Protocol #: HIIN-COPD

TITLE: A CLUSTER RANDOMIZED, STEPPED-WEDGE EVALUATION OF POST DISCHARGE UTILIZATION AMONG PATIENTS WITH AN ACUTE EXACERBATION OF COPD

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The study will be conducted in compliance with the protocol, ICH-GCP and any applicable regulatory requirements.

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Protocol Approved By:

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Daniel Howard, MD

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Date

PROTOCOL SUMMARY	
Study Title	***HIIN – COPD:*** *A Cluster Randomized, Stepped-Wedge Evaluation of Post Discharge Utilization among Patients with an Acute Exacerbation of COPD*
Study Design	A cluster randomized, stepped-wedge quality improvement evaluation
Study Objectives	The primary objective is to evaluate the effectiveness of using a COPD clinical pathway compared to usual care among patients with an acute COPD exacerbation, on 60-day post discharge utilization (ED, inpatient, and observation encounters) The secondary objectives are to examine the COPD clinical pathway's effect on additional patient outcomes, such as the a. CHS Quality, Comfort, and Care 30-day readmission rate. This is a readmission rate among patients with an inpatient readmission to the same CHS facility as the index encounter. b. The patient-centric 30-day readmission rate. This is a readmission rate among patients with an inpatient or observation readmission to any CHS facility. c. The patient-centric 30-day readmission rate where the primary diagnosis of the readmission is COPD. d. Length of stay e. Rate of follow-up visit within 5 days of discharge. f. Antibiotic order rate during admission g. Steroid order rate during admission h. Short acting bronchodilator order rate during admission Additional analyses will be to explore: a. The methodology for identification of COPD exacerbation within the first 24 hours of hospital admission will be compared to retrospective identification through billing codes. b. As a sub-analysis, qualitative outcomes will be collected and measured with patients, providers, and leaders. These outcomes will be collected and evaluated, per a sub-study protocol addendum.
Study Population	Patients 40 years of age or older hospitalized with an acute exacerbation of COPD are included. An acute exacerbation is defined as an encounter where the following criteria are met within 24 hours of admission. • The use of the COPD PowerPlan **or** • A respiratory therapy navigator notification of COPD exacerbation **or** • The use of the respiratory therapy department COPD bronchodilator protocol **or**

	• A historical diagnosis of COPD **or** A history of COPD in the admitting documentation **or** A COPD diagnosis on the problem list **AND** An order of systemic steroids (prednisone or methylprednisolone) For the purposes of this project, the evaluable population will include patients who meet the same age criteria and have a discharge diagnosis of acute exacerbation of COPD
Study Procedures	During this project, patients who are hospitalized at select CHS sites with COPD acute exacerbation symptoms will be treated per the CHS COPD clinical pathway (COPD Pathway). The COPD clinical pathway will include four components: (i) discrete, evidence-based care steps (ii) patient navigation, (iii) daily data driven care gap identification, (iv) monthly leadership huddles. The evidence based care steps include: (1) verification of COPD diagnosis and severity, (2) patient/caregiver education regarding COPD and basic self-management skills, (3) standard pharmacologic bundle of systemic steroids, empiric antibiotics, bronchodilators, (4) pneumococcal and influenza vaccination review and completion, (5) smoking cessation advice and therapy when appropriate, (6) comprehensive care management assessment, (7) recommendations for pulmonary consultation, (8) recommendations for palliative care consultation, (9) use of discharge checklist, (10) recommendations for content of outpatient follow-up, and will be driven primarily by provider utilization of a comprehensive order-set that includes each component and a discharge checklist. Patient navigation will be provided by the COPD Pathway Coordinator (COPD Coordinator) at each site. This role will be filled by an individual (s) who already exists on a site's care team. Because of this, the COPD Coordinator's site role and background may vary by site. The COPD Coordinators will be responsible for daily monitoring of care gaps that exist for COPD patients and their respective sites and alerting appropriate team member to help close those gaps. The COPD Coordinators will receive a daily COPD Gaps list. The COPD Gaps list identifies patients who are hospitalized at that time and the associated gaps in receiving the evidence based care components. The intervention occurs at the site level and sites are randomized to the order they will receive the intervention in clusters of two. Two additional facilities will be added on a rolling basis in 2 month intervals, until all 8 facilities are active in using the COPD pathway. Once added, sites will begin utilizing the COPD Pathway in their daily practice. As a part of the COPD clinical pathway, patients will meet the following discharge checklist criteria: • On a long acting bronchodilator for 24 hours • A short acting bronchodilator is scheduled no more frequently than 4 times daily for 24 hours

	• Be off IV steroids for 24 hours prior to discharge • A steroid prescription, or have completed a 5-day course while admitted • An antibiotic prescribed or have completed a 5-day course while admitted • A scheduled appointment with a care provider within 5 days of discharge • Received COPD education during discharge
Statistical Analysis	Analyses is among patients identified as having an acute exacerbation of COPD based on final billed coding. Comparisons of patients hospitalized during the intervention and usual care periods will be made using generalized estimating equations to control for clustering within hospital and repeated measures within hospital. The primary outcome, 60-day utilization, will be compared between the two groups of patients using a logit link in the generalized estimating equations. Results will be presented with odds ratios and 95% confidence intervals.
Sample Size Analysis	8 hospitals will be randomized to intervention in 2 facilities per 2 month increments. With the assumption of detecting a change in rates of 60-day non-elective acute care utilization from 43% in the control period to 33% in the intervention period, 59 patients with COPD exacerbation per hospital per two months is needed to achieve a power of 0.80 (intra-class correlation coefficients (ICC)=0.05 and two-side α=0.05. To account for this varying cluster size, we inflated the number of patients by 25% resulting in an average of 74 patients per hospital per two months, resulting in a total sample size of 2960 patients among the intervention group.

LIST OF ABBREVIATIONS

AE	Adverse Event or Acute Exacerbation
CHS	Carolinas Healthcare System
COPD	Chronic Obstructive Pulmonary Disease
EHR	Electronic Health Record
ED	Emergency Department
PHI	Private Health Information
PI	Principal Investigator
qid	4 times per day

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1. OBJECTIVES

1.1. Hypothesis

Patients with an acute COPD exacerbation, who receive care at a site using the COPD clinical pathway, will have lower 60-day post discharge utilization than patients that receive usual care.

1.2. Primary Objective

The primary objective is to evaluate the effectiveness of the use of the COPD clinical pathway compared to usual care, on 60-day post discharge utilization (ED, inpatient, observation encounters) among patients with an acute COPD exacerbation.

1.3. Secondary Objectives

a. The secondary objectives are to examine the COPD clinical pathway's effect on additional patient outcomes, such as the
    i. CHS Quality, Comfort, and Care 30-day readmission rate. This is a readmission rate among patients with an inpatient readmission to the same CHS facility as the index encounter.
    ii. The patient-centric 30-day readmission rate. This is a readmission rate among patients with an inpatient or observation readmission to any CHS facility.
b. The methodology for identification of COPD exacerbation within the first 24 hours of hospital admission will be compared to retrospective identification through billing codes.
c. Demographics and comorbid conditions will be characterized among the historical population of patients at CHS with COPD exacerbation.

2. BACKGROUND

Chronic Obstructive Pulmonary Disease (COPD) is a disease characterized by persistent respiratory symptoms, incompletely reversible expiratory airflow obstruction, intermittent episodes of acute airway and alveolar inflammation termed exacerbations. COPD is hallmarked with periods of symptom stability, and periodic acute deteriorations of the patient's disease condition, called exacerbations. Acute COPD exacerbations frequently lead to ED utilization and/or hospitalization in acute care facilities[1]. Reported COPD costs in the U.S. have reached approximately $37 billion annually, with hospitalizations accounting for most the estimated costs, and are only expected to continue rising. Prior to implementation of the CMS Hospital Readmission Reduction Program, approximately 20% of patients admitted to a hospital for AECOPD were readmitted (all cause) within 30 days. Other types of acute care utilization following hospital admission (ED visits, Urgent Care encounters, hospital observation stays have not been studied[2]. Less stringent definitions of care utilization including readmission and ED and/or Urgent Care encounters further than 30 days out, can safely be assumed to be even worse.

With the advent of value based care, and the rise of bundled payments for a single episode or cycle of care, it has become increasingly important to devise innovative care delivery systems and pathways that will both treat patients effectively in the acute setting and prevent readmissions. Further haste driving

innovation and work in this disease state, has been Medicare's identification of COPD as a target for the Hospital Readmission Reduction Program. This program penalizes hospitals for 30-day readmissions among patients for specific index encounters, such as those with COPD[3].

Development and implementation of new acute COPD care models will cost significant investment of time and capital. Such investment and the need to have a valid assessment of benefit, necessitate strategic, a priori evaluation planning and execution prior to widespread implementation.

Healthcare systems are increasingly adopting disease specific Clinical Pathways (CPW's). These pathways are structured, multidisciplinary care plans, often inclusive of order sets, that detail necessary care steps for patients with a specific disease. Despite being present since the 1980's and fairly ubiquitous in many hospitals since the early 2000's, they have a limited evidence base. A 2011 Cochrane review could not draw conclusions on their effects on length of stay and cost, due to variability in study designs. However, review of the resulting data did show reduced hospital complications (OR 0.58; 95% CI 0.36-0.94). Another review showed that a 3-month integrated disease management intervention (multidisciplinary, multi-faceted care) among inpatients was beneficial with 15 patients needing to be treated to eliminate 1 respiratory related hospital admission[4-7]. Particularly in the transition to value based care models, there remains an obligation for further research to prove effectiveness and cost efficacy for care pathways.

There have been ongoing efforts to define the COPD population based on biologic factors, clinical characteristics, and social determinants of health to help identify patients at risk for exacerbations, hospital admission, hospital readmission, and mortality. Some factors associated with increased risk of hospital readmission include congestive heart failure, behavioral health issues, medical frailty, increasing age, and (simply) prior admission for a COPD exacerbation[3,8]. Predictive models and scoring systems have been devised, most commonly using dyspnea scores, measurements of expiratory airflow limitation, previous hospitalizations, age, and chronic comorbidities; however, use of these tools has not been proven to reduce acute healthcare utilization. Attempts at care pathways for delivery of standardized intervention for acute COPD exacerbations and complex care interventions for patients with COPD have produced equivocal results and there is lack of consensus as to whether such clinical care pathways convincingly improve overall patient outcomes.

Even as improvements are made in terms of the understanding of the COPD population, and risk factors for readmission, the optimal method to reduce utilization remains questionable. Attempts at care pathways nationwide, and other interventions for COPD patients have been undertaken with mixed reports of success. The state of research is best summarized by noting that, while several intermediate or process-oriented outcomes (such as patient self-report of ability to manage symptoms or number of follow-up phone calls made to patients) have been impacted by efforts to improve coordination of care, studies to date have yet to convincingly illustrate an improvement in utilization rates after any such intervention[9-11].

3. RATIONALE

To better enhance the care of patients with an acute exacerbation of COPD, Carolinas HealthCare System (CHS) has designed a COPD clinical pathway, a structured multidisciplinary care plan. The care plan utilizes a data system that identifies patients with exacerbation and care gaps in real-time. It includes an EMR based order set, patient education, and discharge criteria. A COPD pathway coordinator who works to close care gaps and ensure a standardized approach is also part of the care plan.

At participating CHS hospital, patients who are admitted with a suspected acute COPD exacerbation, will enter the COPD clinical pathway. The COPD clinical pathway includes the following key components during hospitalization: and an order within 24 hours of being admitted of a short acting bronchodilator, an antibiotic, and a steroid, as well as a standardized discharge plan. A patient's journey through the clinical pathway, ends at discharge. The discharge checklist requires that patients:

- Be on a long acting bronchodilator for 24 hours
- Bo on a short acting bronchodilator is scheduled no more frequently than 4 times daily for 24 hours
- Be off IV steroids for 24 hours prior to discharge
- Have a steroid prescription, or have completed a 5-day course while admitted
- Have an antibiotic prescribed or have completed a 5-day course while admitted
- Have a scheduled appointment with a care provider within 5 days of discharge
- Receive COPD education during discharge

This proposed evaluation is designed to guide CHS strategy and quality improvement for COPD by applying research methodology and data analytics to create valid outcomes. Ultimately, as CHS deploys resource intensive interventions like this, it is important for the system and its patients to know answers to questions such as: Does this process impact readmissions and utilization?

This research project is a pragmatic, randomized quality improvement evaluation which seeks to evaluate the effects of standardizing the use of a COPD clinical pathway across various participating facilities among patients with an acute exacerbation of COPD. The outcomes evaluation of this quality improvement intervention has been designed to integrate into the routine care and minimize frontline staff burden by deploying an evaluation that occurs in a real-world setting with no additional data collection outside of usual care.

4. SUBJECT AND SITE SELECTION

4.1 Accrual

A daily patient list will be generated through an automated process utilizing clinical and patient registration information. The list will indicate patients newly hospitalized (hospitalization within the preceding 24-hour period) with symptoms of suspected acute COPD exacerbation, at any of the eight facilities. The list contains inpatient and observation encounters. The patient list will identify patients at any of the eight facilities throughout the project, not just once the facility has implemented the standardized use of the COPD clinical pathway. For the purposes of this project, we are not enrolling towards a targeted patient accrual. We will enroll patients during a pre-determined data collection period, See Section 6.

4.2 Subjects

An acute exacerbation is defined as an encounter where one the following criteria are met within 24 hours of admission.

- The use of the COPD PowerPlan **or**
- A respiratory therapy navigator notification of COPD exacerbation **or**

- The use of the respiratory therapy department COPD bronchodilator protocol **or**
- A historical diagnosis of COPD **or**
  A history of COPD in the admitting documentation **or**
  A COPD diagnosis on the problem list **AND**
  An order of systemic steroids (prednisone or methylprednisolone)

To identify appropriate records of available clinical data for baseline and historical data collection and analysis, we will provision using the following ICD10 code for COPD: J44.1

4.3 Participating Sites

As part of the research design and rollout of this project, randomization will occur at the site level. CORE has randomized the facility participation order in advance of project kickoff. Site enrollment will begin with two facilities, adding on 2 additional facilities on a rolling basis in 2 month intervals, until all 8 facilities are active in using the COPD pathway. Once added, sites will begin utilizing the COPD clinical pathway in their daily practice with the target patient population.

The following Carolinas Healthcare System sites will be randomized for participation in this project.

- Carolinas HealthCare System Cleveland
- Carolinas HealthCare System Kings Mountain
- Carolinas HealthCare System Lincoln
- Carolinas HealthCare System NorthEast
- Carolinas HealthCare System Pineville
- Carolinas HealthCare System Union
- Carolinas HealthCare System University
- Carolinas Medical Center

4.4 Inclusion\Exclusion Criteria

4.4.1 Inclusion Criteria

Because this is a site-wide intervention, all patients who have a COPD exacerbation, as determined by their clinical care provider will be subject to receiving components of the intervention. Patients will be included in the daily Gap List based on the following criteria:

- $\geq$ 40 years of age at time of admission
- Identified as having an acute exacerbation of COPD within 24 hours of admission

4.4.2 Exclusion Criteria

Subjects must not meet any of the following criteria:

- Death during the index encounter
- Not discharged by the end of the study

4.5 Evaluable Population

Patients included in the evaluable population for this project, will have their data inform the final outcomes assessment. For the purposes of this project, the evaluable population will include patients who meet the same age criteria and have a discharge diagnosis of acute exacerbation of COPD: J44.1

5. OVERALL DESIGN

5.1 Outcome Variables

5.1.1 Primary Outcome Variable

The primary outcome variable is 60-day post discharge utilization (ED, inpatient, and observation encounters).

5.1.2 Secondary Outcome Variable(s)

Secondary outcome variables of the evaluation include:

Examining the COPD clinical pathway's effect on additional patient outcomes, such as the

i. CHS Quality, Comfort, and Care 30-day readmission rate. This is a readmission rate among patients with an inpatient readmission to the same CHS facility as the index encounter.
j. The patient-centric 30-day readmission rate. This is a readmission rate among patients with an inpatient or observation readmission to any CHS facility.
k. The patient-centric 30-day readmission rate where the primary diagnosis of the readmission is COPD.
l. Length of stay
m. Rate of follow-up visit within 5 days of discharge.
n. Antibiotic order rate during admission
o. Steroid order rate during admission
p. Short acting bronchodilator order rate during admission

5.1.3 Additional assessments

The methodology for identification of COPD exacerbation within the first 24 hours of hospital admission will be compared to retrospective identification through billing codes.

As a sub-analysis, qualitative outcomes will be collected and measured with patients, providers, and leaders. These outcomes will be collected and evaluated, per a sub-study protocol addendum.

5.2 Trial Design

5.2.1 Justification for stepped wedge cluster randomized control trial

The primary aim is to assess the effectiveness of a structured multidisciplinary care plans (intervention), compared with standard care (control) on 60-day non-elective acute care utilization (ED visits, observation, and inpatient encounters). The COPD clinical pathway will be delivered at the level of hospital or cluster, thus minimizing contamination and the risk of selection bias, if subjects were randomized at the individual level[12]. Therefore, the unit of randomization and

analysis for this study will be the cluster. Considering logistical constraints and design rigor, the intervention will be rolled out sequentially instead of at the same time. Moreover, substantial and differential cluster-effects may exist because of distinct volume and characteristics of patients in each hospital. Thus, the stepped wedge design is advantageous compared with other alternative designs.

5.2.2 Randomization and allocation

The stepped wedge design implies a baseline period, in which no clusters are exposed to the intervention[12]. Then, at the chosen time interval of two months, two hospitals will be randomized to cross from the control to intervention (**Figure 1**). This process continues until all eight hospitals have crossed over to the intervention. The order of this cross over process will be randomized. We will use block randomization to assign two hospitals at a time to switch from the control to intervention using SAS Enterprise Guide version 6.1. Allocation will be communicated only to hospital senior leadership initially to prevent contamination. Others including providers at the hospital will learn of allocation in the month preceding roll-out. Patients in included hospitals will be blinded to the intervention or control period.

Figure 1. The stepped wedge study design

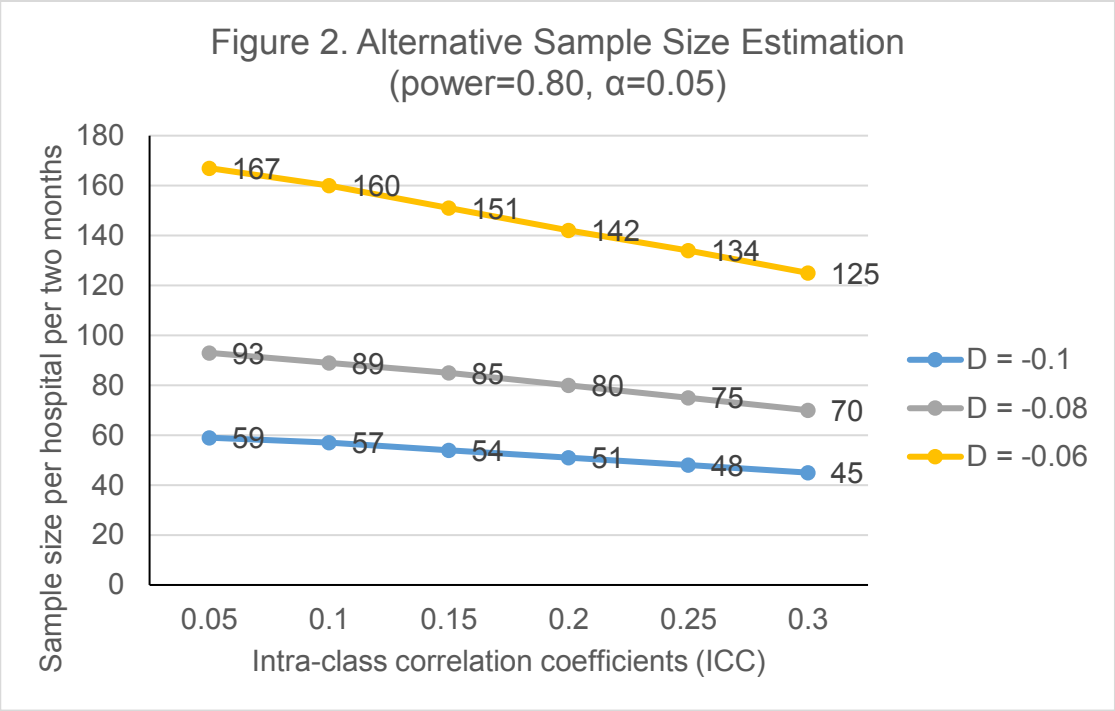
	1-Apr	1-Jun	1-Aug	1-Oct	1-Dec
Cluster 1	0	1	1	1	1
Cluster 2	0	1	1	1	1
Cluster 3	0	0	1	1	1
Cluster 4	0	0	1	1	1
Cluster 5	0	0	0	1	1
Cluster 6	0	0	0	1	1
Cluster 7	0	0	0	0	1
Cluster 8	0	0	0	0	1

0=control
1=intervention

5.2.3 Sample size analysis

Calculations of sample size were based on the primary endpoints of 60-day non-elective acute care utilization. With the assumption of detecting a change in rates of 60-day non-elective acute care utilization from 43% in the control period to 33% in the intervention period, 59 patients with COPD exacerbation per hospital per two months is needed to achieve a power of 0.80 (intra-class correlation coefficients (ICC)=0.05 and two-side α=0.05. Holding other parameters constant, the larger ICC is, the higher the power we will obtain (**Figure 2**). With sample sizes per cluster per two months ranging from 30 to 158, our preliminary data shows that the coefficient of variation (CV) of sample size is approximately 0.5. To account for this varying cluster size, we inflated the number of patients by 25% resulting in an average of 74 patients per hospital per two months[13], resulting in a total sample size of 2960 patients among the intervention group and 5920 patients overall inclusive of our control population. The power was calculated by using the PASS 15[14].

Figure 2. Alternative Sample Size Estimation



5.2.4 Statistical analysis

All data quality monitoring and analysis will be overseen by Dr. Jing Zhao. Distributions of baseline characteristics for hospitals and patients will be compared between the intervention or control periods to assess effectiveness of the randomization, and statistical or clinical differences will be adjusted in sensitivity analyses. All analyses for treatment and control periods comparisons will use an intention-to-treat approach and results will be reported used the CONSORT extension to cluster randomized trials.

5.2.5 Primary aim

The primary outcome for this study is 60-day non-elective acute care utilization. Characteristics of the hospitals and individuals will be summarized by levels of randomization steps, hospitals and individuals. The count, rates and 95% confidence intervals of 60-day non-elective acute care utilization in the -control period will be presented and compared with that in the -treatment period. The primary analysis will be conducted using generalized estimating equations with fixed effects for intervention, time (steps), and intervention multiply by the time, accounting for the cluster randomized trial design with a random cluster (hospitals) effect. We will estimate and report the intra class correlation coefficients for all outcome measures to assess assumptions for sample size analyses and for future investigations using similar designs and outcomes. The primary analyses will follow the intention to treat principle with an additional per protocol analysis including by using denominator in those who had pathway ordered as well as intervention periods when truly occurred. The secondary analyses will include within cluster comparisons of intervention and control periods (not adjusting for any confounding effect of time), as well as comparisons of a series of (unbalanced) quasi-parallel cluster trials between those enrolled and unenrolled clusters at each intervention enrollment period. The same analyses plan will also be applied to secondary outcomes.

5.2.6 Missing data

All the related available electronic data will be pulled without missing any subjects. Thus, the missing of outcome variables are less likely to occur. However, the missing information on covariables is unavoidable. Sensitivity analyses are recommended for trials with missing data. We will compare baseline characteristics such as age, gender, and health insurance status between patients with complete follow-up data to those with missing data by intervention period to assess potential biases that may exist in the complete case analysis. We will conduct sensitivity analyses for the primary and secondary outcomes using several methods which have different missing data assumptions: (1) complete case analyses which assumes missing completely at random; (2) multiple imputation using M=10 imputations, which assumes missing at random; and (3) assigning poor scores and good scores for missing values differentially by treatment group, which aligns with non-ignorable missingness (the data missingness is related to the actual value).

5.3 Training

Beginning two to three weeks prior to first patient enrolment at the respective facility, the COPD pathway coordinator and those responsible for discharge will begin training on the materials supporting the pathway as well as use of the pathway itself. This will include communication touchpoints between the coordinator, discharge facilitator as well as the individuals responsible for the clinical path. Specifically, there will be education on the COPD protocol, Education Checklist, the COPD clinical pathway and order set as well as the criteria and fulfillment options required for discharge.

5.4 Data Collection Dates

The implementation of the COPD clinical pathway will begin on 6/1/17 at the first two facilities.

5.5 Continuation of the Intervention

Participating sites will likely continue treating patients diagnosed with an acute COPD exacerbation per the COPD clinical pathway after the study period has ended. This is outside the purview of the evaluation protocol and will be decided by clinical and administrative leaders at the respective sites.

5.6 Data Collection and Reporting

A daily list of patients with an acute exacerbation of COPD will be generated. Each morning at 06:00 the list is automatically emailed via secure transmission to the appropriate COPD pathway coordinator at each participating facility or stored on a secured server. Patient demographics, comorbid conditions and utilization will be obtained from the electronic medical record and billing systems. A monthly executive summary will be produced showing patient volume and related implementation metrics such as:

1. Rate of use of the COPD PowerPlan
2. Rate of use of the respiratory therapy department COPD bronchodilator protocol
3. Average length of stay
4. Rate of follow-up visit within 5 days of discharge.
5. Antibiotic order rate during admission
6. Steroid order rate during admission
7. Short acting bronchodilator order rate during admission
8. LAMA, LAMA/LABA, LABA/ICS order rate at discharge

6. PROJECT TIMELINE

Project Timeline									2018				
	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
Site/Teammate Training													
First Patient on Study													
Study Duration													
Last Patient on Study													
Final Data Analysis													
Manuscript Prep and Submission													
Conference Presentation/Posters													

7. INTERVENTION PLAN

7.1. COPD CLINICAL PATHWAY

The pathway includes the following components.

- A data system that identifies patients with exacerbation and care gaps in real-time
- A COPD pathway coordinator who works to close care gaps and ensure standardized approach.
- A standardized care pathway inclusive of an EMR based order set, patient education, and discharge criteria.

7.1.1. EMR Based Order Set

The order set includes an order within 24 hours of being admitted of

- A bronchodilator albuterol, ipratropium, ipratropium-albuterol)
- An antibiotic (amoxicillin-clavulanate, doxycycline, azithromycin, ampicillin-sulbactum)
- A steroid (prednisone, methylprednisolone)

7.1.2. Patient Education

Education will be provided by the COPD pathway coordinator and will be aligned to the treatment. The COPD pathway coordinator will use a set of standardized teaching tools and checklists in the process. Some components of the education include:

- Action plan (Living with COPD)
- Home medication review (steroids, antibiotics, etc.)
- Respiratory equipment - technique, what to use and when, tips
- Smoking cessation

7.1.3. Discharge Criteria

At the time of discharge, the patient should have each of the following (unless otherwise stated):

- Stability on a long acting bronchodilator (e.g., spiriva, serevent)
- Not requiring a short-acting bronchodilator more than qid (e.g., albuterol, ipratropium, ipratropium-albuterol)
- Be on an oral steroid for 24 hours prior to discharge (e.g., prednisone, methylprednisolone)
- A steroid prescribed, supplied, or have completed a 5-day course while admitted
- An antibiotic prescribed, supplied, or have completed a 5-day course while admitted
- A scheduled appointment with a care provider within 5 days of discharge
- Received COPD education prior to discharge

7.1.4. Patient Identification and Care Gaps

Patients are identified as described in the 'Subjects' section. Care gaps that are monitored daily include the initiation of the COPD PowerPlan and the Respiratory therapy department COPD bronchodilator protocol. The PowerPlan includes order sets for a bronchodilator, an antibiotic, and a steroid.

7.1.5. COPD Pathway Coordinator

Once a patient is identified, their clinical path will be guided by the pathway coordinator. These individuals will monitor the use of the COPD clinical pathway and assure that all milestones within the patient experience are addressed including assuring that discharge needs are met. The Pathway Coordinator will use the COPD Pathway Program which will inform the flowsheet used to track and record the patients clinical path. The COPD Pathway Coordinator will be responsible for reporting any pathway gaps to both the discharge facilitator and the clinician involved in the patient's care.

8. STUDY GOVERNANCE

This quality improvement trial will be conducted at Carolinas HealthCare System. It will be run jointly by the Center for Outcomes Research and Evaluation (CORE) and the Pulmonology Department. Daniel Howard, MD, (Pulmonologist) will serve as the Principal Investigator and Jason Roberge as the Co-Principal Investigator with oversight from the Executive Committee (EC). The EC will consist of leaders across the System involved in the trial, quality improvement, and implementation (Table 1). The EC will have the overall responsibility of trial oversight and direction. The EC will support dissemination of project findings and next steps. The EC will receive monthly progress reports and will meet periodically for status updates from the team and to set direction. When appropriate, ad hoc committee meetings will be scheduled to discuss pressing concerns.

Table 1. Executive Committee	
Daniel Howard	Pulmonology Department
Jason Roberge	Center for Outcomes Research and Evaluation
Amy Clary	Clinical Services
Scott Furney	CHS Executive Leadership/Internal Medicine
Mary N. Hall	CHS Executive Leadership
James Hunter	CHS Executive Leadership
Scott Rissmiller	CHS Executive Leadership

9. SAFETY RISKS

This project presents no more than minimal risk to patients who participate in the COPD clinical pathway. The deployment of the COPD clinical pathway at participating sites, utilizes care components that are already leveraged in CHS facilities. While based on evidence and present in some facilities, these elements of care are not consistently applied across sites and COPD patients.

There is always the risk of disclosure of a patient's private health information (PHI) or medical information. However, the processes identified in this protocol to enable the execution of this project, do not increase inherent risk of disclosure. Carolinas HealthCare System utilizes several hard and soft safety controls in the protection of patient information and medical records. Security controls include, but are not limited to, multiple system firewalls, access restrictions to patient records and information, locked offices and buildings housing research and patient data, and multiple layers of username and password protected computer and system access. The project team will ensure that appropriate handling of patient PHI follows standard CHS procedure. In the event of PHI disclosure, the appropriate departments will be informed per legislation and privacy regulations.

9.1. Data and Safety Monitoring Plan

The Co-PIs are responsible for the ethical and compliant conduct of this project in accordance with local, state, and federal laws and regulations. Ongoing supervision of the study progress and conduct will be facilitated through at least monthly meetings with key stakeholders and the PIs. These monthly meetings will address data updates, milestones, and concerns. Because this project presents no more than minimal risk to patients, per the FDA Guidance for Clinical Sponsors: Establishment and Operations of Clinical Trial Data Monitoring Committees, this study does not require oversight by a Data and Safety Monitoring Board or Committee.

10. RESEARCH COMPLETION

The Principal Investigator has the right to close the project at any site and at any time.

For any closure, the following applies:

- Closures should occur only after consultation between involved parties.
- All affected institutions must be informed as applicable, according to local law.
- In case of a partial study or site closure, patients still participating in the COPD clinical pathway, or those who are considered in follow-up, must be taken care of in an ethical manner.

The study will be considered complete when one or more of the following conditions is met:

- The enrollment period has ended, and the data collection period is complete.
- The IRB or Principal Investigator discontinues the study.
- The Principal Investigator defines an administrative or clinical cut-off date.

Upon study completion, a final report will be presented to the Executive Committee and all key stakeholders. The final report will detail all findings including primary, secondary and exploratory outcomes. The team will also prepare a manuscript for publication

11. ETHICAL AND LEGAL ISSUES

11.1. Ethical and Legal Conduct of the Study

The procedures set out in this protocol, pertaining to the conduct, evaluation, and documentation of this study, are designed to ensure that the Investigators abide by Good Clinical Practice (GCP) guidelines and under the guiding principles detailed in the Declaration of Helsinki. The study will also be carried out in keeping with the applicable local laws and regulation(s).

Documented approval from appropriate agencies (e.g. IRB) will be obtained before the start of the study, per GCP, local laws, regulations, and organizations.

Strict adherence to all specifications laid down in this protocol is required for all aspects of study conduct; the Investigators may not modify or alter the procedures described in this protocol.

Modifications to the study protocol will not be implemented without consulting the Principal Investigator and the IRB, as applicable. The Principal Investigator must assure that all study personnel, including co-investigators and other study staff members, adhere to the study protocol and all applicable regulations and guidelines regarding research both during and after study completion.

The Principal Investigator will be responsible for assuring that all the required data will be collected and properly documented.

11.2 Confidentiality

All records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available.

11.3 Disclosure of Data

The Principal Investigator, his or her associates and co-workers, and the appropriate regulatory agencies may use the information and data included in this protocol as necessary for the conduct of the study. Information contained in this study, and data and results from the study are confidential and may not be disclosed without the written permission of the Principal Investigator.

12. RETENTION OF RECORDS

Essential documentation including all IRB correspondence, will be retained for at least 2 years after the investigation is completed. Documentation will be readily available upon request.

13. PUBLICATION POLICY

The Principal Investigator or designee must send any draft manuscript, abstract, or conference presentation to members of the project Executive Committee for feedback and transparency, prior to submission of the final version. The Principal Investigator will be responsible for all relevant aspects regarding data reporting and publication.

The Principal Investigator or designee will ensure that the information and results regarding the study will be made publicly available on the internet at www.clinicaltrials.gov.

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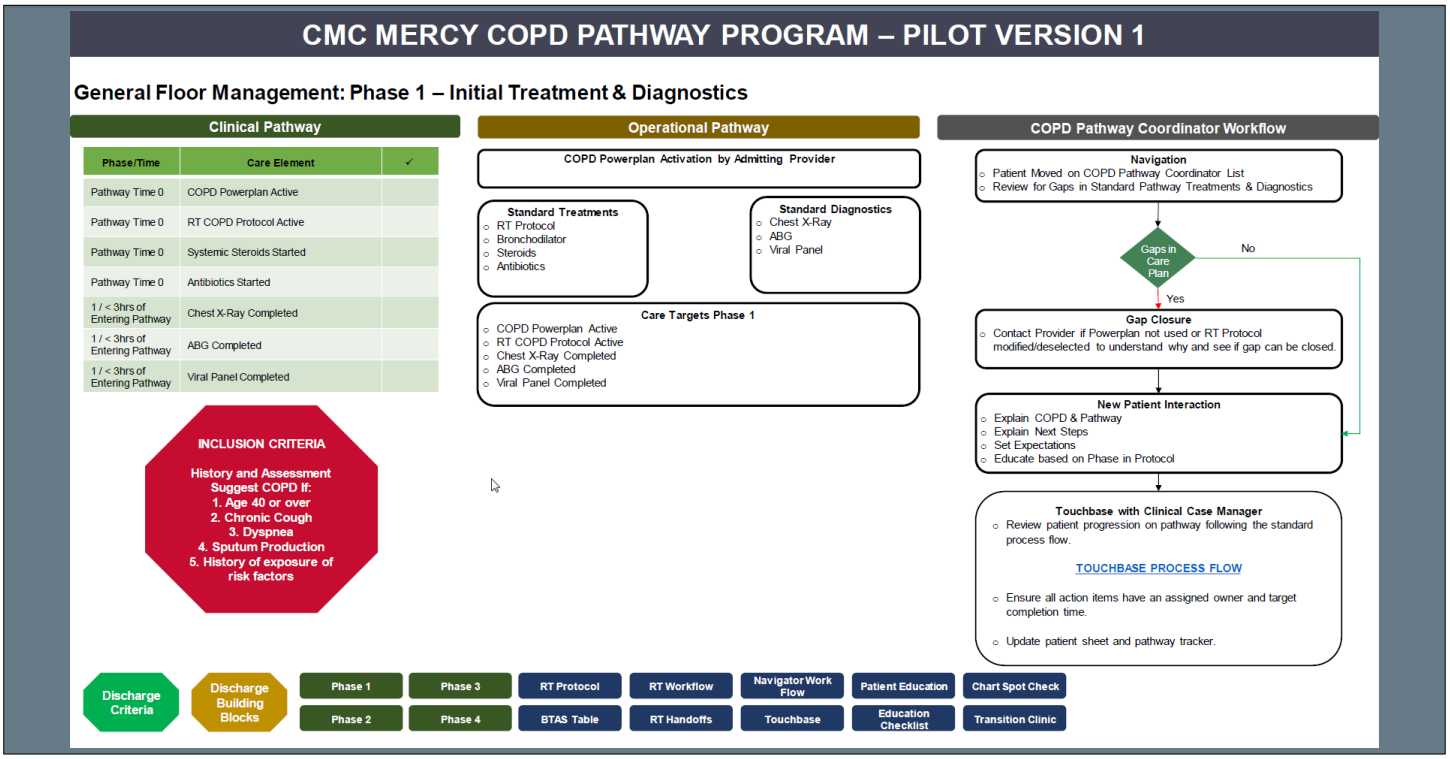
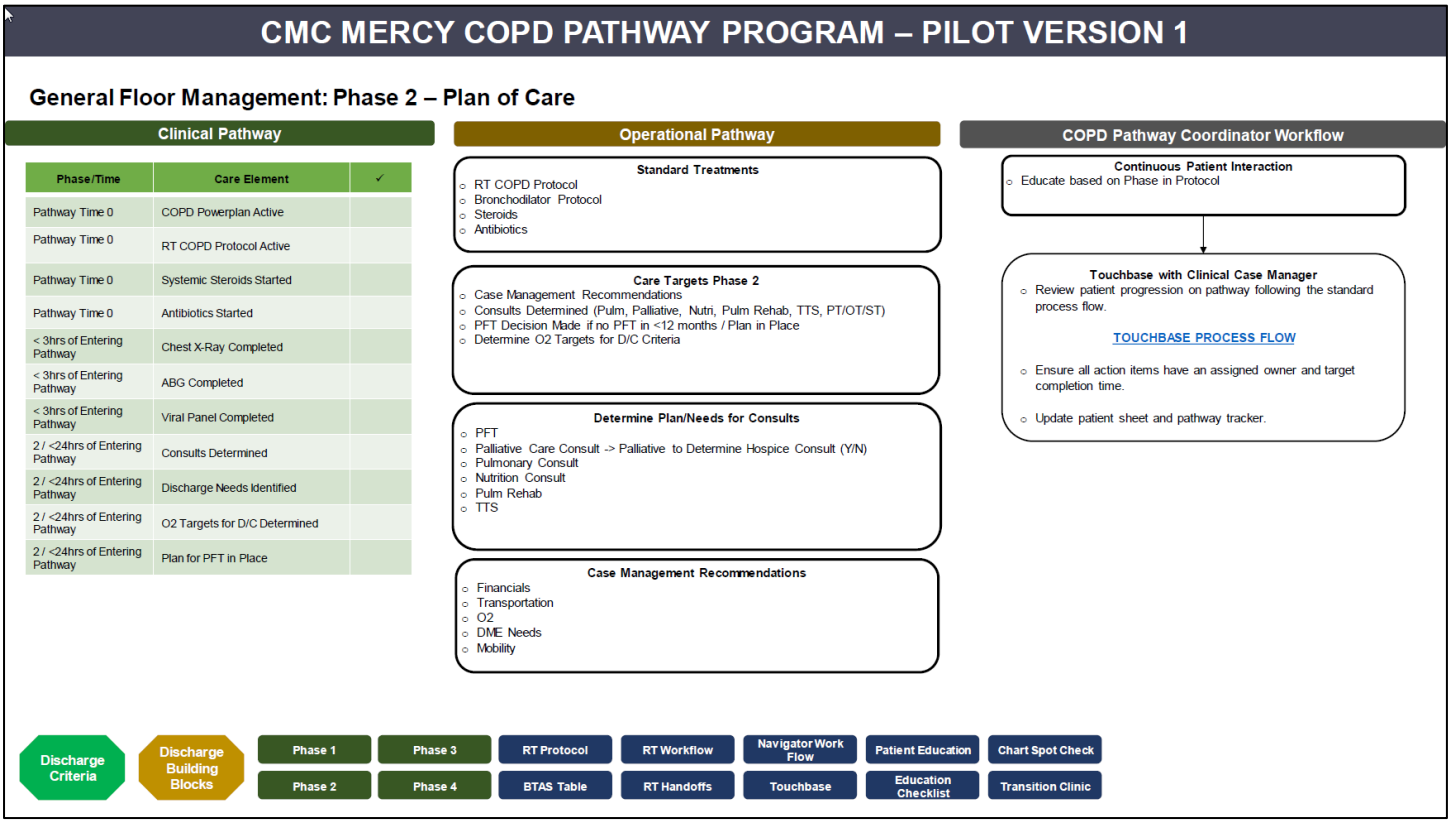
APPENDICES

Appendix A: CHS COPD Clinical Pathway





CMC MERCY COPD PATHWAY PROGRAM – PILOT VERSION 1

General Floor Management: Phase 3 – Discharge Planning

Clinical Pathway

Phase/Time	Care Element	✓
Pathway Time 0	COPD Powerplan Active	
Pathway Time 0	RT COPD Protocol Active	
Pathway Time 0	Systemic Steroids Started	
Pathway Time 0	Antibiotics Started	
1 / < 3hrs of Entering Pathway	Chest X-Ray Completed	
1 / < 3hrs of Entering Pathway	ABG Completed	
1 / < 3hrs of Entering Pathway	Viral Panel Completed	
2 / <24hrs of Entering Pathway	Consults Determined	
2 / <24hrs of Entering Pathway	Discharge Needs Identified	
2 / <24hrs of Entering Pathway	O2 Targets for D/C Determined	
2 / <24hrs of Entering Pathway	Plan for PFT in Place	
3 / 12-36hrs of Entering Pathway	Discharge Needs Fulfillment Blocks Selected	

Operational Pathway

Standard Treatments
- RT Protocol
- Bronchodilator
- Steroids
- Antibiotics

Care Targets Phase 3
- D/C Fulfillment Blocks Selected

Discharge Needs Determination
- Determine Disposition (Home, SNF, ALF, Rehab, Hospice)
- Determine Discharge Needs
- Determine Discharge Needs Fulfillment Blocks
- Identify gaps
- Create plan to Close Gaps
  - Use Transition Clinic if in doubt that discharge needs can be fulfilled

Discharge Clearance
- On track with Clinical Discharge Criteria?
- Identify gaps
- Create plan to Close Gaps

COPD Pathway Coordinator Workflow

Continuous Patient Interaction
- Educate based on Phase in Protocol
- Support discharge planning activities
- *Make Discharge Follow Up Appointments with patient*
- *Setup Transition Clinic if needed*

Touchbase with Clinical Case Manager
- Review patient progression on pathway following the standard process flow.

TOUCHBASE PROCESS FLOW

- Ensure all action items have an assigned owner and target completion time.
- Update patient sheet and pathway tracker.

Discharge Criteria | Discharge Building Blocks | Phase 1 | Phase 2 | Phase 3 | Phase 4 | RT Protocol | BTAS Table | RT Workflow | RT Handoffs | Navigator Work Flow | Touchbase | Patient Education | Education Checklist | Chart Spot Check | Transition Clinic

CMC MERCY COPD PATHWAY PROGRAM – PILOT VERSION 1

General Floor Management: Phase 4 – Discharge from Hospital

Clinical Pathway

Phase/Time	Care Element	✓
Pathway Time 0	COPD Powerplan Active	
Pathway Time 0	RT COPD Protocol Active	
Pathway Time 0	Systemic Steroids Started	
Pathway Time 0	Antibiotics Started	
1 / < 3hrs of Entering Pathway	Chest X-Ray Completed	
1 / < 3hrs of Entering Pathway	ABG Completed	
1 / < 3hrs of Entering Pathway	Viral Panel Completed	
2 / <24hrs of Entering Pathway	Consults Determined	
2 / <24hrs of Entering Pathway	Discharge Needs Identified	
2 / <24hrs of Entering Pathway	O2 Targets for D/C Determined	
2 / <24hrs of Entering Pathway	Plan for PFT in Place	
3 / 12-36hrs of Entering Pathway	Discharge Needs Fulfillment Blocks Selected	
4 / 36-48hrs of Entering Pathway	Clinical Goals for D/C Met	
4 / 36-48hrs of Entering Pathway	Discharge Needs Fulfillment Blocks in Place	

Operational Pathway

Care Targets Phase 4 / Goals for Discharge
- O2 Targets Met
- <Q6 SABA/SAMA
- Resolution of Hypercapnia
- Demonstration of Medication Usage Completed
- F/U Appointments Made \ Steroids Process Explained
- Plan for Fulfillment of D/C Needs Completed

Provider Review of Discharge Readiness
- Clinically Stable Per Criteria? -> click here
- Prescriptions for LABA/LAMA Prescription
- Systemic Steroid Prescription

COPD Pathway Coordinator Workflow

Pre-Discharge Patient Interaction
- Educate and Train on Home Medication Usage
- Explain Steroid Tapering Process
- *Confirm with Rx that Meds are covered?*
- *Setup Transition Clinic if needed/gaps exist*

Touchbase with Clinical Case Manager
- Review patient progression on pathway following the standard process flow.

TOUCHBASE PROCESS FLOW

- Ensure all action items have an assigned owner and target completion time.
- Update patient sheet and pathway tracker.

Post Discharge
- *Pathway list maintenance*
- *Reflect and document learnings*

Discharge Criteria | Discharge Building Blocks | Phase 1 | Phase 2 | Phase 3 | Phase 4 | RT Protocol | BTAS Table | RT Workflow | RT Handoffs | Navigator Work Flow | Touchbase | Patient Education | Education Checklist | Chart Spot Check | Transition Clinic

CMC MERCY COPD PATHWAY PROGRAM – PILOT VERSION 1

Discharge Criteria | Discharge Needs | Fulfillment Options

Discharge Clearance Criteria
- LABA/LAMA Prescription
- Systemic Steroid Prescription
- O2 Targets Met (y / n) if no Pulm consult to clear
- <Q6 SABA/SAMA (y / n)
- Resolution of Hypercapnia
- Demonstration of Medication Usage
- F/U Appointments Made \ Steroids Process Explained
- Plan for Fulfillment of D/C Needs In Place

Telehealth Follow Up after 48 Hours of Tapered Steroid Completion

Discharge Needs
1. Home Health Services
2. DME
3. Follow Up Appointments (PCP, Pulm, Transition Clinic)
   - Option a + b for all patients; if either one can not be fulfilled add option c)
4. Medications (ABX, RT, Steroids)

Fulfillment Options for Need #1
a) Insurance covered
b) Community Sponsored
c) No Means – Community Paramedic through Transition Clinic (not applicable for shelter patients)
d) No Needs

Fulfillment Options for Need #2
a) Insurance covered
b) Community Sponsored
c) No Means – Community Paramedic through Transition Clinic (not applicable for shelter patients)
d) No Needs

Fulfillment Options for Need #3
a) PCP 5-7 days
b) Pulmonologist
c) Transition Clinic (Community Paramedic > 48 hours is plan B

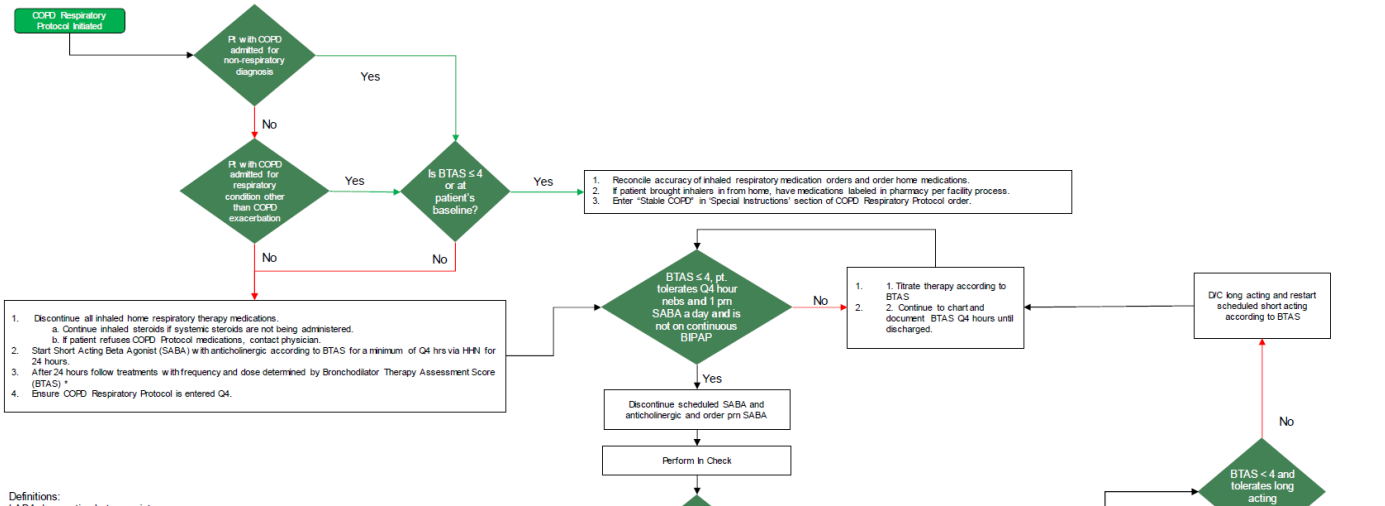
Fulfillment Options for Need #4
a) Prescription Hard Copy/Faxed (call RX to Confirm that $ is covered)
b) Myers Park / Community Sponsored
c) Set Up with Coupons

Need	Fulfillment Option	✓
1. Home Health Services		
2. DME		
3. F/U Apt		
4. Meds		

Discharge Criteria | Discharge Building Blocks | Phase 1 | Phase 2 | Phase 3 | Phase 4 | RT Protocol | BTAS Table | RT Workflow | RT Handoffs | Navigator Work Flow | Touchbase | Patient Education | Education Checklist | Chart Spot Check | Transition Clinic

CMC MERCY COPD PATHWAY PROGRAM – PILOT VERSION 1

Respiratory Therapy COPD Protocol



Definitions:
LABA- long acting beta agonists
LAMA- long acting muscarinic antagonists
SABA- short acting beta agonists
SAMA- short acting muscarinic antagonists

**Nebulized steroids may be started at the discretion of the physician when long acting bronchodilators are started. The formulary recommendation is budesonide 0.5mg Q12hr. Alternatives may be prescribed at physician discretion.

Discharge Criteria | Discharge Building Blocks | Phase 1 | Phase 2 | Phase 3 | Phase 4 | RT Protocol | BTAS Table | RT Workflow | RT Handoffs | Navigator Work Flow | Touchbase | Patient Education | Education Checklist | Chart Spot Check | Transition Clinic

CMC MERCY COPD PATHWAY PROGRAM – PILOT VERSION 1

Respiratory Therapy COPD Assessment & Scoring

*Bronchodilator Therapy Assessment Score					
Breath Sounds	0 Normal/Clear	1 End Exp. Wheeze	2 Pronounced Exp Wheeze	3 Insp. And Exp. Wheeze	4 Absent or near Absent
Dyspnea	0 None	1 Slight	2 Mild	3 Moderate	4 Severe

Total Score	**0**	**1-2**	**3-4**	**5-6**	**7-8**
Frequency	SABA Q4 hrs PRN for increased SOB; continue LABA **and** LAMA **or** SAMA	SABA Q4 hrs PRN for increased SOB; start or continue LABA **and** LAMA **or** SAMA	SABA and Anticholinergic Q4hrs **and** SABA Q2 PRN; start **or** continue LABA **and** LAMA **or** SAMA.	SABA Q2 hrs; if on continuous then wean SABA by 5 mg/hr as tolerated down to 5 mg/hr	SABA Q1hr up to 3 treatments then start Continuous SABA and anticholinergic
Use SABA Albuterol 2.5mg **and** anticholinergic Ipratropium 0.5mg. If Xopenex ordered, follow protocol with substitution of Xopenex 0.63mg at Q8 hr frequency.					
If continuous therapy is indicated, then use: SABA Albuterol 15 mg/hr **and** Ipratropium 0.5 mg/hr, wean dose as indicated above.					

Definitions:
LABA- long acting beta agonists
LAMA- long acting muscarinic antagonists
SABA- short acting beta agonists
SAMA- short acting muscarinic antagonists

**Nebulized steroids may be started at the discretion of the physician when long acting bronchodilators are started. The formulary recommendation is budesonide 0.5mg Q12hr. Alternatives may be prescribed at physician discretion.

Discharge Criteria | Discharge Building Blocks | Phase 1 | Phase 2 | Phase 3 | Phase 4 | RT Protocol | BTAS Table | RT Workflow | RT Handoffs | Navigator Work Flow | Touchbase | Patient Education | Education Checklist | Chart Spot Check | Transition Clinic

CMC MERCY COPD PATHWAY PROGRAM – PILOT VERSION 1

Respiratory Therapist Workflow

COPD Patient Chart Review

1. Do a chart review and check for admitting diagnosis (confirm AECOPD diagnosis, other pulmonary diagnosis or non-respiratory diagnosis)
2. Check current respiratory care medication regime including if any PRNs have been given within last 24 hours
3. Check steroid dose and modality (IV or PO)
4. Review most recent BTAS score and in-check dial completion and score.

Start of Patient Encounter

1. Collect patient medication(s) from Omnicell, med cart or med box
2. Perform appropriate hand hygiene, put on gloves and other appropriate PPE before entering room.
3. Knock on patient door, introduce yourself and state you are from Respiratory Therapy.

Inform Patient of COPD Protocol

1. Explain that you will be completing a respiratory assessment.
2. Explain that the physician ordered the COPD protocol which means they will be assessed every 4 hours and based on their progress their drug therapy will be altered.
3. Be sure to explain that with the protocol they may not be on their home medication during their hospital stay to help them get back to their baseline.
4. With the protocol they can expect to see a RT every 4 hours and if they need a treatment in between to contact nursing to call RT.

COPD Patient Assessment

1. Assess the following:
   a) Breath sounds
   b) SpO2
   c) Heart rate
   d) Ask about dyspnea using the prompt questions in Cerner and record information in the appropriate assessment piece in Cerner.
   e) Be sure to complete both the COPD protocol assessment and the HHN/DPI task.

COPD Patient Treatment

1. Scan patient and medication
2. Place medication in nebulizer med cup and place mask on patient or give mouthpiece to patient to hold.
3. After the treatment is completed complete post treatment assessment:
   a) Breath sounds
   b) SpO2
   c) Heart rate
4. Preform in-check dial and calculate BTAS score in the COPD protocol assessment piece

After first 24 hours, tolerating q4 nebs, no more than 1PRN SABA in last 24 hours, BTAS <4 and in-check dial > 40

1. Cancel q4 Duoneb and q2 PRN albuterol medications and modality task
2. Order Serevent BID, Spiriva daily and PRN SABA medications and modality task

After first 24 hours, tolerating q4 nebs, no more than 1 PRN SABA in last 24 hours, BTAS <4 and in-check dial < 40

1. Cancel q4 Duonebs and q2 PRN albuterol medication and modality task
2. Order Performist 20 mcg BID and Ipatropium 0.5 mg q6 medications and modality task

Patient on continuous bipap

1. Patient on continuous bipap has to be in the ICU
2. Minimum of q4 Duonebs. May increase per BTAS score

Follow Up Assessments

1. Reassess patient with COPD protocol q4 hours using the BTAS score to determine medication frequency per the algorithm.
2. Communicate in report BTAS score and any changes to medications and frequency made by you during your shift.

Discharge Criteria | Discharge Building Blocks | Phase 1 | Phase 2 | Phase 3 | Phase 4 | RT Protocol | BTAS Table | RT Workflow | RT Handoffs | Navigator Work Flow | Touchbase | Patient Education | Education Checklist | Chart Spot Check | Transition Clinic

CMC MERCY COPD PATHWAY PROGRAM – PILOT VERSION 1

Respiratory COPD Handoff
- Therapist to Therapist -

ED to ICU

1. Time of initial order
2. Time of initial treatment and any additional therapies ordered (Bipap, ect.)
3. BTAS score, ABG results, chest xray result and SpO2 saturation
4. Admitting Physician
5. Past medical history including smoking history

ICU to Floor

1. Time of last treatment
2. BTAS score and last in-check dial
3. Current therapies ordered
4. Past medical history including smoking history
5. Attending Physician

ED to Floor

1. Time of initial order
2. Time of initial treatment and any additional therapies ordered
3. BTAS score, ABG results, chest xray result and SpO2 saturation
4. Admitting Physician
5. Past medical history including smoking history

Shift to Shift

1. Time of last treatment
2. BTAS score and last in-check dial
3. Current therapies ordered
4. Past medical history including smoking history
5. Attending Physician

Discharge Criteria | Discharge Building Blocks | Phase 1 | Phase 2 | Phase 3 | Phase 4 | RT Protocol | BTAS Table | RT Workflow | RT Handoffs | Navigator Work Flow | Touchbase | Patient Education | Education Checklist | Chart Spot Check | Transition Clinic

CMC MERCY COPD PATHWAY PROGRAM – PILOT VERSION 1

COPD Pathway Coordinator Workflow

Phase 1 – Initial Patient Review & Gap Closure

1. Identify new COPD Pathway patients (Jason's report)
2. Review EMR for COPD Pathway gaps
   - Patient
   - Room #
   - Pt name
   - MRN
   - Provider
   - Last SABA given: where/when
   - Home respiratory medications
3. PULMO/COPD Exacerbation PP (used)
   - PP initiated by/date-time
   - PP RT orders modified/deselected
   - Page Provider for Navigator call back
   - Understand why PP was modified/deselected
   - Could gap be closed?
4. PULMO/COPD Exacerbation (PP not used)
   - Page Provider for Navigator call back
   - Propose starting COPD pathway
   - Provider to order "Initiate COPD Respiratory Protocol"
5. Notify assigned RT (Patient name, room number, MRN)
   - Verify steroid/antibiotic ordered and administered
   - Respiratory Therapy
   - Initial assessment - Completed by/date-time
   - 1st inpatient SABA treatment - date/time
   - COPD Protocol adherence
   - Incorrect - contact assigned RT
   - Barriers affecting accuracy
   - Assigned RT to correct orders

Phase 2 – Plan of Care & Patient Education

1. Obtain additional EMR information
   - Patient
   - PCP
   - Pulmonologist
   - PFTs completed within last 12 months
   - COPD Protocol
2. Respiratory Therapy adherence
   - Current BTAS
3. **Patient education**
   - Patient identified goals (Living with COPD pg. 1)
   - General disease knowledge (Living with COPD pg. 4)
   - Home medications (Living with COPD pg.3)
   - Respiratory - technique, what to use and when, side effects, tips
   - Other - corticosteroids and antibiotics
   - Evaluate respiratory medication self-administration (Living with COPD pgs. 9,11)
   - Medication delivery device (Living with COPD pgs. 12,14)
   - Cleaning and maintenance
   - Smoking Cessation (Living with COPD - pg. 8)
4. Update/review Patient Pathway

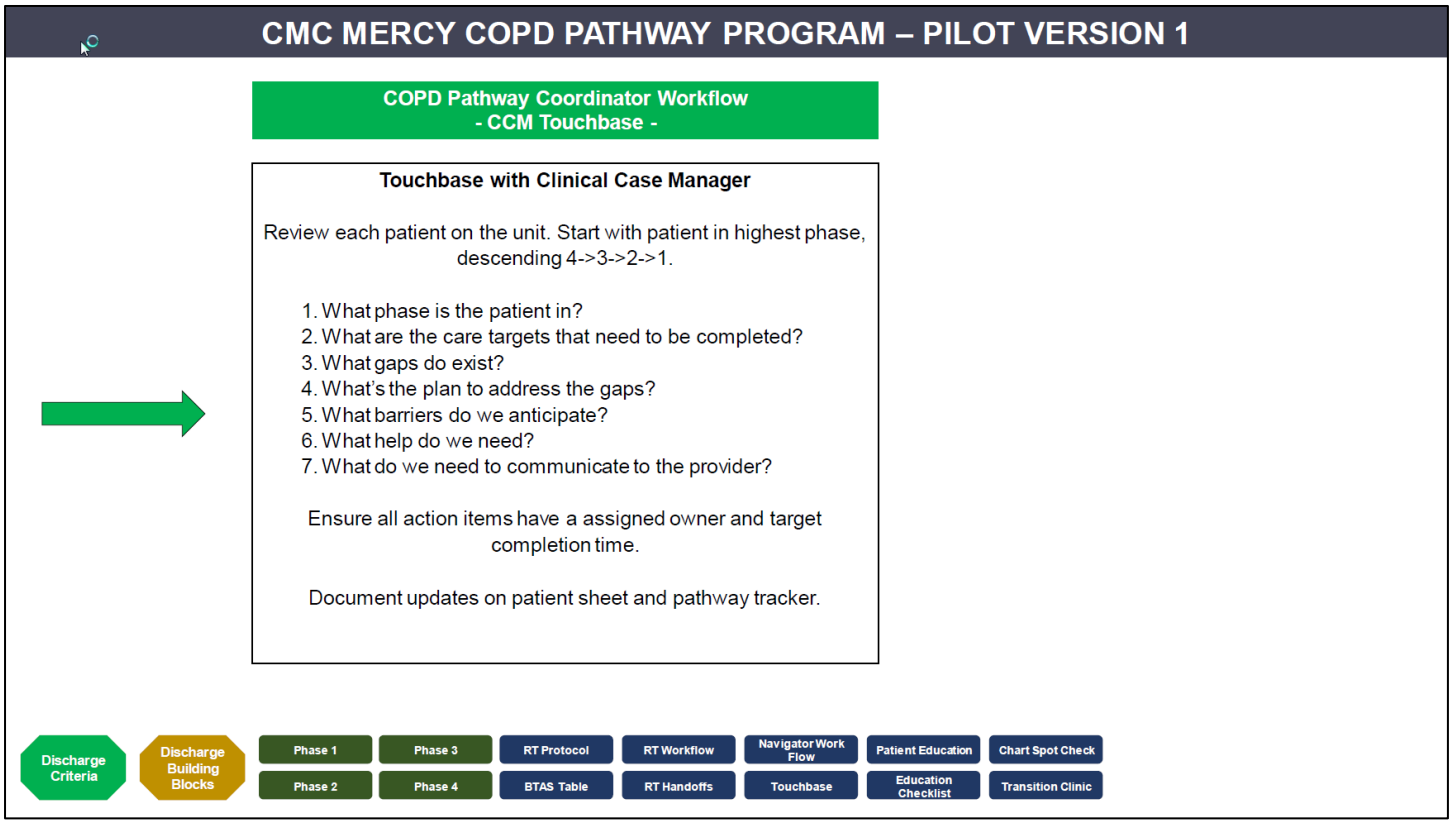
Phase 3 – Discharge Planning

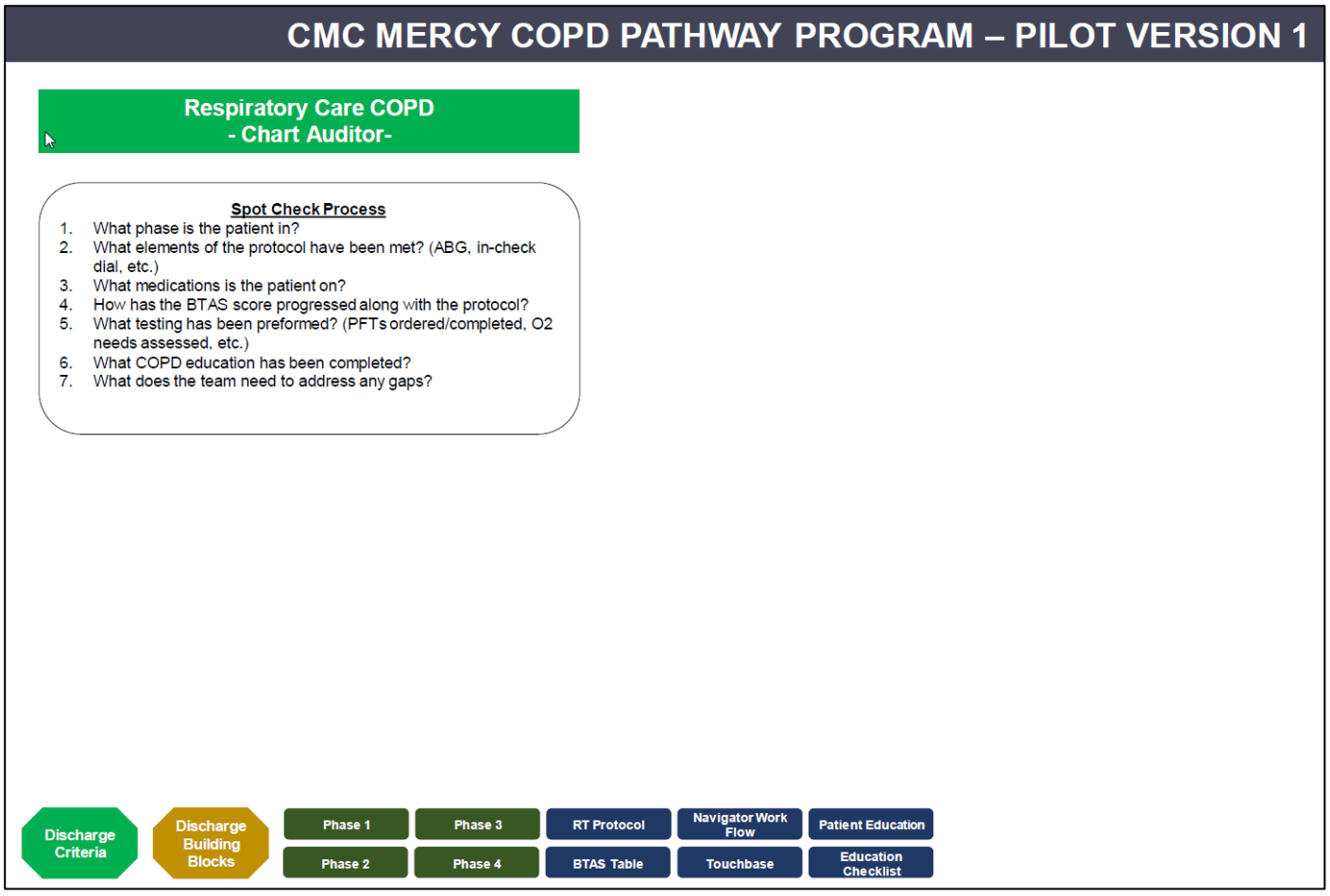
1. Review EMR
2. Check COPD Protocol
3. Review Respiratory Therapy adherence
4. Assess Current BTAS
5. Patient not improving
   - Page Provider for Navigator call back
   - Recommend Pulmonary consult
6. **Patient education**
   - Update/review COPD Patient Pathway
   - Action Plan (Living with COPD - pg.2)
   - Review medications – technique, what to use and when, side effects, tips
   - (Living with COPD pg.3) include corticosteroids and antibiotics
   - Know your triggers (Living with COPD - pg.5)
   - Take care of your health (Living with COPD - pg.6)
   - Smoking Cessation (Living with COPD - pg.8)
   - Discharge preparation
7. **Patient - family/caregiver COPD education session**
   - General disease information
   - Action Plan
   - Home medications
   - Changes in medication/delivery device
   - Administration technique, what to use and when, side effects, tips
   - Adherence
   - Additional needs

Phase 4 – Day of Discharge

1. Review progress towards discharge
2. Patient education – final review
   - Home medications
   - Respiratory - technique, what to use and when, side effects, tips
   - Other - corticosteroids and antibiotics
   - Action Plan
   - Additional discharge information as needed
3. Update pathway tracker
4. What learnings can be shared with team?

Discharge Criteria | Discharge Building Blocks | Phase 1 | Phase 2 | Phase 3 | Phase 4 | RT Protocol | BTAS Table | RT Workflow | RT Handoffs | Navigator Work Flow | Touchbase | Patient Education | Education Checklist | Chart Spot Check | Transition Clinic


CMC MERCY COPD PATHWAY PROGRAM – PILOT VERSION 1
COPD Pathway Coordinator Workflow
- CCM Touchbase -
Touchbase with Clinical Case Manager
Review each patient on the unit. Start with patient in highest phase, descending 4->3->2->1.
1. What phase is the patient in?
2. What are the care targets that need to be completed?
3. What gaps do exist?
4. What's the plan to address the gaps?
5. What barriers do we anticipate?
6. What help do we need?
7. What do we need to communicate to the provider?
Ensure all action items have a assigned owner and target completion time.
Document updates on patient sheet and pathway tracker.
Discharge Criteria
Discharge Building Blocks
Phase 1
Phase 2
Phase 3
Phase 4
RT Protocol
BTAS Table
RT Workflow
RT Handoffs
Navigator Work Flow
Touchbase
Patient Education
Education Checklist
Chart Spot Check
Transition Clinic


CMC MERCY COPD PATHWAY PROGRAM – PILOT VERSION 1
Respiratory Care COPD
- Chart Auditor-
Spot Check Process
1. What phase is the patient in?
2. What elements of the protocol have been met? (ABG, in-check dial, etc.)
3. What medications is the patient on?
4. How has the BTAS score progressed along with the protocol?
5. What testing has been preformed? (PFTs ordered/completed, O2 needs assessed, etc.)
6. What COPD education has been completed?
7. What does the team need to address any gaps?
Discharge Criteria
Discharge Building Blocks
Phase 1
Phase 2
Phase 3
Phase 4
RT Protocol
BTAS Table
Navigator Work Flow
Touchbase
Patient Education
Education Checklist

CMC MERCY COPD PATHWAY PROGRAM – PILOT VERSION 1

COPD Pathway Coordinator Patient Info
COPD Admission – What to Expect

Phase I

Nursing will regularly check your blood pressure, temperature, pulse and respiratory rate. Blood tests, sputum samples and a chest x-ray may be obtained. You may need an intravenous line started.

A Respiratory Therapist will:
- measure your oxygen level to determine if you need extra oxygen
- listen to your chest and assess your breathing
- give you medications to open up your airways and ease your breathing

Your physician may order additional medications to ease your breathing such as steroids and antibiotics.

You will be encouraged to move and care for yourself as much possible without worsening your breathing.

Clinical Case Management will visit you to identify any needs you may have at discharge.

A COPD Navigator will visit you 1-2 times daily to provide COPD (disease specific) education.

Phase 2

Nursing will continue to check your blood pressure, temperature, pulse and respiratory rate

The Respiratory Therapist will continue to
- measure your oxygen levels
- listen to your chest and assess your breathing
- give you breathing medications/treatments

As your breathing improves, Respiratory Therapy may change your respiratory medications/treatments.

Nursing will monitor your mobility and if needed, arrange for Physical Therapy to assess your needs.

The Clinical Case Manager will continue to visit you daily to update you about your discharge needs

The COPD Navigator will continue to visit you daily for ongoing COPD education.

If needed, the COPD Navigator will arrange a family/caregiver meeting for further education.

Phase 3

Phase 4

Discharge Criteria | Discharge Building Blocks | Phase 1 | Phase 2 | Phase 3 | Phase 4 | RT Protocol | BTAS Table | RT Workflow | RT Handoffs | Navigator Work Flow | Touchbase | Patient Education | Education Checklist | Chart Spot Check | Transition Clinic

CMC MERCY COPD PATHWAY PROGRAM – PILOT VERSION 1

COPD Pathway Coordinator
"Teaching Tools/Checklists"

DPI Patient Checklist

- ❑ Identifies medication and knows dosing schedule
- ❑ Verbalizes DPI technique
- ❑ Loads medication correctly – single vs. multi-dose device
- ❑ Breathes OUT completely, away from DPI
- ❑ Places DPI in mouth
- ❑ Breathes in deeply and completely
- ❑ Holds breath for at least 5 seconds
- ❑ Removes DPI from mouth before normal breathing
- ❑ Breathes normally for 30-60 seconds
- ❑ Repeats steps 4-9 to assure complete dose administration
- ❑ Rinses mouth after administration

MDI/Spacer Patient Checklist

- ❑ Identifies medication and knows dosing schedule
- ❑ Verbalizes MDI/spacer technique
- ❑ Shakes inhaler for appropriate length of time
- ❑ Inhaler/spacer set-up correct
- ❑ Breathes OUT completely, away from MDI/spacer
- ❑ Places MDI/spacer in mouth
- ❑ Activates inhaler by pressing down on canister 1 time
- ❑ Breathes in SLOWLY, filling lungs completely
- ❑ Holds breath for at least 5 seconds
- ❑ Removes spacer from mouth before normal breathing
- ❑ Breathes normally for 30-60 seconds
- ❑ Repeats steps 5-11 for 2nd dose if required
- ❑ Rinses mouth after administration

COPD Teaching - Medication Administration Checklist

Basic evaluation
- ❑ What medications do you take at home?
- ❑ How often?
- ❑ Walk me through your technique?
- ❑ Demonstrate your technique?
- ❑ Assess baseline technique
- ❑ Correct identified issues and demonstrate proper technique to patient

Teach-back evaluation
Have patient prepare and administer medication through delivery device
Successful technique = 3 required prior to discharge

Unsuccessful technique
1. If repeat dose administration is required
2. Review proper technique
3. Assist patient with dose administration

Successful technique unlikely
- Discuss with CCM
- Navigator recommended home respiratory regime changes
- Medication/Delivery device
- Continued outpatient education/monitoring – Pulmonary Transition Clinic

COPD Patient Teaching Checklist

1. COPD Patient Pathway Guide
2. General disease information
   - What is COPD? (Living with COPD - pg.4)
3. Managing COPD
   - Goals (Living with COPD - pg.1)
4. Medications - identification and dosing schedule
   - Respiratory Rescue/Maintenance (Living with COPD - pg.3)
   - Device assembly/cleaning (Living with COPD - pgs.12,14)
   - Self-administration/technique (Living with COPD – pgs.9,11)
   - Corticosteroid - inpatient/outpatient
   - Antibiotics - inpatient/outpatient
   - Action Plan (Living with COPD - pg.2)
5. Preventing/treating flare-ups
   - Exacerbation symptom recognition
   - When to call the Doctor
   - Know your triggers (Living with COPD - pg.5)
   - Anxiety/stress
   - Breathing techniques (Living with COPD - pg.7)
   - Take care of your health (Living with COPD - pg.6)
   - Exercise
   - Nutrition
   - Sleep/rest
   - Vaccinations
   - Follow-up appointment compliance - Doctors/Tests
   - Smoking cessation (Living with COPD - pg.8)

Discharge Criteria | Discharge Building Blocks | Phase 1 | Phase 2 | Phase 3 | Phase 4 | RT Protocol | BTAS Table | RT Workflow | RT Handoffs | Navigator Work Flow | Touchbase | Patient Education | Education Checklist | Chart Spot Check | Transition Clinic