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Spirometry: Are we doing enough to assess breathlessness in T_UH Acute Cardiac Patients

Liane Rosalind Jennette Barnes

BSc, GDipMedSc, ACP

This thesis is submitted in the fulfilment of the requirements for the degree of

Master of Philosophy

College of Medicine and Dentistry

James Cook University, Townsville, Queensland, Australia

February 2025

STATEMENT OF SOURCES DECLARATION

I declare that this thesis is my own work and has not been submitted in any form for another degree or diploma at any university or other institution of tertiary education. Information derived from the published or unpublished work of others has been acknowledged in the text and a list of references is given.

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DECLARATION OF ETHICS

The research presented and reported in this thesis was conducted within the guidelines for research ethics outline in the *National Statement on Ethics Conduct in Research Involving Human* (1999), the *Joint NHMRC/AVCC Statement and Guidelines on Research Practice* (1997), the *James Cook University Policy on Experimentation Ethics, Standard Practices and Guidelines* (2001), and the *James Cook University Statement and Guidelines on Research Practice* (2001). The proposed research methodology received clearance from the Townsville Hospital and Health Severe Ethics Review and the James Cook University Experimentation Ethics Review (Approval numbers: THHS Human Ethics Research Committee Approval HREC/QTHS/76245, THHS Research Governance Single Site Approval SSA/QTHS/76245, Queensland Health Public Health Act Approval PHA76245.1, JCU Human Ethics Research Committee Approval H9254).

Student Name

Date

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STATEMENT OF THE CONTRIBUTION OF OTHERS

NATURE OF ASSISTANCE	CONTRIBUTION	NAME AND AFFILIATIONS
INTELLECTUAL SUPPORT	Project design and supervision	A/Prof Suzy Munns, James Cook University A/Prof Anne Jones, James Cook University Ms. Nadine Pyne, Townsville University Hospital
	Editing of manuscript drafts	A/Prof Suzy Munns, James Cook University A/Prof Anne Jones, James Cook University Ms. Nadine Pyne, Townsville University Hospital
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1. TropiQ Townsville Research Symposium – October 2022 Townsville
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2. Australian and New Zealand Society for Respiratory Science Annual Scientific Meeting New Investigator Award Finalist – March 2023 Christchurch *(The quality of spirometry testing: A systematic review)*
3. College of Public Health, Medical & Veterinary Sciences, James Cook University 3MT Competition Winner – August 2023 *(Breathlessness Heart, Lungs or Both?)*
4. College of Public Health, Medical & Veterinary Sciences, James Cook University MPhil Pre-completion seminar – November 2024 *(Spirometry: Are we doing enough to assess breathlessness in TUH Acute Cardiac Patients)*

ABSTRACT

Chronic Respiratory Diseases (CRDs) are the third leading cause of death globally. Patients with CRD are 2-5 times more likely to have co-existing cardiovascular disease (CVD) than those without. Breathlessness is a symptom of both diseases, and this overlap often results in coexisting CRD remaining undiagnosed. Detecting early changes in lung function is essential for enabling treatment effectiveness. Lung function is objectively measured using spirometry and high-test quality maximises its diagnostic utility. Despite the high prevalence of CRDs and CVD, and their frequent coexistence, the use of spirometry in cardiac inpatients remains unclear. This thesis investigated the use and quality of spirometry in breathless cardiac patients.

The quality of spirometry in published literature was critically reviewed and a meta-analysis was conducted using a generalised linear model. Point of care spirometry use and quality was determined in breathless cardiac inpatients using a retrospective cross-sectional investigation.

Only 4% of published studies adequately reported spirometry quality and, in these studies, 25% of tests did not meet international standards. The presence of disease, the type of spirometer, or the standard used did not decrease spirometry quality, but participant age and study setting did. Overall, the risk of bias was low using established tools although these tools lacked specificity. Recommendations included the introduction of internationally standardised reporting methodology, and a proposed spirometry specific risk of bias appraisal tool was designed.

Point of care spirometry was underutilised in cardiac inpatients. During admission, spirometry was only conducted in 12.5% of patients with reported breathlessness, and half of the tests did not meet quality standards. Delivery of spirometry was not matched to patient risk factors. A moderate agreement of spirometry quality grading and a low agreement in airflow pattern interpretation was seen between automated (spirometer algorithms) and manual assessments. This resulted in one third of airflow patterns changing. The primary cause of breathlessness was determined to be both CVD and CRD in 67% of patients with 50% of which having no previous CRD history. The opportunity for case-finding coexisting CRD was lost in 87.5% of breathless cardiac inpatients. Changes in practice are recommended including training, oversight of testing by Respiratory and Sleep Unit, and the creation/update to the diagnostic

procedure for case-finding CRDs, to increase the awareness of coexisting CRDs and the need for spirometry testing in stable cardiac inpatients. The evidence from this thesis will help facilitate synergies between cardiac and respiratory health care teams with the aim of improving patient outcomes.

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LIST OF ABBREVIATIONS

ACSQHC – Australian Commission on Safety and Quality in Health Care

ANZSRS – Australian and New Zealand Society for Respiratory Science

AR – Acceptability and Repeatability

ATS – American Thoracic Society

BMI – Body Mass Index

COPD – Chronic Obstructive Pulmonary Disease

CRD – Chronic Respiratory Disease

CVD – Cardiovascular Disease

DALY – Disability-adjusted life years

ECG – Electrocardiogram

EF – Ejection Fraction

ERS – European Respiratory Society

FER – Forced Expiratory Ration (FEV_1/FVC)

FEV_1 – Forced Expiratory Volume in the First Second

FVC – Forced Vital Capacity

GOLD – Global Initiative for Chronic Obstructive Pulmonary Disease

HRCT – High Resolution Computed Tomography

ILD – Interstitial Lung Disease

ISO – International Organisation for Standardisation

LV – Left Ventricle

NATA – National Association of Testing Authorities

NQPHN – Northern Queensland Primary Health Network

NSQHS – National Safety and Quality Health Service

QLD - Queensland

ROB – Risk of Bias

RSU – Respiratory and Sleep Unit

SDG – Sustainability Development Goals

SDI – Socio-demographic Index

THHS – Townsville Hospital and Health Service

TSANZ – Thoracic Society of Australia and New Zealand

TUH – Townsville University Hospital

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CHAPTER 1

Introduction

As the first and third leading causes of death, cardiovascular disease (CVD) and chronic respiratory diseases (CRDs) are two major health problems worldwide (Andre et al., 2019; Collaborators, 2023; Roth et al., 2020). CRDs and CVD often coexist together sharing similar pathophysiological processes, risk factors, and symptoms like breathlessness (Andre et al., 2019; Chen et al., 2015; Leong et al., 2019; Rabe et al., 2018). In combination, CRDs and CVD are associated with worse outcomes for patients than each disease alone (Andre et al., 2019; Chen et al., 2015; Leong et al., 2019). Combined CRD and CVD are often missed as a patient's presentation is generally attributed to one disease only, and the other being passed over (Leong et al., 2019). CRDs progressively worsen over time, therefore it is essential that early diagnosis, including lung function assessment, and access to treatments occur (Leong et al., 2019; Rabe et al., 2018; World Health Organization, 2021b). The focus of my thesis is to investigate use and quality of lung function assessment, in particular spirometry, for CRD detection in breathlessness CVD patients.

The Lungs and Heart

Respiration, is the respiratory system's main function, involving the exchange of oxygen and carbon dioxide to and from the body via the oxygen cascade (Davies & Misra, 2014; Webster & Karan, 2020). Pulmonary ventilation, or more commonly known as breathing, is a key function for sustaining life (Courtney, 2009). It is the physiological process by which air moves into and out of the lungs during inspiration and expiration (Courtney, 2009; Davies & Misra, 2014; Webster & Karan, 2020). The compliance of the lung tissues and resistance of the airways will determine the amount of ventilation (Kaminsky & Irvin, 2018). External respiration (gas exchange) occurs by allowing oxygen to diffuse from the lungs to the blood for transport to the tissues and *vice versa* for carbon dioxide (Davies & Misra, 2014; Murias et al., 2014). When pulmonary ventilation becomes impaired, often from disease, this affects a person's life, creating symptoms, challenging homeostasis, and compromising overall health (Courtney, 2009).

Oxygenated blood is transported to the tissues and deoxygenated blood (containing carbon dioxide) is return to the lungs for expulsion via the cardiovascular system (Farley et al., 2012). The cardiovascular system, also called the circulatory system, is comprised of the heart and the associated arteries, veins and capillaries (Benjamin et

al., 2018). The respiratory and cardiovascular systems are closely intertwined and work together via the oxygen cascade to continuously move blood throughout the body. Often when one system becomes impaired, it also may cause the other to as well.

The lungs are not fully developed at birth (Agusti et al., 2023; Melen et al., 2024). Until between the ages of 20-25 years when lung function is at its peak, the lungs continue to develop and mature (Agusti & Faner, 2019; Melen et al., 2024; Okyere et al., 2021). What follows is a relatively short plateau then a mild gradual lung function decline, due to physiological aging (Agusti & Faner, 2019; Melen et al., 2024; Okyere et al., 2021). Alteration to one or more of these stages from environmental or genetic factors at any age, including pre and post-natal, can result in a range of lung function trajectories which are associated with predisposition to respiratory diseases, early multimorbidity and premature death (Figure 1.1) (Agusti & Faner, 2019; Melen et al., 2024).

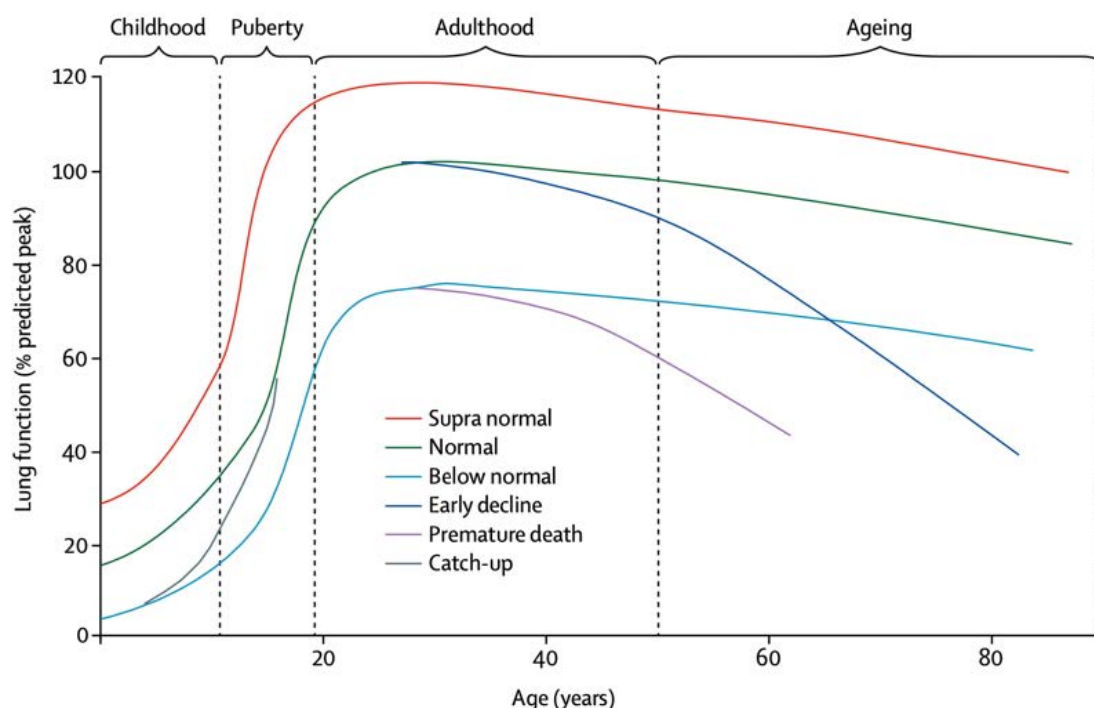


Figure 1.1 Lung Function Trajectories in Health and Disease. Image sourced from Agusti and Faner (2019).

Chronic Respiratory Diseases

Chronic Respiratory Diseases (CRDs) are one of the most common non-communicable diseases worldwide, and are largely triggered by the ubiquity of harmful environmental (e.g. air pollution), occupational, and behavioural (i.e. tobacco smoking)

exposures (Collaborators, 2023). Chronic respiratory diseases cause changes to the airways and other structures of the lungs which decrease function (Yang et al., 2023). Chronic respiratory diseases are preventable, and although they may be symptom controlled, they are not considered curable (Australian Institute of Health and Welfare, 2020c; World Health Organization, 2021b).

Chronic respiratory diseases are the third leading cause of death globally with a total prevalence of 454.6 million cases (Collaborators, 2023). Worldwide estimates from the Global Burden of Disease Study 2019 showed that the overall prevalence and mortality of CRDs have increased by 39.8% and 28.5% respectively since 1990, but the age-standardised rates have dropped (Collaborators, 2023). High Socio-demographic Index (SDI) countries (including Australia) were shown to have the highest prevalence of CRDs whilst in low and low-middle SDI counties, age-standardised death and disability-adjusted life years (DALYs) rates were the highest (Collaborators, 2023). By 2030, the third target of UN Agenda for Sustainability Development Goals (SDG) aims to reduce premature mortality by one third for noncommunicable diseases through prevention and treatment (Collaborators, 2023; Khaltayev & Akselrod, 2021).

In Australia, CRDs account for 7.5% of the burden of disease and injury and are estimated to cost the health system \$4.5 billion per annum (Australian Institute of Health and Welfare, 2020c). Chronic respiratory disease can affect people at any age, with the most common types being Chronic Obstructive Pulmonary Disease (COPD), Asthma and Interstitial Lung Disease (ILD) (Figure 1.2) (Baptista et al., 2021; Collaborators, 2023).

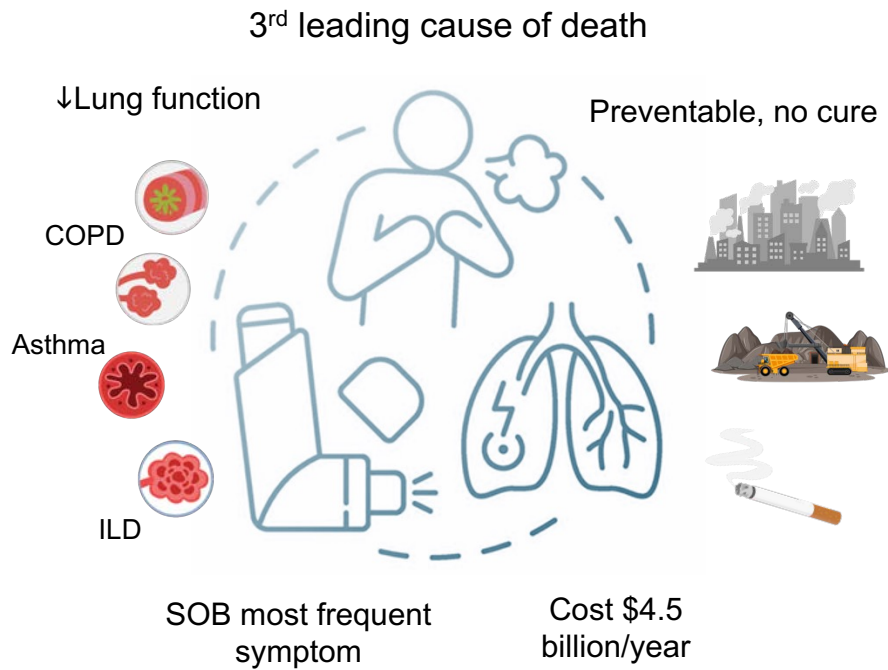


Figure 1.2: Chronic Respiratory Disease – Main types, causes, and burden.

The Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD) defines COPD as “a heterogeneous lung condition characterised by chronic respiratory symptoms (dyspnoea, cough, expectoration) due to persistent abnormalities of the airways (bronchitis, bronchiolitis), and/or alveoli (emphysema), that often results in progressive airflow limitation” (Agusti et al., 2023; Celli et al., 2022). The result of COPD will ultimately cause structural and inflammatory changes leading to airflow limitation, however there are numerous causes and pathobiological mechanisms which may coexist and interact in the same individual (Agusti et al., 2023). Tobacco smoking, indoor, and outdoor air pollution are the main environmental risk factors for COPD (Agusti et al., 2023; Collaborators, 2023). COPD is the highest cause of mortality for all CRDs (Collaborators, 2023).

Characterised by chronic airway inflammation and hyperresponsiveness, Asthma is heterogenous disease that is defined by the history of respiratory symptoms (cough, wheeze, dyspnoea and chest tightness) which worsen overtime (Conrad et al., 2021; Hough et al., 2020). Variable airflow limitation may also persist (Conrad et al., 2021). There are many phenotypes of asthma which may be triggered by exercise, allergen or irritant exposure, weather changes, or viral respiratory infections (Holgate et al., 2015). Reversal of symptoms or airflow limitation may spontaneously occur but are often

resolved in response to inhaled medications (Holgate et al., 2015). Asthma may be present at any age and is the most prevalent CRD worldwide (Collaborators, 2023).

Most Interstitial Lung Diseases (ILD) primarily affect the pulmonary interstitium and it is estimated that the cause may arise from >200 different disorders (Wijsenbeek et al., 2022). Characterised by inflammation or fibrosis within the interstitial space, the main consequence of ILD is impaired gas exchange which leads to breathlessness and in a lot of cases, respiratory failure and death (Wijsenbeek et al., 2022). ILD may be classed as idiopathic, autoimmune-related, exposure-related, ILD with cysts or airspace filling, sarcoidosis, and orphan diseases (Wijsenbeek et al., 2022). The onset of ILD varies from insidious to acute and life-threatening (Wijsenbeek et al., 2022).

Cardiovascular Disease

Cardiovascular disease (CVD) is a broad term used to group disorders including coronary artery disease (also known as coronary/ischaemic heart disease), cerebrovascular disease, peripheral artery disease, and aortic atherosclerosis (Benjamin et al., 2018). The most common denominator for the pathophysiology of CVD is the development of atherosclerosis (i.e. plaque build-up) in the arteries (Barquera et al., 2015; Betancourt Cuellar et al., 2019). The effects of atherosclerosis can be seen in both small and large vessels and may result in aneurysm formation, obstruction of blood flow, vessel rupture, or embolisms causing myocardial infarctions and/or ischaemic strokes (Barquera et al., 2015; Betancourt Cuellar et al., 2019). Most CVDs are preventable, with the main risk factors being environmental (air pollution) or behavioural (tobacco use, diet and exercise) (Roth et al., 2020).

Cardiovascular diseases are the leading cause of mortality, responsible for 32% of all deaths globally (World Health Organization, 2021a). The Global Burden of Disease Study 2019 estimated the total prevalence of CVDs to be 523 million cases, almost doubling from 1990 (Roth et al., 2020). In Australia, CVD accounts for approximately 12% of the total burden of disease and costed the Australian healthcare system \$14.3 billion in 2020-21 (Australian Institute of Health and Welfare, 2024a). The total burden of CVD (adjusted for age) and mortality rate have decreased in Australia by 47% and 78% respectively (Australian Institute of Health and Welfare, 2024a). This has been attributed to major public health improvements including advancements in prevention

and treatment, e.g. Heart Health Checks (Australian Institute of Health and Welfare, 2024a).

Breathlessness and the overlap

The most common CRDs symptom is breathlessness with little to no exertion (Australian Commission on Safety and Quality in Health Care, 2021a). Breathlessness (dyspnoea) is defined as varying intensities of discomfort created by the inability to gain enough air into the lungs. Breathlessness is strongly associated with adverse health outcomes and is the most frequent motivator to seek acute care (Bausewein et al., 2007; Gronseth et al., 2014; Johnson & Hutchinson, 2018; Parshall et al., 2012). Acute exacerbations occur regularly in CRDs and involve sudden worsening of airway function and respiratory symptoms (including breathlessness) and are the main cause of hospital admissions (Australian Commission on Safety and Quality in Health Care, 2021a; Cousins et al., 2020; MacIntyre & Huang, 2008). Each acute exacerbation hastens disease progression and can ultimately lead to respiratory failure (Cousins et al., 2020; MacIntyre & Huang, 2008). Treatments aim to decrease the number and intensity of exacerbations and hospitalisations, provide symptom relief, and improve the patient's quality of life (Australian Commission on Safety and Quality in Health Care, 2021a; World Health Organization, 2021b).

Breathlessness can also result from cardiac disease, either independently or in combination with respiratory disease (Berliner et al., 2016; Ferry et al., 2019). Cardiovascular disease (CVD) is one of the most frequent chronic conditions (comorbidities) associated with CRDs, with the occurrence being 2-5 times higher compared to non-CRD patients (Chen et al., 2015; Leong et al., 2019). The coexistence of diseases significantly increases the length of hospital stays and morality by 2-fold (Kavya et al., 2020). Thus, the overlap of clinical presentations between both CRDs and CVD can increase the difficult in determining the cause of breathlessness (Berliner et al., 2016; Johnson & Hutchinson, 2018).

Breathlessness is a subjective experience and when not evaluated accurately and precisely, the rates of misdiagnosis and mortality along with the burden of diseases increase (Berliner et al., 2016; Johnson & Hutchinson, 2018). Determining the cause of breathlessness requires a combination of diagnostic investigations (blood panels, chest x-ray, electrocardiography and spirometry) in conjunction with a physical

examination. These augment patient history which is normally performed in primary healthcare (Berliner et al., 2016; Ferry et al., 2019; Huang et al., 2018). Further advanced testing may be required if the underlying breathlessness cause is not clear or multifactorial to allow for triaging to respiratory and/or cardiac disciplines (Ferry et al., 2019; Yang et al., 2023).

Spirometry

Spirometry provides an objective assessment of lung function and is the most used diagnostic test for respiratory function (Graham et al., 2019). Spirometry assesses ventilatory efficiency by quantifying the volume and speed of airflow (Graham et al., 2019). The results and interpretation contribute to lung disease diagnosis, the monitoring of lung health, and enable the impact of therapeutic interventions to be quantified (Graham et al., 2019; Swanney et al., 2017). To promote standardised and high-quality spirometry, technical standards for conducting spirometry tests and interpreting the results are jointly authored by the European Respiratory Society (ERS) and the American Thoracic Society (ATS) (Graham et al., 2019). These standards have been adopted by Australia's peak bodies, the Thoracic Society of Australia and New Zealand (TSANZ) and the Australian and New Zealand Society for Respiratory Science (ANZSRS).

In Australia, previous studies have assessed the quantity and quality of spirometry delivery and interpretation in healthcare (Abramson et al., 2010; Borg et al., 2012; Holton et al., 2011; Rochford et al., 2010; Zwar et al., 2011). Mostly performed in primary healthcare facilities, these studies report that the spirometry delivery and interpretation was influenced by time constraints, inadequate funding, and over-confidence in diagnostic skill without evidence of quality testing (Abramson et al., 2010; Zwar et al., 2011). Another key finding was that diagnostic inaccuracy was significantly and positively associated with the presence of comorbidities (Zwar et al., 2011). The only published Australian study to investigate the quality of spirometry in a tertiary care setting found that only 60% of spirometry tests met ATS/ERS criteria for acceptability and repeatability, which improved to >90% after regular review, feedback, and re-education (Borg et al., 2012). International technical standards for spirometry were updated in 2019 and since their release no Australian studies have investigated the quality of spirometry in tertiary care.

Healthcare Quality

Quality, particularly in healthcare, can mean different things to different people depending on who's asked, i.e. the patient, the clinician or the health service (Lippi et al., 2010). In general, quality is defined as the high degree or grade of excellence and in healthcare it is related to receiving the most suitable care, whilst reducing the risk of adverse effects and events which are not directly associated with the disease in question (Lippi et al., 2010). According to the Australian Commission on Safety and Quality in Health Care (2021b, p. 1) (ACSQHC) – “Quality is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge”. In 2021 the ACSQHC developed the second edition of The National Safety and Quality Health Service (NSQHS) Standards with the aim to protect the public from harm and improve the quality of health service provision (Australian Commission on Safety and Quality in Health Care, 2021b). The NSQHS Standards provide quality assurance mechanisms which test whether relevant systems are in place ensuring that expected standards for quality and safety are reached (Australian Commission on Safety and Quality in Health Care, 2021b). The eight NSQHS standards (Figure 1.3) oversee all testing within health services in Australia.



Figure 1.3: Eight National Safety and Quality Health Service Standards. Image sourced from Australian Commission on Safety and Quality in Health Care (2021b).

Diagnostic Testing

Diagnostic testing plays important roles in the screening for risk factors, the determination of the presence or absence of a disease/pathology, and the estimation of a patient's prognosis (Vetter et al., 2018). The clinical utility determines how useful a diagnostic test is in informing clinical decisions to optimise patient outcomes, and healthcare resources (Badrack & Bowling, 2023). The factors in which the clinical utility is reliant on are its sensitivity and specificity and the positive and negative predictive values (Table 1), i.e. the validity of the tests capacity to differentiate whether a disease is present or not (Badrack & Bowling, 2023; Vetter et al., 2018). Additionally, the clinical utility of a diagnostic test can be affected by the cost, availability, and ease of use (Badrack & Bowling, 2023).

Table 1.1: 2x2 Diagnostic Test Accuracy Contingency Table.

		Disease	
		Positive	Negative
Test	Positive	True positive (TP)	False positive (FP)
	Negative	False negative (TN)	True negative (TN)

Diagnostic Quality

To maintain accurate and precise diagnostic testing, quality control and assurance are required which are governed by quality management procedures (Allen, 2013; Müller, 2010). These procedures oversee the pre-analytical, analytical and post-analytical phases of diagnostic testing (Müller, 2010). Quality Control encompasses the operational techniques and activities used to fulfil quality requirements (Cooper & Butterfield, 2009; National Pathology Accreditation Advisory Council, 2018). On the other hand, Quality Assurance focuses on providing the confidence that quality requirements will be fulfilled (Cooper & Butterfield, 2009; National Pathology Accreditation Advisory Council, 2018). Together, quality control and quality assurance are fundamental parts of ensuring the accuracy, reliability, and safety of diagnostic testing (National Pathology Accreditation Advisory Council, 2018).

Internationally recognised standards which outline the requirements for quality and competency are not a novel phenomenon. In medical laboratories, the International Organisation for Standardisation (ISO) provide frameworks (ISO 15189 Standard), which laboratories must adopt and be compliant with, that govern the validity and reliability of pathology testing services (International Organization for Standardization, 2022; National Association of Testing Authorities, 2023). The ISO 15189 standard includes both in laboratory testing as well as point of care testing (International Organization for Standardization, 2022; National Association of Testing Authorities, 2023). In Australia, the National Association of Testing Authorities (NATA) provides the assessment and accreditation of medical laboratories in partnership with the Royal College of Pathologists of Australasia (RCPA) (National Association of Testing Authorities, 2023). For accreditation, laboratories must be compliant with local standards (addresses practice of pathology in the Australian environment) as well as

the ISO 15189 standard, with ongoing competency processes required (National Association of Testing Authorities, 2023). This is essential for laboratories to obtain Medicare benefits (National Association of Testing Authorities, 2023).

Accreditation for Respiratory Function Laboratories has been governed by the Thoracic Society of Australia and New Zealand (TSANZ) since 1992 (The Thoracic Society of Australia and New Zealand, 2016). The aim of the process is to define uniform minimum professional standards and competence for respiratory function laboratories (The Thoracic Society of Australia and New Zealand, 2016). As of February 2025, the TSANZ/NATA Respiratory Function Laboratory Accreditation program will become effective (National Association of Testing Authorities, 2024). Essentially by partnering with NATA, the TSANZ standard has been reviewed and updated to be in line with the ISO 15189 standard raising it to be at an internationally recognised level (National Association of Testing Authorities, 2024). Thus, the new accreditation program will contribute to better treatments and health outcomes for patients with respiratory diseases (National Association of Testing Authorities, 2024).

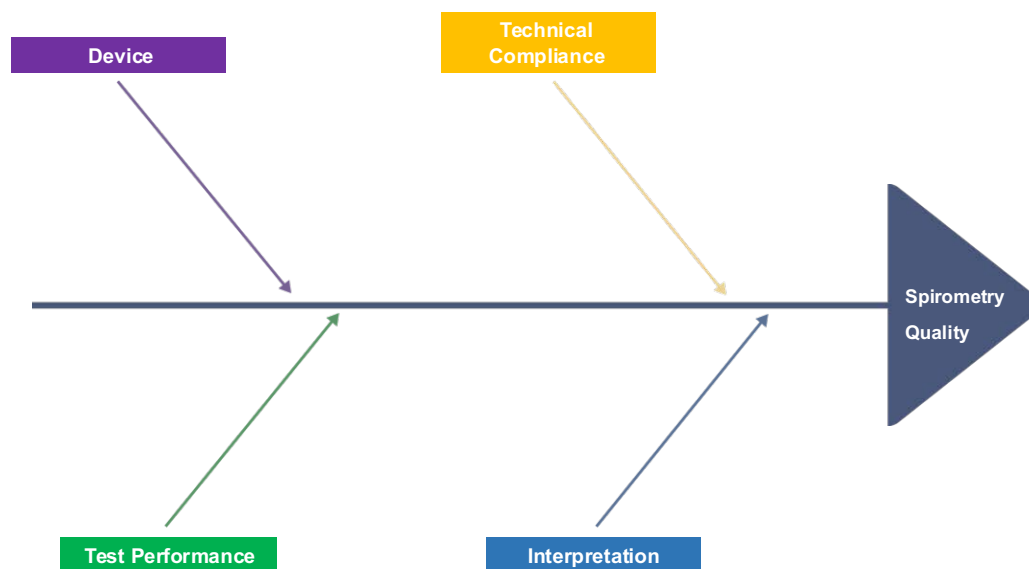


Figure 1.4: Simplified version of the developed Ishikawa (fishbone) model (Chapter 2) for the domains which form spirometry quality. Model based on the ATS/ERS 2019 spirometry standards.

Many factors can influence the quality of spirometry, and thus it's clinical utility. A root cause analysis (Chapter 2) was conducted to broadly grouped these factors into 4 domains, which can be visualised using the developed Ishikawa "fishbone" model based on information contained with the ATS/ERS 2019 spirometry standards (Figure

1.4). The factors included are: the spirometer's accuracy and precision (device), the technical compliance (acceptability and repeatability) and performance of the test, and the interpretation of the results, all of which are influenced by the knowledge (K), skills (S), and confidence (C) of the tester (operating the equipment, instructing the patient, assessing compliance to standards) and the physician (interpreting the results) (Stanojevic et al., 2022; Swanney et al., 2017). As mentioned above, in the respiratory laboratory spirometry testing is regulated through accreditation programs for quality and competency. However, outside the laboratory and in point of care spirometry testing this is not the case, except for in the resource sector. The ANZSRS have recommended competence assessment and certification for those who conduct spirometry outside the respiratory laboratory (Swanney et al., 2017). However, unlike the mandatory competence assessment and certification requirements in the United Kingdom and other developed healthcare systems, the pathway is voluntary in Australia and as a result compliance and engagement is low (Schneider et al., 2021; Swanney et al., 2017). The ANZSRS aim to provide effective spirometry training resulting in participants gaining the required knowledge of spirometry theory and practical skills and thus achieving competence (Schneider et al., 2021; Swanney et al., 2017).

The currency of training and the ability of staff to demonstrate competency in the point of care setting is unclear. The diversity in staff training combined with differences in techniques for assessing acceptability and repeatability and interpreting results are likely to impact spirometry quality, with possible downstream impacts determining the cause of breathlessness.

Research Aims & Thesis Outline

One in two patients with chronic respiratory disease (CRD) have co-existing cardiovascular disease (CVD). Breathlessness is a mutual symptom of both, and this overlap often results in coexisting CRD remaining undetected. Detecting early changes in lung function is essential for enabling treatment effectiveness. Spirometry measures lung function and high-test quality maximises its diagnostic utility. Despite the high prevalence of CRDs and CVD, and their frequent coexistence, the use of spirometry in cardiac inpatients remains unclear. This thesis aimed to investigate the use and quality of point of care spirometry testing provided to patients admitted with

breathlessness within the Cardiac Centre (Cardiac Ward and Coronary Care Unit) at Townsville University Hospital. To achieve this aim, the thesis chapters are structured as follows:

- Chapter 2 systematically examines broadly the quality of spirometry testing (defined as tests meeting international standards for acceptability and repeatability criteria) in established primary literature from 2005 to determine the factors which predict low quality. This chapter also resulted in the development of standardised reporting guidelines for spirometry and a Risk of Bias Quality Assessment tool for spirometry testing.
- The purposed of Chapter 3 was to determine and examine retrospectively the use and quality of spirometry in at specifically high-risk population of breathless patients from December 2022 to May 2023.
- The main findings from Chapters 2 and 3 are discussed in the General Discussion (Chapter 4), highlighting the importance of spirometry in the cardiac inpatient cohort. The limitations of the presented work are also acknowledged and directions for further research are included.

CHAPTER 2

**The Acceptability and Repeatability of Spirometry Testing: A
Systematic Review & Meta-Analysis**

INTRODUCTION

Chronic respiratory diseases (CRDs) decrease lung function by causing structural changes to the airways and other structures of the lungs (Australian Institute of Health and Welfare, 2020c; World Health Organization, 2021b; Yang et al., 2023). Chronic respiratory diseases are considered preventable, and although symptoms can be controlled, they are not curable (Australian Institute of Health and Welfare, 2020c; World Health Organization, 2021b). In 2019, the global prevalence of CRDs reached 454.6 million individuals, increasing by 39.8% from 1990 (Collaborators, 2023). The most common types of CRDs are Chronic Obstructive Pulmonary Disease (COPD) and Asthma which account for 3.9% and 3.6% of the total global disease prevalence respectively (Collaborators, 2023; GBD Chronic Respiratory Disease Collaborators, 2020).

Spirometry plays a crucial role in the diagnosis and management of CRDs and is recognised as the primary and most commonly employed method for assessing lung function (Graham et al., 2019; Yang et al., 2023). Spirometry measures ventilatory efficiency by quantifying both the volume and speed of airflow at maximal effort (Graham et al., 2019). Airflow is then classified into one of four ventilatory patterns (Normal, Obstructive, Restrictive (suggestive), and Mixed (suggestive)) and one of three severity ratings (Mild, Moderate, and Severe) for disease (Stanojevic et al., 2022). The accuracy and precision of both the measurements made and their interpretation impact clinical decision making with respect to diagnosis and treatment (Graham et al., 2019; Yang et al., 2023). It is therefore imperative that spirometry quality be defined, monitored, and assessed.

Quality control and quality assurance are not novel ideas in spirometry testing, particularly in respiratory laboratories. Though, despite being used in the measurement of lung function for over 178-years, the first standardised guideline for conducting spirometry testing was only produced in 1979 by the American Thoracic Society (ATS) (Kouri et al., 2021; Renzetti Jr, 1979). Prior to this, the lack of standardised methodology resulted in extensive measurement and equipment variability and quality (Kouri et al., 2021). Several guidelines have been published since 1979, including those by the European Respiratory Society (ERS), however it wasn't until 2005 that a joint ATS/ERS spirometry standardisation statement was

produced and then rapidly adopted by national peak respiratory science and medical bodies worldwide (Kouri et al., 2021; Miller et al., 2005). This technical guideline was updated in 2019 to its current form (Graham et al., 2019).

The ATS/ERS standards describe the many factors that influence the quality of spirometry and its clinical utility (Graham et al., 2019). These factors and their relationships can be broadly grouped into four domains (Device, Test Performance, Technical Compliance, and Interpretation) which can be visualised using an Ishikawa “fishbone” diagram (Figure 2.1). The “Device” domain encompasses factors related to the spirometer’s accuracy and precision including calibration and verification, device configuration, software capability, electronic database, and the hardware version. Factors related to the delivery of spirometry by the tester include administration of the test, clarity of instructions provided, ability to motivate, corrective subject/machine measures, as well as the test subject’s compliance make up the “Test Performance” domain. The “Technical Compliance” domain consists of adherence to contemporary testing standards including the interpretation of errors, correct selection of reference equations, acceptability, and repeatability. The interpretation of the results, including classification of the airflow pattern and severity rating, form the “Interpretation” domain. Each of these spirometry quality domains is influenced by the knowledge, skills, and confidence of both the tester conducting the procedure and the physician interpreting the results and are interdependent (Swanney et al., 2017). Consequently, the multifaced and interrelated nature of these domains present challenges in objectively quantifying the overall quality of spirometry tests.

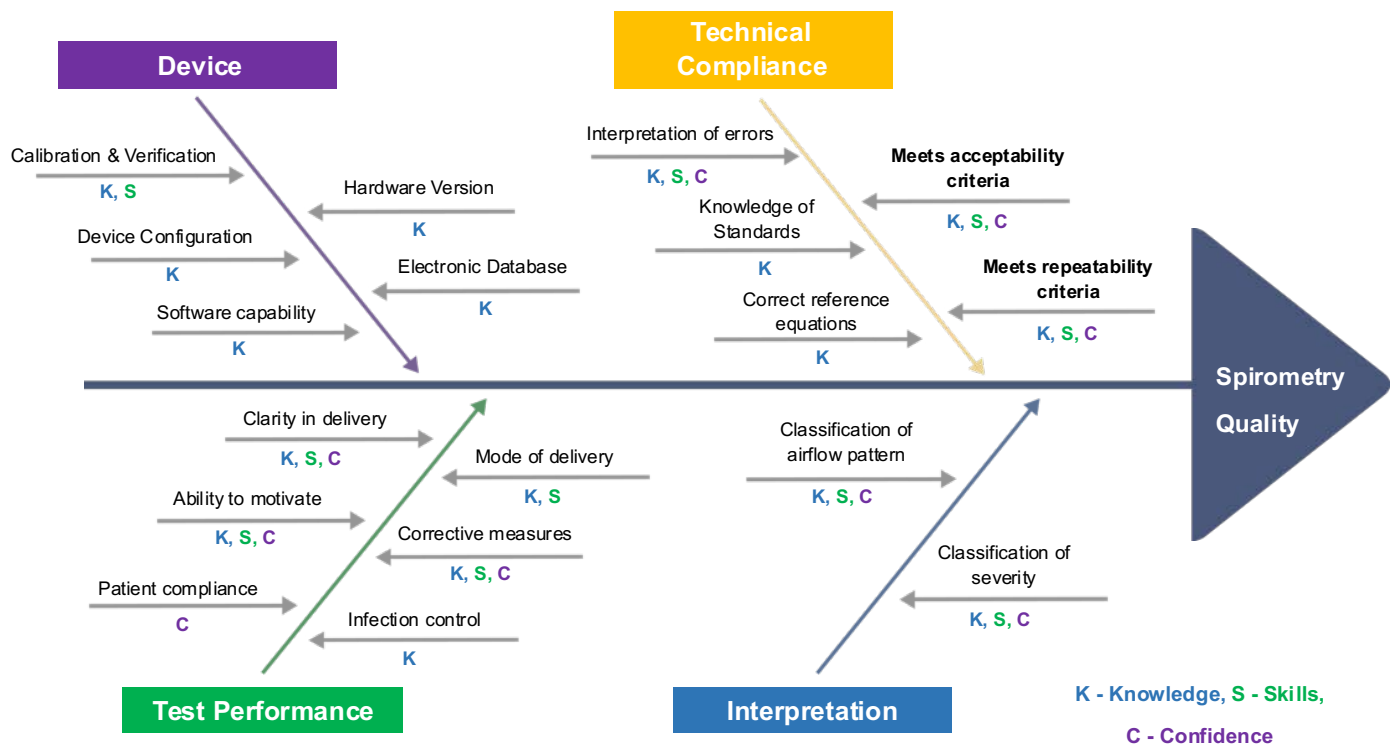


Figure 2.1: Developed Ishikawa (fishbone) diagram of the domains which form spirometry quality. Model based on information contained within the ATS/ERS 2019 spirometry standards.

The intention of the ATS/ERS task force was to enhance the accuracy, precision, and quality of spirometry measurements by developing the minimum criteria required for clinical testing (Graham et al., 2019). These criteria outline the objective processes used to define and obtain acceptable and repeatable measurements (Graham et al., 2019). Three measurements must be first deemed acceptable according to the pre-defined criteria prior to assessing their repeatability (defined as within 150 millilitres of each other for above 6 years of age) (Graham et al., 2019). Only after confirming that measurements are acceptable and repeatable can the interpretation of airflow patterns and severity ratings be made (Graham et al., 2019). Given that the criteria for acceptability and repeatability are clearly defined and that they represent the most standardised and readily assessable components of spirometry, they can be used as a surrogate for overall quality.

Although global and national peak respiratory health bodies have mandated the use of spirometry in the diagnosis of CRDs, it is only performed in 30 to 40% of patients despite being a widely available diagnostic tool (Graham et al., 2019; Han et al., 2007; Hegewald et al., 2016; Joo et al., 2008; Lee et al., 2006). Furthermore, many countries only recommend rather than require certification to perform spirometry testing, which

contributes to variable and/or poor-quality spirometry practices, which adversely impacts patient results and ultimately the diagnosis and treatment (Graham et al., 2019; Han et al., 2007; Hegewald et al., 2016; Joo et al., 2008; Lee et al., 2006; Yang et al., 2023). Therefore, the aims of this systematic review are to determine the overall percentage of acceptability and repeatability (AR) across a broad range of study designs and participant cohorts in the published literature and to determine which factors influence this component of spirometry quality. Gaining this insight will enhance our understanding of the influences and challenges associated with spirometry testing and support the development of evidence-based strategies aimed at improving quality.

METHODS

This systematic review and meta-analysis followed the Preferred Reporting Items for a Systematic Review and Meta-analysis (PRISMA) statement and registered with PROSPERO (ID: CRD42023414685).

Search Strategies

A comprehensive search of the Medline (Ovid), CINAHL, and Scopus databases was performed to identify eligible studies published after August 2005. The search strategy included a combination of both medical subject headings (MeSH) and keyword terms for spirometry and quality (Appendix A Table 4.1). Translated versions of non-English articles were used if available. A forward (citations) and backward (references) search of included studies was conducted using the Systematic Review Accelerator (SRA) tool spider-cite (Clark et al., 2020). Duplicates were identified and removed using an automated tool (SRA de-duplicator tool (Clark et al., 2020)) and results were verified for accuracy, followed by a manual assessment. Title, abstract, and full-text screening were independently performed by two authors (LB and SM). The final study selection was based on consensus, with arbitration by a third author if necessary (AJ).

Selection of Studies

Peer-reviewed primary original studies identified by the search strategy that assessed or reported the acceptability and repeatability of spirometry tests (%AR) were included. Studies published before the ATS/ERS 2005 standardisation of spirometry technical statement (Miller et al., 2005), case reports, editorial letters, comments, and reviews were excluded.

Data Extraction

Data was extracted by one author (LB) and confirmed by another (SM) using a predefined template (Appendix 1 Table 4.2). Discrepancies were revisited by both authors to guarantee database accuracy. Information extracted from each study included: study characteristics (first author, year, countries of study, aim, cohort setting, and spirometry methodology and technical standard used), participant demographics (age and health status) and %AR. The spirometry technical standard deemed appropriate was determined according to the data collection period and age group for each study. The overall percentage of acceptable and repeatable (%AR) spirometry tests was derived from information included in the study (e.g. FEV1 & FVC data) if not explicitly stated. A weighted median %AR was calculated based on the proportionate allocation of the participants across all the publications (the sum of each study's participants divided by all the participants across studies multiplied by each study's %AR).

Studies with participants aged <18 years were classified as paediatric (The Royal Australasian College of Physicians, 2022), >60 years as elderly (Thomas et al., 2019), and participants aged between 18-59 years were classified as adults. Studies were also classified according to the setting in which the study was conducted. Participant cohorts attending hospitals (inpatient, outpatient or clinical trial) at the time of the data collection were classified as "Hospital Based", those attending a general practice or community health centre were classified as "Primary care", those participating in population studies were classified as either "Population Based", or "School Based" studies, and those involved in "Other" setting types were classified as "Occupational" or "Home based" (self-administered) testing. The health status of the recruited study participants was grouped into: "NAD" (no appreciable disease), "disease" or "NAD and disease".

Selection on an appropriate Risk of Bias Tool

This systematic review contains a variety of observational study designs, including cross-sectional, case-control and cohort studies, which made selecting an appropriate risk of bias (ROB) tool challenging. Critical Appraisal Skills Programme (CASP) and Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) tools were found to be unsuitable (Critical Appraisal Skills Programme, 2023; Whiting et al., 2011). CASP

did not have a cross-sectional checklist available at the time of this review and QUADAS-2 was designed to use for only diagnostic accuracy studies.

ROB tools were methodologically screened to determine the which was the most suitable tool for the broad range of study designs, particularly cross-sectional studies. From the literature, the ROB tools were narrowed down to 5 potential tools – Joanna Briggs Institute (JBI), National Institute for Clinical Excellence (NICE), National Institutes of Health (NIH), Appraisal tool for cross sectional studies (AXIS) and Agency for Healthcare research and quality (AHRQ) (Agency for Healthcare Research and Quality, 2013; Downes et al., 2016; Joanna Briggs Institute, 2017; National Heart Lung and Blood Institute, 2013; National Institute for Clinical Excellence, 2012). Each tool's questions were included in an Excel spreadsheet (Appendix 1 Table 4.3) to allow for comparison. The different shades of colour indicate the matching of similar questions/themes across the tools. NICE was determined not to be suitable as it was unable to be adapted for use with cross-sectional studies. The AHRQ guideline on how to interpret the results was very vague, and thus this guideline was excluded.

Although the JBI tools were not as specific in relation to how thorough the questions were compared with other tools, the questions did match similar themes/questions of the other tools. JBI has guidelines for all of the other types of research study designs used in this literature review, with most of the questions being the same across the types of research. It was therefore determined that the JBI tools be used for this review.

Quality Assessment

The design of each study was classified based primarily on spirometry testing and risk of bias (ROB) was assessed using the appropriate Joanna Briggs Institute (JBI) Critical Appraisal checklist for each study design (Cross-Sectional, Cohort, Case-control). Two authors (LB and SM) independently piloted the questions to establish between-reviewer agreement before independently assessing studies. Agreement was reached by consensus, with any disagreement resolved by a third author (AJ). ROB questions were either answered "yes (low)", "unclear", "no (high)" or "not applicable". Summary tables and plots were generated using the Risk-of-bias VISualization (robvis) tool (McGuinness & Higgins, 2021). To facilitate comparisons

across study designs, similar ROB questions were grouped into three domains: selection of participants, data collection, analysis.

Statistical Analysis

Study characteristics were analysed using descriptive and inferential statistics. Normality was assessed using a Kolmogorov-Smirnov test and visual inspection of P-P and Q-Q plots. Data are represented as the median (IQR) for non-parametric tests. Correlations between factors were determined using two-tailed Kendall's tau-b (τ_b) and Spearman's rho (ρ) correlation coefficients and reported with 95% confident intervals. Kruskal Wallis tests were used to assess whether the participant distribution differed between factor groups (age group, study setting, health status, continent, spirometer type, index test). A multinomial logistic regression was used to determine the influence of risk of bias domains on %AR, cohort settings, age groups and health status.

Factors that significantly influenced %AR were determined using a generalised linear model (GLM, gamma distribution with log link function). To facilitate analysis, the percentage of tests not meeting AR ($100 - \%AR$) was used as the dependent variable (P-P plot Appendix 1 Figure 4.1). Final model selection was based on the fit of the data to the GLM model using a backward stepwise regression with Akaike information criterion (AIC). The reference group for comparisons within each factor was Population studies for cohort setting; Adult & Elderly for age group; and NAD for health status. Odds ratios were derived from beta coefficients for interpretation. Collinearity was assessed using Kendall's Tau correlation and despite weak but significant collinearity between age group and health status (Kendall's Tau tests, -0.100 (CI $-0.170, -0.029$), $p=.038$), both factors were retained in the model. Low sample sizes within some factor groups prevented the assessment of interactions between factors. SPSS Statistics v30 (IBM, Denmark) software was used for all analyses and statistical significance was considered when p-values were $<.05$ for all tests.

RESULTS

Study Selection

A total of 9,030 articles were identified following the removal of duplicates. After screening of titles and abstracts, 507 articles were selected for full-text review, of

which 250 were included in the review. An additional 87 articles were added from forward and backward searching of the included articles (Figure 2.2). Characteristics of the 337 included studies are summarised in Appendix 1 Table 4.3. Of the 9225 peer-reviewed primary original studies that were screened (including forward and backward searched studies), 96% either did not report the % of tests that met AR criteria, or the data required to calculate to %AR.

Most studies (74.6%; 247/331) used or modified (1.8%, 6/331) an appropriate ATS/ERS standard for acceptability and repeatability. Either the data collection timeframe or the spirometry standard used was not reported in 19.9% (67/337) of studies, and 6 studies used a non-ATS/ERS standard. Flow-based spirometers were used in 92% of studies (266/337), with volume-based spirometers used 7% (21/337) of studies and a combination of both were used in 1% (4/337). Most studies were conducted in Europe (37%, 125/337), followed by North America (23%, 78/337) and Asia and Oceania (23%, 77/337). The remaining studies were either conducted in South America (10%, 33/337) or on an international scale (7%, 24/337).

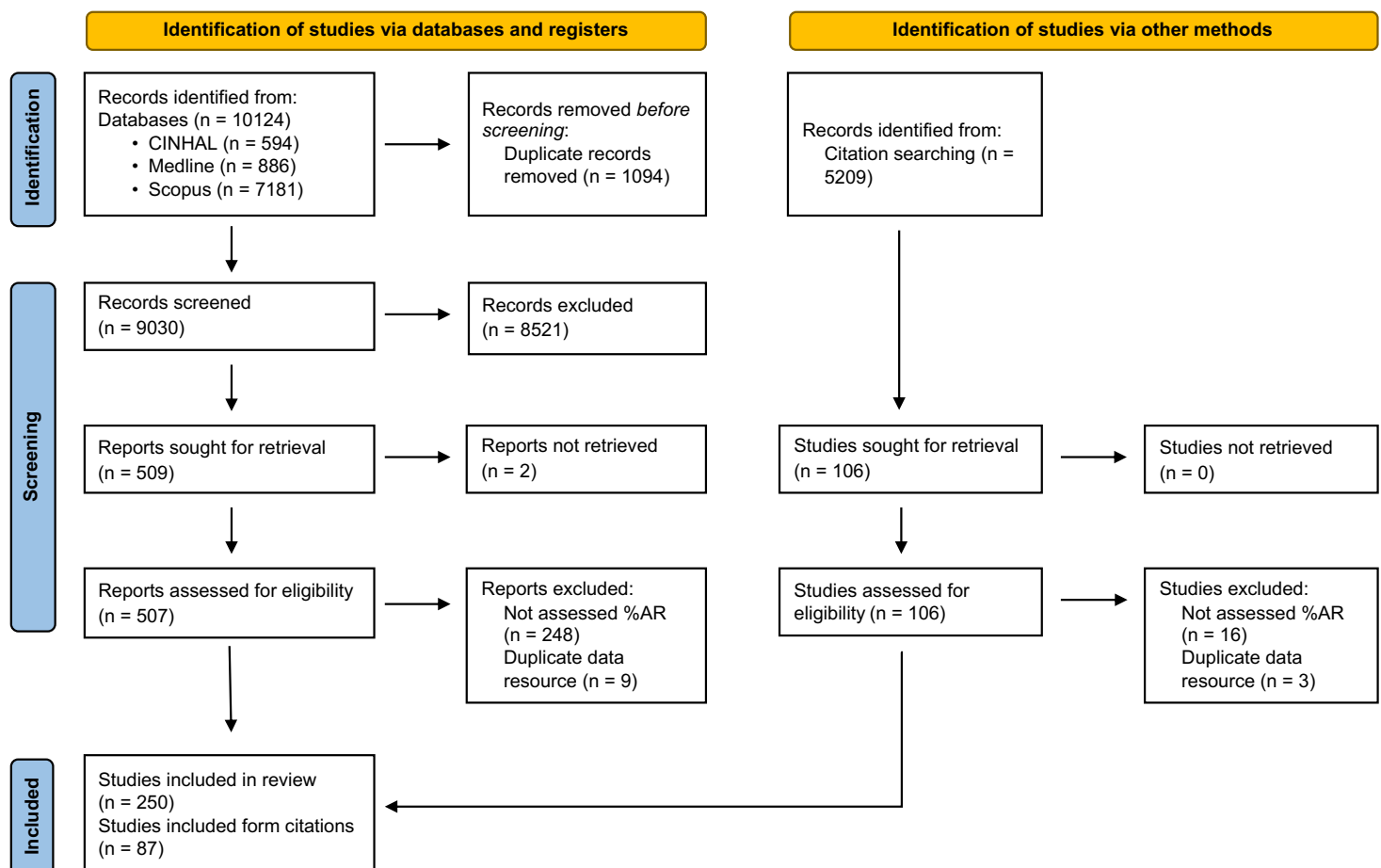


Figure 2.2: PRISMA diagram for the identification of included studies in this review.

Distribution of Patients

A total of 1,141,726 participants were recruited across the 337 studies, with study sample size ranging from 13 to 250,533, with a median of 489 (IQR 1359) participants per study. There were significant differences in both the median and distribution of participant numbers per study across the cohort settings ($p < .001$ for both), age groups ($p < .001$ for both) and health status ($p < .001$, $p = .006$ respectively), but not across continents ($p = .093$, $p = .212$). Most participants were included in studies that were population-based (59.9%); combined adults and the elderly (82.5%), and combined participants with both NAD and disease health statuses (75.4%).

Study Characteristics

Almost half (46.6%; 157/337) of the 337 included studies recruited a combination of adult and elderly participants. Paediatric participants were recruited in 28.5% (96/337) of included studies, and elderly or adult participants were recruited in 6.8% (23/337) and 7.7% (26/337) of studies respectively. The remaining 10.4% (35/337) of studies recruited participants from all age groups (Table 2.1).

Most studies (80.1%; 270/337) were conducted in either primary care (30.6%; 103/337), hospital (29.1%; 98/337), or were population-based studies (20.5%; 69/337), with fewer conducted in school (9.2%; 31/337) or occupational/home care settings (termed “other”, 10.7%; 36/337). In 59 studies (17.5% 59/337) spirometry was collected from participants with no appreciable disease. Almost half of the studies (49.3%, 166/337) included a control (NAD) and disease group. The majority (80.4%; 90/112 studies) of the disease group consisted of participants with chronic respiratory diseases including Chronic Obstructive Pulmonary Disease (COPD) and Asthma. Ten studies focused on neurological conditions (Cognitive impairment, Ataxia Telangiectasis, & Amyotrophic Lateral Sclerosis), one study on Down’s Syndrome and another two on Duchenne Muscular Dystrophy.

Table 2.1: Summary Table of Participants.

	Studies n=377	Participants n=1141726	Median %AR 81.40%	IQR 25.69%
Age Group				
Paediatrics	96	66513	78.00	25.72
2-18 yrs.	30	33375	73.70	34.46
2-6 yrs.	29	9592	78.00	18.80
6-18 yrs.	27	23546	81.80	29.60
Adult	26	43218	84.95	38.68
Elderly	23	22827	67.30	41.32
All Ages	35	66598	75.80	32.54
Adult & Elderly	157	942060	85.21	24.25
Cohort Setting				
Primary Care	103	154933	77.99	31.95
Other (Occupational & Home)	36	187490	80.85	26.53
School Based	31	33562	82.00	19.02
Hospital	98	82030	80.73	25.27
Population Based	69	683711	85.77	19.60
Health Status				
Disease	112	174282	75.45	31.05
NAD & Disease	166	860419	83.00	24.33
NAD	59	107025	84.00	26.00
Standard Used				
ATS 1994	60	96886	86.68	29.37
Other	37	89867	84.09	14.80
ATS/ERS 2007	33	14565	77.40	19.11
ATS/ERS 2005	180	931456	77.52	26.98
ATS/ERS 2019	27	8952	83.00	22.21

AR: Acceptable and Repeatable; ATS: American Thoracic Society; ERS: European Respiratory Society; NAD: No Appreciable Disease; n: number

Acceptable and Repeatable Spirometry

The overall %AR for each publication was highly variable (ranging from 0-99.7%) and nonparametrically distributed ($p<.001$). Median overall %AR was 81.3% (IQR 25.7) (Figure 2.3) and 75.1% (IQR 19.3) when studies were weighted by participant number.

Studies with adult participants, including the adults & elderly group had a higher overall median %AR compared to those with just paediatrics and elderly participants (Table 2.1). The paediatric participant group was stratified by age into three groups – 2-18yrs, 2-6yrs and 6-18yrs. There was an increase in the median overall %AR from 73.7% (IQR 34.5; CI 64.5-81.7) in 2-18yrs to 78% (IQR 18.8; CI 69.5-83.7) in 2-6yrs to 81.8% (IQR 29.6; CI 77.0-88.6) in 6-18yrs.

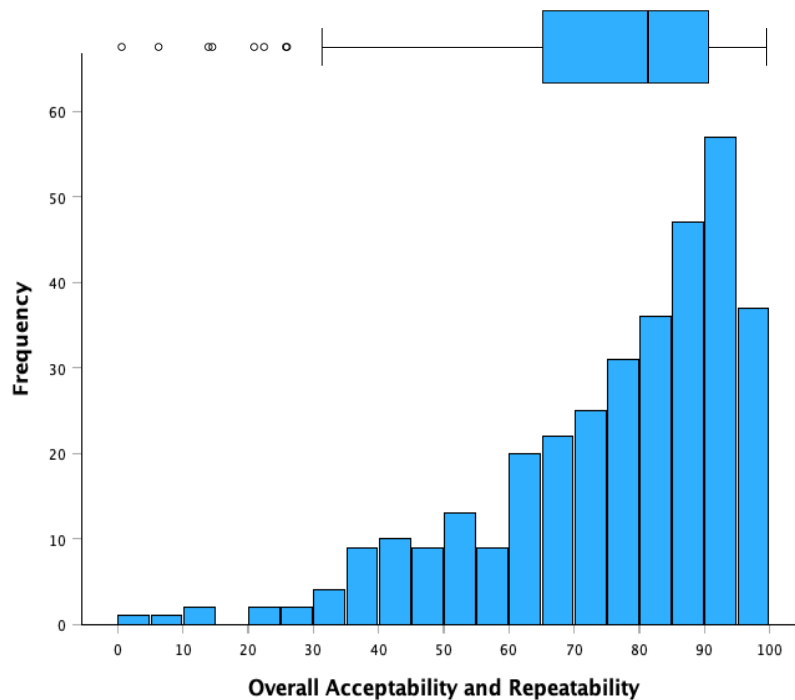


Figure 2.3: Boxplot and bar graph for the distribution of overall percentage of acceptable and repeatable spirometry tests.

Factors Influencing Quality Spirometry

All 337 studies were included in the GLM predicting overall %AR. The best fitting model included the predictors: age group ($p=.003$), cohort setting ($p=.033$), and health status ($p=.299$), with the overall fit of the model being significant ($p<.001$). The type of spirometer ($p=.971$), spirometry standard ($p=.095$) and continent of data collection ($p=.077$) did not significantly influence %AR and were subsequently excluded from the model. The only group of spirometry standards which decreased %AR was the group defined as 'other' ($p=.044$). This group included studies that either used a modified, outdated or not internationally recognised standards.

Studies conducted with paediatric (OR 1.4, $p=.007$), elderly (OR 1.7, $p=.004$), or participants from all ages (OR 1.6, $p=.003$), had a significantly increased probability of reporting lower overall %AR compared to studies conducted with a combination of adult and elderly participants. A significantly increased (OR 1.5, $p=.002$) probability of reporting a lower overall %AR was measured in studies conducted in primary care relative to population-based settings, but this effect was not significant for any other study setting. Overall AR% was not significantly different between health status groups (Figure 2.4).

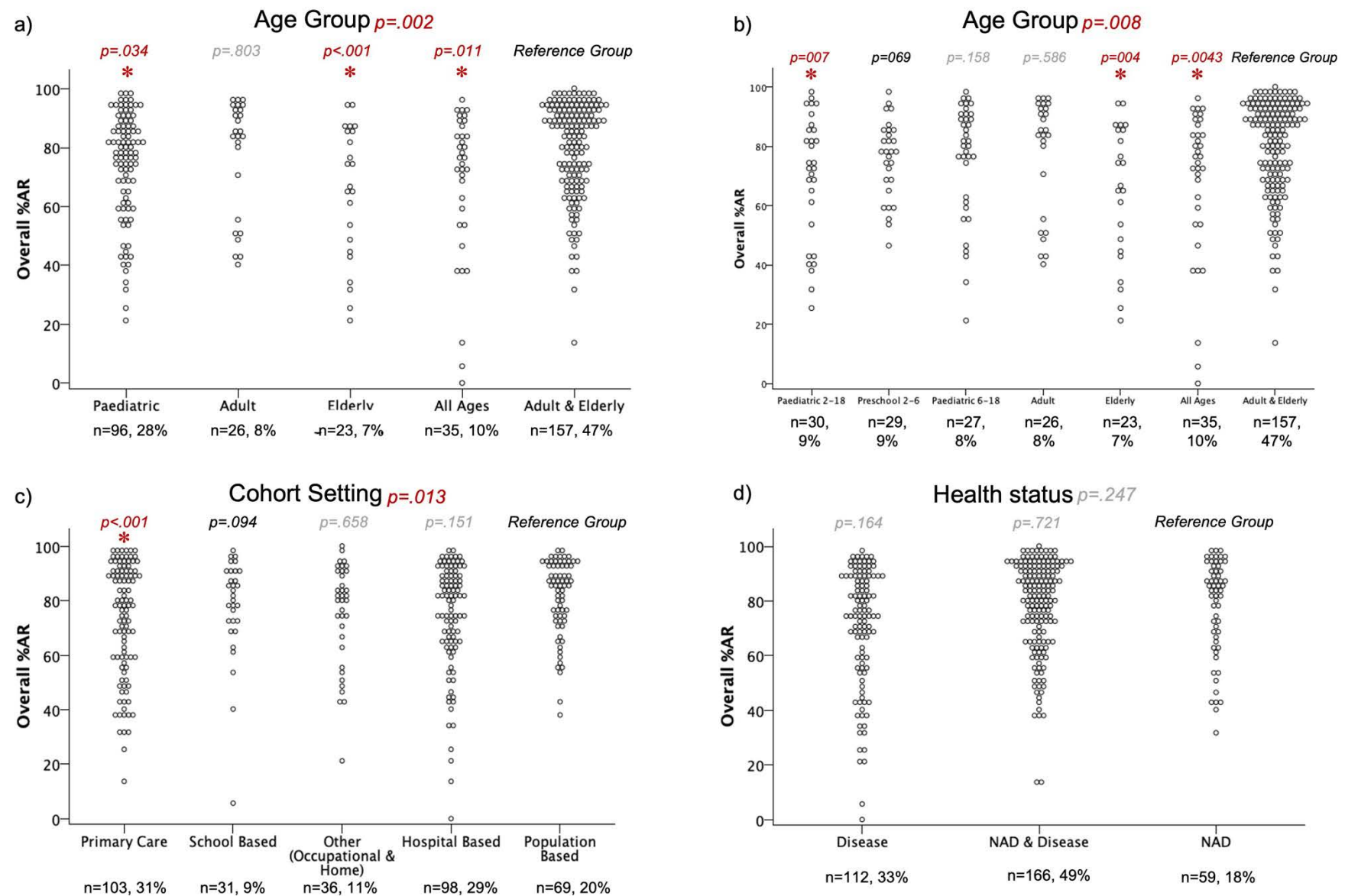


Figure 2.4: Predictors of overall quality of acceptable and repeatable spirometry. a) %AR grouped by age of participants; b) %AR grouped by age of participants with paediatric participants broken down into different classes; c) %AR grouped by cohort setting of study; d) %AR grouped by health status of participants.

Risk of Bias Assessment

The risk of bias quality assessments for each study design are summarised in Figure 2.5. Cross-sectional study designs were most commonly used (84%, 283/337) with 199 analytical, 64 prevalence, and 20 diagnostic accuracy studies. Cased-series (n=33), cohort (n=19), case-control (n=2) studies were less common within the included studies. Overall, the risk of bias was low across the majority of questions within each study design. Additionally, there was no significant impact of any of the risk of bias domains on overall %AR (selection of participants, $p=.078$); data collection, $p=.454$; analysis, $p=.483$). ROB domains had a significant influence on age groups ($p<.001$), particularly questions related to selection of participants ($p<.001$). A high risk of bias occurred most often in studies which included participants of all ages (17%, 6/35) for the selection of participant domain. No significant influence of ROB domains was found in comparison to cohort settings ($p=.115$) or health status ($p=.245$).



Figure 2.5: Risk of Bias Quality Assessment Summaries. a) Cross-sectional Analytical n=199; b) Cross-sectional Prevalence n=64; c) Diagnostic Accuracy n=20; d) Case-control n=2; e) Cohort n=19; Case Series n=33.

DISCUSSION

To the best of my knowledge, this is the first systematic review to evaluate the acceptability and repeatability (AR) of spirometry testing as one component of quality across a broad range of populations, health statuses, ages, and study settings. %AR was vastly underreported in published literature with only 4% of screened original peer-reviewed studies including this measure of spirometry quality. The overall quality of spirometry, as measured by %AR, was 75.1% (weighted median), equating to one in four tests not meeting the international AR standards for spirometry testing. Currently there is no minimum tolerance level set for the percentage of test that should satisfy AR criteria. Previous literature and expert opinions state that achieving AR criteria in 90% of tests is an attainable goal by trained testers regardless of the setting or age group (Giner et al., 2014; Haynes, 2012; Ruppel & Enright, 2012). Lower %AR was associated paediatric and elderly participants, and with studies conducted in the primary care setting. However, participant health status, the type of spirometer and spirometry standard used were not significant predictors of %AR. The overall risk of bias in included studies was low and was not a significant predictor of %AR, further strengthening our results.

Low quality spirometry can change the diagnosis, treatment, and clinical outcomes for patients (Swanney et al., 2017). Spirometry is required as part of the clinical assessment for the diagnostic confirmation of COPD, defined by the presence of fixed airway obstruction (Johns et al., 2014; Yang et al., 2023). Previous literature demonstrates that only 30-40% of patients diagnosed with COPD will have spirometry performed as part of the diagnostic pathway (Graham et al., 2019; Han et al., 2007; Hegewald et al., 2016; Joo et al., 2008; Lee et al., 2006; Yang et al., 2023). In the absence of spirometry, diagnoses are frequently based on symptoms and risk factors alone (Hangaard et al., 2017; Sator et al., 2019). Putting our findings into context, in a random sample of 100 people with COPD, confirmation of the diagnosis using spirometry will have occurred in 30-40 patients, and that spirometry testing will have met acceptability and repeatability standards in only 23-30 patients (75.1%). Absent and/or poor-quality spirometry can have variable impacts on the patient ranging from delayed provision of care (allowing progression of lung damage and increasing morbidity) to the provision of unnecessary care (imposing the cost and potential side effects of unnecessary prescribed medication) (Sator et al., 2019). Given that COPD

ranks as the third leading cause of mortality worldwide, and that its prevalence is increasing (World Health Organization, 2021b), it is vital that a greater number of patients undergo spirometry testing that is of a high standard and quality.

Overall %AR was not affected by the health status of the participants within the studies. When a participant is medically stable and willing and capable of following instructions with coaching and support from the tester conducting spirometry, they are more likely to produce acceptable and repeatable tests (Graham et al., 2019). Over the years as technology has changed and improved, spirometers have transitioned from being volume-based devices to the now used flow-based devices. Our study shows that with this transition, the overall %AR was not affected. A similar result was also seen with the implementation and improvements to international spirometry standards over the years, where overall %AR was not affected. Rather than the disease itself, spirometer used, or standard used, causing quality issues, our study shows that the quality of spirometry is influenced by the age of the participant and the type of cohort setting.

Lower spirometry quality was found in both paediatric and elderly participant groups. Elderly and paediatric subjects often find the test hard to undertake, however with the correct coaching and instruction, spirometry can be performed from approx. 2.5 years of age (Allen et al., 2008; Allen & Baxter, 2009; Graham et al., 2019). As individuals age, the prevalence and severity of CRDs, such as COPD, tends to increase (Yang et al., 2023). This trend underscores the critical importance of high-quality spirometry, which is used not only in the diagnosis and ongoing assessment of CRDs but also for evaluating the effectiveness of therapeutic measures (Graham et al., 2019; Yang et al., 2023). However, with the progression of CRDs, symptoms such as chronic cough, dyspnoea, and fatigue can complicate the ability of older adults to perform spirometry tests that are both acceptable and repeatable (Allen & Baxter, 2009; Allen et al., 2010; Taffet et al., 2014). Six studies exclusively using elderly participants highlighted the challenges posed by age-related cognitive impairment on spirometry performance (Allen & Baxter, 2009; Allen et al., 2010; Allen & Yeung, 2006; Frohnhofer et al., 2011; Queiroz et al., 2018; Turkeshi et al., 2015). This demographic often faces greater challenges in performing the breathing manoeuvres and achieving reliable spirometry results due to cumulative effects of requiring repeated attempts and the presence of

concurrent comorbidities, which can heighten feelings of distress and anxiety related to their health condition (Allen & Baxter, 2009).

Most studies with paediatric participants included preschool-aged children, although 29 studies focused solely on preschool age participants (2-6yrs). This age group often find it challenging to perform acceptable and repeatable spirometry as while they can blow “hard” and “long” they are often unable to do both simultaneously (Beydon et al., 2007). The ATS/ERS published tailored spirometry standards in 2007 which modified the end of test criteria to more accurately represent the physiological development of the respiratory system to better suit preschool aged children (Beydon et al., 2007). Reporting of 0.5 second and 0.75 second timeframes for which forced expiration must be maintained were introduced, since many children in this age group are unable to sustain a forced expiration for at least one second (Beydon et al., 2007). Test repeatability criteria was also altered to account for smaller absolute lung volumes (Beydon et al., 2007). Additionally, children aged two-to-six-years are often characterised by shorter attention spans and a propensity to become easily distracted (Beydon et al., 2007). This forces a more engaged and encouraging approach from the tester throughout the process (Beydon et al., 2007). Studies have shown that as children age, their ability to comprehend and perform spirometry to the required standard improves (Kinghorn et al., 2020; Seo et al., 2009). This trend is evident in our results, which showed an increase in the median %AR when the paediatric group was stratified by age.

Studies completed in primary care were found to have lower quality spirometry relative to population-based cohorts. Many of the population-based studies focused on the development of normal predicted reference equations or were components of larger studies like the Burden of Obstructive Lung Disease Study (Arigliani et al., 2017; Buist et al., 2007; Cooksley et al., 2015; Smolej Narancic et al., 2009; Tan et al., 2013). The testers in the population-based studies were often clinical scientists or pulmonary nurses and physicians who perform spirometry as part of their usual roles. These testers had experience in delivering spirometry and underwent specific specialised training and regular competency assessment to perform spirometry as part of the studies (Blake et al., 2020; Cooksley et al., 2015; Enright et al., 2011). In comparison, in primary care cohorts, staff performing spirometry were less likely to have received

formal training and competency checks (Carr et al., 2011; Hegewald et al., 2016). The frequency of testing was also likely to be higher in the population-based cohorts than in primary care where testing is not routinely performed due to inadequate funding and time limitations, and instead, diagnosis of disease is based on symptoms and risk factors alone (Zwar et al., 2011). As mentioned above, the lack of and/or poor quality of spirometry testing can result in missed, under and overdiagnosis of CRDs impacting care and treatment (Hangaard et al., 2017; Sator et al., 2019).

Ninety-six percent of peer-reviewed primary original studies screened as part of this review did not report sufficient information on tests meeting/not meeting AR criteria. Most studies included a generic phrase similar to 'testing was done in accordance with ATS/ERS standards' while omitting the number of participants that did not meet criteria. Our review represents only a small fraction of all studies using spirometry testing and we therefore recommend the %AR be included in all articles using spirometry, including the percentage of tests not meeting AR criteria. Standardising the reporting of spirometry in published literature will enable readers to determine the quality and accuracy of testing in each study to provide confidence in the reported results.

Standards for spirometry have been developed, updated, and adapted over the last 45 years (Kouri et al., 2021). Many different data collection timeframes were used across the included studies, resulting in different spirometry standards being used for AR criteria. The use of different standards did not significantly influence the quality of AR. However, tests which were classified as not meeting AR criteria at the time of data collection may now meet updated criteria and would therefore increase the overall %AR. For example, tests in which expiratory time was less than 6-seconds despite reaching a plateau were classified as not acceptable in earlier versions of the spirometry standards but would be acceptable in the latest update. Unfortunately, at the time of this review, there have been a limited number of studies published which used the latest ATS/ERS spirometry standards to assess AR and many studies published that used a previous standard are unlikely to have been reanalysed.

An overall low risk of bias was found across each category of study design and groups of similar risk of bias questions did not influence overall %AR. However, due to the large variety of study designs and thus risk of bias assessment questions, similar

questions needed to be grouped for analysis, potentially hiding significant results. Risk of bias questions also lack specificity in relation to spirometry and its testing methodology, thus we recommend the introduction of specifically designed risk of bias critical appraisal for spirometry. A drafted critical appraisal assessment can be found in Appendix 1.

Chronic respiratory diseases are amongst the most common non-communicable disease globally and have increased in prevalence by 40% since 1990 (Collaborators, 2023). Lung function is used as a significant predictor of all-cause mortality and morbidity (Cestelli et al., 2023; Collaro, Chang, Marchant, Chatfield, Dent, et al., 2021; Duong et al., 2019). Given the role of spirometry in the objective evaluation of lung function and its contribution to the diagnosis and management of CRDs, ensuring test quality is crucial. Low percentage of acceptable and repeatable tests was associated with participants who were elderly or paediatric and in testing performed in primary care. These factors are an issue given that primary care is likely the first point of patient contact when seeking healthcare for respiratory related symptoms, that patients aged over 60 are at an increased risk of progressively worsening CRDs, and that in children early diagnosis and treatment can have a profound impact to health-related outcomes. Devising and implementing effective training programs and the introduction of regular competency assessments is essential to ensure high quality spirometry for groups at risk.

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CHAPTER 3

**The Existing Quality and Use of Spirometry Testing at Townsville
University Hospital's Cardiac Centre: A Retrospective Cross-
Sectional Analytical Study**

INTRODUCTION

Breathlessness (dyspnoea) is defined as an experience of breathing discomfort consisting of various uncomfortable respiratory sensations which can be characterised as 'air hunger', 'work' and 'tightness' (Fukushi et al., 2021; Parshall et al., 2012). The symptom of breathlessness is subjective and often varies in the intensities of discomfort (Bausewein et al., 2007; Fukushi et al., 2021; Parshall et al., 2012). Breathlessness is a multi-dimensional symptom (physical, sensory, and emotional) with varying durations. The International Classification of Diseases Revision 11 has recently introduced timeframes for the duration of breathlessness – acute (hours to 3 weeks), subacute (3-8 weeks) and chronic (8+ weeks) (World Health Organization, 2024). In healthy individuals' breathlessness only occurs on exertion and at high altitude. However, breathlessness with little to no exertion is the most common reason for patients to seek acute medical care (e.g. emergency), and is strongly linked with adverse health outcomes (Bausewein et al., 2007; Gronseth et al., 2014; Johnson & Hutchinson, 2018; Parshall et al., 2012). Breathlessness is a prevalent symptom of respiratory and cardiovascular disease, and the cause is often multifactorial (Berliner et al., 2016; Ferry et al., 2019).

The coexistence of chronic respiratory diseases (CRDs) and cardiovascular disease (CVD) worldwide is inconstant, ranging between 20-70% depending on the type of CVD and population (Polman et al., 2024). In Australia the overlap of CRDs and CVD occurs in 26% of COPD patients and 15% of asthma patients (Australian Institute of Health and Welfare, 2020a, 2020b). On acute presentation to emergency departments, patients with breathlessness are more likely to be admitted compared to being discharged home (Ferry et al., 2019; Johnson et al., 2014; Johnson & Hutchinson, 2018). Patients with coexisting CVD and CRDs have both significantly longer hospital stays and increased mortality (2-fold compared to CVD alone) (Kavya et al., 2020). In tertiary care, patients with chronic breathlessness represent approximately 60% of patients seen by a Respiratory Physician and 15-50% seen by a Cardiologist (Berliner et al., 2016; Huang et al., 2018). The overlap in clinical presentation of co-existing (known or unknown) CRDs and CVD can make determining the cause of breathlessness difficult (Berliner et al., 2016; Johnson & Hutchinson, 2018).

The cause/s of breathlessness can be determined by using a combination of diagnostic investigations combined with a physical examination and patient history, performed in primary care (Berliner et al., 2016; Ferry et al., 2019; Huang et al., 2018). Blood panels, chest x-ray, electrocardiography (ECG), and spirometry are the primary diagnostic investigations recommended for evaluating breathlessness (Ferry et al., 2019). If the underlying cause of breathlessness is not clear or is multifactorial based on findings from these investigations, further testing (such as chest computed tomography (CT), complex lung function tests and echocardiography) may be required to triage patients to cardiac and/or respiratory physicians for further care (Ferry et al., 2019; Yang et al., 2023).

The most used cardiac diagnostic investigation is an electrocardiogram (ECG) which measures the electrical impulses of the heart and provides both structural and function information (Kligfield et al., 2007). For suspected cardiac issues an ECG is performed and analysed within ten-minutes of the first emergency clinical contact (Yiadom et al., 2017). No patient effort is required to obtain acceptable results (Yiadom et al., 2017). Thus, ECGs can be conducted whether the patient is conscious or not (Kligfield et al., 2007).

The most common objective assessment of lung function is spirometry which quantifies the volume and speed of airflow in and out of the lungs (Graham et al., 2019). Structural changes in the lungs can be assessed using images produced by chest x-rays and CT scans (Ferry et al., 2019). The structural changes may or may not cause functional changes (Ferry et al., 2019; Huang et al., 2018). In contrast to ECGs, the clinical utility of spirometry is influenced by patient compliance (Graham et al., 2019). Spirometry is highly reliant of both the tester instructing the test and patient performing the test (Graham et al., 2019). The ability of the tester to deliver correct and tailored instructions and to maintain patient engagement are essential (Graham et al., 2019; Holton et al., 2011). In addition, the patient's ability to perform the ideal test technique combined with using maximal effort throughout the test is required.

National and international peak respiratory bodies agree that spirometry is required for the diagnosis of CRDs, particularly in obstructive diseases such as COPD (Graham et al., 2019; Yang et al., 2023). However despite this requirement, spirometry is underutilised worldwide with only 30-40% of patients receiving a test (Graham et al.,

2019; Han et al., 2007; Hegewald et al., 2016; Joo et al., 2008; Lee et al., 2006; Yang et al., 2023). The underutilisation of spirometry testing results in CRDs being diagnosed based on symptoms and risk factors alone increasing the likelihood of missed, over or under diagnoses of CRDs (Hangaard et al., 2017; Sator et al., 2019). This can lead to delayed or unnecessary delivery of care (Sator et al., 2019).

The prevalence of CRDs and CRDs varies across Australia. In outer regional, rural and remote communities of Northern and Western Queensland the risk and presence of chronic diseases, as well as hospitalisation from these diseases is higher compared to Australia overall and to metropolitan areas of Queensland (Australian Institute of Health and Welfare, 2024c; Northern Queensland Primary Health Network, 2021). The Townsville Hospital and Health Service (THHS) has one of the most geographically dispersed catchments in Australia, with patients from as far north as Cape York Peninsula and the Torres Strait Islands, and west to Mount Isa and the Gulf of Carpentaria treated at the facility (Figure 3.1) (Edelman et al., 2020). Townsville University Hospital (TUH) is the only tertiary referral centre in North Queensland, supporting almost 700,000 people from some of Australia's most remote communities (Edelman et al., 2020). Large parts of THHS catchment are considered relatively disadvantaged, with the region having higher rates of chronic diseases, like chronic obstructive pulmonary disease, coronary artery disease and stroke compared to the rest Queensland and Australia (Edelman et al., 2020).

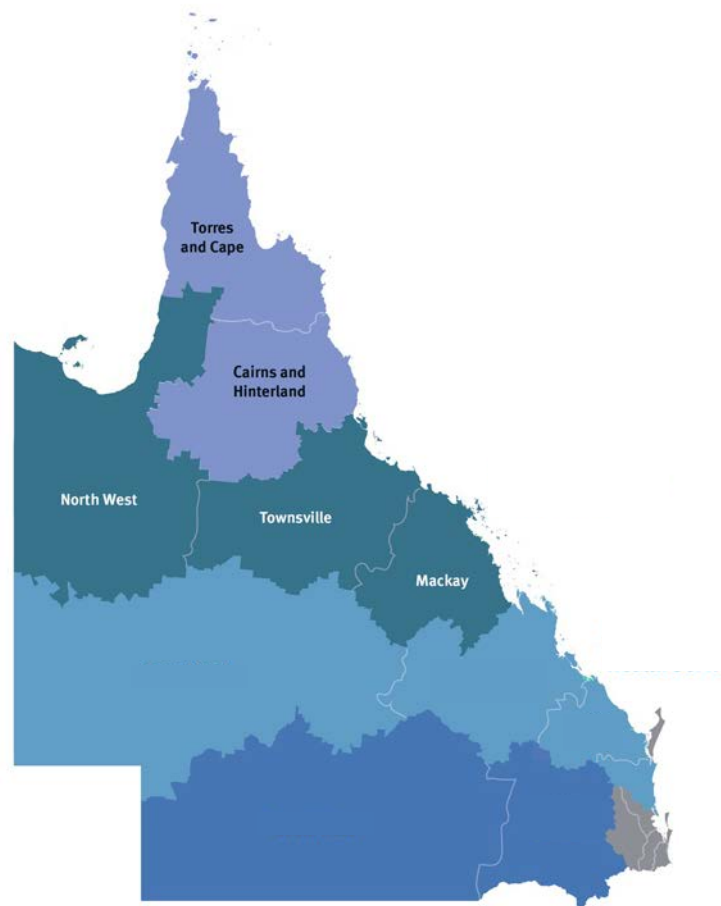


Figure 3.1: Map of Queensland Hospital and Health Services. The areas listed are part of the Townsville Hospital and Health Service referral catchment zone. Image sourced and adapted from Queensland Health (2024).

At TUH, the benchmark for optimal spirometry quality is the testing performed by the scientific staff of the Respiratory and Sleep Unit (RSU) laboratory. The majority of lung function testing undertaken by the RSU is in the outpatient setting, with only complex testing (spirometry with additional investigations) performed on inpatients through the unit. All scientists within the unit undergo specialised training and mandatory competency assessments to perform testing. Competence in testing is reassessed annually in the unit, and scientists are encouraged to sit the Australian and New Zealand Society for Respiratory Science (ANZSRS) Certified Respiratory Function Scientist (CRFS) examination once eligible and be accredited by the Australian Council for Clinical Physiologists (ACCP).

Point of care spirometry is rarely delivered on inpatient wards by the RSU scientific staff. Instead, spirometry is conducted by a range of clinical staff including allied health (physiotherapist or assistant) or nursing staff. Typically, these staff do not receive

specialised spirometry training, only that which is part of their initial degree/certificate or in-service training and there are limited opportunities to upskill or review practice. These staff are encouraged to attend the Queensland (QLD) Health Spirometry training program; however, completion is voluntary, attendance is cost prohibitive, and competency is not reassessed as regularly as it is within the RSU.

Differences in the type of spirometry training of staff across clinical roles results in differences in the assessment of quality and airflow patterns (Table 3.1). The quality of spirometry results within the RSU are critiqued manually by scientific staff for test performance (checking of errors), technical compliance (acceptability and repeatability), and device functionality (including calibration). The clinical interpretation (airflow pattern and severity rating) of the spirometry results is performed by a Consultant Respiratory Physician, after which, finalised results are published to the patient's electronic medical record.

Table 3.1: The differences in spirometry testing and staff training at Townsville University Hospital.

	TUH WARD BASED CLINICAL STAFF (PHYSIO ETC.)	TUH RESPIRATORY SCIENTIST
SPIROMETRY TRAINING	Training part of degree/certificate *QLD Health Training program	Specialised, unit based
NATIONAL CRFS EXAM	No	Yes
COMPETENCY ASSESSMENT	No	Yes
TYPE OF SPIROMETER	Portable, point of care devices	Body plethysmograph, pulmonary function systems, portable devices
SELECTION OF "BEST" FEV1 AND FVC	Software algorithm	Manual
TEST PERFORMANCE ASSESSMENT	Guided by software algorithm	Manual
TECHNICAL COMPLIANCE ASSESSMENT	Guided by software algorithm	Manual
AIRFLOW INTERPRETATION	Guided by software algorithm	Manual

*Highly regarded by not mandatory training.

In contrast, spirometry tests undertaken outside the RSU are more likely to rely on and be guided by software algorithms (within the spirometer) to automatically grade test performance and technical compliance, and to provide airflow pattern interpretation. These assessments are based on the best numerical value of FEV1 and FVC without full consideration of test performance and technical compliance. The provision of airflow pattern interpretation based on tests which may not have met quality standards

for technical compliance and/or test performance can lead to the misinterpretation of results and therefore, misclassification of patient's breathlessness, impacting patient management and care.

North Queensland has a high prevalence and burden of chronic respiratory disease and cardiovascular disease, which often coexist and frequently present with breathlessness. Detecting early changes in lung function is imperative for enabling treatment effectiveness in chronic respiratory disease. The use of point of care spirometry testing in cardiac inpatients within Queensland and Australia is unknown. The aim of this study was to determine the use and quality of spirometry in breathless inpatients in the Cardiac Centre at TUH.

METHODS

Ethics Approval

This study was approved by the human ethics committees at Townsville University Hospital and James Cook University (Project ID numbers: HREC/QTHS/76245 and H9254). As no informed consent was obtained to collect retrospective patient data as part of this study, a Queensland Health Public Health Act Approval was also acquired (PHA76245.1).

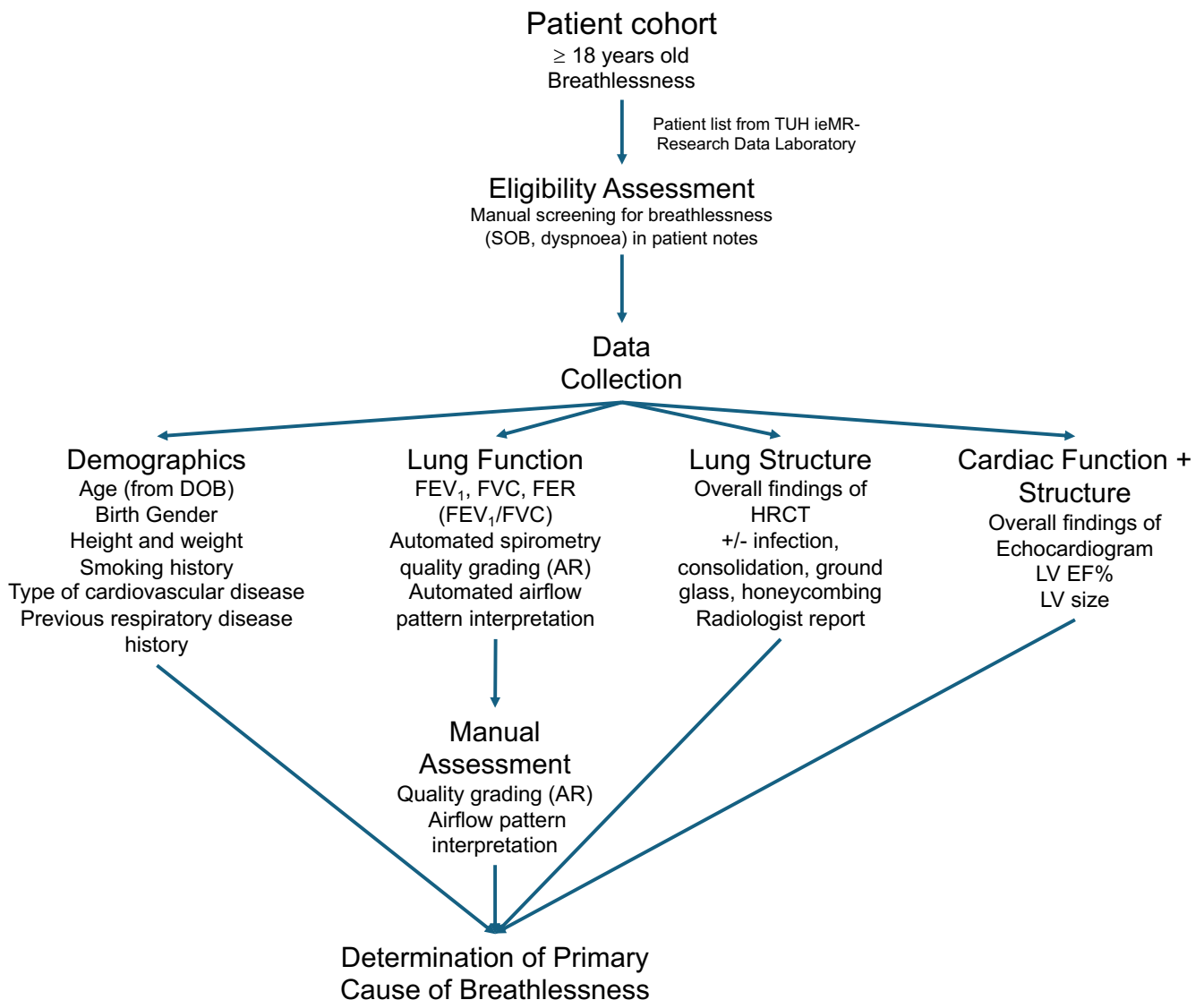
Sampling methodology

This study is a retrospective cross-sectional single-centre analytical audit. Data was collected from patients 18 years of age and older who were admitted to the Cardiac Centre (Coronary Care Unit and Cardiac Ward) at the Townsville University Hospital with breathlessness on or during their admission. Initially, a 3-month period from December 2022 to February 2023 for data collection was approved. However, as a low point of care spirometry testing rate was found, an amendment was sourced and approved for an extension of 3-months to the data collection period bring the endpoint till May 2023. For the each of the data periods, a list of admitted patients was extracted from integrated electronic medical records (ieMR) by the hospital's Research Data Laboratory. Potential patient cases were manually screened for eligibility and, in conjunction with the Research Laboratory, relevant data was extracted from suitable cases. Each patient's Unit Record Number (URN) replaced with a unique sample identification number (RXXX). An electronic version of the re-identifiable raw data set

was securely stored on the RSU network drive at TUH as per PHA procedure. The final dataset was fully anonymised prior to data analysis.

Data Extraction

Patient eligibility and data collection parameters are represented in Figure 3.2.



Lung function testing (Spirometry) performed with a NDD Medical Technologies EasyOne 2001 Spirometer. SOB – Shortness of breath; DOB – Date of Birth, FEV₁ – Forced Expiratory Volume in the First second; FVC – Forced Vital Capacity; FER – Forced Expiratory Ratio; AR – Acceptability and Repeatability; HRCT – High Resolution Computed Tomography; LV – Left Ventricle; EF – Ejection Fraction.

Figure 3.2: Patient eligibility and data collection process.

Interpretation of point of care spirometry results

Spirometry results were manually interpreted according to the internal TUH Respiratory and Sleep Unit protocol. Specifically, manual interpretation was performed

with reference to the Global Lung Initiative (GLI) 2012 normal predicted data set and following ATS/ERS 2019 spirometry standards and ATS/ERS 2022 technical standard on interpretive strategies for routine lung function tests (Graham et al., 2019; Stanojevic et al., 2022). All automated spirometer quality grades were converted to equivalent the ATS/ERS grading as outlined in the 2019 standard (Graham et al., 2019).

Spirometry results were manually re-examined to determine acceptability and repeatability (Table 3.2). Assessment was performed on the information available at time data extraction (single flow-volume loop and best three trials). Upon meeting an A or B acceptability and repeatability grade, results were stratified into one of four possible airflow pattern groups (normal, obstructive, suggestive restrictive, or suggestive mixed). The EasyOne 2001 spirometer software algorithms provided a combined overall acceptability and repeatability grade for FEV1 and FVC. FEV1 and FVC manual grades were combined for an overall grading to allow the comparison of automated versus manual results.

Table 3.3: Simplified table for the ATS/ERS spirometry grading system.

Quality Grade	Number Acceptable of Trials	Repeatable [†]	Acceptability And Repeatability Criteria Both Met?	Usable [‡]
A	3	150mL	Yes	-
B	2	150mL	Yes	-
C	≥2	200mL	No	-
D	≥2	250mL	No	-
E	≥2 or 1	>250mL	No	-
F	0	0	No	No
U	0	0	No	Yes

[†]Difference between two largest acceptable FEV1 and FVC trials.

[‡]No technically acceptable FEV1 or FVC trials, however results may be clinically useful.

Determining the primary cause of breathlessness

The combination of results from routine tests were used to determine the major contributor(s) to a patient's breathlessness. The routine test results included point of care spirometry and if available on patient medical records, echocardiograph and high-resolution computed tomography (HRCT). A simplified representation of the typical patterns of change in these test results are shown in Table 2. The analysis intentionally focuses on respiratory and cardiac causes of breathlessness and does not include non-cardiac or non-respiratory investigations.

Table 3.4: Simplified pattern analysis matrix used to determine the primary cause of each patient's breathlessness‡

Primary Cause	Spirometry outcome	Echocardiogram	HRCT
Cardiac (CVD)	Within normal limits	Abnormal	Not used
Respiratory (CRDs)	Obstructive pattern	Within normal limits	Abnormal
	Restrictive pattern	Within normal limits	Abnormal
	Mixed pattern	Within normal limits	Abnormal
Cardiac (CVD) & Respiratory (CRDs)	Obstructive pattern	Abnormal	Abnormal
	Restrictive pattern	Abnormal	Abnormal
	Mixed pattern	Abnormal	Abnormal

‡Completed in spirometry testing meeting technical compliance standards

Statistical analysis

Study characteristics were analysed using descriptive and inferential statistics using SPSS Statistics v29 (IBM, Denmark). Statistical significance was considered when p-values were $<.05$ for all tests. The presence and strength of relationships between the number of point of care spirometry tests performed, smoking history, and previous history of respiratory disease was determined using Pearsons Chi-square and Cramer's V respectively. The agreement between automated and manual spirometry interpretation was assessed using Cohen's kappa for both quality grading and the categorisation of airflow pattern, with the strength of agreement interpreted using guidelines outlined by McHugh (2012).

Determination of sample size and statistical power

Sample size was estimated for kappa analysis using the methodology by Bujang and Baharum (2022) and for the more conservative comparison of determining inter-rater agreement between automated and manual interpretation across 4 nominal airflow categories (normal, obstructive, restrictive, mixed). Disproportional marginal frequencies across airflow categories were assumed based on national and local prevalence data. Sample size was modelled using effect sizes ranging from small (0.1) to large (0.5) for Cohen's kappa coefficients ranging from 0.3 (minimum expected agreement) to 0.9 (maximum expected agreement). When the power and alpha were pre-specified at 80.0% and 0.05 respectively, minimum sample sizes ranged from 24 for large effect sizes to 246 for small effect sizes (Table 3.4). In this study, clinically meaningful results are most likely to be reflected by medium to large effect sizes. A

sample size of 125 was estimated to provide greater than 80% power for medium to large effect sizes.

Table 3.5: Sample size Modelling for inter-rater agreement (kappa analysis) 80% power, $\alpha=0.05$). Modelling based on a paired comparison of automated vs manual interpretation of the 4 airflow patterns (normal, obstructive, restrictive, mixed), and assuming that representation across airflow categories was not equal (i.e. disproportionate marginal frequencies).

<i>Automated (K₁)</i>	<i>Manual (K₂)</i>	sample size, n	effect size (K₁-K₂)
0.3	0.5	172	0.2
	0.6	74	0.3
	0.7	40	0.4
	0.8	24	0.5
0.5	0.7	152	0.2
	0.8	62	0.3
	0.9	32	0.4
0.7	0.8	446	0.1
	0.9	98	0.2

Scenarios in bold are included with study sample size selected. K – kappa coefficients.

RESULTS

Patient characteristics

A total of 519 patients were admitted to the Cardiac Centre between December 2022 and May 2023 with 212 presenting with the symptom of breathlessness on or during their admission. The characteristics of the 212 breathless patients are described in Table 3.6. The total breathless patient population was 58% male with a median age of 63 years (range 19-87) and a median BMI of 29.9kg/m² (range 15.7-57.3). Twelve patients (6% 12/212) presented with either rib fractures, pneumothorax, or non-cardiac chest pain. Four patients with non-cardiac conditions (rib fractures/pneumothorax) were excluded from further analysis as spirometry was contraindicated throughout the entirety of their admissions.

Table 3.6: Characteristics of breathless patients.

<i>Variable</i>	POC SPIROMETRY PERFORMED			p value (X²)
	All	Yes	No	
AGE-YEARS (RANGE)	63 (19-87)	67 (46-85)	63 (19-87)	0.976
GENDER (MALE)	58% (123/212)	61.5% (16/26)	57.5% (107/186)	0.698
BMI (RANGE)	29.9 (15.7-57.3)	29.3 (23.7-41.4)	29.9 (15.7-57.3)	0.704
SMOKING EVER	69.8% (148/212)	73.1% (19/26)	69.4% (129/186)	0.699
SMOKING CURRENT	30.2% (64/212)	26.9% (7/26)	30.6 (57/186)	0.699

BMI – Body Mass Index.

Cardiovascular disease was present in 96% of the breathless patients (200/208), with 39% (78/200) of CVD aetiologies associated with vessel disease (acute coronary syndrome, myocardial infarction, stroke) and 38% of patients having concurrent CVD aetiologies (75/200). The medical records for 40% (83/208) of breathless patients reported a concurrent history of respiratory disease (Table 3.7). Data on whether spirometry was used in the original diagnosis of CRD was not available. The most common respiratory aetiology was COPD (45%, 37/83) followed by asthma (30%, 25/83). Of the breathless patients, 70% (146/208) had a past or current smoking history and 38% (79/208) had a positive smoking history combined with no previously reported history of respiratory disease.

Table 3.7: Presence of Cardiovascular and Chronic Respiratory Diseases in breathless patients and number of these patients who performed a point of care spirometry test.

	Patients (n)	POC SPIROMETRY PERFORMED		p value (X ²)
		n	%	
TOTAL[‡]	208	26	12.5	<.001
NON-CARDIAC	8	0	0.0	<.001
CARDIOVASCULAR DISEASE				
TOTAL	200	26	13.0	<.001
VESSEL (ACS, MI, STROKE)	78	10	12.8	<.001
HEART FAILURE	4	1	25.0	0.625
ELECTRICAL CONDUCTIVITY	23	0	0.0	<.001
VALVE	6	0	0.0	0.031
MUSCLE (CM)	14	0	0.0	<.001
CONCURRENT CVDS	75	15	20.0	<.001
PREVIOUS HISTORY OF RESPIRATORY DISEASE				
TOTAL	81	11	13.6	<.001
COPD	37	6	16.2	<.001
ASTHMA	24	2	8.3	<.001
COPD/ASTHMA OVERLAP	4	1	25.0	0.625
ILD	3	0	0.0	0.250
OTHER	13	2	15.4	0.022

[‡]Four patients with non-cardiac conditions were excluded from the analysis as spirometry was contraindicated during their admissions. POC – Point of Care, ACS – Acute Coronary Syndrome, MI – Myocardial Infarction, CM – Cardiomyopathy, COPD – Chronic Obstructive Pulmonary Disease, ILD – Interstitial Lung Disease.

Point of Care Spirometry

The frequency of point of care spirometry testing was low, with only 12.5% of breathless patients (26/208) receiving a test. The performance of point of care

spirometry testing was not associated with the presence of any particular cardiovascular disease aetiology or if the patient had any type of previous history of respiratory disease. (Table 3.7). No point of care spirometry was performed in patients with valvular disease, electrical conductivity issues or a previous history of ILD. No significant association was found between a positive smoking history, the age, gender or BMI of breathless patients, and the number of point of care spirometry tests performed (Table 3.6).

A previous history of respiratory disease was reported in 42% (11/26) of the breathless patients who had performed a point of care spirometry test. Five of these eleven patients as well as 11 patients without a CRD history, had previously done spirometry testing in a respiratory laboratory (TUH, Mater Townsville, Cairns Hospital, Mackay Base Hospital). In 28% (19/67) of patients with a combined previous respiratory disease and smoking history, a spirometry test had been performed previously but no point of care test was completed during the current admission (Table 3.8). No point of care spirometry was performed in 87% of patients with a smoking history (127/146) and 88% of patients with a combined history of smoking and respiratory disease (59/67). In patients who had no respiratory disease history but had a smoking history, 86% did not received a point of care spirometry test (68/79), however 4 patients had previously done spirometry before.

Table 3.8: Breakdown of spirometry testing and patient history.

	PAST/CURRENT SMOKER		NEVER SMOKER	
	+ CRD History	- CRD History	+ CRD History	- CRD History
N (% TOTAL)	67 (32.2)	79 (38.0)	14 (6.7)	48 (23.1)
EVIDENCE OF PREVIOUS SPIROMETRY, N (% CATEGORY)	23 (34.3)	9 (11.4)	4 (28.6)	2 (4.2)
NO POC SPIROMETRY PERFORMED, N (% CATEGORY)	59 (88.1)	68 (86.1)	11 (78.6)	44 (91.7)
POC SPIROMETRY PERFORMED, N (% CATEGORY)	8 (11.9)	11 (13.9)	3 (21.4)	4 (8.3)
POC SPIROMETRY PERFORMED & EVIDENCE OF PREVIOUS SPIROMETRY, N (% CATEGORY)	4 (6.0)	5 (6.3)	1 (7.1)	1 (2.1)

Acceptability and Repeatability

Software algorithms within the EasyOne spirometer automatically determined that 54% (14/26) of tests were of an acceptable and repeatable grade (A or B) as per ATS/ERS criteria. The spirometer graded 4 tests as a F (zero acceptable or usable).



Figure 3.2: Alluvial plot of the comparison of Automated vs Manual spirometry grading interpretations.

Table 3.9: Automated vs Manual spirometry grade interpretation.

		MANUAL GRADING							Total
		A	B	C	D	E	F	U	
AUTOMATED GRADING	A	9	1	0	0	0	2	0	12
	B	0	1	0	0	0	0	1	2
	C	0	1	0	0	1	0	1	3
	D	0	0	0	1	3	1	0	5
	E	0	0	0	0	0	0	0	0
	F	0	0	0	0	0	4	0	4
	U	0	0	0	0	0	0	0	0
TOTAL		9	3	0	1	4	7	2	26

Bold = same grade, red = lower grade manual, blue = higher grade manual

Overall, 46% of the tests performed (12/26) were deemed to meet ATS/ERS criteria for grades A and B upon manual reassessment (Figure 3.2, Table 3.9). When acceptability and repeatability were manually reassessed, there was an 11% decrease in tests graded A and a 27% increase in test graded E or F (Figure 3.2). Two tests

were manually determined to be not acceptable but met ATS/ERS usability criteria. A moderate agreement was found between automated and manual interpretation of spirometry tests for acceptability and repeatability, $\kappa=.679$ (95% CI .420 to .938), $p<.001$.

One in five tests that were deemed acceptable and repeatable by the automated algorithms within the spirometer, were not after reassessment (Figure 3.3). One test graded C by the spirometer was reassessed to be a B grade, 2 acceptable trials performed within 150mL. The four tests graded F by the spirometer due to premature termination of airflow and poor expiratory effort remained the same grade after manual reassessment.

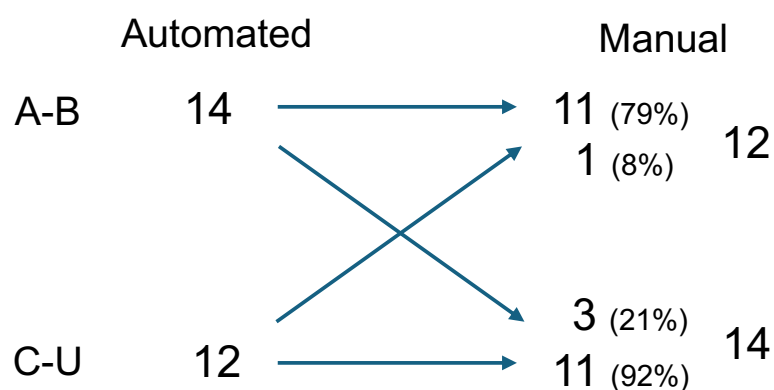


Figure 3.3: Differences in spirometry grading between spirometer algorithms (Automated) and Manual assessment.

No significant association was found between the manual spirometry grading and history of respiratory disease (including type) ($V=.417$, $p=.584$), type of cardiovascular disease ($V=.469$, $p=.326$), smoking history ($V=.392$, $p=.550$), age ($V=.909$, $p=.414$) or gender ($V=.434$, $p=.429$).

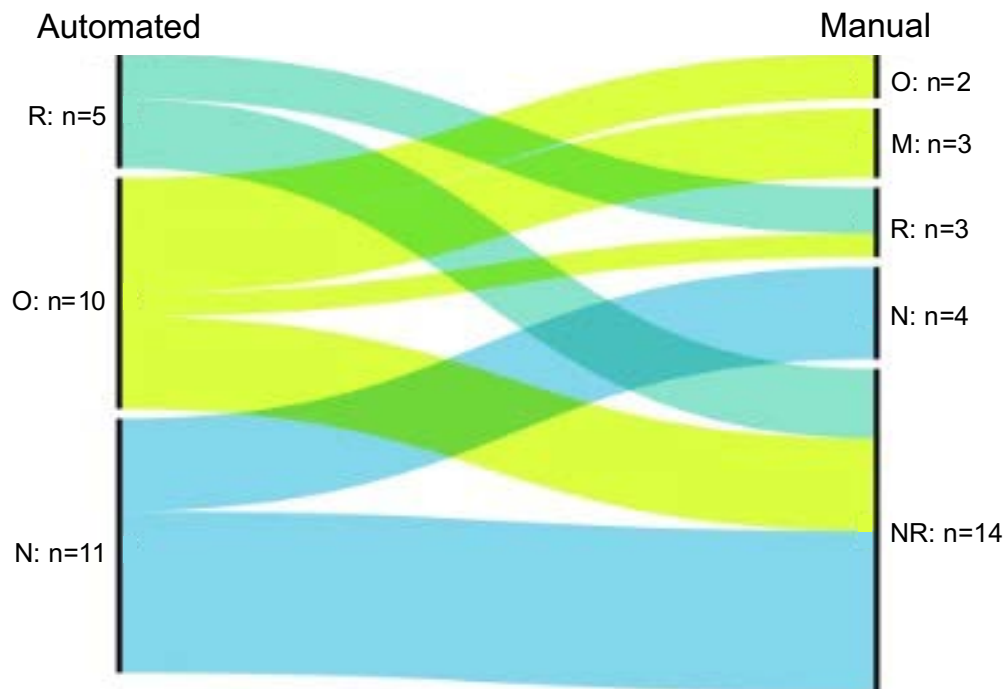
Airflow pattern

The EasyOne spirometer determined the classification of airflow patterns for all 26 spirometry tests despite 12 not being interpretable based on acceptability and repeatability criteria (Table 3.10). Just under half of the spirometry tests were identified as normal according to the spirometer (42%, 11/26), 39% as obstructive (10/26) and 19% as restrictive (5/26).

Table 3.10: Difference in Automated vs Manual interpretation of airflow patterns.

	% Met AR	% Interpreted	% per usable tests via manual			
			N	O	R	M
AUTOMATED	54 (14/26)	100 (26)	42 (11/26)	39 (10/26)	19 (5/26)	0 (0/26)
MANUAL	46 (12/26)	46 (12)	33 (4/12)	17 (2/12)	25 (3/12)	25 (3/12)
DIFFERENCE	-8	-54	-9	-22	+6	+25

Manual interpretation of airflow pattern was not performed on the 54% of tests that did not meet acceptability and repeatability criteria (14/26). Of the twelve tests that met grade A or B criteria (at least 2 acceptable and repeatable trials, within 150mL), 33% were classified as normal airflow (4/12), 17% as obstructive (2/12), and 25% as either suggestive of restrictive (3/12) or mixed patterns (25%, 3/12) (Figure 3). There was minimal agreement between automated and manual interpretation of airflow patterns ($\kappa=.216$ (95% CI .069 to .363), $p<.001$), with airflow classification changing in 33% (4/12) of tests. Obstructive patterns decreased by 22% with three test results being reclassified as mixed patterns. One obstructive pattern was reclassified as a restrictive due to low FVC values (premature end of airflow, unclear if patient or device termination).



N: Normal, O: Obstructive, R: Restrictive, M: Mixed, NR: Not reported.

Figure 3.4: Alluvial plot of the comparison of automated verses manual for airflow pattern interpretations.

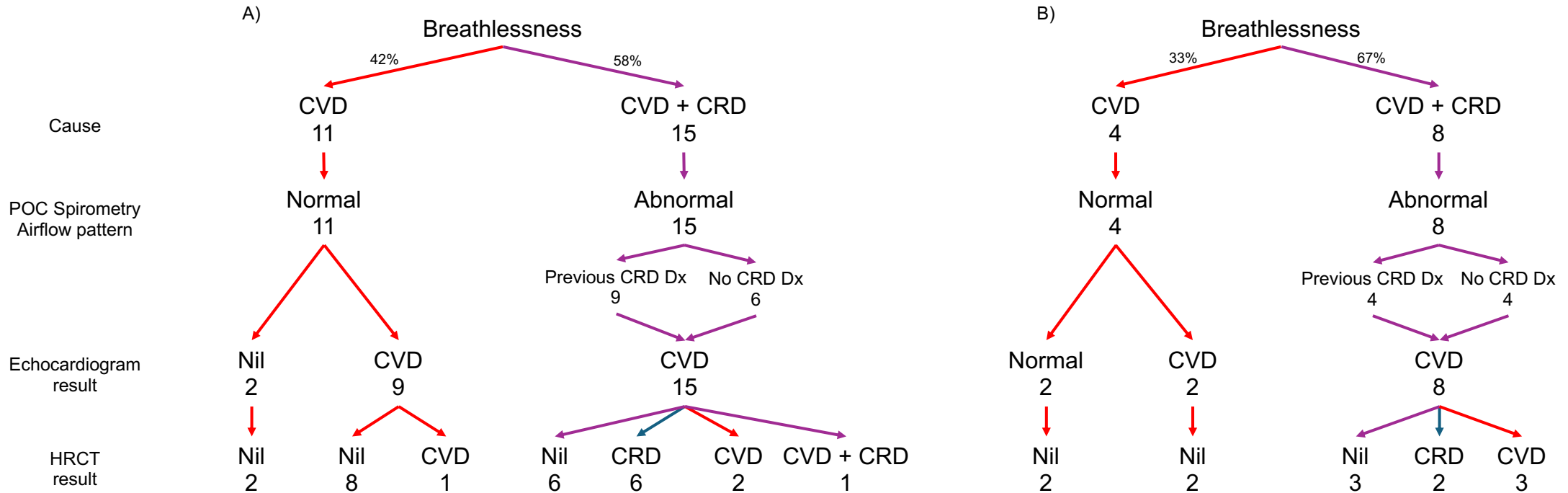
Out of the six patients who had a history of COPD, 83% were unable to produce a point of care spirometry test that was acceptable and repeatable. Patients with no history of respiratory disease had an equal chance of producing/not producing an acceptable and repeatable test (Table 3.11). No association was found overall between manual spirometry test grading and patient's respiratory disease history ($V=.409$, $p=.626$). Four patients with no known history of respiratory disease, had abnormal airflow pattern results, with the remaining 3 patients having a normal airflow pattern. Of the patients with a history of respiratory disease, 2 patients had point of care spirometry results which matched their history, however pre and post spirometry is required to confirm these findings. The other 3 patients had results (mixed or restrictive patterns) which require further investigation with complex lung function testing (including lung volumes testing).

Table 3.11: Breakdown of Respiratory Disease History and Manual spirometry gradings.

		RESPIRATORY DISEASE					Total
		COPD	COPD/Asthma	Asthma	Other Respiratory	Nil	
MANUAL GRADING	A	0	1	2	0	6	9
	B	1	0	0	1	1	3
	D	1	0	0	0	0	1
	E	1	0	0	1	3	5
	F	2	0	0	0	4	6
	U	1	0	0	0	1	2
TOTAL		6	1	2	2	15	26

Determination of the Primary Cause of Breathlessness

The primary cause of breathless was determined for the twelve patients who had produced a valid point of care spirometry test (manually determined). All patients received an echocardiogram; however, HRCT was not performed for seven patients. Cardiovascular disease was the primary cause of breathlessness in 33% of patients, all which had normal airflow patterns on spirometry. The primary cause of breathlessness was related to both respiratory and cardiovascular disease in 67% patients who had abnormal airflow patterns and abnormal echocardiograms (Figure 3.5B). Four of the patients within the combined cardiovascular and respiratory disease group had no previous history of respiratory disease.



CVD: Cardiovascular Disease, CRD: Chronic Respiratory Disease, POC: Point of care, Dx: Diagnosis. Numbers represent number of patients in each category.

Figure 3.5: A) Primary cause/s of breathlessness using automated spirometer algorithms for the interpretation of airflow patterns; B) Primary cause/s of Breathless after manual assessment and interpretation of quality gradings and airflow patterns.

Figure 3.A shows the primary causes of breathlessness using the automated algorithm derived airflow patterns on all 26 spirometry tests. Two patients with cardiovascular disease did not receive an echocardiogram and overall, in 10 patients no HRCT was conducted. In 42% (11/26) of patients, cardiovascular disease was determined to be the primary cause of breathless as the spirometer classified the airflow patterns as normal. Abnormal airflow patterns (obstructive or restrictive) were assigned to the other 58% (15/26) of patients, and because all also had abnormal echocardiograms, the primary cause of breathlessness was determined to be related to both cardiovascular and respiratory disease.

Overall, between the automated and manual interpretation of airflow patterns, the primary cause of breathlessness did not change in the 12 patients that had good quality spirometry. Instead within the combined cardiovascular and respiratory disease group for primary causes of breathlessness the airflow patterns changed from one abnormal pattern to another.

Post-hoc Kappa sample size determination

Post-hoc power analyses were performed to determine if the resultant sample size provided sufficient power for clinically meaningful result interpretation. For the inter-rater agreement between automated and manual assessment of quality grades, it was found that a 7x7 contingency table was required. The breakdown of grade frequencies was similar to the frequencies of the .05, .05, .10, .10, .15, .25, .30 table found in Bujang and Baharum (2022) paper with 80% power and an alpha of .05. This determined that a sample size between 9-35 was sufficient to provide meaningful agreement for medium to large effect sizes (Table 3.12).

Table 3.12: Kappa sample size determination for inter-rater agreement, 80% power, $\alpha=0.05$. Post-hoc modelling based on a paired comparison of automated vs manual assessment of quality grading (A-U), and representation across categories was not equal (i.e. disproportionate marginal frequencies).

<i>Automated (K₁)</i>	<i>Manual (K₂)</i>	<i>sample size, n</i>	<i>effect size (K₁-K₂)</i>
0.3	0.4	454	0.1
	0.5	110	0.2
	0.6	47	0.3
	0.7	25	0.4
	0.8	15	0.5
	0.9	9	0.6
0.5	0.6	360	0.1
	0.7	85	0.2
	0.8	35	0.3
	0.9	18	0.4
0.7	0.8	230	0.1
	0.9	50	0.2

Scenarios in bold are included with study sample size selected. K – kappa coefficients.

For the inter-rater agreement between automated and manual assessment of airflow pattern interpretation, it was found that a 5x5 contingency table was required. The breakdown of grade frequencies was similar to the frequencies of the .10, .10, .10, .10, .60 table found in Bujang and Baharum (2022) paper with 80% power and an alpha of .05. This determined that a sample size between 11-30 was sufficient to provide meaningful agreement for medium to large effect sizes (Table 3.13).

Table 3.13: Kappa sample size determination for inter-rater agreement, 80% power, $\alpha=0.05$. Post-hoc modelling based on a paired comparison of automated vs manual assessment of airflow pattern interpretation (normal, obstructive, restrictive, mixed, no interpretation), and representation across categories was not equal (i.e. disproportionate marginal frequencies).

<i>Automated (K₁)</i>	<i>Manual (K₂)</i>	<i>sample size, n</i>	<i>effect size (K₁-K₂)</i>
0.3	0.4	541	0.1
	0.5	132	0.2
	0.6	57	0.3
	0.7	30	0.4
	0.8	18	0.5
	0.9	11	0.6
0.5	0.6	463	0.1
	0.7	109	0.2
	0.8	45	0.3
	0.9	22	0.4
0.7	0.8	306	0.1
	0.9	66	0.2

Scenarios in bold are included with study sample size selected. K – kappa coefficients.

DISCUSSION

This is the first study in North Queensland to assess the use and quality of point of care spirometry testing in a breathless population, the majority (94%) of which had preexisting cardiovascular disease. This study highlights that point of care spirometry is underutilised, with only 12% of breathless patients admitted to the Cardiac Centre at Townsville University Hospital receiving a test. The age, gender, BMI, smoking history, CRD history, or type of CVD of breathlessness patients were not significant predictors of who completed a point of care test spirometry test, signifying testing was delivered randomly. Of the patients that did perform point of care spirometry, only 54% of tests met the international standards for AR when assessed via automated algorithms within the spirometer. The number of tests which met criteria decreased to 46% when manual reassessment was undertaken, with one third changing to a different airflow pattern. The use of automated grading resulted in 64% of tests being interpreted despite not meeting AR criteria for grades A or B. In patients who had a spirometry test that was AR, 33% without a previous CRD history had an abnormal pattern. The primary cause of breathlessness was both CVD and CRD in 67% of patients and of these patients 50% had no previous CRD history.

Patients living in regional, rural, and remote communities are 11% likely to have one or more chronic conditions than those in metropolitan areas (Australian Institute of Health and Welfare, 2024d). In North Queensland there is a higher burden and prevalence (1.5 to 1.9 times higher DALY rates) of CVD and CRDs compared to the rest of Queensland and all of Australia (Australian Institute of Health and Welfare, 2024d; Northern Queensland Primary Health Network, 2021). As well, North Queensland has higher rates of health-related risk factors such as tobacco smoking, physical inactivity, and obesity compared to the rest of Queensland, all of which are risk factors for chronic diseases like Chronic Obstructive Lung Disease (COPD) and cardiovascular disease (Northern Queensland Primary Health Network, 2021).

This study shows that breathless patients admitted to the Cardiac Centre at TUH had increased rates of risk factors (age, BMI, smoking) for the development of chronic respiratory diseases, supporting the results found in the Australian Burden of Disease Study 2018 (Australian Institute of Health and Welfare, 2021). A positive smoking history (current or past) was found in 70% of the study's breathless patient population.

The studied population also had a median BMI of 29.9kg/m² (overweight to obese), with 67% of patients having BMI >25kg/m². These findings are similar to rates found by the Australian Institute of Health and Welfare for the NQPHN catchment (outer regional, rural and remote) (Australian Institute of Health and Welfare, 2021; Northern Queensland Primary Health Network, 2021). However, compared to all of Australia where the rate of ever smoking has dropped to 35%, in this studies patient population smoking is double (Australian Institute of Health and Welfare, 2024b).

Compared to other parts of Queensland and Australia, North Queensland has some of the highest rates of hospitalisations for chronic respiratory diseases (CRDs) and cardiovascular disease (Australian Institute of Health and Welfare, 2024c; Northern Queensland Primary Health Network, 2021). The number of patients in North Queensland with chronic conditions such as CVD and CRD are predicted to rise an additional 14,000 and 15,000 respectively by 2041 (Northern Queensland Primary Health Network, 2021). Patients must often travel hundreds to thousands of kilometres to reach TUH with many being relatively socioeconomically disadvantaged and thus often coming alone (Edelman et al., 2020). This increases the burden to the patient who does not want to stay for extended periods away from their family and friends and are unlikely to attend follow-up appointments for further investigations away from home (Alturbag, 2024; Paterson et al., 2010). There is an increase burden to the health service as well, as it is cost prohibited for patients to have to travel (through patient travel subsidy scheme) for additional tests which could of be performed during the patient's admission. This is why it is critical that breathless patients are screened for these diseases, particularly when they present at Townsville from rural and remote communities.

Spirometry plays a vital role in the diagnoses and management of chronic respiratory diseases. However, despite spirometry being widely available, previous studies have found that it is only performed in 30 to 40% of patients (Graham et al., 2019; Han et al., 2007; Hegewald et al., 2016; Joo et al., 2008; Lee et al., 2006; Yang et al., 2023). In addition, a systematic review of spirometry quality (Chapter 2) across a broad range of age groups, study settings and health statuses, found that 75% of tests performed met quality standards. Specifically, in hospital-based settings, 81% tests met quality criteria. This study showed that, despite being a high-risk cohort for CRDs admitted to

tertiary care hospital, both the use (12%) and quality of spirometry tests performed (46%) was below what published literature shows.

Manual assessment of point of care spirometry grades resulted in an 8% decrease of tests meeting ATS/ERS acceptable and repeatable standards. A moderate agreement ($\kappa=.679$) for quality grading was found between the automated algorithms and manual assessment. Published literature recommends that an .800 kappa agreement is the minimum acceptable level for inter-rater agreement in a clinical setting (Marchevsky et al., 2020; McHugh, 2012). In this study, the agreement in quality between automated and manual assessment was below the minimum inter-rater agreement threshold indicating that the automated algorithms within the spirometer are not a reliable measure for quality grading. The spirometer was able to recognise significant errors in testing performance including very premature termination of testing and poor peak forced expiratory effort, however, it was unable to identify other errors which were detectable with manual assessment (e.g. incomplete glottic closure). Two tests which were graded acceptable and repeatable by the spirometer were not after manual reassessment. Using the automated spirometer grades for these two tests had significant clinical implications; suggesting that there was no presence of respiratory cause for the patient's breathlessness and thus no further investigations for a respiratory cause were performed. Given after manual reassessment these tests were determined to not be acceptable, resting is required as the presence of no respiratory cause may be inaccurate.

Outside the respiratory laboratory at TUH, spirometry is rarely delivered by scientific staff due to small staffing numbers (~1.5 FTE) and high outpatient testing demand (~350-400 tests/month). Typically, the clinical staff performing point of care spirometry do not receive specialised training as occurs in the the respiratory laboratory and opportunities to upskill and review practice are limited. Staff training programs and increased frequency of performing spirometry have been shown to reduce technical errors and increase staff knowledge and confidence in performing and interpreting spirometry (Borg et al., 2012; Licskai et al., 2012; W. C. Tan et al., 2014). However, with limited staff training and infrequent use, it is likely that the assessment of test quality and the interpretation of airflow patterns may become increasingly guided or even reliant on proprietary automated software algorithms within the spirometer.

Inaccurate assessment of test quality, the inappropriate assessment of airflow in low quality tests, and inaccurate assessment of airflow pattern, alone or in combination, can lead to over, under or missed opportunities to diagnosis chronic respiratory diseases which may also be a cause of the patient's breathlessness.

Despite the spirometer grading 46% of the tests as not acceptable or repeatable, an interpretation of airflow pattern was provided for all of the tests. Unfortunately, at TUH the results of point of care spirometry are unlikely to be validated by a Respiratory Physician for accuracy and correctness of interpretation, as these tests are not conducted by the RSU and no respiratory input from other disciplines is requested. Previous studies have shown that even if a test is conducted by a competent scientist with an accurate spirometer and patient who is able to produce acceptable manoeuvres, the physician who ordered the test may poorly interpret the results and thus make inappropriate decisions about the diagnosis and treatment (Enright, 2012; Poels et al., 2007). The Global Initiative for Chronic Obstructive Diseases and the Australian and New Zealand Guidelines for the management of Chronic Obstructive Pulmonary Disease recommend the use of a fixed FEV1/FVC ratio of 0.70 to detect airflow obstruction (Australian Commission on Safety and Quality in Health Care, 2024; Global Initiative for Chronic Obstructive Lung Disease, 2024). Although this criterion is simple and independent of reference values, the use of a fixed ratio can over-diagnose COPD in the elderly, and under-diagnose COPD, particularly in mild disease, in young adults (Enright, 2012; Global Initiative for Chronic Obstructive Lung Disease, 2024). Compared to the use of Global Lung Initiative equations and z-scores, the fixed ratio can also misclassify normal airflow patterns as impaired (Enright, 2012; Global Initiative for Chronic Obstructive Lung Disease, 2024).

In tests which met grade A or B quality criteria, manual compared to automatic assessment of airflow changed the outcome in 33.3% of tests (25% obstructive to mixed, 8.3% obstructive to restrictive). The automated verses manual determination of obstructive airflow patterns was the most discordant at 80%. As 65.4% of tests were either not reported or had a change of classification of airflow pattern when manually reinterpreted, a minimal inter-rater agreement was found. As the inter-rater agreement was below the minimum agreement threshold, this indicates that the automated

algorithms within the spirometer are not a reliable tool to assess airflow pattern interpretation.

Ninety-four percent of the breathless patients had confirmed cardiovascular disease and 39% had a previous history of respiratory disease. Of the 39% of patients with a previous history of respiratory disease, only 33% patients had had a respiratory function test performed to confirm their diagnosis prior to this study, including 14% who had a point of care spirometry test as part of this study. This rate for patients who had performed testing, whether previously or in this study, is similar to that in published literature where only 30-40% of patients receive spirometry testing as part of the diagnostic pathway (Graham et al., 2019; Han et al., 2007; Hegewald et al., 2016; Joo et al., 2008; Lee et al., 2006; Yang et al., 2023). No analysis was performed to assess the concordance of airflow patterns between previous and current spirometry testing, as the data from previous testings was not included under the PHA approval.

This study showed that 70% of breathless patients had a smoking history either with or without CRD history, therefore case-finding for airflow limitation was missed in 61% of this high-risk cohort. Although 30% patients had never smoked, these patients are also at a high-risk for CRDs due to their coexisting cardiovascular disease and symptom of breathlessness, therefore case-finding opportunities for CRDs was also missed in 89% of these patients. Previous literature and the Lung Foundation of Australia's position statement supports the role of active targeted case-finding, particularly with respect to COPD, to aid in early diagnosis and access to treatments, and help decrease hospitalisations (Haroon et al., 2020; Jordan et al., 2016; Jordan et al., 2010; Lung Foundation of Australia, 2016).

Study Limitations and Assumptions

This study was subject to several limitations and assumptions, namely the calibration/verification of EasyOne spirometers, the use of only prebronchodilator spirometry and sample size.

Many factors, which can be grouped into four domains, impact the quality of spirometry (Chapter 2, Figure 2.1). One of the quality domains is focused on the device and includes calibration and verification. In this study it was assumed that the spirometers used were within the calibration verification parameters outlined by the international

spirometry standards. As this study is retrospective in design and conducted outside of the respiratory laboratory, no access to the calibration logs of the spirometers used was available and it is unknown when or if the spirometers were verified. As all the data was extracted from electronic medical records, no information about calibration verification was available from the generated spirometry report outputs. Therefore, the focus of this study was instead on the test performance, technical compliance and interpretation domains of spirometry quality. Recommendations and future research are explored in detail in Chapter 4 (General Discussion).

This study used only pre-bronchodilator point of care spirometry to assess airflow patterns as no post-bronchodilator spirometry was performed. At TUH point care spirometry usually does not include bronchodilator assessment, and referral to the RSU is required for pre- and post-bronchodilator spirometry. The lack of post bronchodilator spirometry limited the ability to confirm if each obstructive airflow pattern was a result of COPD and/or Asthma and whether there was an Asthma component in the normal airflow patterns. This is considered in further detail in Chapter 4 (General Discussion).

The use of spirometry was surprisingly low over the 6-month retrospective data collection period, despite targeting a cohort likely to have elevated risk factors for chronic lung disease. This, combined with the timeframes required for project approvals (initial and amendments HREC, RGO, PHA), resulted in a low sample size for spirometry quality and interpretation assessments. Despite this, tests of agreement for this study's sample size had a power of 80% or greater for medium to large effect sizes (Tables 3.10 and 3.11) which were considered to be the most clinically meaningful.

CONCLUSIONS

Despite the high prevalence and burden of CRDs, the frequent co-existence of CVD and CRD, combined with the requirements for spirometry to confirm CRD diagnosis, this study found that point of care spirometry testing was significantly underutilised in patients admitted to a cardiac centre. With a combined history of breathlessness and cardiovascular disease, this study's patient cohort is at high risk for the development of chronic respiratory diseases. It is therefore essential that spirometry is not only used more frequently but that both test quality and accuracy of airflow interpretation be

improved. Further research and increased awareness are required to determine the barriers to spirometry use in this setting to enable the assessment of lung function in all breathless cardiac patients.

CHAPTER 4

General Discussion

This thesis investigated spirometry quality broadly across different settings and cohorts, and then focused specifically on a breathless cohort in North Queensland. An Ishikawa diagram was developed (Chapter 2) to define the domains of spirometry quality, including their components and relationships (Figure 2.1). The most standardised and readily assessable components of spirometry are the criteria for acceptability and repeatability, and for this reason, they were used as a surrogate for overall spirometry quality in this thesis. The quality of testing and its predictors was determined across a diverse range settings and participant cohorts using a systematic literature review and meta-analysis of published literature (Chapter 2). The use and quality of spirometry testing were investigated in a targeted population of breathless patients within a tertiary cardiac centre (Chapter 3). This general discussion initially summarises the main findings of this thesis, reviews the clinical implications, provides recommendations, and ends by underlining the limitations and future directions for research.

SUMMARY OF THESIS FINDINGS

The overall aims of this thesis are summarised above. To achieve these aims, seven research questions were devised. These questions and a summary of findings are addressed as follows:

What is the overall quality of spirometry testing in published literature? (Chapter 2)

Expert opinion states that it is possible to achieve good quality spirometry results (defined as acceptable and repeatable, AR) in 90% of tests completed by trained testers across different settings and ages (Haynes, 2012; Ruppel & Enright, 2012). However, currently there is no minimum tolerance level set by international bodies for the percentage of tests satisfying AR criteria and whether this should be the same in both laboratory-based and point of care settings. The literature systematically reviewed in Chapter 2 explored the quality of spirometry across a broad range of study designs, settings and participant ages and cohorts. Only 4% of the studies screened reported %AR (or the data required to derived %AR), revealing that this measure of spirometry quality was largely unreported. Of the studies that did report %AR, the overall quality of spirometry was 75.1% (weighted median by participant number), equating to one in four tests not meeting international standards criteria. In hospital-

based respiratory laboratories 81% (IQR 25%) of tests met AR standards and in primary care where most point of care spirometry is conducted, only 78% (IQR 32%) met AR criteria. With these findings, a 90% benchmark for spirometry quality is likely too high, particularly for point of care testing.

Which factors influenced spirometry quality in published literature? (Chapter 2)

A meta-analysis using a generalised linear model was conducted. Results indicated that participant age, particularly paediatric and elderly, and studies conducted in a primary healthcare setting were associated with lower %AR. The participants health status, the type of spirometer used, and the standard used did not significantly predicted lower %AR. These are important findings given the diagnostic utility of spirometry for CRDs.

What are the major risk factors for patients admitted to a Cardiac Centre with the symptom of breathlessness? (Chapter 3)

Townsville Hospital and Health Service supports and treats some of the most isolated, rural, and remote communities in Australia (Edelman et al., 2020). North Queensland has higher rates of risk factors such as smoking, overweight and obesity compared to the rest of Queensland and Australia (Australian Institute of Health and Welfare, 2024c; Northern Queensland Primary Health Network, 2021). These risk factors increase the likelihood of patients developing chronic respiratory diseases and cardiovascular disease. The cohort of patients investigated in Chapter 3 had the symptom of breathlessness with 94% having cardiovascular disease. Overall, the median age of the patients was 63 years and with a median BMI of 29.9kg/m² (overweight to obese). A smoking history was present in 70% of patients with 39% also having a previous history of respiratory disease. The results of this study support previous findings of high CRV and CVD related risk factors in the North Queensland population (Australian Institute of Health and Welfare, 2021; Northern Queensland Primary Health Network, 2021).

What was frequency of point of care spirometry in breathless patients in the Cardiac Centre, TUH? (Chapter 3)

Between December 2022 and May 2023, 519 patients were admitted to the Cardiac Centre at Townsville University Hospital. Of these patients 212 had breathless

recorded on or during their admission. Four patients were excluded from the analysis as spirometry was contraindicated (pneumothorax and rib fractures) for the entirety of their admissions. Point of care spirometry was performed in 12.5% (26/208) of the breathless patients, indicating that spirometry was underutilised in this population at high-risk for CRDs.

What was the quality of point care spirometry testing, and the impact of automated compared to manual assessment? (Chapter 3)

Spirometry results were assessed both by automated software algorithms and manually according to the ATS/ERS 2019 Standardisation of Spirometry guidelines for acceptability and repeatability (Graham et al., 2019). A moderate agreement was found between automated and manual assessment of acceptability and repeatability. Automated software algorithms within the spirometer deemed 54% of tests were acceptable and repeatable (i.e., grade A or B). Manual reassessment by an experienced respiratory scientist resulted in an 8% decrease in the number of acceptable and repeatable tests and a 27% increase in the number of tests ranked in the lowest two grades (either no acceptable and repeatable trials, or 1 acceptable trial, or >2 acceptable trials with >250mL repeatability).

What was the impact of automated compared to manual interpretation of airflow patterns (Chapter 3)

The ATS/ERS 2022 technical standard on interpretive strategies for routine lung function tests was used to determine the airflow patterns (Stanojevic et al., 2022). A minimal agreement was found between automated and manual interpretations, with the interpretation of airflow patterns changing in 33% of tests following manual re-interpretation. Airflow patterns were determined in all tests by the automated spirometer algorithms including the 46% (12/26) which did not meet AR criteria for grades A or B. No manual interpretation was performed on tests that did not meet AR criteria (54%, 14/26). The most discordant interpretation between automated and manual assessment was of obstructive airflow pattern classification at 80%. Changes in airflow patterns occurred from obstructive to either restrictive or mixed upon manual reinterpretation. Four patients (33%, 4/12) had abnormal airflow patterns with no previous CRD history, establishing the potential of spirometry case-finding for CRDs.

Did automated compared to manual interpretation of spirometry change the primary cause of breathlessness? (Chapter 3)

The primary cause/s of breathlessness was determined using spirometry, echocardiogram and HRCT test results. Using the automated algorithms for airflow pattern interpretation, the primary cause of breathlessness was 42% CVD, and 58% CVD+CRD. Causes from CVD decreased by 9%, with an increase in CVD+CRD causes by 9% after manual reinterpretation of airflow patterns as 54% of tests were not reported manually. In 12.5% of patients who had a point of care spirometry, 67% had CVD+CRD cause for breathlessness, 50% of which had no previous CRD diagnosis. Manual vs automated interpretation change the type of airflow pattern in 33% of patients. Further investigations (e.g. complex lung function testing) are needed to confirm these results and if a change in CRD diagnosis is required.

CLINICAL IMPLICATIONS AND RECOMMENDATIONS

Spirometry has been used as a clinical diagnostic test in the assessment lung function for over 178-years (Kouri et al., 2021). Despite the mandate for spirometry testing by global and national peak respiratory bodies for the confirmation of chronic lung diseases (CRDs), worldwide only 30-40% patients have spirometry performed as part of their diagnostic assessment (Graham et al., 2019; Han et al., 2007; Hegewald et al., 2016; Joo et al., 2008; Lee et al., 2006; Yang et al., 2023). Without spirometry, CRD diagnosis is often based on risk factors and symptoms only (Hangaard et al., 2017; Sator et al., 2019). Cardiovascular disease coexists 2-5 times more in patients with CRDs than without, and symptoms and risk factors often are the same across diseases (Morgan et al., 2018). Challenges arise when spirometry is not performed, as CRDs are often overlooked or missed when CVD is also present (Leong et al., 2019). This creates a huge problem considering that that CVDs and CRDs are the first and third leading causes of mortality worldwide.

North Queensland is known to have higher risk factors, burden of disease, and hospitalisations for both chronic respiratory and cardiovascular diseases (Australian Institute of Health and Welfare, 2024c; Northern Queensland Primary Health Network, 2021). Previous literature shows that spirometry use is limited or missed from the diagnostic assessment for CRDs, particularly in primary healthcare where most patient's first point of contact for seeking help occurs. The systematic review in

Chapter 2 showed that primary healthcare settings and elderly aged participants are significant predictors of lower spirometry quality. Patients aged over 60 are at an increased risk of progressively worsening CRDs. Therefore, given the combination of high-risk factors, the overlapping presentation of CRDs and CVD and the low use and quality of spirometry in primary healthcare, it is vital when patients present to tertiary care with chronic breathlessness and CVD, that once clinically stable, quality spirometry is performed to assess for any respiratory disease. It is especially important at Townsville University Hospital as North Queensland's only tertiary referral centre, given that patients frequently have complex presentations and must often travel long distances to receive tertiary level care.

The evaluation of the use and quality of spirometry testing in a high-risk breathless population (Chapter 3) is the first of its kind in North Queensland. Two major concerns were found; 1) that point of care spirometry testing is underutilised and is not targeted to risk factors or disease aetiology, and 2) that the quality of testing done is low with less than 50% of tests meeting AR criteria and 33% were incorrectly interpreted.

Concern 1): When used, point of care spirometry was not targeted to patient risk factors or to patient's history of cardiovascular or respiratory disease. From the evaluation of patient records during data extraction and 8 years of clinical experience in a respiratory laboratory where cardiac inpatients are referred for complex lung function testing, point of care spirometry testing in the Cardiac Centre at TUH is mainly used for preoperative assessments, however further investigation for confirmation is required which was out of scope for this thesis. Despite the role of spirometry in CRD diagnosis and importance of early diagnosis and treatment, spirometry was underutilised and not targeted to risk factors when used. This suggests the need to increase awareness of the prevalence CRD and CVD comorbidity, the identification of symptoms, and overlap in risk factors for CVD and CRD. The use of a multidisciplinary approach is also required for the prioritisation of point of care spirometry to at high-risk patients for CRDs. Ideally if cost, funding, and staffing were not issues, point of care spirometry should be conducted on all breathless patients with CVD within the Cardiac Centre at TUH. This notion is based on the findings of Chapter 3 where 94% of breathless patients had CVD, and high rates of risk factors in North Queensland (study population: 70% smoking history, median age 63 years, median BMI 29.9kg/m²)

compared to the rest of Queensland and Australia, and when spirometry was performed 33% of patients with abnormal airflow patterns had no previous CRD history.

However, as this is not currently a feasible option, the first step is to educate non respiratory physicians on the importance of spirometry testing in the diagnostic assessment of chronic respiratory diseases and to not overlook/underestimate the coexistence of symptoms and risk factors which can result from both coexisting diseases. This is shown in Chapter 3 where 67% of patients' primary cause of breathlessness resulted from both respiratory and cardiovascular aetiologies. It is also important to inform these staff that chronic respiratory diseases are not curable, however the progression of disease can be slowed with early diagnosis and access to treatment. The introduction of a screening questionnaire as part of the diagnostic procedure to determine the patients at the greatest risk for CRDs is recommend and may be useful to prioritise spirometry to patients at highest risk for CRD. Several studies have compared screening questionnaires, particularly for use in the primary care setting (Bastidas et al., 2023; Perret et al., 2023; Sogbetun et al., 2016). The PRECUSOR (Predicting Your Patient's Risk of Airway Obstruction) tool which has been developed for an Australian population and is based on longitudinal data and design to predict 'early" disease, is a promising tool which may be translated into use for the targeted cohort investigated in this thesis (Perret et al., 2021; Perret et al., 2023).

Concern 2): Spirometry quality consists of four interdependent domains; the device, test performance, technical compliance and interpretation of results. These domains are also influenced by the knowledge, skills, and confidence of both the tester conducting the test and the physician interpreting the results. After manual reassessment of quality grades, 46% of point care spirometry tests met acceptability and repeatability criteria for grades A and B. A moderate agreement between automated and manual assessment of spirometry quality grades was found and only a minimal agreement for the interpretation of airflow patterns was seen. This indicates that the automated algorithms within the spirometer are not a reliable measure for quality grading or interpretation of airflow patterns. As discussed in Chapter 3, point of care spirometry in the Cardiac Centre is frequently reliant on and guided by the

automated algorithms within the spirometer as testing is performed by clinical staff with limited training and upskilling, and the interpretation of results are not validated by respiratory physicians. Several recommendations to address improvements for quality spirometry are as follows:

1. *Device: Replacement of point of care spirometers used in the Cardiac Centre.*

At the time of testing, spirometry was conducted using EasyOne model 2001 diagnostic spirometers. Previous studies have shown that the EasyOne spirometer exceeds the criteria for repeatable FVC results of >200mL and often yields lower results for FEV₁ and FVC than laboratory-based spirometers (Barr et al., 2008; Gerbase et al., 2013; Liistro et al., 2006). This can misclassify airflow patterns resulting in the mis/inaccurate diagnosis of respiratory disease. In chapter 3, 25% of tests were determined to be mixed airflow patterns and 25% to be restrictive airflow patterns after manual reinterpretation. These results may be inaccurate, given the previous findings in literature which showed smaller numbers for FEV₁ and FVC often occur (Barr et al., 2008; Gerbase et al., 2013; Liistro et al., 2006). It is recommended that these spirometers are removed from service and replaced. Replacement of point of care spirometers used in the Cardiac Centre has recently occurred.

2. *Training: Implementation of targeted training programs for both clinical staff performing testing and physicians interpreting the results.*

As mentioned previously training is often limited for clinical staff performing spirometry outside the Respiratory and Sleep Unit. Further training is required to increase the knowledge, skills, and confidence of the clinical staff performing spirometry testing in the Cardiac Centre. Previous studies have shown that the undertaking training programs and increasing the frequency of testing improves spirometry quality (Borg et al., 2012; Licskai et al., 2012; W. C. Tan et al., 2014). It is also important the competency is reassessed regularly to maintain skills (Borg et al., 2010).

3. *Oversight: All point of care spirometry testing at TUH is overseen and regulated by the Respiratory and Sleep Unit (RSU).*

Due to the small number respiratory scientific staff at TUH and the high outpatient demand on the unit, point of care spirometry is rarely delivered by

the RSU. However, it is recommended that the RSU be responsible for training and competency assessment for all TUH staff performing spirometry and managing all spirometer devices within the hospital including purchase requisition, maintenance, and oversight of calibration/verification logs. Initially prioritising training and device management to the Cardiac Centre is required, with future expansion to other units and wards within the hospital. This is not a novel idea, as all point of care pathology testing is managed by the Queensland Pathology Unit within the hospital. It would also align TUH with newly published TSANZ/NATA accreditation standards for Respiratory Function Laboratories (The Thoracic Society of Australia and New Zealand, 2024).

4. *Diagnostic Procedure: Creation/Update of a diagnostic procedure for case-finding CRDs in breathless cardiac inpatients on the Cardiac Centre, TUH.*

As mentioned above, it is recommended to introduce a screening questionnaire (PRECUSOR tool) as part of the diagnostic procedure to determine the patients at the greatest risk for CRDs as it may be useful in determining which breathless CVD patients are need spirometry testing most. The creation/update to a diagnostic procedure should include performing spirometry on the day of discharge, as it holds the greatest advantage as patients will be clinically stable and no contraindications should be present. If the result is an abnormal airflow pattern, patients can be referred to and followed-up by a Respiratory Physician within the RSU, including further complex lung function testing at the time of outpatient review. This minimises the ongoing inpatient costs to the health service by decreasing the length of the admission.

RESEARCH LIMITATIONS

The limitations of this thesis are mentioned within each chapter and are further discussed in this section.

1. *Limited number of studies in published literature which used the current ATS/ERS 2019 spirometry standards to assess AR.*

Despite being five years post the release of the updated standards, there are only a small number of studies which used the 2019 ATS/ERS Standard. The global COVID-19 pandemic severely limited or ceased spirometry testing in both clinical and research settings (Borg et al., 2022; Crimi et al., 2021). Further

studies are required to determine the impacts of the updated standards on spirometry quality including AR.

2. *Lack standardised reporting methodology of spirometry quality in published literature.*

Insufficient information regarding spirometry quality (tests meeting/not meeting AR criteria) was seen in 96% the study screen as part of the systematic review (Chapter 2). A generic phrase like 'testing was conducted in accordance with ATS/ERS standards' was including, however the number of participants that did not meet AR criteria were omitted from the study. It is recommended that all AR information is included in all articles using spirometry testing. By standardising the reporting methodology of spirometry in published literature, this will enable readers to determine the quality and accuracy of testing in studies, providing confidence in the reported results.

3. *Lack of specificity in Risk of Bias Assessment for spirometry testing including methodology.*

An extensive search was undertaken to determine the best risk of bias assessment tool to use for the systematic review completed in Chapter 2. Included studies used a large variety of study designs resulting in a large pool of questions for risk of bias assessment. Questions on similar themes were grouped for statistical analysis which has the potential to hide significant results. A draft spirometry specific critical appraisal assessment was developed to address the key issues (Appendix A).

4. *Calibration Verification of EasyOne Spirometers.*

As mentioned in Chapter 3 the calibration verification logs for the spirometers were unable to be obtained as part of the study. It is unknown if calibration verification procedures, including documentation of these procedures, occur outside of the RSU as no information about calibration verification was available on each patients' generated spirometry report. As per Recommendation 3, having all point of care spirometry testing overseen by the RSU would ensure that calibration verification is performed and documented to ATS/ERS and TSANZ/NATA standards.

4. Use of only pre-bronchodilator point of care spirometry.

As previously stated in Chapter 3 only pre-bronchodilator spirometry was used to assess airflow patterns as bronchodilator response testing is not routinely performed as part of point of care spirometry testing. This only allows the determination of a normal or abnormal (obstructive, restrictive, mixed) airflow pattern without the confirmation of a certain respiratory disease like COPD or Asthma. Recommendation 4 of the creation/update to a diagnostic procedure for case-finding CRDs, will allow for point of care to be used as a screening tool for disease, with referral into and follow up in the RSU upon an abnormal result. Complex lung function test (including bronchodilator response testing) will be performed at the time of outpatient review.

5. Small Sample Size in Chapter 3.

The sample size of spirometry testing in Chapter 3 was surprising low despite an extension to the initial timeframe by 3 months to a 6-month period. Post-hoc sample size analysis of agreements comparison for both spirometry quality grading and airflow pattern interpretation determined that at least 90% power was achieved for medium and large effect sizes measured. The sample size was sufficient to detect statistically significant differences between intra-rater agreement of automated vs manual assessments and the study was not underpowered.

FUTURE DIRECTIONS FOR RESEARCH

The symptom of breathlessness is multifactorial and often has a multimorbid cause. This is particularly important in this thesis given that the 94% of patients with breathlessness had cardiovascular disease with 70% having a smoking history, 59% aged over 60 years and 51% having a BMI classed as overweight or obese. A preexisting history of respiratory disease was also found in 39% of patients. The patient cohort studied in this thesis was at high-risk for the development of chronic respiratory diseases due to the high prevalence of risk factors combined with the symptom of breathlessness. Therefore, to answer the title of my thesis, Spirometry: Are we doing enough to assess breathlessness in TUH Acute Cardiac Patients?

Simply put, no. Ensuring spirometry is performed more frequently and is of good quality is imperative for the detection of CRDs in breathless cardiac patients.

Further research is required to address the following points: 1) Determining the threshold for point of care tests that should meet AR criteria, as the 90% benchmark is likely too high in this setting; 2) Determining if increased awareness and perceived importance/relevance increase use of spirometry; 3) Determining if an increase in targeted testing and training programs increase point of care spirometry quality; 4) Determining if a multidisciplinary approach to diagnosis and treat CRDs increase the use and quality of point of care spirometry; 5) Can a multidisciplinary approach for point of care spirometry be applied to other areas within TUH and more broadly into primary healthcare in North Queensland. A continuation of this research study is currently underway within the Cardiac Centre at TUH to determine if targeted training of clinical staff can increase use and quality of spirometry and how it impacts breathless patients with both underlying chronic respiratory and cardiovascular disease.

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Appendix A

Supplemental Material for Chapter 2

Search Strategies

Table 4.1: Search strategies included a combination of both Medical Subject Headings (MeSH) and Keyword terms for spirometry and quality.

Database	Search Terms (MeSH and Keywords)
Medline	(MH "Spirometry") OR (MH "Forced Expiratory Volume") OR ""accept* and (reprod* or repeat*)"" AND (MH "Quality of Health Care") OR (MH "Quality Improvement") OR (MH "Quality Assessment") OR (MH "Quality Assurance") OR (MH "Sensitivity and Specificity") OR (MH "Quality Control") OR (MH "quality indicators, health care") OR (MH "quality assurance, health care") OR (MH "Reproducibility of Results") Limiters – Published Date: 2005-2024
CINAHL	(MH "Spirometry") OR (MH "Respiratory Airflow") OR (MH "Respiratory Function Tests") OR (MH "Forced Expiratory Volume") OR ""accept* and (reprod* or repeat*)"" OR (MH "Reproducibility of Results") AND (MH "Quality of Health Care+") OR (MH "Quality Improvement") OR (MH "Quality Assessment") OR (MH "Quality Assurance") OR (MH "Quality Control") OR (MH "Sensitivity and Specificity") Limiters – Published Date: 2005-2024
Scopus	(((TITLE-ABS-KEY ("acceptability and repeatability")) OR (TITLE-ABS-KEY ("acceptability and reproducibility")) OR (TITLE-ABS-KEY ("acceptable and reproducible")) OR (TITLE-ABS-KEY ("acceptable and repeatable"))) OR ((TITLE-ABS-KEY ("sensitivity and specificity")) OR (TITLE-ABS-KEY ("quality control")) OR (TITLE-ABS-KEY ("quality of healthcare")) OR (TITLE-ABS-KEY ("quality assessment")) OR (TITLE-ABS-KEY ("quality improvement")) OR (TITLE-ABS-KEY ("quality assurance")))) AND ((TITLE-ABS-KEY ("forced expiratory volume")) OR (TITLE-ABS-KEY ("respiratory airflow")) OR (TITLE-ABS-KEY ("lung function test")) OR (TITLE-ABS-KEY ("respiratory function test")) OR (TITLE-ABS-KEY ("pulmonary function test")) OR (TITLE-ABS-KEY (spirometry))) AND (LIMIT-TO (PUBYEAR, 2024) OR LIMIT-TO (PUBYEAR, 2023) OR LIMIT-TO (PUBYEAR, 2022) OR LIMIT-TO (PUBYEAR, 2021) OR LIMIT-TO (PUBYEAR, 2020) OR LIMIT-TO (PUBYEAR, 2019) OR LIMIT-TO (PUBYEAR, 2018) OR LIMIT-TO (PUBYEAR, 2017) OR LIMIT-TO (PUBYEAR, 2016) OR LIMIT-TO (PUBYEAR, 2015) OR LIMIT-TO (PUBYEAR, 2014) OR LIMIT-TO (PUBYEAR, 2013) OR LIMIT-TO (PUBYEAR, 2012) OR LIMIT-TO (PUBYEAR, 2011) OR LIMIT-TO (PUBYEAR, 2010) OR LIMIT-TO (PUBYEAR, 2009) OR LIMIT-TO (PUBYEAR, 2008) OR LIMIT-TO (PUBYEAR, 2007) OR LIMIT-TO (PUBYEAR, 2006) OR LIMIT-TO (PUBYEAR , 2005))

Data Extraction Template

Table 4.2: Data Extraction Template with example.

Reference code	First Author & Year	Language	Year of Data collection	Country	Continent	Cohort setting	Number of participants	Age group	Health status	Spirometer used	Standard used	Overall %AR	Study design
1	(Abbasi et al., 2012)	English	2009	Pakistan	Asia	Primary care	200	Adult	Asthma /NAD	Flow (Vitalograph New Alpha 6000)	ATS/ERS 2005	94.00%	Cross-sectional prevalence

Included study characteristics

Table 4.3: Characteristics of included studies (N = 337).

Number	Author & Year	Continent	No. participants	Standard	Age Class	Cohort	Disease	Spirometer	%AR
1	(Abbasi et al., 2012)	AS	200	ATS/ERS 2005	Adult	Primary Care	Asthma/No lung disease	Vitalograph New Alpha 6000 (Pn)	94.00%
2	(Adams et al., 2018)	AF	642	ERS 1993	Adult	Occupational	Asthma	Vitalograph S (WB)	90.65%
3	(Akpınar-Elci et al., 2006)	NA	1143	ATS 1994	Adult/Elderly	Occupational	Lung Disease/No lung disease	Ohio 827 (DRS)	99.65%
4	(Aksu et al., 2020)	AS	510	ATS/ERS 2005	All	Hospital Based	Lung Disease/No lung disease	Unknown	62.40%
5	(Al Ghobain et al., 2015)	AS	784	ATS 1994	Adult/Elderly	Population Based	COPD/No lung disease	ndd EasyOne (U)	89.17%
6	(Al-Qerem, 2021)	AS	1744	ATS/ERS 2019	Paediatric	School Based	No lung disease	MIR Spirobank II (T)	90.37%
7	(Al-Qerem & Jarab, 2021)	AS	1118	ATS/ERS 2007	Paediatric	School Based	No lung disease	MIR Minispir (T)	68.40%
8	(Albuquerque et al., 2015)	SA	99	ATS/ERS 2005	Adult	Hospital Based	Obesity/No lung disease	Jaeger MasterScreen (Pn)	85.86%
9	(Alexandraki et al., 2010)	EU	453	ATS 1994	Paediatric	School Based	No lung disease	MIR Spirolab II (T)	91.39%
10	(Allan et al., 2010)	EU	52	ATS/ERS 2005	Adult	Occupational	Asthma/No lung disease	Unknown	85.50%
11	(Allen et al., 2010)	EU	83	ATS/ERS 2005	Elderly	Hospital Based	Cognitive Impairment	Micro Direct Microlabs 3000 (T)	53.01%

12	(Allen & Yeung, 2006)	EU	80	ATS 1994	Elderly	Hospital Based	Cognitive Impairment	Micro Direct Microlabs 3000 (T)	22.00%
13	(Allen et al., 2008)	EU	267	ATS 1994	Adult/Elderly	Hospital Based	Cognitive Impairment	Micro Direct Microlabs 3000 (T), Vitalograph Compact (Pn)	51.00%
14	(Allen & Baxter, 2009)	EU	113	ATS 1994	Elderly	Hospital Based	Cognitive Impairment	Micro Direct Microlabs 3000 (T)	43.00%
15	(Amaral et al., 2016)	EU	250533	ATS/ERS 2005	Adult/Elderly	Population Based	Lung Disease/No lung disease	Vitalograph Pneumotrac 6800 (Pn)	61.27%
16	(Andreeva et al., 2015)	EU	3119	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	MIR Spirobank (T)	95.35%
17	(Araya et al., 2005)	SA	1208	ATS 1994	Adult/Elderly	Population Based	COPD	ndd EasyOne (U)	92.20%
18	(Arigliani et al., 2017)	AF	1258	ATS/ERS 2005	Paediatric	Population Based	No lung disease	Cosmed Pony FX (T)	86.80%
19	(Arnall et al., 2009)	NA	571	ATS 1994	Paediatric	School Based	No lung disease	Ferraris Respiratory Flow-sensing (Unknown)	97.72%
20	(Arne et al., 2010)	EU	207	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD	Different Flow-sensing spirometers (Pn, U, T)	55.00%
21	(Au-Doung et al., 2022)	AS	377	ATS/ERS 2019	Adult/Elderly	Primary Care	COPD/No lung disease	MIR Spirolab (T)	98.94%
22	(Aurora et al., 2011)	EU	93	ATS/ERS 2007	Paediatric	Population Based	Cystic Fibrosis/No lung disease	Jaeger MasterScope (Pn)	74.19%
23	(Averame et al., 2009)	EU	9312	ATS 1994	Adult/Elderly	Primary Care	Asthma/COPD/No lung disease	MIR Spirotel (Pn)	77.99%
24	(Baranski & Zejda, 2022)	EU	441	ATS/ERS 2019	Paediatric	Primary Care	Asthma	ndd EasyOne Air (U)	79.37%
25	(Barbara et al., 2013)	EU	745	ATS 1994	Adult/Elderly	Population Based	COPD/No lung disease	ndd EasyOne (U)	95.30%
26	(Bell et al., 2022)	OC	74	ATS/ERS 2019	Adult	Home Care	Cystic Fibrosis	NuvoAir Air-Next (T), Inofab Spirohome (U)	94.00%
27	(Bellia et al., 2008)	EU	1971	ATS 1994	Elderly	Population Based	Lung Disease/No lung disease	Baires System Volumetric (Stead-Well)	81.87%
28	(Belo et al., 2018)	EU	307	ATS/ERS 2005	Elderly	Hospital Based	No lung disease	Vitalograph Compact (Pn)	85.34%
29	(Berntsen et al., 2016)	EU	50	ATS/ERS 2005	Adult/Elderly	Hospital Based	No lung disease	Jaeger MasterScreen (Pn), SensorMedics Mass Flow (HWA), Micro Medical SpiroUSB (U), Oxycon Pro (T)	67.00%
30	(Blake et al., 2020)	OC	1278	ATS/ERS 2005	Paediatric/Adult	Population Based	Lung Disease/No lung disease	ndd Easy on-pc (U)	86.54%

31	(Bonavia et al., 2009)	EU	296	ATS 1994 ^a	Adult/Elderly	Primary Care	Asthma/COPD/No lung disease	MIR Spirotel (Pn)	48.50%
32	(Borg et al., 2010)	OC	15	ATS 1994	Adult/Elderly	Primary Care	Lung Disease/No lung disease	QRS Diagnostic Spirocard (T), Micro Medical (T)	55.70%
33	(Borg et al., 2012)	OC	707	ATS/ERS 2005	Adult/Elderly	Hospital Based	Lung Disease/No lung disease	Medgraphics Elite and Profiler systems (flow), Micro Medical (T), Jaeger MasterScreen (Pn), SensorMedics Vmax (DRS), SensorMedics Mass Flow (HWA)	77.50%
34	(Borrego et al., 2013)	EU	88	ATS/ERS 2007	Paediatric	Hospital Based	Asthma/No lung disease	Jaeger MasterScreen Body (Pn)	73.86%
35	(Boutin et al., 2015)	EU	139	ATS/ERS 2005	Paediatric	Birth Cohort	Asthma/No lung disease	Medisoft body plethysmograph (Pn)	84.10%
36	(Brozek et al., 2018)	EU	78	ATS/ERS 2005	Paediatric	School Based	No lung disease	ndd EasyOne (U)	62.10%
37	(Brumback et al., 2013)	NA	60	ATS/ERS 2007	Paediatric	Hospital Based	Cystic Fibrosis	nSpire Koko (Pn)	75.00%
38	(Buist et al., 2007)	INT	9425	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	ndd EasyOne (U)	93.10%
39	(Bunge et al., 2018)	EU	108	ATS/ERS 2005	Adult/Elderly	Primary Care	Lung Disease/No lung disease	MIR Minispir light (T)	72.00%
40	(Burgos et al., 2012)	EU	4581	ATS/ERS 2005	Adult/Elderly	Primary Care	Lung Disease/No lung disease	ndd EasyOne (U), Sibel DatoSpir 110 (Pn)	65.50%
41	(Burity et al., 2011)	SA	240	ATS 1994	Paediatric	Primary Care	No lung disease	Creative Biomedics MultiSPIRO (Pn)	46.50%
42	(Burity et al., 2016)	SA	266	ATS/ERS 2007	Paediatric	Primary Care	No lung disease	nSpire Koko (Pn)	60.00%
43	(Busi et al., 2017)	SA	720	ATS/ERS 2007	Paediatric	Hospital Based	Asthma/No lung disease	Unknown	77.40%
44	(Calle Rubio et al., 2017)	EU	5202	Unknown	Adult/Elderly	Hospital Based	COPD	Unknown	86.66%
45	(Canals-Borrajó et al., 2010)	EU	212	SEPAR 2001	Adult	Primary Care	COPD/No lung disease	Sibel DatoSpir 120 (Pn)	84.40%
46	(Capozzolo et al., 2017)	EU	2001	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	MIR Spirolab II (T)	95.95%
47	(Carr et al., 2011)	EU	89	ATS/ERS 2005	All	Primary Care	Lung Disease/No lung disease	Unknown	80.00%
48	(Casas Herrera et al., 2016)	SA	1743	ATS 1994	Adult/Elderly	Primary Care	COPD	ndd EasyOne (U)	88.35%
49	(Castillo et al., 2015)	EU	1423	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	ndd EasyOne (U)	69.40%

50	(Castillo et al., 2009)	EU	86	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	ndd EasyOne (U)	73.00%
51	(Caussade et al., 2015)	SA	1674	ATS/ERS 2005	Paediatric	School Based	No lung disease	Schiller SP100 (Pn)	94.92%
52	(Cawley & Warning, 2018)	NA	119	ATS/ERS 2005	Adult/Elderly	Primary Care	Lung Disease/No lung disease	Unknown	87.00%
53	(Chaiwong et al., 2020)	AS	134	ATS/ERS 2005	Adult/Elderly	Hospital Based	COPD/No lung disease	SensorMedics Vmax Encore 22 Mass Flow (HWA)	89.63%
54	(Chaiwong et al., 2022)	AS	202	ATS/ERS 2005	Adult/Elderly	Hospital Based	Asthma	SensorMedics Vmax Encore 22 Mass Flow (HWA)	98.02%
55	(Chaiwong et al., 2019)	AS	2745	ATS/ERS 2005	Adult/Elderly	Hospital Based	Lung Disease/No lung disease	SensorMedics Vmax Encore 22 Mass Flow (HWA)	90.78%
56	(Chakrabarti et al., 2011)	AS	416	ATS/ERS 2005	Adult/Elderly	Primary Care	Lung Disease/No lung disease	Medikro SpiroStar (Pn)	69.00%
57	(Chan et al., 2023)	AS	917	ATS/ERS 2005	Paediatric	School Based	No lung disease	MIR Spirobank G (T)	96.62%
58	(Checkley et al., 2010)	AS	1322	ATS 1994	Paediatric	Primary Care	No lung disease	Jaeger SpiroPro (Pn)	96.00%
59	(Chen et al., 2018)	AS	241	ATS/ERS 2005	Adult/Elderly	Hospital Based	Lung Disease/No lung disease	Elite DX (Pi), IQspiro (Pn)	79.50%
60	(Chen et al., 2021)	AS	1650	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	Jaeger MasterScreen (Pn)	90.00%
61	(Chinn et al., 2006)	INT	21503	ATS 1994	Adult	Population Based	No lung disease	Biomedin, SensorMedics, Spirotech, Jaeger Pneumotach (Pn), Morgan, Morgan Pneumotach (Pn), Massach Pneumotach (Pn), Vitalograph	96.60%
62	(Christmann et al., 2010)	EU	64	ATS/ERS 2007	Paediatric	Hospital Based	Asthma	Jaeger MasterScreen (Pn)	81.05%
63	(Christopher et al., 2020)	AS	1015	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	ndd EasyOne air (U)	77.54%
64	(Clark et al., 2013)	NA	237	ATS/ERS 2005	All	Primary Care	Lung Disease/No lung disease	Unknown	92.83%
65	(Collaro, Chang, Marchant, Chatfield, Vicendese, et al., 2021)	OC	1276	ATS/ERS 2019	Paediatric /Adult	School Based	Pneumonia/No lung disease	ndd Easy on-pc (U)	72.18%
66	(Constant et al., 2011)	EU	313	ATS/ERS 2005	Paediatric	School Based	Asthma/No lung disease	Micro Medical Microlab (T)	54.00%

67	(Cooksley et al., 2015)	OC	813	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	ndd EasyOne (U)	86.59%
68	(Cristea et al., 2015)	NA	26	ATS/ERS 2005	Paediatric	Hospital Based	Bronchopulmonary Dysplasia	Unknown	82.01%
69	(Cushen et al., 2016)	EU	65	ATS/ERS 2005	Elderly	Home Care	COPD	Micro Medical Microlab (T)	67.30%
70	(Czajkowska-Malinowska et al., 2013)	EU	1271	ATS/ERS 2005	Elderly	Hospital Based	Asthma/COPD	Jaeger MasterScreen (Pn)	33.40%
71	(Dahne et al., 2022)	NA	49	Unknown	Adult/Elderly	Home Care	COPD/No lung disease	Vitalograph asma-1 (T)	79.60%
72	(Dales et al., 2006)	NA	1046	ATS 1994	Adult/Elderly	Primary Care	Asthma/COPD/No lung disease	Micro Medical Microlab 3500 (T)	98.85%
73	(Dalziel et al., 2006)	AS	456	ERS 1993	Adult	Clinical Trial	Asthma/No lung disease	Micro Medical Microlab 3500 (T)	84.00%
74	(Das et al., 2020)	NA	7154	ATS/ERS 2005	All	Population Based	No lung disease	Volume sensing (DRS)	54.00%
75	(Davis et al., 2022)	NA	50	ATS/ERS 2019	Paediatric/ Adult	Home Care	Cystic Fibrosis	NuvoAir Air-Next (T) and MIR Spirobank (T)	46.50%
76	(de Ávila Cabezon et al., 2013)	SA	300	ATS/ERS 2005, SEPAR 2001	All	Primary Care	Asthma/COPD	Unknown	37.35%
77	(de la Hoz et al., 2020)	NA	22571	ATS/ERS 2005	Adult/Elderly	Occupational	Lung Disease/No lung disease	ndd EasyOne (U)	80.45%
78	(De Matteis et al., 2019)	EU	116375	ATS/ERS 2005	Adult/Elderly	Occupational	COPD/No lung disease	Vitalograph Pneumotrac 6800 (Pn)	81.25%
79	(Demirci et al., 2017)	AS	357	Unknown	Adult/Elderly	Primary Care	COPD/No lung disease	Unknown	99.20%
80	(Devakumar et al., 2015)	AS	841	ATS/ERS 2005	Paediatric	Clinical Trial	Lung Disease/No lung disease	ndd EasyOne (U)	94.29%
81	(Dominguez-Martin et al., 2023)	EU	154	ATS/ERS 2019	Paediatric	Hospital Based	Asthma	Vitalograph Pneumotrac (Pn)	81.80%
82	(Donaire et al., 2015)	SA	93	ATS/ERS 2007	Paediatric	Hospital Based	Lung Disease/No lung disease	Schiller SP-100 (Pn)	47.00%
83	(Doumit et al., 2022)	OC	80	ATS/ERS 2019	Paediatric	Home Care	Asthma/ Bronchiectasis/ Cystic Fibrosis	Jaeger Vyntus Spiro (Pn), Inofab Spirohome (U)	89.00%
84	(Duong et al., 2019)	NA	164162	ATS/ERS 2005	Adult/Elderly	Population Based	Lung Disease/No lung disease	Micro Medical microGP (T)	76.97%

85	(Enache et al., 2017)	EU	256	ATS/ERS 2005	Adult/Elderly	Hospital Based	Amyotrophic lateral sclerosis	Unknown	96.70%
86	(Enright et al., 2010)	NA	13599	ATS/ERS 2005	Adult	Occupational	Lung Disease/No lung disease	ndd EasyOne (U)	80.00%
87	(Esendagli et al., 2022)	AS	440	ATS/ERS 2005	Adult/Elderly	Hospital Based	Lung Disease/No lung disease	Micro Medical Microlab (T)	74.95%
88	(Fathima et al., 2017)	OC	167	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	nSpire PiKo-6 (T)	98.13%
89	(Fawke et al., 2010)	EU	388	ATS/ERS 2005	Paediatric	Primary Care	Bronchopulmonary Dysplasia/No lung disease	Jaeger MasterScope (Pn)	89.19%
90	(Fernandez-Plata et al., 2019)	NA	302	ATS/ERS 2007	Paediatric/ Adult	School Based	Down's Syndrome	ndd EasyOne Pro (U)	5.70%
91	(Fernandez-Villar et al., 2018)	EU	179	SEPAR 2013	Adult/Elderly	Hospital Based	COPD	Sibel DatoSpir 120 (Pn)	95.00%
92	(Fettes et al., 2022)	EU	61	ATS/ERS 2019	Paediatric	Home Care	Cystic Fibrosis	NuvoAir Home platform (T)	81.80%
93	(Franca et al., 2016)	SA	195	ATS/ERS 2007	Paediatric	School Based	No lung disease	nSpire KoKo (Pn)	85.00%
94	(Frank et al., 2006)	EU	871	Unknown	Adult/Elderly	Primary Care	COPD/No lung disease	Micro Medical Microlab (T)	94.70%
95	(Friedrich et al., 2016)	SA	148	ATS/ERS 2005	Paediatric	School Based	Lung Disease/No lung disease	nSpire Koko (Pn)	91.20%
96	(Frohnhofer et al., 2011)	EU	1421	Unknown	Elderly	Hospital Based	Cognitive Impairment	Unknown	45.00%
97	(Fuller et al., 2012)	NA	185	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	ndd EasyOne (U)	94.59%
98	(Fung et al., 2019)	NA	49	ATS/ERS 2005	Adult/Elderly	Population Based	Asthma/COPD/No lung disease	MIR Spirolab II (T)	87.76%
99	(Gaffin et al., 2010)	NA	248	ATS/ERS 2007	Paediatric	Hospital Based	Asthma/Cystic Fibrosis	Volume sensing (DRS), Morgan Scientific Flow sensing (Pn)	54.40%
100	(García et al., 2011)	SA	32	ATS/ERS 2005	Paediatric	Population Based	Cystic Fibrosis	H&C Pneumos 300 (Pn)	43.75%
101	(Gerbase et al., 2013)	EU	82	ATS/ERS 2005	Paediatric/ Adult	Population Based	No lung disease	SensorMedics SM2200 (HWA), ndd EasyOne (U)	89.25%
102	(Gillette et al., 2011)	NA	97	ATS/ERS 2005	Paediatric	Primary Care	Asthma	Unknown	25.38%
103	(Giner et al., 2014)	EU	257	ATS/ERS 2005	Adult/Elderly	Hospital Based	Asthma/COPD/No lung disease	Sibel DatoSpir 600 (Pn)	90.70%
104	(Girardot et al., 2006)	NA	721	ATS 1994	Adult/Elderly	Occupational	Asthma/No lung disease	Tyco Healthcare Puritan-Bennett Renaissance II (Pn)	50.90%

105	(Giraud et al., 2016)	EU	142	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	MIR Spirodoc (T)	58.50%
106	(Gleeson et al., 2006)	NA	100	ATS 1994	Adult/Elderly	Hospital Based	Lung Disease/No lung disease	Collins GS Volumetric (Stead-Well)	63.00%
107	(Gochicoa-Rangel et al., 2013)	NA	376	ATS/ERS 2007	Paediatric	Hospital Based	Asthma	SensorMedics Vmax (DRS)	68.00%
108	(Grzetic-Romcevic et al., 2011)	EU	815	ATS 1994	Adult/Elderly	Population Based	COPD/No lung disease	Jaeger MasterScreen (Pn)	94.48%
109	(Guarnieri et al., 2015)	NA	306	ATS 1994	Adult	Occupational	COPD/No lung disease	Micro Medics Microloop (T), ndd EasyOne (U)	90.47%
110	(Gunawardana et al., 2023)	EU	47	ATS/ERS 2019	Paediatric	Hospital Based	Asthma	Jaeger MasterScreen (Pn)	68.00%
111	(Gupta et al., 2016)	NA	418	ATS/ERS 2005	All	Primary Care	Asthma	Unknown	37.80%
112	(Hamers et al., 2006)	SA	157	ATS 1994	All	Primary Care	COPD	Micro Medics Microlab (T)	90.45%
113	(Hampson et al., 2017)	NA	134	ATS/ERS 2005	Adult/Elderly	Clinical Trial	Cognitive Impairment	Vitalograph Pneumotrac 6800 (Pn)	66.42%
114	(Hankinson et al., 2015)	NA	7777	ATS/ERS 2005	All	Population Based	No lung disease	Volume sensing (DRS)	93.00%
115	(Haynes, 2014)	NA	150	ATS/ERS 2005	Adult/Elderly	Hospital Based	COPD/No lung disease	Morgan Scientific CompPAS (Pn)	92.00%
116	(Hegewald et al., 2007)	NA	2863	ATS 1994	Elderly	Population Based	No lung disease	Volume sensing (DRS)	87.71%
117	(Hegewald et al., 2016)	NA	153	ATS/ERS 2005	All	Primary Care	COPD/No lung disease	nSpire KoKo (Pn), ndd EasyOne (U), SDI Diagnostics Astra 300 (T)	60.00%
118	(Herpel et al., 2006)	NA	7101	ATS 1994	Adult/Elderly	Clinical Trial	COPD	Unknown	90.00%
119	(Higbee et al., 2022)	EU	29609	Other	Adult/Elderly	Population Based	Asthma/COPD	Vitalograph Pneumotrac 6800 (Pn)	84.09%
120	(Hill et al., 2010)	NA	1036	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	Unknown	96.81%
121	(Hnizdo et al., 2011)	NA	2043	ATS/ERS 2005	Adult	Occupational	No lung disease	Volume sensing (DRS)	95.00%
122	(Huetto et al., 2006)	EU	171	ATS 1994	Adult/Elderly	Primary Care	Asthma/COPD/No lung disease	Sibel DatoSpir 100 (Pn)	42.10%
123	(Huls et al., 2013)	EU	3133	ATS/ERS 2005	Paediatric	School Based	No lung disease	ndd EasyOne (U)	62.02%
124	(Humphrey et al., 2020)	NA	263	ATS/ERS 2005	All	Primary Care	Lung Disease/No lung disease	ndd EasyOne (U)	53.61%

125	(Hwang et al., 2009)	AS	4816	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	Unknown	56.64%
126	(Hwang et al., 2011)	AS	10523	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	SensorMedics Vmax 2130 (DRS)	65.89%
127	(Idolor et al., 2011)	AS	991	ATS 1994	Adult/Elderly	Population Based	COPD/No lung disease	ndd EasyOne (U)	72.86%
128	(Ioachimescu et al., 2005)	NA	400	ATS 1994	Adult/Elderly	Hospital Based	Lung disease/No lung disease	Jaeger Master Lab Pro (Pn)	82.50%
129	(Islam et al., 2022)	AS	1232	ATS/ERS 2007	Paediatric	Primary Care	Asthma/No lung Disease	ndd EasyOne (U)	88.60%
130	(Ivanova et al., 2020)	AF	212	ATS/ERS 2005	Adult/Elderly	Population Based	No lung disease	ndd EasyOne (U)	73.11%
131	(Iversen et al., 2010)	EU	532	ERS 1993	Adult/Elderly	Clinical Trial	COPD/Heart Disease	Micro Medical Microlab 3300 (T)	95.30%
132	(Jacobs et al., 2014)	EU	3538	ATS/ERS 2005	Paediatric	School Based	Microbial Exposure/No lung disease	ndd EasyOne (U)	77.05%
133	(Jankowski et al., 2021)	EU	9855	ATS/ERS 2005	Adult	Primary Care	COPD/No lung disease	Healthup AioCare (Pn)	49.00%
134	(Janssens et al., 2013)	INT	5993	ATS 1994	Adult/Elderly	Clinical Trial	COPD	nSpire KoKo (Pn)	93.00%
135	(Jarhyan et al., 2021)	AS	284	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	Vitalograph 4000 (Pn), ndd EasyOne (U)	94.00%
136	(Jedrychowski et al., 2010)	EU	258	ATS/ERS 2007	Paediatric	Birth Cohort	Wheeze/No lung disease	QRS SpiroCard PC (T)	54.94%
137	(Jeng et al., 2009)	AS	248	ATS 1994	Paediatric	School Based	No lung disease	Spiroware Exhalyzer S (U)	86.00%
138	(Jensen et al., 2006)	NA	3539	ATS 1987	Adult/Elderly	Primary Care	Lung Disease/No lung disease	Collins Survey II Volumetric (Water Sealed)	96.02%
139	(Jian et al., 2017)	AS	7335	ATS/ERS 2005	All	Population Based	No lung disease	Unknown	97.00%
140	(Jiang et al., 2019)	AS	3120	ATS/ERS 2005	Adult	Hospital Based	COPD/No lung disease	Unknown	50.40%
141	(Jimenez Ortega et al., 2011)	EU	49	ATS/ERS 2007	Paediatric	Hospital Based	Community Acquired Pneumonia	Jaeger Masterlab (Pn)	85.70%
142	(Johnston et al., 2016)	SA	454	ATS/ERS 2005	All	Hospital Based	Asthma/COPD/No lung disease	ndd Easy on-pc (U)	80.40%
143	(Jones et al., 2008)	EU	619	Unknown	Adult/Elderly	Primary Care	COPD/No lung disease	Micro Medical Microlab 3500 (T), Micro Medical Microlab 3300 (T)	93.70%
144	(Kampschmidt et al., 2016)	NA	200	ATS/ERS 2007	Paediatric	Primary Care	Asthma/No lung disease	ndd Easy on PC (U)	60.00%

145	(Kart et al., 2014)	AS	694	ATS/ERS 2005	Adult	Hospital Based	COPD/No lung disease	MIR Spirolab (T)	93.40%
146	(Kattan et al., 2018)	NA	479	ATS/ERS 2007	Paediatric	Birth Cohort	Asthma/No lung disease	Jaeger MasterScreen (Pn)	78.33%
147	(Kaur et al., 2019)	AS	449	ATS/ERS 2019	Adult/Elderly	Primary Care	COPD/No lung disease	MIR Spirolab (T)	87.30%
148	(Keeratchananont et al., 2016)	AS	64	Unknown	Adult/Elderly	Hospital Based	Preoperative pulmonary evaluation	Unknown	96.88%
149	(Khosa et al., 2020)	AF	64	ATS/ERS 2005	Adult	Hospital Based	Tuberculosis	ndd EasyOne (U)	96.88%
150	(Kilci et al., 2021)	AS	60	ATS/ERS 2019	Paediatric	Hospital Based	Nephrotic Syndrome/No lung disease	nSpire Flowhandy ZAN100 (Pn)	75.00%
151	(Kimura et al., 2011)	AS	3761	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	Chestgraph Jr HI-101 (U)	75.22%
152	(Kinghorn et al., 2020)	NA	154	ATS/ERS 2005	Paediatric	Hospital Based	Cystic Fibrosis/ Primary Ciliary Dyskinesia/No lung disease	Unknown	94.00%
153	(Kinnula et al., 2011)	EU	13517	FRS 2006	Adult/Elderly	Primary Care	COPD	Unknown	88.50%
154	(Kirkby et al., 2016)	EU	781	ATS/ERS 2005	Paediatric	School Based	No lung disease	ndd Easy on-pc (U)	97.06%
155	(Kjaer et al., 2008)	EU	404	ATS/ERS 2005	Paediatric	Birth Cohort	Asthma/No lung disease	Micro Medics Microloop (T)	95.30%
156	(Knudsen et al., 2011)	AF	365	ATS/ERS 2005	All	Population Based	No lung disease	ndd EasyOne (U)	89.32%
157	(Ko et al., 2008)	AS	1149	ATS/ERS 2005	Elderly	Primary Care	COPD/No lung disease	Micro Medics Microlab 3300 (T)	87.70%
158	(Komal et al., 2019)	EU	184	SEPAR 2013	Elderly	Hospital Based	Chronic Diseases (incl. lung diseases)	Vitalograph 4000 (Pn), Sibel DatoSpir micro (Pn)	25.54%
159	(Komarow et al., 2012)	NA	117	ATS/ERS 2007	Paediatric	Hospital Based	Asthma/No lung disease	SensorMedics Vmax Encore 20C (HWA)	71.79%
160	(Konstantikaki et al., 2011)	EU	1221	ATS 1994	Adult/Elderly	Primary Care	COPD/No lung disease	nSpire KoKo (Pn)	90.58%
161	(Kotz et al., 2008)	EU	826	ATS/ERS 2005	Adult/Elderly	Clinical Trial	COPD/No lung disease	Vitalograph 2120 (Pn)	86.68%
162	(Koul et al., 2016)	AS	953	ATS 1994	Adult/Elderly	Population Based	COPD/No lung disease	ndd EasyOne (U)	79.43%
163	(Kozłowska et al., 2008)	EU	87	ATS/ERS 2007	Paediatric	Hospital Based	Cystic Fibrosis/No lung disease	Jaeger Masterscope (Pn)	93.10%

164	(Kruizinga et al., 2021)	EU	126	ATS/ERS 2019	Paediatric	Clinical Trial	No lung disease	NuvoAir Air-Next (T)	43.00%
165	(Kruizinga et al., 2020)	EU	58	ATS/ERS 2019	Paediatric	Home Care	Asthma/Cystic Fibrosis	MasterScreen Body Jaeger (Pn)	43.00%
166	(Kumar et al., 2021)	AS	449	ATS/ERS 2005	Elderly	Primary Care	COPD/No lung disease	MIR Spirolab (T)	87.31%
167	(Kupczyk et al., 2021)	EU	78	ATS/ERS 2005	Adult	Home Care	Asthma	Healthup AioCare (Pn)	56.00%
168	(Kuziemski et al., 2009)	EU	222	ATS 1994	Adult/Elderly	Primary Care	COPD	ndd EasyOne (U)	57.00%
169	(Lamprecht et al., 2007)	EU	1349	ATS 1994	Adult/Elderly	Primary Care	COPD/No lung disease	ndd EasyOne (U)	93.00%
170	(Landman et al., 2011)	EU	282	ATS/ERS 2005	Adult/Elderly	Primary Care	Lung Disease/No lung disease	Welch Allyn SpiroPerfect (Pn)	46.10%
171	(Langhan & Spiro, 2009)	NA	34	Unknown	Paediatric/Adult	Hospital Based	Asthma	ndd EasyOne (U)	73.00%
172	(Laniado-Laborin et al., 2011)	SA	2617	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	ndd EasyOne (U)	87.62%
173	(Lawrence et al., 2021)	NA	10019	ATS/ERS 2005	Adult/Elderly	Home Care	Lung Disease/No lung disease	ndd Easy on-pc (U)	75.00%
174	(Lee et al., 2015)	AS	21573	ATS/ERS 2005	Adult/Elderly	Population Based	Restrictive Lung Disease	SensorMedics 2130 (DRS)	69.90%
175	(Lehmann et al., 2007)	EU	3506	ATS 1994	Adult/Elderly	Primary Care	No lung disease	Unknown	94.27%
176	(Lei Burton et al., 2015)	OC	892	ATS/ERS 2005	Adult/Elderly	Primary Care	Asthma	ndd EasyOne (U)	68.50%
177	(Leung et al., 2021)	NA	5176	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	ndd EasyOne (U)	94.53%
178	(Leung et al., 2013)	AS	1909	ATS/ERS 2007	Paediatric	School Based	No lung disease	Jaeger MasterScreen (Pn)	73.40%
179	(Leuppi et al., 2010)	EU	29817	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	ndd EasyOne (U)	60.40%
180	(Liciskai et al., 2012)	NA	2196	ATS/ERS 2005	All	Primary Care	Asthma	Jaeger Masterscope (Pn), SensorMedics Vmax (DRS)	75.80%
181	(Linares et al., 2006)	SA	77	ATS 1994	Paediatric	Hospital Based	No lung disease	Jaeger MasterScreen (Pn)	93.50%
182	(Linares Passerini et al., 2014)	SA	96	ATS/ERS 2007	Paediatric	Hospital Based	Asthma/No lung disease	Jaeger MasterScreen (Pn)	94.50%
183	(Lo et al., 2020)	EU	612	ATS/ERS 2005	Paediatric	Primary Care	Asthma	Unknown	94.00%

184	(Loeb et al., 2008)	NA	393	ATS/ERS 2005	Paediatric	Hospital Based	No lung disease	Sensormedics (HWA)	74.00%
185	(Logie et al., 2020)	OC	22	ATS/ERS 2005	Paediatric	Home Care	Cystic Fibrosis	Micro Medical SpiroUSB (U)	93.22%
186	(Loh et al., 2016)	AS	713	ATS 1994	Adult/Elderly	Population Based	COPD/No lung disease	ndd EasyOne (U)	92.99%
187	(Lopez Varela et al., 2016)	SA	1743	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	ndd EasyOne (U)	88.35%
188	(Lorenzo Hernandez et al., 2017)	EU	54	Unknown	Elderly	Hospital Based	Lung Disease/No lung disease	nSpire PiKo-6 (T)	64.81%
189	(Loth et al., 2013)	EU	6959	ATS/ERS 2005	Adult/Elderly	Population Based	No lung disease	Jaeger SpiroPro (Pn), Jaeger MasterScreen (Pn)	62.14%
190	(Lucas et al., 2009)	EU	72	ATS/ERS 2005	Adult/Elderly	Primary Care	Asthma/COPD/No lung disease	Unknown	98.08%
191	(Lum et al., 2015)	EU	2025	ATS/ERS 2007	Paediatric	School Based	No lung disease	Unknown	93.88%
192	(Lundberg et al., 2020)	EU	172	ATS/ERS 2005	Paediatric	Birth Cohort	Bronchopulmonary Dysplasia/No lung disease	Jaeger MasterScreen (Pn)	59.88%
193	(Lundgren et al., 2007)	SA	89	ATS 1987	Adult/Elderly	Primary Care	COPD/No lung disease	Micro Medics Microloop 3535 (T)	84.27%
194	(Luoto et al., 2016)	EU	2592	ATS 1994	Elderly	Population Based	COPD/No lung disease	Vitalograph 2120 (Pn)	86.32%
195	(Magitta et al., 2018)	AF	496	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	ndd EasyOne (U)	98.00%
196	(Mahboub et al., 2014)	AS	577	Unknown	Adult/Elderly	Primary Care	COPD/No lung disease	Vitalograph Alpha & One Alpha (Pn)	91.00%
197	(Maio et al., 2012)	EU	12448	ERS 1993	Adult/Elderly	Other	COPD/No lung disease	ndd EasyOne (U)	83.50%
198	(Mangione-Smith et al., 2017)	NA	3116	ATS/ERS 2005	Paediatric	Primary Care	Asthma	ndd EasyOne (U)	38.40%
199	(Mapel et al., 2015)	NA	891	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD	Micro Medical Microloop (T)	74.97%
200	(Marina et al., 2016)	EU	1894	ATS/ERS 2005	Adult/Elderly	Primary Care	Asthma/COPD	Unknown	71.30%
201	(Marina Malanda et al., 2014)	EU	7200	ATS/ERS 2005	Adult/Elderly	Primary Care	Asthma/COPD	ndd EasyOne (U), Sibel Datospir (Pn)	75.00%
202	(Marquez-Martin et al., 2015)	EU	Unknown	ATS/ERS 2005,	Adult/Elderly	Primary Care	Asthma/COPD/No lung disease	Different Flow-sensing spirometers (Pn, T)	90.25%

				SEPAR 2001					
203	(Martin de Vicente et al., 2018)	EU	380	ATS/ERS 2007	Paediatric	School Based	No lung disease	Masterscreen Pneumo (Pn)	69.50%
204	(Martinez Eizaguirre et al., 2008)	EU	300	ATS 1994	All	Primary Care	Lung Disease/No lung disease	Unknown	38.50%
205	(Martinez et al., 2008)	NA	697	ATS 1994	Adult/Elderly	Primary Care	COPD	Unknown	42.32%
206	(Martins et al., 2023)	SA	858	ATS/ERS 2019	Paediatric	Population Based	No lung disease	MIR Spirolab (T)	56.10%
207	(Martins et al., 2022)	SA	1217	ATS/ERS 2005	Adult/Elderly	Primary Care	Asthma/COPD/No lung disease	ndd Easy on PC (U)	97.95%
208	(Masa et al., 2011)	EU	261	ATS/ERS 2005	All	Hospital Based	Asthma/COPD/No lung disease	SensorMedics Vmax Encore 20 (HWA)	84.65%
209	(Mascarenhas et al., 2011)	EU	2003	ATS/ERS 2005	Adult/Elderly	Population Based	Obstructive Lung Disease/No lung disease	MIR Spirolab II (T)	37.84%
210	(McEvoy et al., 2023)	NA	213	ATS/ERS 2007	Paediatric	Clinical Trial	No lung disease	Vitalograph Pneumotrac 6800 (Pn)	98.00%
211	(McKibben et al., 2011)	NA	1719	ATS/ERS 2005	Adult/Elderly	Occupational	No lung disease	SensorMedics 922 (DRS)	53.30%
212	(Meghji et al., 2016)	AF	1059	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	ndd EasyOne (U)	70.70%
213	(Melbye et al., 2006)	EU	4102	ATS 1994	Elderly	Population Based	Asthma/COPD/No lung disease	SensorMedics Vmax Encore 20 (HWA)	94.44%
214	(Melo et al., 2019)	SA	25	ATS 1994	Elderly	Hospital Based	Lung/ Cardiovascular/ Cerebrovascular disease	Micro Medical Microlab 3500 (T)	74.00%
215	(Menezes et al., 2014)	SA	2110	ATS/ERS 2005	Adult/Elderly	Population Based	COPD	ndd EasyOne (U)	80.00%
216	(Minas et al., 2010)	EU	1715	ATS 1994	Adult/Elderly	Primary Care	COPD	nSpire Koko Legend (Pn)	89.10%
217	(Mintz et al., 2011)	NA	1288	ATS/ERS 2005	Adult/Elderly	Primary Care	Asthma/COPD	Biomedical Systems (unknown)	66.00%
218	(Miyoshi et al., 2020)	AS	1098	ATS/ERS 2005	Adult/Elderly	Hospital Based	Asthma/COPD/ILD	Unknown	62.20%
219	(Montes de Oca et al., 2016)	SA	1743	ATS 1994	Adult/Elderly	Primary Care	Asthma/COPD	ndd EasyOne (U)	88.35%

220	(Mooe & Stenfors, 2015)	EU	421	ATS/ERS 2005	Adult/Elderly	Hospital Based	Acute coronary syndrome/COPD	Diagnostic Spirare 3 (U)	96.67%
221	(Moya Olivares et al., 2019)	SA	276	ATS/ERS 2007	Paediatric	School Based	No lung disease	Medical Graphics USB (Pi)	73.19%
222	(Mozun et al., 2021)	EU	2213	ATS/ERS 2005	Paediatric	School Based	No lung disease	Jaeger Masterlab (Pn)	79.62%
223	(Mukharesh et al., 2023)	NA	21	ATS/ERS 2019	Paediatric	Clinical Trial	Bronchopulmonary Dysplasia	Morgan Scientific Pneumotrac (Pn), MIR (T)	60.45%
224	(Muller-Brandes et al., 2014)	EU	3133	ATS/ERS 2005	Paediatric	School Based	No lung disease	ndd EasyOne (U)	39.70%
225	(Navuluri et al., 2023)	AF	392	ATS/ERS 2005	All	Population Based	Asthma/COPD	Micro Medical Microloop (T)	77.00%
226	(Ndukwu et al., 2021)	AF	188	ATS/ERS 2005	Paediatric	Primary Care	Lung Disease/No lung disease	ndd EasyOne (U)	77.10%
227	(Nelson et al., 2012)	SA	966	ATS/ERS 2005	Adult/Elderly	Primary Care	Asthma/COPD/No lung disease	Vitalograph asma-1 (T), ndd EasyOne (U)	77.90%
228	(Neve et al., 2006)	EU	207	ATS 1994	Paediatric	Hospital Based	Asthma	Jaeger MasterScreen (Pn)	86.00%
229	(Nkereuwem et al., 2023)	AF	159	ATS/ERS 2019	Paediatric	Population Based	Tuberculosis/No lung disease	ndd Easy on-pc (U)	85.50%
230	(North et al., 2019)	AF	843	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	ndd EasyOne Pro (U)	67.00%
231	(Odo et al., 2013)	NA	1084	ATS/ERS 2005	Adult/Elderly	Occupational	Restrictive Lung Disease/No lung disease	SensorMedics 1022 (DRS)	47.90%
232	(Olaguibel Rivera et al., 2014)	EU	93	ATS/ERS 2007	Paediatric	Hospital Based	No lung disease	Jaeger MasterScreen (Pn)	64.50%
233	(Ozoh et al., 2020)	AF	640	ATS/ERS 2005	Paediatric/Adult	Population Based	Asthma/COPD/No lung disease	Vitalograph Spirotrac V Pneumotrac (Pn)	72.50%
234	(Pagano et al., 2022)	OC	148	ATS/ERS 2019	Adult/Elderly	Primary Care	COPD/No lung disease	ndd EasyOne (U)	90.21%
235	(Pan et al., 2021)	AS	2445	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	Vitalograph COPD-6 (T)	63.30%
236	(Park et al., 2007)	AS	4663	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	SensorMedics 2130 (DRS)	96.30%
237	(Pedone et al., 2010)	EU	1485	ATS/ERS 2005	Elderly	Hospital Based	Asthma/COPD/No lung disease	Baires System Volumetric (Stead-Well)	61.10%
238	(Pellegrino et al., 2005)	EU	243	ERS 1993	Adult/Elderly	Hospital Based	COPD	Different Flow-sensing spirometers (Pn, T)	88.50%
239	(Perez-Padilla et al., 2008)	SA	5315	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD	ndd EasyOne (U)	88.70%

240	(Perez-Yarza et al., 2009)	EU	558	ATS/ERS 2007	Paediatric	Hospital Based	No lung disease	Jaeger MasterScreen (Pn)	81.54%
241	(Pesant et al., 2007)	NA	164	ATS 1994	Paediatric	School Based	No lung disease	Jaeger Masterscope (Pn)	78.00%
242	(Piccioni et al., 2007)	EU	960	ATS/ERS 2005 ^a	Paediatric	School Based	No lung disease	Jaeger Masterscope Rotary (T)	83.70%
243	(Plesner et al., 2016)	EU	273	ERS 1993	Elderly	Hospital Based	COPD/Chronic Kidney Disease	Vitalograph 2120 (Pn)	94.51%
244	(Pothirat et al., 2015)	AS	1003	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	MIR Spirobank (T)	84.87%
245	(Pothirat et al., 2016)	AS	1556	ATS/ERS 2005	Adult/Elderly	Hospital Based	COPD	Unknown	68.50%
246	(Prats et al., 2015)	EU	10768	ATS/ERS 2005	Adult/Elderly	Hospital Based	COPD	Jaeger MasterScreen (Pn)	68.44%
247	(Prieto Centurion et al., 2012)	NA	113	ATS/ERS 2005	Adult/Elderly	Hospital Based	Asthma/COPD	nSpire KoKo (Pn)	73.00%
248	(Queiroz et al., 2018)	SA	245	ATS/ERS 2005	Elderly	Home Care	Cognitive Impairment	Micro Medical Microlab (T)	75.10%
249	(Qvarfordt et al., 2018)	EU	9422	ATS/ERS 2005	All	Population Based	No lung disease	Jaeger Masterscreen (Pn), MIR FlowMIR (T)	82.50%
250	(Rai et al., 2016)	AS	207	ATS/ERS 2005	All	Hospital Based	Lung Disease/No lung disease	Unknown	14.00%
251	(Ramirez-Venegas et al., 2018)	NA	1190	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	ndd EasyOne (U)	81.00%
252	(Rinne et al., 2006)	SA	202	ATS 1994	Paediatric/Adult	Primary Care	Lung Disease/No lung disease	nSpire Koko trek (Pn)	83.66%
253	(Robinson et al., 2012)	SA	1441	ATS/ERS 2005	Paediatric	Population Based	Asthma	Jaeger SpiroPro (Pn)	77.00%
254	(Rosa et al., 2007)	SA	963	ATS 1994	Adult/Elderly	Population Based	COPD	ndd EasyOne (U)	93.10%
255	(Rothnie et al., 2017)	EU	222	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD	Unknown	96.50%
256	(Ruhighira et al., 2023)	AF	234	ATS/ERS 2019	Adult	Hospital Based	Pregnancy	ndd EasyOne (U)	83.85%
257	(Ruiz Aguirre et al., 2005)	EU	235	SEPAR 1998	Adult/Elderly	Primary Care	COPD/No lung disease	Cosmed Pony (T)	81.70%
258	(Sana et al., 2020)	AF	611	ATS 1994	Adult/Elderly	Other	COPD/No lung disease	MIR Spirobank II (T)	92.31%
259	(Sanders et al., 2008)	NA	52	ATS/ERS 2005	Paediatric/Adult	Hospital Based	Cystic Fibrosis	SensorMedics Vmax Encore 22D Mass Flow (HWA)	73.72%

260	(Santos et al., 2013)	EU	1239	ATS/ERS 2007	Paediatric	Hospital Based	No lung disease	Jaeger MasterScreen Body (Pn)	88.00%
261	(Scalco et al., 2018)	SA	24	ATS/ERS 2005	Paediatric	School Based	No lung disease	ndd EasyOne (U)	91.67%
262	(Schaffer et al., 2023)	NA	29	ATS/ERS 2019	Paediatric/Adult	Home Care	Cystic Fibrosis	MIR Spirobank (T)	83.00%
263	(Schermer et al., 2011)	EU	1091	ATS 1994	Adult/Elderly	Primary Care	Asthma/COPD/No lung disease	Welch Allyn SpiroPerfect (Pn)	38.80%
264	(Schermer et al., 2009)	EU	1072	ATS/ERS 2005	Adult/Elderly	Primary Care	No lung disease	Welch Allyn SpiroPerfect (Pn)	31.40%
265	(Schneider et al., 2009)	EU	219	ATS/ERS 2005	Adult	Primary Care	Asthma/COPD/No lung disease	Medikro SpiroStar (Pn)	39.80%
266	(Schneider et al., 2011)	NA	101	ATS/ERS 2005	Paediatric	Hospital Based	Asthma	Tyco Healthcare Puritan-Bennett Renaissance II (Pn)	35.00%
267	(Schwartz et al., 2021)	NA	9988	ATS/ERS 2005	Adult/Elderly	Hospital Based	Lung Disease/No lung disease	Unknown	65.02%
268	(Senevirathna et al., 2022)	AS	342	ATS/ERS 2019	Paediatric	School Based	No lung disease	Cosmed MicroQuark Pony FC (T)	86.50%
269	(Seo et al., 2009)	AS	155	ATS/ERS 2007	Paediatric	Hospital Based	Asthma	Jaeger MasterScreen (Pn)	59.40%
270	(Seyedmehdi et al., 2013)	AS	1004	ATS/ERS 2005	Adult	Occupational	No lung disease	MIR Spirolab (T)	42.60%
271	(Sheshadri et al., 2020)	NA	51	ATS/ERS 2005	Adult/Elderly	Home Care	Allogeneic Hematopoietic Cell Transplantation	Monitored Therapeutics GoSpiro (T)	75.00%
272	(Sheshadri et al., 2021)	NA	50	ATS/ERS 2005	Adult/Elderly	Hospital Based	Cancer	Jaeger MasterScreen (Pn)	89.50%
273	(Shin et al., 2013)	AS	183	ATS/ERS 2007	Paediatric	School Based	No lung disease	Jaeger MasterScreen (Pn)	82.00%
274	(Siddharthan et al., 2019)	AF	1772	ATS/ERS 2005	Adult/Elderly	Population Based	Lung Disease/No lung disease	ndd Easy on-pc (U)	84.80%
275	(Siddharthan et al., 2022)	INT	10709	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	Unknown	96.10%
276	(Silverman et al., 2007)	NA	641	ATS 1994 ^a	Adult	Hospital Based	Asthma	nSpire KoKo (Pn)	93.00%
277	(Singh & Lohia, 2012)	AS	489	ATS/ERS 2005	Adult	Hospital Based	COPD/No lung disease	SensorMedics SM2200 (HWA)	95.50%
278	(Smith et al., 2010)	NA	4549	ATS/ERS 2005	Adult	Population Based	Coronary Artery Disease	Collins Survey Volumetric (Water Sealed), SensorMedics Vmax (DRS)	70.40%

279	(Smolej Narancic et al., 2009)	EU	841	ATS 1987	Elderly	Population Based	Lung Disease/No lung disease	Jaeger Pneumscreen (Pn)	77.40%
280	(Sogbetun et al., 2016)	NA	383	ATS/ERS 2005	Adult/Elderly	Occupational	COPD/No lung disease	Unknown	98.17%
281	(Sonnappa et al., 2015)	INT	1222	ATS/ERS 2007	Paediatric	School Based	No lung disease	ndd Easy on-pc (U)	85.02%
282	(Sorino et al., 2011)	EU	1971	ATS 1994	Elderly	Hospital Based	Lung Disease/No lung disease	Baires System Volumetric (Stead-Well)	65.00%
283	(Soumagne et al., 2020)	EU	4610	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	Medgraphics (Pn)	96.50%
284	(Srisingh et al., 2021)	AS	132	ATS/ERS 2005	Paediatric	Hospital Based	Lung Disease/No lung disease	Platinum Elite Body Plethysmograph (Pi)	71.20%
285	(Stanley et al., 2014)	OC	1453	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	Unknown	72.54%
286	(Stanojevic et al., 2020)	NA	9592	ATS/ERS 2005	Paediatric	Population Based	Cystic Fibrosis/No lung disease	Unknown	98.45%
287	(Stav & Raz, 2007)	AS	1150	ATS 1994	Adult/Elderly	Hospital Based	COPD/No lung disease	Jaeger Dry spirometer (HWA)	92.00%
288	(Steinacher et al., 2012)	EU	101	ATS/ERS 2005	Adult/Elderly	Hospital Based	Chronic Heart Failure/COPD	Jaeger Flowscreen Pro (Pn)	88.10%
289	(Stout et al., 2012)	NA	1028	ATS/ERS 2005	Paediatric	Primary Care	Asthma	ndd EasyOne (U)	32.50%
290	(Strong et al., 2009)	EU	761	BTS 1994	Elderly	Primary Care	COPD	Unknown	31.00%
291	(Sumner et al., 2018)	EU	661	ATS/ERS 2005	Adult/Elderly	Occupational	No lung disease	ndd EasyOne (U)	84.00%
292	(Suojalehto et al., 2017)	EU	60	ATS/ERS 2005	Adult	Occupational	Asthma/No lung disease	Unknown	82.00%
293	(Tamire et al., 2019)	AF	545	ATS/ERS 2005	Adult	Primary Care	No lung disease	ndd EasyOne (U)	42.30%
294	(C. C. Tan et al., 2014)	NA	89	ATS/ERS 2005	Paediatric	Hospital Based	Asthma	Unknown	54.90%
295	(Tan et al., 2013)	NA	4669	ATS 1994	Adult/Elderly	Population Based	COPD/No lung disease	ndd EasyOne (U)	92.50%
296	(W. C. Tan et al., 2014)	NA	5176	ATS/ERS 2005	Adult/Elderly	Population Based	Asthma/COPD	ndd EasyOne (U)	94.00%
297	(Therkorn et al., 2021)	NA	133	ATS/ERS 2019	Adult	Primary Care	No lung disease	ndd Easy on-pc (U)	51.50%
298	(Thompson et al., 2006)	NA	67	ATS 1994 ^a	Paediatric	Home Care	Asthma	ndd EasyOne (U)	77.00%

299	(Thornton et al., 2024)	NA	13	ATS/ERS 2019	Paediatric/Adult	Home Care	Cystic Fibrosis	nSpire PiKo-6 (T)	91.60%
300	(Tilert et al., 2013)	NA	5823	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	Ohio 822/827 (DRS)	94.06%
301	(Tinkelman et al., 2007)	INT	1631	ATS 1994	Adult/Elderly	Primary Care	COPD/No lung disease	ndd EasyOne (U)	50.15%
302	(Tomalak et al., 2008)	EU	233	ATS/ERS 2005	Paediatric	Hospital Based	Asthma	Jaeger Masterlab (Pn)	40.79%
303	(Topole et al., 2023)	INT	2000	ATS/ERS 2005	Adult/Elderly	Clinical Trial	Asthma/COPD	Unknown	88.00%
304	(Torre-Bouscoulet et al., 2015)	NA	558	ATS/ERS 2005	Adult/Elderly	Hospital Based	Obstructive/Restrictive Lung Disease	SensorMedics Vmax (DRS)	90.70%
305	(Tsai et al., 2010)	AS	355	ATS 1994	Paediatric	School Based	No lung disease	Spiroware Exhalyzer S (U)	87.04%
306	(Tuomisto et al., 2008)	EU	489	ATS 1994 ^a	All	Primary Care	Asthma	Unknown	79.00%
307	(Turkeshi et al., 2015)	EU	522	ATS/ERS 2005	Elderly	Primary Care	Cognitive Impairment	MIR Spirobank (T)	49.50%
308	(Turner et al., 2007)	EU	827	ATS/ERS 2005	Paediatric	Birth Cohort	Asthma/No lung disease	Vitalograph Pneumotrac (Pn)	65.00%
309	(van de Hei et al., 2020)	EU	149	ATS/ERS 2005	Adult/Elderly	Primary Care	Asthma/COPD/No lung disease	Unknown	13.40%
310	(van der Velden et al., 2023)	EU	232	ATS/ERS 2019	Adult/Elderly	Hospital Based	COPD/Heart Disease	Vitalograph COPD-6 (T), Healthup AioCare (Pn)	88.80%
311	(van Gemert et al., 2015)	AF	609	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	Vitalograph Pneumotrac (Pn)	97.00%
312	(van Oostrom et al., 2018)	EU	5727	ATS/ERS 2005	Adult	Population Based	Asthma/COPD/No lung disease	Jaeger Pneumo (Pn)	89.15%
313	(Vasankari et al., 2010)	EU	13571	Unknown	Adult/Elderly	Population Based	COPD/No lung disease	Vitalograph S (WB)	87.33%
314	(Veras & Pinto, 2011)	SA	74	ATS/ERS 2007	Paediatric	Hospital Based	Asthma	Cosmed MicroQuark Pony FC (T)	82.40%
315	(Vilozni et al., 2005)	AS	341	ATS 1994, ERS 1993	Paediatric	School Based	Asthma/No lung disease	nSpire Flowhandy ZAN100 (Pn)	78.00%
316	(Vilozni et al., 2010)	AS	28	ATS/ERS 2005	Paediatric/Adult	Hospital Based	Ataxia Telangiectasis	nSpire Flowhandy ZAN100 (Pn)	0.00%
317	(Vilozni et al., 2007)	AS	93	ATS 1994, ERS 1993	Paediatric	Hospital Based	Cystic Fibrosis	nSpire Flowhandy ZAN100 (Pn)	81.72%
318	(Visser et al., 2008)	EU	169	ATS/ERS 2005	Adult/Elderly	Hospital Based	COPD	SensorMedics Vmax Encore 20 (HWA)	85.21%

319	(Walters et al., 2008)	OC	618	ATS 1994	Adult/Elderly	Primary Care	COPD	ndd EasyOne (U)	60.10%
320	(Wang et al., 2015)	AS	862	ATS/ERS 2005	Paediatric	Hospital Based	Asthma	Jaeger MasterScreen (Pn)	44.20%
321	(Wang et al., 2023)	NA	1736	ATS/ERS 2005	Adult/Elderly	Population Based	HIV/No lung disease	ndd Easy on-pc (U), ndd EasyOne Pro (U)	85.77%
322	(R. Wang et al., 2022)	AS	6160	ATS/ERS 2005	Adult/Elderly	Primary Care	COPD/No lung disease	Jaeger MasterScreen (Pn)	91.49%
323	(Y. Wang et al., 2022)	AS	1751	ATS/ERS 2019	All	Primary Care	Lung Disease/No lung disease	Jaeger MasterScreen (Pn)	93.60%
324	(Warman & Silver, 2016)	NA	97	ATS/ERS 2007	Paediatric	Primary Care	Asthma	ndd EasyOne (U)	81.00%
325	(Wasilewska et al., 2021)	EU	14	ATS/ERS 2019	Paediatric	Home Care	Duchenne Muscular Dystrophy	Jaegar Pneumo Screen (Pn), Healthup AioCare (Pn)	20.47%
326	(Wasilewska et al., 2022)	EU	21	ATS/ERS 2019	Paediatric/Adult	Home Care	Duchenne Muscular Dystrophy	Healthup AioCare (Pn)	71.43%
327	(Weaver et al., 2009)	NA	654	ATS 1994	Adult/Elderly	Occupational	Asthma/No lung disease	SensorMedics SM2200 (HWA)	63.00%
328	(Wei et al., 2017)	AS	255	ATS/ERS 2005	Adult/Elderly	Hospital Based	COPD	Jaeger MasterScreen (Pn)	84.31%
329	(White et al., 2005)	EU	101	BTS 1994	Adult/Elderly	Primary Care	COPD	Vitalograph Compact (Pn)	60.00%
330	(White et al., 2007)	EU	212	ATS 1994	Adult/Elderly	Primary Care	COPD/No lung disease	Micro Medical Microloop (T)	68.00%
331	(Wisnivesky et al., 2014)	NA	418	ATS 1994	Adult/Elderly	Occupational	COPD/No lung disease	Schiller America Spirovit SP-1	93.06%
332	(Xing et al., 2023)	AS	11747	ATS/ERS 2005	Adult/Elderly	Population Based	Tuberculosis	Jaeger MasterScreen (Pn)	73.89%
333	(Yamamoto et al., 2017)	AS	2509	ATS/ERS 2005	Adult/Elderly	Hospital Based	Lung Disease/No lung disease	Unknown	64.29%
334	(Yawn et al., 2007)	NA	380	ATS/ERS 2005	All	Primary Care	Asthma/COPD	ndd EasyOne (U)	68.68%
335	(Zachariades et al., 2012)	AS	1315	ATS/ERS 2005	Adult/Elderly	Population Based	COPD/No lung disease	MIR Spirolab II (T)	93.76%
336	(Zanconato et al., 2005)	EU	109	ATS 1994	Paediatric	Primary Care	Asthma	Micro Medical Microloop (T)	78.00%
337	(Zhang et al., 2005)	AS	279	ATS 1994	Paediatric	School Based	No lung disease	Cosmed Pony (T)	77.70%

Abbreviations: AF, Africa; AS, Asia; EU, Europe; INT, International; NA, North America; OC, Oceania; SA, South America; ATS, American Thoracic Society; BTS, British Thoracic Society; ERS, European Respiratory Society; FRS, Finnish Respiratory Society; SEPAR, Spanish Society of Pneumology and Thoracic Surgery; COPD, Chronic Obstructive Pulmonary Disease; HIV, Human Immunodeficiency Virus; DRS, Dry Rolling Seal; HWA, Hot Wire Anemometer; Pi, Pitot; Pn, Pneumotachograph; T, Turbine; U, Ultrasonic; WB, Wedge Bellows.

^a modified version of spirometry standard

Root Cause Analysis of Risk of Bias Critical Appraisal Tools

Table 4.4: Comparison of each risk of bias tool's questions. The different shades of colour indicate the matching of similar questions/themes across the tools.

JB1 cross-sectional	JB1 prevalence	NICE	NIH	AXIS	AHRQ
1. Were the criteria for inclusion in the sample clearly defined?	1. Was the sample frame appropriate to address the target population?	The method of allocation to treatment groups was unrelated to potential confounding factors (that is, the reason for participant allocation to treatment groups is not expected to affect the outcome[s] under study)	1. Was the research question or objective in this paper clearly stated?	1. Were the aims/objectives of the study clear?	1. Define the source of information (survey, record review)
2. Were the study subjects and the setting described in detail?	2. Were study participants sampled in an appropriate way?	Attempts were made within the design or analysis to balance the comparison groups for potential confounders	2. Was the study population clearly specified and defined?	2. Was the study design appropriate for the stated aim(s)?	2. List inclusion and exclusion criteria for exposed and unexposed subjects (cases and controls) or refer to previous publications
3. Was the exposure measured in a valid and reliable way?	3. Was the sample size adequate?	The groups were comparable at baseline, including all major confounding and prognostic factors	3. Was the participation rate of eligible persons at least 50%?	3. Was the sample size justified?	3. Indicate time period used for identifying patients
4. Were objective, standard criteria used for measurement of the condition?	4. Were the study subjects and the setting described in detail?	Based on your answers to the above, in your opinion was selection bias present? If so, what is the likely direction of its effect?	4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?	4. Was the target/reference population clearly defined? (Is it clear who the research was about?)	4. Indicate whether or not subjects were consecutive if not population-based
5. Were confounding factors identified?	5. Was the data analysis conducted with sufficient coverage of the identified sample?	The comparison groups received the same care apart from the intervention(s) studied	5. Was a sample size justification, power description, or variance and effect estimates provided?	5. Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	5. Indicate if evaluators of subjective components of study were masked to other aspects of the status of the participants

6. Were strategies to deal with confounding factors stated?	6. Were valid methods used for the identification of the condition?	Participants receiving care were kept 'blind' to treatment allocation	6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?	6. Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	6. Describe any assessments undertaken for quality assurance purposes (e.g., test/retest of primary outcome measurements)
7. Were the outcomes measured in a valid and reliable way?	7. Was the condition measured in a standard, reliable way for all participants?	Individuals administering care were kept 'blind' to treatment allocation	7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?	7. Were measures undertaken to address and categorise non-responders?	7. Explain any patient exclusions from analysis
8. Was appropriate statistical analysis used?	8. Was there appropriate statistical analysis?	Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?	8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?	8. Were the risk factor and outcome variables measured appropriate to the aims of the study?	8. Describe how confounding was assessed and/or controlled
Overall appraisal	9. Was the response rate adequate, and if not, was the low response rate managed appropriately?	All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up)	9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	9. Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	9. If applicable, explain how missing data were handled in the analysis
	Overall appraisal	a. How many participants did not complete treatment in each group?	10. Was the exposure(s) assessed more than once over time?	10. Is it clear what was used to determined statistical significance and/or precision estimates? (e.g., p values, CIs)	10. Summarize patient response rates and completeness of data collection
		b. The groups were comparable for treatment completion (that is, there were no important or systematic differences between groups in terms of those who did not complete treatment)	11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	11. Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	11. Clarify what follow-up, if any, was expected and the percentage of patients for which incomplete data or follow-up was obtained
		a. For how many participants in each group were no outcome data available?	12. Were the outcome assessors blinded to the exposure status of participants?	12. Were the basic data adequately described?	

b. The groups were comparable with respect to the availability of outcome data (that is, there were no important or systematic differences between groups in terms of those for whom outcome data were not available)
Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?

The study had an appropriate length of follow-up
The study used a precise definition of outcome

A valid and reliable method was used to determine the outcome

Investigators were kept 'blind' to participants' exposure to the intervention

Investigators were kept 'blind' to other important confounding and prognostic factors

Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?

13. Was loss to follow-up after baseline 20% or less?

14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?

Quality Rating

13. Does the response rate raise concerns about non-response bias?

14. If appropriate, was information about non-responders described?

15. Were the results internally consistent?

16. Were the results for the analyses described in the methods, presented?

Discussion

17. Were the authors' discussions and conclusions justified by the results?

18. Were the limitations of the study discussed?

19. Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?

20. Was ethical approval or consent of participants attained?

Gamma Distribution Plots

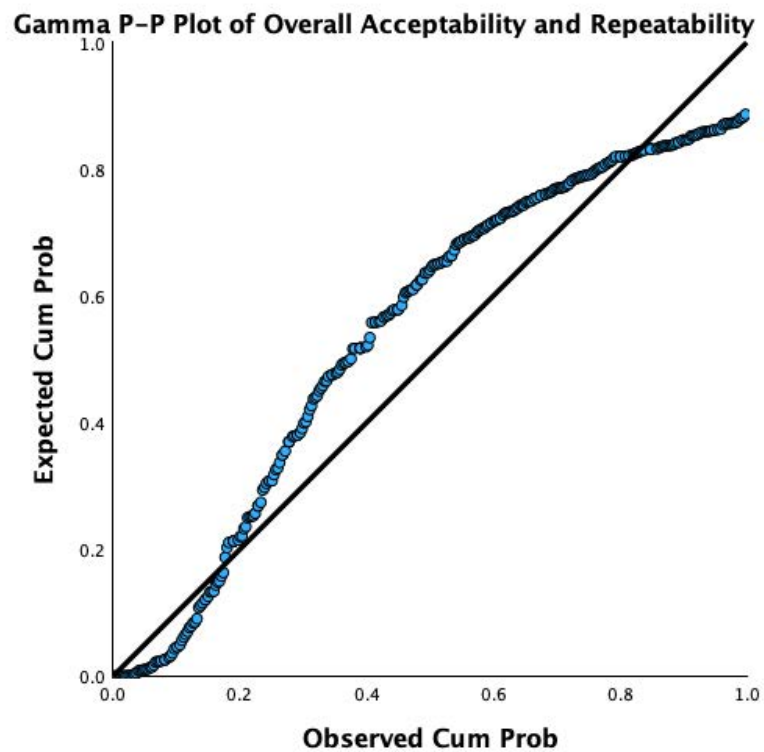
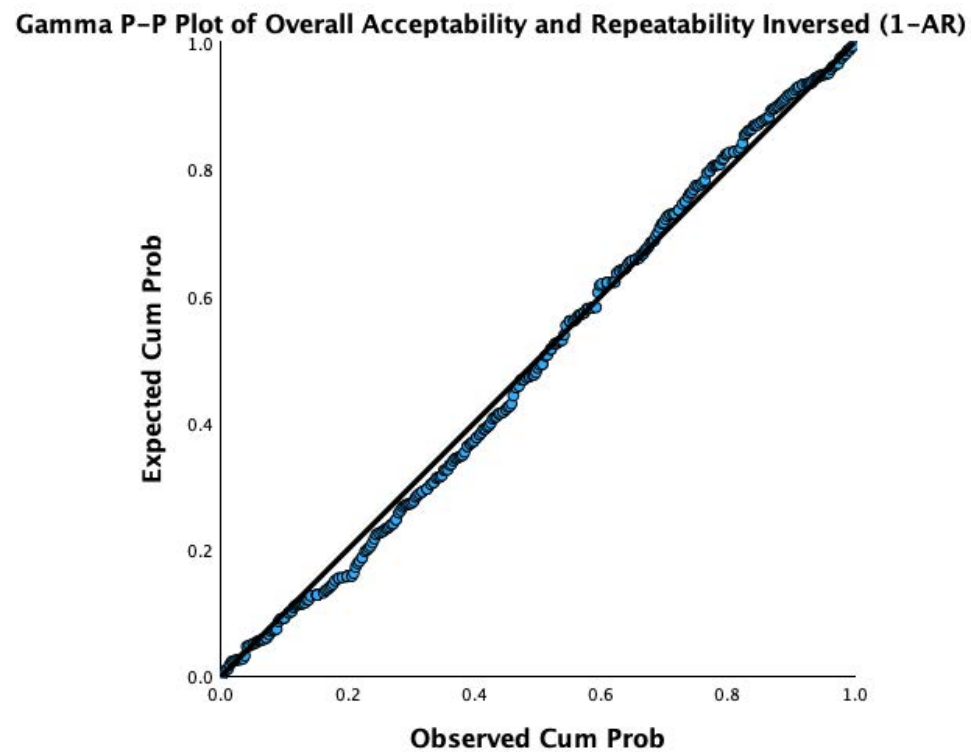


Figure 4.1: Gamma distribution P-P Plots for overall acceptability and repeatability.

Risk of Bias Tables

Table 4.5: Cross-Sectional Risk of Bias Table.

STUDY	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
(RUIZ AGUIRRE ET AL., 2005)	+	+	+	+	+	X	+	-
(AKPINAR-ELCI ET AL., 2006)	+	+	+	+	+	+	+	+
(AKSU ET AL., 2020)	+	X	+	+	+	+	+	+
(AL-QEREM, 2021)	+	+	+	+	+	+	+	+
(AL-QEREM & JARAB, 2021)	+	+	+	+	+	+	+	+
(ALEXANDRAKI ET AL., 2010)	+	+	+	+	+	+	+	+
(ALLAN ET AL., 2010)	+	+	+	+			+	+
(ALLEN ET AL., 2010)	+	+	+	+	+	+	+	+
(ALLEN & YEUNG, 2006)	+	+	+	+	+	+	+	+
(ALLEN ET AL., 2008)	+	+	+	+	+	+	+	+
(ALLEN & BAXTER, 2009)	+	+	+	+	+	+	+	+
(ARIGLIANI ET AL., 2017)	+	+	+	+	+	+	+	+
(ARNALL ET AL., 2009)	+	+	+	+	+	+	+	+
(AVERAME ET AL., 2009)	+	+	+	+	+	+	+	+
(BARANSKI & ZEJDA, 2022)	+	+	+	+	+	+	+	+
(BELO ET AL., 2018)	+	+	+	+	+	+	+	+
(LUNDBERG ET AL., 2020)	+	+	+	+	+	+	+	+
(BONAVIA ET AL., 2009)	+	+	+	+			+	+
(BORREGO ET AL., 2013)	+	+	+	+	+	+	+	+
(BOUTIN ET AL., 2015)	+	+	+	+	+	+	+	+
(BROZEK ET AL., 2018)	X	+	+	X	+	+	+	+

(BUNGE ET AL., 2018)	+	+	+	+			+	+
(BURITY ET AL., 2011)	+	+	+	+	+	+	+	+
(BURITY ET AL., 2016)	+	+	+	+	+	+	+	+
(BUSI ET AL., 2017)	+	+	+	+	+	+	+	+
(PARK ET AL., 2007)	X	X	+	+	+	+	+	+
(CALLE RUBIO ET AL., 2017)	+	+	+	-	+	+	-	+
(CAUSSADE ET AL., 2015)	+	+	+	+	+	+	+	+
(CAWLEY & WARNING, 2018)	+	+	+	+			+	+
(CHAIWONG ET AL., 2020)	+	+	+	+	+	+	+	+
(CHAIWONG ET AL., 2022)	+	+	+	+	+	+	+	+
(CHAIWONG ET AL., 2019)	+	+	+	+	+	+	+	+
(CHAN ET AL., 2023)	+	+	+	+	+	+	+	+
(CHECKLEY ET AL., 2010)	+	+	+	+	+	+	+	+
(CHEN ET AL., 2018)	+	+	+	+	-	-	+	+
(CHINN ET AL., 2006)	+	+	+	+	+	+	+	+
(CHRISTMANN ET AL., 2010)	+	+	+	+			+	+
A. J. COLLARO ET AL., 2021)	+	+	+	+	+	+	+	+
(CRISTEA ET AL., 2015)	+	+	+	+			+	+
CZAJKOWSKA-MALINOWSKA ET AL., 2013)	+	+	+	+	+	+	+	+
(DAHNE ET AL., 2022)	+	+	+	+			+	+
(ALBUQUERQUE ET AL., 2015)	+	+	+	+	+	+	+	+
(DE ÁVILA CABEZÓN ET AL., 2013)	+	+	+	+			+	-
DE OCA ET. AL. 2016	+	+	+	+	+	+	+	+
(DEMIRCI ET AL., 2017)	+	+	+	+	+	+	+	+

(DEVAKUMAR ET AL., 2015)	+	+	+	+	+	+	+	+
(DOMINGUEZ-MARTIN ET AL., 2023)	+	+	+	+	+	+	+	+
DONAIRE ET AL., 2015)	+	+	+	+	+	+	+	+
(DUONG ET AL., 2019)	+	+	+	+	+	+	+	+
(ENRIGHT ET AL., 2010)	+	+	+	+	+	+	+	+
(FERNANDEZ-PLATA ET AL., 2019)	+	+	+	+			+	+
(FRANCA ET AL., 2016)	+	+	+	+			+	+
(FROHNHOFEN ET AL., 2011)	+	+	+	+	+	+	-	+
(GAFFIN ET AL., 2010)	+	+	+	+			+	+
(GARCÍA ET AL., 2011)	+	+	+	+			+	+
(GILLETTE ET AL., 2011)	+	+	+	+			+	+
(GINER ET AL., 2014)	+	+	+	+			+	+
(GIRAUD ET AL., 2016)	+	+	+	+			+	+
(GOCHICOA-RANGEL ET AL., 2013)	+	+	+	+			+	+
(GUNAWARDANA ET AL., 2023)	+	+	+	+			+	+
(HAMERS ET AL., 2006)	+	+	+	+			+	+
(HAYNES, 2014)	+	+	+	+			+	+
(HEGEWALD ET AL., 2007)	+	+	+	+			+	+
(HEGEWALD ET AL., 2016)	X	X	+	+			+	+
(LORENZO HERNANDEZ ET AL., 2017)	+	+	+	X			-	+
(HERPEL ET AL., 2006)	+	+	+	+	+	+	+	+
(CASAS HERRERA ET AL., 2016)	+	+	+	+	+	+	+	+
(HUETO ET AL., 2006)	+	+	+	+	+	+	+	+
(HULS ET AL., 2013)	+	+	+	+			+	+

HUMPHREY ET AL., 2020)	+	+	+	+	+	+	+	+
(IOACHIMESCU ET AL., 2005)	X	+	+	+			+	+
(ISLAM ET AL., 2022)	+	+	+	+			+	-
(IVANOVA ET AL., 2020)	+	+	+	+			+	+
(IVERSEN ET AL., 2010)	+	+	+	+	+	+	+	+
(JACOBS ET AL., 2014)	+	+	+	+	+	+	+	+
(JANKOWSKI ET AL., 2021)	+	+	+	+			+	+
(JEDRYCHOWSKI ET AL., 2010)	+	+	+	+	+	+	+	+
(JENG ET AL., 2009)	+	+	+	+			+	+
(JENSEN ET AL., 2006)	+	+	+	+			+	+
(JIAN ET AL., 2017)	+	+	+	+			+	+
(JIANG ET AL., 2019)	X	+	+	+			+	+
(JOHNSTON ET AL., 2016)	+	+	+	+			+	+
(JONES ET AL., 2008)	+	+	+	+			+	+
(KAMPSCHMIDT ET AL., 2016)	+	+	+	+	+	+	+	+
(KAUR ET AL., 2019)	+	+	+	+	+	+	+	+
(KEERATICHANANONT ET AL., 2016)	+	+	+	-			-	+
(KILCI ET AL., 2021)	+	+	+	+	+	+	+	+
(KIMURA ET AL., 2011)	+	+	+	+			+	+
(KINGHORN ET AL., 2020)	+	+	+	+	+	+	+	+
(KJAER ET AL., 2008)	+	+	+	+	+	+	+	+
(KNUDSEN ET AL., 2011)	+	+	+	+	+	+	+	+
(KOMAL ET AL., 2019)	+	+	+	+	+	+	+	+
(KOMAROW ET AL., 2012)	+	+	+	+			+	+

(KONSTANTIKAKI ET AL., 2011)	+	+	+	+			+	+
(KOTZ ET AL., 2008)	+	+	+	+	+	+	+	+
KUMAR ET AL., 2016)	+	+	+	+			+	-
KUZIEMSKI ET AL., 2009)	X	X	+	+			+	-
(LAMPRECHT ET AL., 2007)	+	+	+	+			+	+
(LANDMAN ET AL., 2011)	+	+	+	+			+	+
(LANGHAN & SPIRO, 2009)	+	+	+	-			-	+
(LANIADO-LABORIN ET AL., 2011)	+	+	+	+	+	+	+	+
(LAWRENCE ET AL., 2021)	+	+	+	+	+	+	+	+
(LEHMANN ET AL., 2007)	+	+	+	+	+	+	+	+
(LEI BURTON ET AL., 2015)	+	+	+	+			+	+
(LEUNG ET AL., 2021)	+	+	+	+			+	+
(LICSKAI ET AL., 2012)	+	+	+	+			+	+
(LINARES ET AL., 2006)	+	+	+	+			+	+
(LO ET AL., 2020)	+	+	+	+			+	+
(LOEB ET AL., 2008)	+	+	+	+			+	+
(LOTH ET AL., 2013)	+	+	+	+	+	+	+	+
(LUCAS ET AL., 2009)	+	+	+	+			+	+
(LUM ET AL., 2015)	+	+	+	+			+	+
(LUNDGREN ET AL., 2007)	X	+	+	+			+	+
MAHBOUB ET AL., 2014)	+	+	+	-	+	+	-	+
(MAPEL ET AL., 2015)	+	+	+	+			+	+
MARINA ET AL., 2016)	X	X	+	+			+	-
MÁRQUEZ-MARTÍN ET AL., 2015)	X	+	+	+			+	+

(MARTIN DE VICENTE ET AL., 2018)	+	+	+	+			+	+
(MARTINEZ EIZAGUIRRE ET AL., 2008)	X	+	+	+			+	+
(MARTINEZ ET AL., 2008)	+	+	+	+	+	+	+	-
(MARTINS ET AL., 2023)	+	+	+	+	+	+	+	+
(MCEVOY ET AL., 2023)	+	+	+	+	+	+	+	+
(MELBYE ET AL., 2006)	+	+	+	+	+	+	+	+
(MELO ET AL., 2019)	+	+	+	+			+	+
(MIYOSHI ET AL., 2020)	+	+	+	+	+	+	+	+
(MOZUN ET AL., 2021)	+	+	+	+			+	+
(MULLER-BRANDES ET AL., 2014)	+	+	+	+			+	+
(NELSON ET AL., 2012)	+	+	+	+	+	+	+	+
(NEVE ET AL., 2006)	+	+	+	+			+	+
(NKEREUWEM ET AL., 2023)	+	+	+	+	+	+	+	+
(ODO ET AL., 2013)	+	+	+	+	+	+	+	+
(OLAGUIBEL RIVERA ET AL., 2014)	+	+	+	+	+	+	+	+
(MOYA OLIVARES ET AL., 2019)	+	+	+	+			+	+
(FRIEDRICH ET AL., 2016)	+	+	+	+			+	+
(JIMENEZ ORTEGA ET AL., 2011)	+	+	+	+			+	X
(OZOH ET AL., 2020)	+	+	+	+	+	+	+	+
(PAGANO ET AL., 2022)	+	+	+	+			+	+
(PEDONE ET AL., 2010)	+	+	+	+	+	+	+	+
(PELLEGRINO ET AL., 2005)	+	+	+	+			+	+
(PEREZ-PADILLA ET AL., 2008)	+	+	+	+			+	+
(PEREZ-YARZA ET AL., 2009)	+	+	+	+	+	+	+	+

(PESANT ET AL., 2007)	+	+	+	+	+	+	+	+
(PICCIONI ET AL., 2007)	+	+	X	+	+	+	X	+
POTHIRAT ET AL., 2016)	+	+	+	+			+	+
(PRIETO CENTURION ET AL., 2012)	+	+	+	+			+	+
(QVARFORDT ET AL., 2018)	+	+	+	+			+	+
(RINNE ET AL., 2006)	+	+	+	+	+	+	+	+
(RUHIGHIRA ET AL., 2023)	+	+	+	+			+	+
(SANTOS ET AL., 2013)	+	+	+	+	+	+	+	+
(SCALCO ET AL., 2018)	+	+	+	+			+	X
(SCHERMER ET AL., 2009)	+	+	+	+			+	+
(SCHERMER ET AL., 2011)	+	+	+	+	+	+	+	+
SCHWARTZ ET AL., 2020)	+	+	+	+	+	+	+	+
(SENEVIRATHNA ET AL., 2022)	+	+	+	+	+	+	+	+
(SEO ET AL., 2009)	+	+	+	+	+	+	+	+
(SHESHADRI ET AL., 2021)	+	+	+	+			+	+
(SHIN ET AL., 2013)	+	+	+	+			+	-
(SIDDHARTHAN ET AL., 2022)	+	+	+	+	+	+	+	+
(SMOLEJ NARANCIC ET AL., 2009)	+	+	+	+	+	+	+	+
(SONNAPPA ET AL., 2015)	+	+	+	+	+	+	+	+
(SORINO ET AL., 2011)	+	+	+	+	+	+	+	+
(SRISINGH ET AL., 2021)	+	+	+	+	+	+	+	+
(STEINACHER ET AL., 2012)	+	+	+	+			+	+
(STRONG ET AL., 2009)	+	+	+	+	+	+	+	+
(PESANT ET AL., 2007)	+	+	+	+	+	+	+	+

(SUMNER ET AL., 2018)	✗	✗	+	+			+	—
(SUOJALEHTO ET AL., 2017)	+	+	+	+			+	+
(TAMIRE ET AL., 2019)	+	+	+	+	+	+	+	+
(TAN ET AL., 2013)	+	+	+	+	+	+	+	+
(W. C. TAN ET AL., 2014)	+	+	+	+	+	+	+	+
(C. C. TAN ET AL., 2014)	+	+	+	+	+	+	+	+
(TINKELMAN ET AL., 2007)	+	+	+	+			+	+
(TOMALAK ET AL., 2008)	+	+	+	+			+	—
(TORRE-BOUSCOULET ET AL., 2015)	+	+	+	+			+	+
(TSAI ET AL., 2010)	+	+	+	+	+	+	+	+
(TUOMISTO ET AL., 2008)	—	—	+	✗			+	+
(TURKESHI ET AL., 2015)	+	+	+	+	+	+	+	+
(TURNER ET AL., 2007)	+	+	+	+	+	+	+	+
(VAN DE HEI ET AL., 2020)	+	+	+	+			+	+
(VAN DER VELDEN ET AL., 2023)	+	+	+	+			+	+
VERAS & PINTO, 2011)	+	+	+	+			+	+
(VILOZNI ET AL., 2005)	+	+	+	+			+	+
(VILOZNI ET AL., 2010)	+	+	+	+			+	+
(VILOZNI ET AL., 2007)	+	✗	+	+	+	+	+	+
(VISSER ET AL., 2008)	+	✗	+	+	+	+	+	+
(WALTERS ET AL., 2008)	+	+	+	+	+	+	+	+
(WANG ET AL., 2023)	+	+	+	+	+	+	+	+
(Y. WANG ET AL., 2022)	+	+	+	+			+	+
(WANG ET AL., 2015)	+	+	+	+			+	+

(WARMAN & SILVER, 2016)	+	+	+	+			+	+
(WEI ET AL., 2017)	+	+	+	+	+	+	+	+
(WHITE ET AL., 2005)	+	X	+	+	+	+	+	+
(WHITE ET AL., 2007)	X	+	+	+			+	+
(WISNIVESKY ET AL., 2014)	+	+	+	+	+	+	+	+
(XING ET AL., 2023)	+	+	+	+	+	+	+	+
YAMAMOTO ET AL., 2017)	+	+	+	+	+	+	+	+
(ZANCONATO ET AL., 2005)	+	X	+	+			+	+
(ZHANG ET AL., 2005)	+	X	+	+			+	+
(WANG ET AL., 2015)	+	+	+	+			+	+

Table 4.6: Cross-Sectional Prevalence Risk of Bias Table.

STUDY	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
(ABBASI ET AL., 2012)	+	+	—	+	+	+	+	+	+
(ADAMS ET AL., 2018)	+	+	+	+	+	+	+	+	+
(AL GHOBAIN ET AL., 2015)	+	+	+	+	+	+	+	+	+
(AMARAL ET AL., 2016)	+	+	+	+	+	+	+	+	+
(ANDREEVA ET AL., 2015)	+	+	+	+	+	+	+	+	+
(ARAYA ET AL., 2005)	—	+	—	+	+	+	+	+	+
(ARNE ET AL., 2010)	+	+	+	+	+	+	+	+	X
(AU-DOUNG ET AL., 2022)	+	+	+	+	+	+	+	+	+
(BARBARA ET AL., 2013)	+	+	+	+	+	+	+	+	+
(BLAKE ET AL., 2020)	+	+	+	+	+	+	+	+	+

(BUIST ET AL., 2007)	+	+	+	+	+	+	+	+	+
(CANALS-BORRAJO ET AL., 2010)	-	+	+	+	+	+	+	+	+
(CAPOZZOLO ET AL., 2017)	+	+	+	+	+	+	+	+	X
(CASTILLO ET AL., 2015)	+	+	+	+	+	+	+	+	+
(CASTILLO ET AL., 2009)	+	+	+	+	+	+	+	+	+
(CHAKRABARTI ET AL., 2011)	+	-	-	+	+	+	+	+	X
(CHEN ET AL., 2021)	-	+	+	+	+	+	+	+	+
(CHRISTOPHER ET AL., 2020)	-	+	+	+	+	+	+	+	+
(CLARK ET AL., 2013)	+	+	-	+	+	+	+	+	+
(CONSTANT ET AL., 2011)	-	+	-	+	+	+	+	+	+
(COOKSLEY ET AL., 2015)	+	+	+	+	+	+	+	+	+
(DALES ET AL., 2006)	-	+	+	+	+	+	+	+	+
(DE MATTEIS ET AL., 2019)	+	+	+	+	+	+	+	+	+
(QUEIROZ ET AL., 2018)	+	+	+	+	+	+	+	+	+
(FATHIMA ET AL., 2017)	+	+	-	+	+	+	+	+	+
(FRANK ET AL., 2006)	+	+	+	+	+	-	-	+	X
(FULLER ET AL., 2012)	+	+	+	+	+	+	+	+	+
(GRZETIC-ROMCEVIC ET AL., 2011)	+	+	X	+	+	+	+	+	+
(HILL ET AL., 2010)	+	+	+	+	+	+	+	+	+
(HWANG ET AL., 2009)	+	+	+	X	+	+	+	+	+
(HWANG ET AL., 2011)	+	+	+	+	+	+	+	+	+
(IDOLOR ET AL., 2011)	-	+	+	+	+	+	+	+	+
(KART ET AL., 2014)	-	+	-	+	+	+	+	+	+

(KO ET AL., 2008)	—	+	+	+	+	+	+	+	+
(KOUL ET AL., 2016)	+	+	+	+	+	+	+	+	+
(KUMAR ET AL., 2021)	+	+	+	+	+	+	+	+	+
(LEE ET AL., 2015)	+	+	+	+	+	+	+	+	+
(LEUNG ET AL., 2021)	+	+	+	+	+	+	+	+	+
(LEUPPI ET AL., 2010)	—	+	+	+	—	+	+	+	+
(LOH ET AL., 2016)	+	+	+	+	+	+	+	+	+
(LOPEZ VARELA ET AL., 2016)	+	+	+	+	+	+	+	+	+
(MAGITTA ET AL., 2018)	—	+	+	+	+	+	+	+	+
(MAIO ET AL., 2012)	+	+	—	+	+	+	+	+	+
(MASCARENHAS ET AL., 2011)	+	+	+	+	+	+	+	+	+
(MEGHJI ET AL., 2016)	+	+	+	+	+	+	+	+	+
(MINAS ET AL., 2010)	+	+	—	+	+	+	+	+	+
(MINTZ ET AL., 2011)	+	+	+	+	+	+	+	+	+
(MOOE & STENFORS, 2015)	+	+	+	+	+	+	+	+	+
(NAVULURI ET AL., 2023)	+	+	+	+	+	+	+	+	+
(NDUKWU ET AL., 2021)	+	+	+	+	+	+	+	+	+
(NORTH ET AL., 2019)	+	+	+	+	+	+	+	+	+
(PLESNER ET AL., 2016)	+	+	+	+	+	+	+	+	+
(POTHIRAT ET AL., 2015)	+	+	+	+	+	+	+	+	+
(RAMIREZ-VENEGAS ET AL., 2018)	+	+	+	+	+	+	+	+	+
(ROBINSON ET AL., 2012)	+	+	+	+	+	+	+	+	+
(SANA ET AL., 2020)	+	+	+	+	+	+	+	+	+

(SIDDHARTHAN ET AL., 2019)	+	+	+	+	+	+	+	+	+
(STAV & RAZ, 2007)	-	+	-	+	+	+	+	+	+
(TILERT ET AL., 2013)	+	+	+	+	+	+	+	+	+
(VAN GEMERT ET AL., 2015)	+	+	+	+	+	+	+	+	+
(VASANKARI ET AL., 2010)	+	+	+	+	+	-	-	+	+
(R. WANG ET AL., 2022)	+	+	+	+	+	+	+	+	+
(WEAVER ET AL., 2009)	+	+	-	+	-	+	+	-	+
(ZACHARIADES ET AL., 2012)	+	+	+	+	+	+	+	+	+

Table 4.7: Cross-Sectional Diagnostic Accuracy Risk of Bias Table.

STUDY	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
(DAS ET AL., 2020)	+	+	+	X		+	+	+	+	+
(DOUMIT ET AL., 2022)	+	+	+	X		+	X	+	+	+
(FUNG ET AL., 2019)	+	+	+	X		+	X	+	+	+
GERBASE ET AL., 2013)	+	+	+	X		+	X	+	+	+
(GLEESON ET AL., 2006)	+	+	+	X	+	+	X	+	+	+
(HANKINSON ET AL., 2015)	+	+	+	-		+	-	+	+	+
(JARHYAN ET AL., 2021)	+	+	+	+	+	+	+	+	+	+
(KRUIZINGA ET AL., 2020)	+	+	+	X		+	X	+	+	+
(MARTINS ET AL., 2022)	+	+	+	+	+	+	+	+	+	+
(MASA ET AL., 2011)	+	+	+	+	+	+	+	+	+	+
(MCKIBBEN ET AL., 2011)	+	+	+	X	+	+	+	+	+	X
(MUKHARESH ET AL., 2023)	+	+	+	X		+	X	+	+	+

(PAN ET AL., 2021)	+	+	+	+	+	+	+	+	+	+
(ROTHNIE ET AL., 2017)	+	+	+	+	+	+	X	+	+	+
(SCHNEIDER ET AL., 2009)	+	+	+	+	+	+	+	+	+	+
(SINGH & LOHIA, 2012)	+	+	+	X	+	+	+	+	+	+
(SOGBETUN ET AL., 2016)	+	+	+	+	+	+	X	+	+	+
(SOUMAGNE ET AL., 2020)	+	+	+	+	+	+	X	+	+	+
(STANLEY ET AL., 2014)	+	+	+	X	+	+	X	+	+	+
(TOPOLE ET AL., 2023)	+	+	+	+	+	+	+	+	+	+

Table 4.8: Case-Control Risk of Bias Table.

STUDY	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
(BELLIA ET AL., 2008)	+	+	+	+	+	—	—	+	+	+
(LINARES PASSERINI ET AL., 2014)	+	+	+	+	+			+	+	+

Table 4.9: Cohort Risk of Bias Table.

STUDY	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11
(AURORA ET AL., 2011)	+	+	+			+	+	+	+	+	+
(BORG ET AL., 2010)	+	+	+			+	+	+	+	X	+
(BORG ET AL., 2012)	+	+	+			+	+	+	+	+	+
(BURGOS ET AL., 2012)	+	+	+			+	+	+	+		+
(CARR ET AL., 2011)	+	+	+			+	+	+	+		—
(DALZIEL ET AL., 2006)	+	+	+			+	+	+	+	+	+

(FAWKE ET AL., 2010)	+	+	+	+	+	+	+	+	+	+	+
(FETTES ET AL., 2022)	+	+	+			+	+	+	+	+	+
(GUARNIERI ET AL., 2015)	+	+	+	+	+	+	+	+	+	-	+
(GUPTA ET AL., 2016)	+	+	+			+	+	+	+	+	+
(HIGBEE ET AL., 2022)	+	+	+	+	+	+	+	+	+	+	+
(JANSSENS ET AL., 2013)	+	+	+	+	+	+	+	+	+	-	+
(KHOSA ET AL., 2020)	+	+	+			+	+	+	+	X	+
(KIRKBY ET AL., 2016)	+	+	+			+	+	+	+	X	+
(KOZLOWSKA ET AL., 2008)	+	+	+	+	+	+	+	+	+	+	+
(MANGIONE-SMITH ET AL., 2017)	+	+	+	+	+	+	+	+	+	+	+
(SCHERMER ET AL., 2011)	+	+	+			+	+	+	+		+
(STANOJEVIC ET AL., 2020)	+	+	+			+	+	+	+		+
(STOUT ET AL., 2012)	+	+	+			+	+	+	+		+

Table 4.10: Case Series Risk of Bias Table.

STUDY	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
(BELL ET AL., 2022)	+	+	+	+	+	+	+	+	+	+
(BERNTSEN ET AL., 2016)	+	+	+	-	-	+	+	+	+	+
(BRUMBACK ET AL., 2013)	+	+	+	+	+	+	+	+	+	+
(CUSHEN ET AL., 2016)	+	+	+	+	+	+	+	+	+	+
(DAVIS ET AL., 2022)	+	+	+	+	+	+	+	+	+	+

(DE LA HOZ ET AL., 2020)	+	+	+	+	+	+	+	+	+	+
(ENACHE ET AL., 2017)	+	+	+	+	+	+	+	+	+	+
(ESENDAGLI ET AL., 2022)	+	+	+	+	+	+	+	+	+	+
(FERNANDEZ-VILLAR ET AL., 2018)	+	+	+	+	+	+	+	+	+	+
(GIRARDOT ET AL., 2006)	+	+	+	+	+	+	+	+	+	+
(HAMPSON ET AL., 2017)	+	+	+	-	-	+	+	+	+	+
(HNIZDO ET AL., 2011)	+	+	+	+	+	+	+	+	+	+
(KATTAN ET AL., 2018)	+	+	+	+	+	+	+	+	+	+
(KINNULA ET AL., 2011)	X	-	-	+	+	X	+	+	+	+
(KRUIZINGA ET AL., 2021)	+	+	+	+	+	+	+	+	+	+
(KUPCZYK ET AL., 2021)	+	+	+	-	-	+	+	+	+	+
(LOGIE ET AL., 2020)	+	+	+	-	-	+	+	+	+	+
(LUOTO ET AL., 2016)	+	+	+	+	+	+	+	+	+	+
(MARINA MALANDA ET AL., 2014)	+	+	+	+	+	X	X	+	+	+
(MENEZES ET AL., 2014)	+	+	+	+	+	+	+	+	+	+
(PRATS ET AL., 2015)	+	+	+	+	+	+	+	+	+	+
(SANDERS ET AL., 2008)	+	+	+	+	+	+	+	+	+	+
(SCHAFFER ET AL., 2023)	+	+	+	+	+	+	+	+	+	+
(SEYEDMEHDI ET AL., 2013)	+	+	+	+	+	+	+	+	+	+
(SHESHADRI ET AL., 2020)	+	+	+	+	+	+	+	+	+	+
(SILVERMAN ET AL., 2007)	+	+	+	+	+	+	+	+	+	+
(SMITH ET AL., 2010)	+	+	+	-	-	+	+	+	+	+
(THERKORN ET AL., 2021)	+	+	+	-	-	+	+	+	+	+
(THOMPSON ET AL., 2006)	+	+	+	+	+	+	+	+	+	+

(THORNTON ET AL., 2024)	+	+	+	+	+	+	+	+	+	+
(VAN OOSTROM ET AL., 2018)	+	+	+	X	X	+	+	+	+	+
(WASILEWSKA ET AL., 2021)	+	+	+	+	+	+	+	+	+	+
(WASILEWSKA ET AL., 2022)	+	+	+	+	+	+	+	+	+	+

Drafted Spirometry Critical Appraisal Assessment

Reviewer: _____ Date: _____

Author: _____ Year: _____ Record Number: _____

Yes No Unclear Not
applicable

Participants and Setting: (selection bias)

- | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. Were the criteria for inclusion/exclusion in the study subjects clearly defined? | ☐ | ☐ | ☐ | ☐ |
| 2. Were the study subjects and the setting described in detail? | ☐ | ☐ | ☐ | ☐ |
| 3. Was the representativeness of the study subjects relative to the target population described? | ☐ | ☐ | ☐ | ☐ |

Performing Spirometry: (performance and confounding bias)

- | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 4. Was the spirometer(s) manufacturer and model clearly described? | ☐ | ☐ | ☐ | ☐ |
| 5. Was an appropriate spirometry standard (e.g. ATS/ERS 2019) used for performing spirometry? | ☐ | ☐ | ☐ | ☐ |
| 6. Was the calibration or verification procedure of the spirometer clearly described? | ☐ | ☐ | ☐ | ☐ |
| 7. Was the expertise of the tester(s) in performing spirometry clearly described (formal training, previous experience, certification, competency reassessment)? | ☐ | ☐ | ☐ | ☐ |

Assessing Results: (detection bias; reporting and attrition bias)

- | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 8. Was the assessment method (manual vs automated algorithm) for spirometry quality and airflow pattern clearly described? | ☐ | ☐ | ☐ | ☐ |
| 9. Was quality grading performed for FEV ₁ data? | ☐ | ☐ | ☐ | ☐ |

- | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 10. Was quality grading performed for FVC data? | ☐ | ☐ | ☐ | ☐ |
| 11. Was the number of acceptable and repeatable tests relative to the total number of tests performed clearly described? | ☐ | ☐ | ☐ | ☐ |
| 12. Were the criteria for and number of exclusions of spirometry results clearly described? | ☐ | ☐ | ☐ | ☐ |
| 13. Was airflow pattern appropriately analysed? | ☐ | ☐ | ☐ | ☐ |
| 14. Was the sample size adequate? | ☐ | ☐ | ☐ | ☐ |
| 15. Was appropriate statistical analysis used? | ☐ | ☐ | ☐ | ☐ |

Overall appraisal: Include ☐ Exclude ☐ Seek further information