

1. Reducing Diagnostic Error to Improve Patient Safety in COPD and Asthma (REDEFINE Study)

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2. STRUCTURED ABSTRACT

Purpose: Spirometry is underutilized in patients with a physician diagnosis of COPD and/or asthma, leading to increased risk for diagnostic error (DE). This can lead to unnecessary respiratory pharmacotherapy and/or missed diagnosis of other disease states. Underserved populations may have increased prevalence of DE due to poor access and multi-morbidities that can present with similar symptoms.

Scope: To determine the DE in asthma and/or COPD patients and to evaluate the effectiveness of the REDEFINE program, compared to usual care, on healthcare utilization and patient outcomes.

Methods: Patient participants with the following were included: ≥ 40 years of age, using ≥ 1 maintenance respiratory medication, diagnosed with asthma and/or COPD, and no spirometry test within the past 3 years. The intervention (INT) group completed a spirometry test at the baseline visit, whereas the usual care (UC) group completed the same test at the 1-year follow-up.

Results: In total, 402 patient participants were recruited; 289 (71.9%) were women, 332 (83.2%) were Black/African American, and 163 (42.2%) had an annual household income (AHI) of $< \$10,000$. Only 131 (43.1%) of participants had spirometry consistent with their initial diagnosis. Overall, 76 (45.0%) in the INT group reported an emergency department visit compared to 111 (48.3%) in the UC group ($p=0.426$). There was an increased number of participants who had an all-cause hospitalization in the UC group compared to the INT group: 48 (20.9%) vs 17 (10.1%), respectively ($p = 0.005$).

Key Words

Chronic Obstructive Pulmonary Disease (COPD), Asthma, Diagnostic Error (DE), Spirometry

3. PURPOSE

Aim 1: Determine the prevalence of and characteristics associated with diagnostic error (DE) in asthma and/or COPD in an underserved population.

Aim 2: Evaluate the effectiveness of the REDEFINE program compared to usual care on healthcare utilization and patient-centered outcomes (including respiratory medication use, all-cause emergency room visits, and all-cause hospitalizations)

Aim 3: Evaluate the cost impact and cost-effectiveness of the REDEFINE program versus usual care

4. SCOPE

Asthma and chronic obstructive pulmonary disease (COPD) are common chronic lung diseases that are diagnosed in more than 30 million adults in the United States.^{1,2} However, diagnostic error (DE), considered one of the most common and harmful of patient-safety problems by the Institute of Medicine,^{3,4} occurs frequently with asthma and/or COPD and disproportionately affects minorities and the underserved. DE leads to lost opportunities to identify other chronic conditions, avoidable morbidity and mortality, unnecessary costs to patients and health systems, and poor quality of care.³⁻⁶

Shortness of breath, or dyspnea, which is a common symptom in asthma and COPD, is also common for many other chronic conditions, such as cardiovascular disease and obesity. A better understanding of the impact of DE and interventions to improve diagnostic accuracy in asthma and COPD are of particular importance for minorities and the underserved who are disproportionately affected by conditions leading to dyspnea.

Spirometry is a simple, mobile, and essential test that is recommended by all major national and international guidelines for the diagnosis of asthma and COPD.⁷⁻¹⁰ However, it is well known that spirometry is not routinely used in the ambulatory primary care setting,¹¹⁻¹⁹ and minorities and the underserved population are less likely to have spirometry, leading to greater prevalence of DE.²⁰⁻²⁵ It has been estimated that 30-50% of people with an existing diagnosis of asthma and COPD were found to be misdiagnosed.^{11,20,21,26-32} Many of these patients misdiagnosed with asthma and/or COPD receive unnecessary respiratory pharmacotherapy, which can pose serious risks, including pneumonia, cardiovascular events, and mortality.³³⁻⁵³ In the setting of DE, these are considered avoidable risks. Unnecessary respiratory pharmacotherapy use in minorities and the underserved, who are already disproportionately affected by cardiovascular disease,⁵⁴⁻⁵⁶ can increase the risk of poorer outcomes. There is also DE in the diagnosis of asthma versus COPD, as these are both clinically distinct respiratory disorders with nuances in treatment recommendations. It is reported that African Americans are considered to have increasing COPD mortality and are disproportionately affected by asthma death rates.⁵⁷⁻⁶⁰ However, as spirometry is not routinely performed and DE is prevalent in asthma and COPD, a component of these poor outcomes may be attributable to missed or delayed diagnoses of other chronic conditions or misdiagnosis within asthma and COPD.

Barriers to the use of spirometry in primary care exist at provider and health system levels. Previous studies show that primary care providers (PCPs) lack knowledge in existing guidelines and in implementing spirometry into primary care clinics.^{11,18,61-64} Beyond these barriers, PCPs struggle with logistical challenges, such as time and workflow constraints, with clinic visits lasting 15 minutes or less in patients with multiple chronic medical conditions.^{62,65} These predisposing and enabling factors explain why prior studies that included interventions to educate PCPs and incorporate spirometry by training personnel in primary care clinics have had limited results.^{32,63,66-68}

A new paradigm to improve guideline-based care for asthma and COPD, which includes spirometry, is needed and can lead to a better understanding of DE and improved patient safety and patient-centered outcomes. Health promoters have been supplementing medical care by disseminating appropriate healthcare practices for underserved minority populations. However, studies that include diagnostic evaluations with spirometry for asthma and COPD have not been performed. The REDEFINE program (Reducing Diagnostic Error to Improve Patient Safety in COPD and Asthma) will incorporate a study team functioning as health promoters working collaboratively with PCPs to address identified barriers to guideline-based care that includes spirometry for the diagnosis of asthma and COPD among patients at risk for DE. We propose a comparative effectiveness study to better understand the epidemiology of DE and to evaluate the effectiveness and economic impact of providing the REDEFINE program to an underserved, predominantly minority population with a diagnosis of asthma and/or COPD at risk for DE.

5. METHODS

Study Design

This study is a cluster-randomized comparative effectiveness trial conducted of patient participants with a primary care provider (PCP) diagnosis of COPD and/or asthma seen in outpatient primary care provider clinics.

Participants

Primary care providers (PCPs) included internal medicine or family medicine physicians and advanced nurse practitioners. PCPs with at least one ½ day per week outpatient clinic session were eligible for the study. PCPs were sent letter and email invitations to participate in the study. After obtaining PCP informed consent and prior to patient recruitment, a 1-hour educational session was conducted. The purpose of this session was to provide education to PCPs about COPD, asthma, spirometry, and GOLD and GINA guidelines (GOLD=Global Initiative for Chronic Obstructive Lung Disease, GINA=Global Initiative for Asthma). PCPs received continuing medical education credit and \$95 for their attendance. PCPs who consented to participate in the study and completed the education session were randomized. Their patients who met eligibility criteria were included in intervention or usual-care groups based on the randomization designation of their PCP.

Patient participants who were included met the following criteria: 1) were at least 40 years of age, 2) were prescribed at least one maintenance respiratory medication in the past 12 months, 3) did not have spirometry performed in the past 3 years, 4) were a past or current smoker, and 5) had at least one of the following diagnoses: asthma and/or COPD, emphysema, or chronic bronchitis.

Patient participants were determined ineligible for the study if they met any of the following exclusion criteria: 1) were unable to perform adequate spirometry, 2) were non-English speaking, 3) were pregnant, 4) had plans to move from the Chicago area within the next year, 5) were seen by pulmonary or allergy specialist in the past 3 years, 6) had any terminal illness with a life expectancy of <6 months, or 7) had a life-threatening respiratory failure event (e.g., Intensive care admission and/or use of mechanical ventilation) in the past year.

Patient participants who were scheduled to be seen in primary care clinic by a recruited PCP 2 weeks in the future were identified. Prescreen of the electronic health records was performed by information systems to identify the following: age ≥ 40 years at the time of the scheduled clinic visit and using at least one maintenance respiratory medication (e.g., long-acting beta agonists (LABA), long-acting anticholinergics (LAA), inhaled corticosteroids (ICS), and at least one of the following: 1) diagnosis of asthma (ICD-9 493.xx or ICD 10 J45.xx) or 2) diagnosis of COPD, emphysema, or chronic bronchitis (ICD-9 491.xx, 492.xx, 496 or ICD 10 J41.xx, J42.xx, J43.xx, J44.xx) and did not have a current procedural testing (CPT) code for spirometry (CPT codes: 94010, 94014, 94015, 94016, 94060, 94070, 94620) or completed order for spirometry testing in the past 3 years). Patient participants who were identified were mailed a recruitment letter with the option to opt out of the study. One week after the letter was sent, the study team called the eligible patient participant; a phone screen to confirm eligibility criteria and review study procedures was conducted. When a patient participant agreed to participate, they were instructed to arrive 90 minutes before their scheduled clinic visit.

Intervention and Comparator (Usual Care)

The baseline visit occurred in a private room in the same building that the patient participants were scheduled to have their primary care visit. During the initial face-to-face visit, prior to the initiation of any study procedures, the patient participant completed a written consent and HIPAA authorization. The baseline data collection included 1) demographic data, 2) socioeconomic status-related measures, 3) health insurance status, 4) current respiratory medication use, 5) multi-morbidities, 6) history of prior healthcare utilization within the past year (i.e., acute care outpatient visits, ED visits, hospitalizations in the past year with associated cause, prednisone use), and 7) tobacco smoking exposure history.

Other data collected included the Modified Medical Research Council (mMRC) dyspnea scale and a respiratory exacerbation history in the past year, both of which were needed in addition to spirometry to assess severity categories using the GOLD criteria for COPD, and a quality of life scale (i.e., EQ-5D-5L).

Spirometry Protocol for the Intervention Group: During the phone screen, patient participants were told to hold their short acting bronchodilator (BD) medications for 8 hours prior to the first visit. During the first visit, a pre- and post- (BD) spirometry test was performed using levalbuterol. The key measurement was forced expiratory volume in 1 second (FEV1), forced expiratory volume (FVC), and the FEV1/FVC ratio which is used to define obstruction.

A one-page printout of the results that included the spirometry values, a flow volume loop, a volume time curve, an interpretation of spirometry results in relation to initial diagnosis, and further recommendations was provided to the PCP at the time of the clinic visit. Post-BD obstruction was defined by a post-BD FEV1/FVC ratio <0.7 , as defined by GOLD guidelines.¹ A post-BD spirometry was considered to have a positive bronchodilator response if the FEV1 increases $>12\%$ and 200 mL compared to pre-BD values. Algorithms were chosen based on the initial PCP diagnosis at baseline. The final diagnosis was determined in combination with the PCPs initial diagnosis and spirometry results. For example, if the spirometry findings supported the PCP's initial diagnosis, then that diagnosis was considered final. If the spirometry findings did not support the initial diagnosis, then a possible new final diagnosis, recommendation for deescalation of inhaled therapies, and repeat spirometry, or an alternative diagnosis with further testing, was provided through established templates. If a final diagnosis of COPD was determined, the template included not only the interpretation of spirometry but also the assessment and treatment recommendations per GOLD guidelines.¹ If a final diagnosis of asthma was suggested, the template included the treatment recommendations per GINA guidelines.² If the findings suggested asthma COPD overlap, then the template included both treatment recommendations. After spirometry testing, the appropriate template based on the initial diagnosis and spirometry findings was chosen and printed out, with a copy provided for the patient participant and provider to use at the clinic visit.

Spirometry de-escalation protocol: If the initial spirometry did not show evidence of post-BD obstruction and was without a BD response, and the PCP considered asthma as a diagnosis, a template was chosen with the recommendation to de-escalate inhalers and repeat spirometry 1-2 weeks after stopping the inhaler at the primary care clinic site when their PCP had a clinic date. The recommendation section of the template recommended stopping maintenance inhalers in a stepwise fashion, starting with long-acting bronchodilators (i.e., long-acting beta-2 agonists and long-acting muscarinic antagonists) followed by inhaled corticosteroids. If the PCP was agreeable, they signed the template, and the health promoters scheduled the patient participant for a return visit for repeat spirometry. If the de-escalation spirometry showed a BD response at any time, the assessment suggested asthma. If the final de-escalation spirometry, performed off all inhaler therapies, did not show a BD response, the final template recommended a methacholine challenge test, expert consultation, or consideration of an alternative diagnosis. The final spirometry was provided to the PCP, and participants were managed by their PCP thereafter.

Baseline Visit for Usual Care (UC) Group: The baseline data collection was identical to the intervention except for spirometry. Similar to the intervention group, the UC group had a spirometry screener to confirm their appropriateness for spirometry, but the spirometry protocol was conducted at the end of the 1-year follow-up for this group.

The spirometry protocol at that time was identical to the intervention group, including the de-escalation protocol. However, the final visit for the UC group did not coincide with a clinic visit but occurred when the PCP had a clinic date, so recommendations for the de-escalation were obtained onsite if needed, similar to the intervention spirometry protocol. The template algorithm was chosen based on the initial provider diagnosis at baseline.

Follow-up and Outcomes/Measures

Electronic medical record chart reviews and telephone follow-ups were completed at four different time points after the initial study visit in the PCP clinic: at 3, 6, 9, and 12 months. The following data were collected at various time points: 1) change in or new diagnosis of COPD and/or asthma, 2) change in health insurance or self-pay status, 3) current respiratory medication use, 4) additional or changes in multi-morbidities, 5) history of prior healthcare utilization within the past 3 months (i.e., acute care outpatient visits, ED visits, hospitalizations and cause, prednisone use, diagnostic cardiac and respiratory testing), 6) tobacco smoking status, and 7) quality of life and dyspnea measures.

Monetary compensation of patient participants:

Baseline visit (T0): Same for INT and UC groups. Patient participants received \$75 in cash upon the completion of the baseline visit.

Follow-ups (T1-T3): Same for INT and UC groups. Patient participants who completed the follow-up, in person or via telephone, received \$20 for each interaction.

Final visit (T4): Same for INT and UC groups. Patient participants received \$95 upon the completion of the last follow-up visit.

Additional spirometry visits after de-escalation of therapy: Patient participants in the INT and UC groups received \$50 in cash for each additional spirometry visit completed.

6. RESULTS

Principal Findings and Outcomes

In total, 402 patient participants were enrolled. Baseline characteristics are shown in Table 1 and were similar in both study arms. Of this group, 289 (71.9%) were women, 332 (83.2%) were African American, 163 (42.2%) had an annual household income (AHI) of <\$10,000, and 181 (45.1%) had an education level $\leq$ high school. At baseline, the patient participants reported having the following respiratory diagnoses: 42 (10.4%) COPD, 298 (74.1%) asthma, and 62 (15.4%) COPD and asthma. Comorbidities at baseline were also similar in both groups, except for a few notable differences (Table 1).

Table 1. Baseline Patient Participant Characteristics			
	Total (N=402)	Intervention (N=171)	Usual Care (N=231)
Age in Years			
40-64	316 (78.6)	135 (78.9)	181 (78.4)
65+	86 (21.4)	36 (21.1)	50 (21.6)
Mean $\pm$ SD	57.6 $\pm$ 10.2	57.7 $\pm$ 10.1	57.6 $\pm$ 10.4
Min-Max	40.0-93.0	40.0-88.0	40.0-93.0
Median (IQR)	57.0 (50.0-63.0)	57.0 (50.0-64.0)	58.0 (50.0-63.0)
Gender			
Female	289 (71.9)	119 (69.6)	170 (73.6)

Race			
Missing	3 (0.7)	1 (0.6)	2 (0.9)
African American	332 (83.2)	139 (81.8)	193 (84.3)
White	41 (10.3)	20 (11.8)	21 (9.2)
Other	26 (6.5)	11 (6.5)	15 (6.6)
Marital Status			
Single/Widowed	297 (73.9)	128 (74.9)	169 (73.2)
Co-habiting/Married	105 (26.1)	43 (25.1)	62 (26.8)
Household Income			
Missing	16 (4.0)	9 (5.3)	7 (3.0)
Less than 10,000	163 (42.2)	71 (43.8)	92 (41.1)
10,000-19,999	72 (18.7)	31 (19.1)	41 (18.3)
20,000+	151 (39.1)	60 (37.0)	91 (40.6)
Education			
Missing	1 (0.2)		1 (0.4)
High school or less	181 (45.1)	78 (45.6)	103 (44.8)
Vocational/ technical school or Some college	142 (35.4)	59 (34.5)	83 (36.1)
Bachelor and above	70 (17.5)	30 (17.5)	40 (17.4)
Other	8 (2.0)	4 (2.3)	4 (1.7)
Respiratory diagnosis			
COPD	42 (10.4)	14 (8.2)	28 (12.1)
Asthma	298 (74.1)	127 (74.3)	171 (74.0)
COPD and Asthma	62 (15.4)	30 (17.5)	32 (13.9)
Coexisting Conditions			
Hypertension	274 (68.2)	116 (67.8)	158 (68.4)
Diabetes	129 (32.1)	53 (31.0)	76 (32.9)
Dyslipidemia	117 (29.1)	47 (27.5)	70 (30.3)
Osteoarthritis	150 (37.3)	66 (38.6)	84 (36.4)
Depression	95 (23.6)	37 (21.6)	58 (25.1)
Anxiety	51 (12.7)	23 (13.5)	28 (12.1)
Obstructive/central sleep apnea	37 (9.2)	16 (9.4)	21 (9.1)
Congestive heart failure (CHF)	29 (7.2)	9 (5.3)	20 (8.7)
Coronary artery disease	22 (5.5)	11 (6.4)	11 (4.8)
Arrhythmia	28 (7.0)	7 (4.1)	21 (9.1)
Autoimmune disease	26 (6.5)	15 (8.8)	11 (4.8)
Cancer	25 (6.2)	13 (7.6)	12 (5.2)
Osteoporosis	17 (4.2)	7 (4.1)	10 (4.3)
Stroke	13 (3.2)	5 (2.9)	8 (3.5)
End stage kidney disease	1 (0.2)	1 (0.6)	0 (0)
Other	15 (3.7)	9 (5.3)	6 (2.6)

Respiratory medication use at baseline was similar in both groups (Table 2).

Table 2. Medication use at baseline by intervention.			
	Total (N=402)	Intervention (N=171)	Usual Care (N=231)
Any Short-acting Rescue Inhaler	395 (98.3)	169 (98.8)	226 (97.8)
Any ICS	252 (62.7)	107 (62.6)	145 (62.8)
Any LABA	4 (1.0)	2 (1.2)	2 (0.9)
Any LAMA	28 (7.0)	11 (6.4)	17 (7.4)
Any ICS + LABA	137 (34.1)	60 (35.1)	77 (33.3)
Any LAMA + LABA	2 (0.5)	1 (0.6)	1 (0.4)
Medications (total)			
0	128 (31.8)	55 (32.2)	73 (31.6)
1	266 (66.2)	113 (66.1)	153 (66.2)
2	6 (1.5)	2 (1.2)	4 (1.7)
3	2 (0.5)	1 (0.6)	1 (0.4)

In total, 131 (43.1%) had a correct initial diagnosis of COPD and/or asthma, as defined by spirometry results consistent with the diagnosis. This baseline finding was similar in the INT (55 (43.0%)) and UC (76 (43.2%)) groups ($p=0.872$).

Healthcare utilization, including all-cause emergency department (ED) visits and hospitalizations, is shown in Table 3. There was no difference seen in the number of ED visits in the 1-year follow-up period. Participants in the UC group experienced more hospitalizations than the INT group (48 (20.9%) vs 17 (10.1%), $p=0.005$).

Table 3. Healthcare utilization in the follow-up period.				
	Total (N=402)	Intervention (N=171)	Usual Care (N=231)	P-value
Emergency Room Visit				0.4259
Missing	3 (0.7)	2 (1.2)	1 (0.4)	
No	212 (53.1)	93 (55.0)	119 (51.7)	
Yes	187 (46.9)	76 (45.0)	111 (48.3)	
Total Number of Emergency Room Visits				0.0614
Missing	3 (0.7)	2 (1.2)	1 (0.4)	
0	252 (63.2)	109 (64.5)	143 (62.2)	
1	73 (18.3)	34 (20.1)	39 (17.0)	
2	33 (8.3)	17 (10.1)	16 (7.0)	

3	22 (5.5)	4 (2.4)	18 (7.8)	
4+	19 (4.8)	5 (3.0)	14 (6.1)	
Hospitalizations				0.0049
Missing	3 (0.7)	2 (1.2)	1 (0.4)	
No	334 (83.7)	152 (89.9)	182 (79.1)	
Yes	65 (16.3)	17 (10.1)	48 (20.9)	
Total number of hospitalizations				0.0019
Missing	3 (0.7)	2 (1.2)	1 (0.4)	
0	334 (83.7)	152 (89.9)	182 (79.1)	
1	47 (11.8)	15 (8.9)	32 (13.9)	
2+	18 (4.5)	2 (1.2)	16 (7.0)	

Discussion

The National Academy of Medicine, formerly the Institute of Medicine, considers DE to be one of the most important safety problems in healthcare.³ DE is a common problem in asthma and COPD and may disproportionately affect minorities and the underserved. Patients with suspected asthma and/or COPD often present with dyspnea or a sense of breathlessness, which is a common symptom for many other chronic conditions, such as cardiovascular disease. Although spirometry is recommended for the diagnosis of asthma and COPD, it has been demonstrated that the routine use of spirometry is limited. Only about a third of patients with a new diagnosis of COPD have spirometry performed along with their diagnosis,⁴⁻¹¹ and only about a third of PCPs reported using spirometry for their patients with asthma,¹² leading to increased risk for DE. The use of spirometry in COPD was noted to be as low as 17.5% in an underserved population, and, when spirometry was performed, 65% of subjects did not have findings consistent with COPD.¹³ African Americans have a higher prevalence of self-reported asthma than White patients, and low-income African Americans have higher rates of smoking.^{14,15} African Americans also have a higher prevalence of obesity and heart disease compared to White patients.¹⁶⁻¹⁹ One study comparing physician diagnosis and spirometry in the diagnosis of COPD found that African Americans were 63% more likely to be misdiagnosed when compared to White patients.²⁰ Underutilization of spirometry increases the risk for DE, which is a patient safety concern. It causes harm not only from inappropriate use of respiratory pharmacotherapy but also from delay or failure to treat the true condition yet to be identified.

Barriers to the use of spirometry exist on several levels. At the provider level, surveys show that there is lack of knowledge of guidelines for the use of spirometry in COPD and, for those who had an office spirometer, there was a lack of knowledge in conducting and interpreting the test.^{4,11,21-24} PCPs also struggle with the logistic challenges presented by complex obstructive lung disease care at the health system level. Time limitation, with patient visits lasting 15 or fewer minutes,²⁵ and workflow constraints are also barriers to spirometry use. PCPs are faced with managing complex patients with multiple medical conditions. Our study showed that they face a multitude of data during a single point of care visit, such as but not limited to glucose levels for diabetes, blood pressure for hypertension, and a lipid profile for hyperlipidemia.²⁶ There is no point-of-care data tool that is routinely implemented in primary care for asthma and COPD. The frenzied nature of a busy practice and an aging patient with many chronic medical conditions results in COPD and asthma management, which include spirometry testing, being a lower priority.²⁶

Prior attempts to introduce and improve spirometry use in COPD and asthma in the primary care setting have included everything from introducing mobile spirometry to onsite clinic training of staff and education, with varying results.^{23,27-30} One study introduced open access spirometry to a primary care area and then reviewed the records of 235 patients with evidence of irreversible airflow obstruction consistent with COPD, and only 139 (59%) had a new diagnosis of COPD.³⁰ The open access spirometry study did not target patients with symptoms, so it related more to screening, which is not consistent with national and international guidelines.^{31,32} A second study randomized practices into two groups: visiting trained nurses (TN) to perform spirometry in primary care versus training existing physicians and staff to perform their own spirometry, considered usual care (UC).²⁸ The study performed opportunistic spirometry as the spirometry was not always performed in conjunction with a clinic visit but was based on patient availability. Spirometry use increased by 8% in the UC group versus 59% in the TN group. However, in the TN group, review of medical records showed that 108 patients had evidence of COPD based on spirometry testing, but only 8% (9/108) had a concomitant physician diagnosis. A third study randomized patients to conventional diagnosis (i.e., history and physical exam) or conventional diagnosis plus in-office spirometry.²⁷ However, frequent protocol violations and inadequate sample size due to poor recruitment by PCPs limited the study results. When asked about the usefulness of office spirometry, the post-study response was not as enthusiastic, which coincided with the fading effect of spirometry use when performed within primary care clinics. A fourth study introduced a 60-minute educational workshop to PCPs and ensured that an office spirometer was available for the practice and found an improvement in the rate of spirometry use over 3 months.²³ However, a lack of engagement was noted, as only 14 of 21 practices enrolled in the study had viable data due to low testing rates or a nonfunctional spirometer. Other important barriers identified included physician and staff unfamiliarity, uncertain interpretation of results, and time.

These studies identify important barriers that were accounted for in the REDEFINE study. The REDEFINE study recruited a targeted population who are at risk for diagnostic error due to an existing diagnosis of COPD and/or asthma without spirometry. By using health promoters who are well trained and mobilized to various clinics, the REDEFINE study shifted the responsibility of testing from primary care clinics to a program better equipped and maintained for quality testing. In summary, the REDEFINE program provided PCPs with necessary information to improve the diagnosis of COPD and asthma and limit DE without distracting workflow.

The REDEFINE intervention resulted in lower all-cause hospitalizations among the intervention group compared to the usual care group. This is not fully explained by simply improving the DE of COPD and/or asthma, as 43.1% of the entire cohort had a correct diagnosis. It is possible that the quality of the management of COPD and/or asthma improved with quantification of disease and guideline-based recommendations. It is also possible that the results of the spirometry testing resulted in providers looking for alternative diagnoses. More in depth analysis of the testing performed in each group is pending.

Conclusion

The REDEFINE intervention reduced all-cause hospitalization at 1 year compared to usual care.

Significance

The REDEFINE study evaluated an innovative approach to reduce DE and improve patient safety for patients with a diagnosis of COPD and asthma in an underserved primary care ambulatory setting. The approach included the incorporation of spirometry testing with guideline-based recommendations within the pragmatic framework of a busy primary care practice.

The approach also addressed limitations in past efforts and barriers to reduce DE in asthma and COPD in an underserved population with multiple chronic medical conditions. The intervention group had fewer all-cause hospitalizations. Further evaluation is planned to determine the cost-effectiveness of the intervention.

Implications

Implementation of this intervention in the real world may improve outcomes for underserved patients at increased risk of diagnostic error in COPD and/or asthma. More in depth analysis of the data to determine other healthcare use and cost-effectiveness of the intervention is in progress.

7. LIST OF PUBLICATIONS AND PRODUCTS

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