NATIONAL QUALITY FORUM

National Voluntary Consensus Standards for Patient Outcomes
Measure Summary

Measure number: OT1-020-09

Measure name: Functional capacity in COPD patients before and after pulmonary rehabilitation

Description: The percentage of patients with COPD who are enrolled in pulmonary rehabilitation (PR) who are found to increase their functional capacity by at least 54 meters (176 feet), as measured by a standardized 6 minute walk test (6MWT).

Numerator statement: Number of patients with clinician diagnosed COPD who have participated in PR and have been found to increase their functional capacity by at least 54 meters (176 feet), as measured by 6MWT distance at the beginning and the end of PR.

Denominator statement: All patients with COPD, during the reporting period, who are enrolled in a pulmonary rehabilitation program.

Level of Analysis: Population: regional/network, Program: other pulmonary rehabilitation provider or pulmonary rehabilitation program

Type of Measure: Outcome

Data Source: Management data, pharmacy data, documentation of original self-assessment

Measure developer: American Association for Cardiovascular and Pulmonary Rehabilitation

Type of Endorsement (full or time-limited): Recommended for time-limited endorsement (Steering Committee vote—May 17, 2010 [Recommend—13, Do not recommend—4, Abstain—1])

Summary Table of TAP Ratings of Subcriteria and Comments:

IMPORTANCE TO MEASURE AND REPORT		
1a. Impact	Partially	Does not measure who dropped out of PR; same issues as OT1-
1b. Gap	Not at all	

1c. Relation to outcomes	Not at all	019-08. 1b—Unknown—no data; suspect a gap exists and likely varies by region. 1c—Benchmark of 54 meters may be set too high; what is attainable? Reidlemeyer (1997) identifies 54 m as benchmark but 38 m is also cited by Goldstein. Using 54 m as the minimal clinical difference indicates that the current published data on pulmonary rehab programs do not meet minimum level of clinical significance, and it is not likely that they ever will. We need a frequency distribution curve to understand how many patients can achieve this benchmark. Developer: "if there is no improvement >54 m then there is no impact on ADLs and other functioning." There is probably a better metric that is more sensitive to improvements in pulmonary rehab which is "constant low endurance time."
SCIENTIFIC ACCEPTABILTY		
2a. Specs	Completely	The 6 MWT is a standardized validated assessment. Specifications are precise. The measure has not been tested for reliability or validity as a quality measure. The benchmark used is not related to function or QoL. PR quitters are excluded. 2e—No need for risk-adjustment as patient is compared to himself. 2f—Meaningful differences are known only about the 6MWT not the measure. Disparities exist as to access to PR as a result of availability and insurance coverage.
2b. Reliability	Completely	
2c. Validity	Partially	
2d. Exclusions	Completely	
2e. Risk adjustment	Completely	
2f. Meaningful differences	Partially	
2g. Comparability	Not applicable	
2h. Disparities	Not applicable	
USEABILITY		
3a. Distinctive	Completely	The 6MWT is easily understandable by public and is widely used. Measure is not publicly reported. Harmonization needed for age. Few programs meet the target of this measure—8 of 14 programs in the literature failed to meet the target.
3b. Harmonization	Not applicable	
3c. Added value	Minimally	
FEASIBILITY		
4a. Data a by product of care	Completely	Registries are proposed to collect and aggregate the data.
4b. Electronic	Not at all	
4c. Exclusions	Completely	
4d. Inaccuracies	Partially	
4e. Implementation	Partially	

Measure Developer Responses:

Topic, Measure # and Title	Follow-Up Issues
Topic Area: COPD **Measure #** OT1-020-09 **Title:** Functional capacity in COPD patients before or after pulmonary rehabilitation	**Conditions for Measure Developer:** As an untested measure, your plans for testing and timeline for completing testing are a big concern. Specifically: • again a time limited recommendation for further study of the distance gained that would be a reasonable effect size, and of course it has to adjust for baseline walking ability—only assessed in persons who have completed the course, examine at the provider level patients clustered within provider • testing required • hard to imagine balance in other factors for patients—compliance, motivation, adherence with other recommendations and as well definition of improvement relative to baseline function • recommend testing the validity of the quality measure itself. Do clinicians feel that this measure (using the 54 m threshold) distinguishes good vs. not good care. What is the variability in the number/percent of patients who do not complete a program and how does that affect quality measure? **Response from Measure Developer:** 1. The Redelmeier, et al. 1997 article (Redelmeier, DA., Bayoumi, AM., Goldstein, RS., Guyatt, GH. Interpreting small differences in functional status: the Six Minute Walk test in chronic lung disease patients. *American Journal of Respiratory & Critical Care Medicine*, v. 155 issue 4, 1997, p. 1278-82) provided the evidence for the 54 meter benchmark. The developers are in agreement that this may be too high of an improvement to be seen in persons from pre- to post-PR. Of note, a newly published study updates the MCID for 6MW in COPD patients from 54 meters to 25 meters (95 percent CI 20-61m). It would be appropriate to modify the benchmark to 25 meters based on this newest evidence. Please see the publication: Holland AE, Hill CJ, Rasekaba T, et al. Updating the Minimal Important

	Difference for Six-Minute Walk Distance in Patients With Chronic Obstructive Pulmonary Disease. *Arch Phys Med Rehabil*. 2010 Feb;91(2):221-225 2. The measure has not been tested; it will require testing. **3.** The age range was left blank to allow for broadest utilization. An age range of 40 or greater is acceptable**.**

Summary Table of SC Ratings of Subcriteria and Comments:

IMPORTANCE TO MEASURE AND REPORT	
	SC Vote on Importance Yes—16 No—1
SCIENTIFIC ACCEPTABILITY	
The measures are based on well-researched and published tools, but none of the measures have been tested as performance measures. Guidelines show that 6 minute walk test is simple and easy to report accurately and has history to be used in CV testing. However, the translation to quality has not been shown, these measures have not been related to the quality of interventions, nor the quality of life.	SC Vote on Scientific Acceptability Completely—4 Partially—12 Minimally—1 Not at all—0
USABILITY	
	SC Vote on Usability Completely—4

	Partially—12 Minimally—1 Not at all—0
FEASIBILITY	
Capturing the data may ultimately be available through a registry. The Steering Committee members did not feel 12 months was a realistic time frame for measure developers to send their testing results.	SC Vote on Feasibility Completely – 5 Partially – 9 Minimally - 3 Not at all -0

Summary table of Biostatistical Review: N/A

Attachments: Attachment AACVPR NQF References.doc

NATIONAL QUALITY FORUM

Measure Evaluation 4.1
January 2010

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The sub-criteria and most of the footnotes from the evaluation criteria are provided in Word comments and will appear if your cursor is over the highlighted area (or in the margin if your Word program is set to show revisions in balloons). Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each sub-criterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the* sub-criteria *(yellow highlighted areas)*.

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the sub-criterion, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few sub-criteria as indicated)

(for NQF staff use) **NQF Review**	**NQF Project:** Patient Outcomes Measures: Phases I and II
MEASURE DESCRIPTIVE INFORMATION	
De.1 **Measure Title:** Functional Capacity in COPD patients before and after Pulmonary Rehabilitation	
De.2 **Brief description of measure**: The percentage of patients with COPD who are enrolled in pulmonary rehabilitation (PR) who are found to increase their functional capacity by at least 54 meters (176 feet), as measured by a standardized 6 minute walk test (6MWT).	
1.1-2 **Type of Measure:** outcome De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** Not part of composite measure	
De.4 **National Priority Partners Priority Area:** care coordination De.5 **IOM Quality Domain**: effectiveness, patient-centered De.6 **Consumer Care Need:** Living With Illness	

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** proprietary measure A.3 **Measure Steward Agreement:** agreement signed and submitted A.4 **Measure Steward Agreement attached:**	**A** **Y**☐ **N**☐

	NQF
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	**B** Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** public reporting, quality improvement 0,0,0,	**C** Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** No, testing will be completed within 12 months D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** Y☐ N☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	Eval Rating
(for NQF staff use) **Specific NPP goal**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** affects large numbers, severity of illness, a leading cause of morbidity/mortality, high resource use, patient/societal consequences of poor quality 1a.2 1a.3 **Summary of Evidence of High Impact:** High impact is related to the significant and progressive disability of COPD, proven effectiveness of PR in reversing deconditioning and the magnitude of COPD, affecting 24 million Americans. 1a.4 **Citations for Evidence of High Impact:** COPD is associated with significant decline in function and disability (Nazir and Erbland 2009). PR has been found to reverse skeletal muscle dysfunction and disability in COPD as well as disabling symptoms (Nici L, Donner C, Wouters C., et al., 2006; Ries, A, Bauldoff G, Carlin B, et al., 2007). According to the global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (GOLD guidelines), exercise training in COPD results in improved exercise tolerance, dyspnea and fatigue. Strength of evidence is graded at level A with evidence from a substantial number of randomized controlled trials involving substantial numbers of participants (Rabe, Hurd et al. 2007). The greatest improvement is seen in GOLD COPD stages II-IV (moderate to very severe COPD). All levels of COPD severity benefit from exercise training programs, (Berry, Rejeski et al. 1999).	**1a** C☐ P☐ M☐ N☐

Comment [KP1]: 1a. The measure focus addresses:
•a specific national health goal/priority identified by NQF's National Priorities Pa… OR
•a… strated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

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Approximately 24 million Americans have COPD; however, fewer than half have been diagnosed or know they have it. (Mannino, Homa et al. 2002).

During 2000, COPD was responsible for 8 million physician office and hospital outpatient visits, 1.5 million emergency department visits, 726,000 hospitalizations and 119,000 deaths (Mannino, Homa et al. 2002).

In addition to underdianosis (Coultas D and Mapel DW, 2003), there is evidence of suboptimal treatment of COPD (Bourbeau J, Sebaldt RJ, Day A, et al.2008).

Measurement of 6 MWD before and after PR will identify a key feature of quality in COPD – improvement in functional capacity and reversal of disabling skeletal muscle dysfunction.

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure:

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
While there are treatments that can help optimize health for persons with COPD, there is evidence of suboptimal care of persons with COPD including limited use of national and international evidence based guidelines (Bourbeau J, Sebaldt RJ, Day A, et al.2008, Yawn, B., Wollan, P..2008).

1b.3 Citations for data on performance gap:
Bourbeau J, Sebaldt RJ, Day A, et al. Practice patterns in the management of COPD in primary care practice: the CAGE study. Can Respir J. 2008;15:13-19.

Yawn, B., Wollan, P. Knowledge and attitudes of family physicians coming to COPD continuing medical education. Int J Chron Obstruct Pulmon Dis. 2008 June; 3(2): 311–318

1b.4 Summary of Data on disparities by population group:
Disparities in COPD care are related to underdiagnosis and suboptimal treatment of this common disorder. Approximately 24 million Americans have COPD; however, fewer than half have been diagnosed or know they have it. (Mannino, Homa et al. 2002). During 2000, COPD was responsible for 8 million physician office and hospital outpatient visits, 1.5 million emergency department visits, 726,000 hospitalizations and 119,000 deaths (Mannino, Homa et al. 2002). In addition to underdianosis (Coultas D and Mapel DW, 2003), there is evidence of suboptimal treatment of COPD (Bourbeau J, Sebaldt RJ, Day A, et al.2008). Disparities in care are particularly evident in women and racial/ethnic minorities who have COPD (Kirkpatrick, 2009).

1b.5 Citations for data on Disparities:
Bourbeau J, Sebaldt RJ, Day A, et al. Practice patterns in the management of COPD in primary care practice: the CAGE study. Can Respir J. 2008;15:13-19.

Coultas, DB, Mapel DW. Undiagnosed airflow obstruction: prevalence and implications. Curr Opin Pulm Med. 2003;9:96-103.

Kirkpatrick P, Dransfield MT. Racial and sex differences in chronic obstructive pulmonary disease susceptibility, diagnosis, and treatment. Curr Opin Pulm Med. 2009 Mar;15(2):100-4.

Mannino DM, Homa DM, Akinbami LJ, Ford ES, Redd SC. Chronic obstructive pulmonary disease surveillance -- United States, 1971-2000. MMWR Surveill Summ 2002;51:1-16. [Medline]

1b
C☐
P☐
M☐
N☐

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** Two national evidence based guidelines identify functional limitation as a major factor of morbidity in COPD (Nici, et al 2006, Rabe, K. F., S. Hurd, et al. 2007).

1c
C☐
P☐
M☐
N☐

Comment [KP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

Comment [k4]: 1c. The measure focus is:
•an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;
OR
•if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
oIntermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
oProcess – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
oStructure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
oPatient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
oAccess – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
oEfficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Comment [k5]: 4 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 step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., ... [1]

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1c.2-3. Type of Evidence: randomized controlled trial

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
The following randomized, controlled trials of pulmonary rehabilitation have shown significant improvement in 6MWD as well as other outcomes

First author	Results
GOLDSTEIN	Significant treatment outcomes, including 37.9 m in 6-min walk distance, 4.7 min increase in submaximal cycle endurance time, improvements in the dyspnea, emotion and mastery components of the CRQ, and a 2.7 unit improvement in the TDI
WIJKSTRA	Significant improvements favoring rehabilitation in work rate, peak oxygen consumption, the 6-min walk distance, exertional dyspnea and health status measured with the CRQ
BENDSTRUP	Significant improvements favoring the treatment group in the 6-min walk distance, activities of daily living and CRQ health status
TROOSTERS	Significant improvements favoring rehabilitation in 6-min walk distance, maximal work rate and oxygen consumption, quadriceps force, inspiratory muscle force, and CRQ-measured health status

Improvements in walk distance and health status exceeded the clinically-meaningful threshold values
CRQ: Chronic Respiratory Questionnaire; TDI: transitional dyspnea index; SGRQ: St. George Respiratory Questionnaire.

Bendstrup KE, Ingemann JJ, Holm S, Bengtsson B. Out-patient rehabilitation improves activities of daily living, quality of life and exercise tolerance in chronic obstructive pulmonary disease. Eur Respir J 1997;10:2801–2806.[Abstract]
Goldstein RS, Gort EH, Stubbing D, et al. Randomized controlled trial of respiratory rehabilitation. Lancet 1994; 344: 1394-1397.
Troosters T, Gosselink R, Decramer M. Short- and long-term effects of outpatient rehabilitation in patients with chronic obstructive pulmonary disease: a randomized trial. Am J Med 2000; 109: 207-212.
Wijkstra PJ, van der Mark TW, Kraan J, van Altena R, Koeter GH, Postma DS. Effects of home rehabilitation on physical performance in patients with chronic obstructive pulmonary disease (COPD). Eur Respir J 1996; 9: 104-110.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**
Randomized controlled studies have identified the number needed to treat, to have one patient with a clinically significant benefit from PR, was three (95% confidence interval, 1.7–6.4) (Troosters , Casaburi, Gosselink, et al, 2005). Others found similar results even if sustained improvement over a 24-month follow-up period was used as a criterion (Guell R, Casan P, Belda J, et al). The addition of pulmonary rehabilitation to the treatment of patients with stable COPD seems to result in more significant improvements in exercise tolerance than adding an additional bronchodilator (Oga T, Nishimura K, Tsukino M, et al).According to ACCP/AACVPR Pulmonary Rehabilitation Evidence based guidelines (Ries AL, Bauldoff GS, Carlin BW, et al 2007), 'a program of exercise training of the muscles of ambulation is recommended as a mandatory component of pulmonary rehabilitation for patients with COPD (Grade of Recommendation 1A). According to the ATS/ERS PR guidelines, PR significantly improves exercise tolerance in patients with COPD (Nici L, Donner C, Wouters C.et al., 2006).

1c.6 Method for rating evidence: American College of Chest Physicians Rating Scale

1c.7 Summary of Controversy/Contradictory Evidence: N/A

1c.8 Citations for Evidence (*other than guidelines***):** The impact of pulmonary rehabilitation in persons with COPD is linked to the improved functional capacity, as measured by the 6-minute walk test. In a meta-analysis by Troosters, Casaburi, Gosselink and Decramer (2005), the pooled effect size of all randomized controlled studies of pulmonary rehabilitation was 49 m, with a 95% confidence interval of 26–72 m. (From Troosters, Casaburi, Gosselink Marc Decramer, AJCCRM 2005)

Troosters T, Casaburi C, Gosselink R and Decramer M. State of the Art - Pulmonary Rehabilitation in Chronic Obstructive Pulmonary Disease http://ajrccm.atsjournals.org/cgi/content/full/172/1/19

Comment [k6]: 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

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1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):** American College of Chest Physicians/American Association of Cardiovascular and Pulmonary Rehabilitation (ACCP/AACVPR) Pulmonary Rehabilitation Evidence based guidelines (Ries AL, Bauldoff GS, Carlin BW, et al 2007), a program of exercise training of the muscles of ambulation is recommended as a mandatory component of pulmonary rehabilitation for patients with COPD (Grade of Recommendation 1A). According to the American Thoracic Society / European Respiratory Society ATS/ERS PR guidelines, PR significantly improves exercise tolerance in patients with COPD (Nici L, Donner C, Wouters C.et al., 2006). **1c.10 Clinical Practice Guideline Citation:** See above **1c.11 National Guideline Clearinghouse or other URL:** **1c.12 Rating of strength of recommendation (***also provide narrative description of the rating and by whom***):** Level A1 for exercise training in COPD in PR setting – level A1 **1c.13 Method for rating strength of recommendation** (*If different from* USPSTF system*, also describe rating and how it relates to USPSTF)***:** American College of Chest Physicians Rating Scale **1c.14 Rationale for using this guideline over others:** The two major evidenced based guidelines for COPD are used: GOLD and ATS/ERS	
TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria **for** *Importance to Measure and Report*?	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report***, met?** **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** Number of patients with clinician diagnosed COPD who have participated in PR and have been found to increase their functional capacity by at least 54 meters (176 feet), as measured by 6MWT distance at the beginning and the end of PR. **2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** Assessments of 6 minute walk test are to be performed within one week of PR program entry and again within one week of PR program completion. The time period between tests should be no more than 3 months. **2a.3 Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):** To perform the 6 minute walk test (6MWT) the patient is instructed to walk as fast and as far as they can in 6 minutes, but they are allowed to stop and rest during the test, if needed. The total distance covered in 6 minutes is measured (in meters or feet).	**2a-specs** **C☐** **P☐** **M☐** **N☐**

Comment [k7]: USPSTF grading system **http://www.ahrq.gov/clinic/uspstf/grades.htm**: **A -** The USPSTF recommends the service. There is high certainty that the net benefit is substantial. **B -** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. **C -** The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. **D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. **I -** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Comment [KP8]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) .

The numerator is calculated by the following formula: A patient is counted as having experienced a significant increase in functional capacity if (6MWT distance at program completion - 6MWT distance at program entry)>= 54 meters (176 feet).

The 6 minute walk test (6MWT) is a practical, simple, standardized, and validated test that measures the distance that a patient can quickly walk on a flat, hard surface in a period of 6 minutes (6MWD). It evaluates the global and integrated responses of all the systems involved during exercise, including the pulmonary and cardiovascular systems, systemic circulation, peripheral circulation, blood, neuromuscular units, and muscle metabolism. The 6MWT provides specific testing related to the activity of daily living, walking.(Guyatt, G.H., et al., 1984. Guyatt, G.H., et al., 1985, Sciurba, F.C. and W.A. Slivka, Steele, B). In performing the 6MWT, it has been reported that a 54 meter (176 feet) difference in 6MW difference is clinically significant (identified as clear change in clinical status) when compared to differences in self-rating of walking ability (Redelmeier, D.A., et al). The strongest indication for the 6MWT is for measuring the response to medical interventions in patients with moderate to severe heart or lung disease.

Specific instructions regarding the administration of the 6MWT have been developed and published by the American Thoracic Society (ATS, 2002).

COPD (chronic obstructive pulmonary disease includes a clinician diagnosis of COPD, chronic bronchitis and / or emphysema (ICD-9 Codes include 490-492, 494, 496: Chronic obstructive pulmonary disease (COPD) includes chronic bronchitis (ICD-9 codes 490-491), emphysema (ICD-9 code 492),bronchiectasis (ICD-9 code 494), and chronic airway obstruction (ICD-9 code 496). These diseases are commonly characterized by irreversible airflow limitation.

Guyatt, G.H., et al., Effect of encouragement on walking test performance. Thorax, 1984. 39(11): p. 818-22.

Guyatt, G.H., et al., The 6-minute walk: a new measure of exercise capacity in patients with chronic heart failure. Canadian Medical Association Journal, 1985. 132(8): p. 919-23.

Redelmeier, D.A., et al., Interpreting small differences in functional status: the six minute walk test in chronic lung disease patients. American Journal of Respiratory and Critical Care Medicine, 1997. 155: p. 1278-1282.

Sciurba, F.C. and W.A. Slivka, Six minute walk testing. Seminars in Respiratory and Critical Care Medicine, 1998. 19(4): p. 383-392.

Steele, B., Timed walking tests of exercise capacity in chronic cardiopulmonary illness. Journal of Cardiopulmonary Rehabilitation, 1996. 16: p. 25-33.

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
All patients with COPD, during the reporting period, who are enrolled in a pulmonary rehabilitation program.

2a.5 Target population gender: Female, Male
2a.6 Target population age range: No age restrictions

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
Up to 3 months from time of PR program entry.

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
All patients with a clinician diagnosis of COPD who are able to perform a 6MWT at PR program entry and at PR program completion, and who have completed at least 10 PR sessions, that include exercise training, within a 3 months period.

The minimum length and duration of PR program is two one hour sessions per week over 6 weeks with at least two sessions per week including exercise training.

2a.9 **Denominator Exclusions (***Brief text description of exclusions from the target population***):** Patients who are unable to perform a 6MWT for health and/or safety reasons, and those who have not completed at least 10 PR sessions within 3 months of program entry.

2a.10 **Denominator Exclusion Details (***All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
Absolute contraindications for the 6MWT include the following: unstable angina during the previous month and myocardial infarction during the previous month. Relative contraindications include a resting heart rate of more than 120, a systolic blood pressure of more than 180 mm Hg, and a diastolic blood pressure of more than 100 mm Hg. Additional exclusion criteria include significant orthopedic, neurological, cognitive or psychiatric impairment.

2a.11 **Stratification Details/Variables (***All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
Data are to be assessed by individual and group outcomes, can be reported as aggregate group data, and can also be stratified and reported for the group by age (by decade of life) and gender (male, female).

2a.12-13 **Risk Adjustment Type:** no risk adjustment necessary

2a.14 **Risk Adjustment Methodology/Variables (***List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
Not applicable

2a.15-17 **Detailed risk model available Web page URL or attachment:**

2a.18-19 **Type of Score:** rate/proportion
2a.20 **Interpretation of Score:** better quality = higher score
2a.21 **Calculation Algorithm (***Describe the calculation of the measure as a flowchart or series of steps***):**
Percentage of patients achieving an increase in functional capacity during PR = (Number of COPD patients in a reporting period who have completed at least 10 sessions of PR in 3 months or less, with >= a 54 meter (176 feet) increase in functional capacity by 6MWT)/(Number of COPD patients enrolled in PR program during the reporting period) x 100%.

2a.22 **Describe the method for discriminating performance** *(e.g., significance testing)***:**
For COPD patients, an increase in functional capacity of at least 54 meters (176 feet), as measured by a 6MWT, has been found to be clinically meaningful and important (Redelmeier, 1997).

2a.23 **Sampling (Survey) Methodology** *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
Review of medical records for all eligible patients during the reporting period.

2a.24 **Data Source (***Check the source(s) for which the measure is specified and tested)*
Management data, pharmacy data, Documentation of original self-assessment

2a.25 **Data source/data collection instrument (***Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
The measured outcome will be collected by the PR program staff on a standardized data collection form (electronic or paper), as recommended in the American Thoracic Society guidelines for administration of the 6MWT.

2a.26-28 **Data source/data collection instrument reference web page URL or attachment:** Attachment 6MWT collection tool ATS.doc

2a.29-31 **Data dictionary/code table web page URL or attachment:**

2a.32-35 **Level of Measurement/Analysis** *(Check the level(s) for which the measure is specified and tested)*
Population: regional/network, Program: Other Pulmonary Rehabilitation Provider or Pulmonary Rehabilitation Program

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

NQF

2a.36-37 Care Settings (*Check the setting(s) for which the measure is specified and tested)*
Ambulatory Care: Hospital Outpatient, Ambulatory Care: Clinic

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*)
Clinicians: Physicians (MD/DO), Clinicians: Nurses, Clinicians: PT/OT/Speech, Clinicians: Respiratory Therapy

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample *(description of data/sample and size)*: One study of 761 patients with severe COPD found excellent reproducibility of the 6MWT, administered at study entry and one week later in each study participant.

Sciurba F, Criner GJ, Lee SM, Mohsenifar Z, Shade D, Slivka W, Wise RA; National Emphysema Treatment Trial Research Group. Six-minute walk distance in chronic obstructive pulmonary disease: reproducibility and effect of walking course layout and length. Am J Respir Crit Care Med. 2003 Jun 1;167(11):1522-7. Epub 2003 Feb 20.

The ATS 6MWD guidelines identify the 6MWT as a highly reproducible measure of functional capacity.

American Thoracic Society: Statement Guidelines for the Six-Minute Walk Test Am J Resp Crit Care Med, 2002;166:111-117.

2b.2 Analytic Method *(type of reliability & rationale, method for testing)*:
Correlation between 6MWT distance before and after PR program participation.

2b.3 Testing Results *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Intraclass correlation coefficient between tests was 0.88 (p<0.0001).

2b
C☐ P☐ M☐ N☐

2c. Validity testing

2c.1 Data/sample *(description of data/sample and size)*: Sample size will include 150 patients with end stage lung disease.

Cahalin L, Pappagianopoulos P, Prevost S, Wain J, Ginns J. The relationship of the 6-min walk test to maximal oxygen consumption in transplant candidates with end-stage lung disease. Chest 1995;108:452-459.

2c.2 Analytic Method *(type of validity & rationale, method for testing)*:
Correlation between 6MWT distance and maximal oxygen consumption measured during cardiopulmonary exercise testing.

2c.3 Testing Results *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
The validity of the 6MWD has been found to be good (r = 0.5) between 6MWT distance and peak oxygen consumption. The validity is strongest (r > 0.7) in patients with more severe functional limitations since the 6MWT in such individuals more closely approximate maximal exercise performance.

2c
C☐ P☐ M☐ N☐

2d. Exclusions Justified

2d
C☐ P☐ M☐ N☐ NA☐

2d.1 Summary of Evidence supporting exclusion(s):
Patients with conditions that preclude them from carrying out the 6MWT or that pose a significant medical risk during the test have been excluded from such testing in clinical trials. In addition, guidelines for administering the 6MWT in patients with COPD recommend exclusion of patients who meet the exclusion

Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
•precisely defined and specified:
–if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category ... [2]

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

NQF

criteria listed in the Specificity section of this application.

2d.2 Citations for Evidence:
American Thoracic Society: Statement Guidelines for the Six-Minute Walk Test Am J Resp Crit Care Med, 2002;166:111-117.

2d.3 Data/sample *(description of data/sample and size)*: Multiple studies and samples, summarized in the ATS Guidelines for the 6MWT (see above).

2d.4 Analytic Method *(type analysis & rationale)*:
As above

2d.5 Testing Results *(e.g., frequency, variability, sensitivity analyses)*:
As above

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 Data/sample *(description of data/sample and size)*: NA

2e.2 Analytic Method *(type of risk adjustment, analysis, & rationale)*:
NA

2e.3 Testing Results *(risk model performance metrics)*:
NA

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: NA

2e
C☐
P☐
M☐
N☐
NA☐

2f. Identification of Meaningful Differences in Performance

2f.1 Data/sample from Testing or Current Use *(description of data/sample and size)*: In 112 patients with stable, severe COPD (50% women), the mean increase in 6MWT distance that was correlated with patients' perception of a clinically meaningful increase in functional capacity was 54 meters (176 feet) (Redelmeier, 1997).

2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance *(type of analysis & rationale)*:
Correlation analysis was used to assess the correlation between patients' perceptions of a clinically meaningful increase in functional capacity and 6MWT distance.

2f.3 Provide Measure Scores from Testing or Current Use *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
The six-minute walk test has been found to be sensitive in differentiating patients with low or high work capacity in patients with moderate to severe COPD (Carter R, et al. 2003). The impact of pulmonary rehabilitation in persons with COPD is linked to the improved functional capacity, as measured by the 6-minute walk test. In a meta-analysis by Troosters, Casaburi, Gosselink and Decramer (2005), the pooled effect size of all randomized controlled studies of pulmonary rehabilitation was 49 m, with a 95% confidence interval of 26–72 m. A meta-analysis investigating whether PR program heterogeneity (length and setting of program) would lead to statistically significant difference in results, however, revealed only a trend for longer programs, with more than 6 months superior to shorter programs and showed a strong trend for enhanced effects when close supervision of the patients was ensured, such as that found in PR programs. (O'Donnell D, McGuire M, Samis L, et al, Cambach W, Chadwick-Straver RVM, et al, Troosters T, Gosselink R, Decramer M. Booker HA., Ringbaek TJ, Broendum E, Hemmingsen L, et al, Wijkstra PJ, van Altena R, Kraan J, et al, Cockcroft AE, Saunders MJ, Berry G,. Engström CP, Persson LO, Larsson S, et al.).

2f
C☐
P☐
M☐
N☐

2g. Comparability of Multiple Data Sources/Methods

2g.1 Data/sample *(description of data/sample and size)*: Assessments of scientific acceptability of the 6MWT have been carried out and reported in a variety of patient populations, population sizes, and in patients with a variety of medical conditions.

2g
C☐
P☐
M☐
N☐

Comment [KP16]: 2e. For outcome measures and other measures (e.g., resource use) when indicated:
•an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care;[Error! Bookmark not defined.] OR rationale/data support no risk adjustment.

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

Comment [KP18]: 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

	NQF
Larsson UE, Reynisdottir S. The six-minute walk test in outpatients with obesity: reproducibility and known group validity. Physiother Res Int. 2008 Jun;13(2):84-93. Vis JC, Thoonsen H, Duffels MG, de Bruin-Bon RA, Huisman SA, van Dijk AP, Hoendermis ES, Berger RM, Bouma BJ, Mulder BJ. Six-minute walk test in patients with Down syndrome: validity and reproducibility. Arch Phys Med Rehabil. 2009 Aug;90(8):1423-7. Ries JD, Echternach JL, Nof L, Gagnon Blodgett M. Test-retest reliability and minimal detectable change scores for the timed "up & go" test, the six-minute walk test, and gait speed in people with Alzheimer disease. Phys Ther. 2009 Jun;89(6):569-79. Epub 2009 Apr 23. Moriello C, Mayo NE, Feldman L, Carli F. Validating the six-minute walk test as a measure of recovery after elective colon resection surgery. Arch Phys Med Rehabil. 2008 Jun;89(6):1083-9. 2g.2 **Analytic Method** *(type of analysis & rationale)*: Correlation between 6MWT and other measures of functional capacity (self-reported exercise capacity, graded exercise testing, etc.) 2g.3 **Testing Results** *(e.g., correlation statistics, comparison of rankings)*: Moderate to good correlation has been reported between 6MWT in multiple patient populations.	**NA**☐
2h. Disparities in Care 2h.**1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: Disparities in COPD care are related to underdiagnosis and suboptimal treatment; fewer than half have of those with COPD been diagnosed (Mannino, Homa et al. 2002). In addition to underdianosis (Coultas D and Mapel DW, 2003), there is evidence of suboptimal treatment of COPD (Bourbeau J, Sebaldt RJ, Day A, et al.2008). Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition) Data will be generated and used by healthcare personnel during the provision of care, e.g., measurement of 6MWD pre and post PR 2h.2 **If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:** N/A	**2h** **C**☐ **P**☐ **M**☐ **N**☐ **NA**☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria **for** *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?** **Rationale:**	*2* **C**☐ **P**☐ **M**☐ **N**☐
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eval Rating
3a. Meaningful, Understandable, and Useful Information 3a.1 **Current Use:** in use 3a.2 **Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*): 6 MWD has been used as a measure of functional capacity before and after PR in many large trials including the National Emphysema Treatment Trial http://www.nhlbi.nih.gov/health/prof/lung/nett/lvrsweb.htm	**3a** **C**☐ **P**☐ **M**☐ **N**☐

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);OR rationale/data justifies why stratification is not necessary or not feasible.

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

	NQF
3a.3 **If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) 3a.4 **Data/sample** *(description of data/sample and size)***:** 44 participants with COPD who participated in a pulmonary rehabilitation program. 3a.5 **Methods** *(e.g., focus group, survey, QI project)***:** Prospective collection of patient data and outcome measures. 3a.6 **Results** *(qualitative and/or quantitative results and conclusions)***:** 6 minute walk test at program entry and program completion is a method of program outcomes that is reliable and easily interpreted. Spencer LM, Alison JA, McKeough ZJ. Six-minute walk test as an outcome measure: are two six-minute walk tests necessary immediately after pulmonary rehabilitation and at three-month follow-up? Am J Phys Med Rehabil. 2008 Mar;87(3):224-8.	
3b/3c. Relation to other NQF-endorsed measures 3b.1 **NQF # and Title of similar or related measures:**	
(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): 3b.2 **Are the measure specifications harmonized? If not, why?**	**3b** C☐ P☐ M☐ N☐ NA☐
3c. Distinctive or Additive Value 3c.1 **Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:**	
5.1 **Competing Measures If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), describe why it is a more valid or efficient way to measure quality:**	**3c** C☐ P☐ M☐ N☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria **for** *Usability*?	**3**
Steering Committee: Overall, to what extent was the criterion, *Usability***, met?** **Rationale:**	**3** C☐ P☐ M☐ N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Rating
4a. Data Generated as a Byproduct of Care Processes	**4a** C☐

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare).

Comment [k26]: 5. Demonstration that the measure is superior to competing measures – new submissions and/or endorsed measures (e.g., is a more valid or efficient way to measure).

Comment [KP27]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

	NQF
4a.1-2 How are the data elements that are needed to compute measure scores generated? coding/abstraction performed by someone other than person obtaining original information,	**P☐ M☐ N☐**
4b. Electronic Sources **4b.1 Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes **4b.2 If not, specify the near-term path to achieve electronic capture by most providers.**	**4b** **C☐ P☐ M☐ N☐**
4c. Exclusions **4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No **4c.2 If yes, provide justification.**	**4c** **C☐ P☐ M☐ N☐ NA☐**
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences **4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.** To help reduce provider variability in the administration of the 6MWT, a standardized test protocol should be utilized in each PR program, and audits of inter- and intra-observer variability should be performed on a regular basis.	**4d** **C☐ P☐ M☐ N☐**
4e. Data Collection Strategy/Implementation **4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:** The 6MWT is a test that is straightforwad to perform, interpret and report, and is used in a large percentage of PR programs. **4e.2 Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** TBD **4e.3 Evidence for costs:** TBD **4e.4 Business case documentation:** TBD	**4e** **C☐ P☐ M☐ N☐**
TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria **for** *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, **met?** **Rationale:**	**4** **C☐ P☐ M☐ N☐**
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited ☐**

Comment [KP28]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

Comment [KP29]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

Comment [KP30]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

Comment [KP31]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable

Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☐** **N☐** **A☐**

CONTACT INFORMATION

Co.1 **Measure Steward (Intellectual Property Owner)**
Co.1 **Organization**
American Association for Cardiovascular and Pulmonary Rehabilitation | 401 N. Michigan Avenue, Suite 2200 | Chicago | Illinois | 60611

Co.2 **Point of Contact**
P. Joanne | Ray | jray@aacvpr.org | 312-673-4746

Measure Developer If different from Measure Steward
Co.3 **Organization**
American Association for Cardiovascular and Pulmonary Rehabilitation | 401 N. Michigan Avenue, Suite 2200 | Chicago | Illinois | 60611

Co.4 **Point of Contact**
P. Joanne | Ray | jray@aacvpr.org | 312-673-4746

Co.5 **Submitter If different from Measure Steward POC**
P. Joanne | Ray | jray@aacvpr.org | 312-673-4746- |American Association for Cardiovascular and Pulmonary Rehabilitation

Co.6 **Additional organizations that sponsored/participated in measure development**

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 **Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
Chris Garvey, FNP, MSN, MPA, Workgroup chair. Other members include Gerene Bauldoff, PhD, RN, Ohio State School of Nursing, Karen Lui, RN, AACVPR, Marjorie King, MD, Helen Hayes Hospital, and Randal Thomas, MD, MS, Mayo Clinic.

Ad.2 **If adapted, provide name of original measure:**
Ad.3-5 **If adapted, provide original specifications URL or attachment**

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 **Year the measure was first released:** 2009
Ad.7 **Month and Year of most recent revision:** 0-0
Ad.8 **What is your frequency for review/update of this measure?** 3 years
Ad.9 **When is the next scheduled review/update for this measure?** 2012-10

Ad.10 **Copyright statement/disclaimers:**

Ad.11 -13 **Additional Information web page URL or attachment:** Attachment AACVPR NQF References.doc

Date of Submission (*MM/DD/YY*)**:** 04/02/2010

Page 3: [1] Comment [k5] **Karen Pace** **10/5/2009 8:59:00 AM**

4 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 step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

Page 8: [2] Comment [KP14] **Karen Pace** **10/5/2009 8:59:00 AM**

2d. Clinically necessary measure exclusions are identified and must be:

- supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;

AND

- a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;

AND

- precisely defined and specified:
  - if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);

if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

References

ATS/ERS COPD Guidelines http://www.thoracic.org/sections/copd/for-health-professionals/index.html

ATS statement: guidelines for the six-minute walk test. American Journal of Respiratory and Critical Care Medicine, 2002. 166(1): p. 111-7.

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