

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29

DR. SUMEET K ASRANI (Orcid ID : 0000-0001-9174-5670)

Article type : Practice Guidance

Corresponding author mail id:- kanwal@bcm.edu

**Development of Quality Measures in Cirrhosis by the Practice Metrics
Committee of the American Association for the Study of Liver
Diseases**

Fasiha Kanwal (1-3), Elliot B. Tapper (4), Chanda Ho (5), Sumeet K. Asrani (6), Nadia Ovchinsky (7), John Poterucha (8), Avegail Flores (9), Victor Ankoma-Sey (10), Bruce Luxon (11), Michael Volk (12).

1. Section of Gastroenterology and Hepatology, Department of Medicine, Baylor College of Medicine, Houston, TX
2. Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey Veterans Affairs Medical Center, Houston, TX
3. Section of Health Services Research, Department of Medicine, Baylor College of Medicine, Houston, TX
4. Division of Gastroenterology and Hepatology, Department of Internal Medicine, University of Michigan, Ann Arbor, MI
5. Department of Transplantation, California Pacific Medical Center, San Francisco, CA
6. Division of Hepatology, Baylor University Medical Center, Dallas, TX
7. Division of Pediatric Gastroenterology, Children’s Hospital at Montefiore, Bronx, NY
8. Division of Gastroenterology, Mayo Clinic, Rochester, MN
9. Division of Gastroenterology, Washington University School of Medicine, St. Louis, MO

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1002/HEP.30489](https://doi.org/10.1002/HEP.30489)

This article is protected by copyright. All rights reserved

1 10. Sherri & Alan Conover Center for Liver Disease & Transplantation, Department of
2 Gastroenterology & Hepatology, Houston Methodist Hospital, Houston, TX

3 11. Department of Medicine, Georgetown University, Washington, DC

4 12. Division of Gastroenterology and Transplantation Institute, Loma Linda University, Loma
5 Linda, CA

6
7
8 **Acknowledgment.** The funding for the development of this document was provided by the
9 American Association for the Study of Liver Diseases. The Expert Panel comprised Amit Singal,
10 MD, Rony Ghaoui, M D, Hashem El-Serag, MD, John Vierling, MD, Bruce Runyon, MD, Arun
11 Sanyal, MD, Scott Biggins, MD, Jasmohan Bajaj, MD, Timothy Morgan, MD, and Guadalupe
12 Garcia-Tsao, MD.

13
14 This document was approved by the American Association for the Study of Liver Diseases on
15 September 8, 2018.

16 17 **ABSTRACT**

18
19 Health care delivery is increasingly evaluated according to quality measures, yet such
20 measures are underdeveloped for cirrhosis. The Practice Metrics Committee of the
21 American Association for the Study of Liver Diseases was charged with developing
22 explicit process- and outcome-based measures for adults with cirrhosis. We identified
23 candidate measures from comprehensive reviews of the literature and input from expert
24 clinicians and patient focus groups. We conducted an 11-member expert clinician panel
25 and used a modified Delphi method to systematically identify a set of quality measures
26 in cirrhosis. Among 119 candidate measures, 46 were identified as important measures
27 to define quality of cirrhosis care, including 26 process measures, 7 clinical outcome
28 measures, and 13 patient-reported outcome measures. The final process measures
29 captured care processes across the entire spectrum from diagnosis, treatment, and
30 prevention for ascites (5 measures), varices/bleeding (7 measures), hepatic
31 encephalopathy (4 measures), hepatocellular cancer (HCC) screening (1 measure),

1 liver transplantation evaluation (2 measures), and other care (7 measures). Clinical
2 outcome measures included survival, variceal bleeding and re-bleeding, early-stage
3 HCC, liver-related hospitalization, and rehospitalization within 7 and 30 days. Patient-
4 reported outcome measures covered physical symptoms, physical function, mental
5 health, general function, cognition, social life, and satisfaction with care. The final list of
6 patient-reported outcomes was validated in 79 cirrhosis patients from 9 institutions in
7 the United States.

8 **Conclusion:** We developed an explicit set of evidence-based quality measures for adult
9 patients with cirrhosis. These measures are a tool for providers and institutions to
10 evaluate their care quality, drive quality improvement, and deliver high-value cirrhosis
11 care. The quality measures are intended to be applicable in any clinical care setting in
12 which care for patients with cirrhosis is provided.

13 **BACKGROUND**

14 Cirrhosis is the final common pathway for all chronic liver diseases. Cirrhosis
15 predisposes to a range of complications, including synthetic dysfunction, ascites,
16 hepatic encephalopathy, variceal bleeding, and hepatocellular cancer (HCC). The
17 prognosis of cirrhosis is highly variable. Patients with compensated disease may live
18 with cirrhosis for a long time (median survival of 12 years¹). However, survival in
19 cirrhosis patients after hepatic decompensation or HCC is dismal (approximately 24 and
20 8 months,^{2,3} respectively). Liver transplantation can be lifesaving in patients with
21 cirrhosis; however, only a small minority undergo transplantation. Cirrhosis is also
22 resource intensive. Most complications require hospitalization,⁴ and nearly 70% of
23 patients are readmitted within 1 year, costing >\$20,000 per admission.⁵ The burden of
24 cirrhosis is amplified by its dramatic impact on quality of life resulting from multiple
25 physical, psychological, cognitive, and social stressors.⁶

26
27 Many clinical practice guidelines that support evidence-based treatments for patients
28 with cirrhosis exist.⁷⁻¹³ Despite these treatments, there are substantial shortfalls in the
29 quality of cirrhosis care,^{14,15} suggesting a role for systematic quality improvement.
30 Furthermore, the recent shift to value-based health care poses an urgent need to
31 measure and improve the quality of cirrhosis care.¹⁶ A major challenge in improving the

1 value of cirrhosis care is the lack of standardized measures for tracking quality within
2 and across health care settings.

3
4 To evaluate the quality of care, most quality improvement programs rely on multiple
5 measures, including a combination of process and outcome measures.¹⁷ A process-
6 based measure evaluates the extent to which health professionals, institutions, or health
7 plans provide or achieve the element of care included in the measure (eg, HCC
8 screening, varices prophylaxis). Process measures have the advantage of requiring less
9 risk adjustment because properly constructed specifications narrowly define the clinical
10 circumstances for indicated care. Outcome-based measures require risk adjustment but
11 define the most critical outcomes in health and health care (eg, physical function,
12 hospitalization, survival). In this context, “risk adjustment” means adjusting for non-
13 modifiable risk factors for poor outcomes.

14
15 Identifying and implementing a standard set of process- and outcome-based measures
16 for cirrhosis is an essential step in promoting value improvement in cirrhosis care. An
17 explicit set of process measures for cirrhosis care was developed over 10 years ago.¹⁸
18 Although these measures have been used to evaluate quality of cirrhosis care in
19 disparate health care settings,^{14,15,19-21} they do not reflect recent advances in cirrhosis
20 management. Furthermore, there has been limited effort in developing outcome
21 measures for patients with cirrhosis. The lack of well-defined outcome measures is a
22 main roadblock in implementing value-based programs in cirrhosis, where value is
23 defined as achieving desired outcomes relative to the cost of care for patients with
24 cirrhosis.

25
26 To fill these gaps, the American Association for the Study of Liver Diseases (AASLD)
27 Practice Metrics Committee recently developed a standard set of quality measures,
28 including process- and patient-centered outcomes for adults with cirrhosis. We aimed to
29 select measures that, if implemented, would allow reliable and accurate measurement,
30 tracking, and ultimately improvement of health care provided to patients with cirrhosis.

31 **METHODS**

1
2 We used a predefined stepwise approach to identify the quality measures set as
3 follows. A working group identified the candidate process and outcome measures based
4 on a structured literature review and clinical experience. The working group then
5 convened a separate 11-member expert panel that used 2-round modified Delphi
6 method to identify the final measures set based on their importance, reach, and
7 performance gap. These criteria were specified a priori and are described in detail in the
8 section below. Patient focus groups and surveys were conducted to obtain patient input
9 (Figure 1). We describe these steps in details below.

10 **AASLD Practice Metrics Committee working group**

11 The working group consisted of 10 AASLD Practice Metrics Committee members,
12 including adult and pediatric hepatologists working in community and academic settings
13 across the United States; several members also had specific expertise in health
14 services research and epidemiology. The working group worked closely with 2 patient
15 representatives (1 patient with decompensated liver disease and 1 caregiver) to ensure
16 that outcomes perceived as important by patients were included in the candidate list.

17 **Identification of the candidate measures set**

18 The working group convened via conference calls between January and October 2017,
19 with 1 face-to-face meeting in September 2017.

20
21 The working group defined the scope of the measures set to include all adult patients
22 with cirrhosis regardless of the type and severity of complications, with few exceptions.
23 The group purposely excluded processes and outcomes of care related to treatment of
24 HCC because it is highly specialized and requires combined efforts from multiple
25 disciplines. Moreover, the target population with HCC might be heterogeneous in terms
26 of the severity of underlying liver disease, stage of tumor, and functional status to allow
27 reliable quality measurement. Similarly, we excluded the processes and outcomes of
28 care that occur immediately before or after transplantation (pre-transplantation
29 evaluation, transplant procedure, post-transplant immunosuppressant use, etc.)
30 because of the highly specialized nature of care.

1
2 For process-based measures, the group started with a published process measures
3 set.¹⁸ The working group reviewed clinical practice guidelines published since
4 development of the previous set to identify additional process measures to be included
5 in the candidate measure list.

6
7 The group recognized that patient-centered outcome measurement in cirrhosis needs to
8 encompass disease complications, hospitalization, and survival (clinical outcomes) as
9 well as measures capturing patients' own assessment of their health status, including
10 symptoms and physical, social, and mental functioning (patient-reported outcomes).²²
11 The working group performed a scoping review of literature to identify a comprehensive
12 set of patient-reported outcomes for inclusion into the candidate measures. The results
13 of this review are published elsewhere.⁶ The working group then reviewed the list of
14 candidate outcome measure and identified additional outcomes that captured the
15 clinical status of patients with cirrhosis.

16
17 To ensure that we included patients' perspective in the outcomes identification, 2
18 separate focus groups of patients with cirrhosis and their caregivers were conducted in
19 August 2017 (guided by MV). These included 7 patients on the liver transplant list and 7
20 caregivers. The discussion was guided by a semistructured format and continued until
21 thematic saturation was reached.²³ Saturation is a widely accepted methodological
22 principle in qualitative research. Thematic saturation occurs when new data (eg,
23 comments, themes) become redundant with data already collected, indicating that
24 further data collection is unlikely to yield additional information.

25 **Modified 2-round Delphi process**

26 We used a modified Delphi approach to identify a set of cirrhosis quality measures.²⁴
27 This is a formal group method in which an expert panel discusses and iteratively rates
28 candidate quality measures by using a 2-round process. In the first round, the experts
29 rate the proposed measures individually without any interaction among the members. In

1 the second round—a face-to-face meeting—their preliminary ratings for the measures
2 were discussed and then re-rated through an equally weighted voting.

3

4 **Expert panel.** A group of 11 hepatologists with content expertise participated in the
5 modified Delphi process (see Acknowledgments section for names and affiliations of the
6 panel members). We selected the panel members based on their recent publications
7 and participation in the Advisory Councils for professional societies. The selection
8 process was designed to maintain the geographic, clinical practice, and research
9 interest diversity among the group.

10 **Pre-meeting ratings (round 1).** We instructed the panel to rate each measure on the
11 following 3 criteria on a 9-point Likert scale: importance (primary criterion), reach, and
12 performance gap. We defined a process measure to be “important” if (a) strong
13 scientific evidence exists demonstrating that compliance with a given process of care
14 improves health care outcomes, (b) the process being measured is closely connected to
15 the outcome it impacts, and (c) the magnitude of effect of performing the measure is
16 large enough that it is worth doing. We defined an outcome to be important if it (a) is
17 important to patients or clinicians, (b) is meaningful across multiple populations, and (c)
18 can help facilitate change and quality improvement. The importance scale ranged from
19 1 (“not important at all”) to 9 (“extremely important”) where 1-3 indicated “definitely not
20 important,” 4-6 indicated “uncertain or equivocal importance,” and 7-9 indicated
21 “definitely important.” The “reach” of a measure was defined as the number of patients it
22 applies to, where 1 indicated “smallest reach: applicable to few or no patients” and 9
23 indicated “largest reach: applicable to almost all patients.” “Performance gap” was
24 defined as the gap between current and desired performance on each process measure
25 or gap between current and desired level for each outcome from 1 (no gap) to 9 (largest
26 gap).

27 We determined the median panel rating and a measure of agreement for each measure
28 for each criterion. Based on a priori considerations, we relied on ratings of importance
29 as the primary criterion to guide measure selection process. Specifically, we selected
30 measures if they were voted as definitely important (group median ≥ 7) with no extreme

1 variation in expert ratings.^{18,24} These selection criteria have been widely used to develop
2 performance measures across several areas of medicine.²⁵⁻²⁹ We defined no extreme
3 variation when >80% of ratings were in the 7-9 range with none in the extreme 1-3
4 range.

5
6 **Face-to-face meeting (round 2).** The panel face-to-face meeting was moderated by
7 FK and MV (nonvoting members). During this half-day meeting, each panelist received
8 a table comparing their scores with the median scores (generated by other panelists) for
9 each measure. Discussion focused on the areas of disagreement to understand the
10 sources of variation. Panel members were also tasked with identifying additional
11 measures not on the original list, modifying existing measures that were imperfectly
12 worded, and deleting measures that were perceived to be problematic or irrelevant.
13 After an updated list of measures was developed, the panelists re-rated the importance,
14 reach, and performance gap of each measure again by using the 9-point scale. We
15 selected measures based on ratings of importance. As above, we considered a
16 measure important if the median rating was 7-9 without any disagreement between the
17 raters. We presented median ratings on the remaining 2 constructs for the final measure
18 set.

19 **Validation of patient-reported outcomes**

20 The final list of patient-reported outcomes was reviewed by 79 cirrhosis patients from
21 hepatology clinics at 9 institutions in the United States. Participants were asked to
22 complete an anonymous survey, rating the importance of each outcome on a 4-point
23 scale (not important, somewhat important, very important, and extremely important) with
24 an option to include additional outcomes in text form.

26 **RESULTS**

27 **Candidate measures**

28 The working group proposed 84 candidate measures, and the expert panel members
29 recommended an additional 35 new measures. Among the set of 119 candidate
30 measures, 63 were process-based and 56 were outcome-based. The process

1 measures included care processes across the entire spectrum of care (diagnosis,
2 treatment, and prevention) for ascites, varices, hepatic encephalopathy, HCC
3 screening, liver transplantation evaluation, and general care. Of the 56 candidate
4 outcome measures, 23 captured clinical (traditional) outcomes such as survival,
5 hospitalization, and complications of cirrhosis. The remaining 33 were patient-reported
6 outcome measures, covering 7 domains: physical symptoms, physical function, mental
7 health, general function, cognition, social life, and satisfaction with care. See
8 Supplementary Table 1 for the full list of candidate measures.

9 **Measures selected based on modified Delphi process**

10 Of the 119 candidate measures, 82 had a median rating of 7 or higher (Supplementary
11 Table 1). Of these, we excluded 28 measures that met our definition of disagreement,
12 as detailed above. Where appropriate, we combined selected measures based on
13 content overlap to produce a final list of 46 measures. For example, experts rated use of
14 intravenous albumin and use of antibiotics as important for patients with spontaneous
15 bacterial peritonitis. We combined these 2 processes in 1 measure because both are
16 recommended to be administered together in the management of spontaneous bacterial
17 peritonitis. Similarly, we combined measures about diuretic use and dietary counseling
18 regarding sodium intake in management of symptomatic ascites.

19
20 Table 1 includes the final process measures set with corresponding median ratings of
21 importance, reach, and gap. Of the final set, 26 were process measures; 5 covered
22 ascites care, 7 variceal bleeding-related care, 4 hepatic encephalopathy, 1 HCC
23 screening, and 2 liver transplantation evaluation, and the remaining addressed general
24 care of patients with cirrhosis. The final measure set also included 7 clinical and 13
25 patient-reported outcomes that were deemed important measures of quality of cirrhosis
26 care by the expert panel (Table 2).

27 **Validation of patient-reported outcomes**

28 In total, 79 patients from 9 institutions completed a paper-based survey to rate the
29 importance of patient-reported outcomes selected as part of the modified Delphi
30 process above. Patients represented a broad spectrum of disease severity, including
31 those with compensated and decompensated cirrhosis. Table 3 displays patient ranking

1 of these outcome measures. Over 80% of patients rated all outcome measures as
2 “somewhat” to “extremely” important except for the alcohol abstinence outcome, which
3 had a marked bimodal distribution. Patient-reported outcomes that were deemed “very
4 or extremely” important by 80% or more patients included reducing abdominal fluid
5 accumulation (ascites), improving concentration and memory, and reducing medication
6 side effects.

7 **Measures by patient subgroups**

8 We grouped the final measures based on the types of cirrhosis patients they apply to.
9 Supplementary Table 2 displays the final set of measures applicable to most patients
10 with cirrhosis as well as those applicable to specific subgroups of cirrhosis patients.
11

12 **Measures applicable to most patients with cirrhosis.** In total, 5 process, 2 clinical,
13 and 8 patient-reported outcomes measures can be used to assess quality of care for
14 most patients with cirrhosis, regardless of the specific clinical complication or stage of
15 disease (Supplementary Table 2). The process measures include endoscopy for
16 variceal screening, HCC screening, hepatitis B vaccination, frailty assessment, and
17 management of patients with excessive alcohol use. Most of these measures were felt
18 to have broad reach (median reach scores 8 to 9) with substantial gaps in current care
19 (see Table 1).
20

21 Patient survival was felt to be the most important clinical outcome measure, followed by
22 liver-related hospitalization. Patient-reported outcomes, each with broad reach and
23 applicability (median reach score >7) included control of cirrhosis symptoms (pruritus,
24 muscle cramps), falls, medication side effects, burden on caregivers, depression,
25 stigma, and alcohol abstinence. Experts felt that there were moderate gaps between the
26 current and ideal clinical and patient-reported outcomes.
27

28 **Measures applicable to patients with ascites.** There were 5 process measures and 2
29 patient-reported outcomes that were deemed important measures of quality of ascites
30 care (Supplementary Table 2). The reach of specific measures ranged from 3
31 (applicable to few patients) for treatment of spontaneous bacterial peritonitis to 7

1 (applicable to some but not all patients) for diagnostic paracentesis in hospitalized
2 patients. The outcome measures included patient self-report of fluid accumulation
3 (abdominal and overall). Experts felt that there were moderate gaps in the current and
4 ideal clinical and patient-reported outcomes.

5
6 **Measures applicable to patients with varices/variceal bleeding.** In total, 7
7 processes and 2 clinical outcomes were considered important for measuring
8 varices/variceal bleeding-related care. These included screening for varices, primary
9 (and secondary) prophylaxis for variceal bleeding, and urgent endoscopy and
10 appropriate therapy for patients with suspected acute variceal bleeding. Two clinical
11 outcomes included first variceal bleeding and development of re-bleeding among
12 patients with prior history of variceal bleeding. The reach of specific measures varied
13 from 4 (for treatment of variceal bleeding) to 8 (for prevention of first episode of variceal
14 bleeding). There were perceived moderate gaps in the current and ideal performance
15 on process and clinical outcomes for variceal bleeding (see Table 1).

16
17 **Measures applicable to patients with hepatic encephalopathy.** There were 4
18 process measures and 3 patient-reported outcomes that were deemed important
19 measures of quality of hepatic encephalopathy care (Supplementary Table 2). The
20 process measures included counseling patients with prior overt hepatic encephalopathy
21 about the risks associated with driving, searching for evidence of precipitating factors
22 and treatment with lactulose in hospitalized patients with acute episodes of overt
23 hepatic encephalopathy, and secondary prophylaxis with lactulose and/or rifaximin after
24 resolution of acute episode. Patient-reported outcomes included self-reported episodes
25 of confusion, impaired concentration and memory, and concern about inability to drive.
26 The reach of process measures was felt to be low to moderate. In contrast, patient-
27 reported outcomes were deemed applicable to a larger subgroup of patients with
28 cirrhosis, with median reach scores in the 7 to 8 range (Table 1). Experts felt that there
29 were moderate gaps in the current and ideal clinical and patient-reported outcomes for
30 hepatic encephalopathy.

31

1 **Measures applicable to patients with HCC.** The final set included 2 measures that
2 can be used to assess quality of care for patients with HCC (Table 1). These included 1
3 process measure (consideration of liver transplantation for patients with HCC meeting
4 transplant criteria) and 1 outcome measure (early-stage HCC at the time of diagnosis).
5 Both measures had moderate reach with moderate gaps between current and ideal
6 performance.

7
8 **Other subgroups.** Several measures were applicable to specific subgroups of cirrhosis
9 patients, including patients who were hospitalized with cirrhosis (Supplementary Table
10 2). Table 1 displays the importance, reach, and gap scores for these measures.

11 12 13 **DISCUSSION**

14 We systematically developed a quality assessment tool that consists of 46 explicit
15 measures, including both process measures as well as outcome measures relevant to
16 the care of patients with cirrhosis. This effort is the first to identify an agreed upon set of
17 outcome-based measures, including clinical and patient-reported outcomes in cirrhosis.
18 Our development method, ie, the comprehensive literature review, the rigorous nature
19 of the modified Delphi expert panel process, and extensive patient input, confers
20 content validity on the selected measures.

21
22 We believe that the measures included in the cirrhosis set will provide a means of
23 evaluating the quality of cirrhosis care in a reproducible manner across different
24 practitioners, settings, and institutions. This comprehensive quality assessment tool
25 spans the spectrum of disease severity and includes several process- and outcome-
26 based measures for different cirrhosis complications, thereby allowing reliable
27 assessment of quality of cirrhosis care. We also present data on potential reach of the
28 measures as well as perceived gaps in the current quality. Collectively, this information
29 can guide practitioners in selecting a subset that best fits their clinical context and
30 quality improvement targets. For example, practices serving compensated patients with
31 cirrhosis, including primary care providers, may select measures that are applicable to

1 most patients with cirrhosis, such as HCC screening, peripheral edema, and survival. In
2 contrast, liver specialty clinics that primarily focus on patients with decompensated
3 cirrhosis may select complication-specific measures (eg, ascites, hepatic
4 encephalopathy, and varices-specific measures). Thus, although the full set (Tables 1
5 and 2) provides health care professionals and institutions with a comprehensive quality
6 assessment tool, we anticipate that individuals and institutions may select the measures
7 that best fit their clinical context and quality goals.

8
9 We recognize that a major barrier to implementing measures in clinical practice is the
10 challenge of collecting data to successfully track and record performance. Successful
11 implementation of these measures will require adaptations in technical infrastructure to
12 allow data collection. Major electronic medical record vendors are creating structured
13 data fields within specialty-specific templates that can allow collection of structured data
14 for consistent and reliable quality assessments. Similarly, several tools exist that
15 support collection and integration of patient-reported data into electronic health records.
16 Future research is needed to determine whether patient surveys can be included and/or
17 imported seamlessly into the electronic charts as discrete fields for easy abstraction.
18 We recognize that, in addition to significant modifications in technical infrastructure,
19 successful implementation of the standard set will require a significant change in clinical
20 attitudes and workflow. Our near-term goal is to implement selected measures as part
21 of the Cirrhosis Quality Collaborative initiative. In this step, we will include specification
22 of case-mix factors as well as exclusion criteria for all measures to adjust for differences
23 between theoretical guidelines and real care practice and to set benchmark
24 performance in cirrhosis. In addition to improving the accuracy of measure, accounting
25 for patient exclusion criteria and case-mix will allow comparisons across health care
26 facilities with different patient populations. We will also develop procedures for
27 implementation and sustainability of data collection—information that will pave the way
28 for broader dissemination and adoption.

29
30 We focused on measures that are intended for quality improvement efforts. We believe
31 that it would be premature to use the measures set to benchmark provider performance

1 without further research. Specifically, implementation of these measures for
2 accountability, in contrast with quality improvement efforts, will require further testing to
3 address a variety of issues pertaining to the identification of a subset that not only is
4 important but also meets the criteria for necessary care (ie, the expected benefits not
5 only outweigh the expected harms, but they do so by such a margin that the provider
6 must offer the service); other issues include methods of data collection, frequency of
7 implementation, comparability among practices, audit requirements, the system of
8 public reporting, and more importantly, the input from stakeholder groups, including
9 third-party payers and policy makers. Future work of the Practice Metrics Committee will
10 evaluate whether some of the measures in the cirrhosis set can be applied for tracking
11 quality for purposes of accountability in cirrhosis.

12
13 Though we are confident that we captured critical processes and outcomes, we also
14 recognize that our measurement set does not encompass all measures that may matter
15 to patients with cirrhosis. Several measures were underrepresented because of
16 limitations related to the quality and quantity of data supporting the measures. For
17 example, although screening for minimal hepatic encephalopathy may be important,
18 available tests lack specificity for the condition.³⁰ Several measures were not included in
19 the candidate list due to difficulty in defining the target condition (such as refractory
20 ascites, refractory variceal bleeding, and stage III/IV hepatic encephalopathy) using
21 readily available data. These conditions would require manual chart reviews to define
22 and might not be feasible in quality improvement efforts that require repeated
23 assessments.³¹ Some measures (such as screening for harmful alcohol use and clinical
24 depression) were not specifically addressed because these measures are applicable to
25 all patients seeking health care and are already included in several quality-reporting and
26 payment programs sponsored by commercial payers and government agencies (eg,
27 Medicare's quality reporting Merit-based Incentive Payment System).

28
29 In summary, we have developed an explicit set of 46 evidence-based measures
30 relevant to several aspects of care in adults with cirrhosis. The measures may provide
31 health care professionals and institutions with a tool to identify processes amenable to

1 quality improvement interventions. The outcome measures included in the final set will
2 be important as we adapt to evolving health care delivery models that attempt to
3 optimize quality of care. The measures are intended to be applicable in different health
4 care settings in which care for patients with cirrhosis is provided.

5

6 LITERATURE CITED

7

- 8 1. D'Amico G, Garcia-Tsao G, Pagliaro L. Natural history and prognostic indicators of
9 survival in cirrhosis: a systematic review of 118 studies. *Journal of hepatology*.
10 2006;44(1):217-231.
- 11 2. Khalaf N, Ying J, Mittal S, et al. Natural History of Untreated Hepatocellular
12 Carcinoma in a US Cohort and the Role of Cancer Surveillance. *Clinical*
13 *gastroenterology and hepatology : the official clinical practice journal of the*
14 *American Gastroenterological Association*. 2017;15(2):273-281.e271.
- 15 3. Llovet JM, Bustamante J, Castells A, et al. Natural history of untreated nonsurgical
16 hepatocellular carcinoma: rationale for the design and evaluation of therapeutic
17 trials. *Hepatology (Baltimore, Md)*. 1999;29(1):62-67.
- 18 4. Ratib S, Fleming KM, Crooks CJ, Aithal GP, West J. 1 and 5 year survival estimates for
19 people with cirrhosis of the liver in England, 1998-2009: a large population study.
20 *Journal of hepatology*. 2014;60(2):282-289.
- 21 5. Volk ML, Tocco RS, Bazick J, Rakoski MO, Lok AS. Hospital readmissions among
22 patients with decompensated cirrhosis. *The American journal of gastroenterology*.
23 2012;107(2):247-252.
- 24 6. Tapper EB, Kanwal F, Asrani SK, et al. Patient Reported Outcomes in Cirrhosis: A
25 Scoping Review of the Literature. *Hepatology (Baltimore, Md)*. 2017.
- 26 7. Backus LI, Boothroyd DB, Phillips BR, Belperio P, Halloran J, Mole LA. A sustained
27 virologic response reduces risk of all-cause mortality in patients with hepatitis C.
28 *Clinical gastroenterology and hepatology : the official clinical practice journal of the*
29 *American Gastroenterological Association*. 2011;9(6):509-516.e501.
- 30 8. Bass NM, Mullen KD, Sanyal A, et al. Rifaximin treatment in hepatic encephalopathy.
31 *The New England journal of medicine*. 2010;362(12):1071-1081.

- 1 9. Bolondi L, Sofia S, Siringo S, et al. Surveillance programme of cirrhotic patients for
2 early diagnosis and treatment of hepatocellular carcinoma: a cost effectiveness
3 analysis. *Gut*. 2001;48(2):251-259.
- 4 10. Gluud LL, Klingenberg S, Nikolova D, Gluud C. Banding ligation versus beta-blockers
5 as primary prophylaxis in esophageal varices: systematic review of randomized
6 trials. *The American journal of gastroenterology*. 2007;102(12):2842-2848; quiz
7 2841, 2849.
- 8 11. Khan A, Tansel A, White DL, et al. Efficacy of Psychosocial Interventions in Inducing
9 and Maintaining Alcohol Abstinence in Patients With Chronic Liver Disease: A
10 Systematic Review. *Clinical gastroenterology and hepatology : the official clinical
11 practice journal of the American Gastroenterological Association*. 2016;14(2):191-
12 202.e191-194; quiz e120.
- 13 12. Santos J, Planas R, Pardo A, et al. Spironolactone alone or in combination with
14 furosemide in the treatment of moderate ascites in nonazotemic cirrhosis. A
15 randomized comparative study of efficacy and safety. *Journal of hepatology*.
16 2003;39(2):187-192.
- 17 13. Stanley MM, Ochi S, Lee KK, et al. Peritoneovenous shunting as compared with
18 medical treatment in patients with alcoholic cirrhosis and massive ascites. Veterans
19 Administration Cooperative Study on Treatment of Alcoholic Cirrhosis with Ascites.
20 *The New England journal of medicine*. 1989;321(24):1632-1638.
- 21 14. Kanwal F, Kramer JR, Buchanan P, et al. The quality of care provided to patients with
22 cirrhosis and ascites in the Department of Veterans Affairs. *Gastroenterology*.
23 2012;143(1):70-77.
- 24 15. Buchanan PM, Kramer JR, El-Serag HB, et al. The quality of care provided to patients
25 with varices in the department of Veterans Affairs. *The American journal of
26 gastroenterology*. 2014;109(7):934-940.
- 27 16. Porter ME. What is value in health care? *The New England journal of medicine*.
28 2010;363(26):2477-2481.
- 29 17. VanLare JM, Conway PH. Value-based purchasing--national programs to move from
30 volume to value. *The New England journal of medicine*. 2012;367(4):292-295.

- 1 18. Kanwal F, Kramer J, Asch SM, et al. An explicit quality indicator set for measurement
2 of quality of care in patients with cirrhosis. *Clinical gastroenterology and hepatology*
3 : the official clinical practice journal of the American Gastroenterological
4 Association. 2010;8(8):709-717.
- 5 19. Orman ES, Ghabril M, Chalasani N. Poor Performance Status Is Associated With
6 Increased Mortality in Patients With Cirrhosis. *Clinical gastroenterology and*
7 *hepatology : the official clinical practice journal of the American Gastroenterological*
8 *Association*. 2016;14(8):1189-1195.e1181.
- 9 20. Ghaoui R, Friderici J, Visintainer P, Lindenauer PK, Lagu T, Desilets D. Measurement
10 of the quality of care of patients admitted with decompensated cirrhosis. *Liver*
11 *international : official journal of the International Association for the Study of the*
12 *Liver*. 2014;34(2):204-210.
- 13 21. Lim N, Lidofsky SD. Impact of physician specialty on quality care for patients
14 hospitalized with decompensated cirrhosis. *PloS one*. 2015;10(4):e0123490.
- 15 22. Porter ME, Larsson S, Lee TH. Standardizing Patient Outcomes Measurement. *The*
16 *New England journal of medicine*. 2016;374(6):504-506.
- 17 23. Creswell JW, Plano Clark V. Choosing a mixed methods design. *Designing and*
18 *conducting mixed methods research*. 2011:53-106.
- 19 24. Fitch K, Bernstein SJ, Aguilar MD, Burnand B, LaCalle JR. *The RAND/UCLA*
20 *appropriateness method user's manual*. RAND CORP SANTA MONICA CA;2001.
- 21 25. Grossman J, MacLean CH. Quality indicators for the care of osteoporosis in
22 vulnerable elders. *Journal of the American Geriatrics Society*. 2007;55 Suppl 2:S392-
23 402.
- 24 26. MacLean CH, Louie R, Leake B, et al. Quality of care for patients with rheumatoid
25 arthritis. *Jama*. 2000;284(8):984-992.
- 26 27. Maggard MA, McGory ML, Shekelle PG, Ko CY. Quality indicators in bariatric surgery:
27 improving quality of care. *Surgery for obesity and related diseases : official journal*
28 *of the American Society for Bariatric Surgery*. 2006;2(4):423-429; discussion 429-
29 430.
- 30 28. McGory ML, Kao KK, Shekelle PG, et al. Developing quality indicators for elderly
31 surgical patients. *Annals of surgery*. 2009;250(2):338-347.

- 1 29. Shekelle PG, MacLean CH, Morton SC, Wenger NS. Acove quality indicators. *Annals of*
 2 *internal medicine*. 2001;135(8 Pt 2):653-667.
- 3 30. Vilstrup H, Amodio P, Bajaj J, et al. Hepatic encephalopathy in chronic liver disease:
 4 2014 Practice Guideline by the American Association for the Study of Liver Diseases
 5 and the European Association for the Study of the Liver. *Hepatology (Baltimore,*
 6 *Md)*. 2014;60(2):715-735.
- 7 31. MacLean CH, Kerr EA, Qaseem A. Time Out - Charting a Path for Improving
 8 Performance Measurement. *The New England journal of medicine*.
 9 2018;378(19):1757-1761.

13 Figure 1 Legend

14
 15 **Steps in the development of cirrhosis quality measures set.** We identified candidate
 16 measures from published set of process measures, a scoping review of the literature,
 17 and input from expert clinicians as well as patient focus groups. Using the modified
 18 Delphi method, an expert panel of clinicians voted on the candidate measures to
 19 systematically identify a set of quality measures in cirrhosis. The final list of patient-
 20 reported outcomes was reviewed and endorsed by cirrhosis patients from 9 institutions.

Table 1. Process Measures		Median		
	Process Measures	Importance	Reach	Gap
1	Patients with ascites who are admitted to the hospital for evaluation and management of symptoms related to ascites or encephalopathy should receive a diagnostic paracentesis during the index hospitalization	9	7	6
2	Patients who are admitted with or develop GI bleeding should receive antibiotics within 24 hours of admission or presentation. Antibiotics should be continued for at least 5 days	9	4	5
3	Patients undergoing large-volume paracentesis (>5 liters removed) should receive intravenous albumin (6-8 grams per liter removed)	8	3	5

4	Hospitalized patients with ascites, with an ascitic fluid polymorphonuclear count of ≥ 250 cells/mm ³ , should receive empiric antibiotics and albumin within 12 hours of the test result. The first dose of albumin should be 1.5 g per kg body weight followed by a second infusion of 1.0 g/kg on day 3.	8	3	6
5	Patients with ascites and/or hepatic hydrothorax should be managed with both sodium restriction and diuretics.	8	3	4
6	Patients who undergo paracentesis should not receive fresh frozen plasma or platelets	8	5	7
7	Patients with cirrhosis, with platelet count $< 150,000/\text{mm}^3$ or liver stiffness measurement > 20 kPa, and no documentation of previous GI bleeding, should receive upper endoscopy to screen for varices within 12 months of cirrhosis diagnosis	8	6	5
8	Patients with decompensated cirrhosis and no documented history of previous GI bleeding should receive upper endoscopy to screen for varices within 3 months of cirrhosis diagnosis	8	4	5
9	Patients with cirrhosis, no documented history of previous GI bleeding, and medium/large varices on endoscopy should receive either nonselective β -blockers or EVL within 1 month of varices diagnosis.	8	5	4
10	Patients with cirrhosis who present with upper GI bleeding should receive upper endoscopy within 12 hours of presentation	9	5	5
11	Patients with cirrhosis who are found to have bleeding esophageal varices should receive EVL or sclerotherapy at the time of index endoscopy	9	4	2
12	Patients with cirrhosis who survive an episode of acute variceal hemorrhage should receive a combination of EVL and β -blockers.	8	4	5
13	Patients with prior overt hepatic encephalopathy should be counseled regarding the risks associated with driving.	8	4	7
14	Patients with hepatic encephalopathy should have a search for evidence of precipitating factors documented in the chart.	8	4	6
15	Patients who are hospitalized and have an acute episode of overt hepatic encephalopathy should receive lactulose.	8	4	4
16	Patients who are discharged after an acute episode of hepatic encephalopathy should receive secondary prophylaxis with lactulose	8	5	6.5

	and/or rifaximin			
17	Patients with cirrhosis and MELD score ≥ 15 who do not have absolute contraindications to liver transplantation should have documentation of evaluation for liver transplantation.	8	5	7
18	Patients with cirrhosis who do not have absolute contraindications to liver transplantation and have HCC meeting the transplant criteria should be considered for liver transplantation, irrespective of their MELD score.	8	5	7
19	Patients with cirrhosis should undergo HCC screening using abdominal imaging with or without serum α -fetoprotein every 6-12 months	9	8	8
20	Patients with cirrhosis should have hepatitis B immune status and/or vaccination documented in the chart.	8	9	6
21	Patients with untreated hepatitis C cirrhosis should be considered for antiviral therapy for hepatitis C	9	6	5
22	Patients with untreated hepatitis B cirrhosis should be considered for antiviral therapy for hepatitis B	9	4	5
23	Patients with cirrhosis should receive counseling or be referred to a substance abuse treatment program within 2 months of positive screening.	9	8	6
24	Patients with cirrhosis who are undergoing abdominal surgery should have documentation of the risk–benefit of undergoing the surgical procedure in the medical record	8	7	7
25	Recently discharged patients with cirrhosis should have a clinic visit with a health care provider within 4 weeks of discharge.	8	5	7
26	Patients with cirrhosis should be assessed for frailty using a systematic screening method	8	7	7.5

1 Abbreviations: EVL, endoscopic variceal ligation; GI, gastrointestinal; HCC, hepatocellular carcinoma;

2 MELD, Model for End-Stage Liver Disease.

3

Table 2. Outcome Measures				
Clinical Outcomes		Importance	Reach	Gap
1	Patient survival	9	9	5

2	First variceal bleeding	8	8	6
3	Variceal re-bleeding among patients with history of variceal bleeding	8	4	5
4	Patients diagnosed at an early stage among patients with HCC	8	7	6
5	Liver-related hospitalization	8	8	6
6	Rehospitalization within 7 days	8	5	6
7	Rehospitalization within 30 days	8	6	6
Patient-Reported Outcomes				
8	Fluid in the legs (edema)	7	6	5
9	Fluid in the belly (ascites)	8	4	6
10	Confusion	8	8	6
11	Concentration and memory	8	7	6
12	Itching	8	3	6
13	Muscle cramps	7.5	6	5
14	Falls	7	6	5
15	Medication side effects	7	7	5
16	Depression	8	7	8
17	Stigma of having liver disease	7	7	6
18	Ability to drive	8	6	7
19	Burden on family	8	7	7
20	Be able to avoid alcohol	8	6	6

1 Abbreviation: HCC, hepatocellular carcinoma.

2

Table 3. Patient Ratings of Patient-Reported Outcomes (%)			
Patient-Reported Item	Not Important	Somewhat Important	Very/Extremely Important
Fluid in the legs (edema)	8.9%	14.1%	76.9%
Fluid in the belly (ascites)	3.8%	5.1%	91.1%
Confusion (encephalopathy)	1.3%	10.1%	88.6%
Concentration/memory	6.4%	16.7%	76.9%
Itching (pruritus)	5.2%	12.9%	81.8%
Muscle cramps	12.9%	36.4%	50.7%
Falls	12.8%	17.9%	69.2%
Medication side effects	8.9%	17.9%	73.1%
Depression	7.6%	21.7%	70.5%
Stigma of having liver disease	5.1%	14.1%	80.8%
Ability to drive	10.1%	22.8%	67.1%
Burden on family	35.1%	5.2%	59.8%
Ability to avoid alcohol	17.1%	18.4%	64.4%

1

Figure 1. Steps in the development of cirrhosis quality measures set

