**Supplemental Digital Content (SDC)**

**SDC APPENDIX**

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SDC Appendix Table 1. **Summary Survey Results for Prioritization Survey for Cardiac Rehabilitation Outcomes**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **AACVPR Survey** | | | **QCC Survey** | | |
|  | **Mean**  **Summary Scorea** | **Question #8**  **(Quality)b** | **Number of Questions**  **Ranked in top 5c** |  | **Mean Summary Score** | **Question #8**  **(Quality)b** |
| Blood pressure control | 3.33 | 2.81 | 8 |  | 3.50 | 3.25 |
| Improvement in functional capacity | 3.32 | 2.88 | 7 |  | 3.54 | 3.50 |
| Diabetes self-management | 3.26 | 2.80 | 7 |  | 3.09 | 2.88 |
| Psychosocial risk | 3.12 | 2.77 | 4 |  | 3.17 | 3.00 |
| Abstinence from tobacco use | 3.04 | 2.44 | 4 |  | 2.79 | 2.38 |
| Health-related quality of life | 3.11 | 2.82 | 2 |  | 3.30 | 3.13 |
| Body composition | 3.08 | 2.44 | 2 |  | 2.88 | 2.38 |
| Adherence to preventive medications | 3.08 | 2.70 | 0 |  | 3.17 | 2.88 |
| Adherence to regular physical activity | 3.07 | 2.68 | 2 |  | 3.15 | 3.00 |
| Appropriate utilization of CR | 3.04 | 2.67 | 1 |  | 3.34 | 3.38 |
| Dietary habits | 3.03 | 2.60 | 1 |  | 3.25 | 3.00 |
| Patient safety during exercise sessions | 3.03 | 2.74 | 2 |  | 3.00 | 2.75 |
| Acute care hospital utilization | 2.90 | 2.54 | 0 |  | 2.50 | 2.13 |
| Adherence to preventive vaccinations | 2.87 | 2.34 | 0 |  | 2.63 | 2.38 |
| **Mean score for all items** | **3.1** | **2.67** | **NA** |  | **3.3** | **2.9** |

Abbreviations: AACVPR, American Association of Cardiovascular and Pulmonary Rehabilitation; CR, cardiac rehabilitation; NA, not applicable; QCC, Quality of Care Committee.

aPotential performance measure topics were ranked across the 8 domains of Table 1 on a scale of 1 to 4 and then averaged with 1 = strongly disagree, 4 = strongly agree.

bAnswers to question 8. This asked participants to rate their level of agreement to this statement, “The scores obtained from measuring an outcome in this category will provide an accurate reflection of the quality of a CR program and can be used to distinguish good and poor quality.”

cEach performance measure was ranked on the 8 domains in Table 1. Within each of these 8 domains, each of the 14 performance measure topics were ranked from 1 through 14, and the total number of highest rankings (in the top 5) for each performance measure was tallied, with a maximum of 8.

Appendix Table 2. **Summary Survey Results for Prioritization Survey for Pulmonary Rehabilitation Outcomes**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **AACVPR Survey** | | |  | **QCC Survey** | |
|  | **Mean Summary Scorea** | **Question #8**  **(Quality)b** | **Number of Questions**  **Ranked in Top 5c** |  | **Mean Summary Scorea** | **Question #8**  **(Quality)b** |
| Improvement in sensation of dyspnea | 3.31 | 2.92 | 8 |  | 3.70 | 3.44 |
| Improvement in functional capacity | 3.39 | 2.72 | 8 |  | 3.57 | 3.20 |
| Appropriate oxygen utilization | 3.25 | 2.92 | 8 |  | 3.33 | 3.33 |
| Health-related quality of life | 3.26 | 3.00 | 7 |  | 3.71 | 3.56 |
| Abstinence from tobacco use | 3.08 | 2.54 | 3 |  | 3.07 | 2.67 |
| Psychosocial risk | 3.11 | 2.72 | 2 |  | 3.11 | 2.89 |
| Frequency of acute exacerbations of COPD | 3.08 | 2.68 | 2 |  | 2.78 | 2.56 |
| Adherence to preventive vaccinations | 3.06 | 2.58 | 1 |  | 2.70 | 2.33 |
| Adherence to regular physical activity | 3.00 | 2.68 | 1 |  | 3.00 | 2.60 |
| Acute care hospital utilization | 3.06 | 2.71 | 0 |  | 2.80 | 2.50 |
| Adherence to inhaled medications | 3.02 | 2.64 | 0 |  | 3.07 | 2.80 |
| Patient safety during PR sessions | 3.00 | 2.72 | 0 |  | 3.11 | 3.00 |
| **Mean score for all items** | **3.14** | **2.73** | **NA** |  | **3.11** | **3.00** |

Abbreviations: AACVPR, American Association of Cardiovascular and Pulmonary Rehabilitation; COPD, chronic obstructive pulmonary disease; NA, not applicable; QCC, Quality of Care Committee.

aPotential performance measure topics were ranked across the 8 domains of Table 1 on a scale of 1 to 4 and then averaged with 1 = strongly disagree, 4 = strongly agree.

bAnswers to question 8. This asked participants to rate their level of agreement to this statement: “The scores obtained from measuring an outcome in this category will provide an accurate reflection of the quality of a CR program and can be used to distinguish good and poor quality.”

cEach performance measure was ranked on the 8 domains in Table 1. Within each of these 8 domains, each of the 12 performance measures topics were ranked from 1 through 12, and the total number of highest rankings (in the top 5) for each performance measure was tallied, with a maximum of 8.

# Abbreviations Used in SDC Appendix

AACP, American College of Chest Physicians

AACVPR, American Association of Cardiovascular and Pulmonary Rehabilitation

ACC, American College of Cardiology

ACS, acute coronary syndrome

ACSM, American College of Sports Medicine

ADL, activities of daily living

AHA, American Heart Association

ASH = American Society of Hypertension

ATS, American Thoracic Society

BDI, Beck Depression Inventory

BDI, baseline dyspnea index

BP, blood pressure

CAD, coronary artery disease

CAT, COPD Assessment Test

CBT, cognitive behavioral therapy

COPD, chronic obstructive pulmonary disease

CR, cardiac rehabilitation

CRQ, Chronic Respiratory Disease Questionnaire

D, denominator

DD, dyspnea diary

ERS, European Respiratory Society

FEV1, forced expiratory volume in 1 sec

FVC, forced vital capacity

GOLD, Global Initiative for Obstructive Lung Disease

HADS, Hospital Anxiety and Depression Scale

HIIT, high-intensity interval training

HRQoL, health-related quality of life

ILD, interstitial lung disease

LVAD, left ventricular assist device

METs, metabolic equivalents

MCID, minimally clinically important difference

mMRC, modified Medical Research Council

N, numerator

PHQ-9, Patient Health Questionnaire

PR, pulmonary rehabilitation

PRFS, Psychosocial Risk Factor Survey

SaO2, arterial oxygen saturation

SGRQ, St George’s Respiratory Questionnaire

TDI, transition dyspnea index

UCSD SOBQ, University of California San Diego Shortness of Breath Questionnaire

6MWT, 6-min walk test

# Performance Measure for Optimal BP Control at Completion of CR

**MEASURE DESCRIPTION**

Percent of patients participating in the CR program who have optimal BP control at program discharge, as defined by the most recent ACC/AHA guidelines

**Definitions**

Blood pressure measurement should be standardized and follow the American Heart Association guidelines1 for proper BP measurement and determination of cuff size.

Evidence-based guidelines are used to define optimal blood pressure control and these guidelines are updated periodically. The most recent AHA/ACC/ASH Scientific Statement on the Treatment of Hypertension in Patients with Coronary Artery Disease2 states that “the <140/90-mm Hg BP target is reasonable for the secondary prevention of cardiovascular events in patients with hypertension and CAD (Class IIa; Level of Evidence B)”.

**Numerator**

Number of patients with documented optimal BP at discharge from CR

**Denominator**

Number of patients who completed CR during the measurement period. A patient is defined as having completed CR when he/she has undergone a final, formal discharge assessment session and updated treatment plan.

*Denominator Exclusions*

* Patients with a LVAD
* Patients with a medical or surgical contraindication to BP measurement

**Period of Assessment**

Up to 12 mo

**Attribution**

CR program staff

**Sources of Data**

Medical record or another database (eg, administrative, clinical, registry)

**Rationale**

Optimal blood pressure control is important to prevent secondary organ system damage and has been associated with decreased incidence of adverse cardiovascular outcomes, including stroke, heart failure, and myocardial infarction. Optimal BP control is recommended for patients with CAD, hypertension, heart failure, and structural heart disease.2,3 In addition, optimal BP is recommended for primary prevention of heart disease.4

There is some variation among guidelines about the exact level for optimal BP control, particularly for elderly patients,4 resulting in controversy among experts. In order to standardize measurement, the most recent ACC/AHA guidelines2 will be used to define optimal BP control for this measure.

CR programs promote adherence to medications and lifestyle modifications5 which are critical for optimal control of BP. In addition, CR staff report abnormal BP and/or signs related to poor BP control to referring practitioners, who can modify medication management based on data.

**References**

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**PERFORMANCE MEASURE FOR OPTIMAL BP CONTROL**

**DATA DEFINITIONS**

**OPTIMAL BP CONTROL**

The definition of optimal BP control is linked to AHA/ACC/ASH scientific statements or guidelines, which are referenced in the measure specifications. Currently, in 2016, optimal BP control is defined as systolic BP <140 mm Hg AND diastolic BP <90 mm Hg.

**PROGRAM COMPLETION**

A patient is defined as having completed CR when he/she has undergone a final, formal discharge assessment session and updated treatment plan.

**DENOMINATOR EXCLUSIONS**

Blood pressure measurement in patients with a LVAD does not produce a systolic and diastolic BP, only a mean pressure. Therefore, patients who have an LVAD should not be included in the measurement of denominator or numerator. Medical or surgical contraindications to BP measurement could include bilateral lymphedema, bilateral mastectomy, upper extremity amputation, bilateral upper extremity thromboembolism, or other contraindications as determined by the patient’s health care provider.

**FREQUENTLY ASKED QUESTIONS**

**Which BP during the final CR session should I use to determine whether the patient met the criteria for the performance measure?**

*You should use the patient’s resting BP at arrival for the final cardiac rehabilitation session, ideally after sitting for 5 min. If the BP is elevated, it is appropriate to check it again to confirm that the elevated BP is not just a transient event, and then use the average of at least 2 BPs, separated by 1 to 2 min as the resting BP for the measure. If the initial resting BP or, if needed, the subsequent averaged BP remains greater than 140/90 mm Hg, then the patient does not have optimal BP control and does not meet the criteria for the measure. If the blood pressure is less than 140/90 mm Hg, the patient does meet the criteria.*

*The intent of this measure is to drive improvement in systems and processes that help patients, CR staff and treating physicians work together to achieve optimal BP control. This is not a research project requiring absolute accuracy with BP measurement. Rather, this measure is intended to reflect the ability of a CR program to impact optimal BP control.*

**Does both the systolic and diastolic BP need to be on target to meet the measure?**

*Yes, the systolic BP must be less than 140 mm Hg and the diastolic BP must be less than 90 mm Hg.*

**What will happen now that the ACC/AHA guidelines recommend a different target BP for patients with heart disease?**

*The Quality of Care Committee of AACVPR is currently updating the performance measure, based on the* 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults*. The committee will also work with the Registry and Program Certification committees to decide when to implement the updated performance measure; most likely when data collection begins for a new program certification cycle.*

**What if the patient drops out of the program without notifying a staff member that this is the last exercise session?**

*The Quality of Care Committee decided to use the Registry definition of Completion of Program to avoid penalizing programs for incomplete treatment plans that result from a patient’s non-adherence to recommendations, such as the prescribed number of CR sessions. For example, if a patient’s treatment plan is to attend 24 sessions, then the resting BP on arrival for the 24th session should be used. However, if the plan was for the patient to complete 36 sessions and the patient drops out of the program before the 36th session without notifying staff, then the staff will not have completed the end of program assessments. That patient should be excluded from the measure, which means that they should not be included in either the numerator or the denominator.*

**Why is this measure applied to all patients in the CR program, regardless of diagnosis?**

Optimal BP control is important for patients with all forms of heart disease, not just those with CAD, including patients with heart failure or valvular heart disease (other than those with severe aortic stenosis who are generally not referred to CR).

**CR Optimal Blood Pressure Control Performance Measure** Algorithm



# PERFORMANCE MEASURE FOR IMPROVEMENT IN FUNCTIONAL CAPACITY AT COMPLETION OF CR

**Measure Description**

The percentage of patients who increase their functional capacity after participation in CR as measured by 1 of the following assessments: (1) symptom-limited graded exercise testing (increase in METs by at least 15%), (2) estimated exercise session peak METs (increase in METs by at least 40%) or (3) 6MWT distance (increase in distance walked by at least 10%).

**Definitions**

Assessment of functional capacity during CR may be performed in 3 ways:

1. Symptom-limited graded exercise testing with or without analysis of expired air is the gold standard measurement, performed at program entry and exit

* Use procedures contained in the current guidelines published by the ACSM.1

1. Estimation of peak exercise intensity in METs during the beginning of the CR program (defined as the third session to account for learning effect) and during the final exercise training session

* Use equations published by the ACSM.1
* Estimate METs only using exercise devices which can be calibrated. Factory calibrated equipment may be used as long as the identical piece of equipment is used for pre- and post-measurement.

1. 6MWT distance performed at program entry and exit

* Follow the procedures of the ATS.2

**Numerator**

Number of patients who increase their functional capacity by the percent specified in the measure description from the beginning to the completion of their CR program, as measured by either symptom-limited graded exercise testing, estimated exercise peak METs, or 6MWT distance.

(Refer to the Definitions section for details about measuring functional capacity.)

**Denominator**

Number of patients who completed CR during the measurement period. A patient is defined as having completed CR if he/she has completed a minimum of 4 wk of the CR program and has undergone a final, formal discharge assessment session and updated treatment plan.

*Denominator Exclusions*

Patients unable to participate in a 6MWT, a graded exercise test, or unable to use an exercise device that can be calibrated to estimate METs, due to physical, cognitive, neurological, psychological, or safety reasons or patients who have not completed 4 wk of CR.

**Period of Assessment**

Up to 12 mo.

**Attribution**

CR program staff.

**Sources of Data**

Medical record or another database (eg, administrative, clinical, registry).

**Rationale**

Of all the clinical factors that predict survival in patients with cardiovascular disease, aerobic exercise capacity and the improvement in functional capacity as a result of exercise training are among the most powerful. It has been determined that for each 1 mL/kg/min increase in peak, cardiovascular mortality is reduced by approximately 10%.3,4  For each 1 MET increase in functional capacity resulting from CR, all-cause mortality is reduced by 25% at 1 y.5  For each increase in 6-min walk distance of 104 m, risk of myocardial infarction and all-cause mortality decreases by 47% and 55%, respectively.6  Finally, for each 1 MET increase in final CR submaximal exercise intensity during training sessions, all-cause mortality is reduced by 34%.7

Average increase in estimated functional capacity measured by graded exercise testing after CR is approximately 1 MET,5 with an average percent increase of 25%.8,9,10 The average increase in submaximal exercise capacity during CR exercise sessions is approximately 3 METs, with an average percent increase of 77%.7 Mean increase in 6-min walk distance after CR ranges from 15% to 19% or 59 to 75 m,11,12,13 with the minimal clinically important difference varying across clinical populations and ranging from 25 to 32 m.14,15

In developing this performance measure, the committee recognizes that there is a broad distribution of functional capacity among individuals entering CR and tremendous variability in the ability of CR participants to increase their functional capacity with CR. Improvements in functional capacity, even if below the average improvement observed in the population, can be beneficial to individual participants and associated with improved outcomes, especially for those individuals with very low baseline functional capacity.16 As a result, the committee recognizes that not all CR participants will be able to achieve the average absolute or percent increases in functional capacity with CR quoted above and has defined the threshold for improvement to achieve this performance measure accordingly.

**References**

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**PERFORMANCE MEASURE FOR IMPROVEMENT IN FUNCTIONAL CAPACITY AT COMPLETION OF CR**

**DATA DEFINITIONS**

**SYMPTOM-LIMITED GRADED EXERCISE TESTING**

Commonly called an exercise stress test. May use any standard protocol and any mode of aerobic exercise, but should gradually and systematically increase workloads and be terminated when the patient can no longer exercise due to fatigue, dyspnea, symptoms suggestive of ischemic heart disease, significant ST-segment abnormalities or arrhythmias.

Refer to ACSM guidelines for more details.1

**ESTIMATED EXERCISE SESSION PEAK METS**

Estimate the peak METS achieved by a patient during an exercise session, calculated using validated ACSM equations. Note that these equations are only accurate for treadmills or cycle ergometers that have been calibrated. Factory calibrated equipment with calculate METS may be used as long as the identical piece of equipment is used for pre- and post-measurements.

**6MWT**

This is a standardized test that measures the distance a patient can walk within 6 min. An ATS statement provides more detailed guidelines.2

**BEGINNING OF THE CR PROGRAM**

Refers to functional capacity as measured by: 1) a 6MWT completed within the first wk of the CR program; 2) estimated peak MET level attained during the third CR exercise session; or 3) a symptom-limited graded exercise test within 1 week prior to beginning the program

**COMPLETION OF THE CR PROGRAM**

Refers to functional capacity as measured by: 1) a 6MWT completed during the last week of the CR program; 2) peak MET level attained during the discharge or last exercise session; or 3) a symptom-limited graded exercise test within 1 week of the last CR session. Patient will participate in CR a minimum of 4 wk to be included in the functional capacity measure.

**DENOMINATOR EXCLUSIONS**

Patients unable to participate in a 6MWT, a graded exercise test, or unable to use an exercise device that can be calibrated to estimate METs, due to physical, cognitive, neurological, psychological, or safety reasons. Patient completing less than 4 wk of CR.

**FREQUENTLY ASKED QUESTIONS**

**What MET level should be reported if HIIT is being used?**

*HIIT has the potential to improve functional capacity in CR patients more than improvements seen with moderate continuous training. MET levels reported for patients using a HIIT protocol should be the highest MET level sustained for a minimum of 3 min to ensure patients are achieving steady-state exercise.*

**Some improvement in functional capacity will be expected because of the normal recovery following hospitalization. How will this be accounted for?**

*Improvement in functional capacity during CR remains at the core of a comprehensive CR program. Multiple randomized controlled, and nonrandomized controlled studies have demonstrated improvement in functional capacity resulting from CR participation that exceeds that in nonparticipating control groups. The threshold for improvement as stated in the performance measure is based on this evidence.*

**Will the same increase in exercise capacity be expected in patients starting CR at high levels of fitness?**

*Most studies show an inverse relationship between initial exercise capacity and the level of improvement shown at program completion. While a smaller increase in exercise capacity will likely be noted in patients with higher initial exercise capacity, these patients should be included in the performance measure.*

From the Performance Measure on Improvement in Functional Capacity:

*“In developing this performance measure, the committee recognizes that there is a broad distribution of functional capacity among individuals entering CR and tremendous variability in the ability of CR participants to increase their functional capacity with CR….As a result, the committee recognizes that not all CR participants will be able to achieve the average absolute or percent increases in functional capacity with CR quoted above and has defined the threshold for improvement to achieve this performance measure accordingly.”*

**Should patients with substantial physical limitations that restrict exercise to only certain types of exercise modalities (ie, upper extremity exercise) be excluded?**

*All patients able to exercise on equipment that is factory calibrated for METS should be included in the denominator. This includes patients able to utilize only upper extremity exercise equipment. In fact, significant improvements in exercise capacity have been demonstrated in CAD patients using upper extremity exercise only. As noted in the performance measure, the same piece of exercise equipment should be used for both pre- and post-measurement.*

**Should patients with all eligible diagnoses be included – or only those with atherosclerotic heart disease?**

*All patients eligible for CR should be included in the denominator. There is sufficient evidence that significant improvement in exercise capacity will occur in patients with a multitude of diagnoses, including heart failure, valve replacement or repair, left ventricular assist devices or heart transplant. In most cases, the increase in functional capacity mirrors that in the atherosclerotic heart disease population. While the magnitude of improvement may vary based on a variety of factors, including diagnosis, age, gender and others, the Quality of Care Committee has selected a level of improvement that, based on the evidence base, would be expected when considering all program participants in the overall program measure.*

**Why are there 3 different methods of measurement included for functional capacity?**

*While symptom-limited graded exercise testing provides the most accurate data related to exercise capacity, fewer CR programs are requiring graded exercise test data either before or after CR participation. For this reason, alternative methods of measuring changes in functional capacity, also having a strong evidence-base were included. The standard 6MWT has shown good reliability when used to measure changes in functional capacity in CR, however routine use of this testing method in the CR setting has not been shown. While an estimation of submaximal MET level during an exercise session is open to the most variability and potential manipulation by CR staff, this measurement is routinely completed in the CR setting and allows for greater inclusion of programs in the measure.*

**CR Functional Capacity Performance Measure Algorithm**



# PERFORMANCE MEASURE FOR IMPROVEMENT IN DEPRESSION AT COMPLETION OF CR

**MEASURE DESCRIPTION**

The percentage of patients with a positive depressive screen who experience a decrease in depressive symptoms as measured by changes in the PHQ-9, BDI-II, PRFS or HADS after completion of CR

**DEFINITIONS**

Assessment of change in depressive symptoms by one or more levels of severity during CR may be performed in one of the following four ways:

1. Reduction of ≥1 level of severity in the PHQ-9 score from baseline to completion of CR. Scores for levels of severity are: mild (5-9), moderate (10-14), moderately severe (15-19) or severe (20-27).

* *The PHQ-9 is a 9-item tool based on a 4-point Likert type scale which screens for depressive symptoms and evaluates change in depressive symptoms. Patient time to complete is <5 min. This scale contains an item which assesses suicidal ideation. This tool is available in the public domain.* <http://www.integration.samhsa.gov/images/res/PHQ%20-%20Questions.pdf>

1. Reduction of ≥1 level of severity in the BDI-II from baseline to completion of CR. Scores for levels of severity are: mild (14-19), moderate (20-28) or severe (29-63).

* *The BDI-II is a 21-item tool based on a 4-point scale which screens for depressive symptoms and evaluates change in depressive symptoms. Patient time to complete is 5-10 min. This test includes an item which evaluates suicidal ideation. This tool is commercially available online for purchase by a qualified psychosocial provider.* <http://www.pearsonclinical.com/psychology/products/100000159/beck-depression-inventoryii-bdi-ii.html>

1. Reduction of ≥1 level of severity in the depression scale of the PRFS from baseline to completion of CR. Scores for levels of severity are: mild (T-score 54-59), moderate (T-score 60-65) or severe (T-score 66 -80).

* *The PRFS is a 70-item tool that screens for depressive symptoms as well as anxiety, anger/hostility, social isolation, and emotional guardedness. Its depression scale was validated against the BDI-II. It is based on a 4-point Likert type scale. Patient time to complete is 15 min. It is commercially available online.* <http://prfs1.com/>

1. Reduction of ≥1 level of severity in the depression scale of the HADS from baseline to completion of CR. Scores for levels of severity are: mild (8-10), moderate (11-15) or severe (16-21).

* *The HADS is a 14- item tool which includes both depression and anxiety subscales. This instrument is based on a 4-point Likert type scale. Patient time to complete is 5-10 min. It is commercially available online.* <http://www.gl-assessment.co.uk/products/hospital-anxiety-and-depression-scale-0>

The baseline assessment will take place at intake. The follow-up evaluation will occur upon completion of CR. The patient is defined as having completed CR when he/she has undergone a final, formal discharge assessment session and updated treatment plan.

**NUMERATOR**

The number of patients whose depression screening score is at least in the mild range at intake to CR who reduce symptom severity by at least 1 level by the time they complete the CR program.

**DENOMINATOR**

The total number of patients who complete a depression screening instrument upon intake and completion of CR, and whose depression screening score is at least in the mild range at intake to CR.

*Denominator Exclusions*

* Inability to complete the depression instruments with reasonable accommodations
  + Examples of Reasonable Accommodations:
    - Staff member reads instrument instructions and questions to the patient
    - Staff member enters patient’s responses to test items to the instrument
* Presence of comprehension limitation that precludes completion of the instrument
* Lack of availability of the tool used by the CR program in a language understood by the patient

**PERIOD OF ASSESSMENT**

Up to 12 mo.

**ATTRIBUTION**

CR program staff.

**SOURCES OF DATA**

Medical record or another database (eg, administrative, clinical, registry).

**RATIONALE**

The AHA has identified post-ACS depression as a risk factor for additional adverse cardiac events and all cause and cardiac mortality.1 AACVPR recommends that CR programs screen for depression and that that properly trained staff ask specifically about depression symptoms during the intake interview.2  The prevalence of depression among CAD patients (15%-20%) is 3 times greater than the rates of the general population.3,4 There appears to be a dose response relationship between level of depression and cardiac related prognosis  in patients with CAD.4 Even minimal depressive symptoms  have been associated with increased mortality following an MI.5  For example,  Bush and colleagues evaluated depressive symptoms with the BDI,6 a reliable and valid tool that has been extensively used to screen for and assess for depressive symptom severity.  The BDI score ranges from 0-63. Scores <10 reflect no or minimal depressive symptoms.  Scores from 10 to 18 are within the mild to moderate range.  Scores from 19-29 reflect moderate to severe symptoms and the severe level includes scores from 30-63.  The investigators found higher mortality rates in MI patients with more elevated BDI scores.  Specifically, the mortality rates of patients with BDI scores of (0-3), (4-9) and (10+) were 2.6%, 17.1%, 23.3%, respectively (*P* < .02).   As such, even patients scoring in the subclinical range experienced significantly higher rates of mortality.

Depressed medical patients are three times less likely to follow medical recommendations than non-depressed patients.7 More specifically, depressed cardiac patients are less adherent to treatment recommendations following an MI,8 which is a critical issue for CR patients who are presented with myriad lifestyle modification recommendations aimed at risk factor reduction.

The literature regarding the impact of cardiac rehabilitation on depression is emerging and the evidence thus far is promising.9,10,11,12,13 More research, including randomized controlled clinical trials investigating the effects of CR on depression are needed.  Moreover, CR consists of multiple components which individually or in combination may reduce depression, such as cardiovascular exercise and stress management 14   Evidence is emerging around the benefits of CBT, problem solving15,16,17 and pharmacotherapy15 in reducing depression in the CAD population.

Rigorous evaluation of validity and reliability of depression measures should be conducted to determine appropriate screening tools to assess depression.  Furthermore, measures that reflect responsiveness to change may more clearly capture the impact of CR on reducing depression symptoms.  The inventories that we propose for inclusion for CR programs seeking basic certification are listed in the sources of data section.  These measures include the PHQ-9,18,19,20 BDI-II,20,21 PFRS22 and the HADS.23,24

Additionally, the depression screen may yield a total score below the mild range but which may contain a positive response to a suicidal question. Regardless of the total score on the depression screen, immediate follow up by qualified staff to further assess and manage suicidal risk is required by CR programs and this screening does not replace the clinical assessment and intervention required by CR programs to provide appropriate care for patients endorsing suicidal ideation.

In developing performance measures, the committee recognizes that there are differences among CR programs and staffing and that a portion of CR patients may present with no depressive symptoms. Also, even a small clinically significant decrease in depression symptom severity is beneficial to CR patients.  As a result, the committee recognizes that not all CR patients will be able to achieve clinically significant improvements in depression and have defined the threshold for improvement to achieve this performance measure accordingly.

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**PERFORMANCE MEASURE FOR IMPROVEMENT IN DEPRESSION**

**DATA DEFINITIONS**

**POSITIVE DEPRESSION SCREEN**

The patient scores as mildly depressed or greater on 1 of the following depression screening tools: PHQ-9, BDI-II, PRFS, or HADS.

**DECREASE IN DEPRESSIVE SYMPTOMS**

Defined in detail in the performance measure. Refers to a reduction of 1 or more levels of severity in depressive symptoms (eg, from moderate to mild, from the score at the beginning of CR to the completion of CR).

**DENOMINATOR EXCLUSIONS**

Patients who dropped out of CR and/or patients whose baseline depression scores did not reach the mild range or greater on a depression screen.

**Frequently Asked Questions**

**Please define “The number of patients whose depression screening score is at least in the mild range at intake to CR who reduce symptom severity by at least 1 level by the time they complete the CR program.”**

*“At least in the mild range” means the patient’s results place him or her in the mild, moderate or severe range of the depression screener. “Who reduce symptom severity by at least one level” means the initial score might have been in the moderate range and is reduced to the mild range by program completion, or reducing from the mild range to the subclinical range. “By the time they complete the CR program” means the patient has undergone a final, formal discharge assessment session and updated treatment plan.*

**Should patients who cannot self-administer the measures (eg, impaired reading due to illiteracy or language barrier) be excluded?**

*It may be appropriate for programs to utilize staff to read items to patients if they are unable to read and have the cognitive capacity to complete the test. This task should not be assigned to family members as it could more easily skew patient responses. Some scales are available in multiple languages if the patients are unable to read in English. Psychometric properties of translated tests would need to meet acceptable standards. Depending on the setting, hospital interpreter staff may be able to read the scale items to patients in the test version that is written in his/her own language if patient is unable to read.*

**Many depression screening tools include measuring depressive symptoms such as change in appetite, sleep, and energy level, all of which may be related to physiological effects of surgery rather than simply depression. These can improve without any specific intervention other than time and recovery.**

*Including physical symptoms in screening tools may inflate depression scores; however, depression may also include somatic symptoms. Multiple tests exclude somatic items to avoid including physical symptoms that may be due to the patient’s medical disease. Either method has potential benefits and risks of excluding items that may spuriously increase the score vs. not capturing symptoms that are present, which will erroneously deflate the score. The selected depression screeners address appetite, sleep, and energy to varying degrees: PHQ-9: 3 of 9 items; BDI-II: 4 of 21 items; PRFS: 1 of 14 items; HADS: 0 of 7 items. Programs can decide on the best fit with which they are comfortable.*

*It is important to note these tools are screeners of potential depressive symptoms and should be used to determine if follow up with a qualified professional is warranted. Tools that include more somatic symptomatology will, in a sense, cast a broader net. Regardless of a patient’s total score on a depression scale, any patient who screens positive on a suicide question requires immediate follow-up and further assessment by qualified program staff to determine whether the patient requires emergent care. Staff need to be aware of applicable hospital policies for the possibilities of patients with suicidal thoughts.*

**How important is it that programs address depression scores that are in the mild range?**

*It is important that even mild range scores are considered significant. There is evidence that even lower levels of depression lead to greater levels of future morbidity. In considering future outcomes for the patient and the program, it is important to ensure this area is addressed optimally.*

**Would patients be excluded if they score in normal range at entry, but increase to mild or greater later?**

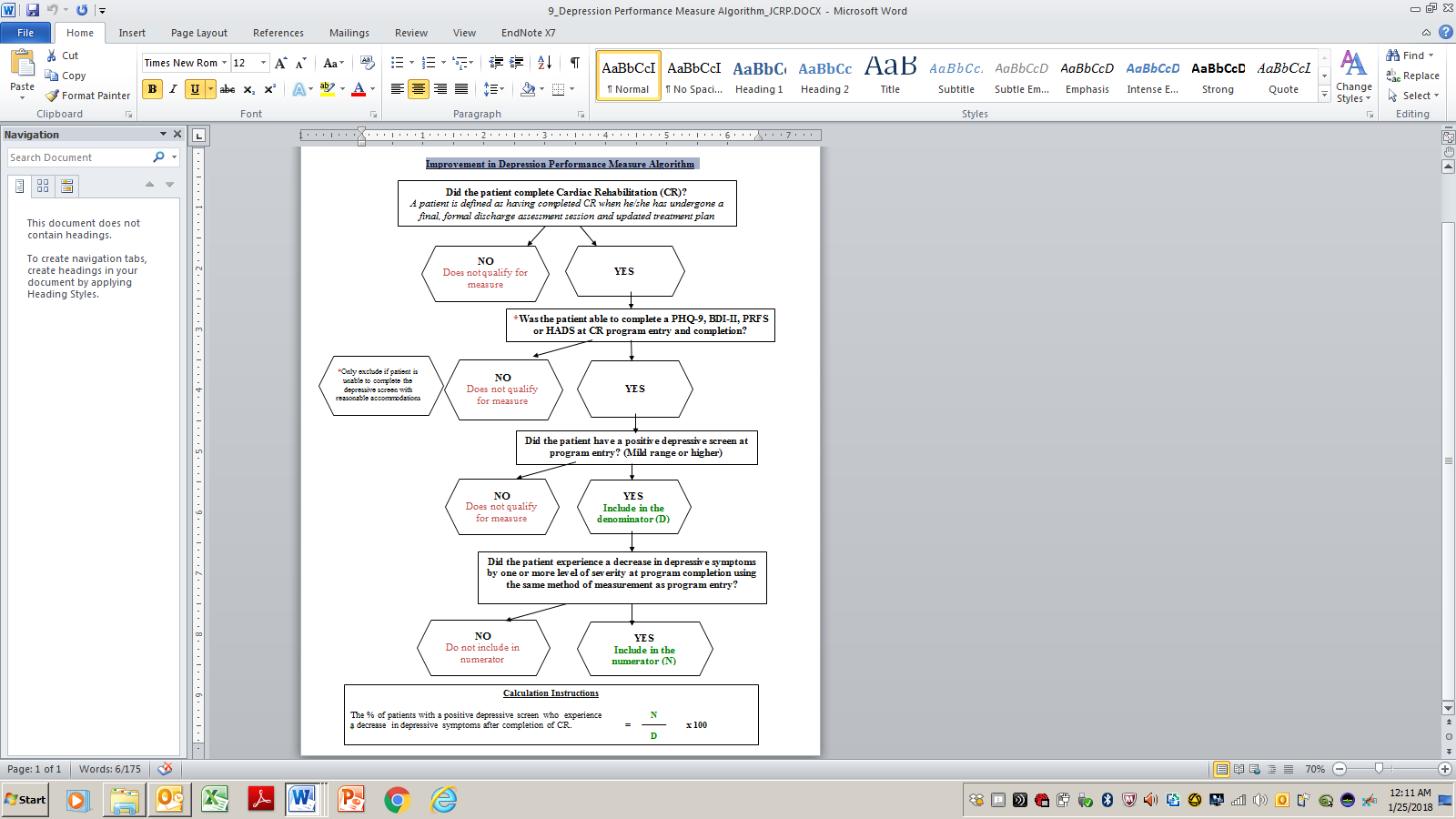
*Patients who initially score below the mild range are excluded from this measure.*

**Depression is a difficult area of our patients’ lives for cardiac rehab professionals to influence. Traditionally, we have sought primarily to notify the referring physician of psychosocial concerns and it is not always predictable whether this area is addressed between the patient and physician. Most programs do not have and/or cannot afford psychosocial providers.**

*Depression is a difficult area for CR professionals to address with the patients and for the patients themselves. It remains important to ensure communication occurs with the referring physician regarding our patients’ psychosocial concerns. However, many programs likely have more psychosocial resources available to them than is immediately recognized and these resources are generally affordable utilizing the CPT 93797 billing code. This code was approved by CMS to allow for individualized care of our patients with activities other than ECG monitored exercise, including psychosocial consultations and psychosocial classes.*

*Additionally, it would be very helpful for staff to be competent in discussing depression’s impact on morbidity and mortality and have at least 1 staff member or consultant proficient in motivational interviewing to assist in helping the patient address this behavior change of addressing psychosocial treatment.*

**Improvement in Depression Performance Measure Algorithm**



# TOBACCO USE INTERVENTION PERFORMANCE MEASURE FOR CR

**MEASURE DESCRIPTION**

Percent of patients participating in the CR program who received a tobacco cessation interventiona if identified as a tobacco userb OR received a relapse prevention interventionc if identified as a recent tobacco user.d

**Definitions**

aTobacco cessation intervention includes any 1 of the following:

1. Tobacco cessation counseling. If the patient is not willing to make a quit attempt, intervention should be aimed at helping the patient improve their readiness for an eventual quit attempt.
2. Tobacco cessation pharmacotherapy. Medication may be provided to patients who are not yet ready to quit, but who are ready to reduce to quit.[1](#_ENREF_1), [2](#_ENREF_2)
3. Referral to a tobacco treatment program or specialist.

bCurrent tobacco use is defined as use of any kind of tobacco product in the 30 d prior to enrolling in CR. This includes cigarettes, cigars, cigarillos, chew tobacco, and e-cigarettes.[3](#_ENREF_3)

cRelapse prevention intervention includes any 1 of the following:

1. Tobacco relapse prevention counseling.
2. Tobacco cessation pharmacotherapy.
3. Referral to a tobacco treatment program or specialist.

dRecent tobacco use is defined as use of any kind of tobacco product in the 6 mo prior to enrolling in CR. This includes cigarettes, cigars, cigarillos, chew tobacco, and e-cigarettes.[3](#_ENREF_3)

**Numerator**

Patients who received a tobacco cessation interventiona if identified as a current tobacco userb

- OR –

Patients who received a relapse prevention interventionc if identified as a recent tobacco userd

To qualify for the numerator, the tobacco cessation or relapse prevention intervention must be documented in the patient’s outpatient CR record. If a patient had previously received a treatment referral or pharmacotherapy from another clinician (such as the patient’s primary physician or cardiologist), these interventions must be documented in the CR record to quality for this performance measure.

**Denominator**

Number of participants in the CR program during the measurement period who were identified as either a current or recent tobacco user at program entry. This includes all participants in the CR program regardless of length of participation in program (1 or more sessions.)

*Denominator Exclusions*

Documentation of a medical reason for not receiving tobacco cessation intervention or tobacco relapse prevention intervention (eg, limited life expectancy).

**Period of Assessment**

Up to 12 mo.

**Attribution**

CR program staff.

**Sources of Data**

Medical record or another database (eg, administrative, clinical, registry).

**Rationale**

Tobacco use is the single most important cause of preventable death in the United States[4](#_ENREF_4) and smoking cessation after development of CAD or myocardial infarction substantially improves mortality.[5](#_ENREF_5) Although tobacco relapse is common, brief counseling, pharmacotherapy, and tobacco treatment programs significantly increase the chances of long-term abstinence. Patients who relapse after an acute coronary event benefit from additional support.[6](#_ENREF_6) Institutional smoking cessation programs and nurse-led smoking cessation interventions can have a substantial impact.[7](#_ENREF_7), [8](#_ENREF_8)

The 6-mo relapse prevention period assures that all patients who are either current tobacco users or who are at high risk of relapse will be identified and provided support during their time in the CR program. Median time to relapse after an acute coronary event is just 19 d after hospital discharge but continues to occur up until 6 mo.[9](#_ENREF_9)

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**PERFORMANCE MEASURE FOR TOBACCO USE INTERVENTION**

**DATA DEFINITIONS**

**PARTICIPATING IN THE CR PROGRAM**

Attended at least 1 CR session.

**TOBACCO USER**

Defined as use of any kind of tobacco product in the 30 d prior to enrolling in CR regardless of current quit status.

**TOBACCO CESSATION INTERVENTION (REQUIRED IF A TOBACCO USER)**

Documentation in the medical record that the patient received any 1 of the 3 interventions listed in the measure. These include

1. Brief tobacco cessation counseling at program entry. If the patient is not willing to make a quit attempt, intervention should be aimed at helping the patient improve their readiness for an eventual quit attempt.
2. Tobacco cessation pharmacotherapy. Medication may be provided to patients who are not yet ready to quit, but who are ready to reduce to quit.
3. Referral to a tobacco treatment program or specialist.

**RECENT TOBACCO USER**

Defined as use of any kind of tobacco product in the 6 mo prior to enrolling in CR.

**RELAPSE PREVENTION INTERVENTION (REQUIRED IF A RECENT TOBACCO USER)**

Includes any one of the following:

1. Brief tobacco relapse prevention counseling at program entry.
2. Tobacco cessation pharmacotherapy.
3. Referral to a tobacco treatment program or specialist.

**DENOMINATOR EXCLUSIONS**

Documentation of a medical reason for not receiving tobacco cessation intervention or tobacco relapse prevention intervention (eg, limited life expectancy).

**FREQUENTLY ASKED QUESTIONS**

**Why does the definition of “tobacco user” include patients who stopped using tobacco even though it has not yet been 30 d since their last tobacco use? Doesn’t this ignore their current efforts?**

*Although the vast majority of patients are well intentioned, research studies show that the first 30 d of a tobacco cessation attempt are the very highest risk period for relapse with more than 60% of relapse happening within the first 30 d. Accordingly, for this performance measure, patients who used tobacco within the past 30 d are considered as if they are current smokers. While congratulating patients for their efforts is essential and important in building confidence, programs should also counsel their patients to avoid situations where relapse is likely, warn them against the significant possibility of relapse, and aggressively provide all the counseling and /or medications necessary to help them stay quit permanently.*

**Why does the definition of “recent tobacco user” extend all the way to 6 mo? Why are we required to make an intervention in these patients?**

*While relapse is less likely between 31 days and 6 months, relapse during this time frame still occurs with considerable frequency. Accordingly, recent tobacco users should be considered at sizable risk of relapse and treated accordingly. While use of a new medication prescription is less likely to be needed, continued adherence to previously prescribed smoking cessation medications should be encouraged and patients should be counseled to avoid situations that could put themselves at risk of relapse. Clinicians may want to inquire into the timing and intensity of nicotine cravings and help patients develop strategies to avoid relapse.*

**What is the minimal standard to meet the definition of brief tobacco cessation counseling? Is there a certain time required?**

*There is no standard definition or time required of brief tobacco cessation counseling. Instead, it is left to each program and clinician to determine what constitutes an effective intervention, although an effective intervention will probably require a reasonable amount of time. Other guidelines recommend this to be at least 3 min but also require documentation of the time spent doing the counseling. Because it was clear that most CR programs do not document the time spent in tobacco counseling, the performance measure committee did not feel it reasonable to require that programs document the time spend providing this intervention.*

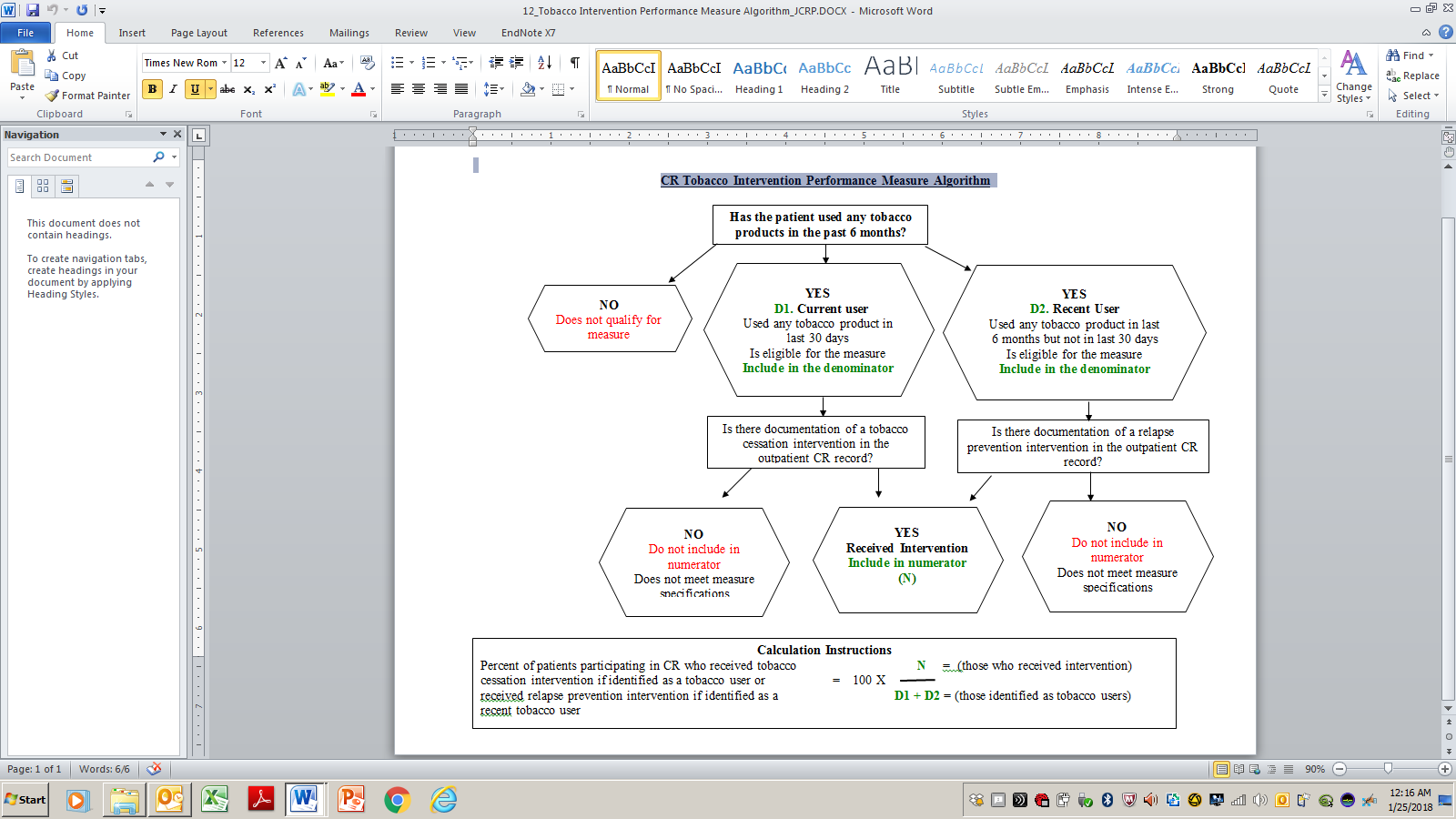
**It appears that this performance measure could be easily gamed, in that programs create automatic templates to assure that “tobacco cessation counseling” is documented, even though there wasn’t an honest attempt to help the patient quit?**

*We agree this is a potential weakness of not having a more prescriptive performance measure, but we trust that programs will do the right thing and make every effort to help their patients permanently quit this very harmful addiction. To do otherwise defeats the purpose of clinical care and CR.*

**Why are e-cigarettes included in the definition of “tobacco use?”**

*Current guidelines from the AHA recommend that e-cigarettes be classified and regulated as all other tobacco products. Additionally, currently there is insufficient scientific evidence to suggest that e-cigarettes are useful as a smoking cessation aid and so their use is strongly discouraged.*

**CR Tobacco Intervention Performance Measure Algorithm**



# PERFORMANCE MEASURE FOR IMPROVEMENT IN DYSPNEA AT COMPLETION OF PR

**MEASURE DESCRIPTION**

The percentage of patients with a primary diagnosis of COPD or interstitial lung disease (ILD), regardless of other diagnoses, who are found to improve their global perception of dyspnea by the MCID, as measured by a valid and reliable instrument after participating in PR.

**Definitions**

**Assessment of Dyspnea:**

* Should be performed within one week of PR program entry and again within 1wk of PR program completion.
* Is conducted using the (mMRC, USCD SOBQ or the BDI/TDI
* Will include impact based on the change in score. The MCID for the specific tool will be used as the unit of measure.

**Examples of Reasonable Accommodations:**

* Read instrument instructions and questions to patient
* Fill in instrument answers as directed by the patient

**Recommended Disease-Specific Instruments:**

* *mMRC*

The mMRC is a single question instrument where the patient selects a grade on a 5-point scale (rating 0-4, with higher grade indicating more dyspnea) that describes everyday situations or activity levels provoking breathlessness (dyspnea) and impairment.1 The scale requires recall. The mMRC has been widely used to describe cohorts and stratify interventions including PR in COPD. It has been used for more than 50 y. The mMRC is the only dyspnea instrument identified in the GOLD guidelines.2 Drawbacks of the mMRC include lack of precise limits leading to potential for low sensitivity to change from interventions3 and relatively scarce data on validation, responsiveness, and sensitivity.4 The mMRC is in the public domain. **The MCID is 1 unit.** This 1-unit change indicates a change in disability.5

* *UCSD SOBQ*

The UCSD SOBQ is a 24-item instrument which assesses the occurrence of shortness of breath on a 6-point scale during 21 ADLs associated with varying levels of exertion. If the activity is not performed, the patient estimates the rating.6 The score ranges from 0 to 120; a higher score is associated with greater dyspnea performing ADLs. The questionnaire is easily administered. It has been shown to be sensitive to various interventions. High level of reliability and validity have been reported.7 Swigris and colleagues reported validity for the UCSD SOBQ in ILD patients to measure dyspnea over time.8 The UCSD SOBQ is copyrighted by UCSD and is currently free (with permission and acknowledgement) for education and research purposes by nonprofit organizations. *For commercial use or for-profit use, UCSD requires an agreement and charges a negotiable fee.* **The MCID is reported to be 5 points.**9

* *BDI/TDI*

Both the BDI and TDI are 24-item instruments that are interviewer administered. The BDI rates severity of dyspnea at single point in time. The TDI assesses changes from baseline dyspnea.10 The BDI scale rates dyspnea on a 5-point scale: 0 = severe, to 4 = un-impaired. The BDI range is 1-12. The TDI uses 7-point scale from -3 (major deterioration) to + 3 (major improvement). The tool has baseline and transition dyspnea ratings. The scale rates according to functional impairment, magnitude of the task and the magnitude of effort.10 BDI significantly correlates with the DD score and SGRQ symptom and activity components. TDI also with changes in DD, SGRQ symptom and activity scores. Construct validity is established by the association between baseline FEV1 and BDI, and ΔFEV1 with the TDI.11 The tool requires permission. Users are required to complete and sign a user agreement. A fee may be incurred depending on context of use. **The MCID of 1 unit has been reported (assessed relative to physician’s global evaluation).**11

**Numerator**

Number of patients with a primary, clinician diagnosed, COPD or ILD, regardless of other diagnoses, who have participated in PR and have been found to improve their dyspnea score by the MCID (AACVPR PR Outcomes Toolkit) as measured by the mMRC (1 unit), the USCD SOBQ (5 points), or the BDI/TDI (1 unit) from the beginning to the end of PR.

**Denominator**

All patients with a primary, clinician diagnosis of COPD or ILD, regardless of other diagnoses, who are able to complete a mMRC, UCSD SOBQ, or BDI/TDI to assess dyspnea at PR program entry and PR program completion, who have completed at least 10 PR sessions within a 3-mo period. However, the PR program can run longer than 3 mo.

*Denominator Exclusions*

* *Inability to complete the dyspnea instruments with reasonable accommodations*
* *Presence of comprehension limitation that precludes completion of the instrument*
* *Lack of availability of the tool used by the PR program in a language understood by the patient*

**Period of Assessment**

Up to 12 mo.

**Attribution**

PR program staff.

**Sources of Data**

Medical record or another database (eg, administrative, clinical, registry).

**RATIONALE**

Dyspnea is the primary disabling symptom of chronic lung disease - and the most common. It is the cardinal symptom when a diagnosis of COPD or ILD is made. A complex phenomenon that varies from person to person, this unpleasant, persistent labored breathing is triggered by increased ventilation secondary to increased work of breathing. However, dyspnea is more than just a physiologic phenomenon. It also has psycho-physiologic components, triggered by such factors as anxiety and fear. Dyspnea is an important and relevant outcome measure in patients with COPD and ILD. Multiple instruments have been described to measure a patient’s global level of dyspnea, with established validity and reliability. According to the ACCP/AACVPR evidence-based guidelines, pulmonary rehabilitation has been shown to improve dyspnea with a recommendation level 1, strength of evidence A (highest possible rating in the ACCP rating system). Two Cochrane systematic reviews demonstrate that PR improves dyspnea symptoms in patients with COPD and ILD. The GOLD guidelines recommend that PR be a part of the treatment plan for patients with moderate to severe COPD.

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15. 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.

**PERFORMANCE MEASURE FOR IMPROVEMENT IN DYSPNEA**

**DATA DEFINITIONS**

**TOOLS USED TO MEASURE DYSPNEA**

These are well defined in the measure specifications and only include valid/reliable tools. This measure stipulates the mMRC survey, the UCSD SOBQ, and the BDI/TDI, as the tools for the measure. Assessment should be completed within 1 wk of both PR program entry and PR program completion.

**COMPLETION OF PR**

This measure defines participation in PR as completing at least 10 PR sessions within a 3-mo period. Patients who do not attend at least 10 PR sessions within a 3-mo period are not considered to have completed the PR program. However, the PR program can run longer than 3 mo.

**DENOMINATOR EXCLUSIONS**

* Inability to complete the dyspnea screening instrument with reasonable accommodations
* Patient refusal to complete the intake and/or discharge dyspnea screening instrument

**MCID**

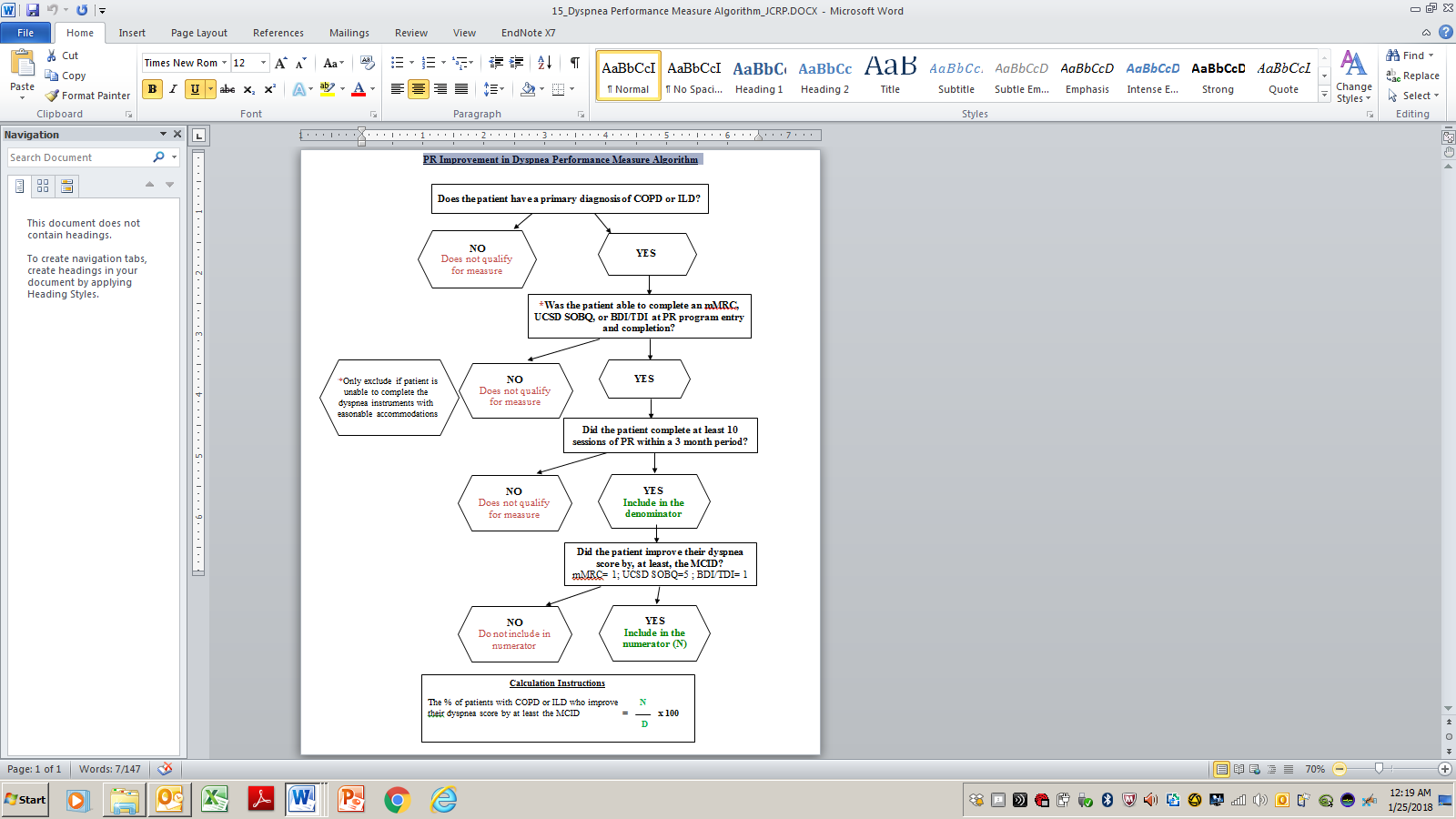
The MCID is the change in score that has been correlated with a meaningful change in patient outcome. According to Jaeschke et al,1 the first to define the MCID, it is “the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management.” (p. 408).

1. Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. *Control Clin Trials*. 1989:10(4):407-415.

**FREQUENTLY ASKED QUESTIONS**

*This performance measure focuses on the perception and impact of dyspnea across activities of daily living. This measure does not focus on dyspnea rating at a specific point in time or during a specific activity, but is rather a global measure of dyspnea. The Borg CR-10 (the Dr. Borg-approved tool) does not address the focus of this measure. However, the clinical utility of use of symptom rating scales remains an important clinical tool.*

*The mMRC is a single question instrument. It has been shown to be valid and reliable. This tool is in the public domain and free to use.*

**PR Improvement in Dyspnea Performance Measure Algorithm**

**PERFORMANCE MEASURE FOR IMPROVEMENT IN HRQoL AT COMPLETION OF PR**

**Measure Description**

The percentage of patients with a primary diagnosis of COPD or interstitial lung disease (ILD), regardless of other diagnoses, who are found to increase their HRQoL score as measured by a valid and reliable instrument after participating in PR.

**Definitions**

Assessment of HRQoL:

* Should be performed within 1 wk of PR program entry and again within one week of PR program completion.
* Is conducted using a valid and reliable instrument such as the CRQ, the SGRQ, or the CAT.
* Will include impact based on the change in score. The MCID for the specific tool will be used as the unit of measure.
* Additional information is available in the AACVPR PR Outcomes Resource Guide/Toolkit (2016).

Examples of Reasonable Accommodations:

* Read instrument instructions and questions to patient.
* Fill in instrument answers as directed by the patient.

Recommended Disease-Specific Instruments:

* *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 CRQ3, a self-report CRQ4 and a standardized CRQ self-report.5 The patient is asked to recall the 5 most important activities that caused breathlessness over past 2 wk. 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). 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.

* *SGRQ*

The SGRQ was developed to measure health status in patients with respiratory disease, eg, 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 recently, 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 poorer health. 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 version8 and IPF-specific version10 are available. Results may be influenced by sex, age, education, and co-morbidities of patients.12 There is significant correlation be-tween SGRQ and FEV1, FVC, resting SaO2, 6MWT distance, 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

* *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.14-16 The CAT has been initially validated in prospective studies conducted in the United States 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 PR.19 Available at: <http://www.catestonline.org/images/pdfs/CATest.pdf> . **While Nagata and colleagues17 note that the MCID is to be determined, others have reported 2 points as a reliable estimate.20,21**

**Numerator**

Number of with a primary, clinician diagnosed, COPD or ILD, regardless of other diagnoses, who have participated in PR and have been found to improve their HRQoL score by the MCID (AACVPR PR Outcomes Toolkit) as measured by the: CRQ (0.5 units); SGRQ (4 units); the CAT (2 units) at the beginning and the end of PR.

**Denominator**

All patients with a primary, clinician diagnosis of COPD or ILD, regardless of other diagnoses, who are able to complete a CRQ, SGRQ, or CAT to assess HRQoL at PR program entry and PR program completion, and who have completed at least 10 PR sessions within a 3 month period. Note that the PR Program may be longer than 3 mo.

*Denominator Exclusions*

* *Inability to complete the dyspnea instruments with reasonable accommodations*
* *Presence of comprehension limitation that precludes completion of the instrument*
* *Lack of availability of the tool used by the PR program in a language understood by the patient*

**Period of Assessment**

Up to 12 mo.

**Attribution**

PR program staff.

**Sources of Data**

Medical record or another database (eg, administrative, clinical, registry).

**Rationale**

HRQoL 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.22 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 HRQoL with a recommendation level 1, strength of evidence A (highest possible rating in the ACCP rating system.23 McCarthy and colleagues report in the updated Cochrane systematic review that significant improvement was noted in 4 important domains for quality of life.24 Effects were found to be larger than the MCID for both the CRQ and SGRQ.24 A new Cochrane Systematic Review also supports PR positive impact on HRQOL in ILD.25 The GOLD guidelines26 recommend that pulmonary rehabilitation be a part of the treatment plan for patients with moderate to severe COPD. Recent Cochrane systematic reviews also report that exercise therapy improves HRQOL in ILD25 and non-malignant dust-related diseases that fall under the ILD umbrella.27

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# PERFORMANCE MEASURE FOR IMPROVEMENT IN HEALTH-RELATED QUALITY OF LIFE AT COMPLETION OF PR

**DATA DEFINITIONS**

**TOOLS USED TO MEASURE HRQOL**

These are well defined in the measure specifications and only include valid/reliable tools. This measure stipulates the CRQ, the SGRQ and the CAT as the tools for the measure. Assessment should be completed within 1 wk of PR program entry and within 1 wk of PR program completion.

**COMPLETION OF PR**

This measure defines participation in PR as completing at least 10 PR sessions within a 3-mo period. Patients who do not attend at least 10 PR sessions within a 3-mo period are not considered to have completed the PR program. However, the PR program can run longer than 3 mo.

**DENOMINATOR EXCLUSIONS**

* Inability to complete the HRQoL screening instrument with reasonable accommodations
* Patient refusal to complete the intake and/or discharge dyspnea screening instrument

**MINIMUM CLINICAL IMPORTANT DIFFERENCE (MCID)**

The minimum change in score that has been correlated with a meaningful change in patient outcome. According to Jaeschke et al1, the first to define the MCID, it is “the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management.” (p. 408).

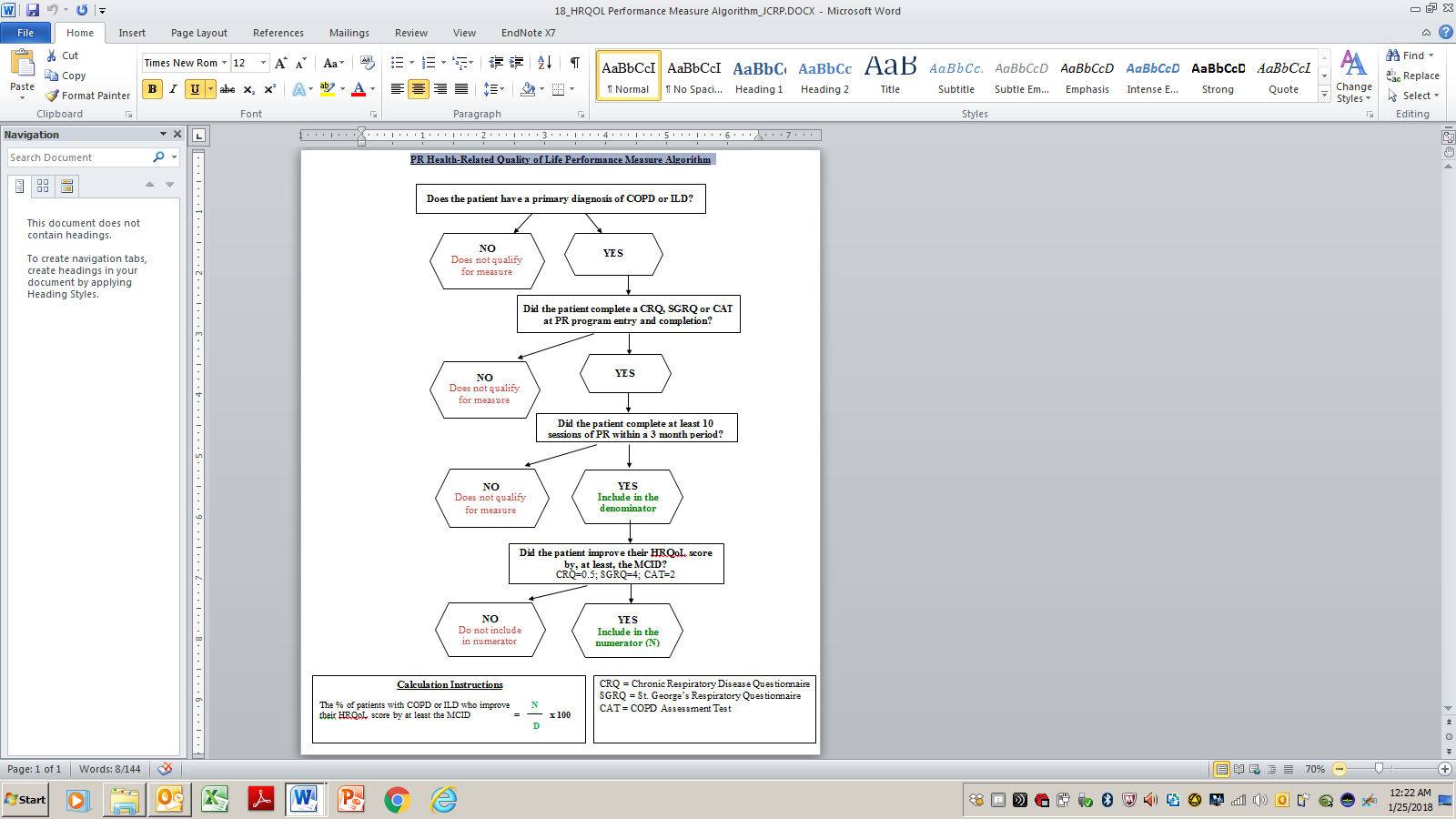
1. Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. *Control Clin Trials*. 1989:10(4):407-415.

**FREQUENTLY ASKED QUESTIONS**

*This performance measure focuses on the perception of health-related quality of life.*

*The COPD Assessment Test (CAT) is an 8-item instrument that provides a single global score. It has been shown to be valid and reliable for both patients with COPD and interstitial lung disease (ILD). This tool is in the public domain and free to use. The US copyrighted version is available through the COPD Foundation site (*[*http://www.copdfoundation.org/*](http://www.copdfoundation.org/)*): (Please register for free access then click at the top of the page on “Learn More”* *→ Educational Materials → Download Library → COPD Assessment Test (CAT) Questionnaire and COPD Assessment Test (CAT) HCP User Guide*

**PR Health-Related Quality of Life Performance Measure Algorithm**



**PERFORMANCE MEASURE FOR IMPROVEMENT IN FUNCTIONAL CAPACITY AT COMPLETION OF PR**

**Measure Description**

The percentage of patients with COPD or Interstitial Lung Disease (ILD) who are found to increase their functional capacity by 30 m. According to the recent ATS/ERS field test statement, the minimal important difference (MID) for the 6MWT in adults with chronic respiratory disease is between 25 and 33 m with a median value across trials of 30 m (98.43 ft), as measured by a standardized 6MWT after participating in PR.

**Definitions**

Assessment of functional capacity during PR using the 6MWT.

* + - Assessments of 6MWT are to be performed within 1 week of PR program entry and again within 1 wk of PR program completion.
    - Follow the procedures described in the ATS/ERS field test statement.1,2
    - To perform the 6MWT the patient is instructed to walk as far as possible in 6 min. They can stop and rest during the test, and resume walking as soon as able. All variables are held constant during the test consistent with the ATS/ERS statement.1,2 The total distance covered in 6 min is measured (in m or ft). All patients who increase the distance walked by at least 30 m (98.43 ft), as measured by the 6MWT performed at PR entry and again at PR completion, should be included in the numerator.
    - Additional information is available in the AACVPR PR Outcomes Resource Guide/Toolkit (2017).

**Numerator**

Number of patients who are found to increase their functional capacity by at least 30 m (98.43 ft), as measured by 6MWT distance at PR program entry and completion.

**Denominator**

All patients with clinician diagnosed COPD or ILD at PR program entry who completed PR during the measurement period and who completed at least 10 PR sessions within 3 mo of PR program entry. However, the PR program can run longer than 3 mo.

*Denominator Exclusions*

* Patients for whom a 6MWT would be contraindicated due to acute or unstable medical conditions (see detailed list in reference 3 for a complete list).
* Patients who are unable to perform a 6MWT due to orthopedic, neurological, cognitive or psychiatric impairments and/or safety reasons.
* Patients who have not completed at least 10 PR sessions within 3 mo of program entry
* Patients with diagnosed pulmonary vascular disease (ie, pulmonary hypertension) or other primary lung disease process (ie, lung cancer).

**Period of Assessment**

Up to 12 mo.

**Attribution**

PR program staff.

**Sources of Data**

Medical record or another database (eg, administrative, clinical, registry).

**RATIONALE**

The 6MWT is a low-cost, reliable, accurate method to assess exercise capacity and response to treatment in persons with chronic lung disease. The test measures the distance walked on a 30-meter (98.43 ft) corridor or track in 6 min. The test is valid in chronic lung disease, including COPD and ILD.1,2 It measures functional capacity in chronic lung disease.

Patients are asked to walk as far as possible in 6 min along a flat corridor.2 Dyspnea and subjective fatigue are measured before and after the 6MWT using validated measurement scales, such as the Borg C-R dyspnea scale.3 The distance walked is inversely related to risk of hospitalization in chronic respiratory disease

The GOLD guidelines recommend that pulmonary rehabilitation be a part of the treatment plan for patients with moderate to severe COPD.4 Pulmonary rehabilitation improves several patient-centered outcomes, including quality of life, dyspnea, and functional capacity.5-9 In the updated Cochrane systematic review, improvement in functional capacity following pulmonary rehabilitation, as measured by increased 6-min walk distance of 48 m (95% CI, 32 - 65; n = 16) trials was reported.10 Cochrane Systematic Reviews also support PR in ILD and non-malignant dust-related lung diseases for improving patient-centered outcomes including quality of life, dyspnea, and functional capacity.11,12 In 2002, the ATS published guidelines for conducting 6MWT.4 Enright and Sherrill first reported reference equations for prediction of total distance walked in 6 minutes by healthy adults, providing predictive reference for the 6MWT.13 A recent review by Singh et al.14 reported the 6MWT is reliable (intra-class correlation coefficients ranged from 0.82 to 0.99 in 7 studies). They also reported that the 6MWT has stronger correlations with peak work capacity (r = 0.59-0.93) and physical activity (r = 0.40-0.85) compared to respiratory function (r = 0.10-0.59). The authors also reported that responsiveness was moderate to high for the 6MWT distance, with greater responsiveness to interventions that included exercise training. This review demonstrates the strength of the 6MWT as a test of functional capacity in persons with chronic lung disease.14 This performance measure allows pulmonary rehabilitation programs to assess the impact of interventions on a clinically meaningful assessment of functional capacity.

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**PERFORMANCE MEASURE FOR IMPROVEMENT IN FUNCTIONAL CAPACITY AT COMPLETION OF PR**

**DATA DEFINITIONS**

**6MWT**

The test is a self-paced test of walking capacity with the distance walked as the primary test outcome. The 6MWT assesses exercise capacity and response to treatment in persons with chronic lung disease. The ATS/ERS field test statement provides more detailed guidelines.1,2

**BEGINNING OF THE PR PROGRAM**

Refers to functional capacity as measured by a 6MWT completed within the first week of the PR program.

**COMPLETION OF THE PR PROGRAM**

Refers to functional capacity as measured by a 6MWT completed during the last week of the PR program. The patient will complete at least 10 PR sessions within a 3-mo period to be included in the functional capacity measure. However, the PR program can run longer than 3 mo.

**DENOMINATOR EXCLUSIONS**

Patients unable to participate in a 6MWT due to physical, cognitive, neurological, psychological, or safety reasons. Patient completing less than 10 PR sessions within a 3-month period.

**MINIMUM CLINICAL IMPORTANT DIFFERENCE (MCID)**

The minimum change in score that has been correlated with a meaningful change in patient outcome. According to Jaeschke et al,1 the first to define the MCID, it is “the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management.” (p. 408). The mean MCID for the 6MWT is estimated at 30 m.

1. Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. *Control Clin Trials*. 1989:10(4):407-415.

**FREQUENTLY ASKED QUESTIONS**

*The test is associated with considerable learning effect. Therefore, 2 tests should be performed with the greatest distance of the 2 tests reported. All variables should be held constant for initial and repeat tests, including test location, track layout, staffing, time of day, oxygen (flow rate, system, and transport), medications, use of usual walking aides, encouragement, and indications for test cessation.*

* *The test has excellent safety when conducted according to standard protocols, including test cessation if the SpO2 is <80%. Contraindications and precautions are the same as CPET.1*
* *Testing should always follow the ATS/ERS 6MWT protocol, including patient instruction, scripts, standardized encouragement, use of validated dyspnea scale, and reason for stopping the test.2*
* *SpO2 and heart rate are measured continuously during testing to ensure SpO2 nadir and the end of test HR are observed and documented.*
* *SpO2 measurements during 6MWT are reliable provided that an adequate pulse signal is obtained.3*

*Dyspnea and subjective fatigue are measured before and after the 6MWT using validated measurement scales, such as the Borg 10-point C-R scale.*

*The 6MWT report should include the distance walked, number of stops, total time stopped, SpO2 nadir, and end of test pulse rate.*

*Public domain; no license agreement is required.*

1. American Thoracic Society/American College of Chest Physicians. ATS/ACCP statement on cardiopulmonary exercise testing. *Am J Respir Crit Care Med*. 2003:211-277.
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**PR Functional Capacity Performance Measure Algorithm**

