Meeting the challenge of COPD care delivery in the USA: a multiprovider perspective

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Summary

The burden of chronic obstructive pulmonary disease (COPD) in the USA continues to grow. Although progress has been made in the development of diagnostics, therapeutics, and care guidelines, whether patients' quality of life is improved will ultimately depend on the actual implementation of care and an individual patient's access to that care. In this Commission, we summarise expert opinion from key stakeholders—patients, caregivers, and medical professionals, as well as representatives from health systems, insurance companies, and industry—to understand barriers to care delivery and propose potential solutions. Health care in the USA is delivered through a patchwork of provider networks, with a wide variation in access to care depending on a patient's insurance, geographical location, and socioeconomic status. Furthermore, Medicare's complicated coverage and reimbursement structure pose unique challenges for patients with chronic respiratory disease who might need access to several types of services. Throughout this Commission, recurring themes include poor guideline implementation among health-care providers and poor patient access to key treatments such as affordable maintenance drugs and pulmonary rehabilitation. Although much attention has recently been focused on the reduction of hospital readmissions for COPD exacerbations, health systems in the USA struggle to meet these goals, and methods to reduce readmissions have not been proven. There are no easy solutions, but engaging patients and innovative thinkers in the development of solutions is crucial. Financial incentives might be important in raising engagement of providers and health systems. Lowering co-pays for maintenance drugs could result in improved adherence and, ultimately, decreased overall health-care spending. Given the substantial geographical diversity, health systems will need to find their own solutions to improve care coordination and integration, until better data for interventions that are universally effective become available.

Introduction
The problem of chronic obstructive pulmonary disease (COPD) in the USA is substantial, and the disease burden on patients, their families, and society at large continues to grow. Although diagnostics, therapeutics, and care guidelines have improved, the actual implementation and accessibility of care are equally, if not more, important. The goal of delivering high-quality care is not unique to COPD, but certain issues faced by patients with COPD do create specific challenges. The patchwork of health-care provider networks in the USA means that access to care varies widely depending on a patient's insurance, geographical location, and socioeconomic status. Further affecting accessibility is the complicated coverage and reimbursement structure of Medicare, the national health insurance programme administered by the US Federal Government for Americans aged 65 years and older who have worked and paid into the system. These complications create particular challenges for patients with chronic respiratory disease, who might need access to several types of services, such as outpatient and inpatient services, inhaled drugs, oxygen therapy, and pulmonary rehabilitation. In such a complex system, it becomes easy to lose sight of the factors that matter most to patients, which might or might not be the same factors that matter most to payers. In this Commission, we provide a comprehensive view of COPD care in the USA by including the perspectives of patients, caregivers, health-care providers, health systems, and insurance companies. By doing so, we aim to identify what is working, what the needs and challenges are, and how patients with COPD can be better served in the future. Although our focus is on COPD care in the USA, common themes are still relevant to patients and providers in other countries. Presented here are real issues that patients and providers face on a daily basis that are seldom addressed in guideline documents or academic research. Our goal is to engage the COPD community in a dialogue, and this Commission is just the beginning.

Part 1: Present state of COPD care

Epidemiology

COPD is an important cause of morbidity and mortality both in the USA and worldwide. In 2011, about 6.5% of US adults (aged 25 years and older) report a physician diagnosis of COPD (including chronic bronchitis, emphysema, and COPD; figure 1). In the USA, prevalence varies widely by state and ranges from 3.1% to 9.3% in adults aged 18 years or older (figure 2). COPD was reported by 7.8% of women and 5.8% of men, and its prevalence varies with ethnic origin: 2.2% in Asians and Pacific Islanders, 3.6% in Hispanic individuals, 6.4% in black (non-Hispanic) individuals, 7.6% in white (non-Hispanic) individuals, and 11.5% in Native Americans and Native Alaskans.

![Figure 1](image1.png)

**Figure 1**
Age-adjusted prevalence of self-reported, physician-diagnosed COPD in adults aged 25 years or older in the USA
As would be expected, smoking affects prevalence, with 13·3% of current smokers, 6·8% of former smokers, and 2·8% of never-smokers reporting COPD. Reported COPD also increases with age: 3·4% in individuals aged 25–44 years, 6·6% in those aged 45–54 years, 9·2% in those aged 55–64 years, 12·1% in those aged 65–74 years, and 11·6% in those aged 75 years and older. Importantly, COPD prevalence is also related to socioeconomic factors. In the USA, the prevalence in 2011 was 9·5% among individuals with less than a high school education, 6·8% among those with a high school education, and 4·6% among those with more than a high school education. A similar trend is seen if socioeconomic status is assessed with annual household income: in 2011, prevalence was 9·9% in people with an annual household income of less than US$25 000, 5·7% in those with $25 000–49 999, 4·2% in those with $50 000–74 999, 2·8% in those with $75 000 or more, and 6·1% if annual household income data were unknown. These socioeconomic factors are particularly relevant to patient access to care and treatment.

Although the strongest risk factor for the development of COPD is tobacco smoking, occupational and environmental exposures are also important, and the heterogeneous patient population that falls under the umbrella term COPD needs to be acknowledged. Data from both the USA and Canada suggest that 25% of those with COPD are never-smokers. Some of these patients are likely to have asthma–COPD overlap syndrome, which encompasses features of both COPD and asthma and is increasingly being recognised. In other individuals, environmental exposures are likely to contribute to airflow obstruction. Results from a 2015 study in Canada (CanCOLD) suggested that predictors of COPD in never-smokers include older age (≥70 years), self-reported asthma, and low education level, although exposures to passive smoke and
biomass fuel heating were also important risk factors in women. Roughly 10% of US households still rely on wood as a primary or secondary source of heat. Roughly 10% of US households still rely on wood as a primary or secondary source of heat. In other patients, events in early childhood and young adulthood (eg, environmental exposures or respiratory infections) are likely to contribute to low peak achieved FEV₁ that ultimately leads to the development of airflow obstruction.

Although the prevalence of self-reported, physician-diagnosed COPD is high (about 15 million adults in the USA), the actual disease burden might be much higher because a larger proportion of patients might have undiagnosed COPD. Data from the US National Health and Nutrition Examination Survey (NHANES) show that, in 2007–10, about 28·9 million (13·5%) adults had evidence of obstruction on the basis of spirometry, suggesting that over half of the people in the USA with evidence of COPD have not been diagnosed. Despite high prevalence estimates of undiagnosed COPD, the US Preventive Services Task Force does not recommend the use of spirometry for population-level screening of adults for COPD, because a high number of individuals would have to be screened to identify one person with COPD, and a diagnosis of airflow obstruction with spirometry would bring low potential benefits, which was deemed by the task force to be at most deferral of a first exacerbation.

Although US adults with evidence of obstruction in the absence of a COPD diagnosis tend to report better health status, have fewer comorbid diseases, and have better lung function than do diagnosed individuals, they also have a higher risk of death compared with those without obstruction (hazard ratio 1·23 [95% CI 1·08–1·40]). Whether spirometry improves smoking cessation rates has mixed evidence, although vaccination of even patients with mild COPD against influenza has been shown to result in cost savings, and a pneumococcal and influenza vaccination combination was reported to reduce the frequency of COPD-related hospital admissions and all-cause mortality. Therefore, some have argued that a so-called case-finding approach with targeted spirometry in symptomatic, at-risk individuals might be the most cost-effective approach. However, the optimal way to do so has not been established.

COPD accounts for a considerable amount of morbidity in the USA, including 10·3 million physician office visits, 1·5 million emergency department visits, and 699 000 hospital discharges in 2010. In 1999–2010, COPD hospital discharge rates decreased from 39·9 per 10 000 population to 31·6 per 10 000 in men and from 40·2 per 10 000 to 32·2 per 10 000 in women. Age-adjusted hospital discharge rates varied substantially by state, ranging from 3·62 per 1000 population in Utah to 22·50 per 1000 population in West Virginia.

COPD is extremely costly, with the total costs from hospital admission and absenteeism in 2010 estimated at $36 billion. However, the actual cost could be nearly double that estimate, because people with COPD often have other comorbidities and hospital treatment costs that are typically difficult to specifically attribute to a particular disease. For example, among 10·3 million adults with diagnosed COPD in 2010, medical costs of $101 billion were incurred, of which $72·7 billion was directly attributed to COPD. As has been noted above, a substantial proportion of people remain undiagnosed and have a higher risk of mortality than individuals without airflow obstruction. Thus, the true cost of COPD might be much higher than these estimates. COPD has been the third leading cause of death in the USA since 2008 and worldwide since 2010. These numbers might also be underestimated, because many people with severe
COPD have their deaths attributed to causes other than respiratory disease. \(^9\) Hence, the growing burden of obstructive lung disease in USA is, without doubt, a major concern for all stakeholders in the health-care system (panel 1 (box1)).

**Panel 1**

**Key messages**

- COPD is a considerable cause of morbidity in the USA and disproportionately affects individuals with low socioeconomic status.

- Patient access to disease-state education, drug therapies, and non-pharmacological interventions (eg, pulmonary rehabilitation) needs to be improved.

- Insufficient disease-specific training remains a problem for health-care providers, particularly for primary care providers, who give the majority of COPD care.

**Key challenges**

- A considerable proportion of individuals with COPD are undiagnosed, but there is no best approach for identification of these patients. Diagnosis in primary care is often done without the use of spirometry, leading to both overdiagnosis and underdiagnosis.

- Care coordination remains a substantial challenge, particularly for patients who are cared for by both primary care providers and specialists, and who transition frequently between outpatient and inpatient settings.

- The absence of written care protocols for inpatients, as have already been established for other diseases, has inadvertently led to COPD having low priority in hospital care.

- Selection of COPD therapy in primary care is often inconsistent with guidelines or evidence, resulting in suboptimal or no treatment for many patients.

- Pulmonary rehabilitation is rarely a part of management in primary care.

- New initiatives to improve care coordination, patient empowerment, and health outcomes should seek input from patients and their caregivers, and be patient-centred to be truly successful.

- Potential ways to improve care include increased exposure to clinical guidelines during medical training, modulation of electronic medical records to provide point-of-care guidance, and increased engagement of primary care providers in COPD guideline development and dissemination.

**Present state of COPD care**

The patient perspective
The COPD Foundation (http://www.copdfoundation.org/), which was established in 2004 to improve the lives of all those affected by COPD, maintains several active communication channels with the patient community, the feedback from which, along with patient surveys and focus groups, has informed this Commission. Given the high morbidity and mortality associated with COPD, it is surprising that the perspective of patients with COPD is not solicited more often. Further dampening this discourse, many patients also perceive a certain degree of stigma associated with their so-called self-inflicted disease, lessening their enthusiasm to advocate for themselves. Although many patients believe that COPD care is better today than 5, 10, or 20 years ago, partly because of advances in treatments, they are usually diagnosed late in the course of disease, provided with little education about disease state, and struggle to access the treatments and social support to improve their health and quality of life. However, every patient is unique. There is no typical patient experience; rather, a multitude of voices are represented here. The present state of COPD care in the USA from the patient perspective also varies substantially with disease stage, geographical location, socioeconomic status, and the type of health-care system from which a patient is receiving care. Of note, a major theme throughout this Commission that affects the patient’s care experience is the evolving push towards value-based payment models versus standard fee-for-service health-care delivery.

Diagnosis

For more than 10 years, the COPD Foundation has provided free COPD screening for those at-risk, to identify the estimated 24 million patients and to increase awareness among patients and care providers. Many patients report some type of delay in diagnosis. Results from the 2014 COPE (Chronic Obstructive Pulmonary Experience) survey showed that patients recall having symptoms, on average, 2 years and 9 months before diagnosis. In this survey, patients cited a combination of issues that led to this delay, including their own behaviour and that of their health-care providers. Patients attributed early symptoms to decreased fitness, being overweight, or ageing, especially individuals who were current or former smokers. Patients also reported self-treatment by reducing or avoiding behaviours that induce shortness of breath, noting that they only initiated the discussion with their primary care provider once the symptoms became an impediment to daily living.

The emotional impact of delayed diagnosis on patients cannot be overstated. While it is difficult for anyone to cope with a new diagnosis of an incurable, progressive chronic disease, it is even more difficult when the patient is additionally being told, at the time of diagnosis, that a substantial proportion of lung function has already been lost. Patients who experience a diagnostic delay need to cope with the harsh reality that interventions could have been taken had the diagnosis been made earlier. Patients have a mixture of reactions to a new diagnosis of COPD. Current smokers wonder whether they would have quit sooner had they known earlier, former smokers look back with regret that they did not quit sooner, and never-smokers try to pinpoint the exposures that could have caused their disease. Nearly all patients with a new diagnosis wonder what would have happened if they had known 5, 10, or more years earlier. Smoking cessation has been shown to have a beneficial effect on lung function at any age, but the benefit is more pronounced in early quitters. The emotional impact of diagnosis is often a barrier to the initiation of immediate lifestyle modifications and treatment regimens that are necessary to manage their health and slow the progression of disease.

Disease education
Patients report severely inadequate education about their disease, prognosis, treatment options, strategies for self-management, and more. Results from the COPE survey\textsuperscript{21} showed that patients need more education and better communication with physicians to improve self-management and prevent exacerbations. Most patients consider themselves less than adequately informed about COPD and treatment options,\textsuperscript{24} and conversations on COPD360Social (http://www.copdfoundation.org/COPD360social/Community/Activity-Feed.aspx), the COPD Foundation patient blog, highlight dissatisfaction with the education provided by physicians, particularly at the time of diagnosis.

Patients report gaps in core knowledge, such as not receiving information about expectations after diagnosis, being told inaccurate information regarding prognosis and treatment options, and almost no education on self-management skills. They wish they had learned these skills early on—eg, how to spot early signs of an exacerbation and what to do about it, and how to stay active and cope with episodes of anxiety and dyspnoea with techniques such as pursed-lip breathing. Despite the importance of avoiding exacerbations, the COPE survey\textsuperscript{21} found that nearly two-thirds of patients did not know much about exacerbations and 16% did not know what an exacerbation was at all, highlighting the fundamental inadequacy of current patient education.

Many patients report they received important education outside the practice setting, via pulmonary rehabilitation and self-directed sources such as online or in-person support groups.\textsuperscript{20} Many agree that the most helpful education they received was delivered by respiratory therapists, either in hospitals or in pulmonary rehabilitation. However, they complain that they rarely have access to respiratory therapists outside these settings, and the patient community is actively advocating for expanded access in efforts to change federal policies.

Many patients are ultimately left to find answers on their own, primarily via the internet. The COPD patient community is increasingly using the internet to interact with their family members and for disease-related support. The COPD Foundation found that only 14% of survey respondents did not use email, and only 22% did not maintain some type of social media account. Although there is still a large proportion of the COPD community that needs to be reached via mail and other community access points, patients perceive an increasing value of online information and support.\textsuperscript{25} An internet search by the COPD Foundation in 2014 found nine online communities dedicated to COPD and countless other health-related websites containing COPD information—eg, from pharmaceutical companies, medical equipment companies, and hospital system websites. Despite the availability of information, patients need to know how to access the information, how to judge its credibility, and how to understand and implement the information. Learning what needs to be done is different from understanding and believing the advice that is given and engaging in appropriate self-management behaviours, such as smoking cessation or taking medication as prescribed.

Access to drug treatments

Overall, results from the COPE survey\textsuperscript{21} showed that 82% of patients were satisfied with their treatment plan, yet a mere 12% responded that their disease was completely controlled.\textsuperscript{21} Results from other patient surveys by the COPD Foundation revealed several patient needs that are related to drug therapy: first, the desire to understand what treatments are available and what the benefits, risks, and alternatives of different
options are; second, the desire to easily access the treatments that they and their doctors have decided are best; and third, the desire to have treatments that have a greater effect on their symptoms or that will halt disease progression.

The first challenge—understanding the different treatment options—is related to the inadequate education provided to patients and a general paucity of guideline-based care for COPD on the part of physicians. Patients need assistance to consider the various treatment options, combinations, and products that could work best for them. They also express a need for increased flexibility of communication with their health-care providers to give feedback and adjust treatment regimens. Improved education and communication could enhance adherence. Roughly 37% of US respondents in the Continuing to Confront COPD survey agreed that having multiple inhalers made it difficult to follow treatment regimens.

However, the biggest challenge by far is actually having access to these drug treatments. About 50% of total COPD treatment-related costs are paid for by Medicare, 25% by Medicaid (a government insurance programme for families and individuals with low income and few resources; and the largest source of funding for medical and health-related services for individuals with low income in the USA), and 18% by commercial insurance plans, with the rest being spread among various other programmes. Access to drugs has improved for many patients, as a result of Medicare Part D that provides reasonably affordable prescription insurance plans. However, in the past 10 years, trends towards cost containment at all levels have led to restrictive formularies and increased co-pays for many COPD treatment options for which there are no lower cost options. Insurers frequently create formularies that include only one brand of drug in a particular class. Further complicating matters, the covered drug frequently changes without warning. Patients are often notified by their pharmacy or via a letter that they have to switch medications, and the alternative treatment is not always suitable. These changes frequently cause considerable confusion and frustration for patients and health-care providers. Even when the drug is covered in the insurance plan, patients often face co-pays of $75–125 or more per drug. As a result, many patients admit to skipping days, not taking full dosages, and not collecting refills. Finally, even when patients have access to these drugs, existing treatment options still do not abolish symptoms. 86% percent of enrollees in the COPD Patient Powered Research Network chose to participate in research because “needing to breathe better” was their number one priority.

Access to non-pharmacological treatments

When patients in the COPD360Social community were asked to describe their biggest success, nearly all mentioned pulmonary rehabilitation. Non-pharmacological treatments have a large role in the quality of life and functional status for patients with COPD. Unfortunately, in the US health-care system, access to pulmonary rehabilitation and other non-pharmacological treatments can be challenging, even among insured patients.

The Medicare reimbursement structure for oxygen delivery devices has led to medical equipment companies providing few options and inadequate service and education. Limited access to convenient oxygen delivery devices results in stress, restricted mobility, and poor adherence. Patients are frequently given equipment that is not a good match for their lifestyles, limiting their mobility outside their home and worsening physical function; they often decide not to use their oxygen delivery device as
prescribed, leaving them susceptible to low saturation levels and other potential negative health effects. Patients also report negative feelings about these devices, especially when first prescribed, because of social anxiety or embarrassment about using such devices in public.

By contrast, pulmonary rehabilitation provides an outlet for patients to interact with their peers, to gain valuable education provided by respiratory and physical therapists, and to reap the physical benefits of monitored exercise. Unfortunately, there is a severe shortage of available pulmonary rehabilitation programmes, limited physician referral to existing programmes, and often resistance from patients to initiate participation. Inadequate reimbursement for pulmonary rehabilitation has discouraged health systems from investing in rehabilitation programmes, and supervision requirements make the establishment of outpatient stand-alone facilities (ie, facilities that are not affiliated with hospital systems) difficult. Patients who have participated in pulmonary rehabilitation typically become convinced of its effectiveness and wish it could continue with less cost.

Care coordination
As this Commission reflects, changes to care coordination and other so-called value-based health reforms are underway. However, patients are often noticeably absent from dialogues on these topics. Patients want their primary care providers, specialists, and the various organisations from which they receive care to communicate with each other, and they want to be able to easily access care. Most of all, patients want to be asked what matters most to them and to have their care personalised to their individual needs and goals. Patients should be at the centre of discussions to better coordinate care and manage transitions of care.

The caregiver perspective
Since COPD is a chronic, progressive disease affecting adults in mid-to-late life, caregivers have substantial responsibilities, but their role has received little attention so far. The population is not well characterised, but results from a 2010 study showed that just over 50% of caregivers of patients with COPD were spouses, 27% were children, and 19% were other family members and friends. Similar to the patient perspective, the caregiver perspective also varies greatly depending on an individual's situation—eg, extended social support, financial stability, and range of responsibilities.

Although little research has been done on how caregiver burden differs for COPD compared with other chronic diseases, there are similarities but also some profound differences. In addition to the expected physical and emotional toll that comes from increased responsibilities associated with caregiving—eg, coordinating food, doctor appointments, and travel—caregivers of patients with COPD also report challenges related to use of oxygen delivery devices, low education levels about the disease, and, in some cases, frustration about the patient's unwillingness to engage in crucial lifestyle modifications such as smoking cessation and routine exercise. Caregivers struggle with managing various hospital admissions and coordinating care across multiple settings as the disease progresses. Without access to comprehensive support and education, caregivers frequently struggle on their own to become informed about the disease, treatment options, oxygen delivery, and resources. Simpson and colleagues found, through caregiver interviews, that many caregivers cope by adopting the attitude of “one day at a time”. Caregivers in this
study, and many in the COPD Foundation’s community who have helped to shape caregiver outreach programmes, describe progressive challenges as the patient comes to terms with losing their previous identity and independence, and the corresponding increase in responsibility and insecurity felt by the caregiver.

With the increased emphasis on keeping patients out of the hospital, caregivers are likely to shoulder an even greater burden of responsibility in the future, especially when patients have exacerbations. By excluding the needs of caregivers when designing COPD-specific programmes, a big opportunity is missed. Holm and colleagues reported that caregivers wish to participate in clinical interventions alongside the patients whom they care for. Three clinical trials funded by the Patient-Centered Outcomes Research Institute specifically include caregivers in patient-centred interventions (NCT02098369, NCT02114515, and NCT02036294).

Even long-distance caregivers might wish to offer their support for patients with COPD. For example, a pilot project at the Carolinas Health System (Charlotte, NC, USA) allowed patients to connect with their family members via an iPad three times per day to discuss treatment adherence and how they were feeling, and to assess unmet needs. New systems are being established monthly that allow remote monitoring that can range from use of the coffee maker to oxygen saturation. These new developments will help to shape caregiver roles in the future. Additionally, efforts to develop alternative payment models that reward high-quality care should create incentives for caregiver engagement in care planning and coordination, with more effort placed on ensuring that caregivers themselves receive the support they need to stay healthy, cope with stress, and keep their own finances in order, so that they can complete their caregiving duties.

**Nursing provider perspective**

Along the continuum of COPD care, patients will typically encounter multiple types of health-care providers. More often than not, nursing providers are central to many aspects of COPD care, and therefore it is important to explore and understand the role of nursing providers.

**Education**

As is the same in most countries, in the USA, nurses interact with patients in both outpatient and inpatient settings. However, most nurses receive only basic education regarding the care of patients with pulmonary disease. Educational backgrounds vary widely because, in the USA, nurses might have either a 2 year associate degree or a 4 year baccalaureate degree in nursing. Data from a cross-sectional study suggested that hospitals with a higher proportion of nurses with baccalaureate or higher degrees have better patient outcomes. Results from a retrospective study showed decreased readmission rates and shortened lengths of stay in inpatient settings in which the nurses are more highly educated. In the USA, roughly 55% of nurses held a baccalaureate or higher degree in 2013. However, even with increased training time, expertise for nurses in any specialty, including COPD, develops from on-the-job training. Many general-care nurses are not familiar with appropriate inhaler technique, a core component in COPD care. The more exposure nurses have to the educational needs of a population, the more skilled they become. Few opportunities exist for nurses to obtain additional training in COPD care; such training, if available, is typically delivered through 1 day seminars or online continuing education programmes. Hence, nurses who have additional training in COPD care are mostly those who have developed expertise by working in pulmonary clinics.
Staffing

In the outpatient setting, the nurse's role ranges from patient education, communication between patients and health-care providers, and assistance with procedures. Ambulatory care employs 25% of the nursing workforce, and nurses assist with the 994 million visits per year to health-care providers. Patients with COPD have to compete for the attention of nurses caring for patients with other medical conditions. A nurse's time is often prioritised to those needing immediate care, followed by routine tasks and, lastly, less-urgent activities that require more time, such as patient education; therefore, the time left to patient education depends on staffing. In general medical clinics, direct interaction with patients with COPD typically occurs only when specific educational needs are assigned (eg, inhaler demonstration and coordination of oxygen therapy at hospital discharge). In pulmonary clinics, nurses are also responsible for drug administration, education regarding inhalers, and triaging of immediate patient issues. However, even in pulmonary clinics, the nurse–patient interaction might be brief or fragmented. In many instances, nurses are supervising the activities of other nurses and medical assistants. As health-care systems strive to reduce costs and increase patient visits, medical assistants are increasingly on the front lines in ambulatory care, with fewer registered nurses providing the skilled care needed in the outpatient setting. Such a change might result in missed opportunities for a trained nurse to assess the patient for urgent issues or to identify family or social issues that might affect care, which is particularly important in COPD. Although nurses in pulmonary clinics have a more defined role and greater familiarity with COPD-specific factors than do general-care nurses, the volume of work and patient load remain high, and the amount of time a nurse can spend with individual patients is still limited.

For inpatient nurses, the time available to spend with patients also depends on staffing ratios and disease acuity, which varies by facility. Nurse staffing (eg, an increased registered nurses to staff ratio) has been shown to affect outcomes such as mortality in inpatients with heart failure. In a busy unit with suboptimal staffing, nurses are too often involved in crisis management, leading to burnout and job dissatisfaction. Nurses' priorities are to ensure that measurements of intravenous therapy and vital signs are done and that treatments are administered, because their performance is measured by these metrics. Any extra time available is spent on charting, interaction with patients and their families, and discharge planning, but this time is unaccounted for in their performance review and is hence not incentivised.

COPD-specific inpatient protocols

Other factors further result in certain diseases being prioritised and gaining more of a nurse's attention. For example, if a plan of care or protocol is in place for the assessment and care of a patient with diabetes, then this plan or protocol is likely to be completed more routinely than assessment of changes in breathlessness in a newly admitted patient with COPD, for whom no protocol has been written. At present, the use of standardised care protocols in COPD care for nurses, physicians, or other care providers is practically non-existent; by contrast, inpatient protocols for managing diabetes and heart failure, for instance, are much more common than those for COPD. The combined use of checklists and protocols for treatment of asthma, COPD, and acute coronary syndrome in the emergency department has been shown to increase provider compliance with standards of care. Hence, development of standard operating procedures for nurses and other providers has the potential to improve COPD care through both standardisation of care and an increased awareness of the disease state.

Care coordination
COPD has not been a priority in inpatient settings. Team ownership for many aspects of care is undefined, and nurses might collaborate with physicians, respiratory therapists, physical therapists, or pharmacists in COPD care. Unfortunately, without coordination, certain aspects of care might be neglected if they are assumed to be the responsibility of someone else. Having multiple care providers working in isolation results in fragmentation of care. For example, the role of instructing patients in inhaler use might be designated to a pharmacist or a respiratory therapist instead of a nurse, and this aspect of care will become less of a priority for the nurse, who will become less skilled. The institution of bedside rounds with a multidisciplinary approach has been shown to enhance communication and improve outcomes such as length of stay. In chronic disease management, the crucial role of a care coordinator for effective care is well established.

Increasing attention has been directed to the high rates of COPD readmissions after hospital discharge, and this is a key area in which nurses can play a part. In particular, discharging patients from the hospital after exacerbations can be complex and challenging for nurses. During an admission, hospitalists, pulmonologists, and primary care providers might all be involved in the care of the same patient, resulting in confusion for the patient and the nurse as to who is responsible for directing care at the time of discharge. This fragmentation and other COPD-specific factors make the discharge of this patient population particularly challenging, because patients with COPD require considerably more continuity than the health-care system provides. For instance, the type of inhalers a patient uses during their time in hospital and the one that they will be using at home after discharge are often different because of differences in hospital formularies and insurance plans. Set-up of home oxygen therapy also poses unique logistical challenges. Furthermore, the decision of when a patient is ready for discharge is often difficult to make; as a result, many such decisions are made on the day of discharge as opposed to several days in advance, leaving the patient, their families, and staff with little time to prepare for the discharge. Patients and their families often do not feel ready to be discharged, which puts the nurse in a difficult position. In some studies, having a perceived “low readiness for discharge” has been associated with patient difficulty in coping after discharge, confusion, and increased readmission rates. Therefore, care coordination remains a substantial challenge for nurses caring for patients with COPD.

Improved follow-up and outpatient care have also been identified as key factors that can help to reduce admissions and readmissions, suggesting a possible role for nurses in designated post-discharge clinics or telephone lines to facilitate follow-up and outpatient care. However, most health systems do not have such clinics, nor are they set up to provide nurses with additional COPD-specific training. Several good models of nursing care for patients with COPD are in place in the Netherlands and the UK, where nurses frequently have a prominent role in outpatient management. The use of nurses as mentors to increase self-management behaviours has been shown to improve many outcomes, including a longer time to readmission. Partnership-based nursing care—which incorporates an open, caring dialogue between nurses, patients, and families to integrate establishment of family involvement, assistance with living with disease symptoms, and facilitation of access to health care—has been suggested to be beneficial for both patients and their families if the complex needs of patients are adequately addressed.

Respiratory therapist perspective
Caring for patients with COPD is a core skill in the training of respiratory therapists, although some also receive additional advanced training in COPD care. The number of respiratory therapists practising in the USA is increasing, with approximately 173,000 according to a 2014 survey, compared with 146,000 in a 2009 survey. Most respiratory therapists in the USA are employed in acute care facilities—according to the American Association for Respiratory Care 2014 Human Resource Study, nearly 75% of respiratory therapists work in inpatient settings, compared with 4% in outpatient facilities, 2% in physician offices, and 6% in home care services.

Central role to inpatient COPD care

As most respiratory therapists in the USA work in inpatient settings, they have a central role in inpatient COPD care. Respiratory therapists are familiar with the emergent administration of measures to relieve dyspnoea, including supplemental oxygen, aerosolised rescue drugs, and the initiation and maintenance of invasive and non-invasive mechanical ventilation. In addition to education about disease state and self-management, most respiratory therapists also provide smoking cessation counselling as appropriate, home oxygen dosing and oxygen device education, and training on use of respiratory drug devices and medication reconciliation. The number of therapeutic interventions provided to inpatients usually depends on the patient’s condition and length of stay, although differences in staffing models and workloads will affect how much time is dedicated to these activities. Patients with acute critical illness in the setting of chronic disease such as COPD are increasingly being transitioned to long-term acute care facilities before returning home after prolonged hospital stay, and more respiratory therapists are working with patients in this setting.

Expanding outpatient roles

Despite the small number of respiratory therapists in outpatient settings, their importance, particularly as part of pulmonary rehabilitation, cannot be understated. Pulmonary rehabilitation is a comprehensive programme that incorporates exercise training, education, and psychosocial support for patients with chronic respiratory disease, with the goal of improving symptoms and functional status. The benefits of pulmonary rehabilitation in patients with COPD include improvements in quality of life, exercise tolerance, and reductions in health-care use. Rehabilitation programmes support independence for daily activities and improve the patient’s ability to participate in self-care activities. Equally important, particularly for patients with advanced disease, is that rehabilitation helps to reduce the burden of dyspnoea and fatigue, and improve muscle function. Unfortunately, the availability and use of rehabilitation programmes are still low. A main reason from the patient perspective is the inability to access transportation to facilities, which might be up to an hour away. From a system perspective, health-care providers frequently have insufficient awareness or knowledge to provide referrals to such services. Further complicating matters, in 2008, Medicare issued a national coverage determination specifying that COPD patients with FEV1 of up to 80% predicted can qualify for pulmonary rehabilitation. As part of this provision, a physician needs to be immediately available and accessible at all times during pulmonary rehabilitation. Such a requirement has been particularly difficult for some facilities to fulfil, particularly for programmes that are not affiliated with hospitals and that offer services in remote locations. Therefore, the American Association of Cardiovascular and Pulmonary Rehabilitation and the American Association for Respiratory Care are promoting legislation that would remove this particular requirement, noting that this creates access issues in rural areas and other areas with physician shortages, and unnecessary costs for low-revenue programmes.
Given the increased focus on care coordination and reduction of readmissions, respiratory therapists are also becoming involved in outpatient management programmes, telemedicine, and home care. Furthermore, evidence supporting a role for non-invasive positive pressure ventilation (NPPV) in hypercarbic COPD is also likely to increase the need for respiratory therapist’s expertise in outpatient settings. However, Medicare continues to reduce reimbursements for services from durable medical equipment companies that provide oxygen delivery devices and ventilator equipment, and does not reimburse for respiratory therapist services related to these equipment. Therefore, although expansion of respiratory therapist services has potential benefits for patients with COPD, the funding of patient access to such services, particularly in the outpatient setting, remains a challenge.

**Primary care perspective**

Most patients with COPD in the USA receive care from family physicians and general internists or general practitioners, with a modest but increasing proportion of care provided by nurse practitioners and physician assistants. Because of the high burden of disease, COPD is a substantial and growing part of all adult primary care practices. Hence, for a primary care provider seeing 20–40 adults daily, 1–4 of those adults will have COPD, of whom half will have unrecognised COPD.

**Diagnosis**

Many barriers continue to delay the recognition and diagnosis of COPD in primary care (figure 3). Complaints of respiratory symptoms and activity limitations might be ignored by both patients and primary care providers, blaming dyspnoea on age, lack of fitness, obesity, or smoking. Some primary care providers believe that they have little to offer patients with COPD, especially those who are not ready or willing to consider smoking cessation or who are not active smokers. Although awareness of COPD and the potential value of pharmacotherapies is increasing, substantial knowledge gaps still exist regarding the need for and ability to complete in-office spirometry to confirm the diagnosis and the benefits of pulmonary rehabilitation on the patient's quality of life, functional status, and lung function.

![Figure 3](image)

**Figure 3**

Barriers to diagnosis of COPD relate to both patient-specific and care-provider-specific factors

COPD=chronic obstructive pulmonary disease. Adapted from Haroon and colleagues.
Routine population-based screening with spirometry is impractical, not cost-effective, and unlikely to improve outcomes. Case finding with questionnaires or peak flow testing, or both, can be used to narrow the population who should undergo further testing with spirometry, but the best way to implement this has not been established. 33–50% of people with newly identified COPD have mild disease, many of whom are not sufficiently symptomatic to require therapeutic intervention other than smoking cessation, which should be a part of care and management for all patients who smoke. Results from these studies suggest that the symptoms identified by case-finding questionnaires might also be different from those reported to physicians. The diagnosis of COPD in primary care most often occurs when patients present with frequent episodes of bronchitis or bad colds that might be COPD exacerbations. A substantial proportion of patients with COPD remain undiagnosed until an exacerbation results in hospital admission. Patients and families often do not report symptoms of cough, dyspnoea, and decreasing functional status, assuming that the symptoms are “normal smoker’s cough” or a result of ageing, obesity, or being unfit. Primary care providers often fail to ask, within short consultation times, specific questions about symptoms, functional status, or changes in ability to do activities of daily living. By the time a diagnosis is made, the average loss of lung function is 40–50% of predicted FEV₁ (ie, moderate to severe COPD) and usual activities are considerably restricted, confirming the substantial delay in diagnosis.

The definition of COPD is based on a combination of symptoms, exposure to risk factors, and abnormal spirometry with confirmed obstruction (FEV₁/FVC <70% predicted after bronchodilator administration). However, for many primary care providers, COPD continues to be diagnosed clinically without confirmation by spirometry. 20–50% of people diagnosed with COPD in primary care have had at least one spirometry assessment, although this proportion seems to have increased in the past 5–7 years. Of note, many primary care providers are more comfortable with the diagnosis and management of asthma than COPD, and might label patients’ chronic respiratory symptoms as asthma rather than considering and assessing for a diagnosis of COPD.

However, improvements in the rate and accuracy of COPD detection in primary care will require more than the simple provision of spirometry equipment to these practices. Primary care providers report many barriers to the use of in-office spirometry other than the unavailability of the equipment, including a shortage of trained medical assistants to perform testing, lack of training in results interpretation, insufficient time to do the test, and low perceived benefit of having the information. Of special concern is the requirement by some guidelines that the diagnosis of COPD be based on post-bronchodilator assessment, which can require up to 40 min and might be disruptive to the workflow of a busy primary care practice.

Even when spirometry is performed, primary care providers are still prone to overdiagnosis and underdiagnosis of COPD. Underdiagnosis occurs when spirometry testing is of poor quality, resulting in diagnoses of so-called restrictive lung disease when the patient’s effort is inadequate, and overdiagnosis can occur when post-bronchodilator testing is not completed or when interpretation is inconsistent with standard definitions. To overcome the low confidence in interpretation of spirometry results, some primary care providers rely on the automated interpretations available on most handheld spirometers. Such automated interpretations can be helpful when they report poor-quality manoeuvres or insufficient reproducibility on repeated testing. However, these interpretations might also lead to further problems—eg,
they might suggest that changes in forced expiratory flow of 25–75% are indicative of obstructive lung disease or that the absence of post-bronchodilator changes in FEV$_1$ means that bronchodilator therapy is not warranted.  However, with training and support, primary care providers can perform valid and reliable spirometry testing that is comparable to that in pulmonary function laboratories (up to 90% validity), which can inform clinical decision making, although not all practices achieve high validity rates. Ongoing support is a key factor in improving use and quality of spirometry in primary care.

To overcome the disruptive aspects of spirometry testing in primary care, in the UK and Australia, COPD clinical nurses travel between practices to provide spirometry and clinical care assessments. Some of these services have been associated with increased diagnostic accuracy, enhanced adherence to guideline-directed management, and decreased rates of exacerbations. Whether this approach would translate well into the US practice environment is not clear because of long geographical distances and multiple payers. The UK has also developed a programme to increase reimbursement for spirometry-based COPD diagnosis and management. Early results suggest that financial incentives might accelerate adherence to quality metrics such as spirometry use.

Therapy and guideline implementation

Guidelines outlining management of COPD are widely available. Despite slightly disparate classifications of disease severity based on lung function, symptoms, functional impairment, and exacerbation frequency, all guidelines suggest a hierarchy of drugs, beginning with short-acting bronchodilators, the first-line treatment in all COPD guidelines, through to using combination therapy as the disease progresses. Despite this clear indication-based framework for drug selection, many primary care providers either choose to deviate from guideline-indicated treatment or are unaware of these guidelines.

Undertreatment is not limited to mild COPD and has been reported across all severities, with up to 12% of patients with severe disease receiving only a short-acting bronchodilator. No patient with COPD symptoms should be without any treatment, but short-acting bronchodilator monotherapy is indicated only in patients with mild to moderate COPD who have infrequent symptoms. Overtreatment has also been well described in many studies of primary care practices in the USA. Although previously the decision to use inhaled corticosteroids (ICS) was based solely on severity assessed by FEV$_1$, their use is now considered appropriate for individuals with less severe COPD but frequent (>2 per year) or severe (requiring hospital admission) exacerbations. The asthma–COPD overlap syndrome has been established as an additional indication for the use of ICS for patients with COPD. Yet, even with these expanded criteria, more than 30% of inhaled corticosteroid prescriptions from primary care providers are without clear indications. Although ICS can be safely discontinued in patients in whom they are not indicated, step-down therapy in COPD is rarely initiated by primary care providers.

Use of non-pharmacological interventions for COPD varies widely. Yearly influenza immunisations are common but not universal. Smoking cessation support appears to be increasing as new therapies become available, but it is still regarded by many primary care providers as a substantial burden. Despite the well established benefits of pulmonary rehabilitation, referral to these programmes is
uncommon among primary care providers. Primary care providers do prescribe oxygen therapy and might do so without the support of specialists or respiratory therapists, especially in small, geographically remote communities. The complexity of selecting appropriate patients, devices, and prescriptions make oxygen therapy an involved process. New regulations and reimbursement limitations imposed on oxygen suppliers have compounded this problem by restricting the in-home support given to patients and their families, and the educational support provided to physicians (discussed further in Part 4). Therefore, many primary care providers prefer to refer all candidates for oxygen therapy to pulmonologists.

Most COPD guidelines also recommend the use of standardised tools for diagnosis, severity assessment, therapy initiation, and disease monitoring. Few primary care providers have integrated any of the symptom assessment tools into their daily practice. Barriers to their use are likely to be similar to those for the use of spirometry—namely, unfamiliarity with the tools, perceived lack of access, disruption of practice routines, and time constraints. In primary care practices, such tools have become available and are often recommended for almost all chronic diseases, making it almost impossible to incorporate all suggested tools into a short visit for patients with multiple chronic diseases. The use of an action plan has not yet become an integral part of COPD management in US primary care.

Patient medication adherence

Inhaled drugs are central to COPD therapy, but unfortunately inhalers are also a major source of poor adherence—both intentional and unintentional—because of inadequate inhaler technique, and such poor adherence can affect therapeutic outcomes. Errors in inhaler technique use are common with all types of inhalers, with some reports of higher error rates with metered dose inhalers than with dry powder inhalers. Many patients receive prescriptions from primary care providers for more than one type of inhaler, but they are seldom taught the inhaler technique appropriate for each type. Loss of correct inhaler technique over time is also well documented, but few primary care practices assess and re-teach inhaler technique on a regular basis. Medication adherence that is unrelated to inhaler technique is also a substantial concern, but it is uncommonly addressed by primary care providers. New US requirements for medication reconciliation might bolster efforts to assess and potentially address the reasons behind poor adherence, including forgetfulness, concerns about side-effects, inability to pay for or access drugs, or an absence of agreement for need of the drug. More time will be needed to determine the full effect of these changes.

Care coordination

People with COPD are often long-term smokers and many have other risky behaviours, resulting in an increased risk of multiple chronic conditions. Additionally, the presence of COPD is also associated with an increased risk for other chronic diseases (appendix p 2 (sec1)). The primary care provider is responsible for management of all of these conditions, often within short visits. With a plethora of patient and family needs, quality metrics to be met, and perceived hierarchy of urgency, COPD frequently receives less attention than do conditions such as heart disease or diabetes, except during exacerbations. Furthermore, as COPD is a slowly progressive disease, patients might adjust their expectations to fit their capabilities; therefore, they might not complain about symptoms or might attribute them to the more widely discussed conditions, such as heart disease and obesity. With the considerable
time constraints, primary care providers might also choose to address conditions with which they are more familiar or conditions for which they are specifically held to quality metrics by payers, such as diabetes and cardiovascular disease.

As with most chronic conditions, care coordination can improve both processes and outcomes of COPD management for patients, health-care professionals, and health systems. The essential element of care coordination is good communication between health professionals, patients, and caregivers to enable access to required and desirable services. Care coordination should be based in the patient’s medical home, which for most patients is the primary care site. Care managers, home health workers, community health workers, and practice nurses are important additions to primary care systems. These individuals can track the patient’s progress and needs of the patient and caregiver that are related to services initiated within primary care, such as medications or referrals, smoking cessation, immunisation provision, spirometry assessments, and follow-up visits. Furthermore, the people overseeing care coordination can also ensure that referrals and follow-up information are shared between primary care and specialty care, emergency departments, hospitals, and pulmonary rehabilitation programmes. Too often, patients move between health-care facilities without adequate information transfer. Care coordinator or practice nurses can collect reports from the emergency department and hospitals, and recommendations from specialists, and they can work with pharmacists for medication reconciliation to avoid duplications and missing therapies. However, these care teams require financial support, because such activities are typically not directly billable. As discussed in Part 2, payers are beginning to change reimbursement structures to support such work. Until these changes are implemented, primary care providers will find it difficult to prevent both missed care opportunities—eg, pulmonary rehabilitation referrals and inhaler technique education—and overlapping, redundant, and conflicting care recommendations from multiple care providers.

End-of-life care
Few people with COPD receive specific end-of-life or hospice care, despite the severe symptoms and high caregiver burden that frequently accompany very severe disease. Palliative care and hospice care (both discussed in Part 4) have been shown to decrease symptom burden, improve health-related quality of life and patient satisfaction, and reduce costs associated with end-of-life care. Although the goals of palliative and hospice care are to provide support to people in the final phases of a terminal illness, with a focus on comfort and quality of life rather than cure, the term hospice also refers to a specific type of benefit through insurance coverage that requires a physician to certify that a patient will die within 6 months if the disease takes its usual course. Unfortunately, many primary care providers are uncomfortable with such a prognosis and the discussion of end-of-life issues with patients, fearing they are giving a message of hopelessness. Patients are often resistant to such discussions until they have a serious event. Unfortunately, outside of the hospice setting, palliative care services in the USA receive little reimbursement, making it essentially unavailable for most people with COPD. Pulmonary rehabilitation, which addresses many of the same issues as palliative care, might be more accepted by patients and their families, since it is often viewed as preventive and progressive therapy and has the additional benefits of the incorporated exercise programme; however, pulmonary rehabilitation is also underused by primary care providers.

Hospital medicine perspective
Most COPD-related costs in the USA are incurred by inpatient care. In the USA, nearly 1 million patients are admitted to the hospital for acute exacerbations per year, and an additional 3.8 million individuals with COPD as a secondary diagnosis are also admitted to the hospital each year—suggesting that about 20% of inpatients have a COPD diagnosis. 145 3.5% of all hospital admissions are estimated to be caused by exacerbations of COPD, and this rate has seen an increase in 2006–10. 48 Furthermore, more than 20% of patients admitted with exacerbations are readmitted within 1 month of discharge. At present, COPD is the third leading cause of hospital readmission. 48 146

Hospitalist care

Hospitalists are physicians who specialise in patient care in the hospital setting, and are providing a progressively growing share of inpatient care. Most hospitals in the USA employ hospitalists, and an estimated 48,000 hospitalists exist in the country. 147 About a third of Medicare inpatients are cared for by hospitalists, 148 with the rest of inpatient care provided mostly by family physicians and general internists. 149 Hospitalists have had a major role in the effort to identify and address preventable early readmissions, which has important implications for the new Hospital Readmission Reduction Program (HRRP) of the Center for Medicare & Medicaid Services (CMS; discussed in Parts 2 and 5). 151 Furthermore, there is a growing movement to use a multidisciplinary and interprofessional team to improve care quality and to provide evidence-based and guideline-recommended care for patients with exacerbations. 147 152 153 However, the exact role of the hospitalist relative to other team members in the care of patients admitted to the hospital for exacerbations has not been established, particularly with respect to the determination of how and when patients should receive pulmonary consultation.

Educational gaps

In the USA, residency training follows medical school, allowing individuals to further specialise. Most hospital care is now assumed by hospitalists, who typically complete either an internal medicine or a family medicine residency but choose to focus on caring for inpatients. Hospitalists typically assume the primary responsibility for inpatient care outside the intensive care unit and in non-surgical settings. Hospitalists, for the most part, transition into their positions directly from their internal medicine or family medicine residencies, and might have educational gaps in training specific to exacerbation care. Beyond the general pulmonary education hospitalists receive through ward and consult rotations, they are unlikely to receive specific training on spirometry, pulmonary rehabilitation, or patient-self management. However, given the growing burden of patients admitted to the hospital with COPD, additional training specific to the needs of patients with COPD is crucial for hospitalists. Unsurprisingly, the care that inpatients receive can vary widely. 154 In one study, 155 up to a third of patients with COPD did not receive guideline-recommended care, and up to 25% of patients received unnecessary testing or treatments (table 1 (tbl1)). Results from another study with a broader set of quality metrics showed that only 55% of patients with COPD received recommended care. 154 Diagnostic and treatment-specific gaps in knowledge for providers have been reported. For instance, approximately half the internal medical residents surveyed in the Chicago Breathe Project 156 did not know the correct order of steps when using the most common rescue inhaler device. Further, spirometric confirmation of COPD is not uniform, spirometry data of inpatients are frequently unavailable, and the usefulness of obtaining spirometry during a hospital stay is not entirely clear. However, in one study of inpatients, spirometry data of adequate quality could be obtained for most adults with a COPD exacerbation. In-hospital spirometry could represent a crucial juncture to obtain needed
information and meet a substantial gap. Education of hospital-based providers, hospitalists or otherwise, regarding the use of spirometry might help to reduce overdiagnosis of obstructive lung disease, and provide often crucial missing data for inpatients with a diagnosis of COPD.

Table 1
Summary of care provided during hospital stay for acute COPD exacerbation at 360 hospitals in the USA

<table>
<thead>
<tr>
<th>Recommended care</th>
<th>Median hospital performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest radiography</td>
<td>96·4%</td>
</tr>
<tr>
<td>Arterial blood gas analysis</td>
<td>65·4%</td>
</tr>
<tr>
<td>Supplemental oxygen</td>
<td>94·5%</td>
</tr>
<tr>
<td>Any bronchodilators</td>
<td>97·6%</td>
</tr>
<tr>
<td>Systemic corticosteroids</td>
<td>85·9%</td>
</tr>
<tr>
<td>Any antibiotics</td>
<td>86·1%</td>
</tr>
<tr>
<td>Chest physiotherapy</td>
<td>4·1%</td>
</tr>
<tr>
<td>Recommended care bundle: chest radiography, supplemental oxygen, bronchodilators, systemic steroids, and antibiotics</td>
<td>66·0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-recommended care</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sputum examination</td>
<td>5·5%</td>
</tr>
<tr>
<td>Acute spirometry</td>
<td>7·7%</td>
</tr>
<tr>
<td>Methylxanthines (bronchodilators)</td>
<td>20·7%</td>
</tr>
<tr>
<td>At least one non-recommended care</td>
<td>45·0%</td>
</tr>
<tr>
<td>Ideal care: all recommended care and no non-recommended care</td>
<td>33·0%</td>
</tr>
</tbody>
</table>

Recommendations are based on the American College of Physicians and American College of Chest Physician guidelines. COPD=chronic obstructive pulmonary disease.

Hospitalists can receive training through many ways. The Society of Hospital Medicine, for example, holds an annual meeting that includes skill-based training. In 2015, it published a COPD toolkit that provides practical information on the development and implementation of evidence-based, guideline-appropriate exacerbation care programmes and quality improvement initiatives to improve inpatient care; summarises and organises high-quality evidence for best practices; and provides instructions on the choice of quality metrics and data analysis, tips to sustain the programme, and helpful practical items such as order sets (which help to standardise and expedite the ordering process for a particular clinical scenario—eg, COPD exacerbation) and interprofessional team frameworks. The American College of Physicians also holds
annual meetings, with skill-based sessions, that discuss updated information about COPD care. More focused training on COPD care during residency could also prepare hospitalists before they start their careers. In the Chicago Breathe Project, 156 residents reported substantially improved knowledge regarding the care for patients with obstructive lung disease after participation in a one-time workshop. 156 However, most hospitalists have many competing demands, that limit their time to devote to any one patient, topic, or specialty. However, as leaders of inpatient care, hospitalists have a crucial role as role models to provide the highest-quality care to all patients, regardless of their diagnosis. For patients with exacerbations, a potential positive outcome of the penalties imposed by the CMS for COPD readmissions is an increased focus on COPD care by both hospitals and health-care professionals, which will hopefully lead to improved training and education for physicians and more coordinated care.

Care coordination

Coordination of care among team members and transitions of care from hospital to home remain key challenges. In general, patients are at high risk of medical errors or adverse events at the time of hospital discharge. 158 159 160 These events can be due to breakdown in communication between the hospital and outpatient services, 161 insufficient patient understanding of their discharge instructions, 162 or problems with medication discrepancies. 163 Further complicating matters, COPD management poses additional unique challenges, because most respiratory drugs require specific devices and rates of misuse are high. 164

Patients are frequently given drugs in the hospital's formulary during hospital stay, which then need to be reconciled with their outpatient insurance formulary at the time of discharge. In many cases, insurance coverage of prescription drugs might not even be fully known at the time of discharge, which limits the hospitalists' ability to ensure that patients know how to properly use their prescribed inhaled drugs.

Recognition of the need for hospital-based programmes to specifically address transitions of care is growing, and many such programmes have been established. 166 167 168 Preliminary data from programmes aimed at older inpatients (≥65 years), particularly those with heart failure, showed reductions in readmissions and mortality, although more data are still needed in a wider range of patients. 169 170 COPD-specific programmes are only beginning to be established, but they might include patient navigators, post-discharge clinic visits, and other ways to improve the transition. However, the national trends towards increased use of interdisciplinary teams and the CMS's focus on reducing COPD readmissions are likely to result in increased attention on COPD care from hospitalists.

Pulmonary medicine perspective

Less than 10% of all ambulatory pulmonary care is provided by pulmonary specialists, 171 and results from a COPD Resource Network survey 24 showed that 30% of patients with COPD receive care from a pulmonologist. The Committee on Manpower for Pulmonary and Critical Care Societies estimated that the number of pulmonologists in the USA was 8000 in 1997 and has remained stagnant since then. 171 With the high prevalence of COPD 1 172 and an ageing population in the USA, pulmonologists are unlikely to care for greater numbers of patients with COPD, and uneven distribution of specialist care by geography and population density further impedes patient access. 173 Hence, the first point of contact with health care for most patients is through their primary care providers. As such, primary care providers remain the frontline in the identification of COPD in early stages. As previously discussed, a substantial lag exists between onset of symptoms and spirometry-confirmed diagnosis in many patients. Data from the Lovelace Patient
Database 174 suggest that up to 80% of patients receive a diagnosis of spirometry-confirmed COPD when their airflow obstruction is at Global Initiative for Chronic Obstructive Lung Disease (GOLD) grade 2 or higher, highlighting the need for a multidisciplinary management of COPD by both primary care providers and specialists.

The role of primary versus specialty care

Although considerable differences in care delivery exist, no studies have been done to assess differences in outcomes when patients are cared for by a primary care provider compared with a pulmonologist. Although pulmonologists claim to be more aware of COPD practice guidelines than do primary care providers, data suggest that they are no more likely to prescribe guideline-recommended therapies. 73 175 Some practice differences do seem to exist between pulmonologists and primary care providers. For example, pulmonologists are more likely to care for patients with advanced disease (GOLD grades 3 and 4) and, accordingly, more frequently prescribe inhaled drugs and oxygen therapy, use pulmonary function testing, and recommend pulmonary rehabilitation. 24 176 By contrast, primary care providers spend more time on important lifestyle modifications. 176 With the advent of new therapies—including immunotherapies and invasive interventions such as bronchoscopic and surgical lung volume reduction procedures—more advanced cases will continue to be cared for by subspecialists. There are scant data on co-management of COPD, although results from a single-centre study 177 showed that 47.3% of patients were managed by primary care providers, 9.8% by pulmonologists, and 41.1% were co-managed. Patients who were co-managed were more likely to receive guideline-adherent drug treatment, 177 suggesting that co-management might be the best option.

The commonly used guidelines have few recommendations on when to refer a patient to a pulmonary specialist. Institution of referral policies would promote reduction of redundant specialist care and decrease waiting times for patients who require such care. North American guideline statements are silent on this issue, whereas guidelines from the UK National Institute for Health and Clinical Excellence provide comprehensive recommendations for referral to a specialist (table 2 (tbl2)). 110

Table 2
Recommended criteria for referral to pulmonary specialist

<table>
<thead>
<tr>
<th>Goal</th>
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<tbody>
<tr>
<td><strong>Diagnostic uncertainty</strong></td>
</tr>
<tr>
<td>Confirm diagnosis and optimise therapy</td>
</tr>
<tr>
<td><strong>Symptoms disproportionate to known lung function defect</strong></td>
</tr>
<tr>
<td>Assess other contributory causes—eg, secondary pulmonary hypertension, dynamic hyperinflation, physical deconditioning, hyperventilation, and comorbidities such as cardiac impairment and depression</td>
</tr>
<tr>
<td><strong>COPD onset before age 40 years or a family history of α1 antitrypsin deficiency</strong></td>
</tr>
<tr>
<td>Test for α1 antitrypsin deficiency and assess whether augmentation therapy is necessary; screen other family members for α1 antitrypsin deficiency</td>
</tr>
<tr>
<td><strong>Severe COPD</strong></td>
</tr>
<tr>
<td>Optimise therapy and consider lung transplantation listing for appropriate candidates</td>
</tr>
</tbody>
</table>
Because of the episodic fluctuations during the course of the disease, care coordination is constrained by important gaps in continuity of care. A substantial proportion of patients discharged from hospital after an acute exacerbation do not have continued prescriptions for their baseline controller therapies. Improvements in medication reconciliation are necessary to overcome this barrier to effective care transition. Although multidisciplinary care is likely to benefit patients with COPD, there is also considerable potential for fragmentation of care and miscommunication. Effective referral policies with standardised guidelines, expectations for communication between specialists and primary care providers, and documentation of responsibilities on each provider's part will help to avoid these issues.

### Non-uniformity of COPD guidelines

COPD care is complicated by the numerous society guidelines and therapeutic strategies, which have their strengths but often provide conflicting recommendations. Perhaps the best known therapeutic strategy is the GOLD guidelines. In 2011, a substantial change was made moving from a spirometry-based grading of severity to a composite gradation based on airflow obstruction, symptoms, and risk of exacerbation. Unfortunately, this change has introduced more complexity. The new COPD Foundation guidelines follow a similar approach of recommending therapy on the basis of severity of airflow obstruction and symptoms, but differ in the spirometric cutoffs for disease severity. None of the guideline-recommended thresholds for disease severity are based on evidence from randomised trials, which lowers practitioner confidence in the guidelines. Although all the guidelines agree that a diagnosis of COPD should be confirmed by spirometry, no consensus exists on the timepoint at which...
spirometry should be done. Although the GOLD and COPD Foundation guidelines state that all patients with symptoms or risk factors for COPD should be screened, the American College of Physicians (ACP), American College of Chest Physicians (ACCP), American Thoracic Society (ATS), and European Respiratory Society (ERS) jointly recommend that only patients with symptoms should be screened, regardless of the presence of risk factors, and this recommendation is echoed by the USA Preventive Services Task Force.  

Although it has been argued that the absence of disease-altering therapy dictates that only patients with serious symptoms are offered therapy, exertional symptoms are diagnosed long after the disease has progressed because patients tend to slow down and mask their symptoms. Whereas GOLD recommends long-acting bronchodilators for symptomatic patients with FEV$_1$ of less than 80% predicted and the COPD Foundation recommend these drugs for anyone with symptoms, the ACP–ACCP–ATS–ERS task force recommends use only when FEV$_1$ falls below 60% predicted. Inhaled corticosteroids are recommended by GOLD once FEV$_1$ drops below 50% predicted or when the risk of exacerbation is increased, whereas the COPD Foundation recommends their use only in those at high risk for exacerbations. The complexity of determining the risk of these events and the absence of mathematical models or scoring systems make decision making on the basis of these guidelines difficult in clinical practice. For example, the new GOLD classification system placed patients in different categories depending on which metric was chosen to define disease activity. With the introduction of new combination therapies, most guidelines do not have sufficient recommendations on their use and need updating on a more frequent basis, perhaps annually or every other year.

Guideline implementation

Little research has been done on the effect of guideline implementation on health-care outcomes in COPD; however, results from several retrospective studies suggest improvements in symptoms, increase in health-care use, and reduction in health-care costs. However, the modest benefits are also likely to result from factors other than physician prescription choices, such as patient non-compliance with treatment in real life (as opposed to clinical trial settings) and insufficient insurance coverage, especially with the scant availability of generic drugs.

Although pulmonologists report more awareness of guidelines than primary care providers, their treatment practices are not very different from those of primary care providers. In 2005, Barr and colleagues reported similar rates of long-acting inhaler use across all stages of disease severity and similar rates of systemic corticosteroid use in patients with stable moderate COPD managed by pulmonologists and those managed by primary care providers. In Diette and colleagues’ large study of claims data in 2007–08, about a third of patients with a history of exacerbations were not on long-acting maintenance drugs. Compared with patients treated by primary care providers, those treated by pulmonologists were more likely to be on long-acting maintenance drugs (78% vs 59%) and were more likely to receive short-term therapy after a visit to the emergency department for an exacerbation (52% vs 43%). By contrast, in a large international study, the use of guideline-concordant therapy was similar in specialist and primary care practices, especially for more advanced disease.

Although most guidelines from national respiratory societies are comprehensive, implementation of these guidelines in clinical practice has been suboptimal. Several barriers that have been identified in other chronic diseases also apply to COPD—eg, physician unfamiliarity with guidelines, disagreements among
guidelines on the best spirometric thresholds for diagnosis, physician disagreement with guidelines and reliance on personal practice habits, difficulties in implementation because of either resource constraints in the clinic or poor insurance coverage, high co-pays even in those with insurance, and patient non-adherence to recommendations.

Successes in the management of other chronic diseases can inform potential solutions to improve guideline compliance in COPD. These solutions are most likely to involve individualised interventions in different practice settings and active dissemination of knowledge about guidelines. Solutions include increasing exposure to guidelines early in medical training with reinforcement, modulation of electronic medical records to provide point-of-care information and disease-specific reminders when guidelines are not being adhered to, enhancing trust in guidelines by increasing transparency and involvement of primary care physicians in guideline development, homogenisation of guideline recommendation with urgent trials comparing efficacy of various recommendations, increasing involvement of patients as partners in health care, and development of pay-for-performance incentives based on guideline implementation. Finally, the complexity of issues related to COPD mandates that practitioners spend more time on an office visit with patients and their families. Unfortunately, modern practice has resulted in shorter visit times relative to the number of issues that need to be addressed, and a typical office visit has remained around 20 min in the past three decades. Time barriers to effective care should be examined in a cost–benefit analysis and reimbursements changed accordingly.

Disease heterogeneity

Disease heterogeneity in COPD adds to the complexity of management. Disease heterogeneity might be due to mechanisms that contribute to airflow limitation (eg, emphysema and airway calibre), varying symptom manifestation, secondary changes (eg, pulmonary hypertension and muscle wasting), and possible differences in therapeutic response. An urgent need is to improve disease classification and clarify diagnostic algorithms. For example, many patients without spirometric airflow obstruction have substantial emphysema on CT imaging with substantial respiratory morbidity. Further, although growing evidence shows that COPD is a complex disease with multiple comorbidities, awareness of this occurrence has not reached practitioners or, in some cases, even the committees who make guideline recommendations. Unfortunately, most clinical trials of COPD therapies exclude patients with serious comorbidities, and the evidence for best practices and management of these comorbidities is therefore sparse or completely absent. Although the fact that not all patients respond well to existing therapies is recognised, there has been little effort to identify predictors of response and tailor appropriate management recommendations. Accurate identification of responders to specific therapy will further the goal of personalised medicine.

Some patients with COPD might warrant specific therapies and are better served by specialists. α1 antitrypsin deficiency is an autosomal co-dominant genetic disorder resulting in inadequate serum α1 antitrypsin. An estimated 100 000 people in the USA have such a deficiency, but only about 5–10% of these patients have been diagnosed. Although guidelines recommend that α1 antitrypsin deficiency should be considered and targeted screening done in all patients with diagnosed COPD, especially in non-smokers and those with early-onset disease and a family history of COPD, substantial delays in diagnosis often exist. On average, the delay from onset of symptoms to diagnosis of α1 antitrypsin deficiency is roughly 8 years, with multiple physicians overlooking this diagnosis in a substantial proportion of patients. Early
recognition can aid smoking cessation efforts in all patients affected, and α1 antitrypsin augmentation therapy in a subset of patients can slow the rate of decline in lung function and decrease exacerbation rates. 204 205

Therapies

A barrier to COPD care is the generalised sense of nihilism among practitioners because therapies are perceived to be ineffective. 206 Other than smoking cessation, oxygen therapy in resting hypoxaemia, and lung volume reduction surgery in a subset of patients with severe emphysema, none of the existing therapies have been conclusively shown to alter disease progression. 207 208 Inhaled drugs are targeted towards symptomatic improvement and exacerbation reduction. These drugs do not seem to slow the rate of decline of lung function, although subgroup and post-hoc analyses have suggested some benefit with tiotropium, fluticasone, and salmeterol. 209 210 Most COPD-related health-care costs arise from hospital admission for acute exacerbations; 211 inhaled drugs can reduce exacerbations, and drugs with novel anti-inflammatory actions have been shown to lead to a modest reduction in hospital admission rates. 212

However, patient access to available therapies remains a continued frustration for pulmonologists and patients. A paucity of generic drugs limits prescription choices for patients who are either uninsured or underinsured. For example, Medicaid covers only five brand-name drugs in total for one patient. As most patients with COPD have other conditions requiring multiple drugs, access to inhaled therapies might be compromised. Being uninsured and high co-pays, rather than physician preference, routinely determine a patient's treatment regimen. However, an equally major problem is substantial underprescription by physicians, regardless of the patient's insurance plans. 107 More than two-thirds of both commercially insured and Medicare patients are routinely not prescribed any long-acting maintenance therapy. 107 Additionally, access to and availability of augmentation therapy for some patients with α1 antitrypsin deficiency remain an issue. 213 Patients with α1 antitrypsin deficiency incur approximately 6 times greater health-care costs than do COPD patients without such deficiency, with half of this cost being direct expenses associated with α1 antitrypsin augmentation.

Although pulmonary rehabilitation has been shown to improve symptoms and health status across a wide range of disease severity, 214 215 rates of use even among pulmonologists remain poor, with slightly more than 50% claiming that they regularly refer their patients to pulmonary rehabilitation. 24 Pulmonary rehabilitation has been shown to decrease exacerbation rates, particularly after hospital discharge. 118 The low rate of use might be affected by poor patient compliance with pulmonary rehabilitation because of transportation and geographical factors that limit access, underlying depression, and a perceived lack of benefit. 216

Care for advanced disease

Pulmonologists generally care for patients with advanced disease. These patients have considerable morbidity and high mortality. Long-term oxygen therapy in those with resting hypoxaemia has been shown to improve survival. 208 217 In specific groups of patients, especially those with upper lobe predominance emphysema and low baseline functional capacity, lung volume reduction surgery can improve survival and morbidity. 218 Data suggest that about 10–15% of patients with GOLD stage 3–4 (ie, severe) COPD might be eligible for this procedure, and the number of potential candidates is estimated to range from a few thousand to greater than 1 million. 219 However, patient access is restricted by the relatively small number
of Medicare-designated centres of excellence for the surgery, insufficient physician awareness of potential benefits and candidate selection, and perceptions regarding risk of the procedure. 220 New, less-invasive bronchoscopic lung volume reduction procedures with one-way valves, coils, sealant, and steam vapour are being tested. Although many of these procedures are approved for use in Europe, none have been approved for clinical use in the USA. 221 222 223 224 A considerable number of patients can potentially benefit from these procedures, and more data and increased awareness are needed.

For patients who are ineligible for these procedures and who have serious symptoms, lung transplantation remains an option. However, eligibility criteria are strict, making lung transplantation not a realistic option for many with severe COPD. Introduction of the lung allocation score in the USA in 2005 has resulted in a relative reduction in the percentage of transplantations performed for COPD, because priority scores for COPD tend to be lower than for other lung diseases given their reasonably favourable short-term survival in the absence of transplantation. 225 226 As of 2014, only 60 centres in the USA perform lung transplantations, thus limiting access for some patients.

Part 2: The economic perspective

Because of the large number of individuals with COPD, health-care expenditures for care in the USA remain high (panel 2 (box2)). Total medical costs attributable to COPD were estimated to be $72.7 billion in 2010. 17 However, these costs continue to rise, with an estimated 53% increase forecasted by 2020. 17 Although these costs are partly covered by federal and private insurance programmes, coverage is incomplete and varies widely. Among patients admitted to the hospital for COPD, roughly 69% were primarily insured through Medicare, 10% through Medicaid, 16% through private insurers, and 3% were uninsured. 145 Although only a minority of patients with disease severe enough to warrant hospital admission are uninsured, the proportion of uninsured outpatients with mild to moderate disease is far higher. 227 228 Additionally, the amount of out-of-pocket costs for patients, even for insured individuals, varies widely. According to results from the 2013 Medical Expenditure Panel (MEP) Survey sponsored by the Agency for Healthcare Research and Quality, 229 out-of-pocket expenses account for approximately 11.5% of total asthma and COPD expenditures, with private insurance covering 30.5%, Medicare 32.3%, and Medicaid 17.5% of costs. In this survey, 229 the reported mean per-person annual expense for patients with asthma or COPD, or both, were $557 for outpatient provider visits, $12,943 for hospital stays, $976 for emergency room visits, and $710 for prescription drugs.

Panel 2

Key messages

- Rising costs are leading payers to work with health-care providers and health systems to improve care coordination for patients with chronic diseases, including COPD. However, COPD-specific quality initiatives and management programmes remain mostly isolated initiatives driven by individual health systems.

- Provisions in the Affordable Care Act and Center for Medicare & Medicaid Services Hospital Readmission Reduction Programme are placing increased pressure on hospitals to integrate...
with health-care providers. Whether such an integration will ultimately result in better COPD care is still unknown.

**Key challenge**

- Out-of-pocket spending, particularly for drugs, is still a substantial burden for patients with COPD, particularly for those with multiple chronic diseases, resulting in reduced adherence and increased overall health-care costs.

**COPD care from an economic perspective**

**The patient viewpoint**

For patients who are admitted to the hospital, the financial consequences can be devastating. In terms of prescription spending, patients with multiple chronic conditions are affected the most. Overall, patient access to medication did improve when the Medicare prescription drug programme (ie, Medicare Part D) began in 2006 (see appendix p 5 (sec1) for explanatory figure). Roughly two-thirds of all Medicare beneficiaries are enrolled in a Part D plan. However, further analysis of the MEP Survey data in 2000–05 found that prescription drug spending as a proportion of out-of-pocket spending increases as the number of chronic conditions increases. Among adults who spent more than 10% of their income in 2 consecutive years on out-of-pocket medical costs, prescription drug spending accounted for more than 50% of spending for those with two or more conditions, which amounts to an average of about $2500 per year in this group.

From the patient’s perspective, an unintended consequence of burdensome out-of-pocket costs is treatment non-adherence. Castaldi and colleagues found that cost-related non-adherence of inhaler therapy was 31% in Medicare patients, and that even a modest $20 monthly co-pay resulted in a significant increase in non-adherence. Compared with other chronic diseases, treatment adherence for COPD is low (figure 4 (fig4)), with only 51% of doses taken as prescribed. For Medicare patients, the problem is complicated further by peculiar aspects in coverage rules that lead to seasonal non-adherence. For Medicare beneficiaries who choose to pay a premium for prescription drug coverage (ie, Medicare Part D), they typically pay 100% of drug costs until a deductible is met. After reaching the deductible, patients pay only a certain percentage of total costs. However, once the plan limit is reached, a coverage gap (commonly known as the donut hole) ensues, and the patient is again responsible for the full costs of drugs, until a larger yearly out-of-pocket spending limit is reached and plan coverage resumes. This coverage gap occurs at different times of the year, depending on the number and cost of individual prescriptions. Patients are often honest with their physicians that they have stopped taking some or all of their drugs because of being “in the donut hole”. Since many patients with COPD have several other chronic diseases and are on multiple drugs, non-adherence due to the coverage gap is a common occurrence. Furthermore, Medicare Part B covers both outpatient services and durable medical equipment, including nebulised drugs. Therefore, some patients who do not have Medicare Part D or who cannot afford the high co-pays associated with most COPD maintenance drugs resort to the use of typically short-acting nebulised drugs that they can receive for a small co-pay through Medicare Part B. Hence, it is not uncommon to see patients with very severe COPD on only nebulised albuterol (also known as salbutamol) and ipratropium.
The pharmaceutical industry has tried to help with access to drugs through various patient assistance programmes. One such strategy is co-payment coupons to reduce out-of-pocket costs. However, such programmes might lead consumers to choose brand-name drugs over generic drugs, particularly when safe and effective generic alternatives are available, thus increasing overall health-care costs. Federal law prohibits the use of these co-pay coupons by patients insured by Medicare and Medicaid. Manipulation of true out-of-pocket costs by pushing a Medicare beneficiary through the coverage gap or keeping them in the coverage gap is considered an inducement to purchase a specific item and violates anti-kickback statutes. However, in the USA, no generic COPD inhalers (including short-acting albuterol and ipratropium) are available, since the unique delivery devices that accompany inhaled drugs are protected by patents that limit generic availability. Generic inhalers that meet Food and Drug Administration (FDA) standards are difficult to manufacture. In 2008, the FDA began phasing out chlorofluorocarbon propellants from metered-dose inhalers to meet environmental standards, leading to the need for new devices, new patents, and a disappearance of generic inhaled drugs from the US market.

Moreover, in the USA, drug prices are set by market competition among pharmaceutical companies, whereas the government in many other countries directly or indirectly sets an allowed national wholesale price for each drug. In many countries—including Canada, the UK, Australia, and members of the European Union—health technology assessment agencies also use an incremental cost-effectiveness ratio (ICER) threshold to inform reimbursement decisions for drugs, although the specific threshold and restrictions vary by agency.²³³

As a result of all these factors, although drug costs account for only 2.3% of COPD-related health-care costs, patients in the USA share a substantial proportion of that burden, resulting in non-adherence. Data suggest that improved access to drugs can generally reduce overall health-care spending, particularly for hospital admissions.²³⁰ For example, in the first full year of the Medicare drug benefit programme, total non-drug medical spending dropped by more than $1000 per beneficiary ( appendix p 6 (sec1) ).

The insurer viewpoint

Because of the increasing disease burden and rising costs, insurers have been examining different ways to improve care and contain costs. How to do so is being explored in numerous ways by the various health insurance organisations and health systems in the USA. One concept that has gained traction is patient-
centred medical home (PCMH), the goal of which is to provide coordinated care across multiple practitioners through a case manager or a care coordinator who is frequently based in the primary care provider’s office. Expectations typically include multidisciplinary care teams, 24 h access to a clinical decision maker by phone, a focus on disease education and prevention, web-based portals for electronic communication between patients and providers, and established mechanisms to notify primary care practices when patients with particular chronic diseases are admitted to and discharged from the hospital. A related concept is the patient-centred medical neighbourhood (PCMN), which focuses on coordination and communication between primary care providers and specialists. The Patient Protection and Affordable Care Act, signed into law in 2010, provided specific funding to support the construction and renovation of 147 PCMH centres in 44 states. The reimbursement model for PCMH is typically a three-part model that incorporates visit-based fee-for-service payments, care coordination payments (so-called bundled care coordination fees) to cover physician and non-physician work that falls outside of a face-to-face visit and for system infrastructure, and performance-based payments that recognise achievement of quality and efficiency goals. This model allows primary care practices to be incentivised to provide improved, coordinated care and recognises that much of this care, particularly for patients with chronic diseases, occurs in settings outside of the typical face-to-face office visit. Although these programmes were not developed specifically for COPD, data suggest that, compared with usual care, the PCMH model can result in fewer emergency room and urgent care visits, and reduce hospital admissions for ambulatory care-sensitive conditions (including COPD).

One of the largest private health insurance organisations in the USA is the Blue Cross and Blue Shield (BCBS) Association, which directly or indirectly provides health insurance to more than 100 million Americans. Groups like BCBS have begun to explore innovative ways in which patients with chronic diseases like COPD can be better managed, and examples include the development of PCMH and PCMN practices. BCBS of Michigan, which has 1551 PCMH-designated practices in its preferred provider organisation network, piloted a high-intensity care management programme that is delivered by the provider, uses multidisciplinary teams, and provides enhanced, proactive care management services to patients with highly complex chronic illnesses who are home-bound or nearly home-bound.

Unfortunately, our request to interview the CMS for this Commission was unanswered. However, Medicare’s policy is beginning to have far-reaching effects on care delivery across the USA. Hospital admissions for acute exacerbations of COPD resulted in more than $6 billion dollars of annual spending in 2008, with an average cost per stay of $7500, which is mostly paid for by Medicare. As of Oct 1, 2014, Medicare patients aged 65 years or older who are admitted to the hospital for an exacerbation will be identified and monitored for any non-planned readmissions within 30 days of discharge. Such readmission is counted towards the index hospital’s HRRP and results in financial penalties that can be as high as 3% of hospital-specific Medicare payments for all discharges (rather than only payments related to excess readmissions). By combining financial incentives and penalties, Medicare’s policy seeks to promote coordination across the continuum of care. This policy change is beginning to affect how health systems approach and treat patients with exacerbations and highlights the need to better handle transitions of care from a health system perspective. As one can imagine, many of the factors that might affect readmissions are beyond the hospital’s control. Therefore, addressing transitions of care poses unique challenges for stand-alone hospitals that are not part of a more integrated health system that includes outpatient practices.
In addition to the potential penalties for excessive readmissions for COPD and other diseases, CMS has begun to transition some of its traditional individual provider and hospital payments to bundled payments in an effort to align reimbursement with outcomes. This Bundled Payments for Care Initiative (BPCI) provides one payment (ie, a target price) for an episode of care that might span inpatient and outpatient settings and involve many physicians and non-physicians. This target price is based on the calculated individual provider and hospital payment data for a similar episode of care in previous years, which is then discounted by 1–3%. The aim is to align payments across an episode of care to encourage health systems and providers to develop more efficient processes, adhere to best practices, better manage transitions of care, and improve overall outcomes. See panel 3 (box3) for an example of a BCPI project.

PANEL 3

Since 2013, the University of Alabama at Birmingham Hospital has been participating in a Bundled Payments for Care Initiative (BPCI) project for admissions related to COPD, in which bundled payments are made for selected COPD diagnostic-related group codes (190–192) for both acute and post-acute care. All non-hospice Medicare charges during an index hospital admission and for up to 90 days after discharge—including home health, skilled nursing care, readmissions, procedures, outpatient visits, and pulmonary rehabilitation—are covered by the bundled payment. Following the conclusion of the 90 day at-risk period, charges are reconciled and any cost savings relative to the target price are shared with individual providers and other stakeholders (including the hospital and home health). If charges exceed the target price, then additional payments to the Centers for Medicare & Medicaid Services (CMS) are required. In response to the BPCI, the hospital developed an integrated practice unit for COPD, with a dedicated care team to identify possible COPD admissions early and provide intensified intervention, including in-hospital visits, standardised inpatient computer order sets (for diagnostic testing and the selection and dosing of systemic corticosteroids, antibiotics, and inhaled bronchodilators), smoking cessation, early outpatient follow-up, medication reconciliation, assessment of treatment adherence, post-discharge phone calls, referral to pulmonary rehabilitation, and referral to home health or palliative care as appropriate. Although similar multidisciplinary efforts that have been started in many health systems have mixed results, a key difference of the BPCI is the linking of the intervention to reimbursement. Results after the first year of the BPCI at this hospital suggest no differences in 30 day or 90 day readmission rates, despite substantially increased use of outpatient services, home health, and pulmonary rehabilitation, as well as increased overall costs. The long-term success of the BPCI and other efforts to link payment to outcomes is unclear. However, despite these disappointing results, patients with COPD who participated in the programme reported improved satisfaction with their care.

University of Alabama at Birmingham health system

The health system viewpoint

Representatives from Kaiser Permanente Northwest and Geisinger Health System were interviewed to better understand how these health systems are addressing COPD care specifically. Kaiser Permanente is a health maintenance organisation providing prepaid comprehensive health care to insured participants through a so-called closed health-care system, in which one organisation owns and manages the inpatient and outpatient facilities. Kaiser Permanente has maintained a COPD-specific care programme for many
years, including a focused outpatient COPD care management clinic and new quality initiatives aimed at improving spirometry use, integration of pulmonary function test results into the electronic medical record, and development of a multidisciplinary care management team for inpatients that is led by respiratory therapists. This programme identifies patients with COPD in the emergency department or when they are admitted to the hospital, and facilitates medication reconciliation, case management, and follow-up care (including pulmonary rehabilitation). Expansion of access to pulmonary rehabilitation is a future priority.

Geisinger is a partially closed health-care system—some of the inpatient and outpatient facilities are owned and operated by the Geisinger group, while others are affiliated but owned independently. Similar to Kaiser Permanente, Geisinger is developing several system-wide initiatives to improve COPD care. The initial goal is to assure that high-quality spirometry is available throughout the system, that the results are readily available in the medical record, and that the staff are trained to interpret the results. This initiative has allowed the development of a registry to prospectively follow-up patients with COPD. Another initiative to improve inpatient care has been the development of a so-called critical pathway for patients admitted for COPD exacerbations. This pathway is a standardised diagnostic and treatment algorithm that is applied to every patient, with the goal of reducing variation in care and improving overall quality. For Geisinger, this care pathway includes steps to correctly establish a diagnosis of COPD, a consultation with a pulmonologist, and rapid follow-up after discharge.

A representative from the Veterans Health Administration was also interviewed. This health system consists of 150 medical centres and nearly 1400 community-based outpatient clinics that provide care to more than 8 million veterans each year. Because of a high prevalence of smoking among veterans, COPD is the fifth most prevalent disease in this population. For inpatients aged 65–74 years, COPD is the fourth most common diagnosis. The Veterans Health Administration currently treats about 1 million patients with COPD, but other estimates suggest that the prevalence of airflow obstruction in veterans might be as high as 33–43%, indicating a large burden of undiagnosed disease. The Veterans Health Administration faces continuing challenges to deliver high-quality care. Some of the key needs are to ensure the appropriate use of diagnostic spirometry, to provide disease-state education and smoking cessation counselling, to procure cost-effective drugs, and to deliver end-of-life and palliative care services. A present goal is to improve availability of spirometry and pulmonary rehabilitation. Tele-health programmes are being examined as a way to extend care to outpatient clinics. Despite being a closed health system, the Veterans Health Administration, similar to other health systems, struggles with issues such as the disconnect between the pharmacy trying to contain costs and the hospital that has to pay for COPD admissions, and the coordination of interdisciplinary care across multiple chronic illnesses.

Another key provision of the Affordable Care Act is the establishment of Accountable Care Organizations. An Accountable Care Organization is a network of doctors and hospitals that share financial and medical responsibility for the provision of coordinated care to patients, with the aim of minimising unnecessary spending. These organisations can include hospitals, specialists, post-acute care providers, and even private companies such as pharmacies. The only required element is primary care providers, who are at the centre of the programme. At present, much of the US health-care system consists of free-standing hospitals with affiliated practices that provide outpatient care, as opposed to closed or partially closed systems. In this more common structure, the inpatient and outpatient cost centres are separate. However, for chronic diseases such as COPD, overall health-care use—including readmissions, planned and unplanned outpatient visits, and emergency room care—is affected by practice patterns in both inpatient and
outpatient settings. The bundled payment structure of an Accountable Care Organization creates financial incentives for hospitals to work with outpatient practices to provide integrated care, with the ultimate goals being quality improvement and cost reduction. As a result of this legislation, large hospital systems have been buying up physician practices as they aim to become Accountable Care Organizations that directly employ most of their providers. Whether this initiative will actually improve care for patients with chronic medical diseases such as COPD is still unknown.

Part 3: COPD research and development

Most COPD research in the USA is funded by the National Institutes of Health (NIH) and the pharmaceutical industry, although organisations such as the COPD Foundation, American Thoracic Society, and American Lung Association also have supporting roles.

The National Institutes of Health

The National Heart, Lung, and Blood Institute (NHLBI), an institute of the NIH, has supported many major clinical studies in COPD, including the Lung Health Study and the National Emphysema Treatment Trial. In 2014, the NIH funded the Pulmonary Trials Cooperative, which includes the creation of a Network Management Core that oversee several multicentre COPD trials. The Network Management Core was designed to function similarly to the contract research organisations used by the pharmaceutical industry to improve the efficiency of drug development. In addition to these randomised trials, the NIH is also supporting two major observational studies in COPD. Investigators of the COPDGene study, a genome-wide association study, have identified genetic determinants of COPD risk and reported several other important findings about the natural history of the disease. The SPIROMICS study categorised patients with COPD on the basis of molecular fingerprinting, with the goal of identifying and validating intermediate outcome measures that will expedite future clinical trials.

We interviewed representatives from the NHLBI about their perspective on COPD research in the USA (panel 4). To overcome the challenges ahead, increased support for the NHLBI is needed, but federal funding for the NIH has been reduced or has remained relatively the same since 2003. In an analysis of NIH funding for research into specific diseases, disability-adjusted life-years (DALYs) was shown to be the best predictor of research funding allocation. However, for COPD, actual research funding falls far short of the funding predicted on the basis of DALYs (figure 5; appendix p 7 for a comparison of deaths with funding by disease category). Compared with other chronic diseases (eg, heart disease and diabetes), COPD receives far less research funding than its attributable mortality warrants—COPD is the third leading cause of death in the USA but the 14th most funded research category at the NIH.

PANEL 4

In the past decade, research in COPD has made substantial progress in the understanding of both pathogenic mechanisms and clinical manifestations of the disease, but many urgent challenges and opportunities remain. An important need is to generate an integrated understanding of the pathobiology of COPD—one that connects the findings so far and provides a coherent picture of how the disease develops, progresses, and differs among individuals. This key aim will require phenotype-specific studies of pathobiology, long-term follow-up of existing observational cohorts, and systems-level analyses of omics data. New therapeutics need to be developed against promising targets.
Clinical trials are needed to determine how best to use existing treatments, including inhaled bronchodilator–corticosteroid combinations, supplemental oxygen, and pulmonary rehabilitation. A particular need is to better understand whether early intervention in patients with very mild disease or those who are particularly susceptible to COPD can change the course of the disease. The long-term goal is to develop interventions aimed at preventing, or at slowing or reversing, disease progression.

Several research approaches will be needed to elucidate susceptibility to, heterogeneity within, and progression of COPD. An essential approach is to do more extensive clinical studies of large numbers of patients with widely varying exposure histories, susceptibilities, age, and severity of disease. In parallel with these clinical observations, researchers need to delve more deeply into the pathobiological mechanisms underlying COPD development and progression at the tissue, cell, and molecular pathway levels. This truly interdisciplinary approach will need to combine clinical, basic science, and translational methods to achieve a more complete understanding of the disease.

The National Heart, Lung, and Blood Institute (NHLBI) contributes to the progress in COPD research in two key ways. First, the NHLBI awards and administers investigator-initiated research grants to the pulmonary and scientific community to support innovative basic science, translational, and clinical research into COPD. Second, the NHLBI releases targeted initiatives that stimulate COPD research through grants or contracts, which are typically initiated in response to a gap identified by the scientific or patient communities. In the past 5–10 years, these communities highlighted the following needs: first, a better understanding of disease pathogenesis at the molecular and cellular level; second, a precise classification of disease subtypes, using biomarkers for prognosis and prediction of therapeutic efficacy; third, improved access to lung tissues from donors with COPD and other lung diseases, and from healthy donors; fourth, a clinical research infrastructure that allows clinical trials to be done expeditiously and efficiently; fifth, encouragement of both the research community and pharmaceutical industry to invest in new COPD-specific treatments; and finally, increased interactions with stakeholders—including patients, advocacy groups, health-care professionals, researchers, and industry—to increase COPD diagnosis, and public awareness and education.

The NHLBI responded to each of these needs with institute-initiated programmes. Examples include a Request for Applications to explore common pathogenetic mechanisms of lung cancer and COPD; clinical cohort studies such as the SPIROMICS and GRADS studies; the Lung Tissue Research Consortium, a biorepository to distribute lung tissues, blood specimens, and phenotypic data (including CT images); clinical trials through the COPD Clinical Research Network, the Long-Term Oxygen Treatment Trial, and the Pulmonary Trials Cooperative; the Specialized Centers of Clinically Oriented Research in COPD and the Centers for Advanced Diagnostics and Experimental Therapeutics in Lung Diseases Stage I and II (CADET I and II); and COPD awareness and education through the Learn More Breathe Better campaign. 242

The NHLBI intends to continue its vigorous promotion of basic science, clinical, and translational research into COPD. Additionally, it is leading federal efforts to develop a national action plan for COPD that will coordinate the work of multiple government agencies and non-governmental
stakeholders. The NHLBI anticipates that progress in COPD research will be substantial in the next 5–10 years, greatly exceeding the successes of the past, since the science of COPD is poised to revolutionise how we diagnose, prevent, and treat this third leading cause of death in the USA.

The NHLBI's perspective on COPD research in the USA

Figure 5
NIH funding in 2006 and disease burden (DALYs) in 2004 for 29 common diseases in the USA
The solid line represents the results of a traditional multivariable analysis, showing the relation between disease-specific DALYs burden in the USA and the actual amount of NIH funding in 2006. The dashed line projects NIH funding levels in a similar multivariable model, with the requirement that a disease with no burden receives no funding (constrained model). Although the two models produce similar results, several diseases that would be considered overfunded in one model are considered underfunded in the other (eg, cervical cancer). COPD is underfunded in both models.
COPD=chronic obstructive pulmonary disease. DALYs=disability-adjusted life-years. NIH=US National Institutes of Health. STDs=sexually transmitted diseases. Adapted from Gillum and colleagues. 243

Pharmaceutical industry
In the past 20 years, the pharmaceutical industry has also invested a substantial amount of money in COPD research, which has led to the publication of several landmark studies and the approval of many new inhaled drugs. These studies include TORCH, 244 a randomised controlled trial to determine whether salmeterol and fluticasone propionate affect mortality; UPLIFT, 245 a randomised controlled trial to study whether tiotropium affects lung function decline; and SUMMIT, 246 a randomised controlled trial of fluticasone furoate and vilanterol in patients with moderate COPD and cardiovascular risk factors to determine the drug's effect on mortality, lung function decline, and a composite cardiovascular endpoint. Findings from these studies have improved the understanding of factors that affect symptoms,
exacerbations, and disease progression. The industry has also made major investments in large observational studies to better understand the natural history and heterogeneity of COPD; one such example is the ECLIPSE study, which examined extensive clinical, physiological, biological and radiological characteristics of patients over 3 years.

One of the goals of ECLIPSE was to identify unique patient subgroups or phenotypes so that targeted therapies can ultimately be developed. Towards that end, members of industry have partnered with the COPD Foundation to form the COPD Biomarker Qualification Consortium (CBQC). The CBQC has pooled data from several trials to create a sufficiently large dataset, from which evidence that supports biomarker qualification by the FDA and European Medicines Agency could be generated. As a result, in July, 2015, plasma fibrinogen was approved by the FDA as a biomarker to identify patients at risk for disease progression for inclusion in clinical trials.

Industry is continuing efforts to identify and develop new therapeutics. New drugs developed for COPD are likely to benefit specific disease phenotypes. As an example, roflumilast, a phosphodiesterase type 4 inhibitor, is the first drug approved for treatment of a specific subgroup of patients with COPD, those with chronic bronchitis and frequent exacerbations (two or more per year). Other drugs that are in phase 3 clinical trials include mepolizumab and benralizumab, interleukin-5 inhibitors that might be effective in eosinophilic COPD. Although this phenotypic approach could lead to the approval of drugs with improved efficacy for certain subpopulations, the small number of patients in each subgroup might complicate the design and implementation of clinical trials, and might also lead to high drug costs because of the small markets.

The industry faces several continuing challenges for drug development and has to meet the often competing demands of payers and regulatory agencies. Whereas regulators value improvements in lung function and quality of life, and reductions in exacerbations in their assessment of new drug applications, payers are heavily focused on minimising costs, which is often not studied in phase 3 trials. Payers in the USA are also increasingly offering fewer drugs or, in many instances, only one drug in a particular class in their coverage policies, and pose pressure on the industry to show how their product performs better than competitors in the same class or provides added value. At the same time, the cost for drug development is higher than it has ever been. According to a 2014 study by the Tufts Center for the Study of Drug Development, the average cost of developing a new drug was $2·6 billion. Fewer than 12% of candidate molecules that enter phase 1 trials are ultimately approved by the FDA.

To conclude, COPD research is a very active area, promoted and funded by federal institutions, the pharmaceutical industry, and patient-advocacy groups, and in many cases with joint efforts. Still, funding, particularly at the federal level, is insufficient compared with the burden of disease.

**PANEL 5**

**Key messages**

- Drug development will increasingly require consideration of cost-effectiveness to meet the needs of payers and patients.
Research funding from the pharmaceutical industry for COPD has increased in the past 20 years, and several new drugs have been developed. However, drug development costs remain high, and the overall number of therapeutic classes for COPD remain low.

Investments from the US National Institutes of Health in COPD research have led to several important findings, but more funding will be needed to answer key questions about the pathogenesis and natural history of the disease. Compared with other diseases with high morbidity and mortality, COPD research remains underfunded.

**Key challenges**

- Drugs targeting subpopulations of patients with specific phenotypic characteristics hold promise for improved efficacy, but have major implications for the logistics of clinical trial design and implementation.

- New classes of drugs that slow or halt disease progression are clearly needed.

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