

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Purple text represents the responses from measure developers.

Red text denotes developer information that has changed since the last measure evaluation review.

Brief Measure Information

NQF #: 3592

Corresponding Measures:

De.2. Measure Title: Global Malnutrition Composite Score

Co.1.1. Measure Steward: Academy of Nutrition and Dietetics

De.3. Brief Description of Measure: This composite measure of optimal malnutrition care focuses on adults 65 years and older admitted to inpatient service who received care appropriate to their level of malnutrition risk and/or malnutrition diagnosis if properly identified. Best practices for malnutrition care recommend adult inpatients to be screened for malnutrition risk, assessed to confirm findings of malnutrition if found at-risk, and have the proper severity of malnutrition indicated along with a corresponding nutrition care plan that addresses the respective severity of malnutrition.

The malnutrition composite measure includes four component measures which are first scored separately. The overall composite score is derived from averaging the individual performance scores.

- 1. Screening for malnutrition risk at admission.
- 2. Completing a nutrition assessment for patients who screened for risk of malnutrition.
- 3. Appropriate documentation of malnutrition diagnosis in the patient's medical record if indicated by the assessment findings.
- 4. Development of a nutrition care plan for malnourished patients including the recommended treatment plan.

These four measures represent the key processes of care and generated markers of malnutrition associated with the risk identification, diagnosis, and treatment of malnutrition in older hospitalized adults as supported by clinical guidelines.

1b.1. Developer Rationale: The components of this composite measure are supported by clinical guidance that recommends the following: (1) malnutrition screening for patients admitted into the acute inpatient care setting; (2) nutrition assessment for patients at-risk of malnutrition in order to form the basis for an appropriate nutrition intervention; (3) appropriate recognition, diagnosis, and documentation of the nutrition status of a patient in order to address their condition with an appropriate plan of care and communicate patient needs to other care providers .

Implementation of this measure has supported hospitals in the timeliness of the malnutrition risk screening process, the hand off of patients at-risk of malnutrition to Registered Dietitian Nutritionists (RDNs) in the hospital for appropriate nutritional assessment and development of nutrition care plans with recommended

nutrition interventions, and the subsequent medical diagnosis and execution of the nutrition care plan with support from the patient's physician. Evidence demonstrates that implementing a standardized protocol for screening, assessment, diagnosis and care planning results in better identification of malnourished patients and subsequent improvements in rates of nutrition intervention for the malnourished. Our outcomes modeling and those reported in other studies also demonstrates the benefits to patient outcomes, specifically reduced risk of 30-day readmissions.

S.4. Numerator Statement: The Global Malnutrition Composite Score is comprised of four component measures which are scored separately and who's population is sourced from the overall composite measure denominator.

- 1. Screening for malnutrition risk at admission
- 2. Completion of a nutrition assessment for patients who screened for risk of malnutrition
- 3. Appropriate documentation of malnutrition diagnosis for patients identified with malnutrition
- 4. Development of a nutrition care plan for malnourished

S.6. Denominator Statement: The measure population from which the composite's component measures are sourced from are patients aged 65 years and older who are admitted to an acute inpatient hospital.

S.8. Denominator Exclusions: All Four Component Measures: patients with a length of stay less than 24 hours

Component Measure #1 only: admission to screening time interval greater than 48 hours

Component Measure #3 and #4 only : Discharge status of hospice or left against medical advice

De.1. Measure Type: Composite

S.17. Data Source: Electronic Health Records

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Most Recent Endorsement Date:

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?

Preliminary Analysis: New Measure

Criteria 1: Importance to Measure and Report

• 1a. Evidence

1a. Evidence. The evidence requirements for a **structure**, **process or intermediate outcome** measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

Systematic Review of the evidence specific to this measure? Xes No
 Quality, Quantity and Consistency of evidence provided? Xes No
 Evidence graded? Xes No

Evidence Summary

- The following guideline was cited for three components of composite measure Mueller C, Compher C & Druyan ME and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Board of Directors. A.S.P.E.N. Clinical Guidelines: Nutrition Screening, Assessment, and Intervention in Adults. J Parenter Enteral Nutr. 2011;35: 16-24.
- Grading of evidence for three components of composite measure was presented as identified by A.S.P.E.N
- The guideline recommendations corresponded with the measure components and suggested the following:
 - screening for nutrition risk for hospitalized patients as it is associated with longer hospital stay. (evidence grade E);
 - utilize nutrition assessment tools to identify malnourished patients, who often have more complications and longer hospitalizations than do patients with optimal nutrition status. (evidence grade E); and
 - Nutrition support intervention is recommended for patients identified by screening and assessment as at risk for malnutrition or malnourished. (evidence grade C)
- Systematic Review of evidence was provided for each component of the composite measure. Several studies were cited for each component demonstrating the impact of using a malnutrition screening tool in a hospital setting, the impact of nutrition risk on hospital outcomes, and the impact of interdisciplinary malnutrition quality improvement initiatives.

Exception to evidence

N/A

Questions for the Committee:

- Questions specific to the measure information provided on evidence
- For structure, process, and intermediate outcome measures:
 - \circ What is the relationship of this measure to patient outcomes?
 - How strong is the evidence for this relationship?
 - \circ ~ Is the evidence directly applicable to the process of care being measured?
 - If derived from patient report, does the target population value the measured process or structure and find it meaningful?

Guidance from the Evidence Algorithm

Process measure based on systematic review (box 3) \rightarrow QQC presented (Box 4) \rightarrow Quantity: high; Quality: moderate; Consistency: moderate (Box 5) \rightarrow Moderate (Box 5b) \rightarrow Moderate

Preliminary rating for evidence: 🗆 High 🛛 Moderate 🗆 Low 🗆 Insufficient

Rationale:

Additional comments provided by the developer regarding the conditional care process for the malnutrition workflow –

The Global Malnutrition Composite Score components reflect a clinical workflow of critical steps for timely identification and treatment of patients identified with malnutrition or at risk. The process for risk identification, diagnosis, and treatment of malnutrition necessitates a multi-disciplinary care team that begins with identification of an initial risk population for more thorough assessment including a nutrition focused physical exam (NFPE) by a registered dietitian nutritionist (RDN) in the first days of the hospital stay (see Figure 1). In turn, the RDN provides the necessary treatment recommendations to address nutritional status and the clinical indicators that inform a medical diagnosis of malnutrition completed by a physician. This care plan is then advanced with the accompanying medical diagnosis, facilitating necessary interventions for the patient. Furthermore, the identification of malnutrition while hospitalized has significant implications for care

coordination at discharge and subsequently post-discharge with the next in line provider (e.g., the primary care physician, a skilled nursing facility, a patient rehabilitation center, home health service, etc.).

Figure 1. Malnutrition Care Workflow



Due to this team-based process, one step is conditional for the next subsequent step to be taken. If an admitting nurse does not screen patients for malnutrition, with few exceptions, most RDNs would not see atrisk patients for a consult to assess for malnutrition. If RDNs do not complete an assessment to identify malnutrition, most of those patients would go missed by the physician who is not trained in nutrition and it is likely not prioritizing it. Finally, the same consideration is necessary for most patients who are malnourished to receive the treatment recommended in the care plan who often require physician approval for certain nutrition orders to be delivered. Therefore, these concepts which are reflected in the four components cannot be removed or they would interrupt the follow through on the cascade of steps.

• 1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

Maintenance measures - increased emphasis on gap and variation

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- Performance data from 56 acute care hospitals and 179,336 patients was provided. The performance scores ranged from 1.18 to 3.77. The median and mean performance scores were 3.32 and 3.07 respectively.
- Race and ethnicity data from the testing cohort included 77.8% White, 9.68% Black, 1.59% Asian or Pacific Islander, and 9.56% Other. In addition 4.91% who were identified as Hispanic.

Disparities

Table below presents Disparities data

Table: Malnutrition and Malnutrition Risk Outcomes By Age, Race/Ethnicity and Gender Strata

Measure	Malnutrition Risk (Relative Diff to Reference)	RD Diagnosis (Relative Diff to Reference)	MD Diagnosis (Relative Diff to Reference)	Malnourished Readmissions (Relative Diff to Reference)	Patients ≥ Median LOS (Relative Diff to Reference)
General Population (Reference)	14.01%	22.21%	6.28%	19.47%	50%
Age 18-34 35-64 ≥65	6.31% (-54.96%) 14.56% (3.93%) 17.63% (25.39%)	14.14% (- 34.33%) 21.21% (-4.50%) 24.56% (10.58%)	1.73% (-72.45%) 6.02% (-4.14%) 8.95% (42.52%)	19.31% (- 0.822%) 19.87% (2.05%) 19.21% (-1.34%)	32.46% (-35.08%) 50.69% (1.38%) 58.73% (17.46%)
Race/Ethnicity White Black Other Hispanic	14.96% (6.78%) 15.13% (7.99%) 11.05% (- 21.13%) 10.12% (-27.77)	21.00% (-5.48%) <i>28.16% (26.79%)</i> 23.98% (7.97%) 20.18% (-9.14%)	6.10% (-2.87%) 8.00% (27.39%) 7.16% (14.01%) 4.32% (-31.21%)	18.69% (-4.01%) 26.15% (34.31%) 15.41% (- 20.85%) 17.50%(-10.11%)	48.58% (-2.84%) <i>59.92% (19.90%)</i> 53.36% (6.72%) 43.07% (-13.86%)
Gender Male Female	<i>16.43% (17.27%)</i> 12.34% (- 11.93%)	23.53% (5.94%) 20.95% (-5.67%)	7. <i>79% (24.04%)</i> 5.23% (-16.72%)	21.00% (7.86%) 17.91% (-8.01%)	55.57% (11.14%) 46.00% (-8.00%)

Questions for the Committee:

- Specific questions on information provided for gap in care.
- Is there a gap in care that warrants a national performance measure?
- If no disparities information is provided, are you aware of evidence that disparities exist in this area of healthcare?

Preliminary rating for opportunity for improvement:	High	🛛 Moderate	🗆 Low	
Insufficient				

1c. Composite – Quality Construct and Rationale

Maintenance measures – same emphasis on quality construct and rationale as for new measures.

1c. Composite Quality Construct and Rationale. The quality construct and rationale should be explicitly articulated and logical; a description of how the aggregation and weighting of the components is consistent with the quality construct and rationale also should be explicitly articulated and logical.

This composite measure includes four component measures which are first scored separately. The overall composite score is derived from averaging the individual performance scores.

- 1. Screening for malnutrition risk at admission.
- 2. Completing a nutrition assessment for patients who screened for risk of malnutrition.
- 3. Appropriate documentation of malnutrition diagnosis in the patient's medical record if indicated by the assessment findings.
- 4. Development of a nutrition care plan for malnourished patients including the recommended treatment plan.

These components represent the malnutrition care recommend adult inpatients to be screened for malnutrition risk, assessed to confirm findings of malnutrition if found at-risk, and have the proper severity of malnutrition indicated along with a corresponding nutrition care plan that addresses the respective severity of malnutrition. It necessitates a multi-disciplinary care team that begins with identification of an initial risk

population for more thorough physical assessment by registered dietitians (RDN). The measure is constructed as an arithmetic average of the four components weighed equally.

Questions for the Committee:

- Are the quality construct and a rationale for the composite explicitly stated and logical?
- Is the method for aggregation and weighting of the components explicitly stated and logical?

Preliminary rating for composite quality construct and rationale:

⊠ High □ Moderate □ Low □ Insufficient

Rationale:

Additional comments from the developer regarding the construct of the composite measure -

In 2016, the component measures were originally presented as four individual process measures reflecting the same core steps with slight modifications from the current component measures in the composite. When submitted, we were much earlier in the development, testing and implementation process, ultimately not receiving endorsement support from the Health and Well-being Committee. However, the committee did make a recommendation to consider combining these measures into a composite measure given the conditional relationship of the measures which each other. The measures were also brought before the Measures Application Partnership for the IQR program and provided the same recommendations. After careful consideration and consultation with experts in the field, we pursued the development and testing of the composite measure currently under review. It was critical that these four components remain a part of the composite because independently, these component measures only provide a fraction of the necessary information on quality of care for patients at-risk of malnutrition and those with a confirmed diagnosis. For example, knowing which patients have been assessed out of those who were initially identified as at-risk, but not knowing if the appropriate proportion of patients were screened upon admission would be an insufficient assessment of quality of care as it would leave out a fraction of the patient population that may be malnourished or at-risk.

• Committee Pre-evaluation Comments: Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence to Support Measure Focus: For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Does it apply directly or is it tangential? How does the structure, process, or outcome relate to desired outcomes? For maintenance measures – are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission? For measures derived from a patient report: Measures derived from a patient report must demonstrate that the target population values the measured outcome, process, or structure.

- Much of the evidence is repeated for each component of the measure. This evidence seems to support
 nutritional intervention and assumes that screening/assessment/diagnosis has taken place. However,
 the evidence linking nutritional status and length of stay or rehospitalization does not consider
 whether nutritional status is independently associated with these outcomes or is a reflection of sicker,
 more complex patients. Some of the evidence for nutritional support includes interventions that occur
 outside the hospital or are of a duration that likely includes post-discharge nutritional support.
- this is fine
- The evidence provided is about the importance of nutrition, and the impact of poor nutrition on outcomes, but does not relate to either the individual care processes that are parts of the composite measure or the measure as a whole. Furthermore, the evidence cited seems to be pretty low quality evidence grade E and C. It's hard to know exactly what these grades mean, but my best interpretation of the Evidence Attachment is that this is pretty weak evidence. There is no evidence for the composite as formulated, or even for one of the four elements.

- This measure was not derived from a patient report.
- directly tied to both process and outcome
- The composite's logic (screen -- > assess --> "grade" in EMR --> develop treatment plan) is well supported by the evidence across all 4 components of the composite.
- The evidence offered for the global malnutrition composite score appears to relate directly to each measure. However, the evidence grade varies from Grade E for malnutrition screening and malnutrition assessment to Grade C for medical diagnosis of malnutrition and implementation of nutrition intervention for malnourished patient. Evidence of the impact of the third and fourth measure suggests a stronger relationship to outcomes (increase length of stay, 30-day readmission risk, mortality risk, infections, complications and high hospital costs). Evidence offered by new studies does not contradict the findings of the earlier systematic literature review. The only untoward effects with malnutrition interventions were problems with tolerance (nausea, vomiting and diarrhea).
- The evidence relates directly to the composite process measure but is somewhat variable and of low grade, E, or level IV and V.
- The composite measure is somewhat supported by the evidence. The 2011 A.S.P.E.N guidance is a bit dated, and the evidence cited is, for the most part "E."
- The measure sponsors submitted an extensive updated summary of the research conducted on each of the four component measures, submitted as a systematic literature review, showing increased level of evidence to support the essential relationship of each key process to identify and treat those who are positive. Updated validation and reliability testing of the composite measure across 56 hospitals with had major findings that those with malnutrition are significantly related to LOS (increased 3-day LOS) and readmissions (reduced relative risk) after controlling for demographics and primary diagnosis. In this vulnerable population with food insecurity, this interdisciplinary approach to healthcare of older adults is essential, supported by hospital care systems. The evidence demonstrates that screening and assessment does result in diagnosed malnourished patients, who are then treated. The quantity, quality and consistency of the evidence is provided and graded. Following the 2016 Health and Well-being Committee's recommendation to pursue composite measure development, rather than separate process measures, enabled the sponsors to create a body of evidence to determine both quality of healthcare and patient outcomes. Each of the four components has equal weighting within the composite measure. The sponsors report that their continued testing and development of their predictive model is comparable as an overall measure to being implemented by CMS for similar purposes (p. 13, testing attachment)
- Not aware of new studies. See comments below regarding reflections on outcomes being measured, etc.

1b. Performance Gap: Was current performance data on the measure provided? How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Disparities: Was data on the measure by population subgroups provided? How does it demonstrate disparities in the care?

- Not clear that malnutrition is a cause or a reflection of factors that contribute to undesirable outcomes.
- standardizing the tool for time in care and age will help reduce disparities bias in screening and improve nourishment approaches by the hospital.
- The data cited here are about disparities in nutrition, not the preventive service.
- This is a process measure. Performance data was provided. There is level IV and V findings that screening, assessing, and intervening for nutritional risk can reduce hospitalizations and complications. The evidence around mortality is mixed. The performance gap is measured those over 65. There is additional opportunity to think about subpopulations by race, ethnicity, and socioeconomic status.

- Data provided
- While evidence is provided in support of a performance care gap overall, the data provided to assess inequities in this process are either incomplete or insufficient (it is difficult to assess which given the paucity of detail/explanation in the "Disparities" table). An important question for discussion: are the developers being asked to assess disparities in malnutrition or in the screening, assessing, etc. for malnutrition? If the latter (which would make sense given the focus on care process disparities) I do not think the table taps into that. Since the composite is conditional on the step that came before, so too must the denominators. Much more contextual/denominator data must be provided before I can assess. I do appreciate the developer not using White as the referent category, though.
- Any disparities observed in The Malnutrition and Malnutrition Risk Outcomes By Age, Race/Ethnicity and Gender Strata are likely related to health-related social needs (income, food security, social isolation, etc.), which were not included in the testing of the measures.
- Current performance data on the measure was provided but was only moderate and barely warrants a national performance measure.
- Performance gap is moderate. However, little is provided about disparities. Data were presented on the =>65 population and disparities data were presented for the =>18 population. Based on the data sources mentioned, there should be demographic and disparities data for the =>65 population.
- The sponsors use a bootstrap resampling methodology to generate a 95% confidence interval around composite score mean. All group providers were then groups in low (below average), moderate and high (above average) levels of performance so that a tiered approach was available to drive improve performance, and appropriately distinguish sites with varying degrees of performance among the component measures. The resulting differences ultimately translated to variation in performance on the overall composite measure. The sponsors reported that the sample of sites included in this testing were relatively homogeneous because the participating hospitals have been targeting improvement on these quality measures for 1-3 years. Published in 2020, their findings of a 4-month QI project involving 27 hospitals reported aggregate improvements across all 4 care processes, with statistically significant improvements in nutrition assessment and malnutrition diagnosis. They also tested the outcome model, from which the relative risk reduction for 30-day readmission was reported: 24% lower likelihood of 30-day readmission for those malnourished older adults with a nutrition care plan.
- I am concerned that the scope of disparities is limited to race, ethnicity and gender. The utility and impact of this screen is also dependent on the patient's insurance status, language and other socio demographic issues.

1c. Composite Performance Measure - Quality Construct (if applicable): Are the following stated and logical: overall quality construct, component performance measures, and their relationships; rationale and distinctive and additive value; and aggregation and weighting rules?

- Overall quality construct: stated and logical. Component performance measures: stated and logical but each subsequent measure is dependent on performance of the prior measures. Unclear how this measure will work if 1) "earlier" components are missing data, but last component indicates nutritional care plan has been implemented. Also unclear how missing vs not/applicable will be handled.
- Yes, though I was a bit surprised the tool mentioned didn't appear to mention lab results or required testing for clinical values. Did I miss it?
- Since the measure involves four steps, each of which must follow from the previous one, I don't believe that a composite score that averages them makes sense. I believe this is the same as the issued raided by the SMP member on p. 9.
- This is a composite performance measure with components around screening, completions of a nutritional assessment, appropriate documentation, and development of a nutrition care plan. There is a logic model. All components are addressed.

- yes
- High rating from me on this.
- The measure developers, based upon the tests of internal consistency (Chronbach's alpha and item-tototal correlations), suggest that equal weighting of each component to the composite score.
- Overall quality construct, component performance measures, their relationships, rationale, and distinctive additive value were fairly well described but somewhat variable in direction and strength in the several studies cited. There were no aggregation and weighting rules described.
- Construct is logical.
- All requirements for the quality construct are stated and logical.
- The components of this measure are highly dependent on the first step, which is screening. The data
 has been limited to patients who have an intake screen within 48 hours, and in cases after 48 hours
 were excluded. It would be helpful to see the typical demographic data for patients who receive
 screening after 48 hours, as it is important to see whether there are demographic characteristics and
 other potential indicators of drivers in health inequities whereby those who are screened later are
 inadvertently excluded from the potential benefit of this recommendation. Do non-English speaking
 patients have delays in screen due to a need for a translation line?

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

2b. Validity: <u>Testing</u>; <u>Exclusions</u>; <u>Risk-Adjustment</u>; <u>Meaningful Differences</u>; <u>Comparability</u>; <u>Missing Data</u>

- $\label{eq:composite} \textbf{2c. For composite measures:} \underbrace{\textbf{empirical analysis}}_{\textbf{composite approach}} \textit{support composite approach}$
 - Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

• Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Composite measures only:

2d. Empirical analysis to support composite construction. Empirical analysis should demonstrate that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct.

eCQM Technical Advisor(s) review (if not an eCQM, delete this section):

Measure	Evidence				
Submitted measure is an HQMF	The submitted eCQMspecifications follow the industry accepted format for eCQM (HL7 Health Quality Measures Format (HQMF)).				
compliant eCQM	HQMF specifications 🛛 Yes 🖾 No				
	N/A – All components in the measure logic of the submitted eCQM are represented using the HQMF, QDM, or CQL standards; OR				
Documentation of HQMF, QDM, or CQL limitations	Submitted eCQM contains components that cannot be represented due to limitations of HQMF, QDM, or CQL and the submission explains the work around for these limitations; OR				
	Submitted eCQM contains components that cannot be represented due to limitations HQMF, QDM, or CQL and the submission does NOT explain the work around for these limitations.				
	The submitted eCQM specifications uses existing value sets when possible and uses new value sets that have been vetted through the VSAC OR				
Value Sets	Some value sets used in the submitted eCQM are not present in the NLM				
	Value Set Authority Center but the measure developer has provided justification for using such value sets				
Measure logic is	Submission includes test results [from a simulated data set] demonstrating the measure logic can be interpreted precisely and unambiguously. – this includes 100% coverage of measured patient population testing with pass/fail test cases for each population; OR				
unambiguous	Submission includes test results [from a simulated data set] demonstrating the measure logic cannot be interpreted precisely and unambiguously.				
	[This section should include summary level results of feasibility scorecard]				
	Number of data elements included in measure calculation:				
	Number of data elements scoring less than 3 on scorecard:				
	[IF data elements score less than 3 –provide following developer responses to questions on Feasibility Plan portion of scorecard]				
Feasibility Testing	Data Element 1				
	 List low scoring domains: Availability – Accuracy – Standards - Workflow 				
	How is the data element used in computation of measure?				
	How the data element is feasible within the context of the measure logic?				
	What is the plan for readdressing the data element?				

Complex measure evaluated by Scientific Methods Panel? \boxtimes Yes \square No

Evaluators: NQF Scientific Methods Panel

Methods Panel Review (Combined)

Methods Panel Evaluation Summary:

This measure was reviewed by the Scientific Methods Panel and discussed on the call. A summary of the measure and the Panel discussion is provided below along with the developer response to some inquires.

Reliability

• Reliability testing conducted at the measure score level to calculate the ICC. With case minimums, the ICC calculated was 0.839, and without case minimums, it resulted in an ICC of 0.647 (The measure specifications are updated to reflect the case minimum requirement of 20 cases for calculation).

• One reviewer suggested an alternate calculation for ICC at the health system level to yield more accurate result for ICC would be B/(B+W/n) where n is the number of sites per system and W/n is the variance of the average of scores across the n sites

Developer Response -

- The composite measure is intended to be implemented at the site level. However, a key limitation of the research data set was the lack of a primary care provider (PCP) indicator, i.e. a variable that facilitated grouping of patient measures by attributed/assigned physician or mid-level clinician within practice sites. As a result, direct derivation of the between- and withinsite provider variance components was not directly supported by the raw data, so we elected to utilize a system-level ICC as a surrogate, understanding that it would likely underestimate the true site-level ICC.
- we developed a complementary approach to ICC estimation whose results are applicable at the site level and continue to support the conclusion that the composite measure's reliability falls within the acceptable range. Specifically, prior to fitting the data to the mixed effects model, five (5) versions of the patient-level data set were generated by randomly assigning patients to provider "blocks" of sizes 10, 20, 30, 40, and 50, respectively, within each practice site. Pragmatically, the provider blocks can be regarded as idealized practice sizes that 1) might be encountered if patients were randomly paneled to providers and 2) the number of physicians practicing at each site was held constant across health systems.
- After creating the provider blocks, the intercept-only mixed effects model was then refitted to each data set, incorporating practice site—instead of health system—as the random effect. In turn, ICC's were generated using the between- and within-site variance components extracted from each model. The model-derived ICC's are presented in the following table:

Number of Providers	Mean Panel Size	ICC
10	320	0.89
20	160	0.82
30	106	0.76
40	80	0.73
50	64	0.65

• As before, the results suggest that composite measure reliability is satisfactory and falls within the acceptable range specified by NQF. Moreover, we anticipate that the between-provider variance and, therefore, the site-level ICC will be higher in the real world, reflecting natural variation that arises from fluctuations in the number of providers per site and panel sizes.

Validity

- Reviewers generally agreed with the analysis. Empirical validity testing conducted at both the measure score and data element level:
- Empirical testing of the construct validity of the overall composite measure at the score level was conducted. A hierarchical linear regression model was used to demonstrate that the predictability of the model significantly improved when the components in aggregate were included into the model over standard predictors of these outcomes such as patient characteristics, primary diagnoses, and comorbidities
- Construct validity of the critical data elements for the individual measure components was tested by developing a generalized linear (logistic) regression model

Overall comments from SMP Members

Although is measure passed on reliability and validity during the preliminary analysis, it was still pulled
for discussion by SMP members. One SMP member highlighted that the process-outcome correlations
to establish validity on the measure were constructed in an unexpected direction. Namely, the
correlations are associated with "worse" outcomes (e.g. longer stay in hospitals) for patients.
Therefore, one SMP member raised concerns that the measure is actually measuring how sick patients
are instead of quality of care. The SMP member also raised questions that the direction of the
correlations between certain component with the outcome is not the always the same direction of the
conditions of how each component of the composite was captured by showing a graphic on the
measure workflow.

Additional comments from developer -

- As reported in the testing attachment, the composite measure results are strongly correlated to important clinical outcomes associated with malnutrition in the literature, 30-day readmissions and length of stay. As supported by decades of evidence, malnutrition and risk of malnutrition are both associated with adverse and poor outcomes for hospitalized patients including longer length of stay, higher 30-day readmission risk, higher mortality, higher risk of infection and complications, etc.
- For the item-level analysis (referenced on page 12 of the testing attachment), we studied the association with the measure populations and outcomes traditionally associated with those populations and found the same correlations in our data. Patients who screened at-risk experienced worse outcomes than those not at-risk or the general population. The same outcome was experienced by those who were assessed compared to those who did not since many of the patients who needed a nutrition assessment were already experiencing higher morbidity which would necessitate a nutrition consult. The same can be said for each of the component measure as each of the four measures ultimately identifies a patient population with higher morbidity than the general population. However, we sought to ensure that the entire process of identification, supported by the development of a care plan to address the malnutrition, was indeed beneficial to patients.
- We ran a measure-level analysis (as described on page 11 of the testing attachment) to see how the quality goal of the composite (care plan for malnourished patients) was associated with patient outcomes.
- The measure-level analysis demonstrated that nutrition care plans may be associated with a reduced risk of 30-day readmission for those with malnutrition vs those who are diagnosed with malnutrition but do not have a nutrition care plan. This specific analysis tested the association between 30-day readmissions and hospital length of stay and the total quality construct of the composite reflected by a comparison of the patients who were indeed identified and diagnosed with malnutrition AND had a nutrition care plan documented versus those that did not have the care plan.
- We identified that although 30-day readmissions were inversely associated, length of stay was not. This is because, out of the patients who are diagnosed with malnutrition by a physician, there is still a significant portion of patients who were diagnosed with malnutrition but never saw a registered dietitian nutritionist or other clinically qualified nutrition professional and almost never had a nutrition care plan documented. These patients often were discharged earlier than those who did get to see a dietitian and receive the proper nutrition treatment plan. This is a quality gap that many of the hospitals which reported the data to us for testing, are actively working to address. As of the last cross-section of all hospitals (N=53) reporting data in Q3 2020, only 73% of patients with a diagnosis of malnutrition had any nutrition care

plan documented. Ultimately, there is overwhelming evidence (as cited in the evidence attachment) that nutrition interventions do indeed support reductions in 30-day readmissions, length of stay, and cost of care. In future studies, we will more thoroughly examine this phenomenon surrounding malnourished patients, nutrition care plans and length of stay in the data that continue to be reported by hospitals around the country.

• At the end of this discussion, the subgroup decided to accept the preliminary analysis decisions for this measure. This measure will move to the Standing Committee for evaluation.

Questions for the Committee regarding reliability:

- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- The Scientific Methods Panel is satisfied with the reliability testing for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The Scientific Methods Panel is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?

Questions for the Committee regarding composite construction:

- Do you have any concerns regarding the composite construction approach (e.g., do the component measures fit the quality construct and add value to the overall composite? Are the aggregation and weighting rules consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible?)?
- The [staff] or [Scientific Methods Panel] is satisfied with the composite construction. Does the Committee think there is a need to discuss and/or vote on the composite construction approach?

Preliminary rating for reliability:	🛛 High	🛛 Moderate	🗆 Low	□ Insufficie	nt
Preliminary rating for validity:	🗆 High	🛛 Moderate	🗆 Low	🗆 Insufficie	ent
Preliminary rating for composite of	construction	: 🗆 High 🛛	Moderate	e 🗆 Low	🗆 Insufficien

The ratings for the SMP review were as follows:

- Reliability: H-2; M-4; L-0; I-2 (Pass)
- Validity: H-0; M-6; L-0; I-2 (Pass)
- Composite: H-2; M-3; L-2; I-1 (Pass)

Committee Pre-evaluation Comments: Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability-Specifications: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

- Given that malnutrition may be associated with other patient factors associated with longer LOS and/or readmission, why no risk adjustment model?
- Established assessment tool, well tested.
- The measure worksheet does not clearly describe the calculation of the measure. I presume that the steps are as follows: (1) for each facility, calculate the proportions corresponding to the four bullets in S.4 (percent of patients who were screened for malnutrition risk at admission, etc.) and (2) average

these proportions for each facility. This needs to be more clearly stated, and the time period over which the proportions are calculated should also be stated. The Methods Panel evaluation summary suggests that the specifications have been changed to require a minimum of 20 cases per calculation. That should be clarified in the measure worksheet. It should also be clarified whether this requirement applies to each of the four components or overall.

- This is a low-burden and non-intensive process that could be consistently implemented. All materials were presented clearly.
- None
- No concerns
- I am unable to judge this criterion based upon available information.
- All data elements are clearly described. No codes were provided. The four steps in the composite
 measure are clear, but it is not obvious that each of the four steps were described in full in the studies
 cited. There was no risk/case-mix adjustment described as the authors felt that the measurement
 process included risk and case-mix factors. The authors plan to use EHR data for the measure, but I'm
 not sure that the EHR information will include all four components of the measure in various settings.
- All screening and all assessments are not of equal value. However, the measure does not specify which
 screenings and assessments are to be used or how a hospital/health system/clinician determines
 which screening and assessment tools to use. Results may vary based on the screening and
 assessment tools, as well as the type of clinician administering the tools.
- The sponsors reported that the reliability testing was conducted Jan-Dec 2019 at the hospital level. They tested a separate and more recent dataset constructed to complete additional testing for the composite measure reliability. A total of 179,336 patients aged 65 years and older were included in the testing population across 56 acute care hospitals in 10 states. With regard to using a calculation of intraclass correlation (ICC) to detect signal to noise, a reliability score of 0.70 or greater is considered acceptable for drawing conclusions about groups. With case minimums, the ICC calculated was 0.839 and without case minimums it resulted in an ICC of 0.647. This statistic indicates that the composite measure is well within the range established as acceptable for reliability, meaning the composite performance measure score is able to detect meaningful differences among provider groups.
- As stated in the methods, this measure necessitates a series of events (the four components are dependent on the one prior in order to be effective)- there is not currently one standardized screening tool, and physician must place the order for the consult and follow-up on the recs in a timely fashion, which I describe below, can make implementation challenging.

2a2. Reliability - Testing: Do you have any concerns about the reliability of the measure?

- Reliability testing produced an inverted bell curve in terms of performance.
- Nope. Established tool, well tested.
- The only empirical reliability testing that was done is essentially to see if the four components hang together. I would like to see reliability studies of the four components individually, e.g. to what degree does the recorded "percent of patients who were screened for malnutrition risk at admission" actually reflect what happened in that facility.
- No
- None
- After reviewing SMP comments and testing / developer responses, I am satisfied.
- Based upon available information, it would seem that the case minimums could influence the performance of the measure(s) for providers with a smaller number of cases.
- I rated reliability as moderate and feel that the committee should discuss this thoroughly, as I have some concerns.

- Yes. The variation in screening and assessment tools does not assure the reliability of the composite measure.
- No concerns
- No

2b1. Validity -Testing: Do you have any concerns with the testing results?

- Not at this time
- No.
- The questions raised by the SMP member summarized on p. 9 (e.g. correlations in the wrong direction) are very troubling to me.
- The results seem to be valid. The logic model does reference decreased mortality rates, but these results are not inclusive. You might consider a revision of the logic model.
- None
- I do not
- No concerns identified.
- I rated validity as moderate but do have some concerns and feel that the committee should discuss this thoroughly.
- See above comments.
- No concerns
- As described above, additional variables would improve the validity of the results.

2b4-7; 2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment) 2b2. Exclusions: Are the exclusions consistent with the evidence? Are any patients or patient groups inappropriately excluded from the measure? 2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? Was the risk adjustment (case-mix adjustment) appropriately developed and tested? Do analyses indicate acceptable results? Is an appropriate risk-adjustment strategy included in the measure?

- Yes, there are strong social risk factor variables associated with the measure focus. No risk-adjustment strategy.
- This is great. Do wish we had it for all ages, not just 65+ folks. Food insecurity is doubled even in my own county right now. Better tools to identify malnourishment as the outcome based on standard approaches would be awesome.
- The Testing Attachment says that there are no exclusions, but the Measure Worksheet in S.8 describes denominator exclusions for 3 of the 4 components.
- There is an opportunity to better understand the social risk factors. The factor most frequently included is age. There is opportunity to better understand socioeconomic status which may influence interventions post hospitalization i.e. understanding the ability of a patient to access nutritional food prior to and post admission. Economic screening is referenced in the clinical guideline but was not referenced in the summarized studies.
- No concerns
- If the fourth element of the composite (treatment) is confined to a plan implemented during the inpatient stay, then I do not see a need for social risk adjustment. However, since one of the outcomes (readmissions) implies the patient has been discharged and elements of the nutrition care plan might fall to the patient, then yes, social risk adjustment should absolutely be considered given community level differences in food access.

- No social risk factor data were collected for testing, which would influence this measure.
- Exclusions are consistent with the evidence. There was little discussion of risk adjustment.
- The JCAHO specifies that screening occur within 24 hours of admission. Those admitted for up to 24 hours are excluded from the measure. No rationale was provided for this exclusion. Patients warranting screening, as specified by JCAHO, may be excluded from what is measured.
- The composite measure is not risk adjusted.
- Because the component measures relate to a sequential process, missing data vs. "Not applicable" could be a threat to validity. The last two components: diagnosis and intervention, reflect meaningful differences in quality and are dependent (sequentially) on the first two components. The evidence provided supports diagnosis and intervention.
- Clinical lab data as a part of the tool was not found in materials, curious if that is evaluated by clinicians on top of the tool.
- I don't know how to interpret the meaningful difference results. I do note the sentence in 2b4 (Our specific sample of sites is relatively homogeneous because the participating hospitals have been targeting improvement on these quality measures for 1-3 years.), which I interpret as saying the measure does NOT distinguish differences among the hospitals in which it was tested.
- No
- Specific to age greater than 65, and inpatient stay without transfer to hospice is focused but appropriate.
- No concerns
- Missing data could present a threat to the measure validity.
- The multiple data sources do raise some threats to validity as not all of the differences are statistically significant. The analysis identifies meaningful differences in some but not all of the studies of the different steps in the composite measures. Not all of the studies produce comparable results, especially when considering outcomes. Missing data does constitute a threat to this measure.
- The tools used for screening and assessing, and how they are administered, may have a substantial
 impact of reliability and validity. Furthermore, data on disparities specific to the target population
 were not provided.
- No concerns
- Yes. None of the evidence presented from which the initial rec was based on offers key information on
 insurance status or other variables that would determine whether this recommendation is broadly
 beneficial for patients 65 and older. Patients at risk for malnutrition may have other oral
 health/dentition issues which further exacerbate. When patients are discharged, whose responsibility
 is it to pay for the dietary recommendations? How was readmission measured is it readmission to the
 same hospital, or readmission to any hospital? If the former, then we may be missing those with
 unstable housing or other risk factors whereby they seek care in different settings.

2c. Composite Performance Measure - Composite Analysis (if applicable): Do analyses demonstrate the component measures fit the quality construct and add value? Do analyses demonstrate the aggregation and weighting rules fit the quality construct and rationale?

- Component measures fit the quality construct. The evidence supports the final two components of the sequential process (diagnosis/intervention). This seems to contradict the decision not to weight.
- Yep.
- I do not think that the analysis in 2d2 supports the quality construct.
- The component measures are each referenced and do fit within the logic model and the algorithm.
- Yes
- No concerns

- Measure developers suggest that the aggregation of components together are better predictors of important patient outcomes of care than just patient characteristics alone. I agree with their underlying logic and the additive value of each measure.
- Yes, analyses demonstrate that the component measures fit the quality construct and add value. There were no weighting rules described.
- The construct is appropriate. The weighing, and rationale for the weighting, is not clear.
- Yes
- Malnutrition overlaps greatly with social risk factors, but the purported benefits listed here are looking
 primarily at hospital length of stay and 30-day readmission rate. What is the minimum length of stay
 needed for a benefit to be seen from the nutritional consult?

Criterion 3. Feasibility

Maintenance measures - no change in emphasis - implementation issues may be more prominent

- **3. Feasibility** is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.
 - Data elements are generated or collected by and used by healthcare personnel during the provision of care.
 - All data elements are in defined fields of the electronic health records.
 - As an eMeasure, the developer has completed the NQF Feasibility Score Card

Questions for the Committee:

- Are the required data elements routinely generated and used during care delivery?
- Are the required data elements available in electronic form, e.g., EHR or other electronic sources?
- Is the data collection strategy ready to be put into operational use?
- If an eCQM, does the eCQM Feasibility Score Card demonstrate acceptable feasibility in multiple EHR systems and sites?

Preliminary rating for feasibility: \Box High \boxtimes Moderate \Box Low \Box Insufficient

- Committee Pre-evaluation Comments: Criteria 3: Feasibility
- 3. Feasibility: Which of the required data elements are not routinely generated and used during care delivery? Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? What are your concerns about how the data collection strategy can be put into operational use?
 - Clear distinction between missing data and not-applicable response.
 - For a patient staying longer than 24 hours in a hospital and more tenured, this is one more screening tool and one more new clinician (dietician) to meet during the blur of a new admission. I could see it being very upsetting to someone to have the qs from a specialist and wonder if the data could be collected by a different clinician (nurse on the less-intense time of a patient's stay, for example). I picture my father-in-law being admitted and screened and immediately being annoyed ;-)
 - No concerns.
 - The data strategy seems feasible to operationalize. It seems that EHRs should be able to accommodate and that it is possible to create performance measures and dashboards if desired. A potential missing

piece is tying the feasibility of the intervention to the patient's socio-economic status, living conditions, and geography i.e. residing in food deserts.

- No concerns
- Definitely feasible
- The developers suggest that all patients aged 65 years and older should be screened, but perhaps there would be additional logic that could be considered to trigger screening? Nursing staff would need training to perform the screening to trigger the process.
- It is not clear that the EHR will capture all of the four components of the composite measures during routine care delivery. Careful attention to including the data for all four of the component measures will be required by participating hospitals to yield significant results. This will require setting up specific processes for recording the data.
- Seems feasible to collect. Limited specificity about the screening and assessment tools, however, may limit the usefulness of the data being collected.
- All data are defined fields in the EMR. No concerns.
- It would be helpful to know the difference in time between when the recommendation is given and when it is actually implemented (when the order is placed) and measuring how often teams face barriers in following recommendations due to insurance or other related issues.

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

• 4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. 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.

Current uses of the measure

Publicly reported?	🛛 Yes 🛛	Νο
Current use in an accountability program?	🗆 Yes 🛛	No 🗌 UNCLEAR
OR		

Planned use in an accountability program? 🛛 Yes 🗌 No

Accountability program details

• The measure is currently under consideration for the Hospital Inpatient Quality Reporting Program by the Centers for Medicare and Medicaid Services, first submitted for consideration for the 2020-2021 measures under consideration review cycle, June 2020.

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- Participants in the Malnutrition Quality Improvement Initiative participate in group technical calls and feedback sessions to share best practices, lessons learned, and troubleshooting of quality improvement efforts. This feedback is captured and surveys are also periodically conducted to assess areas of focus and experience with measure implementation.
- Several organizations have used performance feedback provided by the developer to better inform quality improvement initiatives, publish findings in peer-reviewed literature, and present at academic conferences.

Questions for the Committee:

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use: 🛛 Pass 🛛 No Pass

• 4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- Most recent published data authored by the developer (Valladares et al, 2020) demonstrates improvement across all major component measures.
- The developer's project team has devised the strata into "veteran" participants vs. new participants in the measure implementation, demonstrating same effects witnessed by both groups.
- "Veteran" participants have also seen improvements in new areas such as discharge planning and coordination of nutrition care when transitioning out of the hospital setting.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving highquality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

• The developer has not identified any unexpected findings.

Potential harms

• The developer has not identified any potential harms.

Questions for the Committee:

- How can the performance results be used to further the goal of high-quality, efficient healthcare?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability and use: 🛛 High 🛛 Moderate 🔲 Low 🔲 Insufficient

 Committee Pre-evaluation Comments: Criteria 4: Usability and Use

4a1. Use - Accountability and Transparency: How is the measure being publicly reported? Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? For maintenance measures - which accountability applications is the measure being used for? For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided? 4a2. Use - Feedback on the measure: Have those being measured been given performance results or data, as well as

assistance with interpreting the measure results and data? Have those being measured or other users been given an opportunity to provide feedback on the measure performance or implementation? Has this feedback has been considered when changes are incorporated into the measure?

- N/a
- All good here
- No concerns.
- Health professionals using the process were used in the development of the clinical guideline. The algorithm shows the development of the nutritional plan and references inclusion of the patient in decision-making. I did not find other references to inclusion of those being measured.
- Unknown
- Measure currently under consideration for use in accountability programs and "several orgs" have provided feedback.
- I am unable to comment on this criterion based upon available information. It would be interesting to know whether performance on the measures improved based upon the feedback received within the Malnutrition Quality Improvement initiative.
- The measure is being public ally reported in various peer reviewed journal articles and is therefore available outside of the organizations whose performance is being measured. A credible plan for implementation of the measure was not provided. There was little discussion of feedback.
- Some feedback to users of the individual measures has been provided.
- Performance data so far are only reported as performance feedback and benchmarking information to
 participants of the MQii. Malnutrition Quality Improvement Initiative (Avalere Health and The
 Academy of Nutrition and Dietetics). The current composite measure is under consideration for the
 Hospital Inpatient Quality Reporting Program by the Centers for Medicare and Medicaid Services. The
 sponsors report that it is anticipated that this measure will have been reviewed for appropriateness
 and adequacy prior to being reviewed by this committee. It was first submitted for consideration for
 the 2020-2021 measures under consideration review cycle, June 2020.
- N/a

4b1. Usability – Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations? 4b2. Usability – Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them.

- Seems to support that high quality care includes timely identification of malnutrition and intervention
 may reduce readmission. Reducing length of stay is not so evident. But malnutrition is not something
 that can be "fixed" in the hospital and nutritional support (as described in some of the evidence) is not
 available outside the hospital. So one potential harm is identifying and treating malnutrition in the
 acute setting and then older patients being discharged to home where support is unavailable or not
 covered by Medicare. I don't think this necessarily outweighs measure benefits but identifying and
 treating malnutrition in the acute setting when it arises and must continue to be addressed outside
 the acute setting doesn't seem to improve health in the longer term.
- benefits > harm
- No concerns.
- This is not intensive or burdensome. There is some risk of screening individuals and developing
 recommendations that are not feasible given the individuals circumstances. The benefits of improved
 outcomes outweigh any risk, all of which can be mitigated through intentional understanding of the
 patient's situation and connection to resources.

- None
- No concerns, no obvious "harms"
- The developer indicates that no harms or adverse events to patients were reported in either the clinical practice guideline or systematic review. Evidence of harm / risk to patient from malnutrition screening was not reported in any of the incremental studies since the publication of the systematic review.
- If hospitals institute strict quality control of performing and recording of all the component processes, especially instituting and implementing a dietary improvement plan of care the measure can be used to further the goal of high quality, efficient health care. The authors indicated that there were no unintended consequences of note.
- The composite measure can cause harm. Inadequate screenings and assessments can lead to
 inappropriate plans. Furthermore, a health system may perform "well," even though the screening and
 assessments may not be rigorous or sufficiently evidence based. One system using evidence-based
 screening and assessments administered by appropriate clinicians may score lower than another
 system using inferior screenings and assessments. To score higher, the incentive may be to apply less
 rigor.
- For Quality Improvement
- I am concerned about the hidden costs in implementing this seemingly benign screen. Speaking as a physician who has worked in the hospital setting and collaborated with nutritionists and their recommendations, the reality is that placing and modifying the nutrition orders are low on the list of priorities as compared to labs, imaging and other orders, so they can be easily missed. What is the time-cost for the care team for recommendations that are not covered by insurance or need additional approval, and how does this impact length of stay in waiting for approval? Does it detract from care of their remaining census?

Criterion 5: Related and Competing Measures

Related or competing measures

• The developer did not identify any related or competing measures.

Harmonization

- N/A
- Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

5. Related and Competing: Are there any related and competing measures? If so, are any specifications that are not harmonized? Are there any additional steps needed for the measures to be harmonized?

- None identified
- Not aware of any.
- NA
- Not that I am aware of. It seems aligned with Joint Commission requirements.
- None
- Not that I know of
- I may not be understanding perfectly which screening tools or assessment measures might be in consideration for use, which does have the potential to introduce a need for harmonization.
- There are no related or competing measures.

- No
- No competing measures
- N/a

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 01/26/2021

- No NQF Members have submitted support/non-support choices as of this date.
- No Public or NQF Member comments submitted as of this date.
- Combined Methods Panel Scientific Acceptability Evaluation

Scientific Acceptability: Preliminary Analysis Form

Measure Number: 3592

Measure Title: Global Malnutrition Composite Measure

Type of measure:

Process	Process: Appropriate Use	□ Structure	Efficiency	Cost/Resource Use
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Outcome	🛛 Outcome: PRO-PM	Outcome: Intermediate Clinical Outcome	🛛 Composite
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Data Source:

🗆 Claims	🛛 Electr	onic Health Data	🛛 Electro	nic Health Records	🗆 Man	agement Data
□ Assessme	ent Data	🗆 Paper Medical	Records	□ Instrument-Base	ed Data	🗆 Registry Data
	nt Data	🗆 Other				

Level of Analysis:

□ Clinician: Group/Practice □ Clinician: Individual ⊠ Facility □ Health Plan □ Population: Community, County or City □ Population: Regional and State □ Integrated Delivery System □ Other

Measure is:

New **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented? Xes Do

Submission document: "MIF_xxxx" document, items S.1-S.22

NOTE: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.

2. Briefly summarize any concerns about the measure specifications.

Panel Member #1: None

Panel Member #4: No concerns

Panel Member #6: I have no specific concerns. The measure is a simple composite of four binary indicators.

Panel Member #7: None, assuming the coding criteria are well-established and consistently administered across sites.

Panel Member #8: My major concern is with how component measure 1 is specified. As specified, I don't think component measure 1 is a performance measure. Rather it seems to be a measure of the patient case mix. In MIF S.5 numerator details section, component measure 1 numerator is described as "all patients in the measure population who are documented as at-risk for malnutrition via the completed malnutrition screening.' In MIF S.7 denominator details section, component measure 1 denominator is described as "all patients in the measure population with a documented malnutrition screening no more than 48 hours prior to admission to the hospital." This seems to capture among those patient who were screened within 48 hours prior to admission how many patients were identified as at-risk through that screening. This seems to be very narrowly focused, only focusing on patients who were screened prior to admission. The rate of at-risk patients mostly reflected the patients rather than hospital performance. The second concern I have is with how four component measure scores are combined into the final composite score. Four components measure four sequential steps, by definition, the sample size of four

components are : C1>=C2>=C3>=C4. The composite score is the average of four rates, this seems to imply latter component is weighted more than the earlier component. It is not clear if this is intended. If yes, that needs to be justified. Four components form a natural hierarchy, it may be better to account for that when compositing them.

Additionally, it will be important to specify what sampling scheme will be used.

RELIABILITY: TESTING

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

- 3. Reliability testing level 🛛 🛛 Measure score 🗖 Data element 🗍 Neither
- 4. Reliability testing was conducted with the data source and level of analysis indicated for this measure ☑ Yes ☑ No

Panel Member #3: I'm not sure about this. Reliability analyses appear to be based on a random effects analysis in which health systems rather than practice sites are the cluster-level units

5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of **patient-level data** conducted?

🗆 Yes 🛛 No

6. Assess the method(s) used for reliability testing

Submission document: Testing attachment, section 2a2.2

Panel Member #1: Appropriate: ICC via 2 models

Panel Member #3: Reliability analyses used data from 56 practice sites grouped within 10 health systems. Data were aggregated across patients within practice sites to create a dataset with 1 record per practice site. Variance components were estimated in a random effects model with random intercepts for the 10 health systems. The ICC was calculated as B/(B+W) where B is the estimated between-system variance and W is the estimated within-system residual variance.

Overall, it's not clear to me how such a calculation would shed light on the reliability of estimates calculated at the level of practice sites. In the above model, the within-system variance W reflects the sum of true between-site signal variation and random within-site sampling variation. A reliability calculation relevant to practice-level performance assessment would need to decompose those two sources of between-site variation.

It's unclear to me if the developers are also proposing to implement the measure at the level of health systems. For measurement at the health system level, the reported ICC may under estimate the measure's actual reliability. The developers report B/(B+W) but an alternative calculation (yielding a larger estimate) would be B/(B+W/n) where n is the number of sites per system and W/n is the variance of the average of scores across the n sites.

Panel Member #4: "Composite measure reliability was assessed using the variance components extracted from a linear mixed effects (LME) model—to calculate the intraclass correlation coefficient (ICC)." A mixed model is appropriate as the data are nested.

Panel Member #5: The intraclass correlation coefficient test is appropriate for score level reliability testing. 'Composite measure reliability was assessed using the variance components—extracted from a linear mixed effects (LME) model—to calculate the intraclass correlation coefficient (ICC).' [p7]

Panel Member #6: Intraclass correlation coefficients were estimated, with and without minimum case thresholds.

Panel Member #7: While the mixed effect linear models appeared to produce ICCs that are within NQF guidance for reliability, there is a concern about the statement "a minimum of three reportable measures" constraint. Assuming that statement refers to the four measures included in the composite, it is confusing

since they appear to be conditional (a nutrition care plan for malnourished patients could not be performed without identifying the patient as malnourished, for example) and allowing any 3 of the 4 to be completed could affect the error term. Further, the specifications in Section 1c.1 indicate that the measure is to be used if 2 or more individual performance measures are present, not 3 or more so it is strange that the testing was done for 3 or more.

Panel Member #8: The developer used data from 56 acute care hospitals in 10 states including 179,336 patients for reliability testing. The measure entities would be those 56 acute hospitals, however, the model used for reliability testing is specified to identify the variance among 10 states (or health systems). It is not clear if only health system per state was included, in other words, all hospitals that are from one state also belong to the same health system. If acute care hospitals are the measure entities, then the model was not specified correctly.

Panel Member #9: The method used to establish measure score reliability was appropriate.

7. Assess the results of reliability testing

Submission document: Testing attachment, section 2a2.3

Panel Member #1: Appropriate. ICC: (with case minimums) 0.839

Panel Member #3: Results suggest that the measure may have excellent reliability for measurement at the level of health systems. I'm unable to assess reliability for site-level performance scores (see above). Results reported in Section 2b4 (ability to detect significant differences) suggests that the measure will have high reliability when implemented at the facility.

Panel Member #4: "The measure's reliability was tested with and without case minimums typically recommended by CMS in its quality reporting programs in order to demonstrate the measures reliability with those case minimums in place. With case minimums, the ICC calculated was 0.839 and without case minimums, it resulted in an ICC of 0.647." This results are within an acceptable range.

Panel Member #5: The intraclass correlation coefficient test result of 'model 2' (with case minimums) was good at 0.839. The ICC test result in 'model 1' (without case minimums) was poor to marginal. Would recommend to require case minimums as stated here (i.e. denominator of 20 for each measure in the composite) given these test results.

'Model 1 (Without Case Minimums): ICC: 0.647' [p8]

'Model 2 (With Case Minimums): ICC: 0.839' [p9]

Panel Member #6: Without minimum case thresholds, the ICC was 0.65. With minimum case thresholds, the ICC increased to 0.84.

Panel Member #7: If the above is not the case, results appear to demonstrate adequate reliability given current NQF guidance for signal to noise analysis.

Panel Member #8: Given the issue with the model used, it is not clear how to interpret the results.

Panel Member #9: Reliability is adequate without restrictions on minimum sample sizes, and is good with such restrictions (which aren't clearly specified).

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

Submission document: Testing attachment, section 2a2.2

imes Yes

oxtimes No

□ Not applicable (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

Submission document: Testing attachment, section 2a2.2

imes Yes

🗆 No

Not applicable (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and <u>all</u> testing results):

High (NOTE: Can be HIGH only if score-level testing has been conducted)

⊠ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has <u>not</u> been conducted)

□ **Low** (NOTE: Should rate **LOW** if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

☑ **Insufficient** (NOTE: Should rate **INSUFFICIENT** if you believe you do not have the information you need to make a rating decision)

11. Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.

Panel Member #1: Appropriate testing of reliability, good sample size, and testing of two models with and without case minimums.

Panel Member #4: No concerns

Panel Member #5: As noted in Q7: The intraclass correlation coefficient test result of 'model 2' (with case minimums) was good at 0.839. The ICC test result in 'model 1' (without case minimums) was poor to marginal.

Would recommend to require case minimums as stated here (i.e. denominator of 20 for each measure in the composite) given these test results.

Panel Member #6: Reliability was modest when small groups included. However, I do not understand why even 9 practice sites were excluded when the sample sizes at each practice size were so large.

Panel Member #7: Although there are concerns about the conditional nature of the items (nonindependence) and potential bias this introduces in the analyses performed, the current NQF guidance on reliability would suggest that adequate reliability has been achieved.

Panel Member #8: The model used for reliability testing is for states or health system (if one system per state), the measure is specified for hospital or facility.

Panel Member #9: The rating could be "high" if the developers planned for and then somehow required a minimum per hospital. Reliability is high under that condition. Without that restriction, though, the overall assessment has to be "moderate"

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. Please describe any concerns you have with measure exclusions.

Submission document: Testing attachment, section 2b2.

Panel Member #1: No concerns.

Panel Member #4: No concerns

Panel Member #5: The MIF notes 2 exclusions not stated, & thus not addressed, in the testing form:

- [a] Discharge status of left against medical advice (measure #3, #4)
- [b] Admission to screening time interval greater than 48 hours (measure #1) [p9]

Panel Member #7: None

Panel Member #6: I do not know the magnitude of the exclusion criteria. A simple analysis of differences in component scores with versus without exclusions suggests no significant difference, but this is not a proper analysis of potential bias due to missingness.

Panel Member #8: No concern.

Panel Member #9: No concerns.

13. Please describe any concerns you have regarding the ability to identify meaningful differences in performance.

Submission document: Testing attachment, section 2b4.

Panel Member #1: No concerns.

Panel Member #4: No concerns

Panel Member #5: No concerns. Using a 95% confidence interval, substantial variation in performance was found. 'Among hospitals that meet the case minimum of 20 patients and at least 3 reportable measures, 44.7% of hospitals were in the highest performing Tier 3, 14.9% were in Tier 2, and 40.4% were in Tier 1.' [p16]

Panel Member #6: A bootstrapping analysis was used to estimate 95% confidence intervals for the measure score at each practice site. This analysis indicated that the majority of sites performed significantly better or worse than the mean performance.

Panel Member #7: It appears that the measure is to be used in distribution-based tiers (norm- vs. criterion referenced testing), grouped into 3 levels based on bootstrap generated confidence intervals. However, the method generated the smallest number of hospitals within the group that were not meaningfully difference from the estimated mean. The confidence interval must therefore be very narrow, and it is not clear how meaningfully this process differentiated groups that vary substantially by quality of malnutrition care.

Panel Member #8: No concern

Panel Member #9: The results presented here are a little unusual – normally, measures seeking to identify high vs. low performers against some overall average find small groups at the two tails and a large group in the middle. Here, it's the opposite – big groups at the high and low tails and a small group in the middle. The reason seems to be that the developers have created and used 95% confidence intervals for the overall group mean, but have not then gone on and applied 95% confidence intervals for each hospital's rate. The point estimate of the rate for each hospital is compared to the 95% confidence intervals for the whole group, and a hospital is declared "high" or "low" if the rate falls outside the full group confidence intervals. This seems inappropriate, as the concept of confidence intervals applies just as much to individual hospitals as to the group. If some form of confidence interval were applied to the hospital scores, and only those hospitals flagged as high or low if both sets of confidence intervals were non-overlapping, then many fewer hospitals would be identified as high or low. Most would be in the middle, as is typically the case for quality measures.

14. Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.

Submission document: Testing attachment, section 2b5.

Panel Member #1: N/A

Panel Member #4: No concerns

Panel Member #5: NA - 1 set of specifications used

Panel Member #6: This is not applicable.

Panel Member #8: Given the way component measure 1 is specified, it seems to capture more about patients than facility performance, therefor it is not clear if this composite score can be used to meaningfully compare hospitals.

15. Please describe any concerns you have regarding missing data.

Submission document: Testing attachment, section 2b6.

Panel Member #1: No concerns.

Panel Member #4: No concerns

Panel Member #6: The presented analysis has unclear significance.

Panel Member #7: Each component of the composite appears to be conditional on the response to the prior measure. Therefore differentiating 'missing' vs. not-applicable seems to be important to distinguish. It is not clear to what the 'consistency measure' noted in 2b6.2 refers. In 2b6.3 the developer states that the rates of missing data were consistently low, but does not provide data.

Panel Member #8: No concern

16. Risk Adjustment

16a. Risk-adjustment method 🛛 None 🗌 Statistical model 🗌 Stratification

16b. If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?

\boxtimes Yes \boxtimes No \square Not applicable

Panel Member #5: No response provided to any of the risk adjustment questions. Note the measures comprising the composite are process measures.

16c. Social risk adjustment:

16c.1 Are social risk factors included in risk model? \Box Yes \Box No \boxtimes Not applicable

Panel Member #5: "NA" insofar as the measure is not risk adjusted. There are no responses provided to any of the risk adjustment questions.

16c.2 Conceptual rationale for social risk factors included? \Box Yes \boxtimes No

Panel Member #5: The measure is not risk adjusted. There are no responses provided to any of the risk adjustment questions.

16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? \boxtimes Yes \boxtimes No

Panel Member #5: The measure is not risk adjusted. There are no responses provided to any of the risk adjustment questions.

16d. Risk adjustment summary:

16d.1 All of the risk-adjustment variables present at the start of care? \boxtimes Yes \Box No **Panel Member #5:** NA - The measure is not risk adjusted. There are no responses provided to any of the risk adjustment questions.

16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ⊠ Yes □ No

Panel Member #5: NA - The measure is not risk adjusted. There are no responses provided to any of the risk adjustment questions.

16d.3 Is the risk adjustment approach appropriately developed and assessed? \Box Yes \boxtimes No **Panel Member #5:** NA - The measure is not risk adjusted. There are no responses provided to any of the risk adjustment questions.

16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) □ Yes ⊠ No

Panel Member #5: NA - The measure is not risk adjusted. There are no responses provided to any of the risk adjustment questions.

16d.5. Appropriate risk-adjustment strategy included in the measure? \Box Yes \boxtimes No

16e. Assess the risk-adjustment approach

Panel Member #1: The developer did not present any data on whether risk adjustment was required or not. It would have been helpful if they discussed why they chose not to risk adjust.

Panel Member #4: I have concerns because no risk adjustment was included for the measure. I feel this is especially important because the developers indicate that there are factors that should be adjusted for "Our major finding is that malnutrition indicators are significantly related to LOS and Readmissions after controlling for the other variables that were included in the model (patient demographics and primary diagnosis) known to be predictive of those outcomes." Why then, are these variables (patient demographics and primary diagnosis) not included in a risk adjustment model?

Panel Member #5: NA - The measure is

Panel Member #6: No risk adjustment is employed.

Panel Member #7: This section was blank in the application I received.

Panel Member #8: Process measures, not risk adjusted

Panel Member #9: Absence of risk adjustment is appropriate for this measure, on the assumption that all patients should be assessed for malnutrition and then followed up as necessary. If a Standing Committee feels that only certain patients should be assessed, then some form of risk adjustment would be called for.

For cost/resource use measures ONLY:

17. Are the specifications in alignment with the stated measure intent?

□ Yes □ Somewhat □ No (If "Somewhat" or "No", please explain)

18. Describe any concerns of threats to validity related to attribution, the costing approach, carve outs, or truncation (approach to outliers):

VALIDITY: TESTING

19. Validity testing level: 🛛 Measure score 🛛 Data element 🖄 Both

Panel Member #5: Measure developer states data element testing regarding the component measures (not composite)

- 20. Method of establishing validity of the measure score:
 - □ Face validity
 - Empirical validity testing of the measure score
 - □ N/A (score-level testing not conducted)

Panel Member #5: Measure developer states this testing type for the composite

21. Assess the method(s) for establishing validity

Submission document: Testing attachment, section 2b2.2

Panel Member #1: Appropriate

Panel Member #3: The first set of analyses examined associations of 30-day readmission and length of stay (LOS) with malnutrition variables after adjusting for demographic and clinical covariates. I assume these were patient-level analyses. It wasn't 100% clear to me what variable(s) related to nutrition were assessed in these models. In the first analysis, the developers report on the statistical significance of the observed associations but do not describe the direction or magnitude of these associations.

The second set of analyses examined the associations of 30-day readmission and LOS with having a nutrition care plan among patients who had a malnutrition diagnosis. Having a nutrition care plan was associated with a 26% decrease in the likelihood of 30-day readmission and a 3-day increase in LOS. A shorter LOS would seem to be desirable, all things being equal, so I was not 100% sure how to interpret the result suggesting that nutrition care plans are associated with a longer LOS.

Additional analyses estimated the joint associations between variables used to construct the composite and the endpoints of 30-day readmission and LOS. Based on data in Tables 4 and 5, having a care plan was associated with longer LOS and an increased probability of 30-day readmission. These seem like undesirable outcomes so I am not sure how to interpret them.

Panel Member #4: "Composite Performance Measure Score Validity Testing

To empirically test the construct validity of the overall composite measure at the score level, a hierarchical linear regression was conducted to demonstrate that the predictability of the model significantly improved when the components in aggregate were included into the model over standard predictors of these outcomes such as patient characteristics, primary diagnoses, and comorbidities."

This is an appropriate methodology.

"Validity Testing for Component Measures - Critical Data Elements

Construct validity of the critical data elements for the component measures was tested by developing a generalized linear (logistic) regression model."

This is an appropriate methodology. However, I am torn as to whether the developers should also have done a double check of the EHR data with a manual abstraction to ensure the data elements are what we think they are.

Panel Member #5: The types of validity testing is appropriate for score level and critical data element.

Composite Performance Measure Score Validity Testing

- Construct validity
- assess the association between the main clinical endpoint of the composite measure... and the outcomes most associated with malnutrition' [p10]

Validity Testing for Component Measures – Critical Data Elements

- Construct validity
- Assess the correlation between the components and outcome of the composite measure with clinical outcomes...' [p10]

Panel Member #6: The measure was included in models of 30-day readmission and length of stay.

Panel Member #7: It would have been useful to know the number of applicable items within the composite within and between facilities. Some sense of sample sizes for each indicator in Tables 4 and 5 and error bars for Table 4 would have also helped. Although the relationship among the components of the composite show adequate contributions to the variance in the composite measure (2d2.2), the final column appears to assess Cronbach's (misspelled in the text) alpha if the measure was deleted from the composite, and it is unclear from this section whether list or pairwise deletion was used, important with data in which each item may not apply to the case within facility. Hierarchical linear modeling methods that were used account for the nested nature of the data and for variation in sample sizes. However, given the apparent conditional nature of the data, the use of generalized linear models noted in estimating the relationship of 'critical data elements' would violate the independence assumption may have resulted in biased estimates, model overspecification/inflated model fit, etc.

Panel Member #8: For performance score validity testing, the developer examined the predictive power of the score on outcomes such as readmission and length of stay. Additionally, the developer also examined the association between the key component of the composite and LOS and readmission. The developer considered readmission and length of stay the outcomes most associated with malnutrition.

For component validity testing, the developer examined if those component can predict the malnutrition diagnosis as outcome. This is not really compelling as those components are expected to lead to more malnutrition diagnosis. A better test would be if the composite or component can predict better outcome. The developer did examine the association between the components and readmission and LOS. The equation as specified applies to LOS as outcome but doesn't apply to readmission as outcome (binary).

Panel Member #9: The methods seem appropriate, particularly for a composite measure, involving testing of both the composite score and the component measure scores as predictors of two clinical outcomes (length of stay and readmission).

22. Assess the results(s) for establishing validity

Submission document: Testing attachment, section 2b2.3

Panel Member #1: Acceptable.

Panel Member #3: See above

Panel Member #4: "Composite Performance Measure Score Validity Testing

Our major finding is that malnutrition indicators are significantly related to LOS and Readmissions after controlling for the other variables that were included in the model (patient demographics and primary diagnosis) known to be predictive of those outcomes. The R² statistic for the LOS model was 0.063 prior to the inclusion of the aggregate measure components and 0.288 after (p<0.001), and the c-statistic for the 30-day readmissions model was 0.614 before their inclusion and 0.625 after (p<0.01)."

No concerns

Validity Testing for Component Measures – Critical Data Elements – see tables

No concerns

Panel Member #5: In general, the Composite Performance Measure Score Validity Testing the findings were acceptable. In regard to the Validity Testing for Component Measures – Critical Data Elements c-statistic was strong.

Composite Performance Measure Score Validity Testing

R² statistic for LOS model: 0.063 prior to the inclusion of the aggregate measure components and 0.288 after (p<0.001), and the c-statistic for the 30-day readmissions model was 0.614 before their inclusion and 0.625 after.' [p11]

Validity Testing for Component Measures – Critical Data Elements

Table 3 ... c-statistic: 0.828 [fit of the overall score]' [p12]

Panel Member #6: The measure improved the explanatory capability of statistical models of aforementioned outcomes. A documented nutrition care plan was associated with lower risk of 30-day readmission and shorter length of stay.

Panel Member #7: Although the developer used exogenous variables, 30-day readmission and length of stay, to assess the validity of the malnutrition composite score, it is difficult to interpret the data given the above concerns. Also, detail on the specific analyses used to generate Tables 3,4, and 5 would have helped in interpretation of these results. For example, 'time to assessment' is mentioned as part of the screening in Component Measure 1, the screening for malnutrition on admission measure, but considered as a separate variable in Tables 3-5. Sample sizes for each of the measures in Tables 4 and 5 would have also been useful.

Panel Member #8: The developer found that the composite score lead to improvement in model predictive power as measured by R square and c statistic. However, it is not really comparable to use RTI's model as a bench mark as it was about a complete different outcome.

The findings that documented nutrition plan was associated with reduced readmission rate among patients with a malnutrition diagnosis is most compelling in demonstrating the component validity. Results in Table 4 and 5 support the validity of those components.

Panel Member #9: Results are confusing. Much of the text implies that a better score on the measure is associated with lower rates of readmission, but the graphic in Table (sic) 5 shows the opposite. The text and graphic in Table (sic) 4 show that success on the overall measure and the component measures are associated with longer lengths of stay, which is generally presumed to be a bad thing. So...better scores on the measure are associated with one bad thing (longer LOS) and may be associated with another bad thing (readmission). This is very confusing! First, the developers have to sort out which direction is correct regarding the association with readmission. Then, they have to explain how an association with longer LOS is a sign of good quality vs. bad quality. Finally, they have to explain how this set of findings

points clearly to causality in the direction of measure performance -> outcome vs the other way around - outcome -> measure performance. The suspicion about "reverse causality" is that patients who have some set of risk factors leading to both longer lengths of stay and (maybe) readmission are the ones most likely to get malnutrition assessments and then follow up. The associations really reflect the presence of these risk factors, not a causal arrow from measure performance to outcome.

23. Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?

Submission document: Testing attachment, section 2b1.

🛛 Yes

🖂 No

□ Not applicable (score-level testing was not performed)

Panel Member #9: See comment above about "reverse causality".

24. Was the method described and appropriate for assessing the accuracy of ALL critical data elements?

NOTE that data element validation from the literature is acceptable.

Submission document: Testing attachment, section 2b1.

🛛 Yes

🗌 No

Not applicable (data element testing was not performed)

Panel Member #5: This is challenging to assess given we're evaluating the composite vs. individual measures. We have higher level (vs. detailed) information regarding the measures. For example, we don't have numerator and denominator specifications of the 4 measures comprising the composite. Thus, we're not in the ideal position to evaluate what are the critical data elements to test.

25. OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.

□ High (NOTE: Can be HIGH only if score-level testing has been conducted)

Moderate (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

- Low (NOTE: Should rate LOW if you believe that there are threats to validity and/or relevant threats to validity were **not assessed OR** if testing methods/results are not adequate)
- ☑ Insufficient (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level is required; if not conducted, should rate as INSUFFICIENT.)

26. Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.

Panel Member #1: Appropriate interpretation of the results. Good validity testing methods selected. Some concern with regard to the lack of risk adjustment information.

Panel Member #4: No additional concerns

Panel Member #5: As noted in Q22: In general, the Composite Performance Measure Score Validity Testing the findings were acceptable. In regard to the Validity Testing for Component Measures – Critical Data Elements c-statistic was strong.

Panel Member #6: The measure is strongly associated with clinically important outcomes.

Panel Member #7: More information on the nature of the analyses is needed to assess this measure appropriately.

Panel Member #8: The develop provided some positive results in support of the validity of the components

Panel Member #9: See long note above about results of validity testing. The results presented here seem to contain at least one error (text and chart about readmission contradict each other), and the pattern of results can't be interpreted as evidence of validity of the measure as a quality of care measure. The one finding about better measure performance being associated with lower readmission rates would seem to be evidence for validity, but the text says one thing and the graphic says the opposite.

FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

- 27. What is the level of certainty or confidence that the empirical analysis demonstrates that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct?
 - 🛛 High
 - Moderate
 - 🛛 Low
 - 🛛 Insufficient
- 28. Briefly explain rationale for rating of EMPIRICAL ANALYSES TO SUPPORT COMPOSITE CONSTRUCTION Panel Member #1: Item correlation with total is consistent.

Panel Member #4: The developers do a good job of explaining why each of the measure components are included in the composite measure. The concern I have is that the data elements are nominal level data. When these nominal level data are used for the composite measure they are assigned mathematical properties and used as interval level data as mathematical calculations are then done to create averages. This does not seem appropriate. Can nominal level data be reliably and validly averaged?

Panel Member #5: Reliability and validity testing results are generally acceptable and good. Somewhat disappointed in two areas:

- No defense / rationale of forgoing risk adjustment. However, it's a composite of process measures, which typically result in no need to risk adjust.
- No real rationale for the straight weighting of measures that comprise the composite. There could / should have been a more robust discussion for electing equal weighting.

Panel Member #6: Cronbach alpha coefficients of each component measure were similar.

Panel Member #7: See above.

Panel Member #8: Component measure 1 is not really a performance measure. The way to combine four components could be improved.

ADDITIONAL RECOMMENDATIONS

29. If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.

Panel Member #4: No additional concerns

Panel Member #5: While I noted a couple of issues, none are substantial enough to call for further discussion.

Panel Member #8: Component measure 1 should be examined closely.

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. *Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.*

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

Global_Malnutrition_Composite_Score_Evidence_Attachment.docx

1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

No

• 1a. Evidence (subcriterion 1a)

Measure Number (if previously endorsed):

Measure Title: Screening for Malnutrition Risk at Admission

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Global Malnutrition Composite Measure

Date of Submission: April 6, 2020

1a.1. This is a measure of: (should be consistent with type of measure entered in De.1)

Outcome

Health outcome:

□Patient-reported outcome (PRO):

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, healthrelated behaviors. (A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)

□ Intermediate clinical outcome (*e.g., lab value*):

Process: Completion of a malnutrition screening within 24 hours of hospital admission

□ Appropriate Use Measure:

□ Structure:

- Composite:
- **1a.2. LOGIC MODEL:** Diagram that briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or

outcome being measured.



Nutrition screening completed at admission can identify patients at risk of malnutrition early in the patient stay. Those patients who are identified are then assessed by a registered dietitian who, if appropriate, may recommend a specific nutrition intervention to address the patient's malnutrition, which if addressed early can reduce risk of mortality and post-operative complications and possibly reduce length of stay.

1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured *outcome, process, or structure* and finds it meaningful. (Describe how and from whom their input was obtained.)

**RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) **

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

1a.3. SYSTEMATIC REVIEW (SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

☑ Clinical Practice Guideline recommendation

 \Box US Preventive Services Task Force Recommendation

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

	Other
_	other

Systematic Review	Evidence
Source of Systematic Review: Title Author Date Citation, including page number URL 	Mueller C, Compher C & Druyan ME and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Board of Directors. A.S.P.E.N. Clinical Guidelines: Nutrition Screening, Assessment, and Intervention in Adults. J Parenter Enteral Nutr. 2011;35: 16-24. https://onlinelibrary.wiley.com/doi/epdf/10.1177/01
	<u>48607110389335</u>

Systematic Review	Evidence
Quote the guideline or recommendation verbatim about the process, structure or intermediate	"Screening for nutrition risk is suggested for hospitalized patients" (p.g. 19)
outcome being measured. If not a guideline, summarize the conclusions from the SR.	"Nutrition risk, identified by nutrition screening, is associated with longer length of hospital stay, complications, and mortality. In varied adult populations, patients who are identified as malnourished by various screening tools have longer length of hospital stay, and complications. Mortality risk is also predicted by malnutrition screening. Screening those individuals at risk of malnutrition is the first step in nutrition care." (p.g. 19-20)
Grade assigned to the evidence associated with the recommendation with the definition of the grade	Grade E - Supported by Level IV or V evidence Level IV Evidence: Nonrandomized cohort with historical controls
	Level V Evidence: Case series, uncontrolled studies, and expert opinion
Provide all other grades and definitions from the evidence grading system	Level I Evidence: Large randomized trials with clear-cut results; low risk of false-positive (α) and/or false-negative (β) error
	Level II Evidence: Small, randomized trials with uncertain results; moderate to high risk of false-positive (α) and/or false-negative (β) error
	Level II Evidence: Nonrandomized cohort with contemporaneous controls
Grade assigned to the recommendation with definition of the grade	E – Supported by level IV or V evidence
Provide all other grades and definitions from the recommendation grading	A- Supported by at least 2 level I investigations
system	C- Supported by at least 1 level III investigation
	D- Supported by at least 1 level III investigation
Systematic Review	Evidence
----------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------
 Body of evidence: Quantity – how many studies? Quality – what type of studies? 	9 observational studies (descriptive cohorts) 1 nonrandomized cohort with contemporaneous controls
Estimates of benefit and consistency across studies	Screening for malnutrition risk is a non-intensive and low-burden process for identifying patients in need of further assessment of nutritional status. Nutrition risk as identified by screening can be a strong predictor of hospital length of stay, risk of 30-day readmission, and complications. Some studies also showed a weak association with mortality, but generally the evidence is inconsistent on that outcome.
What harms were identified?	No adverse events were identified
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	Yes several new studies have been completed and published since the SR (see below), but results do not contradict earlier findings and reiterate what was reported in the initial SR.

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

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)

Outcomes from 1a.4: Malnutrition risk identified in patients through nutrition screening was able to predict outcomes including:

Outcome of Interest	Study Findings from Review
Length of Stay (LOS)	There were 2 studies (Kyle, 2006 & Amaral, 2008) that reported predicting OR for increased LOS based off nutrition screening scores from the MUST (OR: 3.1-3.24) and 1 study (Kyle, 2006) reported the NRS 2002 (OR: 2.9), 1 study reported a decrease in LOS in patients who were identified as at risk for malnutrition and were treated early (9.5 days vs 13 days, P=0.02) There were 3 studies that reported nutrition screen score predicted patient
	LOS (P <.001 - 0.022) (Kruizenga, 2005; Stratton, 2006; Scheisser, 2008;
Mortality	In one study (Yang, 2007), the screening score using the Subjective Global Assessment (SGA) predicted mortality (R2=0.2). However, one other study (Atalay, 2008) reported no difference in mortality incidence with increasing malnutrition risk using the SGA (P=0.86).

Outcome of Interest	Study Findings from Review
Post-Operative Complications	The guideline reported 1 study (Putwatana, 2005) reported that the NRC predicted post-operative complications, (OR: 2.92), Scheisser (2008) reported that the NRS 2002 predicted the complication rate in at-risk patients, P<0.001 and severe complications in at-risk patients, P<0.001; OR: 2.8.
	Finally, one study (Scheisser, 2009) reported that the NRS predicted the postsurgical complications, (OR: 4.2).

What harms were studied and how do they affect the net benefit (benefits over harms)?

Harms and adverse events to patients were not reported in either the clinical practice guideline or systematic review. Evidence of harm / risk to patient from malnutrition screening was not reported in any of the incremental studies since the publication of the systematic review.

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

Valladares AF, Kilgore KM, Partridge J, Sulo S, Kerr KW, McCauley S. How a malnutrition quality improvement initiative furthers malnutrition measurement and care: results from a hospital learning collaborative. JPEN J Parenter Enteral Nutr. Published online April 13, 2020.

In this study, the implementation of malnutrition-focused quality improvement practices significantly improved the identification of malnutrition. The prompt identification and treatment of patients at malnutrition risk can improve patient care and health, as well as reduce costly readmissions. Improvements were observed for all 4 malnutrition quality measures. The greatest improvements were achieved as a result of timely nutrition assessment (P = .06) and malnutrition diagnosis (P = .02). Patients ≥ 65 years with a malnutrition diagnosis and nutrition care plan had a 24% lower likelihood of 30-day readmission but a longer mean LOS than did those without a care plan.

Eglseer D, et al. The impact of using a malnutrition screening tool in a hospital setting: a mixed methods study. Eur J Clin Nutr. 2019;73(2):284-292.

The use of the screening tool positively correlated with significant improvements in the process indicators of nutritional care after 1 month, in terms of the number of nutritional interventions and the frequency of documentation of the diagnosis and the patient's weight and height.

Martín-Sánchez FJ, et al. Effect of risk of malnutrition on 30-day mortality among older patients with acute heart failure in Emergency Departments. Eur J Intern Med. 2019;65:69-77.

Secondary analysis of the OAK-3 Registry including all consecutive patients ≥65 years in 749 patients.

Risk of malnutrition was observed in 594 (79.3%) patients. The rate of 30-day mortality was 8.8%. After adjusting for MEESSI-AHF risk score clinical categories (model 1) and after adding all variables showing a significantly different distribution among groups (model 2), the risk of malnutrition was an independent factor associated with 30-day mortality compared to normal nutritional status.

This study reinforces that malnutrition screening detects malnutrition risk in older adults and that Routine screening of risk of malnutrition may help emergency physicians in decision-making and establishing a care plan.

Sauer AC, et al. Prevalence of Malnutrition Risk and the Impact of Nutrition Risk on Hospital Outcomes: Results From nutrition Day in the U.S. JPEN. 2019;43(7):918-926.

This study analyzed data from 2009 to 2015 for all adult patients from participating hospitals. Data was analyzed for 9,959 adult patients from 601 wards. The overall prevalence of malnutrition risk (MST score 2) was 32.7%. On nutrition Day, 32.1% of patients ate a quarter of their meal or less. Hospital mortality hazard

ratio was 3.24 (95% CI: [1.73, 6.07]; P-value < 0.001) for patients eating a quarter compared with those who ate all their meal and increased to 5.99 (95% CI: [3.03, 11.84]; P-value < 0.0001) for patients eating nothing despite being allowed to eat.

This study provides the most robust estimate of malnutrition risk in U.S. hospitalized patients to date, finding that approximately 1 in 3 are at risk. Additionally, patients who have diminished meal intake experience increased mortality risk. These results highlight the ongoing issue of malnutrition in the hospital setting.

Sanson G, et al. Prediction of early- and long-term mortality in adult patients acutely admitted to internal medicine: NRS-2002 and beyond. Clin Nutr. 2019. pii: S0261-5614(19)30184-0.

A retrospective observational study including 5,698 consecutive patients acutely admitted to the internal medicine department. 37.2% of patients were categorized as high risk for malnutrition according to the NRS-2002. Patients classified at high malnutrition risk (NRS-2002 \geq 3) showed a higher and earlier mortality (Logrank test: p < 0.001) compared to subjects in the NRS-2002 "low-risk" group. NRS-2002 \geq 3 was an independent significant (p < 0.01) predictor of mortality in logistic regression at every time interval.

This study showed that malnutrition risk identified upon hospital admission by NRS-2002 independently contributes to early and late mortality in a population including a majority of elderly.

Siegel S, et al. Impact of a Nutrition-Focused Quality Improvement Intervention on Hospital Length of Stay. J Nurs Care Qual. 2018;34(3):203–209.

Retrospective study that reviewed the medical records of 20,697 adult patients to determine whether early initiation of nutrition therapy had reduced hospital length of stay and 30-day readmission rates. Researchers found that the average time from hospital admission to oral nutrition supplement initiation was reduced by 20 hours (20.8%) after the quality improvement initiative was introduced (P < .01). Length of stay decreased 0.88 days (P < .05) more for patients at nutritional risk than patients not at nutritional risk; the probability of 30-day hospital readmission did not differ between groups.

The study highlights the importance of adequate nutrition screening, diagnosis, and treatment for hospitalized patients.

Goldfarb M et al. Malnutrition and mortality in frail and non-frail older adults undergoing aortic value replacement. Circulation 2018 Jul 5. pii: CIRCULATIONAHA.118.033887.

Prospective multicenter cohort study was conducted between 2012 and 2017 in 14 centers in 3 countries. Patients ≥70 years of age who underwent transcatheter or surgical aortic valve replacement were eligible. Overall, 8.7% of patients were classified as malnourished and 32.8% were at-risk for malnutrition. MNA-SF scores were moderately correlated with SPPB scores (Spearman R=0.31, P<0.001). There were 126 deaths in the TAVR group (19.1 per 100 patient-years) and 30 deaths in the SAVR group (7.5 per 100 patient-years). Malnourished patients had a nearly 3-fold higher crude risk of 1-year mortality compared with those with normal nutritional status (28% vs 10%, P<0.001). After adjustment for frailty, STS-PROM, and procedure type, pre-procedural nutritional status was a significant predictor of 1-year mortality (OR 1.08 per MNA-SF point, 95% Cl 1.01-1.16) and of the 30-day composite safety endpoint (OR 1.06 per MNA-SF point, 95% Cl 1.00 to 1.12).

The study found that preprocedural nutritional status is associated with mortality in older adults undergoing aortic valve replacement.

Eglseer D et al. Is the presence of a validated malnutrition screening tool associated with better nutritional care in hospitalized patients? Nutrition 2017 May; 37:104-111.

This was a cross-sectional, multicenter study that collected data using a standardized questionnaire on three levels: institution (presence of a guideline for malnutrition), department (use of a validated screening tool), and patient (e.g., malnutrition prevalence). In all, 53 hospitals with 5255 patients participated. About 45% of the hospitals indicated that they have guidelines for malnutrition. Of the departments surveyed, 38.6% used validated screening tools as part of a standard procedure. The nutritional status of 74.5% of the patients was screened during admission, mostly on the basis of clinical observation and patient weight. A validated

screening tool was used for 21.2% of the patients. Significant differences between wards with and without validated screening tools were found with regard to malnutrition prevalence (P = 0.002) and the following interventions: referral to a dietitian (P < 0.001), provision of energy-enriched snacks (P = 0.038), adjustment of consistency (food/drinks; P = 0.004), monitoring of the nutritional intake (P = 0.001), and adjustment of the meal ambiance (P < 0.001).

The study found that nutritional screening with validated tools in hospitalized patients remains poor. Generally, the nutritional status of patients is screened with unreliable parameters such as clinical observation and body mass index. The results of the present study suggest that the use of validated malnutrition screening tools is associated with better nutritional care and lower malnutrition prevalence rates in hospitalized patients.

Guerra RS, Sousa AS, Fonseca I, et al. Comparative analysis of undernutrition screening and diagnostic tools as predictors of hospitalisation costs. J Hum Nutr Diet. 2016;29(2):165-73.

Study aims (i) to explore whether undernutrition status at hospital admission, as evaluated by different screening and diagnostic tools, can predict patient's hospitalisation costs and (ii) to provide an updated economic analysis of undernutrition burden.

Undernutrition risk according to NRS-2002 and high undernutrition risk according to 'MUST' increased patient's costs, respectively, by 21.1% [95% confidence interval (CI) = 9.0-33.2%] and 28.8% (95% CI = 13.7-39.9%). The cost of a nutritionally-at-risk or undernourished patient is between €416 (95% CI = €156-675) and €617 (95% CI = €293-855) higher than the average of the respective diagnosis-related group.

The study associated malnutrition risk with increased patient costs which was identified using screening tools (NRS-2002 and MUST) which predict risk of malnutrition (termed as undernutrition in this article).

Khalatbari-soltani S, Marques-vidal P. Impact of nutritional risk screening in hospitalized patients on management, outcome and costs: A retrospective study. Clin Nutr. 2016;

Retrospective analysis of administrative data for years 2013 and 2014 from the department of internal medicine of the Lausanne university hospital (8541 hospitalizations, mean age 72.8 ± 16.5 years, 50.4% women). Being nutritionally 'at-risk' was defined as a Nutritional risk screening-2002 score ≥ 3 and nutritional managements were collected from medical records.

Less than half of patients 'at-risk' received any nutritional management, and this value decreased between 2013 and 2014 (46.9% vs. 40.3%, p < 0.05). After multivariate adjustment, 'at-risk' patients had a 3.7-fold (95% confidence interval: 1.91; 7.03) higher in-hospital mortality and higher costs (excess 5642.25 \pm 1479.80 CHF in 2013 and 5529.52 \pm 847.02 CHF in 2014, p < 0.001) than 'not at-risk' patients, while no difference was found for LOS.

This study reinforces the association between risk of malnutrition and mortality (risk ratio: 3.7, p<0.001) as well as with higher cost of care (p<0.001), and a non-significant higher risk of length of stay, p=0.50)

Gomes F, Emery PW, Weekes CE. Risk of Malnutrition Is an Independent Predictor of Mortality, Length of Hospital Stay, and Hospitalization Costs in Stroke Patients. J Stroke Cerebrovasc Dis. 2016;25(4):799-806.

543 patients were recruited from consecutive admissions at 2 hyperacute stroke units in London and were screened for risk of malnutrition (low, medium, and high) according to MUST. Six-month outcomes were obtained for each patient through a national database.

Results showed a highly significant increase in mortality with increasing risk of malnutrition (P < .001). This association remained significant after adjusting for age, severity of stroke, and a range of stroke risk factors. For those patients who survived, the LOS and hospitalization costs increased with increasing risk of malnutrition.

This study showed a statistically significant association between mortality and increasing risk of malnutrition (P<0.001). Increasing risk of malnutrition was associated with longer LOS and increased hospitalization costs (P<.001 and P=0.001, respectively)

Lew CC, Yandell R, Fraser RJ, Chua AP, Chong MF, Miller M. Association Between Malnutrition and Clinical Outcomes in the Intensive Care Unit: A Systematic Review. JPEN. Journal of parenteral and enteral nutrition. 2016.

This systematic review aims to identify the link between malnutrition and poor clinical outcomes in the intensive care unit (ICU). After reviewing 20 out of an original search that included 1168 studies, authors found that the prevalence of malnutrition ranged from 38% to 78%. Malnutrition, as diagnosed by nutrition assessments, was found to be independently associated with increased ICU length of stay, ICU readmission, incidence of infection, and risk of mortality.

Cereda E, Klersy C, Pedrolli C, et al. The Geriatric Nutritional Risk Index predicts hospital length of stay and in-hospital weight loss in elderly patients. Clin Nutr. 2015;34(1):74-8.

Nutritional risk was assessed by the Geriatric Nutritional Risk Index (GNRI) in a prospective multicentre hospital-based cohort study on a sample of 667 patients. The outcomes were LOS and in-hospital WL.

Patients with a high nutritional risk were more likely (OR = 1.89; 95%CI: 1.22-2.92) to stay longer in hospital (fourth quartile, LOS \ge 20 days) compared to those without.

Study supports association with nutritional risk identified from nutrition screening with increased LOS (OR=1.89)

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

1a.4.2 What process was used to identify the evidence?

1a.4.3. Provide the citation(s) for the evidence.

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (if previously endorsed):

Measure Title: Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Global Malnutrition Composite Measure

Date of Submission: N/A

Instructions

- For composite performance measures:
 - A separate evidence form is required for each component measure unless several components were studied together.
 - If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.
- Respond to **all** questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). *Contact NQF staff if more pages are needed.*
- Contact NQF staff regarding questions. Check for resources at <u>Submitting Standards webpage</u>.

Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF's evaluation criteria.

1a. Evidence to Support the Measure Focus

The measure focus is evidence-based, demonstrated as follows:

- **Outcome**: ³ Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
- Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence⁴ that the measured intermediate clinical outcome leads to a desired health outcome.
- **Process:** ⁵ a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured process leads to a desired health outcome.
- **Structure**: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured structure leads to a desired health outcome.
- Efficiency: ⁶ evidence not required for the resource use component.
- For measures derived from **patient reports**, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
- **Process measures incorporating Appropriate Use Criteria:** See NQF's guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

Notes

3. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.

4. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) guidelines and/or modified GRADE.

5. Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one

1a.1. This is a measure of: (should be consistent with type of measure entered in De.1)

Outcome

Health outcome:

□Patient-reported outcome (PRO):

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, healthrelated behaviors. (A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)

□ Intermediate clinical outcome (*e.g., lab value*):

Process: Completion of a nutrition assessment for patients identified to be at-risk of malnutrition from a completed malnutrition screening

□ Appropriate Use Measure:

- Structure:
- Composite:
- 1a.2. LOGIC MODEL: Diagram that briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.



Nutrition screening completed at admission can identify patients at risk of malnutrition early in the patient stay. Those patients who are identified are then assessed by a registered dietitian who, if appropriate, may recommend a specific nutrition intervention to address the patient's malnutrition, which if addressed early can reduce risk of mortality and post-operative complications and possibly reduce length of stay.

1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured *outcome, process, or structure* and finds it meaningful. (Describe how and from whom their input was obtained.)

**RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) **

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

1a.3. SYSTEMATIC REVIEW (SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of

similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

- ☑ Clinical Practice Guideline recommendation
- US Preventive Services Task Force Recommendation

⊠ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

Other

Systematic Review	Evidence
Source of Systematic Review: Title Author Date Citation, including page number URL 	Mueller C, Compher C & Druyan ME and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Board of Directors. A.S.P.E.N. Clinical Guidelines: Nutrition Screening, Assessment, and Intervention in Adults. J Parenter Enteral Nutr. 2011;35: 16-24. <u>https://onlinelibrary.wiley.com/doi/epdf/10.1177/01</u> 48607110389335
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	"Nutrition assessment: Nutrition assessment is suggested for all patients who are identified to be at nutrition risk by nutrition screening: Grade E." (Page 22) "Rationale- Malnourished patients, identified by nutrition assessment tools, have more complications and longer hospitalizations than do patients with optimal nutrition status. Such patients, identified by nutrition assessment tools, have more infectious and noninfectious complications, longer hospital length of stay, and greater mortality. With one exception, studies have shown malnourished patients to have greater mortality." (Page 22)
Grade assigned to the evidence associated with the recommendation with the definition of the grade	Grade E – Supported by level IV or V evidence Level IV Evidence: Nonrandomized cohort with historical controls Level V Evidence: Case series, uncontrolled studies, and expert opinion

Systematic Review	Evidence
Provide all other grades and definitions from the evidence grading system	Level I Evidence: Large randomized trials with clear-cut results; low risk of false-positive (α) and/or false- negative (β) error
	Level II Evidence: Small, randomized trials with uncertain results; moderate to high risk of false- positive (α) and/or false-negative (β) error
	Level III Evidence: Nonrandomized cohort with contemporaneous controls.
Grade assigned to the recommendation with definition of the grade	E – Supported by level IV or V evidence
Provide all other grades and definitions from the recommendation grading system	 A- Supported by at least 2 level I investigations B- Supported by 1 level I investigation C- Supported by at least 1 level III investigation D- Supported by at least 1 level III investigation
 Body of evidence: Quantity – how many studies? Quality – what type of studies? 	9 Case series, uncontrolled studies, and expert opinion
Estimates of benefit and consistency across studies	The assessment of nutritional status by a Registered Dietitian Nutritionist (RDN) can determine the severity of malnutrition which is a strong predictor of hospital length of stay, risk of 30-day readmission, and complications and mortality.
What harms were identified?	No adverse events were identified
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	Yes several new studies have been completed and published since the SR (see below), but results do not contradict earlier findings and reiterate what was reported in the initial SR.

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

If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

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)

Outcome of Interest	Study Findings from Review
Body Composition	Norman (2008) study predicted significant improvement in body weight and body cell mass follow a three-month intervention of high-protein and energy supplements while Odeli (2005), found that patients managed using the nutrition care process experienced less weight loss (mean weight change -4.2 kg +/-6.4 cf8.9 kg +/- 5.9, P = 0.03)
Cost	Kruizenga (2005) found that, to shorten the mean length of hospital stay by 1 d for all malnourished patients, a mean investment of 76 euros (91 US dollars) in nutritional screening and treatment was needed.
Length of Stay (LOS)	Kruizenga (2005) found early screening and treatment of malnourished patients reduced the LOS in malnourished patients with low handgrip strength (i.e., frail patients) and another study found that patients managed using the NP had a shorter length of stay (3.2 days +/- 5.4 cf. 13.5 days +/- 14.1, P = 0.002) (Odeli 2005).
Muscle Function	Persson (2007) found that treated-as-protocol analyses showed that Katz ADL index improved in the I-group (p<0.001; p<0.05 between the groups).
Nutritional Intake	Babineau (2008) reported significant increases in energy (p=0.0001) and protein (p=0.01) intakes, and in serum albumin (p=0.001), prealbumin (p=0.003), transferrin (p=0.024), and hematocrit (p=0.026) levels. An additional study of standardized nutrition care added approximately 600 kcal and 12 g protein to the daily intake of malnourished patients (Kruizenga 2005)
Readmission	Norman (2008) study found dietary counselling patients experienced significantly more readmissions (n=20) than oral nutritional supplement patients (n=10) during the study period (p=0.041). One additional study found that fewer patients managed using standardized nutrition care had an unplanned hospital admission (46% cf. 75%, P = 0.04) (Odeli, 2005).

Lew CC, Yandell R, Fraser RJ, Chua AP, Chong MF, Miller M. Association Between Malnutrition and Clinical Outcomes in the Intensive Care Unit: A Systematic Review. JPEN J Parenter Enteral Nutr. 2016;

http://www.ncbi.nlm.nih.gov/pubmed/26838530

Outcome of Interest	Study Findings from Review
Mortality Associated with Malnutrition Identified from the SGA	Five studies of lower risk of bias (Caporossi, 2012; Fontes, 2014; Sheean, 2013; Lomivorotov, 2013; Merli, 2010) reported that malnutrition identified from a validated nutrition assessment tool was associated with higher hospital mortality, but not independently associated with ICU mortality.
Incidence of Infection (IOI) Associated with Malnutrition Identified from the SGA	Malnutrition was independently associated with higher IOI 4.5 vs 0.6 episodes per patient, adjusted, P = .0001 (Merli, 2010)

Outcome of Interest	Study Findings from Review
Risk of ICU Readmission Associated with Malnutrition Identified from the SGA	Malnutrition was independently associated with risk of ICU readmission (OR=2.27; 95% CI, 1.08–4.80; P<.05)
Percentage of patients discharged to nursing homes vs. own homes	Sheean (2013) reported that the percentage of malnourish elderly patients discharged home was 28.6% lower than well-nourished patients (p=0.001)
Post-operative complications associated with Malnutrition	Lomivorotov (2013) and Sheean 2013 both reported increased risk of postoperative complications for patients diagnosed with malnutrition using the MNA (OR=1.60, 95% CI, 1.10-2.20; P<.01)

1a.7.8. What harms were studied and how do they affect the net benefit (benefits over harms)?

Harms and adverse events to patients were not reported in either the clinical practice guideline or systematic review.

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

Valladares AF, Kilgore KM, Partridge J, Sulo S, Kerr KW, McCauley S. How a malnutrition quality improvement initiative furthers malnutrition measurement and care: results from a hospital learning collaborative. JPEN J Parenter Enteral Nutr. Published online April 13, 2020.

In this study, the implementation of malnutrition-focused quality improvement practices significantly improved the identification of malnutrition. The prompt identification and treatment of patients at malnutrition risk can improve patient care and health, as well as reduce costly readmissions. Improvements were observed for all 4 malnutrition quality measures. The greatest improvements were achieved as a result of timely nutrition assessment (P = .06) and malnutrition diagnosis (P = .02). Patients ≥ 65 years with a malnutrition diagnosis and nutrition care plan had a 24% lower likelihood of 30-day readmission but a longer mean LOS than did those without a care plan.

Pratt KJ, Hernandez B, Blancato R, Blankenship J, Mitchell K. Impact of an interdisciplinary malnutrition quality improvement project at a large metropolitan hospital. BMJ Open Qual. 2020;9(1).

This study evaluated an institution-wide, multipronged model for detecting deficiencies in malnutrition care and implementing changes to address them based on the clinical workflow the malnutrition clinical quality measures are focused on. Following the multipronged series of interventions described above, the hospital documented a 25% (2-day) overall reduction in LOS for malnourished/at-risk patients (from 8 days to 6 days, p<0.01) and a 22.2% (2-day) reduction in LOS for malnourished/at-risk patients with infections (from 9 days to 7 days, p=0.10). Infection rates among malnourished patients declined 35.7% (from 14% to 9%, p<0.01). Changes in readmission rates over time were not statistically significant. Additionally, process improvement was noted for the rate at which nursing staff completed malnutrition risk screening (88% to 95% pre-topostimplementation) and referred those patients for nutrition assessment.

Danis K, et al. Identifying and Managing Malnourished Hospitalized Patients Utilizing the Malnutrition Quality Improvement Initiative: The UPMC Experience. JAND. 2019;119(9): S40-S43. This article's findings demonstrate that use of the malnutrition clinical quality measures to support malnutrition-focused quality improvement projects can improve malnutrition assessment and diagnosis. The quality improvement implementation focused on hospital-wide adoption of the Nutrition Focused Physical Examination (NFPE). The MQii team was guided by the malnutrition electronic clinical quality measures focused on completing a nutrition assessment (the NFPE) within 24 hours of identification of malnutrition risk and ensuring documentation of a malnutrition diagnosis when it was identified. Performance on both measures improved significantly (P<0.01).

Mordarski BA, Hand RK. Patterns in Adult Malnutrition Assessment and Diagnosis by Registered Dietitian Nutritionists: 2014-2017. JAND. 2019;119(2):310-322.

Based on this study's longitudinal survey (n=1,022 in time 1, and n=799 in time 2), use of the Academy/ASPEN Adult Malnutrition Clinical Characteristics to diagnose malnutrition increased demonstrably from 2014 to 2017. Respondents who reported documenting malnutrition using the Academy/ASPEN criteria increased significantly from 57.4% to 71.3% (P<0.001). This parallel increases in hospital patients with a malnutrition diagnosis, which increased from 4.0% to 4.9% between 2014 and 2015 in a multi-institutional database. Finally, respondents reported various barriers to appropriate diagnosis of malnutrition being incorporated in the patient's medical record demonstrating that most often when the diagnosis is not followed through with it is a process failure given there are few barriers from its completion.

Hudson L, Chittams J, Griffith C, Compher C. Malnutrition Identified by Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition Is Associated With More 30-Day Readmissions, Greater Hospital Mortality, and Longer Hospital Stays: A Retrospective Analysis of Nutrition Assessment Data in a Major Medical Center. JPEN J Parenter Enteral Nutr. 2018;

30-day readmissions (primary outcome), hospital mortality, length of stay (LOS) in survivors, and time to discharge alive (TDA) in all patients assessed as malnourished or not malnourished using these criteria in fiscal year 2015. We hypothesized more frequent admissions, greater mortality, longer LOS, and less likely shorter TDA in the malnourished patients. Demographic variables, clinical outcomes, and malnutrition diagnosis for all initial patient admissions were obtained retrospectively from the electronic medical record. Logistic regression was used to compare categorical and Cox proportional hazards for TDA in unadjusted and adjusted (age, sex, race, medical/surgical admission, Charlson Comorbidity Index) models.

Of the 3907 patients referred for nutrition assessment, 66.88% met criteria for moderate or severe malnutrition. Malnourished patients were older (61 vs 58 years, P < .0001), and survivors had longer LOS (15 vs 12 days, P = .0067) and were more likely to be readmitted within 30 days (40% vs 23%, P < .0001). In adjusted models, 30-day readmissions (odds ratio [OR] 2.13, 95% confidence interval [CI] 1.82-2.48) and hospital mortality (OR 1.47, 95% CI 1.0-1.99) were increased, and the likelihood of earlier TDA was reduced (hazard ratio [HR] 0.55, 95% CI 0.44-0.77) in those who had >2-day stay.

Silver HJ, Pratt KJ, Bruno M, Lynch J, Mitchell K, Mccauley SM. Effectiveness of the Malnutrition Quality Improvement Initiative on Practitioner Malnutrition Knowledge and Screening, Diagnosis, and Timeliness of Malnutrition-Related Care Provided to Older Adults Admitted to a Tertiary Care Facility: A Pilot Study. J Acad Nutr Diet. 2018;118(1):101-109.

6-month prospective pilot of 1912 patients recruited from 45 healthcare professionals from geriatric, general medicine, and general surgery units at Vanderbilt University hospital from January to June 2016. Participants were patients aged ≥18 y admitted to medical and surgical wards. The study included a 3-month intervention with training and education modules tailored to type of practitioner and integrated into existing teaching and clinical workflow. Malnutrition knowledge was assessed by 30-item questionnaire; electronic medical record (EMR) documentation; and timeliness of malnutrition screening, diagnosis, intervention, and discharge planning.

Malnutrition knowledge score increased 14%, from 39% to 53% (P=0.009). All patients whose nutrition screen indicated they were malnourished/high risk had registered dietitian nutritionist diagnosis of malnutrition documented in the EMR. The proportion who had medical provider (physician, nurse practitioner, or physician

assistant) malnutrition diagnosis documented in the EMR increased 11.6%, from 26.7% to 38.3% (P=0.08). About 95% of malnourished/high risk patients had a documented intervention addressing malnutrition. Inclusion of malnutrition care in the discharge plan increased 4.8%, from 70.0% to 74.8% (P=0.13).

Guerra RS, Fonseca I, Sousa AS, Jesus A, Pichel F, Amaral TF. ESPEN diagnostic criteria for malnutrition - A validation study in hospitalized patients. Clin Nutr. 2017;36(5):1326-1332.

A prospective observational study took place in a university hospital. Concurrent validity of EDC was evaluated using the Patient Generated Subjective Global Assessment (PG-SGA) nutrition status classification as the reference method. Sensitivity, specificity, positive and negative predictive values were determined. The EDC predictive validity was assessed by its independent association with length of hospital stay (LOS), applying Cox proportional hazards ratio method.

Of the 632 included patients, 455 participants (72%) were nutritionally-at-risk (Nutritional Risk Screening initial screening). For those that had screened positive, 260 (57.1%) and 55 participants (12.1%) were undernourished according to PG-SGA and to EDC, respectively. Compared to PG-SGA, the EDC revealed a sensitivity of 17.1% and a specificity of 98.3%. Positive and negative predictive values were respectively 89.1% and 58.9%. Undernutrition evaluated by EDC was independently associated with lower hazard ratio for being discharged home over time, 0.695 (95% confidence interval: 0.509; 0.950).

Hiller LD, Shaw RF, Fabri PJ. Difference in Composite End Point of Readmission and Death Between Malnourished and Non-malnourished Veterans Assessed Using Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition Clinical Characteristics. JPEN J Parenter Enteral Nutr. 2017;41(8):1316-1324.

A retrospective chart review comparing veterans with malnutrition based on a modified version of the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition consensus characteristics that used 5 of the 6 clinical characteristics to a matched control group of non-malnourished veterans based on age, admitting service, and date of admission who were admitted between August 1, 2012, and December 1, 2014. Data were extracted from the medical record. Multivariate analysis was used to identify predictors of outcomes.

In total, 404 patients were included in the final analysis. All end points were found to be statistically significant. The malnourished group was more likely to meet the composite end point (odds ratio [OR], 5.3), more likely to be readmitted within 30 days (OR, 3.4), more likely to die within 90 days of discharge (OR, 5.5), and more likely to have a length of stay >7 days (OR, 4.3) compared with the non-malnourished group. Length of stay was significantly longer in the malnourished group, 9.80 (11.5) vs 4.38 (4.5) days.

Jeejeebhoy KN et al. Nutritional assessment: comparison of clinical assessment and objective variables for the prediction of length of hospital stay and readmission. *Am J Clin Nutr* 2015; 101: 956-965.

Prospective cohort study of 1022 patients recruited from 18 acute care hospitals (academic and community), from 8 provinces across Canada, between 1 July 2010 and 28 February 2013. Participants were patients aged ≥18 y admitted to medical and surgical wards. Researchers measured the following indicators at admission: subjective global assessment (SGA; SGA A = well nourished, SGA B = mild or moderate malnutrition, and SGA C = severe malnutrition), Nutrition Risk Screening (2002), body weight, midarm and calf circumference, serum albumin, handgrip strength (HGS), and patient-self assessment of food intake. Logistic regression determined the independent effect of indicators on the outcomes of length of hospital stay (<7 d and ≥7 d) and readmission within 30 d after discharge.

The outcome of severe malnutrition (SGA score of C) was an independent predictor of length of stay and 30 day readmissions (OR: 2.12; 95% CI: 1.24, 3.93). This study supports the conclusion that patients who are malnourished in the hospital are at a significantly higher risk of adverse secondary outcomes. If these patients can be identified and subsequently treated for malnutrition, there may be an associated reduction in length of stay and 30-day readmissions.

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

1a.4.2 What process was used to identify the evidence?

1a.4.3. Provide the citation(s) for the evidence.

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (if previously endorsed):

Measure Title: Appropriate Documentation of a Malnutrition Diagnosis

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Global Malnutrition Composite Measure

Date of Submission: N/A

Instructions

- For composite performance measures:
 - A separate evidence form is required for each component measure unless several components were studied together.
 - If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.
- Respond to **all** questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). *Contact NQF staff if more pages are needed.*
- Contact NQF staff regarding questions. Check for resources at <u>Submitting Standards webpage</u>.

Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF's evaluation criteria.

1a. Evidence to Support the Measure Focus

The measure focus is evidence-based, demonstrated as follows:

- **Outcome**: ³ Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
- Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence⁴ that the measured intermediate clinical outcome leads to a desired health outcome.
- **Process:** ⁵ a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured process leads to a desired health outcome.
- **Structure**: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured structure leads to a desired health outcome.
- Efficiency: ⁶ evidence not required for the resource use component.
- For measures derived from **patient reports**, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
- **Process measures incorporating Appropriate Use Criteria:** See NQF's guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

Notes

6. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.

7. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) guidelines and/or modified GRADE.

8. Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one

1a.1. This is a measure of: (should be consistent with type of measure entered in De.1)

Outcome

Health outcome:

□Patient-reported outcome (PRO):

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, healthrelated behaviors. (A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)

□ Intermediate clinical outcome (*e.g., lab value*):

Process: Completion of a nutrition assessment for patients identified to be at-risk of malnutrition from a completed malnutrition screening

□ Appropriate Use Measure:

□ Structure:

Composite:

1a.2. LOGIC MODEL: Diagram that briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Patients who are identified as at-risk for malnutrition are then assessed by a registered dietitian nutritionist (RDN) who, if appropriate, may recommend a specific nutrition intervention to address the patient's malnutrition. The recommendations are shared with the patient's physician team who then make the clinical judgement to diagnose the patient with malnutrition based off the RDN's assessment. If the malnutrition is addressed early can reduce risk of mortality and post-operative complications and possibly reduce length of stay.





Implementation of Nutrition Intervention for Malnourished Patient

↓ Length of Stay, Mortality, Post-Operative Complications

1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured *outcome, process, or structure* and finds it meaningful. (Describe how and from whom their input was obtained.)

**RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) **

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

1a.3. SYSTEMATIC REVIEW (SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables. What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

☑ Clinical Practice Guideline recommendation

□ US Preventive Services Task Force Recommendation

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

Other

Systematic Review	Evidence
Source of Systematic Review: Title Author Date Citation, including page number URL 	Mueller C, Compher C & Druyan ME and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Board of Directors. A.S.P.E.N. Clinical Guidelines: Nutrition Screening, Assessment, and Intervention in Adults. J Parenter Enteral Nutr. 2011;35: 16-24. https://onlinelibrary.wiley.com/doi/epdf/10.1177/01 48607110389335
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	"Nutrition support intervention is recommended for patients identified by screening and assessment as at risk for malnutrition or malnourished. Grade C" (Page 22) "Rationale - Nutrition support intervention in patients identified by screening and assessment as at risk for malnutrition or malnourished may improve clinical outcomes. This guideline places nutrition assessment and screening in the context of intervention as part of nutrition care. Nutrition intervention in malnourished patients was associated with improved nutrition status nutrient intake physical function and quality of life. In addition, hospital readmissions were reduced." (Page 23)
Grade assigned to the evidence associated with the recommendation with the definition of the grade	Grade C- Supported by at least 1 level II investigation Level III Evidence: Nonrandomized cohort with contemporaneous controls.

Systematic Review	Evidence
Provide all other grades and definitions from the evidence grading system	Level I Evidence: Large randomized trials with clear-cut results; low risk of false-positive (α) and/or false-negative (β) error
	Level II Evidence: Small, randomized trials with uncertain results; moderate to high risk of false- positive (α) and/or false-negative (β) error
	Level IV Evidence: Nonrandomized cohort with historical controls
	Level V Evidence: Case series, uncontrolled studies, and expert opinion
Grade assigned to the recommendation with definition of the grade	C- Supported by at least 1 level III investigation
Provide all other grades and definitions from the recommendation grading system	A- Supported by at least 2 level I investigations B- Supported by 1 level I investigation D- Supported by at least 1 level III investigation E – Supported by level IV or V evidence
Body of evidence:	3 small, randomized trials
 Quantity – how many studies? Quality – what type of studies? 	1 nonrandomized cohort with historical controls 1 nonrandomized cohort with contemporaneous controls
Estimates of benefit and consistency across studies	Although the two SR's cited for this measure are not explicit systematic reviews of the "diagnosis of malnutrition" they do demonstrate the impact of nutrition intervention that is a result of a malnutrition diagnosis. More recent individual studies have modeled the impacts of a malnutrition diagnosis more thoroughly.
What harms were identified?	No adverse events were identified
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	New evidence since the publication of these SR's suggest that malnutrition diagnosis is a strong predictor of increase length of stay, 30-day readmission risk, mortality risk, infections, complications and high hospital costs.

OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE

Milne AC, Potter J, Vivanti A, Avenell A. Protein and energy supplementation in elderly people at risk from malnutrition. Cochrane Database Syst Rev. 2009;(2): CD003288.

URL:

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003288.pub3/abstract?systemMessage=Wiley+Onlin e+Library+will+be+unavailable+on+Saturday+14th+May+11:00-14:00+BST+/+06:00-09:00+EDT+/+18:00-21:00+SGT+for+essential+maintenance.Apologies+for+the+inconvenience

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

If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

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)

Mueller et al. Findings from Clinical Guideline

Outcome of Interest	Study Findings from Review
Body Composition	Norman (2008) study predicted significant improvement in body weight and body cell mass follow a three-month intervention of high-protein and energy supplements while Odeli (2005), found that patients managed using the nutrition care process experienced less weight loss (mean weight change -4.2 kg +/-6.4 cf8.9 kg +/- 5.9, P = 0.03) (Odeli, 2005).
Cost	Kruizenga (2005) found that, to shorten the mean length of hospital stay by 1 d for all malnourished patients, a mean investment of 76 euros (91 US dollars) in nutritional screening and treatment was needed.
Length of Stay (LOS)	Kruizenga (2005) found early screening and treatment of malnourished patients reduced the LOS in malnourished patients with low handgrip strength (i.e., frail patients) and another study found that patients managed using the NP had a shorter length of stay (3.2 days +/- 5.4 cf. 13.5 days +/- 14.1, P = 0.002) (Odeli 2005).
Muscle Function	Persson (2007) found that treated-as-protocol analyses showed that Katz ADL index improved in the I-group (p<0.001; p<0.05 between the groups).
Nutritional Intake	Babineau (2008) reported significant increases in energy (p=0.0001) and protein (p=0.01) intakes, and in serum albumin (p=0.001), prealbumin (p=0.003), transferrin (p=0.024), and hematocrit (p=0.026) levels. An additional study of standardized nutrition care added approximately 600 kcal and 12 g protein to the daily intake of malnourished patients (Kruizenga 2005)
Readmission	Norman (2008) study found dietary counselling patients experienced significantly more readmissions (n=20) than oral nutritional supplement patients (n=10) during the study period (p=0.041). One additional study found that fewer patients managed using standardized nutrition care had an unplanned hospital admission (46% cf. 75%, P = 0.04) (Odeli, 2005).

Outcome of Interest	Study Findings from Review
Mortality	48 included studies with a total of 8,031 participants when meta-analyzed, reported an overall relative risk (RR) of 0.92.
	The subgroup analyses suggested that the results were statistically significant or approaching statistical significance when limited to trials in which participants (N = 2461) were defined as undernourished (RR 0.79), and when 400 kcal or more was offered per day in the supplement (N = 7307), (RR 0.89).
	The results were consistent when analysis was restricted to 15 trials (N = 6604) with clearly concealed randomization (RR 0.91)
Cost	24 trials with a total of 6,225 participants were meta-analyzed and overall, reported a statistically significant difference between intervention and control for risk of complications (RR=0.86).
	In subgroup analyses, hip fracture patients were also at reduced risk of complications (RR=0.60).
Length of Stay (LOS)	12 studies were meta-analyzed and pooled weighted mean difference for LOS using a random-effects model showed no benefit from supplementation -0.8 days (-2.8 to 1.3) with significant heterogeneity (chi-square 25.53; df 13; P = 0.02; I2 = 49%). Subgroup analyses for length of stay were too limited to suggest any difference between diagnostic groups.
Quality of Life	Few studies were able to provide data on improvements in functional status or quality of life in general, apart from handgrip data. Measures were too diverse or too limited to combine for meta-analyses.

What harms were studied and how do they affect the net benefit (benefits over harms)?

18 trials discussed adverse effects from nutritional supplementation, but no studies compared intervention group with control groups. Problems with tolerance and side-effects were reported in 12 studies including nausea, vomiting and diarrhea in the intervention group.

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

Valladares AF, Kilgore KM, Partridge J, Sulo S, Kerr KW, McCauley S. How a malnutrition quality improvement initiative furthers malnutrition measurement and care: results from a hospital learning collaborative. JPEN J Parenter Enteral Nutr. Published online April 13, 2020.

In this study, the implementation of malnutrition-focused quality improvement practices significantly improved the identification of malnutrition. The prompt identification and treatment of patients at malnutrition risk can improve patient care and health, as well as reduce costly readmissions. Improvements were observed for all 4 malnutrition quality measures. The greatest improvements were achieved as a result of timely nutrition assessment (P = .06) and malnutrition diagnosis (P = .02). Patients ≥ 65 years with a malnutrition diagnosis and nutrition care plan had a 24% lower likelihood of 30-day readmission but a longer mean LOS than did those without a care plan.

Danis K, et al. Identifying and Managing Malnourished Hospitalized Patients Utilizing the Malnutrition Quality Improvement Initiative: The UPMC Experience. JAND. 2019;119(9):S40-S43.

The quality improvement implementation focused on hospital-wide adoption of the Nutrition Focused Physical Examination (NFPE) and improvement of coordination between registered dietitians and physicians. The care team was guided by the malnutrition electronic clinical quality measures focused on completing a nutrition assessment (the NFPE) within 24 hours of identification of malnutrition risk and ensuring documentation of a malnutrition diagnosis when it was identified. Performance on both measures improved significantly (P<0.01).

Tobert CM, Mott SL, Nepple KG. Malnutrition Diagnosis during Adult Inpatient Hospitalizations: Analysis of a Multi-Institutional Collaborative Database of Academic Medical Centers. J Acad Nutr Diet. 2018;118(1):125-131.

The University Health System Consortium (Vizient) database was retrospectively reviewed for reported rates of malnutrition diagnosis. All adult inpatient hospitalization at 105 member institutions during fiscal years 2014 and 2015 were evaluated for malnutrition diagnosis based on the presence of an International Classification of Diseases (ICD) -Ninth Revision diagnosis code. Hospital volume and publicly available hospital rankings and patient satisfaction scores were obtained. Multiple regression analysis was performed to assess the association between these variables and reported rates of malnutrition.

A total of 5,896,792 hospitalizations were identified from 105 institutions during the 2-year period. It was found that 292,754 patients (5.0%) had a malnutrition diagnosis during their hospital stay. By institution, median rate of malnutrition diagnosis during hospitalization was 4.0%, whereas the rate of severe malnutrition diagnosis was 0.9%. There was a statistically significant increase in malnutrition diagnosis from 4.0% to 4.9% between 2014 and 2015 (P<0.01). Institutional factors associated with increased diagnosis of malnutrition were higher hospital volume, hospital ranking, and patient satisfaction scores (P<0.01).

Meehan A, Loose C, Bell J, Partridge J, Nelson J, Goates S. Health System Quality Improvement: Impact of Prompt Nutrition Care on Patient Outcomes and Health Care Costs. J Nurs Care Qual. 2016.

Quality improvement program that positioned early nutritional care into the nursing workflow. Nurses screened formal nutrition risk at patient admission and then immediately ordered oral nutritional supplements for those at risk. Supplements were given as regular medications, guided and monitored by medication administration records.

Length of stay (-0.77 days or 13.4%), probability of readmissions (-17%) and cost of care (-\$969 or 8.8%) were all reduced (p<0.01).

This observational study supports early intervention on patients who are found to be at-risk of malnutrition.

Snider JT, Jena AB, Linthicum MT, et al. Effect of hospital use of oral nutritional supplementation on length of stay, hospital cost, and 30-day readmissions among Medicare patients with COPD. Chest. 2015;147(6):1477-84.

Retrospective cohort study identified hospitalizations in which ONS was provided, and used propensity-score matching to compare LOS, hospitalization cost, and 30-day readmission rates in a one-to-one matched sample of ONS and non-ONS hospitalizations.

One-to-one matched sample was created with 14,326 cases. In unadjusted comparisons in the matched sample, ONS use was associated with longer LOS (8.7 days vs 6.9 days, P < .0001), higher hospitalization cost (\$14,223 vs \$9,340, P < .0001), and lower readmission rates (24.8% vs 26.6%, P = .0116). However, in instrumental variables analysis, ONS use was associated with a 1.9-day (21.5%) decrease in LOS, from 8.8 to 6.9 days (P < .01); a hospitalization cost reduction of \$1,570 (12.5%), from \$12,523 to \$10,953 (P < .01); and a 13.1% decrease in probability of 30-day readmission, from 0.34 to 0.29 (P < .01).

ONS may be associated with reduced LOS, hospitalization cost, and readmission risk in hospitalized Medicare patients with existing morbidities such as COPD.

Cawood AL, Elia M, Stratton RJ. Systematic review and meta-analysis of the effects of high protein oral nutritional supplements. Ageing Res Rev. 2012;11(2):278-96.

The review concluded that high protein oral nutritional supplements had significant clinical, nutritional and functional benefits in a range of patient groups and health settings.

The authors' conclusions are reasonable but considerable clinical diversity in the included studies causes some uncertainty as to their generalizability. This systematic review involving 36 randomized controlled trials (RCT) (n=3790) (mean age 74 years; 83% of trials in patients >65 years) and a series of meta-analyses of high protein ONS (>20% energy from protein) demonstrated a range of effects across settings and patient groups in favor of the high protein ONS group.

The outcomes analyzed in this meta-analysis support the conclusions made in the systematic review and guideline cited above which include reduced complications (odds ratio (OR) 0.68 (95%CI 0.55-0.83), p<0.001, 10 RCT, n=1830); reduced readmissions to hospital (OR 0.59 (95%CI 0.41-0.84), p=0.004, 2 RCT, n=546).

Somanchi M et al. The facilitated early enteral and dietary management effectiveness trial in hospitalized patients with malnutrition. JPEN 2011 Mar; 35(2):209-16.

A retrospective cohort analysis using demographic data, anthropometric measurements, LOS, and serum albumin levels were collected from 400 patients in 2 medical wards to determine the prevalence of malnutrition and potential delays in nutrition consultation. Based on these results, a nutrition intervention study was conducted in 1 ward; the other ward served as a control. Patients were classified as normally nourished or malnourished. Multivariate general linear regressions were used to reveal the impact of intervention on the change in LOS, controlling for other potential confounding factors on the cohort and a subset with severe malnutrition.

Of the 400 patients assessed, 53% had malnutrition. Multiple general linear regressions showed that nutrition intervention reduced LOS an average of 1.93 days in the cohort group and 3.2 days in the severe malnourished group. Case mix index and female gender were positively associated with LOS in the malnourished group. Nutrition intervention reduced the delays in implementing nutrition support to patients by 47%.

Weiss AJ, Fingar KR, Barrett ML, Elixhauser A, Steiner CA, Guenter P, Brown MH. Characteristics of Hospital Stays Involving Malnutrition, 2013. HCUP Statistical Brief #210. September 2016. Agency for Healthcare Research and Quality, Rockville, MD.

Healthcare Cost and Utilization Project (HCUP) Statistical Brief presents national estimates on the characteristics of malnutrition reported during nonmaternal and non-neonatal hospital inpatient stays in 2013. Although malnutrition can include high caloric intake associated with overweight and obesity when defined broadly as nutritional imbalance, this Statistical Brief examines undernutrition only.

Association of a malnutrition diagnosis with up to 5x risk of in-hospital mortality, up to 2x higher hospital costs, up to 2x longer length of stay. Average hospital costs were higher for stays involving protein-calorie malnutrition (\$25,200) and postsurgical non-absorption (\$23,000) than for other stays without malnutrition (\$12,500).

Fingar KR, et al. Statistical Brief #281: All-Cause Readmissions Following Hospital Stays for Patients With Malnutrition, 2013. Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project. September 2016.

Healthcare Cost and Utilization Project (HCUP) Statistical Brief supplements a 2013 HCUP Statistical Brief that describes inpatient hospital stays among patients with six types of malnutrition: postsurgical non-absorption, nutritional neglect, cachexia, protein-calorie malnutrition, weight loss or failure to thrive, and underweight. The current Statistical Brief presents additional information on the all-cause 30-day rate of readmissions following an initial inpatient hospital stay for patients with malnutrition in the United States in 2013, following the same typology of malnutrition presented in the earlier Statistical Brief.

In 2013, the all-cause 30-day readmission rate for patients with malnutrition was 23.0 per 100, compared with 14.9 per 100 for patients without malnutrition. The average cost per readmission was \$16,900 for patients with protein-calorie malnutrition during an index stay and \$17,900 for patients with postsurgical non-

absorption—26 and 34 percent higher, respectively, than the readmission cost for patients without malnutrition during an index stay (\$13,400).

Deutz NE, Matheson EM, Matarese LE, et al. Readmission and mortality in malnourished, older, hospitalized adults treated with a specialized oral nutritional supplement: A randomized clinical trial. Clinical nutrition (Edinburgh, Scotland). 2016;35(1):18-26.

Patients found at-risk from screening and subsequently assessed for malnutrition (per Subjective Global Assessment), malnourished received nutrition support, which was associated with decreased 30, 60, 90-day mortality. The primary composite endpoint was similar between high-protein oral nutritional supplement (HP-HMB) (26.8%) and placebo (31.1%). No between-group differences were observed for 90-day readmission rate, but 90-day mortality was significantly lower with HP-HMB relative to placebo (4.8% vs. 9.7%; relative risk 0.49, 95% confidence interval [CI], 0.27 to 0.90; p = 0.018). The number-needed-to-treat to prevent 1 death was 20.3 (95% CI: 10.9, 121.4). Compared with placebo, HP-HMB resulted in improved odds of better nutritional status (SGA class, OR, 2.04, 95% CI: 1.28, 3.25, p = 0.009) at day 90, and an increase in body weight at day 30 (p = 0.035).

The study found that compared with placebo HP-HMB decreased mortality and improved indices of nutritional status during the 90-day observation period.

Corkins MR et al. Malnutrition diagnoses in hospitalized patients: United States, 2010.2014 Feb;38(2):186-95.

Examined data from the 2010 Healthcare Cost and Utilization Project (HCUP), the most recent nationallyrepresentative data describing U.S. hospital discharges. Using ICD-9 codes, we constructed a composite variable indicating a diagnosis of malnutrition. 3.2% of all U.S. hospital discharges in 2010 had this diagnosis. Relative to patients without a malnutrition diagnosis, those with the diagnosis were older, had longer lengths of stay and incurred higher costs. These patients were more likely to have 27 of 29 comorbidities assessed in HCUP. Finally, discharge to home care was twice as common among malnourished patients, and a discharge of death was more than 5 times as common among patients with a malnutrition diagnosis. Taken together, these nationally representative, cross-sectional data indicate that hospitalized patients discharged with a diagnosis of malnutrition are older and sicker and their inpatient care is more expensive than their counterparts without this diagnosis.

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

1a.4.2 What process was used to identify the evidence?

1a.4.3. Provide the citation(s) for the evidence.

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (if previously endorsed):

Measure Title: Development of a Nutrition Care Plan for Malnourished Patients

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Global Malnutrition Composite Score

Date of Submission: N/A

Instructions

- For composite performance measures:
 - A separate evidence form is required for each component measure unless several components were studied together.
 - If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.
- Respond to **all** questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). *Contact NQF staff if more pages are needed.*
- Contact NQF staff regarding questions. Check for resources at <u>Submitting Standards webpage</u>.

Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF's evaluation criteria.

1a. Evidence to Support the Measure Focus

The measure focus is evidence-based, demonstrated as follows:

- **Outcome**: ³ Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
- Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence⁴ that the measured intermediate clinical outcome leads to a desired health outcome.
- **Process:** ⁵ a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured process leads to a desired health outcome.
- **Structure**: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured structure leads to a desired health outcome.
- Efficiency: ⁶ evidence not required for the resource use component.
- For measures derived from **patient reports**, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
- **Process measures incorporating Appropriate Use Criteria:** See NQF's guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

Notes

9. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.

10. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) guidelines and/or modified GRADE.

11. Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one

1a.1. This is a measure of: (should be consistent with type of measure entered in De.1)

Outcome

Health outcome:

□Patient-reported outcome (PRO):

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, healthrelated behaviors. (A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)

□ Intermediate clinical outcome (*e.g., lab value*):

Process: Completion of a nutrition assessment for patients identified to be at-risk of malnutrition from a completed malnutrition screening

Appropriate Use Measure:

- Structure:
- Composite:
- 1a.2. LOGIC MODEL: Diagram that briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.





Implementation of Nutrition Intervention for Malnourished Patient ↓ Length of Stay, Mortality, Post-Operative Complications

Nutrition screening completed at admission can identify patients at risk of malnutrition early in the patient stay. Those patients who are identified are then assessed by a registered dietitian who, if appropriate, may recommend a specific nutrition intervention to address the patient's malnutrition, which if addressed early can reduce risk of mortality and post-operative complications and possibly reduce length of stay.

1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured *outcome, process, or structure* and finds it meaningful. (Describe how and from whom their input was obtained.)

**RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) **

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

1a.3. SYSTEMATIC REVIEW (SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses

explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

☑ Clinical Practice Guideline recommendation

□ US Preventive Services Task Force Recommendation

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

Other

Systematic Review	Evidence
Source of Systematic Review: Title Author Date Citation, including page number URL 	Mueller C, Compher C & Druyan ME and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Board of Directors. A.S.P.E.N. Clinical Guidelines: Nutrition Screening, Assessment, and Intervention in Adults. J Parenter Enteral Nutr. 2011;35: 16-24. <u>https://onlinelibrary.wiley.com/doi/epdf/10.1177/01</u> 48607110389335
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	"Nutrition support intervention is recommended for patients identified by screening and assessment as at risk for malnutrition or malnourished. Grade C" (Page 22) "Rationale - Nutrition support intervention in patients identified by screening and assessment as at risk for malnutrition or malnourished may improve clinical outcomes. This guideline places nutrition assessment and screening in the context of intervention as part of nutrition care. Nutrition intervention in malnourished patients was associated with improved nutrition status nutrient intake physical function and quality of life. In addition, hospital readmissions were reduced." (Page 23)
Grade assigned to the evidence associated with the recommendation with the definition of the grade	Grade C- Supported by at least 1 level II investigation Level III Evidence: Nonrandomized cohort with contemporaneous controls.

Systematic Review	Evidence
Provide all other grades and definitions from the evidence grading system	Level I Evidence: Large randomized trials with clear- cut results; low risk of false-positive (α) and/or false- negative (β) error
	Level II Evidence: Small, randomized trials with uncertain results; moderate to high risk of false- positive (α) and/or false-negative (β) error
	Level IV Evidence: Nonrandomized cohort with historical controls
	Level V Evidence: Case series, uncontrolled studies, and expert opinion
Grade assigned to the recommendation with definition of the grade	C-Supported by at least 1 level II investigation
Provide all other grades and definitions	A- Supported by at least 2 level I investigations
from the recommendation grading	B- Supported by 1 level I investigation
system	D- Supported by at least 1 level III investigation
	E – Supported by level IV or V evidence
Body of evidence:	2 small, randomized trials
 Quantity – how many studies? 	1 Nonrandomized cohort with contemporaneous
• Quality – what type of studies?	controls.
	1 nonrandomized cohort with historic controls
	1 uncontrolled observational study
Estimates of benefit and consistency across studies	Nutrition intervention in malnourished patients was associated with improved nutrition status nutrient intake physical function and quality of life. In addition, hospital readmissions were reduced.
What harms were identified?	No adverse events were identified in this SR
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	Yes, additional studies since the publication of the original SR have demonstrated further evidence of the benefits of nutrition intervention for patients with malnutrition. The studies demonstrate the impact of timely nutrition intervention on 30-day readmission risk and hospital length of stay.

OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE

Milne AC, Potter J, Vivanti A, Avenell A. Protein and energy supplementation in elderly people at risk from malnutrition. Cochrane Database Syst Rev. 2009;(2):CD003288.

URL:

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003288.pub3/abstract?systemMessage=Wiley+Onlin e+Library+will+be+unavailable+on+Saturday+14th+May+11:00-14:00+BST+/+06:00-09:00+EDT+/+18:00-21:00+SGT+for+essential+maintenance.Apologies+for+the+inconvenience

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

If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

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)

Mueller et al. Findings from Clinical Guideline

Outcome of Interest	Study Findings from Review
Body Composition	Norman (2008) study predicted significant improvement in body weight and body cell mass follow a three-month intervention of high-protein and energy supplements while Odeli (2005), found that patients managed using the nutrition care process experienced less weight loss (mean weight change -4.2 kg +/-6.4 cf8.9 kg +/- 5.9, P = 0.03) (Odeli, 2005).
Cost	Kruizenga (2005) found that, to shorten the mean length of hospital stay by 1 d for all malnourished patients, a mean investment of 76 euros (91 US dollars) in nutritional screening and treatment was needed.
Length of Stay (LOS)	Kruizenga (2005) found early screening and treatment of malnourished patients reduced the LOS in malnourished patients with low handgrip strength (i.e., frail patients) and another study found that patients managed using the NP had a shorter length of stay (3.2 days +/- 5.4 cf. 13.5 days +/- 14.1, P = 0.002) (Odeli 2005).
Muscle Function	Persson (2007) found that treated-as-protocol analyses showed that Katz ADL index improved in the I-group (p<0.001; p<0.05 between the groups).
Nutritional Intake	Babineau (2008) reported significant increases in energy (p=0.0001) and protein (p=0.01) intakes, and in serum albumin (p=0.001), prealbumin (p=0.003), transferrin (p=0.024), and hematocrit (p=0.026) levels. An additional study of standardized nutrition care added approximately 600 kcal and 12 g protein to the daily intake of malnourished patients (Kruizenga 2005)
Readmission	Norman (2008) study found dietary counselling patients experienced significantly more readmissions (n=20) than oral nutritional supplement patients (n=10) during the study period (p=0.041). One additional study found that fewer patients managed using standardized nutrition care had an unplanned hospital admission (46% cf. 75%, P = 0.04) (Odeli, 2005).

Milne et al. Findings from Clinical Guideline

Outcome of Interest	Study Findings from Review		
Mortality	48 included studies with a total of 8,031 participants when meta-analyzed, reported an overall relative risk (RR) of 0.92.		
	The subgroup analyses suggested that the results were statistically significant or approaching statistical significance when limited to trials in which participants (N = 2461) were defined as undernourished (RR 0.79), and when 400 kcal or more was offered per day in the supplement (N = 7307), (RR 0.89).		
	The results were consistent when analysis was restricted to 15 trials (N = 6604) with clearly concealed randomization (RR 0.91)		
Cost	24 trials with a total of 6,225 participants were meta-analyzed and overall, reported a statistically significant difference between intervention and control for risk of complications (RR=0.86).		
	In subgroup analyses, hip fracture patients were also at reduced risk of complications (RR=0.60).		
Length of Stay (LOS)	12 studies were meta-analyzed and pooled weighted mean difference for LOS using a random-effects model showed no benefit from supplementation -0.8 days (-2.8 to 1.3) with significant heterogeneity (chi-square 25.53; df 13; P = 0.02; I2 = 49%). Subgroup analyses for length of stay were too limited to suggest any difference between diagnostic groups.		
Quality of Life	Few studies were able to provide data on improvements in functional status or quality of life in general, apart from handgrip data. Measures were too diverse or too limited to combine for meta-analyses.		

What harms were studied and how do they affect the net benefit (benefits over harms)?

18 trials discussed adverse effects from nutritional supplementation, but no studies compared intervention group with control groups. Problems with tolerance and side-effects were reported in 12 studies including nausea, vomiting and diarrhea in the intervention group.

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

Valladares AF, Kilgore KM, Partridge J, Sulo S, Kerr KW, McCauley S. How a malnutrition quality improvement initiative furthers malnutrition measurement and care: results from a hospital learning collaborative. JPEN J Parenter Enteral Nutr. Published online April 13, 2020.

In this study, the implementation of malnutrition-focused quality improvement practices significantly improved the identification of malnutrition. The prompt identification and treatment of patients at malnutrition risk can improve patient care and health, as well as reduce costly readmissions. Improvements were observed for all 4 malnutrition quality measures. The greatest improvements were achieved as a result of timely nutrition assessment (P = .06) and malnutrition diagnosis (P = .02). Patients ≥ 65 years with a malnutrition diagnosis and nutrition care plan had a 24% lower likelihood of 30-day readmission but a longer mean LOS than did those without a care plan.

Mullin GE, Fan L, Sulo S, Partridge J. The Association between Oral Nutritional Supplements and 30-Day Hospital Readmissions of Malnourished Patients at a US Academic Medical Center. J Acad Nutr Diet. 2019;119(7):1168-1175.

Of 153,161 inpatient encounters analyzed, a total of 8,713 (5.7%) malnourished adults admitted to an academic medical center hospital in the United States between October 1, 2016, and September 30, 2017 were included in the analyses. Only 3.1% of malnourished patients received ONS. ONS users had 38.8% fewer readmissions compared with non-ONS counterparts (P¼0.017). The reduction in hospital readmissions by ONS was even greater for oncology patients (46.1%, P<0.001). A 50% reduction in time from hospital admission to ONS provision was associated with a 10.2% (P<0.01), 10.2% (P¼0.014), and 16.6% (P<0.01) decrease in LOS for overall, oncology, and intensive care unit encounters, respectively.

This study found that ONS intervention, when used, was associated with 38.8% fewer 30-day readmissions. This association was more pronounced for oncology encounters. Shorter LOS was observed when the interval between admission and ONS initiation was shorter.

Sharma Y, et al. Investigation of the benefits of early malnutrition screening with telehealth follow up in elderly acute medical admissions. QJM. 2017 Oct 1;110(10):639-647.

A randomized controlled trial, 148 malnourished patients were randomized to receive either a nutrition intervention for 3 months or usual care. Intervention included an individualized nutrition care plan plus monthly post-discharge telehealth follow-up whereas control patients received intervention only upon referral by their treating clinicians. Nutrition status was determined by the Patient Generated Subjective Global Assessment (PG-SGA) tool. Clinical outcomes included changes in length of hospital stay, complications during hospitalization, Quality of life (QoL), mortality and re-admission rate.

54 males and 94 females (mean age, 81.8 years) were included. Both groups significantly improved PG-SGA scores from baseline. There was no between-group differences in the change in PG-SGA scores and final PG-SGA scores were similar at 3 months 6.9 (95% CI 5.6-8.3) vs. 5.8 (95% CI 4.8-6.9) (P = 0.09), in control and intervention groups, respectively. Median total length of hospital stay was 6 days shorter in the intervention group (11.4 (IQR 16.6) vs. 5.4 (IQR 8.1) (P = 0.01). There was no significant difference in complication rate during hospitalization, QoL and mortality at 3-months or readmission rate at 1, 3 or 6 months following hospital discharge.

Meehan A, Loose C, Bell J, Partridge J, Nelson J, Goates S. Health System Quality Improvement: Impact of Prompt Nutrition Care on Patient Outcomes and Health Care Costs. J Nurs Care Qual. 2016.

Quality improvement program that positioned early nutritional care into the nursing workflow. Nurses screened formal nutrition risk at patient admission and then immediately ordered oral nutritional supplements for those at risk. Supplements were given as regular medications, guided and monitored by medication administration records.

Length of stay (-0.77 days or 13.4%), probability of readmissions (-17%) and cost of care (-\$969 or 8.8%) were all reduced (p<0.01).

This observational study supports early intervention on patients who are found to be at-risk of malnutrition.

Deutz NE, Matheson EM, Matarese LE, et al. Readmission and mortality in malnourished, older, hospitalized adults treated with a specialized oral nutritional supplement: A randomized clinical trial. Clinical nutrition (Edinburgh, Scotland). 2016;35(1):18-26

A Multicenter, randomized, placebo-controlled, double-blind trial of 652 older (≥65 years), malnourished (Subjective Global Assessment [SGA] class B or C) adults hospitalized for congestive heart failure, acute myocardial infarction, pneumonia, or chronic obstructive pulmonary disease with inpatient and posthospital statuses received standard-of-care plus HP-HMB (n = 328) or a placebo supplement (n = 324), 2 servings/day. Primary composite endpoint was 90-day postdischarge incidence of death or nonelective readmission. Other endpoints included 30- and 60-day postdischarge incidence of death or readmission, length of stay (LOS), SGA class, body weight, and activities of daily living (ADL). The primary composite endpoint was similar between HP-HMB (26.8%) and placebo (31.1%). No betweengroup differences were observed for 90-day readmission rate, but 90-day mortality was significantly lower with HP-HMB relative to placebo (4.8% vs. 9.7%; relative risk 0.49, 95% confidence interval [CI], 0.27 to 0.90; p = 0.018). The number-needed-to-treat to prevent 1 death was 20.3 (95% CI: 10.9, 121.4). Compared with placebo, HP-HMB resulted in improved odds of better nutritional status (SGA class, OR, 2.04, 95% CI: 1.28, 3.25, p = 0.009) at day 90, and an increase in body weight at day 30 (p = 0.035). LOS and ADL were similar between treatments.

Snider JT, Jena AB, Linthicum MT, et al. Effect of hospital use of oral nutritional supplementation on length of stay, hospital cost, and 30-day readmissions among Medicare patients with COPD. Chest. 2015;147(6):1477-84.

Retrospective cohort study identified hospitalizations in which ONS was provided, and used propensity-score matching to compare LOS, hospitalization cost, and 30-day readmission rates in a one-to-one matched sample of ONS and non-ONS hospitalizations.

One-to-one matched sample was created with 14,326 cases. In unadjusted comparisons in the matched sample, ONS use was associated with longer LOS (8.7 days vs 6.9 days, P < .0001), higher hospitalization cost (\$14,223 vs \$9,340, P < .0001), and lower readmission rates (24.8% vs 26.6%, P = .0116). However, in instrumental variables analysis, ONS use was associated with a 1.9-day (21.5%) decrease in LOS, from 8.8 to 6.9 days (P < .01); a hospitalization cost reduction of \$1,570 (12.5%), from \$12,523 to \$10,953 (P < .01); and a 13.1% decrease in probability of 30-day readmission, from 0.34 to 0.29 (P < .01).

ONS may be associated with reduced LOS, hospitalization cost, and readmission risk in hospitalized Medicare patients with existing morbidities such as COPD.

Cawood AL, Elia M, Stratton RJ. Systematic review and meta-analysis of the effects of high protein oral nutritional supplements. Ageing Res Rev. 2012;11(2):278-96.

The review concluded that high protein oral nutritional supplements had significant clinical, nutritional and functional benefits in a range of patient groups and health settings.

The authors' conclusions are reasonable but considerable clinical diversity in the included studies causes some uncertainty as to their generalizability. This systematic review involving 36 randomized controlled trials (RCT) (n=3790) (mean age 74 years; 83% of trials in patients >65 years) and a series of meta-analyses of high protein ONS (>20% energy from protein) demonstrated a range of effects across settings and patient groups in favor of the high protein ONS group.

The outcomes analyzed in this meta-analysis support the conclusions made in the systematic review and guideline cited above which include reduced complications (odds ratio (OR) 0.68 (95%CI 0.55-0.83), p<0.001, 10 RCT, n=1830); reduced readmissions to hospital (OR 0.59 (95%CI 0.41-0.84), p=0.004, 2 RCT, n=546).

Feldblum I et al. Individualized nutritional intervention during and after hospitalization: the nutrition intervention study clinical trial. J Am Ger Soc 2011; Jan;59(1):10-7

Double-blind, randomized, placebo-controlled trial conducted from March 2001 to January 2004 of 225 hospitalized acutely ill older adults. Normal hospital diet plus 400-mL oral nutritional supplements daily for 6 weeks. The composition of the supplement was such as to provide 995 kcal for energy and 100% of the Reference Nutrient Intakes for a healthy older person for vitamins and minerals. Measurements were taken at baseline, 6-week, and 6-month nutritional status and quality of life.

Randomization to the supplement group led to significantly better quality-of-life scores than in the placebo group at 6 months but not at 6 weeks, after adjustment for baseline quality of life, age, and sex. The effect of supplementation was seen in higher physical function, role physical, and social function scores. Corresponding treatment effects were 7.0 (95% confidence interval (CI)=0.5-13.6, P=.04), 10.2 (95% CI=0.1-20.2, P=.047), and 7.8 (95% CI=0.0-15.5, P=.05), respectively. There was no evidence of difference in Barthel scores at 6 months.

Somanchi M et al. The facilitated early enteral and dietary management effectiveness trial in hospitalized patients with malnutrition. JPEN 2011 Mar;35(2):209-16.

A retrospective cohort analysis using demographic data, anthropometric measurements, LOS, and serum albumin levels were collected from 400 patients in 2 medical wards to determine the prevalence of malnutrition and potential delays in nutrition consultation. Based on these results, a nutrition intervention study was conducted in 1 ward; the other ward served as a control. Patients were classified as normally nourished or malnourished. Multivariate general linear regressions were used to reveal the impact of intervention on the change in LOS, controlling for other potential confounding factors on the cohort and a subset with severe malnutrition.

Of the 400 patients assessed, 53% had malnutrition. Multiple general linear regressions showed that nutrition intervention reduced LOS an average of 1.93 days in the cohort group and 3.2 days in the severe malnourished group. Case mix index and female gender were positively associated with LOS in the malnourished group. Nutrition intervention reduced the delays in implementing nutrition support to patients by 47%.

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

1a.4.2 What process was used to identify the evidence?

1a.4.3. Provide the citation(s) for the evidence.

• 1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure (e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

The components of this composite measure are supported by clinical guidance that recommends the following: (1) malnutrition screening for patients admitted into the acute inpatient care setting; (2) nutrition assessment for patients at-risk of malnutrition in order to form the basis for an appropriate nutrition intervention; (3) appropriate recognition, diagnosis, and documentation of the nutrition status of a patient in order to address their condition with an appropriate plan of care and communicate patient needs to other care providers.

Implementation of this measure has supported hospitals in the timeliness of the malnutrition risk screening process, the hand off of patients at-risk of malnutrition to Registered Dietitian Nutritionists (RDNs) in the hospital for appropriate nutritional assessment and development of nutrition care plans with recommended nutrition interventions, and the subsequent medical diagnosis and execution of the nutrition care plan with support from the patient's physician. Evidence demonstrates that implementing a standardized protocol for screening, assessment, diagnosis and care planning results in better identification of malnourished patients and subsequent improvements in rates of nutrition intervention for the malnourished. Our outcomes modeling and those reported in other studies also demonstrates the benefits to patient outcomes, specifically reduced risk of 30-day readmissions.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. (This is required for maintenance of endorsement. *Include mean, std dev, min, max, interquartile range, scores by decile.* Describe the data source including number of measured entities; number of patients;

dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

A total of 179,336 patients aged 65 years and older were included in the testing population across 56 acute care hospitals in 10 states collected in calendar year 2019. Age-wise, the average age was 76.5 and the mean age was 75. In terms of race, the cohort was 77.8% White, 9.68% Black, 1.59% Asian or Pacific Islander, and 9.56% Other. The sample also included 4.91% who were identified as Hispanic.

Table: Summary Statistics

Median 3.32

Mean 3.07

St. Dev. 0.625653

Minimum 1.18

Maximum 3.77

Q1 2.674284

Q3 3.571668

IQR 0.897384

Table: Component Measure Scores and Overall Composite Scores from Reported Data (N=56)

Site	Component Measure #1 Score			Compor	
	Component Measure #4 Score				Overall
1	74%	96%	77%	79%	3.27
2	76%	71%	52%	89%	2.88
3	90%	44%	55%	47%	2.35
4	83%	53%	0%	44%	1.80
5	65%	66%	13%	85%	2.29
6	69%	63%	32%	68%	2.33
7	64%	57%	100%	50%	2.71
8	69%	79%	48%	54%	2.50
9	67%	46%	33%	67%	2.13
10	84%	79%	52%	62%	2.78
11	81%	56%	51%	69%	2.58
12	82%	54%	67%	89%	2.92
13	74%	24%	0%	33%	1.31
14	76%	73%	50%	70%	2.69
15	73%	44%	0%	0%	1.18
16	85%	12%	100%	60%	2.57
17	90%	68%	64%	52%	2.74
18	89%	90%	69%	83%	3.31
19	97%	91%	67%	88%	3.43
20	93%	98%	79%	88%	3.58
21	97%	93%	70%	89%	3.48
22	90%	91%	73%	89%	3.43

Component Measure #1 Score Component Measure #2 Score Component Measure #3 Score Component Measure #4 Score Overall Component Measure Score (0-4)

23	94%	95%	61%	88%	3.38
24	95%	85%	75%	80%	3.36
25	94%	94%	69%	80%	3.38
26	92%	96%	71%	83%	3.42
27	94%	89%	79%	80%	3.42
28	89%	93%	63%	88%	3.33
29	76%	66%	74%	59%	2.75
30	94%	96%	88%	87%	3.65
31	94%	100%	75%	99%	3.67
32	98%	100%	75%	99%	3.72
33	95%	95%	74%	97%	3.62
34	70%	68%	68%	93%	3.00
35	96%	58%	85%	25%	2.64
36	92%	94%	82%	99%	3.66
37	96%	100%	75%	100%	3.71
38	88%	97%	84%	96%	3.64
39	92%	97%	90%	98%	3.77
40	89%	100%	92%	86%	3.67
41	89%	100%	89%	97%	3.75
42	87%	93%	71%	97%	3.47
43	94%	97%	72%	93%	3.56
44	99%	94%	83%	89%	3.66
45	87%	86%	87%	94%	3.54
46	88%	98%	94%	97%	3.77
47	92%	92%	83%	88%	3.55
48	88%	95%	85%	93%	3.60
49	90%	100%	70%	90%	3.50
50	77%	86%	74%	30%	2.67
51	77%	86%	70%	47%	2.79
52	89%	70%	16%	29%	2.03
53	78%	81%	72%	30%	2.61
54	78%	71%	55%	71%	2.75
55	80%	100%	67%	83%	3.30
56	83%	92%	71%	72%	3.18

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

An article (citation below) presents our findings of a national malnutrition quality improvement initiative (MQii) where 27 hospitals implemented quality improvement projects aligned with four malnutrition electronic clinical quality measures (eCQMs) that form the basis of this composite measure. The study demonstrated

process improvements upon completion of 4 month quality improvement projects focused on: malnutrition screening timeliness, nutrition assessment completeness and timeliness, improvements in appropriate diagnosis of malnutrition. The study reported aggregate improvements across all four measures, with statistically significant improvements in nutrition assessment and malnutrition diagnosis. Furthermore, an outcome model was built to understand the relationship between development of a care plan for malnourished patients and risk of 30-day readmissions. This analysis resulted in a strong association between the nutrition care plan for malnourished patients with a relative risk reduction of 30-day readmissions. Patients (65+) with a malnutrition diagnosis and nutrition care plan had a 24% lower likelihood of 30-day hospital readmissions (21.4% vs. 26.5%, respectively) compared to those without a care plan (OR=0.74, 99%, CI=0.558-0.941).

Valladares AF, Kilgore KM, Partridge J, Sulo S, Kerr KW, McCauley S. How a Malnutrition Quality Improvement Initiative furthers malnutrition measurement and care: results from a hospital learning collaborative. JPEN J Parenter Enteral Nutr. 2020.

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. (This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

See attached submission form appendix where presented as table under Importance section, Table: Malnutrition and Malnutrition Risk Outcomes By Age, Race/Ethnicity and Gender Strata.

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

N/A

1c. Composite Quality Construct and Rationale

1c.1. A composite performance measure is a combination of two or more component measures, each of which individually reflects quality of care, into a single performance measure with a single score.

For purposes of NQF measure submission, evaluation, and endorsement, the following will be considered composites:

- Measures with two or more individual performance measure scores combined into one score for an accountable entity.
- Measures with two or more individual component measures assessed separately for each patient and then aggregated into one score for an accountable entity:
 - all-or-none measures (e.g., all essential care processes received, or outcomes experienced, by each patient);

1c.1. Please identify the composite measure construction: two or more individual performance measure scores combined into one score

1c.2. Describe the quality construct, including:

- the overall area of quality
- included component measures and
- the relationship of the component measures to the overall composite and to each other.

This composite measure of optimal malnutrition care focuses on adults 65 years and older admitted to inpatient service who received care appropriate to their level of malnutrition risk and/or malnutrition diagnosis if properly identified. Best practices for malnutrition care recommend adult inpatients to be screened for

malnutrition risk, assessed to confirm findings of malnutrition if found at-risk, and have the proper severity of malnutrition indicated along with a corresponding nutrition care plan that addresses the respective severity of malnutrition.

This malnutrition composite measure includes four component measures which are first scored separately. The overall composite score is derived from averaging the individual performance scores.

- 1. Screening for malnutrition risk at admission.
- 2. Completing a nutrition assessment for patients who screened for risk of malnutrition.
- 3. Appropriate documentation of malnutrition diagnosis in the patient's medical record if indicated by the assessment findings.
- 4. Development of a nutrition care plan for malnourished patients including the recommended treatment plan.

These four measures represent the key processes of care and generated markers of malnutrition associated with the risk identification, diagnosis, and treatment of malnutrition in older hospitalized adults as supported by clinical guidelines.

1c.3. Describe the rationale for constructing a composite measure, including how the composite provides a distinctive or additive value over the component measures individually.

The process for risk identification, diagnosis, and treatment of malnutrition necessitates a multi-disciplinary care team that begins with identification of an initial risk population for more thorough physical assessment by registered dietitians (RDN). The RDN in turn provides the necessary treatment recommendations to address nutritional status and the clinical indicators that inform a medical diagnosis of malnutrition completed by a physician. The four component measures individually only provide a fraction of the necessary information on quality of care for patients at-risk of malnutrition. For example, knowing which patients have been assessed out of those who were initially identified as at-risk, but not knowing if the appropriate proportion of patients were screened upon admission would be an insufficient assessment of quality of care.

1c.4. Describe how the aggregation and weighting of the component measures are consistent with the stated quality construct and rationale.

As studied in the empirical validity testing outlined in the testing attachment, each of the main components of this measure are strongly correlated with outcomes that have been empirically associated with malnutrition including 30-day readmissions and hospital length of stay. In this validity testing, we identified that each measure was correlated in a significant way to both malnutrition as a clinical outcome as well as the sequelae of untreated malnutrition including readmissions and longer length of stay. Therefore, the measure is constructed as an arithmetic average of the four components weighed equally. This is further supported by how the nutrition care process works in practice. Patient who are diagnosed and treated by a care team are most often first identified via a nutrition screening for malnutrition risk completed by a nurse around the time of admission prior to being referred to a registered dietitian for assessment and recommendations for malnutrition diagnosis and nutrition intervention.

2. Reliability and 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. *Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.*

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area (check all the areas that apply):
De.6. Non-Condition Specific (check all the areas that apply):

De.7. Target Population Category (Check all the populations for which the measure is specified and tested if any):

S.1. Measure-specific Web Page (Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)

https://www.eatrightpro.org/practice/quality-management/quality-improvement/malnutrition-quality-improvement-initiative

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is an eMeasure **Attachment:** MalnutritionCompositeScore_v5_91_Artifacts_-3-.zip,Global_Malnutrition_Composite_Measure_Feasibility_Scorecard.xlsx

S.2b. Data Dictionary, Code Table, or Value Sets (and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)

Attachment: Malnutrition_Composite_Data_Dictionary-637317308342961917.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure Attachment:

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

No

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

S.4. Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S. 14).

The Global Malnutrition Composite Score is comprised of four component measures which are scored separately and who's population is sourced from the overall composite measure denominator.

- 1. Screening for malnutrition risk at admission
- 2. Completion of a nutrition assessment for patients who screened for risk of malnutrition
- 3. Appropriate documentation of malnutrition diagnosis for patients identified with malnutrition
- 4. Development of a nutrition care plan for malnourished

S.5. 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, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the riskadjusted outcome should be described in the calculation algorithm (S. 14).

The composite measure is calculated by summing and then averaging the performance scores for each of the four component measures included in the overall composite measure. Each component measure is a proportion measure. CQL-specifications for all data elements used to calculate each component measure are attached to this form.

Component Measure Numerators are listed below:

Component Measure 1 - Screening for Malnutrition Risk at Admission

Numerator - All patients in the measure population who are documented as at-risk for malnutrition via the completed malnutrition screening

Component Measure 2 - Completion of a Nutrition Assessment for Patients who Screened for Risk of Malnutrition

Numerator - Patients at-risk of malnutrition who have a completed nutrition assessment documented

Component Measure 3 - Appropriate Documentation of Malnutrition Diagnosis for Patients Identified with Malnutrition

Numerator - Patients who have been identified as moderately or severely malnourished by the nutrition assessment who also have a documented medical diagnosis of malnutrition in their medical record

Component Measure 4 - Development of a Nutrition Care Plan for Malnourished Patients

Numerator - Patients with a documented medical diagnosis of malnutrition in their medical record who have a documented nutrition care plan with treatment recommendations to address malnutrition

S.6. Denominator Statement (Brief, narrative description of the target population being measured)

The measure population from which the composite's component measures are sourced from are patients aged 65 years and older who are admitted to an acute inpatient hospital.

S.7. Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S. 14).

Component Measure Denominators are Listed Below:

Component Measure 1 - Screening for Malnutrition Risk at Admission

Denominator - All patients in the measure population with a documented malnutrition screening no more than 48 hours prior to admission to the hospital

Component Measure 2 - Completion of a Nutrition Assessment for Patients who Screened for Risk of Malnutrition

Denominator - Patients from the measure population who are documented as at-risk for malnutrition via the completed malnutrition screening

Component Measure 3 - Appropriate Documentation of Malnutrition Diagnosis for Patients Identified with Malnutrition

Denominator - Patients from the measure population who have a completed nutrition assessment documented with findings of moderate or severe malnutrition

Component Measure 4 - Development of a Nutrition Care Plan for Malnourished Patients

Denominator - Patients from the measure population who have a documented medical diagnosis of malnutrition in their medical record

S.8. Denominator Exclusions (Brief narrative description of exclusions from the target population)

All Four Component Measures: patients with a length of stay less than 24 hours

Component Measure #1 only: admission to screening time interval greater than 48 hours

Component Measure #3 and #4 only : Discharge status of hospice or left against medical advice

S.9. Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)

- Patient Length of Stay <24 hours: all patients with a calculated length of stay
- Discharge Status Hospice
- Discharge Status Left Against Medical Advice
- Admission to Screening Time Interval =48 hours

S.10. Stratification Information (Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)

N/A

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

No risk adjustment or risk stratification

If other:

S.12. Type of score:

Continuous variable, e.g. average

If other:

S.13. 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

S.14. Calculation Algorithm/Measure Logic (Diagram or 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; time period for data, aggregating data; risk adjustment; etc.)

As studied in the empirical validity testing outlined in the testing attachment, each of the main components of this measure are strongly correlated with outcomes that have been empirically associated with malnutrition including 30-day readmissions and hospital length of stay. In this validity testing, we identified that each measure was correlated in a significant way to both malnutrition as a clinical outcome as well as the sequelae of untreated malnutrition including readmissions and longer length of stay. Therefore, the measure is constructed as an arithmetic average of the four components weighed equally. This is further supported by how the nutrition care process works in practice. Patient who are diagnosed and treated by a care team are most often first identified via a nutrition screening for malnutrition risk completed by a nurse around the time of admission prior to being referred to a registered dietitian for assessment and recommendations for malnutrition diagnosis and nutrition intervention.

S.15. Sampling (*If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.*)

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

To meet minimum requirements for measure implementation in quality reporting programs, there must be a minimum of 20 eligible encounters per reporting entity for valid performance measure scoring.

S.16. Survey/Patient-reported data (*If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.*)

Specify calculation of response rates to be reported with performance measure results.

N/A

S.17. Data Source (Check ONLY the sources for which the measure is SPECIFIED AND TESTED).

If other, please describe in S.18.

Electronic Health Records

S.18. Data Source or Collection Instrument (Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

N/A

S.19. Data Source or Collection Instrument (available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)

No data collection instrument provided

S.20. Level of Analysis (Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED) Facility

S.21. Care Setting (Check ONLY the settings for which the measure is SPECIFIED AND TESTED)

Inpatient/Hospital

If other:

S.22. COMPOSITE Performance Measure - Additional Specifications (Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)

See CQL Specifications for measure calculation procedures.

2. Validity – See attached Measure Testing Submission Form

Global_Malnutrition_Composite_Measure_Testing_Attachment_Final-637333639882378644.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

No

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include

information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

No

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*): Composite Measure Title: Global Malnutrition Composite Measure Date of Submission: 3/6/2020

Composite Construction:

Improvement to the second seco

All-or-none measures (e.g., all essential care processes received or outcomes experienced by each patient)

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 1.7.

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 sources of data specified and intended for measure implementation. **If different data sources are used for different components in the composite, indicate the component after the checkbox. If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.)**

Measure Specified to Use Data From: (must be consistent with data sources entered in S.17)	Measure Tested with Data From:
abstracted from paper record	abstracted from paper record
□ claims	□ claims
□ registry	□ registry
abstracted from electronic health record	abstracted from electronic health record
☑ eMeasure (HQMF) implemented in EHRs	☑ eMeasure (HQMF) implemented in EHRs
□ other:	□ other:

1.2. If an existing dataset was used, 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).

1.3. What are the dates of the data used in testing? March–October 2018 for Validity Testing; January 2019 – December 2019 for Reliability Testing;

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*)

Measure Specified to Measure Performance of: (must be consistent with levels entered in item S.20)	Measure Tested at Level of:
individual clinician	individual clinician
□ group/practice	□ group/practice
⊠ hospital/facility/agency	⊠ hospital/facility/agency
health plan	health plan
□ other:	□ other:

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*)

	_					
#	State	Hospital Type	Bed Size	Urban/Rural	Total Patients Included	
1	NC	Short Term Acute Care	Medium	Urban	413	
2	NC	Short Term Acute Care	Large	Urban	2064	
3	NC	Community Hospital	Medium	Urban	1042	
4	NC	Academic Medical Center	Large	Urban	2256	
5	NC	Academic Medical Center	Large	Urban	1619	
6	VA	Critical Access Hospital	Small	Rural	135	
7	VA	Critical Access Hospital	Small	Rural	287	
8	VA	Short Term Acute Care	Medium	Rural	281	
9	VA	Short Term Acute Care	Large	Urban	3310	
10	WV	Academic Medical Center	Large	Urban	1403	
11	NY	Academic Medical Center	Large	Urban	1935	
12	NC	Short Term Acute Care	Large	Urban	4297	
13	СО	Academic Medical Center	Large	Urban	1759	
14	РА	Short Term Acute Care	Medium	Urban	1484	
15	РА	Short Term Acute Care	Small	Rural	152	
16	РА	Short Term Acute Care	Medium	Urban	687	
17	РА	Short Term Acute Care	Large	Urban	1363	
18	РА	Short Term Acute Care	Medium	Urban	410	
19	РА	Short Term Acute Care	Medium	Rural	504	
20	РА	Short Term Acute Care	Medium	Urban	362	
21	РА	Short Term Acute Care	Medium	Urban	446	
22	РА	Short Term Acute Care	Large	Urban	1040	
23	РА	Short Term Acute Care	Medium	Rural	415	
24	PA	Short Term Acute Care	Large	Urban	1568	

Table 1 – Description of Measured Entities Included in Measure Testing

#	State	Hospital Type	Bed Size	Urban/Rural	Total Patients Included
25	PA	Academic Medical Center	Large	Urban	1850
26	PA	Academic Medical Center	Large	Urban	2063
27	PA	Short Term Acute Care	Medium	Urban	920

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).

A total of 37,450 patients aged 65 years and older were included in the testing population across 27 acute care hospitals in 6 states. Out of the total, 53.3% were female. In terms of age breakdown, 46% were 65-74, 33.9% were 75-84, and 20.1% were 85+. Race distribution was as follows: 81.8% White, 12% Black, 1.2% Asian or Pacific Islander, 0.2% American Indian or Alaska Native, 1.9% Other, and 2.9% were unable to be determined. Out of the total, 2.2% were of Hispanic ethnicity.

Data quality was a concern for the time-to-screening data point for patients above the 99th percentile and were therefore excluded from the analysis (N=473). The capture of screening data longer than 48 hours prior to admission was not included in the dataset. These screening results are not considered to be clinically reliable according to clinical guidance by expert consensus and as outlined by the Academy of Nutrition and Dietetics. Nutritional status as identified via malnutrition screening should occur during the admission process.

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.

A separate and more recent dataset was constructed to complete additional testing for the composite measure reliability. A total of 179,336 patients aged 65 years and older were included in the testing population across 56 acute care hospitals in 10 states. This newer dataset was similar in demographic breakdown of the validity testing dataset. Age-wise, the average age was 76.5 and the mean age was 75. In terms of race, the cohort was 77.8% White, 9.68% Black, 1.59% Asian or Pacific Islander, and 9.56% Other. The sample also included 4.91% who were identified as Hispanic.

#	State	Hospital Type	Bed Size	Urban/Rural	Total Patients Included
1	NC	Short Term Acute Care	Medium	Urban	27087
2	NC	Short Term Acute Care	Large	Urban	9222
3	VA	Critical Access Hospital	Small	Rural	135
4	РА	Short Term Acute Care	Medium	Urban	3037
5	РА	Short Term Acute Care	Small	Rural	229
6	РА	Short Term Acute Care	Medium	Urban	1556
7	РА	Short Term Acute Care	Large	Urban	2954
8	РА	Short Term Acute Care	Medium	Urban	657
9	PA	Short Term Acute Care	Medium	Rural	965
10	РА	Short Term Acute Care	Medium	Urban	820
11	РА	Short Term Acute Care	Medium	Urban	857
12	РА	Short Term Acute Care	Large	Urban	1887
13	РА	Short Term Acute Care	Medium	Rural	903
14	РА	Short Term Acute Care	Large	Urban	3157
15	PA	Academic Medical Center	Large	Urban	3629
16	РА	Academic Medical Center	Large	Urban	3782

Table 1 – Description of Measured Entities Included in Measure Reliability	Testing
----------------------------------------------------------------------------	---------

#	State	Hospital Type	Bed Size	Urban/Rural	Total Patients Included
17	РА	Short Term Acute Care	Medium	Urban	1984
18	UT	Short Term Acute Care	Small	Urban	1030
19	UT	Short Term Acute Care	Small	Urban	1294
20	ID	Short Term Acute Care	Small	Rural	518
21	UT	Short Term Acute Care	Small	Rural	800
22	UT	Short Term Acute Care	Medium	Urban	8855
23	UT	Critical Access Hospital	Small	Rural	233
24	UT	Short Term Acute Care	Large	Urban	10785
25	UT	Short Term Acute Care	Medium	Urban	2152
26	UT	Short Term Acute Care	Small	Urban	180
27	UT	Short Term Acute Care	Medium	Urban	1682
28	UT	Short Term Acute Care	Large	Urban	5763
29	UT	Short Term Acute Care	Small	Rural	711
30	UT	Short Term Acute Care	Small	Urban	1000
31	UT	Critical Access Hospital	Small	Rural	175
32	UT	Short Term Acute Care	Small	Rural	386
33	UT	Short Term Acute Care	Large	Urban	6386
34	WI	Academic Medical Center	Large	Urban	6081
35	NJ	Academic Medical Center	Large	Urban	11760
36	IA	Short Term Acute Care	Large	Urban	1560
37	IA	Short Term Acute Care	Medium	Urban	4740
38	IA	Short Term Acute Care	Small	Urban	785
39	РА	Short Term Acute Care	Medium	Urban	1071
40	РА	Short Term Acute Care	Medium	Urban	566
41	РА	Short Term Acute Care	Small	Rural	608
42	РА	Short Term Acute Care	Large	Rural	1551
43	PA	Short Term Acute Care	Medium	Urban	326
44	PA	Short Term Acute Care	Small	N/A	859
45	ME	Short Term Acute Care	Medium	Urban	938
46	ΤХ	Short Term Acute Care	Medium	Urban	1391
47	ΤХ	Short Term Acute Care	Small	Urban	873
48	ΤХ	Short Term Acute Care	Medium	Urban	3845
49	ΤХ	Short Term Acute Care	Medium	Urban	3203
50	ΤХ	Short Term Acute Care	Medium	Urban	6280
51	ΤХ	Short Term Acute Care	Medium	Urban	3824
52	ΤХ	Short Term Acute Care	Medium	Urban	5449
53	ΤХ	Short Term Acute Care	Medium	Urban	2036
54	ΤХ	Short Term Acute Care	Large	Urban	4506
55	ΤХ	Short Term Acute Care	Large	Urban	5348
56	ΤХ	Short Term Acute Care	Large	Urban	7061

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

No social risk factor data were collected for testing.

2a2. RELIABILITY TESTING

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.

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

Note: Current guidance for composite measure evaluation states that reliability must be demonstrated for the composite performance measure score.

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

2a2.2. 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*)

Composite measure reliability was assessed using the variance components—extracted from a linear mixed effects (LME) model—to calculate the intraclass correlation coefficient (ICC). The LME framework was employed, because it accommodates inclusion of both fixed and random effects, the latter of which account, statistically, for the correlated or non-independent nature of measures that are hierarchically nested within health systems (N = 10) and practice sites (N = 56). The model variance (σ^2) can then be partitioned into components that are, in turn, used to calculate the ICC.

Drawing on this well-established framework, a three-step process was followed to calculate the ICC. First, an intercept-only LME model was fitted to the composite measure data, incorporating health system (HSYSTEM) as a random intercept term. Second, the between-system ($\sigma^2_{between}$) and within-system (σ^2_{within}) were extracted from the LME model, and, third, the ICC was generated by taking the ratio of the respective variance components:

ICC = $\sigma^2_{between} / (\sigma^2_{between} + \sigma^2_{within})$.

The reliability assessment was carried using the **Ime4** and **performance** packages in R. Specifically, the **Ime4** package was used to fit of the LME model to the composite measure data, and the **performance** package—a bundle of utility functions for assessing statistical model quality—was used to capture the model variance components and ICC.

2a2.3. 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)

The ICC was calculated in two models, without case minimums (Model 1) and with the following exclusion criteria as reflected in the measure specifications (Model 2):

- 1. A minimum of 20 cases in the denominator for each measures
- 2. A minimum of three reportable measures given case minimum as described in 1.

Model 1 (Without Case Minimums)

Number of Observations: 56, Groups (HSYSTEM): 10

Syntax

Linear mixed model fit by REML ['ImerMod']

Formula: MEAS ~ 1 + (1 | HSYSTEM)

Data: data1

Output

REML criterion at convergence: 57.5

Scaled residuals:

Minimum	1Q	Median	3Q	Maximum
-3.5799	-0.2062	0.0798	0.4261	1.5887

Random effects:

Groups Name	Variance	Standard Deviation
HSYSTEM	0.2090	0.4571
Residual	0.1139	0.3375

Fixed effects:

Measure	Estimate	Standard Error	t-value
(intercept)	3.1165	0.1627	19.15

Result

ICC: 0.647

Model 2 (With Case Minimums)

Number of Observations: 47, Groups (HSYSTEM): 10

Syntax

Linear mixed model fit by REML ['ImerMod']

Formula: MEAS ~ 1 + (1 | HSYSTEM)

Data: data2

Output

REML criterion at convergence: 6

Scaled residuals:

Minimum	1Q	Median	3Q	Maximum
-3.3660	-0.3503	0.0652	0.4144	2.6385

Random effects:

Groups Name	Variance	Standard Deviation
HSYSTEM	0.18923	0.4350
Residual	0.03623	0.1903

Fixed effects:

Measure	Estimate	Standard Error	t-value
(intercept)	3.1306	0.1446	21.65

Result

ICC: 0.839

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.e., what do the result s mean and what are the norms for the test conducted?)

With regard to using a calculation of intraclass correlation (ICC) to detect signal to noise, a reliability score of 0.70 or greater is considered acceptable for drawing conclusions about groups. The measure's reliability was tested with and without cases minimums typically recommended by CMS in its quality reporting programs in order to demonstrate the measure's reliability with those case minimums in place. With case minimums, the ICC calculated was 0.839 and without case minimums it resulted in an ICC of 0.647. This statistic indicates that the composite measure is well within the range established as acceptable for reliability, meaning the composite performance measure score is able to detect meaningful differences among provider groups.

2b1. VALIDITY TESTING

Note: Current guidance for composite measure evaluation states that validity should be demonstrated for the composite performance measure score. If not feasible for initial endorsement, acceptable alternatives include assessment of content or face validity of the composite OR demonstration of validity for each component. Empirical validity testing of the composite measure score is expected by the time of endorsement maintenance.

2b1.1. What level of validity testing was conducted?

Critical data elements (data element validity must address ALL critical data elements)

⊠ Composite performance measure score

Empirical validity testing

Systematic assessment of face validity of performance measure score as an indicator of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

☑ Validity testing for component measures (check all that apply)

Note: applies to ALL component measures, unless already endorsed or are being submitted for individual endorsement.

Endorsed (or submitted) as individual performance measures

Critical data elements (data element validity must address ALL critical data elements)

Empirical validity testing of the component measure score(s)

□ **Systematic assessment of face validity of component measure score(s) as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*)

2b1.2. For each level of testing 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)

Composite Performance Measure Score Validity Testing

To empirically test the construct validity of the overall composite measure at the score level, a hierarchical linear regression was conducted to demonstrate that the predictability of the model significantly improved when the components in aggregate were included into the model over standard predictors of these outcomes such as patient characteristics, primary diagnoses, and comorbidities.

The impact of the composite measure components on 30-day readmissions and LOS was assessed using hierarchical regression analysis. Independent variables fell into two categories: "demographic and clinical" and

"malnutrition." A stepwise approach was taken to measure the explanatory power of the malnutrition variables. The hospital 30-day readmissions and LOS models were initially estimated using only the demographic and clinical variables. Next, the models were re-estimated including the malnutrition variables. This approach allowed us to estimate the incremental improvement in goodness-of-fit from including the malnutrition variables. Model goodness-of-fit was reported as adjusted-R² for the hospital LOS model and the concordance statistic (c-statistic) for the 30-day readmissions model. The statistical significance of the improvement of model fit was tested using the change in -2 residual log-likelihood.

A secondary analysis was conducted to specifically assess the association between the main clinical endpoint of the composite measure (nutrition care plans for patients with a diagnosis of malnutrition) and the outcomes most associated with malnutrition (30-day readmissions and length of stay). The analysis intended to understand the association of having a nutrition care plan with a malnutrition diagnosis vs not having a nutrition care plan.

Validity Testing for Component Measures - Critical Data Elements

Construct validity of the critical data elements for the component measures was tested by developing a generalized linear (logistic) regression model. The response variable was Medical Diagnosis (2 levels) as it is the logical outcome of proper screening and assessment for malnutrition. Predictor variables were Screening Result (3 levels), Time to Assessment (3 levels) and Assessment Result (3 levels). An additional test was conducted to ensure the overall linear model for predicting diagnosis was also predictive of the nutrition care plan. The hypothesis for this test is that all predictor variables would be correlated to the outcome of malnutrition diagnosis and that together they would be a strong predictor of the malnutrition outcome, supporting the validity of including these components in the malnutrition composite.

In addition to testing the components of the measure for validity towards the outcome of the composite measure, testing was completed to assess the correlation between the components and outcome of the composite measure with clinical outcomes of patient length of stay (LOS) and 30-day readmissions. This phase of testing assessed the predictive relationship between the set of measure components and LOS and Readmissions, adjusting for differences in patient characteristics. A generalized linear mixed model approach was utilized to conduct the analyses, also known as hierarchical linear modeling.

In the description of the models, the following notation is used:

Measure	Evidence
y _{ij}	Response (dependent) variable for Patient <i>i</i> treated in Site <i>j</i>
	1. LOS
	2. Readmission (yes/no)
eta_0	Overall intercept
$\beta_1 X_1 \cdots B_k X_k$	Main effects for <i>k</i> explanatory (predictor) variables
	 Patient-level predictors (patient sex, race, and Hispanic ethnicity)
	1. Screening result (2 categories: At-risk, Not-at-Risk)
	2. Time-to-Assessment (3 categories: median split & none)
	3. Medical Diagnosis of Malnutrition (2 categories: Yes/No)
	Nutrition Care Plan (2 categories: Yes/No)
	5. Primary Diagnosis (CCS-2 Category Level)
$(\beta_1 X_1 \cdots B_k X_k)$	Two-way interactions of predictor variables
×	
$(\beta_1 X_1 \cdots B_k X_k)$	

Table 2 – Variables Included in the Model

Measure	Evidence
μ_j	Site-specific random effect
ε_{ij}	Individual error term

The model can be defined as:

 $y_{ij} = \beta_0 + (\beta_1 X_1 \cdots B_k X_k) + \left((\beta_1 X_1 \cdots B_k X_k) \times (\beta_1 X_1 \cdots B_k X_k) \right) + \mu_j + \varepsilon_{ij}$

The random effect parameter, μ_j , is included to account for the non-independence of data from patients treated in the same facility. This controls for the different (and unmeasured) characteristics of the separate treatment sites.

2b1.3. What were the statistical results from validity testing? (e.g., correlation; t-test)

Composite Performance Measure Score Validity Testing

Our major finding is that malnutrition indicators are significantly related to LOS and Readmissions after controlling for the other variables that were included in the model (patient demographics and primary diagnosis) known to be predictive of those outcomes. The R² statistic for the LOS model was 0.063 prior to the inclusion of the aggregate measure components and 0.288 after (p<0.001), and the c-statistic for the 30-day readmissions model was 0.614 before their inclusion and 0.625 after (p<0.01).

However, to better characterize the predictability of our current malnutrition outcomes model for length of stay and readmissions, we sought to compare the predictability of CMS' HCC risk-adjustment model. The HCC model predicts total annual costs, and the statistical models which were evaluated by RTI in 2011 demonstrated the predictive ability for individuals of prospective diagnosis-based models had R² values ranging from 0.0186 to 0.1246 (evaluated by RTI in 2011). Given the statistics shared above, the strength of predictability of this model and overall measure is adequate and comparable to those already being implemented by CMS for similar purposes.

The secondary analysis of the relationship between a documented nutrition care plan and risk of 30-day readmissions in patients with a malnutrition diagnosis showed a statistically significant relative risk reduction of 24% (21.4% vs. 26.5%, respectively) in the likelihood of 30-day readmissions (OR=0.74, 99%, CI=0.558-0.941). For LOS, hospitalized patients with a malnutrition diagnosis who had a nutrition care plan had on average, a 3-day longer LOS than malnourished patients without a nutrition care plan (LOS of 9.46 vs. 6.46 days, respectively; p=0.0001).

Validity Testing for Component Measures - Critical Data Elements

Effect	df	Wald Chi-Square	p-value
Screening Result	2	75.1	<.0001
Time to Assessment	2	1094.5	<.0001
Assessment Result	2	2006.8	<.0001
Screening Result * Time to Assessment	4	480.9	<.0001
Screening Result * Assessment Result	4	609.0	<.0001
Effect	df	Fisher's Exact Test	p-value
Malnutrition Diagnosis * Nutrition Care Plan	1	7584.5	< .0001

Table 3 - Results of Generalized Linear Regression Model on Composite Outcome

c-statistic: 0.828 [fit of the overall score]





*TTA = Time to Assessment; The timing was tested at the median split for all hospitals included in the testing dataset.



Table 5 – 30-Day Readmissions Predictability of Malnutrition Composite Measure Components

2b1.4. 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?)

Composite Performance Measure Score Validity Testing

As reported in the results of both analyses, the composite measure results are strongly correlated to important clinical outcomes associated with malnutrition in the literature, 30-day readmissions and length of stay. Furthermore, the secondary analysis demonstrated that nutrition care plans may be associated with a reduced risk of 30-day readmission for those with malnutrition vs those who are diagnosed with malnutrition but do not have a nutrition care plan.

Validity Testing for Component Measures – Critical Data Elements

As outlined in Table 3, all main effects and 2 2-way interactions were highly significant (all p-values <.0001), consistent with our hypotheses. The c-statistic of 0.828 indicates an excellent fit of the model to the malnutrition diagnosis and nutrition care plan. A c-statistic above 0.8 normally indicates a very strong predictive model.

The results in Tables 4 and 5, demonstrate that all components of the malnutrition composite measure, including the outcome of the malnutrition composite measure (malnutrition diagnosis and nutrition care plan) were significantly predictive of the outcome of length of stay (p<0.0001) and 30-day readmissions (p<0.0001).

Note: Applies to the composite performance measure, as well all component measures unless they are already endorsed or are being submitted for individual endorsement.

NA 🗆 no exclusions — skip to section 2b4

2b2.1. 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*)

The two main exclusions for this measure are a length of stay <24 hours as those patients are not in the hospital long enough to receive proper care for malnutrition. Patients who are transferred or discharged to hospice have significantly different requirements for nutrition support and those treatment plans are highly dependent on patient preferences.

Our project team tested measure exclusion criteria for both their impact on the measure performance score and validity statistics for each individual component measure when they were first developed. The project team tested the measure specifications with a set of hypothetical measure exclusions that were determined by consensus agreement of the Technical Expert Panel but were not explicitly identified in the evidence review. We assessed the measure performance score of each respective testing site with the exclusion criteria and without in order to determine the exclusion criteria's impact on the facility's score.

2b2.2. 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)

In the original measure testing of the individual components, we identified that neither of the exclusion criteria had significant impacts on the performance scores. When measures were constructed with and without exclusions no p-values reached significance when a two-tailed t-test was performed on the difference between the performance scores.

Component Measure	t-test p-value
Malnutrition Screening	p>0.3
Nutrition Assessment	p>0.4
Malnutrition Diagnosis	p>0.8
Nutrition Care Plan	p>0.3

2b2.3. 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)

At the individual measure level, there was no significant impact of the measure exclusions on the performance measure scores for all 4 component measures.

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section <u>2b4</u>.

2b3.1. What method of controlling for differences in case mix is used? (check all that apply)

Endorsed (or submitted) as individual performance measures

No risk adjustment or stratification

□ Statistical risk model with risk factors

Note: Applies to all outcome or resource use component measures, unless already endorsed or are being submitted for individual endorsement.

□ Stratification by risk categories

Other,

2b3.1.1 If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g.*, potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care) Also discuss any "ordering" of risk factor inclusion; for example, are social risk factors added after all clinical factors?

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

- Published literature
- 🗆 Internal data analysis
- Other (please describe)

2b3.4a. What were the statistical results of the analyses used to select risk factors?

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors (e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.) Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.

2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used)

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.

If stratified, skip to <mark>2b3.9</mark>

2b3.6. Statistical Risk Model Discrimination Statistics (e.g., c-statistic, R-squared):

2b3.7. Statistical Risk Model Calibration Statistics (e.g., Hosmer-Lemeshow statistic):

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

2b3.9. Results of Risk Stratification Analysis:

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.e., what do the results mean and what are the norms for the test conducted)

2b3.11. Optional Additional Testing for Risk Adjustment (**not required**, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed)

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

Note: Applies to the composite performance measure.

2b4.1. 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? Do not just repeat the information provided related to performance gap in 1b)

A bootstrap resampling methodology was employed to generate a 95% confidence interval around the composite score mean. The 95% confidence interval will then be used to group providers into performance categories (Low, Medium, High).

Specifically, the **resample** package in R was used to generate a bootstrap sample (N = 10,000) from the empirical, i.e. observed, distribution of composite scores across providers. The mean score and standard error—derived from the bootstrap distribution—were estimated, and a 95% CI was generated to drive categorization of provider performance above, within and below the 95% CI of the mean score estimate.

Participating hospitals were categorized into three tiers that reflect those whose composite measure performance scores were above, overlapped with, or were below the 95% estimate generated in the bootstrap analysis. If a hospital's composite score was assigned a Tier 3 score it was above the estimated confidence interval and implies that the specific hospital's performance was above the average of the estimate developed from the aggregate of all reporting sites. A hospital receiving a Tier 2 score means their performance was not meaningfully different than the estimated mean. Finally, a hospital receiving a Tier 1 score implies that their composite performance score fell below the mean estimate interval reflective of lower than expected performance.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined)

Among hospitals that meet the case minimum of 20 patients and at least 3 reportable measures, 44.7% of hospitals were in the highest performing Tier 3, 14.9% were in Tier 2, and 40.4% were in Tier 1.

Category	All Participants: Number of Hospitals	Participants N≥ 20: Number of Hospitals
Tier 3	22, 39.3%	21, 44.7%
Tier 2	3, 5.4%	7, 14.9%
Tier 1	31, 55.3%	19, 40.4%

January 1, 2019 through December 31, 2019

2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities? (i.e., what do the results mean in terms of statistical and meaningful differences?)

This tiering approach informed by the bootstrap sample derived from the observed performance measures was used to appropriately distinguish sites with varying degrees of performance among the component measures. These differences ultimately translated to variation in performance on the overall composite measure. Our specific sample of sites is relatively homogeneous because the participating hospitals have been targeting improvement on these quality measures for 1-3 years.

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS

Note: Applies to all component measures, unless already endorsed or are being submitted for individual endorsement.

If only one set of specifications, this section can be skipped.

Note: This item is directed to measures that are risk-adjusted (with or without social risk factors) **OR** to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to

identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (describe the steps—do not just name a method; what statistical analysis was used)

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.*e., what do the results mean and what are the norms for the test conducted*?)

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

Note: Applies to the overall composite measure.

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

In the database integration process, a test of consistency for the core data elements is conducted to ensure that the main care processes measured (malnutrition screening and nutrition assessment) are not missing data. For instance, if an assessment is performed, data on the assessment result and the time interval between the screening and assessment completion is also present. A consistency measure reflective of the presence of these data corresponding to measured care processes was calculated to see the rate of observed care processes vs expected number of results and time intervals as appropriate.

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g.*, results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each)

The average consistency measure across the sample of hospitals in the testing dataset was >95%.

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias? (i.e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis, provide rationale for the selected approach for missing data)

The rates of missing data were consistently low across all reporting sites due to very high feasibility of the data elements as these data are collected during the care process and do not introduce any burden to clinicians. Due to these factors and the consistency statistic results, we conclude that systematic missing data is not biasing performance for this measure.

2c. EMPIRICAL ANALYSIS TO SUPPORT COMPOSITE CONSTRUCTION APPROACH

Note: If empirical analyses do not provide adequate results—or are not conducted—justification must be provided and accepted in order to meet the must-pass criterion of Scientific Acceptability of Measure Properties. Each of the following questions has instructions if there is no empirical analysis.

2d1. Empirical analysis demonstrating that the component measures fit the quality construct, add value to the overall composite, and achieve the object of parsimony to the extent possible.

2d1.1 Describe the method used (*describe the steps*—*do not just name a method; what statistical analysis was used;* **if no empirical analysis**, *provide justification*)

See component-level measure validity testing described in section 2b1. In this section, we demonstrate how each component contributes to both the quality construct of the composite measure as well as to two patient indicators that are well-measured and correlated with malnutrition.

However, the first-line analyses for length of stay and 30-day readmissions were conducted to compare patients meeting numerator characteristics of the component measures included in the composite measure. Once the predictability of the outcomes of interest was established additional testing was completed to determine difference in outcomes between patients who were diagnosed and had a care plan versus those that did not (i.e., met versus failed the composite measure). The hypothesis for this cross-tabulation analysis was that the outcome of the composite measure, or malnourished patients with a nutrition care plan, should have a reduced likelihood of readmission than those without a care plan. It was also assumed that length of stay would be higher in patients at-risk of malnutrition and/or diagnosed with malnutrition because patients who are at-risk or malnourished tend to have higher acuity than the general population.

2d1.2. What were the statistical results obtained from the analysis of the components? (e.g., correlations, contribution of each component to the composite score, etc.; if no empirical analysis, identify the components that were considered and the pros and cons of each)

See 2b1.2 for component-level measure validity testing.

Patients (65+) with a malnutrition diagnosis and nutrition care plan had a 24% lower likelihood of 30-day hospital readmissions (21.4% vs. 26.5%, respectively) compared to those without a care plan (OR=0.74, 99%, CI=0.558-0.941).

2d1.3. What is your interpretation of the results in terms of demonstrating that the components included in the composite are consistent with the described quality construct and add value to the overall composite? (i.e., what do the results mean in terms of supporting inclusion of the components; if no empirical analysis, provide rationale for the components that were selected)

The results of the validity testing at the both the component and overall composite level support the inclusion of each of the component measures into the composite measure. Each component is independently associated with the quality construct and is predictive of outcomes of interest. In aggregate, the components together are better predictors of important patient outcomes of care than just patient characteristics alone.

The results of this cross-tabulation support the association of the malnutrition composite score outcome (malnutrition diagnosis and nutrition care plan) with an important clinical outcome of 30-day readmissions.

2d2. Empirical analysis demonstrating that the aggregations and weighting rules are consistent with the quality construct and achieve the objective of simplicity to the extent possible

2d2.1 Describe the method used (*describe the steps*—*do not just name a method; what statistical analysis was used;* **if no empirical analysis**, *provide justification*)

Tests of internal consistency (Chronbach's alpha and item-to-total correlations) were completed to confirm the equal weighting of each of the measure component's contribution to the total composite score.

2d2.2. What were the statistical results obtained from the analysis of the aggregation and weighting rules? (e.g., results of sensitivity analysis of effect of different aggregations and/or weighting rules; if no empirical analysis, identify the aggregation and weighting rules that were considered and the pros and cons of each)

Measure	Correlation with Total	Chronbach's Alpha
Component Measure #1	0.49	0.77
Component Measure #2	0.68	0.67
Component Measure #3	0.59	0.72
Component Measure #4	0.58	0.73

2d2.3. What is your interpretation of the results in terms of demonstrating the aggregation and weighting rules are consistent with the described quality construct? (i.e., what do the results mean in terms of supporting the selected rules for aggregation and weighting; if no empirical analysis, provide rationale for the selected rules for aggregation and weighting)

Given the acceptable item-to-total correlations and strong internal consistency indicative of how closely related the components are to the total score, we concluded that no differences in weighting are necessary for each component measure at this time.

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e.*, data elements that are needed to compute the performance measure score are in defined, computer-readable fields) Update this field for maintenance of endorsement.

ALL data elements are in defined fields in electronic health records (EHRs)

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For maintenance of endorsement, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment: Global_Malnutrition_Composite_Measure_Feasibility_Scorecard-637411453876645777.xlsx

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. Describe difficulties (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.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

3c.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).

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of highquality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

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.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
Public Reporting	Quality Improvement (external benchmarking to organizations)
Public Health/Disease Surveillance	Malnutrition Quality Improvement Initiative
Payment Program	http://malnutritionquality.org
Regulatory and Accreditation	
Programs	
Professional Certification or	
Recognition Program	
Quality Improvement (Internal to	
the specific organization)	

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

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

Name of Program: Malnutrition Quality Improvement Initiative (Avalere Health and The Academy of Nutrition and Dietetics)

Purpose: The Malnutrition Quality Improvement Initiative (MQii) is designed to help healthcare provider organizations improve malnutrition care and subsequently achieve better outcomes. The primary goal is to advance evidence-based, high-quality, patient-driven care for hospitalized older adults who are malnourished or at-risk for malnutrition by offering a combination of tools and resources to support quality improvement. **4a1.2.** 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 impede implementation?) Performance data so far are only reported as performance feedback and benchmarking information to participants of the MQii.

4a1.3. If not currently publicly reported OR used in at least one other 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.)

The current composite measure is under consideration for the Hospital Inpatient Quality Reporting Program by the Centers for Medicare and Medicaid Services, it is anticipated that this measure will have been reviewed for appropriateness and adequacy prior to being reviewed by this committee. It was first submitted for consideration for the 2020-2021 measures under consideration review cycle, June 2020.

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

The Malnutrition Quality Improvement Initiative currently represents 105 individual hospitals (academic medical centers, short term acute care centers, community hospitals, critical access hospitals) that have individually reported on the component measures of this composite measure. They receive recurring individual performance feedback reports with their individual performance scores and on a bi-annual basis receive benchmarking data to understand their performance relative to other facilities which reported in the same period. Additionally, reporting sites receive feedback on their overall composite score, hospital readmissions and length of stay data to track and monitor their progress as they continue to implement quality improvement efforts.

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

In addition to what has been described in 4a2.1.1, the MQii program offers monthly educational webinars and technical support group calls to address questions about feedback on the performance reports. These provide opportunities to educate the participating clinical teams on efforts being taken by their colleagues to close quality gaps in malnutrition care. Hospitals are able to see how their performance benchmarked across similar hospital type and size, as well as compared to the mean performance for each reporting period (calculated twice a year for the previous 3 months of performance data).

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

Participants in the MQii participate in recurring group technical calls and feedback sessions sharing their best practices, lessons learned and troubleshooting their quality improvement efforts with each other. These experiences are captured and sometimes are reported for submission to peer-reviewed journals for publication (see 4a2.2.2). Surveys are also periodically conducted to assess areas of focus and experience with measure implementation with program participants.

4a2.2.2. Summarize the feedback obtained from those being measured.

Several organizations have used the performance feedback to better inform their quality improvement initiatives. Many have gone on to publish their findings in peer-reviewed literature:

Wills J. Prioritizing Malnutrition Care Through Discrete eCQM Data Tracking in the Electronic Health Record for an Academic Medical Center. J Acad Nutr Diet. 2019;119(9 Suppl 2):S63.

Danis K, Kline M, Munson M, et al. Identifying and managing malnourished hospitalized patients utilizing the malnutrition quality improvement initiative: the upmc experience. J Acad Nutr Diet. 2019;119(9 Suppl 2):S40-S43.

Goldman A, Siegel S, & Partridge J. Improving Patient Outcomes & Decreasing Hospital Costs Through Nutrition. 2019;119(9 Suppl 2):S70.

Pratt KJ, Hernandez B, Blancato R, Blankenship J, Mitchell K. Impact of an interdisciplinary malnutrition quality improvement project at a large metropolitan hospital. BMJ Open Qual. 2020;9(1).

Nepple KG, Tobert CM, Valladares AF, Mitchell K, Yadrick M. Enhancing identification and management of hospitalized patients who are malnourished: a pilot evaluation of electronic quality improvement measures. J Acad Nutr Diet. 2019;119(9 Suppl 2):S32-S39.

Others have presented at academic conferences:

March 2019. Wills-Gallagher J, Valladares AF, Hemingway S & Spotts M. "Improving Appropriate Identification and Diagnosis of Malnutrition for Hospitalized Patients" – Abstract and oral presentation at the American Society for Parenteral and Enteral Nutrition (ASPEN) Annual Research & Practice Conference. Phoenix, AZ.

May 2017. Fitall E, Bruno M, Jones K, Lynch J, Silver H, Godamunne K, Valladares A, Mitchell K. Malnutrition Care: "Low Hanging Fruit" for Hospitalist Clinical Performance Improvement. Hospital Medicine. Las Vegas, NV

4a2.2.3. Summarize the feedback obtained from other users

N/A

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

The main area of feedback that has been instrumental is on the use of the care plan measure which historically had a numerator tied to another step in the RDN's role of the process. However, we identified after years of feedback that the true gap in care was that of patients not having their nutrition care plans advanced by the physicians despite their being an assessment result indicative of malnutrition. Therefore, when designing the global malnutrition composite score, the care plan measure was updated to reflect need to have a care plan for all patients with a diagnosis of malnutrition documented and agreed to by the caring physician team.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. 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.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

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.

Most recent published data (available in Valladares et al, 2020) demonstrate improvement across all major component measures for the Global Malnutrition Composite Score. As new hospitals join the Collaborative, the project team has divided the strata into longer-term or "veteran" participants vs. new participants who are newly becoming acquainted with measure implementation. This division of new and more experienced participants has demonstrated that the same effects witnessed by the more experienced hospitals (improved identification, risk reduction and referral to treatment) is seen in those new sites. The more veteran sites are seeing the improvements spill over into new areas of focus including discharge planning and coordination of nutrition care when transitioning out of the hospital.

4b2. Unintended Consequences

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 (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

N/A

5. Comparison to Related or 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.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

No

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

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

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure); **OR**

Multiple measures are justified.

5b.1. If this measure conceptually addresses 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.)

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Attachment Attachment: Appendix_Doc_NQF_Endorsement_Submission_Importance.docx

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): Academy of Nutrition and Dietetics

- Co.2 Point of Contact: Sharon, McCauley, smccauley@eatright.org
- Co.3 Measure Developer if different from Measure Steward: Avalere Health
- Co.4 Point of Contact: Angel, Valladares, avalladares@avalere.com, 202-446-2242-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development. Measure Developer/Steward Updates and Ongoing Maintenance Ad.2 Year the measure was first released: Ad.3 Month and Year of most recent revision: Ad.4 What is your frequency for review/update of this measure? Ad.5 When is the next scheduled review/update for this measure? Ad.6 Copyright statement: © Academy of Nutrition and Dietetics Ad.7 Disclaimers: Ad.8 Additional Information/Comments: