



Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to sub criterion 1b).

Brief Measure Information

NQF #: 0700

Corresponding Measures:

De.2. Measure Title: Health-related Quality of Life in COPD patients before and after Pulmonary Rehabilitation

Co.1.1. Measure Steward: American Association of Cardiovascular Pulmonary Rehabilitation

De.3. Brief Description of Measure: The percentage of patients with COPD who are found to improve their health-related quality of life score (HRQoL) as measured by a valid and reliable instrument after participating in pulmonary rehabilitation (PR).

1b.1. Developer Rationale: Health-related QOL has been studied, reported, and accepted as important and relevant outcome measure and marker for disability/health in patients with COPD and ILD. HRQOL is strongly associated with severity of COPD and ILD (1). Multiple organ and disease-specific instruments have been described with strong psychometrics (validity and reliability). According to the ACCP/AACVPR Evidence-based guidelines, PR has been shown to improve health-related quality of life with a Recommendation level 1, strength of evidence A (highest possible rating in the ACCP rating system (2). McCarthy and colleagues report in the updated Cochrane systematic review that significant improvement was noted in 4 important domains for quality of life (3). Effects were found to be larger than the MCID for both the CRQ and SGRQ (4). A new Cochrane Systematic Review also supports PR positive impact on HRQOL in ILD (4). The GOLD Guidelines (15) recommend that pulmonary rehabilitation be a part of the treatment plan for patients with moderate to severe COPD. Based on the GOLD guidelines, the COPD Assessment Test has also been added as a valid and reliable instrument measuring HRQoL in COPD (6). The MCID for the CAT has been defined (12). The CAT has been shown to be sensitive to changes related to pulmonary rehabilitation (13). Recent Cochrane systematic reviews also report that exercise therapy improves HRQOL in ILD (25) and non-malignant dust related diseases that fall under the ILD umbrella (14).

1. Ståhl E, Lindberg A, Jansson SA, Rönmark E, Svensson K, Andersson F, et al. Health-related quality of life is related to COPD disease severity. *Health Qual Life Outcomes*. 2005 Sep 9; 3:56.
2. Ries AL, Bauldoff GS, Carlin BW, Casaburi R, Emery CF, Mahler DA, et al. Pulmonary Rehabilitation: Joint ACCP/AACVPR Evidence-Based Clinical Practice Guidelines. *CHEST* 2007 131, 4S - 42S.
3. . McCarthy B, Casey D, Devane D, Murphy K, Murphy E, & Lacasse Y. Pulmonary rehabilitation for chronic obstructive pulmonary disease. *Cochrane Database Syst Rev* 2015 Issue 2, Article no. CD003793. DOI: 10.1002/14651858.CD003793.pub3
4. . Dowman L, Hill, CJ, & Holland AE. Pulmonary rehabilitation for interstitial lung disease. *Cochrane Database Syst Rev* 2014 Issue 10:CD006322. doi: 10.1002/14651858.CD006322.pub3.
15. GOLD Global Obstructive Lung Disease Initiative. Global Strategy for Diagnosis, Management, and Prevention of COPD. 2015. Retrieved from: http://www.goldcopd.org/uploads/users/files/GOLD_Report_2015_Sept2.pdf
6. Dodd JW, Hogg L, Nolan J, Jefford H, Grant A, Lord VM, et al. The COPD assessment test (CAT): response to pulmonary rehabilitation. A multicentre, prospective study. *Thorax* 2011 66 (5), 425-429. doi: 10.1136/thx.2010.156372. Epub 2011 Mar 12.
12. Kon SS, Canavan JL, Jones SE, Nolan CM, Clark AL, Dickson MJ, et al. Minimum clinically important difference for the COPD Assessment Test: a prospective analysis. *Lancet Respir Med*. 2014 Mar; 2(3):195-203. doi: 10.1016/S2213-2600(14)70001-3. Epub 2014 Feb 4
13. Dodd JW, Hogg L, Nolan J, Jefford H, Grant A, Lord VM, et al. The COPD assessment test (CAT): response to pulmonary rehabilitation. A multicentre, prospective study. *Thorax* 2011 66 (5), 425-429. doi: 10.1136/thx.2010.156372. Epub 2011 Mar 12.
14. . Dale MT, McKeough ZJ, Troosters T, Bye P, & Alison JA. Exercise training to improve exercise capacity and quality of life in people with non-malignant dust-related respiratory diseases. *Cochrane Database Syst Rev* 2015 Issue 11:CD009385. doi: 10.1002/14651858.CD009385.pub2.

S.4. Numerator Statement: Number of patients with clinician diagnosed COPD who have participated in PR and have been found to improve their HRQOL score by the minimum clinical important difference (MCID) as measured by the Chronic Respiratory Disease Questionnaire (CRQ), St. George's Respiratory Questionnaire (SGRQ), or the COPD Assessment Test (CAT) at the beginning and the end of PR.

S.6. Denominator Statement: All patients with clinician diagnosed COPD at PR program entry who completed one of the 3 valid and reliable HRQOL instruments at the beginning and end of PR during the measurement period.

S.8. Denominator Exclusions:

- Inability to read and/or write in order to complete the HRQOL instrument
- Presence of cognitive or neuropsychiatric impairment that impairs the patient's ability to answer the CRQ, SGRQ, or CAT.
- Patients who have not completed at least 10 PR sessions within 3 months of program entry
- Patients with diagnosed pulmonary vascular disease (i.e., pulmonary hypertension) or other primary lung disease process (i.e., lung cancer).

De.1. Measure Type: Outcome: PRO-PM

S.17. Data Source: Other, Registry Data

S.20. Level of Analysis: Clinician : Group/Practice, Other

IF Endorsement Maintenance – Original Endorsement Date: Jan 17, 2011 **Most Recent Endorsement Date:** Jan 17, 2011

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?

1. Evidence, Performance Gap, Priority – 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

[032916_testing_attachment_PR_HRQOL_2016_FINAL.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.

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.

Health-related QOL has been studied, reported, and accepted as important and relevant outcome measure and marker for disability/health in patients with COPD and ILD. HRQOL is strongly associated with severity of COPD and ILD (1). Multiple organ and disease-specific instruments have been described with strong psychometrics (validity and reliability). According to the ACCP/AACVPR Evidence-based guidelines, PR has been shown to improve health-related quality of life with a Recommendation level 1, strength of evidence A (highest possible rating in the ACCP rating system (2)). McCarthy and colleagues report in the updated Cochrane systematic review that significant improvement was noted in 4 important domains for quality of life (3). Effects were found to be larger than the MCID for both the CRQ and SGRQ (4). A new Cochrane Systematic Review also supports PR positive impact on HRQOL in ILD (4). The GOLD Guidelines (15) recommend that pulmonary rehabilitation be a part of the treatment plan for

patients with moderate to severe COPD. Based on the GOLD guidelines, the COPD Assessment Test has also been added as a valid and reliable instrument measuring HRQoL in COPD (6). The MCID for the CAT has been defined (12). The CAT has been shown to be sensitive to changes related to pulmonary rehabilitation (13). Recent Cochrane systematic reviews also report that exercise therapy improves HRQOL in ILD (25) and non-malignant dust related diseases that fall under the ILD umbrella (14).

1. Ståhl E, Lindberg A, Jansson SA, Rönmark E, Svensson K, Andersson F, et al. Health-related quality of life is related to COPD disease severity. *Health Qual Life Outcomes*. 2005 Sep 9; 3:56.
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3. . McCarthy B, Casey D, Devane D, Murphy K, Murphy E, & Lacasse Y. Pulmonary rehabilitation for chronic obstructive pulmonary disease. *Cochrane Database Syst Rev* 2015 Issue 2, Article no. CD003793. DOI: 10.1002/14651858.CD003793.pub3
4. . Dowman L, Hill, CJ, & Holland AE. Pulmonary rehabilitation for interstitial lung disease. *Cochrane Database Syst Rev* 2014 Issue 10:CD006322. doi: 10.1002/14651858.CD006322.pub3.
15. GOLD Global Obstructive Lung Disease Initiative. Global Strategy for Diagnosis, Management, and Prevention of COPD. 2015. Retrieved from: http://www.goldcopd.org/uploads/users/files/GOLD_Report_2015_Sept2.pdf
6. Dodd JW, Hogg L, Nolan J, Jefford H, Grant A, Lord VM, et al. The COPD assessment test (CAT): response to pulmonary rehabilitation. A multicentre, prospective study. *Thorax* 2011 66 (5), 425-429. doi: 10.1136/thx.2010.156372. Epub 2011 Mar 12.
12. Kon SS, Canavan JL, Jones SE, Nolan CM, Clark AL, Dickson MJ, et al. Minimum clinically important difference for the COPD Assessment Test: a prospective analysis. *Lancet Respir Med*. 2014 Mar; 2(3):195-203. doi: 10.1016/S2213-2600(14)70001-3. Epub 2014 Feb 4
13. Dodd JW, Hogg L, Nolan J, Jefford H, Grant A, Lord VM, et al. The COPD assessment test (CAT): response to pulmonary rehabilitation. A multicentre, prospective study. *Thorax* 2011 66 (5), 425-429. doi: 10.1136/thx.2010.156372. Epub 2011 Mar 12.
14. . Dale MT, McKeough ZJ, Troosters T, Bye P, & Alison JA. Exercise training to improve exercise capacity and quality of life in people with non-malignant dust-related respiratory diseases. *Cochrane Database Syst Rev* 2015 Issue 11:CD009385. doi: 10.1002/14651858.CD009385.pub2.

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.*

To measure HRQoL before and after PR, at least one of 3 valid and reliable instruments can be selected for use (CRQ, SGRQ, CAT). For each questionnaire a paired t-test was used to test the within patient change from intake to discharge. The p-value for the proportion with HRQOL improvement testing the hypothesis that more patients improve (by any amount) than decrease or stay the same. This summary measure is based on all patients with a change score for at least one questionnaire. MCID is the established minimum clinically important difference. A negative MCID indicates that a negative change score is considered an improvement. See table in measure testing form.

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.

Several published reports note opportunities for improvement when attempting to address HRQoL in the COPD population. Fischer and colleagues (15) reported that 23% of patients did not complete PR, due to medical, sociodemographic, clinical or other psychological reasons. For patients who completed PR, they attended an average of 92% of scheduled appointments. Garcia-Aymerich and colleagues (16) assessed the prevalence rates of modifiable risk factors in hospitalized COPD patients. They found moderate to high prevalence to modifiable risk factors in this patient subset that included: lack of influenza vaccination, non-attendance to PR, noncompliance with prescribed oxygen therapy, incorrect use of inhaled medications and current smoking. These findings indicate unsatisfactory COPD management. While published guidelines for management are widely available, Phanareth and colleagues (17) reported only a moderate effect of national guidelines on implementation of evidence-based care. Ramsey (18) explores the causes and consequences of the lack of application of evidence-based guidelines.

15. Fischer MJ, Scharloo M, Abbink JJ, van 't Hul AJ, van Ranst D, Rudolphus A, Weinman J, Rabe KF, Kaptein AA. Drop-out and attendance in pulmonary rehabilitation: the role of clinical and psychosocial variables. *Respir Med*. 2009 Oct;103(10):1564-71.
16. Garcia-Aymerich J, Barreiro E, Farrero E, Marrades RM, Morera J, Anto JM. Patients hospitalized for COPD have a high prevalence of modifiable risk factors for exacerbation (EFRAM study), 2001, *Eur Respir J*;16:1037–1042.

17. Phanareth K, Hansen LS, Christensen LK, Laursen LC, Hansen EF. Treatment of acute severe asthma and chronic obstructive pulmonary disease in Danish hospitals. Do national recommendations improve on the quality of the treatment?, 2002, Respir Med;96:653–658.
18. Ramsey SD. Suboptimal medical therapy in COPD. Exploring the causes and consequences, 2000, Chest;117:33S–37S.

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.

There is published evidence that the treatment gaps, and negative impact on HRQOL noted above are even more prevalent for women with COPD than for men.

Haave and colleagues evaluated gender impact on the effects of PR at baseline (enrollment into PR, completion of inpatient PR program and 6 months post PR. There was no significant gender / time effect for perceived health status, perceived QOL, or anxiety over any period of time. For perceived health status and QOL, improvements immediately after PR and subsequent declines at follow-up were similar for women and men. Overall, the results indicated that the PR had similar effects for female and male patients.

19. Haave E, Skumlien S, Hyland ME. Gender considerations in pulmonary rehabilitation. J Cardiopulm Rehabil Prev. 2008 May-Jun;28(3):215-9.

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

See 1b.4

19. Haave E, Skumlien S, Hyland ME. Gender considerations in pulmonary rehabilitation. J Cardiopulm Rehabil Prev. 2008 May-Jun;28(3):215-

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*):

Respiratory, Respiratory : Chronic Obstructive Pulmonary Disease (COPD)

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*):

Elderly

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.*)

Not applicable

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 not an eMeasure Attachment:

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)

No data dictionary Attachment:

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.

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.

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.

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.

The measure has been expanded to include a third instrument. The COPD Assessment Test has been added to the Chronic Respiratory Disease Questionnaire and the St. George's Respiratory Questionnaire. This addition is important from a feasibility and usability standpoint as the CAT is available in the public domain and consists of 8 questions. Updated testing has been completed and provided for reliability and validity.

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).

Number of patients with clinician diagnosed COPD who have participated in PR and have been found to improve their HRQOL score by the minimum clinical important difference (MCID) as measured by the Chronic Respiratory Disease Questionnaire (CRQ), St. George's Respiratory Questionnaire (SGRQ), or the COPD Assessment Test (CAT) at the beginning and the end of PR.

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 risk-adjusted outcome should be described in the calculation algorithm (S.14).

Assessments of HRQOL 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.

To perform the HRQOL assessment, a CRQ, CAT or SGRQ is administered by PR staff to each COPD patient enrolled in PR, in a private interview space.

The numerator is calculated as follows: A patient is counted as having improved his/her HRQOL score (measured by CRQ, CAT or SGRQ) if the HRQOL score at PR program completion has improved by at least the MCID for the tool used over the HRQOL score at PR program entry.

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

All patients with clinician diagnosed COPD at PR program entry who completed one of the 3 valid and reliable HRQoL instruments at the beginning and end of PR during the measurement period.

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).

All patients with a clinician diagnosis of COPD who are able to complete a CRQ, SGRQ, or CAT to assess HRQOL at PR program entry and PR program completion, who have completed at least 10 PR sessions within a 3 month period.

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

- Inability to read and/or write in order to complete the HRQoL instrument
- Presence of cognitive or neuropsychiatric impairment that impairs the patient's ability to answer the CRQ, SGRQ, or CAT.
- Patients who have not completed at least 10 PR sessions within 3 months of program entry
- Patients with diagnosed pulmonary vascular disease (i.e., pulmonary hypertension) or other primary lung disease process (i.e., lung cancer).

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.)

Patients enrolled in PR are to be excluded if he/she is unable to read and/or write, has significant cognitive or neuropsychiatric impairment that would preclude ability to answer the CRQ, SGRQ, or CAT, has not completed at least 10 PR session within 3 months of program entry, or is diagnosed with pulmonary vascular disease or other primary lung disease process.

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.)

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).

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:

Other (specify):

If other: Higher score on the CRQ indicates better mastery across the subscores and the global score. In contrast, higher scores the SGRQ and the CAT indicate more impairment or reduced quality of life. The goal in PR is to see an improvement in the HRQOL outcomes, indicating reduced perception of impairment and better health-related quality of life. HRQOL improvement would be indicated by a CRQ score increase and by a SGRQ or CAT score decrease

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 = Score within a defined interval

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.)

Percentage of patients achieving an improvement in HRQOL during PR = (Number of COPD patients in a reporting period who have completed at least 10 sessions of PR in 3 months or less, who achieved an improvement in their HRQOL score by the MCID as

measured by CRQ, CAT, or SGRQ during PR)/(Number of COPD patients enrolled in PR program during the reporting period) x 100%

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. All eligible patients during the measurement period should be included.

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.

Chronic Respiratory Disease Questionnaire (CRQ)

The CRQ is a 20-item instrument that measures physical- functional and emotional limitations due to chronic lung diseases, including COPD and ILD. It has been primarily applied in rehabilitation trials of COPD (1). However, Holland and colleagues reported improvement in CRQ scores in ILD following exercise training (2). Tools include an interviewer lead CRQ (3), a self-report CRQ (4) and a standardized CRQ self-report (5). The patient is asked to recall the five most important activities that caused breathlessness over past two weeks. A total score as well as individual subscale scores can be calculated. The tool is provider or self-administered. The domains include dyspnea, fatigue, emotion, and mastery. The MCID for each domain is 0.5. MID of 0.5-1.0 has been used (6). Self-report tool should be scored by each domain (dyspnea, fatigue, emotion and mastery). A higher score indicates better HRQoL. The CRQ has been shown to be sensitive to bronchodilator treatment. The tool has not yet been shown to be responsive to long-term disease progression.

St. George's Respiratory Questionnaire (SGRQ)

The SGRQ was developed to measure health status in patients with respiratory disease, e.g. COPD, asthma and ILD (7). Domains include symptoms (frequency and severity of respiratory symptoms), activity (effects on and adjustment of everyday activities), and impact on social and psychological functioning. The SGRQ is widely used in clinical trials as a secondary endpoint to assess the effects of treatment, management and interventions on health status in COPD. More recent adoption has occurred in ILD trials. Section I (symptoms) is a 5-point Likert scale. Sections II (activity) and III (impacts) are dichotomous (yes or no answers). Each item is weighted based on empirical data. Scores range from 0 - 100, with higher scores indicating worse HRQoL. A missing answer is considered as if the patient had answered "no" (indicating better health -status) (8). The tool is self-administered. The most commonly used MCID is 4 (8).

The SGRQ has been shown to be reliable and valid in COPD, asthma and ILD (9-11). A COPD-specific version (8) and IPF-specific version (10) are available. Results may be influenced by subjects' sex, age, education, and co-morbidities (12). There is significant correlation between SGRQ and FEV1, FVC, resting SaO2, 6MWD, MRC, anxiety scores, and depression scores. The SGRQ demonstrated greater ability to discriminate among different levels of severity stages of COPD than generic measures of health (13).

COPD Assessment Test (CAT)

The 8-item questionnaire that uses a 6-point likert-type scale asking questions about cough, mucus congestion, chest tightness, exertional dyspnea, ADL limitation, confidence in leaving the home, sleep quality and energy level. It is scored from 0 to 40, with higher scores indicating greater levels of limitation and worse HRQoL (14-16). The CAT has been initially validated in prospective studies conducted in the USA and Europe and in China but is globally applicable. A recent systematic review of 36 studies support the validity and reliability of the CAT (17). While titled the COPD Assessment test, Nagata and colleagues report that the CAT is valid and reliable for use with interstitial lung disease patients (18). The CAT has been translated and validated for use in more than 50 languages other than English. Only validated translations of the CAT should be used. Sensitive to changes related to pulmonary rehabilitation (19). Available at: <http://www.catestonline.org/images/pdfs/CATest.pdf>. While Nagata and colleagues (17) note that the MCID is to be determined, others have reported 2 points as a reliable estimate (20, 21).

To compare outcomes across the 3 instruments, the minimally clinical important difference (MCID) provides a method to standardize scores.

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

If other, please describe in S.18.

Other, Registry Data

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.

HRQoL is evaluated for this measure using one of 3 valid and reliable instruments: CRQ, CAT or the SGRQ. Please see S.21 for detailed description of the 3 instruments. The instruments can be administered by PR staff or by self-completion. The instruments are most commonly used in paper and pencil form. All 3 instruments have been validated in multiple languages.

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)

Clinician : Group/Practice, Other

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

Outpatient Services

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.)

2. Validity – See attached Measure Testing Submission Form

032916_testing_attachment_PR_HRQOL_2016_v3.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.

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.

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.

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), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry), Other
If other: Survey

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 clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)

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:

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.

The HRQoL instruments are straightforward to administer. The CRQ and SGRQ require score interpretation and coding, but public domain programs are available for this step. The CAT is straightforward and provides a single score. Measurement of HRQoL is used and reported in a large percentage of PR programs.

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).

CAT - No fees for this tool, available in the public domain.

CRQ - Tools are licensed. Fees for interviewer and standardized self-administered tool range from \$150 to \$2000.

SGRQ - The St. George's University of London Medical School grants permission for clinicians to use the SGRQ without charge. The Medical School charges commercial organizations a license fee for use of the SGRQ.

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 high-quality, 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 (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

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?)

We are continuously seeking opportunities to expand use of this measure in government or other programs, including those intended for accountability or public reporting. The AACVPR does not have any policies that would restrict access to the performance measure specifications or results or that would impede implementation of the measure for any application. We would welcome its implementation in emerging applications such as accountable care organizations (ACO), Medicare Advantage insurance plans or health plans selling on the new insurance marketplace.

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.)

Not currently used in public reporting. Future use of the AACVPR PR registry for PR program voluntary certification is planned - anticipated November 2017.

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.

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.

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.

4a2.2.2. Summarize the feedback obtained from those being measured.

4a2.2.3. Summarize the feedback obtained from other users

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.

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.

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.

No unintended negative consequences have been identified via our testing nor have any been reported to us by users of the measure.

4b2.2. Please explain any unexpected benefits from implementation of this measure.

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_-_Measure_700.pdf](#)

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): [American Association of Cardiovascular Pulmonary Rehabilitation](#)

Co.2 Point of Contact: [Mollie, Corbett, mcorbett@aacvpr.org, 312-673-5447-](#)

Co.3 Measure Developer if different from Measure Steward: [American Association of Cardiovascular Pulmonary Rehabilitation](#)

Co.4 Point of Contact: [Mollie, Corbett, mcorbett@aacvpr.org, 312-673-5447-](#)

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.

[AACVPR Members:](#) [Steven Lichtmann, EdD, MAACVPR, Director, Cardiopulmonary Outpatient Rehabilitation Services; Director, Rehabilitation Research; Research Scientist, Helen Hayes Hospital, West Haverstraw, NY; Christine Garvey, MSN, MPA, FNP-BC, FAACVPR, Director of Pulmonary Rehabilitation, University of California, San Francisco Medical Center, San Francisco, CA; Gerene Bauldoff, PhD, RN, FAACVPR, FAAN, Professor of Clinical Nursing, The Ohio State University College of Nursing, Columbus, OH; Todd Brown, MD, FAACVPR, Associate Professor, University of Alabama-Birmingham, Birmingham, AL; Maria Buckley, PhD, Staff Psychologist, Lifespan Physicians Group and Clinical Associate Professor of Psychiatry and Human Behavior, The Warren Alpert Medical School of Brown University, Providence, RI](#)

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: [2009](#)

Ad.3 Month and Year of most recent revision: [03, 2016](#)

Ad.4 What is your frequency for review/update of this measure? [3 years](#)

Ad.5 When is the next scheduled review/update for this measure? [01, 2017](#)

Ad.6 Copyright statement:

Ad.7 Disclaimers:
Ad.8 Additional Information/Comments: