NATIONAL QUALITY FORUM

Memo

TO: ActiveHealth

FR: NQF GI/GU Project Staff

RE: GI/GU Endorsement Maintenance Pilot Project: Stage two checklist

DA: September 28, 2012

GI/GU Endorsement Maintenance Pilot Project, 2012

Thank you for your participation and concept submission to the GI/GU Endorsement Maintenance Pilot Project. Please carefully review the instructions below for next steps.

Preparation for submission of recommended concepts to stage two

1. Keep in mind, while the measure submission forms for recommended concepts opens in early November, approval of concepts is finalized with Board of Directors approval on November 30.

2. Review all requirements for measure submission and criteria to be suitable for endorsement:
   - Consider and address harmonization issues for related concepts
     - #0399 - Hepatitis C: Hepatitis A Vaccination (Paired With #0400), AMA-PCPI
   - Ensure that evidence remains current and consistent with concept
     - Check if there have been any major changes in the evidence base supporting the approved concept. If yes, provide the citation and copy of the study or article and discuss the impact on the measure concept.
     - If there are any changes in the concept from that which was approved, identify those changes and discuss the relevance of the evidence to the approved concept and the updated concept.
   - Ensure that testing requirements have been satisfied
     - Testing requirements are available in the Measure Testing Task Force report

3. Review the Developer Guidebook for additional resources and information for preparing your stage two measure submission. The updated guidebook will be available once stage two submission forms are opened and will also be distributed by NQF Technical Assistance Staff.

4. **Notify NQF project staff by October 25, 2012** if you plan to submit full specifications and testing for approved concepts by the December 19, 2012 stage two measure submission deadline.

5. You will be required to submit at least one of your fully specified and tested measures on or prior to the **technical assistance deadline on December 3, 2012**, for a technical review for completeness and responsiveness by the NQF staff.

6. Measure submissions must be complete and responsive to ALL questions in order to be advanced to the Steering Committee for consideration and evaluation.

Concept(s) Recommended for Approval: ActiveHealth

Provide a response for EACH Committee recommendation describing your rationale for implementing (or not) the recommendation and any additional considerations.

Upload this document to your online measure submission form for review by the Committee in stage two.

0622 GERD - Upper Gastrointestinal Study in Adults with Alarm Symptoms	
Committee Recommendations to Developer	**Developer Response**
This measure should include chronic GERD patients.	The denominator is defined for chronic GERD patient.
The exclusion should be clarified as previous malignancy.	Completed
Barrett's esophagus should be included.	Completed.
The measure should be expanded to include patients under 18 as well; pediatric populations should be included as the same evidence applies.	Completed.
Additional evidence should be provided for evidence criterion.	Completed.
Additional information on performance gap is needed.	Completed
Define/specify the testing/procedures for the numerator more clearly.	Completed

0622 GERD - Upper Gastrointestinal Study in Adults with Alarm Symptoms	
Consider also specifying the numerator in a patient population that would be more broadly impactful (e.g., ie. obese and/or male patients)	We have modified the measure so that it now has 2 separate numerators: one for the general population, and one for those patients at high risk. However, we have not tested this new algorithm because we strongly feel that separating the numerators in such a manner will lead to erroneous reporting. We strongly recommend separating these high risk individuals into another DENOMINATOR and reporting the 2 rates of compliance separately. We await feedback from the NQF on this suggestion.

0635 Chronic Liver Disease - Hepatitis A Vaccination	
Committee Recommendations to Developer	**Developer Response**
The numerator is inconsistent with title of measure; consider changing the title of the measure to more closely align with the measure focus.	If the committee is referring to the inclusion of Antibody testing in the numerator, we plan to remove this test from the numerator and no longer allow testing to be sufficient to complete the numerator. If the committee is referring to some other inconsistency, please specify.
There could be a potential validity issue in stage two with the assumption this concept makes: if a person was tested, they were positive and received the vaccination. Consider how to address this issue.	See above answer**.**
Understanding there are differences in data sources, harmonize with #0399 under review in the NQF Infectious Disease project	We have reached out to the AMA to address harmonization and are awaiting a response.

Measure Submission and Evaluation Worksheet 6.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure 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
(for Endorsement Maintenance Review) Original Endorsement Date: Most Recent Endorsement Date: Evaluation Form Created: March 22, 2013
BRIEF MEASURE INFORMATION
De.1 Measure Title: Chronic Liver Disease - Hepatitis A Vaccination
Co.1.1 Measure Steward: ActiveHealth Management
De.2 Brief Description of Measure: 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.
2a1.4 Denominator Statement: All patients, ages 18 and older, diagnosed with chronic liver disease
2a1.8 Denominator Exclusions: Specific Exclusions: 1. Patients with a previous history of viral hepatitis 2. Patients who report an allergy to Hepatitis A vaccine 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 Measure Type: Process 2a1. 25-26 Data Source: Other, We allow data from several different sources including claims, health information exchanges, provider and patient surveys, our patient health portal, and through feedback given to our nurses via telephonic engagement. All data is processed through ActiveHealth Management's clinical rule engine, CareEngine. Electronic clinical data source for pharmacy, lab, and EHR data is ActiveCareTeam (clinical workflow tool and dashboard) and MyActiveHealth (PHR). Healthcare provider surveys and patient surveys are included as a part of our clinical alerts (aka Care Considerations) feedback section. Patient self-reported data is included as a part of our patient portal (My ActiveHealth) and our disease management program (Active DM). The individual sources for this measure are not tested separately. We ingest and store all data in a centralized warehouse from multiple sources. All data sources are tested simultaneously 2a1.33 Level of Analysis: Population : National 1.2-1.4 Is this measure paired with another measure? No De.3 If included in a composite, please identify the composite measure (*title and NQF number if endorsed*): N/A

1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT
Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

three subcriteria must be met to pass this criterion. See guidance on evidence.
Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact: H☐ M☐ L☐ I ☐
(*The measure 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)*: Prevention : Immunization, Population Health

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

1a.2 If "Other," please describe: N/A

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 measure:
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 Summary of Data Demonstrating Performance Gap *(Variation or overall less than optimal performance across providers)*: [*For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*]
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: [*For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
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 Summary of Data on Disparities by Population Group *(for example by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability, etc. If you do not have data on your specific measure, perform a literature search/review and report data for the measure or similar appropriate concept.)*: [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]
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: [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
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 (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure 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 measure 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☐

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

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 measure pass subcriterion1c? Yes☐ IF rationale supports relationship

SEE ATTACHED EVIDENCE SUBMISSION FORM

Was the threshold 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:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 Measure Web Page *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained?
http://www.activehealth.com/nqf-docs

2a1.1 Numerator Statement *(Brief, narrative description of the measure 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.

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, codes with descriptors, and/or specific data collection items/responses*:
NUMERATOR:
One of the following:
1. Presence of at least 1 fill VACCINE-HEP A from claims or HIE anytime in the past
2. Presence of at least 1 VACCINE-HEPATITIS A procedure from claims or HIE anytime in the past
3. Presence of patient data via online PHR or telephonic nurse assessment confirming at least 1 PDD- HEPATITIS A VAC OBS result anytime in the past
(NOTE: Words written in capital letters are element names. Please refer to the code set for description.)

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 measure is specified and tested if any)*:
Senior Care

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
DENOMINATOR:
All of the following:
1. Patients aged 18 years and older
2. One of the following:

a. Chronic Hepatitis B validation is confirmed (see below)
b. Chronic Hepatitis C validation is confirmed (see below)
c. Presence of at least 2 LIVER DISEASE CHRONIC (EXCL HEP A) diagnosis from claims or HIE in the past 12 Months
CHRONIC HEPATITIS B VALIDATION
One of the following:
1. Presence of at least 2 HEPATITIS B CHRONIC diagnosis from claims or 1HEPATITIS B CHRONIC diagnosis from HIE in the past 24 Months
2. Presence of patient data via online PHR or telephonic nurse assessment confirming at least 1 PDD- HEPATITIS B result anytime in the past
3. Presence of at least 2 HEPATITIS B SURFACE OR E ANTIGEN OR DNA lab result value > 1 in the past 12 months
4. All of the following:
a. Presence of at least 2 HEPATITIS B CHRONIC diagnosis from claims or 1HEPATITIS B CHRONIC diagnosis from HIE anytime in the past
b. One of the following
i.Presence of at least 1 fill HEPATITIS B Rx from claims or HIE in the past 24 Months
ii. Presence of at least 2 INTERFERON (J CODE) procedures from claims or HIE in the past 24 months
CHRONIC HEPATITIS C VALIDATION
One of the following:
1. Presence of at least 1 HEPATITIS C CHRONIC diagnosis from claims in the past 24 Months
2. Presence of at least 2 HEPATITIS C CHRONIC diagnosis from claims or HIE in the past 24 Months
3. Presence of at least 1 HEPATITIS C ANTIBODY OR RNA lab result value > 1 in the past 12 months
4.Presence of patient data via online PHR or telephonic nurse assessment confirming at least 1 PDD- HEPATITIS C result anytime in the past
5. All of the following:
a. Presence of at least 2 HEPATITIS C CHRONIC diagnosis from claims or HIE anytime in the past
b. One of the following:
i. Presence of at least 2 fill HEPATITIS C TREATMENT from claims or HIE in the past 24 Months
ii. Presence of at least 2 HEPATITIS C RX (CPT) procedures from claims or HIE in the past 24 months
(NOTE: Words written in capital letters are element names. Please refer to the code set for description.)

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Specific Exclusions: 1. Patients with a previous history of viral hepatitis 2. Patients who report an allergy to Hepatitis A vaccine 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, codes with descriptors, and/or specific data collection items/responses)*:
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, codes with descriptors, definitions, and/or specific data collection items/responses)*:
None

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: No risk adjustment or risk stratification 2a1.12 If "Other," please describe: N/A

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 2b4.):
N/A

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score:
Rate/proportion

If other: N/A

2a1.19 Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*:
better quality = higher score

2a1.20 Calculation Algorithm/Measure Logic*(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*:
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, codes with descriptors, and/or specific data collection items/responses)
NUMERATOR:
One of the following:
1. Presence of at least 1 fill VACCINE-HEP A from claims or HIE anytime in the past
2. Presence of at least 1 VACCINE-HEPATITIS A procedure from claims or HIE anytime in the past
3. Presence of patient data via online PHR or telephonic nurse assessment confirming at least 1 PDD- HEPATITIS A VAC OBS result anytime in the past
(NOTE: Words written in capital letters are element names. Please refer to the code set for description.)
Denominator Details(All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)
DENOMINATOR:
All of the following:
1. Patients aged 18 years and older
2. One of the following:
a. Chronic Hepatitis B validation is confirmed (see below)
b. Chronic Hepatitis C validation is confirmed (see below)
c. Presence of at least 2 LIVER DISEASE CHRONIC (EXCL HEP A) diagnosis from claims or HIE in the past 12 Months
CHRONIC HEPATITIS B VALIDATION
One of the following:
1. Presence of at least 1 HEPATITIS B CHRONIC diagnosis from claims or HIE in the past 24 Months
2. Presence of patient data via online PHR or telephonic nurse assessment confirming at least 1 PDD- HEPATITIS B result anytime in the past
3. All of the following:
a. Presence of at least 1 HEPATITIS B SURFACE OR E ANTIGEN OR DNA lab result value > 1 in the past 3 months
b. Presence of at least 1 HEPATITIS B SURFACE OR E ANTIGEN OR DNA lab result value > 1 begins in the past 9 months
c. All of the following:
i. Presence of at least 2 HEPATITIS B CHRONIC diagnosis from claims or HIE anytime in the past
ii. Presence of at least 1 fill HEPATITIS B Rx from claims or HIE in the past 24 Months
iii. Presence of at least 2 INTERFERON (J CODE) procedures from claims or HIE in the past 24 months
CHRONIC HEPATITIS C VALIDATION
One of the following:

1. Presence of at least 1 HEPATITIS C CHRONIC diagnosis from claims or HIE in the past 24 Months
2. Presence of at least 2 HEPATITIS C CHRONIC diagnosis from claims or HIE in the past 24 Months
3. Presence of at least 1 HEPATITIS C ANTIBODY OR RNA lab result value > 1 in the past 12 months
4. Presence of patient data via online PHR or telephonic nurse assessment confirming at least 1 PDD- HEPATITIS C result anytime in the past
5. All of the following:
a. Presence of at least 2 HEPATITIS C CHRONIC diagnosis from claims or HIE anytime in the past
b. One of the following:
i. Presence of at least 2 fill HEPATITIS C TREATMENT from claims or HIE in the past 24 Months
ii. Presence of at least 2 HEPATITIS C RX (CPT) procedures from claims or HIE in the past 24 months
(NOTE: Words written in capital letters are element names. Please refer to the code set for description.)
Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)
One of the following:
1. Presence of at least 1 HEPATITIS A INFECTION diagnosis from claims or HIE anytime in the past
2. Presence of patient data via online PHR or telephonic nurse assessment confirming at least 1 PDD- HEPATITIS A VAC ALLERGY result anytime in the past
3. Presence of patient data via online PHR or telephonic nurse assessment confirming at least 1 PDD- HEPATITIS A VAC OBS result anytime in the past
4. Presence of patient data via online PHR or telephonic nurse assessment confirming at least 1 PDD- HEPATITIS A VAC DO NOT KNOW result anytime in the past
(NOTE: Words written in capital letters are element names. Please refer to the code set for description.)
Risk Adjustment Type
No risk adjustment or risk stratification
Statistical risk model and variables
No risk adjustment or risk stratification

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):
This measure is not based on a survey.

2a1.25 Data Source *(Check all the sources for which the measure is specified and tested*). If other, please describe:
Other

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.*):
N/A

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:
We allow data from several different sources including claims, health information exchanges, provider and patient surveys, our patient health portal, and through feedback given to our nurses via telephonic engagement. All data is processed through ActiveHealth Management's clinical rule engine, CareEngine. Electronic clinical data source for pharmacy, lab, and EHR data is ActiveCareTeam (clinical workflow tool and dashboard) and MyActiveHealth (PHR). Healthcare provider surveys and patient surveys are included as a part of our clinical alerts (aka Care Considerations) feedback section. Patient self-reported data is included as a part of our patient portal (My ActiveHealth) and our disease management program (Active DM).
The individual sources for this measure are not tested separately. We ingest and store all data in a centralized warehouse from multiple sources. All data sources are tested simultaneouslyIncluded in attached appendix

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:

Available in attached Excel or csv file
NQF_635_-_CODE_SET_minus_Hep_A_Ab_Testing.xlsx

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

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*:
Other

If other: We do not differentiate between practice settings when testing the measures. All data is used agnostic of practice set

2a. RELIABILITY. Precise Specifications and Reliability Testing: H☐ M☐ L☐ I ☐

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H☐ M☐ L☐ I ☐

2c. Disparities in Care: H☐ M☐ L☐ I ☐ NA☐ (*If applicable, the measure specifications allow identification of disparities.*)

SEE ATTACHED MEASURE TESTING FORM

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?
(*Reliability and Validity must be rated moderate or high*) Yes☐ No☐
Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which potential audiences (e.g., consumers, purchasers, providers, policymakers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations. (evaluation criteria)

3.1 Current and Planned Use *(NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported withi n 6 years of initial endorsement in addition to performance improvement.)*:

Current and Planned Use (check all the current and planned uses; for any current uses that are checked, provide a URL for the specific program)

Planned	Current	For current use, Provide URL
Public Reporting;Quality Improvement (Internal to the specific organization)		

3a. Accountability and Transparency: H☐ M☐ L☐ I ☐
(Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.)

3a.1. For each CURRENT use, checked above, provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included

N/A

3a.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program,

certification, licensing) what are the reasons? *(e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?)*
The ActiveHealth website has recently undergone a renovation to enhance its appearance and user experience. Our measures are an integral part of the ActiveHealth website and have undergone renovation as well. We have recently launched several of our measures on the quality measures web page and anticipate more robust reporting and other capabilities to be developed over the course of the next one to two years, as we fine tune our recent changes.While the measure specifications will be publicly available, the performance results of individuals or organizations will not be reported due to proprietary reasons.

3a.3 If not currently publicly reported OR used in at least one accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. *(Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.)*
Within the next one to two years, performance results for this measure on a year to year basis will be available for public viewing on the ActiveHealth website. Calendar year data from our population of over 20 million lives. will be aggregated, reported, and displayed on our quality measure web page.While the measure specifications will be publicly available, the performance results of individuals or organizations will not be reported due to proprietary reasons.

3b. Improvement: H☐ M☐ L☐ I ☐
(Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.6 If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.)

3b.1. Provide data that demonstrate improvement in performance and/or health. (Not required for initial endorsement unless available.)
Include:

- Source of Data
- Geographic area and number and percentage of accountable entities and patients included
- Progress (trends in performance results, number and percentage of people receiving high-quality healthcare)

For this measure examining the number of people with chronic liver disease who had the Hepatitis A vaccination, we identified a total of 7605 patients from our entire national book of business, who fulfilled the criteria for the denominator from 2005 to 2008. We found a compliance rate of 6% during this 3 year period. In our 2011 test data alone, we identified 5907 people who met the denominator criteria, 2129 people who met the numerator criteria, and a compliance rate of 36%.
Addendum 1/11/2013: The measure is currently undergoing testing with the new changes included. Results will be available shortly and the measure details and testing results information updated accordingly.

3b.2. If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations:
N/A

3c. Unintended Consequences: H☐ M☐ L☐ I ☐
(The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations)

3c.1. Were any unintended negative consequences to individuals or populations identified during testing; OR has evidence of unintended negative consequences to individuals or populations been reported since implementation? If so, identify the negative unintended consequences and describe how benefits outweigh them or actions taken to mitigate them.
None

Overall, to what extent was the criterion, *Usability*, met? H☐ M☐ L☐ I ☐
Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

4a. Data Generated as a Byproduct of Care Processes: H☐ M☐ L☐ I ☐

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition;
Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims)

4b. Electronic Sources: H☐ M☐ L☐ I ☐

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)*:
ALL data elements are in defined fields in a combination of electronic sources

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:
N/A

4d. Data Collection Strategy/Implementation: H☐ M☐ L☐ I ☐

4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues *(e.g., fees for use of proprietary measures)*:
We use a combination of data sources to mitigate the risk of inaccuracies or errors. We recognize that generally, electronic data have inherent errors and inaccuracies related to incorrect coding, or missing data, which can result in less specificity in the definition of the denominator and /or the numerator. To minimize these errors and inaccuracies, we use clinically enriched data (laboratory results, medication lists) to augment the data. In addition, where possible, we corroborate the data. For example, to confirm a patient has diabetes, we not only confirm the presence of an ICD-9 code for diabetes from claims, we also substantiate this finding with the presence of diabetic medications. We have a mechanism in place to solicit feedback from providers via a feedback form, if they detect errors with the measure.
We do not anticipate significant unintended consequences from the implementation of this measure. Our measures are all developed from evidence-based literature or from clinical practice guidelines and are designed to encourage appropriate care of the patient.

4d.2 Describe any fees, licensing, or other requirements to use any aspect of the measure as specified *(e.g., value/code set, risk model, programming code, algorithm)*:
None

Overall, to what extent was the criterion, *Feasibility*, met? H☐ M☐ L☐ I ☐
Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes☐ No☐
Rationale:

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

If the Committee votes No, STOP.
If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

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)
0400 : Paired Measure: Hepatitis C: Hepatitis B Vaccination (paired with 0399)

5a. Harmonization

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

5a.2 If the measure 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. We feel that the measures may need to remain separated, because they are measuring different populations. To determine the overall rate of hepatitis A vaccine received by those indvididuals with chronic liver disease, either caused by Hepatitis B or C, our measure would be necessary. To determine how many people with chronic hepatitis C have received either the hepatitis A or B vaccination, measures 399 and 400 are necessary. One idea would be to combine these measures to form a larger composite measure, examining the poputlation with Chronic Hepatitis B, C, or both that has received the Hepatitis A or B vaccine, or both.

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure 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 Measure Steward (Intellectual Property Owner): ActiveHealth Management

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

Co.3 Measure Developer if different from Measure Steward: ActiveHealth Management

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

ADDITIONAL INFORMATION

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

List the workgroup/panel members' names and organizations.

Describe the members' role in measure development.

Bani Vir, MD: Medical Director, Clinical Research & Development, ActiveHealth Management, Inc.
Lindee Chin, MD: Medical Director, Clinical Research & Development, ActiveHealth Management, Inc.
Ajay Sharma, MD: Medical Director, Clinical Research & Development, ActiveHealth Management, Inc.
George Wu, MD: Medical Director, Clinical Research & Development, ActiveHealth Management, Inc.
Flora Chang, PharmD, Director of Pharmacy Informatics, Clinical Research & Development, ActiveHealth Management.
Rajesh R. Mehta, R.Ph., MS, Director of Pharmacy Informatics, Clinical Research & Development, ActiveHealth Management.
ActiveHealth Management measures are developed by our Quality Measures Management Committee, a division of the Clinical Research and Development Department, composed of physicians of varying specialties and pharmacists. This committee evaluates available clinical evidence guidelines, reliability of data from various sources, and the necessity to develop measures to help improve standards of healthcare.

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2005

Ad.4 Month and Year of most recent revision: 12/2012

Ad.5 What is your frequency for review/update of this measure? Annual

Ad.6 When is the next scheduled review/update for this measure? 09/2012

Ad.8 Disclaimers: N/A

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**.

Measure Testing to Demonstrate Scientific Acceptability of Measure Properties

Measure Title: Chronic Liver Disease - Hepatitis A Vaccination

Date of Submission: 2T

Type of Measure:

☐ Composite	☐ Outcome
☐ Cost/resource	X Process
☐ Efficiency	☐ Structure

This Word document template must be used to submit information for measure testing.

- **For all measures, sections 1, 2a2, 2b2, 2b3, 2b5 must be completed**
- **For outcome or resource use measures**, section **2b4** also must be completed
- If specified for **multiple data sources** (e.g., claims and medical records), section **2b6** also must be completed
- Respond to all questions with answers immediately following the question (*unless meet the skip criteria or those that are indicated as optional*).
- Maximum of 10 pages (*incuding questions/instructions; do not change margins or font size; contact project staff if need more pages*)
- All information on testing to demonstrate meeting the criteria for scientific acceptability of measure properties (2a,2b) must be in this form. An appendix for *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing, (e.g., reliability vs. validity) be sure to indicate the specific differences in question 7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for all the types of data specified and intended for measure implementation*)

Measure Specified to Use Data From:	Measure Tested with Data From:
☐ abstracted from paper record	☐ abstracted from paper record
☐ administrative claims	☐ administrative claims
☐ clinical database/registry	☐ clinical database/registry
☐ abstracted from electronic health record	☐ abstracted from electronic health record
☐ eMeasure implemented in electronic health record	☐ eMeasure implemented in electronic health record
☐ other: We ingest and store data in a centralized warehouse from multiple sources, e. g., administrative claims (including procedure, diagnosis, pharmacy, and lab), electronic clinical data, patient data from electronic personal health records and feedback, provider survey.	☐ other: The individual sources for this measure are not tested separately. We ingest and store data in a centralized warehouse from multiple sources, e. g., administrative claims (including procedure, diagnosis, pharmacy, and lab), electronic clinical data, patient data from electronic personal health records and feedback, provider survey. All data sources are tested simultaneously

1.2. If used an existing dataset, identify the specific dataset (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*).

All the data for the measures are obtained from electronic sources. We ingest administrative claims data, pharmacy-based management systems, laboratory systems, personal health records, health risk assessments, and electronic health records. In addition, we use data from care management systems. All data feeds are electronic and do not require manual medical chart abstraction.

We have over 20 million patient records in our database, consisting of data from provider organizations, hospital systems, healthcare plans, and Medicare and Medicaid. The mean age of the population is 37, and 51% of the population is female.

1.3. What are the dates of the data used in testing? 2T

Data abstraction was performed in 2012.

1.4. What levels of analysis were tested? (*testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)
☐ **individual clinician** ☐ **group/practice** ☐ **hospital/facility/agency** ☐ **health plan**
☐ **other**: Population level/National

1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample*)

We tested this measure on data from 2, 459, 974 patients from a major national commercial health plan, a large national employer based in Texas and Oklahoma, and a state health plan in the Appalachian region of the Southern US, which represent a subset of our total population. The total test population of the commercial health plan was 2,104,194. The total test population of the national employer was 161, 873. The total test population of the state health plan was 193, 097.The average age of the population was 35 years and 52 percent were female. Using our complex algorithms, we were able to identify a subset of the test population who met the criteria for the denominator (e.g., people with chronic liver disease), numerator (those who had Hepatitis A vaccination), and exclusions (see algorithm for details).

1.6. How many and which patients were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis*

(e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample)

We tested this measure on data from 2, 459, 974 patients from a major national health plan, a large national employer, and a state health plan, which represent a subset of our total population. The total test population of the commercial health plan was 2,104,194. The total test population of the national employer was 161, 873. The total test population of the state health plan was 193, 097. In our past experience, this particular subset represents, both demographically and clinically, an accurate cross-section of our overall population of over 20 million lives. Our test population is selected randomly. The average age of the population was 35 years and 52 percent were female. The race of the individuals in our test population was not specified. The test population could have any number of diagnoses. Our rules algorithm determined if an individual met the denominator, numerator, and exclusion criteria.

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

N/A

After discussing with the NQF, we have removed Antibody Testing from the numerator. Testing this measure with the REVISED numerator is currently under way. The testing results currently in the submission form reflect the original measure numerator.

2a2. RELIABILITY TESTING

Note*: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – report validity of data elements in 2b2*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)

☐ **Critical data elements used in the measure** (*e.g., inter-abstractor reliability*)

☐ **Performance measure score** (e.g., *signal-to-noise*)

2a2.2. For each level checked above, describe the method of reliability testing and what it tests (*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

All of our quality measures are electronic and all of the data used to support the measures are electronic. In addition, we receive the data by electronic feeds. We have internal processes to ensure that we receive valid codes and where appropriate the associated values. Our analytic process includes testing a new rule or algorithm on our test database, so that we can be sure of the reliability of the codes.

At the end of the test, we randomly select patients who are either in the numerator, or in the denominator but not the numerator, and review their individual electronic data to ensure that they met the requirements of the rule. As a part of our reliability testing, we check to ensure that we have found the correct people in the denominator or the numerator, across multiple rules with similar definitions. To ensure accuracy, we check a subset of the people who were not in the numerator to ensure that we were accurate in not counting them in the numerator. If we find errors at any stage of the reliability testing, e.g., similar denominators that had significant differences in counts, different compliance rates for similar populations; we update the rules and retest.

2a2.3. For each level checked above, what were the statistical results from reliability testing? (e.*g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis and association with case volume*)
The average proportion of members that had chronic liver disease and the hepatitis A vaccine across the 3 populations that we tested was 39.7%. The Standard Deviation was 6.4%. The signal to noise ratio is 6.

1. The proportion of patients within each client group with diagnosis/procedure claims in the last 365 days was: median 53% (IQR = 10%).

2. The proportion of patients within each client group with at least 1 prescription in the last 365 days was: median 81% (IQR = 8%).

3. The proportion of patients within each client group with lab results in the last 365 days was: median 46% (IQR = 12%).

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)
An SNR of 5 or greater indicates certainty that the data sources are reliable.

The IQR of the proportion of patients with diagnosis/procedure, pharmacy and lab results were 9.79%, 10.69% and 15.71%, respectively, for a large national employer (n = 12,479,154). For our test population (n = 279,666), the IQRs of the proportion of patients with diagnosis/procedure, pharmacy and lab results were 10%, 8% and 12%, respectively.

The IQR values in our test population were low and similar to that of a large national employer. These numbers suggest that the volume of data received on a regular basis demonstrates consistency and reliability of the data we receive and use in this measure.

2b2. VALIDITY TESTING
2b2.1. What level of validity testing was conducted? (*may be one or both levels*)
☐ **Critical data elements**

☐ **Performance measure score**
- ☐ **Empirical validity testing**
- ☐ **Systematic assessment of face validity of <u>performance measure score</u> as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance quality or resource use and can distinguish performance*)

2b2.2. For each level checked above, describe the method of validity testing and what it tests (*describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis*

was used)

All of our quality measures are electronic and all the data used to support the measures are electronic. In addition, we receive the data by electronic feeds. We have internal processes to ensure that we receive valid codes and where appropriate the associated values. The methodology for the development and testing of this measure included (1) extensive literature review by board-certified physicians, (2) creation of computerized algorithms by clinicians, (3) technology testing using data from different populations, (4) analysis of results with manual case review to ensure accuracy of the alert, (5) periodic review of provider and patient feedback.

Our analytic process includes testing a new rule or algorithm on the standard data set so that we can be sure of the reliability of the code. At the end of the test, we randomly select patients who are either in the numerator, or in the denominator but not the numerator, to ensure that they met the requirements of the rule. As a part of our validity testing, we check to ensure we have found the correct people in the denominator or the numerator. To ensure accuracy, we manually review the electronic data of a subset of the people who were not in the numerator to ensure that we were accurate in not counting them in the numerator. If we find errors at any stage, then we update the rules and retest.

2b2.3. What were the statistical results from validity testing? (*e.g., correlation; t-test, ANOVA*)
The algorithms and code sets used for the measures are all electronic. Once we test the rules, the results are reviewed by our clinical research and development committee, composed of physicians of varying specialties, pharmacists, and nurses.

We randomly select up to 10% of patients who are either in the numerator, or in the denominator but not the numerator, to ensure that they met the requirements of the rule. As a part of our validity testing, we check to ensure we have found the correct people in the denominator or the numerator. To ensure accuracy, we manually review the electronic data of a subset of the people who were not in the numerator to ensure that we were accurate in not counting them in the numerator. If we find errors at any stage, then we update the rules and retest. Of the 5907 people who met the inclusion criteria, 60 people were randomly selected for validity testing. After reviewing the patient level data, 100% of those randomly selected were found to have accurately met the requirement of the rule algorithm

2b2.4. What is your interpretation of the results in terms of demonstrating validity? (i.*e., what do the results mean and what are the norms for the test conducted?*)

During validity testing of this measure, we found that the appropriate patients were included in numerator and denominator, and accurately excluded.

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2b3. EXCLUSIONS ANALYSIS
NA ☐ no exclusions — *skip to #2b5*

2b3.1. Describe the method of testing exclusions and what it tests (*describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

We do not test exclusions separately from our other data elements. Exclusion and inclusion criteria for each measure is based on a systematic review of current literature, as well the expert opinion of our clinical team—a panel of over 30 physicians, nurses, and pharmacists. Literature findings are presented to a group of clinicians on a regular basis, and after review of said literature, a consensus is reached on the algorithms of our numerator, denominator, and exclusions. We then test our algorithms on a subset of clinical and administrative data, using data from a large national health plan, large national employer, and state health plan. Our analytic process includes testing a new rule or algorithm on the standard data set so that we can be sure of the reliability of the code sets. At the end of the test, we randomly select patients who are either in the numerator, or in the denominator but not the numerator, to ensure that they met the requirements of the rule. As a part of our validity testing, we check to ensure we have found the correct people in the denominator or the numerator. To ensure accuracy, we manually review the electronic data of a subset of the people who were not in the numerator to ensure that we were accurate in not counting them in the numerator. If we find errors at any stage, then we update the rules and retest.

For this particular measure, our clinician team reached a consensus to exclude those patients with a previous diagnosis of viral hepatitis A.

2b3.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)

See above.

Out of a total test population of 2, 459, 974 patients, 5907 fell into the denominator. 646 (11%) of these individuals were excluded, based on the exclusion criteria in our algorithm. The excluded populations were 0,0, and 646, for the large national employer, state health plan, and large national insurance payor, in our test data, respectively.

2b3.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., the value outweighs the burden of increased data collection and analysis. Note: **If patient preference is an exclusion**, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)

The cost and potential harmful effects of Hepatitis A vaccination are small relative to the cost and health burdens of Hepatitis A infection. Our exclusion criteria and rules algorithm allow for specificity when identifying those patients that would otherwise receive unnecessary doses of the Hepatitis A vaccine.

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2b5. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b5.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified

(*describe the steps—do not just name a method; what statistical analysis was used)*

For this particular measure, our clinician team reached a consensus to exclude those patients who had already received a Hepatitis A vaccine or had reported an allergy to the vaccine. We tested this measure on data from 2, 459, 974 patients from a major national health plan, a large national employer, and a state health plan, which represent a subset of our total population. We used the average performance measurement scores and 95% confidence intervals to determine statistically significant meaningful differences in the performance measure scores among the test population.

2b5.2. What were the statistical results from testing the ability to identify differences in performance measure scores across measured entities? (*at a minimum, the distribution of performance measure scores for the measured entities by decile/quartile, mean, std dev; preferably also number and percentage statistically different from mean or some benchmark, different form expected, etc.*)

The statistical test results in performance measure scores for each of the three test populations were, as follows:

1. National Health Plan: 35% (lower and upper 95% CI: 34-36%)
2. State Health Plan: 37% (lower and upper 95% CI: 32-41%)
3. Large National Employer: 47% (lower and upper 95% CI: 43-51%)

2b5.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and clinically/practically meaningful differences in performance across measured entities? (i.*e., what do the results mean and what are the norms for the test conducted?*)

The test results of the measure illustrate significant variation in performance/compliance across the 3 populations. We conclude that our test results will have the ability to identify statistically significant and clinically/practically meaningful differences in performance across different entities.

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If not an intermediate or health outcome or resource use measure, this section can be deleted

NQF ID	RULE TYPE	ELEMENT NAME	ATOM	ICD-10	DESCRIPTION
635	NUMERATOR	VACCINE-HEP A	19053	#N/A	hepatitis A virus vaccine - DISPOSABLE SYRINGE (ML) 1440/ML
635	NUMERATOR	VACCINE-HEP A	23153	#N/A	hepatitis A virus vaccine - VIAL (SDV,MDV OR ADDITIVE) (ML) 1440/ML
635	NUMERATOR	VACCINE-HEP A	23154	#N/A	hepatitis A virus vaccine - VIAL (SDV,MDV OR ADDITIVE) (ML) 360/0.5ML
635	NUMERATOR	VACCINE-HEP A	25924	#N/A	hepatitis A virus vaccine - VIAL (SDV,MDV OR ADDITIVE) (ML) 720/0.5ML
635	NUMERATOR	VACCINE-HEP A	25925	#N/A	hepatitis A virus vaccine - DISPOSABLE SYRINGE (ML) 720/0.5ML
635	NUMERATOR	VACCINE-HEP A	26195	#N/A	hepatitis A virus vaccine - DISPOSABLE SYRINGE (ML) 50 UNIT/ML
635	NUMERATOR	VACCINE-HEP A	26196	#N/A	hepatitis A virus vaccine - DISPOSABLE SYRINGE (ML) 25/0.5ML
635	NUMERATOR	VACCINE-HEP A	26202	#N/A	hepatitis A virus vaccine - VIAL (SDV,MDV OR ADDITIVE) (ML) 50 UNIT/ML
635	NUMERATOR	VACCINE-HEP A	26203	#N/A	hepatitis A virus vaccine - VIAL (SDV,MDV OR ADDITIVE) (ML) 25/0.5ML
635	NUMERATOR	VACCINE-HEP A	47924	#N/A	hepatitis A & B virus vaccine - VIAL (SDV,MDV OR ADDITIVE) (ML) 720-20/ML
635	NUMERATOR	VACCINE-HEP A	47925	#N/A	hepatitis A & B virus vaccine - DISPOSABLE SYRINGE (ML) 720-20/ML
635	NUMERATOR	VACCINE-HEP A	62142	#N/A	hepatitis A virus vaccine (PF) - DISPOSABLE SYRINGE (ML) 720/0.5ML
635	NUMERATOR	VACCINE-HEP A	62706	#N/A	hepatitis A virus vaccine (PF) - VIAL (SDV,MDV OR ADDITIVE) (ML) 720/0.5ML
635	NUMERATOR	VACCINE-HEP A	62760	#N/A	hepatitis A virus vaccine (PF) - DISPOSABLE SYRINGE (ML) 1440/ML
635	NUMERATOR	VACCINE-HEP A	62812	#N/A	hepatitis A virus vaccine (PF) - DISPOSABLE SYRINGE (ML) 50 UNIT/ML
635	NUMERATOR	VACCINE-HEP A	62816	#N/A	hepatitis A & B vaccine (PF) - DISPOSABLE SYRINGE (ML) 720-20/ML
635	NUMERATOR	VACCINE-HEP A	62817	#N/A	hepatitis A & B vaccine (PF) - VIAL (SDV,MDV OR ADDITIVE) (ML) 720-20/ML
635	NUMERATOR	VACCINE-HEP A	63059	#N/A	hepatitis A virus vaccine (PF) - VIAL (SDV,MDV OR ADDITIVE) (ML) 1440/ML
635	NUMERATOR	VACCINE-HEP A	63909	#N/A	hepatitis A virus vaccine (PF) - VIAL (SDV,MDV OR ADDITIVE) (ML) 25/0.5ML
635	NUMERATOR	VACCINE-HEP A	63910	#N/A	hepatitis A virus vaccine (PF) - VIAL (SDV,MDV OR ADDITIVE) (ML) 50 UNIT/ML
635	NUMERATOR	VACCINE-HEP A	69368	#N/A	hepatitis A virus vaccine (PF) - DISPOSABLE SYRINGE (ML) 25/0.5ML
635	NUMERATOR	VACCINE-HEPATITIS A	3215F	#N/A	DOCUMENTED IMMUNITY HEPATITIS A
635	NUMERATOR	VACCINE-HEPATITIS A	4148F	#N/A	HEPATITIS A VACCINE ADMIN OR PREVIOSLY RECVD
635	NUMERATOR	VACCINE-HEPATITIS A	4154F	#N/A	HEP A VACCINE SERIES RECOMMENDED
635	NUMERATOR	VACCINE-HEPATITIS A	4155F	#N/A	HEPATITIS A VACCINE SERIES PREVIOUSLY RECEIVED
635	NUMERATOR	VACCINE-HEPATITIS A	90632	#N/A	HEPATITIS A VACCINE ADULT FOR INTRAMUSCULAR USE
635	NUMERATOR	VACCINE-HEPATITIS A	90633	#N/A	HEPATITIS A VACCINE PEDIATRIC 2 DOSE SCHEDULE IM
635	NUMERATOR	VACCINE-HEPATITIS A	90634	#N/A	HEPATITIS A VACCINE PEDIATRIC 3 DOSE SCHEDULE IM
635	NUMERATOR	VACCINE-HEPATITIS A	90636	#N/A	HEPATITIS A & B VACCINE HEPA-HEPB ADULT IM
635	NUMERATOR	PDD- HEPATITIS A VAC OBS	AA.1698.5040	#N/A	Have you had testing for Hepatitis A or been vaccinated for Hepatitis A?: **Yes**
635	NUMERATOR	PDD- HEPATITIS A VAC OBS	AA.22190.82742	#N/A	Have you been vaccinated for hepatitis A?: **Yes**
635	NUMERATOR	PDD- HEPATITIS A VAC OBS	ATV.1698.5040	#N/A	Have you had testing for Hepatitis A or been vaccinated for Hepatitis A?: **Yes**
635	NUMERATOR	PDD- HEPATITIS A VAC OBS	ATV.22190.82742	#N/A	Have you been vaccinated for hepatitis A?: **Yes**
635	NUMERATOR	PDD- HEPATITIS A VAC OBS	HMT.112.1	#N/A	Have you been tested for hepatitis A or been vaccinated against hepatitis A?: **Yes**
635	NUMERATOR	PDD- HEPATITIS A VAC OBS	HMT.114.1	#N/A	Have you been tested for hepatitis A or been vaccinated against hepatitis A?: **Yes**
635	NUMERATOR	PDD- HEPATITIS A VAC OBS	PHR.112.1	#N/A	Have you been tested for hepatitis A or been vaccinated against hepatitis A?: **Yes**
635	NUMERATOR	PDD- HEPATITIS A VAC OBS	PHR.114.1	#N/A	Have you been tested for hepatitis A or been vaccinated against hepatitis A?: **Yes**
635	NUMERATOR	PDD- HEPATITIS A VAC OBS	PHR.200001025.1	#N/A	Have you been tested for or vaccinated against Hepatitis A?: **Yes**
635	NUMERATOR	PDD- HEPATITIS A VAC OBS	PHR.459.1	#N/A	Have you been tested for or vaccinated against Hepatitis A?: **Yes**