COPD
FOUNDATION

CONNECT COPD Dissemination Framework Report

Dissemination & Implementation of COPD-Related Evidence

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A PATIENT'S PERSPECTIVE:
WHY DISSEMINATING COPD RESEARCH TO PATIENTS MATTERS BY WILLIAM CLARK

Patients are no longer "suffering in silence" and are using the vast available online information to become better educated about COPD. As a result, for the first-time patients are experiencing hope for their future. The research community has found a new impetus to pursue patient-directed research to address relevant gaps in treatment with a vision towards a cure.

Patients and caregivers are quickly becoming the drivers of their treatment, and as such they require extensive and complete knowledge of relevant research and treatment options. Support networks of peers working together with their healthcare teams will provide better outcomes. However, unless current research is disseminated to all members of the team and they work together to address the implications of such research, little will change.

There is little question that research will lead to new treatments and cures, but unless a mechanism is developed that adequately and efficiently delivers the results to the treatment team, and especially the patient, the benefits of the research will never be completely realized. The CONNECT Project hopes to achieve these results by developing an intuitive and functional mechanism that helps improve the way research teams communicate information and what it means for patients and caregivers.

The COPD Foundation's founder, John Walsh, a patient himself, believed that we can do so much more together; that together we can make a true difference in the lives of millions who suffer from COPD, and together, we can eliminate the scourge of COPD.

It is my sincere hope that targeted dissemination of research will result in the implementation of that research consistent with the reason it was conducted; improved patient benefit and quality of life. Patient health outcomes and quality of life will be improved, and as such, so will their outlook about their own future, and their desire that someday others will no longer experience a life with COPD.

A CAREGIVER'S PERSPECTIVE:
WHY DISSEMINATING COPD RESEARCH TO CAREGIVERS MATTERS BY ELIZABETH BERGER

Shortness of breath is a classic, life-altering symptom of COPD that makes the most basic tasks very difficult. By the time my mother was diagnosed, she was physically unable to perform previously pursued activities due to shortness of breath – this eventually progressed such that she was unable to leave the house, and even had difficulties getting around the house. Unfortunately, there were several barriers to improving her quality of life while living with this disease. While some treatments, such as pulmonary rehabilitation have been proven to improve shortness of breath, my mother was never able to access such a program as the closest center was over an hour away and booked solid. Similarly, her access to a specialist was limited due to a lack of providers in the rural area where we lived. Insurance constraints affected her access to treatments, certain medications such as inhalers, and even the quality of care in the emergency room.

My mother managed her illness with a primary care doctor who had limited expertise in treating COPD, an approach often referred to as the 'one-size-fits-all' method. About twenty years after my mother was diagnosed with COPD, she passed away without having received access to evidence-based care, having only seen a specialist two times before her death. While managing care with the primary care doctor helped with symptom management, there were many times when my mother received suboptimal care that was not up to par with current clinical recommendations. Her treatment was consistently suboptimal even though promising treatments did exist. This burden was magnified due to our residing in a rural area, further away from resources.

My mother deserved greater access to specialists, treatments, and individualized care, as do other people with COPD. Like many COPD patients and their caregivers, my family and I were largely unaware of what steps we could take to improve my mother's quality of life. As a result, COPD not only robbed my mother of the years in her life, but it robbed the life from her years. Unfortunately, while my mother's story is devastating, it is not all that uncommon. As dissemination and implementation of evidence-based care remains inconsistent, patients and families will continue to unnecessarily suffer.

INTRODUCTION

The COPD Dissemination Framework represents an effort to provide guidance to support the effective dissemination of COPD related research, with a core focus on the results generated from the patient-centered research funded by the Patient Centered Outcomes Research Institute (PCORI). This Framework and accompanying tools were developed with the support of a Eugene Washington Engagement Award and were informed by a team of patient, caregiver, clinician, researcher and advocacy organization advisors.

The Framework builds on the robust information contained in the **PCORI Dissemination and Implementation Framework and Toolkit** (PCORI Framework) to provide contextual factors specific to dissemination in the COPD community. Background information, dissemination barriers and stakeholder priorities are explored, with a focus on patient, caregiver and primary care audiences. For each of the five core elements of the PCORI Framework, we provide additional considerations and recommendations to help guide research and advisor teams seeking to create and implement effective dissemination strategies for COPD-related evidence. The CONNECT COPD team has also created robust tools including templates and examples for disseminating results to patients and caregivers and a searchable directory of organizations and their dissemination capabilities.

About the COPD Foundation

The COPD Foundation, a 501(c)(3) nonprofit organization, was founded in 2004 by an individual with COPD, in partnership with research and community leaders. The Foundation was established to undertake initiatives that result in expanded services for individuals with COPD and improve the lives of those individuals affected by COPD. The activities of the COPD Foundation focus on achieving these results through research, education, and advocacy programs. The mission of the Foundation is to prevent and cure chronic obstructive pulmonary disease and to improve the lives of all people affected by COPD.

For the last 15 years, the COPD Foundation has operated with a philosophy of "educate, empower and engage." The Board of Directors, staff and volunteer leaders believe that a community and a movement can form when people understand how to LIVE with their disease, BELIEVE that they can do something proactive to help themselves and are given the PLATFORM to act on.

As a response to the growing burden of COPD both nationally and globally, the COPD Foundation created COPD360 in 2014. COPD360 includes three areas of focus encompassing research, care delivery and community that collectively enable us to engage directly with the entire COPD community to create an environment that opens pathways to cures for COPD in the future and improves the health and quality of life of individuals with COPD today. A full explanation of COPD Foundation programs, including the Patient-Powered Research Network, COPD360Social and PRAXIS the care delivery hub, can be found on our website at www.copdfoundation.org.

About COPD

Chronic obstructive pulmonary disease (COPD) is a prevalent, progressively debilitating health condition that affects 15-30 million Americans and is the fourth leading cause of death. This staggering number disproportionately affects women, elderly, those without a high-school diploma, those unable to work or unemployed, those living in rural areas and those in households with income less than $25,000 a year[1].

COPD primarily encompasses emphysema, chronic bronchitis or both, though other obstructive airways diseases are often included under the umbrella of a COPD diagnosis. People with COPD face significant hurdles that span from delayed diagnosis, inadequate education and support, no disease modifying therapies and multiple challenges accessing high quality care and the medication and non-medication treatments that are effective in improving symptoms and in few cases, extending life.

Conversations shared on COPD Foundation's COPD360Social community of over 44,000 members demonstrate that individuals are frustrated by their situation and are seeking better solutions. Frequent questions include topics such as disease progression, steps to take to slow the disease, as well as available treatments, tips for completing activities of daily living and how to deal with the mental health and social isolation that can often accompany a COPD diagnosis. These sentiments were echoed in the two focus group discussions which were held in the information gathering phase of this project. Patients in these groups expressed interest in receiving education that would be beneficial to them. They also expressed concern that there seems to be a shortage of resources available for them. There is also a good deal of insecurity surrounding finding quality information and knowing how to know the information is reliable.

Simply put, COPD patients are faced with two challenges, areas where there is little evidence of what works best AND a lack of implementation of what we do know works. Efforts have been made to identify discrepancies between the information needed and sought by patients, and sources of information available to them. While we knew that the knowledge gap was wide, there was little research to show the information seeking related preferences of patients and caregivers and what is important to them as consumers.

Given the real and perceived lack of education and information shared about the illness, the disease burden of COPD is great. The impact of COPD is substantial and spans a variety of domains of everyday life. Because of disease severity, COPD symptoms have a negative impact on patient health-related quality of life (HRQoL), sleep quality, anxiety, and depression. Additionally, COPD symptoms do not occur in isolation; these patients are dealing with anywhere from one to four other comorbid conditions on average.

As the illness progresses, the individual will experience an exacerbation, or worsening of respiratory symptoms. The frequency and severity of exacerbations tend to increase over time. These exacerbations account for much of COPD-related morbidity, hospitalizations, mortality, and cost. Stakeholders in all spaces on the care continuum have an interest in reducing hospitalizations and lengths of stay. In fact, about 50% of all Medicare readmissions were related to respiratory disorders[2].

COPD patients face numerous barriers to optimal, patient-centered care, including access to evidence-based care itself. One analysis showed only 55 percent of COPD patients receive evidence based care,[3] and results are even more concerning when considering the relatively weak strength of evidence supporting what interventions should be undertaken in the hospital and in the period following hospitalization as shown in the conditional recommendations in the most recent European Respiratory Society/American Thoracic Society guidelines for exacerbation management[4].

To address gaps in evidence, COPD related research is moving in several important directions. First, a better understanding of the heterogeneity of COPD---not all COPD is the same, progresses the same way or requires the same diagnostic and therapeutic approach. For example, work from COPDGene and Spiromics (NHLBI funded) have demonstrated a group of individuals who do not meet lung function abnormality criteria currently considered diagnostic of COPD. Yet these individuals have symptoms and disabilities, and even progression of those problems like people with COPD. Research continues to try to elucidate how to identify and treat these individuals and how their disease relates to COPD.

Secondly, work continues to investigate the best methods to add physical activity to COPD therapy recommendations, including in a PCORI-funded study that explored phone-based physical activity coaching. Other research is exploring how to expand the reach of pulmonary rehabilitation by new mechanisms such as telehealth and community facilities as well as what combination of activity level and education programming is necessary to impact COPD symptom level and progression. And of course, work is ongoing in areas of new approaches to COPD therapy. With approval of new endobronchial valves for treating COPD-related emphysema, a new treatment option is available for a subset of the population. Work on biologics and more tailored approaches to COPD-related inflammation and tissue destruction is being done, primarily with industry funding. COPD research bridges the full spectrum from basic pathophysiology of COPD to clinical research of better methods to make existing therapies available to patients.

Families dealing with COPD stand to benefit from information resulting from studies nearly completed and those in progress. For example, a better understanding of the best diagnostic approach to COPD could facilitate earlier and more accurate diagnosis. This may require a sea change in the diagnostic approach and its confirmation. Spirometry may no longer be adequate to confirm a COPD diagnosis. This will require widespread effective communication with healthcare from primary care to subspecialty clinicians, health systems, payers and quality metrics groups.

Direct to public education may be an even more effective approach but requires work to identify and test broad dissemination approaches and effective content development. Similar dissemination challenges exist for expanding the spectrum of interventions included in pulmonary rehabilitation. Work on new surgical and pharmacotherapeutic approaches to COPD requires careful consideration of matching therapies to appropriate and eligible individuals—matching disease and patient characteristics to treatments or individualizing therapy becomes more important as the risks increase along with the benefits of newer therapies.

While research is advancing and the healthcare system is becoming more and more sophisticated, the average COPD patient can often be left behind. The focus in the hospital setting of late has been on reducing readmissions, but the real focus should be on improving care overall and improving the quality of life for the patients the system serves. This subtle shift in focus will likely achieve the goal of reducing readmissions as well as help COPD patients and their families regain and maintain control of their illness.

Improvements in the evidence guiding COPD care and how it is delivered can only be realized if there are extraordinary efforts to overcome the unique barriers to disseminating and implementing the findings in clinical care and in patient and caregiver outreach. Over the course of this project, the CONNECT team has worked to develop a dissemination framework which aligns with PCORI Dissemination and Implementation Framework but addresses the specific needs of the COPD community.

The COPD Dissemination Framework report provides insights on barriers and facilitators to dissemination, key stakeholder group's priorities for obtaining new evidence and specific considerations related to COPD for each of the core elements of PCORI's Framework. Additionally, practical tools and a dissemination capabilities directory to aid research teams in identifying outlets for their dissemination efforts are included on the COPD Foundation's website.

SECTION 2
FACILITATORS AND BARRIERS TO DISSEMINATION AND IMPLEMENTATION IN COPD:

The more we learn about COPD, the more questions we have. We know that there are many factors that make treating COPD challenging. For many years, COPD treatment was one size fits all. We now know that COPD varies widely not only in presentation, but in underlying cause and response to treatment. While the promise of precision medicine for COPD is still in its infancy, there are differences in the underlying cause and makeup of the lung damage and in comorbid conditions, that can be assessed to help healthcare professionals determine appropriate treatment plans, but this complexity makes it much more difficult to provide evidence-based treatment in primary care settings where the majority of COPD patients are seen. We know that rural areas have higher COPD prevalence and in these areas people with COPD must rely on critical access hospitals and isolated remote practices that are not equipped to recognize and address early signs of COPD and COPD exacerbations.

There are also differences in symptom presentation, response to medications and ability to use their unique delivery devices, and the need for supplemental oxygen. Additionally, COPD progression varies widely among patients. Why is it that some patients are disabled by symptoms early in the disease course while others are still employed full time? Why do some patients experience frequent exacerbations with limited differences in exposure to risk factors? Why do some patients require supplemental oxygen earlier than others? With so many questions, finding accurate, timely information can be challenging.

There are barriers which often keep patients from seeking care in the first place, and these same issues prevent them from seeking out needed education or help to deal with worsening symptoms that can lead to hospitalizations and death. We can break these barriers down into six categories:

1. **Accessibility**
   The issues of accessibility include both proximity to specialists as well as a shortage in resource availability such as pulmonary rehab and support groups. The need for specialists is important because a person with COPD is typically dealing with multiple comorbid conditions. To treat the COPD effectively, the healthcare team must consider these coexisting conditions in order to maximally medically manage the patient and not tip the scales in one of the other illnesses. Often these same patients are under the care of their primary care clinician who is managing all their

chronic conditions and may not have the time or latest current knowledge to address specific needs related to COPD. The participants in the focus groups we met with indicated that they would love to have COPD support groups or pulmonary rehab centers in their area, but sadly, they were left to find alternatives to those programs since they were not available. Even when the resource of pulmonary rehab is available in an area, it is very often underutilized, or patients are sent at late stages of the disease when they are often deconditioned and lack exercise tolerance. Accessibility issues also present barriers related to rurality and internet access as the prevalence of COPD is nearly double in rural areas. COPD patients also experience difficulty with access to transportation and support to coordinate their healthcare needs like prescriptions, home oxygen, and site-based treatment, limiting opportunities for interaction and information sharing.

2. Socio Economic

Several related components are bundled under the umbrella of socio-economic issues. We know that most people with COPD are diagnosed later in life, have lower incomes, are more likely to leave their prescriptions unfilled due to cost, and are often vulnerable to medical misinformation. This combination of issues leaves the COPD patient at-risk for frequent exacerbations and high healthcare utilization.

Many of the common pharmacologic treatments cost more than $100 per medicine. The cost of the drugs makes it difficult for many patients to purchase them every month. When the medicines are this hard to procure, the patient will skip doses or even whole days of treatment in order to make the drug last as long as possible.

3. Inactivity

Shortness of breath is the symptom that often leads to the diagnosis of COPD when that symptom becomes problematic. At the time the patient states they are experiencing shortness of breath, their lung function is, on average, around 50%. Inactivity becomes a hurdle because the person is experiencing shortness of breath on exertion, so they stop doing things that cause exertion. When they stop exerting themselves, they become even more deconditioned which causes more dyspnea – a vicious cycle. Inactivity makes the body less efficient in using the oxygen it gets and weakens important muscle groups. This cycle leads to social isolation. missed doctor appointments, and more frequent hospitalizations.

4. Shame or guilt

It is estimated that as many as 75% of COPD cases are caused by smoking or other environmental exposure. With numbers like that, many patients harbor feelings of guilt or shame that their behavior caused their illness and that they are somehow less deserving of treatment than other people with chronic diseases. This shame and guilt can keep them from seeking medical care initially and can keep them from being proactive in their care going forward. Often, COPD patients are left feeling that healthcare professionals are reluctant to help them with their illness since they 'did this to themselves' and don't want to be a bother. This mindset contributes to poor self-care and more frequent exacerbations.

5. Social isolation

With physical limitations, shortness of breath, and the fear of having an embarrassing episode in front of other people all very real struggles for COPD patients, they often limit their treks outside of their home. They miss special events, give up their jobs, and begin to feel that their world is closing in on them. This social isolation can keep people from the relationships they need to maintain good mental health. A COPD patient is often left wondering if what they are going through is normal, or how to adapt to their new reality. Social isolation is a huge obstacle to be overcome, but there are few resources to meet the need. Additionally, there is some emerging research that patients learn best from other patients, so participating in support groups, either virtually or in person, are important in keeping the social well-being of the person intact.

6. Trust

In recent years, there have been attempts by payers to be more involved in the dissemination and implementation of new evidence, especially when its related to clinical and self-management strategies. Payers have attempted to provide resources- both educational and supportive for COPD patients. Examples of these would include offering in-person support groups and telephonic support as well as structured COPD classes for their customers. During the conversations held with our focus groups, the groups were asked about such offerings from the payer groups, and the response was one of distrust and skepticism. The participants said the motives of the insurance companies were suspicious and they felt they could not trust information given to them from such sources. This response is similar to that of clinical information provided by payers and pharmaceutical companies directly to healthcare professionals. CONNECT patient advisors also noted that people with COPD rarely have access to a trusted and consistent healthcare professional to turn to for guidance on COPD-related issues. With this lack of trust underpinning the additional barriers to care, sources for trusted COPD information is extremely important to the COPD community.

Primary Care Related Barriers

In addition to the patient focused barriers, dissemination and implementation in COPD is challenging due to most of these complex patients being managed in primary care settings, with many areas lacking access to pulmonologists within reasonable driving distances.

Primary care has many unique barriers to dissemination and implementation of COPD-related research data. First, many researchers and COPD experts overlook the marked limitations inherent in many studies of COPD. The patients included in many published studies have more severe disease, fewer comorbid diseases, are likely not current smokers and may have different socio-demographic factors that impact access, health literacy and ability to adhere to treatment plans compared to patients seen in primary care.

Primary care is including increasing numbers of diverse clinicians with differing levels of exposure and education in pulmonary issues. In primary care, COPD and respiratory health is only one of many areas that must be incorporated into daily practice. Continued concerns about the lack of COPD cures and few therapies other than smoking cessation that are shown to modify the course of COPD disease progression can result in reluctance to make COPD a major focus of continuing education and practice improvement. While quality metrics, alternative payment models and risk-sharing have grown in importance, COPD-related measures have mostly been left out, leaving busy primary care clinicians to focus more on what is being measured. And finally, on a daily or weekly basis, COPD may remain an important but uncommonly recognized reason for patient/clinician interactions.

Primary care clinicians must choose what guidelines to review, what quality metrics to focus on and what educational opportunities they select. This will require that dissemination be focused, interesting, related to identified needs, and done in an efficient and effective format.

Why a COPD Dissemination Framework?

One might ask why there needs to be a special focus on a dissemination framework for COPD. Are the barriers and facilitators to effectively translating evidence into practice for COPD so different from other diseases? The answer is yes. COPD is different in the ways we have discussed – the diagnosis and determination of appropriate treatment plans are complex, yet it is primarily treated in primary care settings, it impacts those with lower education and lower wage earners, there are large gaps in current application of evidence based therapy, new treatments are trending towards only being applicable to small subsets of the population and more.

It also different in that it is the 4th leading cause of death in the United States but it barely registers on the radar of our national health improvement conversation. There is relatively little investment in COPD research compared to the burden of disease, there is no investment in public health interventions for COPD outside of tobacco control and COPD quality measures are inadequate and rarely included in major reporting programs. With such discrepancy between disease burden and response, there is little wonder why the COPD patient population continues to bear such a high disease burden.

SECTION 3
STAKEHOLDERS PRIORITIES IN COPD

Most prioritization efforts in COPD have focused on research topic prioritization and rarely include robust patient and caregiver perspectives. To build on existing knowledge about research gaps in COPD, and to infuse a stronger patient and caregiver perspective about what topics they consider most important for their own lives, the CONNECT team conducted a series of engagements, including an online survey and in-person discussions with individual stakeholders and groups of patients and caregivers. Following completion of the draft Framework, an additional phone focus group, written interviews and three test dissemination presentations with evaluations were conducted. We encourage you to read the full description of these engagement activities and key findings in Appendix 2.

The engagement activities intended to identify areas that may be dissemination gaps rather than a research need. Ongoing stakeholder engagement will build on the survey findings and future work to identify patient and caregiver priorities and preferences will enhance our understanding of evidence gaps vs dissemination gaps.

The CONNECT survey included a series of three ranking exercises and questions to understand more about the respondents such as disease severity, insurance status, demographics and type of healthcare professional. Three slightly customized ranking exercises were presented for patients, caregivers and healthcare professionals. In the first ranking exercise, respondents were asked to rank a series of broad domains based on their perception of how strong the evidence is within each topic. In the second exercise, respondents ranked the same domains based on which topics they felt were most important to receive more information or evidence about. In the last ranking exercise, a series of subtopics were presented within each of the broad domains and respondents ranked them in the same fashion as in the second exercise. A summary of the ranking exercise results can be found in Appendix 2.

Overall, the survey found that patients and healthcare professionals reported COPD management and diagnosis related issues were most important to them, with less emphasis on comorbidities, technology, and end of life care. There was some overlap between patients and healthcare professionals regarding how much information they thought was available already for each of the listed concerns. For example, both patients and healthcare professionals felt little information was available for use of technology in helping COPD and palliative and end of life care, in contrast with pulmonary rehabilitation, comorbidities, and vaccine recommendations which were considered to have more information available.

There were a few differences between patient and healthcare professional’s responses that are worth noting. Patients felt that there was a lot of information available for self-education about COPD, while healthcare professionals largely disagreed. In contrast, healthcare professionals felt there was a lot of information available on choosing the right medications and clinical management, while patients ranked these items toward the lower end of the spectrum.

It is worth noting that our healthcare professional sample included mostly respiratory therapists which may have affected these results, particularly those concerning pulmonary care (e.g. pulmonary rehabilitation, clinical management, oxygen). Respiratory therapists tend to be very experienced in these areas but they do not provide direct COPD medical management. They may have access to different resources than other types of healthcare professionals. This may indicate that dissemination needs are different among distinct groups of healthcare professionals.

SECTION 4
DISSEMINATION FRAMEWORK KEY ELEMENTS AND RECOMMENDATIONS: ADAPTED FOR COPD PURPOSES

1. PCORI Framework Element: EVIDENCE ASSESSMENT: *Is the evidence ready for use? Does it respond to stakeholder concerns?*

PCORI published the Dissemination and Implementation Framework to improve the pace and effectiveness of research results reaching the community and ultimately being adopted by end-users, whether that is an individual patient, clinicians, health systems or policy makers. The Framework was informed by stakeholder input and provides broad guidance and suggestions that can be leveraged in the planning, execution and evaluation of dissemination efforts.

Due to the broad-based nature of the Framework, there is a need to create additional resources and tools that will provide more context and recommendations for specific disease or topic areas. The following sections build on the five core PCORI Framework elements by addressing factors unique to the COPD community, and the available resources and stakeholders that can support effective dissemination strategies.

As we have stated throughout the document, there are critical gaps in the evidence as it relates to COPD prevention, diagnosis, treatment and care, AND there are systemic problems with ensuring the knowledge and treatments we do have are applied in practice, understood by patients and implemented in their own lives.

To date the evidence base for many elements of COPD care remain limited. Several of the questions below are being explored in existing research efforts that could immediately inform changes to COPD care or reinforce existing strategies if they were effectively disseminated and implemented.

For example: Current data on the exact use of spirometry or lung function testing in confirming COPD and how to achieve that remains unclear. Is the current requirement of an FEV1/FVC <.7 really the best metric?[5] *How do we increase access to readily available, accurate and reproducible lung function testing? While pulmonary rehabilitation improves many COPD symptoms and patient's functional status on a short-term basis, how do we extent that impact? Does pulmonary rehabilitation improve survival and in which groups of patients? Can pulmonary rehabilitation be delivery in multiple formats such as through telehealth in addition to in person settings. Who can deliver pulmonary rehabilitation? What is the best approach in developing biologics for COPD and how does it differ from those used in asthma? What are the best options of delivering oxygen outside the hospital, who needs it and when? How can we assure that patients and families receive the best support when using supportive respiratory devices whether it is oxygen, CPAP or home-based monitoring?*

In COPD, as in many other complex chronic conditions, whether evidence is ready for dissemination is never a clear-cut decision. For example, in COPD, a major policy change, the addition of COPD exacerbations to the Medicare Hospital Readmissions Reduction Program, forced hospitals to make immediate decisions on how to implement COPD-focused transitional care strategies. In most cases these decisions were not made based on evidence we would likely qualify as ready for broad dissemination, however the reality dictated otherwise. Ultimately many of the strategies that were implemented were based on the sharing of experiences, quality improvement data, and in a few cases, clinical trials. People in charge of implementing changes had little to go on to judge if someone else's experiences, population, system structure and tactics were relevant to them.

Patients with COPD also face hurdles in understanding how or if to apply information they receive about their health in their own lives. COPD's complexity and its unique presentation makes these decisions even more difficult for patients and families. With that said, given the appropriate information, patients and families can become active participants in making informed decisions about an appropriate response to research results.

PCORI Evidence Assessment Question: Is the evidence ready for use in a COPD population? COPD Considerations and Examples

PCORI suggests dissemination plans should address three major questions during evidence assessment;

- *i. Determine how the evidence relates to existing evidence*
- *ii. Determine why the evidence matters to patients, other stakeholders, health policy and practice*
- *iii. Anticipate barriers to use in decision making*

Within this framework the following considerations related to COPD can guide the evidence assessment process and help researchers and broader stakeholder groups answer the questions PCORI outlines for this phase. *The CONNECT patient advisors strongly recommended that research teams review the results with patient and caregivers prior to beginning the evidence assessment phase of dissemination and felt that they could help refine the types of considerations researchers should consider.* Advisors also suggested that the first question to consider is what is the desired end result of the dissemination planning and of the evidence itself. In other words, what action do you expect the target audience to take with the evidence in question.

- Who was the population studied and is it reasonable to apply the findings to additional populations?
    - » Did the study include specific groups of COPD patients, for example; different ethnic and racial subgroups, those with advanced vs moderate disease, emphysema vs chronic bronchitis, smokers vs non-smokers, oxygen users, specific combinations of comorbid diseases, those diagnosed and managed in primary care
- What was the setting of the study?
    - » The needs of stakeholders and the barriers for implementation will differ based on the type of setting(s) of the study. For example, was the study conducted solely in academic institutions or with community based hospitals, was it in an urban vs rural area, did it involve primary care or only pulmonology or other specialists, were there other factors specific to the study setting that would influence the applicability of the results such as geographic factors, minority serving institution, safety net hospitals, unique infrastructure or partnerships already in place
- How was the study designed?
    - » Traditional vs pragmatic, tightly controlled intervention vs tailored multi-component intervention, intensive intervention, multiple exclusion criterion like excluding non-smokers or broad inclusion
- Who is the decision maker/end user for this evidence?
    - » Who can help put the findings into practice? For example, is it medication/treatment evidence that can be applied by individual healthcare professionals, a health system intervention that requires decision making by department or hospital management, or is it related to individual actions that can be taken by patients and caregivers directly or an intervention that CMS, insurers or other policy makers must act on.

- What was the effectiveness of the intervention on the primary outcome and secondary outcomes and how does it relate to previous evidence in the topic area?
  - » Was the efficacy of the intervention studied already well established?
  - » Do other studies confirm effectiveness of the intervention?
  - » Did the study achieve its primary effectiveness outcomes?
  - » Did the study achieve its secondary effectiveness outcomes?
  - » Did the study confirm effectiveness in a population with COPD?
  - » Are the study findings confirming prior effectiveness study findings?
  - » Does it make sense to accept the secondary outcomes if the primary outcomes were not achieved?
- Does the evidence contradict previously held beliefs about how COPD should be treated?
  - » There are many ingrained beliefs that remain as influencers in the way COPD patients are treated. Examples include;
    - ▪ A belief that only smokers get COPD
    - ▪ Predetermined image of what a COPD patient looks like including gender, weight, age and function
    - ▪ Overall nihilistic attitudes that those who smoke get COPD and no amount of intervention will alter their outcomes
    - ▪ Misconception that if a patient continues to smoke than there is no reason to initiate treatment for COPD
    - ▪ Disbelief in the benefits of pulmonary rehabilitation
    - ▪ Belief that people with COPD are all elderly and likely not capable of utilizing technology-based interventions
    - ▪ A belief in a one size fits all approach when addressing COPD therapy including medications and oxygen
    - ▪ Disbelief in the need to refer to a pulmonologist or when to refer to a pulmonologist
- Where does the evidence fit in the stakeholder priorities for COPD?
  - » Additional information on stakeholder priorities is in section [3]. However, when assessing evidence for broad vs limited dissemination, it is important to think about all those who can ultimately influence patient outcomes, including the patients and caregivers themselves. A brief matrix of key stakeholders and highlights of their key driving priorities follows;

PATIENTS	Help me understand and accept my diagnosis and how I can achieve goals that matter to me; help me live my best life for as long as possible; help me communicate with my many healthcare professionals to get them to work together and to help me understand the impact of other conditions co-existing with COPD; help me understand my treatment options and identify a regimen I can maintain; help me understand when to seek care for problems or exacerbations.
CAREGIVERS	Help me understand the daily challenges and limitations of living with COPD, what medications and devices my loved one are supposed to use and how to use them; help me know how to provide encouragement and how to be a better advocate for my loved one.
PRIMARY CARE	Help me efficiently and effectively identify the full range of diagnostic and treatment options for people with COPD; help me figure out how to tailor treatment options; help me monitor disease progression in people with COPD; help me understand the impact of comorbidities; help me figure out how to implement this information in busy daily practice; help me connect my patients to education and community resources and specialists when needed; help me identify pulmonary rehabilitation resources or tools for exercise support when rehab isn't locally available.
PULMONOLOGY	Help me to collaborate with patients, caregivers and clinicians who refer to me; help better understand value of phenotyping; help me determine how to: identify and address co-morbid conditions, initiate collaboration with primary care, incorporate non-physician clinicians into practice, provide the patient education services expected of a specialist's office, increase access to pulmonary rehabilitation, include newer treatment opportunities such as valves as well as considerations for transplant or lung volume reduction surgery.
HEALTH SYSTEM MANAGEMENT	Help me find ways to raise the quality of care without adding costs, comply with required reporting and measurement programs; help me to identify evidence based tools and support to recommend to patients and caregivers; help me design quality improvement programs that address complex patients in primary care and to support collaborative care with specialists inside and outside our system.
DURABLE MEDICAL EQUIPMENT PROVIDERS	Help me identify ways to meet individual's equipment needs within existing resource barriers; help me identify new information and policies that should guide how I deliver services; help me understand patient barriers and concerns to successful use of my products.
INSURERS	Help me design payment policies and incentives that will result in better outcomes for patients and lower costs; help me understand the impact of formularies that require patients to frequently change medications.
EMPLOYERS	Help me keep my employees (patients and caregivers) able to function at work; help me purchase health plans that provide high value care for COPD; help me recognize any occupational exposures that may negatively impact people with COPD.

POLICY MAKERS	Help me identify how to assess return on investment for COPD related care; help me identify how to incorporate comparative effectiveness research results into policy decisions including coverage and payment policies, public health funding and new innovations.
HEALTH PROFESSIONAL EDUCATION PROGRAMS	Help me identify new areas that support healthcare professionals achieve the best outcomes in COPD that can be funded; help me figure out how to include a broad range of healthcare professionals and their educational needs.
PATIENT ADVOCACY GROUPS	Help me incorporate research results into our programs and services; help me communicate how research results are relevant to patients and caregiver's lives; help me communicate efficiently within our resource limitations.
COMMUNITY LEADERS	Help me understand the needs and gaps in services for my community members dealing with COPD; help me identify tools to support patients and caregivers as well as healthcare professionals.
RESEARCH FUNDERS	Help me identify the full spectrum of research needed, not only in "bench" and randomized trials but also pragmatic and implementation studies; help me identify study designs that address a broad scope of issues including patients with multiple comorbidities.

Evidence Assessment in COPD: An example from PCORI research

The PELICAN Study was a PCORI funded CER trial and the INVEST Study was a pilot wearable device study with recruitment based in the COPD Foundation's PCORI supported Patient Powered Research Network (PPRN). The PELICAN Study examined the effectiveness of a proactive peer-led phone education and coaching program to improve adherence to oxygen and other patient centered outcomes like anxiety and sleep quality compared to reactive access to a peer coach and to usual care with a national population of COPD patients. The INVEST assessed the ability of people with moderate to severe COPD to wearable a snug vest overnight for 5 of 7 nights. The vest housed multiple devices to track biometric data that could be used in studies or COPD therapies. The study team included a patient investigator identified by the COPDF.

Both studies have full results and provide practical examples of evidence assessment processes that will likely be applicable to future COPD PCOR.

CONSIDERATION	PELICAN	INVEST
Who was the population studied and is it reasonable to apply the findings to additional populations?	People over 18 with all stages of COPD were included. Only those in hospice or who used liquid oxygen were excluded. All participants had a prescription for 24 hour a day supplemental oxygen. Only English speakers were included. Participants resided in nearly all 50 states in the U.S.	People with moderate to severe COPD were included in the pilot to assess ability to include a larger population of people with COPD in future studies. Participants primarily resided in a retirement community in Southern Florida with higher than average income compared to the broader COPD population. Only English speakers were included.
What was the setting of the study?	The enrollment, intervention and outcomes assessment were done via phone. Printed materials were sent to the enrollee's home in the proactive and reactive arms. In a subset of patients, home visits by the DME company were used to collect adherence data.	Enrollees attended an in-person training, but the study procedure was completed in their home with wireless transmission from the vest. Data transmission was automatic and no patient intervention was required.
How was the study designed?	The study was designed initially by a team consisting of representatives from a patient organization, A DME company, a patient and multi-disciplinary group across 3 institutions. Following approval, the study design was finalized with the input of multiple in-person and phone-based focus groups and the ongoing support of a diverse stakeholder advisory board with broad US representation. It was a randomized, combined effectiveness and implementation pragmatic trial.	Initial design was by the sponsor, but the study design was modified based on input from COPDF researchers and the patient investigator. It was a pilot observational study.
Who is the decision maker/end user for the evidence?	Ultimately the end user would be organizations providing health coaching programs via phone, especially those considering providing peer-to-peer support programs. These are likely to be a combination of patient advocacy organizations, individual health systems, integrated healthcare networks, payers or public health agencies.	For the pilot study the end user was the sponsor who wanted to assess the ability to include the vest in larger trials of people with COPD. The information obtained could also be useful to people with COPD who may desire or need to have overnight biometric data collected.
What was the effectiveness of the intervention on the primary outcome and secondary outcomes?	Neither the proactive telephone-based peer coaching intervention nor the reactive informational arm increased adherence to oxygen. The proactive coaching significantly lessened the burden of depressive symptoms and sleep disturbance compared to usual care. Compared to reactive care, the proactive coaching improved depressive symptoms. These were secondary outcomes. Unexpectedly, adherence was significantly worse in the proactive group compared to the reactive group.	All enrollees in the pilot study were able to wear the vest without interference with their or their partner's sleep. For one person there was no appropriately sized vest.
Does the evidence contradict previously held beliefs about how COPD should be treated?	The study results showing worse adherence were surprising and counter to the belief that more education and support will result in improved adherence.	The study demonstrated that despite some concerns about patient's ability to wear the vest overnight, biometric data can be collected continuously overnight with high patient satisfaction.
Where does the evidence fit in the stakeholder priorities for COPD?	Patient's want education and support that will help them deal with a variety of symptoms, including comorbid conditions like depression, for which the study found a positive effect. It is unclear the role the evidence can play in helping end-users assess if peer coaching is economically viable since it did not improve adherence. The overall economic impact of improved depressive symptoms and better sleep quality is not known. DME companies and other healthcare professionals may be interested in the results to guide their own oxygen patient outreach, education and future research.	This wearable vest is early in the process of identifying and confirming its value in both COPD care and COPD clinical studies.

2. PCORI Framework Element: AUDIENCE AND PARTNER IDENTIFICATION: *Who will benefit from this evidence? Who can help reach the audience?*

The second element in the PCORI Framework is a vital step that is often done only through a narrow lens of traditional academic publication and presentation, a paradigm that is changing through PCORI's efforts and through the increasing involvement of patient advocacy organizations in the planning, conduct, evaluation and dissemination of research.

To inform the two questions PCORI poses in this Framework element, we have created a grid of the key decision points in a COPD patient's journey, illustrating the role different audiences can play in improving outcomes for individuals with COPD.

As a result of the CONNECT team's engagement with select PCORI-funded research teams that conducted COPD-related studies, we feel it is important to focus more of the content in the COPD Framework on dissemination to patients, caregivers, primary care professionals and policy makers. It was simply not on the radar of the investigators the CONNECT team spoke with, despite this group already having embraced the role of patient and stakeholder engagement in the planning and conduct of research.

The first stage of PCORI Framework Element Two is ***engaging stakeholders to help identify the audience and partners***, in other words, who should be advising research teams as they plan their dissemination strategies. In the COPD space, an emerging understanding and appreciation for the role of stakeholder engagement has led to increased involvement from non-traditional partners in PCORI funded research , and increasingly in pharmaceutical and NIH funded work. Challenges such as the diffusion of patient and stakeholder engagement across the research enterprise still require significant attention.

In COPD there are challenges engaging those with the greatest capacity to influence outcomes in study advisory boards and planning groups for the purpose of dissemination planning. These groups deserve more focus and effort should be made to overcome obstacles so that their insight is incorporated in a routine way throughout the planning, conduct AND dissemination of the study.

Examples of hard to engage stakeholders and stakeholder groups for the purposes of dissemination planning;

- **Primary Care**
  Primary care clinicians have massive competing time demands, which often prevent them from participating in advisory groups and other dissemination planning projects. Significant advanced planning is required to minimize disruptions in their clinical schedules, which can conflict with the desire or need to get new research or best-practice standards out as quickly as possible. In addition, researchers, especially academic sub-specialty researchers, may not consider including primary care clinicians or other health professionals or forget they are the experts in primary care settings and care provision. Primary care clinicians may also feel uncomfortable with participation and believe that they may be treated as if they are unable to provide high quality care for people with COPD, or they may believe this themselves, and are thus reluctant to participate in events they feel are not relevant to their practice. Evaluating their needs, expectations, and desires for easily-to-use support tools is therefore essential.

- **Patients**
  People with COPD may be reluctant to participate due to basic logistical issues; this population often faces barriers with activities of daily living, to say nothing of the logistics involved in meetings and advisory boards. Many may also feel historically marginalized by their providers and/or the healthcare system in general, and thus lack the confidence or self-efficacy for advocacy and advice. The COPD population, as with many others, has substantial variation in health literacy levels, creating a barrier for this group to understand the importance of participation. Finally, a sense of shame and blame of having caused their disease, anxiety, depression, or other intra- and interpersonal factors reduce self-confidence and the likelihood of participation. CONNECT patient advisors who participated in dissemination planning activities all had previously engaged in community activities and have profiles that were atypical of the barriers described in this section. They indicated that they engaged in dissemination activities

because they felt their voices made a difference and they were interested in giving back to the greater good of the community.

► **Caregivers**

Caregivers play an essential, yet often overlooked in relaying health information to people with COPD. As with primary care clinicians, caregivers have significant time constraints related to their ongoing responsibilities, not only related to the person in their care but their external lives as well (career, other family, etc.). This group has been traditionally de-emphasized in research and policy evaluation, which likely contributes to a lack of self-understanding of their role and contributions. Caregivers also face many of the same barriers as their charges, including the potential for low health literacy, travel/logistical barriers, and lack of access to evidence based information.

► **Advocacy Groups**

While it may appear paradoxical, many COPD advocacy groups also face significant barriers to participation in the planning and dissemination process. These groups are highly dependent on volunteers for operations, establishing many of the same time constraints other segments of the COPD community face, as well as the prospect of turnover diminishing commitment and sustainability. In addition, there are relatively few COPD-specific advocacy groups, particularly at the state and local levels, placing more of the burden on general lung health groups required to divide their time and resources between COPD and other pulmonary conditions, potentially diluting effectiveness. In many cases, researchers may be simply unaware of the capacity of advocacy organizations to participate in the research and dissemination planning process.

All these factors emphasize the critical importance of bringing each group to dissemination discussions, in order to create the most immediately actionable communications possible.

PCORI also suggests that research teams ***identify partners that can help reach the audience***. To support this objective, we have begun to identify partners that can reach priority audiences with COPD-related research results. Organization profiles can be found in the Dissemination Capabilities Directory section of the COPD Foundation website.

Lastly, PCORI suggests that research teams document the target audience's ***needs, values, motivations and expectations, in addition to identifying the context for adoption, the incentives necessary for change and the barriers or disincentives that may hinder adoption.*** Researchers seeking to disseminate COPD related research are encouraged to complete the valuable worksheets contained in the PCORI Framework. To guide their planning, we have begun preparation of a grid that will contain stakeholder informed answers for commonly targeted audiences in COPD dissemination and implementation. View Appendix 3 for an example of clinician, health system, payer and policy maker information. This is a living document and will be updated as additional information is developed through ongoing COPD Foundation engagement activities.

3. PCORI Framework Element: DISSEMINATION: *How can we make the evidence available? What info about the evidence will people need?*

In this action-oriented section, PCORI suggests addressing two core questions; What information about the evidence will help people make decisions; and in what ways can that information be provided?

Our goal is to provide research teams and advisory groups with practical information about where people involved in the care of COPD go for information, informed by in-person engagements, surveys and the experiences of the diverse stakeholder group involved in the CONNECT project. As with other sections, more emphasis has been placed on the core stakeholder groups of patients, caregivers, primary care clinicians and advocacy organizations. The information below will support the completion of worksheets found in the PCORI Dissemination and Implementation Toolkit .

Primary Care Dissemination in COPD-Current State

There has been an uptick in interest in COPD among primary care communities as newer therapies have become available, as evidence has demonstrated the ability of primary care practices to do accurate and reproducible lung function assessment and as COPD quality metrics have gained more wide acceptance. Dissemination of research results into primary care practices is still primarily done through two general methods: educational opportunities for healthcare professionals and programs initiated at the practice level.

Educational programs have moved from simple didactic sessions to case-based learning, on demand online education, patient inclusion in education and practical educational tools that can be implemented directly into practice such as assessment tools, patient directed inhaler educational videos and education and support for non-prescribed health professionals such as medical assistants and nursing staff. It is unclear what impact educating individual healthcare professionals has accomplished. Most outcomes from education programs are done via pre-and-post knowledge assessment or self- reported surveys asking health professionals what changes they may have made in practice after completing an educational program.

Health system level programs often use published evidence as well as information from best practices shared among professional networks. These health system or clinic wide programs are usually multi-component and may incorporate findings from many studies, making it difficult to know how to disseminate data from a single study in the context of these programs. To date, few of the programs have been rigorously assessed or described, so it is difficult to evaluate the best way to disseminate information to those who develop and implement these programs. This illustrates an important learning opportunity and area for expanded collaboration.

Primary Care-Tips for Making the Right COPD Related Info Available

CHALLENGES REACHING THE AUDIENCE	• Identifying communication channels that reach large audiences of primary care clinicians • Creating content that meets the needs of primary care with different levels of education on COPD • Making your content stand out due to multiple competing priorities and limited time to consume new information
TIPS FOR OVERCOMING THE CHALLENGES REACHING THE AUDIENCE	• Identify organizations that employ or coordinate large groups of primary care clinicians, especially those participating in risk-based/shared-savings payment models • Identify national AND regional groups that serve different groups of primary care clinicians, e.g. National Association of Physicians Assistants, National Association of Nurse Practitioners, American Academy of Family Physicians • Create actionable headlines, identify why the evidence relates to the overall care of the patient primary care sees, include key takeaways and how to implement the evidence
BROAD BASE DISSEMINATION TACTICS	• Consider outreach at the group practice associations, integrated delivery systems and other arrangements like accountable care organizations to identify the communication channels available through their infrastructure and tailor messaging according to their needs • Identify funders in COPD related continuing medical education and approach stakeholders in the COPD community to design impactful CME programming focused on delivering actionable information within the context of primary care settings • Identify practice or health system level champions to facilitate and guide educational activities
OTHER TARGETED DISSEMINATION TACTICS	• Identify others in primary care that are delivering similar interventions in other disease areas and target communications with the purpose of enticing them to expand focus to COPD (ex. Another medical group doing exercise coaching for pre-diabetes may be more prepared to consider implementing exercise coaching for COPD)

An Example: The CAP Study Dissemination in Primary Care

The Community Acquired Pneumonia in people with COPD (the CAP study) was a widely disseminated study that used the PCORI-funded COPD Patient-Powered Research Network to identify and enroll individuals with COPD that had a recent case of pneumonia. The study is further described in the example tools located in www.copdfoundation.org/Research/CONNECT-Dissemination-Resources/COPD-Dissemination-Tools.aspx. When seeking to reach a primary care audience, we first used traditional techniques of dissemination to healthcare professionals including publication of the results (http://bit.ly/COPDPneumoniaStudy) and presentation of the results in poster and oral poster presentations at the American Thoracic Society annual meeting. However, it was clear that these methods did little to reach primary care clinicians.

As a second step we included the results in several presentations designed specifically to reach large number of primary care and other clinicians: as part of COPD management talk at the American Academy of Family Physicians meeting (500 family physicians) as well in online presentations hosted by commonly accessed continuing medical education sites (Medscape, WebMD and Integratis) which log over 10,000 downloads over a period of 6 months and demonstrated improved knowledge regarding use of prevention strategies for CAP among people with COPD. One of those presentations included an infographic that was downloaded as resource over 3,000 times. We believe that this dissemination was successful and reached the greatest number of primary care clinicians of the above strategies.

Patient and Caregiver Dissemination in COPD-Current State

PCORI has shifted the paradigm of patient and caregiver's roles in the research process, including in planning for dissemination. They have also advanced efforts to share research results with lay populations, however significant effort is still required to make dissemination direct to patients and caregivers a part of the normal thought process of research teams rather than an afterthought if at all.

The majority of COPD related research dissemination to patients and caregivers is filtered through healthcare professionals or patient advocacy organizations. Increasingly, more patients and caregivers also turn to online sources, however this varies greatly and presents large trust issues with the information communicated to patients. Unfortunately, for the most part, the mainstream media coverage of COPD studies, drug and device approvals is severely lacking, so while patients and caregivers often hear summaries of new studies in the news, COPD rarely rises to the radar for this type of coverage.

Given the challenges faced in delivering evidence based care for COPD, direct dissemination of COPD related research results can both empower patients and caregivers to be a source of dissemination to primary care, and educate them on the types of strategies that they themselves may be able to implement in their own lives where appropriate.

The CONNECT team conducted three test dissemination examples via webinar to an audience of patient and caregivers, as well as a few respiratory therapists, to inform the answers below and the development of the tools found on the CONNECT webpage.

Patient and Caregivers-Tips for Making the Right COPD Info Available

CHALLENGES REACHING THE AUDIENCE	• The COPD population in the US is large, spread out, with more in rural areas, trends older and lower income and COPD can be debilitating especially in the severe state, so traditional direct to consumer communication techniques may not reach them or those non-digital techniques that will, are prohibitively expensive • Patient advocacy organizations can be effective, but only reach a small fragment of the population who has already demonstrated a propensity towards digital engagement and information seeking
TIPS FOR OVERCOMING THE CHALLENGES REACHING THE AUDIENCE	• Identify groups that serve as trusted community organizations such as senior service agencies, rural services and faith-based community leaders. Learn about how your evidence relates to other existing priorities for the organizations and those they serve to customize your outreach and messaging • Learn about patient advocacy organizations that have networks of community advocates who can extend their reach "on the ground" with easy to communicate messages about your research results • Identify a consistent point of contact within the healthcare system to serve as a trusted educator to patients and caregivers and provide that person with easy to use communication messages and tools when new research is produced
BROAD BASE DISSEMINATION TACTICS	• Publish graphic summaries with each scientific paper that can be disseminated via social media and other digital engagement • Send lay summaries to the national and regional patient advocacy organizations listed in the dissemination capabilities directory with specific requests regarding what channels they disseminate info to. Ensure articles highlight what you found, how patients should evaluate if the information is relevant to them, what actions patients and caregivers can take as a result of the info ect • Provide patients and caregivers with a list of reliable information sources that has been vetted by a trusted medical professional
OTHER TARGETED DISSEMINATION TACTICS	• Identify information relevant to specific subgroups of patients and caregivers and send targeted graphics and messages to groups who serve these communities (ex. Medical device companies can reach patients on oxygen and would be more likely to disseminate information that leads with results specific to a device related intervention) • Provide free, easy to use communication tools with actionable information to hospital discharge coordinators or transitional care program staff who can communicate directly with patients and caregivers

Our initial dissemination of the CAP results to members of the COPD community was a short summary of the main results in our Patient Powered Research Network (PPRN) newsletter in order to inform participants and other in the PPRN of the results of a study for which they had been recruited and in which several hundred had participated. That presentation also included a link to the article that was published in the medical journal. In addition, our team completed interviews with journalists that wrote lay and health professional summaries for blogs and patient and healthcare professional magazines. However, the presentation that was most liked by our PPRN patient lead governing board was the infographic (xxxxx link). That infographic will be shared with our PPRN and a link included on our website. We are considering how it can be used to generate discussion and interest on the COPDF 360social online site.

Advocacy Organizations Dissemination in COPD-Current State

We have discussed the overwhelming discrepancy in the scope of the efforts dedicated to improving COPD outcomes compared to the disease burden. In addition to resulting in less awareness of COPD, slower research progress and less focus on COPD in policy, the discrepancy also manifests in the shape of limited funding available for patient advocacy organizations in the COPD space.

Even with this limitation, remarkable progress has been made in the last 10-15 years and now, more than ever, the patient advocacy community is growing in reach and in scope related to the planning, conduct and dissemination of research. The two primary national organizations serving patients with

COPD include the COPD Foundation and the American Lung Association, the latter of which also serves a broader lung disease mission. Both organizations have communications infrastructure, outreach programs and research infrastructure that can refine messages and disseminate direct to patients and caregivers. In addition, several regionally focused organizations incorporate COPD into their mission and several patient-led digital efforts exist that facilitate simple patient-to-patient dissemination.

Despite the progress in recent years, the overall reach of the organizations is still limited compared to the numbers of people affected by the disease. Organizations also have limited capacity and these resource limitations must be recognized and addressed by research teams seeking to leverage the organization's established communication channels and credibility with the patient and caregiver audience

Advocacy Organizations-Tips for Making the Right COPD Info Available

CHALLENGES REACHING THE AUDIENCE	• Most advocacy organizations are not dedicated to COPD alone except for a few like the COPD Foundation and smaller patient run digital efforts, making it more challenging to fit within an organization's priorities and bandwidth • Many lung disease related advocacy organizations are regionally focused, adding challenges related to research team bandwidth to manage multiple partner relationships
TIPS FOR OVERCOMING THE CHALLENGES REACHING THE AUDIENCE	• Engage advocacy organizations early in the research or early in the dissemination planning if not already engaged, and compensate appropriately with appropriate expectations for time and turnaround • Do the research to understand an organization's leadership, priorities and opportunities for dissemination before reaching out to them and tailor your requests accordingly • Create content and graphics that organizations can have input on but makes it easier for them to participate, ensure content builds on past communication and survey efforts in similar topics
BROAD BASE DISSEMINATION TACTICS	• Share lay summaries and prepared content with identified organization leaders and scientific advisors • Ask a patient advocacy organization representative who participated in the study advisory group to be the lead author on an article or letter to the advocacy community highlighting the importance of the results and why they must be communicated through to the communities they serve
OTHER TARGETED DISSEMINATION TACTICS	• Identify successful dissemination examples that advocacy organizations have conducted for adult populations in other chronic conditions such as congestive heart disease, arthritis and Alzheimer disease

4. PCORI Framework Element: IMPLEMENTATION: *How can we support adoption? What strategies will lead to widespread implementation?*

Prior sections of the COPD Dissemination and Implementation Framework have explored contextual factors about the COPD population that collectively with the nature of the COPD related research funded by PCORI, make supporting successful adoption of effective interventions particularly challenging. We have attempted to outline challenges that are most relevant to the list of PCORI funded studies that include COPD. Additionally, we have highlighted existing COPD related tools and strategies that can be leveraged by research teams and target implementors to improve their chances of success.

Challenges to implementation of PCOR evidence in COPD

- Topics explored may involve interventions that are considered "ad-on" and not currently covered as reimbursable services (ex. Physical activity coaching, peer coaching)
- Limited populations included (BREATHE-very low income, urban etc.)

- Highly tailored interventions that will be difficult to replicate in different settings (BREATHE and PArTNER both tailored on individual barriers, peer coaching and exercise coaching also varied in some components based on needs)
- Limited infrastructure in place to support adoption of some strategies tested in PCORI funded studies (e.g. Community health workers, telephone coaching programs)
- Unknown costs of the required infrastructure and resources to implement the interventions
- Limited efficacy of interventions in COPD populations from several PCORI funded COPD-related studies demonstrating the complexity of addressing needs of the COPD population.
- Discomfort with changing usual behaviors at both clinical and patient level (e.g. Belief in value/safety of peer coaching)

Tools and resources that may help support implementation of COPD evidence

- COPD Pocket Consultant Guide Mobile Application
- Electronic Medical Record Tools: COPD related order sets, reminders, analytics
- Project ECHO educational and peer health professional support model
- Payer based tools
- Group practice arrangements that support team and collaborative care
- Implementation guides, curriculums for coaching programs
- Visuals, video, slides, e-course for implementors
- Decision guides for patients, healthcare professionals and caregivers
- Business case template statements

5. PCORI Framework Element: EVALUATION: How will the effectiveness of dissemination and implementation strategies be assessed? What data will be used to assess success?

As PCORI notes in their Dissemination and Implementation Framework, there is a lack of resources and focus on evaluating the effectiveness of dissemination and implementation strategies themselves, with more focus being spent on the outcomes of the interventions being implemented. Since the PCORI efforts have made extensive overall suggestions regarding the types of evaluation strategies and types of data collection to consider, our focus incorporates some practical suggestions for COPD related tools that can facilitate such evaluation efforts and on providing some examples.

There are different resources available to support dissemination and implementation evaluation in the COPD community, depending on the topic and type of intervention being implemented, the geographic scope of the efforts and the extent to which the dissemination strategies are broad or targeted in nature.

The following examples may be relevant for COPD evaluation efforts;

- Metrics of audience reach built into digital tools like the COPD Pocket Consultant Guide App (PCG):
  - » If dissemination and implementation efforts utilized tools like the PCG, evaluation strategies can utilize built in metrics that reach beyond the typical audience reach numbers generated from website visitors or advertising reach estimates. Apps require proactive downloads and have vast potential to build in further analytics that track activity after download.

  - » A new version of the PCG App, released in summer of 2019, allows for further collection of user metrics.There are many possibilities for data usage, and the COPD Foundation team is working to refine the tool to make it more useful for the healthcare professionals who utilize it and improve the quality of care for the COPD Community.

- Online and phone focus groups with stakeholders to evaluate how information was received, evaluated and communicated beyond the initial receiver
  - » The COPD Foundation regularly engages patient, caregiver, healthcare professional and research stakeholders in phone and online focus group style conversations and one on one interviews to investigate perspectives that are important to Foundation partners in a neutral setting.

- The use of national level patient reported registries such as the Patient-Powered Research Network to evaluate short- and long-term outcomes related to scaling patient directed, remotely delivered interventions (e.g. If we took PELICAN national, we can leverage the PPRN to understand who is participating, how they consume the content and coaching, short- and long-term patient reported outcomes and process/satisfaction outcomes among others.)
- Consider tools like smart inhaler technology and the metrics made available by the companies for evaluating adherence outcomes in widely implemented interventions or the potential secondary impacts of interventions in patients who may use these devices even when the intervention isn't itself focused on medication adherence (e.g. Propeller health and Kaiser activity coaching potential.)

SECTION 5
WRAP UP - WHAT'S NEXT

The CONNECT team includes representation from the patient, caregiver, research, primary care, respiratory therapy and patient advocacy community. Input was also obtained via a patient, caregiver and healthcare professional prioritization survey, multiple patient and caregiver focus groups, healthcare professional interviews and a series of test presentations and evaluations from COPD Foundation State Captains, community volunteer leaders from across the country. Through this engagement we refined our focus on priority audiences of patients, caregivers, primary care clinicians and advocacy organizations as they are the most overlooked target audience for COPD research dissemination and implementation efforts. They are not the only ones that stand to benefit from more and better dissemination and implementation strategies. Health system executives, payers, policy makers, DME companies and other members of the COPD ecosystem can and should be targets as well.

As the COPD Foundation continues to engage in a 360-degree approach to improving patient outcomes through community, care delivery and research initiatives, expect to see the resources contained on the CONNECT webpage expand to additional audiences. Perhaps most importantly, expect to see more frequent communication of research results coming from the COPD Foundation in the future thanks to the work the CONNECT team has done in creating the templates thus far. We invite you to join us along the way. Do you have suggestions for additional tools, or do you want to identify ways you can communicate your recent research results to the COPD community? Reach out to us at ***info@copdfoundation.org*** and let us know how we can help!

SECTION 6
RESOURCES/APPENDIX

- Prologues
- Engagement Summaries and Survey Results
- Stakeholder Priorities Grid
- Running Overview of PCORI Funded COPD Related Research and Contacts

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Extended Prologues:

Patient Perspective from William Clark:

There is no dispute in saying that COPD has been around for probably as long as humans have existed. It also cannot be disputed that for many years treatment for COPD has seen little in innovation, with even less technology development. Pulmonary specialists were the exception as opposed to the rule. Primary physicians were often lax to diagnose and when diagnosed provided the bulk of treatment and education for the patient. Research was largely scarce as was funding for targeted research directed towards patient consensus as to their perceived needs. What COPD patients saw was little reason for hope; which was something they craved more than the alternatives they were presented.

This was what I found when I was diagnosed with a genetic form of COPD called Alpha-1 almost 18 years ago. At the time, I was informed by the doctor that little could be done other than to treat some of the symptoms and that most likely I would have a life expectancy of 7 years…if I was lucky. Following my instincts as a teacher I responded the only way I knew how; research everything I could find. In my quest back then I found that COPD was a disease hidden from the public through mechanisms such as shame and blame and most significantly, a lack of hope on a part of the patient that the eventual outcomes were “set in stone” and as such the patient and their caregivers felt powerless.

This was the past; however recently with the ascendancy of the internet, I discovered a new and exciting trend occurring. Patients are no longer “suffering in silence” and are using the vast available online information to become better educated as to COPD and as a result for the first time are experiencing hope for their future. The formation of patient social forums such as COPD360 Social have provided a loud and clear patient voice and perspective along an increased urgency directed towards new treatments and an eventual cure. Pulmonary specialists have now become the predominant suppliers of COPD healthcare. The research community has found a new impetus to pursue patient directed research in addressing relevant gaps in treatment with a vision towards a cure.

What has not occurred is noticeably improved outcome for patients. Patients, through necessity, have had to become their own advocates, research their own treatment options and then try to express their concerns to their doctor. The doctors unaware of new research and treatments are often reticent to initiate more innovative treatment. Many patients are not capable of accomplishing the amount of research needed which in effect restricts their treatment to the sole discretion of their doctor. While the concept of patient support networks with all medical specialties represented has been a positive step (Mayo Clinic for example has been doing this for several years), treatment has been driven by the team and not by the patient; neglecting valuable input and patient experience along with the lack of information of new developments that could drastically improve their patients’ outcomes.

It has long been said that “knowledge is power”, but unless all parties in a support network are aware of current research and disseminate the information to the entire team; and then work as a team to address the implications of such research, little will change. John Walsh, the founder of the COPD

Foundation envisioned a time when patient voice would be the primary driver of how COPD would be researched, treated and ultimately cured. The patient voice is educated as to current and ongoing research and its relevancy their contribution will be diminished and as a result decreases the ability of their support network to succeed. Patients and caregivers are quickly becoming the drivers of their treatment, and as such they require extensive and complete knowledge of all relevant research and treatment options.

There is little question that research will lead to new treatments and cures, but unless a mechanism is developed that adequately and efficiently delivers the results to the treatment team, and especially the patient, the benefits of the research will never be completely perceived. Connect looks to develop that result by developing an intuitive and functional mechanism that informs relevant parties regarding current research and its' implications to the benefit of the patients the research addresses.

As a patient, it is my sincere hope that dissemination of targeted research will result in the implementation of that research consistent with the reason it was conducted; improved patient benefit and quality of life. Patient health outcomes and quality of life will be improved, and while not specifically measurable, their outlook as to their future and their desire that someday others will no longer experience a life with COPD.

Caregiver Perspective from Elizabeth Berger:

As my mother was diagnosed with emphysema when I was very young, I have witnessed the debilitating impact of COPD on one's everyday life. Throughout my youth, I watched her struggle simultaneously with her physical health and the mental challenge of quitting smoking. She eventually quit 'for good' after many years, leveraging assistance from support groups and nicotine replacement therapy. I remember her talking about how hard it was to quit because "cigarettes are so widely available. You can get them anywhere, and you constantly see [people smoking] them out in the open." She also faced numerous co-morbidities, such as arthritis, chronic back pain, depression/anxiety, and recurring instances of pleurisy, all of which impacted *and* were impacted by her COPD. My mother's case was further complicated as she had a lung collapse during a bad pneumonia infection when she was just seven years old; meaning that she only had one lung for most of her life. I was always so proud of her for being resilient and determined despite her compromised and debilitating health, and her story highlights how crucial these qualities are for living well with COPD.

Shortness of breath, the classic symptom of COPD, can make even the most basic tasks very difficult. This was the case for my mother, who eventually was physically unable to perform many of her previously pursued activities. This not only isolated her from the world, but also reduced her stamina to fight back against infections and exacerbations of COPD. As such, her health was consistently declining, and she was constantly forced to adapt to new physical and emotional challenges throughout the course of her COPD. It was hard for her to adjust to the lack of independence she associated with her need for constant reliance on family members, both financially and physically. This was especially complicated as she often felt burdened by guilt and stigma associated with the disease. In the earlier years, my mother could still take precautions and have a decent quality of life. Over time though, her cough worsened, her skin became more wrinkled, and she gradually walked shorter distances. At first I was in denial of many of these changes, but eventually it became clear that she was slowly dying—so much that my parents updated their wills, knowing that 'we would be lucky' if she would be able to attend my high school graduation. Her exacerbations became more frequent, and it became harder for her to go places as she would get winded easily. This eventually progressed to the point where she had difficulties simply getting around the house and was unable to perform everyday tasks (e.g. laundry, dishes, going upstairs) without great effort. During the course of her respiratory illness, she became much more sensitive to strong scents and minor germs of any kind, which discouraged her from 'getting out' more often.

Two severe exacerbations in the years 2005 and 2009 landed her in the Intensive Care Unit (ICU) and would serve as major negative turning points in her illness. The latter was due in part to a medical screening mistake in which the doctor failed to test for swine flu and misdiagnosed bronchitis instead. She was sent home with antibiotics yet continued to get worse, to the point where she nearly stopped breathing entirely. My mother did not regularly use oxygen, but my father rushed her to the hospital where she was immediately admitted and hooked up to machines. I remember the fear we felt for days on end, wondering whether she would live to make it home. Thankfully, she did make it home, albeit in pretty rough shape. I was shocked at the transition from hospital to home, as she had virtually no discharge instructions other than to follow up with her primary care provider. Thankfully the $12,000+ bill was covered by insurance, though this experience still serves as a great example of how expensive and life-changing just one exacerbation can be. My mother slowly recovered, but never restored to her pre-exacerbation baseline. At the time, we didn't realize how badly each exacerbation would set her back in terms of her COPD, though we soon became aware that her symptoms and quality of life worsened long-term as a result of each one.

Despite living with chronic pain, my mother was always so positive. When you would ask her how she was doing, her response would something akin to "Doing okay—just plugging along!" If she verbalized anything remotely negative, it was an indicator that it was a *really* bad day. I know this was due in part to her feeling 'guilty' about her illness and being overwhelmed by the stigma, so she often would hide how she was feeling to avoid negative and hurtful comments. It made me so sad that she was struggling so much more than she would ever let anyone see. One of the most common things I heard from folks after she died was, "I didn't know she was *so* sick." This is just another example of how COPD is an 'invisible illness'-- there is a huge lack of awareness regarding how incapacitating it can truly be, barring some individuals from even leaving their homes. This is especially complicated when the stigma is so great that the patient doesn't feel comfortable verbalizing how they are feeling.

Like many other patients, my mother managed her COPD as best as she could with a primary care doctor, even though primary care doctors are not as well-informed about treating COPD (largely because they are not specialists and it is not included as part of their standard medical curriculum). For example, the benefits from using non-pharmacological therapies (e.g. the use of pulmonary rehabilitation in improving exercise tolerance and reducing frequency of hospitalizations) are substantial yet rarely are proactively conveyed to patients, as was the case with my mother. Similarly, there are times when primary care doctors rely on the generic 'one-size-fits-all' method of COPD treatment while failing to determine whether the benefits of different treatments truly outweigh the cons. For example, under the direction of her primary care doctor, my mother used oral steroid medications for COPD management so frequently that they caused devastating long-term effects (e.g. thinning of the skin, increased prevalence and difficulty healing from cuts/bruises, hair loss, dental issues, severe bloating which decreased her ability to exercise, and appetite loss, which caused its own set of issues).

Primary care was one of my mother's only outlets to treat her COPD, as accessing a pulmonologist was challenging due to the large disparity between patients and providers, particularly in the rural area. This routine went on for many years before she was referred to a pulmonologist, whom she saw a mere two or three times during the course of her illness, at which point she was already considered 'severe.' At this time, he educated my family on the proper use of oral steroids, advising my mother to take them intermittently *when needed*, but that she would receive *no significant additional benefits* from taking them more than five days at a time. This was contrary to information received from the primary care doctor that she had relied on in the past. In addition to the overwhelming side effects, at this time my mother was faced with the additional challenge of the withdrawal from the medication, which took about 4-6 months. In sum, this was one of the many things regarding COPD treatment that we wish we would have known sooner.

Part of the challenge in seeing the pulmonologist was that he was not local; rather, he traveled around to serve a larger area due to the disparity between patients and providers. As such, he was extremely booked and appointment availability was few and far between. In addition to his stiff and cold demeanor, he was restricted by insurance constraints and patient volume, and thus was largely unable to spend quality time with his patients – let alone get to know them and learn about their personal experiences with COPD. While seeing the pulmonologist was somewhat helpful, my mother's care remained suboptimal due to pulmonologist's heavy workload, which significantly reduced his ability to develop a trusting relationship with my mother and individualize her treatment plan. This is a challenge that many COPD patients face, and highlights a prudent need to improve individualized care as well as coordination of care between primary care doctors, COPD specialists, hospital providers, and caregivers, so that there is better communication overall, serving as a multi-faceted way to better tailor treatment plans to each patient.

In its current state, the knowledge of treatment is difficult because primary care physicians are not specialists and COPD is such a broad classification. This reality is even more complicated for patients with co-morbidities, as treatment of multiple conditions requires a delicate balance of varying therapeutic options. Because treatment of one issue can exacerbate another, it doesn't take long before the patient is on several medications from different doctors who don't communicate with each other. This lack of coordinated care increases the chance for something to slip through the cracks (e.g. when my mother was treated with oral steroids for longer than clinically appropriate), which can decrease patient access to evidence-based care. Additionally, typical patients do not have the background or capacity to understand their diagnosis or treatment in the same depth that healthcare professionals do, so it is critical that doctors communicate across the care continuum in order to convey details about pertinent medical information that the patient may not fully understand. In a similar vein, lack of multi-disciplinary care also increases burden on patients and caregivers to be sure they accurately understand the recommendations made by various doctors. Relative to the impact of COPD in the U.S. and the world, very little is known about how to treat the disease, particularly in terms of individualized care.

The common approach to COPD treatment is often the 'one-size-fits-all' method that my mother experienced, where the primary focus is on symptom alleviation with little focus on preserving lung function and actually living better with COPD. While the research on how to treat COPD is underdeveloped, there are *some* promising treatments that are vastly underutilized due to a lack of dissemination and implementation of such efforts. For example, pulmonary rehabilitation has been proven to improve exercise tolerance stamina, yet is sparsely implemented, not always covered by insurance, and thus can be difficult to access particularly for individuals residing in rural areas.

As a caregiver, I did my best to make my mother's life easier. I learned to prepare and administer nebulizers, assisted with pharmacy/grocery trips and other chores, prepared meals, and most importantly provided emotional support and encouragement. My mother did live to see me graduate high school and college, as well as the beginning of my research career. At this time I dedicated a portion of my life to learning about COPD—both in terms of how to increase quality of life for my mother, as well as personal perusing of the literature regarding different treatments and accessibility to patients. I was always finding articles and sending them to my family members, and I would often do research upon request for whatever she needed (e.g. 'how to minimize hair loss and stimulate new growth when thinning from steroid use'). While I knew there was no cure for COPD, I was convinced that it was possible to improve her quality of life and I was determined to do everything in my power to make that happen.

The more I learned, the more disappointed I became. I learned that pulmonary rehabilitation is a very promising practice, but that my mother would likely never able to access it—the closest center was over an hour away, which was out of the question because my mother couldn't drive. They also did not have regular openings, and the treatment was not fully covered by insurance. My parents were paying so much money for maintenance medications and insurance premiums, meaning that finances were another barrier to accessing evidence-based care. It bothered me so much knowing that she was never able to access the care she so desperately needed. Unfortunately, this is a very common experience, particularly for patients residing in rural areas. Related to access issues, insurance barriers presented additional challenges for her obtaining inhaler refills when she needed them, and she was often forced to spend the money out-of-pocket as she was physically unable to go without medication for days.

About twenty years after being diagnosed, my mother passed away at the young age of 60 as a result of her emphysema. Her death was sudden and began with her just 'not having a good day'. We always thought we would have more 'warning,' but that simply was not the case. When her breathing started to plummet, my father made an oxygen tank from supplies in the garage and proceeded to call the doctor. The doctor insisted she'd have to go to the hospital, but my father knew she wouldn't survive the drive. Knowing what was going to unfold, the doctor got in touch with hospice and arranged delivery of a real oxygen tank. It was around this time that my father called to inform me of the news, giving me a timeline of three to seven days. I rushed home to find my mother lying in her chair nearly lifeless, her chest rising up and down violently, as she breathed heavily through pursed lips and above the sound of the oxygen tank. While she managed to verbalize a weak "hi, honey," the most movement I saw out of her that night was when she would jerk upright every once in awhile to vomit, due to nausea caused by the pain medication.

The whole situation didn't feel real, but it was clear that time was passing because snow was accumulating hour by hour. My family and I worked together around the clock to keep my mother as comfortable as possible—administering medication, giving her ice water through straws, continuously placing cool cloths on her forehead to balance the heat generated by her discomfort and inability to breathe, and providing words of comfort. Keeping her comfortable became very challenging as she lost her ability to verbalize. We shifted to communication through a series of hand squeezes and yes/no questions, and also took to watching her movements and breathing to deduce whether she seemed to be in pain. At night, my siblings and I occupied the living room floor while my father took the couch. Sleep came intermittently throughout the duration of the agonizing 105 hours. After the fourth sleep, I woke up suddenly around 3:00 AM and immediately realized that my mother's chest was no long violently moving. I woke up my father, who whispered, "is it time for more medication?" to which I replied, "I don't think she's going to need any more medication." Knowing my mother was ready to make her departure, my family and I gathered around her chair, placed her favorite rosary in her hands, and prayed as her faint heartbeat slowly faded away. Finally, we removed the oxygen tank from her nose. After the experience, one of the most shocking things about it all was how quickly she faded in just four days. It was almost as if her COPD just jumped off a cliff, taking her with it.

Unfortunately, while my mother's story is devastating, it is not all that uncommon. Throughout the course of her COPD, her treatment was consistently suboptimal as she was not able to receive evidence-based care due to various challenges noted above. This burden is especially great for people residing in rural areas as they are further away from resources. Regardless of geography, though, there is also a lack of awareness about which treatments work best for whom. Not all COPD is the same, and we need more research to better understand how to individualize care and enhance effectiveness of current treatments. For example, different types of COPD may respond differently to treatments, and there is some variety how symptoms affect one's everyday life, as well as how symptoms progress over time. If one manages another health condition in addition to COPD, this can also affect the effectiveness of care management as well as the negative effects of different treatments.

Further, there is a lack of awareness about effective implementation and dissemination of evidence-based treatments (e.g. pulmonary rehab), such that treatments are sparsely located and not well-known or publicized. A low ratio of treatment centers to patients coupled with inadequate insurance coverage presents additional challenges to accessing care. Thus, like my mother, patients often manage their COPD via primary care doctors with limited specialties and expertise to treat COPD. While this helps with symptom management and is certainly better than no care at all, patients require better tools and education to preserve lung function and reduce progression of the disease.

Improved implementation of evidence-based programs and dissemination of information would have mattered in the quest to improve the health and quality of life for my mother. Like many COPD patients and their caregivers, my family and I were largely unaware of what steps we could take to improve my mother's quality of life. Evidence-based research is not well-translated or disseminated outside of the academic community, creating a large information gap between researchers, the medical community, and by extension, patients and families. As implementation of evidence-based programs remains inconsistent, patients and caregivers are not regularly provided with adequate resources to learn about the disease. Thus, for the longest time my family was uneducated on topics such as: proper use of oral steroids, pulmonary rehabilitation and other evidence-based therapies, triggers to avoid, early signs of an exacerbation, proper inhaler technique, and others. My mother would instead turn to peers and other organizations such as the COPD Foundation and the Pulmonary Wellness Institute to gain information about how to manage her disease. These connections were valuable to her and she trusted the information coming from a specific and reputable network. Ideally, this type of information should be more readily accessible at doctors' offices, hospitals, senior citizen communities, and other public forums. This information should also be informed by the input of various stakeholders and should be screened for accuracy before wide dissemination.

Dissemination and implementation of new and existing research results is a critical step toward increasing patient accessibility to evidence-based treatments, as effective dissemination and implementation the patient-level ensures that information is reaching the intended audience. As such, investigators should consider disseminating directly to patients and other nonclinical stakeholders such as community health leaders, foundations, and caregivers. This step is critical to promote education and awareness of COPD-related topics, in hopes of improving patient access to evidence-based practices.

Dissemination efforts can also be used to foster excitement for new and/or developing treatments among patients.

Overall, an increased awareness of promising treatments and their effectiveness in the patient and provider community will generate increased interest (i.e. demand) for evidence-based practice and encourage broader implementation in clinical settings (i.e. supply). The proposed framework will lay the groundwork of how to improve dissemination and translation of research findings, as well as where and how to focus implementation efforts to reach the target audiences and yield the greatest benefit for patients' quality of life. This project directly supports the mission of the COPD Foundation to improve the lives of patients with COPD through research and education, with its goal of implementing evidence-based programs consistently across clinical settings and thereby increasing access to such treatments, improving patient quality of life.

Introduction

The CONNECT Project leveraged multiple methods of engaging stakeholders to inform the creation of a COPD specific Dissemination and Implementation Framework, modeled after the PCORI Dissemination and Implementation Framework, example tools for dissemination and a repository of organizations that can aid in the dissemination of COPD-related research results. The following provides a summary of survey results and key takeaways from these engagement activities.

Methodology

CONNECT Survey

To inform the creation of the COPD Dissemination Framework, the CONNECT team developed an online ranking exercise for patients, caregivers and healthcare professionals. The team recognized the need to capture background on the respondent's COPD diagnosis, comorbidities and other demographics that would potentially inform how they ranked the topics in each ranking exercise. A total of 18 questions were selected to help us understand the disease severity and comorbidities as well as the socio-economic, education, and age of the respondents. Questions also provided insight into how recently they had received their COPD diagnosis, frequency of exacerbations, and whether the cost of care or medications was keeping them from maximally medically managing their illness.

The first two ranking exercises assessed perspectives on the strength of available information and the priorities for new information about broad topics relevant to COPD prevention, diagnosis, treatment and management. The final ranking exercise provided a list of sub-topics within each broad topic and respondents were asked to rank the importance of receiving more information of each sub-topic to get a better sense of individual considerations in a broad area that may be most important.

The survey development was informed by the full CONNECT team representing patients, caregivers, researchers, primary care, respiratory therapy and advocacy organizations. Additionally, the list of questions and the topics for the ranking exercises were vetted and refined in collaboration with the COPD Patient-Powered Research Network's Advocacy Organization Advisory Board members and patients from the Governing Board. Stakeholders were provided the full list of questions and topics under consideration and a conference call was held to review the purpose of the survey effort and obtain feedback. Additional testing and feedback were submitted via email. The feedback was most useful in refining the topic and sub-topic list as we were able to clarify potential confusion about the topics and group the sub-topics appropriately. We also used the feedback to refine the list of 18 questions to include, though many more questions were suggested by the group, indicating a wide-ranging interest in learning more about the backgrounds and conditions of people with COPD.

The survey was programmed on SurveyMonkey with logic to ensure patients, caregivers and healthcare professionals received the appropriate questions where there were differences. The survey was disseminated primarily through the COPD Foundation's digital channels, COPD360social, Facebook and Electronic Newsletters. In addition, stakeholder partners were provided template language and unique links to disseminate within their own communities.

Focus Groups and Interviews

There were two in-person focus group discussions, one phone focus group and several one-on-one interviews with stakeholders to further inform our understanding of priorities and dissemination barriers. General discussion guides were developed to guide the conversations and in the phone focus group, the draft Framework Report was used as an outline for gaining feedback on gaps or statements about patient priorities in the draft content. The CONNECT team identified key gaps in our knowledge that would be necessary for making practical dissemination recommendations and as such, much of the focus group time and interviews were spent exploring how they sought out information, what information they trusted most, how they assessed whether or not information was relevant to their lives and the types of information they prioritized over others.

One in-person group discussion was a hospital-based support group in Nashville, TN and the other was a Harmonicas for Health group convened by the county health department in Ithaca, New York. These groups were chosen because they had group members who were relatively comfortable sharing their input, and because most of the group members are living with COPD or are caregivers for someone with COPD. It was also noted that the group in Nashville is a group from an urban area while the group in Ithaca represented a more rural community. These groups were also available during the time frame of this portion of the project for coordination of information. Additional interviews were conducted with stakeholders from a rural hospital in Ithaca, a nurse case manager responsible for managing a team of outpatient nurses in a large multi-group practice arrangement, the sole pulmonologist in Ithaca and others from the public health department. Structured, written feedback was also obtained from a primary care, pulmonology, durable medical equipment and insurer representative. The phone focus group included the patient members of the COPD PPRN's Governing Board who agreed to participate as CONNECT advisors.

It should be noted that all three focus groups were made up of individuals who are proactive in seeking care and information about their illness. These participants also had the benefit of either participating in a pulmonary rehab prior to joining the support group, or had the ability to join a Harmonicas for Health class like the group in Ithaca. With that said, they were able to reflect on the differences that the additional engagement with medical professionals and peers had made in their COPD journey.

The strengths of the Nashville group were that they were well informed about COPD, and all in the group were being treated by a pulmonologist which gave them an advantage in the area of COPD management. The Ithaca group also had strengths. They were driven to find reliable sources of information, and most of them were under the care of the only pulmonologist in the area, though they did note that her availability was limited. Each of the groups had weaknesses as well. The sample size of the Nashville group was small (five in attendance) so the breadth of their experiences shared may be limited. With a larger group, the findings may have been more representative of disease severity and experiences. The Ithaca group was limited in their ability to discuss questions around programs such as pulmonary rehab or other types of interventions associated with PR because there is not one available in that region.

Test Case Evaluations

Following the completion of the draft Framework, we conducted a series of three-monthly test research results presentations, followed by a formal evaluation for those who were willing to complete it. The presentations were made via live webinar and a recording was offered to participants unable to attend live. The research was selected to represent different research methods and different phases of research. The evaluations were structured to inform the draft Framework, particularly the third element of the PCORI Framework on dissemination itself. Participants were asked to provide feedback on how useful and how understandable the presentation was. They were also asked to provide comments on what could have been better. Additionally, participants shared information about their intentions to share the research they just learned about, with whom they would consider sharing research with, their preferred methods for sharing, tools that would be most helpful and past experiences sharing research results with others.

Results

Survey Results

Sample Characteristics

We received 418 useable surveys completed primarily by patients reporting they had been diagnosed with COPD, with fewer responses from health care professionals and a very few responses from caregivers.

Table 1. Respondent designations		
Of 418 respondents:	Count	Percent
Patients	293	70.1%
Caregivers	11	2.6%
Health Care Professionals	114	27.8%

Patient Sample Characteristics

While we obtained a total of 293 responses from patients, there was some attrition throughout the course of the survey contributing to partial item non-response. Averages are based on valid responses only, while percentages are computed accordingly based on the number of people responding to each particular item. There were no major differences in observed patient characteristics when comparing the aggregate patient sample (see Table 2 below) with the sub-samples completing Exercise 1 and 2.

The average age of the patients was 62.7 years (SD=9.2, n=174) with 83.4% (n=146) of the patients women and 16.6% (n=29) men. Most (73.7%) had been diagnosed with COPD 4 or more years ago with almost one-third having been diagnosed more than 10 years ago. The severity of disease reflected the duration of the diagnosis with only slightly more than one quarter of patients reporting mild or moderate COPD. Of the patients answering the detailed demographic questions, most had seen a pulmonologist for their COPD (91.2%, n=198) and many more than the average population of people with COPD (51.6%, n=112) had completed pulmonary rehabilitation. Oxygen was reported to be used by 66.8% of responding patients (n=145) and most (67.3%, n=146) had experienced one or more exacerbations in the past year. Overall, this was not a group of individuals with a very recent COPD diagnosis.

In summary, the patient respondents are an experienced group of COPD patients with significant duration of disease and severe to very severe diseases.

Table 2 Patient Sample Characteristics	N (%)
Age	174 (100%)
45 and younger	48 (18.8%
46-55	51 (20.0%)
56-65	81 (31.8%)
66-75	68 (26.7%)
76 and older	7 (2.7%)

Gender	175 (100.0%)
Women	146 (83.4%)
Men	29 (16.6%)
Education level	177 (100.0%)
Some high school	8 (4.5%)
High school graduate	51 (28.8%)
Some college	67 (37.9%)
College graduate	43 (24.3%)
Years since diagnosis	290 (100.0%)
Within the last year	30 (10.3%)
1-3 years ago	46 (15.9%)
4-5 years ago	47 (16.2%)
5-10 years ago	75 (25.9%)
Over 10 years ago	92 (31.7%)
Disease severity	279 (100.0%)
Mild to Moderate	75 (26.88%)
Severe	119 (42.7%)
Very Severe	76 (27.2%)
Don't Know/Unsure	8 (2.9%)
Seen pulmonologist	
Yes	198 (91.2%)
Use oxygen	
Yes	145 (66.8%)
Participated in pulmonary rehabilitation	
Yes	112 (51.6%)

Healthcare Professional Sample Characteristics

Of the health care professionals (n=113), most (70.8%) were respiratory therapists and therefore do not represent the full spectrum of those caring for and managing the care of people with COPD.

Table 3. Healthcare Professional Type (N=113)	HCP Count	HCP Percent
Other Nurse Type (RN=2, Pulmonary Reg. Nurse=1, Condition Management Nurse=1, BScn RN CRE=1)	5	4.4%
Student (Med student, RT student, etc.)	5	4.4%
Nurse case manager	6	5.3%
Nurse practitioner	4	3.5%
Other (see list)	8	7.08%
Physician	5	4.4%
Respiratory therapist	80	70.8%

Results of Ranking Exercises

All survey respondents completed ranking exercises representing the subjective importance of different concerns related to COPD as well as their opinions on how much information is available for them for each of the listed concerns. Due to partial non-response caused by respondent attrition throughout the survey, respondent counts vary across ranking exercises. Researchers looked at the demographics individually for the full sample (excluding missing) as well as the samples for each ranking exercise. There were no major differences in aggregate sample characteristics when comparing the demographics across the three samples.

Importance of COPD-related Concerns Ranking Exercise

Individuals were asked to rank from most important to least important, a list of common concerns related to COPD. Specifically, respondents were asked which topics they would like to have more information on in order to guide their decision-making. The lower the number, the more important the item was considered.

Patient Rankings

Overall, patients thought the most important issues were pharmacotherapy and clinical management followed by oxygen, COPD diagnostic methods, and pulmonary rehabilitation. In fact, all of the first 6 items dealt with COPD management. Palliative and end of life care was considered least important of the items available for ranking. A total of 217 patients completed this ranking exercise.

Table 4. Patients' Rankings from Most to Least Important (N=217)		Average Rank	SD
1	Choosing the Right Medications	3.5	2.5
2	Clinical Management of COPD	4.6	2.6
3	Oxygen	5.4	2.3
4	How COPD is Diagnosed	5.4	3.4
5	Pulmonary Rehabilitation	5.6	2.7
6	Vaccine Recommendations	6.3	2.5
7	Self-Education About COPD	6.5	3.7
8	How Technology Can Help COPD	6.9	3.4
9	Comorbidities	6.9	2.4
10	Smoking Cessation	7.0	3.4
11	Palliative and End of Life Care	7.9	3.0

The rankings varied little based on patient characteristics including patient's age, whether they lived in an urban, suburban or rural setting, highest educational level attained, whether they were a current or former smoker, and number of comorbid conditions. Not surprisingly, those with very severe disease which are the group most likely to require oxygen therapy ranked oxygen issues as more important than those with moderate to severe disease (See Table 5).

Table 5. Patient Rankings by Disease Severity

Note: lower numbers indicative of higher importance

	Mild to Moderate (N=61)			**Severe (N=89)**			**Very Severe (N=61)**		
Category ***(sorted in order of total ranking; most to least important)***	**Ranking**	**Mean**	**SD**	**Ranking**	**Mean**	**SD**	**Ranking**	**Mean**	**SD**
Choosing the Right Medications	1	3.5	2.6	1	3.5	2.5	1	3.5	2.4
Clinical Management of COPD	2	4.2	2.5	2	4.7	2.7	3	4.8	2.6
Oxygen	5	5.9	2.3	4	5.5	2.5	2	4.7	2.0
How COPD is Diagnosed	3	4.8	3.2	3	5.3	3.2	6	6.5	3.6
Pulmonary Rehabilitation	4	5.5	2.4	5	5.6	2.5	4	5.6	2.5
Vaccine Recommendations	6	6.4	2.7	7	6.2	2.6	5	6.3	2.4
Self-Education About COPD	9	6.8	3.9	6	6.1	3.6	8	6.7	3.7
How Technology Can Help COPD	8	6.7	3.4	9	7.0	3.3	10	6.9	3.4
Comorbidities	7	6.7	2.4	10	7.2	2.4	9	6.8	2.6
Smoking Cessation	10	7.1	3.3	8	6.7	3.5	11	7.7	3.5
Palliative and End of Life Care	11	8.5	2.6	11	8.2	2.6	7	6.5	3.5

Healthcare Professional Rankings

Healthcare professionals, represented primarily by respiratory therapists, had very similar rankings for those topics ranked as most important, issues of clinical management. The rankings were very similar to those of the patients. A total of 95 healthcare professionals completed this ranking exercise.

Table 6. Healthcare Professionals' Rankings from Most to Least Important (N=95)		**Average Rank**	**SD**
1	Choosing the Right Medications	3.9	2.7
2	Clinical Management of COPD	4.4	2.7
3	Pulmonary Rehabilitation	5.5	2.7
4	How COPD is Diagnosed	5.7	3.9
5	Smoking Cessation	5.8	3.0
6	Self-Education about COPD	5.8	3.7
7	Oxygen	6.6	2.3

8	Palliative and End of Life Care	6.8	3.1
9	Comorbidities	7.1	2.5
10	How can Technology Help COPD/Vaccine Recommendations	7.2	3.2,2.6

Overall, patients and the responding health care professionals reported issues of COPD management and diagnosis were most important to them with less emphasis comorbidities, technology, and end of life care.

Availability of Existing Information Ranking Exercise

Individuals were asked to rank from of 1-4 (1 represents the least amount of information available while 4 represents the most amount of information available), the amount of information they felt was available for each of the topics discussed above. This question was used to gauge respondents' knowledge of availability of different evidence. Thus, it stands to reason that lower rankings would correlate to topics that stakeholders need more information on, therefore highlighting key areas of focus for dissemination efforts.

Patient Rankings

A total of 258 patients ranked how much information they felt was available for each topic area. Results showed that patients felt that the least amount of information was available for palliative and end of life care, followed by use of technology, choosing the right medications, and clinical management, all of which had similar averages rankings ranging from 2.4 to 2.5 out of 4. Smoking cessation was undeniably the highest ranked category among patients, revealing that they felt information was most available in this area. The difference between smoking cessation and its preceding ranking (vaccine recommendations) represents the largest average increase between adjacent categories (a difference of 0.09 out of 4). Comorbidities, oxygen, diagnosis, pulmonary rehabilitation, self-education about COPD, and vaccine recommendations were also ranked similarly, with average rankings ranging from 2.52 and 2.62, revealing that patients felt a moderate amount of information was available for these topics.

However, this sample was comprised of less than 12% of current smokers, with the majority of patients being former smokers. This may have affected results, particularly those regarding smoking cessation, as these patients may have access to different resources than current smokers. Interestingly, this inference is supported when comparing the average ranking of the 'smoking cessation' category between current and former smokers (with average rankings of 2.65 and 2.71, respectively, or a difference of .06 out of 4). However, these findings may not be generalizable and should be interpreted with caution due to large differences in sample size between groups (33 current smokers compared to 205 former smokers).

Table 7. Patients' Rankings from Least to Most Information (N=258)		Average Rank
1	Palliative and End of Life Care	2.40
2	How can Technology Help COPD	2.42
3	Choosing the Right Medications	2.42
4	Clinical Management	2.49
5	Comorbidities	2.52
6	Oxygen	2.53

7	COPD Diagnosis	2.54
8	Pulmonary Rehabilitation	2.56
9	Self-Education About COPD	2.60
10	Vaccine Recommendations	2.62
11	Smoking Cessation	2.71

Healthcare Professional Rankings

A total of 99 healthcare professionals, primarily respiratory therapists, also ranked how much information they felt was available for each topic area. Overall, healthcare professionals felt that the least amount of information was available for self-education about COPD, followed by use of technology, palliative and end of life care, and smoking cessation, all of which received an average ranking between 2.4 and 2.5 out of 4. Oxygen was undeniably the highest ranked category among healthcare professionals, revealing that they felt information was most available in this area. The difference between oxygen and its preceding ranking (vaccine recommendations) represents the largest average increase between adjacent categories (a difference of 0.13 out of 4). Pulmonary rehabilitation, comorbidities, choosing the right medications, clinical management, and vaccine recommendations were also ranked similarly, with average rankings between 2.5 and 2.6, highlighting that healthcare professionals felt there was a moderate amount of information available on these topics. However, this sample included mostly respiratory therapists which may have affected these results, particularly those concerning pulmonary care (e.g. pulmonary rehabilitation, clinical management, oxygen). Respiratory therapists tend to be very experienced in these areas and may have access to different resources than other types of healthcare professionals, which may reflect dissemination needs that are different from the remainder of the population.

Table 8. Healthcare Professionals' Rankings from Least to Most Information (N=99)		**Average Rank**
1	Self-Education About COPD	2.42
2	How can Technology Help COPD	2.43
3	Palliative and End of Life Care	2.43
4	Smoking Cessation	2.49
5	Pulmonary Rehabilitation	2.51
6	Comorbidities	2.56
7	Choosing the Right Medications	2.57
8	Clinical Management	2.59
9	Vaccine Recommendations	2.60
10	Oxygen	2.73

There was some overlap between patients and healthcare professionals regarding how much information they thought was available for each of the listed concerns. For example, both patients and healthcare professionals felt little information was available for use of technology in helping COPD and palliative and end of life care, receiving average rankings ranging from 2.40 and 2.43 across respondent type. Similarly, healthcare professionals and patients were in general agreement regarding the amount of information available on pulmonary rehabilitation and comorbidities, which both received average rankings between 2.51 and 2.56 for both groups. Vaccine recommendations were also similarly ranked between healthcare professionals and patients, with average rankings of 2.60 and 2.62, respectively.

Interestingly there are a few differences worth noting. Patients felt that there was a lot of information available for self-education about COPD, while healthcare professionals largely disagreed (ranking 9 and 1 out of 11, respectively). In contrast, healthcare professionals felt there was a lot of information available on choosing the right medications and clinical management (ranking 7 and 8 out of 11, respectively), while patients ranked these items toward the lower end of the spectrum (ranking 3 and 4 out of 11, respectively). Healthcare professionals tended to believe there was a decent amount of information available regarding oxygen and COPD diagnosis (ranking 10 and 11 out of 11, respectively), while patients felt there was only a moderate amount of information available on these topics (ranking 6 and 7, respectively).

Results from Focus Groups and Interviews

In-Person Focus Groups

Dissemination plans must include decisions on not only what to share but how to share the information. These focus groups were used to help identify the current methods that people living with COPD obtain information as well as their recommendations regarding where and how they would like to receive information.

A focus group was held in upstate New York that included individuals living with COPD. A second group was included who are part of an ongoing program called Harmonicas for Health (H4H). They meet weekly and are all under the care of a pulmonologist. These comments are combined from both groups.

The groups were queried regarding current and desired sources of health related and especially COPD related information, their level of trust in different types of resources, how they receive and contextualize new information or research results regarding COPD treatments and management, perceived gaps in their knowledge and the knowledge of their health care professionals and what they wish they had known.

The attendees stated the most trusted source is from their physicians but do sometimes worry that it may not be the latest information. For those visiting a pulmonologist, they had less concern about the information's validity and timeliness. Stating that the 'best' place to receive information is from their pulmonologist, but that it is difficult to get the information they need in a timely manner. Often the information they need is due to an acute episode or for something new they are experiencing, and it may take weeks or months to see the doctor. They would like to receive more information from their practice site outside of visits and liked health programs led by their practice site. They would like to perhaps even receive online or telephone information from their physicians or clinics if they have signed up for such a program.

In addition to health care professional provided information, the attendees were very interested in learning from others with COPD, especially related to ways to live with COPD and non-medication treatments for COPD. In addition to things like online peer information they thought it would be good to have information in libraries, at community centers and senior centers and housing complexes. These sites needed to have information available in formats other than online since they felt many older adults with COPD might not use or have access to the internet.

Those attendees who used the internet cited some groups such as WebMD, Mayo online information and Medscape as potential resources, but noted that not all the material was presented at a useable or sufficiently detailed level for them to decide to trust or use it. Determining which sites to trust was also of concern. They indicated they were unsure of their ability to separate reliable sources from unreliable ones. In general, sites from insurers and pharmaceutical companies were considered to be of greatest concern regarding trust---did these groups have an agenda related to profits that might not be in the best interests of all patients.

Several noted that all the information given during hospitalizations became overwhelming and might be better given over time in courses such as one held in their community.

Healthcare Professionals Interview Results

Healthcare professionals are also the recipients of COPD related information both as clinical updates on new treatments and new management approaches but also as part of quality improvement initiatives. We completed one on one interviews with a pulmonologist, a respiratory therapist and a primary care health system care management director.

The pulmonologist stated that most of the information she received and used came from medical meetings, although attending them was often difficult to fit into her practice schedule. She did note that email alerts from journals and professional specialty groups helped guide her acquisition of new data. She wondered if pulmonologists might be able to assemble, summarize and contextualize new information regarding COPD for primary care physicians and other clinicians. However, she did note that this could be time consuming.

The respiratory therapist focused primarily on the severe lack of pulmonary rehabilitation programs in the US and therefore the lack of patient and health care professional knowledge regarding pulmonary rehabilitation. She noted that people who start and facilitate support groups need help in identifying new information to share within those groups. She stressed that new research can be shared in a support group setting if facilitators are given the information in the right format for them to understand and share with patients and families.

The care manager discussed how information is used in quality improvement programs noting first that evidence used to develop programs often comes from the physicians' and other health care professionals' current knowledge using sources of new information more for problem solving than for developing programs. Sometimes information from the existing care system is used to identify problems. However, the presence of multiple types of EMR even in moderately small communities can make this very difficult. She also noted that the role of insurers in helping support quality improvement systems and sharing information about successful programs needs to be clarified and stressed.

When disseminating information to health care professionals, several potential tools are available but that information from local resources can be the most trusted. Weekly brief "headlines" may be read but she noted that health professional "fatigue" from the many program that primary care is asked to address is becoming a greater barrier. The most effective communications appear to be simple action-oriented headlines with data, clickable PDFs with easy to forward functions that are easy to save, nurses appear to be most responsive to immediately actionable items.

Phone Focus Group and Written Feedback Results

Key highlights from the phone focus group and written feedback we received are summarized by the overarching question presented to the participants. The questions were created based on the draft Framework document and specific areas where more stakeholder feedback was needed as determined by the CONNECT team.

Question 1: We want to help research teams decide if their COPD research is ready for dissemination and to which group of people their results apply to. If a research team was going to run through a list of questions to help guide them on who their research was applicable to, what would you tell them to ask themselves?

Many patients agreed that researchers should work more actively with patients during the research study as they can help provide context in both who could benefit from the study, important factors to consider when studying the population, and gain their perspectives on the research findings. Patients felt this would improve the relevance of studies to the patient population by improving the design to fit the needs of the population, while also resolving retention problems by increasing incentives for patients to participate in the trial. In addition, allowing patients to comment on findings can help produce discussion about future research questions and where we should go next. Another theme among patients was that researchers could do a better job of looking at individualized factors related to COPD, such as gender, race/ethnicity, work environment, comorbid states, and the like.

DMEs commented that researchers should better consider who stands to benefit the most from the research, and whether that information is being displayed in a format that the intended recipient can understand (i.e. summarized in a brief and meaningful way).

Insurers’ perspectives focused on the long-term goal of the research, commenting that researchers should better consider their desired end result and work backwards to collaborate with the right people and build the right design. For example, should the outcome be improved education, policy changes, or better health outcomes, researchers should strategize based on what they would like to see come as a result of the research.

Question 2: Sometimes there are ingrained beliefs about how things should be done in COPD and even good research showing otherwise doesn’t change their minds. What are some of those ingrained beliefs in COPD? If a research team is better aware of what those ingrained beliefs in COPD are, they will be better able to design their dissemination strategies and messaging to directly confront the incorrect beliefs and hopefully get beyond them.

Patients generally agreed that primary care physicians need more education on COPD, including ‘red flags,’ and moving past the ‘one size fits all’ treatment method. Patients also commented that a consistent ingrained belief is that COPD patients have a specific look to them. In general, science and medicine need to agree on a solid approach to COPD treatment and stick to it. It seems that some of the information out there is confusing to some COPD patients and it makes it harder for them to make informed decisions. For example Medicare plans are targeting and are pushing patients into purchasing plans when the plan may in fact limit drug availability and payment amounts for certain types of therapy.

DMEs and insurers agreed that a common misconception is COPD patients bring this on themselves, and that all COPD patients are non-compliant. Thus, many groups believe there is no point in making changes or putting effort into this cause.

Question 3: We want to help researchers understand what barriers patients and caregivers face in COPD management as it can help them improve the way they think about evidence dissemination and strategies for implementing new knowledge in practice. Please review the following list of barriers patients might have to receiving care. Is this list accurate? Is it complete? What should be added or edited?

According to patients, barriers include late recognition of COPD, as well as the issue that rural areas have more people with COPD yet fewer resources in terms of hospitals, pulmonologists, and pulmonary rehab programs. Distribution of easy to understand information, such as infographics, research summaries, and potentially other patient-resources via a local partner (such as a state respiratory) association was suggested by many of the patients. Similarly, having access to a person knowledgeable of COPD issues is needed outside of physicians' offices and would be highly valuable to patients. Participants noted that the motives of the insurance companies were suspicious and they felt they could not trust information given to them from such sources. With this lack of trust underpinning the additional barriers to care, sources for trusted COPD information is extremely important to the COPD community.

Insurers commented that common barriers include fear, ignorance, and lack of support such as someone to help coordinate picking up prescriptions, setting up home oxygen, arranging transportation for pulmonary rehab, and assistance with household tasks.

Question 4: Have you ever been asked to help a research team plan dissemination of research results? What was the circumstance if so and how did it go? If you were to be asked to participate in this type of activity, what would help you decide to participate? For example: time commitment, type of training provided, compensation etc.

Patients commented that they were frequently and currently involved in research work focusing on reviewing layperson summaries and findings from research studies. The primary reason for patients' involvement in research projects was to assist in making information more understandable and accessible for patients. Patients agreed they would do regardless of the money because they feel it's important and the right thing to do.

DMEs and insurers both said they have not been asked to participate, but that time commitment would be the biggest hurdle in doing so.

Question 5: This table (see page 13 of the COPD Framework) is intended to succinctly capture the types of issues that each stakeholder involved in COPD needs the most help with, i.e. what would they like new evidence to help them with overall. Take a moment and review the following table. From your perspective, have we captured the right types of challenges that the listed stakeholders might report needing help with?

Patients provided some additional thoughts for the table, such as how to afford treatments and medication, how to learn more and keep up to date on the latest treatments, how to know which information and whom to trust for both internet and non-internet resources, how to find effective exercise programs in absence of pulmonary rehab, how to communicate with my family and help them understand the patient experience, and how to accept a COPD diagnosis and move forward. While not all of the suggestions were ultimately incorporated in the table due to a desire to keep it high level, their suggestions were incorporated in other areas such as Section 2 on barriers.

Insurers commented that primary care providers should consider how to quickly align a COPD patient with resources, how to ensure there is good participation on the part of the patient and follow up with specialists or general practitioner, and how to identify the social stressors and align patients with appropriate resources when needed.

Question 6: The table below (see page 20 of the COPD Framework document) begins to capture some of the challenges that research teams currently face in disseminating information directly to patients and caregivers. We would also like to give them some suggestions for how to make the right information available in a limited or broad way. Please review the table and think about additional suggestions we can make to research teams.

Patients frequently commented on the fact that many COPD patients live in rural settings and may not have access to a pulmonologist. Thus, it was common for patients to note that we need to take advantage of trusted groups already doing things in rural areas – such as churches, schools, senior centers, meal sites, public libraries, and even transportation systems. For example, churches that provide meals at night for people who can’t afford them could be used, while some public library systems (such as Hawaii State Public Library System) will disseminate info to all their branches upon request.

In a similar vein, themes from patient focus groups included the need for access to reliable and trustworthy information outside of their physician’s office. Educational materials should be accessible and vetted by someone skilled in communicating with people who are of lower education, may not be health literate, and might be quite suspicious of most companies. The use of pictures and infographics to illustrate data and complex findings was a preferred method of communication among patients to help them easily digest and apply information.

DMES commented that researchers should better ensure they are reaching every caregiver and supplier that touches each patient. Specifically, DMEs elaborated that COPD patients would benefit from more collaborative models that include Palliative and Chronic Care Management.

Insurers suggested channeling information to post discharge coordinators in hospitals for more effective dissemination.

Results from Test Research Presentations

A total of 3 test cases were conducted including results from the NIH funded COPDGene Study, the PCORI funded PELICAN (pre-publication) and PArTNER trials, and the results from the CONNECT priorities survey. Participants were primarily COPD patients, however in each presentation there were also caregivers and respiratory therapists. Each presentation was given by a member of the research teams associated with the studies. Each presentation lasted approximately 30 minutes, though the webinar itself was one hour long and covered additional COPD Foundation related updates.

Usefulness of the information presented: Overall respondents were pleased with the evidence that was presented and overwhelmingly found it useful. The COPDGene presentation included results that were more applicable to our overall understanding of COPD diagnosis and development and how this information might be used to guide new therapeutic development in the future. Despite the presentation not being immediately actionable by patients, participants expressed great interest and appreciation for the information, even indicating that it gave them hope for the future. This showed that even the most basic science research can and should be communicated at a level that patients can understand, even if there isn't an obvious action as a result. Overall 80% and 87% of the respondents found the PELICAN/PArTNER and CONNECT presentations respectively to be useful or very useful. We changed the format of the evaluation to capture more quantitative information following the first COPDGene session.

Throughout the evaluations, respondents indicated a desire for additional graphics and images which they felt helped them digest the information. Additional suggestions included providing a "top takeaway" highlight list when presenting results and finding ways to facilitate questions after the live presentation had been completed.

Intentions to Share Information: Respondents were asked if they intended to share the information they learned after each session. While two of the 4 studies discussed did include unpublished data, preventing some dissemination from happening right away, many did indicate they wished to share when allowed. They expressed interest in following the COPDGene Study moving forward to see future results and across the three presentations respondents said they have or intended to sharing the information with groups such as their local support group, to their own healthcare professionals, with other advocacy or professional organizations, on their personal websites or to use in guiding their approach to COPD care in the case of healthcare professional respondents.

Tools for Sharing: Respondents were asked how useful different communication tools would be if they were asked to share the results. Nearly all options presented were thought to be useful to some degree. Powerpoint slides, infographic display of the results and template content for digital communications stood out to the CONNECT team as useful and feasible options for providing specific instructions, a template that can be reused and an example from a PPRN study.

Past Research Sharing Behavior: We asked respondents if they have shared research information in the past with different types of stakeholders. In two of the three evaluations, large majorities had shared with healthcare professionals. About half in all three evaluations had shared with a spouse and on social media in the past. Nearly 80% of respondents in the first evaluation also indicated they had shared results with an advocacy organization. Faith based organizations and senior centers received the lowest percentages.

Other Details: Respondents weighed in on the ideal length of webinars and the majority felt between 45 and 60 minutes was ideal. Over 70% of respondents indicated that receiving results from a study they participated in would increase the likelihood that they would participate in future studies when asked. Nearly 70% of respondents indicated use of Facebook, nearly the same levels of use as the Foundation's own COPD360social online community. Twitter and Linkedin were used by about a third of participants with other forums decreasing in use, however less than 10% indicated that they do not use any form of social media.

Appendix 3: PCORI FRAMEWORK ELEMENT 2 AREAS: NEEDS

Clinicians

- Access to spirometry, earlier diagnosis
- Access to networks of trusted pulmonary rehab providers and/or payment reimbursement for providing one through the office
- Standardized triage tool for rapid decision-making in the hospital setting to assess risk levels and take necessary precautions
- How to identify candidates for disease modifying interventions
- Identification of existing components within facility that may be integrated into D&I effort
- Data extraction and management capabilities (e.g. can current data systems identify COPD cases retrospectively and in real time? Can the elements be obtained electronically?)
- Guideline of best practices and how to adhere to GOLD standards
- Availability of consult teams with pulmonologists and other specialists available
- Best practice guidelines for oxygen therapy
- Info on how to prevent patients from acquiring sickness within the clinical setting, as COPD patients are at higher risk for infections
- A network of individuals and ability to directly communicate with each other regularly (particularly post-hospital discharge)
- Info on how to administer COPD self-management education plans and encourage patient education
- Standardized educational materials to provide to patients
- Enhanced access to complete and timely information re: patient medical record
- Development of regularly occurring educational programs on COPD for providers at events to review current guidelines and opportunities for improving care
- Links to important studies with commentary to provide context (for instance Info on different kinds of COPD, how to individualize care based on exacerbation risk, severity of illness, other comorbidities, medication management, etc.)
- Guidance that makes providing the right care at the right time easier
- Resources to educate and support COPD patients and caregivers when other post-acute services are not indicated.
- Awareness of tools to support COPD care.
- Business case for doing spirometry in practice

Health System

- Integration of medical care among healthcare professionals using a patient-centered approach/ comprehensive care, continuity of care
- Interdisciplinary or case management team with a common goal (e.g. hospital leadership, pulmonologists, pharmacists, RTs, RNs)
- Designated person to provide inpatient consults to patients and provide resources post-discharge to improve transition of care
- Need leaders to take roles in the improvement process (e.g. project sponsor who facilitates timely and successful implementation, project leader who manages the day-to-day, quality review team who measures baseline metrics and tracks progress, process owners such as pulmonologists who actually provide care to patients but are not leading project)
- Standardized ways to measure current processes
- Staff education requirements
- Determine COPD case volume and prioritize hospital unit or primary care locations
- Information systems specialist to help design the care for inpatients- such as designing medication reconciliation plans, improving discharge plans, etc.
- Standardized care recommendations/guidelines
- Greater facilitation of conversations with patients about planning for end of life care (rather than waiting for the ‘dire’ moment)
- Greater facilitation in all clinical settings of conversations with patients about how COPD has affected them over time such as what they can no longer do, what their goals are, what they currently find fulfilling (this will help with the patient-centered aspect)
- Standardized recommendations for discharge instructions (e.g. medication reconciliation, timing and use of PR and exercise, approaches to family education for self-management, etc)
- Accurate medication reconciliation- identifying all meds the patient is taking and using this list to reference anywhere in the healthcare system
- Ensure visibility of COPD initiatives on the floor – posters etc.
- Continuing medical education program led by physician leaders with expertise in COPD, RN education campaign to include all members of interdisciplinary team
- Dissemination of info about quality initiatives at staff meetings
- Need a dedicated acute lung service so that patients with COPD can receive full medical therapy and continuous respiratory monitoring until exacerbation has stabilized
- COPD-specific resources in inpatient clinical settings
- Evidence of implementable systems that are feasible across a spectrum of systems
- Evidence of ROI
- Network of post-acute resources to support patients after discharge.
- Assessment of impact of moving spirometry out of primary care
- Assessment of business case for including RTs in home care and primary care practices

Payers

- Evidence and high-rigor replication studies showing that pharmacological and non-pharmacological therapies “work”
- Awareness of a shared need/common vision: i.e. early diagnosis and/or preventive care reducing exacerbations can decrease overall costs and data to prove this concept
- Validated framework that has been “test driven” or effectiveness data
- Identification of factors impacting odds of hospital readmission
- Outcome measures that evaluate the effects of promising interventions
- Standardized performance metrics highlighting effectiveness
- Universal diagnostic screening services and standards for effective management of this condition
- Evidence of ROI
- Utilization of standards of care in all markets independent of proximity to specialists

Policy Makers

- Network of trusted opinion leaders who support implementation of recommendations to policy
- Need to understand impact on their constituents (e.g. COPD prevalence and impact can vary state to state)
- Data showing adherence of hospitals/primary care to COPD-related processes (e.g. spirometry eval, tobacco use screening and cessation intervention, flu vaccines)
- Need standardized performance metrics to assess programs
- Actionable measures focused on implementation goals
- Process measures that evaluate what providers and healthcare systems do, and whether that would be affected by implementation efforts
- Structural measure that evaluates existing resources
- Personnel present to support the processes and outcomes
- Universal diagnostic screening services and standards for effective management of this condition
- Evidence to show the discrepancies in access to programs/therapies important to COPD community (e.g. Pulmonary Rehab, Pulmonary Specialists, etc.)
- Evidence to support healthcare expansion.
- Evidence of ROI

PCORI FRAMEWORK ELEMENT 2 AREAS: VALUES

Clinicians	Health System	Payers	Policy Makers
• Improve quality of life: reduce mortality, slowing disease progression, reduce incidence and severity of exacerbations • Desire and willingness to work with COPD patients • Therapeutic optimism • Recognition of the limitations of one's own personal knowledge • Recognition of the value of client input into treatment goals/patient empowerment/patient-centeredness • Appropriateness of care • Continuum of meeting patient needs and improved health outcomes relative to money spent • Patient satisfaction • Office visits or utilizations that are impactful, but not requiring longer visits or unfunded mandates on personnel. • Improve patient confidence in managing disease	• Quality of life post-hospital discharge • Patient centeredness • Therapeutic optimism • Continuum of care meeting patient needs • Cutting costs • Increasing efficiency of communication between providers • Recognition that improved hQOL or healthy life years is often defined differently for those with COPD. • Providing services that may not bring in large revenue streams such as pulmonary rehab can go a long way in reducing admissions and readmissions • Focus on strategies that generate long-term improvements in quality measures	• Cutting costs/cost-effectiveness and efficiency • Outpatient care utilization and telehealth/virtual care • Effective collaborations between providers and payers • Becoming partners in healthcare instead of perceived as adversarial or obstructionist, offering services for benefit of the patient, providing supportive programs • Evidence of ROI	• Turning recommendations into research and public health care actions • Appease the majority (and get re-elected) • Prevention- and policy-related collaborations among partner organizations • Development of policies that reduce risk of COPD • Recognizing the negative impact that the disease has on constituent base, workers for industry in home district, impact on economy and future growth of their home region

PCORI FRAMEWORK ELEMENT 2 AREAS: MOTIVATIONS

Clinicians	Health System	Payers	Policy Makers
• Exacerbations account for most of the morbidity, mortality and costs associated with COPD • Having patients understand the likelihood of achieving their goal can preserve autonomy while being able to provide recommendations for care • Palliative and anticipatory end-of-life discussions can help patients discern preferences, understand advanced directives, and plan for therapies at end of life • Disease management involves partnering with nurses and respiratory therapists to assist in education, shared-decision making, and improving patient adherence to plan • Tailored, evidence-based and patient-focused approaches that include medication reconciliation, education, smoking cessation, optimizing inhaler use, pulmonary rehabilitation, nutritional assessment, and appropriate oxygen use can improve symptoms and reduce the likelihood of exacerbations. • Quality metrics and requirements (Pay for Performance) from health systems drive the workflow and interactions	• Certain indicators of past healthcare utilization (e.g. ER visits, number of daily drugs) can increase probability of readmission • Transitions are stressful for patients and families and can result in harm through discontinuity and fragmented care. This often causes adverse events that could be preventable • Failure to identify patients with an increased risk for adverse events after discharge can increase readmission • Failure to assess what the patient and family may need at time of discharge can worsen outcomes • Adverse events related to medication errors arising during hospitalization are unfortunately common • Transitional care elements can improve outcomes for patients with COPD - can be incorporated into a bundle, including patient education, smoking cessation counseling, vaccination, referral to pulmonary rehabilitation, nutrition assessment and scheduling a follow-up appointment • Despite the availability of accredited specialist training in the management of COPD, use and interpretation of spirometry, and smoking cessation, many practices lack the access to appropriately trained personnel • Readmission penalties and associated costs. • Reducing lengths of stay per admission and having an appropriate step-down level of care • Patient satisfaction	• Reduce use of healthcare resources • Poor coordination of care from hospital to home increases re-admission • Tailored, evidence-based and patient-focused approaches can reduce the likelihood of exacerbations and save money/resources • Decisions driven by the need to keep large amounts of funding in reserve. • -Education programs as interventional strategy are needed in order to continue cost savings for large payer groups.	• Reduce use of healthcare resources • Inadequacies of care mean that we may need oversight agencies to increase provider accountability, linking reimbursement to performance through value-based arrangements and the use of quality measures. • Patients with COPD must pass through mild and moderate stages before they have the most debilitating, costly and potentially fatal severe stage. Despite this, most patients with COPD are diagnosed only when the disease has progressed to moderate or severe forms. (Many patients with a smoking history who suffer repeated chest infections with sputum production are still treated with repeated courses of antibiotics and not investigated further) • Balance needs of constituents with the concern to hold 'party lines'

PCORI FRAMEWORK ELEMENT 2 AREAS: EXPECTATIONS

Clinicians	Health System	Payers	Policy Makers
• Expect patients to have desire to change/quit smoking • Clinicians may be concerned over patient perception about end of life care discussions • Information will be presented in a useable format designed for the primary care space • Programs suggested will not require more staff or unfunded staff time	• One-size-fits-all treatment method • Many expect people with COPD to be expensive with repeated utilizations and limited improvement in outcomes. • Resistant to implementing programs such as Pulmonary Rehab for fear it will not be sustainable or affordable over time	• Assume that lack of replication studies means that certain types of programs should not be covered • One-size-fits all treatment method • Better to be reactive rather than proactive (don't want to spend money not knowing what the outcome might be) • Increase profit or reserves • High ROI	• 'Effective' policies are those that appease peoples' emotions rather than focusing on research and evidence • They will receive information and lobbying related to needs.

PCORI FRAMEWORK ELEMENT 2 AREAS:GAPS

Clinicians	Health System	Payers	Policy Makers
• Clinicians may not have clear understanding of patient goals, making it hard to develop a trusting relationship with patient and better individualize their care • -It is clinician's responsibility to inform patient of how to achieve their goal (if possible) and explore whether the treatment they are on is aligned to achieve said goals • -Laying out the expected trajectories and outcomes associated with care and then revisiting their progress over time can provide a productive dynamic that facilitates follow-up conversations • -Demonstrating empiric evidence about how the treatment is consistent with expected outcomes can build trust and reassure patients • -Device education training for patients / dissemination of checklists for providers to assess inhaler technique, nutrition, oxygen use at home, goals, etc. • -How to operationalize program effectiveness? How to anticipate and balance potential unintended consequences of treatment methods based on COPD type, severity, co-morbidities, etc.	• No consistent follow-up and reassessment of patients over time (particularly after hospital discharge) • Discharge planning should be more precise, standardized with best practice recommendations, and begin as soon as patient is admitted to hospital. Caregiver and patient along with multi-disciplinary teams should all be involved and continue to follow up with the patient post-discharge • Often patients and families are not educated in a patient-centered manner, so patients do not know how to stay healthy after hospital discharge • Currently there is a failure to address key concerns of patients and families, health professionals don't spend a ton of time explaining the details to patients, leaving them largely informed • Need to have a brief discussion w/individual about their COPD and goals in order to better determine treatment plan. Get an idea of what kind of caregiver support they have, what resources they have access to • Need to confirm patients have adequate understanding of discharge instructions, encourage 'teach back' approach • Inadequate communication between primary care and other aftercare providers about patient's hospital course and ongoing treatment plans – need to share discharge plans, etc. • Call patients and ask them about their experiences at the hospital • Connect patients to resources in the community • Continually assess patient oxygen needs • Current acute care model is more reactive than proactive, can lead to gaps between communication and collaborations of services and providers • Limited funding for cost benefit studies • Pressure to perform as a business without direct input from consumers—direct input is from shareholders and those they employ	• Research findings are very mixed, no consistent effort to fund more research • Very different kinds of COPD, hard to know what works best • Outcome measures are limited because most are only minimally determined, and require complex methods to adjust for risks and control for other determinants to feasibly compare quality • Often rely on approximate trends from interventions • Lack of response to individuals rather than policy makers	• Need to develop/adapt new policies that are aligned with patient-centeredness • Determine what resources are needed for broader implementation and what those best practices would be • How to operationalize program effectiveness? How to anticipate and balance potential unintended consequences of sweeping policy? • Structural components are often designed to ensure necessary aspects of the care delivery but are limited by minimally linking to outcomes of healthcare delivery • Need to enhance collaborations between COPD-related programs at national, state, and local levels • Need to identify existing best practices

PCORI FRAMEWORK ELEMENT 2 AREAS: CONTEXT FOR ADAPTATION

Clinicians	Health System	Payers	Policy Makers
• Usually requires approval and support of health system if the evidence is something other than simple addition to formulary or change in use of available drug therapies. • Requires consideration of when and how it would be adopted and additional resources that may be required	• Must have idea of ROI • Frequently adopted after a shift to pay for performance or other large quality initiatives such as those from CMS, e.g. rehospitalization non-payment. • Financial status of the company	• Federal and state laws that have little to do with health of individuals or evidence • Currently making large amounts of profit or reserves. • Lack of direct impact of patient satisfaction on their actions.	• Requires a vocal champion to place an issue on the legislative agenda. • Likelihood of success varies based on other priorities on the legislative and regulatory agenda and the emergence of new health issues. • Adoption is likely also dependent on who lines up in support or against of the change and their political

Appendix 5-PCORI Funded Studies Involving COPD

The database of PCORI-funded research was used to create this list. Studies that specifically involve COPD are listed first, followed by studies focused on older adults with chronic disease that are likely to produce results highly relevant to a COPD population.

For specifics on individual projects, visit the PCORI website at www.pcori.org and search in the "research and results" section. Another helpful resource to view study registration is https://hsrproject.nlm.nih.gov/.

Title	Principle Investigator	Institution	Start Date	End Date	Aim of Project	Project Status	Notes
Monitoring and Peer Support to Improve Treatment Adherence and Outcomes in Patients with Overlap Chronic Obstructive Pulmonary Disease and Sleep Apnea via a Large PCORnet Collaboration (O2VERLAP)	Carl Stepnowski, PhD (David M. Mannino, MD, was the original principal investigator for this project)	COPD Foundation	Mar-16	Jul-20	O2VERLAP results will provide answers for clinicians seeking the best ways to remove barriers to treatment adherence and strategies for providing efficient educational and coaching platforms. The results will also help patients understand the benefits of their treatment. Additionally, the findings will help provide guidance for using social media, peer-to-peer support, and viral messaging to help recruit and enroll new participants, with the ultimate goal of improving the patient infrastructure for PCORnet and its Commons	In progress; Enrollment complete	The COPD Foundation is partnering with the American Sleep Apnea Association on this project.
Smoking Cessation Versus Long-Term Nicotine Replacement among High-Risk Smokers	Edward Ellerbeck, MD, MPH	University of Kansas Medical Center Research Institute	Dec-13	Mar-18	The research team compared two ways to help people with COPD quit cigarette smoking. The first way was long-term nicotine replacement therapy, or LT-NRT. This therapy lets people slowly cut back on their smoking by using nicotine patches, gum, and lozenges while they continue to smoke. The second way was standard smoking cessation, or SSC. The team wanted to see if LT-NRT was better than SSC at helping patients with COPD quit smoking.	Completed; PCORI Public and Professional Abstracts, and Final Research Report Posted	**Study results:** After one year, the research team found no difference between the two groups in the number of people who had stopped smoking. The study also found no differences between the groups in the number of cigarettes smoked per day, the number of times patients tried to quit smoking, and the amount of unhealthy chemicals they breathed in. There were no differences in how well their lungs worked or in how many times they had to go to the hospital or emergency room. Patients in the SSC group took less time to complete the program and had fewer side effects than those in the LT-NRT group.
Patient-Centered Physical Activity Coaching to Improve Outcomes in COPD: A Pragmatic Trial	Huong Q. Nguyen, PhD, RN	Kaiser Foundation Research Institute	Sep-14	Sep-19	To test the effectiveness of a patient-centered, physical activity coaching (PAC) program in a real-world healthcare system and measure outcomes of greatest importance to patients, such as staying out of the hospital, perception of support, and quality of life compared to standard care (SC).	In PCORI Peer-Review Process	The primary outcome will be hospitalizations in the 12 months after patients start the PAC intervention because staying out of the hospital is highly valued by patients and their families. The research team will measure patients' care experience and quality of life. Researchers will also measure other health service use and clinical outcomes that can be
Health Coaching to Reduce Disparities for Patients with Chronic Obstructive Pulmonary Disease	David Hinton Thom, MD, MPH, PhD	University of California, San Francisco	Dec-13	Apr-18	To examine whether health coaches can improve the management of COPD in a population of vulnerable patients cared for in "safety-net" clinics. The study is designed as a randomized controlled trial for patients with moderate to severe COPD. Patients were randomized into a health coaching group and a usual care group. Those in the health coaching group received 9 months of active health coaching followed by 6 months of follow up to see if improvements can be maintained. The study will determine whether patients who receive health coaching have a better quality of life, fewer exacerbations, and better exercise capacity than patients who receive usual care.	Completed; PCORI Public and Professional Abstracts, and Final Research Report Posted	**Study Results:** The study found no significant differences between the two groups in COPD-related quality of life, dyspnea, self-efficacy for COPD self-management, exercise capacity, or number of COPD exacerbations.
A Comprehensive Disease Management Program to Improve Quality of Life in Disparity Hispanic and African American Patients Admitted with Exacerbation of Chronic Pulmonary Diseases	Negin Hajizadeh, MD, MPH	Feinstein Institute for Medical Research	Jul-16	Nov-18	To determine if telehealth therapy can help Hispanic and African-American patients with COPD improve their health and avoid going back to the hospital compared with getting therapy at a clinic.	In progress; Enrollment complete	This study will compare rehospitalization rates in COPD patients who receive telehealth pulmonary rehabilitation led by a respiratory therapist vs. standard pulmonary rehabilitation at an
Comparing Effectiveness of Self-management and Peer Support Communication Programs amongst Chronic Obstructive Pulmonary Disease Patients and their Family Caregivers	Hanan J. Aboumatar, MD, MPH	Johns Hopkins University	Apr-16	Jun-20	To compare two ways of helping patients and their caregivers learn to manage COPD: patients receive education and support from a respiratory therapist, or patients receive education and support from a respiratory therapist plus learn ways to manage the disease from a peer. A peer is a patient with COPD or a caregiver who has successfully managed COPD and knows the challenges patients face.	In progress; Data collected	The outcomes of this study will look at change in health-related quality of life and combined COPD-related hospitalizations and ED visits per participant.

Roflumilast or Azithromycin to Prevent COPD Exacerbations (RELIANCE)	Jerry A. Krishnan, MD, PhD	University of Illinois at Chicago	Jan-16	Jul-24	To compare long-term roflumilast use with long-term azithromycin use. The team wants to learn how well these medicines work in preventing serious COPD episodes and understand the benefits and harms of long-term use.	In progress; Not yet recruiting	The primary study outcome is all-cause hospitalization or death. Secondary outcomes are patient-reported measures of physical function, problems with sleep, fatigue, anxiety, and ability to perform usual activities, measured using the NIH-PROMIS instruments. Participants will be followed up for a period of 6 months (minimum) to 36
Comparative Effectiveness of Peer-Led Supplemental O2 Infoline for Patients and Caregivers (PELICAN)	Jerry A. Krishnan, MD, PhD	University of Illinois at Chicago	Sep-13	Sep-18	To compare the effect of two peer coaching interventions with usual care on adherence to prescribed home oxygen therapy in patients with chronic obstructive pulmonary disease (COPD)	Completed; PCORI Public and Professional Abstracts, and Final Research Report Posted	**Study Results:** Use of oxygen: Calls from peer health coaches didn't increase oxygen use. Patients who received five calls from peer health coaches used oxygen for fewer hours each day than patients who didn't receive calls. Patient health: Patients who received calls from peer health coaches had fewer symptoms of depression and sleep problems than patients who didn't receive calls from peer health coaches. But calls from peer health coaches didn't help patients feel less tired or anxious. The calls also didn't improve patients' abilities to take part in social or physical activities.
An Integrative Multilevel Study for Improving Patient-Centered Care Delivery among Patients with Chronic Obstructive Pulmonary Disease	Hanan J. Aboumatar, MD, MPH	Johns Hopkins University	Sep-13	Oct-18	To develop and pilot test a Patient and Family-centered Transitional Care Intervention (PFI) that starts within hospital and continues for 3 months. The program will help meet hospitalized patients' individual needs and build capacity of COPD patients/family caregivers to manage this disease and advance their problem solving, and coping skills; conduct a randomized controlled trial, recruiting 214 patients admitted to one academic center and measure the effects of PFI on health-related quality of life, survival, and rates of re-hospitalizations and emergency room visits, compared to usual care; evaluate PFI impact on patient activation, confidence, and behaviors; and evaluate the impact on family caregiver confidence, stress, and coping skills.	Completed; PCORI Public and Professional Abstracts, and Final Research Report Withdrawn Pending Revisions	The study's original results and scientific publication were withdrawn after an error was found in the database that affected the results. In this single-site randomized clinical trial that included 240 patients with COPD, a 3 month program that combined transition and long-term management support, compared with usual care, resulted in a greater number of COPD-related hospitalizations and emergency department visits (1.40 vs 0.72 per participant); this comparison was statistically significant. There was no significant change in health-related quality of
Expanding Access to Home-Based Palliative Care through Primary Care Medical Groups	Susan Enguidanos, PhD, MPH	University of Southern California	Dec-16	Nov-22	This study will test the effectiveness of integrating an evidence-based model of home-based palliative (HBPC) within primary care clinics on patient and caregiver outcomes. The investigators will conduct a randomized controlled trial, randomizing seriously ill patients (and family caregivers) who receive primary care from 10 regional accountable care organizations (ACOs) in California to one of two study groups: HBPC or enhanced usual care (EUC). Follow-up data will be collected via telephone surveys with patients at 1- and 2-months and with caregivers at 1- and 2-months, and, as appropriate, following the death of the patient.	In progress; Recruiting	The study will determine whether HBPC, compared with EUC, results in greater reduction in patients' pain, symptoms, depression, and anxiety while improving hope and increasing survival. The research team will also determine whether HBPC is more effective in reducing emergency department visits and hospital stays, and whether HBPC, compared with EUC, results in greater improvement in caregiver depression, anxiety, and burden while improving
Comparative Effectiveness and Safety of Inhaled Corticosteroids and Antimicrobial Compounds for Non-CF Bronchiectasis	Kevin Winthrop, MD, MPH	Oregon Health & Science University School of Medicine,	Sep-15	Dec-18	This study will compare the benefits and harms of steroids, primarily inhaled corticosteroids (ICS), and antibiotics used in patients with non-CF bronchiectasis.	In PCORI Peer-Review Process	The COPD Foundation and NTM Info & Research (NTMir), as well as lung and infectious disease doctors, will participate in the project.

PATient Navigator to rEduce Readmissions -- The PArTNER Study	Jerry A. Krishnan, MD, PhD	University of Illinois at Chicago	May-13	Nov-18	When patients go home from the hospital, having information about what to expect is important for their recovery. Patients may need to know how to plan follow-up care or get help from community organizations. In this study, the research team compared two ways to help people recover at home after a hospital stay. The first was the navigator and peer coach program. In this program, two types of trained professionals helped patients. Patient navigators met with patients once, in person, at the hospital and once at home to talk about patients' recovery needs. For example, if patients needed help with housing or food, navigators told patients about community resources. Then, peer coaches checked in with patients by phone for six weeks. Peer coaches encouraged patients and helped them with any new questions about their illnesses or their recovery. The alternative approach was usual care. Patients learned about their illnesses and went over their medicines with a nurse at the hospital. They also received printed instructions before they left the hospital.	Completed; PCORI Public and Professional Abstracts Posted	**Study Results:** After two months, patients in the two groups reported similar levels of: 1) Feeling anxious or supported, 2) Mental or physical health, and 3) Use of healthcare services. The two groups also didn't differ in how many patients went back to the hospital or died. After one month, compared to the start of the study, patients in both groups felt less anxious and more supported. After two months, patients in both groups had better mental and physical health.
Leveraging Visual Analytics for the Identification of Patient Subgroups: Application to Improving the Prediction of Hospital Readmission in the Elderly	Suresh K. Bhavnani, PhD	The University of Texas Medical Branch at Galveston	Jul-16	Dec-19	This project will 1) develop a computational method to automatically identify and visualize patient subgroups and their characteristics in datasets, such as from Medicare, and electronic medical records; 2) use the approach to identify patient subgroups in three index conditions—**chronic obstructive pulmonary disease**, congestive heart failure, and hip/knee arthroplasty—common in the elderly obtained from the Medicare database, and engage stakeholders to infer the disease processes underlying each patient subgroup, with the goal of refining the variables included in the analysis; 3) develop, validate, and test the improvement of regression models that incorporate patient subgroup information compared with the existing models in all three index conditions; and (4) use feedback from PCOR researcher stakeholders to operationalize the method	In PCORI Peer-Review Process	This project focuses on using a visual analytical method to 1) quantitatively identify the number, size, and statistical significance of patient subgroups and their most highly co-occurring characteristics; and 2) visualize that information through a network to reveal the relationships within and across patient subgroups. This approach is designed to enable stakeholders to infer the disease processes underlying each patient subgroup, with the goal of iteratively refining the variables to predict those subgroups.
Improving Communication between Patients with Multiple Chronic Conditions and Their Primary Care Doctors	Richard W. Grant, MD, MPH	Kaiser Foundation Research Institute	Sep-14	Mar-19	To study ways to help patients with multiple health problems talk to their doctors about their health concerns and priorities so that office visits focus on what matters most to patients. In this study, the team is comparing usual care with an app for tablet computers called Visit Planner. The app helps patients get ready for primary care visits.	Completed; PCORI Public and Professional Abstracts, and Final Research Report Posted	**Study Results:** After six months, patients in the two groups didn't differ in closure of care gaps. Compared with patients who didn't receive the visit planner, those who did were more likely to say they: 1) Prepared questions for their doctors, and 2) Told their doctors about their top concerns at the start of their visits. The two groups didn't differ in how often patients: 1) Were satisfied with their care, 2) Were offered treatment choices, 3) Were asked about their ideas and goals for their care, 4) Took medicine as directed by their doctors, and 5) Attended follow-up visits
Effectiveness of Collaborative Goal-Setting Versus IMPaCT Community Health Worker Support for Improving Chronic Disease Outcomes	Judith A. Long, MD	University of Pennsylvania	Sep-14	Oct-18	To evaluate whether collaborative goal-setting plus IMPaCT is more effective than goal-setting alone at improving outcomes suggested to us by low-SES, chronically ill patients. Theresearchers will also explore whether the intervention works differently across various types of primary care settings, whether the effects of the intervention last after it ends, whether achieving health goals makes people feel better, and what patients and CHWs think about the intervention and how it works.	Completed; PCORI Public and Professional Abstracts, and Final Research Report Posted	**Study Results:** After nine months, patients with and without CHW support didn't differ in how they rated their physical health. Patients in both groups had higher ratings of physical health at the end of the study. Compared with patients who didn't have CHW support, those who did reported higher quality of health care. Patients with CHW support were also less likely to have more than one hospital stay during the study or return to the hospital in the same month if they did have a hospital stay. After nine months, patients with and without CHW support didn't differ in: 1) Management of ongoing health problems, 2) Mental health, 3) Confidence to manage their health, 4) Time spent in the hospital, and 5) if

Multicenter Randomized Pragmatic Clinical Trial Comparing Two- versus Three-Antibiotic Therapy for Pulmonary Mycobacterium Avium Complex Disease	Kevin Winthrop, MD, MPH	Oregon Health & Science University School of Medicine, Department of Infectious Disease	Apr-18	Jun-23	Because the development of new drugs for nontuberculous mycobacteria (NTM) lung infection, including Mycobacterium avium complex (MAC), is many years away, the research team will evaluate two common treatment regimens; guidelines suggest that treatment with two drugs may be similar (noninferior) three drugs with regards to treatment response and improve tolerability, measured by the proportion of patients who complete 12 months of assigned therapy.	Awarded; Contract pending	While this research project is not directlly related to COPD, this project has the potential of benefitting patients with COPD. Mycobacterium avium complex (MAC) ung disease disproportionately affects the elderly and women, as well as those with existing **underlying lung diseases like emphysema or bronchiectasis**.
Emergency-Department Initiated Palliative Care in Older Adults with Advanced Illness	Corita R. Grudzen MD, MS	New York University School of Medicine	Jul-17	Dec-23	Palliative care focuses on easing suffering and improving quality of life for patients with a serious illness and their families. This type of care can include physical, emotional, social, and spiritual support. But not all patients with a serious illness get palliative care. Going to the emergency department, or ED, can be a sign that people with serious illness need more help managing their health problem. Half of older Americans visit the ED in the last month of life. This study is comparing two ways to give palliative care to older adults with serious illness. The first way is phone calls from a nurse case manager. The second way is in-person help at a clinic that specializes in palliative care.	In progress; recruiting	The full project title is "Emergency-Department Initiated Palliative Care in Older Adults with Advanced Illness," and thus, there are many other diseases that are examined within the framework (such as kidney disease, cancer, heart failure, etc.). However, the research is still expected to benefit COPD patients as they are included in the proposed sample.
A Cluster-Randomized Trial Comparing Team-Based versus Primary Care Clinician-Focused Advance Care Planning in Practice-Based Research Networks	Annette M. Totten, PhD, MPA	Oregon Health and Science University	Jul-17	Dec-22	The research team wants to compare two ways for primary care practices to do advance care planning for people with serious illnesses. One way is for one primary care provider to talk to a patient, set goals, and make plans. The other way is for a primary care team to share the responsibility for advance care planning. People with serious illnesses, their families, and their healthcare providers often have to make decisions about tests and treatments in the last year or two of life. Patients who talk with healthcare providers about what is most important to them are more likely to get the care they want when their health worsens. Primary care practices, where many people get care even when they have serious conditions, don't always have the training or the processes to help people talk about what they want, make plans, and adjust plans as they get sicker.	In progress; Recruiting	The proposed population includes adults with serious illness, and thus is not directly related to COPD. However, COPD is included in the sample, so the research will pertain to this population to some extent. Data will be drawn from 42 primary care practices in the U.S. and Canada.
Reducing Disparities in the Quality of Palliative Care for Older African Americans through Improved Advance Care Planning (EQUAL ACP)	Kimberly Johnson, MD, MS	Duke University	Aug-17	Jan-24	Patients who are seriously ill may benefit from advance care planning. In advance care planning, patients make decisions about care they would want to receive if they become unable to speak for themselves. Planning can help patients make sure that the care they receive at the end of life reflects their wishes. For example, patients may think about who should make medical decisions on their behalf, what medical treatment they want or don't want, and cultural beliefs that may affect their decisions. Blacks are less likely than whites to take part in advance care planning. Compared with whites, blacks are more likely to receive costly, poor-quality care that doesn't reflect their wishes at the end of life. Blacks are also less likely to use hospice care, more likely to have preventable hospital stays, and more likely to have poor communication with doctors than whites. Researchers don't know if these differences relate to differences in patients' cultural beliefs, knowledge, or access to advance care planning. This study is comparing two approaches to advance care planning to see whether they increase advance care planning overall and for different racial groups.	In progress; Recruiting	While the research is not specifically focusing on COPD, the project is still expected to benefit people with COPD because they will be a part of the sample. Data will be drawn from clinics caring for seriously ill persons within the southern United States. Caregivers are being asked to enroll. Patients in the study are at high risk losing the ability to do daily tasks, having a hospital stay, or dying. Half the patients are black and half are white. The team is assigning clinics by chance to offer one of two approaches to advance care planning.
Population-Based Comparison of Evidence-Based, Patient-Centered Advance Care Planning Interventions on Advance Directive Completion, Goal Concordant Care and Caregiver Outcomes for Patients with Advanced Illness	Neil S. Wenger MD, MPH	Regents of the University of California, Los Angeles	Aug-17	Dec-23	In this study, the research team is looking at three ways to help patients create an advance directive. The team is comparing how well the approaches work to help patients get care that matches their values and goals. Patients don't always receive health care that matches their wishes at the end of life. Advance care planning, or ACP, is when patients discuss their goals for end-of-life care with their doctor and caregivers and write them down. ACP can help patients receive end-of-life care that fits their values and preferences. Advance directives are written statements that	In progress; Recruiting	The population is not specifically focused on COPD. Rather, it includes About 4,000 patients with advanced illness at 27 clinics at 3 University of California sites (University of California, Los Angeles; University of California, San Francisco; and University of California, Irvine). The study is still expected to benefit COPD patients as they are a

A Non-Inferiority Comparative Effectiveness Trial of Home Based Palliative Care in Older Adults (HomePal)	Huong Q. Nguyen, PhD, RN	Kaiser Foundation Research Institute, a Division of Kaiser Foundation Hospitals	Sep-17	Jan-24	In this study, the research team is comparing two ways of providing home-based palliative care. The team is looking at how each method improves patients' symptoms and quality of life for the patient and their caregiver. Palliative care focuses on improving the quality of life of patients with serious illness and their caregivers by preventing and treating suffering. Patients with serious illness may find it hard to travel to a clinic for palliative care. Home-based palliative care gives them an easier way to get care and may help relieve caregiver burden.	In progress; Not yet recruiting	This was funded under the announcement, "Community-Based Palliative Care Delivery for Adult Patients with Advanced Illnesses and their Caregivers," and thus incorporates a large sample that is diverse. However, because COPD patients are a subgroup in the study, the research is expected to benefit COPD patients. The study is an RCT comparing two groups: in one group, a nurse and a nurse practitioner or doctor visit the patient at home. In the second group, a nurse uses video technology to talk with a doctor while visiting the patient's home. All patients in the study receive care to relieve pain and manage symptoms to optimize their quality of life. Patients and caregivers also receive
Leveraging Integrated Models of Care to Improve Patient-Centered Outcomes for Publicly-Insured Adults with Complex Health Care Needs	James M. Schuster, MD, MBA	UPMC Center for High-Value Health Care	Sep-17	Jan-23	In this study, the research team is comparing three ways to help patients who have two or more chronic conditions manage their health and health care after a hospital stay. In the first, called High-Touch, care managers give intensive, in-person support in patients' homes and communities. The second, called High-Tech, helps patients manage their health and health care using technology. It includes virtual visits with a care manager. The third option is usual care, where care managers carry out routine discharge planning to help patients transition home after a hospital stay. Patients in the usual care group also have access to community-based services. In the United States, about 25 percent of adults have two or more chronic health conditions, such as high blood pressure, diabetes, and depression. Managing multiple chronic conditions can be hard. Many patients have frequent visits with different doctors and take multiple medicines. Patients with multiple chronic conditions are also more likely to need help with everyday tasks, spend time in the hospital, or die at an earlier age compared with patients who do not have these complex conditions.	In progress; Recruiting	The full project title is, "Leveraging Integrated Models of Care to Improve Patient-Centered Outcomes for Publicly-Insured Adults with Complex Health Care Needs," and thus aims to incorporate a sample that is more diverse than just COPD. However, research is expected to benefit COPD patients as this is a subgroup included in the study. The study is an RCT and the proposed sample includes 1,927 adults ages 21 and older living in Pennsylvania who qualify for Medicaid or who are dual (Medicare-Medicaid) eligible; have been discharged from the hospital within 30 days; and who have multiple comorbidities, polypharmacy, and/or risk of high future healthcare utilization.
Improving Self-Care Decisions of Medically Underserved African-Americans with Uncontrolled Diabetes: Effectiveness of Patient-Driven Text Messaging versus Health Coaching	James Bailey, MD, MPH	University of Tennessee Health Sciences Center	Jan-16	Sep-21	Studies have shown that working with health coaches or getting encouraging text messages from doctors' offices can help patients make healthy choices. The research team wants to compare how well these approaches help African Americans with diabetes improve their self-care. Types of self-care include diet, exercise, blood sugar testing, foot care,	In progress; Recruiting	The project sample does not specifically pertain to COPD, however it does have some focus on smoking cessation and self care, which are highly relevant to COPD research areas.
Integrating Behavioral Health and Primary Care	Benjamin Littenberg, MD	University of Vermont and State Agricultural College	Aug-15	Apr-22	Patients with behavioral health problems may see their primary care doctors first and then get a referral to specialist trained to treat behavioral health issues. These specialists include psychologists or social workers. But finding a behavioral-health specialist, making an appointment, and getting to the visits can make it hard to get care. This study is comparing two ways of delivering health care to see which is better at improving health and functioning in adults with both physical and behavioral health problems: One way puts behavioral-health providers and primary care doctors in the same place or nearby. This is called colocation. The second way puts behavioral-health providers and primary care doctors together, but it also adds training for behavioral-health providers, medical providers, nurses, and office staff to work together as a team. This is called integrated behavioral health.	In progress; Enrollment complete	While this study does not pertain to COPD specifically, it does pertain to integrating behavioral and physical health care which is a topic of relevance to the COPD population.

An Emergency Department-to-Home Intervention to Improve Quality of Life and Reduce Hospital Use	Donna Lynne Carden, MD	University of Florida	Dec-13	Dec-18	Before patients leave the emergency room, or ER, hospital staff give instructions on how to care for their illness or injury at home. These instructions include getting follow-up care from their regular doctors. For older adults with long-term health issues, follow-up care is important so patients don't need to return to the ER. In this study, the research team tested the use of coaches for patients with Medicare insurance who had recently gone home after a visit to the ER. Coaches were from two Area Agencies on Aging, which offer programs and services that help older adults live on their own. Coaches helped patients: Schedule follow-up doctor appointments, Learn to identify and respond to signs of their health getting worse, Review concerns and instructions for taking medicines, Talk about care goals with their doctors, and Arrange for services such as meal delivery and rides to doctor visits. The research team compared patients who worked with these coaches with patients who received usual care from the ER. The team looked at quality of life, the number of times patients had to return to the ER or hospital for care, and the number of times patients went to their regular doctors after their ER visits.	Completed; PCORI Public and Professional Abstracts Posted	**Study Results:** Patients who worked with coaches and those who didn't had similar ratings of quality of life, numbers of times they had to return to the ER or hospital, and numbers of visits with their regular doctors. Compared with patients who didn't work with a coach, patients who worked with a coach were less likely to have a hospital stay if they did return to the ER.
Health System Intervention to Improve Communication About End-of-Life Care for Vulnerable Patients	J. Randall Curtis, MD, MPH	University of Washington	May-13	Oct-18	When patients are seriously ill, discussions between patients and their doctors can make it more likely that patients get the care they want. Because family members may help make decisions about patients' care, they should also understand what patients want. In this study, patients with serious illnesses filled out a form about their goals for care and how they'd like to discuss those goals. The research team compared communication and care for two groups. In one group, patients, doctors, and families saw information from the form before a visit. The other group didn't see the results.	Completed; PCORI Public and Professional Abstracts, and Final Research Report Posted	**Study results:** Compared with the group that didn't see the results of the form, patients in the group that did: 1) Were more likely to talk with their doctors about goals for care, 2) Reported better communication with their doctors, and 3) Were more likely to report receiving care in line with their goals, as long as those goals didn't change later in the study. There were no differences in patients' depression and anxiety symptoms or the rate of referrals doctors provided to care that
The Houston Home-based Integrated Intervention Targeting Better Asthma Control (HIIT-BAC) for African Americans	Winifred J. Hamilton, MS, PhD	Baylor College of Medicine	Dec-13	Mar-20	Usually, patients get care for and advice about asthma at the doctor's office. The research team wants to find out if helping patients remove or reduce asthma triggers in their homes can help them control their asthma better than when they only get care at the doctor's office. The team is conducting the study with African Americans with asthma in Harris County, Texas, which includes the city of Houston. African-American adults with asthma living in this area die at twice the rate of white or Hispanic/Latino adults with asthma living in the same area. This study can help healthcare system leaders, payers, and providers decide whether to offer home visits along with clinical care to help patients control their asthma.	In PCORI Peer-Review Process	PCORI has identified childhood asthma in African Americans and Hispanics/Latinos as an important research topic. Asthma affects African-American and Hispanic/Latino people at higher rates than whites, but African-American and Hispanic/Latino children are less likely to receive recommended care. Patients, clinicians, and others want to learn: What interventions will best help doctors and families assure that children receive the care recommended by the National Heart, Lung, and Blood Institute? While this does not pertain specifically to COPD, it does pertain to better implementation to enhance