Stakeholder priorities for comparative effectiveness research in COPD: a Workshop report

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ONLINE DATA SUPPLEMENT

METHODS

CONCERT is a multi-institutional interdisciplinary consortium of clinicians and investigators at six academic and community healthcare centers that provide care to diverse patient populations in managed and non-managed care settings at private and government institutions in the U.S. CONCERT convened two workshops in collaboration with a diverse group of stakeholders to prioritize comparative research effectiveness (CER) agendas for COPD in each of the following four areas: 1) chronic care, 2) care coordination, 3) acute care, and 4) transitions in care between healthcare settings.

At the onset of this project, we were unable to find a published precedent for engaging stakeholders to prioritize research questions for CER in COPD, so we relied on general principles of engaging a diverse pool of stakeholders, including patients and caregivers, clinicians, healthcare payers, and health services researchers. We identified groups within each of these stakeholders, in consultation with the AHRQ program officer, before sending invitations to stakeholder groups to nominate representatives. We were encouraged that a high proportion of invited stakeholder groups agreed to participate; however, not all stakeholder groups participated (a list of groups who were invited but declined or did not respond in time to participate is presented in the legend for Table 1 in the published report).

First workshop: Chronic COPD care and care coordination (May 2009)

Stakeholders participated via teleconference in one of two Working Groups (Chronic COPD care; COPD care coordination) to plan the workshop. Each Working Group was asked to

propose approximately ten Provisional Topics using three criteria for nomination: (1) evidence gaps in effectiveness or implementation strategies, (2) evidence indicating gaps in quality of care compared to guidelines, and (3) the potential to improve healthcare delivery and clinical outcomes. (E1-E4) To ensure that topics were selected using an explicit, evidence-based approach, Working Group members were instructed to conduct literature searches using electronic databases to substantiate the need for CER. Databases searched included the Computer Retrieval of Information on Scientific Projects (now replaced by NIH RePORTER), ClinicalTrials.gov, and Cochrane Central Register of Controlled Trials. (E5-E8) Deliberations occurred via teleconference calls and e-mail exchanges, concluding with a pre-workshop provisional prioritization vote. Each member of the Working Group was asked to rate, via an anonymous vote, the importance of topics by assigning an importance score between 1 (very important) and 9 (most unimportant) following a modified Delphi approach. (E9, E10) A Briefing Book (Table E2) including background material for the Provisional Topics and the results of the pre-workshop prioritization vote (Table 2 in main manuscript) was distributed prior to the in-person workshop.

The first workshop day consisted of presentations by speakers, including a representative of the Centers for Medicare and Medicaid Services, the Joint Commission, and experts in effectiveness and implementation research. On the second day, Working Group co-chairs moderated discussions among stakeholder representatives to rank research topics. As the pre-workshop prioritization vote demonstrated ceiling effects, we modified the final voting to employ ranks (1 [most important] to 9 [most unimportant]). To more clearly observe differences in priorities within each CER area, stakeholders were informed that no two topics should be assigned the

same importance rank. All workshop participants contributed to discussions, but the final prioritization vote (with procedures to ensure anonymity) was limited to a single individual for each stakeholder organization. At the conclusion of the first workshop, attendees completed a 10-question online satisfaction survey to provide anonymous feedback regarding the format and content of the meeting and to improve the planning for the second workshop.

Second workshop: Acute COPD care and Transitions in COPD care (May 2010)

In an effort to advance the consensus methodology, two changes were made in the methods employed for the second workshop. First, stakeholders were asked to vote on the importance of various criteria for setting CER priorities. The ballot included criteria that were identified during discussions with stakeholders about provisional research topics and supplemented with criteria proposed in the Affordable Care Act for comparative effectiveness research.(E11) Second, the Analytical Hierarchy Process (AHP) was used to quantify the relative preferences for different CER topics. (E12-E14) The AHP is a structured technique for organizing, analyzing, and making complex group decisions in a variety of settings, including government, business, industry, and education. In the AHP, pairs of options from the set of all options being considered are formed (e.g., option 1 vs. 2, option 1 vs. 3, option 2 vs. 3). Each voter is asked to record the relative importance of each pair of options by assigning it a score between 1/9th as important and 9 times as important. Votes are aggregated, producing "normalized priorities" representing the proportion of the total importance across all topics that voters ascribe to a particular research topic. Topics can be then be ranked from most to least important by their normalized priorities. The ratio of normalized priorities for any two topics indicates their relative importance or preference (idealized priority). The voting patterns using AHP can be compared with random

judgments (random voting patterns). A Consistency Ratio (CR) greater than 0.1 suggests, by convention, that voting patterns are not sufficiently different from a random voting pattern to be trustworthy (i.e., a CR >0.1 indicates that voting patterns were not internally consistent). The CR for acute care voting (0.01) and for transition in care voting (0.01) were each less than 0.1, suggesting that expressed preferences by stakeholders were overall internally consistent. Thus, the AHP approach quantifies the separation between any two options (e.g., how much more important is the most highly ranked topic compared to the second most highly ranked topic) while also evaluating the internal consistency of expressed preferences. We are not aware of other published reports using AHP for quantifying stakeholder support for CER topics.

Comments from stakeholders

Prior to finalizing this workshop report, stakeholders, including government agencies, and the CONCERT External Advisory Committee were invited to submit comments to a draft containing the prioritized research agenda.

Strengths and limitations of methodology

The methodology employed in our stakeholder engagement process had multiple strengths. It promoted and sustained dialogue between diverse stakeholders, prioritized different aspects of COPD care, and evaluated the relative importance of different criteria used when stakeholder groups set CER priorities. In Year 2, AHP provided a structured approach to quantify and compare preferences for different CER topics and to evaluate the internal consistency of voting patterns. Limitations include the disproportionate influence that a dynamic speaker may have had on consensus building. These effects were partially mitigated by our use of experienced

workshop chairs, a large diverse group of stakeholders who applied a modified Delphi methodology to provide an opportunity for all discussants to contribute to the consensus building process, and procedures used for in-person voting that ensured anonymity. The list of research topics and questions may not have been as comprehensive as one generated by more stakeholders or a different group of stakeholders. For example, we invited Pharmaceutical Research and Manufacturers of American (PhRMA), the leading trade organization for the pharmaceutical industry and biotechnology companies, to identify a representative for participating in the research conferences. However, only Boehringer Ingelheim Pharmaceuticals, Inc., one of the PhRMA members, participated in the research conferences. Also, representatives of other segments of industry (e.g., device manufacturers) were not participants. The appropriate balance of patients/caregivers in setting research priorities is unclear and many groups have sought to increase patient involvement in response to funding opportunities from the Patient-Centered Outcomes Research Institute (PCORI). Two patient groups (Respiratory Health Association, and COPD Foundation) were involved in conference activities and contributed to discussions and voting. Even greater patient engagement may be appropriate and, as with industry representation, future efforts may benefit from including a wider cross-section of stakeholder representatives. Also, we did not ask stakeholders to rank order the importance of research across the four areas (e.g., chronic care vs. care coordination); this aspect of prioritization could be a subsequent step. Face-to-face meetings are costly, but appear to be important as they received high levels of stakeholder support and led to changes in CER priorities compared to results of pre-workshop votes. We did not conduct qualitative approaches to identifying a comprehensive set of criteria used by stakeholders when setting research priorities; we believe

further research to identify a parsimonious list of the most important criteria is needed to facilitate full deployment of AHP.

We invited stakeholder organizations to nominate individuals who could represent the interests of the organization in a multi-stakeholder meeting and we published a short biography of each participant and their role in the stakeholder organization in the Briefing Books for the meeting. We did not, however, ask participants to disclose potential clinical, intellectual (e.g., research areas) or financial conflicts of interest. Disclosure and management of potential conflicts of interest has gained substantial traction in recent years, particularly in clinical guideline development. We recommend a similar approach in future efforts to define research priorities.

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190

191 **Table E1.** Provisional research topics and questions identified by stakeholders

192

Topic	Questions
	Year 1: Chronic COPD Care
Spirometry for diagnosis and treatment	• What is the comparative effectiveness of different approaches to implementing use of spirometry in primary care to confirm the diagnosis of COPD (e.g., increased reimbursements, use of EMRs and other tools to serve as cues/reminders)? • What is the comparative effectiveness of using symptoms vs. spirometry in increasing patient and adherence to COPD treatment guidelines? In improving patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)? • What is the comparative effectiveness of using a fixed FEV1/FVC ratio vs. an age-adjusted FEV1/FVC ratio in increasing the accuracy of COPD diagnosis? In improving patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)? • What is the comparative effectiveness of early identification and treatment of GOLD Stages 1-2 COPD through the use of screening spirometry in high risk populations vs. usual care in these populations on patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?
Effectiveness of Pulmonary rehabilitation	• How well do community-based pulmonary rehabilitation programs adhere to guidelines compared to hospital based pulmonary rehabilitation programs? • What is the comparative effectiveness and cost-effectiveness of community-based vs. hospital-based pulmonary rehabilitation programs? • What factors serve as barriers / facilitators for access to pulmonary rehabilitation as part of chronic COPD care? • What is the comparative effectiveness of short-term vs. chronic (indefinite) pulmonary rehabilitation on patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)? • What factors serve as barriers / facilitators for patient adherence to pulmonary rehabilitation for COPD care?
Effectiveness of COPD care and guideline translation	• How can guideline recommendations be implemented into community practice in a way that is feasible, usable, relevant, and cost-effective? (examples are use of care management, translation of chronic care

	model, and EMR based tools) • How can we best develop, harmonize, and use performance measures for COPD care to increase patient-centered, effective, safe, timely, efficient, and equitable care?
Home care	• What is the comparative effectiveness and cost-effectiveness of nurse-assisted home care (patient education to improve self-management skills and nurse implementation of COPD action plans) vs. usual care on patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?
Development of performance measures	• What is the sensitivity and specificity of current approaches based on administrative/billing data to identify patients with COPD for quality improvement initiatives? Which approach offers the optimal combination of sensitivity and specificity? • What is the validity of administrative/billing data to evaluate the quality of COPD care as part of quality improvement initiatives? What care practices can be assessed using these data? • How do patient factors (e.g., presence of comorbid conditions), provider factors (e.g., training or board-certification), and practice factors (e.g., for vs. not-for-profit) affect the validity of administrative data to identify patients with COPD and evaluate the validity of indicators for assessing the quality of COPD care?
Oxygen therapy	• How well do patients with COPD adhere to continuous Long-term Oxygen Therapy (LTOT) and how do differences in adherence modify the effectiveness of continuous LTOT on patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)? • How well do patients with COPD adhere to non-continuous LTOT (e.g., prescribed during exercise or during sleep only) and how do differences in adherence modify the effectiveness of non-continuous LTOT on patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)? • What factors are associated with reducing or increasing adherence to LTOT for COPD? • What can be done in primary care settings to increase appropriate provider assessment of the need for oxygen and prescription of LTOT? • What is the comparative effectiveness of prescribing continuous LTOT in COPD that targets fixed oxygen flow rates vs. oxygen saturation on patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)? • What is the comparative effectiveness and cost-effectiveness of continuous LTOT in COPD via nasal cannula, reservoir cannula, transtracheal catheter, and demand oxygen pulsing devices on patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)? What is the comparative effectiveness of interventions delivered by the Home Medical Equipment (HME) supplier of oxygen for COPD patients to improve adherence vs. usual care on patient-reported

	outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?

193

Palliation of symptoms	• Does palliative care and/or hospice care as practiced across communities improve end-of-life care for COPD – specifically, does it reduce the burden of symptoms, improve HRQoL and satisfaction, reduce utilization in last 6 months of life (i.e. hospital visits, cost, invasive ventilation use, etc), improve the end-of-life experience, and increase the concordance of place of death to expressed patient preferences? • What is currently done in clinical practice to measure and characterize dyspnea in patients with chronic COPD and how do different assessment approaches function with respect to guiding management and improving patient's symptoms and health-related quality of life? • Do palliative care interventions improve symptom management for patients with advanced COPD who are not within 6 months of death?
Pharmaceutical treatment	• What is the prevalence of triple therapy using LABAs, ICS, and tiotropium in large and diverse populations of patients with moderate to severe COPD? • What is the comparative effectiveness of triple therapy with LABAs, ICS, and tiotropium compared to LABAs, or tiotropium, or LABAs plus ICS, or tiotropium plus ICS, in terms of COPD exacerbations and hospitalizations? • What is the cost-effectiveness of triple therapy with LABAs, ICS, and tiotropium compared to LABAs, or tiotropium, or LABAS plus ICS, or tiotropium plus ICS?
Smoking cessation	• What barriers and facilitators modify the effectiveness of smoking cessation programs in patients with COPD? • What is the comparative effectiveness and cost effectiveness of counseling plus nicotine replacement vs. counseling plus bupropion vs. counseling plus varenicline on smoking cessation rates, patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations), and COPD and non-COPD morbidity/mortality? • What is the comparative effectiveness of usual care vs. enhanced reimbursement (tied to the level of adherence to smoking cessation guidelines) on rates of providing appropriate smoking cessation care and smoking cessation rates in patients with COPD? • What is the comparative effectiveness of an on-site smoking cessation program embedded within a medical clinic vs. off-site referral to a smoking cessation program on smoking cessation rates and patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)? • What is the comparative effectiveness and cost-effectiveness of community-based vs. hospital-based smoking cessation programs on smoking cessation rates and patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality,

exacerbations)?

194

Year 1: COPD Care Coordination	
Management of COPD in the presence of comorbidity	• Does a protocol-based screening for commonly occurring comorbid conditions in patients with COPD (eg. CAD, CHF, depression, sleep apnea) improve management and outcomes for patients with COPD? • How should providers coordinate management strategies and treatment goals in patients with COPD and other co-existing chronic diseases? • What is the comparative effectiveness and safety of guideline-recommended COPD care in patients with 'few' vs. 'many' clinically significant (e.g., depression, sleep disorder, cardiovascular) comorbidities? • What should be the clinical endpoints in frail elderly vs. other patients with COPD when titrating COPD care? • How do we generalize our educational efforts such that multiple co-morbidities and their self-care can be addressed?
Pulmonary rehabilitation as model for care coordination	• What interventions can be used to increase access to pulmonary rehabilitation services? • Can pulmonary rehabilitation integrate rehabilitation for other chronic conditions in a way that truly optimally manages people with multimorbidity?
Impact of depression and mental health management	• What is the impact of screening for depression on outcomes of patients with COPD? • Does an automatic referral to a mental health provider in patients with COPD and acute depressive disorder episode(s) improve quality of depression care and outcomes in patients with COPD? • Does a care coordination program improve the detection and treatment of co-morbid depression in patients with COPD? • Does Integrated Mental Health Care and COPD treatment improve outcomes for both conditions?
Measurement of quality of care coordination	• What are the measurable important components of care coordination?
Quality of care coordination	• How good is the quality of care coordination for patients with isolated COPD? • How good is the quality of care coordination for patients with COPD and other co-existing conditions? • What factors are associated with high quality care coordination in patients with COPD?

195

196

Comprehensive COPD patient education	• What is the impact of an organized, comprehensive, COPD patient education program, on medication delivery effectiveness, care plan adherence, appropriate use of LTOT and Pulmonary Rehabilitation? Metrics could include incidence and severity of exacerbations, and health care resource consumption. • What are the essential components/techniques of an effective self-management patient education program, and how do we measure success, (i.e. self-efficacy)? • How do we generalize our educational efforts such that multiple co-morbidities and their self-care can be addressed? • What is the comparative effectiveness of brief interventions to teach patients respiratory inhaler use (e.g., verbal and written instructions) vs. teach-to-goal interventions (brief interventions plus demonstration of correct technique, patient teach-back, feedback, and repeat instruction if needed) on respiratory inhaler technique and patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?
Cost-effectiveness of care coordination	• Are care coordination models in COPD cost-effective?
Case management	• What is the effectiveness of a case management program compared to usual care in patients with COPD? • What is the effectiveness of case management programs and other chronic conditions (eg. heart failure, diabetes) compared to usual care in patients with COPD? • How is effectiveness related to how linked the intervention is to the person's physicians and primary source of care?
Developing a tool for risk stratification	• Can a tool be developed to group patients into risk categories for resource utilization?
Patient-centered medical home	• Does the presence of a patient-centered medical home improve outcomes in patients with COPD compared to usual care? • Does a patient-centered medical home improve outcomes relative to other care coordination or care management strategies?
Scheduled multidisciplinary team consultation	• Does use of periodic and automatic multidisciplinary team consultation improve care and health outcomes of patients with COPD?

197

198

Year 2: Acute COPD Care	
Implementation of COPD Exacerbation checklist	• Does implementation of a checklist designed to improve the care of patients with COPD exacerbations result in greater adherence to guideline recommendations? • Does implementation of a checklist designed to improve the care of patients with COPD exacerbations results in improved patient outcomes
Co-morbid conditions in the acute setting	• What treatment modalities are effective for patients with a combined diagnosis of AE-COPD with other co-morbid diseases? • What outcomes measures are reliable for patients with combination diagnosis (AE-COPD + other co-morbid conditions)? • What is the comparative effectiveness of prescribing statin medications versus placebo to patients with exacerbations of COPD who do not have known vascular disease? • What is the comparative effectiveness of prescribing ACE-inhibitors versus placebo to patients with exacerbations of COPD who do not have known left ventricular dysfunction? • Is there a role for these medications in patients with more mild COPD who do not present with acute exacerbations? • Does of screening for pulmonary embolisms in COPD exacerbations improve COPD-related 30-day and 6-month mortality? Does the utility of screen for PE correlate with severity of disease in COPD?
Effectiveness and Implementation of NIV in acute respiratory failure	• What is the comparative effectiveness of a Non-invasive vs. Invasive Positive Pressure Ventilation Protocol for managing acute respiratory failure due to acute exacerbations of COPD • Compare in-hospital mortality for patients presenting with ARF-COPD who are managed in emergency departments utilizing a NIPPV Implementation Protocol versus emergency departments practicing usual care. • Compare hospital length of stay and costs for patients presenting with ARF-COPD who are managed in emergency departments utilizing the CONCERT NIPPV Implementation Protocol versus emergency departments practicing usual care. • Compare duration of ventilator support (invasive and non-invasive) and hospital length of stay for patients who require invasive ventilation due to ARF-COPD that are managed by a NIPPV based weaning protocol versus usual care. • Compare hospital mortality for patients who require invasive ventilation due to ARF-COPD that are managed by a NIPPV based weaning protocol compared versus usual care. • What is the percentage of ideal candidates for treatment with noninvasive ventilation that receive this therapy in routine clinical practice? • How much variation is there in the use of noninvasive ventilation across hospitals? • What are the patient, physician and hospital characteristics associated with higher rates of use among ideal candidates?

	• To what extent do the outcomes of patients treated with non-invasive ventilation vary across hospitals? • What are the organizational characteristics and practices of hospitals that apply noninvasive ventilation to a high percentage of ideal candidates?; what are the facilitators and barriers to successful implementation and delivery of noninvasive ventilation?
Role of antibiotics in acute exacerbations	• Can using macrolide antibiotics in COPD exacerbations reduce time to recovery to baseline and length of stay? • What is the optimal timing and dosing strategy for the anti-inflammatory effects of macrolides (*e.g.* a 1-time loading dose in the ED)? • What are the comparative benefits of oral corticosteroids and antibiotics versus oral corticosteroids alone for outpatient COPD exacerbation? • What are the comparative harms of each of the treatment groups? • What is the incremental cost-effectiveness of the intervention from a societal perspective? • What is the longitudinal effectiveness of the intervention for patients who have multiple exacerbations? • What is the effectiveness of the telemonitoring system to detect COPD exacerbations? • What is the effectiveness of the telemonitoring system to trigger treatment for COPD exacerbations? • Can serum procalcitonin measurement be used to safely identify patients with COPD exacerbations who do not require antibiotic therapy? • Can repeated / serial serum procalcitonin measurements be used to safely reduce the duration of antibiotic administration for patients with COPD exacerbations?
Quality of care assessment	• How can guideline recommendations be implemented into COPD exacerbations care practice in a way that is feasible, usable, relevant, and cost-effective? • How can we best develop, harmonize, and use performance measures for COPD exacerbations care to increase patient centered, effective, safe, timely, efficient, and equitable care? • What is the sensitivity and specificity of current approaches based on administrative/billing data to identify COPD exacerbations patients for quality improvement initiatives? Which approach offers the optimal combination of sensitivity and specificity? • What is the validity of administrative/billing data to evaluate the quality of COPD exacerbations care as part of quality improvement initiatives? What care practices can be assessed using these data? • How do patient factors (e.g., presence of comorbid conditions), provider factors (e.g., training or board-certification), and practice factors (e.g., for vs. not-for-profit) affect the validity of administrative data to identify patients with COPD and evaluate the validity of indicators for assessing the quality of COPD care? • What are national benchmarks for quality of care (needs a registry)?

Dyspnea crisis in COPD	• Identification, risk assessment, and first response • Efficient utilization, communication, and care coordination • Utility of patient education and provider aid products • Translational research into audit quality enhancement tools
Oxygen therapy post-exacerbation	• Should LTOT requirements be based on targeted oxygen saturations at rest and during activity, lower utilization of health care resources, or improvement of the patient's respiratory quality of life?
Interventions for acute airway obstruction	• Is there a role for tiotropium in addition to nebulizer treatments in acute COPD exacerbations, particularly in terms of reducing utilization of nebulizer treatments, recovery to baseline, and reducing length of stay?

201

202

Year 2: Transitions in Care	
Integrated healthcare strategies during transitions in COPD care	• Which programs or program elements are most critical (the "active ingredients") in improving quality of life, reducing hospitalizations, reducing emergency department visits, and increasing survival? • What is cost effectiveness of multi-component COPD programs? • Do regularly structured visits by social workers as part of the interdisciplinary COPD health care team assist patients and family members in dealing with transitions of care (e.g., use of home care services to long term care, hospital to home with home care services)? • Does having a nominated Primary Care Provider (continuous and comprehensive) on discharge or prior to admission improve the process of transition, delay readmission, expedite discharge or reduce health care costs? • Do admission rates for COPD exacerbations change over time as universal coverage is introduced in the USA? • Will early admission to a Pulmonary Rehabilitation program following a hospitalization for COPD reduce the likelihood of readmission within the following year? • Will a COPD symptom self-management plan augment the benefits of Pulmonary Rehabilitation? • What is the most effective time to implement the transition from hospitalization to rehabilitation following a COPD exacerbation admission? • What is the clinical and economic impact of a case management program that is hospital–based, with monthly telephonic visits from a health care professional with expertise in respiratory care? • How do patient and provider factors support/deter patients' ability to participate in pulmonary rehabilitation post-exacerbation? • How often is pulmonary rehabilitation prescribed for patients post-exacerbation and what factors influence this prescription?

203

204

Multimorbidity and transitions in COPD care	• What is the effectiveness of guideline recommendations for chronic obstructive pulmonary disease (COPD) care in patients with multimorbidity, including angina, heart failure, atrial fibrillation, diabetes mellitus, hypertension, and osteoporosis, vs. patients without these conditions? • What is the effectiveness of guideline recommendations for COPD care in patients with baseline-reduced physical function, including reduced activities of daily living (ADL), incontinence, sensory impairment, and/or poor upper-extremity function, vs. patients without these conditions? • What is the effectiveness of guideline recommendations for COPD care in patients with baseline-reduced cognitive function, including reduced executive function, vs. patients without reduced cognitive function? • What is the effectiveness of guideline recommendations for COPD care in patients with psychosocial difficulties, including those who are socially isolated, depressed, anxious, have low levels of education, or are alcohol dependent, vs. patients without these conditions? • What is the rate of misclassification of diagnosis (COPD vs. not) when using a fixed FEV/FVC ratio to diagnose COPD in older patients? • How does multimorbidity, reduced physical function, reduced cognitive function, and psychosocial difficulties modify the ability to implement COPD guidelines?
Patient and Family Activation during transitions in COPD care	• Does the use of professional translation and/or interpretation services in acute care settings (e.g. emergency departments, hospitals, or acute care clinics) make a difference in the health care outcomes (e.g. readmission rates) after discharge for limited English Proficiency (LEP) patients who are diagnosed with COPD? • What is the effectiveness of using already developed transition of care (TOC) tools such as patient and family caregiver checklists to improve health and psychosocial outcomes for persons with COPD who are transitioning between settings? • What is the effectiveness of communication about Goals / Preferences of Care during transitions in COPD care? • In patients hospitalized with COPD, what is the comparative effectiveness of a teach-to-goal strategy versus usual care on the ability to use respiratory inhalers and re-admissions after hospital discharge? • In patients hospitalized with COPD, what is the cost-effectiveness of a teach-to-goal strategy versus usual care? • Does one-on-one COPD education in the primary care physician's office by a qualified Respiratory Educator improve patient Quality of Life, health care utilization and exercise tolerance whilst maintaining lung function? • Does one-on-one COPD education in the primary care physician's office by a qualified Respiratory Educator reduce health care costs? • What type of family input is sought in development of these programs? • What do families identify as most important components of these programs? • When considering economic impact of interventions, is “informal care” by family members a part?

205

206

End of Life/Palliative Care and transitions in COPD care	• Do persons with a primary diagnosis of COPD who transition to hospice benefit from client engagement efforts to identify and address psychosocial needs? • Do patients with COPD have more successful transitions from hospital to long term care, or from home to long term care or to receiving hospice services, if they participate in support groups led by professional social workers to assist patients with dealing with locus of control issues as they live with an incurable disease and struggle to breathe? • Among patients with COPD, determine if interventions to improve clinicians' end of-life communication enhances patient-centered outcomes (e.g. concordance of care, death and dying experience, patient/family satisfaction with end-of-life care). • Among patients with COPD who are at high risk for mortality, determine whether outpatient referral to palliative care improves the patients' dying experience when compared to usual care. • Among patients with COPD, examine the effect of COPD-specific advance care planning versus usual advance care planning on the quality of end-of-life care and patient-centered outcomes. • Does palliative care and/or hospice care, as practiced across communities during transitions in care, improve end-of-life care for patients with COPD – specifically, does it reduce the burden of symptoms, improve HRQoL and satisfaction, reduce utilization in last 6 months of life (i.e. hospital visits, cost, invasive ventilation use, etc), improve the end-of-life experience, and increase the concordance of place of death to expressed patient preferences? • What is currently done in clinical practice to measure and characterize dyspnea in patients with chronic COPD and how do different assessment approaches affect patients during transitions, especially with respect to guiding management and improving patient's symptoms and health-related quality of life? • Do palliative care evaluations and interventions improve symptom management for patients with advanced COPD receiving care in emergency departments and what is the effectiveness of programs in acute settings that aid transitions to comfort-focused care preferences?
Early diagnosis and treatment of COPD	• What topics and methods of presentation are most useful to enhance patient participation in and adherence to COPD therapies?
Modeling effects of interventions and transitions in COPD status	• What measures other than PFT data can be used to predict risk of relapse (e.g., re-hospitalization, urgent care visit, or ED visit) following hospital discharge after treatment of COPD exacerbations? • What measures other than PFT data can be used to predict risk of COPD exacerbations (e.g., hospitalization, urgent care visit, or ED visit for COPD exacerbations)?

207

208

Table E2. Briefing Book for Workshop in Year 1: Chronic COPD care, and Care coordination for patients with COPD

2009 CONCERT Workshop Briefing Book

Setting Effectiveness and Translational Research Priorities to Improve COPD Care

SETTING EFFECTIVENESS AND TRANSLATIONAL RESEARCH PRIORITIES TO IMPROVE COPD CARE

May 21-22, 2009, San Diego, CA

"The Edge" room, Hard Rock Hotel – San Diego

Table of Contents

*List of speakers and pre-workshop voting results have been removed from the briefing book because they are included in the main body of the manuscript

SETTING EFFECTIVENESS AND TRANSLATIONAL RESEARCH PRIORITIES TO IMPROVE COPD CARE

May 21-22, 2009, San Diego, CA

"The Edge" room, Hard Rock Hotel – San Diego

Day 1 (May 21, 2009)

Morning Facilitators: Shannon Carson, MD; Mary Ann McBurnie, PhD; Supriya Janakiraman, MD, MPH

Time	Title	Speaker
7:30A-8:30A	*Breakfast/Registration*	
8:30A-8:40A	Introduction/Welcome: COPD as a growing health problem and the CONCERT collaboration	Jerry A. Krishnan, MD, PhD, University of Chicago
8:40A-9:20A	State-of-the art in COPD treatment in chronic care settings	Bartolome Celli, MD, COPD Foundation
9:20A-10:00A	Gaps in the quality of COPD care and race/gender disparities in care: What is known and unknown?	Richard Mularski, MD, MSHS, MCR, Center for Health Research, Kaiser Permanente Northwest
10:00A-10:10A	*Break*	
10:10A-10:50A	Successes and barriers to measuring the quality of COPD care: Lessons from the Physician Quality Reporting Initiative	Mark A. Levine, MD, Centers for Medicare and Medicaid Services
10:50A-11:30A	Certification programs for best practices in COPD	Caroline B. Isbey RN, MSN, CDE, The Joint Commission
11:30A-12:30P	*Lunch*	

Afternoon Facilitators: Barbara Yawn, MD, MSc; Gerene Bauldoff, PhD, RN; Supriya Janakiraman, MD, MPH

12:30P-1:10P	Epidemiology of multiple chronic conditions and elderly patients with COPD	Todd Lee, PharmD, PhD, Center for Management of Complex Chronic Care, Hines, VA
1:10P-1:50P	Challenges to the care of patients with multiple chronic conditions	Cynthia Boyd, MD, Johns Hopkins University
1:50P-2:00P	*Break*	
2:00P-2:40P	Improving COPD care in rural populations	Michael Glasser, PhD, National Center for Rural Health Professions
2:40P-3:20P	Disease management programs: lessons learned from heart failure	Frederick Masoudi, MD, MSHP, University of Colorado
3:20P-3:50P	Conclusions/Wrap-Up	William Vollmer, PhD

Day 2 (May 22, 2009)

Two half-day sessions will focus on developing a consensus-based clinical effectiveness and implementation research agenda on 1) *Chronic COPD care*; and *2) Care coordination in COPD.*

Time	Title	Speaker
8:00A-9:00A	Breakfast	
9:00A-12:00P	Evaluating and improving chronic COPD care	Chairs: R. Mularski, MD, MSHS, MCR, & W. Vollmer, PhD
12P-1:00P	Lunch	
1:00P-4:00P	Evaluating and improving COPD care coordination	Chairs: P. Lindenauer, MD, MS, & T. Lee, PharmD, PhD

Chronic COPD Care Provisional Topics

Provisional Topic: Oxygen Therapy

Background/rationale:
The benefit of supplemental oxygen for patients with COPD and severe resting hypoxemia has been well established in a few landmark randomized trials (NOTT and MRC) performed more than 30 years ago. Oxygen therapy is one of the few treatment modalities shown to improve mortality in such patients. These results have helped to spawn a major industry in supplemental oxygen therapy and the development of innovative techniques to improve oxygen delivery to patients (e.g., oxygen conservation devices). Given the proliferation and variety of oxygen therapy devices, the absence of standardization, limited evaluation of the efficacy of such devices in comparison to standard continuous flow oxygen in patients with chronic lung disease, and the market forces that drive selection and use of oxygen therapy modalities, it appears that providers who prescribe supplemental oxygen have limited knowledge of the options available and are unaware of the variation in oxygen delivery provided in devices generally chosen by the Durable Medical Equipment supply company. Also, given the fact the oxygen is generally prescribed based on assumed equivalency to continuous flow rates rather than to any measures of effect (e.g., oxygen saturation), there is no assurance that patients are being adequately oxygenated by available devices.

Long-term oxygen therapy (LTOT) prolongs life of patients with COPD whose resting PaO2 is lower than 60 mmHg at sea level (NOTT, MRC). And other than smoking cessation, LTOT (>12 - 15h / day) confers the greatest mortality benefit. Although Medicare guidelines assume that individuals who demonstrate inclusion criteria of NOTT and MRC trials will benefit from LTOT and those who fail to exhibit inclusion requirement will not benefit, cohorts of these two trials unlikely represent all patients with COPD. (CMS; Croxton) Specifically, Medicare reimbursed LTOT is available for patients with:

- PaO2 55 mmHg or less at rest or during sleep.
- PaO2 55 mmHg or less during exercise, if supplemental oxygen is demonstrated to improve the exercise-associated hypoxemia.
- PaO2 of 56-59 mmHg if they also have dependent edema, pulmonary hypertension or hematocrit higher than 56%.

While indications for LTOT largely are based on mortality data, some studies also have suggested improvements in other outcome measures, including a mild beneficial effect on mean pulmonary arterial pressure, Chronic Respiratory Questionnaire (dyspnea domain) scores, exercise capability, quality of life, frequency of hospitalizations, depression, and cognitive function. (Croxton; Eaton; McDonald; Fletcher; Timms; Nonovama; Bradley; Cranston). Contrary to NOT and MRC trials, other findings strongly suggest that individuals with less severe COPD do not, as a group, derive any survival benefit from LTOT. For example, when resting mean PaO2 is 60 mmHg or higher, no survival advantage is associated with LTOT (Gorecka; Chaouat).

Several relevant oxygen therapy trials are underway (1 & 2) or planned (3 & 4) including:

1. Effectiveness of Long-Term Oxygen Therapy in Treating People With Chronic Obstructive Pulmonary Disease (The Long-Term Oxygen Treatment Trial [LOTT]) – Sponsored by National Heart, Lung, and Blood Institute (NHLBI) and Centers for Medicare and Medicaid Services.
2. Effect of Oxygen in Normoxaemic COPD Patients Who Desaturate During Exercise -- Sponsored by Hvidovre University Hospital.
3. Long-Term Oxygen Treatment (LTOT) in Chronic Obstructive Pulmonary Disease: Factors Influencing Survival – Sponsored by Association Nationale pour le Traitement à Domicile de l'Insuffisance Respiratoire.
4. Long-Term Oxygen Therapy (LTOT) in Chronic Obstructive Pulmonary Disease (COPD) Patients With Moderate Chronic Hypoxemia and Chronic Heart Failure (CHF) – Sponsored by University of Modena and Reggio Emilia.

Recent advances in technology include oxygen conservation devices as well as portable oxygen concentrators (POC). Devices may not deliver a constant nor accurate liter flow. Patients and providers also stress exercise and activity for COPD patients and some LTOT devices may require a more dynamic titration than a static liter flow. Amongst obstacles to translation are recent literature that is sparse about dosing of LTOT. This is especially frustrating since with the newer pulse-dose POCs, dosing may be more appealing to patients than traditional continuous flow. Since the 1980s, (Celli BR Eur Respir J 2004) the accepted standard has been to simply elevate the arterial oxygen tension to 60 mm Hg (or) the SPO2 to 90%. When blood oxygen levels fall below these levels, adverse cardiovascular consequences (pulmonary hypertension, cor pulmonale) are seen and concern in practice still exists regarding altering a patient's hypoxic drive with too much oxygen. A recent study (Strickland) where the mean SPO2 was 95% and no adverse consequences were reported. It should be noted that the authors did not actually seek a specific saturation target - - the patients only used their study portable devices for 5 minutes before the 6 MWT, so the saturation levels reached were not controlled. Finally, the EFRAM study (Garcia-Aymerich) suggested that under-dosing of LTOT was a risk factor for exacerbations. Newer devices have been developed to overcome barriers and facilitate adherence, but it is not clear whether such devices are as effective in providing adequate oxygenation for these patients. Patients also often have very poor understanding of the indications and rationale for oxygen therapy.

Provisional questions:

- How well do patients with COPD adhere to continuous Long-term Oxygen Therapy (LTOT) and how do differences in adherence modify the effectiveness of continuous LTOT on patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?
- How well do patients with COPD adhere to non-continuous Long-term Oxygen Therapy (LTOT; e.g., prescribed during exercise or during sleep only) and how do differences in adherence modify the effectiveness of non-continuous LTOT on patient-reported

outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?

- What factors are associated with reducing or increasing adherence to LTOT for COPD?
- What can be done in primary care settings to increase appropriate provider assessment of the need for oxygen and prescription of LTOT?
- What is the comparative effectiveness of prescribing continuous LTOT in COPD that targets fixed oxygen flow rates vs. oxygen saturation on patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?
- What is the comparative effectiveness and cost-effectiveness of continuous LTOT in COPD via nasal cannula, reservoir cannula, transtracheal catheter, and demand oxygen pulsing devices on patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?
- What is the comparative effectiveness of interventions delivered by the Home Medical Equipment (HME) supplier of oxygen for COPD patients to improve adherence vs. usual care on patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?

Pertinent references:

- Nocturnal Oxygen Therapy Trial Group. Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease: a clinical trial. Ann Intern Med 1980;93:391–398.
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- Croxton TL, Bailey WC. Long-term oxygen treatment in chronic obstructive pulmonary disease: Recommendations for future research. An NHLBI workshop report. Am J Respir Crit Care Med 2006;174:373–378.
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- McDonald CF, Blyth CM, Lazarus MD, Marschner I, Barter CE. Exertional oxygen of limited benefit in patients with chronic obstructive pulmonary disease and mild hypoxemia. Am J Respir Crit Care Med 1995;152:1616-1619.
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- Timms RM, Khaja FU, Williams GW. Hemodynamic response to oxygen therapy in chronic obstructive pulmonary disease. Ann Intern Med 1985;102:29-36.
- Nonoyama ML, Brooks D, Lacasse Y, Guyatt GH, Goldstein RS. Oxygen therapy during exercise training in chronic obstructive pulmonary disease. Cochrane Database Syst Rev 2007 Apr 18;(2):CD005372.
- Bradley JM, O'Neill B. Short-term ambulatory oxygen for chronic obstructive pulmonary disease. Cochrane Database Syst Rev 2005 Oct 19;(4):CD004356.
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- Celli B, MacNee W, and committee members. Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. Eur Respir J 2004;23:932-946
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- Chaouat A, Weitzenblum E, Kessler R, et al. A randomized trial of nocturnal oxygen therapy in chronic obstructive pulmonary disease patients. Eur Respir J 1999;14:1002-1008.
- Garcia-Aymerich J, Farrero E, et al. Risk factors of readmission to hospital for a COPD exacerbation: a prospective study. Thorax 2003;58:100-105
- Strickland SL, Hogan TM, et al. Randomized multi-arm repeated-measures prospective study of several modalities of portable oxygen delivery during assessment of functional exercise capacity. Respir Care 2009;54(3):344-349

Provisional Topic: Palliation of symptoms

Background/rationale:
COPD is a chronic progressive disorder that results in debilitating symptoms such as dyspnea and severe reductions in activity, is characterized by increasingly severe exacerbations of breathing difficulty that may lead to unwanted or unbeneficial healthcare utilization at the end of life, and contributes to death - currently COPD is the 4th leading cause of death and increasing (National Consensus Project; ATS-Lankin; ACCP-Selecky; all 3 COPD guidelines, Claussens; Lynn; Bausewein; Bruera; Edmonds; Curtis). Palliative management in advanced disease like COPD is targeted as a priority for clinical research and quality improvement, however not much is known about the patient-level experience or effects of palliative and end-of-life care on patient-centered outcomes in generalized practice for COPD (Rabow, Curtis, Edmonds, Yohannes, Creagh-Brown). Breathlessness has been documented in >90% in patients with advanced COPD and is a significant cause of disability leading to severe reductions in activity and health-related quality of life (Claussens; Lynn; Bausewein; Bruera; Edmonds; Curtis).

Evaluation and palliative management of dyspnea in advanced disease like COPD is priority for clinical research, translation, and quality improvement (National Consensus Project; ATS-Lankin; ACCP-Selecky; COPD guidelines). Improving dyspnea care in widespread practice requires the use of valid, reliable, and responsive measurement of the dyspnea symptom experience. Although over 40 tools exist to assess dyspnea, there is no consensus on how dyspnea should be characterized for quality measurement (Dorman; Bausewein). Research gaps include standards for clinical dyspnea care, data to guide selection of optimal assessment tools for use in advanced diseases like COPD, and information on the evaluation of the efficacy of dyspnea.

Provisional questions:

- Does palliative care and/or hospice care as practiced across communities improve end-of-life care for COPD – specifically, does it reduce the burden of symptoms, improve HRQoL and satisfaction, reduce utilization in last 6 months of life (i.e. hospital visits, cost, invasive ventilation use, etc), improve the end-of-life experience, and increase the concordance of place of death to expressed patient preferences?
- What is currently done in clinical practice to measure and characterize dyspnea in patients with chronic COPD and how do different assessment approaches function with respect to guiding management and improving patient's symptoms and health-related quality of life?
- Do palliative care interventions improve symptom management for patients with advanced COPD who are not within 6 months of death?

Pertinent references:

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- Edmonds P, Karlsen S, Khan S, et al. A comparison of the palliative care needs of patients dying from chronic respiratory diseases and lung cancer. Palliat Med 2001; 15:287-295
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- Yohannes AM. Palliative care provision for patients with chronic obstructive pulmonary disease. Health and quality of life outcomes. Health Qual Life Outcome 2007; 5:17-22.

Provisional Topic: Spirometry for diagnosis and treatment

Background/rationale:
COPD is underdiagnosed. The lack of recognition of COPD risk by physicians and patients themselves is well known, with many undiagnosed COPD patients presenting for the first time with late stage COPD. Currently used cut-points based on a fixed ratio of FEV1/FVC may overestimate the number of elderly patients with COPD, particularly with mild disease, because of changes in lung volumes with aging. It has been suggested that using a cut-point based on the normal distribution of FEV1/FVC values may decrease the misclassification rate. Other strategies have been proposed for risk assessment as adjuncts to diagnostic classification (e.g., Fragoso et al. J Am Geriatr Soc 2008, 56:1014-1020). Pertinent references: Guideline #1 in Qaseem et al., strong recommendation, moderate-quality evidence; GOLD, 2008 and the 2005 American Thoracic Society/European Respiratory Society Task Force Report, standards for the diagnosis and management of patients with COPD.

Although there are ample guidance to help providers identify and evaluate patients likely to have earlier stage COPD (including combinations of a semi-quantitated smoking history, and/or symptoms of cough, wheeze and/or dyspnea), few of these patients are referred to spirometric testing. Subsequent spirometry provides a good working yield of true positives, which is frequently superior to pre-test probabilities of other, more complex and expensive medical tests commonly ordered for other conditions. If merely being 50 years old can result in a colonoscopy for about half of Americans, and routine lung cancer management accomplishes complex staging assessments and treatment, why is it so much more difficult to recognize the person with COPD and provide them with spirometry? COPD will remain undertreated as long as it remains underdiagnosed.

Provisional questions:

- What is the comparative effectiveness of different approaches to implementing use of spirometry in primary care to confirm the diagnosis of COPD (e.g., increased reimbursements, use of EMRs and other tools to serve as cues/reminders)?
- What is the comparative effectiveness of using symptoms vs. spirometry in increasing patient and adherence to COPD treatment guidelines? In improving patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?
- What is the comparative effectiveness of using a fixed FEV1/FVC ratio vs. an age-adjusted FEV1/FVC ratio in increasing the accuracy of COPD diagnosis? In improving patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?
- What is the comparative effectiveness of early identification and treatment of GOLD Stages 1-2 COPD through the use of screening spirometry in high risk populations vs.

usual care in these populations on improve patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?

Pertinent references:

- Celli B, MacNee W, and committee members. Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. Eur Respir J 2004;23:932-946
- National Heart Lung and Blood Institute. 2007 NHLBI Morbidity and Mortality Chart Book. Available at http://www.nhlbi.nih.gov/resources/docs/cht-book.htm. Accessed 12/01/2008.
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Provisional Topic: Pulmonary Rehabilitation (effectiveness of care)

Background/rationale:
Pulmonary rehabilitation is a well established therapy that can improve function, symptoms, and quality of life and reduce health care expenditures for patients with chronic lung diseases. Despite a growing and sound scientific evidence base, pulmonary rehabilitation is not widely available to the large majority of patients who could benefit. Under Congressional legislative mandate, CMS is developing a national coverage policy for pulmonary rehabilitation to be implemented in 2010. Nevertheless, it remains unclear whether the coverage policies and associated payment schedules will promote widespread availability.

Provisional questions:

- How well do community-based pulmonary rehabilitation programs adhere to guidelines compared to hospital based pulmonary rehabilitation programs?
- What is the comparative effectiveness and cost-effectiveness of community-based vs. hospital-based pulmonary rehabilitation programs?
- What factors serve as barriers / facilitators for access to pulmonary rehabilitation as part of chronic COPD care?
- What is the comparative effectiveness of short-term vs. chronic (indefinite) pulmonary rehabilitation on patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?
- What factors serve as barriers / facilitators for patient adherence to pulmonary rehabilitation for COPD care?

Pertinent references:

- Ries AL, Bauldoff GS, Carlin BW, Casaburi R, Emery CF, Mahler DA, Make B, Rochester CL, ZuWallack R, Herrerias C. Pulmonary rehabilitation: joint ACCP/AACVPR evidence-based clinical practice guidelines. Chest 2007; 131(suppl):4S-42S.
- American Thoracic Society and European Respiratory Society. ATS/ERS statement on pulmonary rehabilitation. Am J Respir Crit Care Med 2006; 173:1390-1413.
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Provisional Topic: Smoking Cessation

Background/rationale:
Tobacco cessation is the primary strategy to prevent and slow the progression of COPD in those who smoke. Despite multiple efficacy studies, translation into practice and community-based understanding of cost-effective and broadly efficacious intervention strategies are lacking. Comparative studies of different regimens and of different settings of care would aid policy makers, providers, and health care organizations in selecting and implementing care and improving the otherwise dismal progress in reducing smoking rates.

Provisional questions:

- What barriers and facilitators modify the effectiveness of smoking cessation programs in patients with COPD?
- What is the comparative effectiveness and cost effectiveness of counseling plus nicotine replacement vs. counseling plus bupropion vs. counseling plus varenicline in smokers with COPD on smoking cessation rates, patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations), and COPD and non-COPD morbidity/mortality?
- What is the comparative effectiveness of usual care vs. enhanced reimbursement (tied to the level of adherence to smoking cessation guidelines) on rates of providing appropriate smoking cessation care and smoking cessation rates in patients with COPD?
- What is the comparative effectiveness of an on-site smoking cessation program embedded within a medical clinic vs. off-site referral to a smoking cessation program on smoking cessation rates and patient reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?
- What is the comparative effectiveness and cost-effectiveness of community-based vs. hospital-based smoking cessation programs on smoking cessation rates and patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?

Pertinent references:

- Celli B, MacNee W, and committee members. Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. Eur Respir J 2004;23:932-946
- Mularski RA, Asch SM, Shrank WH, et al. The quality of obstructive lung disease care for adults in the United States as measured by adherence to recommended processes. Chest 2006; 130: 1844-50.
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Provisional Topic: Effectiveness of COPD Care and Guideline Translation

Background/rationale:

Guidelines are based on evidence from the medical literature often developed in specialty care and academic setting and interpreted by experts who provide valuable summaries. However, seldom are those guideline summaries written in a manner that can be used to direct the process of care within everyday primary care practices. (Mularski 2006, Lindenauer 2006) Most physicians treating COPD recognize some of the limitations of the evidence and therefore the resulting guidelines: the evidence often gathered in patients with few co-morbid conditions and good control over adverse life style habits. This limits the generalizability of the evidence and the guidelines across all practices. But for primary care additional barriers exist to guideline use. The evidence summaries for COPD contained in the GOLD guidelines suggest that therapy is initiated based on spirometry results and symptoms. However, no specific tools are recommended to assess current symptoms or the progression of symptoms over time. Nor are care process measures outlined that provide describe how to assess the range of reasons for continuing or progressive symptoms: e.g. lack of adherence to therapy, resumption of smoking, progression of disease, progression of a comorbid condition or patient deconditioning.

Guidelines require more than simple dissemination to impact daily primary care practice and patient outcomes. They require attention to physician attitudes, development of flexible practice tools and systems easily implementable in everyday practice. (Woolf 2007, Yawn 2008a) Such tools and care processes have been developed and tested in other chronic conditions such as diabetes and asthma (Yawn 2008) but not yet for COPD. Doing so will require knowledge of COPD guidelines, guidelines for the other common COPD co-morbid conditions as well as knowledge of primary care systems and successful methods to implement change in primary car practice system. (Bolibar 2009)

Provisional questions:

- How can guideline recommendations be implemented into community practice in a way that is feasible, usable, relevant, and cost-effective? (examples are use of care management, translation of chronic care model, and EMR based tools)
- How can we best develop, harmonize, and use performance measures for COPD care to increase patient-centered, effective, safe, timely, efficient, and equitable care?

Pertinent references:

- Lindenauer PK, Pekow P, Gao S, et al. Quality of care for patients hospitalized for acute exacerbations of chronic obstructive pulmonary disease. Ann Intern Med 2006; 144: 894-903.

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Provisional Topic: Development of performance measures

Background/rationale:

Chronic obstructive pulmonary disease (COPD) is a key health condition that affects over 12 million people and is responsible for 140,000 deaths and $32 billion in healthcare expenditures each year in the U.S. Unlike the other leading causes of death in the nation, the prevalence of COPD continues to rise and is expected to become the third leading cause of death in the U.S., surpassing cerebrovascular accidents, by 2020. Studies indicate that the care and outcomes of patients with COPD in clinical settings vary substantially and that many patients are not benefiting from advances in care identified in clinical trials ('research-to-practice gap'). In addition, the evaluation and management of patients with COPD are frequently complicated by the presence of other co-morbid conditions (e.g., heart failure, depression) and the need for care coordination between the various healthcare providers (e.g., primary care physicians, pulmonologist, non-pulmonary specialists, and non-physician providers). Transitions in care are common in patients with COPD as they cycle between healthcare settings during acute exacerbations (e.g., outpatient clinics, emergency department visits and/or hospitalizations). These issues present challenges to patient care and highlight the need to develop strategies to evaluate and improve practices across healthcare settings.

While originally developed for epidemiologic purposes (e.g., to develop estimates of disease burden and track changes in disease burden), ICD-9-CM codes have become critical for billing and for health services research. More recently, ICD-9-CM codes have also been used to identify patients eligible for quality improvement initiatives, including the Centers for Medicaid and Medicare (CMS) Reporting Hospital Quality Data for Annual Payment Update program. ICD-9-CM codes and other administrative/billing data are routinely available on all patient health encounters, raising the possibility that these data can be used to identify COPD and evaluate the quality of COPD care.

The specificity and sensitivity of ICD-9-CM codes for identifying medical conditions appear to vary depending on both the condition examined and the ICD-9-CM algorithms used. For example, malignancies and major surgical procedures appear to be captured more reliably than respiratory conditions or dementia. To increase specificity, some investigators have used age thresholds (e.g., age> 40 years) or excluded patients with specific conditions (e.g., asthma). To increase sensitivity, other investigators have employed groups of ICD-9-CM codes (algorithms) that incorporate combinations of codes, such as respiratory failure to identify patients with higher levels of acuity. Likewise, the most optimal approach to evaluate COPD care is unclear. Many current approaches rely on chart abstraction by coders and/or providers to self-report the quality of care. These approaches raise concerns about the reliability and are time-intensive. The extent to which computerized searches of electronic medical records (EMR) and/or billing/pharmacy data can be used to track and evaluate the quality of care is unclear. Despite the enormous health and financial burden of for COPD, there is currently no consensus

regarding the validity of administrative/billing data to identify COPD or evaluate the quality of COPD care.

Provisional questions:

- What is the sensitivity and specificity of current approaches based on administrative/billing data to identify patients COPD for quality improvement initiatives? Which approach offers the optimal combination of sensitivity and specificity?
- What is the validity of administrative/billing data to evaluate the quality of COPD care as part of quality improvement initiatives? What care practices can be assessed using these data?
- How do patient factors (e.g., presence of comorbid conditions), provider factors (e.g., training or board-certification), and practice factors (e.g., for vs. not-for-profit) affect the validity of administrative data to identify patients with COPD and evaluate the validity of indicators for assessing the quality of COPD care?

Pertinent references:

- Lindenauer PK, Pekow P, Gao S, et al. Quality of care for patients hospitalized for acute exacerbations of chronic obstructive pulmonary disease. Ann Intern Med 2006; 144: 894-903.
- Mularski RA, Asch SM, Shrank WH, et al. The quality of obstructive lung disease care for adults in the United States as measured by adherence to recommended processes. Chest 2006; 130: 1844-50.
- National Heart Lung and Blood Institute. 2007 NHLBI Morbidity and Mortality Chart Book. Available at http://www.nhlbi.nih.gov/resources/docs/cht-book.htm. Accessed 12/01/2008.
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Provisional Topic: Pharmaceutical Treatment

Background/rationale:
Most patients with moderate or severe COPD experience progressive dyspnea that is not alleviated by short acting bronchodilators. Over the last 10 years, a series of efficacy studies have demonstrated benefit of several classes of long-acting inhaled medications including long-acting beta agonists (LABAs), combinations of LABAs and inhaled corticosteroids (ICS), and a long-acting anticholinergic agent (tiotropium). These studies have used multiple clinical outcomes including number of exacerbations, measures of dyspnea, and quality of life. Only one large randomized trial has been conducted to assess the efficacy of the combination of a LABA, an ICS, and tiotropium compared to either single agent. There was no benefit of the three way combination for the primary outcome, number of exacerbations, but there appeared to be some benefit for multiple secondary outcomes including disease-specific quality of life and number of hospitalizations.

Despite the absence of clear proven benefit, the use of this triple therapy combination of long-acting inhaled medications is becoming more frequent in practice, owing in part to the prevalence of refractory symptoms and the availability of the medications despite high costs. However this practice has clear cost implications and possible safety concerns. Studies need to be conducted to determine the prevalence of triple therapy prescription and to assess the comparative effectiveness of triple therapy versus more simple combinations of long-acting medications.

Provisional questions:

- What is the prevalence of triple therapy using LABAs, ICS, and tiotropium in large and diverse populations of patients with moderate to severe COPD?
- What is the comparative effectiveness of triple therapy with LABAs, ICS, and tiotropium compared to LABAs, or tiotropium, or LABAs plus ICS, or tiotropium plus ICS, in terms of COPD exacerbations and hospitalizations?
- What is the cost-effectiveness of triple therapy with LABAs, ICS, and tiotropium compared to LABAs, or tiotropium, or LABAS plus ICS, or tiotropium plus ICS?

Pertinent references:

- Aaron et al. Tiotropium in combination with placebo, salmeterol, or fluticasone-salmeterol for treatment of chronic obstructive pulmonary disease. A randomized trial. Annals of Internal Medicine. 2007;146:545-55.
- van Noord JA, Aumann JL, Janssens E, Smeets JJ, Verhaert J, Disse B, et al. Comparison of tiotropium once daily, formoterol twice daily and both combined once daily in patients with COPD. Eur Respir J. 2005;26:214-22.

- van Noord JA, Aumann JL, Janssens E, Verhaert J, Smeets JJ, Mueller A, et al. Effects of tiotropium with and without formoterol on airflow obstruction and resting hyperinflation in patients with COPD. Chest. 2006;129:509-17.

Provisional Topic: Home Care

Background/rationale:
Many COPD patients, especially those with advanced disease are largely home-bound and receive care by various kinds of providers ranging from community nurses to paid caregivers to family members. There appear to be a number of different models for home care provision described in the literature but no clearly dominant model. Selecting Home care as a research topic might have strategic value in terms of incorporating a stronger allied health and nursing care perspective to this project. Innovative strategies to educate patients through online and multimedia resources are also emerging. A changing paradigm for the healthcare provider and patient relationship whereby more and more decision-making is shared and more responsibilities lie with the patient fits well with the self management agenda.

Provisional questions:

1. What is the comparative effectiveness and cost-effectiveness of nurse-assisted home care (patient education to improve self-management skills and nurse implementation of COPD action plans) vs. usual care on patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?

Pertinent references:

- Johnston SK, Nguyen HQ, Wolpin S. Designing and testing a web-based interface for self-monitoring of exercise and symptoms for older adults with chronic obstructive pulmonary disease. Comput Inform Nurs. 2009;27(3):166-74.
- Rogers A, Lee V, Kennedy A.Continuity and change? Exploring reactions to a guided self-management intervention in a randomised controlled trial for IBS with reference to prior experience of managing a long term condition. Trials. 2007 Feb 22;8:6
- Hermiz O, Comino E, Marks G, Daffurn K, Wilson S, Harris M. Randomised controlled trial of home based care of patients with chronic obstructive pulmonary disease. BMJ. 2002;325(7370):938.
- Coultas D, Frederick J, Barnett B, Singh G, Wludyka P. A randomized trial of two types of nurse-assisted home care for patients with COPD. Chest 2005; 128(4):2017-24.

COPD Care Coordination Provisional Topics

Provisional Topic: Pulmonary rehabilitation in COPD (as model for care coordination)

Background/rationale:
Pulmonary rehabilitation has been shown to improve several outcomes in patients with COPD. Evidence indicates that pulmonary rehabilitation increases exercise capacity, reduces breathlessness, improves health related quality of life, reduces hospitalizations and days in the hospital, and reduces anxiety and depression. A Cochrane review of pulmonary rehabilitation in COPD showed that the improvement in dyspnea, fatigue, emotional function and perception of control of disease were moderately large and clinically significant and thus is an important part of the management of patients with COPD (Lacasse 2006). Additionally, referral to pulmonary rehabilitation following acute exacerbations also suggests beneficial effects in terms of reduced hospital admissions and health-related quality of life (Puhan 2009).

Principals of pulmonary rehabilitation apply regardless of location; consequently, it has been shown to be effective across various settings. Inpatient pulmonary rehabilitation is better suited to patients with severe deconditioning and lack of support for home management or limited transportation. Inpatient rehabilitation can provide similar benefits as outpatient programs. Potential disadvantages include high cost and lack of insurance coverage. Outpatient programs are the most widely available and may be hospital or community based. The majority of studies describing the benefits of pulmonary rehabilitation are derived from hospital-based outpatient programs. Home-based programs may offer the greatest convenience for the patient and may prolong its benefits. In severely disabled patients, home-based programs may not be as effective. Potential disadvantages of home-based rehabilitation include lack of group support, limited presence of multidisciplinary team, variable availability of exercise equipment, a lack of safe facilities, and cost of visits by health care professionals. Properly conducted pulmonary rehabilitation offers clinical benefits in all settings that have so far been studied; however, few clinical trials offer direct comparison among various setting.

A recent Cochrane review examined home versus center-based physical activity programs in older adults (Ashworth 2005). Among patients with COPD, the evidence is conflicting with one study showing home-based programs are superior, and another showing center-based programs result in better outcomes. Overall there is a lack of evidence on the use of pulmonary rehabilitation and integration with rehabilitation programs for other chronic illnesses among patients with COPD and other chronic conditions. Finally, an important aspect of pulmonary rehabilitation is the improvement in the access to and use of such programs for patients with COPD.

Provisional questions:
- What interventions can be used to increase access to pulmonary rehabilitation services?
- Can pulmonary rehabilitation integrate rehabilitation for other chronic conditions in such a way to truly optimally manage people with multimorbidity?

Pertinent references:

- Lacasse Y, Goldstein R, Lasserson TJ, Martin S. Pulmonary rehabilitation for chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2006 Oct 18;(4):CD003793. Review.
- Puhan M, Scharplatz M, Troosters T, Walters EH, Steurer J. Pulmonary rehabilitation following exacerbations of chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2009 Jan 21;(1):CD005305. Review.
- Goldstein RS, Gort EH, Stubbing D, Avendano MA, Guyatt GH. Randomised controlled trial of respiratory rehabilitation. *Lancet.* Nov 19 1994;344(8934):1394-1397
- Behnke M, Taube C, Kirsten D, Lehnigk B, Jorres RA, Magnussen H. Home-based exercise is capable of preserving hospital-based improvements in severe chronic obstructive pulmonary disease. *Respir Med.* Dec 2000;94(12):1184-1191.
- Hernandez MT, Rubio TM, Ruiz FO, Riera HS, Gil RS, Gomez JC. Results of a home-based training program for patients with COPD. *Chest.* Jul 2000;118(1):106-114.
- Ashworth NL, Chad KE, Harrison EL, Reeder BA, Marshall SC. Home versus center-based physical activity programs in older adults. *Cochrane Database Syst Rev.* 2005(1):CD004017.

Provisional Topic: Comprehensive COPD patient education

Background/rationale:
Educational programs, improvement in patient empowerment, and motivational interviewing are components of care that improve the overall care of patients with chronic illness. Comprehensive educational programs for patients with COPD have the potential to improve the ability to self monitor and take care of their chronic condition from a more independent standpoint. A recent systematic review of self-management education in patients with COPD concluded that more evidence was needed in the form of larger comparative effectiveness studies that provided long-term follow-up (Effing 2007). In addition, because of the heterogeneity in the programs included in the review, a focus on the components of patient education and self-management programs is also needed. In conditions other than COPD, a variety of self-management programs exist with varying degrees of evidence of success. An important issue remains the type of program and components necessary to produce a desired effect over the long-term. Finally, many of the education and self-management programs are targeted at single diseases or chronic conditions while the majority of patients with COPD have other chronic conditions, therefore it is important to understand whether these programs translate to patients with multiple chronic conditions.

Provisional questions:

- What is the impact of an organized, comprehensive, COPD patient education program, on medication delivery effectiveness, care plan adherence, appropriate use of LTOT and Pulmonary Rehab? Metrics could include incidence and severity of exacerbations, health care resource consumption.
- What are the essential components/techniques of an effective self-management patient education program, and how do we measure success, (i.e. self-efficacy)?
- How do we generalize our educational efforts such that multiple co-morbidities and their self-care can be addressed?
- What is the comparative effectiveness of brief interventions to teach patients respiratory inhaler use (e.g., verbal and written instructions) vs. teach-to-goal interventions (brief interventions plus demonstration of correct technique, patient teach-back, feedback, and repeat instruction if needed) on respiratory inhaler technique and patient-reported outcomes (symptom frequency, activities of daily living, quality of life, sleep quality, exacerbations)?

Pertinent references:

- Bourbeau J, Collet JP, Schwartzman K, Ducruet T, Nault D, Bradley C. Economic benefits of self-management education in COPD. Chest. 2006 Dec;130(6):1704-11.
- Marks R, Allegrante JP, Lorig K. A review and synthesis of research evidence for self-efficacy-enhancing interventions for reducing chronic disability: implications for health education practice (part II). Health Promot Pract. 2005 Apr;6(2):148-56.

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- Holman H, Lorig K. Patient self-management: a key to effectiveness and efficiency in care of chronic disease. Public Health Rep. 2004 May-Jun;119(3):239-43.
- Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. JAMA. 2002 Nov 20;288(19):2469-75.
- Foster G, Taylor SJ, Eldridge SE, Ramsay J, Griffiths CJ. Self-management education programmes by lay leaders for people with chronic conditions. Cochrane Database Syst Rev. 2007 Oct 17;(4):CD005108. Review.

Provisional Topic: Scheduled multidisciplinary team consultation

Background/rationale:

Primary care physicians, rather than specialists, provide care to most patients with COPD. Patients with COPD often also have other co-morbid conditions. These issues may present opportunities for care coordination with multi-disciplinary teams with expertise in COPD. Patients with COPD who meet certain criteria could be automatically scheduled for periodic consultation with a multidisciplinary team consisting of nutritionist, pulmonary rehabilitation nurse, social worker and pulmonologist to optimize COPD treatment through a systematic, protocolized, approach to addressing guideline recommendations / evidence based care standards. Similar approaches have been implemented successfully in patients with diabetes and draw from concepts of the chronic care model (Wagner 2001). In diabetes chronic care clinics, patients are managed by their PCP and come to diabetes clinic every 6 months where that is the only focus of the visit. Evaluation of chronic care clinics for a geriatric population did not result in improved outcomes (Coleman 1999); therefore, it is important to understand which patients with COPD are best enrolled in chronic care clinics.

Provisional questions:

1. Does use of periodic and automatic multidisciplinary team consultation improve care and health outcomes of patients with COPD?

Pertinent references:

- Wagner EH, Grothaus LC, Sandhu N, Galvin MS, McGregor M, Artz K, Coleman EA. Chronic care clinics for diabetes in primary care: a system-wide randomized trial. Diabetes Care. 2001 Apr;24(4):695-700.
- Coleman EA, Grothaus LC, Sandhu N, Wagner EH. Chronic care clinics: a randomized controlled trial of a new model of primary care for frail older adults. J Am Geriatr Soc. 1999 Jul;47(7):775-83.

Provisional Topic: Developing a tool for risk stratification

Background/rationale:
In patients with COPD, there is a disproportionate use of resources across the patient population with some patients consuming a higher share of healthcare resources than other patients. This is particularly important as these patients may be those for whom it is most important to target interventions. Healthcare payers have long been interested in developing predictive models for identifying high users of healthcare resources. A risk stratification tool has the potential to aid in targeting the right patients for interventions as it may be economically infeasible to include all patients in a disease management program or other similar intervention. In COPD, work has been performed to develop models that are predictive of mortality (e.g., the BODE index). There is growing interest and focus on examining the ability to detect patients that are most likely to be those that use a significant amount of healthcare services. Development of a tool could be very important in guiding implementation of interventions in patients with COPD.

Provisional questions:
1. Can a tool be developed to group patients into risk categories for resource utilization?

Pertinent references:

- Soler-Cataluña JJ, Martínez-García MA, Sánchez LS, Tordera MP, Sánchez PR. Severe exacerbations and BODE index: two independent risk factors for death in male COPD patients. Respir Med. 2009 May;103(5):692-9.
- Marin JM, Carrizo SJ, Casanova C, Martinez-Camblor P, Soriano JB, Agusti AG, Celli BR. Prediction of risk of COPD exacerbations by the BODE index. Respir Med. 2009 Mar;103(3):373-8.
- Cote CG, Pinto-Plata VM, Marin JM, Nekach H, Dordelly LJ, Celli BR. The modified BODE index: validation with mortality in COPD. Eur Respir J. 2008 Nov;32(5):1269-74.
- Martinez FJ, Han MK, Andrei AC, Wise R, Murray S, Curtis JL, Sternberg A, Criner G, Gay SE, Reilly J, Make B, Ries AL, Sciurba F, Weinmann G, Mosenifar Z, DeCamp M, Fishman AP, Celli BR; National Emphysema Treatment Trial Research Group. Longitudinal change in the BODE index predicts mortality in severe emphysema. Am J Respir Crit Care Med. 2008 Sep 1;178(5):491-9.
- McKellar A, Cottrell WN, Whelan A. BODE score is a useful predictor of hospital admission in rural patients with chronic obstructive pulmonary disease. Respirology. 2008 May;13(3):438-43.
- Celli BR, Cote CG, Marin JM, Casanova C, Montes de Oca M, Mendez RA, Pinto Plata V, Cabral HJ. The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease. N Engl J Med. 2004 Mar 4;350(10):1005-12.
- Lusuardi M, Lucioni C, De Benedetto F, Mazzi S, Sanguinetti CM, Donner CF. GOLD severity stratification and risk of hospitalisation for COPD exacerbations. Monaldi Arch Chest Dis. 2008 Dec;69(4):164-9.

o Bryden C, Bird W, Titley HA, Halpin DM, Levy ML. Stratification of COPD patients by previous admission for targeting of preventative care. Respir Med. 2009 Apr;103(4):558-65.

Provisional Topic: Measurement of quality of care coordination

Background/rationale:

While there are a number of potential models of care coordination that may be applicable for patients with COPD, there is a need to develop standardized measures to assess the quality of care coordination across the different approaches. A recent evidence review from AHRQ focused on care coordination and how it may be used to close the gap in quality of care highlighted the need to develop measures of the important aspects of care coordination in order to understand what components are necessary and which are associated with high quality care coordination. The following is excerpted from the AHRQ technical review:

> " Determining the effectiveness of care coordination also requires more research on measures of care coordination. Assessing whether an intervention improves patient outcomes or lowers costs is the main goal of effectiveness studies. However, other coordination-oriented measures such as those that assess relational coordination, information exchange, enabling resources, and patient perceptions of coordination are important for refining interventions when they do not work. More research is needed on the validity of these measures, and about the relationship of these coordination-centric measures to outcomes of care. In addition, new measures need to be developed for areas that are not yet covered adequately (e.g., patient utilities/preferences for coordination, intensity of intervention)."

This excerpt highlights the need to be able to measure the components of a care coordination program and link them to patient outcomes which would facilitate the development of a quality measure for care coordination programs.

Provisional questions:

1. What are the measurable important components of care coordination?

Pertinent reference:

- McDonald KM, Sundaram V, Bravata DM, Lewis R, Lin N, Kraft S, McKinnon M, Paguntalan H, Owens DK. Care Coordination. Vol 7 of: Shojania KG, McDonald KM, Wachter RM, Owens DK, editors. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies. Technical Review 9 (Prepared by the Stanford University-UCSF Evidence-based Practice Center under contract 290-02-0017). AHRQ Publication No. 04(07)-0051-7. Rockville, MD: Agency for Healthcare Research and Quality. June 2007.

Provisional Topic: Cost-effectiveness of care coordination

Background/rationale:

While there is limited evidence to suggest that some models of care coordination in COPD may be efficacious, little is known about the costs to implement such programs and therefore their cost effectiveness is unknown. The cost-effectiveness or cost-utility of care coordination programs have not been evaluated in many diseases. One example showed that a care coordination program in veterans with diabetes had an incremental cost-utility ratio of more than $60,000 per QALY gained compared to usual care (Barnett 2007). Other evaluations have shown that care coordination programs implemented in telehealth framework may not be costly to implement (Darkins 2008); however their overall value relative to their interventions is not clear. There is an opportunity to examine the value of care coordination programs among patients with COPD.

Provisional questions:

1. Are care coordination models in COPD cost-effective?

Pertinent references:

- Darkins A, Ryan P, Kobb R, Foster L, Edmonson E, Wakefield B, Lancaster AE. Care Coordination/Home Telehealth: the systematic implementation of health informatics, home telehealth, and disease management to support the care of veteran patients with chronic conditions. Telemed J E Health. 2008 Dec;14(10):1118-26.
- Barnett TE, Chumbler NR, Vogel WB, Beyth RJ, Ryan P, Figueroa S. The cost-utility of a care coordination/home telehealth programme for veterans with diabetes. J Telemed Telecare. 2007;13(6):318-21.

Provisional Topic: Case management

Background/rationale:

Case management is one of the models of care coordination that has been studied in the ambulatory setting for patients with mental health conditions, diabetes and heart failure. There is some evidence that these programs can be beneficial in preventing re-hospitalization in mental health and improving glycemic control in diabetes. There is growing evidence on the impact of case management among patients with COPD. A recent systematic review summarized findings from 13 studies of a disease-management program in COPD (Peytremann-Bridevaux 2008). The results showed that disease management programs had modest effects on exercise capacity, health-related quality of life and hospitalizations. There was substantial heterogeneity in the effects across studies which highlights the need to further examine what models of disease management or case management are most effective in patients with COPD and how can these be implemented in clinical practice.

Provisional questions:

- What is the effectiveness of a case management program in patients with COPD compared to usual care?
- What is the effectiveness of case management programs on patients with COPD and other chronic conditions (e.g., heart failure, diabetes) compared to usual care?
- How is effectiveness related to how linked the intervention is to the person's physicians and primary source of care?

Pertinent references:

- Aiken LS, Butner J, Lockhart CA, Volk-Craft BE, Hamilton G, Williams FG. Outcome evaluation of a randomized trial of the PhoenixCare intervention: program of case management and coordinated care for the seriously chronically ill. J Palliat Med. 2006 Feb;9(1):111-26.
- Taylor SJ, Candy B, Bryar RM, Ramsay J, Vrijhoef HJ, Esmond G, Wedzicha JA, Griffiths CJ. Effectiveness of innovations in nurse led chronic disease management for patients with chronic obstructive pulmonary disease: systematic review of evidence. BMJ. 2005 Sep 3;331(7515):485.
- Egan E, Clavarino A, Burridge L, Teuwen M, White E. A randomized control trial of nursing-based case management for patients with chronic obstructive pulmonary disease. Lippincotts Case Manag. 2002 Sep-Oct;7(5):170-9.
- Poole PJ, Chase B, Frankel A, Black PN. Case management may reduce length of hospital stay in patients with recurrent admissions for chronic obstructive pulmonary disease. Respirology. 2001 Mar;6(1):37-42.
- Peytremann-Bridevaux I, Staeger P, Bridevaux PO, Ghali WA, Burnand B. Effectiveness of chronic obstructive pulmonary disease-management programs: systematic review and meta-analysis. Am J Med. 2008 May;121(5):433-443.e4. Review.
- Niesink A, Trappenburg JC, de Weert-van Oene GH, Lammers JW, Verheij TJ, Schrijvers AJ. Systematic review of the effects of chronic disease management on quality-of-life

in people with chronic obstructive pulmonary disease. Respir Med. 2007 Nov;101(11):2233-9. Epub 2007 Sep 4. Review.

Provisional Topic: Management of COPD in the presence of comorbidity

Background/rationale:

COPD is a disease that typically presents in the fifth or sixth decade of life and its primary risk factor is cigarette smoking. These two characteristics of COPD make it a condition that frequently co-occurs with other chronic conditions. Because it is common and frequently co-occurs with other diseases, understanding how to manage the COPD and other chronic conditions for these patients is important. COPD is associated with short-term mortality rates that are fairly high. These high mortality rates make understanding the incremental value of treating co-existing conditions important in patients with COPD. It is important to determine if there is value in aggressively managing other conditions or if time and resources should be focused on treatment of COPD. A potential factor is that the presence of COPD and its associated symptoms may overwhelm other chronic conditions. The focus of treatment may move to COPD with limited attention paid to treatment and control of co-occurring conditions. Alternatively, co-occurring conditions may continue to be managed with limited impact on overall mortality among patients with COPD. For providers to be able to aid patients in making informed decisions it is important to have information regarding the incremental value of treatments in these situations. This information does not currently exist and providers are faced with treating based on clinical judgment when weighing all of the pros and cons associated with COPD and other chronic conditions. For example, there may be limited value in tightly controlling HbA1c in a patient that has COPD and diabetes because it will have relatively little impact on the five-year mortality estimates in these patients. We currently lack evidence to support whether or not this is the case. In addition, the high prevalence of co-existing conditions highlights the importance of coordination across providers when making treatment recommendations for patients with COPD (i.e. is the treatment approach / goal aligned across each provider that is caring for the patient).

Provisional questions:

1. Does a protocol-based screening for commonly occurring comorbid conditions in patients with COPD (eg. CAD, CHF, depression, sleep apnea) improve management and outcomes for patients with COPD?
2. How should providers coordinate management strategies and treatment goals in patients with COPD and other co-existing chronic diseases?
3. What is the comparative effectiveness and safety of guideline-recommended COPD care in patients with 'few' vs. 'many' clinically significant (e.g., depression, sleep disorder, cardiovascular) comorbidities?
4. What should be the clinical endpoints in frail elderly vs. other patients with COPD when titrating COPD care?
5. How do we generalize our educational efforts such that multiple co-morbidities and their self-care can be addressed?

Pertinent references:

- Braunstein JB, Anderson GF, Gerstenblith G, et al. Noncardiac comorbidity increases preventable hospitalizations and mortality among Medicare beneficiaries with chronic heart failure. J Am Coll Cardiol 2003;42:1226–1233.
- Fonarow GC, Heywood JT, Heidenreich PA, et al. Temporal trends in clinical characteristics, treatments, and outcomes for heart failure hospitalizations, 2002 to 2004: findings from Acute Decompensated Heart Failure National Registry (ADHERE). Am Heart J 2007;153:1021–1028.
- Havranek EP, Masoudi FA, Westfall KA, et al. Spectrum of heart failure in older patients: results from the National Heart Failure project. Am Heart J 2002;143:412–417.
- Curkendall SM, DeLuise C, Jones JK, et al. Cardiovascular disease in patients with chronic obstructive pulmonary disease, Saskatchewan Canada cardiovascular disease in COPD patients. Am Epidemiol 2006;16:63–70.
- Holguin F, Folch E, Redd SC, et al. Comorbidity and mortality in COPD-related hospitalizations in the United States, 1979 to 2001. Chest 2005;128:2005–2011.
- Mapel DW, Dedrick D, Davis K. Trends and cardiovascular co-morbidities of COPD patients in the Veterans Administration Medical System, 1991-1999. COPD 2005; 2:35–41.
- Sidney S, Sorel M, Quesenberry CP Jr, et al. COPD and incident cardiovascular disease hospitalizations and mortality: Kaiser Permanente Medical Care Program. Chest 2005;128:2068–2075.

Provisional Topic: Quality of care coordination

Background/rationale:
As noted above, there is limited evidence on the quality of care coordination programs. A recent AHRQ-sponsored review indicated the need for additional research on the quality of care coordination and linking components of care coordination with patient outcomes. Following development of measures of care coordination quality it would be important to evaluate the quality of care coordination provided to patients with COPD. It would be important to assess the level of care coordination for patients with COPD and identify patient and practice level factors associated with better or worse care coordination performance. This would build off of the development of a tool for the measurement of care coordination quality.

Provisional questions:

- How good is the quality of care coordination for patients with isolated COPD?
- How good is the quality of care coordination for patients with COPD and other co-existing conditions?
- What factors are associated with high quality care coordination in patients with COPD?

Pertinent references:

- McDonald KM, Sundaram V, Bravata DM, Lewis R, Lin N, Kraft S, McKinnon M, Paguntalan H, Owens DK. Care Coordination. Vol 7 of: Shojania KG, McDonald KM, Wachter RM, Owens DK, editors. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies. Technical Review 9 (Prepared by the Stanford University-UCSF Evidence-based Practice Center under contract 290-02-0017). AHRQ Publication No. 04(07)-0051-7. Rockville, MD: Agency for Healthcare Research and Quality. June 2007.

Provisional Topic: Impact of depression and mental health management

Background/rationale:
Depression among COPD patients is a common problem with important consequences for health outcomes. The prevalence of depressive symptoms among COPD patients has been estimated to be 40%-50%.(Clary 2002; Mikkelsen 2004; Norwood 2005) In COPD patients, depression is a strong predictor of COPD treatment failure,(Dahlen 2002) diminished functioning,(Weaver 1997; Kim 2000) quality of life,(Ng 2007; Felker 2001; Cully 2006) and mortality.(Ng 2007; Yohannes 2005; Almagro 2002)

There has been a recent emphasis on improving the quality of depression care, particularly for patients with comorbid medical conditions. Evidence-based, practice guidelines for depression care are associated with fewer depressive symptoms and lower risk for psychiatric hospitalization (Hepner 2007; Charbonneau 2004). What is unclear from these studies is how evidence-based depression care impacts outcomes for persons with depression and a medical comorbidity in clinical settings. There is limited evidence that antidepressant medication adherence is associated with better adherence to comorbid disease medication,(Katon 2005) but the relationship between antidepressant medication adherence and comorbid treatment adherence has not been examined in patients with depression and COPD. Patients with COPD may have poor acceptance of antidepressants for treatment of depression, and as such, have lower adequacy of acute phase antidepressant treatment in depressed veterans with COPD.(Pirraglia 2006) However, patients that receive guideline-concordant depression care may more successfully manage their COPD in the near term, reducing their risk of hospitalization and mortality.

Because depression is an important comorbid condition among patients with COPD and has the potential to influence COPD management and outcomes it may be important to consistently screen for depression among patients with COPD. Understanding the best model for depression screening and how to appropriately manage those that screen positive is an important component of care coordination focused on the mental health of patients with COPD.

Provisional questions:

- What is the impact of screening for depression on outcomes of patients with COPD?
- Does an automatic referral to a mental health provider in patients with COPD and acute depressive disorder episode improve quality of depression care and outcomes in patients with COPD?
- Does a care coordination program improve the detection and treatment of co-morbid depression in patients with COPD?
- Does Integrated Mental Health Care and COPD treatment improve outcomes for both conditions?

Pertinent references:

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Provisional Topic: Patient-centered medical home

Background/rationale:
The patient-centered medical home is receiving significant attention as a management strategy for improving care and outcomes in patients with chronic conditions. In COPD, patients often have co-existing conditions which may lead to care by several healthcare providers which can lead to fragmentation of care. Understanding the role of the patient-centered medical home in patients with COPD is an important area for research.

Provisional questions:

- Does the presence of a patient-centered medical home improve outcomes in patients with COPD compared to usual care?
- Does a patient-centered medical home improve outcomes relative to other care coordination or care management strategies?

Pertinent references:

- Friedberg MW, Safran DG, Coltin KL, Dresser M, Schneider EC. Readiness for the Patient-Centered Medical Home: structural capabilities of Massachusetts primary care practices. J Gen Intern Med. 2009 Feb;24(2):162-9.

Table E3. Briefing Book for Workshop in Year 2: Acute COPD care, and Transitions in COPD care

2010 CONCERT Workshop Briefing Book

Setting Effectiveness and Translational Research Priorities to Improve COPD Care

Setting Effectiveness and Translational Research Priorities to improve COPD Care
May 20-21, 2010, New Orleans, LA
Wyndham Riverfront New Orleans

Table of Contents

*List of stakeholders/speakers and pre-workshop voting results have been removed from the briefing book because they are included in the main body of the manuscript

CONCERT Workshop
Acute COPD Care/Transitions in COPD Care

May 20-21, 2010, New Orleans, LA
Wyndham Riverfront New Orleans

Day 1
May 20, 2010
Facilitators: Shannon Carson, MD, David Au, MD, MS

Time	Title	Speaker
7:30A-8:30A	Breakfast & Registration	
8:30A-8:40A	Introduction/Welcome: Acute COPD as a growing health problem and the CONCERT collaboration	Jerry A. Krishnan, MD, PhD, University of Chicago
Talk: 8:40A-9:10A Discussion: 9:10A-9:20A	Treatment of acute COPD: what is the state-of-the-art?	Robert A. Wise, MD, Johns Hopkins University
Talk: 9:20A-9:50A Discussion: 9:50A-10:00A	Quality of acute COPD care: what's known and unknown?	Peter Lindenauer, MD, MS, Baystate/Tufts University
10:00A-10:10A	*Break*	
Talk: 10:10A-10:50A Discussion: 10:50A-11:10A	Canadian-US Research Networks and Acute Respiratory Comparisons	Brian H. Rowe, MD, MSc University of Alberta
Talk: 11:10A-11:40A Discussion: 11:40A-11:50A	HCUP: Hospital and Emergency Department Administrative Data for COPD Research	Anne Elixhauser, PhD, Agency for Healthcare Research and Quality
11:50A-1:00P	*Lunch*	
Talk: 1:00P-1:30P Discussion: 1:30P-1:40P	Improving patient hospital discharge transitions	Mark Williams, MD, Northwestern University
Talk: 1:40P-2:10P Discussion: 2:10P-2:20P	Palliative care in COPD and transitioning to end-of-life care	Richard Mularski, MD, MSHS, MCR, Center for Health Research, Kaiser Permanente Northwest
2:20P-2:30P	*Break*	
Talk: 2:30P-3:00P Discussion: 3:00P-3:10P	Lessons from CMS pay-for-performance program for hospitalized patients	Mark A. Levine, MD, Centers for Medicare and Medicaid Services
Talk: 3:10P-3:40P Discussion: 3:40P-3:50P	"Get with the guidelines" - Lessons learned from quality of care initiatives in cardiology	Kenneth LaBresh, MD, RTI International/American Heart Association
3:50P-4:00P	CONCLUSIONS/WRAP-UP	Group

Day 2
May 21, 2010

Time	Title	Chairs
8:00A-9:00A	Breakfast	
9:00A-12:00P	Evaluating and improving acute COPD care	Shannon Carson, MD; MaryAnn McBurnie, PhD
12:00P-1:00P	Lunch	
1:00P-4:00P	Evaluating and improving transitions in COPD care	David Au, MD, MS; Jerry Krishnan, MD, PhD

Two half-day sessions will be led by CONCERT investigators to identify gaps in the evidence base in *acute care/transitions in COPD care* and to prioritize an effectiveness/implementation research agenda.

Acute COPD Care Provisional Topics

Provisional Topic: Co-morbid conditions in the acute setting
Subtopic: Screening for PE in patients with COPD exacerbations

Question:
Does of screening for pulmonary embolisms in COPD exacerbations improve COPD-related 30-day and 6-month mortality? Does the utility of screen for PE correlate with severity of disease in COPD?

Rationale:
Recent evidence has drawn attention to a higher prevalence of pulmonary embolism in COPD patients than previously suspected – up to 25% of patients hospitalized with acute exacerbations. While several diagnostic algorithms exist for evaluating for
VTE/PE, a tipping point at which screening becomes routine may occur. Further, as COPD advances, patients become more sedentary increasing the PE risk, in addition to the inherent disruptions in pulmonary blood flow, mechanics, and inflammation. Also for consideration is the most effective screening modality for this subset of patients.

References:
Rizkallah J, Man SF, Sin DD. Prevalence of pulmonary embolism in acute exacerbations of COPD: A systematic review and meta analysis. Chest. 2009;135(3):786-793 [PMID 18812453].

Provisional Topic: Co-morbid conditions in the acute setting
Subtopic: Effectiveness of systemic therapies directed at cardiovascular disease in patients with COPD

Questions:

1. What is the comparative effectiveness of prescribing statin medications versus placebo to patients with exacerbations of COPD who do not have known vascular disease?
2. What is the comparative effectiveness of prescribing ACE-inhibitors versus placebo to patients with exacerbations of COPD who do not have known left ventricular dysfunction?
3. Is there a role for these medications in patients with more mild COPD who do not present with acute exacerbations?

Rationale:

Recent clinical studies have indicated that patients with COPD who take medications typically prescribed for vascular disease have better outcomes than patients who do not take those medications. Whether this is due to beneficial effects on comorbid vascular disease or whether there is a specific anti-inflammatory effect in the lungs is not clear. Research on whether these agents should be routinely prescribed for patients with COPD who do not have known vascular disease or heart failure is warranted.

References:

Antoniu SA. Reducing mortality for chronic obstructive pulmonary disease: Role of statins and angiotensin-converting enzyme inhibitors. Expert Rev Pharmacoecon Outcomes Res. 2009;9(6):523-525 [PMID 19941429].

Barr RG, Bluemke DA, Ahmed FS, et al. Percent emphysema, airflow obstruction, and impaired left ventricular filling. N Engl J Med. 2010;362(3):217-227 [PMID 20089972].

Di Marco F, Guazzi M, Vicenzi M, et al. Effect of enalapril on exercise cardiopulmonary performance in chronic obstructive pulmonary disease: A pilot study. Pulm Pharmacol Ther. 2010;23(3):159-164 [PMID 20096799].

Mancini GB, Etminan M, Zhang B, Levesque LE, FitzGerald JM, Brophy JM. Reduction of morbidity and mortality by statins, angiotensin-converting enzyme inhibitors, and angiotensin receptor blockers in patients with chronic obstructive pulmonary disease. J Am Coll Cardiol. 2006;47(12):2554-2560 [PMID 16781387].

Mortensen EM, Copeland LA, Pugh MJ, et al. Impact of statins and ACE inhibitors on mortality after COPD exacerbations. Respir Res. 2009;10:45 [PMID 19493329].

Provisional Topic: Co-morbid conditions in the acute setting
Subtopic: Treatment and outcomes of patients with AE-COPD and other co-morbid conditions such as asthma, heart failure, and pulmonary embolism

Questions:

1. What treatment modalities are effective for patients with a combined diagnosis of AE-COPD with other co-morbid diseases?

2. What outcomes measures are reliable for patients with combination diagnosis (AE-COPD + other co-morbid conditions)?

Rationale:

Few diseases exist in isolation. Patients with multiple co-morbid conditions do not fall into an easily treatable guideline or a specific outcome measure. While there are guidelines and outcomes measurements for specific disease states there are not guidelines or tools for treatment of the COPD patient with asthma or heart failure.

References:

Estban, C., Quintanam JM., Egurrola, M., et al. 2009. Classifying the severity of COPD: are the new severity scales better than old? Int J Tuberc Lung Disease, 13(6), 783-790.

Global initiative for chronic obstructive lung disease. (2009). retrieved from www.goldcopd.org

Halbert, RJ., Tinkelman, DG., Globe, DR., & Lin SL. (2009). Measuring asthma control is the first step to patient management: a literature review. Journal of Asthma, 46(7), 659-664.

Provisional Topic: Effectiveness and Implementation of NIV in acute respiratory failure
Subtopic: Non-invasive vs. Invasive Positive Pressure Ventilation Protocol for managing acute respiratory failure due to AE-COPD

Questions:

- What is the comparative effectiveness of a Non-invasive vs. Invasive Positive Pressure Ventilation Protocol for managing acute respiratory failure due to acute exacerbations of COPD
- Compare in-hospital mortality for patients presenting with ARF-COPD who are managed in emergency departments utilizing a NIPPV Implementation Protocol versus emergency departments practicing usual care.
- Compare hospital length of stay and costs for patients presenting with ARF-COPD who are managed in emergency departments utilizing the CONCERT NIPPV Implementation Protocol versus emergency departments practicing usual care.

Rationale:

Noninvasive positive pressure ventilation (NIPPV) is the only intervention that has been shown in efficacy studies to improve mortality in patients presenting with respiratory failure due to exacerbations of COPD (ARF-COPD). Guidelines strongly recommend use of NIPPV in appropriate patients with ARFCOPD. However observational studies (paper under review, Holguin, Krishnan, et al.) indicate that NIPPV is utilized in less than 26% of patients with ARF-COPD and that patients who subsequently require definitive therapy with invasive positive pressure ventilation (IPPV) have higher mortality than patients who received IPPV as initial therapy. These data suggest challenges in the implementation of NIPPV, including possibly delays in providing definitive respiratory support in *real world practice*. This suggests the need for validated implementation strategies for use of NIPPV in ARF-COPD with comparison to outcomes from usual care.

References

Hess DR. The evidence for noninvasive positive-pressure ventilation in the care of patients in acute respiratory failure: A systematic review of the literature. Respiratory Care. 2004; 49:810-829.

Brochard L, Mancebo J, Wysocki M, Lofaso, F, et al. Noninvasive ventilation for acute exacerbations of chronic obstructive pulmonary disease. N Engl J Med. 1995; 333:817-822.

Keenan SP, Sinuff T, Cook DJ, Hill NS. Which patients with acute exacerbation of chronic obstructive pulmonary disease benefit from noninvasive positive-pressure ventilation? A systematic review of the literature. Ann Intern Med. 2003; 138:861-870.

Peter JV, Moran JL, Phillips-Hughes J, Warn D. Noninvasive ventilation in acute respiratory failure—A meta-analysis update. Crit Care Med. 2002; 30:555-562.

Sinuff T, Cook DJ, Randall J, Allen CJ. Evaluation of a practice guideline for noninvasive positive-pressure ventilation for acute respiratory failure. Chest. 2003; 2062-2073.

Provisional Topic: Effectiveness and Implementation of NIV in acute respiratory failure
Subtopic: Non-invasive Versus Invasive Positive Pressure-based weaning protocol vs. usual care

Questions:

- Compare duration of ventilator support (invasive and non-invasive) and hospital length of stay for patients who require invasive ventilation due to ARF-COPD that are managed by a NIPPV based weaning protocol versus usual care.
- Compare hospital mortality for patients who require invasive ventilation due to ARF-COPD that are managed by a NIPPV based weaning protocol compared versus usual care.

Rationale:

Even with ideal practice, a significant number of patients with ARF-COPD will fail NIPPV and require invasive ventilation. Efficacy studies have shown that protocolized extubation of these patients to NIPPV for weaning after 48 hours of mechanical ventilation results in significant decreases in required days of ventilator support. It is unknown how often this practice is being used and whether it is more effective than usual ventilator weaning protocols.

References:

Girault C, Daudenthun I, Chevron V, Tamion F, Leroy J, Bonmarchand G. Noninvasive ventilation as a systematic extubation and weaning technique in acute-on-chronic respiratory failure: a prospective, randomized controlled study. Am J Respir Crit Care Med 1999; 160(1):86-92.

Nava S, Ambrosino N, Clini E, Prato M, Orlando G, Vitacca M, et al. Noninvasive mechanical ventilation in the weaning of patients with respiratory failure due to chronic obstructive pulmonary disease: a randomized, controlled trial. Ann Intern Med 1998;128(9): 721-728.

Provisional Topic: Effectiveness and Implementation of NIV in acute respiratory failure
Subtopic: Implementation and outcomes of non-invasive ventilation in routine clinical practice

Questions:

- What is the percentage of ideal candidates for treatment with noninvasive ventilation that receive this therapy in routine clinical practice
- How much variation is there in the use of noninvasive ventilation across hospitals
- What are the patient, physician and hospital characteristics associated with higher rates of use among ideal candidates?
- To what extent to the outcomes of patients treated with noninvasive ventilation vary across hospitals?
- What are the organizational characteristics and practices of hospitals that apply noninvasive ventilation to a high percentage of ideal candidates; what are the facilitators and barriers to successful implementation and delivery of noninvasive ventilation

Rationale:

1. COPD common, morbid, costly yet little known about overall quality of care or variations across hospitals
2. Noninvasive ventilation is the only therapy that has been shown to improve short term survival for patients hospitalized for AECOPD
3. No empiric data on use of noninvasive ventilation in routine clinical practice, yet survey data suggest that there may be wide variations in use. Audit studies have also suggested that noninvasive ventilation may be underused
4. Implementation of noninvasive ventilation is a complex sociotechnical endeavor; requiring knowledge of its use, personnel with specialized training/expertise, equipment, guidelines/protocols.
5. Identifying gaps in care and facilitators and barrier are critical first steps towards ultimately improving the use of noninvasive ventilation and improving outcomes for patients hospitalized with AECOPD

References:

1. Lightowler JV, Wedzicha JA, Elliott MW, Ram FSF. Non-invasive positive pressure ventilation to treat respiratory failure resulting from exacerbations of chronic obstructive pulmonary disease: Cochrane systematic review and meta-analysis. BMJ. 2003 Jan 25;326(7382):185.

2. Maheshwari V, Paioli D, Rothaar R, Hill NS. Utilization of noninvasive ventilation in acute care hospitals: a regional survey. Chest. 2006 May;129(5):1226-1233.

3. Schettino G, Altobelli N, Kacmarek RM. Noninvasive positive-pressure ventilation in acute respiratory failure outside clinical trials: experience at the Massachusetts General Hospital. Crit. Care Med. 2008 Feb;36(2):441-447.

4. Sweet DD, Naismith A, Keenan SP, Sinuff T, Dodek PM. Missed opportunities for noninvasive positive pressure ventilation: a utilization review. J Crit Care. 2008

Mar;23(1):111-117.

5. Pierson DJ. Translating evidence into practice. Respir Care. 2009 Oct;54(10):1386-1401.

Provisional Topic: Implementation of AE-COPD Care
Subtopic: Using checklist to improve the quality of care and outcomes for patients hospitalized with AE-COPD.

Questions:

- Does implementation of a checklist designed to improve the care of patients with AECOPD result in greater adherence to guideline recommendations?
    a. Potential checklist components
        i. Antibiotics
        ii. Steroids
        iii. NIV
        iv. Discharge medication 'bundle' (ICS, etc)
        v. Oxygen assessment
        vi. Smoking cessation
        vii. Pulm rehab
        viii. Other
- Does implementation of a checklist designed to improve the care of patients with AECOPD results in improved patient outcomes
    a. Reduced risk of mortality
    b. Reduced risk of late mechanical ventilation / transfer to ICU
    c. Reduced risk of ED visit
    d. Reduced risk of readmission
    e. Decreased inpatient cost
    f. Decreased length of stay

Rationale:

1. Hospital admissions for COPD are common, morbid, costly.
2. Studies of quality of care for patients hospitalized for COPD have suggested opportunities to improve the use of beneficial therapies while potentially reducing the use of unnecessary treatments and services, and have documented substantial variation in care across hospitals
3. While inpatient mortality rates in AECOPD appear to be declining, readmission rates are high and mortality and readmission rates vary across hospitals.
4. 'Checklists' are a form of clinical decision support borrowed from aviation that have been shown to enhance adherence to recommended care processes and to improve outcomes in the prevention of catheter associated blood stream infection (CA-BSI), and for patients undergoing surgical operations.
5. Checklists can be implemented through a variety of means, including paper and within EMRs (either within an order set or through clinical documentation)
6. Checklists may be an effective strategy for increasing adherence to recommended treatments and improving outcomes among patients hospitalized for AECOPD as part of a multidimensional quality improvement effort.

References:

1. Pronovost P, Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S, et al. An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU. N Engl J Med. 2006 Dec 28;355(26):2725-2732.

2. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AS, Dellinger EP, et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. N Engl J Med. 2009 Jan 29;360(5):491-499.

3. Robb E, Jarman B, Suntharalingam G, Higgens C, Tennant R, Elcock K. Using care bundles to reduce in-hospital mortality: quantitative survey. BMJ. 2010 Mar 31;340(mar31_3):c1234.

4. Levy MM, Dellinger RP, Townsend SR, Linde-Zwirble WT, Marshall JC, Bion J, et al. The Surviving Sepsis Campaign: results of an international guideline-based performance improvement program targeting severe sepsis. Intensive Care Med. 2010 Feb;36(2):222-231.

5. Gao F, Melody T, Daniels DF, Giles S, Fox S. The impact of compliance with 6-hour and 24-hour sepsis bundles on hospital mortality in patients with severe sepsis: a prospective observational study. Crit Care. 2005;9(6):R764-770.

Provisional Topic: Role of antibiotics in acute exacerbations
Subtopic: Comparative effectiveness of therapy with corticosteroids alone vs. corticosteroids plus antibiotics in outpatients with acute exacerbations of COPD

Questions:

- What are the comparative benefits of oral corticosteroids and antibiotics versus oral corticosteroids alone for outpatient COPD exacerbation?
- What are the comparative harms of each of the treatment groups?
- What is the incremental cost-effectiveness of the intervention from a societal perspective?
- What is the longitudinal effectiveness of the intervention for patients who have multiple exacerbations?
- What is the effectiveness of telemonitoring system to detect COPD exacerbations?
- What is the effectiveness of the telemonitoring system to trigger treatment for COPD exacerbations?

Rationale:

Acute exacerbations of COPD (AECOPD) are common and lead to significant decrements in functional status, HRQoL, and lung function. They also lead to significant utilization of healthcare resources. There is substantial practice variation in treatment regimens for AECOPD due to limited data from small efficacy trials. Three treatment combinations are primarily used for AECOPD, antibiotics, steroids, and antibiotics + steroids. While most clinicians favor the use of steroids, recent and past meta-analysis suggest that the role of antibiotics is limited (Saint, Puhan) among patients with mild-moderate disease/exacerbations. Yet most (if not all) efficacy trials included antibiotics.

There is ample evidence for overuse of antibiotics; conservative estimates indicate that antibiotics are used for millions of COPD exacerbations each year. Overuse leads to increased healthcare costs, antibiotic resistance, and treatment-related complications.

References:

1. Puhan MA, Vollenweider D, Steurer J, Bossuyt PM, Ter Riet G. Where is the supporting evidence for treating mild to moderate chronic obstructive pulmonary disease exacerbations with antibiotics? A systematic review. BMC Med. 2008 Oct 10;6:28.

2. Saint S, Bent S, Vittinghoff E, Grady D. Antibiotics in chronic obstructive pulmonary disease exacerbations. A meta-analysis. JAMA. 1995 Mar 22-29;273(12):957-60.

3. Wilkinson TM, Donaldson GC, Hurst JR, Seemungal TA, Wedzicha JA. Early therapy improves outcomes of exacerbations of chronic obstructive pulmonary disease. Am J Respir Crit Care Med. Jun 15 2004;169(12):1298-1303.

4. Koff PB, Jones RH, Cashman JM, Voelkel NF, Vandivier RW. Proactive integrated care improves quality of life in patients with COPD. Eur Respir J. May 2009;33(5):1031-1038.

Provisional Topic: Role of antibiotics in acute exacerbations
Subtopic: Procalcitonin guided therapy vs. usual care for patients hospitalized with AE-COPD

Questions

- Can serum procalcitonin measurement be used to safely identify patients with AECOPD who do not require antibiotic therapy?
- Can repeated / serial serum procalcitonin measurement be used to safely reduce the duration of antibiotic administration for patients with AECOPD

Rationale

1. Respiratory infections appear to be the most frequent cause of COPD exacerbation, accounting for 50%-80% of all exacerbations.
2. Although as many as 2/3 of these may be viral infections, guidelines recommend antibiotic treatment for patients with purulent sputum and either an increase in sputum production or an increase in dyspnea.
3. As a consequence, nearly 90% of patients who are hospitalized for exacerbations of COPD are treated with antibiotics, despite the fact that most exacerbations are not believed to be the result of acute bacterial infection
4. Distinguishing patients who benefit from antibiotics from those who do not has the potential to reduce antibiotic exposure to hundreds of thousands of patients who are hospitalized for acute exacerbations of COPD and millions who are treated with antibiotics in the ambulatory setting. This can reduce costs, antibiotic related complications (eg C.Dif) and reduce resistance.
5. In a single center trial in Switzerland Stolz, et al. demonstrated that withholding antibiotics from COPD patients with normal procalcitonin resulted in comparable health outcomes with 32% less antibiotic use.
6. In a 6 center multicenter trial conducted in Switzerland, Schuetz et al. demonstrated that procalcitonin guided therapy led to reduced percentage of patients receiving antibiotic therapy as well as a 50% decrease in the duration of therapy for antibiotic treated patients.

References:

1. Groenewegen KH, Wouters EFM. Bacterial infections in patients requiring admission for an acute exacerbation of COPD; a 1-year prospective study. Respir Med. 2003 Jul;97(7):770-777.

2. Lieberman D, Lieberman D, Ben-Yaakov M, Lazarovich Z, Hoffman S, Ohana B, et al. Infectious etiologies in acute exacerbation of COPD. Diagn. Microbiol. Infect. Dis. 2001 Jul;40(3):95-102.

3. Rosell A, Monsó E, Soler N, Torres F, Angrill J, Riise G, et al. Microbiologic determinants of exacerbation in chronic obstructive pulmonary disease. Arch. Intern. Med. 2005 Apr 25;165(8):891-897.

4. Stolz D, Christ-Crain M, Bingisser R, Leuppi J, Miedinger D, Müller C, et al. Antibiotic treatment of exacerbations of COPD: a randomized, controlled trial comparing procalcitonin-

guidance with standard therapy. Chest. 2007 Jan;131(1):9-19.

5. Daubin C, Parienti J, Vabret A, Ramakers M, Fradin S, Terzi N, et al. Procalcitonin levels in acute exacerbation of COPD admitted in ICU: a prospective cohort study. BMC Infect. Dis. 2008;8:145.

6. Schuetz P, Christ-Crain M, Thomann R, Falconnier C, Wolbers M, Widmer I, et al. Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA. 2009 Sep 9;302(10):1059-1066.

Provisional Topic: Role of antibiotics in acute exacerbations
Subtopic: Macrolide antibiotics for acute COPD

Question:
Can using macrolide antibiotics in COPD exacerbations reduce time to recovery to baseline and length of stay? What is the optimal timing and dosing strategy for the anti-inflammatory effects of macrolides (*e.g.* a 1-time loading dose in the ED)?

Rationale:
Recent bench research suggests that macrolides seem to have an anti-inflammatory effect beyond the antimicrobial effect akin to statin use in AMI. However, use of macrolide antibiotics is limited due to bacterial resistance issues, necessitating the identification of which dosing regimen has greatest benefit with the fewest risks.

Note: COPD CRN is conducting an efficacy trial of long-term macrolides in pts with COPD to prevent COPD exacerbations

References:
Macrolide azithromycin to prevent rapid worsening of symptoms associated with chronic obstructive pulmonary disease. ClinicalTrials.gov [NCT00325897].

Seemungal TA, Wilkinson TM, Hurst JR, Perera WR, Sapsford RJ, Wedzicha JA. Long-term erythromycin therapy is associated with decreased chronic obstructive pulmonary disease exacerbations. Am J Respir Crit Care Med. 2008;178(11):1139- 1147 [PMID 18723437].

Amsden GW. Anti-inflammatory effects of macrolides--an underappreciated benefit in the treatment of community-acquired respiratory tract infections and chronic inflammatory pulmonary conditions? J Antimicrob Chemother. 2005;55(1):10-21 [PMID 15590715].

Siddiqui J. Immunomodulatory effects of macrolides: Implications for practicing clinicians. Am J Med. 2004;117 Suppl 9A:26S-29S [PMID 15586561].

Tamaoki J, Kadota J, Takizawa H. Clinical implications of the immunomodulatory effects of macrolides. Am J Med. 2004;117 Suppl 9A:5S-11S [PMID 15586558].

Provisional Topic: Quality of Care Assessment
Subtopic: Implementation of AE-COPD Care

Questions:

- How can guideline recommendations be implemented into AE-COPD care practice in a way that is feasible, usable, relevant, and cost-effective?
- How can we best develop, harmonize, and use performance measures for AE-COPD care to increase patient centered, effective, safe, timely, efficient, and equitable care?

Rationale:

Guidelines are based on evidence from the medical literature often developed in specialty care and academic setting and interpreted by experts who provide valuable summaries. However, seldom are those guideline summaries written in a manner that can be used to direct the process of care within everyday primary care practices. (Mularski 2006, Lindenauer 2006) Most physicians treating COPD recognize some of the limitations of the evidence and therefore the resulting guidelines: the evidence often gathered in patients with few co-morbid conditions and good control over adverse life style habits. This limits the generalizability of the evidence and the guidelines across all practices. But for "real world" care additional barriers exist to guideline use. Nor are care process measures well-defined. Guidelines require more than simple dissemination to impact practice and patient outcomes. They require attention to physician attitudes, development of flexible practice tools and systems easily implementable in everyday practice. (Woolf 2007, Yawn 2008a)

References:

Mularski RA, Asch SM, Shrank WH, et al. The quality of obstructive lung disease care for adults in the United States as measured by adherence to recommended processes. Chest 2006; 130: 1844-50.

Lindenauer PK, Pekow P, Gao S, et al. Quality of care for patients hospitalized for acute exacerbations of chronic obstructive pulmonary disease. Ann Intern Med 2006; 144: 894-903.

Woolf SH. The meaning of translational research and why it matters. JAMA 2008;299(2):211-3

Yawn B, Wollan P. Knowledge and attitudes of family physicians coming to COPD continuing medical education. Int J Chron Obstruct Pulm Dis. 2008;3(2):311-7.

Provisional Topic: Quality of Care Assessment
Subtopics: Development of performance measurement for AE-COPD care
Development of a registry for assessing care quality

Questions:

- What is the sensitivity and specificity of current approaches based on administrative/billing data to identify AE-COPD patients for quality improvement initiatives? Which approach offers the optimal combination of sensitivity and specificity?
- What is the validity of administrative/billing data to evaluate the quality of AE-COPD care as part of quality improvement initiatives? What care practices can be assessed using these data?
- How do patient factors (e.g., presence of comorbid conditions), provider factors (e.g., training or board-certification), and practice factors (e.g., for vs. not-for-profit) affect the validity of administrative data to identify patients with COPD and evaluate the validity of indicators for assessing the quality of COPD care?
- What are national benchmarks for quality of care (needs a registry)?

Rationale:

The extent to which computerized searches of electronic medical records (EMR) and/or billing/pharmacy data can be used to track and evaluate the quality of care is unclear. Despite the enormous health and financial burden of for COPD, there is currently no consensus regarding the validity of administrative/billing data to identify COPD or evaluate the quality of COPD care.

References:

Lindenauer PK, Pekow P, Gao S, et al. Quality of care for patients hospitalized for acute exacerbations of chronic obstructive pulmonary disease. Ann Intern Med 2006; 144: 894-903.

Mularski RA, Asch SM, Shrank WH, et al. The quality of obstructive lung disease care for adults in the United States as measured by adherence to recommended processes. Chest 2006; 130: 1844-50.

Stein BD MD, Holguin F, Lindenauer PK, Bautista A, Schumock GT, Charbeneau JT, Krishnan JA. How You Count Hospitalizations for Acute Exacerbations of COPD (AECOPD) Matters. Am J Respir Crit Care Med 2008. 2008;177:A133.

Quan H, Sundararajan V, Halfon P, et al. Coding algorithms for defining comorbidities in ICD-9-CM and ICD-10 administrative data. Med Care. Nov 2005;43(11):1130. 9.

Ginde AA, Tsai CL, Blanc PG, Camargo CA, Jr. Positive predictive value of ICD^{7} 9^{7} CM codes to detect acute exacerbation of COPD in the emergency department. Jt Comm J Qual Patient Saf. Nov 2008;34(11):678-80.

Provisional Topic: Dyspnea Crisis in COPD
Subtopics: Identification, risk assessment, and first response
Efficient utilization, communication, and care coordination
Utility of patient education and provider aid products
Translational research into audit and quality enhancement tools

Rationale:
Consensus statements by ACCP and ATS on dyspnea describe management of chronic and episodic dyspnea. In COPD a priority of research includes acute crises of dyspnea that may result in intensive medical utilization, especially near the end of life. This clinical entity has been defined as a *dyspnea crisis* - "sustained and severe resting breathing discomfort that occurs in patients with advanced, often life-limiting illness and overwhelms the patient and caregivers' ability to achieve symptom relief." Although efficacy studies and synthesizes have identified a number of therapies for management, primarily opiates, effectiveness studies and implementation improvement research is needed. Additional subtopics for research in COPD for dyspnea crisis include identification, risk assessment, and first response; ethical and professional considerations; efficient utilization, communication, and care coordination; clinical management of dyspnea crisis with algorithm components; utility of patient education and provider aid products; and translational research into audit and quality enhancement tools.

References:
American Thoracic Society. Dyspnea. Mechanisms, assessment, and management: a consensus statement. American Thoracic Society. Am J Respir Crit Care Med. Jan 1999;159(1):321-340.

The Hospice and Palliative Medicine National Consensus Guidelines. Available at www.nationalconsensusproject.org. 2004. Accessed on 5-14-2009.

Mahler DA, Selecky PA, Harrod CG, Benditt JO, Carrieri-Kohlman V, Curtis JR, Manning HL, Mularski RA, Varkey B, Campbell M, Carter ER, Chiong JR, Ely EW, Hansen-Flaschen J, O'Donnell DE, Waller A. Management of dyspnea in patients with advanced lung or heart disease. Chest 2010; 137(3):674-691.

Lanken PN, Terry PB, Delisser HM, Fahy BF, Hansen-Flaschen J, Heffner JE, Levy M, Mularski RA, Osborne ML, Prendergast TJ, Rocker G, Sibbald WJ, Wilfond B, Yankaskas JR. An official American Thoracic Society clinical policy statement: palliative care for patients with respiratory diseases and critical illnesses. Am J Respir Crit Care Med 2008;177:912-927.

Bausewein C, Farquhar M, Booth S, Gysels M, Higginson IJ. Measurement of breathlessness in advanced disease: a systematic review. Respir Med 2007;101:399-410.

Dorman S, Byrne A, Edwards A. Which measurement scales should we use to measure breathlessness in palliative care? A systematic review. Palliat Med 2007;21:177-191

Mularski RA, Campbell ML, Asch SM, Reeve BB, Basch E, Maxwell TL, Cuny J, Clauser SB, Snyder CF, Seow H, Wu, AW, Dy S. A review of quality of care evaluation for the palliation of dyspnea. Am J Respir Crit Care Med. Mar 2010;181(3):534-38

Provisional Topic: Interventions for acute airway obstruction
Subtopic: Tiotropium vs. nebulized bronchodilators for acute COPD

Question:
Is there a role for tiotropium in addition to nebulizer treatments in acute COPD exacerbations particularly in terms of reducing utilization of nebulizer treatments, recovery to baseline, and reducing length of stay?

Rationale:
Initiating tiotropium concurrently with rapid-onset nebulizer treatments to more quickly regain better control throughout the day. This may yield less total albuterol nebulizer usage and perhaps quicker turnaround time.

Reference:
Tashkin DP. Preventing and managing exacerbations in COPD--critical appraisal of the role of tiotropium. Int J Chron Obstruct Pulmon Dis. 2010;5:41-53 [PMID 20368910].

Provisional Topic: Oxygen therapy post-exacerbation
Subtopic: LTOT based on O2 saturation at rest vs. rest plus activity

Question:
Should LTOT requirements be based on targeted oxygen saturations at rest and during activity, lower utilization of health care resources and improve the patient's respiratory quality of life?

Rationale:
We had some discussion regarding the variability of delivery systems last year. Since that time, a small study has been published which documents the wide variance in oxygen output when pulse dose devices are employed. Since LTOT has been shown to be the only clinical intervention which has a positive effect on COPD patient mortality, given the recent published evidence albeit limited, there is a strong indication that LTOT delivery technology efficiency and accuracy will vary among devices. This could result in under-dosing patients.

Reference:
Palwai A, Skowronski M, Coreno A, Drummon C, McFadden ER. Critical comparisons of clinical performance of oxygen conserving devices. Am J Respir Crit Care Med. 2010;181(10):1061-71.

Transitions in COPD Care Provisional Research Areas & Topics

Provisional Topic: Integrated healthcare strategies during transitions in COPD care
Subtopic: Chronic disease management programs in COPD in primary and secondary care

Questions:
Which programs or program elements are most critical, the "active ingredients" in improving quality of life, reducing hospitalizations, reducing emergency department visits, and increasing survival?

Rationale:
More research is needed on chronic disease management programs in patients with COPD across primary and secondary care. Niesink et al (2007) conducted a systematic review of these programs, and included RCTs of outpatient programs, "including at least one of the following components: (1) multidisciplinary care team, (2) clinical pathway,(3) clinical follow-up, (4) case management, and (5) self-management or patient education." Other components may also be important, and have not been studied in a systematic review of COPD care to date.

References:
A. Niesinka, J.C.A. Trappenburga, G.H. de Weert-van Oenea, J.W.J. Lammersb, T.J.M. Verheija, A.J.P. Schrijversa. Systematic review of the effects of chronic disease management on quality-of-life in people with chronic obstructive pulmonary disease. Respiratory Medicine 2007; 101: 2233–9.

Provisional Topic: Integrated healthcare strategies during transitions in COPD care
Subtopic: Cost effectiveness of multi-component COPD programs

Question:
What is cost effectiveness of multi-component COPD programs?

Rationale:
This area remains a challenge due to scarce methodologically sound studies that demonstrate significant improvements on process, intermediate and end results of care. Well-designed health economic studies are needed to decrease the current decision uncertainty. The current evidence regarding efficacy, effectiveness and cost effectiveness for COPD is severely limited by the amount and quality of well-designed studies and the evidence that has been published so far reveals results that are far below expectations. The systematic reviews of Weingarten, Ofman, and Mattke consistently show that disease management is less effective for COPD than it is for chronic conditions such as diabetes, congestive heart failure and depression.

References:
Steuten L M G, Lemmens, K M M, Nieboer, A P, Vrijhoef, HJM. Identifying potentially cost effective chronic care programs for people with COPD. International Journal of COPD. 2009;4: 87–100

Weingarten SR, Henning JM, Badamgarav E, et al. Interventions used in disease management programmes for patients with chronic illness – which ones work? Meta-analysis of published reports. BMJ. 2002;325:925–932.

Ofman JJ, Badamgarav E, Henning JM, et al. Does disease management improve clinical and economic outcomes in patients with chronic diseases? A systematic review. Am J Med. 2004;117:182–192.

Mattke S, Seid M, Ma S. Evidence for the effect of disease management: is $1 billion a year a good investment? Am J Manag Care. 2007;13:670–676.

Provisional Topic: Integrated healthcare strategies during transitions in COPD care
Subtopic: Social Work Services for transitions to home/home care in COPD

Question:
Do regularly structured visits by social workers as part of the interdisciplinary COPD health care team assist patients and family members in dealing with transitions of care (e.g., use of home care services to long term care, hospital to home with home care services)?

Rationale:
Social workers can play important roles as a member of the health care team specializing in working with persons who have COPD. There is a need for effectiveness research to demonstrate the effectiveness of social work services, including outreach, use of support groups, psycho-educational services and care coordination for persons with COPD. Through home visits, social workers can assist persons with COPD examine life style issues and provide guidance on every day adjustments to manage the illness and reduce periods of exacerbation.

As many older people, particularly those previously employed in the mining industry, see breathing problems as a consequence of aging rather than a specific illness, there is often a tendency not to seek treatment, which means that advice and guidance about managing the illness are not obtained.

Home care services can also support family members or others who are caring for the person with COPD to help provide needed support and limit social isolation to avoid the emotional, health and or physical problems that are sometimes associated with long term caregiving.

References:
http://www.ciswo.org.uk/

asthma.bsd.uchicago.edu/AboutCenter/activities.html. Assessing caregiver strains and providing psychosocial supports can help to lessen transitions among home, hospital, long term care settings and also make transitions from hospital to home more effectives.

Provisional Topic: Integrated healthcare strategies during transitions in COPD care
Subtopic: Gaps in medication reconciliation in the transitions of care the COPD patient

Question:
Does the use of an individual who specializes in care of COPD patients for medication reconciliation improve patient safety and outcomes?

Rationale:
There is an aggressive push for medication reconciliation among the various regulatory agencies since the prominent highlighting of the significant number of medication errors prevalent in medical care. Medication errors are well known to contribute to patient mortality and morbidity and have thus been the focus of identifying and addressing gaps in medication reconciliation. In COPD patients, there does not appear to be any literature addressing medication errors with medication reconciliation in their transition of care. Literature is present on the benefits of the complex medical patient receiving counseling; however specifically addressing the unique aspects of the COPD patient is not available. Traditional models and studies to date usually utilize a nurse or a pharmacist in this role. Are these providers the best to address the needs of the complex CPOD patients, or should a more specialized individual in COPD care such a respiratory therapist be utilized?
By better managing and addressing the proper medication usage, the risk of errors of improper use, under use as well as overuse will hopefully lead to an increase in patient safety with a decrease in mortality and morbidity.

References:
Velthove KJ, et al. Medication changes prior to hospitalization for obstructive lung disease: a case-crossover study. Annals of Pharmacotherapy 2010; 444: 267.

http://phx.corporate-ir.net/phoenix.zhtml?c=183405&p=irol-newsArticle&ID=1412280&highlight= (1 of 4)

Provisional Topic: Integrated healthcare strategies during transitions in COPD care
Subtopic: Effects of Primary Care Actions on Transitions of Care in COPD

Questions

- Does having a nominated Primary Care Provider (continuous and comprehensive) on discharge or prior to admission improve the process of transition, delay readmission, expedite discharge or reduce health care costs?

- Do admission rates for acute exacerbations of COPD change over time as universal coverage is introduced in the USA?

Rationale Acute exacerbations of COPD are the commonest reason for hospital admission in Edmonton, Alberta and have the longest Length of Stay (14-16 days) of all acute medical conditions including AMI, CHF etc. The statistics are similar throughout North America and readmission rates are amongst the highest (over one per year for patients with severe COPD). Many patients in North America do not have a nominated primary care physician. This is as true in Canada (due to physician shortages) as in the USA where lack of health care coverage is an additional factor.

References:

Lewanczuk R. Innovations in primary care: Implications for hypertension detection and treatment. Can J Cardiol 2006: 22(7):614-616

Provisional Topic: Integrated healthcare strategies during transitions in COPD care
Subtopic: The effectiveness of early admission to a Pulmonary Rehabilitation program and self-management tools in preventing re-hospitalizations and improving quality of life following an AECOPD.

Questions:

1. Will early admission to a Pulmonary Rehabilitation program following a hospitalization for COPD reduce the likelihood of readmission within the following year?
2. Will a COPD symptom self-management plan augment the benefits of Pulmonary Rehabilitation?
3. What is the most effective time to implement the transition from hospitalization to rehabilitation following a COPD exacerbation admission?

Rationale:

A hospital admission or readmission in patients with chronic obstructive pulmonary disease (COPD) is a clinically and economically undesirable event. For the patient, it may signal the beginning of the terminal phase of the illness.[1] For the health services system, it represents a major part of the cost of care for a condition that is increasingly burdensome. However, little is known now about interventions in COPD to decrease hospitalization. COPD exacerbations are defined as a change in symptoms that requires a change in management.[5]. In patients with COPD, the last few years of life are frequently characterized by repeated episodes of exacerbations that culminate in hospital admission. Exacerbations are clearly associated with a declining state of health.[6] Severe exacerbations require admission to the hospital and are responsible for up to 70% of the direct healthcare costs associated with COPD.7 Exacerbations are also associated with increased mortality,[4, 8-10] decreased quality of life,[3] and decreased lung function.[2] During a COPD-related hospitalization, patients generally undergo a flurry of activity at the beginning of the admission, and this is followed by days of observed inactivity. As a result, patients may leave the hospital weaker than when they were admitted. It is highly plausible that a recovery in physical activity through rehabilitation would improve the patients' clinical progress. The authors of a recent systematic review on the effect of PR after hospital discharge reported that patients who received post-hospitalization PR had a significantly lower risk of re-hospitalization than those who did not.[9]

References:

1. Morgan MD. Preventing hospital admissions for COPD: role of physical activity. Thorax 2003;58(2):95-6.
2. Donaldson GC, Seemungal TA, Bromwich A, Wedzicha JA. Relationship between exacerbation frequency and lung function decline in chronic obstructive pulmonary disease. Thorax 2002;57(10):847-52.
3. Spencer S, Calverley' PM, Burge PS, Jones PW. Impact of preventing exacerbations on deterioration of health status in COPD. Eur Respir J 2004;23(5):698-702.
4. Alfaro P, Callboy E, Ochoa de Echaguen A, et al. Mortality after hospitalization for COPD. Chest 2002;121(5):1441-8.

5. Rodriguez-Roisin R. Toward a consensus definition for COPD exacerbations. Chest 2000;117(5 Suppl 2):398S-401S.
6. Seemungal TA, Donaldson GC, Paul EA, Bestall JC, Jeffries DJ, Wedzicha JA. Effect of exacerbation on quality of life in patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1998;157(5 Pt 1):1418-22.
7. Halpern MT, Stanford RH, Borker R. The burden of COPD in the U.S.A.: results from the Confronting COPD survey. Respir Med 2003;97 Suppl C:S81-9.
8. Puhan M, Scharplatz M, Troosters T, Walters EH, Steurer J. Pulmonary rehabilitation following exacerbations of chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2009 Jan 21;(1):CD005305.
9. Puhan MA, Scharplatz M, Troosters T, Steurer J. Respiratory rehabilitation after acute exacerbation of COPD may reduce risk for readmission and mortality – a systematic review. Respir Res. 2005; 6(1):54.

Provisional Topic: Integrated healthcare strategies during transitions in COPD care
Subtopic: Hospital based case management vs. post-discharge telephone calls by respiratory therapist

Question:
What is the clinical and economic impact of a case management program that is hospital-based with monthly telephonic visits from a health care professional with expertise in respiratory care?

Rationale:
Compliance or adherence to physician care plans continues to be a challenge. Recently published evidence demonstrates that an education intervention undertaken by hospital staff coupled with monthly telephonic follow-ups can reduce hospital admissions, emergency department visits and compliance relating to patient use of "controller medications."
Consistent use of "controller medications" continues to be a problem. A recent study has shown that a short patient education session provided to COPD patients can contribute to earlier recognition of exacerbations on the part of the patient, more timely use of prescription medications including antibiotics, and greater adherence to the physician's care plan can decrease cost triggered by COPD patients. Their exacerbations require ED visits, hospital admissions or consumption of other health care resources.

Reference:
Rice KL, Dewan N, Bloomfield HE, Grill J, Schult T, et al.. Disease management program for chronic obstructive pulmonary disease: a randomized controlled trial. Am J Respir Crit Care Med. 2010; 182:890-896.

Provisional Topic: Integrated healthcare strategies during transitions in COPD care
Subtopic: Factors affecting implementation of Pulmonary Rehabilitation post AE-COPD

Questions:

1. How do patient and provider factors support/deter patients' ability to participate in pulmonary rehabilitation post-exacerbation?

2. How often is pulmonary rehabilitation prescribed for patients post-exacerbation and what factors influence this prescription?

Rationale:

"Evidence from small studies of moderate methodological quality suggests that pulmonary rehabilitation is a highly effective and safe intervention to reduce hospital admissions and mortality and to improve health-related quality of life in COPD patients after suffering an exacerbation" (Cochrane Collaboration, 2009). Pulmonary rehabilitation is an accepted intervention in COPD but there is no consensus on its effects on exacerbations (Seemungal, Hurst, & Wedzicha, 2009). Is more data needed from efficacy studies for this group of patients? Respiratory nurses support the need for this type of research. From their experience they believe that pulmonary rehabilitation is undervalued and underutilized.

References:

Clini EM, Crisafulli E, Costi S et al. Effects of early inpatient rehabilitation after acute exacerbation of COPD. Respir Med 2009; 103(10): 1526-1531.

Puhan M, Scharplatz M, Trooster T, Walters EH, Steurer J. Pulmonary rehabilitation following exacerbations of chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2009; 1(1): CD005305.

Seemungal TA, Hurst JR, Wedzicha JA. Exacerbation rate, health status and mortality in COPD - a review of potential interventions. Int Chron Obstruct Pulm Dis. 2009; 4: 203-223.

Provisional Topic: Multimorbidity and transitions in COPD care
Subtopic: Effectiveness of guideline recommendations in multi-morbid patients

Questions:
1. What is the effectiveness of guideline recommendations for chronic obstructive pulmonary disease (COPD) care in patients with multimorbidity, including angina, heart failure, atrial fibrillation, diabetes mellitus, hypertension, and osteoporosis vs. patients without these conditions?

2. What is the effectiveness of guideline recommendations for COPD care in patients with baseline reduced physician function, including reduced activities of daily living (ADL), incontinence, sensory impairment, and/or poor upper-extremity function, vs. patients without these conditions?

3. What is the effectiveness of guideline recommendations for COPD care in patients with baseline reduced cognitive function, including reduced executive function, vs. patients without reduced cognitive function?

4. What is the effectiveness of guideline recommendations for COPD care in patients with psychosocial difficulties, including those who are socially isolated, depressed, anxious, low levels of education, alcohol dependent vs. patients without these conditions?

5. What is the rate of misclassification of diagnosis (COPD vs. not) when using a fixed FEV/FVC ratio to diagnose COPD in older patients?

Rationale:
Prior work has shown that only 58%-to-66% of individuals who have COPD receive recommended care, but reasons underlying this low rate of adherence have not been established.[1,2] In particular, because COPD involves predominantly a middle-aged and older population, it is unknown whether aging-related factors adversely affect the effectiveness and/or implementation of current clinical practice guidelines for the diagnosis and management of COPD as a function of age-related transitions in health status.

We postulate that, in an aging population, the implementation and effectiveness of clinical practice guidelines for COPD diagnosis and management will be impeded by the following domains:

I. **Multimorbidity:** Comorbidities often result in complex regimens, with a substantial number of competing risks and benefits.[3] This may lead to polypharmacy that may be further characterized by non-adherence and medication-related adverse events.[3-5] In addition, multimorbidity is more likely to require complex transitions of care (regardless of initial setting), including prolonged hospitalizations and higher rates of re-admission and long-term care placement.
II. **Reduced physical function:** Individuals with ADL (including self-care and driving), restricted mobility (e.g. unable to walk one block, use of an assistive device, prior

falls, etc), incontinence (bladder or bowel), sensory impairment (vision or hearing), and/or poor upper-extremity function (especially hand-related function) are also likely to require complex transitions of care. In addition, these individuals may not be able to complete ATS-acceptable spirometry, which is the basis of current COPD-treatment guidelines.[6,7]

III. **Reduced cognitive function:** Individuals who have cognitive impairment, particularly executive dysfunction, are also likely to have high frequencies of medication non-adherence and adverse events**;** to require more complex transitions of care; and to not be able to complete spirometry. In addition, these individuals are at high risk of developing delirium during hospitalizations for COPD exacerbations.[8]

IV. **Psychosocial difficulties:** Individuals who are socially isolated (i.e., live alone), depressed, anxious, in a state of bereavement, dependent on a caregiver (or are caregivers themselves), poor, less educated, and/or regularly consume alcohol are also likely to require more complex transitions of care and higher frequencies of medication non-adherence and adverse events

Lastly, implementation of clinical practice guidelines for COPD, as published by the Global Initiative for Obstructive Lung Disease (GOLD), may not be acceptable to many in the medical community. This is because GOLD designates a diagnosis of COPD based on a fixed threshold for the ratio of forced expiratory volume in 1-second to forced vital capacity (FEV1/FVC), a practice that is seriously flawed in an aging population.[9]

References

1. Chest 2006;130:1844-50.
2. Ann Intern Med 2006;144:894-903.
3. JAMA 2005;294:716-724
4. JAMA 2008;300:1439-1450.
5. JAMA 2008;300:2407-2416.
6. Am J Respir Crit Care Med 2007;176:532-555.
7. Age and Ageing 2006; 35: 304-16.
8. NEJM 2006;354:1157-1165.
9. Am J Respir Crit Care Med 2010;181;446-451

Provisional Topic: Multimorbidity and transitions in COPD care
Subtopic: Barriers to implementing guideline recommendations in multi-morbid patients

Question:
How do the factors listed below modify the ability to implement COPD guidelines?

Rationale:
Prior work has shown that only 58%-to-66% of individuals who have COPD receive recommended care, but reasons underlying this low rate of adherence have not been established.[1,2] In particular, because COPD involves predominantly a middle-aged and older population, it is unknown whether aging-related factors adversely affect the effectiveness and/or implementation of current clinical practice guidelines for the diagnosis and management of COPD as a function of age-related transitions in health status.

We postulate that, in an aging population, the implementation and effectiveness of clinical practice guidelines for COPD diagnosis and management will be impeded by the following domains:

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II. **Reduced physical function:** Individuals with ADL (including self-care and driving), restricted mobility (e.g. unable to walk one block, use of an assistive device, prior falls, etc), incontinence (bladder or bowel), sensory impairment (vision or hearing), and/or poor upper-extremity function (especially hand-related function) are also likely to require complex transitions of care. In addition, these individuals may not be able to complete ATS-acceptable spirometry, which is the basis of current COPD-treatment guidelines.[6,7]

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1. Chest 2006;130:1844-50.
2. Ann Intern Med 2006;144:894-903.
3. JAMA 2005;294:716-724
4. JAMA 2008;300:1439-1450.
5. JAMA 2008;300:2407-2416.
6. Am J Respir Crit Care Med 2007;176:532-555.
7. Age and Ageing 2006; 35: 304-16.
8. NEJM 2006;354:1157-1165.
9. Am J Respir Crit Care Med 2010;181;446-451

Provisional Topic: Patient and family activation during transitions in COPD care
Subtopic: Patient activation and shared decision making in COPD

Rationale:
More research is needed on the role of patient activation in COPD – including when shared decision making helps patients manage their illness, and adhere to treatment recommendations. Research on shared decision making has shown many positive effects, but little has been done targeted at COPD patients.

Provisional Topic: Patient and family activation during transitions in COPD care
Subtopic: Professional translation/interpretation services to address Health Literacy in acute COPD care settings

Question:
Does the use of professional translation and/or interpretation services in acute care settings (e.g. emergency departments, hospitals, or acute care clinics) make a difference in the health care outcomes (e.g. readmission rates) after discharge for limited English Proficiency (LEP) patients who are diagnosed with COPD?

Rationale:
For individuals who speak a language other than English, the challenges to receiving health care, as well as, other crucial services can be, at times, insurmountable. In the United States, there are over 55 million people who speak a language other than English at home (U.S. Census Bureau, 2008). This include individuals with limited English proficiency (LEP) who have a insufficient ability to speak, read, write, or understand English (U.S. Dept. Health and Human Services, Office of Civil Rights,(2002).

Studies have shown how the absence of language services give rise to barriers and reduce the quality of care for LEP individuals causing their medical treatment to be significantly compromised (Bancroft, 2007). For example, medical errors and patient noncompliance increased and trust and satisfaction with their health care providers decreased (Families U.S.A.,2010) .

In addition, LEP individuals are less likely to have primary and preventative care visits, and more likely to use emergency rooms for their health care services (Chen 2007).

References:

Bancroft, Marjory, *Overcoming Language Barriers in Health Care Best Practices* (Ellicott City, MD: Cross Cultural Communications, April 23, 2007), available online at http://www.dhmh.state.md.us/hd/presentation/pdf/24MajorieBancroft.pdf

Chen, Alice et. al., "The Legal Framework for Language Access in Healthcare Settings: Title VI and Beyond," Journal of General Internal Medicine 22(November 2007):362.

Families U.S.A. Improving Access: CHIPRA Provides Increased Funding For Language Services, Feb. 2010 retrieved March 24, 2010 at: http://www.familiesusa.org/assets/pdfs/chipra/improving-language-access.pdf

Provisional Topic: Patient and family activation during transitions in COPD care
Subtopic: COPD and use of Transitions of Care Tools for patients and family caregivers

Question:
What is the effectiveness of using already developed transition of care (TOC) tools such as patient and family caregiver checklists to improve health and psychosocial outcomes for persons with COPD who are transitioning between settings?

Rationale:
The National Transitions of Care Coalition (NTOCC) and others, with participation of NASW, have developed several tools to assist both patients and caregivers in being engaged in the TOC process. Selected examples of tools are listed below. While practice and some research evidence was used to inform the development of these checklists they need to be tested through research studies in real world settings related to the different transition points.

References:
NTOCC consumer/caregiver checklist—can be used across settings—available in Spanish & French: http://www.ntocc.org/Portals/0/Taking_Care_Of_My_Health_Care.pdf

NTOCC consumer/caregiver toolkit for hospital stay—includes previous checklist: http://www.ntocc.org/Portals/0/Hospital_Guide.pdf

Consumers Advancing Patient Safety (CAPS) toolkit for hospital discharges—mostly for consumers/caregivers, though one part is for providers: http://patientsafety.org/page/transtoolkit/

CMS hospital discharge consumer checklist—also available in Spanish: http://www.medicare.gov/Publications/Pubs/pdf/11376.pdf

Commonwealth Fund-supported project to prevent avoidable hospitalizations from nursing homes: http://interact.geriu.org/ (already being piloted—see website for details)

Provisional Topic: Patient and family activation during transitions in COPD care
Subtopic: Communication about Goals / Preferences of Care in COPD (Transitions)

Question:
What is the effectiveness of communication about Goals / Preferences of Care during transitions in COPD care?

Rationale:
COPD is a chronic progressive disorder that results in debilitating symptoms such as dyspnea and severe reductions in activity and it is characterized by increasingly severe exacerbations (AE-COPD) of breathing difficulty that may lead to unwanted or unbeneficial healthcare utilization at the end of life. Further, COPD is frequently a progress disorder that contributes to death - currently COPD is the 4th leading cause of death and the only top ten killer on the rise. Research in lung diseases and from other fields (palliative management in advanced diseases) suggests that communication is an important clinical skill and should be targeted as a priority for clinical research and quality improvement in COPD, especially during transitions of care. Improved clinician communication can improve patient knowledge and enhance the therapeutic alliance between patient and provider, potentially enhancing patients' self management skills, and can lead to better health outcomes. Studies indicate a broad range of deficiencies in how clinicians discuss treatments, preferences for care, and optimize quality of life amongst patients with COPD. Communication between COPD patients and clinicians has been associated with quality of care and may enhance confidence in dealing with breathing problems; attention to specific communication strategies may lead to improvements in the care of patients with COPD. Not much is known across real-world settings about the patient experience or effects of different communication strategies. Research gaps include observational studies during transitions, research with comparative effectiveness of different communication strategies, and implementation studies across real-world settings regarding end-of-life planning and documentation of preferences in COPD.

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Provisional Topic: Patient and family activation during transitions in COPD care
Subtopic: Teaching appropriate use of inhalers in hospitalized settings

Questions:

- In patients hospitalized with COPD, what is the comparative effectiveness of a teach-to-goal strategy versus usual care on the ability to use respiratory inhalers and re-admissions after hospital discharge?

- In patients hospitalized with COPD, what is the cost-effectiveness of a teach-to-goal strategy versus usual care?

Rationale:

Transitions in care from hospitals to home are increasingly recognized as a vulnerable period in which patients and their caregivers are asked to assume greater responsibility for their healthcare. Poor self-management skills are thought to contribute to high readmission rates, including in patients with COPD. These findings have led to substantial attention by clinical practice guidelines recommending patient education at all points of care, including hospitals, and inclusion of patient education for selected health conditions as a publicly reportable metric for the quality of care provided in U.S. hospitals. Although it is widely recognized that patients with respiratory conditions, including COPD, are often unable to use inhalers correctly, very little is known about how best to implement recommendations to provide patient education prior to hospital discharge.

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Provisional Topic: Patient and family activation during transitions in COPD care
Subtopic: COPD education in the Primary Care Physician's Office

Question:

- Does one on one COPD education in the primary care physician's office by a qualified Respiratory Educator improve patient Quality of Life, health care utilization and exercise tolerance whilst maintaining lung function?

- Does one on one COPD education in the primary care physician's office by a qualified Respiratory Educator reduce health care costs?

Rationale: Chronic Disease management by non-physician health professionals is one of the new models of primary care provision in teams**.** We have recently concluded a pilot study (181 patients) of the attachment of qualified Respiratory Educators to 29 practices in Alberta. The educators delivered a standardized but patient-centered program over three sessions in a randomized control study. Results suggest that education in this way can reduce urgent visits to the family physician and to ER , can improve some aspects of the SGRQ and preserve pulmonary function over one year. Each of these findings are of low or inadequate significance. **The study needs repeating in an improved form in a multi-centered randomized study to confirm the results before the widespread adoption of educators in primary care practices.**

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Provisional Topic: Patient and family activation during transitions in COPD care
Subtopic: Role of family members in prevention and post-discharge follow-up programs

Questions:

1. What type of family input is sought in development of these programs?

2. What do families identify as most important components of these programs?

3. When considering economic impact of interventions, is "informal care" by family members a part?

Rationale:

In a nationally representative survey completed in the United States, Langa et al. (2002) estimated that carers of those with chronic lung disease contributed 5.1 hours per week of "informal care" when compared to those without lung disease. This represented an annual cost of over $2 billion dollars. A major worry of COPD family members is the patient's condition and whether or not the patient will recover from acute exacerbations. The uncertain nature of the illness trajectory of COPD places a particular burden on families who have to learn to monitor changes in the patient and to discern between kinds of attention needed to respond to symptoms (Jonsdottir 2007) . It is very difficult for family members to know when an exacerbation is coming or when sick means sick enough to require a visit to the health care provider. The task of making decisions and watching to prevent activity the patient cannot perform because of breathing problems is seen as particularly onerous. Researchers have described this everyday burden in terms of outcomes, including actual illness burden, loneliness, depression, mood, or amount of disturbance. They have further attempted to delineate factors associated with these areas (Cain and Wicks 2000, Cossette and Levesque 1993, Kara and Mirici 2004, Keele-Card *et al.* 1993, Ross and Graydon 1997, Takata *et al.* 2008), including types of caregiving tasks performed and emotional support required by the patient (Cossette and Levesque 1993) .

The presence of a significant other/carer in the home can have a significant impact on outcomes in COPD patients. Despite this consideration as well as the effect of COPD on family members, no studies were found that follow family impact and functioning over time nor were any intervention studies found that aim to facilitate families' providing care to COPD patients in the home. This dearth of research has been reported by other authors (Caress *et al.* 2009). In examining various approaches to providing care to COPD patients such as home-based respiratory care or telephone services, family focus was not included in any of the studies (Jonsdottir 2008).

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Provisional Topic: End of life/palliative care and transitions in COPD care
Subtopic: COPD & Hospice, Palliative Care and Advanced Directives

Questions:

1. Implementation Research Question: Do persons with a primary diagnosis of COPD who transition to hospice benefit from client engagement efforts to identify and address psychosocial needs?
2. Efficacy/Effectiveness Research Question: Do patients with COPD have more successful transitions from hospital to long term care or from home to long term care or to receiving hospice services if they participate in support groups led by professional social workers to assist patients with dealing with locus of control issues as they live with an incurable disease and struggle to breathe?

Rationale:

Persons who transition between settings and suffer from COPD may experience locus of control issues as they struggle to breathe and deal with discomfort and other medical conditions as well as end of life issues. Additional research is needed on how psychosocial supports can assist such patients in coping with these multiple issues.

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Provisional Topic: End of life/palliative care and transitions in COPD care
Subtopic: Advanced directives/palliative care/end of life care in COPD

Questions:

- Among patients with COPD, determine if interventions to improve clinicians' end of-life communication enhances patient-centered outcomes (e.g. concordance of care, death and dying experience, pt-family satisfaction with end-of-life care).

- Among patients with COPD who are at high risk for mortality, determine whether outpatient referral to palliative care improves the patients' dying experience when compared to usual care.

- Among patients with COPD, examine the effect of COPD-specific advance care planning versus usual advance care planning on the quality of end-of-life care and patient-centered outcomes.

Rationale:
To test and demonstrate the effectiveness of communication interventions specific to patients with COPD which can be implemented across health care settings to improve the quality of end-of-life care.

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Provisional Topic: End of life/palliative care and transitions in COPD care
Subtopic: Palliative Care in Transitions of COPD care

Questions:
1. Does palliative care and/or hospice care as practiced across communities during transitions in care improve end-of-life care for COPD – specifically, does it reduce the burden of symptoms, improve HRQoL and satisfaction, reduce utilization in last 6 months of life (i.e. hospital visits, cost, invasive ventilation use, etc), improve the end-of-life experience, and increase the concordance of place of death to expressed patient preferences?

2. What is currently done in clinical practice to measure and characterize dyspnea in patients with chronic COPD and how do different assessment approaches effect patients during transitions especially with respect to guiding management and improving patient's symptoms and health-related quality of life?

3. Do palliative care evaluations and interventions improve symptom management for patients with advanced COPD receiving care in emergency departments and what is the effectiveness of programs in acute settings that aid transitions to comfort-focused care preferences?

Rationale:
COPD is a chronic progressive disorder that results in debilitating symptoms such as dyspnea and severe reductions in activity, is characterized by increasingly severe exacerbations (AE-COPD) of breathing difficulty that may lead to unwanted or unbeneficial healthcare utilization at the end of life, and contributes to death - currently COPD is the 4th leading cause of death and the only top ten killer on the rise (National Consensus Project; ATS-Lankin; ACCP-Selecky; COPD guidelines; Claussens; Lynn; Bausewein; Bruera; Edmonds; Curtis). Palliative management in advanced disease like COPD is targeted as a priority for clinical research and quality improvement, however not much is known about the patient-level experience or effects of palliative and end-of-life care on patient-centered outcomes during transitions, especially those occurring after AE-COPD (Rabow, Curtis, Edmonds, Yohannes, Creagh-Brown). Breathlessness has been documented in >90% in patients with advanced COPD and is a significant cause of disability leading to severe reductions in activity and health-related quality of life (Claussens; Lynn; Bausewein; Bruera; Edmonds; Curtis). Evaluation and palliative management of dyspnea in advanced disease like COPD across care settings from hospital to home to hospice is recognized as a priority for clinical research, translation, and quality improvement (National Consensus Project; ATS-Lankin; ACCP-Selecky; COPD guidelines). Improving dyspnea care in widespread practice requires the use of valid, reliable, and responsive measurement of the dyspnea symptom experience. Although over 40 tools exist to assess dyspnea, there is no consensus on how dyspnea should be characterized for quality measurement (Dorman; Bausewein). Research gaps include standards for clinical dyspnea care, data to guide selection of optimal assessment tools for use in advanced diseases like COPD, and information on the evaluation of the effectiveness of palliative care.

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Provisional Topic: Early diagnosis and treatment of COPD
Subtopic: Transition from non-patient to COPD patient status in primary care setting.

Questions:
What topics and methods of presentation are most useful to enhance patient participation in and adherence to COPD therapies?

Rationale:
The transition from being healthy even not having COPD to being told you have COPD can be a difficult transition. Patients and family often go through similar stages as those of grieving as described by Kubler-Ross.[1] During this critical time one study has suggested that smoking cessation success is enhanced.[2] However, little other research has focused on this time period. The GOLD guidelines recommend educating patients and their families about disease presentation, progression, symptoms, treatment options and to answer questions.3 However, the best way to determine what should be taught, to determine when a patient or family is ready for new material, how depression or anxiety is to be addressed in the context of patient and family education and selection of appropriate methods of information presentation have not been addressed as they have in studying disease management programs.[4-10] This period deserves study to assess the effect of different types and goals of health care team and patient and family communication on adherence and patient participation in care outcomes.

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Provisional Topic: Psychosocial barriers during transitions in COPD care
Subtopic: Psychosocial support of patients with COPD during transitions in healthcare settings Illness

Question:
What are effective and sustainable psychosocial support strategies that can assist persons with severe mental illness who are also coping with COPD, tobacco cessation and issues of aging as they transition from emergency department to hospital settings, hospital to sub-acute care?

Rationale:
High rates of tobacco use are experienced by persons with severe mental illness. This can be due to past efforts to provide cigarettes as a 'calming & coping' strategy and may also be due to efforts at self-medication. This results in high rates of COPD for persons who have a history of severe mental illness. This is then exacerbated by aging and the development of other co-occurring conditions including diabetes and/or substance abuse. Transitions of care and moving from one setting to another creates risks of exacerbating mental health problems, creating greater risks.

Provisional Topic: Psychosocial barriers during transitions in COPD care
Subtopic: Community-Based Participatory Research to implement treatment guidelines and reduce health disparities

Question:
How can Community-Based Participatory Research methods be used to test the effectiveness of interventions to improve health care quality and improve the treatment outcomes for African American patients with COPD who transition from home to hospitals and who do not receive care based on expert guidelines at the same rate as other populations, especially as this relates to where services are provided? [translational study]

Rationale:
According to systematic review of research African American patients with COPD are less likely to receive the recommended regime of care due to where they receive care. Therefore efforts need to be taken to improve the quality of care in rural hospitals and in certain geographic settings. Using methods of CBPR will help to engage communities and current and future patients with COPD in transitioning to new settings.

Provisional Topic: Psychosocial barriers during transitions in COPD care
Subtopic: Mental health screening and treatment during transitions in COPD care

Question:

1. How can tools to screen for depression for persons experiencing COPD improve outcomes and reduce hospitalizations for patients who are transitioning to new settings (e.g. home to hospital, hospital to rehab, rehab to home) and to new stages of oxygen dependence?

2. How can use of Cognitive-Behavioral Treatments (CBT) decrease anxiety and increase well-being in persons coping with COPD as they transition to oxygen dependence?

Rationale:

There is a need for regular mental health screening and interventions when identifying and treating persons with depression in primary care and other health settings, especially since depression co-occurs with medical diagnosis and treatment and with transitions to new settings (e.g. home to hospital, hospital to sub-acute or long term nursing home placements). Among the research that might be translated and tested with COPD is that of Kathleen Ell and her colleagues in cancer and diabetes.

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Provisional Topic: Modeling the effects of interventions and transitions in COPD status
Subtopic: Modeling the effects of prevention and treatment interventions in COPD

Question:

Rationale:
Like other chronic illnesses, modeling of the disease and various interventions is useful in "testing" out the implications of any consensus or guideline recommendation, if such models exist. More research is needed to build and apply models to the highest priorities for COPD effectiveness and implementation studies.

We have identified one SMDM member with a published a paper on the prevention and control of influenza in patients who have COPD in the International Journal of COPD (Plans-Rubio; 2007), where he reviewed the cost-effectiveness of preventive interventions. These types of models help answer the question "what is the effectiveness and cost-effectiveness of preventive interventions in the COPD population?" A related question is how to use this information to support health insurance coverage decision-making for these interventions.

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Provisional Topic: Modeling the effects of interventions and transitions in COPD status
Subtopic: Modeling risk of transitions from chronic to acute care settings for patients with COPD

Questions

- What measures other than PFT data can be used to predict risk of relapse (e.g., re-hospitalization or urgent care visit or ED visit) following hospital discharge after treatment of AE-COPD?

- What measures other than PFT data can be used to predict risk of AE-COPD (e.g., hospitalization or urgent care visit or ED visit for AE-COPD)?

Rationale

1. A majority of COPD outcomes projects rely on patients indentified in administrative or healthcare utilization databases, such as Medicare data, Veterans Administration files, and private health system utilization data.
2. Retrospective data is highly subject to a variety of biases.
3. COPD patients are notoriously non-compliant with therapy.
4. Pulmonary function data are rarely found in utilization databases, forcing use of other parameters to adjust for severity, such as clinic visits and respiratory drug fills.
5. Statistical modeling techniques are often used to attempt to adjust for problems with variability in disease severity or treatment exposure.
6. The statistical models themselves are based on a variety of assumptions, few of which are critically examined in published COPD studies.
7. Inappropriate application of statistical models can introduce biases instead of resolving them.
8. Imprecise measures of disease severity may result in residual confounding.

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