National Clinical Guideline

Management of Chronic Obstructive Pulmonary Disease (COPD)

National Clinical Effectiveness Committee

V 5 July 2020

Version History

Date	Version	Details
May 2014	1	New
Aug 2017	2	Updated table of contents and Introductory pages (GDG, credits and acknowledgements etc.)
Nov 2019	3	Updated from new GOLD guidelines
June 2020	4	Updated full first version
July 2020	5	Updated on GDG feedback

CEU - this top section left intentionally blank for addition of logos.

GDG *must provide all the required logos (high definition images sized at 100% and the d.p.i. should be 300. JPGS, TIFFS and EPS are the required format. They must be sent*

This National Clinical Guideline has been developed by the Guideline Development Group supported by the National Clinical Programme for Respiratory.

Using this National Clinical Guideline

This National Clinical Guideline applies to the management of adults with COPD. . This National Clinical Guideline is relevant to all healthcare professionals caring for people with COPD.

Disclaimer

NCEC National Clinical Guidelines do not replace professional judgment on particular cases, whereby the clinician or health professional decides that individual guideline recommendations are not appropriate in the circumstances presented by an individual patient, or whereby an individual patient declines a recommendation as a course of action in their care or treatment plan. In these circumstances the decision not to follow a recommendation should be appropriately recorded in the patient's healthcare record.

Users of NCEC National Clinical Guidelines must ensure they have the current version (hardcopy, softcopy or App) by checking the relevant section in the National Patient Safety Office on the Department of Health website: http://health.gov.ie/national-patient-safety-

Published by:

The Department of Health
Hawkins House, Hawkins Street, Dublin 2, D02 VW90, Ireland
Tel: +353 (1) 6354000
www.health.gov.ie

ISSN 2009-6259.

CEU Citation text

Department of Health (yyyy). Title (NCEC National Clinical Guideline No. XX). Available at: http://health.gov.ie/national-patient-safety-office/ncec/
In text citation (Department of Health YYYY)

Membership of the Guideline Development Group (GDG)

The GDG was chaired by Dr Desmond Murphy (2020 to date) and Prof Tim McDonnell, (2014 -2019) as Clinical Leads of the National Clinical Programme for Respiratory. This National Clinical Guideline is supported by the GDG National Clinical Programme for Respiratory, The Chronic Disease Team, Irish College of General Physicians (ICGP), Irish Thoracic Society (ITS), and Royal College of Physicians Ireland (RCPI).

Membership nominations were sought from a variety of clinical and non-clinical backgrounds so as to be representative of all key stakeholders within the respiratory services. GDG members included those involved in COPD clinical practice, education, administration, research methodology, clinical risk and quality assurance as well as two persons representing patients and the public. Membership nominations were sought from a variety of clinical and non-clinical backgrounds so as to be representative of all key stakeholders within the acute and community sectors whilst also being cognisant of geographical spread and urban/rural representation. GDG members included those involved in clinical practice, education, administration, research methodology, and persons representing patients and family carers and support groups.
Members were recruited and invited to partake in the GDG on the provision that they provided justifiable expertise and /or viewpoints to the group, offering valuable contributions based on their extensive knowledge in the field of COPD, and/or professional experience of working with people with COPD, and/or knowledge of a healthcare sector. Appendix 1 contains the terms of reference for the GDG. Members were not compensated to be involved or contribute to the GDG and were informed that it was on a voluntary basis.

Table 1: Members of the COPD GDG

Name	Job title and affiliation
Dr Desmond Murphy (2020) **Prof Tim McDonnell (Chair 2014-2019)**	**Clinical Leads, National Clinical Programme for Respiratory, HSE**
Mark O Kelly	**ICGP HSE Primary Care Lead for Integrated Care Programme (COPD)**
Michael Drohan	**Patient Representative**
Ms. Rosie Hassett (2018-2020) **Ms. Patricia Davis (2020)**	**Nurse Service Planner (interim), National Clinical Programme for COPD**
Ms. Eimir Hurley	**BSc (Pharm) MBiostat, HRB (SPHeRE) PhD Scholar in Population Health & Health Service Research, (contributer)**

Ms. Linda Kearns (2014-2018)	**Programme Manager, National Clinical Programme for COPD, HSE**
Ms. Susan Curtis (2019- date)	**Programme Manager, National Clinical Programme for Respiratory, HSE**
Maureen O'Callaghan (2017)	**Joint Therapy Leads (Physiotherapy), National Clinical Programme for Respiratory**
Ms. Anne Lanigan & Ms. Brenda Deering	
Ms. Patricia McQuillan	**Professional Development Co-coordinator for Practice Nurses, HSE**
Ms. Sarah O Connor	**CEO of Asthma Society Ireland**
Ms. Geraldine Nolan	**Respiratory Physiologist Lead National Clinical Programme Respiratory**
Dr Marissa O'Callaghan	**St Vincent's University (Contributor)**
Dr Miriam Owens (2019- date)	**Public Health Specialist, Department of Public Health , HSE**
Dr Máire O'Connor (2018)	**Public Health Specialist, Department of Public Health, HSE**
Peter O'Toole	**Advanced Nurse Practitioner, representative National Clinical Programme**
Damien Peelo (2013-2017)	**CEO of COPD Support Ireland (Patient Representative group)**
Ms. Bernie Murphy (2017-2018)	**CEO of COPD Support Ireland (Patient Representative group)**
Ms. Joan Johnston (2020)	**National Coordinator, COPD Support Ireland**
Ms. Edel Russell (2019)	**Dietetic Representative, National Clinical Programme for Respiratory**

Ms. Suzanne Seery (2016-2017)	**Dietetic Representative, National Clinical Programme for Respiratory**
Ms. Marian Wyer (2017)	**Nursing & Midwifery Planning & Development (NMPD) Officer, HSE**

Credits

The role of the NCEC is to prioritise, quality assure and recommend clinical guidelines to the Chief Medical Officer for endorsement by the Minister for Health. It is intended through Ministerial endorsement that full implementation of the guideline will occur through the relevant service plans.

The NCEC and the Department of Health acknowledge and recognise the Chair and members of the Guideline Development Group (GDG) for development of the guideline. The NCEC and Department of Health wish to express thanks and sincere gratitude to all persons contributing to this National Clinical Guideline; especially those that give of their time on a voluntary basis.

Acknowledgments

The Chair of the GDG, Dr Desmond Murphy wishes to acknowledge the COPD guideline development group as contributors to the development of NCG. All members approved the final clinical guideline. Ms. Susan Curtis and Dr Desmond Murphy submitted the guideline proposal to the NCEC. The GDG would like to acknowledge and thank GOLD and Rebecca Decker for their assistance and contributions. Paul Carty and the HRB- CICER teams carried out a systematic review of cost effectiveness, as well as conducting the budget impact analysis. The evidence synthesis team from NUI Galway prepared two reports: (1) Considerations of International clinical guidelines to inform an ADAPTE methodology; and (2) a systematic review of settings for delivery of pulmonary rehabilitation for COPD. Dr Desmond Murphy, Prof. Tim McDonnell, Dr. Miriam Owens, Mark O' Kelly, Linda Kearns and Susan Curtis, *prepared the logic model and implementation plan. Ms. Susan Curtis and Dr Desmond Murphy* successfully submitted the proposal/guideline for NCEC quality assurance. All authors approved the final guideline.

The external reviews carried out by Professor Stephen Bourke and Dr X. is acknowledged. A full list of members of the Guideline Development Group is available in the previous page/s.

Signed by the Chair(s) _  Date*: _13/07/20*_____

National Clinical Guidelines

Providing standardised clinical care to patients in healthcare is challenging. This is due to a number of factors, among them diversity in environments of care and complex patient presentations. It is self-evident that safe, effective care and treatment are important in ensuring that patients get the best outcomes from their care.

The Department of Health is of the view that supporting evidence-based practice, through the clinical effectiveness framework, is a critical element of the health service to deliver safe and high quality care. The National Clinical Effectiveness Committee (NCEC) is a Ministerial committee set up in 2010 as a key recommendation of the report of the Commission on Patient Safety and Quality Assurance (2008). The establishment of the Commission was prompted by an increasing awareness of patient safety issues in general and high profile health service system failures at home and abroad.

The NCEC on behalf of the Department of Health has embarked on a quality assured National Clinical Guideline development process linked to service delivery priorities. Furthermore, implementing National Clinical Guidelines sets a standard nationally, to enable healthcare professionals to deliver safe and effective care and treatment while monitoring their individual, team and organisation's performance.

The aim of these National Clinical Guidelines is to reduce unnecessary variations in practice and provide an evidence base for the most appropriate healthcare in particular circumstances. As a consequence of Ministerial mandate, it is expected that NCEC National Clinical Guidelines are implemented across all relevant services in the Irish healthcare setting.

The NCEC is a partnership between key stakeholders in patient safety. NCEC's mission is to provide a framework for national endorsement of clinical guidelines and clinical audit to optimise patient and service user care. The NCEC has a remit to establish and implement processes for the prioritisation and quality assurance of clinical guidelines and clinical audit so as to recommend them to the Minister for Health to become part of a suite of National Clinical Guidelines and National Clinical Audit. The aim of the suite of National Clinical Guidelines is to provide guidance and standards for improving the quality, safety and cost-effectiveness of healthcare in Ireland. The implementation of these National Clinical Guidelines will support the provision of evidence-based and consistent care across Irish healthcare services.

NCEC Terms of Reference

1. Provide strategic leadership for the national clinical effectiveness agenda.
2. Contribute to national patient safety and quality improvement agendas.
3. Publish standards for clinical practice guidance.
4. Publish guidance for National Clinical Guidelines and National Clinical Audit.
5. Prioritise and qualities assure National Clinical Guidelines and National Clinical Audit.
6. Commission National Clinical Guidelines and National Clinical Audit.
7. Align National Clinical Guidelines and National Clinical Audit with implementation levers.
8. Report periodically on the implementation and impact of National Clinical Guidelines and the performance of National Clinical Audit.

9. Establish sub-committees for NCEC work streams.
10. Publish an annual report.

Table of contents

Annex

NUIG 2 reports:

1. Guidelines for the management of Chronic Obstructive Pulmonary Disease (COPD), a systematic search, screening and quality assessment as part of the ADAPTE process = Annex A
2. The setting of pulmonary rehabilitation for Chronic Obstructive Pulmonary Disease (COPD), a systematic review = Annex B

HRB-CICER 2 reports:

1. Systematic review of cost effectiveness - Management of Chronic Obstructive Pulmonary Disease in adults = Annex C
2. Budget impact analysis - Management of Chronic Obstructive Pulmonary Disease in adults = Annex D

Logic Model & Implementation plan Annex E

ADAPTE Toolkit – available on request

List of table's in main text

List of figures in main text

List of figures in appendix

2 Glossary of terms

ADAPTE Process	Process for adapting clinical guidelines
AECOPD	Acute exacerbation COPD
AOT	Ambulatory Oxygen Therapy
BIA	Budget impact analysis
CAT	COPD Assessment Tool
CCQ	Clinical COPD Questionnaire
CEA	Cost-effectiveness analysis
CDM	Chronic Disease Management
COPD	Chronic obstructive pulmonary disease
CRQ	Chronic Respiratory Questionnaire
CUA	Cost-utility analysis
DALY	Disability-adjusted life year
EAD	Early assisted discharge
ED	Emergency department
EQ-5D	EuroQol five dimensions
FEV1	Forced expiratory volume in one second
GDG	Guideline development group
GOLD	Global Initiative for Chronic Obstructive Lung Disease
HCP	Healthcare professional
HRB-CICER	Health Research Board – Collaboration in Ireland for Clinical Effectiveness Reviews
HRQoL	Health related quality of life
HSE	Health Service Executive
GP	General practitioner
HRQoL	Health related quality of life
HTA	Health technology assessment
ICS	Inhaled corticosteroid
KPI	Key performance Indicator
LTOT	Long term oxygen therapy
MECC	Making every contact count
MOC	Model of care
NCP	National Clinical Programme
NIV	Non Invasive Ventilation
PIPOH	Population, Intervention, Professionals, Outcomes, Healthcare settings and context
PaO^2	Pressure of arterial oxygen
PRP	Pulmonary rehabilitation programme
QALY	Quality-adjusted life-year
OECD	Organisation for economic co-operation

	and development
RCT	Randomised controlled trial
SaO^2	Saturation of arterial oxygen

Section 1 National Clinical Guideline recommendations

1.1 Summary of recommendations

This National Clinical Guideline outlines recommendations for healthcare professions on the care of individuals with COPD and is based on the highest quality scientific evidence currently available. This guideline is not intended to replace the healthcare professional's expertise or experience but is a tool to assist the practitioner in their clinical decision making process with consideration to their patients' preferences. To assist the reader of this guideline the key to the grading of evidence and recommendations is as follows.

Table 3 Grades of recommendation

Grades of recommendation (adapted from GOLD 2017 and training from DOH)	
Note the grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation	
A	**Randomised controlled trials, Rich body of high quality evidence without any significant limitation or bias.** Evidence is from endpoints of well-designed Randomised controlled trials (RCT) that provide consistent findings in the population for which the recommendation is made without any important limitations. Requires high quality evidence from ≥ 2 clinical trials involving a substantial number of subjects, or a single high quality RCT involving substantial numbers of patients without any bias.
B	**Randomised controlled trials with important limitations, limited body of evidence.** Evidence is from RCTs that include only a limited number of patients, post hoc or subgroup analyses of RCTs or meta analyses of RCTs. Also pertains when few RCTs exist, or important limitations are evident (methodologic flaws small numbers, short duration, undertaken in a population that differs from the target population of the recommendation or the results are somewhat inconsistent)
C	**Non-randomised trials, Observational studies**

	Evidence is from outcomes of uncontrolled or non-randomised trials or from observational studies
D	**Panel consensus judgment** Provision of guidance is deemed valuable but clinical literature addressing the subject is insufficient. Panel consensus is based on clinical expertise or knowledge that does not meet the above stated criteria
Good Practice points	Recommended best practice based on the clinical experience of the guidance development group

Guideline Recommendations

Pharmacological Management of COPD		
Recommendation		**Grade of recommendation**
Recommendation 1 *Short acting bronchodilators*	**1.1** Inhaled short acting beta 2 agonists (SABAs) should be prescribed to patients with confirmed COPD where rescue therapy is needed. (Grade A) ***(GOLD)***	***Grade A***
Recommendation 2 *Long acting bronchodilators*	**2.1** Long acting bronchodilators should be offered to patients with confirmed stable COPD who continue to have respiratory symptoms (e.g. dyspnoea or cough). *(Grade A)* ***(GOLD)*** **2.2** Inhaled long acting muscarinic agents (LAMAs) should be offered to patients as first line maintenance therapy in patients with confirmed stable COPD who have continued respiratory symptoms (e.g. dyspnoea, cough) or who have a history of exacerbations with COPD. *(Grade A)* ***(GOLD)*** **2.3** In patients with confirmed stable COPD who are on inhaled LAMAs or inhaled LABAs alone and have persistent dyspnoea on mono therapy combination therapy with both LAMAs and LABAs is recommended is superior	***Grade A*** ***Grade A*** ***Grade A***

	to LAMA's or LABA's alone is recommended. *(Grade A)* ***(GOLD)***	
Recommendation 3 *Inhaled corticosteroids*	**3.1** Offering an inhaled cortical steroid (ICS) in symptomatic patients with confirmed stable COPD as first line therapy is not recommended. *(Grade A)* ***(Department of Veteran Affairs)*** ***(Implied in GOLD)*** **3.2** Regular treatment with ICS increases the risk of pneumonia especially in those with severe disease (Grade A) **3.3** An ICS combined with a LABA is more effective than individual components in improving function and health status and reducing exacerbations in patients with exacerbations moderate to very severe COPD (Grade A) **3.4** In patients with confirmed COPD who are on combination therapy with LAMAs and LABAs and have persistent dyspnoea or frequent COPD exacerbations, it is suggested that the addition of an ICS may be reasonable. Blood eosinophil count may be used as a biomarker for estimating the efficacy of inhaled corticosteroids (ICS) for the prevention of exacerbations. It has been recognised that there is a continual relationship between the effects of an ICS and eosinophil counts. *(Grade B)*	***Grade A*** ***Grade B***

Recommendation 4 *Inhaler technique*	**4.1** It is recommended that each patient commenced on an inhaler device would be provided with instructions and a demonstration of proper inhalation technique prior to using the device and that such technique is checked on a regular basis subsequently. Inhaler technique and adherence to therapy should be assessed before concluding that current therapy is insufficient and a change in therapy considered. **(Expert Opinion)** ***(GOLD)***	**Expert Opinion**
Recommendation 5 *Roflumilast*	**5.1** In selected patients with the chronic bronchitic phenotype of COPD with severe to very severe air flow obstruction and history of exacerbations, a phosphodiesterase-4 (PDE-4) inhibitor may be reasonable add on to therapy with a LAMA and LABA and possibly ICS. This recommendation is not reimbursement by the HSE. *(Grade B)* ***(GOLD)***	**Grade B**
Recommendation 6 *Theophyllines*	**6.1** In certain selected patients, the addition of a theophylline may be reasonable. *(Grade B*) **(GOLD)**	**Grade B**
Recommendation 7 *Prophylactic use of Macrolide Antibiotics*	**7.1** In patients who have severe COPD with two treated exacerbations and are non-smokers, the addition of azithromycin may be considered for one year *(Grade A*). ***(GOLD)*** This needs to be done in conjunction with Respiratory Specialist advice with surveillance for bacterial resistance and side effects such as impaired hearing and cardiac arrhythmias.	***Grade A***
Recommendation 8 *Antioxidants and mucolytics*	**8.1** The use of mucolytic and antioxidants in routine practice for management of patients with COPD is **not recommended**. ***(GOLD)***	
Recommendation 9 *Leukotriene antagonists*	**9.1** A role for leukotriene receptor antagonists in the management of patients with COPD is **not recommended.** ***(GOLD)***	

Recommendation 10 *Alpha One Anti-trypsin (AATD) Augmentation Therapy*	**10.1** It is recommended that AATD augmentation therapy might be considered in young patients who are never or ex-smokers with an FEV 1 of 35-60% predicted with continued and progressive disease. This recommendation is not reimbursed by HSE. (Grade B*) **(GOLD)***	**Grade B**

Non-Pharmacological Management of COPD		
Recommendation		**Grade**
Recommendation 11 *Smoking cessation*	**11.1** Smoking cessation measures are recommended for the prevention of COPD, to include advice on smoking cessation, nicotine replacement therapy and pharmacotherapy. (Grade A) **(GOLD)** At the moment, the effectiveness and safety of E. cigarettes as a smoking cessation aid is uncertain.	***Grade A***
Recommendation 12 *Influenza vaccination*	**12.1** The provision of annual influenza vaccination is recommended. (Grade A) **(GOLD)**	***Grade A***
Recommendation 13 *Pneumococcal vaccination*	**13.1** The provision of the pneumococcal vaccination is recommended. (Grade B) **(GOLD)**	***Grade B***
Recommendation 14 *Pulmonary rehabilitation*	**14.1** The provision of pulmonary rehabilitation to stable patients with exercise limitation despite pharmacological treatment is recommended. (Grade A) **(GOLD)** **14.2** The provision of pulmonary rehabilitation to patients who have recently been hospitalised for an acute exacerbation of COPD is recommended. (Grade B) **(GOLD)**	***Grade A*** ***Grade B***

Recommendation 15 *Oxygen Therapy*	**15.1** The provision of long-term oxygen therapy to patients with chronic stable hypoxemia with a PaO_2 less than 7.3 Kpa or a $Pa0_2$ between 7.3 and 8Kpa with signs of tissue hypoxia (haematocrit greater than 55%, pulmonary hypertension or cor pulmonale) is recommended. *(Grade A)* ***(GOLD)*** **15.2** The provision of oxygen for patients with moderate hypoxemia, nocturnal desaturation, or exercise-induced desaturation in patients with COPD is not routinely recommended. (Grade A) ***(GOLD)***	***Grade A*** ***Grade A***
Recommendation 16 *Nutritional support*	**16.1** Nutritional support should be considered in all malnourished patients with COPD (Grade B) ***(GOLD)***	**Grade B**
Recommendation 17 *Lung volume reduction surgery*	**17.1** Lung volume reduction surgery is recommended for carefully selected patients with upper lobe emphysema and low post rehabilitation exercise capacity. (Grade A) ***(GOLD)*** **17.2** In selected patients, bullectomy can also be recommended. (Grade C) ***(GOLD)*** **17.3** In selected patients with advanced emphysema, bronchoscopic interventions can reduce end-expiratory lung volume and improve exercise tolerance; health status and lung function at 6 to 12 months following	***Grade A*** ***Grade C***
Recommendation 18 *Lung transplantation*	**18.1** It is recommended that appropriately selected patients with very severe COPD be considered for lung transplantation surgery. (Grade C) ***(GOLD)***	***Grade C***
Recommendation 19 *Monitoring of Spirometry*	**19.1** In stable, diagnosed COPD patients, FEV 1 can be tracked by spirometry every two years. *(Expert Opinion)* ***(Guideline Development Group)***	***Expert Opinion***

Recommendation 20 *Role of Palliative Care*	**20.1** For advanced COPD care, patients should be referred to a palliative care specialist as appropriate. ***(Expert Opinion***) ***(Guideline Development Group)***	***Expert Opinion***
Management of Exacerbations in COPD		
Recommendation 21 *Bronchodilator therapy*	**21.1** The initiation of short acting acute bronchodilator therapy (salbutamol plus or minus ipratropium) is recommended for patients with an exacerbation of COPD (Grade C) (***GOLD***)	***Grade C***
Recommendation 22 *Steroids*	**22.1** A course of systemic steroids (prednisone equivalent of 40mgs for five days) to be administered orally to all patients is recommended. Therapy should not routinely be administrated for longer than this. *(Grade A*) ***(GOLD)***	***Grade A***
Recommendation 23 *Antibiotics*	**23.1** Oral antibiotic use for patients with exacerbations of COPD associated with increased dyspnoea and associated increased sputum purulent or volume is recommended. First line antibiotic choices should include doxycycline, amoxicillin or a macrolide. Reserving broader spectrum antibiotics such as quinolones for specific indications is recommended. The choice of antibiotics may be modified due to local bacterial resistance patterns or an individual's sputum microbiology. (Grade B) ***(GOLD/Expert Opinion)***	***Grade B***
Recommendation 24 *Non-invasive ventilation (NIV)*	24.1 The use of non-invasive ventilation in patients with acute exacerbations of COPD who develop acute respiratory failure associated with respiratory acidosis is recommended i.e. a $PaCO_2$ greater than 6KPa and an arterial PH less than 7.35 which is persistent following rationalization of delivered oxygen therapy. **(Grade A)** ***(GOLD)***	***Grade A***

Recommendation 25 *COPD Outreach service*	**25.1** The involvement of the COPD outreach team as early as possible for patients admitted to hospital with an exacerbation of COPD. *(Expert Opinion)* **(Guideline Development Group)**	***Expert Opinion***
Recommendation 26 *Specialist Respiratory Physiotherapists and Nurses*	**26.1** It is recommended that respiratory specialist physiotherapists and nurses are key in delivering COPD outreach, NIV, oxygen assessment and pulmonary rehabilitation to patients who have exacerbations of COPD and stable COPD (Expert Opinion) ***(Guideline Development Group)***	***Expert Opinion***
Recommendation 27 *Theophyllines*	**27.1** The use of theophylline in acute exacerbations of COPD is not recommended. (Grade B) ***(GOLD)***	***Grade B***
Oxygen therapy prescribing and monitoring in COPD		
Recommendation 28	**28.1** *Oxygen therapy prescribing and monitoring in COPD* Patients discharged home following hospitalisation on oxygen therapy should be evaluated for the need to remain on long term oxygen therapy 30-90 days after discharge. Long term oxygen therapy should not be continued if patients do not meet the criteria. *(Expert Opinion)* ***(Guideline Development Group)*** **28.2** Routinely offering ambulatory LTOT for patients with chronic stable isolated exercise hypoxemia is not recommended. (Grade A) ***(GOLD)***	***Expert Opinion*** ***Grade A***

Pathways, Bundles and Checklists for Managing Acute Exacerbation of COPD		
Recommendation 29	**29.1** It is recommended that an admission and discharge bundle be applied to all patients admitted to hospital with an exacerbation of COPD. (Expert Opinion) ***(Guideline Development Group)***	**Expert Opinion**

Section 2: Development of the National Clinical Guideline

2.1 Background

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) defines Chronic Obstructive Pulmonary Disease (COPD) as (1): *"a common preventable and treatable disease that is characterised by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases".*

The disease is pathologically made up of two components; obstructive bronchiolitis with chronic bronchitis and parenchymal destruction (emphysema). The relative contribution of each component varies from patient to patient.

COPD has considerable impact on the quality of life of the patient, families and carers, involving on-going medical care, frequent hospital admissions for treatment of exacerbations and often resulting in premature death.

At least 1,500 patients die each year of this disease and over 15,000 patients are admitted to hospital with COPD. It has a profound effect on patients but also has a significant strain on the health service (2).

COPD is the most prevalent respiratory disease in adults. As COPD prevalence in Ireland has never been measured at a national level, exact figures for its prevalence and burden in Ireland are not known. Based on the 2011 consensus, it is estimated that almost 500,000 people aged 40 years and over in Ireland have COPD, of whom over 200,000 have moderate or severe disease and only half are likely to be diagnosed (34).The lowest estimates of prevalence are those based on self-reporting of a doctor diagnosis of COPD or equivalent condition. For example, most national data show that less than 6% of the adult population has been told that they have COPD (1). Many with COPD may be undiagnosed, especially those with milder disease, but diagnosed at a late stage, COPD health interventions are both less effective and more expensive. All studies show an increase with age; in people aged >70 years, the prevalence maybe 20% in men and 15% in women (3). Most studies confirm an increased prevalence in men. Probably in part due to different age distribution and varying environmental exposures, prevalence varies considerably between European countries (4).The global international, population-based Burden of Lung Disease (BOLD) studies, which use standardised survey methods and a spirometric criterion for COPD, report a prevalence of moderate – severe COPD (i.e. excludes mild disease) in Europe of 10% (3). Given the mortality and relatively high rate of hospitalisations for COPD in Ireland, Irish prevalence figures may well be as high. Extrapolating from studies done elsewhere in Europe suggests a prevalence of 275,000 cases based on a doctor made diagnosis, to 500,000 cases based on cross-sectional surveys (4).

The population aged >35 years in Ireland could increase by a factor of 51%-94% by 2036. This ageing Irish population together with current and historical smoking prevalence means that the health burden of COPD in Ireland will continue to increase and be a significant burden to people, health services and society for the foreseeable future. With the increasing convergence in smoking rates between males and females, the prevalence rate for COPD in women may in the future equal or even surpass that of men (5).

Projected estimates by the Institute for Public Health for 2020 suggest that in Ireland there is likely to be a 23% increase in the number of adults with clinically diagnosed chronic airway obstruction, with one third of this increase due to increases in the size of the population and two thirds due to population ageing (6). Risk factor identification is important both for prevention and treatment of COPD (2, 6-8).

Table 4 Risk factors for COPD

Host Factors	Environmental Factors
Genes (C) Gender (A) Age (A) Growth and development of the lung (A) Oxidative stress Respiratory airway hypersensitivity (A) Comorbidities (A)	Inhalational particles Outdoor air pollution (C if heavy) Indoor air pollution (C if heavy) Occupational exposures (C if heavy) Tobacco smoke (C) Social and economic level* (A) Respiratory Infections (A)

(A) Additive, (C) causal adapted from The Australian Lung Foundation (2001)

*Social and economic factors are proxies for nutritional status, crowding, exposure to pollutants including work exposures and smoking exposure, access to health care and early respiratory infections

Smoking Prevalence

Smoking is a factor in 85% of those with COPD. The prevalence of COPD is directly related to the prevalence of cigarette smoking but not all people with the same smoking history will develop COPD. Most of those affected have smoked over 20 pack years (20 per day for 20 years) (9-11). Up to 50% of lifelong smokers develop COPD. Genetic and other factors modify an individual's risk from smoking (12). The proportion of the risk of COPD attributable to smoking is estimated at 40–60%, depending on how many risk factors are taken into account. Although never-smokers are less likely to have COPD, never-smokers comprise about one-quarter of those classified with moderate-severe disease (GOLD stage II+ COPD) (14). Individuals highly exposed to passive smoking (>40hr/week for >5 years) are 48% more likely to present with COPD than are unexposed individuals (13, 14).
The results of Healthy Ireland survey published in 2015 found that 19% of the population (aged 15 and over) smoke on a daily basis (15). A further 4% identify themselves as occasional smokers. Figures from the Irish National Tobacco Control Office in December 2012 reported a smoking rate of 21.7% (22.6% of men, 20.9% of women). Smoking rates were highest among young adults (18-34 years), reaching 29.4% in the 25-34 year old age group. The highest cigarette smoking prevalence rates were in the lower income groups – 25.5% of those in C2 (skilled manual workers and those manual workers with responsibility for other people) and 26% of those in DE (D Semi skilled and unskilled manual workers, E Those entirely dependent on the state long-term plus those

unemployed for period exceeding 6 months) categories. The rate amongst those in C1 was 18.7%. The lowest smoking rates (16.1% and 14%) were among farmers (F) and higher socio-economic groups (AB). Given that the adverse effects of cigarettes in terms of COPD can have a lag period of 15-20 years; these rates have significant health implications for the medium and long term.

Social and Economic Factors

COPD is inversely associated with socio-economic status. The association between COPD and socio-economic factors relates not just to an individual's lifestyle and genetic determinants but also to socio-economic public policies such as housing standards, air pollution, and nutrition and service provision. The effects are reflected in risk factors for COPD – the smoking rates in Ireland among those in more deprived social groups as reported above are high compared with the national rate. Among homeless men in Dublin the smoking prevalence was 78% (16). These social and economic gradients are reflected not just in the prevalence of smoking but also in the prevalence of COPD and the outcome for those with COPD in terms of morbidity and mortality.

Other Contributing Factors

A serious, but often unrecognised, risk factor for COPD is lack of awareness among HCPs and the public. Lack of awareness is a risk factor in terms of delayed diagnosis and delayed effective intervention to slow progression of the disease. People with COPD often delay seeking medical help. Polymorphisms of many genes or combinations of genes may increase (or decrease) the risk of an individual developing COPD. The best documented genetic risk factor for COPD is hereditary α_1-Antitrypsin Deficiency. The incidence of severe (ZZ homozygotes) α_1-Antitrypsin Deficiency in the Irish population is estimated to be 1 in 2,100 (17).

Early Life Environmental factors such as mothers who smoke, frequent respiratory infections and asthma in childhood and bronchial hyper-reactivity are increasingly recognised as important risk factors for COPD. The proportion of the risk of COPD attributable to these early childhood events may be as great as that attributable to smoking. There is an overlap of up to 30% between people with a diagnosis of COPD and asthma (18, 19).

The World Health Organization (WHO) estimates that urban air pollution causes 1% of COPD cases in high-income countries such as Ireland (20). It also plays a role in the exacerbation of COPD in those with the disease. In Dublin, in the year following the banning of bituminous coal there were approximately 116 fewer respiratory deaths (21). The relevance of short-term, high peak exposures compared with long-term, low-level exposures is not yet known.

Occupational dust, chemicals and vapours can both cause and increase the risk of COPD independently of cigarette smoking but they also increase the risk of the disease in the presence of those exposed to smoke.(13) Among adults aged 30-75 years the percentage portion of COPD attributable to work is estimated at 19.2% overall. In never-smokers, the percentage portion of COPD attributable to occupational exposure is estimated to be 30% (22).

While current understanding of risk factors for COPD is incomplete, it is sufficient for action.

Burden of Disease in Ireland

COPD has considerable impact on the quality of life of the patient, involving long term medical care, frequent hospital admissions for many and often resulting in premature death. As with many chronic conditions, COPD not only affects the patient, but also has significant impact on the carer and family as well as the health services and wider society. The burden of COPD, as for other chronic diseases, is expressed in terms of disability-adjusted life years (DALYs), which are a composite of life lost due to premature death from COPD (YLL), and years lived with disability due to COPD (YLD). The Global Burden of Disease (GBD) Study compared the contribution of major diseases worldwide in 2010. Among leading causes of death, COPD ranked 3rd, while for years lived with disability (YLD), it ranked 5th (14, 34). When death and disability are combined as disability-adjusted life years (DALYs), globally COPD ranked 9th in 2010. In the same study, COPD was the 4th highest cause of DALYs in Ireland.

Morbidity

It is difficult to get a measure of the prevalence of the burden of COPD in Ireland and estimates vary widely. The 2015 Irish Health Survey conducted by the CSO asked survey respondents about whether they had suffered from chronic bronchitis, chronic obstructive pulmonary disease, or emphysema in the previous 12 months CSO (2017) Personal communication (23). From this, they estimated the prevalence of same to be 3% in those aged 45 to 54; 7% in those aged 55 to 64 yrs., 7% in those aged 65 to 74, and 8% in those aged 75 and above. The link between socio-economic status and prevalence of COPD is clear; with 2% of those in the 'very affluent' category reporting on a diagnosis of COPD (and related), and 6% of those in the 'very disadvantaged' category reporting same. The majority of those with COPD are managed in General Practice and GP presentation data would provide an excellent account of the burden of COPD in Irish Society. However, data on the number of COPD consultations in General Practice are not available. It is estimated that approximately 14.5% of all GP consultations are for respiratory disease (24).

Mortality

The Global Burden of Disease (GBD) study reported COPD as the 3rd leading cause of death globally in 2010 (25). The age standardised (to the European Standard Population) death rate for COPD, as reported in 2011, was 27.87 for Ireland compared with 18 per 100,000 inhabitants for the WHO European region. Only three countries (Denmark, Moldova, and Hungary) had rates higher than Ireland (3).

In 2013, the most recent year for which comparable EU data are available, rates of mortality from respiratory diseases (incl. cancer of trachea, bronchus and lung) were 40% higher in Ireland than the EU-28 average (193.1/100,000 vs. 137.1/100,000) (26).

In Ireland in 2016, there were 3,856 deaths registered as respiratory disease (excluding lung cancer). Deaths due to chronic lower respiratory disease (n = 1,711) and deaths due to pneumonia (n = 1049) account for 72% of these deaths. When cancer of the larynx/trachea/bronchus/lung are included (a further 1,928 deaths), respiratory diseases accounted for 19% of all registered deaths in 2016.

Deaths registered as due to chronic lower respiratory disease are under-estimates, as people with COPD often succumb to other COPD comorbidities especially pneumonia, or

non-respiratory causes in particular cardio-vascular disease. While the size of this under-estimation is unknown in Ireland, the literature would suggest that for more than 60% of people with COPD, comorbidity other than COPD may be listed as the primary cause of their death. Under recognition and under diagnosis of COPD affect the accuracy of mortality data. While COPD is frequently the primary cause of death it may be listed as a contributory cause of death or omitted from that certificate entirely. An Irish audit showed that the in-hospital mortality for those with COPD was 3.3% and the 90-day mortality was 8.3% (27).

In Ireland, almost 70% of excess winter mortality from respiratory disease arises in the poorest three socio-economic groups (28). An Irish study which looked from respiratory disease was greater than 200% between the lowest and highest occupational class (29). More recent data for the period 2007-2012, shows a difference in COPD mortality in the order of 303%, in the lower classes compared with the upper classes for males aged 15+. For the age group, 15-64 years, the excess is even higher at 366%. In other words, deaths from COPD in the period 2007-2012 were three times higher in the lower social class compared with the upper social class, implying a much greater mortality for lower social classes from COPD (CSO, 2014). Such data show that the greatest burden in terms of COPD mortality is borne by those in the lower social classes.

2.2 Clinical and financial impact of condition/disease

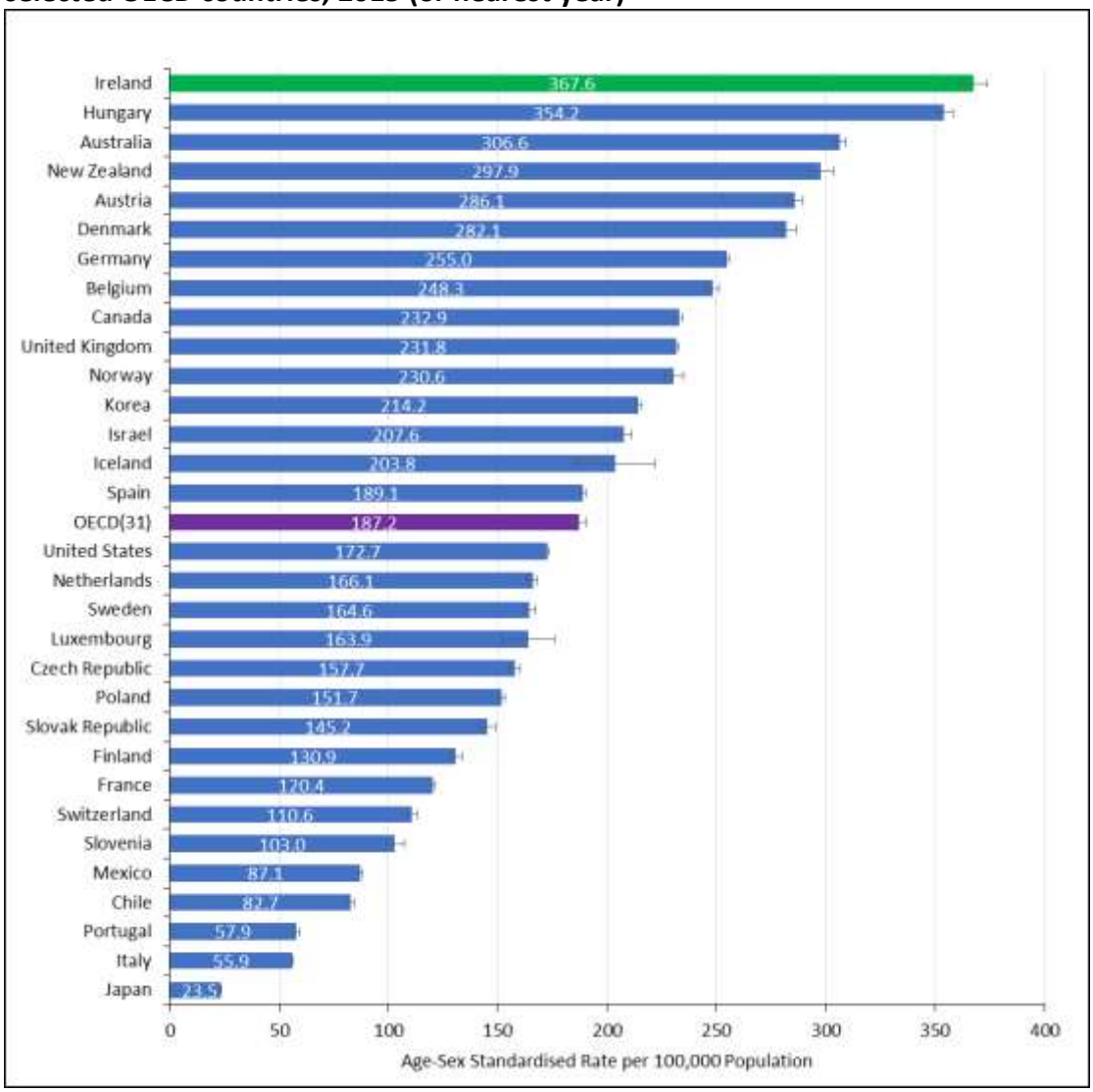
BURDEN ON HEALTH SERVICES PLUS WIDER ECONOMIC AND SOCIAL BURDEN OF COPD

Associated with the disease burden of COPD evidenced in the above section, is a significant economic and social cost. The impact of COPD on healthcare facilities is profound, but it also has wider social and economic effects. For the individual patient, COPD is associated with a significant economic burden in terms of the direct medical costs associated with it and also indirect costs including care provided by family members.

HOSPITAL UTILISATION

Patients with severe disease may suffer frequent exacerbations requiring medical attendance, potential hospitalisation and severe disruption of their quality-of-life. Data for admissions to acute public hospitals are of use as proxy measures of disease burden especially for those at the more severe end of the COPD spectrum. Of those hospitalised in Ireland with COPD, over 90% have additional co-morbidities while 6.5% require ventilation (24).

Fig 1: Age-sex standardised hospitalisation rates for COPD per 100,000 populations for selected OECD countries, 2015 (or nearest year)

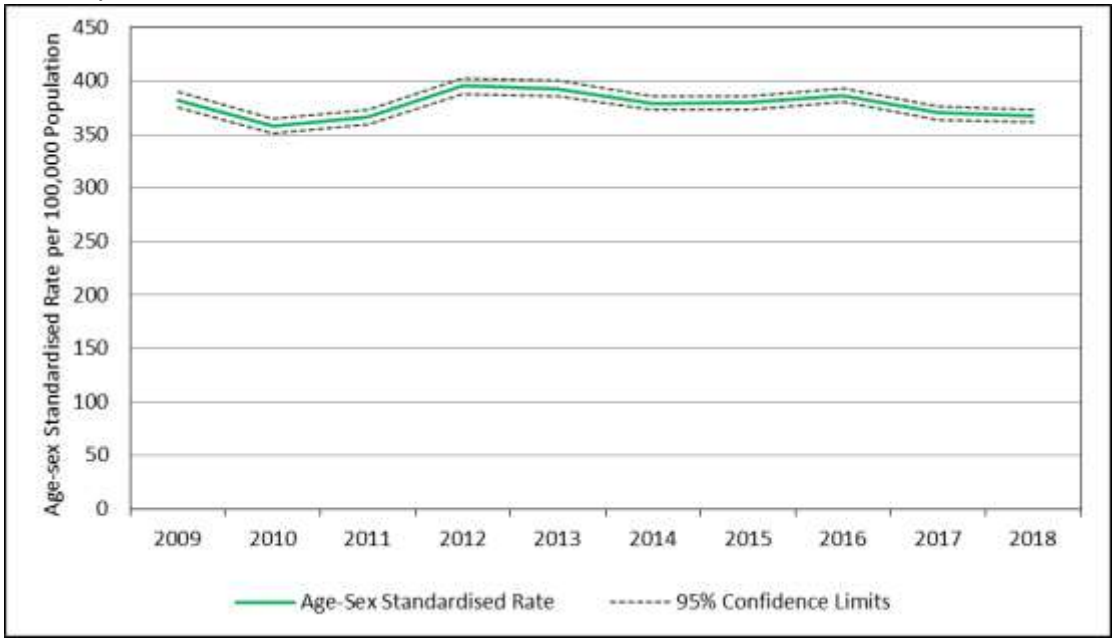


Source: OECD Health Statistics.

Ireland has the highest rate of hospitalisation for COPD of all OECD countries (Fig 1). In 2015 (the latest year for which OECD data are currently available), the age-standardised hospitalisation rate in Ireland based on OECD age standardisation 367/100,000, 00,000 populations. The national age-sex standardised hospitalisation rate for COPD increased slightly between 2009 and 2018, with 354 per 100,000 populations in 2018 compared with 303 hospitalisations per 100,000 populations in 2009 (Fig 2). Most countries in the OECD have reported a reduction in hospitalisation rates for COPD over recent years, perhaps as a result of improvements in access to, and the quality of, primary care. As in previous years, the OECD reported that Ireland had the highest age-sex standardized hospitalisation rate for COPD in 2015, the latest year for which international data is available. While Ireland's average rate has decreased from 379 hospitalisations per 100,000 populations in 2005 to 367 in 2016, the OECD average also declined (214 to 187). In Ireland during the three-year period from 2016-2018, the age-sex standardised

hospitalisation rate by county of residence ranged from 242 hospitalisations per 100,000 populations in Kerry to 552 hospitalisations per 100,000 populations in Offaly (Fig 3) (34).

Fig. 2: Age-sex standardised hospitalisation rates for COPD per 100,000 population in Ireland, 2009 - 2018



Source: Hospital In-Patient Enquiry (HIPE)

This discrepancy may be due – in part - to differences in how countries code their hospitalisation data; Ireland uses the ICD-10-AM/ACHI coding system and other countries that use this system were also above the OECD average, suggesting that comparability across the OECD as a whole may be inappropriate. This caveat notwithstanding however, differences in coding alone cannot explain why hospitalisation rates in Ireland are the highest among all of the countries listed.

The hospitalisation figures for episodes of care for patients with a diagnosis of COPD discharged from adult acute public hospitals are shown in Table 6 below. Also presented are the numbers of inpatient bed days used (BDU) and mean and median length of stay (LOS) over this time period. Across acute hospitals in 2017, COPD accounted for 3.9% of all discharges and 4.4% of all bed days used (in adults aged 35 years and older). In addition to the 15,127 discharges with a primary diagnosis of COPD from these hospitals, there were a further 14,514 episodes of care where COPD was recorded as a secondary diagnosis implying that for 7.6% of inpatient discharges (in adults aged 35 years and older) in adult acute hospitals, COPD was a factor. Episodes of care with a primary or secondary diagnosis of COPD accounted for almost 12% of in-patient bed days in adult acute hospitals in 2016, again amongst adults aged 35 years and older (see Table 7).
Day case activity for COPD was considerably lower: - 1,914 episodes in 2016 across all hospitals reporting to HIPE.

Table 5 COPD Hospital Admission Rates per 100,000 Population by County of Residence, 2016 - 2018

County of Residence	Number of Cases	Age-Sex Standardised Admission Rate	Lower 95% Confidence Limit for Admission Rate	Upper 95% Confidence Limit for Admission Rate
Carlow	622	495.0	456.1	533.9
Cavan	660	376.3	347.5	405.2
Clare	762	264.3	245.5	283.2
Cork	3,956	313.7	303.9	323.4
Donegal	2,013	488.4	467.1	509.7
Dublin	11,341	401.5	394.1	408.9
Galway	1,949	338.3	323.3	353.4
Kerry	890	224.6	209.7	239.4
Kildare	1,452	381.7	361.5	401.8
Kilkenny	776	327.0	304.0	350.0
Laois	815	506.5	471.2	541.9
Leitrim	268	289.9	255.0	324.8
Limerick	1,769	384.0	366.1	401.9
Longford	423	439.3	397.4	481.2
Louth	1,159	418.2	394.1	442.3
Mayo	1,346	363.5	344.1	383.0
Meath	1,220	338.7	319.5	358.0
Monaghan	412	282.4	255.1	309.6
Offaly	975	552.8	518.1	587.6
Roscommon	758	407.0	378.0	436.0
Sligo	706	405.9	376.0	435.7
Tipperary	1,745	419.1	399.4	438.7
Waterford	826	292.2	272.2	312.1
Westmeath	1,005	520.2	488.0	552.4
Wexford	1,713	463.3	441.3	485.2
Wicklow	883	274.7	256.4	293.0
National	**40,444**	**375.7**	**372.1**	**379.4**

Table 6 In-patient discharges with a primary diagnosis of COPD* in adult acute public hospitals, 2009-2017 (adults aged 35 years and older)

Year	Discharges COPD*	% of all in-patient discharges	Rate/100,000 population	Bed days used[&] COPD*	% of all in-patient bed days used	Mean [&] LOS (SD)	Median[&] LOS (IQR)
2009	11,026	3.6%	507	102,907	4.1%	9.3 (13.5)	6 (3-10)
2010	10,615	3.5%	478	98,718	4.0%	9.3 (15.4)	6 (3-10)
2011	11,364	3.7%	500	99,269	4.1%	8.7 (13.2)	6 (3-10)
2012	13,059	3.9%	567	105,132	4.3%	8.0 (13.2)	5 (3-9)
2013	13,830	4.0%	590	109,048	4.4%	7.8 (13.5)	5 (2-9)
2014	14,140	3.9%	591	111,349	4.4%	7.8 (11.7)	5 (2-9)
2015	14,489	4.0%	592	115,593	4.4%	7.9 (12.1)	5 (2-9)
2016	15,460	4.1%	614	119,787	4.5%	7.7 (11.8)	5 (2-9)
2017	15,127	3.9%	591	119,845	4.4%	7.8 (12.7)	5 (2-9)

Source: HIPE 2009-2017.

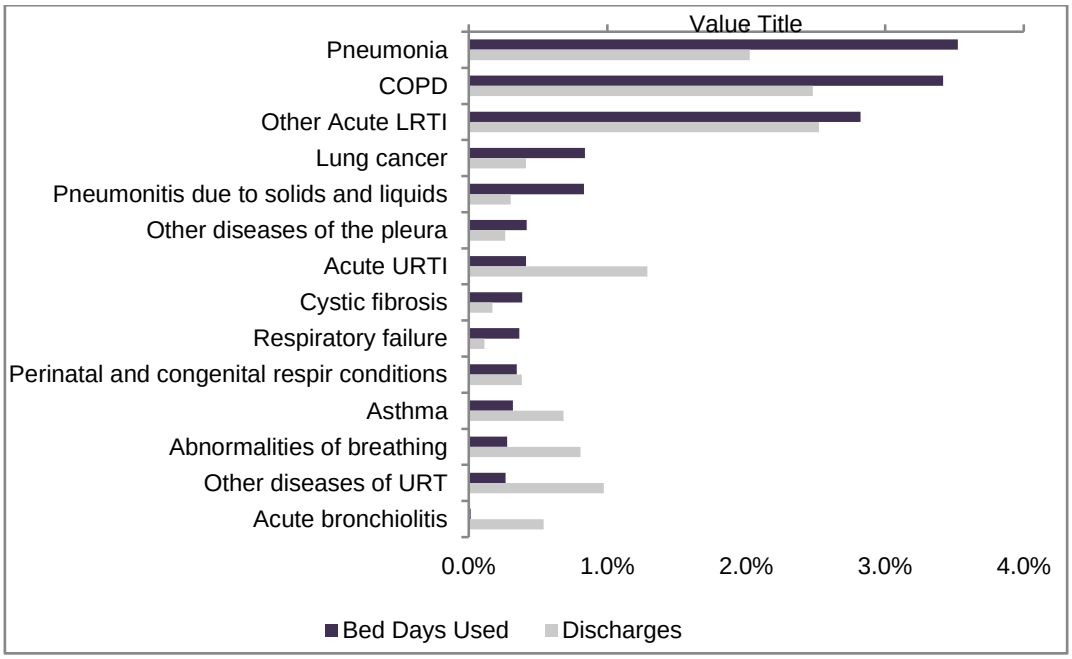
Table 7 In-patient discharges with a primary or secondary diagnosis of COPD* in adult acute public hospitals, 2009-2017 (adults aged 35 years and older)

Year	Discharges COPD*	% of all in-patient discharges	Rate/100,000 population	Bed days used[&] COPD*	% of all in-patient bed days used
2009	22,445	7.2%	1033	268,947	10.8%
2010	23,422	7.6%	1056	282,243	11.5%
2011	24,218	7.9%	1065	279,596	11.7%
2012	26,876	7.9%	1167	283,969	11.5%
2013	27,924	8.0%	1191	290,307	11.8%
2014	28,007	7.8%	1171	291,325	11.5%
2015	28,133	7.7%	1150	307,555	11.7%
2016	29,780	7.8%	1182	317,993	11.9%
2017	29,641	7.6%	1158	317,075	11.6%

Source: HIPE 2009-2016

Putting respiratory in-patient admissions in context, in 2016, lung disease (including cancer of the trachea, bronchus and the lung) accounted for 14.0% of all discharges from Irish hospitals (across all categories and age groups) and 15.8% of bed days used. COPD, pneumonia and other acute lower respiratory tract infections (as primary diagnoses) were collectively responsible for 7.0% of in-patient discharges and 9.7% of bed days used in 2016 (Figure 3) (30).

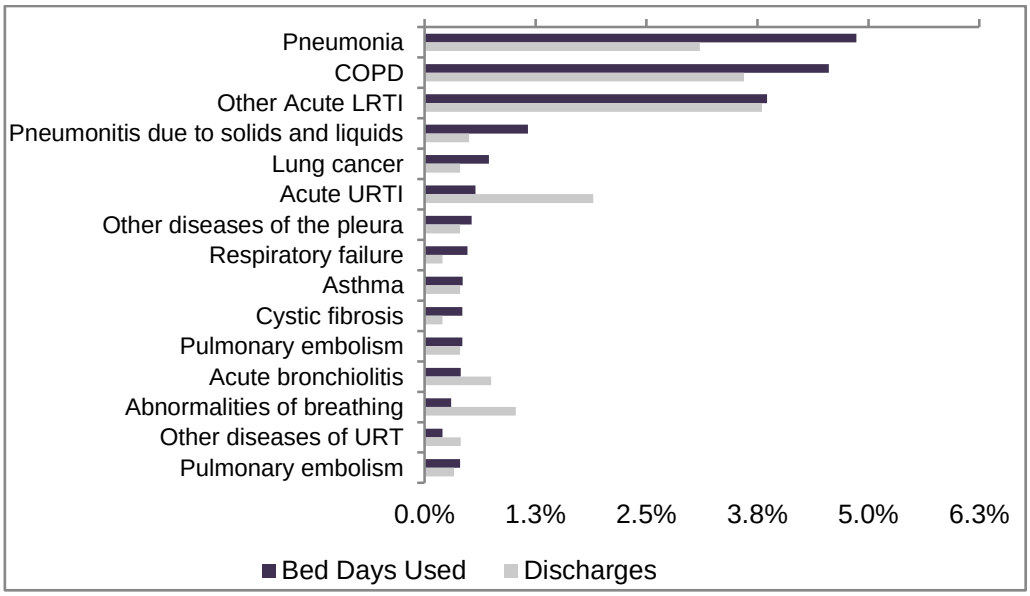
Figure 3 Percentage of in-patient discharges and bed days used by respiratory conditions



Source: HIPE data 2016. Denominator is all in-patient admissions discharged from all hospitals reporting data to HIPE (all ages).

An analysis of emergency in-patient admissions discharged from hospitals in 2016 reveals that 19% of in-patient emergency admissions (across all ages) were due to lung disease and related cancers (as defined above) and these admissions were responsible for 20% of bed days used by all emergency admissions to hospital. COPD, pneumonia and other acute lower respiratory tract infections (again as primary diagnoses) were collectively responsible for 10.5% of emergency in-patient admissions and 13.7% of bed days used (Figure 4) (30).

Figure 4 Percentage of emergency admissions and bed days used by respiratory conditions, 2016



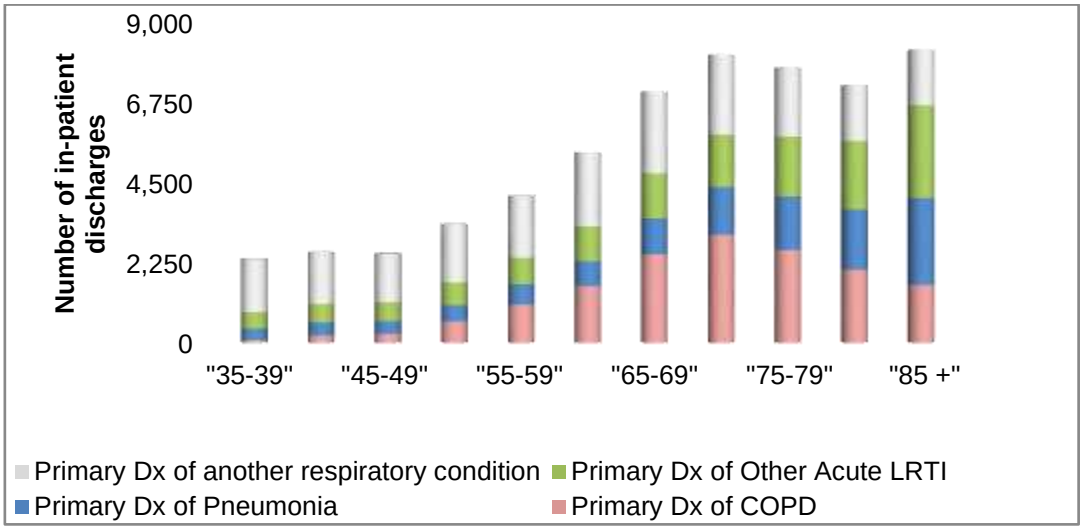
Source: HIPE data 2016.

Age specific trends in hospitalisation

Hospitalisations for COPD clearly increase with age. In 2016, across all age categories there were almost 16,000 in-patient discharges with a primary diagnosis of COPD, with higher numbers seen in those over 60 years. Putting this in context of all hospital in-patient activity, 6.5% of in-patient activity (across all hospitals reporting data to HIPE) in the 65 to 74-year age bracket was for episodes with a primary diagnosis of COPD, and 5.4% in the 75 plus age group (Figures 5&6) (30).

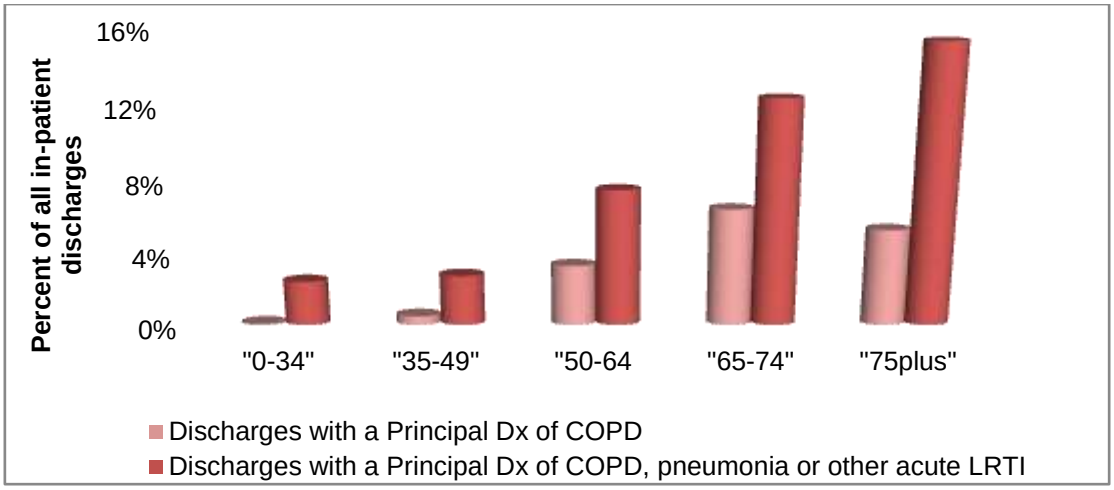
If we look at those with a primary diagnosis of COPD, pneumonia or other acute LRTI as is commonly reported in the UK, the figures are even more startling (31). In total there were over 45,000 in-patient discharges with a primary diagnosis of COPD, pneumonia or other acute LRTI in 2016, again heavily skewed to the older age groups (Figure 6). In those aged 65 to 74 years, 12.5% of all in-patient hospital episodes had a primary diagnosis of COPD, pneumonia or other acute LRTI. This number rises to 15.4% in those aged 75 and above (Figure 6) (30).

Figure 5 In-patient respiratory discharges, and discharges with a primary diagnosis of COPD, pneumonia or other acute respiratory tract infection (LRTI), 2016



Source: HIPE data 2016. Includes all hospitals reporting data to HIPE

Figure 6 Proportion of in-patient discharges with a primary diagnosis of COPD or a primary diagnosis of COPD/ pneumonia/other acute LRTI 2016



Source: HIPE data 2016.

Spend on pharmaceuticals

In Ireland in 2016, government reimbursement for respiratory medications in the GMS population was 113.7 million (11% of the GMS budget) and 10.7 million (12% of the DPS budget). Of that, expenditure on medications prescribed for COPD (R03AK - adrenergic in combination with corticosteroids or other drugs for obstructive airway disease airway, and R03BB - anticholinergics, and R03AL-adrenergics in combination with anticholinergics) accounted for approximately 67.6 million in the GMS population (32, 33).

These costs do not include additional drugs such as antibiotics or steroids nor long term oxygen therapy (LTOT), supply of nebulisers, vaccines etc., or the supply of medication in hospitals. Neither do they account for the out-of-pocket costs by patients who pay privately for their medication (i.e., those not eligible for a GMS card, or whose monthly medication costs fall below the 144 euro threshold). Hence these figures grossly underestimate the spend on pharmaceuticals for the management of COPD in Ireland.

2.3 Rationale for this National Clinical Guideline

This document describes the Model for the National Clinical Programme for Respiratory, following international best practice to be delivered within an integrated service approach. It covers the full spectrum of care provided in hospitals and in the community.

The Model for COPD outlined in this document details how physicians, nurses, and other health care professionals (HCPs) will work with patients to make the clinical decisions most appropriate to their circumstances, to allow empowerment of patients to self-manage where possible and to promote collaboration with and between specialist colleagues in providing optimal care for patients in the Irish healthcare system.

Improving Outcomes for People with COPD

COPD is a major cause of morbidity and mortality for patients in this country. At least 1500 patients die each year of this disease and over 15,000 patients are admitted to hospital with COPD. It has a profound effect on patients but also has a significant strain on the health service. Furthermore, we do know there is considerable variability in the delivery of care for such patients with, for instance, variation in length of stay between various hospitals and in access to Pulmonary Rehabilitation and COPD Outreach.

There are many reasons why COPD management has not received the attention and care it merits. There is considerable confusion about the name itself with patients frequently being told that they have asthma or getting confused about the possibility they have emphysema. There is a long progression for the disease so that symptoms appear gradually as opposed to other chronic diseases such as ischaemic heart disease and cerebral vascular disease, which often have a sudden onset. There has been a degree of therapeutic nihilism surrounding the disorder, which has led to undue pessimism amongst healthcare providers. This has led to a sense of inertia about determining best care for these patients. There may be other social factors at work in that the disease and associated mortality is concentrated in patients from more socio-economic disadvantaged groups which are well recognised to experience inadequate healthcare provision. There may also be a degree of prejudice involved in that the disease is frequently regarded as self-inflicted and this inhibits patients from seeking appropriate levels of healthcare. This is not the case for other chronic diseases, which have lifestyle related risk factors. This is despite the fact that 10% of patients have never been smokers and many patients with COPD have stopped smoking many years previously.

The National Clinical Programme for Respiratory wants Ireland to overcome these attitudes and defines in their model of care (2) the best care that should be delivered to patients with COPD.

The MOC takes a holistic, person centered and life course approach to the provision of services. It reflects the principles of integrated care which in essence is to provide patients with the right care at the right time by the right team in the right place. It reflects the goals of *Healthy Ireland*, which are to increase the proportion of people who are healthy at all stages of life, to reduce health inequalities, to protect the public from threats to health and wellbeing and to create an environment where every individual and sector of society can play their part in achieving a healthy Ireland. *The Healthy Ireland Framework* sets out a whole of government and whole of society approach to address the determinants of health and wellbeing across the life course.
The National Clinical Programme for Respiratory proposes to change how we deliver care to people with COPD and support a National Model of Integrated Care. The integrated care will be developed with the joint involvement of primary, secondary and tertiary sectors.

2.4 Aim and objectives

This National Clinical Guideline for COPD has been developed to define the way health services for people with COPD are delivered. This document is to assist heath care professionals in all healthcare settings in assessing and making decisions on the

management of COPD by outlining evidence based treatment protocols. It also aims to assist policy makers and those planning services for COPD patients. The document outlines the best practice integrated care and services for a person with, or at risk of developing, COPD as they progress through the stages of their condition. Specifically, the key aims of the Model are to:

- prevent or delay the onset of COPD
- improve the delivery of care to people with COPD across all levels of care
- save the lives of people with COPD

Through the implementation of this Model of Care, the Irish health service will be ensuring that the right care is delivered to people with COPD at the right time and in the right place.

Integrated Model of Care

The Model of Care for COPD reflects the full spectrum of care and service provided in hospitals and in the community for people with COPD, which is guided by international best practice. The spectrum of services, ranging from primary prevention to tertiary care**,** includes:

- Primary prevention and health promotion
- Risk factor identification and management
- Early detection of disease and diagnosis
- Secondary prevention
- GP led Primary care management of disease
- Shared primary and secondary care management of disease
- Secondary care management of chronic disease
- Tertiary care

The spectrum of services is ideally delivered across four Levels of Service delivery /settings which are (Level 1) General Practice, (Level 2) Specialist Support for General Practice, (Level 3) Specialist Ambulatory Care and (Level 4) Hospital Inpatient Specialist Care. The four levels of service are described in the End to End Model of Care for COPD (2019) (2).

2.5 Guideline Scope

The scope of this guideline was based on the PIPOH format: Population, Intervention, Professionals/patients, Outcomes and Healthcare settings and context. Corresponding health questions were used to define the scope of the guideline.

The **population** was defined as diagnosed with COPD (i.e. confirmed as having COPD on spirometry) and over the age of 35. For some questions this also included experiencing an acute exacerbation. Gender was male or female.
The i**nterventions** included five PIPOH's identified by the GDG.
These were

- Pharmacological management of COPD
- Non-pharmacological management of COPD
- Management of acute exacerbation of COPD
- Oxygen therapy prescription and monitoring in COPD
- Pathways, bundles and checklists for managing acute COPD exacerbation

The providers included Consultant Physicians, GPs, Public Health Specialists, nurses, nurse prescribers, ambulatory care services, physiotherapists and pharmacists.

The Outcomes were stratified into:

- **Patient outcomes** included survival, mortality, hospitalisations, readmissions, morbidity, disease specific quality of life, exercise tolerance and lung function e.g. FEV1,Duration of episode of an exacerbation, less hazards to patients due to inappropriate prescriptions of oxygen
- **System outcomes** included reduction of direct and indirect system costs. Costs related to hospitalisation due to exacerbation, costs for prescription of oxygen, direct and indirect costs related to length of hospital stay and readmissions.
- **Public Health Outcomes** were mortality and morbidity as previous

The Healthcare settings included other stakeholders such as the HSE, Hospitals, primary care and the Department of Health as well as patient groups such as COPD Support Ireland

2.6 Conflict of interest statement

The GDG adhered to the conflict of interest policy set out by the NCEC. All members of the group completed the required Conflict of Interest Declaration form. No interests stated were deemed to be conflicts in relation to the recommendations of this guideline.

2.7 Sources of funding

The Department of Health funded the literature search. The economic review and the budget impact analysis for the guideline were carried out by the Health Research Board Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER). The evidence

synthesis team from NUI Galway prepared two reports: (1) Considerations of International clinical guidelines to inform an ADAPTE methodology; and (2) a systematic review of settings for delivery of pulmonary rehabilitation for COPD.

2.8 Guideline methodology

Many clinical guidelines exist internationally that address the management of COPD, but none are specifically adapted to the Irish context. The NCP COPD approached the NCEC wishing to prepare a national clinical guideline. The first step involved assembling a Guideline Development Group (GDG) from relevant stakeholders including members of the NCP and other groups (see table for members). The first meeting of the GDG in 2016 established the scope of the guideline and the overall work plans the project. It was agreed that the broad focus would be (1) Pharmacological management of COPD (2) Non-pharmacological management of COPD (3) Management of acute exacerbation of COPD (4) Oxygen therapy prescription and monitoring in COPD and (5) Pathways, bundles and checklists for managing acute COPD exacerbation

The development of the guideline was supported by evidence synthesis teams from NUI Galway and HRB-CICER. The evidence synthesis team (EST) from NUI Galway prepared two reports: (1) Considerations of International clinical guidelines to inform an ADAPTE methodology; and (2) a systematic review of settings for delivery of pulmonary rehabilitation for COPD. HRB-CICER completed a systematic review of cost-effectiveness and a budget impact analysis to support the development of the guideline.

Step 1: Formulate the key questions

This process began with the development of priority questions requiring evidence synthesis that the GDG felt were most relevant to the management of COPD in Ireland.

The evidence synthesis team (NUIG) implemented strategies to ensure a shared and clearly

articulated scope and question for each review. This would begin with a scoping search for the review, which will be used to explore the likely extent of literature on a particular topic and to guide the development or refinement of the population, intervention, comparison and outcome (PICO) parameters of the review. The initial scoping search was discussed by NUIG and the GDG and informed decisions on potential review objectives. The evidence synthesis team following this initial discussion, prepared draft objectives, which were shared with the GDG and agreement sought.

The GDG and NUIG developed a shared understanding of the scope, timeframe and deliverables for each review question. Once this was agreed, a protocol for each review was developed. The NUIG formulated 5 key health questions during their review of international guidelines. The 5 “health questions” could be presented in a table 8 with full questions defined using the PIPOH framework in Annex A.

Table 8: 5 health questions formulated during review by NUIG

Question 1	What pharmacological interventions (beta agonists (LABAs), long acting muscarinic agents (LAMAs), inhaled corticosteroids (ICSs) and phosphodiesterase-4 inhibitors) are effective at reducing mortality and morbidity in patients over 35 years of age with COPD?
Question 2	What non pharmacological agents (such as pulmonary rehabilitation, oxygen therapy and vaccinations) are effective at reducing mortality and morbidity in patients over 35 years of age with COPD?
Question 3	What interventions (nebulised bronchodilators, steroids, antibiotics, chest physiotherapy) are effective at reducing mortality and morbidity in patients over 35 years of age with exacerbations of COPD?
Question 4	What is the appropriate prescription of oxygen therapy effective to reduce mortality and morbidity for patients over 35 years of age with COPD, and what are the optimal monitoring strategies and assessment frequency for patients receiving oxygen therapy?
Question 5	In patients admitted to hospital with an acute exacerbation of COPD, which clinical pathways, admission and discharge bundles or checklists are most effective at improving patient care by reducing length of hospital stay and readmissions and by reducing patient mortality and morbidity?

Step 2 Search methodologies,

In developing a national clinical guideline for Ireland, the GDG decided to adapt existing guidelines using the ADAPTE process. The Evidence Synthesis Centre conducted three parts of the ADAPTE process: (1) Assisting the guideline group in defining the scope and purpose of the guideline; (2) Conducting a systematic search for existing guidelines; and (3) Assessing the quality of included guidelines overview. See Annex 3.

A comprehensive search was performed to identify relevant guidelines. This included searches in PubMed, Embase, CINAHL and DynaMed databases, as well as grey literature sources including guideline clearinghouses and national websites, professional bodies ‘websites and Google. Searches were limited to guidelines published in English in the last 10 years. Due to the large number of guidelines meeting the inclusion criteria, a second round of screening was conducted to reduce the number of guidelines to be made available to the GDG. This was based on the “Rigour of Development” dimension of the AGREE II quality assessment tool, 3 as recommended in the ADAPTE manual.1. The Rigour of Development dimension contains eight items. Guidelines were included only if they met all items 1-6. Specific PIPOHs (Population, intervention, professionals, outcomes, healthcare setting) were identified for each set of questions the GDG wished to address through the ADAPTE process, These PIPOHs (n=5) relate to (1) the pharmacological and (2) non-pharmacological management of COPD, (3) the management of acute exacerbations, (4) the use and monitoring of oxygen therapy, and (5) the use of checklists, bundles and pathways in the care of patients with acute exacerbations of COPD.

Once the draft clinical recommendations were formulated, HRB-CICER conducted a systematic review of cost-effectiveness. The full report is presented in Annex C.
In summary, 10 review questions were developed in line with the PICOS framework (Appendix 3). A systematic search for studies published since 2008 was performed in Medline, Embase and grey literature sources. Screening, data extraction and critical appraisal were performed independently by two reviewers with any conflicts resolve through discussion. Assessment of quality and applicability of the international studies was conducted using the CHEC-list and ISPOR tools, respectively. Due to the heterogeneity of economic studies, the evidence was synthesised narratively.

Further search methodology can be found in Appendix 2.

Step 3: Screen and appraise the evidence

Records were screened by two reviewers independently and a third reviewer resolved any conflicts. The quality of guidelines was assessed by two independent reviewers using the AGREE II tool 3 and average percentage scores were calculated for each of the seven domains. The findings of the quality assessment of the 17 included guidelines are presented in table 9. The average percentage score for each domain of the AGREE II tool and the average overall percentage score judgement is also provided.If a procedure to update the guideline was provided, and then this item (item 14) of the rigour domain was judged satisfactory in accordance with the AGREE II manual, even if no recent version of the guideline had been published. Hence, it was recommended to look at the date of publication of the guidelines as well as the rating. Overall AGREE II scores ranged from 64.3% to 100%, and the applicability domain scored the lowest most frequently. The NICE guideline scored the highest in all domains and overall. However, certain guidelines with a more narrow scope that answered a specific PIPOH also scored high in quality; for example the British Thoracic society‘s guidelines on pulmonary rehabilitation, home oxygen, or emergency oxygen. Thus, our recommendations are primarily based on the recommendations from the high-quality existing guidelines. For details of which guideline informed each key question, please refer to individual guideline. The relevant recommendations within these guidelines were mainly adapted rather than adopted, as indicated in the relevant sections and related evidence tables.

Table 9 AGREE II Quality assessment

No	Guideline (most recent first)	AGREE II domains (Standardised domain scores: average percentage scores for each domain)							
		Scope & Purpose (1)	Stakeholder involvement (2)	Rigour of development (3)	Clarity & presentation (4)	Applicability (5)	Editorial independence (6)	Overall assessment (7)	Recommend?
1	Global Strategy for Diagnosis, Management, and Prevention of COPD – 2017.	100	100	100	100	50	50	89.3	Yes
2	Hardinge M, Annandale J, Bourne S, Cooper B, Evans A, Freeman D, et al. British Thoracic Society guidelines for Home Oxygen use in adults. Thorax. 2015;70:i1-i43. Hardinge M, Suntharalingam J, Wilkinson T. Guideline update: The British Thoracic Society Guidelines on home oxygen use in adults. Thorax. 2015;70(6):589-91.	100	100	100	100	65	100	92.3	Yes
3	AARC clinical practice guideline: effectiveness of pharmacologic airway clearance therapies in hospitalized patients. American Association for Respiratory Care. 2015.	100	64	65	97	10	50	64.3	Yes with modification
4	Prevention of acute exacerbations of chronic obstructive pulmonary disease: American College of Chest Physicians and Canadian Thoracic Society Guideline. 2015.	100	100	100	100	38	50	85.7	Yes
5	Clinical Practice Guideline on Adult Domiciliary Oxygen Therapy: Executive summary	100	33	100	100	13	50	75	Yes

	from the Thoracic Society of Australia and New Zealand. 2016. (But published as a report in 2014)								
6	British Thoracic Society (BTS) guideline on pulmonary rehabilitation in adults: Accredited by NICE. 2013.	100	100	100	100	52	50	92.9	Yes
7	Managing dyspnea in patients with advanced chronic obstructive pulmonary disease: A Canadian Thoracic Society clinical practice guideline. 2011.	100	67	100	100	25	100	85.7	Yes
8	Diagnosis and Management of Stable Chronic Obstructive Pulmonary Disease: A Clinical Practice Guideline from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society. 2011.	100	67	100	100	0	100	85.7	Yes
9	Department of Veterans Affairs/Department of Defense (VA/DoD) clinical practice guideline on management of outpatient COPD. 2015. Institute for Clinical Systems Improvement (ICSI); Chronic Obstructive Pulmonary Disease (COPD), Diagnosis and Management of. 2016.	100	100	99	100	60	100	85.7	Yes

	Ontario Guidelines Advisory Committee (GAC) Recommended Clinical Practice Guidelines. COPD: Exacerbation. Ontario Guidelines Advisory Committee (GAC) Recommended Clinical Practice Guidelines. COPD: Improving Survival. Ontario Guidelines Advisory Committee (GAC) Recommended Clinical Practice Guidelines. COPD (Stable): Treatment.								
10	Canadian Medical Association Infobase, Clinical practice guidelines for the use of noninvasive positive-pressure ventilation and noninvasive continuous positive airway pressure in the acute care setting. 2011.	100	61	100	100	27	100	85.7	Yes
11	McKim DA, Road J, Avendano M, Abdool S, Côté F, Duguid N, et al. Home mechanical ventilation: A Canadian Thoracic Society clinical practice guideline. Canadian respiratory journal. 2011;18(4):197-215.	100	89	100	100	0	100	85.7	Yes
12	CTS Guideline Optimizing pulmonary rehabilitation in chronic obstructive pulmonary disease - practical issues. 2010.	100	67	88	100	0	100	85.7	Yes

13	National Institute for Health and Care Excellence (NICE) CG101: Chronic obstructive pulmonary disease in over 16s: diagnosis and management. 2010. (+2012 evidence update; second link) National Institute for Health and Care Excellence (NICE) National costing report: chronic obstructive pulmonary disease: Implementing NICE Guidance. 2011. National Institute for Health and Clinical Excellence (NICE) Evidence Update 5 – Chronic obstructive pulmonary disease. February 2012. Pathway: Chronic obstructive pulmonary disease. Quality Standard QS10: Chronic obstructive pulmonary disease in adults (QS10). 2011. (+ see more info in second link)	100	100	100	100	94	100	100	Yes
14	Non-invasive ventilation in chronic obstructive pulmonary disease. Royal College of Physicians of London – RCP. 2006.	94	97	84	100	21	54	78.6	Yes
15	2008 Update CTS Guideline - Highlights for Primary Care - Recommendations for Management of COPD. 2007 Update CTS Guideline - Recommendations for Management of COPD.	100	50	100	100	25	100	75.0	Yes

16	British Thoracic Society (BTS) guideline on emergency oxygen use in adult patients. 2008 + correction: Thorax 2009 Jan;64(1):91. Commentary	100	100	100	100	75	50	92.3	Yes
17	British Thoracic Society. Intermediate care—Hospital-at-Home in chronic obstructive pulmonary disease: British Thoracic Society guideline. 2007.	100	64	80	100	60	0	85.7	Yes

Step 4: Develop and grade the recommendations

The GDG used the "Adapte Process Workbook" to guide the process.
This also involved looking at different processes including the Adapte process, developing subgroups, draft recommendations, permissions, response tracker and guidelines relevant to the PIPOHs. Meetings continued which included using the Adapte tool kit and Process workbook which was an excel style workbook included sections on lists of guidelines, tool matrix, search and selection tool, validity, applicability and tool application for each PIPOH (Annex E).

The synthesized information was made available to the GDG with an emphasis on concise narrative and the use of evidence profiles. The GDG then provided feedback to the evidence synthesis team on the information synthesized. The GDG used this information to generate recommendations from the evidence. This involved meetings for discussions about which recommendations from existing guidelines to adopt and/or adapt where pre-meeting emailed feedback from GDG members was collated to guide the discussions.

Once the recommendations were developed, each recommendation went through a process of approval by the GDG. This was called "Acceptability and Application" of recommendations. Each recommendation was sent to each GDG member via a web link which graded the recommendations. The grading included "recommendation is acceptable" and the "recommendation is applicable to patients in the context of use".
Recommendations were finalised based on consensus responses.

Some recommendations were adapted from guidelines primarily GOLD and the US Department of Veteran Affairs document on the management of COPD. In cases where no recommendations were suitable or available, expert opinion from the GDG group was used. The process for this included the group of experts working using a nominal group technique to brainstorm and talk through and agree the important issues. The system reviews were used to assist and support these sessions. Each recommendation was assigned a grade for quality of evidence and strength of recommendation as per Table 3. The quality of evidence
grade reflected the overall level of evidence upon which the recommendation was based, including the directness of the evidence to the clinical question, and whether further research is likely to change the recommendation. The strength of recommendation was primarily based on the quality of evidence.

Finally, Good Practice Points were developed by the GDG to provide guidance on
important aspects of COPD management that had little existing evidence base but were agreed by GDG consensus.

The draft guideline was progressed through GDG sub-group meetings in May to July 2020. Members were asked to verify if any key documents, resources, bodies or organisations had been omitted. Once the GDG agreed the final recommendations and supporting text, the guideline document was forwarded to two expert reviewers for consultation and was sent for national stakeholder review in July 2020 (Appendix 4: Consultation report).

2.9 Consultation summary

The COPD GDG ensured that all stakeholders had an opportunity to contribute to the revision of the COPD national clinical guideline.

- *The final draft of NCG COPD (2020) was circulated to the following for review and feedback* Group Directors and Directors of Nursing all Hospital Groups and all acute hospitals
- Clinical Directors Hospital Groups and acute hospitals, Hospital/Group CEOs and GMs
- ONMSD and all NMPDUs/CNMEs
- National Clinical Programme Clinical Leads
- Chief Clinical Officer, HSE
- Nursing and Midwifery Board of Ireland (NMBI)
- Schools of Nursing and Midwifery, HEIs, Ireland
- Colleges of Medicine, HEIs, Ireland
- Patient groups- COPD Support Ireland, Irish Patient's Association
- Regulatory bodies
- Department of Health
- CNO office DOH
- Quality Improvement Division
- National Quality Assurance and Verification Division
- Quality and Patient Safety,
- Acute Hospitals Division Office of the Nursing and Midwifery Services
- Hospital Group Clinical Directors
- Hospital Group CDONM's
- Hospital Directors of Nursing,

- Acute Division Hospital Chief Executive Officers and General Managers,
- Acute Division Hospital Clinical Directors,
- Acute Division National Director for Clinical Strategy and Programmes Division
- Nurse Leads, Clinical Strategy and Programmes Division
- Clinical Leads, Clinical Strategy and Programmes Division
- Programme Managers, Clinical Strategy and Programmes Division
- Directorate National Clinical Advisor and Group Lead for Acute Hospitals
- HSE National Director of Acute Hospitals
- HSE Deputy National Director of Acute Hospitals
- Hospital Group Directors of Nursing
- Hospital Group Chief Executive Officers
- NWIP
- National Ambulance Service
- PHECC
- HPSC
- HSPC
- Microbiology

2.10 External review

International external review of the revised COPD guideline was completed by two experts in their respective fields:

Names: to be inserted on completion

The COPD GDG is very grateful to these reviewers and appreciates the time commitment and expertise that was involved in their review. Reviewers were asked to consider the guideline in accordance with the questions recommended by the National Quality Assurance Criteria for Clinical Guidelines Version 2 (HIQA/NCEC, 2015, p.14). External

reviewers were also asked to provide any additional feedback they felt was relevant. All feedback will be reviewed and incorporated into the revised guideline where appropriate.

2.11 Implementation

A comprehensive implementation plan for this guideline is outlined in Appendix x. Each hospital's senior management team and Primary care General Manager in conjunction with the designated local implementation leads should review NCEC NCG No.1 COPD (2020), to appropriately plan implementation and recognise the system-wide implications.

It is recommended that teams use quality improvement (QI) methodology when implementing recommendations. Such methods enhance stakeholder engagement, empowerment and adoption through the use of testing, measurement and feedback on key interventions. The plan advocates for local governance groups are established to direct ongoing implementation and evaluation. Governance groups should be multidisciplinary, have a designated senior clinical lead and senior management sponsorship. There should be designated local COPD coordinators within the membership of the governance group to coordinate implementation, education and evaluation, inclusive of audit. The governance group should regularly report directly to senior management team and should actively engage with the quality and risk governance structures. Patient representation should be strongly considered on these governance groups. Patient outcomes aligned to effective management of COPD.

Some of the potential enablers and barriers for implementation of COPD are listed in Table 4. Local issues should be identified and action plans initiated to manage improvement at local hospital level. Hospital Groups may consider the use of a quality improvement collaborative style approach.

Table 10. Summary of enablers and barriers to the implementation of recommendations (2020)

Enablers	Barriers
• Stakeholder engagement • Clinical champion(s) and good local leadership • Clearly defined roles and responsibilities • Effective governance with direct reporting to senior management teams • Effective multidisciplinary teamwork • Effective communication pathways • Ongoing targeted education and training and reinforcement of learning • Regular audit and evaluation with the results informing quality improvement work • Patient/family/carer engagement and coproduction of improvements • HSE Tools for Self-Management and chronic disease • Support groups and helplines • Model of Care for COPD • CPD	• Staff familiarity with current COPD Model of Care and resistance to change of practice • Absence of clearly defined roles and responsibilities • Ill-defined or inappropriate governance arrangements • Lack of adequate resources e.g. staff, equipment, audit, time designated to provide clinical leadership • Inadequate communication systems lacking in clarity, standardisation, accountability • Inadequate access to education, lack of development of appropriate skill set required integrated care • Inadequate audit and evaluation schedule and resources. Lack of adequate systems to support audit e.g. ICT, data and analytics expertise • Resistance to patient/family/carer involvement with audit, evaluation, improvement

Barriers to implementation should be identified and addressed as part of the organisational quality improvement and patient safety agenda. Attention to the enablers listed above and in the implementation plan in Appendix 6 (under completion draft version) will provide guidance to local sites and Hospital Groups for service planning, development and implementation.

For full implementation of this guideline, it is essential that all healthcare professionals responsible for the care of adult COPD understand their responsibility, accountability and authority for improving care. Improvement should occur in all phases to include

anticipation, recognition, escalation, response, assessment, intervention, reassessment, evaluation, education and governance. This must be supported by clear lines of accountability, which include systems that can detect, and correct lapses in appropriate, reliable safe care in a timely basis.

Funding for COPD implementation and improvement is subject to service planning and the estimates process. However many recommendations in COPD represent a reiteration of previous good practice (full BIA report available in Annex D – to be included once available from HRB-CICER)

Senior Manager Responsibilities:

- Agree and provide a local governance structure to support the implementation, ongoing audit and evaluation of patient outcomes pertaining to the recommendations of the NCEC NCG No. x COPD (2020).
- Assign personnel with delegated responsibility, accountability authority and autonomy to implement and evaluate the NCEC NCG No. x COPD (2020). Provide documented clear roles and responsibilities for staff.
- Provide managers and clinician leads with support to implement the NCEC NCG No. x COPD (2020) and ensure clinical staff has access to and undertake education and training as appropriate to the successful implementation and evaluation of COPD.
- Ensure local policies, protocols and procedures are in place to support implementation and are regularly adapted based on new learning and as a result of quality improvement work.
- Seek regular reports on implementation and evaluation of COPD from the COPD governance group and provide direction on subsequent action plans
- Enable and support implementation coordinators and governance group by providing a direct link to corporate governance team/senior management team.
- Plan for the procurement and implementation of digital technologies through the estimates and service planning processes to support implementation and evaluation of NCEC NCG No. x COPD (2020).

Clinician responsibilities:

- Ensure familiarity with and comply with the NCEC NCG No. COPD (2020) and related policies, protocols and procedures
- Adhere to relevant code of professional conduct and scope of professional practice appropriate to role and responsibilities
- Develop and maintain relevant competencies in the management of COPD.

- Be aware of the role of clinical judgment, anticipatory care and delegation, in using the NCEC NCG No. x COPD (2020)
- Seek to provide clinical leadership, mentorship of staff and ongoing education of multidisciplinary team.
- Advocate on behalf of patients and staff to hospital senior management for the robust development of systems and service improvement to support implementation, improvement and evaluation of NCEC NCG No.x COPD (2020).
- Create and lead engagement with patient/family/carer to co-produce quality improvement initiatives for COPD.
- Participate in relevant education programmes and contribute to education and training programme development
- Advocate for and use digital technologies to support implementation and evaluation of NCEC NCG No. x COPD (2020).
- Promote and engage in research to improve COPD.
- Assist with the performance of clinical and healthcare audits associated with COPD.

Tools provided as supports for the implementation of NCEC NCG No. x COPD (2020)

- Model of care for COPD 2020
- Implementation guidance is included in detail in Appendix 6
- Implementation guide Pulmonary rehabilitation
- Implementation guide COPD Outreach
- Bundles of care

2.12 Monitoring and audit

Monitoring and evaluation

The key **implementation process outcomes** for this guideline overall, and for specific recommendations, are listed in the logic model and the implementation table in Appendix 6. A key focus of monitoring and evaluation will be the implementation of recommendations. Thus, the Implementation Team will monitor the degree to which the guideline is disseminated and available for use in all clinical areas caring for people with COPD. The aim is that, in acute and community settings, all doctors, nurses, pharmacists, and health and social care professionals are aware of the guideline and will understand, accept
and adopt the guideline. This needs to be monitored during implementation by a combination of methods, to allow the implementation process to be adapted and tailored to the needs of certain settings/groups. The key **service outcome** for this

guideline is a more integrated service with care across the continuum. The key **patient-related outcome** of successful implementation of this guideline is improved patient safety, with decreased mortality and morbidity associated with inappropriate prescribing of medications and access to services.

Monitoring, evaluation and audit are an important part of the implementation of this initiative. Regular audit is required to support implementation of the recommendations within this revised NCG. It is recommended that the audit process is coordinated locally by the MDT in each area by the local Committee, as per the NCEC NCG No x COPD (2020) recommendations. It is recommended that the audit process is undertaken from a multidisciplinary perspective where appropriate. In planning the audits to be undertaken, consideration should be given to the frequency of the audits and competencies required to conduct, interpret, and compile the final report and recommendations.

COPD Audit Datasets: Datasets currently exist for COPD Outreach and RIC services and are submitted to the NCP Respiratory and the BIU.

Process Measures: For process audits the recommended standard required is 100% compliance. Where the compliance is less than 80% it is proposed that local action plans are put in place.

Outcome Measures

The following suggested outcome measures are based on international best practice and should be included in planned audit cycle.

- Patient outcome measures e.g. Hospital length of stay (HLOS), mortality rates, readmission rates

Structural Measures

Education/Training audit

- Audit of COPD education/training and evaluation record
- Database of staff trained - each hospital to make their own local arrangement to best meet their needs

Key Performance Indicators (KPIs)

COPD implementation is supported by National KPIs, which are reported quarterly to the Acute Business Information Unit (BIU), HSE.

Audit Results

The audit results and reports should be discussed at the appropriate COPD Governance group and findings fed upwards to the Hospital Clinical Governance Committee/ Hospital Senior Management Team and to all levels of staff .The hospital's healthcare audit/clinical audit cycle as part of the continuous quality improvement process should inform the audit plan.

Results and learning points can be used in the on-going education delivered by the designated COPD Coordinator and in the local quality improvement initiatives.

Additional databases

NQAIS Clinical is an online interactive application that analyses hospitals' HIPE data and can provide detailed feedback to clinicians and managers. Hospitals can explore NQAIS Clinical to look at patient outcomes, for example, cardiopulmonary arrest and ICU length of stay.

Further details on Monitoring and audit in appendix 8

2.13 Plan to update this National Clinical Guideline

The COPD GDG agreed that the COPD guideline should be reviewed on a three-yearly basis and updated in line with NCEC procedures. As a result NCG No. 1 (COPD) (2020) will require updating in 2023 by the GDG.

Section 3 National Clinical Guideline

3.1 Pharmacological Interventions for the Management of COPD

HEALTH QUESTION 1: What pharmacological interventions (beta agonists (LABAs), long acting muscarinic agents (LAMAs), inhaled corticosteroids (ICSs) and phosphodiesterase-4 inhibitors) are effective at reducing mortality and morbidity in patients over 35 years of age with COPD?
POPULATION (Specify patient and condition characteristics)
Age
Age over 35
Clinical circumstances
Patients diagnosed with COPD (i.e. confirmed as having COPD on spirometry)
Gender
Male or female
INTERVENTIONS (Specify intervention(s) type(s) and characteristics)
Treatments/care
Pharmacological interventions (including beta agonists (LABAs), long acting muscarinic agents (LAMAs), inhaled corticosteroids (ICSs) and phosphodiesterase-4 inhibitors)
Follow up
Any follow up time between receiving the diagnosis of COPD and death
PROFESSIONALS/(PATIENTS) (Targeted users)
Providers
Physicians, nurse prescribers
Stakeholders
Dept. of Health, HSE, hospitals, primary care
Patients
Patients with COPD
OUTCOME (Purpose of the guideline)
Patient outcomes

	Survival, mortality, exacerbations, hospitalisations, readmissions, morbidity (disease-specific quality of life, exercise tolerance, lung function e.g. FEV1)
	System outcomes
	Reduce direct and indirect system costs
	Public health outcomes
	Mortality and morbidity as above
HEALTH CARE SETTING/CONTEXT	
	Organisations
	Hospitals and primary care

Evidence statement for Question 1

As needed use of SABAs and LAMAs improves FEV 1 and symptoms. Bronchodilator dose-response (FEV 1 change) curves are relatively flat with all classes of bronchodilators. Increasing the dose of either a beta 2 -agonist or an anticholinergic by an order of magnitude, especially when given by a nebulizer, appears to provide subjective benefit in acute episodes but is not necessarily helpful in stable disease. Combinations of SABAs and SAMAs are superior compared to either medication alone in improving FEV 1 and symptoms.

LAMA treatments (tiotropium) improve symptoms and health status. They also improve the effectiveness of pulmonary rehabilitation and reduce exacerbations and related hospitalizations. Clinical trials have shown a greater effect on exacerbation rates for LAMA treatment versus LABA treatment.

There are numerous combinations of a LABA and LAMA in a single inhaler available. These combinations improve lung function compared to placebo; this improvement is consistently greater than long acting bronchodilator monotherapy effects although the magnitude of improvement is less than the fully additive effect predicted by the individual component responses.

One study in patients with a history of exacerbations indicated that a combination of long-acting bronchodilators is more effective than long-acting bronchodilator monotherapy for preventing exacerbations. Another study in patients with a history of exacerbations confirmed that a combination LABA/LAMA decreased exacerbations to a greater extent than an ICS/LABA combination.

In vitro evidence suggests that COPD-associated inflammation has limited responsiveness to corticosteroids. In vivo data suggest that the dose-response relationships and long-term (> 3 years) safety of inhaled corticosteroids (ICS) in patients with COPD are unclear

and require further investigation. Most studies have found that regular treatment with ICS alone does not modify the long-term decline of FEV 1 nor mortality in patients with COPD. Studies and meta-analyses assessing the effect of regular treatment with ICS alone on mortality in patients with COPD have not provided conclusive evidence of benefit.

In patients with moderate to very severe COPD and exacerbations, an ICS combined with a LABA is more effective than either component alone in improving lung function, health status and reducing exacerbations. Clinical trials powered on all-cause mortality as the primary outcome failed to demonstrate a statistically significant effect of combination therapy on survival.

Post-hoc analyses from several trials suggest that eosinophil counts in sputum and blood may serve as a biomarker to predict the efficacy of ICS in particular regarding exacerbation prevention.

There is high quality evidence from randomized controlled trials (RCTs) that ICS use is associated with higher prevalence of oral candidiasis, hoarse voice, skin bruising and pneumonia. Patients at higher risk of pneumonia include those who currently smoke, are aged > 55 years, have a history of prior exacerbations or pneumonia, a body mass index (BMI) < 25 kg/m 2, a poor MRC dyspnoea grade and/or severe airflow limitation.

Adding a LAMA to existing LABA/ICS improves lung function and patient reported outcomes, in particular exacerbation risk. A recent RCT demonstrated that adding ICS to LABA plus LAMA in patients with severe COPD as based on spirometry with a history of exacerbations was associated with a reduction in exacerbations and hospitalisations.

A number of recent studies have shown that blood eoisinophil counts may protect the magnitude of the effect of ICS added to regular maintenance bronchodilator treatment in preventing future exacerbations. Increasing effects may be observed at higher eosinophil counts. Data has suggested that ICS containing regimens have little or no effect with an eosinophil count of <100 cells per microlitre. This threshold is used to identify patients with a low likelihood of treatment benefit with ICS. Patients with an eosinophil count of >300 cells per microlitre appear to have the greatest likelihood of treatment benefit with ICS.

Consequently, ICS treatment can be considered in patients with a strong history of exacerbations of COPD with more than two exacerbations per year or one hospitalisation, an eosinophil count of >300 cells per microlitre or a history suggestive of asthma. Conversely factors against the use of ICS would include repeated pneumonias or an eosinophil count of <100 cells per microlitre.

When a treatment is given by the inhaled route the importance of education and training in inhaler device technique cannot be over-emphasized. Inhalation devices include nebulizers, metered-dose inhalers (MDIs) used without spacers, soft-mist inhalers and breath-actuated devices i.e., breath-actuated MDIs (BAIs) and single-dose and multi-dose dry powder inhalers (DPIs).

Randomized controlled trials have not identified superiority of one device/formulation. However, patients included in these trials are usually those who master inhalation technique and receive proper education and follow-up regarding this issue, and therefore

may not be reflective of normal clinical practice. On average more than two thirds of patients make at least one error in using an inhalational device.

Observational studies have identified a significant relationship between poor inhaler use and symptom control in patients with COPD. Determinants of poor inhaler technique in COPD patients include: older age, use of multiple devices, and lack of previous education on inhaler technique. In such populations, education improves inhalation technique in some but not all patients, especially when the “teach-back” approach (patients being asked to show how the device has to be used) is implemented. It is important to check that patients continue to use their device correctly. Lack of placebo devices within clinical areas is often a limitation and barrier to providing quality inhaler technique instruction to patients. Encouraging a patient to bring their own devices to clinic is a useful alternative. Those who do not reach mastery may require a change in inhalational delivery device.

The main errors in delivery device use relate to problems with inspiratory flow, inhalation duration, coordination, dose preparation, exhalation maneuver prior to inhalation and breath holding following dose inhalation. There is no evidence for superiority of nebulized therapy over hand-held devices in patients who are able to use these devices properly.

The PDE4 inhibitor roflumilast is a once daily oral medication with no direct bronchodilator activity. Roflumilast reduces moderate and severe exacerbations treated with systemic corticosteroids in patients with chronic bronchitis, severe to very severe COPD, and a history of exacerbations. The effects are also seen when roflumilast is added to long-acting bronchodilators, and in patients who are not controlled on fixed-dose LABA/ICS combinations. The major issue with roflumilast is tolerability with weight loss, abdominal discomfort, nausea and diarrhea often causing discontinuation.

There is limited and contradictory evidence regarding the effect of low-dose theophylline on exacerbation rates. Toxicity is a particular problem with xanthine derivatives and is dose-related, which is a particular problem with xanthine derivatives because their therapeutic ratio is so small.

Recent studies have demonstrated a reduction in exacerbation frequency with the macrolide antibiotic azithromycin taken 250mg once daily for 12 months and also using a dosing regimen of 500mg three times weekly. There was a statistical significant association with hearing loss in the treatment group in 1 study while a further study identified diarrhea as a frequent side-effect. In a post hoc analysis it was suggested that the benefit observed with azithromycin may be reduced in active smokers.

In COPD patients not receiving inhaled corticosteroids, regular treatment with mucolytics such as carbocysteine and N-acetylcysteine may reduce exacerbations and modestly improve health status. Due to the heterogeneity of studied populations, treatment dosing and concomitant treatments, currently available data do not allow one to identify precisely the potential target population for antioxidant agents in COPD.

Leukotriene modifiers have not demonstrated repeated benefit in COPD although studies examining their utility in COPD patients are limited.

Because AATD is rare, formal clinical trials to assess efficacy with conventional spirometric outcome have never been undertaken. However, a number of observational studies suggest a reduction in spirometric progression in treated versus non-treated patients and that this reduction is most effective for patients with FEV 1 35-49% predicted. Never or ex-smokers with an FEV 1 of 35-60% predicted have been suggested as those most suitable for AATD augmentation therapy.

More recently studies using sensitive parameters of emphysema progression determined by CT scans have provided evidence for an effect on preserving lung tissue compared to placebo. However, not all patients with AATD develop or persist with rapid spirometric progression especially following smoking cessation. Since the purpose of augmentation therapy is to preserve lung function and structure it seems logical to reserve such expensive therapy for those with evidence of continued and rapid progression following smoking cessation. Individual discussion is recommended with consideration of the cost of therapy and lack of evidence for much benefit. The main limitation for this therapy is very high cost.

Recommendation 1

Short acting bronchodilators

Inhaled short acting beta 2 agonists (SABAs) should be prescribed to patients with confirmed COPD where rescue therapy is needed.

Grade of recommendation: *(Grade A)* ***(GOLD)***

Recommendation 2

Long acting bronchodilators

2.1. Long acting bronchodilators should be offered to patients with confirmed stable COPD who continue to have respiratory symptoms (e.g. dyspnoea or cough) *(Grade A)* ***(GOLD)***

2.2. Inhaled long acting muscarinic agents (LAMAs) should be offered to patients as first line maintenance therapy in patients with confirmed stable COPD who have continued respiratory symptoms (e.g. dyspnoea, cough) or who have a history of exacerbations with COPD. *(Grade A)* ***(GOLD)***

2.3. In patients with confirmed stable COPD who are on inhaled LAMAs or inhaled LABAs alone and have persistent dyspnoea on mono therapy combination therapy with both LAMAs and LABAs is superior to LAMAs or LABAs alone and is recommended. *(Grade A)* ***(GOLD)***

Strength of recommendation: *Grade A* ***(GOLD)***

Recommendation 3

Inhaled corticosteroids

3.1. Offering an inhaled corticosteroid (ICS) in symptomatic patients with confirmed stable COPD as first line therapy is not recommended. *(Grade A)*

3.2 *Regular treatment with ICS increases the risk of pneumonia especially in those with severe disease (Grade A)*

3.3 *An ICS combined with a LABA is more effective than individual components in improving function and health status and reducing exacerbations in patients with exacerbations moderate to very severe COPD (Grade A)*

3.4 In patients with confirmed COPD who are on combination therapy with LAMAs and LABAs and have persistent dyspnoea or frequent COPD exacerbations, it is suggested that the addition of an ICS may be reasonable. Blood eosinophil count may be used as a biomarker for estimating the efficacy of inhaled corticosteroids (ICS) for the prevention of exacerbations. It has been recognised that there is a continual relationship between the effects of an ICS and eosinophil counts. *(Grade B)* ***(GOLD)***

Strength of recommendation: Grade A & B

Recommendation 4

Inhaler technique

4.1. It is recommended that each patient commenced on an inhaler device would be provided with instructions and a demonstration of proper inhalation technique prior to using the device and that such technique is checked on a regular basis subsequently. Inhaler technique and adherence to therapy should be assessed before concluding that current therapy is insufficient and a change in therapy considered. ***(GOLD)***

Strength of recommendation: Expert Opinion

Good practice point

Offering advice and education alone is not sufficient to assist patients with adherence and Self-Management with medications. They should be encouraged to be partners in decisions about their treatments in particular when it comes to inhaler device selection.

Recommendation 5

Roflumilast

In selected patients with the chronic bronchitic phenotype of COPD with severe to very severe air flow obstruction and history of exacerbations, a phosphodiesterase-4 (PDE-4) inhibitor may be reasonable add on to therapy with a LAMA and LABA and possibly ICS. This recommendation is not reimbursement by the HSE. *(Grade B) (GOLD)*

Strength of recommendation: Grade B

Recommendation 6

Theophyllines

In certain selected patients, the addition of a theophylline may be reasonable. *(GOLD)*

Strength of recommendation: Grade B

Recommendation 7

Prophylactic use of Macrolide Antibiotics

In patients who have severe COPD with two treated exacerbations and are non-smokers, the addition of azithromycin may be considered for one year. *(GOLD)* This needs to be done in conjunction with Respiratory Specialist advice with surveillance for bacterial resistance and side effects such as impaired hearing and cardiac arrhythmias.

Strength of recommendation: Grade A

Recommendation 8

Antioxidants and mucolytics

The use of mucolytic and antioxidants in routine practice for management of patients with COPD **is not recommended**. *(GOLD)*

Strength of recommendation: Expert Opinion

Recommendation 9

Leukotriene antagonists

A role for leukotriene receptor antagonists in the management of patients with COPD **is not recommended**. *(GOLD)*

Strength of recommendation: Expert Opinion

Recommendation 10

Alpha One Anti-trypsin (AATD) Augmentation Therapy

It is recommended that AATD augmentation therapy might be considered in young patients who are never or ex-smokers with an FEV 1 of 35-60% predicted with continued and progressive disease. This recommendation is dependent on reimbursement approval by HSE. *(GOLD)*

Strength of recommendation: Grade B

3.1.2. Non-Pharmacological Management of COPD

HEALTH QUESTION 2. What non pharmacological agents (such as pulmonary rehabilitation, oxygen therapy and vaccinations) are effective at reducing mortality and morbidity in patients over 35 years of age with COPD?
POPULATION (Specify patient and condition characteristics)
Age
Age over 35
Clinical circumstances
Patients diagnosed with COPD (i.e. confirmed as having COPD on spirometry)
Gender
Male or female
INTERVENTIONS (Specify intervention(s) type(s) and characteristics)
Treatments/care
Prescription and monitoring of oxygen therapy
Follow up
Any follow up time between prescription of oxygen and death
PROFESSIONALS/(PATIENTS) (Targeted users)
Providers
Physicians, nurse prescribers, physiotherapists
Stakeholders
Dept. of Health, HSE, hospitals, primary care
Patients
Patients with COPD
OUTCOME (Purpose of the guideline)
Patient outcomes
Survival, mortality, readmissions, morbidity (disease-specific quality of life, exercise tolerance, lung function e.g. FEV1), less hazard for patients due to inappropriate prescription
System outcomes

Costs for prescription of oxygen,
Public health outcomes
Mortality and morbidity as above
HEALTH CARE SETTING/CONTEXT
Organisations
Hospitals and primary care, ambulatory care/home care

Evidence statement for Question 2
Recommendation 11 Smoking Cessation

Smoking cessation has the greatest capacity to influence the natural history of COPD. If effective resources and time are dedicated to smoking cessation, long-term quit success rates of up to 25% can be achieved. Pharmacotherapy and nicotine replacement reliably increase long-term smoking abstinence rates.

The effectiveness and safety of e-cigarettes as a smoking cessation aid is uncertain at present.

Recommendation 12 Influenza Vaccination

Influenza vaccination can reduce serious illness (such as lower respiratory tract infections requiring hospitalization) and death in COPD patients. Only a few studies have evaluated exacerbations and they have shown significant reduction in the total number of exacerbations per vaccinated subject compared with those who received placebo. Findings from a population-based study suggested that COPD patients, particularly the elderly, had decreased risk of ischemic heart disease when they were vaccinated with influenza vaccine over many years. Occurrence of adverse reactions is generally mild and transient.

Recommendation 13 Pneumococcal Vaccination

The 23-valent pneumococcal polysaccharide vaccine PPSV23 has been shown to reduce the incidence of community-acquired pneumonia in COPD patients aged <65 with an FEV1 < 40% predicted and in those with comorbidities). In the general population of adults over 65 years the 13-valent conjugated pneumococcal vaccine (PCV 13) has demonstrated significant efficacy in reducing bacteraemia and serious invasive pneumococcal disease.

Recommendation 14 Pulmonary rehabilitation

Pulmonary rehabilitation is defined as “a comprehensive intervention based on thorough patient assessment followed by patient-tailored therapies that include, but are not limited to, exercise training, education, Self-Management intervention aiming at behaviour change, designed to improve the physical and psychological condition of

people with chronic respiratory disease and to promote the long-term adherence to health-enhancing behaviours."

Pulmonary rehabilitation should be considered part of integrated patient management, and usually includes a range of healthcare professionals to ensure optimum coverage of the many aspects involved. Patients should undergo careful assessment prior to enrolment, including identification of the patient's goals, specific healthcare needs, smoking status, nutritional health, Self-Management capacity, health literacy, psychological health status and social circumstances, comorbid conditions as well as exercise capabilities and limitations. Optimum benefits are achieved from programs lasting 6 to 8 weeks.

Pulmonary rehabilitation is appropriate for most patients with COPD. The benefits to COPD patients from pulmonary rehabilitation are considerable and rehabilitation has been shown to be the most effective therapeutic strategy to improve shortness of breath, health status and exercise tolerance.

Limited data exist regarding the effectiveness of pulmonary rehabilitation after an acute exacerbation of COPD, but systematic reviews have shown that among those patients who have had a recent exacerbation (≤ 4 weeks from prior hospitalization), pulmonary rehabilitation can reduce readmissions and mortality. However, initiating pulmonary rehabilitation before the patient's discharge may compromise survival through unknown mechanisms.

Pulmonary rehabilitation can be conducted at a range of sites and there does not appear to be any advantage of delivering pulmonary rehabilitation in a hospital setting over services in the community.

Pulmonary rehabilitation also allows the promotion of Self-Management initiatives. Systematic reviews have provided evidence that Self-Management interventions improve outcomes in COPD. A Cochrane review on COPD Self-Management reported that Self-Management interventions that include written negotiated action plans for worsening symptoms led to a lower probability of both respiratory-related hospitalization and all cause hospitalizations. Self-Management interventions also improved health status.

Recommendation 15 Oxygen Therapy

The long-term administration of oxygen (> 15 hours per day) to patients with chronic respiratory failure has been shown to increase survival in patients with severe resting hypoxemia. Long term oxygen therapy does not lengthen time to death or first hospitalization or provide sustained benefit for any of the measured outcomes in patients with stable COPD and resting or exercise-induced moderate arterial oxygen desaturation.

Although air travel is safe for most patients with chronic respiratory failure who are on long-term oxygen therapy, patients should ideally maintain an in-flight PaO^2 of at least 6.7 kPa. Studies indicate that this can be achieved in those with moderate to severe hypoxemia at sea level by supplementary oxygen at 3 liters/min by nasal cannula. Those with a resting oxygen saturation > 95% and 6-minute walk oxygen saturation > 84% may travel without further assessment, although it is important to emphasize that resting oxygenation at sea level does not exclude the development of severe hypoxemia when travelling by air. Careful consideration should be given to any comorbidity that may

impair oxygen delivery to tissues (e.g., cardiac impairment, anaemia). Also, walking along the aisle may profoundly aggravate hypoxemia.

Recommendation 16 Nutritional Support

Low body mass index and particularly low-fat free mass is associated with worse outcomes in people with COPD. In malnourished patients with COPD, nutritional supplementation promotes significant weight gain and leads to significant improvements in respiratory muscle strength and overall health-related quality of life.

Recommendation 17 Lung Volume Reduction Surgery

LVRS is a surgical procedure in which parts of the lungs are resected to reduce hyperinflation, making respiratory muscles more effective pressure generators by improving their mechanical efficiency. , LVRS increases the elastic recoil pressure of the lung and thus improves expiratory flow rates and reduces exacerbations. , In an RCT that included severe emphysema patients, with an upper lobe emphysema and low post-rehabilitation exercise capacity, LVRS resulted in improved survival when compared to medical treatment.

Bullectomy is an older surgical procedure for bullous emphysema. Removal of a large bulla that does not contribute to gas exchange and is, or has been, responsible for complications decompresses the adjacent lung parenchyma. In selected patients with relatively preserved underlying lung, bullectomy is associated with decreased dyspnoea, improved lung function and exercise tolerance.

Bronchoscopic approaches have been used to provide a less invasive approach to reduce hyperinflation. These techniques have different approaches but all have a similar objective of reducing thoracic volume to improve respiratory mechanics. Bronchial stenting has been demonstrated not to be effective but a large multi centre, prospective randomised controlled trial of endobronchial valve placement in patients with heterogenous emphysema distribution and little or no collateral ventilation demonstrated significant clinically meaningful benefits over standard care in lung function, dyspnoea, exercise capacity and quality of their life out to at least 12 months post procedure. Other studies have shown similar results however the procedure does have a high pneumothorax rate. Other smaller studies using thermal paper ablation or implanted coils have shown similar results.

Recommendation 18 Lung Transplantation

In appropriately selected patients with very severe COPD, lung transplantation has been shown to improve health status and functional capacity but not prolong survival. Lung transplantation is limited by the shortage of donor organs.

Recommendation 19 Monitoring of Spirometry

COPD is a slowly progressive disorder which does not display significant differences in spirometric values over a short period of time. There is some evidence in clinical practice that pulmonary function studies are done repetitively in patients for no apparent clinical benefit. There are obviously costs involved in doing these studies and an opportunity cost in terms of other patients not been able to access studies due to pressure on resources.

Consequently, it is reasonable to perform spirometry only at an interval of approximately two years in stable patients.

Recommendation 20 Role of Palliative Care

Palliative care is a broad term that encompasses approaches to symptom control as well as management of terminal patients close to death. The goal of palliative care is to prevent and relieve suffering, and to support the best possible quality of life for patients and their families, regardless of the stage of disease or the need for other therapies. Even when receiving optimal medical therapy many patients with COPD continue to experience distressing breathlessness, impaired exercise capacity, fatigue, and suffer panic, anxiety & depression. Some of these symptoms can be improved by wider use of palliative therapies that in the past have often been restricted to end-of-life situations.

Opiates, neuromuscular electrical stimulation (NMES), chest wall vibration (CWV) and fans blowing air onto the face can relieve breathlessness. There is no evidence for a beneficial effect of benzodiazepines. Oxygen may offer some benefit even if the patient is not hypoxemic (Sp0 2 > 92%). Pulmonary rehabilitation is effective and in severe cases non-invasive ventilation can also reduce daytime breathlessness. Refractory dyspnoea may be more effectively managed with a multidisciplinary integrated palliative and respiratory care service.

In many patients, the disease trajectory in COPD is marked by a gradual decline in health status and increasing symptoms, punctuated by acute exacerbations that are associated with an increased risk of dying. End of life care should also include discussions with patients and their families about their views on resuscitation, advance directives and place of death preferences. At an individual level, prediction of 6-month survival in patients with COPD is unreliable and therefore early discussion of these issues is important.

Recommendation 11

Smoking Cessation

Smoking cessation measures are recommended for the prevention of COPD, to include advice on smoking cessation, nicotine replacement therapy and pharmacotherapy. *(GOLD)*

At the moment, the effectiveness and safety of E. cigarettes as a smoking cessation aid is uncertain

Strength of recommendation: Grade A

Good practice point

- **All patients with tobacco dependence, should be given brief smoking cessation advice at every intervention**
- **Referral to smoking cessation services should be offered and facilitated**
- **All staff should be familiar with the 5 A strategy to aid those with tobacco dependence: Ask, Advise, Assess, Assist and Arrange**

Recommendation 12

Influenza vaccination

The provision of annual influenza vaccination is recommended. ***(GOLD)***

Strength of recommendation: Grade A

Recommendation 13

Pneumococcal vaccination

The provision of the pneumococcal vaccination is recommended. ***(GOLD)***

Strength of recommendation: Grade B

Good practice point

When offering vaccinations staff should illustrate benefits, potential side effects and provide HSE patient information leaflets on flu and pneumonia vaccinations. If patient is recommended to have vaccinations by specialist staff this should be documented in letters to their GP.

Recommendation 14

Pulmonary rehabilitation

The provision of pulmonary rehabilitation to stable patients with exercise limitation despite pharmacological treatment is recommended. ***(Grade A)*** ***(GOLD)***

The provision of pulmonary rehabilitation to patients who have recently been hospitalised for an acute exacerbation of COPD is recommended. ***(Grade B)*** ***(GOLD)***

Strength of recommendation: Grade A &B

Good practice point

- All patients who fit the criteria should be offered referral to a Pulmonary Rehabilitation Programme
- Self-Management education is key to supporting patient with COPD to give them the skills, knowledge and confident to manage their condition. HCP provide education on COPD, medication management, Self-Management and life style changes.

Recommendation 15

Oxygen *Therapy*

15.1 The provision of long-term oxygen therapy to patients with chronic stable hypoxemia with a PaO2 less than 7.3 Kpa or a Pa02 between 7.3 and 8Kpa with signs of tissue hypoxia (haematocrit greater than 55%, pulmonary hypertension or cor pulmonale) is recommended. (Grade A) (GOLD)

15.2 The provision of oxygen for patients with moderate hypoxemia, nocturnal desaturation, or exercise-induced desaturation in patients with COPD is not routinely recommended. (Grade A) ***(GOLD)***

Strength of recommendation: Grade A

Good practice point

- Patients who require an assessment for oxygen therapy should be referred to an oxygen assessment clinic for a formal assessment
- Patients on LTOT should be reviewed on a regular basis
- Education and training on the safe use of LTOT should be part of initial and subsequent assessments and on commencement of Ambulatory Oxygen Therapy (AOT)

Recommendation 16

Nutritional support

Nutritional support should be considered in all malnourished patients with COPD ***(GOLD)***

Strength of recommendation: Grade B

Good practice point

- **Weight should be monitored on a regular basis**
- **Referral to dietetic services should be considered in patients with obesity and evidence of malnourishment**
- **Those with muscle wastage can be considered for referral along with exercise prescription**

Recommendation 17

Lung volume reduction surgery

17.1. Lung volume reduction surgery is recommended for carefully selected patients with upper lobe emphysema and low post rehabilitation exercise capacity. ***(Grade A)*** *(GOLD)*

17.2. In selected patients, bullectomy can also be recommended. ***(Grade C)*** *(GOLD)*

17.3 In selected patients with advanced emphysema, bronchoscopic interventions can reduce end-expiratory lung volume and improve exercise tolerance; health status and lung function at 6 to 12 months following treatment. Interventions can include endobronchial valves (Grade A); lung coils (Grade B); and paper ablation (Grade B***)***

Strength of recommendation: Grade A & C

Recommendation 18

Lung transplantation

It is recommended that appropriately selected patients with very severe COPD be considered for lung transplantation surgery. *(GOLD)*

Strength of recommendation: Grade C

Recommendation 19

Monitoring of Spirometry

In stable diagnosed COPD patients, decline in FEV 1 need not be tracked by spirometry more frequently than every two years.

Strength of recommendation: *(Expert Opinion)* *(Guideline Development Group)*

Good practice point

It is recommended that staff conducting spirometry should have undertaken a recognised training programme and relevant updates to ensure quality assured spirometry.

Recommendation 20

Role of Palliative Care

For advanced COPD care, patients should be referred to a palliative care specialist as appropriate.

Strength of recommendation: (Expert Opinion) *(Guideline Development Group)*

Good practice point

- Patients experiencing refractory cough or breathlessness having been provided optimal treatment should have referral to palliative care considered for support and opinion regardless of stage of disease.
- Careful sensitive explanation as to the nature of the referral needs to be had with patients prior to referral.

3.1.3. Management of acute exacerbations of COPD

HEALTH QUESTION 3. What interventions (nebulised bronchodilators, steroids, antibiotics, chest physiotherapy) are effective at reducing mortality and morbidity in patients over 35 years of age with exacerbations of COPD?
POPULATION (Specify patient and condition characteristics)
Age
Age over 35
Clinical circumstances
Patients diagnosed with COPD (i.e. confirmed as having COPD on spirometry) experiencing an acute exacerbation
Gender
Male or female
INTERVENTIONS (Specify intervention(s) type(s) and characteristics)
Treatments/care
Pharmacological and non-pharmacological interventions (including nebulised bronchodilators, steroids, antibiotics, chest physiotherapy)
Follow up
Follow up time of up to 30 days post-exacerbation
PROFESSIONALS/(PATIENTS) (Targeted users)
Providers
Physicians, nurse prescribers,nurses, physiotherapists
Stakeholders
Dept. of Health, HSE, hospitals, primary care
Patients
Patients with COPD

OUTCOME (Purpose of the guideline)
Patient outcomes
Survival, mortality, readmissions, morbidity (disease-specific quality of life, exercise tolerance,) Duration of episode of the exacerbation
System outcomes
Costs related to hospitalisation due to exacerbation.
Public health outcomes
Mortality and morbidity as above
HEALTH CARE SETTING/CONTEXT
Organisations
Hospitals and primary care

Evidence statement for Question 3

Recommendation 21 Bronchodilator therapy

Short-acting inhaled beta agonists, with or without short-acting anticholinergics, are recommended as the initial bronchodilators to treat an acute exacerbation. A systematic review of the route of delivery of short-acting bronchodilators found no significant differences in FEV 1 between using metered dose inhalers (MDI) (with or without a spacer device) or nebulisers to deliver the agent, although the latter may be an easier delivery method for sicker patients.

Recommendation 22 Steroids

Short-acting inhaled beta agonists, with or without short-acting anticholinergics, are recommended as the initial bronchodilators to treat an acute exacerbation. A systematic review of the route of delivery of short-acting bronchodilators found no significant differences in FEV 1 between using metered dose inhalers (MDI) (with or without a spacer device) or nebulisers to deliver the agent, although the latter may be an easier delivery method for sicker patients.

Recommendation 23 Antibiotics

Data from studies indicate that systemic glucocorticoids in COPD exacerbations shorten recovery time and improve lung function (FEV 1). They also improve oxygenation, the risk of early relapse, treatment failure, and the length of hospitalization. A dose of 40 mg prednisone per day for 5 days is recommended. There is no need to taper the dose. Therapy with oral prednisolone is equally effective to intravenous administration. Oral therapy is associated with lower overall doses of corticosteroid and may be associated with earlier discharge.

Although the infectious agents in COPD exacerbations can be viral or bacterial the use of antibiotics in exacerbations remains controversial. The uncertainties originate from studies that did not differentiate between bronchitis (acute or chronic) and COPD exacerbations, studies without placebo-control, and/or studies without chest X-rays that do not exclude that patients may have had underlying pneumonia. There is evidence supporting the use of antibiotics in exacerbations when patients have clinical signs of a bacterial infection e.g., increased sputum purulence. A systematic review of placebo-controlled studies has shown that antibiotics reduce the risk of short-term mortality by 77%, treatment failure by 53% and sputum purulence by 44%. The review provides evidence to treat moderately or severely ill patients with COPD exacerbations and increased cough and sputum purulence with antibiotics.

The recommended length of antibiotic therapy is 5-7 days. The choice of the antibiotic should be based on the local bacterial resistance pattern. Usually initial empirical treatment is an aminopenicillin with clavulanic acid, macrolide, or tetracycline.

Recommendation 24 Non Invasive Ventilation

Non-invasive ventilation (NIV) in the form of non-invasive positive pressure ventilation (NPPV) is the standard of care for decreasing morbidity and mortality in patients hospitalized with an exacerbation of COPD and acute respiratory failure. Non-invasive ventilation should be the first mode of ventilation used in COPD patients with acute respiratory failure.

NIV is indicated if at least one of the following is present: respiratory acidosis $PaCO2 \geq 6.0$ K PA and arterial $pH \leq 7.35$. Severe dyspnoea with clinical signs just respiratory muscle fatigue and persistent hyperaemia despite supplemental oxygen therapy.

NIV has been studied in RCTs showing a success rate of 8085%. NIV has been shown to improve oxygenation and acute respiratory acidosis i.e., NIV increases pH and decreases PaCO 2. NIV also decreases respiratory rate, work of breathing and the severity of breathlessness but also decreases complications such as ventilator associated pneumonia, and length of hospital stay. More importantly, mortality and intubation rates are reduced by this intervention.

Recommendations 25 COPD Outreach service

Early Supported Discharge by Outreach Services is a specific subtype of intermediate care, where active treatment is provided by healthcare professionals in the patient's own home for a condition that otherwise would have required hospital care; this treatment is always for a limited time period. Research shows that for a proportion of COPD patients, early discharge to an outreach service is safe, well tolerated and an economic alternative to hospital admissions. The benefits to the patient include being able to recuperate in their own environment with family support and reduced cost associated with hospital visits. The scheme provides for a high quality, professional, holistic patient focused service in the patient's home, which aims to improve the patient's quality of life and increase their social functioning.

An outreach Team comprises a Clinical Nurse Specialist (Respiratory) and a Senior Physiotherapist recruited to each site. The role of the CNS and Physiotherapist is to work

within the hospital and community setting as part of the Outreach Team, in consultation with the Respiratory Physicians and other relevant clinical services.

Recommendation 26 Specialist respiratory physiotherapists and nurses

Respiratory Physiotherapists and Respiratory Nurse Specialists play an integral role in the treatment of people with an exacerbation of COPD, with high level evidence that interventions aid recovery and prevent reoccurrence. In addition to their role in COPD outreach, Physiotherapists with their background in exercise prescription, are usually the coordinators of Pulmonary Rehabilitations services and are involved in all processes of the rehabilitation programme from recruitment of patients, assessment and identification of problems, delivery of the rehabilitation and liaison with the community services to enhance lifelong behavioural change. Respiratory Physiotherapists and Respiratory Nurse Specialists are frequently involved in the delivery of non-invasive ventilation, including assessment and referral of appropriate patients, establishing patients on treatment, titration of pressures, optimising patient tolerance and monitoring treatment effects. Non-invasive ventilation may assist in the delivery of other treatments such as early mobilisation and airway clearance. Respiratory Physiotherapists and Respiratory Nurse Specialists play a key role in oxygen assessment, carrying out six-minute walk tests, overnight oximetry and can perform arterial blood gases to facilitate the prescription of long-term oxygen therapy. Physiotherapists and Nurses also provide oxygen education to patients, families and carers both in inpatient settings and in their homes as part of the COPD outreach Services.

Recommendation 27 Theophyllines

Intravenous methylxanthines (theophylline or aminophylline) are not recommended to use in patients with an exacerbation of COPD due to significant side effects and no appreciable advantage over nebulised bronchodilators.

Recommendation 21

Bronchodilator Therapy

The initiation of short acting acute bronchodilator therapy (salbutamol plus or minus ipratropium) is recommended for patients with an exacerbation of COPD *(GOLD)*

Strength of recommendation: Grade C

Recommendation 22

Steroids

A course of systemic steroids (prednisone equivalent of 40mgs for five days) to be administered orally to all patients is recommended. Therapy should not be routinely administrated for more than this. *(GOLD)*

Strength of recommendation: Grade A

Recommendation 23

Antibiotics

Oral antibiotic use for patients with exacerbations of COPD associated with increased dyspnoea and associated increased sputum purulent or volume is recommended. First line antibiotic choices should include doxycycline, amoxicillin or a macrolide. Reserving broader spectrum antibiotics such as quinolones for specific indications is recommended. The choice of antibiotics may be modified due to local bacterial resistance patterns or an individual's sputum microbiology. (Grade B) (GOLD/Expert Opinion)

Strength of recommendation: Grade B

Recommendation 24

Non-invasive ventilation

The use of non-invasive ventilation in patients with acute exacerbations of COPD who develop acute respiratory failure associated with respiratory acidosis is recommended i.e. a PaCO2 greater than 6KPa and an arterial PH less than 7.35 which is persistent following rationalization of delivered oxygen therapy (Grade A) (GOLD)

Strength of recommendation: Grade A. ***(GOLD)***

Recommendation 25

COPD Outreach Service

The involvement of the COPD outreach team as early as possible during a COPD exacerbation when it is being treated in hospital is recommended

Strength of recommendation: *(Expert Opinion)* ***(Guideline Development Group)***

Good practice point:
All patients who fit the criteria should be referred to COPD outreach service

Recommendation 26

Respiratory Physiotherapy & Respiratory Nurse Specialists

It is recommended that respiratory physiotherapists and respiratory nurses are key in delivering COPD outreach, NIV, oxygen assessment and pulmonary rehabilitation to patients who have exacerbations of COPD and stable COPD

Strength of recommendation: *(Expert Opinion)*

Good practice point:
Specialist Physiotherapists and Nurses should be involved as appropriate in all aspects of patients care in hospital and community settings in providing specialist support, advice and education.

Recommendation 27
Theophyllines
The use of theophylline in acute exacerbations of COPD is not recommended.

Strength of recommendation: *(Grade B)* ***(GOLD)***

3.1.4. Oxygen therapy prescription and monitoring in COPD

HEALTH QUESTION 4. **What is the appropriate prescription of oxygen therapy effective to reduce mortality and morbidity for patients over 35 years of age with COPD, and what are the optimal monitoring strategies and assessment frequency for patients receiving oxygen therapy?**
POPULATION (Specify patient and condition characteristics)
Age
Age over 35
Clinical circumstances
Patients diagnosed with COPD (i.e. confirmed as having COPD on spirometry)
Gender
Male or female
INTERVENTIONS (Specify intervention(s) type(s) and characteristics)
Treatments/care
Prescription and monitoring of oxygen therapy
Follow up
Any follow up time between prescription of oxygen and death
PROFESSIONALS/(PATIENTS) (Targeted users)
Providers
Physicians, nurse prescribers, nurses, physiotherapists
Stakeholders

Dept. of Health, HSE, hospitals, primary care
Patients
Patients with COPD
OUTCOME (Purpose of the guideline)
Patient outcomes
Survival, mortality, readmissions, morbidity (disease-specific quality of life, exercise tolerance, lung function e.g. FEV1), less hazard for patients due to inappropriate prescription
System outcomes
Costs for prescription of oxygen,
Public health outcomes
Mortality and morbidity as above
HEALTH CARE SETTING/CONTEXT
Organisations
Hospitals and primary care, ambulatory care/home care

Evidence statement for Question 4

Recommendation 28 Oxygen therapy Prescribing and monitoring

Once placed on long-term oxygen therapy (LTOT) the patient should be re-evaluated after 60 to 90 days with repeat arterial blood gas (ABG) or oxygen saturation while inspiring the same level of oxygen or room air to determine if oxygen is therapeutic and still indicated.

Recommendation 28

Oxygen therapy prescribing and monitoring in COPD

28.1 Patients discharged home from hospitalisation on oxygen therapy should be evaluated for the need for long term oxygen therapy 30-90 days after discharge. Long term oxygen therapy should not be continued if patients do not meet the criteria.
(Expert Opinion) (Guideline Development Group)

28.2 Routinely offering ambulatory LTOT for patients with chronic stable isolated exercise hypoxemia is not recommended. *(Grade A) (GOLD)*

28.3. Once the causes of nocturnal hypoxia have been evaluated, routinely offering oxygen therapy for the treatment of isolated nocturnal hypoxia is not recommended. ***(Grade A)*** *(GOLD)*

Strength of recommendation: ***(Grade A)*** *(GOLD)*

3.1.5 Pathways, bundles and checklists for managing acute COPD exacerbations

HEALTH QUESTION 5. **In patients admitted to hospital with an acute exacerbation of COPD, which clinical pathways, admission and discharge bundles or checklists are most effective at improving patient care by reducing length of hospital stay and readmissions and by reducing patient mortality and morbidity?**
POPULATION (Specify patient and condition characteristics)
Age
Age over 35
Clinical circumstances
Patients diagnosed with COPD (i.e. confirmed as having COPD on spirometry), admitted to hospital with an acute exacerbation
Gender
Male or female
INTERVENTIONS (Specify intervention(s) type(s) and characteristics)
Treatments/care
Any clinical pathway, admission and discharge bundle or checklist used for the management of acute exacerbations of COPD in hospital. • Care bundles, defined as a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices — generally three to five — that, when performed collectively and reliably, have been proven to improve patient outcomes (HIQA, 2014). • Checklists, defined as tools that condense a large volume of information and allow for systematic verification of steps or practices (Hewson et al., 2006; Hales et al., 2008; WHO 2008). • Patient care pathways are defined as a multidisciplinary care plan that outlines the main clinical interventions that are carried out by different healthcare practitioners for patients with a specific condition or set of symptoms. They are usually locally agreed, evidenced-based plans that can incorporate local and national guidelines into everyday practice (NCEC, HIQA, 2015.
Follow up
From hospital admission to 90 days post discharge (readmissions)
PROFESSIONALS/(PATIENTS) (Targeted users)
Providers

Physicians, nurse prescribers, nurses, physiotherapists
Stakeholders
Dept. of Health, HSE, hospitals
Patients
Patients with COPD
OUTCOME (Purpose of the guideline)
Patient outcomes
Length of stay in hospital, readmissions, survival, mortality, possibly morbidity (disease-specific quality of life, exercise tolerance,)
System outcomes
Direct and indirect costs related to length of hospital stay and readmissions.
Public health outcomes
Mortality and morbidity related to COPD
HEALTH CARE SETTING/CONTEXT
Organisations
Hospitals

Evidence statement for Question 5

The introduction of care bundles at hospital discharge to include education, optimization of medication, supervision and correction of inhaler technique, assessment and optimal management of comorbidities, early rehabilitation, telemonitoring and continued patient contact have all been investigated to address these issues. Whereas these measures all seem sensible there is insufficient data that they influence either readmission rates or short-term mortality and there is little evidence of cost-effectiveness. Nevertheless, it remains good clinical practice to cover these issues before discharge with the possible exception of instituting rehabilitation before discharge as there is some evidence that this factor is associated with increased mortality, although the reasons remain unknown.

Recommendation 29
Pathways, Bundles and Checklists for Managing Acute Exacerbation of COPD
It is recommended that an admission and discharge bundle be applied to all patients admitted acutely with an exacerbation of COPD.

Strength of recommendation: (Expert Opinion) *(Guideline Development Group)*

Good practice point:

A COPD admission and discharge bundle should be initiated on patients admitted with exacerbations with COPD as soon as arrival in the ED department

Section 4: Appendices

Appendix 1: Guideline Development Group terms of reference

GDG Terms of Reference: To develop a national evidence-based clinical guideline for the management of COPD.

COPD (2020) NCG No.X Guideline Development Group
Terms of Reference (agreed 31st January 2016)

---

1. Purpose

The purpose of this Guideline Development Group (GDG) is to develop the NCG for COPD to reflect current best evidence.

2. Objectives

The objectives of the GDG are to:

- Ensure adherence to the NCEC methodology in drafting the clinical guideline
- Include a budget impact analysis in the updated guideline
- Translate evidence from the HRB-CICER literature review to guideline recommendations and best practice points
- Include an improvement strategy in the guideline
- Prepare a draft guideline
- Circulate draft guideline for consultation and external review
- Finalise and approve the updated clinical guideline
- Submit to stakeholders for review and approval
- Submit finalised updated guideline to NPSO/NCEC, DOH for approval, endorsement and ministerial launch

3. Scope

The scope of the GDG is to draft the NCG COPD to reflect the End to End Model of COPD and the care of individuals with COPD

4. Working Arrangements

a) A schedule of meetings will be agreed with the Chair for the year. Work will be undertaken between meetings and members will contribute to, and approve work, via e-mail correspondence (and teleconference when available).

b) The Chair and Deputy Chair will be responsible for circulating papers and minutes of meetings. Papers for meetings will be circulated no later than 3 working days before meetings and minutes will be circulated no later than 2 weeks after meetings.

c) The group will be quorate if a third of total membership (8) is present.

d) Apologies should be sent in advance of meetings. If a group member does not attend more than three consecutive meetings the Chair or Deputy Chair will contact him/her to seek confirmation of continued participation or if they would like to nominate a replacement.

e) Members of the GDG will be accountable to the specialist groups and individual organisations they represent and will report through the relevant organisation's governance structures.

f) Decision-making: the agenda will identify items that require important decisions to be made at the meeting. Where group members are unable to attend they may submit comments to the Deputy Chair, by e-mail, by 5pm on the day prior to the meeting. The Deputy Chair will bring forward all comments received for consideration by the group in attendance. Decisions will be made by the group attending the meeting. Meeting notes will detail such decisions to group members who are not in attendance.

g) There may be a requirement to establish various working groups to advance actions as guideline development progresses. The Chair of the working group will report to the GDG on progress and outputs and seek further advice or decisions where appropriate.

h) GDG members may be required to participate in educational workshops relevant to guideline development work at various stages throughout the guideline development process

NEWS GDG member Roles and Responsibilities

Note: As the guideline review process evolved and the magnitude of the work became apparent the Chair and Deputy Chair roles were reconfigured to Co-Chair roles.

GDG Chairperson/Deputy Chairperson Role and Responsibility

- Develop and agree terms of reference
- Ensure guideline is developed using NCEC methodology and that each stage of the stages of the clinical guideline path are addressed
- Set and agree timelines (using a standard project management approach where possible)

- Set and circulate the agenda of each meeting to members
- Encourage broad participation from members in discussion
- Identify and assign tasks
- Agree a process for dealing with conflicts of interest
- Identify and oversee the progress of specific sub-groups
- End each meeting with a summary of decisions and actions
- Act as a point of contact for GDG members

GDG Member Roles and Responsibilities

- Review and agree group membership to reflect all key stakeholders
- Agree timelines for meetings and the clinical guideline development process
- Convene as required
- Give consideration to each of the stages of the clinical guideline path
- Review existing policies, guidelines, national and international evidence of best practice, relevant scientific and clinical expert opinion pertaining to the clinical guideline area
- Determine whether to adapt, adopt or develop a new clinical guideline
- Draft clinical guideline using NCEC methodology
- Consult with relevant interested parties and the public
- Review and incorporate feedback from consultation process as appropriate
- Finalise and approve clinical guideline for submission to Steering Group

GDG Service user Roles and Responsibilities (in addition to above)

- Ensure that key questions are informed by issues that matter to the service user
- Identify outcome measures they think are important for each key question
- Assist the GDG with the collection of service user views e.g. by helping to prepare questions for focus groups
- Help the GDG with consultation arrangements
- Identify areas where service users' preferences and choices may need to be acknowledged in the clinical guideline
- Help write the information for the service users section of the clinical guideline including identifying sources of further information

- Help ensure that the clinical guideline is clearly and sensitively worded

**List of GDG members can be seen in Table 1, page 4.*

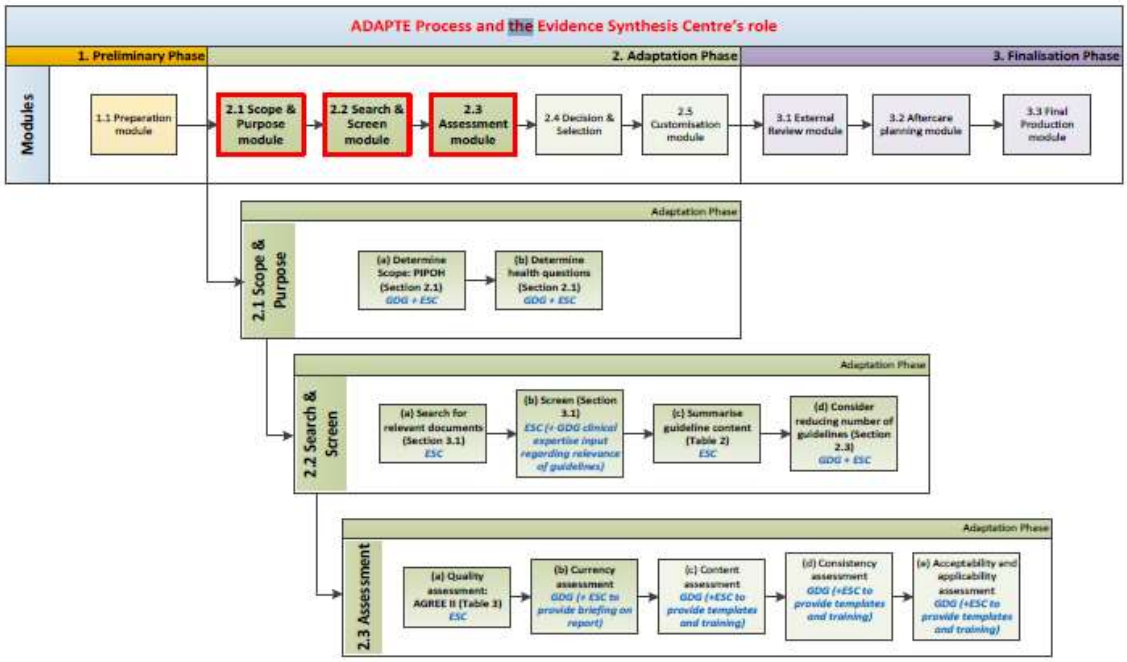
External Reviewers
<Names, titles and organisations>

To be added once completed

Appendix 2 Search strategy

The Evidence Synthesis Centre conducted three parts of the ADAPTE process, which we have presented in this report: (1) Assisting the guideline group in defining the scope and purpose of the guideline; (2) Conducting a systematic search for existing guidelines; and (3) Assessing the quality of included guidelines. An overview of the role of the ESC is provided in below.

Overview of ADAPTE process and detailed steps of the three modules in which the ESC are involved



The methods, described in this section, were adapted from ADAPTE collaboration manual1. Data extraction tool and quality assessment tools were also adapted from the CAN-IMPLEMENT© toolkit, which uses the ADAPTE process and was originally developed for the Canadian Guideline Adaptation Group.5 These toolkits are available in the reference links provided.

Screening for inclusion

All retrieved records were screened by at least two reviewers independently (FW, BW, MM), using the PIPOH criteria. Consensus was reached by involving a third reviewer (DD). Due to the large number of guidelines meeting the inclusion criteria, a second round of screening was conducted to reduce the number of guidelines to be made available to the GDG. This was based on the ‗Rigour of Development' dimension of the AGREE II quality assessment tool,3 as recommended in the ADAPTE manual.1 The Rigour of Development dimension contains eight items (Table 1). Guidelines were included only if they met all items 1-6. This was again conducted independently by two reviewers (FW, BM) who subsequently discussed and resolved any discrepancies.

Systematic methods were used to search for evidence.
2. The criteria for selecting the evidence are clearly described.
3. The strengths and limitations of the body of evidence are clearly described.
4. The methods for formulating the recommendations are clearly described.
5. The health benefits, side effects, and risks have been considered in formulating the recommendations.
6. There is an explicit link between the recommendations and the supporting evidence.
7. The guideline has been externally reviewed by experts prior to its publication.
8. A procedure for updating the guideline is provided.

Quality assessment

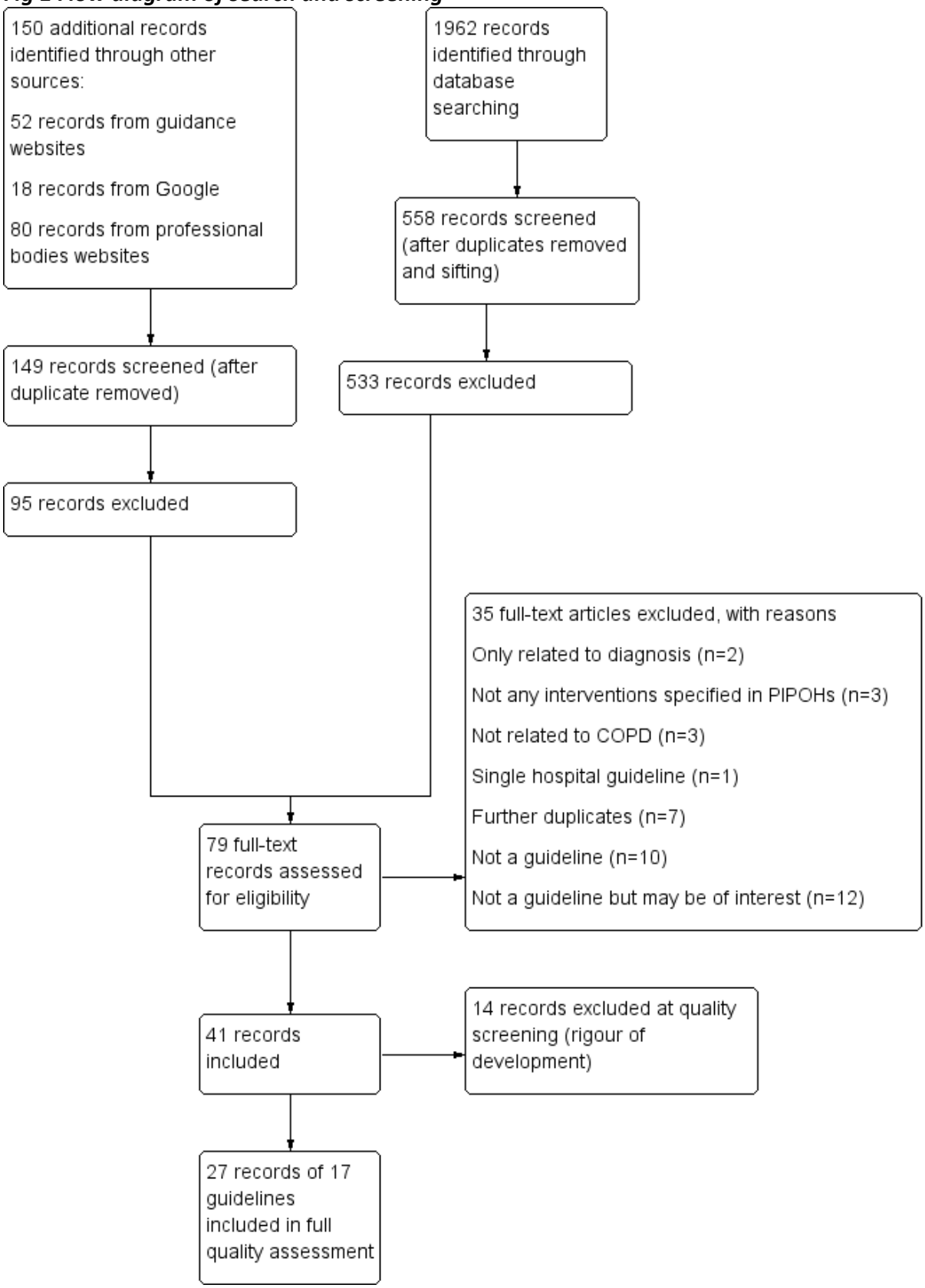
Two reviewers (FW, BM) independently assessed the quality of included guidelines using the AGREE II instrument3. Scores were calculated and reported in accordance with the AGREE II manual, including the average percentage score and the overall assessment score. Inter-rater agreement was also assessed by subtracting the scores of the two reviewers, and, if there was a difference of more than two for any item, this was discussed to reach consensus

Search and screening results

1962 records were identified from searching databases. The information specialist sifted all 1962 records and removed duplicates, leaving 558 records to screen. Following title and abstract screening, 553 records were excluded. The remaining 25 records were screened at full-text. In addition, we identified 150 records from grey literature resources, of which 54 were screened at full-text level. Thirty-eight records of the total of 79 were excluded at full-text. The most common reason for exclusion was that a record was not a clinical guideline (n=22); using the NCEC's definition1.

Documents that were not guidelines but thought to be of interest to the guideline committee (n=12) were not included but are listed in this report for GDG information. Following screening based on the rigour of development dimension of the AGREE II tool, 27 records that related to 17 guidelines met the inclusion criteria and were included for complete quality assessment and mapping of the content according to the scope (Sections 3.2 and 3.3). An overview of the search results is presented below.

Fig 1 Flow diagram of search and screening



Search strategy for guidelines for COPD management in adults

a. Databases searched

Main databases to be searched:

- PubMed
- Embase
- CINAHL
- DynaMed

b. Guideline internet sites and clearinghouses

Guideline Internet Sites	URL
Department of Health (including National Clinical Guidelines)	http://health.gov.ie
Health Service Executive (HSE)	www.hse.ie
Health Information and Quality Authority (HIQA)	www.hiqa.ie
National Institute for Health and Care Excellence (NICE)	http://www.nice.org.uk/page.aspx?o=ourguidance
Guidelines and Audit Implementation Network / The Regulation and Quality Improvement Authority	http://gain-ni.org/index.php/audits/guidelines
NHS Evidence (incorporating Scottish Intercollegiate Guidelines Network (SIGN) & Guidelines International Network (GIN))	www.evidence.nhs.uk
Institute for Clinical Systems Improvement (ICSI)	http://www.icsi.org/knowledge
Food and Drug Administration	http://www.fda.gov/cder/guidance/index.htm
National Guidelines Clearinghouse (NGC)	www.guideline.gov
New Zealand Guidelines Group	http://www.nzgg.org.nz
National Health and Medical Research Council (NHMRC) Australian Clinical Guidelines	www.clinicalguidelines.gov.au
Canadian Agency for Drugs and Technology in Health	http://www.cadth.ca
Canadian Medical Association Infobase	https://www.cma.ca/En/Pages/clinical-practice-guidelines.aspx
Haute Autorité de Santé (HAS)	http://www.has-sante.fr/portail/jcms/c_6056/fr/recherche-avancee?portlet=c_39085&search_antidot=&lang=en&typesf=guidelines
Ontario Guidelines Advisory Committee (GAC) Recommended Clinical Practice Guidelines	http://www.gacguidelines.ca
Finnish Medical Society Duodecim	http://www.kaypahoito.fi
World Health Organisation	www.who.int

A Professional bodies' websites searched

Professional Bodies		
Ireland	Irish Thoracic Society	www.irishthoracicsociety.com
	Respiratory Nurses Association of Ireland	www.anail.ie
	Royal College of Physicians Ireland	www.rcpi.ie
	Royal College of Surgeons Ireland	www.rcsi.ie
	Irish Medical Council	www.medicalcouncil.ie
	Irish College General Practitioners	www.icgp.ie
	Irish Society of Chartered Physiotherapists	www.iscp.ie
	Irish Nurses and Midwives Organisation	www.inmo.ie
UK	British Thoracic Society	www.brit-thoracic.org.uk
	Scottish Thoracic Society	https://sts.rcpe.ac.uk
	Welsh Thoracic Society	www.welshthoracicsociety.org.uk
	Royal College of Physicians London	www.rcplondon.ac.uk
	Association of Respiratory Nurse Specialists (UK)	http://arns.co.uk
Europe	European Respiratory Society	www.ersnet.org
	European Respiratory Nurses Association	www.erna.eu
	Forum for European Respiratory Societies	www.fersnet.org
	European Society of Thoracic Surgeons	www.ests.org
North America	American Thoracic Society	www.thoracic.org
	American Association for Thoracic Surgery	www.aats.org
	American College of Chest Physicians	www.chestnet.org
	American Association for Respiratory Care	www.aarc.org
	California Thoracic Society	https://03e5d8e.netsolhost.com/CalThoracic
	Oregon Thoracic Society	http://action.lung.org/site/TR?fr_id=13880&pg=entry
	Canadian Thoracic Society	www.respiratoryguidelines.ca
	Registered Nurses Association of Ontario	http://www.rnao.org
Australia & Oceana	Thoracic Society of Australia and New Zealand	www.thoracic.org.au

Professional Bodies		
Asia	Hong Kong Thoracic Society	http://hkresp.com/index.php/about-joomla
	Malaysian Thoracic Society	www.mts.org.my/index.asp
	Thoracic Society of Nepal	http://thoracicsociety.org
	Saudi Thoracic Society	http://saudithoracic.com
Africa	South African Thoracic Society	www.pulmonology.co.za
	Pan African Thoracic Society	www.africanthoracic.org
Other	Forum of International Respiratory Societies	www.firsnet.org
	International Primary Care Respiratory Group	www.theipcrg.org
	Global Initiative for Chronic Obstructive Lung Disease (GOLD)	http://new2.goldcopd.it

B Google search

The first 10 pages of Google were searched.

a. Search terms used

Search Terms		
Details	**Free Text Terms**	**Thesauri Terms**
Population: Adult patients over 35 years of age with a diagnosis of COPD	COPD OR chronic obstructive pulmonary disease OR COAD OR chronic obstructive airway disease OR chronic obstructive lung disease OR chronic airflow obstruction OR chronic airflow obstructions adult OR adults OR adulthood	*MeSH:* pulmonary disease, chronic obstructive *Emtree:* chronic obstructive lung disease *CINAHL:* pulmonary disease, chronic obstructive *MeSH*: adult (explode) *Emtree*: adult (explode) *CINAHL*: adult (explode)
Guidance documentation	guideline OR guidelines OR guidance OR policy OR policies OR procedure OR procedures OR protocol OR protocols OR position statement OR position statements OR consensus statement OR consensus statements OR practice parameter OR practice parameters OR best practice OR best practices OR standard OR standards OR CPG OR CPGs OR pathway OR pathways OR path OR paths OR recommendation OR	*MeSH*: Guideline [Publication Type], guidelines as topics, Practice Guideline [Publication Type], Health Planning Guidelines *Emtree*: practice guideline (explode term) *CINAHL*: practice guidelines

	recommendations OR care plan OR care plans OR good clinical practice OR good clinical practices OR map OR maps OR algorithm OR algorithms	

b. Filters/limits used

Limits/filters:

- Date: past 10 years
- Language: English only

Field headings (eg. title, abstract, and keyword) were used if deemed appropriate.

Appendix 3 : PICOs for questions

Table 1.PICOS for review question 1 – pulmonary rehabilitation

Population	Adults with stable COPD who have exercise limitation despite pharmacological treatment or adults with COPD that have recently been hospitalised with an acute exacerbation of COPD
Intervention	Pulmonary rehabilitation* plus usual care
Comparator	Usual care (without pulmonary rehabilitation)
Outcomes	Any relevant measures of costs and benefits
Study design	Systematic reviews of economic evaluations, full economic evaluation studies (cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis), costing studies and comparative resource use studies.

Key: COPD – chronic obstructive pulmonary disease.

*Minimum inclusion criteria for pulmonary rehabilitation programmes are defined in section 2.7.1**.**

COPD outreach service (recommendation 25)

Table 2 PICOS for review question 2 – COPD outreach service*

Population	Adults who have been hospitalised with an exacerbation of COPD
Intervention	COPD outreach service within 72 hours of admission**
Comparator	No outreach service
Outcomes	Any relevant measures of costs and benefits
Study design	Systematic reviews of economic evaluations, full economic evaluation studies (cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis) and comparative resource use studies.

Key: COPD – chronic obstructive pulmonary disease.

*Minimum inclusion criteria for outreach services are defined in section 2.7.2**.**

**This broad inclusion criterion was applied to the intervention to enable review of all relevant literature.

Long-term oxygen therapy (recommendation 15)

Table 3 PICOS for review question 3 – long-term oxygen therapy

Population	Adults diagnosed with chronic stable hypoxemia with a PaO2 less than 7.3 Kpa or a Pa02 between 7.3 and 8Kpa with signs of tissue hypoxia (haematocrit greater than 55%, pulmonary hypertension or cor pulmonale)
Intervention	LTOT plus usual care
Comparator	Usual care
Outcomes	Any relevant measures of costs and benefits
Study design	Systematic reviews of economic evaluations, full economic evaluation studies (cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis), costing studies and comparative resource use studies.

Key: Kpa – kilopascal; LTOT – long-term oxygen therapy; PaO2 – partial pressure of oxygen.

*Recommending against the provision of oxygen does not require economic consideration. The recommendation is based on evidence from the clinical literature and a reduction in inappropriate oxygen provision is likely to lead to cost savings. Therefore, the economic question does not address the second component of recommendation 15.

Pharmacological management of COPD

Long acting bronchodilator combination therapy (recommendation 2)

Table 4 PICOS for review question 4 – long acting bronchodilator combination therapy

Population	Adults diagnosed with stable COPD on either LABA or LAMA
	monotherapy that present with continued respiratory symptoms (e.g.
	persistent dyspnoea) or with a history of exacerbations**
Intervention	Inhaled LABA and LAMA combination therapy
Comparator	Inhaled LABA or LAMA monotherapy
Outcomes	Any relevant measures of costs and benefits
Study design	Systematic reviews of economic evaluations, full economic evaluation studies (cost-effectiveness analysis, cost-utility analysis and cost- benefit analysis), costing studies and comparative resource use studies

Key: COPD – chronic obstructive pulmonary disease; LABA – long acting beta2-agonist; LAMA – long acting muscarinic antagonist.

*Offering long acting bronchodilators (LABAs or LAMAs) to COPD patients who continue to have respiratory symptoms is considered standard practice. Therefore, the economic question does not address the first two components of recommendation 2.

**Exacerbations are defined by GOLD as an acute and sustained worsening of respiratory symptoms that result in additional therapy. These events may be: mild (where the patient is treated with short acting bronchodilators only); moderate (where the patient is treated with steroids); or severe (where the patient is hospitalised).

Inhaled corticosteroids (recommendation 3)

Table 5 PICOS for review question 5 – inhaled corticosteroids

Population	Adults diagnosed with COPD who have persistent dyspnoea or frequent
	exacerbations despite LABA and LAMA combination therapy
Intervention	ICS in addition to inhaled LABA and LAMA combination therapy
Comparator	Inhaled LABA and LAMA combination therapy only
Outcomes	Any relevant measures of costs and benefits
Study design	Systematic reviews of economic evaluations, full economic evaluation studies (cost-effectiveness analysis, cost-utility analysis and cost- benefit analysis), costing studies and comparative resource use studies.

Key: COPD – chronic obstructive pulmonary disease; ICS – inhaled corticosteroid; LABA – long acting beta2-agonist; LAMA – long acting muscarinic antagonist.

*Recommending against offering ICS does not require economic consideration. The recommendation is based on evidence from clinical literature and a reduction in inappropriate provision of ICS is likely to lead to cost savings. Therefore, the economic question does not address the first component of recommendation 3.

Prophylactic use of Macrolide Antibiotics (recommendation 7)

Table 6 PICOS for review question 6 – prophylactic use of azithromycin

Population	Adults with severe COPD that have had one or more treated exacerbations and are non-smokers (former or never smokers)**
Intervention	Addition of oral azithromycin prophylaxis to usual care for one year only
Comparator	Usual care (inhaled LABA, LAMA, combination or triple therapy)
Outcomes	Any relevant measures of costs and benefits
Study design	Systematic reviews of economic evaluations, full economic evaluation studies (cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis), costing studies and comparative resource use studies.

Key: COPD – chronic obstructive pulmonary disease; ICS – inhaled corticosteroid; LABA – long acting beta2-agonist; LAMA – long acting muscarinic antagonist.

*A broader inclusion criterion of one or more exacerbations was considered for the economic review question to capture all available relevant literature.

**Exacerbations are defined by GOLD as an acute and sustained worsening of respiratory symptoms that result in additional therapy. These events may be: mild (where the patient is treated with SABAs only); moderate (where the patient is treated with corticosteroids); or severe (where the patient is hospitalised). In this case, severe refers to patients that fall into the severe category or Group D according to the GOLD refined

ABCD assessment tool. The refined ABCD assessment tool combines information regarding severity of airflow limitation (see Table 1.2) with information regarding symptom burden and risk of exacerbation.

Non-pharmacological management of COPD

Lung volume reduction procedures (recommendation 17)

Table 7 PICOS for review question 7.1 – lung volume reduction procedures

Population	Adults with upper lobe emphysema and low-post rehabilitation exercise capacity
Intervention	Lung volume reduction procedures (including surgery, endobronchial coils and endobronchial valves)
Comparator	No surgery or delayed surgery
Outcomes	Any relevant measures of costs and benefits
Study design	Systematic reviews of economic evaluations, full economic evaluation studies (cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis), costing studies and comparative resource use studies.

Table 8 PICOS for review question 7.2 – lung volume reduction surgery

Population	Adults with upper lobe emphysema and low-post rehabilitation exercise capacity

Intervention	Lung volume reduction surgery with bullectomy
Comparator	No surgery
Outcomes	Any relevant measures of costs and benefits

Lung transplantation (recommendation 18)

Table 9 PICOS for review question 8 – lung transplantation

Population	Adults with very severe COPD*
Intervention	Lung transplantation surgery plus usual care
Comparator	Usual care without transplant surgery
Outcomes	Any relevant measures of costs and benefits
Study design	Systematic reviews of economic evaluations, full economic evaluation studies (cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis), costing studies and comparative resource use studies.

Key: COPD – chronic obstructive pulmonary disease.

*Very severe COPD or Group D as defined according to the GOLD refined ABCD assessment tool. The refined ABCD assessment tool combines information regarding severity of airflow limitation (see Table 1.2) with information regarding symptom burden and risk of exacerbation.

Monitoring of spirometry (recommendation 19)

Table 10 PICOS for review question 9 – monitoring of spirometry

Population	Adults diagnosed with COPD that is stable
Intervention	Spirometry performed every two years
Comparator	Spirometry performed more frequently than every two years
Outcomes	Any relevant measures of costs and benefits
Study design	Systematic reviews of economic evaluations, full economic evaluation studies (cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis), costing studies and comparative resource use studies.

Key: COPD – chronic obstructive pulmonary disease.

Management of exacerbations in COPD

Non-invasive ventilation (recommendation 24)

Table 11 PICOS for review question 10 – non-invasive ventilation

Population	Adults with acute exacerbations of COPD that develop respiratory

	acidosis*
Intervention	Non-invasive ventilation plus usual care
Comparator	Usual care
Outcomes	Any relevant measures of costs and benefits
Study design	Systematic reviews of economic evaluations, full economic evaluation studies (cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis), costing studies and comparative resource use studies.

Key: COPD – chronic obstructive pulmonary disease.

*Respiratory acidosis was defined as an arterial pH less than 7.35.

Appendix 4 Consultation process

Appendix 4: Consultation report

To be completed post consultation

.

Date	
Patients groups	
External review	
Clinical Programmes and healthcare divisions	

National committees	
Professional groups	

Name	Title and Organisation

Appendix 5 Economic assessment

ANNEX D: Budget impact analysis currently in draft awaiting final version

Appendix 6 Logic Model & Implementation Plan

See Annex E & F

Appendix 7: Supporting tools

End to End COPD Model of Care
https://www.hse.ie/eng/about/who/cspd/ncps/copd/moc/end-to-end-copd-model-of-care-december-2019.pdf

COPD Communication Card:
https://www.hse.ie/eng/about/who/cspd/ncps/copd/resources/copd-communication-card.pdf

COPD Self-care plan
https://www.hse.ie/eng/about/who/cspd/ncps/copd/resources/copd-self-care-plan.pdf

COPD Acute management bundle
https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/copd-acute-management-bundle.pdf

COPD Discharge Plan
https://www.hse.ie/eng/about/who/cspd/ncps/copd/resources/copd-discharge-bundle-nccp-2018.pdf

Appendix 8: Monitoring and audit

1 Monitoring

1.1 Monitoring the implementation process

The key implementation process outcomes for this guideline overall, and for specific recommendations, are listed in the logic model and the implementation table in Appendix 6. One focus of monitoring and evaluation will be that that the guideline is widely disseminated and available for use in all clinical areas caring for people with COPD, and that all doctors, nurses and pharmacists in acute and community settings have access to it.

The other key implementation process outcome is that doctors, nurses and pharmacists understand, accept and adopt the NCG.

1.2 Monitoring the outcome on service

The key service outcome for this guideline overall is that a more appropriate prescribing process is used when considering COPD medications. A key purpose of the guideline is to decrease variation (both within and between services and regions) and to guide care to an appropriate standard across the healthcare system. This outcome will be monitored through chart audit, by local champions.

1.3 Monitoring the outcome on patient-related outcomes

The key patient-related outcome of successful implementation of this guideline is improved patient safety, with decreased mortality and morbidity associated with inappropriate prescribing of pharmacological and non-pharmacological treatments.

In addition, user satisfaction with the decision-making process around

COPD medication prescribing will be proposed for inclusion in the national patient experience survey.

2 Evaluations

2.1 Formal evaluation of the implementation programme

The Guideline Development Group strongly recommends that there is a formal evaluation of the implementation of this guideline, to guide future implementation of related guidelines, and other national quality improvement initiatives. Most of the data will be available from the within implementation and monitoring processes (pre-and post-implementation data, where available). A collation and presentation of key implementation data in an implementation report is recommended.

3 Audit plan

There is a need for two levels of clinical audit to maximise the success of implementation of the guideline local self-audit, and national monitoring audit.

3.1 Local self-audit

It is important that the implementation of the guideline is audited to ensure that this guideline positively impacts on the care of a person with COPD. It is envisioned that local services will self-audit to support local implementation – feedback of local results to local clinicians and management can support culture change by demonstrating a need for

improved practice, or demonstrating good practice, and/or can support local business cases for enhanced resources to support quality improvement. Thus, it is recommended that local services ideally perform a "baseline" practice review early on in the implementation programme, and follow-up audit once local staffs has received training and practice change is expected to have embedded. Depending on the results, it is recommended that the audit is repeated annually to year 5 of implementation.
The following settings should consider self-audit, as follows:

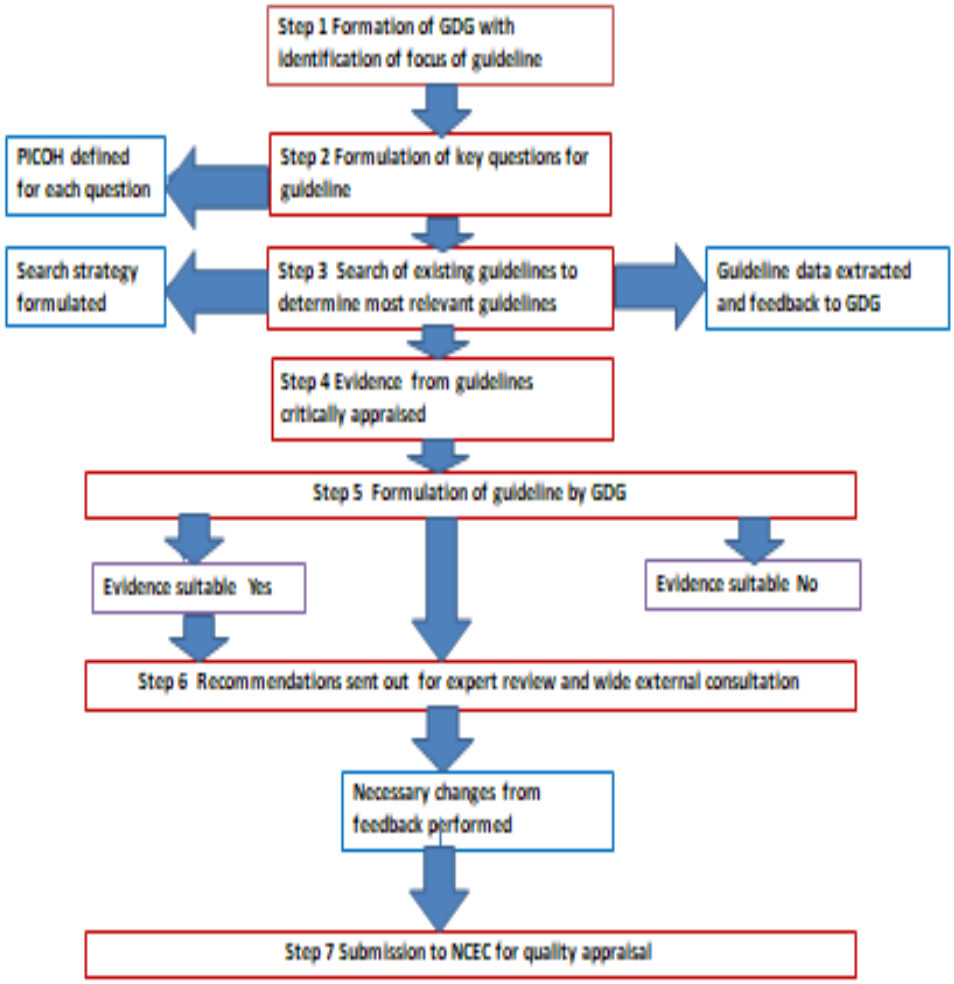
• All acute hospitals: the local implementation team should work closely with the acute unit to identify audit champions and potentially non-consultant hospital doctors willing to perform the audit as part of their annual audit requirement for professional competence assurance. The results of the audit should also be fed back to the local teams for broader consideration including the need for enhanced resources to facilitate best practice. Results should also be available to the National Implementation Team.

• General Practitioners (GPs)/Primary Care Teams: Ideally, GPs and GP practices would self-audit as per other services. However, although GPs have to perform one audit annually, there is no onus on them to choose an audit on COPD management. The National Implementation Team will work closely with the Irish College of GPs and GP COPD champions to promote the value of this audit, as part of the engagement around GP training in the guideline content. The possibility of Primary Care Teams performing an audit within their service will be explored with the Community Healthcare Organisation Local teams.

3.2 National monitoring/evaluation audits
As well as local self-audits that will support local implementation, it is important to ultimately demonstrate that the national implementation programme was successful, and also, during implementation, to highlight settings or regions where it has not reached full potential and who may need further support or resources to improve practice. The Guideline Development Group consider this monitoring mid-implementation and final evaluation to be a key part of the overall implementation programme, but recognise that this level of audit requires resourcing.

The following national audits are recommended:
• An external audit in a sample of all acute hospitals at years 3 and 5 of guideline implementation, purposively sampled within and across hospital groups. It is proposed that this would be performed by the HSE Quality Assurance and Verification team, using the hospital with the required quality assurance and collation of data into a national report.

Appendix 9 Process for NCEC Guideline



References

1 Global Initiative for Chronic Obstructive Chronic Lung Disease (2020) Global Strategy for the Diagnosis , Management and Prevention of Chronic Obstructive Lung Disease [Internet]. Available from: https://goldcopd.org/gold-reports/

2. HSE End to End COPD Model of Care (2019) https://www.hse.ie/eng/about/who/cspd/ncps/copd/moc/end-to-end-copd-model-of-care-december-2019.pdf

3. European Respiratory Society, European Lung Foundation. ERS - Respiratory health and disease in Europe [Internet]. Available from: https://www.erswhitebook.org/

4. O'Farrell A, DeLaHarpe D, Johnson H, Bennett K. (2011) Trends in COPD Mortality and In-Patient Admissions in Men and Women: Evidence of Convergence IMJ. 104(8):245–8.

5 Institute of Public Health (2012)Chronic Airflow Obstruction Briefing [Internet]. Available from: http://chronicconditions.publichealthwell.ie/chronic-airflow-obstruction

6. Lung Foundation Australia. COPD: The statistics | Lung Foundation Australia [Internet]. Available from: https://lungfoundation.com.au/health-professionals/clinical-resources/copd/copd-the-statistics/

7. Lomas D, Philips R, Patel B. (2005) The importance of genes in COPD.

8. Pascual, T, Roca J.(2008) Chronic Obstructive Pulmonary Disease. Timely Topics in Medicine Prous Science.

9. Lundbeck B, Lindberg, A, Lindstrom M.(2003) Not 15 but 50% of smokers develop COPD? Report from the Obstructive Lung Disease in Northern Sweden Studies. Respiratory Medicine 97:115–22.

10. Rennard S, Vestbo J. (2006) COPD: the dangerous underestimate of 15%. Lancet 367:1216–9.

11. Manino D, Watt G, Hole D. (2006) The natural history of chronic obstructive pulmonary disease. European Respiratory Journal [Internet]. 27: 627–43. Available from: http://erj.ersjournals.com/content/erj/27/3/627.full.pdf

12. Smith CA, Harrison DJ. (1997) Association between polymorphism in gene for microsomal epoxide hydrolase and susceptibility to emphysema. The Lancet [Internet].Aug;350(9078):630–3. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0140673696080610

13. Yin P, Jiang C, Cheng K, Lam T, Lam K, Miller M, et al. (2007) Passive smoking exposure and risk of COPD among adults in China: the Guangzhou Biobank Cohort Study. The Lancet [Internet]. Sep; 370(9589):751–7. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0140673607613786

14. Menezes AM, Hallal PC. (2007) Role of passive smoking on COPD risk in non-smokers Ana M B Menezes, Pedro C Hallal. The Lancet. 370.

15. Ipsos MRBI. (2015)Healthy Ireland Survey. Department of Health.

16. Korn B, Horan L. Respiratory health status of homeless men in a Dublin City Centre Homeless shelter. (2007) Irish Thoracic Society Annual Scientific Meeting.

17. Carroll TP, O'Connor CA, Floyd O, McPartlin J, Kelleher DP. (2011) The prevalence of alpha-1 antitrypsin deficiency in Ireland. 10.

18. Soriano JB, Davis KJ, Coleman B, Visick G, Mannino D, Pride NB. (2003)The Proportional Venn Diagram of Obstructive Lung Disease*: Two Approximations From the United States and the United Kingdom. Chest [Internet]. [cited 2018 Apr 17]; 124(2):474–81. Available from: http://www.sciencedirect.com/science/article/pii/S0012369215333274

19. Rijcken B, Schouten JP, Xu X, Rosner B, Weiss ST. (1995) Airway hyperresponsiveness to histamine associated with accelerated decline in FEV1. American Journal of Respiratory and Critical Care Medicine [Internet]. 151(5):1377–82. Available from: http://www.atsjournals.org/doi/abs/10.1164/ajrccm.151.5.7735588

20. Lopez A, Mathers C, Ezzati, M, Jamison D, Murray C. Global Burden of Disease and Risk Factors [Internet]. Washington (DC0: The International Bank for Reconstruction and Development / The World Bank; Available from: https://www.ncbi.nlm.nih.gov/books/NBK11812

21. Clancy L, Goodman P, Sinclair H, Dockery DW. (2002)Effect of air-pollution control on death rates in Dublin, Ireland: an intervention study. The Lancet [Internet].360(9341):1210–4. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0140673602112815

22. Hnizdo E. (2002) Association between Chronic Obstructive Pulmonary Disease and Employment by Industry and Occupation in the US Population: A Study of Data from the Third National Health and Nutrition Examination Survey. American Journal of Epidemiology [Internet]. Oct 15;156(8):738–46. Available from: https://academic.oup.com/aje/article-lookup/doi/10.1093/aje/kwf105

23. Personal Communication from CSO. 2017.

24. Brennan N, McCormack S, O'Connor T.(2008) Ireland Needs Healthier Airways and Lungs - the Evidence (INHALE) 2nd Edition. Irish Thoracic Society;

25. Lozano R, Naghavi M, Foreman K, Lim S, Shibuya K, Aboyans V, et al. (2012)Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010. The Lancet [Internet]. 380(9859):2095–128. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0140673612617280

26. Department of Health. (2016)Health in Ireland. Key Trends.

27. Crinion K, Cotter O, Kennedy B, O'Connor B, Curran B, et al. (2013) COPD exacerbations: a comparison of Irish data with European data from the ERS COPD audit. IMJ. 106: 268–72.

28. Collins K. (1986)Low indoor temperatures and morbidity in the elderly. Age and Ageing. 15:212–20.

29. Balanda KP, Wilde J, (2001) Institute of Public Health in Ireland. Inequalities in mortality: 1989-1998 : a report on all-Ireland mortality data. Dublin: Institute of Public Health in Ireland; .

30. Hurley E. (2018) Trends in hospitalisations for Chronic Obstructive Pulmonary Disease (COPD), 2009-2017, Report prepared for the COPD National Clinical Programme. Dublin. Dublin:

31. British Lung Foundation(2016) The Battle for Breath - the impact of lung disease in the UK

32. Hurley, E. (2018) An analysis of medication use for respiratory disease amongst those with GMS eligibility (2015 - 2016) - a focus on Chronic Obstructive Pulmonary Disease (COPD). Report prepared for the COPD National Clinical Programme.

33. pcrs-annual-report-20161.pdf [Internet]. [Cited 2018 May 14]. Available from: https://www.hse.ie/eng/staff/pcrs/pcrs-publications/pcrs-annual-report-20161.pdf

34. Department of Health.(2017 & 2019) National Healthcare Quality Reporting system. Annual reports 2017 & 2019.

Annex

Wuytack F, Devane D, Conway A, McDonnell MJ, McDonnell T, McCarthy B (2016). Guidelines for the management of Chronic Obstructive Pulmonary Disease (COPD), a systematic search, screening and quality assessment, as part of the ADAPTE process. National Clinical Effectiveness Committee, Department of Health: Dublin

Wuytack F, Devane D, Stovold E, McDonnell MJ, Casey M, McDonnell TJ, Gillespie P, Raymakers A, Lacasse Y, McCarthy B (2016). The setting of pulmonary rehabilitation for Chronic Obstructive Pulmonary Disease (COPD), a systematic review. National Clinical Effectiveness Committee, Department of Health: Dublin