24_2009.pdf
3. http://www.aasld.org/practiceguidelines/documents/hepatitis%20c%20update.pdf

1c.4.3. **Identify guideline number and/or page number**:
Page 3 – CDC/MMWR
Page 7 – Hepatitis B Guideline
Page 1364 – Hepatitis C Guideline

1c.4.4. **Quote verbatim, the specific guideline recommendation**:
For citation references, please see 1c.4.1 above:

1. "Vaccinate any person seeking protection from hepatitis A virus (HAV) infection and persons with any of the following indications:
   ….persons with chronic liver disease…"
2. "All persons with chronic hepatitis B not immune to hepatitis A should receive 2 doses of hepatitis A vaccine 6 to 18 months apart"
3. "All persons with chronic HCV infection who lack antibodies to hepatitis A and B should be offered vaccination against these two viral infections (Class IIa, Level C)."

1c.4.5. **Grade assigned to the recommendation with definition of the grade**:
CDC – None

AASLD Hepatitis B – II-3 (multiple time series, dramatic uncontrolled experiments) and referral to the CDC
AASLD Hepatitis C – Class IIa, Level C (weight of evidence/opinion is in favor of usefulness/efficacy, and the evidence is only consensus opinion of experts, case studies, or standard-of-care)

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes☒ No☐ *If no, skip to #1c.6*

If yes, *answer 1c.5.1. (**Note:** Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)*
1c.5.1. **Grade assigned to the body of evidence with definition of the grade**:
AASLD Hepatitis B – II-3 (multiple time series, dramatic uncontrolled experiments)

Table 1. Quality of Evidence on Which a Recommendation is Based

Grade	Definition
I	Randomized controlled trials
II-1	Controlled trials without randomization
II-2	Cohort or case-control analytic studies
II-3	Multiple time series, dramatic uncontrolled experiments
III	Opinions of respected authorities, descriptive epidemiology

AASLD Hepatitis C – Class IIa, Level C

Table 1. Grading System for Recommendations

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.

1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? *(other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF)*
Yes☒ No☐ *If no, skip to #1c.7*

If yes, *answer 1c.6.1-1c.6.3. (**Note:** Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)*
1c.6.1. **Citation** (*including date*):
Changes in Hepatitis A and B Vaccination Rates in Adult Patient with Chronic Liver Diseases and Diabetes in the U.S. Population
Hepatology 2011;54:1167-1178

1c.6.2. **URL** (*if available online*):
N/A

1c.6.3. **Grade assigned to the body of evidence with definition of the grade**:
N/A

If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8

1c.7. If a systematic review of the body of evidence was not identifed and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes☐ No☒

If yes, *answer 1c.7.1-1c.7.3. (**Note:** Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)*

1c.7.1. **Who conducted the measure developer's systematic review of the body of evidence**?

1c.7.2. **Grade assigned to the body of evidence with definition of the grade**:

1c.7.3. **Describe the process used for the systematic review**:

If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.

FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)

1c.8. What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range: 1980-2010

QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are inlcuded in the body of evidence? (*e.g., 3 randomized controlled trials and 1 observational study*)

CDC: Hepatitis A FAQs for Health Professionals
http://www.cdc.gov/hepatitis/HAV/HAVfaq.htm#general

1c.10. What is the overall quality of evidence across studies in the body of evidence? (*discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

The limitations of this study include the absence of hepatitis A antibody titers and the inability to predict immunity despite a loss of detectable antibodies on certain individuals. In addition, this study did not look into hospitalized or incarcerated patients.

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

This study reviews the low hepatitis A vaccination rate in patients with chronic liver disease and this indirectly accentuates the given public health implications of acute hepatitis A infection in patients with chronic liver disease.

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?

N/A

UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes☐ No☒ *If no, stop*

If yes,

1c.13.1. **For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**.