

***Rural Maine Health Demonstration Project:  
Chronic Obstructive Pulmonary Disease Initiative***

Prepared for:

Eastern Maine Healthcare and the Institute for Medical  
Improvement

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Prepared by:

PUBLIC HEALTH RESEARCH INSTITUTE  
120 Exchange Street, Suite 200 • Portland, ME 04101  
(207) 761-7093 Telephone • (207) 871-7105 Fax

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## I. Introduction / Project Overview

Chronic conditions have become leading causes of death, disability, and illness within the US population.<sup>1</sup> As such, they contribute heavily to health care costs in the US: approximately 75% of annual US health care costs are related to chronic diseases.<sup>2</sup> In response to this development, researchers, managed care organizations, and health care providers have attempted to address chronic disease care through various novel methods. For example, the American Lung Association has developed an interactive website designed to help providers make decisions about treatment for individual asthma patients based on best-practice guidelines.<sup>3</sup>

Chronic Obstructive Pulmonary Disease (COPD) – a term used to collectively describe two related conditions, Chronic Bronchitis and Emphysema, that gradually lead to loss of lung function – represents a major component of the chronic disease burden among adults in the US.<sup>4</sup> Research indicates that it is under-diagnosed in the population and is often not addressed until patients are in later stages of the disease. Although studies indicate that it is a major public health issue, the health care system has done little to address it as such. The Institute for Medical Improvement's *Rural Health Demonstration Project – COPD Initiative* is an attempt to address COPD in rural Maine by demonstrating the effectiveness of system-wide change and implementation of best-practice care methods.

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<sup>1</sup> "Chronic Disease Prevention: Chronic Disease Overview." Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion. 4 October 2004.

<<http://www.cdc.gov/nccdphp/overview.htm>>

<sup>2</sup> Marks, J. "The Burden of Chronic Disease and the Future of Public Health." January 13, 2003. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion. 4 October 2004. <[http://www.cdc.gov/nccdphp/burden\\_pres/](http://www.cdc.gov/nccdphp/burden_pres/)>

<sup>3</sup> "Treatment Options and Support: Asthma NexProfilers." American Lung Association. 4 October 2004. <<http://www.lungusa.org/site/pp.asp?c=dvLUK9O0E&b=38472>>

<sup>4</sup> "Data Fact Sheet: Chronic Obstructive Pulmonary Disease." US Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute. 4 October 2004.

<[http://www.nhlbi.nih.gov/health/public/lung/other/copd\\_fact.pdf](http://www.nhlbi.nih.gov/health/public/lung/other/copd_fact.pdf)>

## II. Background

### A. *Health Planning Report for Northern, Eastern and Central Maine – COPD in Maine*

Eastern Maine Healthcare (EMH) completed a Community Health Needs Assessment of rural areas of Maine in 2001, with findings from the assessment published in its report, the *Health Planning Report for Northern, Eastern and Central Maine*. The report reviewed the poor health status of residents in these areas and suggested that inadequate management of severe chronic health conditions was a priority issue. The Institute for Medical Improvement (IMI) subsequently developed an initiative focused on improving care for patients with Chronic Obstructive Pulmonary Disease (COPD), one of the severe chronic health conditions identified in the report. The following summarizes findings related to COPD and associated risk factors in Aroostook County:

- COPD hospitalization rates among 18+ year olds are elevated by 60-200% over the peer comparison group and state rates despite non-elevated disease prevalence
- Smoking prevalence is 40% higher than the state average
- COPD mortality rate among those aged 65 years and older is the highest in the state at 39% above average
- Inadequate availability of COPD treatment resources (e.g., rehabilitation facilities)

Also identified were several underlying system-wide issues that contribute to inadequate management of chronic respiratory disease in Aroostook County:

- Inconsistency in primary care providers' awareness and use of nationally accepted treatment guidelines and pharmaceutical usage for COPD and asthma management
- Primary care physicians often consult specialists too late and lack expertise and resources in counseling patients and in managing COPD (e.g., non-systematic staging and monitoring of lung disease progression by the use of spirometry, diagnostic studies and medications)
- Primary care providers may not allow the necessary time to effectively counsel patients on smoking cessation, allergy, and environmental factor control
- Poor patient compliance with prevention counseling and chronic treatment regimens (e.g., high smoking rates among those with diagnosed COPD)

The Institute's *COPD Initiative* was developed with these issues in mind, with particular focus on the lack of consistency among providers with regard to evidence-based care.

### B. *The Institute for Medical Improvement (IMI)*

The Institute for Medical Improvement (IMI) is a collaborative effort led by Eastern Maine Healthcare (EMH) and involves multiple organizations associated with health care in Maine.<sup>5</sup>

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<sup>5</sup> For more information on the *Institute for Medical Improvement*, visit [http://www.emh.org/emhs\\_view\\_article.asp?id=28&cat=5](http://www.emh.org/emhs_view_article.asp?id=28&cat=5)

IMI brings together physicians, employers, payers, hospitals, health care consumers, researchers and patients to promote the delivery of evidenced-based health care services in health care practice settings.

The Public Health Research Institute (PHRI) is the evaluation partner of the IMI. PHRI has participated in program planning, implementation and evaluation components of the *COPD Initiative*. The Maine Network for Health (MNH) has provided day-to-day management of the *COPD Initiative*.

### **C. Project Plan and Support**

IMI applied to the US Health Resources and Services Administration (HRSA) for funding to support the *COPD Initiative* in May 2003. The proposal for the one-year *COPD Initiative* described two key phases: (1) a health care system assessment with regard to COPD care delivery and (2) a pilot study demonstrating systems change. Funding was awarded and work began on the project in August 2003.

### **D. Methods Overview**

The methodology that supports the *COPD Initiative* is consistent with the Chronic Care Model (CCM) and the Institute for Healthcare Improvement's (IHI) "Breakthrough Series" change methods. The CCM, developed by Ed Wagner, MD, MPH, is focused on systemic change that provides for better chronic illness management.<sup>6</sup> IHI change methods rely on group collaboration as a means of educating health care providers and support staff in new ideas and techniques.<sup>7</sup> Once providers have become familiar with new "best-practice" methods, practice-wide changes are planned, attempted, reviewed/evaluated, and if they were successful, potentially integrated into everyday care.

There are six elements that Dr. Wagner identifies in the CCM as being essential for a system that promotes high-quality disease management:

- Community – links to community programs and organizations that provide support
- Organization of health care – 'improving health care' ideally part of organization's vision
- Self-management support – support for patients that will help them to manage their disease outside of the physician's office
- Delivery system design – clear roles for those involved with delivering care to patients
- Decision support – clearly outlined care and treatment process based on proven guidelines
- Clinical information systems – patient-level data registry to allow tracking of individual patients as well as groups of patients

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<sup>6</sup> "The Chronic Care Model." Improving Chronic Illness Care. 4 October 2004. <<http://www.improvingchroniccare.org/change/index.html>>

<sup>7</sup> *The Breakthrough Series: IHI's collaborative model for achieving breakthrough improvement*. Institute for Healthcare Improvement, 2003.

The above components and supporting methods described in the CCM and in the IHI Breakthrough Series provided the logic model for the *COPD Initiative*.

Under the IHI change model, changes are managed through a series of “Plan, Do, Study, Act” (PDSA) cycles:

- “Plan” consists of generating ideas for changes within the practice and planning the “who, what, when, where” components of their implementation.
- The “Do” phase involves carrying out the plan.
- “Study” refers to the evaluation phase. Each change that is planned involves an evaluation component – i.e., practices choose the way success will be measured, perform the measurement, and then analyze the data.
- During the “Act” phase, changes are chosen for implementation based on findings from the “Study” phase.

The PDSA-cycle methodology and suggestions for supporting activities are presented to practices during group Learning Sessions (described in detail later). During these periods of learning, PDSA cycles are emphasized as being an extremely important fundamental component of learning to initiate and manage change.

One of the main goals for initiatives based on the CCM, such as the *COPD Initiative*, involves successful adoption of “new” methods by providers. In order to facilitate this, guidelines and materials should be tailored toward patient and provider populations of interest. This customization is accomplished primarily through barrier assessments – focus-group type sessions where barriers to success and other issues are discussed – for both the patient and provider groups. Information from these sessions is then used to improve and customize messages and materials used later on in the intervention. In the case of the current project, as described below, the population focus was the rural patient population and rural primary care physician’s office.

## **E. Goals and Deliverables**

The overall goal of the *COPD Initiative* was to facilitate the adoption of evidence-based clinical guidelines for the management of COPD by rural primary care practices. There were seven primary deliverables associated with this goal:

- An easy-to-apply set of *Practice Guidelines* based on nationally accepted disease management guidelines, endorsed by the American Lung Association and key medical societies, tailored toward rural practices
- A *Change Package* to assist providers in planning changes and incorporating guideline use into their practices
- A *Communications and Support Infrastructure* designed by local practitioners, patients and community agencies to address the common need for information, mutual support and coordination

- An *Evaluation Tool Kit* to provide validated tools for evaluation of the effectiveness of practice changes over time
- An online *COPD Resource Directory* posted on a public website or listserv for the benefit of patients, providers and community organizations
- An *Evaluation Report* that documents the project's methods and success in completing work products and in meeting goals and objectives
- A *Change Guide* that serves as a comprehensive step-by-step guide for groups interested in implementing evidence-based COPD care guidelines in their practice or groups of practices

The deliverables are mentioned throughout the description of the Project Implementation.

### **III. Project Implementation / Methodology**

#### **A. Expert Group and Findings**

An important first step in the *Initiative* was to assemble a group of experts that would provide the expertise necessary to guide the initial steps in the project's implementation and provide continued support for the project. Initial meetings included the selection and endorsement of evidence-based best practice guidelines, development of a Change Package template consistent with IHI methods, development of a COPD Collaborative Charter and measurable goals, discussion of the COPD Resource Directory and its content, and review of area practices to be considered for recruitment into the project.

The group, consisting of pulmonologists, primary care physicians, home health care nurses, local pulmonary rehabilitation specialists, and researchers, met three times over a span of approximately four months. Participants provided insight regarding COPD in Maine based on their first-hand experiences with patients and other practitioners. Experts also presented their suggestions for resources (e.g., Global Initiative COPD Guidelines) and other supporting material based on individual viewpoints and current literature. These discussions helped inform the decision-making process that supported the development of study protocols and other detailed components of the project.

The Expert Group developed the COPD Collaborative Charter soon after the project began. Included in the Charter is a section focused on measurable goals for the Collaborative. The following summarizes these goals:

- 90% of COPD patients over age 45 with one or more risk factors (tobacco smoking, occupational dusts and chemicals, indoor air pollution, outdoor air pollution, second hand smoke) will have evidence of being assessed for COPD by the presence of a documented detailed medical history, documented spirometry results and classification by severity (Stage 1-4).
- 100% of visits will show documentation of COPD patient smoking status and smoking cessation counseling will be done at each office visit for those patients who continue to smoke.

- 90% of COPD patients will have a stepwise treatment plan that reflects assessment and severity of the disease process. All newly diagnosed patients classified as Stage 2 or greater will have treatment that correlates with the stage of illness. Pharmacological intervention will be prescribed according to evidence-based guidelines for treatment of COPD.
- 90% of COPD patients will have an annual influenza vaccination and current pneumococcal vaccine.
- 100% of COPD patients will have a referral to a pulmonary rehab program that lasts a minimum of 2 months, and then will have a continued documented exercise program.
- 90% of COPD patients will have documented self-management goals and patient education in the office record for each regularly scheduled appointment, and reassessment of self-management goals will occur between the practitioner and patient upon acute exacerbation.

The Collaborative Goals and other aspects of the Charter served as a concise guide that provided participants with information related to the purpose of the project throughout its duration (Appendix A). The second Gap Analysis provided the means for measuring the success of the *Initiative* in reaching the Collaborative Goals.

### **B. Practice Recruitment – Pilot Sites**

The bulk of the *COPD Initiative* focused on developing a program that supported and facilitated the adoption of best-practice COPD guidelines by rural primary care practitioners. The *Initiative* also supported demonstration of these methods through the pilot study in an effort to evaluate and refine the program to support future spread. Two practices were chosen to participate in the *Initiative* as “pilot sites.” Both were Eastern Maine Health Care Systems primary care practices located in rural Aroostook County and part of Horizons Health Services, a division of The Aroostook Medical Center.

### **C. Guideline Review and Summarized COPD Guidelines**

During the first Expert Group meeting, several published evidence-based best practice guidelines and other materials were presented. The goal of this process was to discuss current best-practice guidelines and endorse, as a group, those that seemed most appropriate given the overall goals of the *Initiative*. Materials included a special report on the management of acute exacerbations of COPD, an algorithm published by the American College of Physicians, and the *Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease* guidelines from the Global Initiative for Chronic Obstructive Lung Disease.<sup>8,9</sup>

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<sup>8</sup> Evidence base for management of acute exacerbations of chronic obstructive pulmonary disease. American College of Chest Physicians and the American College of Physicians, 2001.

<sup>9</sup> *Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease*. Global Initiative for Chronic Obstructive Lung Disease, National Heart, Lung, and Blood Institute and the World Health Organization, 2004 revision.

The review and endorsement of a selection of best-practice guidelines led to the development of a summary document that became the primary reference guide for assessment and monitoring of COPD within the *Initiative*. Given their comprehensive nature, the Global Initiative GOLD guidelines were relied upon considerably during the development of the *Summarized COPD Guidelines*. The *Summarized Guidelines* represents a convenient, concise reference document that captures the most important elements of best-practice care (Appendix B). These elements include:

- Requirements for a detailed medical history
- Spirometry testing guidelines
- Testing guidelines for each stage of COPD
- Therapy guidelines for each stage of COPD
- Medication reference table

#### **D. Provider Barriers Assessment**

Assessing barriers to successful outcomes – e.g., barriers to reduction in exacerbations that require hospitalization – serves three primary purposes: (a) barriers identified by physicians and practice staff can be discussed within the context of the program, during Learning Sessions, etc., which leads to a better understanding of its purpose; (b) barriers identified at baseline and throughout the program can inform the ongoing tailoring/customization process for materials and messages delivered to the group; and (c) change in barriers identified – i.e., barriers identified baseline compared to those identified upon completion of the program – can provide insight into the effectiveness of the program from the perspective of practice. An ideal outcome and example of the latter may include a physician identifying “lack of confidence in ability to counsel patients who smoke” as a barrier at baseline, and after receiving materials, attending Learning Sessions and completing the program, no longer identifying this as a barrier. No longer considering that they are unable to offer quality smoking cessation counseling sessions during an office visit may indicate that the physician has developed a proactive approach to working with patients (e.g., now uses the “5 A’s” approach to counseling patients, as described in the GOLD COPD Guidelines). Barrier-related issues important to consider are summarized as follows:

- Attitudes toward COPD patients (including perception of and attitude toward level of patient motivation to quit)
- Attitudes toward delivering smoking cessation services to COPD patients who smoke
- Opinion/feeling about why COPD patients continue to smoke
- Attitudes toward and/or current practice regarding pharmacotherapy and nicotine replacement therapy
- Level of commitment toward providing services that are in line with COPD guidelines (including attitude when comparing guidelines-based methods vs. methods already established in practice)
- Perception of effectiveness of COPD guidelines-based treatment
- Perception of ability to integrate new methodology for delivery of COPD care given demanding schedule and cost/reimbursement concerns

- Thoughts regarding institutional barriers that exist, including the degree to which institutional policies and procedures may be associated with previously identified barriers

Practice barriers were assessed during the first meeting of the Expert Group (baseline) and once again during the final Learning Session. The following summarizes barriers that were identified during each session:

#### Baseline practice barriers assessment

- Difficulty providing comprehensive COPD care due to lack of pulmonary rehabilitation specialty services in area
- Lack of efficient provision of smoking prevention messages
- Lack of ability to efficiently identify COPD, or risk of developing COPD, early
- Patients are non-compliant with physician orders and medications
- Non-uniform standard of care to reference
- Lack of quality support system for patients
- Lack of tools needed to support clinicians' delivery of quality care

#### Final practice barriers assessment

- Issues related to the amount of time delivery of COPD care took during routine office visits utilizing new methods
- Lack of pulmonary rehabilitation services
- Patients' inability to exercise at home
- Some patients cannot quit smoking
- Cost of visit for patient sometimes too great or provides disincentive for regular/maintenance visits
- Lack of patients' interest in trying new things
- Maintenance of proper documentation was difficult/time consuming

Findings from the series of practice barriers assessments suggest that many of the barriers identified initially were resolved through the *COPD Initiative* (e.g., tools needed to support best-practice care delivery). Some of the issues identified in the final assessment will likely be resolved as time progresses and these methods become no longer "new" (e.g., amount of time it takes to deliver COPD care, difficulty regarding maintenance of proper documentation). However, others will most likely continue to be problematic unless system changes are made (e.g., lack of pulmonary rehabilitation services).

### **E. COPD Resource Directory**

Provision of standardized, consistent patient care among a group of health care providers necessitates the adoption of the same care methods across members of the group. The *Initiative* was designed to support the adoption of best-practice guidelines for the care of patients with COPD by care providers in rural Maine. To facilitate this, a Resource Directory was created to provide the entire COPD community with convenient web-based access to a comprehensive

collection of standard resources. The Directory is available to providers, patients, and other members of the COPD community, and is customized according to the user (i.e., content displayed for providers differs from that which is accessible to patients). Information available in the Directory not only includes national publications, guidelines, and web links, but also regional information. It is maintained by the Maine Network for Health and is available through their website (<http://www.mainenetwork.org>).

#### **F. Patient Focus Group**

Although the long-term goal of the *COPD Initiative* involves improved patient health outcomes, most of the program does not actually include direct interaction with patients. The Patient Focus Group provided the means for building patient input into the *Initiative*. Delivery of care according to best-practice guidelines can be more effective when methods are adapted to the specific population of interest. Feedback from COPD patients residing and seeking care in rural Maine was used for this purpose.

The Focus Group was planned during the first Expert Group meeting. Criteria for inclusion, questions for participants, and other related issues were discussed. Expert Group members agreed that the primary purpose of the Focus Group was to collect information on the barriers to good respiratory health that COPD patients experience (Appendix C; Questions for COPD Focus Group). The Focus Group was held soon after the first Expert Group meeting; participants varied in age, length of time with COPD, number of co-morbidities, and other factors. The following summarizes the findings of the Patient Focus Group:

##### *Access Barriers*

- Limited number of primary care physicians in area
- Limited number of respiratory specialists in area
- No COPD support groups
- “Hurried” atmosphere at every office visit, which leads to patients feeling pressured; too little time spent at each visit
- Duration of pulmonary rehabilitation program was not long enough

##### *Treatment Barriers*

- Inadequate communication between patients and providers, for example, results of tests are not always communicated to patient
- Primary care provider does not always seem to know about the latest treatment information regarding COPD
- Seemingly contradictory treatment advice comparing primary care physician to specialist
- Lack of continuity and/or coordination of care (e.g., from Emergency Department to Primary Care Physician, from physician to physician in a particular primary care office)
- Little encouragement/guidance to self-manage from physicians
- Lack of communication from physicians regarding purpose of treatment

## *Prevention Barriers*

- Primary care physician unable to communicate proper relaxation techniques to avoid exacerbations
- Pulmonary rehabilitation program too short
- Lack of information about respiratory irritants, such as household cleaning agents, that could help prevent exposure and/or exacerbations
- Lack of helpful information from dietician
- Lack of support group (e.g., group of “COPD veterans” to provide support to new patients)

Findings from the Patient Focus Group were presented for discussion during the second Expert Group meeting. Members of the Expert Group focused mostly on patients’ perceived lack of available support network. In an effort to address the notion that an organized network among patients with COPD in the geographic area might help patients manage their disease better and improve other outcomes, the Change Package was modified to include “assess development of a support group” as a change example for practices to consider. Additional barriers and other issues discussed during the Focus Group were addressed during Learning Sessions and otherwise considered as materials were developed for the *Initiative*.

### **G. *Electronic Patient Registry***

The Clinical Information System is an essential component of the Chronic Care Model. The COPD electronic patient registry was developed and maintained by the Maine Network for Health for use by providers in managing COPD-related information from patient office visits. It is a password-protected patient-level database that providers access via a secure internet site. Ability to query, generate reports, exporting capability, and other functionality has been built into the system and it provides users with an efficient method of tracking best-practice COPD-related outcomes. Growth of the registry will include the ability to use the data to prepare patient visit updates, send letters to patients regarding test results or services needed (e.g., reminder to visit the office for an influenza vaccine), and other activities that will be determined based on the practices’ patient profiles and individual needs and suggestions.

### **H. *Baseline Patient-level Assessment: Gap Analysis #1***

Prior research has demonstrated the effectiveness of the CCM/IHI method and adoption of best-practice guidelines at the patient level. In addition to other measures of the effectiveness of the *COPD Initiative*, change in care at the patient level was assessed. This was accomplished primarily through a series of “gap analyses” whereby the measurement of the “gap” was assessed – i.e., the current care methods in each practice were compared to the ideal or “gold standard” evidence-based methods.

The first gap analysis assessed the degree to which current practices differed from “best” practices, before the start of the project. This provided a baseline from which to gauge the effectiveness of the intervention – i.e., the implementation of the gold standard practices – at the

patient level. Results from a subsequent gap analysis (Gap Analysis #2), performed upon completion of the intervention, were compared to baseline results to measure the intervention's effectiveness.

### **I. Change Package**

The movement toward providing consistent care to COPD patients that is based on evidence-based best-practice guidelines requires change and departure from current methods. The IHI model suggests that specific changes should be developed, evaluated, and potentially implemented by each individual organization.<sup>10</sup> This is based upon the underlying notion that although each organization is working toward the same outcome – i.e., implementing the same guidelines – the changes that are required to arrive at a successful outcome are likely to be different since methods, attitudes, culture, and other system-wide processes vary from one practice to the next.

The Change Package helps practices manage changes that they develop. IHI has created an example of the Change Package and made it available for organizations to consider using for this purpose. The Change Package that was developed for the *COPD Initiative* is a template derived from the IHI example. It is organized into six categories that follow the IHI model and *COPD Initiative* Goals: patient self-management, delivery system design, decision support, clinical information systems, community resources and policies, and health system–organization of health care. Each category contains a table that allows the user to organize ideas and planned activities related to each change into Plan, Do, Study, Act (PDSA) components. Changes and associated PDSA cycles can be managed over time using the Change Package.

Information from the Summarized COPD Guidelines, discussion from the first Expert Group meeting, and findings from the Practice Barriers Assessment and Patient Focus Group were used to develop examples of changes that practices could consider implementing using the Change Package. These examples were incorporated directly into the Change Package, which provided a customized tool for practices to use (Appendix C).

### **J. Learning Sessions and Action Periods**

The IHI model for practice change is based on group collaboration. Meeting, as a group, to review and discuss IHI concepts and methods required for successfully planning and managing changes, receiving materials to support this process, and also to obtain reports on the status of the project occurs through “Learning Sessions.” Methods learned and ideas generated through Learning Sessions are then implemented during “Action Periods” that immediately follow. Learning Sessions subsequent to the first include discussions of participants’ experiences since the previous Learning Session (e.g., review of lessons learned as changes were planned and evaluated). The IHI model recommends that organizations complete a series of three Learning Sessions and Action Periods as part of a comprehensive initiative.

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<sup>10</sup> “Draft Improving Flow Change Package.” Institute for Healthcare Improvement. 4 October 2004. <<http://www.ihl.org/IHI/Topics/Flow/PatientFlow/EmergingContent/DRAFTImprovingFlowChangePackage.htm>>

The goals of the first *COPD Initiative Learning Session* were to:

- Provide participants with a comprehensive overview of the project and underlying methodology, including results from the first Gap Analysis
- Review the overall change process, IHI change methods, Chronic Care Model, guidelines that had been endorsed by the Expert Group, and other supporting materials
- Introduce materials that were developed to help participants manage the change process, including the Change Package and *Summarized COPD Guidelines*
- Facilitate the use of materials to allow practices to begin to contemplate ideas and strategies related to changes that might make sense for them
- Prepare participants for the upcoming Action Period

The first Learning Session, in essence, served as the kickoff meeting for the post-planning, “active” period of the *Initiative*. As such, providing a comfortable atmosphere, encouraging discussion, and developing a positive, productive relationship among participants was a key process-related goal for the meeting. The following summarizes the content of the first Learning Session:

- Presentation of a video describing the change process and its importance (“Changing Practices, Changing Lives” – courtesy of IHI)
- PowerPoint presentation of the ICIC CCM and IHI Collaborative Process
- Presentation of COPD evidence-based guidelines
- Introduction to the IHI-style Change Package
- Presentation of a video demonstrating the process of quality improvement (“The Quality Improvement Process in Action” – courtesy of IHI)
- Breakout Sessions for discussion of presentations/activities and drafting “Project Plans”
- Presentation and discussion regarding upcoming the Action Period and Second Learning Session

#### **K. Patient-level Assessment: Gap Analysis #2**

The second Gap Analysis was performed toward the end of the intervention, approximately 24 weeks after the first. The analysis was performed using the same materials and methods as the baseline analysis, therefore data quality and results were comparable. The series of gap analyses provided the means for evaluation of the program’s effectiveness from the patient perspective (e.g., whether or not a COPD patient received a spirometry test at each visit); additional methods, such as those described under “Practice Change Assessment,” were utilized to evaluate effectiveness from other perspectives (e.g., whether or not practices established an area in their waiting room for COPD education materials).

#### **L. Practice Change Assessment**

The primary goal of the Practice Change Assessment was to review, in detail, changes that practices reported having made during the intervention. During the Assessment, information was collected from practices specifically focused on changes that were implemented subsequent to beginning of the initiative (e.g., changes implemented that were suggested in Change Package). This component of the program's evaluation provided insight into the methods that were used to bring about actual change in patient care. It also provided a means for evaluating how effective the intervention was in terms of influencing the behavior of physicians and other practice staff.

#### **M. Evaluation Tool Kit**

One of the final deliverables planned for the *Initiative* included an Evaluation Tool Kit, designed to help practices track changes over time (Appendix C). The Tool Kit is essentially a collection of evaluation instruments used throughout the *Initiative* and includes the Change Package, Chart Review Tools from the Patient-level Assessment, and Practice Change Survey. The Tool Kit comprises the collection of materials that supports the evaluation component of the comprehensive Change Guide.

### **IV. Evaluation**

Evaluation of the *COPD Initiative* involved two primary components: evaluation of *process* (i.e., program implementation) and *program/intervention effectiveness*.

#### **A. Process Evaluation**

The implementation of the *COPD Initiative* was evaluated with the aid of the Evaluation Form, a process-monitoring tool developed specifically for this project. Throughout the project, objectives were documented and respective timeliness of completion assessed. Specific events, such as meetings and focus groups, were evaluated for quality and usefulness through surveys and other means. Quarterly process evaluation reports were sent to stakeholders for the duration of the project. This provided efficient means of updating stakeholders regarding the project status.

#### **B. Program Effectiveness**

Evaluating the effectiveness of the *Initiative* included the Practice Change Assessment – an assessment of changes that practices made to existing protocols, procedures, and methods (i.e., systemic practice change) – as well as the series of Gap Analyses which measured actual changes in care at the patient level (e.g., comparison of the method of assessment of COPD

disease stage before and after the changes in practice methodology were implemented). Findings from both components together provided answers to important, basic evaluative questions such as “How successful was the *COPD Initiative*?”, “How did practices go about changing their delivery of care for COPD patients?” and “How did patient care change?”.

## 1. Change Assessment

The Practice Change Assessment involved the collection of information directly from practice staff, including physicians. The second Learning Session was used as an opportunity to collect information on any changes that practices recalled making during the *Initiative*. This was followed up with a one-page survey (Appendix C; Practice Change Survey) that included a list of questions related to specific activities. The survey also prompted responders to provide the temporal context for each response – i.e., to allow for determination of whether each activity was practiced prior to the beginning of the *Initiative* or if the activity had been implemented afterward. The following summarizes the results from the Practice Change Assessment:

Changes that the practices reported making over the course of the *Initiative* during the second Learning Session:

- Expanded the profile for COPD patients
- Increased use of spirometry which, by reviewing results and implications with patients, led to increased smoking quit rates
- Use of COPD Flow Sheet (e.g., to better understand patient medication profile)
- Increased use of preventive care
- Displayed COPD educational board in the practice waiting room for patients to view
- Increased support/use of patient self-management with prednisone to avert hospital admission
- Implementation of “staging” program – i.e., classifying COPD patients according to severity of disease according to algorithm
- Improved management of COPD patients’ immunizations (e.g., influenza)
- Improved documentation and management of COPD patients’ pulmonary rehabilitation process
- Implementation of smoking cessation program according to suggestions outlined in the GOLD COPD Guidelines
- Improved general COPD patient documentation

### COPD Practice Change Survey

Activities practices indicated they implemented during the *Initiative*:

- Routine provision of education materials to those at risk of developing COPD
- Provision of anti-smoking materials to COPD patients if applicable
- Development of an area of the patient waiting room where education materials for COPD patients are kept

- COPD poster display in the office
- GOLD COPD guidelines put in central location for easy reference by practice staff
- When applicable, patients are provided with the contact information for the Maine Tobacco HelpLine
- Routine recommendations/suggestions regarding indoor and outdoor air pollution to COPD patients
- GOLD COPD guidelines put in central location for easy reference by practice staff
- Routine provision of education to staff about COPD standards of care and/or the office's approach to COPD care
- Utilization of tools on the Maine Network for Health website to facilitate developing a self-management program with COPD patients
- Utilization of specific referral guidelines for referring COPD patients to pulmonary rehabilitation
- Utilization of the "Needs Assessment of Patients with Lung Disease" workbook to help develop COPD management programs with new patients

Through both data collection methods, practices reported substantial systemic change as a result of the *Initiative*. Additionally, each practice had already been performing several important best-practice activities that are not reflected above (e.g., both already suggest nicotine replacement therapy and/or pharmacotherapy to patients interested in quitting smoking). The combination of newly implemented activities and those that had already been implemented has brought each practice closer to providing best-practice care. There were, however, some important best-practice activities that practices had not yet implemented that should be considered for the future, such as referral to community resources and following up with patients in support of this activity.

## **2. Patient-level Assessment**

The primary purpose of the Patient-level Assessment, which consisted of a series of gap analyses, was to measure the effectiveness of the *Initiative* at the patient level (i.e., patient-level impact). This was accomplished by measuring the degree to which practice care followed best-practice guidelines at baseline (Gap Analysis #1) and comparing it to a subsequent measurement (Gap Analysis #2) to quantify improvement in care methods (i.e., closure of the gap).

Charts from COPD patients within each practice were reviewed and summarized in terms of the care those patients had received, as documented in the chart, within the context of the project (i.e., the guidelines for COPD patient care that are being implemented). Chart abstraction tools were used for this review process (Appendix C). Results from the first Gap Analysis were presented to participants prior to the First Learning Session to demonstrate potential focus areas and also introduce some of the evaluation methodology. Results from the second Gap Analysis, including comparison to the first to demonstrate improvement, were presented to participants during the Second Learning Session.

### Gap Analysis #1

The chart review tool used for the first Gap Analysis was developed primarily using the Summarized COPD Guidelines (Appendix B) as well as the COPD Collaborative Charter

(Appendix A). The tool was designed to allow reviewers to peruse the patient chart and choose a “yes/no” answer for most items (e.g., “Is the COPD patient classified by severity?”). The tool included all aspects of the Summarized Guidelines related to care at the patient level. Highlights from the first Gap Analysis are as follows:

- Among the two practices, 49 patients met inclusion criteria
- 27% of COPD patients had a documented “detailed medical history” (according to criteria for “detailed medical history” set forth in the Guidelines)
- Smoking history, including intensity and duration, were often missing from the patient’s chart
- 53% of patients had documented spirometry results
- 18% of patients were classified according to severity of COPD
- 57% of patients had documented smoking status
- 47% of COPD patients were current smokers; of these, 20% were offered cessation counseling at every visit
- 35% of patients had documented annual influenza vaccination; 47% had documented pneumococcal vaccine
- 22% of patients were offered education on COPD, and this included only education on smoking cessation and medication use
- No patients had a documented self-management goals; 20% had documented plan addressing self-management during exacerbations

Participants agreed that some of the most remarkable observations were the prevalence of (continued) smoking, lack of consistent smoking cessation counseling for smokers, lack of an established self-management program, and lack of consistent documentation/management of vaccination information. Presentation of these results “personalized” the *Initiative* for each practice and provided some preliminary ideas for change.

### Gap Analysis #2

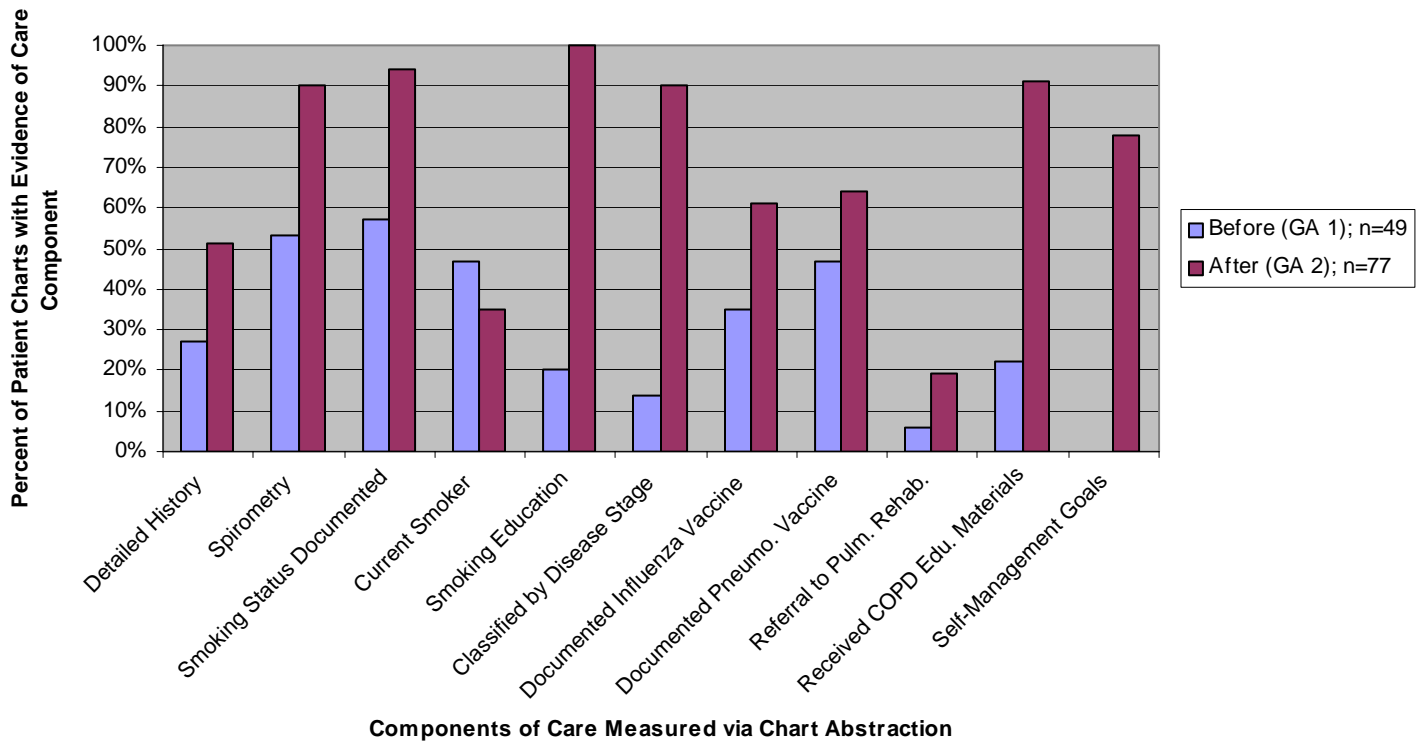
The tool used for the second Gap Analysis was identical to the first; however, it also contained some additional questions designed primarily to elucidate how patients who were new to the practice since the beginning of the *Initiative* were being managed. The following table describes the findings from the series of Gap Analyses (GA 1 and GA 2; Table 1):

Table 1. Patient-level Assessment: Results and Comparison

| Measure   | GA 1<br>(n=49) | GA 2<br>(n=77) | Change |
|---|----------------|----------------|--------|
| Had one or more risk factors (tobacco smoke, occupational dusts/chemicals, indoor/outdoor air pollution, second hand smoke) | 98%            | 100%           | +2%    |
| Had detailed medical history  | 27%            | 51%            | +24%   |
| Documented spirometry results in chart  | 53%            | 90%            | +37%   |
| Classified by severity of disease   | 14%            | 90%            | +76%   |
| Documented smoking status   | 57%            | 94%            | +37%   |
| Current smoker  | 47%            | 35%            | -12%   |
| Received smoking cessation counseling at every office visit   | 20%            | 100%           | +80%   |
| Documented stepwise treatment plan  | 59%            | 83%            | +24%   |
| Documented annual influenza vaccine   | 35%            | 61%            | +26%   |
| Documented pneumococcal vaccine   | 47%            | 64%            | +17%   |
| Received referral to pulmonary rehabilitation   | 6%             | 19%            | +13%   |
| Documented informal exercise program  | 0%             | 20%            | +20%   |
| Received COPD education materials   | 22%            | 91%            | +69%   |
| Documented self-management goals  | 0%             | 78%            | +78%   |
| *Had smoking as a risk factor   |                | 98%            |        |
| *Had COPD Flow Sheet as part of the chart   |                | 68%            |        |
| *Had "well visits" scheduled  |                | 100%           |        |

\*not assessed during first Gap Analysis

Figure 1. Results of Gap Analyses



Results from the second Gap Analysis and comparison to the results from the first Gap Analysis suggest remarkable improvements in care at the patient level (Figure 1). It also demonstrates that practices were successful in implementing many of the best-practice methods that were presented during the program.

Although the Gap Analyses were focused on all patients with a COPD diagnosis (i.e., regardless of COPD diagnosis date) in each practice overall, the second Gap Analysis also focused on those who had been diagnosed with COPD since the start of the *Initiative*. Thirty-one of the 77 patients included in the second Gap Analysis were diagnosed with COPD between the beginning of the *Initiative* and the date of the second chart review. The following summarizes the findings for the group of new patients:

- 90% had documented spirometry results
- 90% were classified according to stage of disease
- 87% had documented self-management goals
- 58% had detailed medical history
- 48% had documented influenza vaccination
- 48% had documented pneumococcal vaccination
- 39% had documented informal exercise program
- Mean age of 61 (mean age of entire study population at the time of the second Gap Analysis was 66)

Thirty-one new COPD diagnoses were made during this short timeframe, which suggests that the practices improved their ability to detect the disease in their patient population, perhaps due to increased use of spirometry for those with risk factors for the disease. Early detection is an extremely important aspect of best-practice COPD care; these findings (i.e., mean age of 61) suggest that the practices have been successful in doing this. Most important activities had favorable completion rates, however, some were less favorable. The rate associated with the Detailed Medical History activity, for example, suggests that it may require additional attention. The activity itself is difficult to address during an office visit since a comprehensive assessment is a relatively time-consuming process. It can, however, provide valuable insight for care associated with the individual patient. For example, identification and understanding of a patient's comorbidities may lead to a different course for suggestions for physical activity than would have ordinarily been suggested.

## V. Limitations

There are several important limitations of the *COPD Initiative* that should be considered when reviewing measures of the program's effectiveness.

*Sample of Practices.* The Initiative involved only two practices, both of which were part of the same healthcare system (EMH and local leadership). Both practices may have had similar success due to the strong interest and dedication demonstrated by the administrative leadership. System-wide support is essential for the success of the program; outcomes may have been different if one or both of the practices had been associated with less supportive administration, even if the primary care physicians themselves offered strong support.

*Outcome Measurement.* The Patient-level Assessment involved audits of COPD patients' charts at baseline, then again after the intervention. Due to the nature of the program and this measurement strategy, the measured effectiveness may be greater than the actual effectiveness. For example, if a spirometry test was administered to a patient and this was not noted in the patient's chart by the practitioner, the chart auditor, unaware of the test because of lack of documentation, would not have noted that a test had occurred. This scenario is more likely to have occurred before the intervention than afterward, since, once the program began, practitioners most likely improved documentation because they were aware that the program's effectiveness would be measured, in part, through chart audits. If these assumptions are correct, the magnitude of success as indicated in Table 1 is larger than the actual success.

Each chart audit was conducted by the same individual on both occasions and was therefore consistent. However, due to the nature of the patient charts, the information associated with many of the outcomes that were being measured required some interpretation by the auditor. The lack of precision introduced by this method most likely did not significantly affect the results.

*Generalizability.* The *COPD Initiative* was carried out among patients and primary care practices in rural northern Maine. Geography, culture, and other aspects of this population that make it unique may be associated with the *Initiative's* success. Although it is likely that similar success could be demonstrated in other populations (e.g., urban communities), this must not be assumed. The spread of the program to additional practices and populations would provide the opportunity to better characterize its effectiveness in groups outside of the rural Maine community.

## VI. Conclusions

The *COPD Initiative* began in response to a need for improved COPD care that has developed in the rural Maine community. Results from the first year of the program suggest that the chronic care/collaborative learning methodology, when used in the rural primary care setting, is an effective approach to improving COPD care. Those involved with the *Initiative* agree that the success that was demonstrated would not have been possible without the strong support that the project received across the board, particularly among providers and staff members in each of the pilot practices.

Commitment to the activities, materials, and making change, particularly by practices' leadership staff, is essential for success. Participants in the *COPD Initiative* have suggested that the most difficult time that they experienced as they began implementing changes and ideas learned through the program was during the initial stages. They have also suggested that without commitment through the early stages, the rewards that they have experienced – including reducing the time associated with COPD assessment for most patients to 2-3 minutes using the new methodology – would likely not have been possible. Future implementation of the *COPD Initiative* by additional practices should include a strong focus on encouragement and commitment, especially through the initial phase of the implementation.

The *COPD Initiative* represents a successful model for improving COPD care in the rural primary care setting. While immediate positive impacts related to provider perceptions and care at the patient level were observed, long-term benefits are expected to include streamlined provision of COPD-related care, improved patient health, and patients' decreased utilization of health care services due to improved disease self-management. Findings from the *Initiative* will serve as the foundation for the development of a comprehensive COPD Change Guide that will provide physician practices and other organizations with a complete step-by-step package designed to support the successful implementation of best-practice COPD care.

**VII. Appendix A: COPD Collaborative Charter**

## COPD Collaborative Charter

### **Introduction:**

In 2001, EMH undertook a Community Health Needs Assessment. That study substantiated the urgent need for comprehensive efforts to address severe chronic health conditions, to reduce the high cost of care and to expand critical access to comprehensive services in rural areas of Maine. The *Health Planning Report for Northern, Eastern and Central Maine*, an outgrowth from the Health Needs Assessment, presented several concerns associated with the prevalence and management of chronic respiratory diseases including chronic obstructive pulmonary disease (COPD). Two disease management areas were identified as problematic; one involved access issues and the other was lack of consistency in implementing proven practices in COPD management.

In response to these and other findings, EMH established the **Institute for Medical Improvement** (IMI). The IMI is a collaborative effort driven by EMH, which involves physicians, employers, payers, hospitals, health care consumers and patients in a proactive approach to assure the delivery of evidenced-based health care services in rural health care provider settings. This organization is acting as the facilitator for implementing changes to resolve these problematic areas. A secondary goal of the IMI project would be to improve access to Primary care and other respiratory services through additional capacity created by improved operating efficiencies.

The IMI endorses and utilizes the Institute for Healthcare Improvement's (IHI) "change management" approach that identifies systems, not people, as the opportunity for significant improvement<sup>1</sup>. Leadership from Pulmonologists and the Primary Care Physician community, as well as active participation from multi-disciplinary respiratory health care providers will be recruited to this effort. Additionally, patients will be recruited through Focus Group Activities to maximize input to achieve sustainable gains. The key components of the project will be identification and adaptation of COPD primary care "evidence based" guidelines, initial development of office practice "Change Tools", establishment a communication infrastructure, design an evaluation tool kit for practices and the creation of a COPD Resource Directory. (Further described in Project Plan). This project will address the patient population with COPD within Primary Care Physician practices in rural Maine. This work will serve as a foundation for wider spread and refinement in Year Two of this project.

## **Problem Statement:**

Specific items identified in the *Health Planning Report for Northern, Eastern and Central Maine*, include the following issues in rural Aroostook County:

- COPD hospitalization rates among 18+ year olds are elevated by 60-200%, despite a non-elevated disease prevalence;
- Smoking prevalence is 40% higher than the State average.
- The 65+ year olds COPD mortality rate in Aroostook is the highest in the state at 39% above average.
- Inadequate availability of COPD treatment resources (e.g. rehabilitation facilities)

The Health Planning Report also identified several systemic issues that contribute to sub-optimal management of chronic respiratory disease:

- Inconsistency in primary care providers' awareness and use of nationally accepted treatment guidelines and pharmaceutical usage for COPD and asthma management;
- Primary care physicians often consult specialists too late and lack expertise and resources in counseling patients and in managing COPD (e.g. Non-systematic staging and monitoring of lung disease progression by the use of office spirometry, diagnostic studies, medications).
- Uncertainty about the primary care provider allowing the necessary time to effectively counsel patients on smoking cessation, allergy, and environmental factor control.
- Poor patient compliance with prevention counseling and chronic treatment regimens (e.g., high smoking rates among the diagnosed COPD population)

Without an organized effort such as this project, there is no reason to assume change will occur that will modify clinical behaviors. Implementation of this project and resolution of these issues will result in improved access to evidence based care for rural patients with COPD.

## **MISSION:**

Participating health care providers and the Institute for Medical Improvement, represented by the Public Health Research Institute and the Maine Network for Health, will work together for a period of 12 months to implement a model of care for people with COPD. The principles used to improve care for these patients may serve as a template for managing a variety of chronic illnesses. We will strive to meet the Collaboratives goals in 12 months by sharing ideas and knowledge, learning and applying methodology for organizational change, system-wide implementation of a chronic disease management model with related proven concepts, and measuring progress. Methodology for spreading organizational change across the health system will be stressed as well. The clinical priorities of COPD management will be based on the currently available scientific evidence. Participants in this Collaborative will learn and implement an organizational approach to caring for people with COPD in a primary care setting. The system is population-based, and creates practical, supportive, evidenced-based interactions between an informed, activated patient and a prepared, proactive practice team. It is documented that compliance with the evidence-based protocols will result in improved quality of care for the COPD population as well as cost savings for the practice and health care system.

## **COLLABORATIVE GOALS:**

The long-range goal of this Collaborative is to maximize the length and quality of life for patients with COPD and satisfy patient and caregiver needs while maintaining or decreasing the cost of care. This will be achieved by implementing a system-wide model of care, which focuses on improving interactions between patients and providers. The Institute for Medical Improvement through the Public Health Research Institute, Maine Network for Health and the Collaborative Planning Group will strive to help each participating organization achieve the Collaborative goals and its own specific aims. Examples of potential goals for participating organizations that are consistent with the mission include:

1. 90% of COPD pt.'s >age 45 with one or more risk factors (tobacco smoking, occupational dusts and chemicals, indoor air pollution, outdoor air pollution, second hand smoke.) will have evidence of being assessed for COPD by the presence of a documented detailed medical history, documented spirometry results and classification by severity (Stage 1-4).
2. 100% of visits will show documentation of COPD pt. smoking status and smoking cessation counseling will be done at each office visit to those patients who continue to smoke.
3. 90% of all COPD patients will have a stepwise treatment plan that reflects assessment and severity of the disease process. All newly diagnosed patients classified as Stage 2 or greater will have treatment that correlates with the stage of illness. (Bronchodilator reversibility testing, inhaled glucocorticosteroid trial, CXR, ABG measurement, and Alpha 1 antitrypsin deficiency screening if indicated). Prescribed pharmacological intervention will be prescribed according to evidence based guidelines for treatment of COPD.
4. 90% of all COPD pt. will have an annual influenza vaccination and an up to date pneumococcal vaccine.
5. 100% or all COPD pt. will have a referral to a pulmonary rehab program that lasts a minimum of 2 months, and then will have a continued documented exercise program or regime.
6. 90% of all COPD pt. will have documented self management goals and patient education in the office record for each regularly scheduled appointment, and reassessment of self management goals will occur between the practitioner and patient with acute exacerbation.

Each team is expected to focus on at least four goals to help focus their implementation of the Chronic Care Model.

## **Methods:**

Each health system is expected to identify a specific population of COPD patients that can be monitored during the duration of the Collaborative. This pilot population is defined by the specific group of clinics/practitioners. A patient database (simple or sophisticated) must be available during the Collaborative to document and track results of interventions. Participating health systems must be open to changing actions and systems in order to improve clinical management and office efficiency. The Institute for Medical Improvement will aid participating organizations to capitalize on the learning and improvement from the focused project by simultaneously coaching senior leaders in participating organizations to develop a system for spreading the practice redesign to other locations/ offices/clinics as desired.

## **Collaborative Expectations:**

The Institute for Medical Improvement, the Collaborative chairs and the Planning Group will:

- Provide evidence-based information on subject matter, application of that subject matter and methods for process improvement throughout the course of the project;
- Offer coaching to organizations;
- Provide communication strategies to keep organizations connected to the Planning Group and colleagues during the Collaborative.

Participating Organizations are expected to:

- Perform pre-work activities to prepare for the first Learning Session;
- Connect the goals of the Collaborative work to a strategic initiative in the organization;
- Provide a senior leader to serve as sponsor for the team working on the Collaborative, serve as champion for spread of the changes in practice within their healthcare system, and attend at least the first Learning Session;
- Send a team to all Learning Sessions;
- Provide resources to support their team including resources necessary for attending Learning Sessions, time to devote to testing and implementing changes in the practice and active senior leadership involvement;
- Provide expert staff (Financial, Information System, Clinical Policy Development) to the team on an as needed basis;
- Perform tests of change leading to implementing changes in the organization and the conduct of their office practice;
- Make well-defined measurements that relate to their aims at least monthly and plot them over time for the duration of the Collaborative. Key changes will be annotated on these graphs of the measures;
- Share information with the Collaborative, including details of changes made and data to support these changes, both during and between Learning Sessions.

## **VIII. Appendix B: Summarized COPD Guidelines**

# Summarized COPD Guidelines

## Assessment and Monitoring

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A **detailed medical history** of a new patient known or thought to have COPD should assess:

- Possibilities for reducing risk factors, especially smoking cessation.
- Exposure to risk factors, including intensity and duration.
- Past medical history, including asthma, allergy, sinusitis or nasal polyps, respiratory infections, and other respiratory diseases.
- Family history of COPD or other chronic respiratory disease.
- Pattern of symptom development.
- History of exacerbations or previous hospitalizations for respiratory disorder.
- Presence of comorbidities, such as heart disease and rheumatic disease, that may also contribute to restriction of activity.
- Appropriateness of current medical treatments.
- Impact of disease on patient's life, including limitation of activity; missed work and economic impact; effect on family routines; and feelings of depression or anxiety.
- Social and family support available to the patient.
- Assess for acid reflux disease

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In addition to **spirometry**, the following **other tests** should be undertaken for the assessment of a patient with Moderate (Stage II), Severe (Stage III), and Very Severe (Stage IV) COPD.

- **Bronchodilator reversibility testing:** To rule out a diagnosis of asthma and guide initial treatment decisions.
- **Inhaled glucocorticosteroid trial (6 weeks to 3 months):** To identify patients with airflow limitation that is responsive to inhaled glucocorticosteroid treatment. If objective benefit is not demonstrated, inhaled glucocorticosteroid should be discontinued.
- **Chest X-ray:** Seldom diagnostic in COPD but valuable to exclude alternative diagnoses, e.g., pulmonary tuberculosis.
- **Arterial blood gas measurement:** Perform in patients with FEV1 < 40% predicted or with clinical signs suggestive of respiratory failure or right heart failure. The major clinical sign of respiratory failure is cyanosis. Clinical signs of right heart failure include ankle edema and an increase in the jugular venous pressure. Respiratory failure is indicated by PaO<sub>2</sub> < 8.0 kPa (60 mm Hg), with or without PaCO<sub>2</sub> > 6.7 kPa (50 mm Hg) while breathing air at sea level.
- **Alpha-1 antitrypsin deficiency screening:** Perform when COPD develops in patients under 45 years, or in patients with a strong family history of COPD.

A memory acronym that can assist in recall of these guidelines is **I-STIR**. **I** = **identify risk factors**, **S** = **Smoking Cessation and Shots**, **T** = **Tests**, **I** = **Inhalers**, **R** = **Rehabilitation**.

(Over)

## Therapy at Each Stage of COPD

| Current Staging | 0: At Risk  | I: Mild   | II: Moderate   | III: Severe  | IV: Very Severe  |
|-----------------|---|---|--|--|--|
| Characteristics | <ul style="list-style-type: none"> <li>Chronic symptoms</li> <li>Exposure to risk factors</li> <li>Normal spirometry</li> </ul> | <ul style="list-style-type: none"> <li>FEV1/FVC &lt; 70%</li> <li>FEV1 ≥ 80%</li> <li>With or without symptoms</li> </ul> | <ul style="list-style-type: none"> <li>FEV1/FVC &lt; 70%</li> <li>FEV1 50% to 79%</li> <li>With or without symptoms</li> </ul> | <ul style="list-style-type: none"> <li>FEV1/FVC &lt; 70%</li> <li>FEV1 30% to 49%</li> <li>With or without symptoms</li> </ul> | <ul style="list-style-type: none"> <li>FEV1/FVC &lt; 70%</li> <li>FEV1 &lt; 30% or presence of chronic respiratory failure or right heart failure</li> </ul> |
|                 | Avoidance of risk factor(s); influenza vaccination  |   |  |  |  |
|                 |   | Add short-acting bronchodilator when needed and pneumococcal vaccination  |  |  |  |
|                 |   |   | Add regular treatment with one or more long-acting bronchodilators<br>Add rehabilitation                                       |  |  |
|                 |   |   | Add inhaled glucocorticosteroids and assess efficacy and value with spirometry   |  |  |
|                 |   |   |  |  | Add long-term oxygen if chronic respiratory failure. Consider surgical treatments  |

## Commonly Used Formulations of Drugs for COPD

| Drug   | Inhaler (μg)                                    | Solution for Nebulizer (mg/ml) | Oral                       | Vials for Injection (mg) | Duration of Action (hours) |
|--|---|--------------------------------|----------------------------|--------------------------|----------------------------|
| <b>β<sub>2</sub>-agonists</b>  |   |                                |                            |                          |                            |
| <b>Short-acting</b>  |   |                                |                            |                          |                            |
| Fenoterol  | 100-200 (MDI)                                   | 1                              | 0.05% (Syrup)              |                          | 4-6                        |
| Salbutamol (albuterol)   | 100, 200 (MDI & DPI)                            | 5                              | 5mg (Pill)<br>Syrup 0.024% | 0.1, 0.5                 | 4-6                        |
| Terbutaline  | 400, 500 (DPI)                                  | —                              | 2.5, 5 (Pill)              | 0.2, 0.25                | 4-6                        |
| <b>Long-acting</b>   |   |                                |                            |                          |                            |
| Formoterol   | 4.5—12 (MDI & DPI)                              |                                |                            |                          | 12+                        |
| Salmeterol   | 25-50 (MDI & DPI)                               |                                |                            |                          | 12+                        |
| <b>Anticholinergics</b>  |   |                                |                            |                          |                            |
| <b>Short-acting</b>  |   |                                |                            |                          |                            |
| Ipratropium bromide  | 20, 40 (MDI)                                    | 0.25-0.5                       |                            |                          | 6-8                        |
| Oxipropium bromide   | 100 (MDI)                                       | 1.5                            |                            |                          | 7-9                        |
| <b>Long-acting</b>   |   |                                |                            |                          |                            |
| Tiotropium   | 18 (DPI)  |                                |                            |                          | 24+                        |
| <b>Combination short-acting β<sub>2</sub>-agonists plus anticholinergic in one inhaler</b>     |   |                                |                            |                          |                            |
| Fenoterol/Ipratropium  | 200/80 (MDI)                                    | 1.25/0.5                       |                            |                          | 6-8                        |
| Salbutamol/Ipratropium   | 75/15 (MDI)                                     | 0.75/4.5                       |                            |                          | 6-8                        |
| <b>Methylxanthines</b>   |   |                                |                            |                          |                            |
| Aminophylline  |   |                                | 200-600 mg (Pill)          | 240 mg                   | Variable, up to 24         |
| Theophylline (SR)  |   |                                | 100-600 mg (Pill)          |                          | Variable, up to 24         |
| <b>Inhaled glucocorticosteroids</b>  |   |                                |                            |                          |                            |
| Beclomethasone   | 100, 250, 400 (MDI & DPI)                       | 0.2-0.4                        |                            |                          |                            |
| Budesonide   | 100, 200, 400 (DPI)                             | 0.20, 0.25, 0.5                |                            |                          |                            |
| Fluticasone  | 50-500 (MDI & DPI)                              |                                |                            |                          |                            |
| Triamcinolone  | 100 (MDI)                                       | 40                             |                            | 40                       |                            |
| <b>Combination long-acting β<sub>2</sub>-agonists plus glucocorticosteroids in one inhaler</b> |   |                                |                            |                          |                            |
| Formoterol/Budesonide  | 4.5/80, 160 (DPI)<br>(9/320) (DPI)              |                                |                            |                          |                            |
| Salmeterol/Fluticasone   | 50/100, 250, 500 (DPI)<br>25/50, 125, 250 (MDI) |                                |                            |                          |                            |
| <b>Systemic glucocorticosteroids</b>   |   |                                |                            |                          |                            |
| Prednisone   | 10-2000 mg                                      | 5-60 mg (Pill)                 |                            |                          |                            |
| Methylprednisolone   |   | 4, 8, 16 mg (Pill)             |                            |                          |                            |

MDI = Metered Dose Inhaler, DPI = Dry Powder Inhaler

(Over)

## **IX. Appendix C: Evaluation Tool Kit**

The following tools, referred to in the report text, were used to conduct the evaluation of the *COPD Initiative*. A copy of the tools may be obtained through a request to PHRI.

- Questions for COPD Focus Group
- Change Package
- Practice Change Survey
- Chart Abstraction Tool – Patient-level Assessment – Gap Analysis #1
- Chart Abstraction Tool – Patient-level Assessment – Gap Analysis #2