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

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Health care delivery is increasingly evaluated according to quality measures, yet such measures are underdeveloped for cirrhosis. The Practice Metrics Committee of the American Association for the Study of Liver Diseases was charged with developing explicit process-based and outcome-based measures for adults with cirrhosis. We identified candidate measures from comprehensive reviews of the literature and input from expert clinicians and patient focus groups. We conducted an 11-member expert clinician panel and used a modified Delphi method to systematically identify a set of quality measures in cirrhosis. Among 119 candidate measures, 46 were identified as important measures to define the quality of cirrhosis care, including 26 process measures, 7 clinical outcome measures, and 13 patient-reported outcome measures. The final process measures captured care processes for ascites (n = 5), varices/bleeding (n = 7), hepatic encephalopathy (n = 4), hepatocellular cancer (HCC) screening (n = 1), liver transplantation evaluation (n = 2), and other care (n = 7). Clinical outcome measures included survival, variceal bleeding and rebleeding, early-stage HCC, liver-related hospitalization, and rehospitalization within 7 and 30 days. Patient-reported outcome measures covered physical symptoms, physical function, mental health, general function, cognition, social life, and satisfaction with care. The final list of patient-reported outcomes was validated in 79 patients with cirrhosis from nine institutions in the United States. *Conclusion:* We developed an explicit set of evidence-based quality measures for adult patients with cirrhosis. These measures are a tool for providers and institutions to evaluate their care quality, drive quality improvement, and deliver high-value cirrhosis care. The quality measures are intended to be applicable in any clinical care setting in which care for patients with cirrhosis is provided. (Hepatology 2019;69:1787-1797).

Cirrhosis is the final common pathway for all chronic liver diseases. Cirrhosis predisposes to a range of complications, including synthetic dysfunction, ascites, hepatic encephalopathy, variceal bleeding, and hepatocellular cancer (HCC). The prognosis of cirrhosis is highly variable. Patients with compensated disease may live with cirrhosis for a long time (median survival of 12 years[(1)]). However, survival in patients with cirrhosis after hepatic decompensation or HCC is dismal (approximately 24 and 8 months,[(2,3)] respectively). Liver transplantation can be lifesaving in patients

Abbreviations: AASLD, American Association for the Study of Liver Diseases; EVL, endoscopic variceal ligation; GI, gastrointestinal; HCC, hepatocellular cancer.

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with cirrhosis; however, only a small minority undergo transplantation. Cirrhosis is also resource intensive. Most complications require hospitalization,[4] and nearly 70% of patients are readmitted within 1 year, costing more than $20,000 per admission.[5] The burden of cirrhosis is amplified by its dramatic impact on quality of life, resulting from multiple physical, psychological, cognitive, and social stressors.[6]

Many clinical practice guidelines support evidence-based treatments for patients with cirrhosis exist.[7-13] Despite these treatments, there are substantial shortfalls in the quality of cirrhosis care,[14,15] suggesting a role for systematic quality improvement. Furthermore, the recent shift to value-based health care poses an urgent need to measure and improve cirrhosis care quality.

To evaluate the quality of care, most quality improvement programs rely on multiple measures, including a combination of process and outcome measures.[17] A process-based measure evaluates the extent to which health professionals, institutions, or health plans provide or achieve the element of care included in the measure (e.g., HCC screening, varices prophylaxis). Process measures have the advantage of requiring less risk adjustment, because properly constructed specifications narrowly define the clinical circumstances for indicated care. Outcome-based measures require risk adjustment but define the most critical outcomes in health and health care (e.g., physical function, hospitalization, survival). In this context, "risk adjustment" means adjusting for nonmodifiable risk factors for poor outcomes.

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

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

Materials and Methods

We used a predefined, stepwise approach to identify the quality measures set as follows. A working group identified the candidate process and outcome measures based on a structured literature review and

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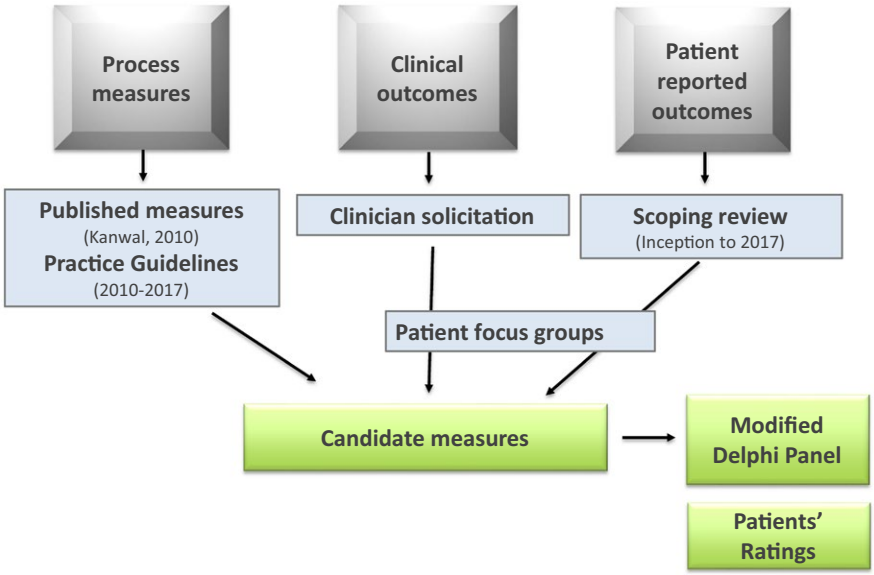

FIG. 1. Steps in the development of the set of cirrhosis quality measures. We identified candidate measures from a published set of process measures, a scoping review of the literature, and input from expert clinicians as well as patient focus groups. Using the modified Delphi method, an expert panel of clinicians voted on the candidate measures to systematically identify a set of quality measures in cirrhosis. The final list of patient-reported outcomes was reviewed and endorsed by patients with cirrhosis from nine institutions.

clinical experience. The working group then convened a separate 11-member expert panel that used a two-round modified Delphi method to identify the final measures set based on their importance, reach, and performance gap. These criteria were specified a priori and are described in detail in the subsequent section. Patient focus groups and surveys were conducted to obtain patient input (Fig. 1). We describe these steps in detail in the following.

AASLD PRACTICE METRICS COMMITTEE WORKING GROUP

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

IDENTIFICATION OF THE CANDIDATE MEASURES SET

The working group convened through conference calls between January and October 2017, with one face-to-face meeting in September 2017.

The working group defined the scope of the measures set to include all adult patients with cirrhosis, regardless of the type and severity of complications, with few exceptions. The group purposely excluded processes and outcomes of care related to treatment of HCC, because it is highly specialized and requires combined efforts from multiple disciplines. Similarly, we excluded the processes and outcomes of care that occur immediately before or after transplantation (e.g., pretransplantation evaluation, transplant procedure, posttransplant immunosuppressant use), because of the highly specialized nature of care.

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

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

To ensure that we included patients' perspectives in the outcome identification, two separate focus groups of patients with cirrhosis and their caregivers were conducted in August 2017 (guided by M.V.). These included 7 patients on the liver transplant list and 7 caregivers. The discussion was guided by a semistructured format and continued until thematic saturation was reached.[23] Saturation is a widely accepted methodological principle in qualitative research. Thematic saturation occurs when new data (e.g., comments, themes) become redundant with the data already collected, indicating that further data collection is unlikely to yield additional information.

MODIFIED TWO-ROUND DELPHI PROCESS

We used a modified Delphi approach to identify a set of cirrhosis quality measures.[24] This is a formal group method in which an expert panel discusses and iteratively rates candidate quality measures. In the first round, the experts rate the proposed measures individually without any interaction among the members. In the second round, a face-to-face meeting, their preliminary ratings for the measures were discussed and then rerated through an equally weighted voting.

Expert Panel

A group of 11 hepatologists with content expertise participated in the modified Delphi process (see "Acknowledgments" for names and affiliations of the panel members). We selected the panel members based on their recent publications and participation in the advisory councils for professional societies. The selection process was designed to maintain the geographic, clinical practice, and research interest diversity among the group.

Premeeting Ratings (Round 1)

We instructed the panel to rate each measure on the following three criteria on a 9-point Likert scale: importance (primary criterion), reach, and performance gap. We defined a process measure to be "important" if (1) strong scientific evidence exists demonstrating that compliance with a given process of care improves health care outcomes, (2) the process being measured is closely connected to the outcome it affects, and (3) the magnitude of effect of performing the measure is large enough that it is worth doing. We defined an outcome to be important if (1) it is important to patients or clinicians, (2) it is meaningful across multiple populations, and (3) it can help facilitate change and quality improvement. The importance scale ranged from 1 ("not important at all") to 9 ("extremely important"), where 1-3 indicated "definitely not important," 4-6 indicated "uncertain or equivocal importance," and 7-9 indicated "definitely important." The "reach" of a measure was defined as the number of patients it applies to, where 1 indicated "smallest reach: applicable to few or no patients" and 9 indicated "largest reach: applicable to almost all patients." "Performance gap" was defined as the gap between current and desired performance on each process measure or gap between current and desired level for each outcome from 1 (no gap) to 9 (largest gap).

We determined the median panel rating and a measure of agreement for each measure for each criterion. Based on previous considerations, we relied on ratings of importance as the primary criterion to guide the measure-selection process. Specifically, we selected measures if they were voted as definitely important (group median ≥ 7) with no extreme variation in expert ratings.[18,24] These selection criteria have been used widely to develop performance measures across several areas of medicine.[25-29] We defined no extreme variation when more than 80% of the ratings were in the 7-9 range, with none in the extreme 1-3 range.

Face-to-Face Meeting (Round 2)

The panel face-to-face meeting was moderated by F.K. and M.V. (nonvoting members). During this half-day meeting, each panelist received a table

comparing their scores with the median scores (generated by other panelists) for each measure. Discussion focused on the areas of disagreement to understand the sources of variation. Panel members were also tasked with identifying additional measures not on the original list, modifying existing measures that were imperfectly worded, and deleting measures that were perceived to be problematic or irrelevant. After an updated list of measures was developed, the panelists rerated the importance, reach, and performance gap of each measure again by using the 9-point scale. We selected measures based on ratings of importance. As done previously, we considered a measure important if the median rating was 7-9 without any disagreement between the raters. We presented median ratings on the remaining two constructs for the final measure set.

Validation of Patient-Reported Outcomes

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

Results

CANDIDATE MEASURES

The working group proposed 84 candidate measures, and the expert panel members recommended an additional 35 new measures. Among the set of 119 candidate measures, 63 were process-based and 56 were outcome-based. The process measures included care processes across the entire spectrum of care (diagnosis, treatment, and prevention) for ascites, varices, hepatic encephalopathy. They also included measures capturing HCC screening, liver transplantation evaluation, and general care. Of the 56 candidate outcome measures, 23 captured clinical (traditional) outcomes such as survival, hospitalization, and complications of cirrhosis. The remaining 33 were patient-reported outcome measures, covering seven domains: physical symptoms, physical function, mental health, general function, cognition, social life, and satisfaction with care. See Supporting Table S1 for the full list of candidate measures.

MEASURES SELECTED BASED ON MODIFIED DELPHI PROCESS

Of the 119 candidate measures, 82 had a median rating of 7 or higher (Supporting Table S1). Of these, we excluded 28 measures that met our definition of disagreement, as detailed previously. Where appropriate, we combined selected measures based on content overlap to produce a final list of 46 measures. For example, experts rated the use of intravenous albumin and the use of antibiotics as important for patients with spontaneous bacterial peritonitis. We combined these two processes in one measure because both are recommended to be administered together in the management of spontaneous bacterial peritonitis. Similarly, we combined measures about diuretic use and dietary counseling regarding sodium intake in the management of symptomatic ascites.

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

VALIDATION OF PATIENT-REPORTED OUTCOMES

In total, 79 patients from 9 institutions completed a paper-based survey to rate the importance of patient-reported outcomes selected as part of this modified Delphi process. Patients represented a broad spectrum of disease severity, including those with compensated and decompensated cirrhosis. Table 3 displays the patient ranking of these outcome measures. Over 80% of patients rated all outcome measures as “somewhat” to “extremely” important, except for the alcohol abstinence outcome, which had a marked bimodal distribution.

TABLE 1. Process Measures

	Process Measures	Median Importance	Median Reach	Median 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 L removed) should receive intravenous albumin (6-8 g/L 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/kg of 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/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 previous 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 and/or rifaximin	8	5	6.5
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, regardless 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

TABLE 1. *Continued*

	Process Measures	Median Importance	Median Reach	Median Gap
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

Abbreviations: EVL, endoscopic variceal ligation; GI, gastrointestinal; and MELD, Model for End-Stage Liver Disease.

Patient-reported outcomes that were deemed "very or extremely" important by 80% or more patients included reducing abdominal fluid accumulation (ascites), improving concentration and memory, and reducing medication side effects.

MEASURES BY PATIENT SUBGROUPS

We grouped the final measures based on the types of patients with cirrhosis they apply to. Supporting Table S2 displays the final set of measures applicable to most patients with cirrhosis as well as those applicable to specific subgroups of patients with cirrhosis.

Measures Applicable to Most Patients With Cirrhosis

In total, five process, two clinical, and eight patient-reported outcomes measures can be used to assess the quality of care for most patients with cirrhosis, regardless of the specific clinical complication or stage of disease (Supporting Table S2). The process measures include endoscopy for variceal screening, HCC screening, hepatitis B vaccination, frailty assessment, and management of patients with excessive alcohol use. Most of these measures were felt to have broad reach (median reach scores 8 to 9) with substantial gaps in current care (Table 1).

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

Measures Applicable to Patients With Ascites

There were five process measures and two patient-reported outcomes that were deemed important measures of quality of ascites care (Supporting Table S2). The reach of specific measures ranged from 3 (applicable to few patients) for treatment of spontaneous bacterial peritonitis to 7 (applicable to some but not all patients) for diagnostic paracentesis in hospitalized patients. The outcome measures included patient self-report of fluid accumulation (abdominal and overall). Experts felt that there were moderate gaps in the current and ideal clinical and patient-reported outcomes.

Measures Applicable to Patients With Varices/Variceal Bleeding

In total, seven processes and two clinical outcomes were considered important for measuring varices/variceal bleeding-related care. These included screening for varices, primary (and secondary) prophylaxis for variceal bleeding, and urgent endoscopy and appropriate therapy for patients with suspected acute variceal bleeding. Two clinical outcomes included first variceal bleeding and development of rebleeding among patients with previous history of variceal bleeding. The reach of specific measures varied from 4 (for treatment of variceal bleeding) to 8 (for prevention of first episode of variceal bleeding). There were perceived moderate gaps in the current and ideal performance on process and clinical outcomes for variceal bleeding (Table 1).

TABLE 2. Outcome Measures

	Clinical Outcomes	Importance	Reach	Gap
1	Patient survival	9	9	5
2	First variceal bleeding	8	8	6
3	Variceal rebleeding 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	Ability to avoid alcohol	8	6	6

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

Measures Applicable to Patients With Hepatic Encephalopathy

There were four process measures and three patient-reported outcomes that were deemed important measures of quality of hepatic encephalopathy care (Supporting Table S2). The process measures included counseling patients with previous overt hepatic encephalopathy about the risks associated with driving, searching for evidence of precipitating factors and treatment with lactulose in hospitalized patients with acute episodes of overt hepatic encephalopathy, and secondary prophylaxis with lactulose and/or rifaximin after resolution of acute episode. Patient-reported outcomes included self-reported episodes of confusion, impaired concentration and memory, and concern about inability to drive. The reach of process measures was felt to be low to moderate. In contrast, patient-reported outcomes were deemed applicable to a larger subgroup of patients with cirrhosis, with median reach scores in the 7 to 8 range (Table 1). Experts felt that there were moderate gaps in the current and ideal clinical and patient-reported outcomes for hepatic encephalopathy.

Measures Applicable to Patients With HCC

The final set included three measures that can be used to assess quality of care for patients with HCC (Table 1). These included two process measure (consideration of liver transplantation for patients with HCC meeting transplant criteria) and HCC screening; and one outcome measure (early-stage HCC at the time of diagnosis). These measures had moderate to large reach with moderate gaps between current and ideal performance.

Other Subgroups

Several measures were applicable to specific subgroups of patients with cirrhosis, including patients who were hospitalized with cirrhosis (Supporting Table S2). Table 1 displays the importance, reach, and gap scores for these measures.

Discussion

We systematically developed a quality assessment tool that consists of 46 explicit measures, including

both process measures as well as outcome measures relevant to the care of patients with cirrhosis. This effort is the first to identify an agreed upon set of outcome-based measures, including clinical and patient-reported outcomes in cirrhosis. Our development method (i.e., the comprehensive literature review, the rigorous nature of the modified Delphi expert panel process, and extensive patient input) confers content validity on the selected measures.

We believe that the measures included in the cirrhosis set will provide a means of evaluating the quality of cirrhosis care in a reproducible manner across different practitioners, settings, and institutions. This comprehensive quality assessment tool spans the spectrum of disease severity and includes several process-based and outcome-based measures for different cirrhosis complications, thereby allowing reliable assessment of quality of cirrhosis care. We also present data on the potential reach of the measures as well as perceived gaps in the current quality. Collectively, this information can guide practitioners in selecting a subset that best fits their clinical context and quality improvement targets. For example, practices serving compensated patients with cirrhosis, including primary care providers, may select measures that are applicable to most patients with cirrhosis, such as HCC screening. In contrast, liver specialty clinics that focus primarily on patients with decompensated cirrhosis may select complication-specific measures (e.g., ascites, hepatic encephalopathy, varices-specific measures). Thus, although the full set (Tables 1 and 2) provides health care professionals and institutions with a comprehensive quality assessment tool, we anticipate that individuals and institutions may select the measures that best fit their clinical context and quality goals.

We recognize that a major barrier to implementing measures in clinical practice is the challenge of collecting data to successfully track and record performance. Successful implementation of these measures will require adaptations in information technology infrastructure to allow data collection. Major electronic medical record vendors are creating structured data fields within specialty-specific templates that can allow collection of structured data for consistent and reliable quality assessments. Similarly, several tools exist that support collection and integration of patient-reported data into electronic medical records. We recognize that, in addition to significant modifications in technical infrastructure, successful implementation of the standard set will require a significant change in clinical attitudes and workflow. Our near-term goal is to implement selected measures as part of the Cirrhosis Quality Collaborative initiative. In this step, we will include specification of case-mix factors as well as exclusion criteria for all measures, to adjust for differences between theoretical guidelines and real care practice and to set benchmark performance in cirrhosis. In addition to improving the accuracy of measure, accounting for patient exclusion criteria and case mix will allow comparisons across health care facilities with different patient populations. We will also develop procedures for implementation and sustainability of data collection—information that will pave the way for broader dissemination and adoption.

We focused on measures that are intended for quality improvement efforts. We believe that it would be premature to use the measures set to benchmark provider performance without further research. Specifically, implementation of these measures for accountability, in contrast to quality improvement efforts, will require further testing to address a variety of issues pertaining to the identification of a subset that not only is important but also meets the criteria for necessary care (i.e., the expected benefits not only outweigh the expected harms, but they do so by such a margin that the provider must offer the service); other issues include methods of data collection, frequency of implementation, comparability among practices, audit requirements, the system of public reporting, and more importantly, the input from stakeholder groups, including third-party payers and policy makers. Future work of the Practice Metrics Committee will evaluate whether some of the measures in the cirrhosis set can be applied for tracking quality for purposes of accountability in cirrhosis.

Although we are confident that we captured critical processes and outcomes, we also recognize that our measurement set does not encompass all measures that may matter to patients with cirrhosis. Several measures were underrepresented because of limitations related to the quality and quantity of data supporting the measures. For example, although screening for minimal hepatic encephalopathy may be important, available tests lack specificity for the condition.[30] Several measures were not included in the candidate list due to difficulty in defining the target condition (such as refractory ascites, refractory variceal bleeding,

and stage III/IV hepatic encephalopathy) using readily available data. These conditions would require manual chart reviews, and might not be feasible in quality improvement efforts that require repeated assessments.[31] Some measures (such as screening for harmful alcohol use and clinical depression) were not specifically addressed because these measures are applicable to all patients seeking health care and are already included in several quality-reporting and payment programs sponsored by commercial payers and government agencies (e.g., Medicare's quality-reporting Merit-based Incentive Payment System).

In summary, we have developed an explicit set of 46 evidence-based measures that are relevant to several aspects of care in adults with cirrhosis. The measures may provide health care professionals and institutions with a tool to identify processes that are amenable to quality improvement interventions. The outcome measures included in the final set will be important as we adapt to evolving health care delivery models that attempt to optimize quality of care. The measures are intended to be applicable in different health care settings in which care for patients with cirrhosis is provided.

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REFERENCES

1) D'Amico G, Garcia-Tsao G, Pagliaro L. Natural history and prognostic indicators of survival in cirrhosis: a systematic review of 118 studies. J Hepatol 2006;44:217-231.
2) Khalaf N, Ying J, Mittal S, Temple S, Kanwal F, Davila J, et al. Natural history of untreated hepatocellular carcinoma in a US cohort and the role of cancer surveillance. Clin Gastroenterol Hepatol 2017;15:273-281.e271.
3) Llovet JM, Bustamante J, Castells A, Vilana R, Ayuso Mdel C, Sala M, et al. Natural history of untreated nonsurgical hepatocellular carcinoma: rationale for the design and evaluation of therapeutic trials. Hepatology 1999;29:62-67.
4) Ratib S, Fleming KM, Crooks CJ, Aithal GP, West J. 1 and 5 year survival estimates for people with cirrhosis of the liver in England, 1998–2009: a large population study. J Hepatol 2014;60:282-289.
5) Volk ML, Tocco RS, Bazick J, Rakoski MO, Lok AS. Hospital readmissions among patients with decompensated cirrhosis. Am J Gastroenterol 2012;107:247-252.
6) Tapper EB, Kanwal F, Asrani SK, Ho C, Ovchinsky N, Poterucha J, et al. Patient reported outcomes in cirrhosis: a scoping review of the literature. Hepatology 2018;67:2375-2383.
7) Backus LI, Boothroyd DB, Phillips BR, Belperio P, Halloran J, Mole LA. A sustained virologic response reduces risk of all-cause mortality in patients with hepatitis C. Clin Gastroenterol Hepatol 2011;9:509-516.e501.
8) Bass NM, Mullen KD, Sanyal A, Poordad F, Neff G, Leevy CB, et al. Rifaximin treatment in hepatic encephalopathy. N Engl J Med 2010;362:1071-1081.
9) Bolondi L, Sofia S, Siringo S, Gaiani S, Casali A, Zironi G, et al. Surveillance programme of cirrhotic patients for early diagnosis and treatment of hepatocellular carcinoma: a cost effectiveness analysis. Gut 2001;48:251-259.
10) Gluud LL, Klingenberg S, Nikolova D, Gluud C. Banding ligation versus beta-blockers as primary prophylaxis in esophageal varices: systematic review of randomized trials. Am J Gastroenterol 2007;102:2842-2848; quiz 2841, 2849.
11) Khan A, Tansel A, White DL, Kayani WT, Bano S, Lindsay J, et al. Efficacy of psychosocial interventions in inducing and maintaining alcohol abstinence in patients with chronic liver disease: a systematic review. Clin Gastroenterol Hepatol 2016;14:191-202.e191-194; quiz e120.
12) Santos J, Planas R, Pardo A, Durández R, Cabré E, Morillas RM, et al. Spironolactone alone or in combination with furosemide in the treatment of moderate ascites in nonazotemic cirrhosis. A randomized comparative study of efficacy and safety. J Hepatol 2003;39:187-192.
13) Stanley MM, Ochi S, Lee KK, Nemchausky BA, Greenlee HB, Allen JI, et al. Peritoneovenous shunting as compared with medical treatment in patients with alcoholic cirrhosis and massive ascites. Veterans Administration Cooperative Study on Treatment of Alcoholic Cirrhosis with Ascites. N Engl J Med 1989;321:1632-1638.
14) Kanwal F, Kramer JR, Buchanan P, Asch SM, Assioun Y, Bacon BR, et al. The quality of care provided to patients with cirrhosis and ascites in the Department of Veterans Affairs. Gastroenterology 2012;143:70-77.
15) Buchanan PM, Kramer JR, El-Serag HB, Asch SM, Assioun Y, Bacon BR, et al. The quality of care provided to patients with varices in the department of Veterans Affairs. Am J Gastroenterol 2014;109:934-940.
16) Porter ME. What is value in health care? N Engl J Med 2010;363:2477-2481.
17) VanLare JM, Conway PH. Value-based purchasing—national programs to move from volume to value. N Engl J Med 2012;367:292-295.
18) Kanwal F, Kramer J, Asch SM, El-Serag H, Spiegel BM, Edmundowicz S, et al. An explicit quality indicator set for measurement of quality of care in patients with cirrhosis. Clin Gastroenterol Hepatol 2010;8:709-717.
19) Orman ES, Ghabril M, Chalasani N. Poor performance status is associated with increased mortality in patients with cirrhosis. Clin Gastroenterol Hepatol 2016;14:1189-1195.e1181.
20) Ghaoui R, Friderici J, Visintainer P, Lindenauer PK, Lagu T, Desilets D. Measurement of the quality of care of patients admitted with decompensated cirrhosis. Liver Int 2014;34:204-210.
21) Lim N, Lidofsky SD. Impact of physician specialty on quality care for patients hospitalized with decompensated cirrhosis. PloS One 2015;10:e0123490.
22) Porter ME, Larsson S, Lee TH. Standardizing patient outcomes measurement. N Engl J Med 2016;374:504-506.

23) Creswell JW, Plano Clark V. Choosing a mixed methods design. In: Designing and Conducting Mixed Methods Research. Thousand. Oaks, CA: Sage Pubications; 2011:53-106.
24) Fitch K, Bernstein SJ, Aguilar MD, Burnand B, LaCalle JR. The RAND/UCLA Appropriateness Method User's Manual. Santa Monica, CA: RAND Corp; 2001.
25) Grossman J, MacLean CH. Quality indicators for the care of osteoporosis in vulnerable elders. J Am Geriatr Soc 2007;55(Suppl 2):S392-S402.
26) MacLean CH, Louie R, Leake B, McCaffrey DF, Paulus HE, Brook RH, et al. Quality of care for patients with rheumatoid arthritis. JAMA 2000;284:984-992.
27) Maggard MA, McGory ML, Shekelle PG, Ko CY. Quality indicators in bariatric surgery: improving quality of care. Surg Obes Relat Dis 2006;2:423-429; discussion 429–430.
28) McGory ML, Kao KK, Shekelle PG, Rubenstein LZ, Leonardi MJ, Parikh JA, et al. Developing quality indicators for elderly surgical patients. Ann Surg 2009;250:338-347.
29) Shekelle PG, MacLean CH, Morton SC, Wenger NS. Acove quality indicators. Ann Intern Med 2001;135(Pt 2):653-667.
30) Vilstrup H, Amodio P, Bajaj J, Cordoba J, Ferenci P, Mullen KD, et al. Hepatic encephalopathy in chronic liver disease: 2014 Practice Guideline by the American Association for the Study of Liver Diseases and the European Association for the Study of the Liver. Hepatology 2014;60:715-735.
31) MacLean CH, Kerr EA, Qaseem A. Time out—charting a path for improving performance measurement. N Engl J Med 2018;378:1757-1761.

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