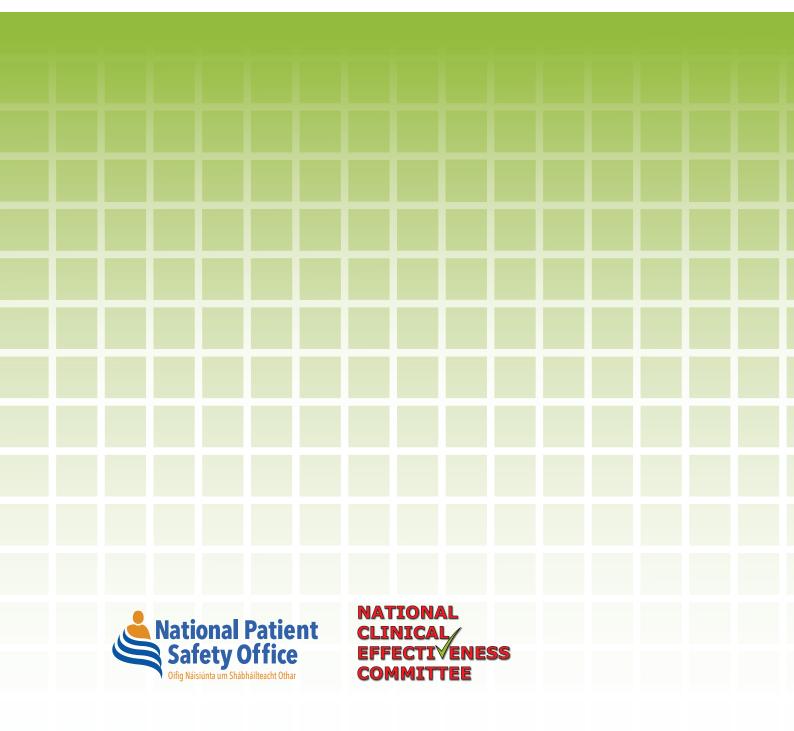


# Management of Chronic Obstructive Pulmonary Disease (COPD)

National Clinical Guideline No. 27

November 2021





This National Clinical Guideline has been developed by the Guideline Development Group (GDG) 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 and is relevant to all healthcare professionals caring for people with this condition.

#### 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 by checking the relevant section in the National Patient Safety Office on the Department of Health website: <a href="https://www.gov.ie/en/collection/c9fa9a-national-clinical-guidelines/">https://www.gov.ie/en/collection/c9fa9a-national-clinical-guidelines/</a>

Whilst every care has been taken to ensure that all information contained in this publication is correct, the Department of Health cannot accept responsibility for any errors or omissions which may have occurred.

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#### 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 the Clinical Leads of the National Clinical Programme (NCP) for Respiratory. This National Clinical Guideline is supported by the GDG NCP for Respiratory, the Integrated Care Programme for Chronic Disease, Irish College of General Practitioners (ICGP), the Irish Thoracic Society (ITS), and the 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 for their involvement or contribution to the GDG and were informed that it was on a voluntary basis.

 Table 1: Members of the COPD Guideline Development Group

Name	Job title and affiliation
Dr Desmond Murphy (Chair 2020 to date) Prof. Tim McDonnell (Chair 2014-2019)	Clinical Lead, NCP for Respiratory, HSE
Dr Mark O Kelly	ICGP HSE Primary Care Lead for Integrated Care Programme (COPD)
Mr Michael Drohan	Patient Representative
Ms Rosie Hassett (2018-2020) Ms Patricia Davis (2020- 2021)	Interim Nurse Service Planner, NCP for COPD/Respiratory
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Ms Maureen O'Callaghan (2017) Ms Anne Lanigan Ms Siobhan Healy (Oct 2020- 2021)	Joint Therapy Leads (Physiotherapy), NCP for Respiratory HSCP Lead
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Mr Peter O'Toole	Advanced Nurse Practitioner, representative NCP
Mr Damien Peelo (2013-2017) Ms Bernie Murphy (2017-2018) Ms Joan Johnston (2020 to date)	CEO of COPD Support Ireland (Patient Representative group) CEO of COPD Support Ireland (Patient Representative group) National Coordinator, COPD Support Ireland
Ms Edel Russell (2019)	Dietetic Representative, NCP for Respiratory
Ms Suzanne Seery (2016-2017)	Dietetic Representative, NCP 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 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 have given of their time on a voluntary basis.

#### Acknowledgments

The Chair of the GDG, Dr Desmond Murphy wishes to acknowledge the COPD GDG 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 Ms Rebecca Decker for their assistance and contributions. Mr 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, Dr Mark O' Kelly, Ms Linda Kearns and Ms 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 Professor Fernando Martinez are acknowledged. A full list of members of the GDG is available in the previous page/s.

Signed by the Chairs:

Des Murphy

Date: \_16/03/21\_\_\_\_\_

#### **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 allow delivery of 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 an expectation 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 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 provide quality assurance for 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.

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See Appendix 5 for evidence grading systems used. See Appendix 12 for Glossary of Terms and abbreviations.

# **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 (HCPs) expertise or experience but is a tool to assist the practitioner in their clinical decision-making process with consideration to their patients' preferences. COPD is a complex disease that requires the input of multiple care providers.

As recognised in Sláintecare, the 10-year cross political vision for the future of Irish healthcare services, improvement and sustainability of Irish healthcare is dependent on a shift from acute to primary care. In line with Sláintecare and the End-to-End COPD Model of Care (2019) from the NCP Respiratory, the GDG recommend that although each recommendation is considered separately in this document, as a model for COPD we advocate for a wide spectrum of care across integrated respiratory services.

This will be achieved by increasing integration and collaboration between acute hospitals, community services and General Practitioners (GP) thereby enabling patient care delivery closer to home.

The responsibility for implementation of this guideline rests with relevant Consultants, GPs, nurses, physiotherapists, pharmacists, and other HCPs.

To assist the reader of this guideline, details of the key to the grading of evidence and recommendations are in Appendix 5.

Pharmacological Management of COPD		
Recommendation		Grade of recommendation
<b>Recommendation 1</b> Short-acting bronchodilators	<b>1.1</b> Inhaled short-acting beta 2 agonists (SABAs) or short-acting anti-muscarinic (SAMAs) should be prescribed to patients with confirmed COPD where rescue therapy is needed.	Grade A (GOLD)
<b>Recommendation 2</b> Long-acting bronchodilators	<b>2.1</b> 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)
	<b>2.2</b> Inhaled long-acting muscarinic antagonists (LAMAs) and long-acting beta agonists (LABAs) both significantly improve lung function, breathlessness and reduce exacerbations.	Grade A (GOLD)
	<b>2.3</b> LAMAs have a greater impact on exacerbation frequency compared to LABAs.	Grade A (GOLD)
	<b>2.4</b> LABA/LAMA combination therapy has a more profound impact on forced expiratory volume in one second (FEV1) and symptoms than monotherapy.	Grade A (GOLD)
	<b>2.5</b> LAMA/LABA in combination has a greater impact on exacerbation frequency than monotherapy.	Grade A (GOLD)
Recommendation 3 Inhaled corticosteroids	<b>3.1</b> Offering an inhaled corticosteroid (ICS) to patients with confirmed stable COPD as first line therapy is not routinely recommended.	Grade A (Department of Veteran Affairs) (Implied in GOLD)
	<b>3.2</b> Regular treatment with ICS increases the risk of pneumonia especially in those with severe disease and should be considered before considering addition of ICS in such patients.	Grade B (GOLD)
	<b>3.3</b> ICS should however be considered in patients with Asthma-COPD Overlap Syndrome (ACOS).	Expert Opinion (GDG)
	<b>3.4</b> Stable state blood eosinophil levels may be used to influence whether or not ICS should be used. Patients with blood eosinophils less than 0.1 x10 <sup>9</sup> are deemed unlikely to benefit while those with levels greater than 0.3x10 <sup>9</sup> are most likely to benefit.	Grade B (GOLD)

	<ul> <li><b>3.5</b> An ICS combined with a LABA is more effective than the individual components in improving function and health status and reducing exacerbations in patients with exacerbations and moderate to very severe COPD.</li> <li><b>3.6</b> Triple inhaled therapy with ICS/LAMA/LABA improves lung function sumptoms and health</li> </ul>	Grade A (GOLD) Grade A (GOLD)
	improves lung function, symptoms and health status and reduces exacerbations compared to ICS/LABA, LAMA/LABA or LAMA monotherapy.	
Recommendation 4 Inhaler technique	<b>4.1</b> 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 with re-education 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 (GDG) (GOLD)
<b>Recommendation 5</b> <i>Roflumilast</i>	<b>5.1</b> 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 therapy with a LAMA and LABA and possibly ICS. Roflumilast is not approved for reimbursement under the community drug schemes.	Grade A (GOLD)
Recommendation 6 Theophylline	<b>6.1</b> In certain selected patients, the addition of a theophylline may be reasonable.	Grade B (GOLD)
<b>Recommendation 7</b> Prophylactic use of macrolide antibiotics	<b>7.1</b> In patients who have severe COPD with two treated exacerbations, the addition of azithromycin may be considered for one year.	Grade A (GOLD)
	<b>7.2</b> 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. The potential for benefit may be less in active smokers. The use of azithromycin in this manner represents an off-label use of this medicine but is recommended in many guidelines. When considering treatment, patients should be otherwise on optimal therapy.	Expert Opinion (GDG)

<b>Recommendation 8</b> Antioxidants and mucolytics	<b>8.1</b> The use of mucolytic and antioxidants in routine practice for management of patients with COPD is <b>not recommended</b> .	There are currently insufficient studies to recommend use in COPD
<b>Recommendation 9</b> <i>Leukotriene antagonists</i>	<b>9.1</b> A role for leukotriene receptor antagonists in the management of patients with COPD is <b>not recommended</b> .	Expert Opinion (GDG)
<b>Recommendation 10</b> <i>Alpha One Anti-trypsin Deficiency</i> <i>(AATD) Augmentation Therapy</i>	<ul> <li>10.1 It is recommended that AATD augmentation therapy might be considered in young patients who have not smoked or are ex-smokers with an FEV1 of 35-60% predicted with continued and progressive disease.</li> <li>The National Centre for Pharmacoeconomics did not recommend reimbursement of AATD augmentation therapy in an Irish context following completion of a pharmacoeconomic evaluation, as cost-effectiveness was not demonstrated.</li> </ul>	Grade B (GOLD)
Non-Pharmacological Managemer	nt of COPD	
<b>Recommendation 11</b> Smoking cessation	<ul><li><b>11.1</b> Smoking cessation measures are recommended for the prevention, delay, and management of COPD, to include advice on smoking cessation, nicotine replacement therapy (NRT) and pharmacotherapy.</li><li>At the moment, the effectiveness and safety of E cigarettes as a smoking cessation aid remains uncertain.</li></ul>	Grade A (GOLD)
Recommendation 12 Influenza vaccination	<b>12.1</b> The provision of an annual influenza vaccination is recommended.	Grade A (GOLD)
Recommendation 13 Pneumococcal vaccination	<b>13.1</b> The provision of the pneumococcal vaccination is recommended.	Grade B (GOLD)
<b>Recommendation 14</b> Pulmonary rehabilitation	<b>14.1</b> The provision of pulmonary rehabilitation to stable patients with exercise limitation despite pharmacological treatment is recommended.	Grade A (GOLD)
	<b>14.2</b> The provision of pulmonary rehabilitation to patients who have recently been hospitalised for an acute exacerbation of COPD is recommended.	Grade B (GOLD)

<b>Recommendation 15</b> <i>Oxygen therapy provision</i>	<ul> <li>15.1 The provision of long-term oxygen therapy to patients with chronic stable hypoxemia with a PaO<sub>2</sub> less than 7.3kPa or a PaO<sub>2</sub> between 7.3 and 8kPa with signs of tissue hypoxia (haematocrit greater than 55%, pulmonary hypertension or cor pulmonale) is recommended.</li> <li>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.</li> </ul>	Grade A (GOLD) Grade A (GOLD)
<b>Recommendation 16</b> Nutrition support	<b>16.1</b> Nutrition support should be considered in all malnourished patients with COPD.	Grade B (GOLD)
<b>Recommendation 17</b> <i>Lung volume reduction</i>	<b>17.1</b> Lung volume reduction surgery is recommended for carefully selected patients with upper lobe emphysema and low post rehabilitation exercise capacity.	Grade A (GOLD)
	<b>17.2</b> In selected patients, bullectomy can also be recommended.	Grade C (GOLD)
	<b>17.3</b> 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. Endobronchial valves (Grade A); Lung coils (Grade B); Vapour ablation (Grade B).	Grade A/B (GOLD)
<b>Recommendation 18</b> Lung transplantation	<b>18.1</b> It is recommended that appropriately selected patients with very severe COPD be considered for lung transplantation surgery.	Grade C (GOLD)
<b>Recommendation 19</b> <i>Monitoring of spirometry</i>	<b>19.1</b> In stable, diagnosed COPD patients, FEV1 may be tracked by spirometry every two years.	Expert Opinion (GDG)
Recommendation 20 Role of palliative care	<b>20.1</b> For advanced COPD care, patients should be referred to a palliative care specialist as appropriate.	Expert Opinion (GDG)
Management of Exacerbations in	COPD	
<b>Recommendation 21</b> Bronchodilator therapy	<b>21.1</b> The initiation of short-acting acute bronchodilator therapy (salbutamol, ipratropium, or combination) is recommended for patients with an exacerbation of COPD.	Grade C (GOLD)

<b>Recommendation 22</b> <i>Steroids</i>	<b>22.1</b> A course of systemic steroids (prednisolone recommended dose of 40mgs once daily 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)
Recommendation 23 Antibiotics	<b>23.1</b> Oral antibiotics use for patients with exacerbations of COPD associated with increased dyspnoea and associated increased sputum purulence 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 are recommended. However, the choice of antibiotics may be modified due to local bacterial resistance patterns or an individual's sputum microbiology.	Grade B (GOLD/Expert Opinion GDG)
<b>Recommendation 24</b> <i>Non-invasive ventilation (NIV)</i>	<b>24.1</b> 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 <sub>2</sub> greater than 6kPa and an arterial pH less than 7.35, which is persistent following rationalisation of delivered oxygen therapy.	Grade A (GOLD)
<b>Recommendation 25</b> COPD Outreach Service	<b>25.1</b> The COPD outreach team should be involved as early as possible in the care of patients admitted to hospital with an exacerbation of COPD.	Expert Opinion (GDG)
<b>Recommendation 26</b> COPD care should be delivered by a multidisciplinary team	<b>26.1</b> It is recommended that a multidisciplinary team of respiratory specialists are key to delivering integrated care for COPD.	Expert Opinion (GDG)
Recommendation 27 Theophylline	<b>27.1</b> The use of theophylline in acute exacerbations of COPD is <b>not recommended</b> .	Grade B (GOLD)

Oxygen therapy prescribing and monitoring in COPD		
<b>Recommendation 28</b> Oxygen therapy prescribing and monitoring in COPD	<b>28.1</b> For acutely unwell patients with COPD who are hypoxic and potentially at risk for hypercapnia a target saturation range (SpO <sub>2</sub> ) of 88-92% is suggested pending arterial blood gas (ABG) results.	Expert Opinion (GDG)
	<b>28.2</b> Patients discharged home following hospitalisation on oxygen therapy should be evaluated for the need to remain on long term oxygen therapy (LTOT) 60-90 days after discharge and during a period of relative clinical stability. LTOT should not be continued if patients do not meet the criteria.	Expert Opinion (GDG)
	<b>28.3</b> Routinely offering ambulatory LTOT for patients with chronic, stable COPD and isolated exercise-induced hypoxemia is <b>not recommended</b> .	Grade A (GOLD)
	<b>28.4</b> Patients with stable COPD, with persistent evidence of hypoxaemia (i.e. SpO <sub>2</sub> ≤92%) should be assessed for LTOT	Expert Opinion (GDG)
	<b>28.5</b> The provision of long-term oxygen therapy to patients with chronic stable hypoxemia with a $PaO_2$ less than 7.3 kPa or a $PaO_2$ between 7.3 and 8kPa with signs of tissue hypoxia (haematocrit greater than 55%, pulmonary hypertension or cor pulmonale) is recommended.	Grade A (GOLD)
	<b>28.6</b> 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)
Pathways, Bundles and Checklists for Managing Acute Exacerbation of COPD		
<b>Recommendation 29</b> Pathways, bundles, and checklists for managing acute exacerbation of COPD	<b>29.1</b> It is recommended that an admission and discharge bundle be applied to all patients admitted to hospital with an exacerbation of COPD.	Expert Opinion (GDG)

# **1.2** Summary of Good Practice Points

Table 2: Summary of good practice points from recommendations

Recommendation 4: Inhaler technique	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. Technique and adherence should be checked at every clinical appointment for their COPD.
Recommendation 11: Smoking cessation	The determination of smoking status, delivery of a brief intervention, prescription for stop smoking medications and referral to intensive stop smoking support services should be considered standard for the prevention and treatment/management of COPD.
	• Smoking status should be recorded and treatment with NRT/stop smoking medication as well as referral to intensive stop smoking services should be offered on hospital admission as well as on discharge with supporting clinical forms and documentation amended to include this.
	<ul> <li>Intensive stop smoking services should be included in both the prevention and treatment/management of COPD including consideration of referral to HSE QUIT services.</li> </ul>
	• Promotion of the local stop smoking services and the National Quit line to include potential referral/self- referral if agreeable, and include advice/education on the benefits of quitting for COPD.
	• All patients with tobacco dependence should be given brief smoking cessation advice by a suitably trained healthcare professional at every intervention.
	• Staff should be trained in brief intervention techniques as such as the 5 A strategy to aid those with tobacco dependence: Ask, Advise, Assess, Assist and Arrange and Making Every Contact Count (MECC) training.
Recommendation 12: Influenza vaccination Recommendation 13:	When offering or recommending vaccinations staff should illustrate benefits, potential side effects and provide HSE patient information leaflets on influenza and pneumonia vaccinations.
Pneumococcal vaccination	• If a patient is recommended to have vaccinations by specialist staff this should be documented in correspondence to their GP.
Recommendation 14: Pulmonary rehabilitation	<ul> <li>All appropriate patients should be offered referral to a Pulmonary Rehabilitation Programme.</li> </ul>
	• Self-management education is key in supporting patients with COPD to give them the skills, knowledge, and confidence to manage their condition.
	<ul> <li>Healthcare professionals should provide education on COPD, medication management, self-management and life-style changes.</li> </ul>
	Teams should be multi-disciplinary.

Recommendation 15: Oxygen therapy provision	Patients who require an assessment for oxygen therapy should be referred to an oxygen assessment and review 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).
	• Risk assessments should be performed before prescribing oxygen.
Recommendation 16: Nutrition support	Malnutrition screening should be carried out by trained healthcare staff, across all settings, using a validated screening tool.
	• Attention should be paid to changes in weight in older adults, particularly if the change is more than 3kg. Malnutrition screening should follow.
	<ul> <li>Individuals identified as being at risk of malnutrition, and/or obesity, should be considered for referral for a nutrition assessment – see local referral criteria. (Note: Obesity and malnutrition can co-present).</li> </ul>
	• Those with muscle wastage (sarcopenia) should be considered for referral to a dietitian for nutritional assessment along with exercise prescription.
	• Nutrition support should be considered in people with, or at high risk of, malnutrition and COPD.
	• Referral to Speech and Language Therapy (SLT) should be considered in patients with swallowing difficulties and/or in patients with evidence of recurrent aspiration-related infections, to determine if silent aspiration may be a contributing factor to a patient's symptoms.
Recommendation 19: Monitoring of spirometry	It is recommended that staff conducting spirometry should have undertaken a recognised training programme and relevant updates to ensure quality assured spirometry.
	• Ensuring accurate diagnosis is fundamental to the effective implementation of guidelines. It is reliant on the clinical history and confirmation of airflow obstruction by spirometry.
	• Quality assured spirometry should be provided with the ability for results to be accessed routinely from both primary and secondary care.

Recommendation 20: Role of Palliative Care	Patients experiencing refractory cough or breathlessness having been provided optimal treatment should be considered for referral to palliative care for symptom management.		
	Aspects of non- specialist palliative care to consider early in the disease include the following:		
	• Symptom management, including targeting dyspnoea, pain, fatigue		
	<ul> <li>Responding to anxiety and depression that is prevalent with the disease.</li> </ul>		
	<ul> <li>Assisting in understanding the disease trajectory and advice and support relating to advanced planning.</li> </ul>		
	• Consider the use of a handheld fan and low-dose oral morphine for the management of breathlessness in the end-stage COPD patient.		
	Triggers for referral to specialist palliative care services include the following:		
	• FEV1 less than 30%.		
	<ul> <li>Increased hospitalisations (greater than 3 in the last year) with advanced age or multiple co-morbidities.</li> </ul>		
	Poor functional status.		
	Patients on long-term oxygen therapy.		
	• mMRC grade 4.		
	• Breathlessness at rest or on minimal exertion between exacerbations.		
	Signs and symptoms of right heart failure.		
	• More than six weeks of systemic steroids for COPD in the preceding six months.		
	• Careful sensitive explanation as to the nature of the referral needs to be had with patients prior to referral.		
	<ul> <li>Referral to SLT for discussions regarding the patient's preferences in relation to eating and drinking, in particular patients may choose to eat and drink accepting risk of aspiration for quality of life purposes. SLTs can provide recommendations regarding comfortable consistencies. SLTs may assist in providing communication support for clients at the End of Life stage to promote quality of life.</li> </ul>		
Recommendation 25: COPD Outreach service	All patients who fit the criteria should be referred to a COPD outreach service.		
Recommendation 26: COPD care should be delivered by a multidisciplinary team	Physicians, specialist physiotherapists and nurses should be involved as appropriate in a patients care to promote integrated services across hospital and community settings in providing specialist support, advice and education.		
······	<ul> <li>Referrals to other MDT members are made on an individual case by case basis.</li> </ul>		

Recommendation 28: Oxygen therapy prescribing and monitoring in COPD	<ul> <li>Once oxygen is commenced in the hospitalised patient close monitoring of blood gases is required to ensure satisfactory oxygenation without carbon dioxide retention and/or worsening acidosis.</li> <li>A requirement to increase supplemental oxygen delivery to maintain a patient's targeted SpO<sub>2</sub> may be a sign of acute clinical deterioration which requires immediate medical review.</li> </ul>			
	• Oxygen therapy in the hospitalised patient with COPD;			
	The Irish National Early Warning System (INEWS) is a monitoring/scoring system used in all Irish acute hospitals to assist in the recognition and management of the acutely unwell non-pregnant adult ( $\geq$ 16 years) inpatient. One of the limitations of this system is in patients with COPD and hypercarbic respiratory failure. INEWS allocates a score of between 0 (least risk) and 3 (highest risk) to each of seven physiological parameters including respiratory rate, supplemental oxygen and oxygen saturation (SpO <sub>2</sub> ). A score of '3' (highest risk) is allocated for any supplemental oxygen. INEWS also captures but does not allocate a score to the mode of oxygen delivery (i.e. nasal cannula, facemask etc.). Furthermore, a requirement to increase supplemental oxygen delivery to maintain a patient's targeted SpO <sub>2</sub> is a sign of acute clinical deterioration which requires immediate medical review. This increasing oxygen requirement is not captured in INEWS (a score of 3 is given for ANY oxygen) thus this further patient deterioration may not be reflected in the patient's INEWS score. INEWS V2 has been published in 2021 and recognises that patients with a confirmed diagnosis of COPD or other chronic respiratory conditions often have a tolerance for lower baseline SpO <sub>2</sub> levels and in most COPD patients the target saturations should be lower. This lower baseline SpO <sub>2</sub> combined with a score of 3 for supplemental oxygen can cause unnecessary triggering of the INEWS system in ill but otherwise stable patients. INEWS V2 addresses this problem through the use (at the discretion of a Registrar or Consultant) of a Modified Escalation and Response Protocol. For further information please refer to the full NCEC NCG No. 1 INEWS V2 (57).			
	Long Term Oxygen Therapy			
	• 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 AOT.			

Recommendation 29: Pathways, Bundles, and checklists for managing acute exacerbation of COPD	A COPD admission and discharge bundle should be initiated on patients admitted with exacerbations of COPD upon arrival in the Emergency Department or Acute Medical Assessment Unit. For further information and resources see "End to End COPD Model of Care 2019 " and following link . https://www.hse.ie/eng/about/who/cspd/ncps/copd/resources/copd- discharge-bundle-nccp-2018.pdf	
	https://www.hse.ie/eng/services/publications/clinical-strategy-and- programmes/copd-acute-management-bundle.pdf	
	Recording of smoking status and treatment with NRT/stop smoking medications and referral to intensive stop smoking services should be considered at admission.	
	On the discharge bundle, in addition to consideration of referral to stop smoking services, where NRT/stop smoking medications were administered during hospital admission, a prescription for NRT/stop smoking medications should be provided if the patient is amenable to same.	
	Given the high risk of medication errors at the points of admission to and discharge from secondary care, pharmacy input at these stages of the patient pathway is recommended to minimise the risk of medication errors, provide additional patient education, and help optimise outcomes for patients.	

# 2 Development of this National Clinical Guideline

#### 2.1 Background

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) defines Chronic Obstructive Pulmonary Disease (COPD) as: "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".(2)

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.(3)

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 in Ireland. It has a profound effect on patients but also has a significant strain on the health service. (1)

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 census, 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. (4) 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. (2)

Many with COPD may be undiagnosed, especially those with milder disease, but when diagnosed at a late stage, COPD health interventions are both less effective and more expensive. All studies show an increase in COPD prevalence with increasing age; in people aged greater than 70 years, the prevalence may be 20% in men and 15% in women. (5) 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 used standardised survey methods and a spirometric criterion for COPD, reported a prevalence of moderate – severe COPD (i.e., excluding mild disease) in Europe of 10%. (5)

Given the mortality and relatively high rate of hospitalisation 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. (6) It is estimated that the population aged greater than 35 years in Ireland could increase by 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. (7) 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. (1, 8-10)

#### Management of Chronic Obstructive Pulmonary Disease (COPD)

#### Table 3: Risk factors for COPD

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

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

#### Footnote:

\*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.

#### 2.1.1 Smoking and COPD

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). (11-13) Up to 50% of lifelong smokers develop COPD. Genetic and other factors modify an individual's risk from smoking. (14) 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 (greater than 40hr/ week for greater than 5 years) are 48% more likely to present with COPD than are unexposed individuals. (15, 16)

The results of the Healthy Ireland survey published in 2019 found that 17% of the population (aged 15 and over) smoke on a daily basis, this has reduced from 23% in 2015. (17) Of this, 14% admitted to smoking daily, while a further 3% identified themselves as occasional smokers (this 17% represented 19% of the male and 16% of the female population, respectively). Smoking rates were highest among young adults (25 years). Twenty-eight percent of the population were ex-smokers. Smoking rates were higher in more deprived areas (24%) than in more affluent areas (14%). Smoking rates were also higher in the unemployed (40%) and in those without a third level education (20%), than they were for those in employment (18%) and in those with degree level education (11%). Nineteen percent of parents of children aged under 18 were smokers. Twenty-one percent of fathers and 17% of mothers were smokers. Forty percent of current smokers had tried to quit during the previous year, and 28% were either trying to quit or actively planning to do so.

#### 2.1.2 E-cigarettes

Five percent of the population use e-cigarettes and a further 12% have tried them at some point. Ten percent of current smokers use e-cigarettes, with 13% of ex-smokers using them. Twenty-five percent of those aged between 25 and 34 years of age have tried e-cigarettes, with 8% currently using them. Twenty percent of men have tried e-cigarettes compared to 14% of women. Five percent of men and 3% of women currently use them. Given that the effects of cigarettes on COPD development can have a lag period of 15-20 years; these rates may have significant health implications for the medium and long term.

#### 2.1.3 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, 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%. (18) 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.

#### 2.1.4 Other Contributing Factors

A serious, but often underappreciated risk factor for COPD is lack of awareness of the condition 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  $\alpha$ 1-Antitrypsin Deficiency. The incidence of severe (ZZ homozygotes)  $\alpha$ 1-Antitrypsin Deficiency in the Irish population is estimated to be 1 in 2,100. (19)

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. (20, 21)

The World Health Organization (WHO) estimates that urban air pollution causes 1% of COPD cases in high-income countries such as Ireland. (22) 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. (23) 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%. (24) While the current understanding of risk factors for COPD is incomplete, it is sufficient for action to be taken.

#### 2.1.5 COPD & COVID-19

The first case of coronavirus recorded in the Republic of Ireland was on 29th February 2020; with the first death from COVID-19 occurring on 11th March 2020. (25) Although a new virus, knowledge is accumulating rapidly about the characteristics of the virus, the course of the illness, the manner of transmission and the management of those who acquire the infection. It has been clear from early on that patients with chronic respiratory illness, including COPD are more susceptible to the effects of the virus.

The respiratory symptoms associated with COVID-19 are similar to those experienced by patients with COPD, including shortness of breath and cough. There is likely to be some overlap between the symptoms, however the main symptom which appears to differentiate usual COPD exacerbations from COVID-19 is the presence of a "new" fever. Fever is the most common of any symptom in confirmed cases of COVID-19. (26)

Where possible the clinical management of the patient will aim to facilitate and support their care at home and in the community. This will be led by the patient's GP and public health policy, including prompt implementation of recommended infection prevention and control measures and supportive management of complications. COPD patients should continue all current treatments to improve their overall level of disease control, thereby reducing the risk of exacerbation.

Chronic respiratory diseases such as COPD are possible factors associated with an increased risk for severe disease. In severe cases, COVID-19 may lead to respiratory failure. Patients with this level of disease will clearly require hospital-based management. Guidelines and pathways have been completed to support care in this cohort of patients.

The focus of the NCP Respiratory has been on restoring services in both the acute and community settings as quickly as possible but within infection control guidelines. This has included the potential redesign of services where possible and providing sustainable changes to minimise the impact on respiratory services going forward.

COVID-19 has accelerated the need for integrated respiratory services to continue the treatment of respiratory patients including both COPD and COVID-19 patients. The NCP Respiratory is building on current momentum with practical strategies to actively restructure and redesign respiratory services preparing for a long-term commitment for integrated community-based teams to meet patient's needs. There is a need to enhance and sustain the progress made during the on-going crisis. The scope of this NCEC document has allowed the GDG with the NCP to adapt recommendations where appropriate for COPD patients with COVID-19 .The recommendations still apply and some cases have been expanded to incorporate telehealth such as Virtual Pulmonary Rehabilitation, Virtual Early Supported Discharge/Outreach and escalating the need to provide more community-based services.

# 2.2 Clinical and financial impact of condition/disease

#### 2.2.1 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.(4,16) When death and disability are combined as DALYs, globally COPD ranked 9th in 2010. In the same study, COPD was the 4th highest cause of DALYs in Ireland.

#### 2.2.2 Morbidity

It is difficult to get a measure of the prevalence of the burden of COPD in Ireland and estimates vary widely. In 2015 the Irish Health Survey was conducted by the CSO office. Participants were questioned about their conditions for the 12-month period previous to the survey. Conditions included chronic bronchitis, COPD, or emphysema. (27) The results estimated the prevalence of COPD to be 3% in those aged 45 to 54 years; 7% in those aged 65 to 74 years, and 8% in those aged 75 years and above. The link between socio-economic status and prevalence of COPD is clear; with 2% of those in the 'very affluent' category reporting a diagnosis of COPD (and related), and 6% of those in the 'very disadvantaged' category reporting same.

The majority of people with COPD are managed in General Practice. Hence, GP patient presentation data would provide an excellent guide as to the burden of COPD in Irish society. However, data on the number of COPD consultations in General Practice is not available. It is estimated that approximately 14.5% of all GP consultations are for respiratory disease. (28)

#### 2.2.3 Mortality

The Global Burden of Disease (GBD) study reported COPD as the third leading cause of death globally in 2010. (29) 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.(5) In 2013, the most recent year for which comparable EU data are available, rates of mortality from respiratory diseases (including 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). (30)

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 co-morbidities 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, co-morbidity 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 is also true that 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%. (31)

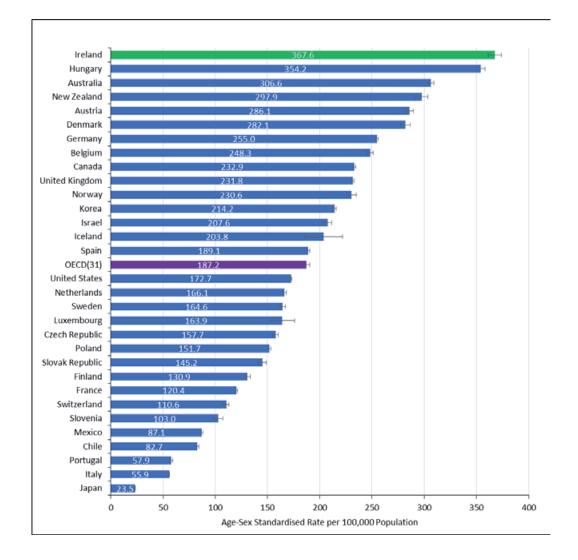
In Ireland, almost 70% of excess winter mortality from respiratory disease arises in the poorest three socioeconomic (SE) groups. (32) An Irish study described mortality in Ireland over a 10-year period. It concluded that respiratory disease was one of the main causes of death with mortality rate in the lowest occupational class 200% higher than the rate in the highest occupational class. (33) More recent data for the period 2007-2012, shows a difference in COPD mortality in the order of 303% in lower SE groups compared with upper SE groups for males aged 15+ years. 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 SE group compared with the higher SE group, implying a much greater mortality for lower SE groups from COPD. (27) Such data show that the greatest burden in terms of COPD mortality is borne by those in the lower SE groups.

# 2.2.4 Burden on health services plus wider economic and social burden of COPD

Associated with the disease burden of COPD outlined in the previous 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.

# 2.2.5 Hospital utilisation

Patients with severe disease may suffer frequent exacerbations requiring medical attendance, potential hospitalisation, and profound negative impact on their quality-of-life. Data for admissions to acute public hospitals serve 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. (30)



**Figure 1:** Age-sex standardised hospitalisation rates for COPD per 100,000 population for selected OECD countries, 2015 (or nearest year). (5)

Ireland has the highest rate of hospitalisation for COPD of all OECD countries (Figure 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 equated to 367 per 100,000 population. The national age-sex standardised hospitalisation rate for COPD increased slightly between 2009 and 2018, with 354 per 100,000 population in 2018 compared with 303 hospitalisations per 100,000 population in 2009 (Figure 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 standardised hospitalisation rate for COPD in 2015. While Ireland's average rate has decreased from 379 hospitalisations per 100,000 population 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 population in Kerry to 552 hospitalisations per 100,000 population in Offaly (Table 4). (4)

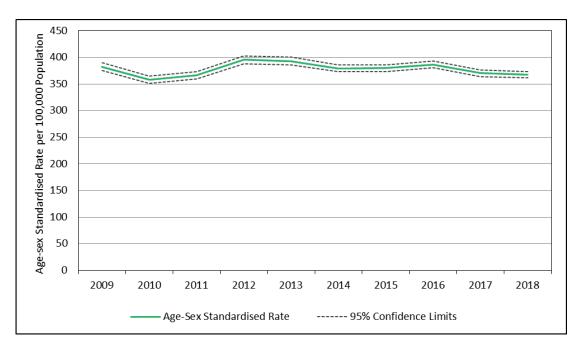


Figure 2: Age-sex standardised hospitalisation rates for COPD per 100,000 population in Ireland, 2009 – 2018. (5)

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 deriving inference from comparisons across the OECD as a whole may be inappropriate. This caveat notwithstanding however, it is difficult to propose differences in coding alone as the explanation as to why hospitalisation rates in Ireland are the highest among all of the countries listed.

The hospitalisation rate figures for episodes of care for patients with a diagnosis of COPD from adult acute public hospitals are shown in Table 5. 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) (Table 5).

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 suggesting 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 Ireland in 2016, again amongst adults aged 35 years and older (see Table 6). Day case activity for COPD was considerably lower: - 1,914 episodes in 2016 across all hospitals reporting to HIPE.

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
Мауо	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 4: COPD Hospital Rates per 100,000 Population by County of Residence, 2016 – 2018.(5)

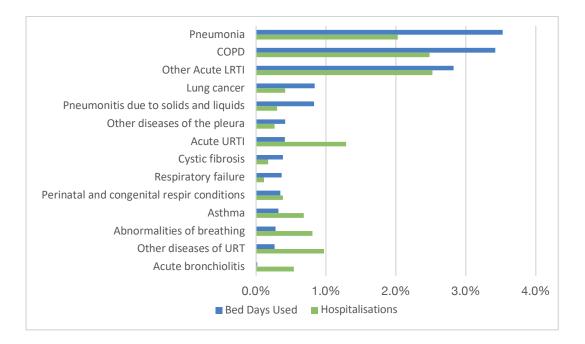
Table 5: In-patient discharges with a primary diagnosis of COPD in adult acute public hospitals, 2009-2017	
(adults aged 35 years and older). (34)	

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)

**Table 6:** In-patient discharges with a primary or secondary diagnosis of COPD in adult acute public hospitals,2009-2017 (adults aged 35 years and older). (34)

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%

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 admissions to Irish hospitals (across all categories and age groups) and 15.8% of bed days used. COPD, pneumonia, and other acute lower respiratory tract infections (LRTIs) (as primary diagnoses) were collectively responsible for 7.0% of in-patient admissions and 9.7% of bed days used in 2016 (Figure 3). (35)



**Figure 3:** Percentage of in-patient hospitalisations and bed days used by respiratory conditions. (Denominator is all in-patient admissions discharged from all hospitals reporting data to HIPE (all ages)). (35)

An analysis of discharges following emergency admission from Irish 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 that these admissions were responsible for 20% of bed days used by all emergency admissions to hospital. COPD, pneumonia, and other acute LRTIs (again as primary diagnoses) were collectively responsible for 10.5% of emergency in-patient admissions and 13.7% of bed days used (Figure 4). (35)

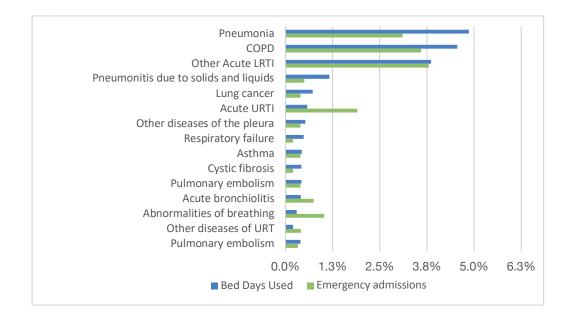
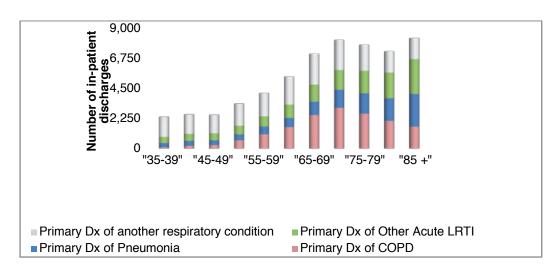


Figure 4: Percentage of emergency admissions and bed days used by respiratory conditions, 2016. (34)

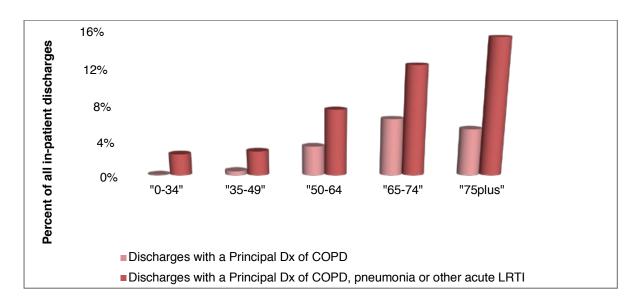
# **2.2.6** Age specific trends in hospitalisation

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) was for episodes with a primary diagnosis of COPD in the 65 to 74-year age bracket, and 5.4% in those aged 75 years and over (Figures 5&6). (35)

When activity is analysed by grouping patients with a primary diagnosis of COPD, pneumonia or other acute LRTI, in a manner commonly utilized for such analysis in the UK, there were over 45,000 in-patient discharges with a primary diagnosis of COPD, pneumonia or other acute LRTI in Ireland in 2016. The number of discharges was again highest in older age groups (Figure 6). (36) 12.5% of all in-patient hospital episodes in those aged 65 to 74 years had a primary diagnosis of COPD, pneumonia or other acute LRTI. This figure rises to 15.4% in those aged 75 years and above (Figure 6). (35)



**Figure 5:** In-patient respiratory discharges, and discharges with a primary diagnosis of COPD, pneumonia or other acute respiratory tract infection (LRTI), 2016. (34)



**Figure 6:** Proportion of in-patient discharges with a primary diagnosis of COPD or a primary diagnosis of COPD/ pneumonia/other acute LRTI 2016. (34)

#### 2.2.7 Spend on pharmaceuticals

In Ireland government reimbursement for respiratory medications is recorded for both General Medical Services (GMS) and Drugs Payment Scheme (DPS). In 2016 in the GMS population this totalled €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 - anticholinergic, and R03AL-adrenergics in combination with anticholinergic) accounted for approximately €67.6 million of the total €113.7 million in the GMS population. (37)

These costs do not include additional drugs such as antibiotics, steroids, LTOT, supply of nebulisers, vaccines etc. or the supply of medication in hospitals. Neither do they account for the out-of-pocket costs to 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 threshold). Hence, it is highly probable that these figures grossly underestimate overall spending on pharmaceuticals for the management of COPD in Ireland.

# 2.3 Rationale for this National Clinical Guideline

This document describes the Model for the NCP 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, physiotherapists and other HCPs will work with patients to make the clinical decisions most appropriate to a patient's circumstances. It is envisaged that this will facilitate self-management by patients at home through their empowerment and by promoting collaboration with and between specialist HCPs in providing optimal care.

#### 2.3.1 Improving outcomes for people with COPD

COPD is a major cause of morbidity and mortality for patients in Ireland. At least 1500 patients die of this disease and over 15,000 patients are admitted to Irish hospitals with COPD every year. It has a profound effect on patients but also represents a significant strain on the health service. Furthermore, across the healthcare service there is considerable variability in the delivery of care for COPD, including variation in length of stay between various hospitals and access to Pulmonary Rehabilitation and COPD Outreach services.

There are many possible explanations as to why issues pertaining to COPD management have not received the attention they merit. There is often confusion about the name of the condition itself, with patients frequently being told that they have asthma or the often-interchangeable use of the terms emphysema, COPD, and chronic bronchitis. The disease generally progresses slowly with the result that symptoms usually appear gradually as opposed to the clinical course of other chronic diseases such as ischaemic heart disease and cerebral vascular disease, which often have a sudden onset. Furthermore, 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 around developing measures to determine 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. It is well recognised that such groups often experience inadequate healthcare provision. In addition, there may be a degree of prejudice in society towards COPD, with the disease frequently regarded as self-inflicted. This may unfortunately discourage patients from seeking appropriate levels of healthcare. This is often not the case in other chronic diseases despite the presence of overlapping lifestyle related risk factors. In fact, 10% of COPD patients have never been smokers and many patients with COPD have stopped smoking many years previously.

The NCP Respiratory wants Irish society to overcome these attitudes and defines in their MOC the best care that should be delivered to patients with COPD. (1)

The MOC takes a holistic, person-centred 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. (38)

The NCP Respiratory proposes to change how we deliver care to people with COPD and support a National Model of Integrated Care. 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 has been written with the intention of providing assistance to HCPs in all healthcare settings when assessing and managing COPD, by outlining evidence-based treatment protocols. In doing so, 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 are to:

- Prevent or delay the onset of COPD;
- Improve the delivery of care to people with COPD across all levels of care; and
- Save the lives of people with COPD.

Through the implementation of the End-to-End COPD MOC, 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.

# 2.4.1 Integrated Model of Care

The MOC for COPD reflects the full spectrum of care and service provided in hospitals and in the community for people with COPD. It is guided by international best practice. The spectrum of services, ranging from primary prevention to tertiary care, within this MOC 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; and
- 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 MOC for COPD (2019). (1) The specific interventions considered are included in Section 3 – please see PIPOH tables. This list is not exhaustive in terms of possible interventions for COPD however does consider the interventions included in the scope of this guideline.

# 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 years. For some questions this also included experiencing an acute exacerbation. Gender was male or female.

The **interventions** included five PIPOHs identified by the GDG. These were:

- Pharmacological management of COPD;
- Non-pharmacological management of COPD;
- Management of an acute exacerbation of COPD;
- Oxygen therapy prescription and monitoring in COPD; and
- Pathways, bundles, and checklists for managing an 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 mortality, decreasing number and severity of exacerbations, hospitalisations, readmissions, morbidity, disease specific quality of life, exercise tolerance and lung function (e.g. FEV1), duration of an exacerbation episode, 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.

The **Healthcare settings** included other stakeholders such as the HSE, Irish hospitals, primary care, and the Department of Health as well as patient advocacy 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 (BIA) 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 (Annex A) and (2) a systematic review of settings for delivery of pulmonary rehabilitation for COPD (Annex B).

# 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 for COPD approached the NCEC wishing to prepare a national clinical guideline. The first step involved assembling a GDG from relevant stakeholders including members of the NCP and other groups. The first meeting of the GDG in 2016 established the scope of the guideline and the overall work plans for 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 an acute exacerbation of COPD (4) Oxygen therapy prescription and monitoring in COPD and (5) Pathways, bundles, and checklists for managing an acute exacerbation of COPD.

The development of the guideline was supported by evidence synthesis teams from NUI Galway and HRB-CICER.

#### 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 began with a scoping search for the review, which was 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 five key health questions during their review of international guidelines. The five "health questions" are presented in Table 7 with the full questions defined using the PIPOH framework in Annex A.

Question 1	What pharmacological interventions LABAs, LAMAs, ICSs, macrolide antibiotics and PDE-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, smoking cessation 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?

#### Table 7: Five health questions formulated during review by NUIG

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 GDG in defining the scope and purpose of the guideline; (2) Conducting a systematic search for existing guidelines; and (3) Performing an assessment of the quality of included guidelines overview. See Annex A.

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 clearing houses 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, as recommended in the ADAPTE manual. (39) The Rigour of Development dimension contains eight items. Guidelines were included only if they met all items 1-6. Specific PIPOHs 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) nonpharmacological management of COPD, (3) the management of acute exacerbations of COPD, (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 costeffectiveness. The full report is presented in Annex C.

In summary, 10 review questions were developed in line with the PICOS framework (Appendix 4). 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 resolved 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 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 Appendix 3. The average percentage score for each domain of the AGREE II tool and the average overall percentage score judgment is also provided. If a procedure to update the guideline was provided, 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 their 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, and 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.

#### Step 4: Developing and grading 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 and included sections on lists of guidelines, tool matrix, search and selection tool, validity, applicability, and tool application for each PIPOH.

The synthesised 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 synthesised. 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 process 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 Appendix 5. 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 was felt 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 6: 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 through a public consultation process.

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 Chief Executive Officers, and General Managers ONMSD and all NMPDUs/CNMEs.
- NCP 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.
- Chief Nursing Officer office, DOH.
- HSE Quality Improvement Division.
- National Quality Assurance and Verification Division.
- HSE Quality and Patient Safety.
- Acute Hospitals Division Office of the Nursing and Midwifery Services.
- Hospital Group Clinical Directors.
- Hospital Groups Chief Director of Nursing and Midwifery.
- 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.
- National Women and Infants Health Programme.
- National Ambulance Service.
- Pre-Hospital Emergency Care Council (PHECC).
- Health Protection Surveillance Centre.
- HSE Microbiology.

## 2.10 External review

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

- 1. Professor Stephen Bourke, Consultant Respiratory Physician for Northumbria Healthcare NHS Foundation Trust, and Honorary Professor of Respiratory Medicine, Newcastle University.
- 2. Professor Fernando J Martinez, Chief of the Division of Pulmonary and Critical Care Medicine at Weill Cornell Medicine in New York City.

Biographical details available in Appendix 1.

Professor Stephen Bourke and Professor Fernando J Martinez are recognised internationally as experts in respiratory medicine and in particular COPD. 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. External reviewers were also asked to provide any additional feedback they felt was relevant. All feedback was reviewed and informed the final revised guideline.

## 2.11 Implementation

A comprehensive implementation plan for this guideline is outlined in Appendix 7. Each hospital's senior management team and primary care General Manager in conjunction with the designated local implementation leads should review NCEC NCG No. 27 COPD (2021), 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 the establishment of local governance groups to direct on-going implementation and evaluation of the guidelines. 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 the senior management team and should actively engage with the quality and risk governance structures. Patient representation should be strongly considered on these governance groups, with patient outcomes aligned to the effective management of COPD.

Some of the potential enablers and barriers for implementation of COPD are listed in Table 8. Local issues should be identified, and action plans initiated to manage improvement at a local hospital level. Hospital Groups may consider the use of a QI collaborative style approach.

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

 Table 8: Summary of enablers and barriers to the implementation of recommendations (2021)

Barriers to implementation should be identified and addressed as part of the organisational QI and patient safety agenda. Attention to the enablers listed above and in the implementation plan in Appendix 7 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 HCPs responsible for the care of COPD patients 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 (full BIA report available in Annex D).

#### Senior Manager Responsibilities:

- Agree and provide a local governance structure to support the implementation, on-going audit and evaluation of patient outcomes pertaining to the recommendations of the NCEC NCG No. 27 COPD (2021).
- Assign personnel with delegated responsibility, accountability, authority, and autonomy to implement and evaluate the NCEC NCG No. 27 COPD (2021). Provide documented clear roles and responsibilities for staff.
- Provide managers and clinician leads with support to implement the NCEC NCG No. 27 COPD (2021) 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, evolving evidence and as a result of QI 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 the 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. 27 COPD (2021).

#### **Clinician responsibilities:**

- Ensure familiarity with and compliance with the NCEC NCG No. 27 COPD (2021) and related policies, protocols, and procedures.
- Adhere to the relevant code of professional conduct and scope of professional practice appropriate to the 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. 27 COPD (2021).
- Seek to provide clinical leadership, mentorship of staff and on-going education of the 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. 27 COPD (2021).
- Create and lead engagement with patients, families, and carers to help better inform QI 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. 27 COPD (2021).
- 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. 27 COPD (2021)

- HSE End to End MOC for COPD 2020.
- Implementation guidance is included in detail in Appendix 7.
- Implementation guide for pulmonary rehabilitation.
- Implementation guide for COPD Outreach services.
- Bundles of care.

## 2.12 Monitoring and audit

#### 2.12.1 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 7. 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 involved in the delivery of care to people with COPD. The aim is to ensure awareness, understanding, acceptance and adoption of the guideline, in both acute and community settings, among doctors, nurses, pharmacists, and health and social care professionals. Data will be used for improvement and QI methods to assist in determining effectiveness of implementation of key areas of the guideline.

This needs to be monitored during implementation through a combination of methods, to allow the implementation process to be adapted and tailored according to the needs of certain settings/groups. One example is the recent RCPI COPD collaborative focused on respiratory specialist review, compliance with an admission clinical bundle, use of DECAF for clinical risk stratification and compliance with discharge processes. (40) Among the many benefits observed was a reduction in length of stay (median) by 1.75 days.

The key service outcome for this guideline is a more integrated service with care across the continuum of healthcare delivery settings. The key patient-related outcomes of successful implementation of this guideline are improvements in patient safety, decreased mortality and morbidity (including that associated with inappropriate prescribing of medications) and improvements in 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 27 COPD (2021) recommendations. It is recommended that the audit process is undertaken from a multidisciplinary perspective where feasible and 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.

#### 2.12.2 COPD audit datasets

Datasets currently exist for COPD Outreach and Respiratory Integrated services including Pulmonary Rehabilitation and are submitted to the NCP Respiratory and the Business Intelligence Units.

#### 2.12.3 Smoking cessation

The new patient management system for stop smoking services, QUIT Manager will be launching a new referral module before year end which will facilitate direct referrals into the service from identified key referrers. As per recommendation 11, stop smoking services would be able to report on the number of referrals from COPD services to enable and support the monitoring and audit of this guideline.

#### 2.12.4 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.

#### 2.12.5 Outcome measures

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

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

#### 2.12.6 Education/Training audit

- Audit of COPD education/training and evaluation record. See Appendix 8 for Sample Audit Tool
- Database of staff trained each hospital to make their own local arrangement to best meet their needs.

#### 2.12.7 Key Performance Indicators (KPIs)

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

#### 2.12.8 Audit results

The audit results and reports should be discussed at the appropriate COPD governance group and the findings delivered upwards to the Hospital Clinical Governance Committee/ Hospital Senior Management Team and thereafter to all levels of staff. The hospital's healthcare audit/clinical audit cycle as part of the continuous QI 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 QI initiatives.

#### 2.12.9 Additional databases

National Quality Assurance and Improvement System (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 can be found in Appendix 10.

## 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. 27 (COPD) (2021) will require updating in 2024 by the GDG.

## 3 National Clinical Guideline

## 3.1 Healthcare key questions and evidence statements

## **3.1.1** Pharmacological Interventions for the Management of COPD

HEALTH QUESTION 1: What pharmacological interventions LABAs, LAMAs, ICSs, prophylactic macrolides and PDE-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
<b>INTERVENTIONS</b> (Specify intervention(s) type(s) and characteristics)
Treatments/care
Pharmacological interventions [including LABAs, LAMAs, ICSs, prophylactic macrolides and PDE-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
Department of Health, HSE, hospitals, primary care
Patients
Patients with COPD
OUTCOME (Purpose of the guideline)
Patient outcomes
Mortality, exacerbations, hospitalisations, readmissions, morbidity (disease-specific quality of life, exercise tolerance, lung function e.g. FEV1)
exercise tolerance, fung function e.g. FEV1)
System outcomes
System outcomes
System outcomes Reduce direct and indirect system costs
System outcomes         Reduce direct and indirect system costs         Public health outcomes
System outcomes         Reduce direct and indirect system costs         Public health outcomes         Mortality and morbidity as above

## 3.1.1.1 Evidence statement for Question 1

All studies used to form the basis of the recommendations are available in more detail including their strength and limitations in Annex A and Annex D. In addition to the information in this guideline, the HSE-Medicines Management Programme has previously published Prescribing and Cost Guidance on Inhaled Medicines for COPD. (41)

## Recommendation 1 & 2: Bronchodilators

As indicated the use of SABAs and SAMAs improve FEV1 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 nebuliser, 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 FEV1 and symptoms.

LAMA treatments (e.g. tiotropium) improve symptoms and health status. They also improve the effectiveness of pulmonary rehabilitation and reduce exacerbations and related hospitalisations. 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 the effect of long-acting bronchodilator monotherapy, 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 demonstrated that combination LABA/LAMA decreased exacerbations to a greater extent than an ICS/LABA combination. However, differences in washout periods and the study populations in clinical trials mean that definitively deciding whether to utilise a therapeutic strategy containing ICS or not depends upon the target group and in particular whether or not patients may have ACOS or a raised eosinophil count.

#### **Recommendation 3: Steroids**

*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 (greater than 3 years) safety of 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 in FEV1 or 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.

There is high quality evidence from randomised 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 greater than 55 years, have a history of prior exacerbations or pneumonia, a body mass index (BMI) less than 25 kg/m<sup>2</sup>, 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 eosinophil counts may predict the magnitude of the effect of ICS added to regular maintenance bronchodilator treatment in preventing future exacerbations. A stablestate blood eosinophil count should be considered when considering this addition. Increasing effects may be observed at higher eosinophil counts (greater than  $0.3 \times 10^9$  cells per litre or 300 cells per microliter), with little or no effect seen in patients with an eosinophil count of  $0.1 \times 10^9$  cells per litre or less than 100 cells per microliter.

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 greater than  $0.3 \times 10^9$  cells per microliter or a history suggestive of asthma. Conversely factors against the use of ICS would include repeated episodes of pneumonia or an eosinophil count of less than  $0.1 \times 10^9$  per litre.

## **Recommendation 4: Inhaler technique**

When a treatment is given by the inhaled route the importance of education and training in inhaler device technique cannot be over-emphasised. Inhalation devices include nebulisers, metered-dose inhalers (MDIs) used both with and 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).

Randomised controlled trials have not identified superiority of one device/formulation over another. However, patients included in these trials are usually those who master inhalation technique and receive proper education prior to inclusion and have on-going follow-up regarding this issue throughout the trial, and therefore the findings may not always be reflective of those in 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, cognitive issues, 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. A lack of placebo devices within clinical areas is often a 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 in their inhaler technique may require a change in inhalational delivery device.

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

#### **Recommendation 5: Roflumilast**

The PDE4 inhibitor roflumilast is a once daily oral medication with no direct bronchodilator activity. Roflumilast reduces moderate and severe exacerbations of COPD requiring treatment with systemic corticosteroids in patients with chronic bronchitis, severe to very severe COPD, and a history of exacerbations. These benefits 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 diarrhoea often causing discontinuation of therapy.

#### **Recommendation 6: Theophylline**

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.

#### **Recommendation 7: Antibiotics**

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 statistically significant association with hearing loss in the treatment group in one study while a further study identified diarrhoea 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.

#### **Recommendation 8: Antioxidants and mucolytics**

In COPD patients not receiving ICS, regular treatment with mucolytics such as carbocisteine 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 precisely identify the potential target population for antioxidant agents in COPD.

## **Recommendation 9: Leukotriene**

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

## Recommendation 10: Alpha 1 Antitrypsin Deficiency (AATD) Augmentation Therapy

All COPD patients should be considered for screening and referred to the Alpha 1 Foundation Ireland.

A serum AAT level of more than  $1 \cdot 1$  g/L in the absence of an acute phase response can be taken to suggest a normal result. (42)

Because AATD is rare, formal clinical trials to assess the efficacy of augmentation therapy using 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 an FEV1 of 35-49% predicted. Never or ex-smokers with an FEV1 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 progressive, rapid spirometric deterioration 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. An individual discussion is recommended before initiating therapy in patients, with consideration of the cost of therapy and evidence or lack thereof of benefit. The main limitation for utilisation of this therapy is the very high associated cost. The National Centre for Pharmacoeconomics did not recommend reimbursement of AATD augmentation therapy in an Irish context, following completion of a pharmacoeconomic evaluation, as cost-effectiveness was not demonstrated.

#### **Recommendation 1: Short-acting bronchodilators**

**1.1** Inhaled short-acting beta 2 agonists (SABAs) or short acting anti-muscarinics (SAMAs) should be prescribed to patients with confirmed COPD where rescue therapy is needed (Grade A) (GOLD).

**Responsibility for implementation:** Doctors, nurse prescribers and pharmacists.

#### **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) and long-acting beta agonists (LABAs) both significantly improve lung function, breathlessness and reduce exacerbations (Grade A) (GOLD).
- **2.3** LAMAs have a greater impact on exacerbation frequency compared to LABAs (Grade B) (GOLD).
- **2.4** LABA/LAMA combination therapy has a more profound impact on FEV1 and symptoms than monotherapy (Grade A) (GOLD).
- **2.5** LAMA/LABA in combination has a greater impact on exacerbation frequency than monotherapy (Grade B) (GOLD).

**Responsibility for implementation:** Doctors, nurse prescribers and pharmacists.

#### **Recommendation 3: Inhaled corticosteroids**

- **3.1** Offering an ICS in patients with confirmed stable COPD as first line therapy is not routinely 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) and this should be considered before prescribing ICS in these patients (GOLD).
- **3.3** ICS should however be considered in patients with ACOS (Expert Opinion) (GDG).
- **3.4** Stable state blood eosinophil levels may be used to influence whether or not ICS should be used. Patients with blood eosinophils less than  $0.1x10^9$  are deemed unlikely to benefit while those with levels greater than  $0.3x10^9$  are most likely to benefit (Grade B) (GOLD).
- **3.5** An ICS combined with a LABA is more effective than the individual components in improving function and health status and reducing exacerbations in patients with exacerbations and moderate to very severe COPD (Grade A) (GOLD).
- **3.6** Triple inhaled therapy with ICS/LAMA/LABA improves lung function, symptoms and health status and reduces exacerbations compared to ICS/LABA, LAMA/LABA or LAMA monotherapy (Grade A) (GOLD).

**Responsibility for implementation:** Doctors, nurse prescribers and pharmacists.

#### 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 with re-education 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) (Expert Opinion)

#### **Responsibility for implementation:** Doctors, nurses and health and social care professionals.

#### Good practice points:

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. Technique and adherence should be checked at every clinical appointment for their COPD.

#### **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 therapy with a LAMA and LABA and possibly ICS. Roflumilast is not approved for reimbursement under the community drug schemes (Grade A) (GOLD).

**Responsibility for implementation:** Doctors, nurse prescribers and pharmacists.

#### **Recommendation 6: Theophylline**

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

**Responsibility for implementation:** Doctors, nurse prescribers and pharmacists.

#### **Recommendation 7: Prophylactic use of macrolide antibiotics**

- 7.1 In patients who have severe COPD with two treated exacerbations, the addition of azithromycin may be considered for one year (Grade A) (GOLD).
- **7.2** 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. The potential for benefit may be less in active smokers. The use of azithromycin in this manner represents an off-label use of this medicine but is recommended in many guidelines. When considering treatment, patients should be otherwise on optimal therapy (Expert opinion)(GDG).

**Responsibility for implementation:** Doctors, nurse prescribers and pharmacists.

#### **Recommendation 8: Antioxidants and mucolytics**

The use of mucolytic and antioxidants in routine practice for management of patients with COPD **is not recommended** (There are currently insufficient studies to recommend use in COPD).

**Responsibility for implementation:** Doctors, nurses, health and social care professionals and pharmacists.

#### **Recommendation 9: Leukotriene antagonists**

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

**Responsibility for implementation:** Doctors, nurses, health and social care professionals and pharmacists.

#### Recommendation 10: Alpha One Anti-Trypsin Deficiency (AATD) Augmentation Therapy

**10.1** It is recommended that AATD augmentation therapy might be considered in young patients who have not smoked or are ex-smokers with an FEV 1 of 35-60% predicted with continued and progressive disease (Grade B) (GOLD).

The National Centre for Pharmacoeconomics did not recommend reimbursement of AATD augmentation therapy in an Irish context following completion of a pharmacoeconomic evaluation, as cost-effectiveness was not demonstrated.

Responsibility for implementation: Doctors.

## 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
Department 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

#### 3.1.2.1 Evidence statement for Question 2

#### **Recommendation 11: Smoking cessation**

Irish data from 2016 estimates that 34,000 inpatient hospital admissions are attributable to smoking and exposure to second-hand smoking. Results also showed that 57% of inpatient admissions for respiratory conditions (including COPD) can be attributed to smoking or exposure to second-hand smoke. Relating this to all admissions due to any cause, one in five inpatient admissions can be attributed to smoking or exposure to second-hand smoke. (43) Both the cost-effectiveness and clinical effectiveness of smoking cessation interventions (both behavioural & pharmacotherapy) have been well-documented in the HIQA Health Technology Assessment (HTA) of Smoking Cessation report in 2017. (44) In 2013, the estimated cost to the healthcare system was over €460 million, the cost of lost productivity was over €1 billion, and the cost of loss of welfare was over €9 billion.

Smoking cessation substantially reduces the risk of developing most smoking-related diseases and also reduces the risk of death. A diverse range of smoking cessation interventions and services are currently funded by the public health system in Ireland.

Smoking cessation has the greatest capacity to positively influence or reduce/delay the progression of COPD. If effective resources such as stop-smoking behavioural support, medication and time are dedicated to smoking cessation, long-term quit success rates of up to 25% can be achieved. Behavioural support and tobacco dependence treatment reliably increase long term smoking abstinence rates. Smoking cessation is important in the prevention and management of COPD as well as a "treatment" in the management of acute exacerbations of COPD. Of note an NCEC national clinical guideline on "Stop Smoking" is due for submission to the NCEC in 2021.

#### E-cigarettes:

Currently, the HSE does not recommend e-cigarettes as a smoking cessation strategy. There are a variety of licensed evidence based supports which the HSE does recommend including NRT and stop smoking medications.

#### **Recommendation 12: Influenza vaccination**

Influenza vaccination can reduce serious illness (such as LRTIs requiring hospitalisation) and death in COPD patients. Only a few studies have evaluated exacerbations and they have shown significant reductions 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. The annual influenza vaccine usually becomes available to patients in September or October of each year. The National Immunisation guidelines on influenza vaccine should be followed with regard to administering of the vaccine. (45)

#### **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 less than 65 with an FEV1 less than 40% predicted and in those with co-morbidity. (2) 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. The provision of pneumococcal vaccination is not straightforward and the National Immunisation guidelines on Pneumococcal vaccination should be followed. (46)

#### **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 aimed 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 is an important element in the long-term management of COPD and is part of a wider integrated respiratory pathway including community services and secondary care services, which should support patient flow and care across the healthcare system. It is one of the common ambulatory care strategies for the prevention of admission for COPD.

The enhancement of community pulmonary rehabilitation services will improve the standard of healthcare offered to people living with COPD.

Community pulmonary rehabilitation services will provide timely, integrated rehabilitation, after an acute event and will compliment other ambulatory services such as COPD Outreach in acute hospitals to enable earlier hospital discharge in a safe manner with better patient outcomes and overall healthcare experience.

Pulmonary rehabilitation should be considered as part of integrated patient management, and usually includes a range of HCPs to ensure optimum coverage of the many aspects involved in providing such management. Teams may include doctors, physiotherapists, nurses, pharmacists, social workers, occupational therapists (OTs), dietitians, speech therapists, self-management support staff, health and wellbeing teams and palliative care services.

Patients should undergo careful assessment prior to enrolment on a rehabilitation programme, 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, co-morbid 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 in this group.

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 hospitalisation), pulmonary rehabilitation can reduce readmissions and mortality. However, initiating pulmonary rehabilitation before the patient's discharge may compromise survival through unknown mechanisms.

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 hospitalisation and all cause hospitalisations. Self-management interventions also improved health status. The COPD self-care plan and COPD communication card (Appendix 9) are important tools in encouraging patients to self-manage and guiding HCPs in patient management.

Individualised self-management plans should be developed in collaboration with each person with COPD and their family members or carers (as appropriate). This includes an action plan for persons at risk of an exacerbation. Plans should be reviewed at future appointments. Action plans should also include a cognitive behavioural component to help in the management of any potential associated anxiety and help patients to cope with breathlessness if indicated. (47)

## **Recommendation 15: Oxygen therapy provision**

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

Once placed on LTOT the patient should be re-evaluated after 60 to 90 days during a period of clinical stability with repeat ABG or oxygen saturation measurement while inspiring the same level of oxygen or room air to determine if oxygen is therapeutic and still indicated.

Oxygen assessment and review clinics should be developed as part of integrated respiratory service. (30)

An initial preliminary assessment of risk should be performed by the prescribing team; however, a detailed risk assessment to incorporate facets of oxygen delivery in the home should be carried out by the supplying company at the time of installation. For information see British Thoracic Society & Irish Thoracic Society Guidelines. (48-49)

## **Recommendation 16: Nutrition support**

**Malnourished/Malnourishment/ Malnutrition:** Malnutrition (under nutrition form) is a state of nutrition in which a deficiency of energy, protein and other nutrients causes measurable adverse effects on body structure and function, and clinical outcome. (50-51)

Individuals with COPD are nutritionally vulnerable and approximately 30% are at high risk of malnutrition and should be screened regularly. Those identified as at nutritional risk should be considered for referral to a dietician. Dietitians can deliver targeted education on dietary strategies to help overcome a range of nutrition issues that are commonly experienced by individuals with COPD, and which can negatively impact on nutritional status. They can include fatigue, dry mouth, taste changes, early satiety, gastrointestinal reflux, bloating, constipation, poor dentition, and dysphagia. (52-55)

Referral to SLT should be considered in patients with swallowing difficulties and/or in patients with evidence of recurrent aspiration-related infections, to determine if silent aspiration may be a contributing factor in symptomatic patients. Onward referral for objective swallow examinations should also be considered. For further information please see NCEC guideline No 22 *Nutrition screening and use of oral nutrition support for adults in acute care setting (2020)*. (56)

## **Recommendation 17: Lung volume reduction**

Lung volume reduction (LVR) may be performed by surgical and non-surgical methods. 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 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 otherwise relatively well-preserved underlying lung, bullectomy is associated with decreased dyspnoea, and improvements in both lung function and exercise tolerance.

Bronchoscopic approaches have been used to provide a less invasive approach to hyperinflation reduction. These techniques have different approaches, but all have a similar objective of reducing lung volume to improve respiratory mechanics. Techniques employed include placement of endobronchial valves (Grade A); lung coils (Grade B); and vapour ablation (Grade B).

Bronchial stenting has been demonstrated to be ineffective. In contrast, endobronchial valve placement in patients with severe emphysema (both heterogeneous and homogeneous distribution) and little or no collateral ventilation has demonstrated benefits over standard care in terms of improved lung function, dyspnoea, exercise capacity and quality of life, out to at least 12 months post procedure in RCTs. However, the procedure does have a high pneumothorax rate. Other smaller studies using thermal vapour ablation, or the use of implanted coils have also shown benefit.

For more guidance on lung volume reduction procedures, see the NICE interventional procedures guidance on lung volume reduction surgery, endobronchial valves and endobronchial coils. (57)

## **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 suitable 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 with no apparent clinical benefit. There are obviously costs involved in doing these studies and an opportunity cost in terms of other patients not being 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. However, it may be reasonable to repeat spirometry after optimisation of therapy or following withdrawal of ICS in selected patients.

#### Recommendation 20: Role of palliative care

Some people with COPD experience a rapid decline in lung function which may lead to an early death, while others have a gradual, progressive decline punctuated by severe exacerbations. This uncertainty in the disease trajectory of COPD can make it very difficult to broach the subject of death with a patient. However, morbidity and mortality associated with the condition are high and adopting a palliative care approach can be invaluable. 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.

Aspects of non-specialist palliative care to consider early in the disease include the following:

- Symptom management, including targeting dyspnoea, pain, and fatigue.
- Responding to anxiety and depression that is prevalent with the disease.
- Assisting in understanding the disease trajectory and advice and support relating to advanced planning.
- Consideration of the use of a handheld fan and low-dose oral morphine for the management of breathlessness in the end-stage COPD patient.

Triggers for referral to specialist palliative care services include the following:

- FEV1 less than 30%.
- Increased hospitalisations (greater than 3 in the last year) with advanced age or multiple co-morbidities.
- Poor functional status.
- Requirement for long-term oxygen therapy.
- Modified Medical Research Council (mMRC) grade 4.
- Breathlessness at rest or on minimal exertion between exacerbations.
- Signs and symptoms of right heart failure.
- More than six weeks of systemic steroids for COPD in the preceding six months.

Opiates, neuromuscular electrical stimulation, chest wall vibration and fans blowing air onto the face can help relieve breathlessness. There is no evidence for a beneficial effect of benzodiazepines. 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 and on-going discussion of these issues is important.

#### **Recommendation 11: Smoking cessation**

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

#### **Responsibility for implementation:** Doctors, nurses and health and social care professionals.

#### Good practice points:

- The determination of smoking status, delivery of a brief intervention, prescription for stop smoking medications and referral to intensive stop smoking support services should be considered standard for the prevention and treatment/management of COPD.
- Smoking status should be recorded and treatment with NRT/stop smoking medication as well as referral to intensive stop smoking service should be offered on hospital admission as well as on discharge with supporting clinical forms and documentation amended to include this.
- Intensive stop smoking services should be included in both the prevention and treatment/ management of COPD including consideration of referral to HSE QUIT services.
- Promotion of the local stop smoking services and National Quit line to include potential referral/ self- referral if agreeable and include advice/education on the benefits of quitting for COPD.
- All patients with tobacco dependence should be given brief smoking cessation advice by a suitably trained Health Care Professional at every intervention.
- Staff should be trained in brief intervention techniques as such as the 5 A strategy to aid those with tobacco dependence: Ask, Advise, Assess, Assist and Arrange and Making Every Contact Count (MECC) training

#### **Recommendation 12: Influenza vaccination**

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

**Responsibility for implementation:** Doctors, nurses and health and social care professionals, HSE influenza leads.

#### **Recommendation 13: Pneumococcal vaccination**

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

**Responsibility for implementation:** Doctors, nurses and health and social care professionals.

#### Good practice points:

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

#### **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).

**Responsibility for implementation:** Doctors, nurses and health and social care professionals.

#### Good practice points:

- All appropriate patients should be offered referral to a PRP.
- Self-management education is key in supporting patient with COPD to give them the skills, knowledge, and confidence to manage their condition.
- Healthcare professionals should provide education on COPD, medication management, selfmanagement and lifestyle changes.
- Teams should be multidisciplinary.

#### **Recommendation 15: Oxygen therapy**

- **15.1** The provision of long-term oxygen therapy to patients with chronic stable hypoxemia with a PaO<sub>2</sub> less than 7.3kPa or a PaO<sub>2</sub> 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 exerciseinduced desaturation in patients with COPD is not routinely recommended (Grade A) (GOLD).

**Responsibility for implementation:** Doctors, nurses and health and social care professionals and oxygen teams.

#### Good practice points:

- Patients who require an assessment for oxygen therapy should be referred to an oxygen assessment and review 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 AOT.
- Risk assessments should be performed before prescribing oxygen.

#### **Recommendation 16: Nutrition support**

Nutrition support should be considered in all malnourished patients with COPD (Grade B) (GOLD).

**Responsibility for implementation:** Doctors, nurses and health and social care professionals and dietitians.

#### Good practice points:

- Malnutrition screening should be carried out by trained healthcare staff, across all settings, using a validated screening tool.
- Attention should be paid to changes in weight in older adults, particularly if the change is more than 3kg. Malnutrition screening should follow.
- Individuals identified as being at risk of malnutrition, and/or obesity, should be considered for referral for a nutrition assessment – see local referral criteria. (Note: Obesity and malnutrition can co-present).
- Those with muscle wastage (sarcopenia) should be considered for referral to a dietitian for nutritional assessment along with exercise prescription.
- Nutrition support should be considered in people with, or at high risk of, malnutrition and COPD.
- Referral to SLT should be considered in patients with swallowing difficulties and/or in patients with evidence of recurrent aspiration-related infections, to determine if silent aspiration may be a contributing factor to a patient's symptoms.

#### **Recommendation 17: Lung volume reduction**

- **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 endexpiratory lung volume and improve exercise tolerance; health status and lung function at 6 to 12 months following treatment. Endobronchial valves (Grade A); Lung coils (Grade B); Vapour ablation (Grade B) (GOLD).

**Responsibility for implementation:** Doctors and thoracic surgeons.

#### **Recommendation 18: Lung transplantation**

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

**Responsibility for implementation:** Doctors and thoracic surgeons.

#### **Recommendation 19: Monitoring of spirometry**

In stable diagnosed COPD patients, FEV1 can be tracked by spirometry every two years (Expert Opinion) (GDG).

**Responsibility for implementation:** Doctors, nurses and health care professionals and pulmonary physiologists.

#### Good practice points:

- It is recommended that staff conducting spirometry should have undertaken a recognised training programme and relevant updates to ensure quality assured spirometry.
- Ensuring accurate diagnosis is fundamental to the effective implementation of guidelines. It is reliant on the clinical history and confirmation of airflow obstruction by spirometry.
- Quality assured spirometry should be provided with the ability for results to be accessed routinely from both primary and secondary care.

#### **Recommendation 20: Role of palliative care**

For advanced COPD care, patients should be referred to a palliative care specialist as appropriate. (Expert Opinion) (GDG)

**Responsibility for implementation:** Doctors, nurses and health and social care professionals and specialist palliative teams.

#### Good practice points:

• Patients experiencing refractory cough or breathlessness having been provided optimal treatment should be considered for referral to palliative care for symptom management.

Aspects of non-specialist palliative care to consider early in the disease include the following:

- Symptom management, including targeting dyspnoea, pain, fatigue.
- Responding to anxiety and depression that is prevalent with the disease.
- Assisting in understanding the disease trajectory and advice and support relating to advanced planning.
- Consider the use of a handheld fan and low-dose oral morphine for the management of breathlessness in the end-stage COPD patient.

Triggers for referral to specialist palliative care services include the following:

- FEV1 less than 30%.
- Increased hospitalisations (greater than 3 in the last year) with advanced age or multiple co-morbidities.
- Poor functional status.
- Patients on long-term oxygen therapy.
- mMRC grade 4.
- Breathlessness at rest or on minimal exertion between exacerbations.
- Signs and symptoms of right heart failure.
- More than six weeks of systemic steroids for COPD in the preceding six months.
- Careful sensitive explanation as to the nature of the referral needs to be had with patients prior to referral.
- Referral to SLT for discussions regarding the patient's preferences in relation to eating and drinking, in particular patients may choose to eat and drink accepting risk of aspiration for quality-of-life purposes. SLTs can provide recommendations regarding comfortable consistencies. SLTs may assist in providing communication support for clients at the End-of-Life stage to promote quality of life.

### 3.1.3 Management of acute exacerbations of COPD

physiothe	QUESTION 3. What interventions (nebulised bronchodilators, steroids, antibiotics, ches erapy) are effective at reducing mortality and morbidity in patients over 35 years of age wit tions of COPD?
	<b>ION</b> (Specify patient and condition characteristics)
Age	
0	e over 35
	nical circumstances
	ients diagnosed with COPD (i.e., confirmed as having COPD on spirometry) experiencing an te exacerbation
Ger	nder
Ma	le or female
INTERVE	NTIONS (Specify intervention(s) type(s) and characteristics)
Tre	atments/care
	armacological and non-pharmacological interventions (including nebulised bronchodilators, roids, antibiotics, chest physiotherapy)
Foll	low up
Foll	low up time of up to 30 days post-exacerbation
PROFESSI	IONALS/(PATIENTS) (Targeted users)
Pro	viders
Phy	vsicians, nurse prescribers, nurses, physiotherapists
Sta	keholders
Dep	partment of Health, HSE, hospitals, primary care
Pat	ients
Pati	ients with COPD
оитсом	E (Purpose of the guideline)
Pat	ient outcomes
	vival, mortality, readmissions, morbidity (disease-specific quality of life, exercise tolerance,) ration of episode of the exacerbation
Sys	tem outcomes
Cos	ts related to hospitalisation due to exacerbation
Pub	olic health outcomes
Мо	rtality and morbidity as above
HEALTH C	CARE SETTING/CONTEXT
Org	ganisations
Hos	spitals and primary care

## 3.1.3.1 Evidence statement for Question 3

#### **Recommendation 21: Bronchodilator therapy**

Short-acting inhaled beta agonists, with or without SAMAs, 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 FEV1 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**

Data from studies indicate that systemic glucocorticoids in COPD exacerbations shorten recovery time and improve lung function (FEV1). They also improve oxygenation, the risk of early relapse, treatment failure, and the length of hospitalisation. A dose of 40 mg prednisolone once daily for five days is recommended. There is no need to taper the dose. Therapy with oral prednisolone is equally as effective as intravenous steroid administration. Oral therapy is associated with lower overall doses of corticosteroid and may be associated with earlier discharge. However, a risk / benefit analysis needs to be performed by the prescribing clinician.

#### **Recommendation 23: Antibiotics**

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 did not exclude patients that 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 antibiotic should be based on the local bacterial resistance pattern. Usually, initial empirical treatment is an aminopenicillin with clavulanic acid, macrolide, or tetracycline. For further information refer to the Antibiotic Prescribing Guidelines for Treatment of Community Infection. (58) https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/

#### **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 hospitalised with an exacerbation of COPD and acute hypercapnic respiratory failure. Non-invasive ventilation should be the initial mode of ventilation used in COPD patients with acute respiratory failure.

NIV is indicated if there is evidence of type 2 respiratory failure with respiratory acidosis  $PaCO_2 \ge 6.0$  kPa and arterial pH  $\le 7.35$ .

NIV has been studied in RCTs showing a success rate of 80-85%. NIV has been shown to improve oxygenation and acute respiratory acidosis i.e. NIV normalises pH and decreases PaCO<sub>2</sub>. 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**

Community COPD Outreach comprises a model of Early Supported Discharge and a model of admission avoidance by outreach services. This is a specific subtype of intermediate care; whereby active treatment is provided by HCPs 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 the financial savings associated with reduced hospital visits. The scheme provides for a high quality, professional, holistic, patient-focused service, which aims to improve the patient's quality of life and increase their social functioning. An outreach team comprises a Clinical Nurse Specialist (CNS) (Respiratory) and a Clinical Specialist 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, and under the clinical governance of the respiratory physicians and other relevant clinical services.

## Recommendation 26: COPD care should be delivered by a multidisciplinary team

Specialist respiratory physiotherapists and specialist respiratory nurses play an integral role in the treatment of people with an exacerbation of COPD, with high level evidence that interventions instigated by both aid recovery and prevent reoccurrence of exacerbations. In addition to their role in COPD outreach, physiotherapists with their background in exercise prescription are usually the coordinators of pulmonary rehabilitation services with support often provided by specialist respiratory nurses. These teams 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 in an effort to enhance lifelong patient behavioural change.

Specialist respiratory physiotherapists and specialist respiratory nurses provide support to GPs in the diagnosis of COPD through respiratory integrated care services. These roles provide spirometry, self-management support, and inhaler optimisation and deliver education programmes to both patients and community staff.

Specialist respiratory physiotherapists and specialist respiratory nurses 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. This service delivery takes place in the outpatient, inpatient and home settings. Non-invasive ventilation may assist in the delivery of other treatments such as early mobilisation and airway clearance. Specialist respiratory physiotherapists and specialist respiratory nurses play a key role in oxygen assessment, carrying out sixminute walk tests, overnight oximetry, and ABGs to facilitate the prescription of long-term oxygen therapy. These teams have in-depth knowledge of the different oxygen modalities available and are ideally placed to provide comprehensive oxygen education to patients, families, and carers.

Oxygen education and support programmes are delivered in both the inpatient and home setting often as part of the COPD outreach services. In addition, other professions are crucial in the holistic management of COPD. For further information on the MDT roles see Appendix 11.

## **Recommendation 27: Theophylline**

Intravenous methylxanthines (theophylline or aminophylline) are not recommended in the treatment of patients with an exacerbation of COPD due to their significant side effect profile, and no appreciable advantage over nebulised bronchodilators.

## **Recommendation 21: Bronchodilator therapy**

**21.1** The initiation of short-acting acute bronchodilator therapy (salbutamol, ipratropium, or combination) is recommended for patients with an exacerbation of COPD (Grade C) (GOLD).

**Responsibility for implementation:** Doctors, nurse prescribers and pharmacists.

#### **Recommendation 22: Steroids**

**22.1** A course of systemic steroids (prednisolone recommended dose 40mgs once daily 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).

#### **Responsibility for implementation:** Doctors, nurse prescribers and pharmacists.

#### **Recommendation 23: Antibiotics**

**23.1** Oral antibiotic use for patients with exacerbations of COPD associated with increased dyspnoea and associated increased sputum purulence 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. However, the choice of antibiotics may be modified due to local bacterial resistance patterns or an individual's sputum microbiology (Grade B) (GOLD) (Expert Opinion GDG).

#### **Responsibility for implementation:** Doctors, nurse prescribers and pharmacists.

#### Recommendation 24: Non-invasive ventilation

**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<sub>2</sub> greater than 6kPa and an arterial PH less than 7.35 which is persistent following rationalisation of delivered oxygen therapy (Grade A) (GOLD).

**Responsibility for implementation:** Doctors, nurses and health and social care professionals.

#### **Recommendation 25: COPD outreach service**

**25.1** The involvement of the COPD outreach team as early as possible in the care of patients admitted to hospital with an exacerbation of COPD (Expert Opinion) (GDG).

# **Responsibility for implementation:** Doctors, nurses, health and social care professionals and ED teams.

#### Good practice points:

All patients who fit the criteria should be referred to a COPD outreach service.

#### Recommendation 26: COPD care should be delivered by a multidisciplinary team

**26.1** It is recommended that a multidisciplinary team of respiratory specialists are key to delivering integrated care for COPD (Expert Opinion) (GDG).

**Responsibility for implementation:** Doctors, nurses, health and social care professionals, hospital managers, HSCP and nurse managers.

#### Good practice points:

- Physicians, specialist physiotherapists and nurses should be involved as appropriate in a patients care to promote integrated services across hospital and community settings in providing specialist support, advice and education.
- Referrals to other MDT members are made on an individual case by case basis.

#### **Recommendation 27: Theophylline**

27.1 The use of theophylline in acute exacerbations of COPD is not recommended (Grade B) (GOLD).

**Responsibility for implementation:** Doctors, nurse prescribers and pharmacists.

## 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
Department 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

#### 3.1.4.1 Evidence statement for Question 4

# Recommendation 28: Oxygen therapy prescribing and monitoring Acute setting/Hospitalised patients:

The clinical presentation of COPD exacerbation is heterogeneous; thus, we recommend that in hospitalised patients the severity of the exacerbation should be based on the patient's clinical signs. Validated scoring systems at admission include the DECAF score, while the NEWS-2 score has been shown to be clinically useful for continuous monitoring of in-patients with COPD. (59)

Oxygen therapy is a key component of hospital treatment of an exacerbation of COPD. Supplemental oxygen should be titrated to improve the patient's hypoxaemia with a target saturation of 88 – 92%. Once oxygen is commenced, close monitoring of ABGs is required to ensure satisfactory oxygenation without carbon dioxide retention and/or worsening acidosis.

The long-term administration of oxygen (greater than 15 hours per day) to patients with chronic respiratory failure has been shown to increase survival in patients with severe resting hypoxemia. LTOT does not lengthen time to death or first hospitalisation or provide sustained benefit 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<sub>2</sub> 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 3litres/ min by nasal cannula. Those with a resting oxygen saturation greater than 95% and 6-minute walk oxygen saturation greater than 84% may travel without further assessment, although it is important to emphasise 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 co-morbidity that may impair oxygen delivery to tissues (e.g., cardiac impairment, anaemia). Also, walking along the aisle may profoundly aggravate hypoxemia. Oxygen assessment and review clinics should be part of integrated respiratory services. A hypoxic challenge test may be used to assess whether patients need in-flight oxygen. However, access to this test is not currently universal.

Once placed on LTOT the patient should be re-evaluated after 60 to 90 days during a period of clinical stability. Repeat ABG should be performed or oxygen saturation measured while inspiring the same level of oxygen or room air, to determine if oxygen is therapeutic and still indicated. Oxygen assessment and review clinics should be components of integrated respiratory services. For further guidance on AOT please see British Thoracic Society (BTS): British Thoracic Society quality standards for home oxygen use in adults Quality statement 9 - AOT (BTS, 2017). (48)

#### Recommendation 28: Oxygen therapy prescribing and monitoring in COPD

- **28.1** For acutely unwell patients with COPD who are hypoxic and potentially at risk for hypercapnia a target saturation range (SpO<sub>2</sub>) of 88-92% is suggested pending ABG results (Expert Opinion) (GDG).
- **28.2** Patients discharged home following hospitalisation on oxygen therapy should be evaluated for the need to remain on long term oxygen therapy (LTOT) 60-90 days after discharge and during a period of relative clinical stability. LTOT should not be continued if patients do not meet the criteria (Expert Opinion) (GDG).
- **28.3** Routinely offering ambulatory LTOT for patients with chronic, stable COPD and isolated exercise-induced hypoxemia is **not recommended** (Grade A) (GOLD).
- 28.4 Patients with stable COPD with persistent evidence of hypoxaemia (i.e. SpO<sub>2</sub> ≤92%) should be assessed for LTOT (Expert Opinion GDG).
- **28.5** The provision of long-term oxygen therapy to patients with chronic stable hypoxemia with a PaO<sub>2</sub> less than 7.3 kPa or a PaO<sub>2</sub> between 7.3 and 8kPa with signs of tissue hypoxia (haematocrit greater than 55%, pulmonary hypertension or cor pulmonale) is recommended (Grade A) (GOLD).
- **28.6** The provision of oxygen for patients with moderate hypoxemia, nocturnal desaturation, or exerciseinduced desaturation in patients with COPD is not routinely recommended (Grade A) (GOLD).

**Responsibility for implementation:** Doctors, nurses, health and social care professionals and oxygen teams.

#### Good practice points:

- Once oxygen is commenced in the hospitalised patient close monitoring of blood gases is required to ensure satisfactory oxygenation without carbon dioxide retention and/or worsening acidosis.
- A requirement to increase supplemental oxygen delivery to maintain a patient's targeted SpO<sub>2</sub> may be a sign of acute clinical deterioration which requires immediate medical review.
- Oxygen Therapy in the Hospitalised Patient with COPD.

The Irish National Early Warning System (INEWS) is a monitoring/scoring system used in all Irish acute hospitals to assist in the recognition and management of the acutely unwell non- pregnant adult ( $\geq$ 16 years) in-patient. One of the limitations of this system is in patients with COPD and hypercarbic respiratory failure. INEWS allocates a score of between 0 (least risk) and 3 (highest risk) to each of seven physiological parameters including respiratory rate, supplemental oxygen and oxygen saturation (SpO<sub>2</sub>). A score of '3' (highest risk) is allocated for any supplemental oxygen. INEWS also captures but does not allocate a score to the mode of oxygen delivery (i.e., nasal cannula, facemask etc.). Furthermore, a requirement to increase supplemental oxygen delivery to maintain a patient's targeted SpO<sub>2</sub> is a sign of acute clinical deterioration which requires immediate medical review. This increasing oxygen requirement is not captured in INEWS (*a score of 3 is given for ANY oxygen*) thus this further patient deterioration may not be reflected in the patient's INEWS score.

INEWS V2 was published in 2020 and recognises that patients with a confirmed diagnosis of COPD or other chronic respiratory conditions often have a tolerance for lower baseline  $SpO_2$  levels and in most COPD patients the target saturations should be lower. This lower baseline  $SpO_2$  combined with a score of 3 for supplemental oxygen can cause unnecessary triggering of the INEWS system in ill but otherwise stable patients. INEWS V2 addresses this problem through the use (at the discretion of a Registrar or Consultant) of a Modified Escalation and Response Protocol. For further information please refer to the full NCEC NCG No. 1 INEWS V2. (60)

Long Term Oxygen Therapy

- 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 AOT.

## **3.1.5** Pathways, bundles, and checklists for managing acute COPD exacerbations.

FUFUF	LATION (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
INTER	VENTIONS (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.
	<ul> <li>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, whe performed collectively and reliably, have been proven to improve patient outcomes. (61)</li> </ul>
	• Checklists, defined as tools that condense a large volume of information and allow for systemati verification of steps or practices. (62)
	<ul> <li>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 cal incorporate local and national guidelines into everyday practice.</li> </ul>
	Follow up
	From hospital admission to 90 days post discharge (readmissions)
PROFE	SSIONALS/(PATIENTS) (Targeted users)
	Providers
	Physicians, nurse prescribers, nurses, physiotherapists
	Stakeholders
I	Department of Health, HSE, hospitals
	Patients
I	Patients with COPD
ουτο	OME (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
I	Mortality and morbidity as above
	H CARE SETTING/CONTEXT

## 3.1.5.1 Evidence statement for Question 5

The introduction of care bundles at hospital discharge to include education, optimisation of medication, supervision and correction of inhaler technique, assessment and optimal management of co-morbidities, early rehabilitation, telemonitoring and continued patient contact have all been investigated to address these issues. Although 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 address these issues before patient discharge, with the possible exception of instituting rehabilitation prior to discharge as there is some evidence that this may be associated with increased mortality, although the reason for this observation remains unclear.

#### Recommendation 29: Pathways, Bundles and Checklists for Managing Acute Exacerbation of COPD

**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) (GDG).

**Responsibility for implementation:** Doctors, nurses, health and social care professionals and ED teams.

#### **Good practice points:**

A COPD admission and discharge bundle should be initiated on patients admitted with exacerbations of COPD upon arrival in the ED or Acute Medical Assessment Unit. For further information and resources see "End to End COPD MOC 2019", "COPD Discharge Plan" and "COPD Acute management bundle" (Appendix 9).

Recording of smoking status and treatment with NRT/stop smoking medications and referral to intensive stop smoking services should be considered at admission.

On the discharge bundle, in addition to consideration of referral to stop smoking services, where NRT/stop smoking medications were administered during hospital admission, a prescription for NRT/stop smoking medications should be provided if the patient is amenable to same.

Given the high risk of medication errors at the points of admission to and discharge from secondary care, pharmacy input at these stages of the patient pathway is recommended to minimise the risk of medication errors, provide additional patient education, and help optimise outcomes for patients.

## 3.2 Summary budget impact analysis

A BIA of the national clinical guideline for the Management of COPD was conducted by HRB-CICER from the perspective of the publicly funded health and social care system, the HSE and estimated over a five-year time horizon. The full BIA is presented in Annex D.

As part of on-going health system reform in Ireland, an Integrated Care Programme for Prevention and Management of Chronic Disease is being introduced on a phased basis. Under the Programme, community healthcare services will be provided through primary care teams and Community Healthcare Networks (CHNs), with the aim of caring for more people in the community and ensuring better coordination between acute and community care pathways. Funding has been allocated under the Sláintecare Community Enhancement Fund and HSE Winter Plan 2020/21 to support this health system reform.

Based on the guideline's recommendations and implementation plan, the resource implications comprise the expanded provision of:

- 32 additional PRP teams
- 15 additional COPD outreach teams
- 32 additional oxygen assessment clinic sites
- 32 specialist teams to support community diagnostics

Expansion of these services was prioritised by the GDG due to insufficient service capacity to adequately address the needs of COPD patients.

The expansion of these services will be implemented over a two-year time horizon at an estimated cost of €19.8 million (95% CI: €15.9m to €23.8m). Funding, from the HSE's Winter Plan 2020/21 and the HSE Acute Hospitals budget, has been allocated to the Integrated Care Programme for Prevention and Management of Chronic Disease to support the expansion of these services over the initial two-year time horizon.

The overall incremental budget impact was estimated at &64.6 million (95% CI: &52.2m to &77.3m) over a five-year time horizon. Across the five-year time horizon, recruitment and opportunity costs were estimated at &65.5 million (95% CI: &61.2m to &70.0m) and &8.6 million (95% CI: &7.8m to &9.4m), respectively. Cost savings accruing from rehospitalisation avoidance were estimated at &8.8 million (95% CI: 0.03m to 17.0m), cost offsets from the release of hospital capacity from patients receiving outreach were estimated at &0.8 million (95% CI: 0.5m to 1.2m) over the five-year time horizon.

The estimated budget impact shows that achieving better outcomes for COPD will require substantial investment; however, outcomes for COPD patients (particularly in terms of international comparisons) indicate that investment in these services is warranted.

## 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 (2021) NCG No.27 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 BIA 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.

#### **COPD 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 the 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.

#### **External Reviewers**

#### Name: Professor Stephen Bourke

Professor Bourke qualified from Queen's University Belfast with Honours in 1991. He is currently a consultant respiratory physician for Northumbria Healthcare NHS Foundation Trust, and Honorary Professor of Respiratory Medicine, Newcastle University. He leads the COPD and NIV services and Respiratory Research Programme, chaired the British Thoracic Society COPD Specialist Advisory Group and served on the Royal College of Physicians National COPD Audit Committee from 2016 to 2019, and currently sits on the British Thoracic Society Standards of Care Committee. He helped develop the British Thoracic Society NIV Quality Standards 2017/18 and leads an internationally recognised COPD and NIV research programme. This includes the development of clinical risk scores to help clinicians identify which patients with COPD can be safely managed at home and those who would benefit from much closer monitoring, both in-hospital and after discharge (the 'DECAF' and 'PEARL' scores). This has led to the establishment of new clinical services for patients, a National Institute of Health Research (NIHR) Clinical Research Impact of the year award 2016 and NIHR Signal 2018, identifying research

most likely to influence clinical practice. Other significant research includes an RCT of NIV in Amyotrophic Lateral Sclerosis; surveys in the UK and France showed a substantial increase in use of NIV following publication.

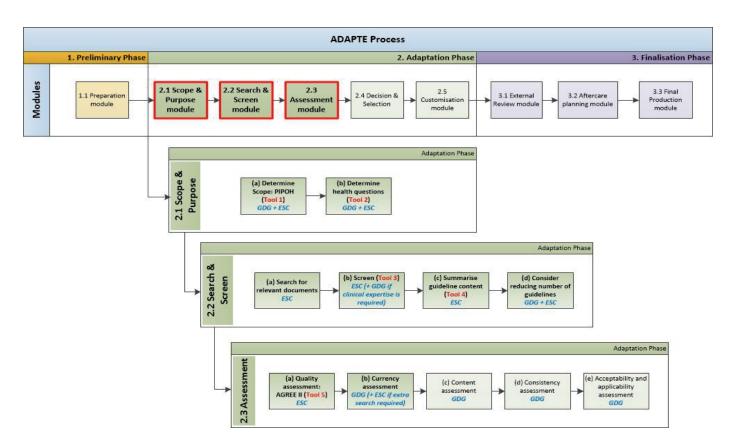
#### Name: Professor Fernando J Martinez

Professor Martinez is currently the Chief of the Division of Pulmonary and Critical Care Medicine at Weill Cornell Medicine in New York City. Prior to this he was Professor of Internal Medicine and Associate Chief for Clinical Research in the Division of Pulmonary and Critical Care Medicine at the University of Michigan Health System, Ann Arbor, Michigan, as well as Medical director of its Pulmonary Diagnostic Services and Co-Medical director of the Lung Transplantation Program. He graduated from the University of Florida School Of Medicine in Gainesville, Florida. His research interests include chronic obstructive pulmonary disease (COPD), interstitial lung disease, lung transplantation, and lung volume reduction. He is a member of numerous societies, including the American Thoracic Society, the European Respiratory Society, the American College of Chest Physicians, and the Fleischer Society. He was previously, a member of the American Thoracic Society Committees which generated guidelines for the management of COPD, respiratory infections, and cardiopulmonary exercise testing, and he is the former chair of the Clinical Problems Assembly of the American Thoracic Society. He is also a member of the GOLD Science Committee and sits on a number of editorial boards, including the Journal of COPD and American Journal of Respiratory and Critical Care Medicine.

# Appendix 2: Literature 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 ESC are involved



The methods, described in this section, were adapted from ADAPTE collaboration manual. 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. These toolkits are available in the reference links provided.

#### **Screening for inclusion**

All retrieved records were screened by at least two of three 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, as recommended in the ADAPTE manual. The Rigour of Development dimension contains eight items. 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.

- 1. 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 instrument. 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 definition.

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.

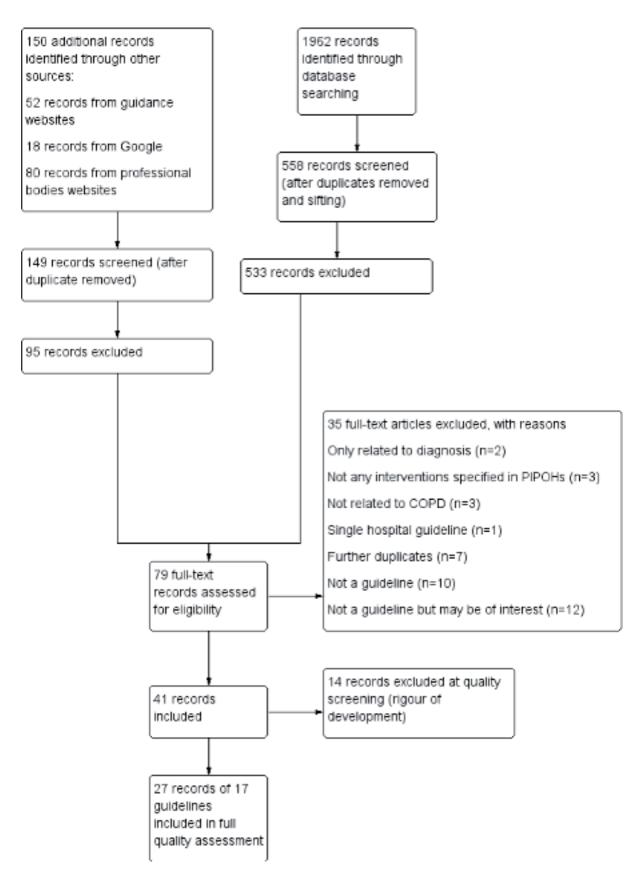


Figure 7: Flow diagram of search and screening

# 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	http://health.gov.ie
Clinical Guidelines)	
Health Service Executive (HSE)	www.hse.ie
Health Information and Quality Authority (HIQA)	www.hiqa.ie
National Institute for Health and Care	http://www.nice.org.uk/page.as
Excellence (NICE)	px?o=ourguidance
Guidelines and Audit Implementation Network /	http://gain-
The Regulation and Quality Improvement	ni.org/index.php/audits/guidelin
Authority	es
NHS Evidence (incorporating Scottish	www.evidence.nhs.uk
Intercollegiate Guidelines Network (SIGN) &	
Guidelines International Network (GIN))	
Institute for Clinical Systems Improvement (ICSI)	http://www.icsi.org/knowledge
Food and Drug Administration	http://www.fda.gov/cder/guida
	nce/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/re
	cherche-
	avancee?portlet=c_39085&sear
	ch_antidot=⟨=en&typesf=g
	uidelines
Ontario Guidelines Advisory Committee (GAC)	http://www.gacguidelines.ca
Recommended Clinical Practice Guidelines	
Finnish Medical Society Duodecim	http://www.kaypahoito.fi
World Health Organisation	www.who.int

## A Professional bodies' websites searched

Profession	rofessional 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 of 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	American Thoracic Society	www.thoracic.org				
America	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				

Professio	nal 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	COPD OR chronic obstructive pulmonary disease OR COAD OR chronic obstructive	MeSH: pulmonary disease, chronic obstructive
over 35 years	airway disease OR chronic obstructive lung	Emtree: chronic obstructive lung disease
of age with a diagnosis of	disease OR chronic airflow obstruction OR chronic airflow obstructions adult OR	CINAHL: pulmonary disease, chronic obstructive
COPD	adults OR adulthood	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 recommendations OR care plan OR care plans OR good clinical practice OR good clinical practices OR map OR maps OR algorithm OR algorithms	MeSH: Guideline [Publication Type], guidelines as topics, Practice Guideline [Publication Type], Health Planning Guidelines Emtree: practice guideline (explode term) CINAHL: practice guidelines

### b. Filters/limits used

Limits/filters:

- Date: past 10 years
- Language: English only

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

ž	No Guideline		AGREE II doi	mains (Standardi	sed domain sco	res: average pe	AGREE II domains (Standardised domain scores: average percentage scores for each domain)	or each domai	n)	_
		Scope & Purpose (1)	Stakeholder involvement (2)	Rigour of development (3)	Clarity & presentation (4)	Applicability (5)	Editorial independence (6)	Overall assessment (7)	Recommend?	
-	British Thoracic Society. Intermediate care—Hospital-									
	at-Home in chronic	100	64	80	100	60	0	85.7	Yes	
	obstructive pulmonary	2	)	)	)	}	)		-	
	alsease: britisn Inoracic Society guideline. 2007.									
7	British Thoracic Society (BTS)									
	guideline on emergency				_					
	oxygen use in adult patients.	100	100	100	100	75	50	92.3	Yes	
	2008 + correction: Inorax									
	2009 Jan;64(1):91. Commentary									
e	2008 Update CTS Guideline -									1
	Highlights for Primary Care -				_					
	Recommendations for									
	Management of COPD.	100	50	100	100	25	100	75.0	Yes	
	2007 Update CTS Guideline -									
	Recommendations for									
	Management of COPD.									
4	Non-invasive ventilation in				_					
	chronic obstructive		1						:	
	pulmonary disease. Royal	94	97	84	100	21	54	78.6	Yes	
	College of Physicians of									
4	London - RCP. 2008. National lastitute for Hoalth									
0	AUTORIAL INSTITUTE TOL HEALT				_					
	CG101: Chronic obstructive				_					
	pulmonary disease in over									
	1 6s: diagnosis and	001	100	1001	100	70	100	100	Yac	
	management. 2010. (+2012	2	00	000	00	t	22	22	50-	
	evidence update; second				_					

See also Annex A for original document

Table 3. Quality assessment of included guidelines

# Appendix 3: Guideline search results - AGREE II

National Institute for Health and Care Excellence (NICE)

link)

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			I	
	Yes	Yes	Yes	Yes
	85.7	85.7	85.7	85.7
	100	001	001	100
	o	0	27	60
	100	001	100	100
	88	100	100	99
	67	68	وا	100
	100	100	100	100
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)	CTS Guideline Optimizing pulmonary rehabilitation in chronic obstructive pulmonary disease - practical issues. 2010.	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.	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 settina, 2011.	Department of Veterans
	9	2	ω	9

Attairs/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. Ontario Guidelines Advisory Committee (GAC) Recommended Clinical Practice Guidelines. COPD: Exacerbation. Ontario Guidelines. COPD: Exacerbation. Ontario Guidelines. COPD: Exacerbation. Ontario Guidelines. COPD: Improving Survival. Ontario Guidelines. COPD: Improving Survival. Ontario Guidelines. COPD: Improving Survival. Ontario Guidelines. COPD: Improving Survival. Ontario Guidelines. COPD Recommended Clinical Practice Guidelines. COPD (Stable I: Treatment. Diagnosis and Management of Stable Chronic Obstructive Pulmonary Disease: A Clinical Practice Guidelines. COPD (Stable I: Treatment. Diagnosis and Management of Stable Chronic Obstructive Pulmonary Disease: A Clinical Practice Guidelines. COPD (Stable I: Treatment. Diagnosis and Management of Stable Chronic Obstructive Physicians, American College of Physicians. American College of	01 20	100	100	0	81	85.7	Š ∑
atory							
Managing dyspnea in patients with advanced chronic obstructive pulmonary disease: A	100 67	100	100	25	100	85.7	Yes
Canadian Thoracic Society							

	Yes	Yes	Yes	Yes with modification	Yes	Yes
	92.9	52	85.7	64.3	92.3	89.3
	50	50	50	50	100	50
	52	13	ŝ	0	65	50
	100	100	100	26	100	100
	100	100	100	65	8	100
	100	33	001	64	00	100
	100	100	001	100	00	100
clinical practice guideline. 2011.	British Thoracic Society (BTS) guideline on pulmonary rehabilitation in adults: Accredited by NICE. 2013.	Clinical Practice Guideline on Adult Domiciliary Oxygen Therapy: Executive summary from the Thoracic Society of Australia and New Zealand. 2016. (But published as a report in 2014)	Prevention of acute exacerbations of chronic obstructive pulmonary disease: American College of Chest Physicians and Canadian Thoracic Society Guideline. 2015.	AARC clinical practice guideline: effectiveness of pharmacologic airway clearance therapies in hospitalized patients. American Association for Respiratory Care. 2015.	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;70:11-143. 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.	Global Strategy for Diagnosis, Management, and Prevention of COPD – 2016.
	12	13	14	15	16	17

# **Appendix 4: Clinical questions in PICOs format**

**Table 9:** 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 (CEA), cost-utility analysis (CUA), and cost- benefit analysis), costing studies and comparative resource use studies.

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#### COPD outreach service (recommendation 25)

Table 10: 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 (CEA, CUA and cost- benefit analysis) and comparative resource use studies.

#### Long-term oxygen therapy (recommendation 15)

Table 11: PICOS for review question 3 – long-term oxygen therapy

Population	Adults diagnosed with chronic stable hypoxemia with a $PaO_2$ less than 7.3 kPa or a $PaO_2$ 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 (CEA, CUA, and cost- benefit analysis), costing studies and comparative resource use studies.	

\*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 12:** 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 (CEA, CUA, and cost- benefit analysis), costing studies and comparative resource use studies.	

\*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 13: 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 (CEA, CUA and cost- benefit analysis), costing studies and comparative resource use studies.

\*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 14: PICOS for review question 6 – prophylactic use of azithromycin

Population	Adults with severe COPD that have had one or more treated exacerbations.	
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 (CEA, CUA and cost- benefit analysis), costing studies and comparative resource use studies.	

\*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 with information regarding symptom burden and risk of exacerbation.

#### Non-pharmacological management of COPD Lung volume reduction procedures (recommendation 17)

Table 15: 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 (CEA, CUA and cost- benefit analysis), costing studies and comparative resource use studies.

#### Table 16: PICOS for review question 7.2 – lung volume reduction surgery

Population	Adults with upper lobe emphysema and low-post rehabilitation exercise capacity.	
Intervention	ung volume reduction surgery with bullectomy.	
Comparator	No surgery.	
Outcomes	Any relevant measures of costs and benefits.	

#### Lung transplantation (recommendation 18)

**Table 17:** 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 (CEA, CUA and cost- benefit analysis), costing studies and comparative resource use studies.

Е

\*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 with information regarding symptom burden and risk of exacerbation.

#### Monitoring of spirometry (recommendation 19)

#### Table 18: 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 (CEA, CUA and cost- benefit analysis), costing studies and comparative resource use studies.	

#### Management of exacerbations in COPD

#### Non-invasive ventilation (recommendation 24)

#### Table 19: PICOS for review question 10 - non-invasive ventilation

Population	Adults with acute exacerbations of COPD who 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 (CEA, CUA and cost- benefit analysis), costing studies and comparative resource use studies.

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

# Appendix 5: Evidence Grading System

Grades of recommendation (adapted from GOLD and training from the 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.	
Α	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 (RCTs) 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.
В	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 (methodological 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.

# **Appendix 6: Consultation report**

Date	17/07/20-07/08/20
Patients' groups	Via COPD Support Ireland & Asthma Support Ireland
External review	Professor Stephen Bourke Professor Fernando Martinez
Clinical Programmes	Office of Nursing and Midwifery Services Director
and healthcare divisions	Office of Chief Clinical Officer, HSE
	Generic all users' emails HSE
	NCPs
	NCP Respiratory Clinical Advisory Group
	National Director and Deputy Director Acute settings Division HSE
	Chief Executive Officers/General Managers and Clinical Directors Acute settings
	National Clinical and Advisory Group Leads
	Acute Operations / relevant hospital groups
	Medicine management programme
Professional groups	Nursing and Midwifery Board of Ireland (NMBI)
	Irish Nurses and Midwives Organisation
	CORU
	Health and Social Care Professional groups,
	Irish College of General Practitioners
	ANAIL - Respiratory Nurses Association of Ireland
	Chartered Physiotherapists in Respiratory Care (CPRC)
	RIC teams
	COPD Outreach Teams
	Royal College of Surgeons, Ireland (RCSI)
	Irish Thoracic Society
Other	Department of Health
	Health Information and Quality Authority

# Feedback received from the following

Name	Title and Organisation
Dr Siobhán Ní Bhriain	Integrated Care Lead, on behalf of Chief Clinical Officer
Liam Woods	National Director Acute Operations
Paul Gilvarry	Senior Pharmacist, Acute Hospitals Drugs Management Programme
Dr David Hanlon	National Clinical Adviser and Group Lead Primary Care
Dr Paul Gregan	Consultant in Palliative Medicine, Blackrock Hospice
Dr Thomas Carroll	Alpha-1 Foundation Ireland.
Edel Russell	Dietitian Manager CHO Area 8- Louth/ Meath
Dr James Hayes	Consultant Respiratory Physician, Cavan General Hospital
Noreen McNamara	Registered Advanced Nurse Practitioner Clonmel
Professor Karen Redmond	Consultant Thoracic & Transplant Surgeon, Mater
Avilene Casey Dr Miriam Bell	National Deteriorating Patient Recognition & Response Improvement Programme (DPIP)
Patricia Gohery Dr Kenneth Bolger	Nurse Tutor, Centre for Nurse & Midwifery Education, HSE West (LCNTR)
Niki Byrne	CNSp- Respiratory Integrated Care, Galway Community Healthcare West & Galway University Hospitals
Olivia Lee	Advanced Nurse Practitioner, NGH
Anny Varghese,	Nurse Tutor ,Kerry Centre of Nursing & Midwifery Education (CNME)
Leanne Madigan	NMPD Officer, NMPDU, Dublin South, Kildare and Wicklow
Maura Grogan	Quality Manager, South Tipperary General Hospital, Clonmel
Rachel McDonnell	RCPI Quality Improvement
Viji Matthew	COPD Outreach CNS, Our Lady of Lourdes Hospital, Drogheda,
Caroline Doyle	Respiratory CNS, Pulmonary Outreach / Rehabilitation Programme Midlands Regional Hospital
Rosie Hassett	Respiratory CNS, Primary Care Mullingar
Ciara Breen	Interim Occupational Therapist Manager In Charge III Galway University Hospitals
Claire Maidment	Temporary Occupational Therapist Manager, University Hospital Waterford
Elaine Kerins	Senior Speech and Language Therapist, St. Ita's Hospital, Co. Limerick,
Aine Lawlor	Senior Speech and Language Therapist, Primary Care Dublin south east
Jacinta Curley	Senior Speech-Language Therapist, Wexford General Hospital
Maresa McGettigan	Health Promotion & Improvement Officer , Health and Wellbeing, CHO1
Maeve Carmody	Self-management Support Coordinator for Long-term Health Conditions, Health & Wellbeing   Cork-Kerry Community Healthcare

Kate O' Connor	Self-management Support Coordinator for Chronic Conditions, Kilkenny
Dr Emmet O'Brien	Consultant Respiratory Physician, Beaumont Hospital
Bernard Duggan,	Chief II Pharmacist, HSE-Medicines Management Programme,
Aishling Sheridan	Evidence & Information Officer, Tobacco Free Ireland Programme, HSE
Aisling Madden	Respiratory Candidate Advanced Nurse Practitioner, Beaumont Hospital
Esther-Mary D'Arcy	Professional Advisor, Irish Society of Chartered Physiotherapists
Bernadette Jackson	President, Academy of Clinical Science and Laboratory Medicine
Emer O Shea	Physiotherapist on behalf of CPRC

The consultation period opened on 17th July 2020 and ended on 7th August 2020. A standard invitation letter and feedback form was used (attached at end of this Appendix). All feedback received was collated using an excel spread sheet. A summary of the feedback was then generated reducing duplicate comments to a single item. This was reviewed by the GDG in August 2020 and amendments, or clarifications were made where appropriate. Collated feedback can be obtained from the NCP Respiratory team on request through Clinical Design and Innovation.

Stakeholder feedback was received from 35 groups and individuals in total as well as two international reviewers.

The GDG would like to acknowledge the time and effort of the stakeholders who provided feedback, and in particular the expert reviewers.

The following pages contain the invitation email and consultation form.

#### Invitation email

Dear Colleagues,

The National Clinical programme for COPD and Guideline Development Group would welcome your feedback on the draft COPD Management – National Clinical Guideline (2020) before submission to the National Clinical Effectiveness Committee in August. Many thanks to all who have contributed to the update of this guideline. Your advice and expertise have been very much appreciated.

The guideline can be downloaded from https://www.hse.ie/eng/about/who/cspd/ncps/copd/

The closing date for feedback is COB of August 7th 2020. Feedback will only be accepted via the questionnaire which is attached and this must be emailed to susan.curtis@hse.ie

Please share this email with anyone who you feel appropriate.

Best regards,

The National Clinical Programme for Respiratory (COPD & Asthma)

#### Feedback Form

# COPD

# **National Clinical Guideline**

# **Consultation feedback form**

Consultation closing date: The deadline for comments is **Friday 7th August 2020 at 5pm** using feedback sheet via email to: **susan.curtis@hse.ie** 

# Introduction

We would like to hear your views on the draft National Clinical Guideline for COPD (2020). All comments received on this form by the deadline will be considered and used to inform the final clinical guideline.

Clinical guidelines are an important contributor to safe high-quality healthcare. Good clinical guidelines help change the process of healthcare, reduce variation, improve outcomes for service users and ensure the efficient use of healthcare resources (NCEC p.6).

Further information on the NCEC and National Clinical Guidelines is available from

http://health.gov.ie/national-patient-safety-office/ncec/

#### Notes:

- 1. Feedback received may be edited and/or summarised.
- 2. This consultation is conducted in line with requirements of the Freedom of Information (FOI) Acts as applicable and Data Protection requirements. Please note your submission may be published under this or in a report on the consultation. This may be on a website or in a document.
- 3. Submissions which are not attributable to an individual or group will not be considered.
- 4. Organisations making submissions should be aware of their obligations under the terms of the Regulation of Lobbying Act 2015.

# Scope of draft clinical guideline

This guideline is relevant to all clinical staff caring for adult patients ( $\geq$  16 years) in all healthcare settings.

It is designed to guide clinical judgement but not replace it. In individual cases a healthcare professional may, after careful consideration, decide not to follow guideline recommendations if it is deemed to be in the best interests of the patient. Clinical decisions and therapeutic options should be discussed with a senior clinician on a case-by-case basis as necessary and documented in the clinical notes.

# How to submit your feedback

How to submit your feedback:

- All feedback must be submitted on this form if it is to be considered.
- Ensure you have completed your details or your group's details.
- Identify clearly the recommendation your feedback relates to by identifying recommendation number and inserting your comments into aligned row.
- Each comment should be in a separate box.
- Specifically, you must explain the rationale for your comment, which should be written clearly and concisely.
- Submit the form as a word document via email.
- Organisations should submit one collated response.
- Use full terms for abbreviations on first use.
- If you refer to sources of evidence, please detail the reference (with web link if available)

## **Consultation questions**

This consultation focuses on how user friendly the document is, the content (evidence statements and recommendations) and the implementation of the draft guideline.

#### 1. Content

- a) Do the recommendations cover the scope of the COPD Guideline?
- b) Do the recommendations clearly link to the evidence presented or otherwise to best practice?
- c) Does the draft guideline consider the views and needs of specific population groups?
- d) Does the draft guideline consider gaps in current practice?

#### 2. Implementation

- a) Is the guideline suitable for routine use as intended?
- b) Which areas do you think may be difficult to put into practice? Please explain why.
- c) What would help users to implement the guideline?

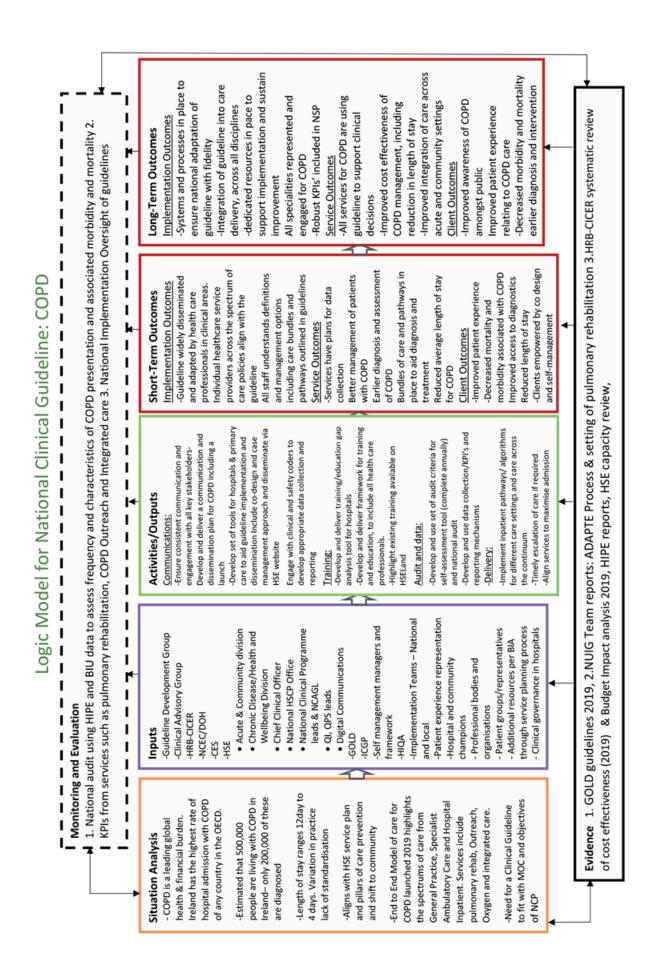
# **Your details**

Name of person completing form	
Organisation name	
Are you commenting? (tick box)	As an individual On behalf of an organisation
Organisation Name	
Contact Name (if different to above)	
Contact Telephone Number	
Contact Email Address	
Date of feedback	

# Feedback

Summary of Recommendations
Comment/feedback
Development of the National Clinical Guideline
Comment/feedback
National Clinical Guideline recommendations
Comment/feedback

Please document and other relevant comments that you would like to make below. (Please detail below the page number, rationale, and any supporting documentation)



# **Appendix 7: Logic Model & Implementation Plan**

) on: COPD	
NCG	
Guideline	
Clinical	
National	
for	
Plan fc	
Implementation	

Ite action       Vent 2       Vent 3       Vent 4       Vent 4 <th>Guideline recomm- endation or</th> <th>Implementation barriers / enablers</th> <th>Action / intervention / task to implement recommendation</th> <th>Lead responsibility for deliverv of</th> <th>Tin o</th> <th>Timeframe for completion</th> <th>or 1</th> <th>Expected outcome and verification</th>	Guideline recomm- endation or	Implementation barriers / enablers	Action / intervention / task to implement recommendation	Lead responsibility for deliverv of	Tin o	Timeframe for completion	or 1	Expected outcome and verification
Enablers:       Develop and roll-out a communication and Stateholder       Envelop and roll-out a communication and dissemination strategy, including public engagement       Envelopment       X <ul> <li>Patient engagement</li> <li>Patient engagement</li> <li>Exampions</li> <li>Champions</li> <li>Champions</li> <li>Champions</li> <li>Grout active development of divical champions</li> <li>Grout active development of clinical champions</li> <li>Grout active development of divical champions</li> <li>Grout active development of clinical champions</li> <li>Grout active development of divical champions</li> <li>Freeheatti</li> <li>Teleheatti</li> <li>Active development of divical champions</li> <li>Teleheatti</li> <li>Grout active development of divical champions</li> <li>Teleheatti</li> <li>Grout active development of divical champions</li> <li>Teleheattive development of divical champions</li> <li>Teleheattive development of divical champions</li> <li>Teleheattive divical divical champions</li> <li>Teleheattive divical divical divica across learning sites</li> <li>Teleheattive divical divica across learning sites</li> <li>Teleheattive divica divica across learning sites</li> <li>Teleheattive divical divica divica across learning sites</li> <li>Teleheattive divica divica div</li></ul>	number(s)			the action	Year 1	Year 2	Year 3	
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ement engagement tengagement volvement Engagement to explore development of uolsement gand sig and clinical champions sig and clinical champions clinical champions sponsors for full implementation and tract resourcing – currently in process with HSE resourcing – currently in process with HSE alth and networks e effective e effective e effective ship	implementation	<ul> <li>Stakeholder</li> </ul>	dissemination strategy, including public		:			1.Improved awareness and knowledge
t engagement t engagement to explore development of volvement g and ing and ing CHNs seek mandate from COPD programme tract resourcing – currently in process with HSE resourcing – currently in process with HSE and networks and networks es effective es effective immething ites and networks ship		engagement	engagement					of guideline
volvement Engagement to explore development of ions clinical champions ig and Seek mandate from COPD programme cing CHNs sponsors for full implementation and tract sponsors for full implementation and intent resourcing – currently in process with HSE with development of enhanced community c disease and networks es effective es effective es effective ship		<ul> <li>Patient engagement</li> </ul>						2. More promotion and support for
view clinical champions lig and cing CHNs Seek mandate from COPD programme cing CHNs Seek mandate from COPD programme butract sponsors for full implementation and ment resourcing – currently in process with HSE with development of enhanced community care for chronic disease across learning sites alth and networks es effective es effective and networks terment, cing, & clinical ship		and involvement	Engagement to explore development of					guideline implementation
ing and Seek mandate from COPD programme cing CHNs sponsors for full implementation and nent resourcing – currently in process with HSE with development of enhanced community care for chronic disease across learning sites and networks and networks estification is cling. & clinical ship		<ul> <li>Champions</li> </ul>	clinical champions					3. Mandate and resources for
cing CHNs Seek mandate from COPD programme tract sponsors for full implementation and tract resourcing – currently in process with HSE with development of enhanced community c disease across learning sites and networks and networks and networks failing & clinical ship		<ul> <li>Building and</li> </ul>						implementation secured
tract sponsors for full implementation and ment resourcing – currently in process with HSE list teams with development of enhanced community c disease arross learning sites alth and networks and networks es effective es effective ship		resourcing CHNs	Seek mandate from COPD programme					
nent resourcing – currently in process with HSE list teams with development of enhanced community c disease across learning sites and networks and networks and networks cing, & clinical ship		<ul> <li>GP contract</li> </ul>	sponsors for full implementation and					Verification:
list teams with development of enhanced community c disease across learning sites care for chronic disease across learning sites and networks and networks and networks cing. & clinical ship		agreement	resourcing – currently in process with HSE					<ol> <li>Records of dissemination activities</li> </ol>
c disease care for chronic disease across learning sites and networks and networks and networks clinical ship		<ul> <li>Specialist teams</li> </ul>	with development of enhanced community					2.Champion network
ialth es effective e ement, cing, & clinical ship		chronic disease	care for chronic disease across learning sites					3.Budget
Barriers: • Requires effective change management, resourcing, & clinical leadership		<ul> <li>Telehealth</li> </ul>	and networks					
Barriers: • Requires effective change management, resourcing, & clinical leadership								
Requires effective change management, resourcing, & clinical leadership		Barriers:						
change management, resourcing, & clinical leadership		<ul> <li>Requires effective</li> </ul>						
management, resourcing, & clinical leadership		change						
resourcing, & clinical leadership		management.						
		resourcing & clinical						
		leadership						

	patients with confirmed COPD where	Outcomes 1. Improved awareness and knowledge of guideline 2. Improved recognition and response when therapy is required when therapy is required Urr oversight in place to see implementation and KPIs and audits 2. Records of disseminated activities
	cribed to	
	d be pres	
OPD	As) should	×
lagement of C	-muscarinic (SAM	GDG team Medical Doctors involved in the care of people with COPD Nurse Prescribers
Pharmacological Management of COPD	Short acting bronchodilators 1.1 Inhaled short acting beta 2 agonists (SABAs) or short-acting anti-muscarinic (SAMAs) should be prescribed to patients with confirmed COPD where rescue therapy is needed (Grade A) (GOUD).	Develop and roll-out a communication and dissemination strategy, including public engagement
	Short acting bronchodilators 1.1 Inhaled short acting beta 2 agor rescue therapy is needed (Grade A)	Enablers: • Stakeholder engagement • Patient engagement and involvement Barriers • Cost of medication for patients who are not eligible for General Medical Scheme
	Recommendation 1	

g. dyspnoea ithlessness	d knowledge nd response ce for d activities
espiratory symptoms (e. prove lung function, brea ide A) (GOLD).	Outcomes 1. Improved awareness and knowledge of guideline 2. Improved recognition and response when therapy is required 3. Local governance in place for implementation 1. NCP oversight in place to see implementation and KPIs 2. Records of disseminated activities communication materials
e to have r ificantly im nerapy <b>(Gr</b> a	
no continu both signi <u>soto</u> ). an monotl	
e COPD wh ts (LABAs) <b>rrade B) (</b> in monoth	×
confirmed stable ting beta agonist ared to LABAs <b>(G</b> on FEV1 and sym	<ul> <li>Medical Doctors involved in the care of people with COPD</li> <li>Nurse Prescribers</li> <li>Pharmacists</li> </ul>
<ul> <li>Long acting bronchodilators</li> <li>Long acting bronchodilators should be offered to patients with confirmed stable COPD who continue to have respiratory symptoms (e.g. dyspnoea or cough) (<i>Grade A</i>) (GOLD).</li> <li>Land long acting muscarinic antagonists (LAMAs) and long acting beta agonists (LABAs) both significantly improve lung function, breathlessness and reduce exacerbations (Grade A) (GOLD).</li> <li>LAMAs have a greater impact on exacerbation frequency compared to LABAs (Grade B) (GOLD).</li> <li>LABA/LAMA combination therapy has a more profound impact on FEV1 and symptoms than monotherapy (Grade A) (GOLD).</li> <li>LAMA/LABA in combination has a greater impact on exacerbation frequency than monotherapy (Grade B) (GOLD).</li> </ul>	Develop and roll-out a communication and dissemination strategy, including public engagement
Long acting bronchodilators 2.1 Long acting bronchodilators shou or cough) ( <i>Grade A</i> ) ( <i>GOLD</i> ). 2.2 Inhaled long acting muscarinic an and reduce exacerbations ( <b>Grade A</b> ) 2.3 LAMAS have a greater impact on 2.4 LABA/LAMA combination therapy 2.5 LAMA/LABA in combination has a	Enablers: • Stakeholder engagement • Patient engagement and involvement involvement involvement • Cost of medication for patients who are not eligible for General Medical Scheme
Recommendation 2	

	Inhaled corticosteroids	S				
3	3.1 Offering an inhale	3.1 Offering an inhaled corticosteroid (ICS) in patients with confirmed stable COPD as first line therapy is not routinely recommended (Grade A)	nfirmed stable COPI	D as first li	ne therapy is	not routinely recommended <i>(Grade</i>
	(Department of Vetera 3.2 Regular treatment v	(Department of Veteran Affairs3) (Implied in GOLD). <b>3.2</b> Regular treatment with ICS increases the risk of pneumonia especially in those with severe disease <b>(Grade A)</b> (GOLD)	pecially in those wit	h severe di:	ease <b>(Grade A</b>	(eorp)
	<ul> <li>3.3 ICS should however</li> <li>3.4 Stable state blood e</li> </ul>	<ol> <li>3.3 ICS should however be considered in patients with ACOS (Expert Opinion) Guideline Development Group).</li> <li>3.4 Stable state blood eosinophil levels may be used to influence whether or not ICS should be used. Patients with blood eosinophils less than 0.1 x10<sup>9</sup> are deemed unlikely to henefit while these with levels greater than 0.3 x10<sup>9</sup> are most likely to henefit (Grade R) (GOL OL</li> </ol>	ert Opinion) Guideli whether or not ICS s n 0 3×10 <sup>9</sup> are most I	ne Develop should be us ikalv to her	ment Group). ied. Patients w efit (Grade B)	ith blood eosinophils less than 0.1 x10
	<b>3.5</b> An ICS combined with exacerling the state of the st	are decined dimension benefit while drose with every greater than 0.0000 are most mery to benefit <b>or add by potent</b> <b>3.5</b> An ICS combined with a LABA is more effective than the individual components in improving function and health status and reducing exacerbations in patients with exacerbations and moderate to very severe COPD <b>(Grade A)</b> (GOLD).	dual components in i (Grade A) (GoLD).	improving f	unction and he	alth status and reducing exacerbation
	<b>3.6</b> Triple inhaled therapy with ICS/LAMA/ LAMA/LABA or LAMA monotherapy <b>(Grad</b>	<b>3.6</b> Triple inhaled therapy with ICS/LAMA/LABA improves lung func LAMA/LABA or LAMA monotherapy <b>(Grade A)</b> (GOLD).	ction, symptoms an	d health sta	itus and reduce	(LABA improves lung function, symptoms and health status and reduces exacerbations compared to ICS/LABA, e A) (GOLD).
	Enablers: • Stakeholder engagement • Patient • Patient engagement and involvement involvement • Cost of medication for patients who are not eligible for General Medical Scheme	Develop and roll-out a communication and dissemination strategy, including public engagement	<ul> <li>Medical Doctors involved in the care of people with COPD</li> <li>Nurse Prescribers</li> <li>Pharmacists</li> </ul>	×		Outcomes 1.Improved awareness and knowledge of guideline 2. Improved recognition and response when therapy is required when therapy is required I. NCP oversight in place to see implementation and KPIs 2. Improved knowledge and competencies of HCP

	IIIIIaiei reciiiidae					
4	4.1 It is recommended	4.1 It is recommended that each patient commenced on an inhaler device would be provided with instructions and a demonstration of proper	device would be pr	rovided w	/ith instructions	and a demonstration of proper
	inhalation technique pr	inhalation technique prior to using the device and that such technique is checked with re-education on a regular basis subsequently. Inhaler technique	ue is checked with	re-educa	ation on a regula	ir basis subsequently. Inhaler technique
	and adherence to thera	and adherence to therapy should be assessed before concluding that current therapy is insufficient and a change in therapy considered (Experi	at current therapy i	is insuffic	ient and a chang	ge in therapy considered (Expert
	Opinion) (Guideline De	evelopment Group) (GOLD).			-	-
	Enablers:		• HSE	×	×	Outcomes
	<ul> <li>Stakeholder</li> </ul>	<ul> <li>Develop and roll-out a communication and</li> </ul>	<ul> <li>Community</li> </ul>			1. Improved awareness and knowledge
	engagement	dissemination strategy, including public	Pharmacists			of guideline
	<ul> <li>Patient</li> </ul>	engagement	<ul> <li>Medical</li> </ul>			2. Awareness raising in relation to the
	engagement and		Doctors			role of healthcare professionals in
	involvement	<ul> <li>Provision of access for pharmacists to an</li> </ul>	involved in the			demonstrating and assessing inhaler
	Provision of	inhaler technique education module.	care of people			technique
	consideration to		with COPD			3. Engage with Irish Institute of
	initiatives such as	<ul> <li>In the acute setting, Respiratory Nurses and</li> </ul>	<ul> <li>Respiratory</li> </ul>			Pharmacy on developing inhaler
	Inhaler Technique	Physiotherapists to ensure patients can use	Nurses			technique module for pharmacists
	Check	their inhaler properly through supervised	<ul> <li>Respiratory</li> </ul>			which can be accessed through IIOP
	<ul> <li>HSE's Living Well</li> </ul>	inhaler use. In the community, Community	Physiotherapists			website. Next steps to be confirmed
	with a Chronic	Pharmacists to demonstrate inhaler	<ul> <li>Respiratory</li> </ul>			following engagement.
	Condition:	technique when a patient is prescribed a new	Physiologists			
	Framework for Self-	inhaler. Where in place, Respiratory	<ul> <li>Practice</li> </ul>			Verification
	Management	Integrated Care Clinical Nurse Specialists to	Nurses			1.Staff training records available for
	Support	educate Practice Nurses on how to	<ul> <li>COPD Support</li> </ul>			audit
		demonstrate inhaler technique to patients	Ireland			2.improved knowledge and
	Barriers		<ul> <li>Irish Institute</li> </ul>			competencies for HCP
	<ul> <li>Lack of awareness</li> </ul>	<ul> <li>Create awareness of the availability of</li> </ul>	of Pharmacy			
	among healthcare	inhaler technique videos on COPD Support	•			
	professionals	Ireland website. HSE to consider providing	Pharmaceutical			
	regarding their role	access through HSELand so CPD points can be	Society of			
	in demonstrating	assigned to healthcare professionals.	Ireland			
	and assessing inhaler		<ul> <li>Irish</li> </ul>			
	technique	<ul> <li>Pharmaceutical companies should be</li> </ul>	Association of			
	<ul> <li>Lack of funding and</li> </ul>	encouraged to supply placebo inhaler devices	Respiratory			
	capacity for staff	to assist with demonstrations to patients	Scientists			
	training	Consider expanding "Inhaler Technique	•			
	<ul> <li>Time constraints</li> </ul>	Check" initiative to all hospitals	Pharmaceutical			
	on staff during		companies			
	patient review					

	Rofumiliast         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 phosoholdicestrases-4 (PE-4) inhibitor may be reasonable add on therapy with a LAMA and LABA and possibly (CS. Rofumiliast is not approved for inhibitor may be reasonable add on the communication and interval area constructions involvement involvement involvement and involvement and involvement and involvement and involvement and involvement and involvement area compared for area construction and interval area construction area construction and interval area construction and interval area construction area construction and area construction area construction and area construction area construction and area constructing area area construction area area area constructing are
	Roflumilast         5.1 In selected patients with the chronic bronchitic phenotype of COPD v         phosphodiesterase-4 (PDE-4) inhibitor may be reasonable add on therapreinbursement under the community drug schemes (Grade A) (GOLD).         Enablers:
<ul> <li>Limited access to placebos in order to demonstrate inhaler technique with patients</li> </ul>	Roflumilast 5.1 In selected patients phosphodiesterase-4 (P reimbursement under t Enablers: • Stakeholder engagement • Patient • • • • • • • • • • • • • • • • • • •
	5 5

Recommendation 6	Theophylline 6.1 In certain selected	Theophylline 6.1 In certain selected patients, the addition of a theophylline may be reasonable <i>(Grade B</i> ) (	be reasonable <i>(Gr</i>	<i>ide B</i> ) (GC	)LD).	
	Enablers: • Stakeholder engagement • Patient engagement and involvement Barriers: Nil expected as current practice	Develop and roll-out a communication and dissemination strategy, including public engagement	<ul> <li>Medical Doctors involved in the care of people with COPD</li> <li>Nurse Prescribers</li> <li>Pharmacists</li> </ul>	×		Outcomes 1. Improved awareness and knowledge of guideline 2. Improved recognition and response when therapy is required Werification: 1. Improved knowledge and competencies for HCP
7 7	Prophylactic use of macrolide antibiotics7.1 In patients who have severe COPD wit7.2 This needs to be done in conjunction vhearing and cardiac arrhythmias. The pote use of this medicine but is recommended0 pinion) (Guideline Development Group)Enablers:• Stakeholderengagementengagementand involvementengagementBarriersNil expected as current	Prophylactic use of macrolide antibiotics       Prophylactic use of macrolide antibiotics         7.1 In patients who have severe COPD with two treated exacerbations, the addition of azithromycin may be considered for one year (Grade A) (GOLD).         7.2 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. The potential for benefit may be less in active smokers. The use of azithromycin in this manner represents an off-label use of this medicine but is recommended in many guidelines. When considering treatment, patients should be otherwise on optimal therapy (Expert option) (Guideline Development Group).         Emablers: <ul> <li>• Medical</li> <li>• Medic</li></ul>	ons, the addition of t advice with survei ess in active smoke ess in active smoke - Medical Doctors involved in the care of people with COPD • Nurse Prescribers • Pharmacists	f azithrom illance for ers. The us ment, pati X	ycin may be cons bacterial resistar se of azithromycir ients should be o	h two treated exacerbations, the addition of azithromycin may be considered for one year (Grade A) (GOLD).         with Respiratory Specialist advice with surveillance for bacterial resistance and side effects such as impaired ential for benefit may be less in active smokers. The use of azithromycin in this manner represents an off-label in many guidelines. When considering treatment, patients should be otherwise on optimal therapy (Expert         • Medical       • Medical       I. Improved awareness and knowledge of guideline         • Medical       I. Improved awareness and knowledge of guideline       I. Improved recognition and response with COPD         • Nurse       I. Improved knowledge of guideline       I. Improved knowledge of guideline         • Nurse       I. Improved knowledge and competencies for HCP         • Pharmacists       • Pharmacists

Recommendation 8	Antioxidants and mucolytic 8.1 The use of mucolytic and	Antioxidants and mucolytic 8.1 The use of mucolytic and antioxidants in routine practice for management of patients with COPD is not recommended <sup>studies</sup> to recommend use in COPD	anagement of pati	ents with	COPD is not reco	mmended (There are currently insufficient studies to recommend use in COPD)
	Enablers: • Stakeholder engagement • Patient engagement and involvement	Develop and roll-out a communication and dissemination strategy, including public engagement	Medical     Doctors     involved in the     care of people     with COPD	×		Outcomes 1. Improved awareness and knowledge of guideline 2. Improved recognition and response when therapy is required
	<b>Barriers:</b> Nil expected as not widely used		<ul> <li>Nurse</li> <li>Prescribers</li> <li>Pharmacists</li> </ul>			<b>Verification</b> 1. Improved knowledge and competencies for HCP
Recommendation 9	Leukotriene antagonists 9.1 A role for leukotriene	Leukotriene antagonists 9.1 A role for leukotriene receptor antagonists in the management of patients with COPD is not recommended (Expert Opinion (Guideline Development Group)	of patients with C	OPD is <b>no</b>	t recommended (	Expert Opinion (Guideline Development Group)
	Enablers: • Stakeholder engagement • Patient engagement and involvement	Develop and roll-out a communication and dissemination strategy, including public engagement	Medical     Doctors     involved in the     care of people     with COPD	×		Outcomes 1. Improved awareness and knowledge of guideline 2. Improved recognition and response when therapy is required
	<b>Barriers</b> Nil expected as current practice		<ul> <li>Nurse</li> <li>Prescribers</li> <li>Pharmacists</li> </ul>			Verification 1. Improved knowledge and competencies for HCP

Recommendation 10	Alpha One Anti-trypsi 10.1 It is recommende	Alpha One Anti-trypsin (AATD) Augmentation Therapy 10.1 It is recommended that AATD augmentation therapy might be considered in young patients who have not smoked or are ex-smokers with an FEV	considered in young p	atients who have	not smoked or s	are ex-smokers with an FEV
	1 of 35-60% predicted with continued and	with continued and progressive disease (Grade B)	de B) (GOLD).			
	The National Centre fo following completion c	The National Centre for Pharmacoeconomics did not recommend reimbursement of AATD augmentation therapy in an Irish context following completion of a pharmacoeconomic evaluation, as cost-effectiveness was not demonstrated.	eimbursement of AATI ffectiveness was not d	D augmentation the monstrated.	nerapy in an Irisl	h context
	Enablers:		<ul> <li>Medical</li> </ul>		Outcomes	Sč
	<ul> <li>Stakeholder</li> </ul>	Develop and roll-out a communication and	Doctors		1. Impro	1. Improved awareness and knowledge
	engagement	dissemination strategy, including public	involved in the		of guideline	ine
	<ul> <li>Patient engagement</li> </ul>	engagement	care of people		2. Impro	2. Improved recognition and response
	and involvement		with COPD		when the	when therapy is required
	Funding for AATD	Engagement with HSE in relation to			3. Engage	3. Engage with HSE stakeholders to
	шегару		<ul> <li>nuise</li> <li>Prescribers</li> </ul>		AATD au	discuss possibility of remibul sement for AATD augmentation therapy
	Barriers				Verification	tion
	<ul> <li>Access to AATD</li> </ul>		<ul> <li>Pharmacists</li> </ul>		1. improv	<ol> <li>improved knowledge and</li> </ol>
	Therapy as not				compete	competencies for HCP
	currently tunded by HSE					

Recommendation 11	Smoking cessation 11.1 Smoking cessation measures are recom nicotine replacement therapy and pharmaco At the moment, the effectiveness and safety	Smoking cessation 11.1 Smoking cessation measures are recommended for the prevention, delay and management 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 remains uncertain.	ntion, delay and m. 11D). noking cessation a	anagemei id remain	nt of COPI s uncertai	), to inclu 1.	de advice on smoking cessation,
	Enablers:		Department	×	×	×	Outcomes
	<ul> <li>Stakeholder</li> <li>engagement</li> </ul>		of Health				<ol> <li>Improved awareness and knowledge of guideline</li> </ol>
	<ul> <li>Patient engagement</li> </ul>		• HSE				2. Awareness rising around importance
	and involvement						of smoking cessation and the role of the
	HSE's Making Every	Develop and roll-out a communication and	All healthcare				healthcare professional
	<ul> <li>Contact Count initiative</li> <li>HIOA Health</li> </ul>	dissemination strategy, including public engagement	protessionals				<ol> <li>Established patient-centred smoking reseation services in CHNs</li> </ol>
	Technoloøv Assessment		COPD Support				
	of Smoking Cessation		Ireland				
	Interventions						Verification:
	<ul> <li>HSE QUIT Team</li> </ul>						1. Patient satisfaction
	<ul> <li>Tobacco Cessation</li> </ul>						2. Improved knowledge and
	Support Programme						
	<ul> <li>COPD Support Ireland</li> </ul>						
	<ul> <li>COPD Advice line</li> </ul>						
	Development of Health						
	and well-being						
	community networks						
	Barriers:						
	<ul> <li>Cost of treatment</li> </ul>						
	<ul> <li>Lack of recognition</li> </ul>						
	that smoking is an						
	addiction						
	<ul> <li>Failure to tailor</li> </ul>						
	treatment to the						
	individual						
	<ul> <li>Lack of services and</li> </ul>						

	time to undertable the						
	intervention.						
Recommendation	Influenza vaccination						
12	<b>12.1</b> The provision of a	<b>12.1</b> The provision of an annual influenza vaccination is recommended (Grade A) (GOLD).	ded <b>(Grade A) (</b> G <b>O</b> )	гр).			
	Enablers:	Ondertake a targeted information	<ul> <li>All healthcare</li> </ul>	>	>	>	Outcomes
	<ul> <li>Stakeholder</li> </ul>	educational campaign for Respiratory	professionals	<	<	<	1. Improved awareness and knowledge
	engagement	Professionals, including consultants, through	caring for				of guideline
	<ul> <li>Patient engagement</li> </ul>	the Irish Thoracic Society.	people with				2. Awareness raising around importance
	and involvement	<ul> <li>Undertake a targeted education campaign</li> </ul>	COPD (primary				of the vaccination and role of healthcare
	National Immunisation	of all Consultants via the Irish Hospital	care,				professionals
	Office	Consultants Association	community				3. Explore feasibility of undertaking an
	<ul> <li>COPD Support Ireland</li> </ul>		including				audit of vaccination uptake or survey of
	<ul> <li>COPD Advice line</li> </ul>	<ul> <li>Undertake a targeted educational campaign</li> </ul>	pharmacies,				barriers in various settings.
		for all healthcare workers caring for patients	Long Stay,				
	Barriers	with COPD	Hospitals)				Verification:
	<ul> <li>Lack of awareness</li> </ul>	<ul> <li>Offer vaccination prior to discharge from</li> </ul>					<ol> <li>KPIs for uptake of vaccination</li> </ol>
	among patients,	hospital for anyone with COPD. At every OPD	• COPD				2.Reporting by local Hospital
	policy-makers,	visit for those with COPD, ask about and	Support Ireland				management and Hospital Group
	healthcare	encourage vaccination					management.
	professionals and	<ul> <li>Broaden access to the vaccination through</li> </ul>	<ul> <li>Hospital</li> </ul>				
	general public around	Community Pharmacists	Group/Hospital				
	the importance of the	<ul> <li>COPD Support Ireland to promote</li> </ul>	Managers/				
	vaccination for people	importance of vaccination for people with	Hospital				
	with COPD	COPD	Flu/CHO flu				
	• Lack of clarity on the	•Develop and roll-out a communication and	Leads				
	role of fiealthcare	dissernination strategy, including public					
	delivering the vaccine		Prescribers				
	<ul> <li>Existence of</li> </ul>						
	misconceptions						
	regarding possible side						
	effects of the vaccine						
	<ul> <li>People with COPD</li> </ul>						
	not featuring						
	prominently as a high-						

up in annual ins frocus on with COPD not g prominently -risk group in ampaigns endation by enal action Advisory for some als to on because of on sof COPD	Pneumococcal Vaccination 13.1 The provision of the pneumococcal vaccination is recommended (Grade B) (GOLD).	
risk group in annual campaigns • Lack of focus on people with COPD not featuring prominently as a high-risk group in annual campaigns despite annual campaigns despite recommendation by the National Immunisation Advisory • Access for some individuals to vaccination because of restrictions of COPD	Pneumococcal Vaccination 13.1 The provision of the pn	• As above for Recommendation 12
	Recommendation 13 [Priority	Recommendation]

Recommendation	Pulmonary rehabilitation	ion						
14	<b>14.1</b> The provision of p A) (GOLD).	<b>14.1</b> The provision of pulmonary rehabilitation to stable patients with exercise limitation despite pharmacological treatment is recommended (Grade A) (GOLD).	ith exercise limitat	ion despit	e pharma	icological	treatment is recommended (Grade	
	14.2 The provision of p	14.2 The provision of pulmonary rehabilitation to patients who have recently been hospitalised for an acute exacerbation of COPD is recommended	e recently been ho	spitalised	for an ac	ute exace	rbation of COPD is recommended	
	(Grade B) <i>(GOLD)</i> .							
	Enablers:	<ul> <li>Increase awareness of decision-makers</li> </ul>	• HSE	Х	X	X	Outcomes	
	<ul> <li>Stakeholder</li> </ul>	around importance and benefits of		:		:	1. Improved awareness and knowledge	_
	engagement	Pulmonary Rehabilitation for people with	<ul> <li>Medical</li> </ul>				of guideline	_
	<ul> <li>Patient engagement</li> </ul>	COPD	Doctors				2. Awareness raising of benefits of PR	_
	and involvement	<ul> <li>Secure funding for Respiratory Consultants</li> </ul>	involved in the				and include in discharge planning and	_
	<ul> <li>Local champions</li> </ul>	in hospitals that are currently without a	care of people				integrated care planning	_
	<ul> <li>Funding</li> </ul>	Respiratory Consultant	with COPD				3. It is estimated that 32 additional PR	
	<ul> <li>Space</li> </ul>	<ul> <li>Secure funding to increase medical</li> </ul>					Teams are required to meet need for PR	
	<ul> <li>Staffing</li> </ul>	respiratory physiotherapists in the acute	<ul> <li>Respiratory</li> </ul>				for people who have been hospitalised	
	<ul> <li>NCP Model of care PR</li> </ul>	setting and explore the expansion of	Physiotherapist				and are at risk of re-admission.	
	HSE's National Needs	Respiratory Integrated Care Physiotherapists					Support for funding for the recruitment	
	Assessment for	for the community	<ul> <li>Respiratory</li> </ul>				of additional PR Teams will be sought	_
	Pulmonary	<ul> <li>The inclusion of the role of medical</li> </ul>	Nurses				over 2 years (11 in Year 1; 21 in Year 2)	_
	<b>Rehabilitation Services</b>	respiratory physiotherapist in Pulmonary					through annual estimates process. If	_
					-			-

Management of Chronic Obstructive	
Pulmonary Disease (COPD)	

1. Inclusion in service plan, reporting of

Verification

PR service

2. Learning from other sites

KPIs. Budget,

I

funding secured the Team would be appointed in the year following the resources have been secured to expand

4. Selected sites engaged with in relation to roll-out of service once

request for funding.

Group/Hospital

or CHO

Develop and roll-out a communication and

dissemination strategy, including public

engagement

Support

Develop a full time

pulmonary

rehabilitation team across 3 networks in line with Community

Enhancement fund

Barriers

plan.

 Lack of existing capacity nationally

 Availability of physiotherapists

Rehabilitation to be included in their job

description

Condition: Framework for Self-Management

HSE's Living Well

with a Chronic

Hospital

Management

	<ul> <li>Funding for Pulmonary Rehabilitation</li> <li>Physical capacity</li> <li>Physical capacity</li> <li>Challenges- lack of space</li> <li>Transportation of patients to and from location of PRP</li> </ul>						
Recommendation 15	Oxygen Therapy 15.1 The provision of long-term oxygen with signs of tissue hypoxia (haematocr 15.2 The provision of oxygen for patien not routinely recommended (Grade A)	Oxygen Therapy 15.1 The provision of long-term oxygen therapy to patients with chronic stable hypoxemia with a PaO <sub>2</sub> less than 7.3kPa or a PaO <sub>2</sub> between 7.3 and 8kPa with signs of tissue hypoxia (haematocrit greater than 55%, pulmonary hypertension or cor pulmonale) is recommended ( <i>Grade A</i> ) ( <i>GOLD</i> ). 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 ( <i>Grade A</i> ) ( <i>GOLD</i> ).	ıronic stable hypox nary hypertension . a, nocturnal desatı	emia with or cor puln ıration, or	a PaO <sub>2</sub> less 1onale) is r exercise-in	than 7 ecomme duced d	3kPa or a Pa0 <sub>2</sub> between 7.3 and 8kPa ended <b>(Grade A) (GOLD).</b> esaturation in patients with COPD is
	<ul><li>Enablers:</li><li>Stakeholder</li><li>Bagement</li><li>Patient engagement</li></ul>		<ul> <li>HSE</li> <li>Hospitals/Hosp</li> <li>ital Group</li> </ul>	×	×	×	<b>Outcomes</b> 1. Consultation with stakeholders and dissemination of National Clinical Guideline for the Management of COPD
	and involvement Integrate oxygen clinics into new roles of RIC team and Outreach team in Community	Develop and roll-out a communication and dissemination strategy, including public engagement	Management • CHO Management				<ol> <li>Awareness raising of benefits of LTOT and role of HCP</li> <li>Involve in discharge planning</li> <li>Oxygen clinic set up to be incorporated into new job descriptions</li> </ol>
	enhancement fund plan Barriers • Lack of awareness		<ul> <li>Medical Doctors involved in the care of people</li> </ul>				for RIC teams and outreach teams in the Community network plans Verification
	<ul> <li>Absence of education around correct prescribing</li> <li>Cost of therapy Change of practice in sites Resource requirements</li> </ul>		with COPD <ul> <li>Nurse</li> <li>Prescribers</li> </ul>				Steering group on LTOT, evidence planning and pathways for oxygen clinics

	Recommendation	Nutritional Support						
<ul> <li>Dieticians</li> <li>Develop and roll-out a communication and dissemination strategy, including public engagement</li> <li>Medical Doctors involved in the Dissemination of HSE Standard Oral Nutritional Supplements Prescribing List for Adults Living in the Community (guide to prescribers re ONS)</li> <li>HCP involved in the care of people with COPD</li> </ul>		16.1 Nutritional suppo	rt should be considered in all malnourished p	atients with COPD	(Grade B	(GOLD).		
Develop and roll-out a communication and dissemination strategy, including public engagement involved in the Dissemination of HSE Standard Oral Nutritional Supplements Prescribing List for Adults Living in the Community (guide to prescribers re ONS) - HCP involved in the care of people with COPD		Enablers:		<ul> <li>Dieticians</li> </ul>	×	×	×	Outcomes
dissemination strategy, including public engagement Dissemination of HSE Standard Oral Nutritional Supplements Prescribing List for Adults Living in the Community (guide to prescribers re ONS)		<ul> <li>Stakeholder</li> </ul>	Develop and roll-out a communication and		:	:	:	1. Improved awareness and knowledge
engagement Dissemination of HSE Standard Oral Nutritional Supplements Prescribing List for Adults Living in the Community (guide to prescribers re ONS)		engagement	dissemination strategy, including public	<ul> <li>Medical</li> </ul>				of guideline
Dissemination of HSE Standard Oral Nutritional Supplements Prescribing List for Adults Living in the Community (guide to prescribers re ONS)		<ul> <li>Patient engagement</li> </ul>	engagement	Doctors				2. Awareness rising of benefits of
Dissemination of HSE Standard Oral Nutritional Supplements Prescribing List for Adults Living in the Community (guide to prescribers re ONS)		and involvement		involved in the				nutrition for staff and patients
Nutritional Supplements Prescribing List for Adults Living in the Community (guide to prescribers re ONS)			Dissemination of HSE Standard Oral	care of people				3. Improved recognition and response
Adults Living in the Community (guide to prescribers re ONS)		Barriers	Nutritional Supplements Prescribing List for	with COPD				when therapy is required
prescribers re ONS)		<ul> <li>Lack of awareness of</li> </ul>	Adults Living in the Community (guide to					
		the importance of	prescribers re ONS)					
		dieticians in the		<ul> <li>HCP involved</li> </ul>				Verification
		management of COPD		in the care of				Local audit
		<ul> <li>Absence of specialist</li> </ul>		people with				
the care of people with COPD - Inconsistent use of nutritional screening tools to detect malnutrition in people with COPD		dietetic input/posts in		COPD				
COPD •Inconsistent use of nutritional screening tools to detect malnutrition in people with COPD		the care of people with						
Inconsistent use of Intritional screening tools to detect malnutrition in people with COPD		COPD						
nutritional screening tools to detect malnutrition in people with COPD		<ul> <li>Inconsistent use of</li> </ul>						
tools to detect malnutrition in people with COPD		nutritional screening						
malnutrition in people with COPD		tools to detect						
with COD		malnutrition in people						
		with COPD						
-								

17	<b>17.1</b> Lung volume reduction surgery capacity (Grade A) (GOLD).	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).	selected patients w	/ith uppe	r lobe em	physema	and low post rehabilitation exercise
	17.2 In selected patien 17.3 In selected patien	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	irade C) (GOLD). ic interventions car	reduce	end-expir	atory lung	s volume and improve exercise
	tolerance; health status and lung function (Grade B) (GOLD).	us and lung function at 6 to 12 months follow	ving treatment. End	lobronchi	al valves	(Grade A)	at 6 to 12 months following treatment. Endobronchial valves (Grade A); Lung coils (Grade B); Vapour ablation
	Enablers:		<ul> <li>Medical</li> </ul>	×	×	×	Outcomes
	Stakeholder		Doctors	:	:	:	1. Improved awareness and knowledge
	<ul> <li>engagement</li> <li>Datient engagement</li> </ul>	Develop and roll-out a communication and	involved in the				of guideline 2. Immoved recommition and reconnee
	and involvement	dissemination strateev including public	with COPD				2: IIIIproved recognition and response when therapy is required
	Barriers	engagement					3. Awareness raising
	• The small volume of		<ul> <li>Thoracic</li> </ul>				4. Access to surgery
	suitable patients has		Surgeons				
	led to a lack of						Verification
	awareness of the						1. Reporting by local Hospital
	importance of lung						management and Hospital Group
	volume reduction						management.
	surgery in some cases						
Recommendation	Lung transplantation						
18	<b>18.1</b> It is recommended that appropriately		ery severe COPD b	e conside	ered for lu	ung transp	selected patients with very severe COPD be considered for lung transplantation surgery (Grade C) (GOLD).
	Enablers:		• HSE	×	×	×	Outcomes
	<ul> <li>Stakeholder</li> </ul>				:	:	1.Improved awareness and knowledge
	engagement		<ul> <li>Department</li> </ul>				of guideline
	<ul> <li>Patient engagement</li> </ul>	Develop and roll-out a communication and	of Health				2. Improved recognition and response
	and involvement	dissemination strategy, including public	Medical				when therapy is required
	campaign		Doctors				Verification
			involved in the				1. Reporting by local Hospital
	Barriers		care of people				management and Hospital Group
	<ul> <li>Limited availability of</li> </ul>		with COPD				management.
	organ donors						
	<ul> <li>Lack of awareness of</li> </ul>		<ul> <li>Thoracic</li> </ul>				
	lung transplantation for		Surgeons				

Recommendation 19	Monitoring of Spirometry 19.1 In stable, diagnosed COPD patients,	COPD patients,	irometry every tw	o years <b>(E</b>	xpert Op	inion) (G	FEV 1 can be tracked by spirometry every two years <b>(Expert Opinion</b> ) (Guideline Development Group).
	Enablers: • Stakeholder • Stakeholder engagement • Patient engagement and involvement • Practice Nurses • Spirometry Training Course provided by the Irish Association of Respiratory Scientists Expanding diagnostics into the community through the community through the community enhancement fund Barriers Lack of awareness of role of spirometry in management of COPD	<ul> <li>Increase awareness of performing spirometry on stable COPD patients at appropriate time interval</li> <li>Continue to raise awareness in relation to availability of Spirometry Training Course for healthcare professionals</li> <li>Develop and roll-out a communication and dissemination strategy, including public engagement</li> </ul>	<ul> <li>Hospital Group Management</li> <li>All healthcare professionals providing care to people with COPD</li> <li>Irish</li> <li>Irish</li> <li>Irish</li> <li>Scontion of Respiratory</li> </ul>	×	×	×	Outcomes 1. Improved awareness and knowledge of guideline 2. Training for HCP 3. Posts for spirometry for community to support community enhancement fund plan Verification: 1. Attendance records at training QI projects based on training
Recommendation 20	Role of Palliative Care 20.1 For advanced COF Group). Enablers: • Stakeholder engagement • Patient engagement and involvement Specialist Palliative Care Teams • Patient material e.g. Planning for the Future with COPD • Guidance documents developed by the	Role of Palliative Care       Role of Palliative Care       Role of Palliative Care       Sappropriate (Expert Opinion) (Guideline Development Group)         20.1 For advanced COPD care, patients should be referred to a palliative care specialist as appropriate (Expert Opinion) (Guideline Development Group)       20.1 For advanced COPD care, patients should be referred to a palliative care specialist as appropriate (Expert Opinion) (Guideline Development Group)         Group).       Emablers: <ul> <li>Increase awareness of the role of Palliative</li> <li>Stateholder</li> <li>Promotion of Palliative Care Needs</li> <li>Perimetion of Palliative Care Needs</li> <li>Premotion of Palliative</li> <li>Promotion of Palliative</li> <li>Premotion of Palliative</li> <li>Premotion of Palliative</li> <li>Premotion of Palliative</li> <li>Premotion of Palliative</li> <li>Promotion of Palliative</li> <li>Promotion of Palliative</li> <li>Promotion of Palliative</li> <li>Premotion of Palliative</li> <li>Promotion of Palliative</li></ul>	ative care specialis • Palliative Care Specialists and Team • Medical Doctors involved in the care of people with COPD • Respiratory Nurses	x as appr	ppriate (E ×	xpert Op ×	<ul> <li>(nion) (Guideline Development Group).</li> <li>Outcomes <ol> <li>Improved awareness and knowledge of guideline</li> <li>Protocol for management of care agreed</li> <li>Improved recognition and response when therapy is required response when therapy is required</li> </ol> </li> <li>Verification <ol> <li>Reporting by local Hospital management and Hospital Group</li> </ol> </li> </ul>

management.																											
	<ul> <li>Respiratory</li> </ul>	Physiotherapists		HSE - National	Clinical	Programme for	Palliative Care																		 	 	
National Clinical	Programme for COPD	(Palliative Care Needs	Assessment, Role	Delineation	Framework,	Competency	Framework, Palliative	Care Model of Care)	Barriers:	Existing	misconceptions in	relation to the role of	palliative care in the	management of COPD	among healthcare	professionals, patients	and their	families/carers.	<ul> <li>Lack of awareness of</li> </ul>	services available	through Specialist	Palliative Care Teams		 	 	 	 

		Managemen	Management of Exacerbations in COPD	ions in C	OPD	
Recommendation 21	Bronchodilator therapy 21.1 The initiation of short acting exacerbation of COPD (Grade C)	Bronchodilator therapy 21.1 The initiation of short acting acute bronchodilator therapy (salbutamol, ipratropium or combination) is recommended for patients with an exacerbation of COPD (Grade C) (GOLD).	Ibutamol, ipratrop	bium or col	mbination) is reco	mmended for patients with an
	<ul> <li>Enablers:</li> <li>Stakeholder</li> <li>Bragement</li> <li>Patient engagement</li> <li>and involvement</li> </ul>	Develop and roll-out a communication and dissemination strategy, including public engagement	Medical     Doctors     involved in the     care of people     with COPD	×		Outcomes 1. Improved awareness and knowledge of guideline 2. Improved recognition and response when therapy is required
	<b>Barriers</b> Nil expected as funding is available		<ul> <li>Nurse</li> <li>Prescribers</li> <li>Pharmacists</li> </ul>			<b>Verification</b> Local audit
Recommendation 22	<b>Steroids</b> <b>22.1</b> A course of system recommended. Therap'	<b>Steroids</b> <b>22.1</b> A course of systemic steroids (prednisolone recommended dose of 40mgs once daily for five days) to be administered orally to all patients is recommended. Therapy should not routinely be administrated for longer than this <i>(Grade A) (GOLD</i> ).	se of 40mgs once longer than this <b>(G</b>	daily for fi <b>5rade A) (</b> (	ve days) to be ad <u>50LD</u> ).	ministered orally to all patients is
	Enablers: • Stakeholder engagement	Develop and roll-out a communication and dissemination strategy, including public engagement	<ul> <li>Medical Doctors involved in the care of people with COPD</li> </ul>	×		Outcomes 1. Improved awareness and knowledge of guideline 2. Improved recognition and response when therapy is required
	<ul> <li>Patient engagement and involvement</li> </ul>		<ul> <li>Nurse</li> <li>Prescribers</li> </ul>			
	<b>Barriers</b> Nil expected as funding is available		<ul> <li>Pharmacists'</li> </ul>			

Recommendation 23	Antibiotics 23.1 Oral antibiotic use volume is recommende such as quinolones for patterns or an individu	Antibiotics 23.1 Oral antibiotic use for patients with exacerbations of COPD associated with increased dyspnoea and associated increased sputum purulence 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. However, the choice of antibiotics may be modified due to local bacterial resistance patterns or an individual's sputum microbiology (Grade B) (GOLD/Expert Opinion Guideline Development Group).	sociated with incre e doxycycline, amo er, the choice of al <i>Sxpert Opinion Gui</i>	ased dysp xicillin or a ntibiotics <i>deline De</i>	onoea and a a macrolide may be mo <i>velopmen</i> t	associate e, reserv dified di <i>Group</i> ).	d increased sputum purulence or ing broader spectrum antibiotics ue to local bacterial resistance
	<ul> <li>Enablers:</li> <li>Stakeholder</li> <li>engagement</li> <li>Patient engagement</li> <li>and involvement</li> </ul>	Develop and roll-out a communication and dissemination strategy, including public engagement	Medical     Doctors     involved in the     care of people     with COPD	×			Outcomes 1. Improved awareness and knowledge of guideline 2. Improved recognition and response when therapy is required
	<b>Barriers</b> Nil expected as funding is available		<ul> <li>Nurse</li> <li>Prescribers</li> <li>Respiratory</li> <li>Physiotherapists</li> </ul>				Verification
			Nurse     Prescribers				
Recommendation 24	Non-invasive ventilation 24.1 The use of non-invasive ventilation i acidosis is recommended i.e. a PaCO <sub>2</sub> gre oxygen therapy (Grade A) (GOLD).	Non-invasive ventilation 24.1 The use of non-invasive ventilation in patients with acute exacerbations of COPD who develop acute respiratory failure associated with respi acidosis is recommended i.e. a PaCO <sub>2</sub> greater than 6kPa and an arterial PH less than 7.35 which is persistent following rationalization of delivered oxygen therapy (Grade A) (GOLD).	erbations of COPD erial PH less than 7	who deve .35 which	elop acute i is persister	respirato nt follow	in patients with acute exacerbations of COPD who develop acute respiratory failure associated with respiratory ater than 6kPa and an arterial PH less than 7.35 which is persistent following rationalization of delivered
	Enablers: • Stakeholder • Stakeholder engagement • Patient engagement and involvement • Education - Centre for Nurse and Midwifery Education provides NIV training Barriers • Lack of resources	<ul> <li>Increase NIV protocol awareness</li> <li>Increase awareness of NIV training</li> <li>Develop and roll-out a communication and dissemination strategy, including public engagement</li> </ul>	<ul> <li>Medical Doctors involved in the care of people with COPD</li> <li>Respiratory</li> <li>Nurses</li> <li>HSE</li> </ul>	×	×	×	<b>Outcomes</b> 1. Improved awareness and knowledge of guideline 2. Improved recognition and response when therapy is required 3. Pathways criteria in place Verification 1. Pathways in place 2. local service audit

	(funding not available) • Lack of familiarity/use of NIV • Lack of training to deliver NIV						
Recommendation	COPD Outreach Service	Ð					
25	25.1 The involvement	25.1 The involvement of the COPD outreach team as early as possible in the care of patients admitted to hospital with an exacerbation of COPD	ble in the care of p	atients ad	Imitted to	hospital	with an exacerbation of COPD
[Priority	(Expert Opinion) (Guid	leline Development Group).					
Recommendation]	Enablers: • Stakeholder	<ul> <li>Hospital Group/Hospital Management to seek COPD Outreach Service from HSE.</li> </ul>	• HSE	×	×	×	Outcomes 1.Improved awareness and knowledge
	engagement	<ul> <li>Increase awareness of benefits of Outreach</li> </ul>	<ul> <li>Hospital</li> </ul>				of guideline
	<ul> <li>Patient engagement</li> </ul>	Service in the management of COPD	Group				2. Improved recognition and response
	and involvement	<ul> <li>Develop and roll-out a communication and discomination strategy including public</li> </ul>	Management				when Outreach is indicated 3-14 is actimated that 15 sites require a
	NCP Outreach	engagement	<ul> <li>Respiratory</li> </ul>				COPD Outreach Service. Support for
	Implementation guide		Medical Doctors				funding for expansion of sites through
			involved in the				recruitment of staff will be sought over
	Barriers		care of people				3 years (4 sites in Year 1; 11 sites in Year
	<ul> <li>Lack of availability of</li> </ul>		with COPD				2) through annual estimates process. If
	trained staff to provide						funding is secured, appointments would
	the service		<ul> <li>Respiratory</li> </ul>				be made in the year following funding
	<ul> <li>Lack of awareness of</li> </ul>		Clinical Nurse				submission.
	benefits of Outreach		Specialists				4. Selected sites engaged with in
	Service for people with						relation to roll-out of service once
	COPD		<ul> <li>Respiratory</li> </ul>				resources have been secured to provide
	<ul> <li>Lack of funding to</li> </ul>		Physiotherapists				an Outreach service
	expand service to new		COPD Support				Verification
	sites		Ireland				1. Inclusion in service plan, reporting of
							KPIs. Budget,
							2. System in place to share
							implementation experiences and
							learning between sites.
							3. local reporting

Recommendation 26	Respiratory Health Care Professionals 26.1 It is recommended that a multidis (Guideline Development Group).	Respiratory Health Care Professionals 26.1 It is recommended that a multidisciplinary team of respiratory specialists are key in delivering integrated care for COPD (Expert Opinion) (Guideline Development Group).	· specialists are key	in delive	ring integ	rated car	e for COPD (Expert Opinion)
	Enablers - Advanced and on- going workforce planning and CPD support for HCP Barriers - Costs - Lack of specialist respiratory physiotherapists & CNSsp - Lack of awareness of importance of role of HCP in the management of COPD - Failure to recognise the value of HCP in the management of COPD	<ul> <li>Raising awareness of role of physiotherapists and CNSp amongst medical practitioners</li> <li>Development of physiotherapist &amp; CNSp led clinics</li> <li>Increasing the profile of physiotherapists and CNSp within a service e.g. presenting at Grand Rounds, engagement with GPs</li> </ul>	<ul> <li>Respiratory</li> <li>Consultants</li> <li>Physiotherapists</li> <li>Physiotherapists</li> <li>Physiotherapy</li> <li>Allied</li> <li>Healthcare</li> <li>Professional</li> <li>Managers</li> <li>Hospital Group</li> <li>and CHO</li> <li>Managers</li> <li>Hospital Group</li> <li>and CHO</li> <li>Managers</li> <li>Hospital Group</li> <li>and CHO</li> <li>Managers</li> <li>Professions</li> <li>Insh Social</li> <li>Health &amp; Social</li> <li>Care</li> <li>INMO</li> <li>Office</li> <li>INMO</li> </ul>	×	×	×	<b>Outcomes</b> 1. Consultation with stakeholders and dissemination of National Clinical Guideline for the Management of COPD 2. Improved recognition and awareness of roles of respiratory health professionals <b>Verification</b> 1. MDT meetings and case management

Recommendation 27	Theophylline 27.1 The use of theophy	Theophylline 27.1 The use of theophylline in acute exacerbations of COPD is not recommended (Grade B) (GOLD).	mmended (Grade B)	(GOLD).			
	Enablers: • Stakeholder engagement • Patient engagement and involvement	Develop and roll-out a communication and dissemination strategy, including public engagement	Medical     Doctors     involved in the     care of people     with COPD	×			Outcomes 1. Improved awareness and knowledge of guideline 2. Improved recognition and response when therapy is required
	<ul> <li>Barriers</li> <li>Resistance to change</li> <li>Nil expected as</li> <li>funding is available</li> </ul>		Nurse     Prescribers				Verification 1. Increased knowledge and competencies of HCP
Recommendation	Oxygen therapy prescribing and monitorin	ribing and monitoring in COPD	-				
28	<b>28.1</b> For acutely unwell patients with COPD	ll patients with COPD who are hypoxic and po	otentially at risk fo	r hyperca	pnia a tar	get satura	who are hypoxic and potentially at risk for hypercapnia a target saturation range (SpO <sub>2</sub> ) of 88-92% is
[Priority Recommendation]	suggested pending art 28.2 Patients discharg	suggested pending arterial blood gas results (Expert Opimon) (Guideline Development Group). 28.2 Patients discharged home following hospitalisation on oxygen therapy should be evaluated for the need to remain on long term oxygen therapy	therapy should be	e evaluate	d for the	need to r	emain on long term oxygen therapy
	60-90 days after discharge and during a per the criteria (Expert Opinion) (Guideline Der	60-90 days after discharge and during a period of relative clinical stability. Long term oxygen therapy should not be continued if patients do not meet the criteria <i>(Expert Opinion) (Guideline Development Group).</i>	ability. Long term	oxygen th	erapy sho	uld not b	e continued if patients do not meet
	28.3 Routinely offering	28.3 Routinely offering ambulatory LTOT for patients with chronic, stable COPD and isolated exercise-induced hypoxemia is not recommended (Grade	stable COPD and i	solated ex	kercise-ind	luced hyp	ooxemia is not recommended (Grade
	28.4 Patients with stable COPD with persist	ole COPD with persistent evidence of hypoxae	emia (i.e.: SpO <sub>2</sub> ≤9:	2%) shoul	d be asses	sed for lo	ent evidence of hypoxaemia (i.e.: SpO₂ ≤92%) should be assessed for long term oxygen therapy (Expert
	Opinion) Guideline Development Group.	ivelopment Group.		dtim cimo		5 2 4 2 2	2 Lbs of a Dod hot the the the
	8kPa with signs of tissu	<b>26.3</b> The provision of fourg-term oxygen unerapy to partents with chromic statute hypoxening with a rady ress than 7.5 kra of a rady between 7.5 and 8kPa with signs of tissue hypoxia (haematocrit greater than 55%, pulmonary hypertension or cor pulmonale) is recommended ( <b>Grade A</b> ) (GOLD).	ulmonary hyperter	Ision or co	or pulmon	ale) is re	commended (Grade A) (GOLD).
	<b>28.6</b> The provision of c not routinely recomme	28.6 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).	a, nocturnal desati	uration, o	r exercise	-induced	desaturation in patients with COPD is
	Enablers:	The development of regional centres	• HSE	×	×	×	Outcomes
	<ul> <li>Stakeholder</li> </ul>	providing oxygen assessment and review	<ul> <li>Hospital</li> </ul>	<	<	<	1. Improved awareness and knowledge
	engagement	(OAR) clinics which have capacity to provide	Group				of guideline
	<ul> <li>Patient engagement and involvement</li> </ul>	home visits and link with community respiratory teams should be funded and	<ul> <li>Management</li> <li>CHO</li> </ul>				<ol><li>Improved education and competency of Oxygen therapy for HCP</li></ol>
	<ul> <li>Incorporate oxygen</li> </ul>	prioritised.	Management				Improved recognition and response
	clinics into roles of RIC	Hospital/Hospital Groups to seek funding	Medical				when therapy is required
	team and Outreach	from HSE for expansion of oxygen clinics	Doctors				3. It is estimated that 32 sites require an

Oxygen Assessment Clinic. Support for funding for expansion of sites through recruitment of staff will be sought over 2 years (11 sites in Year 1; 21 sites in Year 2 through annual estimates process. If funding is approved, appointments will be made in the year following the submission for funding 4. Selected sites engaged with in relation to the establishment of clinics once resources have been securedVerification 2. Pathways in place for clinics and prescription and follow up 3. Education material staff and patients 4. Patient satisfaction survey 5. Service audit	Pathways, Bundles and Checklists for Managing Acute Exacerbation         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 Option) (Guideline Development Group).         29.1 It is recommended that an admission and discharge bundle search at a dmission and discharge bundle and more and and and recellars and promotion of the vary of crup regenent: <ul> <li>• Extender</li> <li>• Extender</li> <li>• Extender</li> <li>• extent to group of the and mission of the vary forup regenent:</li> <li>• materials tad promotion of the vary forup and involvement.</li> <li>• Pathways and bundles of care of guideline</li> <li>• Improved a tectorically so no large scale and involvement.</li> <li>• Dutomes development of pathways</li> <li>• Dutomes of the pathways</li></ul>
involved in the care of people with COPD • Respiratory Nurses • Respiratory Physiotherapists • Nurse Prescribers • Oxygen companies	e applied to all patients - COPD Clinical Advisory Group Medical Doctors involved in the care of people with COPD - Respiratory Nurses - Hospital Group Management
<ul> <li>Develop and roll-out a communication and dissemination strategy, including public engagement Irish Guidelines on Long Term Oxygen Therapy in Adults 2015</li> <li>Irish Guidelines on the Administration of Oxygen Therapy in the Acute Clinical Setting in Adults 2017</li> </ul>	A Checklists for Managing Acute Exacerbation A that an admission and discharge bundle be a velopment Group). Increase awareness through dissemination of materials relating to pathways, bundles and checklists and promotion of the value of implementing the materials. Materials to be circulated electronically so no large scale printing or postage costs incurred.
teams for Community enhancement fund plans Barriers • Lack of formal follow up for many patients prescribed domiciliary oxygen • Lack of dedicated oxygen assessment and review services • Lack of awareness around benefits of oxygen assessment	Pathways, Bundles and Checklists for29.1 It is recommended that an admisOpinion) (Guideline Development Grant29.1 It is recommended that an admis29.1 It is recommended that an admisCopinion) (Guideline Development Grant• Patient engagement• Programme for COPD• Resistance to change• In practice• Resistance to changein practice• Resistance to changein practice• Resistance to changein practice• Resistance to changein practice• Resourcing and timeconstraints for MedicalDoctors involved in theconstraints for MedicalDoctors involved withCOPD to applypathways, bundles andchecklistschecklists
	Recommendation 29 Recommendation]

## Implementation of overall guideline

While the implementation plan is specific to the individual recommendations in the guideline, some actions will assist with guideline implementation as a whole. These include establishing an implementation team, developing a dissemination and communication plan and developing specific implementation tools and resources. In the boxes below, please give a high-level description of how these actions will be incorporated into the implementation of your guideline:

**Implementation team:** Describe the structure and governance of your implementation team, list your implementation team members and specify meeting frequency. Outline planned training and capacity building for team members.

- Central Respiratory National Team NCP Respiratory / PMO / Chronic Disease Team
- Local Level Local Implementation Governance Groups (LIGG) to include Practice Development and QI Team. Example of membership would be executive manager, clinical lead /consultant, senior nurse manager, frontline staff, education facilitator, self-management support, respiratory leads, risk management

**Dissemination and communication plan:** Describe your communications strategy and dissemination plan for distributing, sharing, promoting and applying guideline recommendations e.g. publications/articles, presentations, awareness-raising activities, media, knowledge transfer, collaboration and networking.

- HRB CICER Publication
- Communication / Marketing: NCP Respiratory Website /NCP Respiratory Email Account / Twitter / Flyers / Infographics/ local hospital newsletters/intranets/ National conferences e.g. Patient Safety Conference
- Organise an inaugural Respiratory Integrated Care international conference for Ireland
- Case scenarios to be used in undergraduate/CPD education
- Communicate with hospitals on their key responsibilities and expectations e.g. all staff to have protected time to participate in education, review and improvement of governance, embed in existing forums/meetings, journal clubs, ground rounds etc.

Key communication messages:

- Shift to integrated care
- Supports implementation of Sláintecare

**Implementation tools:** List the supporting tools and resources developed to support this guideline/PPPG and where these tools can be accessed, e.g. materials on website, patient information leaflets, training linked to CPD, e-learning, podcasts, study days, research, checklists, audit tools, seminars, conference, patient pathways, toolkits, algorithms, teaching aids, presentations.

- Education Programme: Blended Learning Programme e- learning / face to face training / simulation training / study days / education forums / case scenarios to use for undergraduate and postgraduate training
- Communication / Marketing: NCP Respiratory Website / NCP Respiratory Email Account / Twitter / Flyers / Infographics/ local hospital newsletters/intranets/ National conferences e.g. Patient Safety Conference
- Clinical Audit Tools / Data Collection Tools / Reporting Tools / Clinical Outcome Monitoring Tools.
- Research Proposals

## **Appendix 8: COPD Audit Tool**

## **COPD Audit Tool**

Choose the criteria from below on which to conduct your audit and then set your standard (sometimes known as your target). This is your desired level of performance and is usually stated as a percentage. Beware of setting standards of 100%; standards should be realistic for your practice (perfection may not be possible).

There is no minimum or maximum number of patients stipulated, however your sample should include current/ recent patients. In general, if you have a very small number of patients with the condition being considered, it is recommended that you examine a greater number of criteria in these patients. By contrast in an audit of a very large number of patients it may only be necessary to examine one criterion.

## Criteria

- Spirometry should be performed to diagnose COPD.
- All COPD patients should be offered an annual influenza immunisation.
- All COPD Patients should be offered pneumococcal vaccine
- Patients smoking status should be recorded and if smoking, should be given brief smoking cessation advice at every contact with a health professional.
- Inhaler technique training and review at contact with appropriate health professional.
- Timely referral and access to Pulmonary rehabilitation
- Timely referral and access to COPD outreach and early support discharge services.
- Timely referral and access to oxygen therapy
- Number of above who received a personalised holistic review to include:
- Comorbidities, frailty, medicines optimisation, plan for exacerbation, end of life care
- Standards of care to include admission pathway, post exacerbation pathway, discharge bundle and seamless transition between hospital and community care.
- Self-management plan for managing exacerbations
- Referral and access to MDT support

## **Data Collection Tool**

## Criteria 1:

- Number of cases of COPD reviewed for this audit.
- Number of the above that have had diagnostic spirometry.

## Criteria 2:

- Number of cases of COPD reviewed for this audit.
- Number of the above that were offered influenza vaccination in the last flu season.

## Criteria 3

- Number of cases of COPD reviewed for this audit.
- Number of the above that have ever had pneumococcal vaccination.
- Number of those who had not, who were offered pneumococcal vaccination.

## Criteria 4

- Number of cases of COPD reviewed for this audit.
- Number of the above that have their smoking status recorded.
- Number of above who are current smokers.
- Number of the above given smoking cessation advice

#### Criteria 5

- Number of cases of COPD reviewed for this audit.
- Number of above where inhaler technique reviewed and recorded at last visit.

#### Criteria 6

- Number of cases of COPD reviewed for this audit.
- Number of above with referral to a PRP

## Criteria 7

- Number of cases of COPD reviewed for this audit.
- Number of above who received a personalised holistic review to include:
- Comorbidities, frailty, medicines optimisation, plan for exacerbation, end of life care

#### Criteria 8

- Number of cases of COPD reviewed for this audit.
- Number of Inpatient cases treatment in accordance with End-to-End MOC for COPD standards including admission pathway, post exacerbation pathway, discharge bundle and seamless transition between hospital and community care

#### Criteria 9

- Number of cases of COPD reviewed for this audit.
- Number of above with a self-management plan for managing an exacerbation

## Criteria 10

- Number of cases of COPD reviewed for this audit.
- Number of above with referral and timely access to COPD Outreach

## Criteria 11

- Number of cases of COPD reviewed for this audit.
- Number of above with referral and timely access to oxygen assessment and therapy

## Criteria 12

- Number of cases of COPD reviewed for this audit.
- Number of above with access to specialist services for severe COPD e.g., oxygen therapy, lung volume reduction and NIV.

## Criteria 13

- Number of cases of COPD reviewed for this audit.
- Number of above with access to MDT supportive care approach

## The next steps are to:

- Analyse and interpret your data via comparison with your target.
- Decide on what changes need to be made and to implement these changes.
- Re-audit

Adapted from ICGP Audit Toolkit, which is available on the ICGP Website at: http://www.icgp.ie/audit

# **Appendix 9: Supporting tools**

End to End COPD MOC.

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-managementbundle.pdf

COPD Discharge Plan.

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

A guidance document for setting up Pulmonary Rehabilitation for Healthcare Professionals (2020).

https://www.hse.ie/eng/about/who/cspd/ncps/copd/resources/hse-guidance-document-on-pulmonaryrehabilitation.pdf

A guidance document for setting up COPD Outreach services for Healthcare professionals (2020).

<u>https://www.hse.ie/eng/about/who/cspd/ncps/copd/resources/national-clinical-programme-for-respiratory.</u> <u>pdf</u>

National Framework for the Integrated Prevention and Management of Chronic Disease in Ireland 2020-2025

https://www.hse.ie/eng/about/who/cspd/icp/chronic-disease/documents/national-framework-integratedcare.pdf

National Framework for the Integrated Prevention and Management of Chronic Disease in Ireland 2020 – 2025: A 10 step guide

https://www.hse.ie/eng/about/who/cspd/icp/chronic-disease/documents/the-chronic-disease-integratedcare-programme-10-step-guide.pdf

Integrated MOC for the Prevention and Management of Chronic Disease

https://www.hse.ie/eng/about/who/cspd/icp/chronic-disease/documents/chronic-disease-service-modelimplementation-resource-pack.pdf

## Appendix 10: 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 7.

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 QI initiatives. Most of the data will be available from the within implementation and monitoring processes (preand 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 QI. 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 ICGP 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. For sample tool see Appendix 8.

# **Appendix 11: Roles of the multidisciplinary teams**

COPD Multidisciplinary Team	
Consultant Respiratory Physician	<b>Hospital based.</b> Provides a point of reference for specialist advice and support on the management of COPD patients to members of the MDT looking after such patients in primary and secondary care. Responsible for the development of integrated care to encompass appropriate inpatient care including supervision of oxygen assessment and non- invasive ventilation. Supervises the provision of diagnostic facilities in the community as well as in hospital.
	Facilitates the development of Pulmonary Rehabilitation both in hospital and in the community.
	Provides support and advice to the secondary care and integrated care respiratory nurses and physiotherapist and cANP.
General Practitioner (GP)	<b>Primary Care Service</b> Key health professional for the majority of patients with COPD. They provide assessment, diagnosis, treatment, and on-going monitoring of patients with COPD. Referral for specialist respiratory services when required.
Practice Nurse	<b>Primary Care Service</b> Works with GP, providing regular structured review, performs spirometry for diagnosis, education, support, and advice on lifestyle changes including smoking cessation, provision of vaccination, instruction in inhaler technique and self-management.
Hospital Pharmacist	Hospital based. Provides and supports medicine reconciliation on admission, during the inpatient stay and discharge. Assists the nursing and medical team in providing medicine advice and the education and training of patients in the correct use of medications.
Community Pharmacist	Plays a key role in helping COPD patients manage the disease. Provides information on medication and medication review, inhaler technique training together with an explanation of self-management plans if suitably skilled. They can also provide assistance in education in smoking cessation and general health and wellbeing.

Respiratory - Integrated Care Nurse (CNSp)	<ul> <li>Primary Care</li> <li>Provides specialist support to general practice in review of COPD patients, providing direct clinical care, information, education and support.</li> <li>Facilitates evidence-based diagnosis and management of patients with COPD, providing spirometry testing, assessment and advice on management, review of inhaler therapy and technique, supporting self-management, lifestyle changes including smoking cessation, exercise and breathing control techniques, oxygen assessment and care of NIV, and supporting/providing symptom control management and provide or refer to the PRP.</li> </ul>
	Provides COPD related education to patients, their families/carers and the wider MDT.
	Provides an integrated link to secondary care specialist support
Respiratory Clinical Nurse Specialist (CNSp)	<b>Hospital based</b> The hospital based respiratory nurse cares for patients and their families/carers with COPD by providing direct clinical care, information, education and support.
	Facilitates evidence-based diagnosis and management of patients with COPD, providing spirometry testing, assessment and advice on management, review of inhaler therapy and technique, supporting self-management, lifestyle changes including smoking cessation, exercise and breathing control techniques, oxygen assessment and care of NIV, and supporting/providing symptom control management and PRP.
	Provides education for patients, their families/carers and the wider MDT.
Advanced Nurse Practitioner (ANP)	Hospital based Works autonomously to provide care for patients and their families/ carers with COPD. Provides independent nurse led clinics for COPD patients, facilitating evidenced based diagnosis and management and oxygen assessment (including distinct oxygen assessment clinics) Provides case management and support for the on-going care of specific patients in collaboration with the Patient's Consultant, GP, and the wider MDT. Provides education for patients, their families/carers and the wider MDT.

Senior Physiotherapist – Integrated Care	<b>Community Service</b> Works within the community setting with the main focus to support the development of the PRP in the community.
	Also provides spirometry testing, assessment and review of inhaler therapy and technique and education in self-management strategies. Focuses on developing patient knowledge and skills in airway clearance, breathing control and exercise.
	Provides education with, patients, their families/carers and the wider MDT in, disease education evidenced based management the prevention of disease progression and self-management support.
	Provides an integrated link to secondary care specialist support.
Respiratory Physiotherapist	<b>Hospital based</b> The hospital based respiratory physiotherapist manages patients with COPD, and provides care through breathlessness management, use of NIV, exercise prescription, oxygen assessment, supporting self-management and airway clearance where applicable.
Advanced Practice Physiotherapists	Hospital based Provides and interprets spirometry.
	Takes and interprets ABGs, advises on LTOT and AOT and assessment and management of a consultant caseload. COPD Outreach and Respiratory Integrated Care Physiotherapists are involved in these clinical activities.
Respiratory Physiologist	Hospital based Service Provides pulmonary function testing in both the hospital and community setting for the diagnosis of COPD. Provides a resource and training for staff in the provision of quality assured community based spirometry testing.
Palliative Care	Provides care and support to patients and their families to maintain the best possible quality of life and end of life care for appropriate patients.
	Assists in the management of symptoms such as pain, breathlessness or fatigue.
	Gives patients and their family psychological support to assist and adapt to the progression of disease and help patients plan for the future.
Smoking Cessation Team	Provides one to one or group sessions to support people through their quit smoking process, providing:
	<ul> <li>Assessment of quit history coping strategies;</li> </ul>
	<ul> <li>Information on available drug treatments;</li> </ul>
	<ul> <li>Measurement of carbon monoxide levels;</li> </ul>

Social Work- Hospital Based/Community Based - Primary Care/Palliative Care	The social worker will conduct comprehensive psychosocial assessments as part of an interdisciplinary team (IDT) to inform holistic management of COPD through:
	<ul> <li>Identifying social, psychological and community factors that may impact on the ability to cope with their illness and treatment;</li> </ul>
	<ul> <li>Supporting a greater understanding the psychosocial impact of their condition or disease thereby increasing medical compliance and engagement in care;</li> </ul>
	<ul> <li>Identifying factors that may limit a person from being able to adhere to their treatment regime and addressing these;</li> </ul>
	<ul> <li>Fostering relationship base practice to support active engagement with identified treatment plans;</li> </ul>
	<ul> <li>Identifying and problem solving around high risk psychosocial factors impacting on care planning.</li> </ul>
	Social Workers will actively promote, support and provide:
	<ul> <li>Referral to other professionals/agencies to support individuals &amp; families;</li> </ul>
	<ul> <li>Relationship based intervention and communication between the patient, the IDT and community resources;</li> </ul>
	<ul> <li>Conflict management and resolution during times of high stress/crisis;</li> </ul>
	<ul> <li>The development of coping strategies for individuals and their families – including psychoeducation to support adapting to a chronic illness;</li> </ul>
	<ul> <li>Emotional support around bereavement to individuals and their families (anticipatory and active grief);</li> </ul>
	<ul> <li>Support to patients in accessing practical and social supports for additional needs impacting on disease management (housing/financial etc.);</li> </ul>
	<ul> <li>Advocacy on the patients' behalf as needed;</li> </ul>
	Discharge planning within the inpatient setting.

Senior Occupational Therapist – Integrated Care	As a healthcare clinician trained in incorporating physical, psychological, social and environmental factors into functional performance, the OT plays a pivotal role in maximising the client's mental, physical and social wellbeing. Completes activity analysis of client's performance particularly in relation to their ability to manage activities of daily living. Addresses the impact of COPD and the impact of their symptoms on their ability to manage activities of daily living. Provides education in self-management strategies. Focuses on developing patient knowledge and skills in maximising their functional independence. Prescribes assistive enabling devices to maximise functional performance. Advises on environmental / structural alterations / adaptations to promote continued independence in the home environment. Provides an integrated link to secondary care specialist support.
Occupational Therapist	Hospital based Provides occupation based input to maximising and maintaining the client's functional independence. A key role in assisting with patient flow between acute and community care. Assists with stabilising the patient at home upon discharge with the aim of reducing the risk of representation to the ED. In conjunction with hospital, community and Integrated Care based OT develops individual programmes to maintain individuals in the community / their homes and to prevent hospital admissions. Prescribes assistive enabling devices to maximise functional performance.
	<ul> <li>Advises on environmental / structural alterations / adaptations to promote continued independence in the home environment.</li> <li>Completes activity analysis of the client's performance, particularly in relation to their ability to manage activities of daily living.</li> <li>Addresses the impact of COPD and the impact of their symptoms on their ability to manage activities of daily living. Ensures that people with COPD have access to Occupational Therapy to anticipate and address problems of daily living. Works with clients to foster a range of coping strategies and skills to assist them to self-manage their</li> </ul>
Administrative Support	<ul> <li>condition and in turn using these self-management skills helps clients to engage in activities which add value and meaning to their lives.</li> <li>Provides support to staff for administrative functions, including communicating with patients in specific service areas, but also across the continuum of services. The role supports the COPD team to maintain patient local registers, schedule appointments and collect /collate data sets.</li> </ul>

Psychologist	Provides support to clients with long term health conditions, either in a group or in one to one sessions, by validating the impact of their condition on their mental and physical wellbeing (a bidirectional relationship). Works with clients to foster a range of skills to assist them in the self-management of their condition. These self- management skills help clients to break their symptom cycle, giving them confidence to positively impact their mental and physical wellbeing.
Speech & Language Therapist	<b>Primary Care/ Hospital</b> Assessment and management of swallow dysfunction for any person with recurring exacerbations/ LRTIs and for anyone reporting swallowing difficulties. Provide respiratory specific swallowing rehabilitation including goals, equipment and advice to optimise and maintain function and promote well-being, in liaison with the MDT. This includes assessment and management of swallowing in oxygen-dependent patients, those who require the use of secretion clearance devices, nebulisers or inhalers, (which can aid or impede swallow function). Support the person with COPD to recognise swallow function changes (including during exacerbations), and to self-manage to the safest extent possible. SLTs role in PRPs includes targeting dysphagia education, screening, and management to support overall self-management of chronic respiratory disease and dysphagia. Assessment and management of dysphonia, chronic cough, xerostomia and laryngeal sensitivity, which can co-occur in people with COPD.
Dietitian	Hospital Based Patients admitted to acute settings are screened by nursing staff and identified as at risk of malnutrition should be referred to the dietitian for assessment and nutrition support as clinically indicated.
	Secondary and community settings
	Assesses the individual's nutritional status and risk of malnutrition.
	Develops evidence-based nutrition care plans based on the individual's need.
	Provides education for wider MDT, including the use of nutrition screening tools.
	Provides advice regarding the use of therapeutic artificial nutrition support in line with best practice guidelines.
Laboratory	Assistin operational training HCP 's in the correct handling and analysis of blood gas samples, including sample handling requirements, the correct operation of the equipment for measurement, interpretation of results, limitations and interferences, and contact and referral pathways for abnormal results and other analytical issues. This is run through Local Point of Care Services with robust Internal Quality Control and External Quality Assurance programmes.

# **Appendix 12: Glossary of terms and abbreviations**

AATD	Alpha-one antitrypsin deficiency
ABG	Arterial blood gas
ACOS	Asthma-COPD Overlap Syndrome
ADAPTE Process	Process for adapting clinical guidelines
AOT	Ambulatory Oxygen Therapy
BAI	Breath actuated inhaler
BDU	Bed days used
BIA	Budget impact analysis
BOLD	Burden of lung disease
BTS	British Thoracic Society
CAT	COPD Assessment Tool
CCQ	Clinical COPD Questionnaire
CEA	Cost-effectiveness analysis
CEO	Chief Executive Officer
CHN	Community health network
CNME	Centre of Nursing and Midwifery Education
COPD	Chronic Obstructive Pulmonary Disease
CPD	Continuing Professional Development
CPRC	Chartered physiotherapists in respiratory care
CSO	Central Statistics Office
CUA	Cost-utility analysis
DALY	Disability-adjusted life year
DOH	Department of Health
DPI	Dry powder inhaler
DPS	Drugs payment scheme
ED	Emergency department
FEV1	Forced expiratory volume in one second
GDG	Guideline development group
GM	General Manager
GMS	General Medical Services
GOLD	Global Initiative for Chronic Obstructive Lung Disease
GP	General practitioner
НСР	Healthcare professional

HEI	Higher Education Institute
HIPE	Hospital In-patient Enquiry scheme
HPSC	Health Protection Surveillance Centre
HRB	Health Research Board
HRB-CICER	Health Research Board – Collaboration in Ireland for Clinical Effectiveness Reviews
HSCP	Health and Social Care Professions
HSE	Health Service Executive
HTA	Health technology assessment
ICGP	Irish College of General Practitioners
ICS	Inhaled corticosteroid
ICT	Information and Communications Technology
INEWS	Irish National Early Warning System
ITS	Irish Thoracic Society
КРІ	Key performance Indicator
kPa	Kilopascal
LABA	Long-acting beta agonist
LAMA	Long-acting muscarinic antagonist
LOS	Length of stay
LRTI	Lower respiratory tract infection
LTOT	Long term oxygen therapy
LVR	Lung volume reduction
MDI	Metered dose inhaler
MDT	Multidisciplinary team
MECC	Making every contact count
mMRC	Modified medical research council
MOC	Model of care
NCEC	National Clinical Effectiveness Committee
NCG	National Clinical Guideline
NCP	National Clinical Programme
NICE	National Institute for Health and Care Excellence
NIV	Non Invasive Ventilation
NMPDU	Nursing and Midwifery Planning and Development Unit
NPSO	National Patient Safety Office
NQAIS	National Quality Assurance and Improvement System

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NRT	Nicotine replacement therapy
NUI	National University of Ireland
NWHIP	National Women and Infants Health Programme
ONMSD	Office of the Nursing and Midwifery Services Director
ОТ	Occupational Therapist
PaO <sub>2</sub>	The partial pressure of arterial oxygen
PDE-4	Phosphodiesterase- 4
PICO	Patient/population, intervention, comparison and outcomes
РІРОН	Population, Intervention, Professionals, Outcomes, Healthcare settings and context
PRP	Pulmonary rehabilitation programme
QALY	Quality-adjusted life-year
OECD	Organisation for economic co-operation and development
QI	Quality Improvement
RCPI	Royal College of Physicians, Ireland
RCT	Randomised controlled trial
SABA	Short-acting beta agonist
SAMA	Short-acting muscarinic antagonist
SaO <sub>2</sub>	Oxygen saturation of arterial blood
SE	Socioceconomic
SpO <sub>2</sub>	Oxygen saturation as determined by pulse oximetry
SLT	Speech and Language Therapist
YLD	Years lived with disability

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