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Title: Accuracy of diagnosis and classification of COPD in primary and specialist nurse-led respiratory care in Rotherham UK: a cross sectional study.

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Abstract

Background
Studies have suggested that COPD is commonly misdiagnosed and misclassified in primary care, but less is known about quality of diagnosis in specialist respiratory care.

Aims
To measure accuracy of COPD diagnosis and classification of airway obstruction in primary care and at a specialist respiratory centre. To explore associations between misdiagnosis and misclassification and a range of explanatory factors.

Methods
Data were obtained for 1205 referrals to a specialist respiratory centre between 2007 and 2010. Standard analysis methods were used.

Results
The majority of patients were referred for pulmonary rehabilitation (676/1205, 56%). Of 1044 patients with a primary care COPD diagnosis 211 (20.0%) had spirometry inconsistent with COPD. In comparison, of 933 specialist centre diagnoses 65 (6.5%) had inconsistent spirometry. There was poor agreement between the airflow obstruction grade recorded on the referral and that based on spirometry (kappa=0.26, n=448), whereas agreement between the respiratory centre assessment of airflow obstruction and spirometry was good (kappa=0.88, n=1016). Referral by practice nurse was associated with accuracy of airflow obstruction classification in primary care (OR 1.85, 95%CI 1.33, 2.57). Males were more likely than females to have an accurate specialist care classification of airway obstruction (OR 1.40, 95%CI 1.01, 1.93). Grade of airway obstruction changed between referral and assessment in 56% of cases.

Conclusions
In primary care a proportion of patients diagnosed with COPD do not have COPD, and misclassification of grade of airflow obstruction is common. Misdiagnosis and misclassification is less common in the specialist care setting of BreathingSpace.

Introduction

The timely diagnosis of COPD allows early adoption of interventions that have been shown to be beneficial in improving quality of life and health outcomes. Effective interventions include pneumococcal and flu vaccination[1-3], referral to smoking cessation[4-6], pulmonary rehabilitation[7-9] and pharmacological therapy.[10] Once diagnosed, the accurate classification of disease according to the degree of airflow obstruction predicts prognosis in COPD,[11, 12] allows the tailoring of pharmacological treatment,[10] and can inform the prioritisation of resources to those who are in the greatest need.[10] Conversely, a false positive diagnosis of COPD may lead to treatment that is either of no benefit or harmful. A false diagnosis of COPD may also cause the true underlying diagnosis to be missed, resulting in a failure to implement the appropriate effective therapy. For example, if asthma is misdiagnosed as COPD then the patient may be prescribed a long acting bronchodilator without an inhaled corticosteroid (a treatment regimen that is contraindicated) rather than an inhaled corticosteroid.[13]

An important complicating factor in the diagnosis and classification of COPD is the highly heterogeneous nature of the condition, with severity of symptoms poorly correlated with degree of airflow obstruction.[14] It is not surprising then that many diagnoses of COPD are not supported by spirometry,[15, 16] and for those that are, the agreement between recorded disease severity and degree of airflow obstruction can be poor.[17]

Guidance is available to assist in the diagnosis and subsequent management of COPD, internationally through the GOLD initiative,[18] and within England and Wales from the National Institute for Health and Care Excellence (NICE).[10, 14] Within both NICE and GOLD guidance the diagnosis of COPD and its severity classification is based on the degree of airflow obstruction as measured by spirometry. However, conducting spirometry is not straightforward,[19, 20] and can be of poor quality even with training.[17, 21] It has therefore been suggested that GPs should be provided with a *spirometry service* (in which spirometry is performed by a dedicated trained individual), rather than *spirometers*.[22-24]

The primary aim of this study was to assess the accuracy of COPD diagnosis and the accuracy of the classification of airway obstruction, both in primary care and in a specialist respiratory care setting. A secondary aim was to compare the diagnosis and grade of airway obstruction at the time of referral from primary to specialist care with that subsequently found on assessment.

Our study took place in Rotherham, a mixed urban and rural district in the north of England with a population of approximately 250,000. Primary medical care in Rotherham is provided by 36 general practitioner (GP) practices, and secondary care is provided in a single large district general hospital. Rotherham also has a specialist nurse-led respiratory care centre, "BreathingSpace". The unit is led by a respiratory nurse consultant and has a team of nursing, physiotherapy and occupational therapy staff providing outpatient assessment, diagnosis and treatment for those with COPD and other chronic respiratory conditions. Clinical and spirometric assessment for new referrals is performed by respiratory nurse specialists. The unit also has 15 inpatient beds for the care of patients with acute exacerbations of cardio respiratory conditions. The aim of the BreathingSpace outpatient service is to ensure that Rotherham patients with respiratory conditions are accurately diagnosed and optimally managed. Patients are primarily referred to the outpatient service for pulmonary rehabilitation, confirmation of diagnosis, management of symptoms and medication review.

Methods

Data collection

Data were collected on all outpatient referrals from primary care to BreathingSpace. Medical record data are held by BreathingSpace in an electronic clinical system. Referrals to BreathingSpace are made using a standard form, and this information is uploaded to the clinical system at the time of referral. The details of each clinical encounter within BreathingSpace are also recorded on the system.

For the purposes of this study an anonymised dataset was extracted from the clinical system and checked for completeness and accuracy by BreathingSpace staff. Data were extracted for all individuals who were referred from primary care to BreathingSpace for outpatient assessment, and who had their initial consultation at the centre between 1st May 2007 and 31st May 2010. Patients who attended BreathingSpace for reasons unrelated to COPD (i.e. those patients who were not suspected of having COPD on referral and who were not subsequently found to have COPD), were excluded, as were patients who did not attend their BreathingSpace appointment. If a patient was referred more than once only the first referral was selected.

The following fields were included in the dataset: age, sex, the Index of Multiple Deprivation (IMD2010) measure of socioeconomic deprivation linked to the patient's postcode,[25] date of referral, who the referrer was (either practice nurse or GP), the reason(s) for referral, any pre-referral diagnoses, the severity of airway obstruction stated in the referral (if COPD diagnosed), the most recent spirometry result stated in the referral (obtained from a spirometer tracing if this was included, otherwise as entered on the referral form), the date of

initial assessment at BreathingSpace, the BreathingSpace spirometry result, any diagnoses made at BreathingSpace and the grade of airflow obstruction based on the BreathingSpace assessment.

Definition of categories for reason for referral
We defined the following categories for reason for referral: assessment for pulmonary rehabilitation, symptom management, medication review, oxygen assessment, diagnostic assessment, patient request, education and other. We recorded the numbers of referrals in each category. Some patients had more than one reason for referral recorded.

Study case definition for COPD and classification of airflow obstruction
The diagnosis of COPD and classification of airflow obstruction was based on the 2004 NICE Clinical Guideline (CG012) since this was the guidance that clinicians in Rotherham were expected to follow during the study period.[14] Under this guidance, a diagnosis of COPD was made if the pre-bronchodilator FEV1 was less than 80% predicted and if the pre-bronchodilator FEV1/forced vital capacity (FVC) ratio was less than 0.7. Airflow obstruction was then classified as mild if the FEV1 was greater than or equal to 50% predicted, moderate if the FEV1 was greater than or equal to 30% and less than 50% predicted, and severe if the FEV1 was less than 30% predicted. We refer to this as the "grade" rather than "severity" of airflow obstruction, to avoid any confusion with the severity of disease as experienced by the individual.

Note that the 2004 NICE Clinical Guideline CG012 was replaced by NICE Clinical Guideline CG101 in June 2010. Airflow obstruction is classified differently in the later guidance; hence we included in our study only patients seen in BreathingSpace up to the end of May 2010.

Diagnostic accuracy in primary care – is each diagnosis of COPD and grade of airway obstruction consistent with the primary care spirometry?
We calculated the proportion of those referred with a primary care diagnosis of COPD whose primary care spirometry results were not consistent with COPD. We explored the association between diagnostic accuracy for COPD and a range of potential explanatory variables (patient's age, patient's sex, deprivation score linked to patient's postcode, referrer's profession and date of referral) in a multivariate logistic regression model.

We assessed the agreement between the grade of airway obstruction as reported on the referral form and the grade of airflow obstruction based on the spirometry reported in the referral form. As our measure of agreement we used Cohen's weighted kappa coefficient.[26] We also explored the association between airway obstruction grade agreement as a binary variable (i.e. agreement between stated grade and spirometry, versus disagreement) and a range of potential explanatory variables (patient's age, patient's sex, deprivation score linked to patient's postcode, referrer's profession and date of referral) in a multivariate logistic regression model.

Diagnostic accuracy in specialist care – is each diagnosis of COPD and grade of airway obstruction consistent with the specialist care spirometry?
We calculated the proportion of those diagnosed with COPD by BreathingSpace whose results from the spirometry conducted at BreathingSpace were not consistent with COPD. We explored the association between diagnostic accuracy for COPD and a range of potential explanatory variables (patient's age, patient's sex, deprivation score linked to patient's postcode and date of assessment) in a multivariate logistic regression model.

We assessed the agreement between the grade of airflow obstruction recorded at the BreathingSpace assessment and the grade of airway obstruction based on the assessment spirometry conducted at BreathingSpace. We explored the association between agreement

and the following potential explanatory variables: patient's age, patient's sex, deprivation score linked to patient's postcode and date of assessment.

We used Chi-squared analyses to test for the difference between primary care and BreathingSpace in the proportions of patients misdiagnosed, and for the difference in the proportions misclassified with respect to grade of airway obstruction.

Comparison of the referral diagnosis and grade of airway obstruction with that found on specialist care assessment – are primary and specialist care findings consistent?
We calculated the proportion of patients with a primary care diagnosis of COPD whose spirometry conducted at BreathingSpace were not consistent with COPD. We explored the association between consistency (versus inconsistency) and a range of potential explanatory variables (patient's age, patient's sex, deprivation score linked to patient's postcode, referrer's profession and date of referral) in a multivariate logistic regression model.

We compared the grade of airway obstruction stated on the referral form with that found on spirometric assessment at BreathingSpace. We explored the association between agreement and the following potential explanatory variables: patient's age, patient's sex, deprivation score linked to patient's postcode, referrer's profession and length of time between referral and assessment.

We declared statistical significance at the conventional level of 5%. We considered values of Cohen's weighted kappa below 0.4 as indicating poor agreement, values between 0.4 and 0.75 as indicating moderate to good agreement, and values above 0.75 as indicating very good agreement.[27] All analyses were conducted in R 2.15.3.[28]

Ethics approval
The Rotherham Research Alliance at The Rotherham NHS Foundation Trust reviewed the protocol of this study and deemed it as service audit not requiring ethical approval. The project was registered as a clinical audit at NHS Rotherham.

Results
A total of 1205 patients met the inclusion criteria for the study. The mean age of the patients was 68 years (sd 10.2 years) and just over half were male (630/1205, 52%). Table 1 reports reasons for referral. The majority of referrals were for assessment for pulmonary rehabilitation.

< Table 1 here >

Diagnostic accuracy in primary care
COPD was listed as a primary care diagnosis in 1044 (87%) of the 1205 patients in the study. In 211 of these 1044 cases (20.0%, 95% CI 17.9% to 22.8%) the spirometry result reported on the referral form was inconsistent with a diagnosis of COPD. In a multivariate logistic regression model a spirometry-compatible diagnosis of COPD was not significantly associated with patient's gender, age, patient's age, postcode linked deprivation score, referrer's profession or date of referral.

Table 2 reports the cross-classification between the grade of airflow obstruction as stated on the referral form, and the grade based on the spirometry reported in the referral form. In 348 of the 1205 referrals both these pieces of information were available. There was only moderate agreement between stated grade and that based on the primary care recorded spirometry (43.4% of patients were misclassified; Cohen's weighted kappa 0.44, 95% CI 0.32, 0.56). In a multivariate logistic regression model referral by practice nurse (versus by doctor) was positively associated with agreement versus non-agreement (OR 1.85, 95% CI

1.33, 2.57). There was no significant association with patient's gender, age, postcode linked deprivation score or date of referral.

<Table 2 here>

Diagnostic accuracy in specialist care

COPD was diagnosed by the specialist centre clinicians in 993 (82%) of the 1205 patients in the study. Of these 993 cases, 65 (6.5%, 95% CI 5.2%, 8.3%) had a spirometry result that was inconsistent with a diagnosis of COPD. In a multivariate logistic regression model spirometry-compatible diagnosis of COPD was more likely in males than in females (OR 2.03, 95% CI 1.22, 3.46), but was not significantly associated with patient's age, postcode linked deprivation score or date of referral.

Table 3 reports the cross-classification between the grade of airflow obstruction recorded by BreathingSpace, and the grade based on the assessment spirometry conducted at BreathingSpace. In 1016 of the 1205 referrals both these pieces of information were available. There was very good agreement between the grade in the BreathingSpace record and that based on the BreathingSpace assessment spirometry (9.3% of patients were misclassified; Cohen's weighted kappa 0.88, 95% CI 0.81, 0.96). A multivariate logistic regression analysis suggests that males are more likely to be correctly classified than females (OR 1.40, 95% CI 1.01, 1.93). There was no significant association between agreement and patient's age, postcode linked deprivation score or date of referral.

<Table 3 here>

The proportion of patients who had a diagnosis of COPD that was not supported by spirometry was significantly greater in primary care (20.2%) than at BreathingSpace (6.5%), χ^2=80.0, p<0.0001. The proportion of patients misclassified with respect to grade of airway obstruction was also significantly greater in primary care (43.4%) than at BreathingSpace (9.3%), χ^2=202.7, p<0.0001.

Comparison of diagnosis and airway obstruction grade between primary and specialist care

Of the 1044 patients with a primary care diagnosis of COPD, 197 (18.9%, 95% CI 16.6% to 21.4%) had spirometry results at BreathingSpace that were inconsistent with a diagnosis of COPD. The most common diagnosis that was subsequently made on assessment at BreathingSpace was asthma (86 patients). Other diagnoses (with five or more patients) were bronchiectasis (12 patients), restrictive lung disease, (13 patients), and non-obstructive emphysema (5 patients). Thirty-three patients were found to have no respiratory disease.

In a multivariate logistic regression model the following factors were associated with agreement between the primary care diagnosis of COPD and the BreathingSpace spirometry: the patient being male (OR 1.50, 95% CI 1.09, 2.06) and the referral being made by a practice nurse (OR 1.65, 95% CI 1.18, 2.33). There was no association with patient's age, postcode linked deprivation score or length of time between referral and assessment.

Table 4 reports the cross-classification between the grade of airflow obstruction as stated on the referral form, and the grade based on the assessment spirometry conducted at BreathingSpace. In 448 of the 1205 referrals both these pieces of information were available. The grade of airway obstruction found on spirometric assessment at BreathingSpace was different to that stated on the referral in 54.0% of patients (Cohen's weighted kappa 0.26, 95% CI 0.16, 0.36). In a multivariate logistic regression model referral by practice nurse (versus by doctor) was positively associated with agreement versus non-agreement (OR 2.20, 95% CI 1.61, 3.00). There was no significant association with

patient's gender, age, postcode linked deprivation score or length of time between referral and assessment.

<Table 4 here>

Discussion

Main findings

We found that diagnostic accuracy and accuracy of classification of airway obstruction grade was better in specialist respiratory care than in primary care. The grade of airflow obstruction found on assessment in the specialist centre did not agree with that stated on the referral form in over half of cases.

Strengths and limitations of this study

As far as we are aware our study is the first to compare diagnostic accuracy for COPD between primary and specialist care. A key strength of the study is the large sample size, which represents approximately 20% of the known cases of COPD in Rotherham.[29] The study does however have a number of limitations.

Rotherham represents only a single health administrative area in England, and we should therefore be cautious in generalising the results more widely. In particular, we cannot be sure that our findings regarding BreathingSpace, a specialist respiratory centre that is somewhat unusual in being nurse-led, apply to specialist respiratory care settings in general.

We must be careful in attributing the differences we report between primary care and BreathingSpace to differences in the care provided. Case mix may also have differed in ways that could have impacted upon the outcomes that we measured. We did not, for example, record whether a patient was experiencing an exacerbation at the time of spirometric assessment (either in primary care or BreathingSpace). If there were differences in the proportion of patients who were experiencing an exacerbation (or who were unwell for other reasons) at time of assessment between primary care and BreathingSpace, then this could explain some of the differences we have seen.

The study took place between 2007 and 2010, during the period in which the NICE 2004 guidance was in place. Practice is likely to have changed since then, in part due to the updated guidance issued by NICE in 2010. We do not know if the accuracy of diagnosis or of airway obstruction classification is better or worse under the new guidance.

As with any cross sectional study we cannot infer causation. Specifically, we do not know whether the associations that we report in the regression analyses are causal, or related to unobserved confounding factors.

Although the grade of airflow obstruction can be determined using spirometry, spirometry alone does not give an adequate assessment of the disease severity experienced by an individual.[10] To fully understand the impact of COPD on an individual it is necessary to assess not only airflow obstruction, but also symptoms, exercise capacity, risk of exacerbation and degree of comorbidity.[30] It is possible that in some instances clinicians used the terminology "mild", "moderate", "severe" to refer to the severity of disease (even though no such classification exists within the NICE guidance), rather than the grade of airflow obstruction. This could account for some of the discrepancy seen in both primary and specialist care. An alternative would be to use composite scores such as DOSE or BODE.[31, 32] These can help in the assessment of severity and prognosis,[31-33] but their validity across the wide range of routine clinical settings is unknown.[30]

Our study population was drawn from those who were either diagnosed with COPD, or who were suspected of having COPD. We therefore could not assess the degree to which COPD is *underdiagnosed* in the general population, although we know that this is likely to be significant.[34, 35] The number of patients in Rotherham who have a diagnosis of COPD recorded on their primary care record can be determined from the "QOF" dataset. The Quality and Outcomes Framework (QOF) is a pay-for-performance scheme for UK general medical practitioners that requires practices to keep patient registers for a range of chronic diseases, including COPD. The total number of cases recorded in the QOF dataset for Rotherham in March 2012 was 6,431.[29] This is considerably lower than the estimated number of cases that would be expected based on Rotherham's distribution of age, sex, ethnicity, rurality, smoking status and deprivation, which is approximately 10,000.[36] Rotherham is not unusual in this respect; the number of diagnosed cases of COPD in England is approximately half that expected.[34] Underdiagnosis is of particular concern because suboptimal management of COPD may lead to reduced quality of life, poorer outcomes and avoidable admission to hospital.

Interpretations of findings in relation to previously published work

Our findings regarding diagnostic accuracy are broadly consistent with those found previously. One recent study similar to ours found that out of 180 of patients with a diagnosis of COPD who were referred to a specialist service in London, 35 (19.4%) had no evidence of COPD on assessment.[37] The prevalence of inconsistent spirometric findings in those diagnosed with COPD has also been reported in Sweden (Arne et al[15]) where it was 15% (n=533), in two Australian studies, Walters et al[16] where it was 31% (n=341) and Zwar et al[38] where it was 48% (n=445), in Austria (Lamprecht et al[39]) where it was 49% (n=68) and in two other UK studies, Frank et al (32%, n=88),[40] and Hassett et al (25%, n=189)[41]. With regard to the accuracy of classification of airflow obstruction grade, an audit of the quality of spirometry in the Rotherham COPD population found only moderate agreement between of the description of severity in the medical record and that based on spirometry (Cohen's kappa 0.34, 95% CI 0.30 – 0.38).[17]

Of those patients with a primary care referral diagnosis of COPD who were subsequently found not to have COPD, a significant proportion had a diagnosis of asthma. This highlights the difficulty of differentiating between these two conditions in some patients.[42] For example, in an elderly smoker who presents with breathlessness, wheeze and cough there may be a tendency to diagnose COPD on the basis of the history, even in the presence of reversibility of airway obstruction.

When we compared the grade of airflow obstruction recorded on the referral form and that based on the BreathingSpace spirometry we found that in only 46% of cases was the grade unchanged. This may well reflect the natural history of the disease as much as any problem of misclassification. The degree of airflow obstruction in COPD changes over time, for example due to worsening of disease (either acutely during an exacerbation, or more gradually over time) or due to improvement in disease post exacerbation. Differences in grade of airflow obstruction between primary care assessment and BreathingSpace assessment may also be explained by changes in smoking status, treatment regimen or degree of comorbidity.

Implications for research, policy and practice

The findings suggest that in patients referred to specialist care, the primary care diagnosis of COPD and the classification of airflow obstruction should always be reviewed. Equally importantly our findings highlight the need for good access to education for all health care professionals who have responsibility for the management of people with respiratory disease, in particular to education and training that relates to the interpretation of spirometry.

Diagnosis of COPD and its severity classification remain problematic. There is still no absolutely clear guidance on diagnosis and severity classification, even in the updated NICE guidance published in 2010.[10] We suspect that this contributes to the problems of diagnostic inaccuracy that we have observed and we would urge guideline producers to address this issue.

We found that the grade of airflow obstruction was more likely to be accurately recorded in referrals from practice nurses compared with referrals from GPs. This may reflect the central role of nurses in managing the routine care of patients with chronic disease, a better familiarity with the interpretation of spirometry, more time, or perhaps a greater propensity to follow guidance strictly. Unfortunately our study was not designed to determine why nurses were more accurate in reporting than doctors. There is however growing evidence to suggest that nurses represent an appropriate resource to deliver care to people with COPD throughout the whole of the disease pathway.[43] Further research is needed to determine the relative effectiveness and cost-effectiveness of nurse-led versus GP-led care in the context of COPD.

Conclusions

Our results suggest that a proportion of patients diagnosed with COPD in primary care do not have COPD. Misdiagnosis is less common in specialist care. Misclassification of the grade of airflow obstruction is common in primary care and uncommon in specialist respiratory care.

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Conflicts of interest: The authors declare that they have no conflicts of interest in relation to this article.

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Tables

Table 1 – Reason for referral to BreathingSpace

Reason for referral	**n (%)**
Assessment for pulmonary rehabilitation	676 (56.1%)
Management of symptoms	210 (17.4%)
Diagnostic assessment	197 (16.3%)
Medication review / optimisation	60 (5.0%)
Education	29 (2.4%)
Patient request	17 (1.4%)
Oxygen assessment	16 (1.3%)
Other	139 (11.5%)

Note: Some patients have more than one reason for referral, and therefore percentages do not sum to 100%.

Table 2 – Numbers of patients cross-categorised by airway obstruction grade as stated on the referral form and that based on the spirometry reported in the referral form.

	Airway obstruction grade based on referral spirometry				
Airway obstruction grade as stated on referral	Spirometry not consistent with COPD	Mild	Moderate	Severe	Total
No COPD diagnosis	1	4	0	0	5
Mild	44	88	4	0	136
Moderate	18	37	84	0	139
Severe	10	1	33	24	68
Total	73	130	121	24	348

Note: Cohen's kappa for agreement = 0.44 (95% CI 0.32, 0.56)

Table 3 – Numbers of patients cross-categorised by airway obstruction grade as stated in the BreathingSpace record and that based on the spirometry conducted at BreathingSpace.

	Airway obstruction grade based on BreathingSpace spirometry				
Airway obstruction grade recorded by BreathingSpace	Spirometry not consistent with COPD	Mild	Moderate	Severe	Total
No COPD diagnosis	144	22	7	0	173
Mild	37	377	3	0	417
Moderate	8	11	312	0	331
Severe	1	0	5	89	95
Total	190	410	327	89	1016

Note: Cohen's kappa for agreement = 0.88 (95% CI 0.81, 0.96)

Table 4 – Numbers of patients cross-categorised by airway obstruction grade as stated on the referral form and that based on the spirometry conducted at BreathingSpace.

	Airway obstruction grade based on BreathingSpace spirometry				
Airway obstruction grade as stated on referral	Spirometry not consistent with COPD	Mild	Moderate	Severe	Total
No COPD diagnosis	7	30	33	16	86
Mild	32	103	11	0	146
Moderate	14	49	71	4	138
Severe	1	9	43	25	78
Total	54	191	158	45	448

Note: Cohen's kappa for agreement = 0.26 (95% CI 0.16, 0.36)

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