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A Pilot Study of the Impact of a Pulmonary Clinical Decision Unit on Outcomes in Patients with Chronic Obstructive Pulmonary Disease

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A PILOT STUDY OF THE IMPACT OF A PULMONARY CLINICAL DECISION UNIT ON OUTCOMES IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Introduction

In today's competitive environment, healthcare leaders are driven to reduce waste, remove inefficiency, and eliminate unnecessary hospital readmissions in ordered to achieve goals outlined in Section 3025 of the Affordable Care Act. Hospitalization accounts for nearly one-third of the total $2 trillion spent on healthcare in the United States (Locker, 2011). While some readmissions are appropriate and unavoidable, a fragmented healthcare system and lack of care coordination causes patients to be admitted back into the hospital. Rehospitalizations are expensive, potentially harmful, and a sign of suboptimal care delivery.

Attention to this issue has intensified with a new Hospital Readmission Reduction Program (HRRP), which penalizes hospitals for having high readmissions rates (Robert Wood Johnson Foundation, 2013). Rates of patients readmitted within 30 day of discharge from the hospital impact the HRRP defined by the Center for Medicare and Medical Services (CMS). The HRRP is CMS's most noteworthy regulatory program, with potential reductions in future reimbursement according to performance relative to a baseline period. In 2013, penalties were imposed up to 1%, with rates increasing per program mandates up to 3% in 2015. Performance at or above national levels enables acute care facilities to retain the 3% at risk amount, while below standard rates translate into decreased reimbursement (The CMS Blog, 2013).

Background and Significance

More than 2,000 hospitals across the United States were penalized by the government in October 2013, because their patients were re-admitted back to the hospital within 30-day of discharge. Together these hospitals will forfeit about $280 million in Medicare funding over the

next 5 years. This represents a major paradigm shift in healthcare payment structure, in which a new reimbursement structure is reliant on patient outcomes (Rau, 2012). The fee-for-service system, as well as some capitation methods, offer few incentives for preventing readmissions that result from poor outpatient care or complications related to an initial hospitalization. One in twelve adults discharged from the hospital are readmitted within 30 days. The cycle of readmissions added $16 billion to the cost of healthcare in the United States. Due to the astronomical cost, the HRRP is a method designed to ensure hospitals are accountable to making certain that systems and structures are in place to reduce unplanned readmissions. (Reid, 2012).

According to Jencks, Williams and colleagues (2009), 19.6% of the 11,855,702 Medicare beneficiaries were rehospitalized within 30 days and 34% were rehospitalized within 90 days; 67.1% of patients who had been discharged with medical conditions and 51.5% of those who had been discharged after surgical procedures were rehospitalized or died within the first year after discharge (Jencks, Williams, & Coleman, 2009). Among patients who were re-hospitalized within 30 days after a surgical discharge, 70.5% were rehospitalized for a medical condition. About 10% of rehospitalizations were likely to have been planned. The average length of stay of rehospitalized patients was 0.6 days longer than that of patients in the same diagnosis-related group (DRG) whose most recent hospitalization had been at least 6 months previously (Jencks et al., 2009). The study provided supporting evidence that rehospitalization among Medicare beneficiaries is widespread and costly.

Re-admissions are measured by a ratio, dividing a hospital's number of "predicted" 30-day re-admission diagnoses by the number that would be expected. Ratio is a comparison of the average re-admission rates with other hospitals with similar patients. The HRRP policies currently apply to patients who meet the operational definition for 30-day re-

admission for diagnoses of Acute Myocardial Infarction (AMI), Heart Failure (HF) and Pneumonia (PN) ("Re-admission Reduction Program," 2013). However, in Fiscal year 2015, the HRRP expanded the list of patient types to include Chronic Obstructive Pulmonary Disease (COPD), Coronary Artery Bypass Grafts (CABG), Percutaneous Transluminal Coronary Angioplasty (PTCA), Stroke, other vascular surgical procedures (The CMS Blog, 2013).

Over 5% of all deaths and one in eight admissions from the emergency department are patients with COPD. In the state of Kentucky, more than 9% of the population has a diagnosis of COPD according to the 2013 Behavioral Risk Factor Surveillance System Survey (Center for Disease Control and Prevention, 2012). According to the data specific to COPD 30-day hospital readmission rates for Norton Audubon Hospital, the baseline in 2013 was 18.4%.

It is predicted that COPD will move from the 12th leading cause of disability to the 5th place by the year 2020 (Sridhar, Dawson, Roberts & Partridge, 2008). COPD is one of the most common medical conditions associated with re-admissions. Two targeted strategies being used to improve readmission rates of patient with COPD are the development of Observation Units and admission of patients classified as observation status. Observation Units, also known as Clinical Decision Units (CDU) and or Short Stay Units (SSU), are designed for patients whose clinical conditions are unclear and for whom additional evaluation is needed in order to make a clinical decision to admit the patient to inpatient. The names used to identify observation location are interchangeable: CDU, OU, and SSU. These locations where patients are managed, utilize the same principal for providing care to patient between 8 – 24 hours. Services provided to patients in observation areas are typically protocol driven interventions to determine appropriate monitoring, diagnostic testing, assessment of clinical symptoms, laboratory testing, and response

to treatment in order to determine whether a patient requires additional treatment or if the patient is to be admitted as an inpatient.

Furthermore, the quality of life for patients with COPD is often compromised due to the course of the disease. COPD impairs the quality of life, by preventing people with this condition from socializing and enjoying life and hobbies they love. Patients with COPD experience limited energy levels and may feel frustrated and angry about an inability to do what they want to do in life (Zamzam, Azab, Wahsh, Ragab & Allam, 2012). Anxiety and depression are frequently associated with diseases which further contribute to rehospitalization. When patients with COPD are admitted to the hospital, condition treatment and medication adjustment are the primary goals of getting the patient well enough for discharge. Unfortunately healthcare many opportunities for addressing underlying issues that contribute to unplanned readmissions. Hospitalized patients and /or their families often receive limited education about self-care and the prevention of unplanned readmissions. There is no formal hand-off to post-acute care providers, nor are socioeconomic factors impacting the disease discussed with the patient. When subsequent exacerbation arises, the emergency room is the typical solution (Graf et al., 2012).

Acute Exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD) represents a major burden to the healthcare system. A study by Reid (2012) reported that the cost of readmission increased to $97 billion annually when including patients readmitted within one year. Patients with COPD are frequently readmitted due to the growing numbers of co-morbidities and mortalities associated with the disease. These patients utilize an enormous amount of healthcare resources.

Diez and colleagues (2008) evaluated social determinates and predictors of the cost of care associated with COPD patients in primary care and acute care settings. The authors identified

that the largest component of cost associated with the treatment and management of COPD occurred during hospitalization. On average, the total cost per COPD patient admitted to an acute care facility was $1,922.72 ± $2,306.44. The cost varied according to the admission status. Patients, assigned to an observation status, spend less time in the hospital than patients assigned to an inpatient status. Patient status ensures the avoidance or abuse of the hospital system by not admitting patients who are not "sick" enough to require an inpatient stay. Observation status is defined by CMS as the utilization of a bed for periodic patient monitoring to evaluate the patient's condition in order to determine the need for an inpatient admission (Diez et al., 2008).

Hospitals are capitalizing on this distinction through the introduction of observation units (OUS). When patients are classified as status observation, and /or are admitted to an OU, the billing is different than an inpatient admission. Observation status is reimbursed according to the Outpatient Prospective Payment System. Observation is an alternative to inpatient admissions since it enables the provider the opportunity to determine if an admission is necessary (Schmidt & Schmidt, 2014). When patients are discharged from an observation area, the time spent in observation status does not count as an inpatient admission; thereby, OUs and observation status affect hospital readmission rates. OUs enable the provider to determine if the patients' condition warrants medical necessity for an inpatient and has been frequently used with cardiac patients. However, the effectiveness of this approach with COPD has not been thoroughly evaluated.

Purpose Statement

The purpose of this retrospective study was to analyze the impact of a pulmonary clinical decision unit (PCDU) on patient outcomes related to COPD. At Norton Audubon Hospital (NAH), patients with COPD who were not ready for discharge from the emergency department

(ED) and who did not meet inpatient criteria were admitted to the hospital as observation status to a PCDU during the time period from January 28, 2014 - August 31, 2014. The PCDU staff provided expedited evaluation and utilized protocols to provide therapeutic interventions and coordinated services in order to discharge patients home or to determine the need for an inpatient admission. The study will measure the impact of cohorting patients with COPD in a PCDU on the cost of care, 30-day hospital readmission rates, and subsequent emergency department visits within 7 days of discharge

Literature Review

An integrative review was performed on evidence-based literature relating to use of OUs. The following databases were searched from the years 2004 to present: CINAHL, PubMED, Medline and Cochrane database Systemic Reviews. Key words used in the database were: Patient Protection Affordable Care Act, hospital re-hospitalization, preventable COPD re-admissions, and COPD cost of care, clinical decision unit, short stay unit and observation units. The search was limited to human adults over 18 years from 2004 to 2014. Inclusion criteria included a focus on high risk readmissions, clinical decision units, CMS criteria for admission as compared to observation status, ED visits for COPD, and COPD readmission strategies. Out of 150 citations reviewed, 15 studies met the inclusion criteria.

The use of Observation Units (OUs), is gaining popularity as a strategy for decreasing emergency department crowding, reducing hospital admissions and lowering costs. According to Suri (2011), observation units (OUs) first became popular after the paradigm shift from fee-for-service to value-based purchasing. The purpose of the OU within the structure of an Accountable Care Organization (ACO), to increase healthcare systems' accountability by developing and implementing strategies to improve patient outcomes while also lowering

healthcare costs. ACOs achieve cost savings by reducing avoidable admissions, preventing unplanned readmissions, and decreasing ED visits. Delivering healthcare services while offering hospitals financial incentives are the governing principles associated with an ACO model. Challenges confronted by hospitals in terms of controlling cost, decreasing crowded emergency departments , and improving outcomes for patients support the business case for implementing observation units or CDUs. (Suri, 2011).

Decker and colleagues (2008) performed a prospective, randomized trial of an emergency department observation unit (EDOU) for acute onset of atrial fibrillation. The purpose of the study was to investigate an EDOU protocol for managing acute onset of atrial fibrillation and to compare the treatment of EDOU patients to those under usual hospital admission management. The study was done over 3 years (September 1999- December 2002) in the EDOU of a tertiary referral center. The EDOU utilized protocols to manage patients admitted to the area. At the end of the 39 month study period, 85% of EDOU patients were converted to Sinus rhythm versus 73% in the routine care group (difference 12%; CI -1% to 25%; $P < .06$). The mean LOS was 10.1 versus 25.2 hours, (difference 15.1 hours; 95% CI 11.2 to 19.6; $P <.001$) for EDOU and in hospital respectively. Nine EDOU patients required inpatient admission. Eleven percent of EDOU group had recurrence of Atrial fibrillation during follow-up versus 10% of the routine inpatient care group (difference 1%; 95% CI -9% to 11%; $P < .93$) (Decker, et al 2008,). In summary, the EDOU integrated protocols to control heart rate and cardiovert patients when necessary. The length of stay in the EDOU was significantly better in these patients when compared to those under routine care.

The majority of CDU research has been conducted on patients with HF. Because the population is living longer, HF is mostly observed in the elderly population. Due to the

prevalence of HF, more studies have been conducted with this population. The diagnosis of HF is the most expensive diagnosis for Medicare healthcare systems exceeding $34.8 billion in 2005 (Linden & Milstein, 2008.). Unfortunately, frequently reoccurring symptoms of HF result in multiple ED visits which are followed by multiple readmissions. Heart Failure is a disease that is characterized by frequent visits to the ED due to the steady deterioration of the patients' clinical presentation and patterns. As the disease progresses, the quality of life is negatively affected over time.

Peacock and colleagues (2006) reviewed innovative options for managing decompensated heart failure in an EDOU. EDOU protocol driven patient management was integral to the success of the unit. In a pre and post study of 154 decompensated HF EDOU patients, the investigators demonstrated that protocol-driven EDOU treatment of decompensated HF is an effective and safe method to manage patients and to decrease inpatient admissions. The ED revisit rate decreased by 56% (0.90- 0.51; $P < 0.000$) during the 90-day follow-up period. Another statistically significant outcome from the study demonstrated a reduction in 90-day inpatient readmission rate of 64% (0.77 – 0.50; $P < 0.007$). Finally, 90-day mortality and ED readmission decreased from 4% to 1% ($P= .096$). A structured outpatient EDOU management protocol positively decreases 90-day rates of emergency department revisit rate and decreases inpatient hospitalizations (Peacock, 2005).

Another study examined optimizing patient care in an OU to decrease HF readmission rates (Peacock, 2005). Patients received specialized treatment plans in the cardiac OU for acute decompensated HF. The OU provided an alternative strategy to lowering hospital readmissions rates. Entry to the OU was determined by a set of criteria and treatment protocols once the patient was admitted to the OU. To determine appropriate patient placement to an observation

unit for heart failure, the following information was collected while the patients were in the emergency department: the medical history and physical, chest x-ray, measurement of B-type natriuretic peptide (BNP), ECG and cardiac markers. According to the results, the investigators concluded that the implementation of an observation unit with patient specific protocols and standing orders for decompensated HF was associated with a 56% reduction in the 90-day HF emergency department revisit rate (P <.0001) and a reduction in the 90-HF Rehospitalization rate (P=.007). Additional benefits associated with the observation units were a reduction in 90-day mortality rate from 4% to 1% (P < .096) (Peacock et al., 2006).

Proactive evaluation and effective management of HF in an OU, prevents unforeseen complications associated with decompensated heart failure. Aggressive patient management, education and follow-up discharge planning supports the business case for implementing an OU as a component of patient care. Jagminas and colleague (2004) examined the optimal location for an OU. A retrospective study was conducted for the purpose of comparing the utilization of an EDOU, to an in hospital observation unit (IHOU) for chest pain in the same acute care facility. There were 440, or 36.9% of 1190 patients, with chest pain presenting to the ED over a 5 month period who were admitted to the EDOU, while the IHOU admitted, 973 or 69.3% of 1404 patients from the ED. There were fewer patients with chest pain who were converted to an inpatient status from the EDOU, 35 patients or 7.9% of 440 (P < 0.000), when compared with the IHOU, n = 187(19.2%) or 973; (P <.001). The average cost of care for each EDOU patient was $889.87 (95% CI 862.8 – 916.9) as compared to $1,039.70 (95% CI 991.7 – 1087.7) for each IHOU patients (Jagminas & Partridge, 2005). According to the findings, the cost of care was higher when patients were in the IHOU as compared with the EDOU for managing low-risk to moderate risk patients with chest pain. In summary, observation units have proven to reduce

inpatient admissions, decrease emergency room crowding and control cost (Suri, 2011). Furthermore, the cost of care for managing low-risk patients with disease specific protocols in an OU is an efficient method for managing patients (Jagminas & Partridge, 2004).

When considering a location for an observation unit and the strength of evidence for managing patients in an EDOU, the majority of studies were conducted on patients with decompensated HF. A structured protocol- driven EDOU for the treatment of decompensated HF has been proven to be an effective and safe method to managing patients and decreasing inpatient admissions (Peacock, 2005). There is a growing body of evidence in support of observation units for managing patients with HF. Observation units that implemented decision trees according to 3 process maps to differentiate patients at low, intermediate and high risk of in hospital mortality, provided guidance for providers and structure to ensure that the patient's condition meets the criteria for admission to an observation unit (Peacock et al. 2006).

The goal of observation status and the utilization of OUs to decrease cost by creating incentives for efficient, effective healthcare. Healthcare is making positive gains to limit cost by proactively preventing complications and avoidable days in the hospital. Studies support observation medicine by cohorting specific patient types to an observation unit or clinical decision unit. Due to the growing number of patients diagnosed with COPD, cohorting patients and using protocol driven order sets, enables physicians to spend more time to stabilize the patient and to determine medical necessity (Decramer & Wim, 2013). The protocol driven care for COPD is based on the Gold recommendations (Vestbo, et al. 2013). Regardless of where OUs are within the hospital environment, the evidence supports deploying and executing resources to ensure these specialty areas are equipped and staffed with qualified healthcare

workers. OUs contribute to improved care, and to control the cost of healthcare for vulnerable patient population.

Methods

Development of Interventions

An innovative approach to preventing unplanned admissions, reduce cost, and reduce ED visits between admissions is to apply a data-driven, quality strategy to improve patient outcomes. The design and implementation of the PCDU at NAH followed the DMAIC model (Define, Measure, Analyze, Improve and Control). DMAIC is a subcomponent of Six Sigma Performance Improvement Methodology. The fundamental objective of Six Sigma methodology is to implement evidence-based strategies by means of focusing on process improvement and eliminating variations (Six Sigma, 2009).

The Six Sigma DMAIC is performance improvement methodology consisting of five phases. During the Define phase, the executive leadership team at Norton Audubon Hospital (NAH) identified that COPD 30-day hospital readmission rates were higher than the national average. The United States average 30-day hospital readmission rate for Medicare patients with a diagnosis of COPD is 18.0 % (Agency for Healthcare Research and Quality, 2013). NAH readmission baseline rate for COPD was 18.4% in 2013. The length of stay for patients with COPD is 4.52 days and cost of care is $2,966 per patient. These factors associated with managing COPD led to the development of a committee to address these issues.

In the define phase, the champion for the project contacted the lead investigator and requested assistance in leading a committee to address COPD outcomes. The lead investigator and the project sponsor, created a multidisciplinary team to develop processes and to implement evidence based strategies to improve outcomes for patients with COPD. To make

certain that the committee members accurately represented the healthcare team, an in-depth analysis was completed to determine which internal and external stakeholders affect the process. The stakeholders were identified as representatives from nursing, information services, pulmonologists, pastoral care, respiratory care and care management. The team created a charter, which defined the scope of the project, as well as identified how the problem affects the patient and the organization (see Appendix A). Due to the shift in hospital payment and more focus on value, the committee validated that patients with a diagnosis of COPD are at the greatest risk for readmissions due to the number of co-morbidities associated with the disease. The scope of this project was specific to patients admitted and discharged with a primary diagnosis of COPD.

The Measure phase involved gathering information on the physical characteristics accompanying COPD and the current situation in order to provide an understanding of the improvement efforts. This phase was crucial in understanding current performance and processes impacting readmissions and the cost of care. The data were abstracted from the electronic medical records to determine the demographics related to patients with COPD; age, discharge disposition and gender (see Appendix B). Additional data, measuring the cost of care, length of stay, Emergency Department visits within 7 days and 30 day readmission rates were used to determine the financial impact of COPD (see Appendix C).

During the Analyze phase, the team identified root causes of variations and gaps in care affecting clinical outcomes associated with COPD. Variations identified by the team consisted of inconsistent utilization of outdated protocols, lack of a mechanism for identifying patients at risk for readmissions, inconsistent education provided to staff regarding pulmonary disease management, absence of or no pulmonary physician consulted on the case, patients admitted to

different nursing units, and patients with no medical home or primary care physician. In the Improve phase, the team developed the future state map, goals and researched best practice for managing AECOPD. According to the evidence, hospitals that admitted patient with AECOPD to an OU had a reduction in 30-day hospital readmission rates and cost of care (Decramer & Wim, 2013). During this phase, the project sponsor collaborated with the chief finance officer, the chief nursing officers and Pulmonologists to develop a business plan which included timelines for opening a PCDU for patients who were assigned an observation status with pulmonary disease. The clinical experts on the committee developed the protocols associated with the PCDU (see appendix D). The focus on multidimensional care which was patient-centered, safe, cost-effective, efficient, evidence based and culturally competent was the foundation supporting the PCDU. The PCDU was located on 4 east nursing area. The unit was a 23-hour observation unit specifically designed for patient with pulmonary diagnoses. The PCDU had 8 observation beds which allowed patients to be assessed using evidence-based strategies with optimal resource utilization. Optimal care of patients with diagnoses of COPD was the goal of staff members who worked in the PCDU.

The staff were provided with in-depth education which was specific for the management of COPD. The education materials were created using the COPD "Gold Standards" as the best practice for managing COPD (Vestbo, et al. 2013). COPD protocols were created by the clinical leadership team representing the PCDU. Based on the evidence, the education provided to the staff covered the following areas; medication use, recognition and management of chronic obstructive pulmonary disease exacerbation symptoms, lab values, bronchial hygiene, oxygen modalities, breath sounds, smoking cessation, and advance directives. The care of the patient with COPD is very challenging and complex. The comprehensive education and training

provided to the staff was an essential component to providing an infrastructure within the PCDU to ensure that the staff working in the PCDU were consciously and clinically competent. The PCDU opened January 27, 2014. Patients admitted to the observation unit were required to meet the following criteria:

- High likelihood of correction to baseline status within 48 hours.
- Acceptable vital signs: blood pressure. >100/60, respiratory rate < 28, pulse < 120.
- Pulse oximetry 90% or higher on room air, correctible to > 90% on oxygen, on < 50% FiO2.
- No sign or symptoms of fatigue or impending fatigue
- Alert and without any medical status changes
- Chest X-Ray without an apparent acute process.

Once patients were admitted to the PCDU, the protocol order set was initiated. If the patient did not have a pulmonologist, an automatic referral was sent to the pulmonary specialists. While in the PCDU, all patients with COPD were seen during multidisciplinary rounding. Patients are provided with the COPD education folder, which includes the booklet "Learning to Live with COPD". The booklets were given to the patient upon initial diagnosis and available for reference upon subsequent admissions. Patient education was progressive while in the PCDU. Information taught to the patient and/or family members consisted of, living in a smoke free environment, medication compliance, maintaining comfortable breathing by using directives (e.g. pursed-lip breathing technique, forward body positions), managing stress, preventing and treating COPD exacerbation, maintaining an active life style and healthy diet. While in the PCDU, the nursing staff discussed the benefits associated with pulmonary rehabilitation as an opportunity for successful long-term COPD management. Once the patient was stable and in

agreement with the transitional plan for pulmonary rehabilitation, a referral was sent to the department. The nursing staff in the PCDU were responsible for scheduling a follow-up appointment with the patients' primary care physician prior to discharge. These strategies ensured that those patients were able to manage their disease once discharged from the hospital.

Another component to the Improve phase consisted of leveraging available technology to identify patients at risk for readmission. Predictive analytics were embedded into the PCDU clinical work flow. A predictive analytic tool was built into the electronic health record. Epic Readmission Manager (RAM) was a health intelligence platform which proactively identifies patients at risk for hospital readmissions. The strategy for preventing unplanned readmissions by using Epic RAM, in conjunction with admitting patients with Acute Exacerbation Chronic Obstructive Pulmonary Disease (AECOPD) to the PCDU. Epic RAM forecasts the probability of a patient being readmitted. The forecast was based on the number of prior emergency department visits within the past 6 months, the time since the last discharge, the name of the primary care physician, age, living arrangements, and the ability to perform activities of daily living, residence type and reliable transportation. These markers are included in Epic RAM readmission predictive index (PI). This score was used to risk stratify patients and to identify patients who require advanced discharge planning or additional care transitional services to prevent an unplanned readmission. The Care Manager assigned to the PCDU would track and monitor PI scores of 6 or greater. A PI score of 6 or greater is an alert to the care manager to further evaluate the patient by using the Risk Readmission Assessment tool in Epic (see appendix E).

The final phase is Control. Control involves making certain the improvement strategies were hardwired into the culture (Six Sigma, 2009). The Control phase involves creating a process

control plan and to sustain the improvements. Developing and implementing evidence-based strategies for improving outcomes for patients with a diagnoses of COPD is a priority within Norton Healthcare (NHC). The evidence supports hospital environments that embraced OUs as a means of managing patients with chronic disease.

Evaluation Plan

Sample criteria were analyzed and evaluation has been completed for patients treated during the time period from January 28 – August 31, 2014 with the following diagnostic related groups (DRGs) and International Statistical Classification of Disease ICD codes (ICD-9 codes) for COPD: 190, Chronic Pulmonary COPD WMCC, 191, Chronic Obstructive Pulmonary Disease, W CCMS and 192, Chronic Obstructive Pulmonary Disease W/OCC/MCC MS (Schmidt & Schmidt, 2014). Additional data analysis were completed with patients who were admits to the PCDU as observations according to ICD-9 codes (See appendix F for CMS reimbursement rates for COPD). These codes are based on disease types and are utilized by healthcare settings in the United States and many other parts of the world (Mitus, 2008). ICD 9 codes are a common language that is used for understanding outpatient diagnoses the same way. ICD 9 codes for COPD observation are as follow 491.21, Chronic obstructive asthma with status asthmatic, 491.22, Chronic Obstructive Asthma, with Acute exacerbation, 491.9, Unspecific Chronic Bronchitis and 492.8, other emphysema. ICD-9 codes are assigned to patients who are admitted as observation.

Design

The study was a pilot of a retrospective study of data on patients admitted with COPD exacerbations to two different hospital settings within NHC. Norton Audubon Hospital (NAH) is a 432-bed acute care hospital specializing in cardiac, cancer, surgical, pulmonary,

neurology, and orthopedic, vascular, emergency and diagnostic care. The treatment group involved patients admitted as observation NAH on 4 East and 4 West. Patients who are assigned to an observation status primary diagnosis are based International Classification of Disease, Ninth Revision.

The other acute care facility included in the study is Norton Hospital (NH) a licensed 642-bed hospital with particular emphasis on advanced diagnostic and surgical procedures. NH served as the comparison facility. The hospital is a teaching facility for the University of Louisville School of Medicine. Norton Hospital's patients with COPD are the comparison group in the study. According to availability of beds in Norton Hospital, patients with COPD are admitted to different medical-surgical units.

Data Collection Plan

The data collection plan consisted of the following data elements for patients admitted as observation for COPD: the facility, admitting unit, discharge unit, discharge disposition, primary diagnosis, hospital status, co-morbidities, and length of stay in hours, age, and gender, charges per case, direct variable cost, observation hours and Pulmonologist on case. The evaluation of the outcome indicators will measure hours in observation, COPD 30-day readmission rates ED, 7day ED readmissions, variable cost per case and charges (see the Appendix G).

The primary outcomes associated with the proposal are: Thirty day readmission rates, the cost of care and ED 7 day readmission. The operational definitions for the financial variable associated with the cost of care are: charges- a price for services render while in the hospital, and variable cost- includes the cost for medications and supplies (Modern Healthcare, 2012). The

project timelines illustrates the road map for completing the requirements associated with the capstone project (see Appendix H).

Required Approval

The approval of the System Vice President of Medical Affairs and Care Continuum, The University of Louisville Institutional Review Board (IRB) office, and Norton Healthcare Office of Research Administration was received. The waiver was the required documentation for approval for evaluating the pilot project (see Appendix I).

Ethical Consideration

Permission to conduct the study was obtained according to policies outlined in the Institutional Review Board at Bellarmine University and Norton Healthcare. The analysis of existing data qualified this study for an exempt status. The project was retrospective analysis based on data retrieved from the electronic medical record. Confidentiality was maintained by using the medical record number. The data were password protected and kept on a personal computer in a locked office at NHC.

Data Analysis

Descriptive statistics were used to determine the characteristics of age, gender, discharge disposition, payer source, attending physician and secondary comorbidities. The Mann-Whitney U test was used to determine statistically significant difference in charges, variable cost and hours in observation between the control group and the intervention group. The Mann-Whitney U test is a nonparametric analysis that statistically verifies the likelihood that two independent groups have been taken from the same population. The Mann-Whitney U test is based on the comparison of each observation from the control group with each observation from the intervention group (Plichta & Garon, 2009). In other words, the Mann-Whitney test enables the

researcher to observe and compare difference between the performance of the control group and the intervention group.

Results

Pilot Characteristics

The pilot consisted of twenty-seven patients. Eight patients were in the intervention group and nineteen patients were in the control group. In the study, females with COPD diagnosis were more likely to be admitted to an observation status. Medicare and Kentucky Exchange were the major payer source and the majority of attending physicians overseeing the care of these patients were internal medicine specialists. Internal medicine specialists at NAH and NH are hospitalists employed by NHC. All patients in the study were discharged from observation status to home. Both groups had patients with secondary diagnoses including atrial fibrillation, acute or chronic renal failure, and diabetes accompanied by a primary diagnoses of COPD (Table 1).

Table 1. Characteristics difference between the control group and intervention group

	Mean (SD)	
	Control Group (N = 19)	Intervention Group (N = 8)
Age	62 (SD= 12.25)	61 (SD = 13.57)
Gender		
Male	8 (42%)	4 (50%)
Female	11(58%)	4 (50 %)
Payer		
Medicare	7 (37.%)	4 (50%)
Kentucky Exchange	8 (42%)	3 (37.5%)
Humana	1 (3.7%)	1 (12.5%)
United Healthcare	1 (3.7%)	
Private	1 (3.7%)	
Discharge disposition		
Home	19 (100%)	8 (100%)
Attending Physician		
Pulmonologists	1 (5.2%)	

Internal Medicine	12(63%)	8 (100%)
Family Medicine	4 (21%)	
Infectious Disease	1 (5.2%)	
Intervention Cardiology	1 (5.2%)	
Comorbidity		
Atrial Fibrillation	1 (12.5%)	1 (12.5%)
Tobacco Use Disorder	2 (10.52%)	
Iron Deficiency	1 (12.5%)	
Diabetes	1 (5.26%)	1 (12.5%)
Hypertension	4 (21%)	
History of Tobacco Use		1 (12.5%)
Acute Respiratory Failure	1 (5.26%)	
Acute and Chronic Respiratory Failure	1(5.26%)	1(12.5%)
Shortness of Breath	1(5.26%)	
Long Term Use Meds	1(5.26%)	
Coronary Artery Disease		2 (25%)
Chest Pain	2 (10.52%)	
Chronic Asthma		1 (12.5%)
Chronic Pulmonary Heart Disease	2 (10.52%)	
Convulsion Necrosis		1 (12.5%)
Pneumonia Organism	1(5.26%)	
Hypothyroidism	1 (5.26%)	

Observation Hours

Hours in observation for the control group, ranged from 22 hours to 96 hours with a mean of 38.47(SD = 20.01). The intervention hours in observation ranged from 16 hours to 48 hours with a mean of 34.50 (SD =13.42) The mean rank represents observation hours per patient while in observation status with COPD. The control groups (*Mdn* = 14.05) did not differ significantly from the intervention group (*Mdn* = 13.88, *U* = 75, *z* = 0.0265, p = 0.38). Observation hours were about the same in both hospitals over the same period of time. (Table 2).

Table 2. Observation hour for the control group and intervention group

	Mean(SD)				
	Control Group (N = 19)	**Intervention Group (N = 8)**	**z**	**P**	
Mean Rank	14.05	13.88	0.027	0.38	ns*

Observation hours	38.47(SD = 20.01)	34.50 (SD = 13.42)

*ns = not statistically significant

Charge Results

Financial analyses were performed to compare the cost associated with charges acquired while in observation. Charges were calculated utilizing the cost per day of caring for a patient in observation. Charges in the control group ranged from $7,012 to $24,853 a mean of $13,437 (SD =5,133) The intervention group charges ranged from $7,462 to $15,510 with a mean $10,265(SD = 2,982) The mean rank represent charges per patient while in observation status with COPD. The control groups (*Mdn* = 15.47.) did not differ significantly from the intervention group (*Mdn* = 10.5), $U = 48$, $z = 1.4602$, $p = 0.1443$. Charges were calculated utilizing the cost per day of caring for a patient in observation. (Table 3)

Table 3. Charge results comparing the control group and intervention group

	Mean(SD)				
	Control Group (N = 19)	**Intervention Group (N = 8)**	**z**	**P**	
Mean Rank	15.47	10.5	1.4602	0.1443	ns*
Charges	$13,437 (SD= 5,133)	$10,265 (SD = 2,982)			

*ns = not statistically significant

Direct Variable Cost

Direct variable cost while in observation in the control group ranged from $627 to $3,444 with a mean of $1,306 (SD = 655) The intervention group variable cost ranged from $216 to $1,125 with a mean $725 (SD =303) The mean rank represents charges per patient while

in observation status with COPD. The control groups (*Mdn* = 16.58) differ significantly from the intervention group (*Mdn* = 7.88 , *U* = 27 , *z* = 2.5753 , p = 0.00988. The PCDU provided a site to cohort patients with COPD which has demonstrated a significant reduction in direct variable cost. (Table 4)

Table 4. Direct variable cost comparing the two groups

	Mean(SD)				
	Control Group (N = 19)	**Intervention Group** (N = 8)	z	P	
Mean Rank	16.58	7.88	2.5753	0.00988	s*
Direct variable cost	$1,306(SD = 655)	$725 (SD = 303)			

*s = statistical significant

Readmission Outcomes

Evaluation of readmission data relating to the control group and the intervention group was conducted to compare the difference between 7-day ED readmission and 30-day readmission percentages. The data indicated that there are variations among the two groups when comparing readmission rates (Table 5).

Table 5. Readmission Percentages

	Percentage	
	Control Group (N = 19)	**Intervention Group (N = 8)**
7- day ED readmission	0	1 (12.5%)
30-day readmission	1 (5.2%)	0

Discussion and Conclusion

The primary objective of this quality improvement pilot was to determine if the PCDU reduced COPD 7-day and 30-day readmissions rates, lowered direct variable cost and decreased charges occurred while in the hospital. The capstone pilot was conducted on a small group of patients who were admitted to observation status with a diagnosis of COPD. Research in the development and use of observation units is still early in its adoption and implementation.

Multiple studies have demonstrated the clinical effectiveness of care delivery in specialty observation units (Suri, 2011). In the intervention group, patients were admitted in observation status to the 4th floor at Norton Audubon Hospital. The patients in this group were managed using protocols and order sets that were evidence based using the GOLD Standard for COPD as cited in Decramer & Wim, 2013. The control group consisted of patients admitted to Norton Hospital under observation status. The patients were not limited to any specific units, and there was no standardization in treatment. The findings are not surprising due to the length of the pilot and the sample size.

Comparison of the outcomes of readmission between the two groups did not reveal any trends. There was one 7-day readmission in the intervention group and no readmission at 30 days. The control group had no 7-day readmission and one readmission in 30 days. However, there was a statistically significant difference in direct cost, with a lower cost in the control group ($10,265 vs. $13,437; p=0.000988). A longer period of evaluating the effectiveness of the PCDU would be ideal in order to determine the potential long term impact of the unit.

Healthcare organizations are creating observation beds within ED's or within a nursing unit. During the pilot, the location of the PCDU was on the fourth floor of Norton Audubon Hospital . The PCDU was created by converting 8 existing beds on a 36-bed medical surgical unit. The conversion of the observation beds decreased inpatient bed capacity on that unit to 28

inpatient beds. Therefore, in the pilot, the analysis does not consider the startup cost associated with the PCDU.

The average daily patient census for the PCDU was 4 patients per day which converts into 50% unused capacity. At the same time with the escalating patient census associated with the Kentucky Exchange insurance program, inpatient volume increased by 20%. Due to the influx of patients from the ED requiring inpatient beds, the unused beds in the PCDU were frequently assigned to other admission status. Keeping in perspective, the PCDU was designed to admit pulmonary observation patients to the area. The influx of patients with different admission status and diagnosis types to the PCDU, was a primary factor that contributed to converting the PCDU beds back to medical-surgical beds.

Another crucial factor that contributed to the conversion of the PCDU back to medical-surgical beds was a lack of physician support. Physicians refused to admit patients to the PCDU due to personal preference and their lack of confidence with the PCDU staff's ability to provide care. Resources allocated to staff the PCDU were much lower as compared to acute care or an inpatient bed. The staffing in the PCDU was 1:5 nurse patient ratio. Staffing in medical-surgical units in the same hospital were 1:4 nurse patient ratio. A supportive leadership team and a systematic approach intended for the treatment of AECOPD are necessary in order for the PCDU to have remained open (Jagminas & Partridge, 2004) . Lack of physician support to admit patients to the PCDU is a major concern for future endeavors

Limitations

There were several limitations associated with this pilot. The optimal metric for determining the success of observation units is by measuring readmission rates. The literature supports observation units, not only to determine medical necessities, but also to reduce costs

associated with unplanned readmissions of patients with chronic disease (Ringquist, 2014). About $25 billion dollars each year is spent on 30-day hospital readmission for patients with chronic disease in United States (Robert Wood Johnson Foundation, 2013). Impacting readmission rates is a complex endeavor which requires healthcare organizations to create systems and structures to ensure that patients are able to manage their disease once they are discharged from the hospital. The operational definition for determining 30-day hospital readmissions defined by CMS does not include race, socioeconomics or noncompliance. Further research is necessary to address healthcare equity, language barriers, health literacy, social determinates and noncompliance in order to provide patients with the tool and resources to help manage their disease (Billings et al., 2012). Therefore, this should be an area of critical importance for future studies that will share the results of multiple organizations and the utilization of observation units to lower readmission rates.

The second limitation associated with the pilot is being able to control COPD observations of patients admitted to other nursing units within NAH. Although patients with AECOPD were admitted to the PCDU, the feasibility of replicating this strategy in another NHC facility is unknown.

Because the study was a retrospective evaluation, the third limitation of the pilot was the functionality of the EMR predictive model. Unplanned hospital admissions in the current EMR are not identified according to patients with the diagnosis of COPD. In order to determine if the readmission was planned or unplanned, the physician must document the reason for readmission in the EMR. Risk factors built in the EMR are generalized to the entire patient population. The current version of the EMR prediction model does not have the capability of

pulling data across multiple encounters. Therefore, the current readmission indicators within the model are very limited and without the evidence to support the validity of the model.

Finally, there is no method for determining the severity of illness when patients are assigned to observation due to the fact that patients in observation status are billed using outpatient codes. Each code is assigned a dollar amount which translates to the cost of care. When calculating the cost of care, claims data according to outpatient codes are collected by payment and not by research. Methods for determining the cost of care are dependent on accurately coding the information documented in the chart for reimbursement.

Recommendations

Recommendations for bringing observation units into practice have many implications. The literature supports that using standardized practices can result in improved outcomes by reducing avoidable readmissions, and reducing direct variable cost (Decker et al., 2008). The intervention analyzed in the pilot used a standardized process and did show a reduction in direct variable cost. Prior to the implementation of the PCDU, there was no contingency plans to address the issues of potential low patient census in the unit. The business decision to pilot the PCDU was based on historical volumes of an average daily census of 7 patients per day who were in observation for COPD at Norton Audubon Hospital . Therefore, according to the data, the assumptions were that the volumes would support the PCDU. Additional studies with attention to developing stronger physician acceptance and process improvement holds opportunities. Without the support from non-hospital employed Pulmonologists, the survival of the PCDU was a constant threat. Finally staffing was a major concern to physicians who sent their patients to the PCDU. Additional research is required in this area in order to ensure safe patient nurse ratios are in alignment with the evidence.

NAH successfully developed a clinical decision unit specifically for cardiovascular disease. Lessons learned from that experience were that the unit was closed, with admission only by a cardiologist, and there were well developed processes driven by protocols and order sets. Consideration of establishing a unit with a narrowly defined focus on COPD appears to have potential benefits in reducing costs and outcomes. The standardization of the process should involve the engagement of the physicians coordinating care, and would require a close relationship and communication among hospitalists and pulmonary specialists to develop the protocols and details of order sets to maximize return of adequate pulmonary function. The process would have to be designed to rapidly identify patients that would benefit from acute inpatient treatment. By having a standard approach, the training and focus of the nursing staff will improve the competencies of managing a complex set of patients. Coordinating care in this way encourages improved communication between physicians, nurses and patients, and subsequently reduce unnecessary and costly admissions.

Conclusion

The Affordable Care Act has transformed our nation's healthcare system and reimbursement structure. The shift in payment structures to improve quality, lower cost and to create a culture of sustainable outcomes has created urgency in today's healthcare environment. Technology is an important aspect of care coordination across the continuum for patients with chronic disease. In 2016, NHC is implementing an evidence-based predictive model in the EMR. Having a well-established electronic medical record with the capacity to drive analytics to determine contributing factors associated with hospital readmission is crucial in healthcare. Strategies to reduce hospital re-admissions are targeting high-risk patients.

Reducing the number of patients who are readmitted to the hospital with COPD is a priority within NHC. Hospitals must make certain that systems and structures are in place to ensure that patients receive the right level of care at the right time and right place. Diagnosis specific observation units are an innovative approach for providing an alternative level of care in which patients could benefit from an extended observation period. Studies have shown that OUs reduce re-admission rates, control cost, reduce the LOS, and impact the utilization of ED visits (Suri, 2011). Further research is recommended to identify other deliberate practices that can contribute to better outcomes.

Appendices

Appendix A. Capstone Charter

Program Sponsor	Jo Ellen Carpenter, DNP, Chief Nursing Officer	**Performance Improvement Leader**	Shirl Johnson
Business Owner	Amanda Newman		
Start/Target Date	September 21, 2013	**Project End Date:**	March 31, 2014
Project Description	At the present time, patients typically placed under observation status are not placed in one geographic location. These patients are mixed with inpatients, throughout the nursing units. Due to this, the nursing staff is focused on inpatient care and may not be accustomed to the pace and urgency necessary to move observation patients quickly. The healthcare space is undergoing significant financial and clinical disruption. As a result of these changes, NHC must improve processes associated with the clinical management of patients with Chronic Disease. The scope of this project is specific to patients admitted and discharged with a diagnosis of Chronic Obstructive Pulmonary Disease, COPD. Cost per case for treating COPD is higher as compare to national benchmarks. COPD. COPD patients also have a high readmission rate. This team will develop processes and tools to assist in cohorting patients, keeping patients out of the hospital and streamline orders set by identifying best practice for managing patients with COPD.		
Project Scope	The project extends to patients that present in the Emergency Department and do not require patient admission but do not meet criteria to be discharged and can benefit from further observation. Select direct admit patients that meet admission criteria may also be serviced in the Clinical Decision Unit.		
Goal (what will success look like?):	• Transition the placement of patients typically placed as observation from being distributed throughout the hospital to a dedicated location. • Utilize criteria for admission and discharge of the patients served in the unit. • Prioritize the workload by focusing on targeted patient populations being managed through other clinical effectiveness initiatives creating the opportunity to maximize outcomes. • Maximize clinical outcomes by implementing evidence based protocols and order sets, reduce length of stay, visits to the Emergency Department patients and decrease readmission rates.		
Metric	Metric (Decrease in): 1. Overall cost per case and other major cost drivers 2. Overall LOS 3. 31 day readmission rates (proper disease management function would focus and understand readmission failures) 4. ED visits between admission		
Business Results	In October 2012, the center of Medicare and Medicaid will financially penalty acute care facilities for patients readmitted within 30 days for any reason. Norton Healthcare needs to develop processes that will decrease readmissions and decrease the cost of care per case yet maintain or improve the quality of that care.		
Benefit to Customers	Patients are cohorted to one area Patients do not return to the hospital. Physicians will know their cost of care.		

Appendix B: Chronic Obstructive Pulmonary Disease Report Demographics

N= 692	**Average Age**	**Std deviation**
	65.45	11.83
Gender	**No. Discharges**	**Percentage**
Female	476	68.8%
Male	216	31.2%
Discharge disposition	**No. Discharges**	**Percentage**
Home, self-care	536	77.5%
Expired	3	0.4%
Skilled Nursing Facility	61	8.8%
Hospice	7	1.0%
Home Health Services	73	10.5%
Discharge/ transferred to rehab facility	7	1.0%
Against medical advice	5	0.7%
No.	692	100%

Appendix C. Measure Phase, Chronic Obstructive Pulmonary Disease Report-(DRG, 190,191 and 192)

Measure	Average	Std deviation	No. Discharges
Direct variable Cost	$ 2,966	$2,294	692
Length of Stay	4.52	2.87	692
	Rate	**No. Readmits**	**No. Discharges**
Any ED 7 days readmission	3.1%	21	684
Any reason 30 day readmission	18.4%		

Appendix D***Clinical Decision Unit Physician Orders for COPD and Asthma Exacerbation Admission	
NOTE: Check boxes below to initiate order	
Date:	Time:
Place for observation Service Level: Admitting Physician: Anticipated length of stay: Anticipated post discharge needs: Bed request comment: **Adult Code Status** (Single Response) {}Full Code {}Allow a natural death (DNR) {}Adult DNR with comfort measure panel **POC**	
{}POCT blood glucose monitor	Routine, 4 times daily before meals and at bedtime
{}POCT blood glucose monitor	Routine, Once for 0 occurrence
{}POCT blood glucose monitor	Routine, every 6 hours
Laboratory	
{}CBC w/Diff	Routine, Morning draw at 0400 for 1 o occurrence
{} Blood Gas , Arterial	Routine, Once
{}NT-ProBNP	Routine, Once
{}Basic Metabolic Panel (BMP)	Routine, Morning draw at 0400 for 1 occurrence
{}HCG, Qualitative	STAT , once for 1 occurrence, if not done in the ED
{}Comprehensive Metabolic Panel (CMP)	STAT , once for 1 occurrence, if not done in to the ED
Radiology	
{} XR Chest 2 VW	Routine1 time imaging for 1 occurrence Reason for exam: COPD/Asthma. Is patient pregnant? What is the patient's sedation requirement?

Appendix D (continues)***Clinical Decision Unit Physician Orders for COPD and Asthma Exacerbation Admission

NOTE: Check boxes below to initiate order

CT

{} CT Chest wo contrast — Routine 1 time imaging for 1 reason for for exam: COPD or Asthma
Is patient pregnant?
What is the patient's sedation requirement?

{} CT Chest wo & w contrast — Routine 1 time imaging for 1 reason for for exam: COPD or Asthma
Is patient pregnant?
What is the patient's sedation requirement?

Cardiac Status

ECG

{}EKG 12 lead — Routine, Once
Consult/Referring Cardiologist:
Family Physician:
Reason for exam: COPD/Asthma

VTE Prophylaxis and Core Measure

Mechanical Device, Medication and Contradictions
All adult IP admission must be evaluated for VTE prophylaxis within 4 hours of admission.
At least one of the following orders must be selected for these patients
NOTE: If VTE screening score is greater than 1, please order mechanical compression device to comply with Core Measure requirements.

{}Place mechanical compression device — Routine every 12 hours
Mechanical Compression Device: Calf length
{} Fondaparinux (Arixtra) injection — 2.5 mg, Subcutaneous, every 24 hours
Routine
{} Enoxaparin (Lovenox) syringe — 40 mg, subcutaneous, every 24 hours
Routine

{}Low risk- no VTE prophylaxis needed
{}INR greater than 3- no VTE prophylaxis needed
{}Patient refused VTE prophylaxis
{}Patient is possible risk for VTE but there is a contraindication to Mechanical and medication VTE prophylaxis - Admission
{} Contraindication for Mechanical VTE

Appendix D (continues) ***Clinical Decision Unit Physician Orders for COPD and Asthma Exacerbation Admission

NOTE: Check boxes below to initiate order

Antibiotics

{} Azithromycin (Zithromax) : 500mg oral, daily ,routine

{} Doxycycline (Vibramycin) : 100mg, oral 2 times daily, routine

Beta-2 Agonist

{} Ipratropium-Albuterol Minineb& treatment and linked panel

- {} Albuterol-Ipratropium (Duo-neb) 0.5 – 2.5 mg/dl nebulizer Nebulization, every. 4 hours (RT)
- {} Nebulizer Treatment routine , every 4 hours (RT) Routine

{} Ipratropium-Albuterol Minineb & treatment And Linked Panel

- {} Albuterol-Ipratropium (Duo-neb) 0.5 – 2.5 mg/dl nebulizer Nebulization, every 2. hours (RT) Shortness of Air. Routine
- {} Nebulizer Treatment (RT) Routine, every 2 hours.

Corticosteroids (Single Response)

- {} Methyl Prednisolone Sodium Succinate) Solumedrol 60 mg, Intravenous, Every 8 hours Injection, Routine
- {}Methylprednisolone sodium succinate (Solumedrol) 40 mg, Intravenous Every 8 hours Injection, Routine
- {} Methyl Prednisolone Sodium Succinate)Solumedrol 20 mg, Intravenous, Every 8 hours Injection, Routine
- {} Methylprednisolone sodium succinate (Solumedrol) 40 mg, oral, daily with breakfast

Leukotriene Receptor Antagonists

- {}Montelukast (Singular) tablet 10 mg, Oral, Nightly, Routine

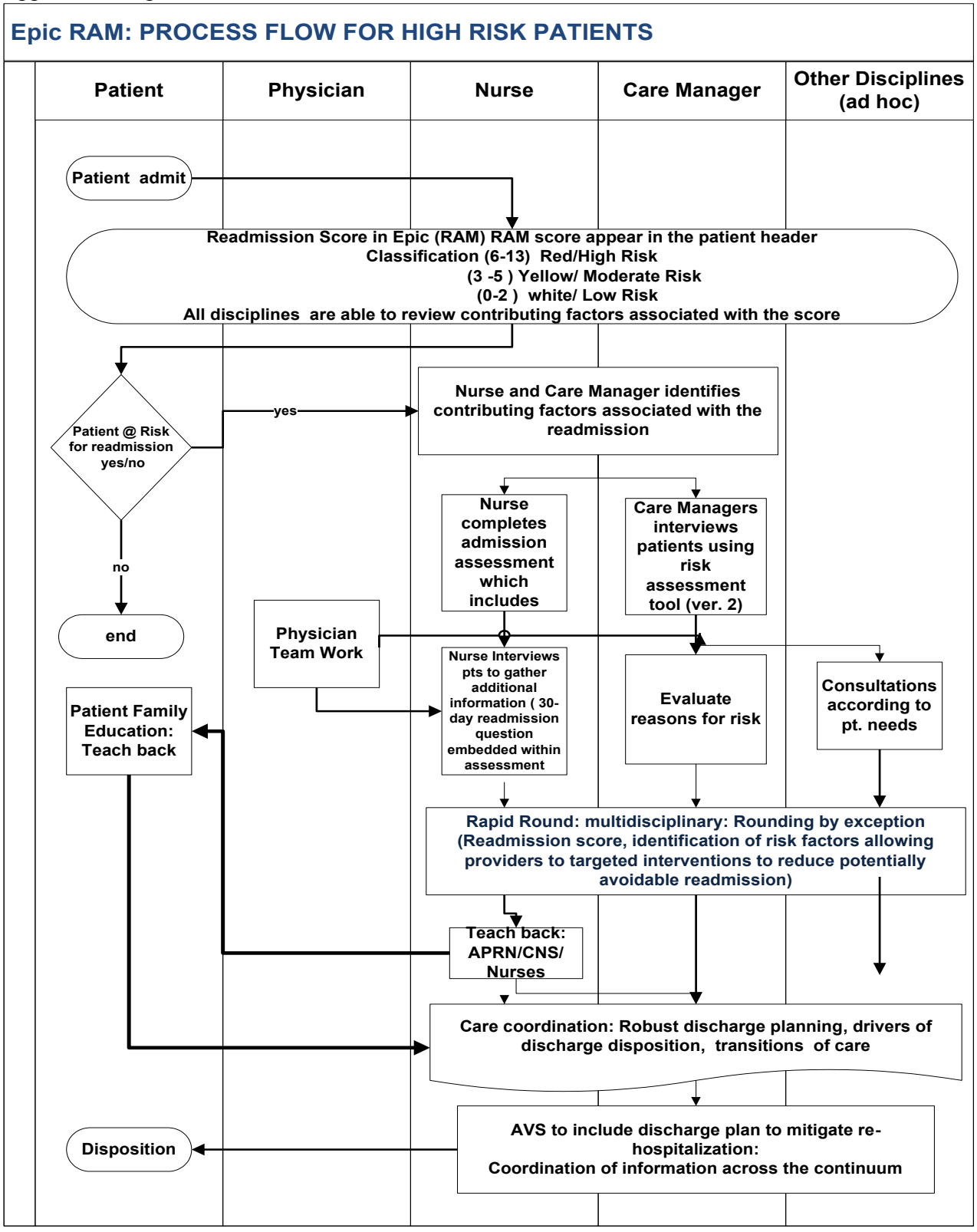
Stress Ulcer Prophylaxis (Single Response)

- {}Pantoprazole (Protonix) EC table 40 mg, Oral, Nightly,, Routine
- {} Famotidine (Pepcid) tablet 20 mg, Oral, 2 times daily , Routine

Other

- {}Nicotine (Nicoderm C Q) 21 mg/24hr 1 patch, Transdermal, daily, starting today at 9:00 AM

Appendix E. Epic RAM work flow



Appendix F. Medicare Diagnoses Related Group Reimbursement Benchmarks for COPD

DRG	Description	GMLOS	AMLOS	Relative Weight	National Payment Rate
190	Chronic Obstructive Pulmonary Disease W MCC	4.2	5.1	1.11743	$6,332.71
191	Chronic Obstructive Pulmonary Diseas WCC	3.4	4.2	0.937	$5,052.87
192	Chronic Obstructive Pulmonary Disease W/O CC/MCC	2.7	3.3	0.719	$3,877.38

The National average payment for DRG is calculated by multiplying the current weight of the DRG by the national average hospital Medicare base rate. The national average hospital Medicare rate is the average of the full up to date labor related and non-labor related amount published in the Federal Register, FY 2015, and Final Rule. This information is provided as a benchmark reference only. There is no official publication of the average hospital base rate: therefore, the national average payments provided in this table are approximated (Schmidt & Schmidt, 2014, p. 588).

Appendix G. Outcome Measurements

Outcome Measurements
January 28, 2014 - August 30, 2014

What to Measure		**Why does it need to be measured?**					
Outcome/Process Indicator	Measure/Operational Definition	Rationale for Measure Selection	**Data Collection Approach**	How often is it collected?	Who will be doing the collection ?	Norton Healthcare Baseline 2013	Target/Improve Medicare Claims Data
Inpatient In patient: CODP 30-day Readmission Rates (190, Chronic Pulmonary COPD WMCC, 191, Chronic Obstructive Pulmonary Disease, W CCMS and 192, Chronic Obstructive Pulmonary Disease W/OCC/MCC)	Re-admissions are measured by a ratio, by dividing a hospital's number of "predicted" 30-day re-admission diagnosis by the number that would be expected, based on comparing the average re-admission rates with other hospitals with similar patients.	Readmission within 30 days of discharge as an inpatient, is costly and a sign that the healthcare system failed the patient	How will it be collect?	Monthly	The raw data will be provided to me from the Clinical Information Analysts.	Mean: 16.8%	Reduce monthly readmission rates for COPD to meet or exceed CMS national performance
Observation Status : 491.21, Chronic obstructive asthma with status asthmatic, 491.22, Chronic obstructive Asthma , with acute exacerbation, 491.9, Unspecific chronic bronchitis and 492.8, other emphysema	International Statistical Classification of Disease ICD-9 codes. ICD-9 codes are assigned to patients who are admitted as an observation status. Theses codes are based on disease types and are utilized by healthcare settings in the United States and many other parts of the world .	ICD codes are a common language that is used for understanding outpatient diagnoses the same way	Readmission queries are built in Epic by the Clinical Information Analysts	Monthly	The raw data will be provided to me from the Clinical Information Analysts.	method to calculate COPD observation numbers. The system does not have a method to calculate obs conversion rates at this time. The number of Observation patients that code out as observation is the only mechanism for capturing	none
Length of Stay	Length of stay is the number of nights the patient remained in the hospital for his or her stay.	LOS is a guide to hospital economic, performance and is often a indicator of efficiency.	Observation queries are built in Epic by the Clinical Information Analyst	Monthly	The raw data will be provided to me from the Clinical Information Analysts.	(Combine cost for DRG 190, 191, 192) Mean: 4.76, std 3.13	Medicare Rates
Cost of Care	Charges- a price for services render while in the hospital Variable cost- includes the cost of medication and supplies	Cost control is thus fundamental to the nation's fiscal sustainability and economic well-being. Because of that, it is the key to successful health care reform.	Length of stay is calculated by subtracting the day of admission from the day of discharge.	Monthly	The raw data will be provided to me from Strategic and Business Planning Department	Norton Health Care Variable cost (Combine cost for DRG 190, 191, 192): Average Mean $3,156, std $2,895	See DRG Medicare reimbursement chart below
Emergency department 7-day ED readmission	ED visit 7 day readmission after discharge from the hospital	Patients who most likely to visit the ED post discharge are patients with COPD		Monthly	The raw data will be provided to me from Strategic and Business Planning Department	NAH 7 day ED readmission: Baseline 3.1%	NHC 2014 Goal: 2.5%

Appendix H: Program Study Timeline: A Pilot Study of a Pulmonary Clinical Decision Unit on Outcomes in Patients with Chronic Obstructive Pulmonary Disease

	Aug 2014	Sep 2014	Oct 2014	Nov 2014	Dec 2014	Jan 2015	Feb 2015	Mar 2015	Apr 2015	May 2015	Jun 2015	Jul 2015	Aug 2015	Sep 2015	Oct 2015	Nov 2015	Dec 2015
Project Approval/Development	X																
Update Review of Literature	X																
Communicate with Capstone chairs		X															
Stakeholder Involvement			X														
Develop Methodology				X													
First Pass : Draft to Chair				X													
Confirm Technology and pathway for gathering data from Epic					X												
					X												
Finalize Proposal						X											
Defend Proposal							X										
IRB Protocol and Approval, if appropriate											X						
Conduct Project : Gather componts											X						
Residency																	
Gather Retrospective Data											X						
Assemble Components											X						
Input Data											X						
Analyze Data											X						
Write Project													X	X	X		
Defend Project																X	
Graduation																	X

Appendix I:

UNIVERSITY OF LOUISVILLE

Human Subjects Protection Program Office
MedCenter One – Suite 200
501 E. Broadway
Louisville, KY 40202-1798
Office: 502.852.5188 Fax: 502.852.2164

DATE: August 06, 2015

TO: Shirl D Johnson

FROM: The University of Louisville Institutional Review Board

IRB NUMBER: 15.0459

STUDY TITLE: A Retrospective Analysis: The Impact of a Pulmonary Clinical Decision Unit on Outcomes in Patients with Chronic Obstructive Pulmonary Disease

REFERENCE #: 353981

DATE OF REVIEW: 08/03/2015

IRB STAFF CONTACT: Name: Sherry Block
Phone: 852-2163
Email: slbloc04@louisville.edu

The revised document(s) for the above referenced study have been received and contain the changes requested in our letter of 07/22/2015. This study was reviewed on 08/03/2015 by the Chair/Vice-Chair of the Institutional Review Board (IRB) and approved through the Expedited Review Procedure, according to 45 CFR 46.110(b), since this study falls under Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

This study was also approved through 45 CFR 46.116(D), which means that it has been granted a waiver of informed consent because it meets the following criteria:

- The research involves no more than minimal risk to the subjects
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, the subjects will be provided with the additional pertinent information after participation.

The following items have been approved:

Submission Components			
Submission Form			
Title	Version Number	Version Date	Outcome
data collection tool 07/24/2015	Version 1.0	07/24/2015	Approved
Complete Waiver	Version 1.0	06/04/2015	Approved
Research Proposal	Version 1.0	02/28/2015	Approved

This study now has final IRB approval from 08/03/2015 through 08/02/2016. The committee will be advised of this action at their next full board meeting.

Site Approval

If this study will take place at an affiliated research institution, such as KentuckyOne Health, Norton Healthcare or University of Louisville Hospital, permission to use the site of the affiliated institution may be necessary before the research may begin. If this study will take place outside of the University of Louisville Campuses, permission from the organization should be obtained before the research may begin. Failure to obtain this permission may result in a delay in the start of your research.

Privacy & Encryption Statement

The University of Louisville's Privacy and Encryption Policy requires such information as identifiable medical and health records: credit card, bank account and other personal financial information; social security numbers; proprietary research data; dates of birth (when combined with name, address and/or phone numbers) to be encrypted. For additional information: http://security.louisville.edu/PolStds/ISO.PS018.htm.

Implementation of Changes to Previously Approved Research

Prior to the implementation of any changes in the approved research, the investigator will submit any modifications to the IRB and await approval before implementing the changes, unless the change is being made to ensure the safety and welfare of the subjects enrolled in the research. If such occurs, a Protocol Deviation/Violation should be submitted within five days of the occurrence indicating what safety measures were taken, along with an amendment to revise the protocol.

Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs)

In general, these may include any incident, experience, or outcome, which has been associated with an unexpected event(s), related or possibly related to participation in the research, and suggests that the research places subjects or others at a greater risk of harm than was previously known or suspected. UPIRTSOs may or may not require suspension of the research. Each incident is evaluated on a case by case basis to make this determination. The IRB may require remedial action or education as deemed necessary for the investigator or any other key personnel. The investigator is responsible for reporting UPIRTSOs to the IRB within 5 working days. Use the UPIRTSO form located within the iRIS system to report any UPIRTSOs.

Continuation Review Requirements

You are responsible for submitting a continuation review 30 days prior to the expiration date of your research study. Investigators who allow their study approval to expire have committed significant non-compliance with federal regulations. Such lapses may require reporting to federal agencies, a program audit by compliance auditors to ensure that subjects were not enrolled during the expired period, and may lead to findings of serious and continuing non-compliance if expiration were to occur a second time.

1099 Information (If Applicable)

As a reminder, in compliance with University policies and Internal Revenue Service code, all payments (including checks, gift cards, and gift certificates) to research subjects must be reported to the University Controller's Office. Petty Cash payments must also be monitored by the issuing department and reported to the Controller's Office. Before issuing compensation, each research subject must complete a W-9 form.

For additional information, please contact the Controller's Office at (502) 852-8237 or control@louisville.edu.

If you have any questions, please contact the HSPPO at (502) 852-5188 or hsppofc@louisville.edu

Thank you for your submission.

Serge A. Martinez, M.D., J.D., Vice Chair,
Biomedical Institutional Review Board

UofL Institutional Review Boards
IRB NUMBER: 15.0459
IRB APPROVAL DATE: 08/03/2015

COMPLETE WAIVER OF AUTHORIZATION

Study Title	
Retrospective Analysis: The Impact of a Pulmonary Clinical Decision Unit on Outcomes in Patients with Chronic Obstructive Pulmonary Disease	
PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR (PI/PD)	
Name (Last Name, First Name, MI) Johnson, Shirl	**Email Address** Shirl.johnson@nortonhealthcare.org
Mailing Address – Include University Department (if applicable) 234 E. Gray Street, Suite 364 Louisville, KY 40202	**Telephone Number** 502-494-2700
	Pager/Cell Phone Number
	Fax Number

Please indicate the Covered Entities from which you will seek PHI in this research. Please check (✓) all that apply.

Affiliated Sites		**Non-Affiliated Sites**	
[✓]	University of Louisville (Do not remove this check.)	[ ]	Louisville Metro Department of Public Health & Wellness
[ ]	Jewish Hospital & St. Mary's Healthcare	[ ]	KY Cabinet for Health & Family Services
[✓]	Norton Healthcare, Inc., including Kosair Children's Hospital	[ ]	Seven Counties Services
[ ]	University of Louisville Hospital/J. Graham Brown Cancer Center	[ ]	Other(s):

University of Louisville Research Foundation (ULRF) Clinical Sites. Please check (✓) all that apply.

[ ]	Children & Youth Clinic	[ ]	UL Pathology Flow Cytometry Lab (BCC)
[ ]	Dentistry Clinics (Undergraduate DMD; Graduate, Perio, Endo and Ortho; Oral Surgery and GPR at ACB; Faculty Practice, Graduate Pedodontic Clinic)	[ ]	UL Pathology Special Procedures Lab
[ ]	Family Medicine – (Newburg and Central Station; also Geriatrics and Sports Medicine at Central Station)	[ ]	University Health Services (HSC and Belknap)
[ ]	Harambee Nursing Center	[ ]	Weisskopf Child Evaluation Center
[ ]	Kidney Disease Program (Dialysis Unit and UL Renal Transport Lab)	[ ]	WHAS Crusade For Children Audiology & Speech Pathology Center
[ ]	Neonatal Follow Up Program	[ ]	WINGS Clinic – (ACB)

Faculty Practice Group Sites. Please check (✓) all that apply. If Other, please specify.

[ ]	University Anesthesiology Associates, PSC	[ ]	University Pediatrics Foundation, Inc. d/b/a University Child Health Specialists, Inc. (UCHS)
[ ]	University Radiological Associates, PSC	[ ]	University Children's Sleep Specialists, LLC
[ ]	University Physicians Associates (UPA)/ UPG – Radiology, PSC	[ ]	University Children's Infectious Dis. Specialists, LLC
[ ]	University Emergency Medicine Associates, PSC	[ ]	University Children's Kidney Specialists, LLC

[ ]	University Family Practice Associates, PSC	[ ]	University Children's Sedation Service, LLC
[ ]	University Physicians Associates (UPA), PSC	[ ]	University Pediatric Endocrinology, LLC
[ ]	University Medical Associates, (UMA), PSC	[ ]	Bone Marrow Transplant, LLC
[ ]	Associates in Dermatology, PLLC	[ ]	Neonatal Associates, PSC
[ ]	University Neurologists, PSC	[ ]	Pediatric & Perinatal Pathology Associates, PSC
[ ]	Neurosurgical Institute of Kentucky, PSC	[ ]	Pediatric Cardiology Associates, PSC
[ ]	University GYN/OB Foundation, Inc.	[ ]	Pediatric Hematology/Oncology Specialists, PSC
[ ]	University OB/GYN Associates, PSC	[ ]	Pediatric Pulmonary Medicine, PSC
[ ]	Ophthalmological Services, Inc. – Primary Eye Clinic	[ ]	University Psychiatric Foundation, Inc.
[ ]	Eye Specialists of Louisville, PSC	[ ]	University Psychiatric Services, PSC
[ ]	Kentucky Vision Center, Inc.	[ ]	University Radiotherapy Associates, PSC
[ ]	Shea, Tillett, Malkani, Caborn, PSC	[ ]	University Surgical Associates, PSC
[ ]	Spine Institute, PSC	[ ]	University Pediatric Surgery Associates, PSC
[ ]	Orthopedic Trauma Associates, PSC	[ ]	University Cardiothoracic Surgical Associates, PSC
[ ]	University Pathologists, PSC	[ ]	University Urology, PLLC
[ ]	Louisville Pathology Laboratory Associates, Inc.	[ ]	Other(s):

This form is to be used when it is not feasible to obtain an authorization prior to viewing PHI (PHI means health information plus one or more of the 18 identifiers under the HIPAA regulations).		
1.		Please explain why your research project cannot be done using de-identified information. If you need to look at identified information, but only will be collecting de-identified information, this is still using identified information for your research project. (NOTE: Responses "b" and "c" cannot both be checked.) [ ] a. This project requires health information from multiple holders that needs to be linked using identifiers. [✓] b. This project requires the retention of identified health information to answer the research question. [ ] c. While this project does not require the retention of identifiable information, identifiable information must be accessed to extract the de-identified information. [ ] d. Other - please explain:
2.	a.	For your research activities, please specify the health information that will be viewed, collected, or disclosed by you and the research team to conduct this research. (Some examples of health information may include: consultation reports, operative records, medical progress notes, or diagnostic test results.)
		Viewed: Name, medical record number, Facility, admitting unit, discharge unit, discharge disposition, primary diagnosis, hospital status, co-morbidities, length of stay, age, gender, cost per case
		Collected: Medical record number, Facility, admitting unit, discharge unit, discharge disposition, primary diagnosis, hospital status, co-morbidities, length of stay, age, gender, cost per case
		Disclosed (shared with anyone other than key personnel listed in the research application): Facility, admitting unit, discharge unit, discharge disposition, primary diagnosis, hospital status, co-morbidities, length of stay, age, gender, cost per case
	b.	Please describe why the information you wish to view, collect, and/or disclose is the minimum necessary for the research project based on the protocol (reference protocol section(s) or page(s)). Do not state "See protocol." The information collected will help determine if there is any impact on a pulmonary clinical decision unit for patients with COPD.

3.	a.	The health information identified in 2, combined with one or more of the identifiers listed below becomes PHI. Please indicate which of the following identifiers, if any, of the subject, relative of subject, household member of the subject, or employer of the subject, will be viewed, collected, and/or disclosed by you or any other investigator for this research project. Please check (✓) all that apply.		
		[✓]	1.	Name (including initials)
		[ ]	2.	All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code.
		[✓]	3.	All elements of dates except year, for dates directly related to an individual, e.g., date of birth, admission date, discharge date, date of death. For individuals who are 90 years or older, all elements of date, including year, is considered a "direct identifier." Note: if such ages and elements are aggregated into a single category of "age 90 or older" then it is not considered to be a direct identifier.
		[ ]	4.	Telephone numbers
		[ ]	5.	Facsimile numbers
		[ ]	6.	Electronic mail addresses
		[ ]	7.	Social Security numbers (full or partial, including the final four digits)
		[✓]	8.	Medical Records numbers, prescription numbers
		[ ]	9.	Health Plan numbers
		[ ]	10.	Account Numbers
		[ ]	11.	Certificate/license numbers
		[ ]	12.	Vehicle identification/serial numbers/license plate numbers
		[ ]	13.	Device identifiers/serial numbers
		[ ]	14.	Universal Resource Locators (URLs) for Web sites
		[ ]	15.	Internet Protocol (IP) Address
		[ ]	16.	Biometric Identifiers, e.g. fingerprints, voice prints
		[ ]	17.	Full face or comparable photographic images
		[ ]	18.	Any other unique number, characteristic, or code that could be used to identify the individual. (If you abstract any unique identifiers, please specify.)
	b.	Additionally, if you are collecting demographic information (e.g. age, gender, ethnicity, education, income, etc.), please specify the information that will be viewed, collected and/or disclosed for this research study. Age and gender will be collected and disclosed.		
	c.	Please attach a copy of the data collection form when submitting the Complete Waiver. If the data collection form is unavailable, please explain: **If the data collection form is unavailable for submission, please note that a data collection form determined to be inconsistent with this waiver may impact the ongoing status of your study.**		
4.		Please indicate your sources of the PHI that will be viewed, collected, and/or disclosed for this research study. Please check (✓) all that apply.		
		[✓]	1.	Physician/clinic records
		[✓]	2.	Hospital/medical records
		[ ]	3.	Databases collected for informational/reporting purposes
		[ ]	4.	Data previously collected for research purposes
		[✓]	5.	Diagnostic test results
		[ ]	6.	Interviews/questionnaires
		[ ]	7.	Other – Please describe:

5.		In order for the Privacy Board to determine that the use and disclosure of PHI involves minimal risk to a subject's privacy, please respond to a, b, and c below.		
	a.	By law/regulation/policy/study site you may be required to disclose PHI to one or more of the following oversight agencies/offices: OHRP, OCR, CMS, FDA, NHORA, ULH RIO, JHSMH CAM, UofL IRBs/Privacy Boards, HSPPO, UofL Privacy Office. Are you planning to disclose PHI from one covered entity to an outside entity or other individuals outside the Research Team? Yes [ ] No [✓] If No, go to 6.b.		
		If so, to whom will you disclose (share) the PHI?		
		[ ]	1.	Sponsor and/or agents of the sponsor
		[ ]	2.	Research oversight offices and collaborators at other institutions
		[ ]	3.	Other, please identify:
	b.	Are you planning to retain identifiers in paper and/or electronic format to conduct this study? (Note: If you are retaining identifiers such as a list of dates of service, medical record numbers, list of names, etc., then you must protect the identifiers you will use to identify potential subjects.) Yes [✓] No [ ] If no, proceed to the **"Attestation of Investigator."** If yes, please select the longest policy or regulatory retention requirement that is applicable to your research project from the list below. If there is a reason to retain identifiers longer than any period listed below, please describe in the "Other" section below. [ ] University Record Retention Policy (retain research information 5 years post submission for publication or publication, whichever is longer) [✓] Common Rule (retain research information 3 years following closure of the study) [ ] FDA (retain 2 years following FDA submission, approval or FDA notification of discontinuation of investigation, whichever is longer) [ ] Contractual requirements [ ] Other (please explain)		
	c.	Describe your plan to protect identifiers in paper format from improper use and/or disclosure by completing the applicable questions below.		
	c.1.	Are you storing PHI in paper form? Yes [ ] No [✓] If No, please proceed to "ATTESTATION OF INVESTIGATOR."		
		Please describe the permanent location of the paper form.		
		Please describe the security measures that you will put in place for stored data. Will the data be kept in a locked file cabinet? Yes [ ] No [ ] Will the cabinet be kept in a locked office or store room? Yes [ ] No [ ] Will the area be a locked/limited access area? Yes [ ] No [ ] Describe any additional security measures, including the security measures for paper data in transit.		

ATTESTATIONS OF INVESTIGATOR

By submitting this document for Privacy Board approval and electronically signing your submission in IRIS, you attest, that PHI will not be reused/disclosed to any other person or entity, except:

1) as required by law,
2) for authorized oversight of the research project, or
3) for other research for which use/disclosure of PHI would be permitted by the HIPAA privacy regulations.

The researcher, listed below, and his/her entire research team agree:

1) that this Complete Waiver will be used to access only the specific PHI identified in this document.
2) that only the undersigned will be permitted to use this Complete Waiver to obtain PHI from the entities identified in this document.
3) to share the PHI obtained under this document only with those persons or entities identified by this document.
4) to provide sufficient documentation to any covered entity where PHI is obtained so that an accounting of disclosures can be generated.
5) **to maintain, store, and/or transmit any PHI, obtained during this study, on any electronic media (server, desktop computer, laptop, PDA/Smart phone, USB drive, DVD/CD or any other electronic storage media) in a manner consistent with the University of Louisville Information Security Policies and Standards.**

PRINCIPAL INVESTIGATOR:
Shirl Johnson

RESEARCH TEAM:
List all research team members:
Shirl Johnson, MSN, CNS, MHA
Elizabeth Couch

NORTON HEALTHCARE
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August 7, 2015

Shirl Johnson, RN, MSN, CNS, MHA
234 E Gray Street
Louisville, KY 40202

NHORA# 15-N0056 / IRB# 15.0459 / Retrospective Analysis: The Impact of a Pulmonary Clinical Decision Unit on Outcomes in Patients with Chronic Obstructive Pulmonary Disease

Dear Ms. Johnson:

The Norton Healthcare Office of Research Administration (NHORA) is pleased to notify you that your application to conduct the above-mentioned research study in the following Norton Healthcare (NHC) facility has been approved.

- **Norton Audubon Hospital** **Norton Hospital**

Please note: NHORA approval reflects permission to conduct the study within a Norton Healthcare facility from a regulatory and contractual perspective, and is independent of approval by the sponsor for initiation of the study. The sponsor or site may have additional requirements to address before the study can begin.

The following items must be submitted to the NHORA if your study continues to be conducted in a NHC facility and are applicable to your study:

- **Annual Progress Report/Continuation Review form**
- **Annual Approval letters and current Informed Consent Forms approved by the IRB, if applicable**
- **Amendments and Amendment Approval letters**
- **Revised HIPAA documents such as revised Partial Waivers/Complete Waivers of authorization for each change in personnel**
- **Changes in the Conflict of Interest status**
- **Status change of study, i.e. closed to enrollment, study termination etc.**

To comply with HIPAA regulations:

- **A copy of the Partial Waiver of Authorization must be filed with the medical record of every patient screened for the study, if applicable.**
- **For retrospective chart reviews, a copy of the Complete Waiver of Authorization must be filed with the medical record of every patient whose chart is reviewed for the study.**

For studies utilizing an Informed Consent Form, **a signed copy of the Informed Consent Form and Research Authorization must be filed with the medical record of each subject enrolled in your study in a NHC facility.**

If applicable, the Research Patient ID form must be submitted to NHORA Billing daily with reportable activity. Please email the form to NHORABilling@nortonhealthcare.org. Please contact Regina Schaefer at 502-629-3580 for specific instructions regarding the notification of your subject enrollment at NHC.

We look forward to the successful completion of your study. If you have any further questions or need assistance, please contact the NHORA at (502) 629-3501.

Please let us know how we are doing. Follow the link https://www.surveymonkey.com/s/NHORAsatisfaction to complete the NHORA Satisfaction Survey in less than two minutes. Your feedback helps NHORA improve the services we provide and meet the needs of the research community.

Sincerely,

Rhonda A. Hoffman

Rhonda Hoffman
System Director Research

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