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"When you can't breathe... nothing else matters"™

The Australian Lung Foundation Position Paper on the Use of COPD screening devices for targeted COPD case finding in community settings

Why is targeted COPD case-finding needed in community settings?

Chronic obstructive pulmonary disease (COPD) is a major cause of global morbidity and mortality.[1-3]

- In 2008, about 2 million Australians, or one in five aged over 40, were estimated to have COPD and, of these, 1.2 million are estimated to have lost at least 50% of their lung capacity.[4]
- Moreover, COPD is a leading cause of death after heart disease, stroke, and cancer, and was responsible for 3.7% of all deaths in Australia and 45.2% of deaths arising from respiratory disease in 2005.[5]
- By 2030, the World Health Organization projects that COPD will be ranked seventh as a disease burden and the fourth highest cause of mortality worldwide.[3]
- Despite these concerning projections, the total burden of COPD is substantially under-estimated.

COPD is not apparent until symptoms appear in the more advanced stages, which has led to concerning rates of under diagnosis and misdiagnosis.[6-14]

- In addition, a lack of awareness among patients about chronic respiratory conditions[15, 16] and the causal factors of COPD have contributed to the under diagnosis of this condition.
- Although cigarette smoking is the most well-recognised and important causal factor for COPD in people aged 40 years or older, other non-smoking factors, particularly in younger (20 to 44 years) populations, women, and developing countries, are contributing to a substantial proportion of the burden of disease.[17, 18]

The rates of under diagnosis and misdiagnosis of COPD in Australia are substantial.

- The Australian Lung Foundation estimates that at least 600,000 Australians with moderate to severe COPD do not know they have COPD and, therefore, are not taking appropriate interventions.[4, 19]
- In addition, data from a random sample of 1,224 45- to 70-year old Australian adults showed that, of the 39 individuals with spirometry-confirmed COPD (GOLD Stage 2 or 3), 49% reported not being diagnosed with a respiratory condition, 36% had been misdiagnosed with asthma, and only 10% had been diagnosed with COPD.[8] One-third of the individuals with spirometry-confirmed COPD were non-smokers.
- Of the 138 individuals with confirmed COPD or asthma, only 32% had seen a general practitioner (for any reason) in the previous 12 months and, of the individuals who had seen a general practitioner in the previous 12 months, only one-third had undergone a respiratory function test.[8]

To reduce the burden of COPD, a greater awareness of COPD among primary care patients and their health care providers is needed.

- This will help decrease the time to diagnosis so that patients can receive early and appropriate interventions.[20]

How is COPD diagnosed?

COPD is diagnosed in at-risk individuals on the basis of clinical assessment and a finding of fixed airway obstruction that is detected using spirometry.

- Diagnostic spirometry is the 'gold standard' for fixed airway obstruction[21, 22] and is essential for the early diagnosis and staging of COPD.[23, 24]
- Spirometry measures how quickly and effectively an individual can empty their lungs of air after inhaling as much air as possible before measurement.
- The ratio of the amount of air that can be exhaled in the first second relative to the total amount of air able to be exhaled (FEV_1/FVC) provides a measure of airway limitation that is used for the diagnosis of COPD (Table 1).
- An FEV_1/FVC ratio < 0.70 is considered to indicate airflow obstruction which may indicate COPD.[21]

Identification of the severity of COPD by spirometry allows progression of the disease to be monitored objectively and the most appropriate interventions to be identified for each patient.

- The Australian and New Zealand guidelines for management of chronic obstructive pulmonary disease (COPD-X; Table 2) describe three levels of severity (mild, moderate, severe).[25]
- Other guidelines, such as the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines for COPD diagnosis,[21] are also sometimes used in clinical practice.

Table 1. Lung Function Parameters

Parameter	Definition	Instrument
FVC	The maximum volume of air that can be forcibly exhaled	Spirometer only
FEV_1	The volume of air that can be forcibly exhaled in 1 second	Spirometer, COPD screening device
FEV_6	The volume of air that can be forcibly exhaled in 6 seconds	Spirometer, COPD screening device
FEV_1/FVC	The ratio of air exhaled during the first 1 second of expiration relative to the maximum amount of air able to be exhaled	Spirometer only
FEV_1/FEV_6	The ratio of air exhaled during the first 1 second of expiration relative to the amount exhaled during the first 6 seconds	Spirometer, COPD screening device

FEV, forced expiratory volume; FVC, forced vital capacity.

Table 2. The Australian and New Zealand COPD Guidelines (COPD-X)

COPD Severity	Post-bronchodilator FEV_1	Functional Assessment
Mild	60 to 80% predicted	– Few symptoms – No effect on daily activities – Breathless on moderate exertion
Moderate	40 to 59% predicted	– Increasing dyspnoea – Breathless on the flat – Increasing limitation of daily activities
Severe	< 40% predicted	– Dyspnoea on minimal exertion – Daily activities severely curtailed

COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second.

What are the advantages and disadvantages of diagnostic spirometry?

- The advantages of spirometry are that it is an objective diagnostic test that is non-invasive and safe to use.[24]
- However, spirometry remains underutilised in clinical practice[26, 27] and is considered by some not to be cost-effective for routine screening for COPD in primary care settings.[28]
- The barriers encountered with routine spirometry include equipment and training costs, low reimbursement, low confidence with use and interpretation of results, a perceived lack of utility, and quality assurance issues.[28-32]
- In addition, the measurement of FVC during spirometry can be physically demanding for elderly patients or those with airway disease, some of whom can take up to 20 seconds to fully exhale.[33]
- As a result, the longer expiration times that these patients experience during spirometry, combined with their low rates of air flow, can contribute to a reduction in the repeatability and reliability of FVC and, consequently, FEV_1/FVC.

What is a COPD screening device?

A simple lung function tool to assist practitioners in the screening of individuals who are at risk of COPD.

- In contrast to diagnostic spirometry, COPD screening devices do not require individuals to completely empty their lungs of air, and are easy-to-use, requiring minimal training to conduct the procedure and to interpret the results.
- Patients are asked to inhale as much air as possible and to blow out continuously into the device for at least 6 seconds.
- The devices measure the amount of exhaled air in the first 1 and 6 seconds of expiration (FEV_1, FEV_6) and calculate FEV_1/FEV_6, which is the ratio of the amount of air forcibly exhaled in the first second relative to the first 6 seconds (Table 1).
- The validated devices available in Australia include the Vitalograph copd-6™ (Vitalograph Ltd, UK) and the PiKo-6 (nSpire Health, Inc., USA).

Can FEV_1/FEV_6 reliably identify patients at risk of COPD?

FEV_1/FEV_6 is emerging as a valid alternative to FEV_1/FVC for the screening of patients at risk of COPD.[34-37]

- Findings from a meta-analysis of 11 studies that compared the diagnostic accuracy of FEV_1/FEV_6 with FEV_1/FVC have shown FEV_1/FEV_6 to have high sensitivity and specificity for detection of COPD in adult populations.[35] However, findings from this meta-analysis are confounded by the various FEV_1/FEV_6 cut-off points (lower limit of normal, 0.70 to 0.76) and FEV_1/FVC standards used for detection of COPD.
- Two studies have explored the sensitivity and specificity of FEV_1/FEV_6 for the detection of COPD using an FEV_1/FVC cut-off ratio < 0.70.[38, 39] Both studies found an FEV_1/FEV_6 ratio < 0.73 to be a reliable and accurate measure for detecting COPD in adult (20 to 80 years)[39] and elderly (> 60 years)[38] populations. To standardise procedures, all of the studies described above were conducted using spirometry for each of the lung function parameters. While such standardised studies are needed for comparative purposes, similar studies conducted using COPD screening devices are needed to confirm the utility of FEV_1/FEV_6 in community settings.

Published evidence for the use of COPD screening devices in the identification of patients at risk of COPD

- Several studies have investigated the use of COPD screening devices in primary care settings[37, 40] and outpatient clinics,[41] in individuals at risk of COPD,[42, 43] and as a tool for raising awareness of lung function tests for detecting chronic obstructive respiratory diseases in a national campaign.[44]
- Of these, only two studies were designed to investigate the accuracy of FEV_1/FEV_6 for the detection of COPD using validation statistics compared with diagnostic spirometry (Table 3); one in a primary care setting[40] and one in a pulmonary function clinic.[41] Findings from these two validation studies suggest that an FEV_1/FEV_6 cut-off ratio < 0.75 provides optimal sensitivity and specificity for discriminating between patients with and without spirometry-confirmed COPD (Table 3). Moreover, one study showed that the accuracy of FEV_1/FEV_6 < 0.75 as a cut-off with a COPD screening device exceeded the accuracy of validated COPD diagnostic questionnaires in Australian primary care practices.[40]

Table 3. Validity of COPD Screening Devices Compared with Diagnostic Spirometry

Device	Setting	N	Mean age (yr)	FEV_1/ FVC	FEV_1/ FEV_6	Result
PiKo-6[40]	Primary care	CF = 204 DD = 93	CF = 61 DD = 62	< 0.7	< 0.70	CF, Sens: 51%; Spec: 93% DD, Sens: 69%; Spec: 88%
					< 0.75	CF, Sens: 81%, Spec: 71% DD, Sens: 86%, Spec: 67%
					< 0.80	CF, Sens: 93%, Spec: 48% DD, Sens: 94%, Spec: 44%
						ROC_{AUC}, CF: 0.85; DD: 0.88
copd-6[41]	Pulmonary function clinic	180	56	< 0.7	< 0.70	Sens: 58%; Spec: 100%
					< 0.73	Sens: 83%; Spec: 98%
					< 0.75	Sens: 87%; Spec: 96%
					< 0.80	Sens: 96%; Spec: 76%
						ROC_{AUC}: 0.97

CF, case finding: current and former smokers with no previous respiratory diagnosis; COPD, chronic obstructive pulmonary disease; DD, differential diagnosis: current and former smokers with a diagnosis of asthma; FEV_1/FEV_6, forced expiratory volume in 1 second / forced expiratory volume in 6 seconds; FVC, forced vital capacity; ROC_{AUC}, area under the receiver operating characteristic; Sens, sensitivity; Spec, specificity.

Is there a role for targeted case-finding in the diagnosis and management of COPD?

Population-based screening is the process where a test is systematically offered to all individuals who present to a health care worker.

- This approach is not recommended for COPD as spirometry has been shown to identify many individuals with clinically insignificant COPD who are unlikely to benefit from intervention.[28]
- However, the substantial numbers of people with clinically significant COPD who are not diagnosed highlight the need for targeted case-finding strategies for COPD in primary care as this is a place where it may be possible to identify them.[8, 14, 28]

The main aim of targeted COPD case-finding with a COPD screening device is to identify those at risk of COPD and avoid unnecessary spirometry in those with normal lung function.

- Such an approach will allow identification of 'at-risk' individuals for standard diagnostic spirometry who are likely to benefit from early intervention and disease management.[45]
- However, individuals with respiratory symptoms and normal spirometry at the time of testing may be at risk of other airway disease or developing COPD in later life.
- These individuals should be referred to their local health practitioner for further assessment and, if appropriate, encouraged to commence preventative strategies, such as quitting smoking, that may stop or slow the onset of COPD.
- This approach will have the added benefit of raising awareness of lung health in the community and ensuring that individuals take the symptoms of lung disease seriously.

Objective of this Position Paper

- To guide health care professionals in the appropriate use of COPD screening devices as part of a targeted case-finding strategy to support the early and timely diagnosis of COPD in primary care.
- The audience for this position paper includes those who might use the devices in a community or primary care setting including, but not exclusive to, general practitioners, general practice nurses, respiratory- and other hospital-based nurses, respiratory scientists, physiotherapists and other allied health personnel, exercise physiologists, pharmacists, community health workers, multi-cultural health workers, aboriginal health workers, and The Australian Lung Foundation staff.

Recommendation

- The Australian Lung Foundation recommends the use of a screening symptom checklist and a COPD screening device with an FEV_1/FEV_6 cut-off < 0.75 for the targeted screening of COPD in previously undiagnosed, at-risk individuals aged 35 years or older.
- A screening algorithm that summarises The Australian Lung Foundation recommendations for the use of COPD screening devices in primary care is shown in Figure 1.

Guidelines for Use

Identification of individuals at risk of COPD

- Individuals with a previous diagnosis of COPD or who are currently being treated for COPD should not be screened using a COPD screening device. These individuals should be encouraged to visit a general practitioner for diagnostic spirometry and further assessment.

- Individuals aged 35 years or older who meet at least one of the following criteria may be at risk of COPD and should undergo screening:
  - Smoker or ex-smoker
  - Work or worked in a job where he / she was exposed to dust, gas, or fumes
  - Cough several times most days
  - Cough up phlegm or mucus most days
  - Out of breath more easily than others of a similar age
  - Experience chest tightness or wheeze
  - Have frequent chest infections

Use of the COPD screening device

- Operators of the COPD screening device can include, but are not exclusive to, general practitioners, general practice nurses, respiratory- and other hospital-based nurses, physiotherapists and other allied health personnel, exercise physiologists, pharmacists, community health workers, multi-cultural health workers, aboriginal health workers, and The Australian Lung Foundation staff.
- Minimal training is required to operate a COPD screening device. The Australian Lung Foundation recommends that operators who are new to the COPD screening device complete the online training module that is available at http://www.lungfoundation.com.au/professional-resources/copd-screening-devices-in-the-community . In addition, The Australian Lung Foundation recommends the use of the one-page instruction sheet that accompanies the online training module also available on the above webpage.
- Minimal facilities are required. There are no special requirements for operation of the COPD screening device. However, individuals to be screened should be seated comfortably, in an upright position. COPD screening devices are battery-operated and, therefore, do not require a power source.
- COPD screening devices should be cleaned at least monthly, depending on the frequency of use, and calibrated or replaced annually.
  - Parts of the device that come in contact with the breath of individuals being screened should be disinfected according to the manufacturer's instructions.
- A new mouthpiece should be used for each individual to be screened.
  - Allow at least 5 minutes between individuals for settling of any air-borne particles.
- Refer to the manufacturers' instructions for further details on the use and maintenance of each COPD screening device.

Recommended screening parameter

- The ALF recommends a cut-off FEV_1/FEV_6 ratio < 0.75 when using the COPD screening device.
- Individuals with an FEV_1/FEV_6 ratio < 0.75 should be referred for diagnostic spirometry and further assessment.

- Individuals with an FEV_1/FEV_6 ratio ≥ 0.75 and who are symptomatic or have a risk factor identified in screening checklist should be encouraged to visit their general practitioner as they may be at risk of other diseases or lung conditions.

Referral pathways and duty of care

- Two pathways, which are based on where the screening is conducted and by whom, are recommended:
  - Practice-based screening (eg, general practitioners, practice nurses, respiratory and other hospital-based nurses, any health worker working under a medical practitioner's supervision). The duty of care and referral policies and procedures of the practice or hospital where the screening is conducted should be followed.

  - Community-based screening (eg, physiotherapists and other allied health personnel, exercise physiologists, pharmacists, community health workers, multi-cultural health workers, Aboriginal health workers, and The Australian Lung Foundation staff). The operator of the COPD screening device in this setting should provide symptomatic or at-risk individuals with an FEV_1/FEV_6 ratio < 0.75 with a written results form to see their doctor. This can be found at http://www.lungfoundation.com.au/professional-resources/copd-screening-devices-in-the-community . The Australian Lung Foundation does NOT recommend a formalised referral to the general practitioner as a result of a community screening activity. If the information about the screening is provided to the patient with a recommendation that they consult their medical practitioner, there is no duty of care on behalf of the person who conducts the screening.

Conclusion

- The Australian Lung Foundation recommends that COPD screening devices can be operated by general practitioners, practice-based health workers, and individuals within the community with minimal training.
- Previously undiagnosed individuals aged 35 years or older should be screened with the screening symptom checklist, followed by a COPD screening device with an FEV_1/FEV_6 cut-off < 0.75.
- Symptomatic or at-risk individuals with an FEV_1/FEV_6 ratio < 0.75 should be recommended or referred to a general practitioner for diagnostic spirometry.
- Symptomatic or at-risk individuals with an FEV_1/FEV_6 ratio ≥ 0.75 should be encouraged to visit their general practitioner as they may be at risk of other diseases or lung conditions and may require more formalised testing.
- Please refer to the screening algorithm (Figure 1) that summarises the Australian Lung Foundation recommendations for the use of COPD screening devices in primary care settings.

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Competing interests

- Each advisory board member is required to report their competing interests to The Australian Lung Foundation annually.

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For further information, contact The Australian Lung Foundation's Director of COPD National Program at 1 800 654 301 or visit www.lungfoundation.com.au.

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Figure 1. Screening Algorithm for COPD