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Position Paper: COPD case finding in community settings

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 LFA staff.

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]

COPD is a lung disease that affects 14.5% (or one in seven) Australians aged 40 or over. This figure increases to 29.2% in Australians aged 75 or over.[4]

7.5% of Australians aged 40 or over have COPD that has progressed sufficiently to where symptoms may already be present and affecting daily life, even though half of them will not know they have it.[5]

COPD is the second leading cause of avoidable hospital admissions.[6]

Despite falling death rates, COPD is still a leading cause of death and disease burden after heart disease, stroke and cancer.[7]

By 2030, the World Health Organization has projected that COPD will be ranked seventh as a disease burden and the third highest cause of mortality worldwide.[3, 8]

World Health Organisation data released from 2012 shows that COPD is already the third highest cause of mortality worldwide,[8] so ranking projections for 2030 for COPD have already been reached.

COPD is not apparent until symptoms appear in the more advanced stages, which has led to concerning rates of under diagnosis and misdiagnosis.[9-17]

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.[20-21]

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

Of those with COPD currently, Lung Foundation Australia estimates that over 750,000 Australians[4,22] have COPD that has progressed to a stage at which symptoms such as breathlessness may already be present and affecting their daily lives. Half of these people do not have a doctor's diagnosis of COPD and are therefore not taking the important steps to slow down the progression of the disease.[5] Another 700,000 Australians[4,22] have a mild form of COPD where symptoms may not yet be present. Many of these will go on to develop more severe COPD.

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.[11] 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.[11]

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.[23]

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[24-25] and is essential for the early diagnosis and staging of COPD.[26-27]

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.[24]

COPD screening devices should not be used to diagnose COPD as they can result in an overestimation of airflow obstruction.[28]

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).[29]

Other guidelines, such as the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines for COPD diagnosis,[24] 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 Recurrent chest infections
Moderate	40 to 59% predicted	Increasing dyspnoea Breathless walking on level ground Increasing limitation of daily activities Cough and Sputum production exacerbations requiring oral corticosteroids and/or antibiotics.

Severe	< 40% predicted	Dyspnoea on minimal exertion Daily activities severely curtailed Chronic cough Experiencing regular sputum production Exacerbations of increasing frequency and severity

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

Issues incorporating spirometry into practice

The advantages of spirometry are that it is an objective diagnostic test that is non-invasive and safe to use.[27]

However, spirometry remains underutilised in clinical practice[30-31] and is considered by some not to be cost-effective for routine screening for COPD in primary care settings.[32]

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.[32-36]

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.[37]

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?

COPD screening devices are simple lung function tools to assist practitioners identify individuals who are at risk of COPD.

COPD screening devices such as the PiKo-6 and COPD-6 do not require individuals to completely empty their lungs of air so are less physically demanding. They are also easy-to-use, requiring minimal training to conduct the procedure and to interpret the results.

They enable easy and cost-effective screening of respiratory conditions, helping to rule out patients that are unlikely to have COPD.

Patients are asked to inhale as much air as possible and to 'blast the air out' forcibly into the device for at least 6 seconds, making sure their lips are firmly sealed around the mouthpiece.

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.

The Air Smart Spirometer which can also be used for COPD case finding requires the patient to completely empty their lungs after a full inhalation, and calculates an FEV_1, FVC, FEV_1/FVC and peak expiratory flow (PEF). It also provides predicted values taking into consideration gender, height and age.

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 identification of patients at risk of COPD.[38-41]

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.[39] 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.[42-43] 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)[43] and elderly (> 60 years)[42] 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.

The use of COPD screening devices which measure FEV_1/FEV_6 can provide primary health professionals with a simple and reliable method to preselect patients for diagnostic spirometry.[28]

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[28,41, 44-45] and outpatient clinics,[46] in individuals at risk of COPD,[47-48] and as a tool for raising awareness of lung function tests for detecting chronic obstructive respiratory diseases in a national campaign.[49]

The use of a questionnaire combined with a COPD screening device can lead to increased diagnosis of COPD in a primary care setting compared to usual care.[46]

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[44] and one in a pulmonary function clinic.[46] 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.[44]

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.[32]

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.[11, 17, 32]

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.[50, 28, 45]

However, individuals with respiratory symptoms and normal spirometry at the time of testing may be at risk of other airway or lung disease or of developing COPD in later life.

These individuals should be referred to their local health practitioner for further assessment and investigation as needed, 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.

Recommendation

LFA recommends the use of a symptom checklist and a COPD screening device with an FEV_1/FEV_6 cut-off < 0.75 (PiKo-6 and COPD-6) or FEV_1/FVC < 0.7 (Air Smart Spirometer) for the targeted screening of COPD in previously undiagnosed, at-risk individuals aged 35 years or older.

A screening algorithm that summarises LFA's 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

Check for Contraindications

Prior to administering a test with a COPD screening device individuals should be assessed to determine if they have any contraindications that may exclude them from the test. Ask the individual if:

- within the last 8 weeks they have had:
- abdominal, thoracic or eye surgery
- heart attack or chest pain
- collapsed lung (pneumothorax).
- within the last 6 weeks they have had a serious lung infection (e.g. pneumonia, tuberculosis).
- they are currently:
- coughing up blood (haemoptysis)
- at increased risk of fainting (syncope)
- suffering from nausea or vomiting
- have an intracranial aneurysm.

If they answer yes to any of these contraindications, they are not eligible to undertake the test until their status has changed. If coughing up blood then they will require referral or additional assessment for this.

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 LFA staff.

The training required to operate a COPD screening device is simpler than for full spirometry. LFA recommends that operators who are new to the COPD screening device complete the online training module that is available at https://lungfoundation.com.au/events/diagnosis-of-copd-online-training/. In addition, LFA recommends the use of the one-page instruction sheet *COPD Screening Using the Piko-6* available at https://lungfoundation.com.au/health-professionals/conditions/copd/diagnosis/.

Minimal facilities are required. An area that allows for privacy where individuals undertaking the test cannot be viewed by people other than the operator and engagement in a private conversation can transpire. 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. These devices have a 1 year warrantee and usually last about 3 years.

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 (disposable one-way valve) 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

LFA recommends a cut-off FEV_1/FEV_6 ratio < 0.75 (PiKo-6 and COPD-6) or FEV_1/FVC <0.7 (Air Smart Spirometer) when using the COPD screening device.

Individuals with an FEV_1/FEV_6 ratio < 0.75 (PiKo-6 and COPD-6) or FEV_1/FVC <0.7 (Air Smart Spirometer) should be referred for diagnostic spirometry and further assessment.

For people diagnosed with asthma with an FEV_1/FEV_6 ratio < 0.75 (PiKo-6 and COPD-6) or FEV_1/FVC <0.7 (Air Smart Spirometer) recommend that asthma is reassessed by their doctor.

Individuals with an FEV_1/FEV_6 ratio ≥ 0.75 (PiKo-6 and COPD-6) or FEV_1/FVC >0.7 (Air Smart Spirometer) and who have a symptom identified in the screening checklist should be encouraged to visit their general practitioner as they may be at risk of other diseases or lung conditions.

Discuss options for individuals with an FEV_1/FEV_6 ratio ≥ 0.75 (PiKo-6 and COPD-6) or FEV_1/FVC >0.7 (Air Smart Spirometer) and who have a risk factor identified in the screening checklist. Some of them may need action and others will require monitoring. For example, an ex-smoker with no other symptoms/risk factors should not be referred to the GP as they have already quit smoking. They should however be monitored on an annual basis as they still have the risk factor.

Referral pathways and duty of care

Two pathways are recommended, which are based on where the targeted case-finding is conducted and by whom:

Practice-based targeted case-finding (e.g. 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 targeted case-finding (e.g. physiotherapists and other allied health personnel, exercise physiologists, pharmacists, community health workers, multi-cultural health workers, Aboriginal health workers, and LFA staff). The operator of the COPD screening device in this setting should provide symptomatic or at-risk individuals found to have an FEV_1/FEV_6 ratio < 0.75 with a written results form to see their doctor. This can be found at https://lungfoundation.com.au/wp-content/uploads/2018/09/Information-Paper-COPD-Case-Finding-Results-Form-Community-Pharmacy-Oct2018.pdf. LFA 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

LFA 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 at risk individuals aged 35 years or older should be screened with the risk factor and symptom checklist, and then if eligible checked for contraindications and administered a test with a COPD screening device, FEV_1/FEV_6 cut-off < 0.75 (PiKo-6 and COPD-6) or FEV_1/FVC <0.7 (Air Smart Spirometer).

Symptomatic or at-risk individuals with an FEV_1/FEV_6 ratio < 0.75 should be (PiKo-6 and COPD-6) or FEV_1/FVC <0.7 (Air Smart Spirometer) recommended or referred to a general practitioner for diagnostic spirometry.

Symptomatic or at-risk individuals with an FEV_1/FEV_6 ratio ≥ 0.75 (PiKo-6 and COPD-6) or FEV_1/FVC >0.7 (Air Smart Spirometer) 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 LFA recommendations for the use of COPD screening devices in primary care settings.

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Competing interests

Each advisory group member is required to report their competing interests to Lung Foundation Australia annually.

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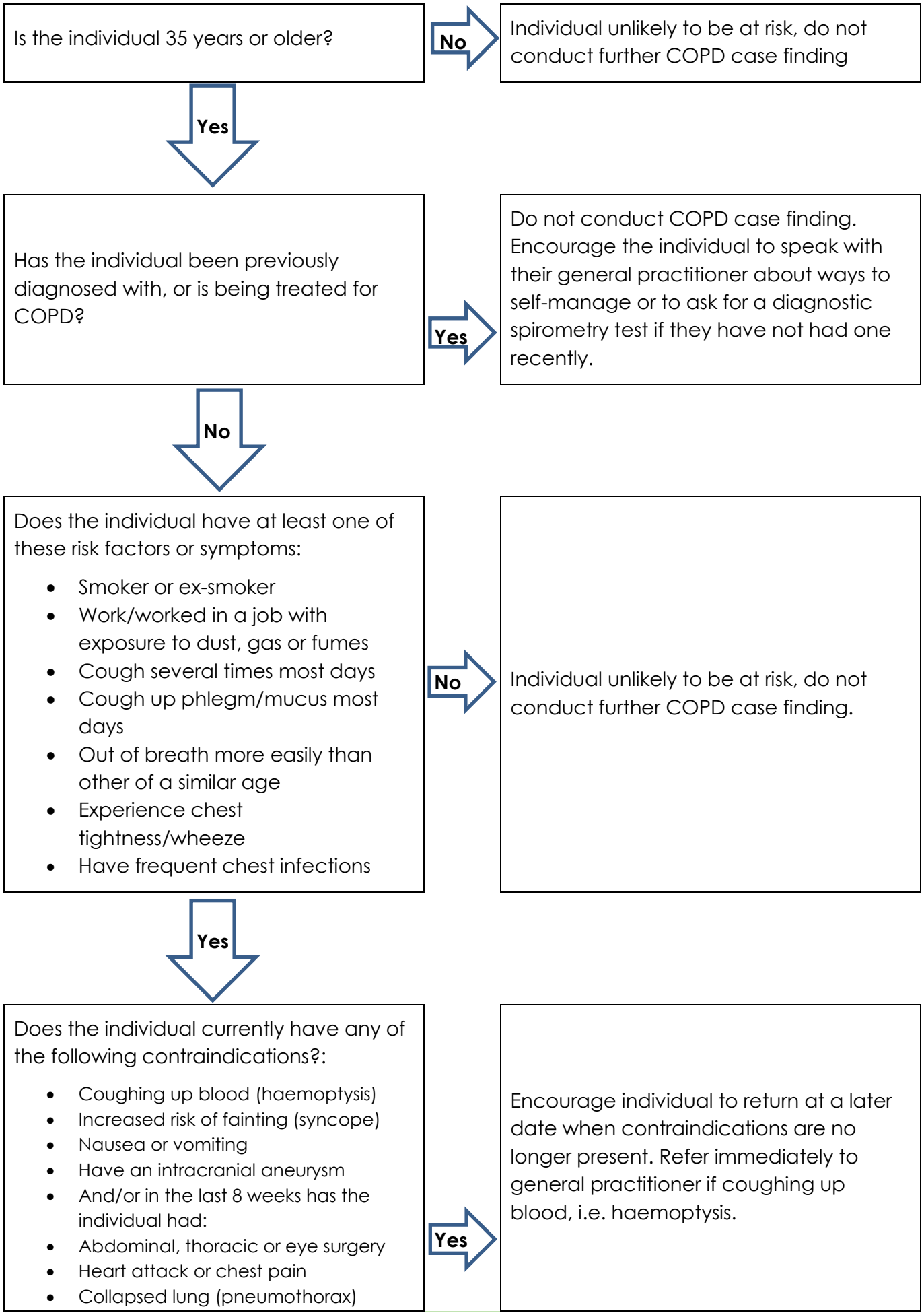
Figure 1. Case finding algorithm for COPD



- Lung infection (e.g. pneumonia, tuberculosis)

No

Perform the test with a COPD screening device. In reference to the results does the individual have an FEV_1/FEV_6 ratio<0.75 (PiKo-6 and COPD-6) or FEV_1/FVC <0.7 (Air Smart Spirometer)?

No

COPD unlikely. Encourage the individual to visit their general practitioner to discuss symptoms and/or if still smoking.

Yes

Use Screening Results Form to provide a written recommendation to the individual to visit their general practitioner for diagnostic spirometry.