

Diagnosing COPD and supporting smoking cessation in general practice: evidence–practice gaps

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The known Guidelines for the management of COPD recommend spirometry testing when diagnosing COPD. Smoking cessation reduces the risk of developing COPD and slows lung function decline.

The new More than one-third of participants managed for COPD did not meet the spirometric definition of the disorder, while one in six participants not previously diagnosed with COPD had spirometry test results consistent with COPD.

The implications Case finding and effective use of spirometry could improve the diagnosis of COPD in primary care. Health professionals need to understand the smoking cessation support preferences of smokers, offer evidence-based advice, and closely monitor any difficulties or side effects during quit attempts.

Chronic obstructive pulmonary disease (COPD) is globally a major public health problem that has significant effects on mortality, morbidity, and health resource utilisation; it is the fifth leading cause of death in Australia.¹ The prevalence of moderate to severe COPD is 7.5% among Australians aged 40 years or more, and 29.2% among those aged 75 years or more.²

COPD is characterised by airflow limitation. The Global Initiative for Obstructive Lung Disease (GOLD)³ and the national COPD-X guidelines⁴ each advocate using spirometry for diagnosing COPD, but it is not undertaken in primary care settings as frequently as recommended.⁵ This may contribute to delaying diagnosis of COPD and the treatment of patients at high risk.

Tobacco smoking is the most preventable risk factor for COPD. Although the overall prevalence of smoking in Australia has declined, 12% of people aged 14 years or more smoke daily.⁶ As many as 50% of smokers develop clinically significant COPD.⁷ Smoking cessation is the key to preventing and treating COPD.

About one in five patients attending general practices is a smoker.⁸ Clinic visits provide good opportunities for general practitioners to review respiratory symptoms and exposure to risk factors, to suggest changes in smoking behaviour, and to provide advice about cessation strategies, potentially reducing the risk of COPD. Knowledge of the smoking experiences and cessation preferences of smokers can inform individualised cessation interventions that can be sustained by those attempting to quit. GPs are also well placed to identify patients at higher risk of COPD.⁵ The optimal application of case-finding approaches and diagnostic tools,

Abstract

Objectives: To review the accuracy of diagnoses of chronic obstructive pulmonary disease (COPD) in primary care in Australia, and to describe smokers' experiences with and preferences for smoking cessation.

Design, setting and participants: Patients were invited to participate if they were at least 40 years old and had visited participating general practice clinics in Melbourne at least twice during the previous 12 months, reported being current or ex-smokers with a smoking history of at least 10 pack-years, or were being managed for COPD. Interviews based on a structured questionnaire and case finding (FEV₁/FEV₆ measurement) were followed, when appropriate, by spirometry testing and assessment of health-related quality of life, dyspnoea and symptoms.

Results: 1050 patients attended baseline interviews (February 2015 – April 2017) at 41 practices. Of 245 participants managed for COPD, 130 (53.1%) met the spirometry-based definition (post-bronchodilator FEV₁/FVC < 0.7) or had a clinical correlation; in 37% of cases COPD was not confirmed, and no definitive result was obtained for 9.8% of patients. Case finding and subsequent spirometry testing identified 142 new COPD cases (17.6% of participants without prior diagnosis; 95% CI, 15.1–20.5%). 690 participants (65.7%) were current smokers, of whom 360 had attempted quitting during the previous 12 months; 286 (81.0% of those attempting to quit) reported difficulties during previous quit attempts. Nicotine replacement therapy (205, 57.4%) and varenicline (110, 30.8%) were the most frequently employed pharmacological treatments; side effects were common. Hypnotherapy was the most popular non-pharmacological option (62 smokers, 17%); e-cigarettes were tried by 38 (11%). 187 current smokers (27.6%) would consider using e-cigarettes in future attempts to quit.

Conclusions: COPD was both misdiagnosed and missed. Case finding and effective use of spirometry testing could improve diagnosis. Side effects of smoking cessation medications and difficulties during attempts to quit smoking are common. Health professionals should emphasise evidence-based treatments, and closely monitor quitting difficulties and side effects of cessation aids.

Trial registration: Australian New Zealand Clinical Trials Registry ACTRN12614001155684.

including spirometry, can improve the diagnosis and management of COPD in primary care.

In this study, we reviewed the accuracy of COPD diagnoses in primary care, and explored the quitting experiences and preferences of smokers attending general practice clinics.

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Methods

The Review of Airway Dysfunction and Interdisciplinary Community-based care in Adult Long-term Smokers (RADICALS)⁹ study is an ongoing cluster randomised controlled trial assessing an interdisciplinary model of care for reducing the burden of COPD and smoking in Australian primary care. Baseline data were obtained from participants enrolled between February 2015 and April 2017.

Recruitment of and data collection from clinics and participants

The trial protocol has been reported elsewhere.⁹ Briefly, 43 general practice clinics in Melbourne were recruited with the assistance of primary health networks and key informants, and by direct recruitment. After obtaining signed agreement, clinics were randomised to the control or intervention arms of the study. For the purposes of this analysis, baseline data from the two groups have been combined. Two clinics withdrew from the study before they commenced recruiting participants.

At each clinic, a research assistant searched the practice database to identify eligible patients, and contacted them by mail or telephone to seek their participation. Patients were invited if they were at least 40 years old and had visited a participating clinic at least twice during the previous 12 months, reported being a current or ex-smoker with a smoking history of at least 10 pack-years, or were being managed for COPD. Patients who had a documented diagnosis of COPD or were currently treated with COPD-specific medications (muscarinic antagonists or long-acting muscarinic antagonist/long-acting β -adrenergic agonist combination therapies), were deemed to have a prior diagnosis of COPD. Those with no history of smoking were also eligible if they had spirometry-confirmed COPD or were treated with COPD-specific medications. After providing written informed consent, eligible participants were interviewed at the practice (one hour). Baseline demographic and clinical data were collected, followed by case-finding procedures and referral for spirometry, if indicated.¹⁰

Case finding, spirometry and COPD questionnaires

During the baseline interview, forced expiratory volume in 1 second/forced expiratory volume in 6 seconds (FEV₁/FEV₆) was measured with the COPD-6 device (Vitalograph) according to Lung Foundation Australia recommendations.¹⁰ Patients with an FEV₁/FEV₆ value below 0.75, or who found COPD-6 testing difficult, were referred for spirometry testing and assessment of health-related quality of life, dyspnoea, and symptoms with the St George's Respiratory Questionnaire (SGRQ),¹¹ the modified Medical Research Council (mMRC) dyspnoea scale,¹² and the COPD Assessment Test (CAT).¹³ If results from recent spirometry testing undertaken outside the trial were available, they were also assessed.

Pre- and post-bronchodilator spirometry testing was performed with Easy on-PC spirometers (nDD Medizintechnik) by trained research assistants in accordance with the American Thoracic Society/European Respiratory Society guidelines.¹⁴ Post-bronchodilator spirometry testing was performed 10–15 minutes after 400 μ g salbutamol was delivered by a metered dose inhaler and spacer. Best efforts at forced expiration were selected according to the spirometer algorithm. The COPD diagnosis was deemed to be confirmed if the post-bronchodilator FEV₁/forced vital capacity (FVC) ratio was less than 0.7. We devised an

algorithm with the assistance of respiratory scientists to guide research assistants in determining whether spirometry test results were consistent with COPD (online [Appendix 1](#)). If results were ambiguous and required further interpretation, the report was sent to a respiratory scientist or respiratory physician. Patients were defined as having a misdiagnosis if they had been treated for COPD or had a documented diagnosis of COPD, but did not meet the spirometric definition of COPD.

Smoking

Data collected from smokers (regardless of whether they had COPD) included smoking status (according to both self-report and exhaled carbon monoxide testing), age at which they started smoking, years of smoking, smoking-related behaviour, pharmacological and non-pharmacological strategies tried during attempts to quit in the preceding 12 months, side effects of previous pharmacotherapy, and difficulties associated with previous attempts to quit. The participants' preferred methods of smoking cessation for future attempts and their motivation for and confidence in giving up smoking were also assessed.

Statistical analysis

Data were entered into an Access (Microsoft) database, and analysed in Excel (Microsoft) and SPSS 24.0 (IBM). The characteristics of the recruited clinics and the baseline characteristics of participants were summarised as means (with standard deviations [SDs]), medians (with interquartile ranges [IQRs]), or numbers (and percentages), depending on the type and distribution of data. The characteristics (age, sex, country of birth, language spoken at home, education, employment status, marital status, current living arrangements, smoking status, spirometric confirmation of COPD) of those previously diagnosed with or treated for COPD were compared with those of participants without a prior COPD diagnosis. Age, sex, current smoking status, SGRQ score, mMRC grade, CAT score, FEV₁/FVC ratio, and the severity of disease in incident cases of COPD were also compared with those of participants with a prior diagnosis of COPD. The statistical significance of differences between groups was assessed in χ^2 or Fisher exact tests (categorical variables), Student *t* tests (continuous variables) or Mann–Whitney *U* tests (ordinal variables). Confidence intervals (CIs) for proportions were estimated with the exact binomial distribution. *P* < 0.05 (two-sided) was deemed statistically significant.

Ethics approval

This project was approved by the Monash University Human Research Ethics Committee and the La Trobe University Human Ethics Committee (reference, CF14/1018–2014000433).

Results

The characteristics of the recruited clinics are summarised in [Box 1](#). Spirometers were available in 16 of 43 practices. Many clinics had had no staff trained in spirometry testing, smoking cessation, or COPD management in the previous 2 years.

Of the 37 646 patients screened, 10 744 satisfied the inclusion criteria; of these, 1050 (9.8%) attended baseline interviews at 41 clinics ([Box 2](#); demographic and clinical characteristics: online [Appendix 2](#), table 1). Almost all participants underwent FEV₁/

1 Characteristics of the 43 recruited clinics*

Characteristic

Characteristic	
Type of practice	
Single GP practice	6 (14%)
Group GP practice/community health centre/interdisciplinary practice	37 (86%)
Number of GPs, median (IQR)	5 (4–10)
Number of patients on database, median (IQR)	8214 (2000–18 309)
Spirometer available	16 (43%)
Staff training in the previous 2 years	
Spirometry	13 (35%)
Smoking cessation	6 (17%)
COPD management	7 (20%)

COPD = chronic obstructive pulmonary disease; IQR = interquartile range. * Two practices withdrew from the study after enrolment and before participant recruitment. Some data are missing for all variables, except for practice type and number of GPs. ♦

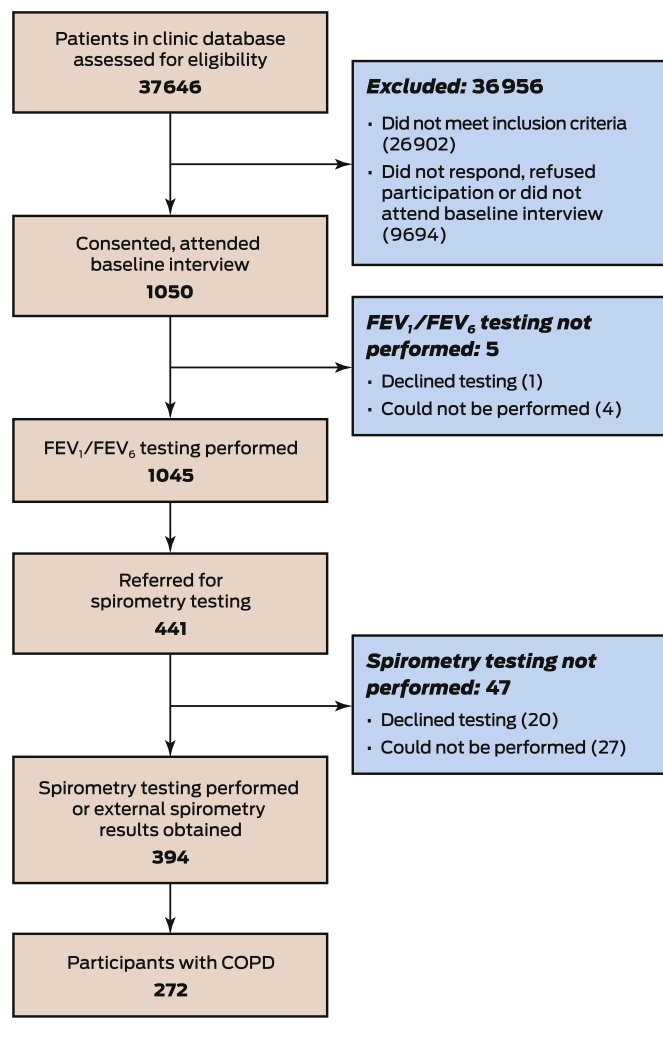
FEV₆ testing during their baseline interview (1045, 99.5%); 272 (25.9% of all participants [95% CI, 23.3–28.7%] and 69.0% [95% CI, 64.2–73.6%] of those who underwent spirometry) had COPD according to their spirometry test results.

Of the 245 participants with a prior COPD diagnosis, 91 (37%) did not meet the spirometric definition of COPD or have a clinical correlation (Box 3): 68 did not meet the criteria for spirometry referral after COPD-6 testing, the spirometry results for 14 were inconsistent with COPD after further interpretation or clinical correlation, those for eight were within normal limits, and the result for one participant was inconsistent with the spirometry-based definition of COPD, but possibly reflected a reversible obstructive disorder, such as asthma. Further, 142 of 805 participants without a prior COPD diagnosis (17.6%; 95% CI, 15.1–20.5%) had spirometry results consistent with COPD (Box 3). The characteristics of 142 participants with prior COPD diagnoses (prevalent cases) and 130 with new diagnoses confirmed by spirometry (incident cases) are compared in Box 4.

Of the 1050 participants who attended a baseline interview, 690 (65.7%) were current smokers, most of whom smoked daily (646, 93.6% of smokers) (Box 5, Box 6). Of the current smokers, 360 (52.2%) had attempted to quit at least once during the previous 12 months. The pharmacological treatments most frequently tried were nicotine replacement therapy (205, 57.4%) and varenicline (110, 30.8%) (Box 7). Non-evidence-based treatments, including hypnotherapy (62, 17%) and electronic cigarettes (38, 11%), were also frequently tried. Most smokers (286, 81.0%) reported difficulties during past attempts to quit, including urges to smoke (195, 55.2%) and irritability or aggression (152, 43.1%) (online Appendix 2, table 2). Of the 242 smokers who reported using cessation medications, more than half (157, 68.9%) reported side effects (data not shown).

Current smokers would consider a variety of strategies in future attempts to quit. Pharmacotherapy was the most popular (272, 39.9%); e-cigarettes would be considered by more than one-quarter of smokers (187, 27.6%) (online Appendix 2, table 3).

2 Flow of participants through eligibility assessment, COPD-6 testing, and spirometry testing



Discussion

More than one-third of participants with a prior diagnosis of COPD did not meet the spirometric definition of the disorder, while one in six participants not previously diagnosed with COPD had spirometry test results consistent with COPD. The mean age of patients with a prior diagnosis of COPD was higher than for those without an existing COPD diagnosis; the proportions of patients in this group with lower education levels, without fulltime employment, without a partner, or living alone were also larger than among participants without an existing diagnosis (online Appendix 2, table 1). The mean age for incident cases of COPD was lower and the disease severity milder than for prevalent cases; lung function was better in incident cases, and SGRQ and CAT scores were lower. The proportion of patients with a prior diagnosis of COPD who were current smokers (44%) was significantly smaller than that of those newly diagnosed on the basis of spirometry test results (77%), and was also smaller than the proportion of all participants without a prior COPD diagnosis (72%), but still high. A slight majority of current smokers had unsuccessfully attempted to quit during the previous year; difficulties during these attempts were common. More than half of those attempting to quit reported using nicotine replacements or varenicline; side

3 Spirometric confirmation of chronic obstructive pulmonary disease (COPD) by spirometry test results or clinical correlation

	All participants	No prior diagnosis of COPD	Prior diagnosis of COPD	P
Number of participants	1050	805	245	
Number referred for spirometry	441 (42.0%)	264 (32.8%)	177 (72.2%)	
Number who underwent spirometry	394 (37.5%)	234 (29.1%)	160 (65.3%)	
COPD confirmed	272 (25.9%)	142 (17.6%)	130 (53.1%)	< 0.001
COPD not confirmed	716 (68.2%)	625 (77.6%)	91 (37%)	
No result*	62 (5.9%)	38 (4.7%)	24 (9.8%)	

* It was not possible to obtain interpretable results from 62 participants referred for spirometry testing (uncontactable or declined spirometry, 47; inconclusive results, 15). ♦

effects were frequent. Interest in non-evidence-based smoking cessation strategies was high.

Our study highlights the importance of applying evidence-based guidelines to COPD management and smoking cessation support in Australian primary care. COPD diagnosis and management guidelines are widely disseminated in Australia,¹⁵

4 Characteristics of participants with prior and new diagnoses of chronic obstructive pulmonary disease (COPD) confirmed by spirometry testing

Characteristic	Incident cases (no prior COPD diagnosis)	Prevalent cases (prior COPD diagnosis)	P
Number of participants	142	130	
Age (years), mean (SD)	62.0 (10.7)	67.4 (10.2)	< 0.001
Sex (men)	89 (63%)	78 (60%)	0.65
Currently smoking	109 (77%)	57 (44%)	< 0.001
SGRQ score,* mean (SD)	26.3 (16.5)	38.6 (17.7)	< 0.001
mMRC grade,† median (IQR)	1 (0–1)	1 (1–2)	< 0.001
CAT score,‡ mean (SD)	11.3 (7.0)	15.3 (7.9)	< 0.001
Post-bronchodilator FEV ₁ /FVC ratio, median (IQR)§	0.62 (0.56–0.67)	0.56 (0.46–0.62)	< 0.001
Severity of disease§,¶			< 0.001
Mild	117 (83.6%)	73 (57%)	
Moderate	16 (11%)	40 (31%)	
Severe	7 (5%)	16 (12%)	

FEV₁/FVC = forced expiratory volume in 1 second/forced vital capacity ratio; IQR = interquartile range; SD = standard deviation. * St George's Respiratory Questionnaire: 50-item questionnaire for assessing health status in patients with diseases of airway obstruction; range, 0–100; higher scores indicate lower health-related quality of life. Data missing for 14 participants (six incident, eight prevalent cases). † Modified Medical Research Council dyspnoea scale: scale consisting of five statements; range, 0 (no dyspnoea) to 4 (very severe dyspnoea). Data missing for one incident case. ‡ COPD Assessment Test: eight-item questionnaire for assessing health status of patients with COPD; range, 0–40; higher scores indicate poorer health. Data missing for one incident case. § Data missing for three participants (one prevalent and two incident cases) because only pre-bronchodilator spirometry was performed. ¶ Severity of COPD based on FEV₁% predicted values (mild, 60–80% predicted; moderate, 40–59% predicted; severe, < 40% predicted).⁴ Eighty participants had FEV₁% predicted values of more than 80, but had characteristic symptoms of mild COPD. ♦

but diagnostic spirometry is not employed appropriately. In an earlier study in Australian primary care, only 58% of patients receiving treatment for COPD met the spirometric criteria for the disorder.¹⁶ Lack of access to a spirometer, inadequate training in performing spirometry and interpreting the results, and poor remuneration are among the many challenges for lung function testing in primary care.^{16,17} Lack of awareness of the need for spirometry testing for diagnosing COPD may lead to diagnoses based on social history, symptoms, or chest x-rays alone. Misdiagnosis can lead to unnecessary or inappropriate treatment, potentially with adverse consequences. Underdiagnosis delays initiation of lifestyle changes and targeted therapy, leading to an increased risk of exacerbations and pneumonia.¹⁸

The approach to diagnosing COPD in Australia is reactive; formal diagnosis follows the initial presentation of symptoms by patients, and there is inadequate emphasis on case finding in smokers.¹⁹ Our case-finding approach — FEV₁/FEV₆ testing of high risk patients followed by spirometry testing and symptom questionnaires — identified 142 new cases of COPD that may not have been recognised until symptoms developed as the disease progressed.

Recommendations about screening for early identification of COPD are inconsistent. The United States Preventive Service Task Force (USPSTF) found no overall benefit in spirometry-based screening of asymptomatic individuals.²⁰ However, the National Institute for Health and Care Excellence (NICE) guidelines recommend opportunistic case finding based on risk factors such as age, smoking, and symptoms.²¹ Lung Foundation Australia recommends using symptom questionnaires to assist with COPD case finding and diagnosis, especially in conjunction with FEV₁/FEV₆ assessment, for which an upper threshold of 0.75 is highly sensitive and specific.²² All case-finding approaches increase the detection of COPD in primary care, although the effects on clinical care and patient outcomes need to be further investigated.²³

The reported rates of pharmacological and non-pharmacological agent use in our study were similar to those found by an earlier study of smoking cessation aids used by smokers admitted to three Victorian hospitals,²⁴ in which nicotine replacement therapy was also the most frequently used pharmacotherapy and hypnotherapy the most common non-pharmacological therapy. Combination nicotine replacement therapy and varenicline are the most effective quitting aids, and are of similar efficacy.²⁵ In our study, only one-third of current smokers reported trying varenicline, despite strong evidence for its effectiveness.²⁵ Further, it is reported that few smokers continue pharmacotherapy for the recommended duration of treatment.²⁴

Nicotine replacement therapy is widely available from pharmacies and supermarkets, while varenicline is a prescription-only drug, requiring a visit to a GP and Pharmaceutical Benefits Scheme authority approval. Many of our participants reported interest in using medications in future attempts to quit, but more than one-quarter would also consider going “cold turkey”. As the success rate of unassisted

5 Characteristics of the 1050 participants who completed the baseline interview

Characteristic	Total participants	No prior diagnosis of COPD	Prior diagnosis of COPD	P
Number of participants	1050	805	245	
Age (years), mean (SD)	60.5 (11.1)	58.5 (10.4)	67.1 (10.6)	< 0.001
Sex (men)	564 (53.7%)	433 (53.8%)	131 (53.5%)	0.93
Born in Australia*	735 (70.3%)	571 (71.2%)	164 (67.5%)	0.27
Current smokers	690 (65.7%)	582 (72.3%)	108 (44.0%)	< 0.001
Daily smokers	646 (61.5%)	542 (67.3%)	104 (42.4%)	< 0.001
Occasional smokers	44 (4.2%)	40 (5.0%)	4 (1.6%)	0.022
Ex-smokers	350 (33.3%)	222 (27.6%)	128 (52.2%)	< 0.001
Never smokers	10 (1.0%)	1 (0.1%)	9 (3.7%)	< 0.001

COPD = chronic obstructive pulmonary disease; SD = standard deviation. * Data missing for five participants. Additional demographic data is included in online [Appendix 2](#), table 1. ♦

cessation is low, it should be recommended to all smokers interested in quitting that they seek assistive pharmacotherapy, together with counselling and support, unless there are contraindications.²⁶ Consultations with smokers in general practice provide opportunities for counselling and motivational support, crucial to successful quitting. The Royal Australian College of General Practitioners (RACGP) guidelines (specifically, the 5As structure: ask, assess, advise, assist, and arrange follow-up) should guide smoking cessation support.²⁶

Smokers frequently try non-evidence-based methods for quitting. Although hypnotherapy was popular with our participants, evidence for its efficacy is scant.²⁷ The degree to which participants have used e-cigarettes as cessation aids and the relatively high interest in trialling them in future attempts is worrying. The efficacy of e-cigarettes as a smoking cessation aid and their long term safety are unknown.²⁸ Despite widespread popularity in some countries, e-cigarettes are not approved by the Therapeutic Goods Administration, nor are they recommended by the National Health and Medical Research Council as a cessation aid.²⁹

We recruited a large sample of participants from a diverse range of practices across Melbourne (including specialised clinics serving people from lower socio-demographic status areas, and drug and alcohol addiction clinics). The smoking status of

6 Characteristics of the 690 participants who were current smokers

Characteristic	
Number of years of smoking, mean (SD)	37.2 (11.0)
Exhaled carbon monoxide level* (ppm), median (IQR)	21 (13–28)
Motivation to give up smoking, median (IQR)†	6 (4–8)
Confidence in giving up smoking, median (IQR)‡	5 (3–7)

IQR = interquartile range; SD = standard deviation. * Exhaled carbon monoxide level below 7 ppm confirms participant is a non-smoker (manufacturer's recommended cut-off). Carbon monoxide breath tests could not be obtained from six participants; 46 current smokers (self-report) had levels below threshold, 21 non-smokers (self-report) had levels at or above threshold. † Scale, 1 (low) to 10 (high); data missing for six participants. ‡ Scale, 1 (low) to 10 (high); data missing for seven participants. ♦

participants was objectively confirmed by exhaled carbon monoxide testing when possible. However, we also relied upon participant reports, which are subject to recall bias. Response and social desirability bias may have also influenced survey responses.

As with other general practice studies of smokers and COPD populations, the participation rate was modest (10%), possibly affecting our estimates of prevalence and incidence rates and the generalisability of our results. However, the characteristics of our participants were similar to those of a group recruited for a comparable study across 44 general practices in Sydney that found similar rates of COPD misdiagnosis.¹⁶ Patients who volunteered for the trial may have been more motivated than those who did not, and may therefore not be representative of all eligible patients. We could not verify the self-reported use of smoking cessation aids in medical records or dispensing and prescribing data, but the research assistants responsible for collecting information were practising pharmacists familiar with smoking cessation medications and in taking medication histories.

Some patients used their COPD medications on the day of spirometry testing, possibly causing detection errors.

Conclusions and implications for practice

Evidence-based guidelines for the optimal diagnosis and management of COPD must be actively promoted and implemented in Australian primary care. GPs and other primary care practitioners should be educated about the role of spirometry testing in COPD diagnosis, and provided with resources and incentives for adopting it in practice. Early identification of potential COPD in individuals at high risk by case finding may facilitate earlier diagnosis and initiation of treatment.

In accordance with RACGP guidelines, smoking cessation strategies of proven effectiveness should be recommended to all smokers. Patients may ask health professionals about the efficacy and safety of non-evidence-based methods, including e-cigarettes, hypnotherapy and acupuncture; e-cigarettes, in particular, should not be recommended. Past experience

7 Self-reported pharmacological and non-pharmacological treatments by 360 current smokers who had attempted to quit at least once in the previous year

Treatment*	
Evidence-based treatments	
Nicotine replacement therapy	205 (57.4%)
Varenicline	110 (30.8%)
Quitline	29 (8%)
Bupropion	25 (7%)
Non-evidence-based treatments	
Hypnotherapy	62 (17%)
E-cigarettes	38 (11%)
Acupuncture	21 (6%)
Other†	41 (12%)

* Multiple selections possible; missing data for three participants. † For example, cold turkey, herbal cigarettes, homeopathic remedies, DVDs or books, counselling, Quit smoking group, online program. ♦

with attempts to quit, reasons for relapse, and preferences for future smoking cessation attempts should inform recommendations about cessation and assessment of the need for monitoring.

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