Enacting Process Changes to Improve Outcomes in Idiopathic Pulmonary Fibrosis: A Quality Improvement Education Initiative

ABSTRACT

Introduction. Idiopathic pulmonary fibrosis (IPF) is a rare and fatal pulmonary disease that many clinicians find challenging to recognize and diagnose. The aim of this study was to evaluate a quality improvement education (QIE) intervention designed to improve provider performance on quality measures.

Methods. The project aimed to raise the index of suspicion for IPF; improve the diagnostic process via a stepped work-up; and shorten referral time. We assessed baseline clinic data in primary care practices with no pulmonary service line; designed and implemented an educational intervention to address QI deficits; and evaluated QI data using a pre-post comparative design. Sites participated in regularly scheduled conference calls intended to facilitate interaction and maintain the QI cycle by reporting progress in data collection.

Results. A significant increase in accuracy of SOB diagnosis coding (59% vs 35%) occurred and fewer patients had an inaccurate code for chronic cough (40% vs 63%). The number of average days decreased between first presentation in primary care and diagnostic assessment and time to referral decreased by 7 days for cardiology and 4 days for pulmonology.

Discussion. This QIE intervention raised the local index of suspicion for IPF; increased the number of patients identified with SOB by 24%; improved accuracy of documentation for SOB

and chronic cough diagnosis coding; and reduced miscoding for chronic cough. QIE offers an effective intervention to improve processes that support timely referral to pulmonology and earlier consideration of therapy for patients with IPF.

Keywords. Idiopathic pulmonary fibrosis, quality improvement education, process change, primary care

BACKGROUND

Idiopathic pulmonary fibrosis (IPF) is a rare and fatal type of chronic fibrosing interstitial pneumonia of unknown cause.[1,2] Both the prevalence and incidence of IPF are more common among men than women and increase with advancing age.[3] The disease course of IPF varies, and includes acute exacerbations that can be rapid and unpredictable. Risk factors for IPF include a history of tobacco smoking, occupational and environmental factors, and family history. Overall, IPF has an extremely poor prognosis, considerable impact on patient quality of life, and an average survival time of three to five years from time of diagnosis.[2,4-6] Although there are no curative therapies for IPF, nintedanib and pirfenidone are associated with slowing disease progression, while lung transplantation is considered an effective intervention for prolonging survival.[7-9] Once lung function is lost, it is unrecoverable and therefore the earlier detection of IPF enables the earlier consideration of therapy and facilitates the preservation of lung function. Hence, timely evaluation and early diagnosis are imperative for positive outcomes in IPF; however, the presentation of IPF is often insidious and the average delay between symptom

onset and diagnosis is one to two years.[10] IPF is also frequently misdiagnosed as chronic obstructive pulmonary disease (COPD), bronchitis, emphysema, asthma, or heart disease.[11,12]

Patients with symptoms of IPF often present in primary care. Key symptoms include dyspnea on exertion/shortness of breath (SOB) and chronic cough, yet these are easily confused with symptoms of more common diseases, such as COPD, bronchitis, asthma, or heart failure.[11-13] Therefore the key to diagnosis is the stepwise discrimination between IPF and other common respiratory and cardiovascular causes of SOB, as well as differentiation from other interstitial lung diseases (ILDs), including immunologic diseases, as well as inhalational, infectious, or neoplastic conditions.[14] Diagnostic tools available to primary care providers that might support a diagnosis of IPF include spirometry, chest x-ray (CXR), echocardiogram, and high-resolution computed tomography (HRCT) scan of the chest.[14] The presence of pulmonary or coronary disease risk factors generally drive the direction and sequence of diagnostic testing in a primary care setting. In patients with coronary heart disease presenting with chronic cough and/or exertional dyspnea, tests such as chest x-ray, echocardiogram, and stress testing should be used to exclude non-respiratory causes of breathlessness, such as heart failure, ischemic heart disease and pulmonary hypertension. Chest x-ray and pulmonary function tests such as spirometry can be used to confirm or exclude a diagnosis of COPD in patients who present with any combination of breathlessness and chronic cough. Spirometry can differentiate between obstructive disease as is seen typically in COPD and restrictive disease which usually (but not always) accompanies ILD, including IPF.

A stepped diagnostic work-up that excludes non-respiratory causes of breathlessness will usually provide a clue to the presence of ILD, either through changes seen on the CXR or if obtained, through changes seen on HRCT. A history of exposure to risk factors may further raise the index of suspicion for IPF, but such risk factors may not be present in all cases. Referral to a pulmonologist for further evaluation should be the next step, which unfortunately is sometimes delayed. Specifically, a lack of clinician familiarity with ILD and IPF symptoms poses a barrier to initiating a stepped work-up and may contribute to misdiagnosis, which can lead to inappropriate treatment, unchecked disease progression, impaired quality of life, and lower survival rates.[12]

Quality improvement combined with continuing education (QIE) offers potential to improve provider performance on quality measures and so enhance care coordination and improve patient outcomes.[15] We designed and implemented a QIE initiative to improve the diagnosis and subsequent care of patients with IPF. Our overall goals were to reduce time to diagnosis and time to specialist referral for patients who present in the primary care setting with new onset or unexplained SOB and/or unexplained cough.

METHODS

We adopted a Plan-Do-Study-Act (PDSA) methodology to identify delayed diagnosis of IPF as a QI problem, assess baseline clinic data, design and implement an educational intervention, and evaluate QI data. *Planning* involved developing a gap analysis to identify the QIE goals, target metrics, data collection process, and assessment of current site processes related to each metric. *Doing* involved identifying and incorporating team and system practice changes and data entry.

Studying occurred during regularly scheduled web conferences among all sites, where weekly data, experiences, challenges, and suggestions for improvement were shared. *Acting* occurred when individual sites decided upon their own course correction and began the PDSA cycle again.

The QI project was conducted at primary care practice settings using a pre-post comparative design and is reported according to the SQUIRE checklist.[16] The study was approved by the Western Institutional Review Board. Organizational culture is a critically important component of successful QI process change; therefore, the inclusion criteria for this pilot program were as follows:

1. Small to medium primary care practices with no hospital affiliation.
2. Practices with no pulmonary service line.
3. Practices located within or bordering Ohio and/or the lower Mississippi River as these states have been identified by the US Centers for Disease Control and Prevention with the highest prevalence of COPD.[17]
4. Men and women patients aged 60 years and older with any smoking history who present with new onset or unexplained SOB and/or unexplained cough.
5. Ability to establish a QIE Champion.
6. Capability to invest resources and time for training on quality metrics and data collection.

Intervention

Site Selection, Support, and Education

We identified sites from health systems and hospitals across the Southeast US. The sites included small to medium sized primary pare practices with no hospital affiliation that were located within or bordering Ohio and/or the lower Mississippi River. We managed onboarding, training, and helped identify a clinical and operational Champion within each site to serve as the primary site contact, coordinate education webcasts, disseminate information, and provide ongoing motivation. Practice managers were involved as operational Champions at each site. The QIE initiative did not require clinicians to perform new administrative or data entry tasks. Only Champions entered patient, physician, and site-level data into a custom database on a weekly basis. We audited data entry to identify timeliness of entry issues, accuracy of data, etc. Sites participated in regularly scheduled Web-based conference calls intended to facilitate interaction and maintain the QIE cycle by reporting progress in practice-level and site-level data collection.

We designed the educational intervention in collaboration with faculty with expertise in IPF to achieve the following goals:

1. Increase PCPs' awareness and understanding of IPF epidemiology, symptoms, and clinical manifestations;
2. Improve the IPF diagnostic process for patients who present in a primary care setting with new onset or unexplained SOB and/or unexplained cough;
3. Recognize the importance of considering IPF early in the work-up;
4. Order and interpret appropriate tests to complete a stepped diagnostic work-up; and
5. Refer patients to pulmonary and/or cardiology specialists for further evaluation.

Following review of the importance of national guidelines and measures, as well as the initiative objectives, an education webcast was delivered live at each site between December 2017 and March 2018. The educational webcast was certified to provide continuing education credit (1 hour) for physicians (ACCME) and nurses (AANP and ANCC). During live webcasts participants were able to ask faculty questions about IPF. Following education exposure, participants discussed the site's current practices and protocols, target outcomes, a redesign of current care delivery, new organizational protocols, approaches to overcoming barriers, and unanswered questions. Lastly, the site reviewed the data collection and reporting process.

Measures

The project objectives were as follows:

1. Raise the index of suspicion for IPF in a primary care setting
2. Improve the process of exclusion of other known causes of cough and new onset or unexplained SOB
3. Improve diagnosis via a stepped work-up
4. Shorten time to referral for patients with concerning symptoms to a pulmonologist

We identified a range of process metrics based on literature review and input from expert faculty:

1. Diagnosis of shortness of breath or chronic cough
2. Time to Spirometry or PFT within primary care office or time to referral for Pulmonary Function Testing (PFT)
3. Time to Chest X-ray within primary care office or time to referral for

Chest X-ray at another site

4. Time to Computed Tomography (CT) Scan or high-resolution CT of the chest
5. Average days between diagnostic order and completion date
6. Total number of referrals
7. Time to refer diagnosed patients to pulmonology and cardiology

1. Time to Echocardiogram: Breathlessness and cough are seen in many diseases that commonly occur in middle-aged and elderly patients, most notably COPD and heart failure. Echocardiograms can detect the presence of heart failure, cardiomyopathies, valve abnormalities, and pulmonary hypertension thereby excluding important non-respiratory causes of breathlessness.
2. Time to Chest X-ray: PCPs typically order chest x-rays in patients with respiratory symptoms, such as shortness of breath and chronic cough; chest X-rays can provide clues to the presence of conditions such as COPD, asthma and congestive heart failure. A primary reason to obtain a chest radiograph in a patient with either a chronic cough or exertional dyspnea is to exclude these and other alternative diagnoses including pneumonia, pneumothorax, pleural effusion and lung masses. The suspicion of IPF should be raised in patients with evidence of interstitial changes on CXR. These can be subtle and might be missed with patients afforded a presumptive diagnosis of another more common condition such as obstructive lung diseases or congestive heart failure.
3. Time to Spirometry: Spirometry is used to confirm a COPD diagnosis; in a primary care setting, the diagnosis of COPD should be considered in patients who present with any combination of breathlessness and chronic cough. Pulmonary function tests such as

spirometry can assess the nature and degree of lung involvement and differentiate between a restrictive, obstructive or mixed physiologic pattern of impairment. Most interstitial lung diseases such as IPF present as restrictive disorders, which is in contrast to obstructive disorders such as asthma, COPD, and emphysema. Notably, patients with IPF can also present with normal lung volumes and therefore normal spirometry does not exclude a diagnosis of IPF.

4. Time to Computed Tomography (CT) Scan: A primary reason to obtain a CT scan of the chest in a patient with either a chronic cough or exertional dyspnea is to discern specific abnormalities that may be themselves be diagnostic, or at least guide subsequent testing needed to attain a specific diagnosis. CT scan has greater sensitivity and specificity than standard chest radiography.
5. Time to Referral to Pulmonologist: Once non-respiratory causes of breathlessness have been excluded upon completion of a stepped diagnostic work-up, PCPs should consider the possibility of IPF in middle-aged or elderly patients, who present with unexplained symptoms of breathlessness or chronic cough. PCPs should refer patients to a pulmonologist specialist to continue the work-up and confirm the diagnosis of IPF and differentiate this from other causes of ILD.

Outcome Data Collection

Champions at each site were trained to enter data to a HIPAA compliant and personal health information-secure cloud-based data capture platform that supports real-time reporting and enables rapid-cycle process improvement. Data collection occurred between January 3 to June 1, 2018. Baseline data using these QI process change metrics were collected from each site upon

initiation of the QIE program and mapped to health system site data sources and clinical workflows. Champions and administrators were able to review data trends on an aggregate level; access to personal health information (PHI) was restricted to site Champions.

Evaluation and Analysis

Moore's outcomes provided the framework for analysis of educational outcomes.[5] Ongoing practice data derived from the Insight+ dashboard were used to describe processes changes and changes in clinician practice.

RESULTS

Participants

Five sites that met the inclusion criteria were selected to participate in the QIE initiative with a total of 24 clinicians. These sites had some familiarity with continuing education and QI process change as well as engaged care teams with an interest in learning how to improve workflow processes. All clinicians in each practice were invited to participate in the live webcast; however, participation was tiered. All solo practitioners (n=3) completed the education webcast, two clinicians from each of the larger practices (n=4) participated in the live webcast, and a recording of the webcast and the slides were shared with the remaining clinicians in each practice (n=17). At the request of the larger practice, we shared a recording and download of education materials with their clinicians. This is an educational format that the larger practice has used in past QIE interventions to enhance the scalability of the intervention and internal engagement of clinicians in their practice. Although completion of the recorded webcast among the remaining clinicians was not validated, feedback from ongoing weekly calls suggest that all clinicians in five

practices were exposed to the educational intervention. The total number of pre-pilot patients was 100.

Accuracy of Diagnosis Coding

At baseline, 35% of patients (n=88) were accurately coded as having a diagnosis for SOB and 63% of patients were miscoded as having a diagnosis of chronic cough (Figure 1). In the pre-pilot, some practices lacked clear attribute differentiation between SOB vs. chronic cough coding and one practice was not coding at all for SOB at baseline. The education intervention clearly addressed these issues and changed the accuracy of diagnosis coding. Following the intervention, a significant increase in accuracy of SOB diagnosis coding (59%) occurred and fewer patients had an inaccurate code for chronic cough (40%) in the pilot.

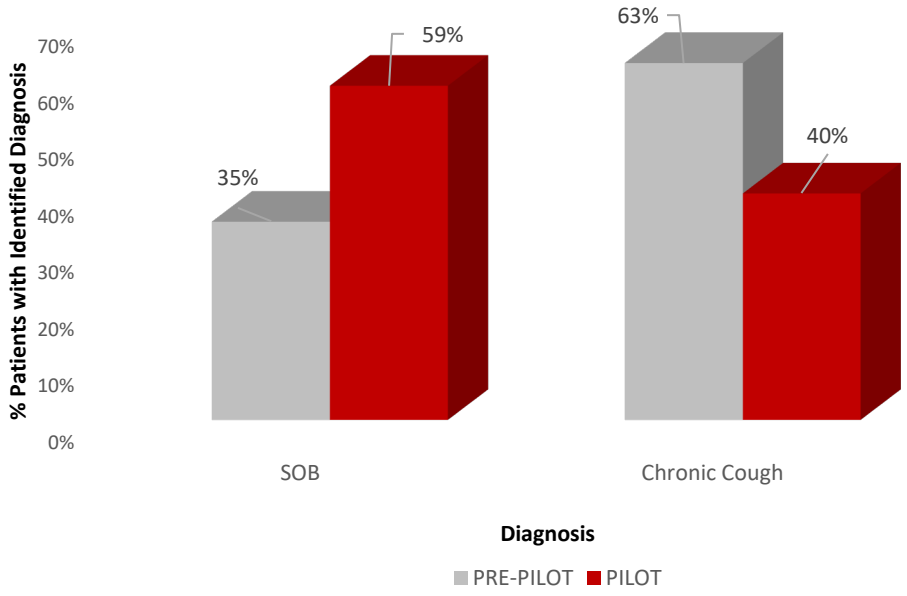

Figure 1. Increase in Accuracy of (SOB) Diagnosis Coding with a Resulting Decrease in Miscoding for Chronic Cough.

Time to Diagnostic Testing

The number of average days decreased between first presentation in primary care and diagnostic assessment via X-Ray, and CT scan (Figure 2). For example, X-ray ordering at baseline was 46 days. Following the educational intervention, x-rays were immediately ordered on the same day as the initial primary care visit and the total number of x-rays appropriately ordered also increased. Another positive process changes which occurred was adoption of PFT ordering by the practices, as an appropriate diagnostic test. At baseline, there was a lack of awareness regarding the importance of PFTs as an appropriate diagnostic tool. Per the educational intervention, the use of PFT testing increased and was adopted by practices. The number of average days also decreased for ordered CT diagnostics with sequential ordering and completion of X-ray and PFT. As a result, linkages for appropriate care improved based on diagnostic test type being ordered in a sequential timely manner, during the pilot and post educational intervention.

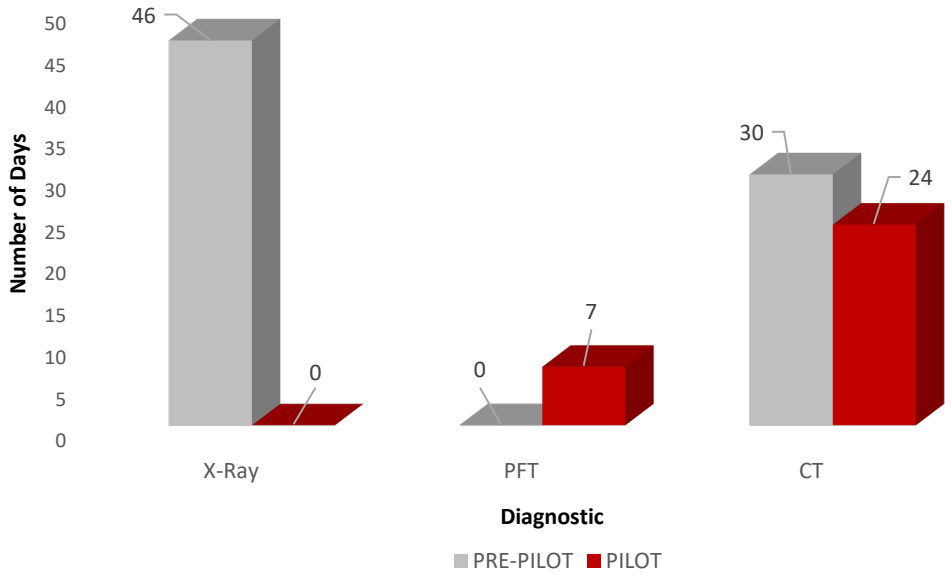

Figure 2. Average Days Between Initial PCP Visit and Ordering of Diagnostic Testing

During pre-pilot, follow through on ordered diagnostics was inadequate or not optimal. In pilot, the number of average days decreased between the diagnostic order and completion date for X-ray, PFT and Echo (Figure 3). The educational intervention and training of staff played a significant role in reducing days to completing diagnostic orders. Practices implemented EHR alerts for outstanding orders, trained staff on the importance of the stepped-up diagnostic process, and to be more alert of overdue orders. Making sure the patient received coordinated care for timely follow-up of diagnostic testing not available in the office was also a focus of process improvements.

In pre-pilot, practices already had good existing workflows in place to manage other chronic conditions and the data for days between diagnostic order and completion date was previously

available, since the practices were coding the data. However, the educational intervention trained practices to look at the right data and how to use the data. Practices became more effective at identifying care gaps with existing organizational workflows, which orders were overdue, and which patients need to be prompted for follow-up. The practice of regularly reviewing the data and applying a more population health approach was the resultant process change in the pilot.

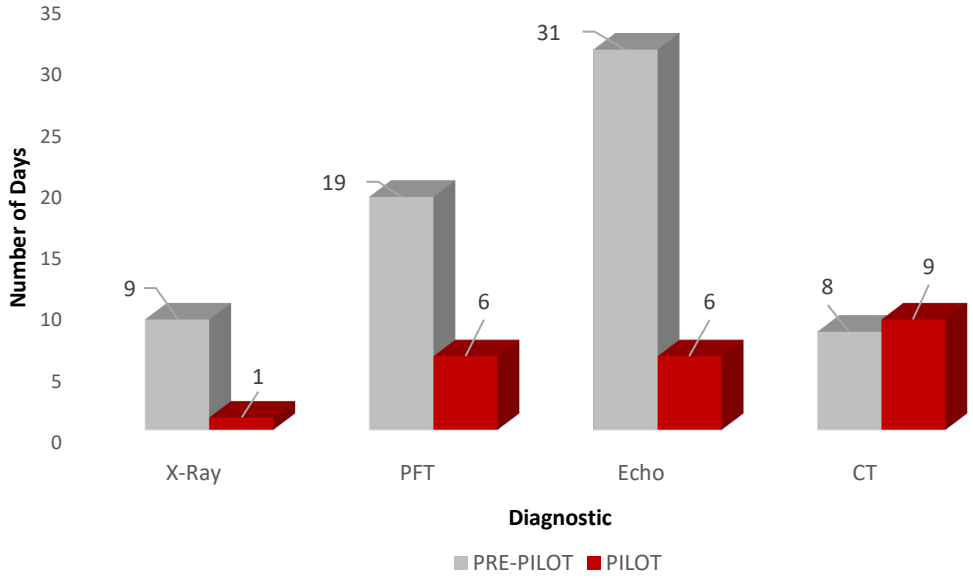

Figure 3. Decrease in Average Days Between Diagnostic Order and Completion Date

Time to Referral

The time to referral decreased from pre-pilot baseline by 7 days for cardiology and 4 days for pulmonology (Figure 4). When compared to pre-pilot, this improvement in diagnosis and referral was due to better documentation and coding as well as shorter time periods for the initial order of appropriate diagnostic tests.

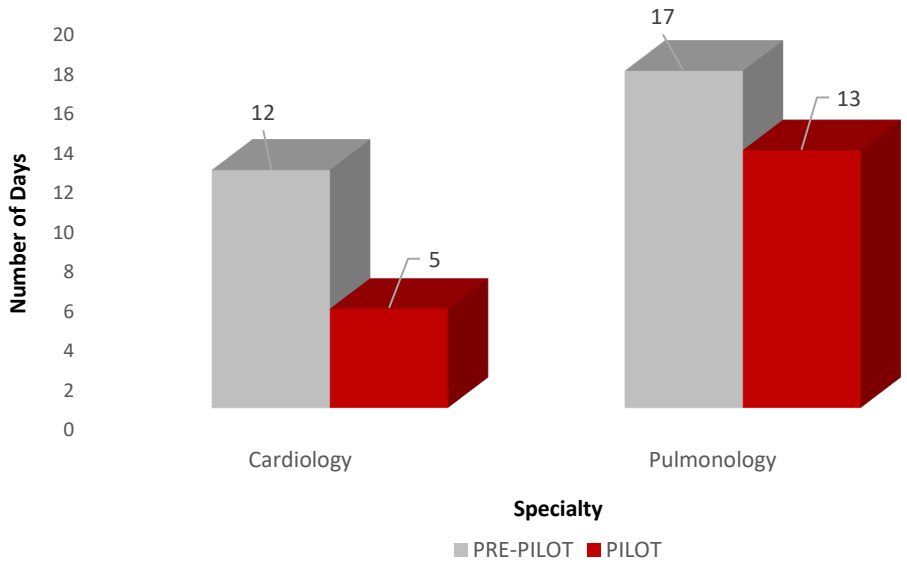

Figure 4. Decrease in Time to Specialist Referral with Potential IPF-related Symptoms

DISCUSSION

Process Changes

This QIE project raised the local index of suspicion for IPF in five primary care setting and increased the number of patients identified with SOB by 24%. The intervention improved accuracy of documentation for SOB and chronic cough diagnosis coding and reduced miscoding for chronic cough. At baseline, most practices were unable to clearly differentiate coding for SOB versus chronic cough and one practice had never coded for SOB. The live webcast emphasized how to differentiate between these symptoms and likely helped to raise awareness of IPF and differentiation between these two symptoms. The project improved the differential diagnosis for IPF, improved awareness and use of recommended diagnostic tools, and improved the timeliness of appropriate specialist referrals for patients with potential IPF symptoms.

Referrals to cardiology occurred 58% sooner than baseline and 24% sooner for pulmonology. The linkage to appropriate care improved based on the type of testing being completed appropriately and in a timely manner. At baseline, practices were unaware of the role of PFTs in a stepped IPF work up. Following education, practices ordered PFT, chest x-ray, and CT scan more expeditiously as appropriate diagnostic tools for patients with SOB and/or chronic cough.

Our study results show that more appropriate tests were being ordered compared with baseline; however, our results do not reveal what happened in the seven days between patient visit and PFT ordering, nor do our results indicate the sequence of test ordering. Therefore, results are likely to reflect the availability of community resources, for instance, ordering an x-ray on the day of visit and waiting for results before ordering PFT. There was also a trend toward more rapid test completion (Figure 4). Raised awareness within participating practices about the need for improving time to test request and specialist referral, as well as improved care coordination, follow-up on ordered tests, and enhanced work flow processes already in place for other conditions might explain this adoption of a more rapid, stepped approach to diagnosis. Providing appropriate education on which symptoms to look for, which data to collect, and how to use these data, may have enabled sites to identify care gaps such as overdue test orders and follow-up. We were unable to determine significant differences in documentation and data exporting process across practices; however, the documentation accuracy rate was higher and the time taken to fulfill a referral was lower within the larger group. These differences might be due to the existence of cross-training and more specialized roles in the larger group, such as a referral specialist that primarily ensures that patients are being appropriately referred and that appointments have been completed.

The Role of Data Transparency in Process Change

Overall, the project improved QI processes and data transparency concerning IPF and, in doing so, illuminated a rare condition that participating sites had little knowledge of prior to the pilot. By virtue of their PTN membership the practices in this pilot had already committed to building a culture of process change and embraced the idea of using small projects as opportunities to build QI skills that are conducive to process change. This project offered an additional opportunity for participating practices to integrate population health concepts into the workflow and consolidate a rapid cycle PDSA approach to creating and sustaining a quality-focused organizational culture. The initiative was able to build on this established culture of QI to create transparent data collection, coding, and documentation processes in the context of ongoing education related specifically to IPF. The Dashboard enabled clinicians to know which symptoms to be aware of in relation to IPF, which is an important resource given that IPF is rare and many clinicians in primary care are unfamiliar with its presentation. Following education, participants were able to use the Dashboard to share information about symptoms to be aware of with clinic staff. Knowing that certain patient populations are potentially vulnerable to IPF symptoms and knowing which symptoms potentially point to IPF were key process changes.

Study Strengths and Limitations

There are limitations to this study. The sample size was small for the number of participating clinics and patients. However, given the rarity of IPF we did not expect to identify a large pool of patients with potential IPF symptoms. Additionally, the QI Champion in one practice transitioned to another practice. It would be prudent in future QIE initiatives to develop

opportunities for broader, cross-practice QI leadership training to mitigate gaps in QI leadership. Despite these limitations, it was encouraging to see that busy primary groups were enthusiastic about participating in a QIE project to learn more about a relatively rare condition as well as how to better identify patients with IPF symptoms. This engagement is especially encouraging in an area that does not yet have implications for QI reimbursement and is not considered a common priority area.

CONCLUSION

Although IPF prevalence has been increasing in the US in recent years, current treatment modalities can slow disease progression or prolong survival.[7-9] Therefore, it is increasingly important to refer patients for specialist evaluation earlier in their diagnostic journey. Consistent, ongoing QIE offers an effective intervention to improve processes that support more rapid referral to pulmonology and earlier consideration of therapy.

Lessons for Practice

- QIE is an effective intervention to improve processes and data transparency concerning IPF in primary care.
- Education focused on which symptoms to look for, which data to collect, and how to use these data, and may have enabled sites to identify care gaps such as overdue test orders and follow-up.
- In the setting of IPF, QIE improved the differential diagnosis for IPF, raised awareness and use of recommended diagnostic tools, and enhanced the timeliness of appropriate specialist referrals for patients with potential IPF symptoms.

REFERENCES

1. Raghu G, Collard HR, Egan JJ, et al. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. *Am J Respir Crit Care Med.* 2011;183(6):788-824.
2. Vancheri C, Failla M, Crimi N, Raghu G. Idiopathic pulmonary fibrosis: a disease with similarities and links to cancer biology. *Eur Respir J.* 2010;35(3):496-504.
3. Esposito DB, Lanes S, Donneyong M, et al. Idiopathic Pulmonary Fibrosis in United States Automated Claims. Incidence, Prevalence, and Algorithm Validation. *Am J Respir Crit Care Med.* 2015;192(10):1200-1207.
4. Raghu G, Chen SY, Yeh WS, et al. Idiopathic pulmonary fibrosis in US Medicare beneficiaries aged 65 years and older: incidence, prevalence, and survival, 2001-11. *The Lancet Respiratory medicine.* 2014;2(7):566-572.
5. Moore DE GJ, Gallis HA. Achieving desired results and improved outcomes: integrating planning and assessment throughout learning activities. *JCEHP.* 2009;29:1-15.
6. Yu YF, Wu N, Chuang CC, et al. Patterns and Economic Burden of Hospitalizations and Exacerbations Among Patients Diagnosed with Idiopathic Pulmonary Fibrosis. *Journal of managed care & specialty pharmacy.* 2016;22(4):414-423.
7. King TE, Jr., Bradford WZ, Castro-Bernardini S, et al. A phase 3 trial of pirfenidone in patients with idiopathic pulmonary fibrosis. *N Engl J Med.* 2014;370(22):2083-2092.
8. Richeldi L, du Bois RM, Raghu G, et al. Efficacy and safety of nintedanib in idiopathic pulmonary fibrosis. *N Engl J Med.* 2014;370(22):2071-2082.

9. Raghu G, Rochwerg B, Zhang Y, et al. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline: Treatment of Idiopathic Pulmonary Fibrosis. An Update of the 2011 Clinical Practice Guideline. *Am J Respir Crit Care Med.* 2015;192(2):e3-19.
10. Collard HR, Tino G, Noble PW, et al. Patient experiences with pulmonary fibrosis. *Respir Med.* 2007;101(6):1350-1354.
11. Zibrak JD, Price D. Interstitial lung disease: raising the index of suspicion in primary care. *NPJ Prim Care Respir Med.* 2014;24:14054.
12. Lee AS, Mira-Avendano I, Ryu JH, Daniels CE. The burden of idiopathic pulmonary fibrosis: an unmet public health need. *Respir Med.* 2014;108(7):955-967.
13. Schoenheit G, Becattelli I, Cohen AH. Living with idiopathic pulmonary fibrosis: an in-depth qualitative survey of European patients. *Chronic respiratory disease.* 2011;8(4):225-231.
14. Nathan SA BW, King CS. Guide to Clinical Management Idiopathic Pulmonary Fibrosis. In: Switzerland: Springer 2016.
15. Diamond L KJ, Sulkes D. *The Quality Improvement Education (QIE) Roadmap: A Pathway to our Future* The Alliance for Continuing Education in the Health Professions 2015.
16. Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. Squire 2.0 (Standards for Quality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. *American journal of critical care : an official publication, American Association of Critical-Care Nurses.* 2015;24(6):466-473.

17. Prevention. UCfDCa. Chronic obstructive pulmonary disease (COPD). Work-Related Lung Disease (WoRLD) Surveillance System. http://www.cdc.gov/copd/data.htm. Accessed.