

The Centers for Medicare & Medicaid Services (CMS) seeks stakeholder comments on the following clinical quality measure under development:

Title: Functional Status Assessment and Target Setting for Patients with Congestive Heart Failure

Description: Percentage of patients 18 years of age and older with congestive heart failure for whom a score from a select list of validated functional status assessments (FSAs) was recorded at least twice during the measurement period and for whom a target was documented and linked to the initial assessment

We seek comments from the public about the measure concept and specifications, the potential for the measure to improve health care quality, and the possible barriers to measure implementation.

This document provides information about the measure background about the project developing the measure and an overview of proposed approach to developing outcomes measures.

Project background

CMS has contracted with Mathematica Policy Research to develop new clinical quality measures for potential use by eligible professionals¹ in CMS quality reporting programs. CMS has an interest in the development of provider-level electronic clinical quality measures of patient-reported outcomes (PROs) to assess progress toward the National Quality Strategy aims of better care, healthy people and communities, and affordable care.

Assessment tools are a means to quantify a patient's health, functional, or disease status. These tools provide a series of questions that the patient can answer or the patient and physician or care provider can answer. The tools can assess general health or can focus on a particular disease or condition. For the tools we have considered for our proposed measures, the literature provides evidence on the tools' validity and reliability to assess the severity of disease. Providers can record scores as discrete data in the electronic health record.

Assessing PROs is challenging and requires appropriate (reliable and valid) assessment tools coupled with the recognition and understanding that each patient is unique with regard to disease severity, ability to tolerate treatment regimens, and expectations for patient-reported score

¹ Eligible professionals (EPs) are health care professionals who meet the eligibility criteria of CMS quality reporting programs and who report electronic clinical quality measures under these programs. Within the quality reporting programs, the definition of EPs can vary but generally include physicians in medicine or osteopathy, dental surgery or dental medicine, podiatric medicine, optometry, and chiropractic medicine. The Physician Quality Reporting System (PQRS) defines EPs to include physician assistants, nurse practitioners, clinical social workers, and clinical psychologists as well, among others. To see the complete list of EPs under the PQRS and the Electronic Health Record Incentive Programs, please refer to the following:

[https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_List_of_Eligible_Professionals.pdf)

[Instruments/PQRS/Downloads/2015 PQRS List of Eligible Professionals.pdf](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_List_of_Eligible_Professionals.pdf)

<https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/eligibility.html>.

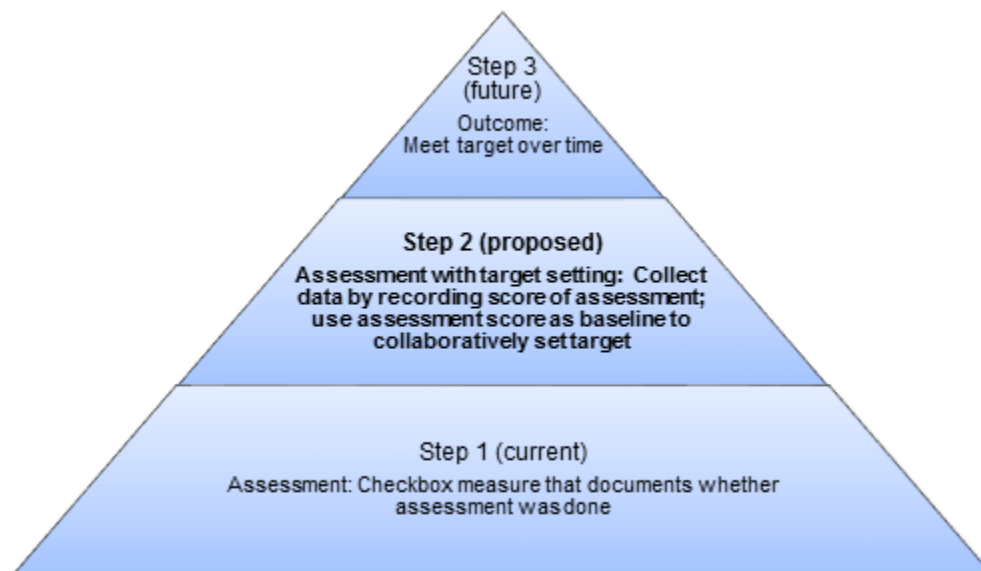
changes over time (such as improvement of health status, maintenance of health status, or decline in health status).

Overview of proposed approach to developing outcome measures

To address these measurement challenges, we propose a stepwise approach to PROs at the provider level. We propose development of a provider-level measure that requires the documentation of a PRO score to quantify health status and the documentation of a PRO-based target. Assessment and target setting foster patient engagement and promote patient-provider communication, which can then drive patient-centered care. Targets that are collaboratively set account for an individual patient's status, capabilities, and outcome expectations. As depicted in Figure 1, our proposed measure is more advanced than existing PRO assessment measures that document whether an assessment was completed because the proposed measure requires documentation of scores and targets.

For successful numerator performance, the measures we propose require the capture of two assessment scores and a quantitative target. By focusing on the processes of assessment and collaborative target setting between the patient and provider, we give credit to providers who undertake these activities. These measures will build the structural foundation in terms of clinical workflows and electronic capabilities for future measures to evaluate outcomes.

Figure 1. Framework for assessment of patient-reported outcomes



We recognize the current limited use of PRO instruments in care delivery. Workflows to support the use of PROs in care delivery are rare and data from care delivery situations are limited. However, we believe the proposed measure would help foster the development of necessary workflows and the resulting data, which are needed to assess the validity and reliability of future outcome measures.

Although the use of assessment tools in clinical care addresses the challenge of quantifying a patient's health status, we still have to account for individual differences in patients' health,

function, and disease status. The approach we recommend requires the patient and his or her provider to use the assessment score to set a target score. Introduction of target setting offers several advantages. A collaboratively set target can serve as an individual benchmark for measurement of future outcomes. Target setting is patient-centered, which will help avoid promoting a target that is not appropriate for an individual patient. Finally, target setting reflects the difficulty of risk adjusting outcomes to account for underlying disease or health severity. In place of risk adjustment, target setting can enable patients and their providers to set reasonable, attainable, and individual targets.

Future provider-level outcome measures could take a number of forms—including, measuring whether patient performance targets are met, measuring a patient assessment score against a defined benchmark, or measuring a change in the assessment score over time. It will be important and necessary to collect and analyze data from the proposed assessment and target setting measures in order to determine the validity and reliability of scoring potential outcome measures and to obtain input from providers concerning the validity and usability for improving patient engagement and care. This process should help determine the best outcome measure.

Summary of measure specifications

eMeasure title	Measure description	Denominator	Numerator	Exclusions and exceptions
Functional Status Assessment and Target Setting for Patients with Congestive Heart Failure	Percentage of patients 18 years of age and older with congestive heart failure for whom a score from one of a select list of validated functional status assessments (FSAs) was recorded at least twice during the measurement period and for whom a target was documented and linked to the initial assessment	Patients 18 years of age and older with an active diagnosis of heart failure prior to and during the measurement period and with an encounter during the measurement period	Patients for whom a score from one of a select list of validated FSA was recorded at least twice during the measurement period and for whom a target was documented and linked to the initial assessment	<p>Exclusions: Patients with severe cognitive impairment during the measurement period</p> <p>Exceptions: Patients with an index FSA visit during the last 105 days of the measurement period for whom a score from one of a select list of validated FSAs was recorded at least once during the measurement period and for whom a quantitative target was documented during or up to 72 hours following the index FSA visit and was linked to the index assessment</p>

eMeasure Title	Functional Status Assessments and Target Setting for Patients with Congestive Heart Failure		
eMeasure Identifier (Measure Authoring Tool)		eMeasure Version number	
NQF Number	Not applicable	GUID	
Measurement Period	January 1, 20xx through December 31, 20xx		
Measure Steward	Centers for Medicare & Medicaid Services		
Measure Developer	National Committee for Quality Assurance (NCQA)		
Endorsed By	None		
Description	Percentage of patients 18 years of age and older with congestive heart failure (CHF) for whom a score from one of a select list of validated functional status assessments (FSAs) was recorded at least twice during the measurement period and for whom a target was documented and linked to the initial assessment		
Copyright	<p>Limited proprietary coding is contained in the measure specifications for user convenience. Users of proprietary code sets should obtain all necessary licenses from the owners of the code sets. NCQA disclaims all liability for use or accuracy of any CPT or other codes contained in the specifications.</p> <p>CPT(R) contained in the measure specifications is copyright 2004–2015 American Medical Association. LOINC(R) copyright 2004–2015 Regenstrief Institute, Inc. This material contains SNOMED Clinical Terms(R) (SNOMED CT[R]) copyright 2004–2015 International Health Terminology Standards Development Organisation.</p>		
Disclaimer	<p>These performance measures are not clinical guidelines, do not establish a standard of medical care, and have not been tested for all potential applications.</p> <p>THE MEASURES AND SPECIFICATIONS ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND.</p> <p>Due to technical limitations, registered trademarks are indicated by (R) or [R] and unregistered trademarks are indicated by (TM) or [TM].</p>		
Measure Scoring	Proportion		
Measure Type	Process		
Stratification	None		
Risk Adjustment	None		
Rate Aggregation	None		
Rationale	<p>Patients living with CHF often have poor functional status and health-related quality of life, which declines as the disease progresses (Allen et al. 2012). In addition, their care is often complicated by multiple comorbidities. To assist in managing these complex patients, the American College of Cardiology Foundation and American Heart Association recommend collecting initial and repeat assessments of a patients' function and ability to complete desired activities of daily living (Hunt et al. 2009). The American Heart Association has also released scientific statements emphasizing the collection of patient-reported health status (for example, functional limitations, symptom burden, quality of life) from CHF patients as an important means of establishing a dynamic conversation between patient and provider regarding care goals and the patient's priorities (Allen et al. 2012; Rumsfeld et al. 2013).</p>		

Clinical Recommendation Statement	<p>American College of Cardiology Foundation/American Heart Association (2013): Every patient with HF should have a clear, detailed, and evidence-based plan of care that ensures the achievement of GDMT (guideline-directed medical therapy) goals, effective management of comorbid conditions, timely follow-up with the health care team, appropriate dietary and physical activities, and compliance with secondary prevention guidelines for cardiovascular disease. This plan of care should be updated regularly and made readily available to all members of each patient's health care team. (Class of recommendation: I; Level of evidence: C)</p> <p>Level C: Only consensus opinion of experts, case studies, or standard of care Class I: Procedure/treatment should be performed/administered</p>
Improvement Notation	A higher score indicates better quality.
Reference	Allen, L.A., L.W. Stevenson, K.L. Grady, et al. "Decision Making in Advanced Heart Failure: A Scientific Statement from the American Heart Association." <i>Circulation</i> , vol. 125, 2012, pp. 1928–1952. doi: 10.1161/CIR.0b013e31824f2173.
Reference	Hunt, S.A., W.T. Abraham, et al. "2009 Focused Update Incorporated into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults." <i>Circulation</i> , vol. 119, 2009, pp. e391–e479. doi: 10.1161/CIRCULATIONAHA.109.192065.
Reference	Rumsfeld, J.S., K.P. Alexander, D.C. Goff, et al. "Cardiovascular Health: The Importance of Measuring Patient-Reported Health Status: A Scientific Statement from the American Heart Association." <i>Circulation</i> , vol. 127, no. 22, 2013, pp. 2233–2249. doi: 10.1161/CIR.0b013e3182949a2e.
Reference	American College of Cardiology Foundation/American Heart Association. "Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines." <i>Circulation</i> , vol. 128, 2013, pp. e240–e327. doi: 10.1161/CIR.0b013e31829e8776.
Definition	<p>Index FSA visit: The encounter linked to the initial FSA score and the encounter during which the patient sets a target linked to the index FSA.</p> <p>Initial FSA score: The first FSA score during the measurement period. The initial FSA does not need to occur during an in-person encounter to be considered valid; it can occur in the 14 days prior to an in-person encounter.</p>
Guidance	<p>Patients must have completed an FSA from the following list. The same FSA instrument must be used for the initial and follow-up assessment.</p> <ul style="list-style-type: none"> - Veterans RAND 12 Item Health Survey (VR-12) - PROMIS 10 Global Health Short Form - Minnesota Living with Heart Failure Questionnaire (MLHFQ) - Kansas City Cardiomyopathy Questionnaire (KCCQ) <p>The FSA score documented in the electronic health record must be the total score.</p> <p>The initial FSA score must be linked to an encounter (the index FSA visit). Completion of the FSA must occur 14 days prior to or during the encounter.</p> <p>A quantitative target based on an FSA total score, a subscore, or an item-level score must be set and documented during or up to 72 hours following the index FSA visit.</p> <p>Any member of the care team (physician, nurse, nurse practitioner, physician's assistant, care manager, and so on) may set a target with the patient.</p> <p>Patients must also complete the same FSA instrument at least 90 days after the index FSA; the second FSA must be completed during the measurement period.</p>

	Patients with an index FSA visit during the last 105 days of the measurement period may not be able to complete a second FSA at least 90 days after the initial FSA and during the measurement period. These patients are denominator exceptions.
Transmission Format	TBD
Initial Population	Patients 18 years of age and older with an active diagnosis of CHF prior to and during the measurement period and with an encounter during the measurement period
Denominator	Initial population
Denominator Exclusions	Patients with severe cognitive impairment during the measurement period
Numerator	Patients for whom a score from one of a select list of validated FSA was recorded at least twice during the measurement period and for whom a target was documented and linked to the initial assessment
Numerator Exclusions	Not applicable
Denominator Exceptions	Patients with an index FSA visit during the last 105 days of the measurement period for whom a score from one of a select list of validated FSA was recorded at least once during the measurement period and for whom a quantitative target was documented during or up to 72 hours following the index FSA visit and was linked to the initial assessment
Measure Population	Not applicable
Measure Observations	Not applicable
Supplemental Data Elements	For every patient evaluated by this measure, also identify payer, race, ethnicity, and sex.