An Roinn Sláinte
Department of Health

Management of Chronic Obstructive Pulmonary Disease (COPD)

National Clinical Guideline No. 27

Annex D: COPD Budget impact analysis - Management of Chronic Obstructive Pulmonary Disease in adults.

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

CICER
Collaboration in Ireland for Clinical Effectiveness Reviews

Budget impact analysis –

Management of Chronic Obstructive Pulmonary Disease in Adults

February 2021

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

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RCSI

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About HRB-CICER

In 2016, the Department of Health requested the Health Research Board (HRB) to fund a dedicated multidisciplinary research group to support the activities of the Ministerial appointed National Clinical Effectiveness Committee (NCEC). Called HRB-CICER (Collaboration in Ireland for Clinical Effectiveness Reviews), a five-year contract (2017 to 2022) was awarded following a competitive process to the Health Information and Quality Authority (HIQA). The HRB-CICER team comprises a dedicated multidisciplinary research team (including expertise in health economics, qualitative and quantitative research methods and epidemiology) supported by staff from the Health Technology Assessment (HTA) team in HIQA and the HRB Centre for Primary Care Research at the Royal College of Surgeons in Ireland (RCSI), as well as national and international clinical and methodological experts.

Guideline development groups submit clinical guidelines for appraisal and endorsement by the NCEC as National Clinical Guidelines. HRB-CICER provides independent scientific support to guideline development groups tailored according to their specific needs. The main role of the HRB-CICER team is to undertake systematic reviews of the clinical effectiveness and cost-effectiveness of interventions included in the guidelines and to estimate the budget impact of implementing the guidelines. Additional support can be provided by HRB-CICER to guideline development groups including; providing tailored training sessions and working closely with the guideline development groups to develop clinical questions and search strategies; performing systematic reviews of international clinical guidelines; supporting the assessment of their suitability for adaption to Ireland and assisting in the development of evidence-based recommendations.

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List of abbreviations that appear in this report

BIA	Budget impact analysis
BOLD	Burden of obstructive lung disease
CHN	Community Healthcare Network
CHO	Community Healthcare Organisation
COPD	Chronic obstructive pulmonary disease
DRG	Diagnosis related group
ED	Emergency department
GDG	Guideline development group
GP	General practitioner
GLM	Generalised linear model
GMS	General Medical Services
HIPE	Hospital In-patient Enquiry scheme
HIQA	Health Information and Quality Authority
HRB-CICER	Health Research Board Collaboration in Ireland for Clinical Effectiveness Reviews
HRQoL	Health-related quality of life
HSE	Health Service Executive
HTA	Health technology assessment
ICD	International Statistical Classification of Diseases and Related Health Problems
LTOT	Long-term oxygen therapy
OECD	Organisation for Economic Co-operation and Development
PaO_2	Pressure of arterial oxygen
PRP	Pulmonary rehabilitation programme
PRSI	Pay Related Social Insurance
RCT	Randomised controlled trial
SaO_2	Saturation of arterial oxygen
WTE	Whole-time equivalent

1. Introduction

1.1 Scope of work

A budget impact analysis (BIA) addresses the expected changes in the expenditure of a healthcare system after the adoption of a new intervention.[1] The completion of a BIA is a required step in the development of National Clinical Guidelines in Ireland.[2] In the context of guideline development, the purpose of the BIA is to quantify the resource implications of the guideline's implementation plan, developed by the Guideline Development Group (GDG). That is, to synthesise the best available knowledge in order to estimate the additional resources and costs for the healthcare system from implementing the guideline's recommendations.[3] This BIA was developed by HRB-CICER to support the GDG, who have prepared the clinical guideline, *Management of Chronic Obstructive Pulmonary Disease (COPD) in Adults*, for the Irish healthcare system.

1.2 The burden of COPD

COPD is 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.[4] The chronic airflow limitation results from a combination of small airways disease (for example, obstructive bronchiolitis) and parenchymal destruction (emphysema), the relative contributions of which vary by individual. COPD can be due to long-term exposure to irritating gases (such as air pollution from burning fuels) or particulate matter (such as occupational dusts and chemicals), but is mainly caused by smoking tobacco.[4] Although effective management can improve quality of life, COPD is a life-long condition for which no cure currently exists.

Without treatment, people with COPD experience gradual impairment as episodes of acute exacerbations contribute to the deterioration of their health. Consequently, the utilisation of healthcare services often increases due to frequent hospitalisations in the later stages of the disease. Given a rising prevalence of chronic conditions in higher income countries, the economic and social burden associated with COPD, in terms morbidity and healthcare use, is becoming an increasingly important public health issue.[5, 6]

The economic and social burden of COPD in Ireland is substantial, with international estimates suggesting that Ireland has one of the highest rates of hospital admissions for exacerbations of COPD in the Organisation for Economic Co-operation and Development (OECD).[7] Additionally, Ireland has one of the highest death rates for COPD in the European Union, with COPD accounting for almost 5% (1,554 deaths (ICD codes: J40-44, J47)) of all deaths in those

aged 15 and over in Ireland in 2017.[8] It is estimated that up to 10% of the Irish population (500,000 people) may have COPD, including those both diagnosed and undiagnosed.[4, 9, 10]

Acute exacerbations represent the principal drivers of direct costs for COPD care accounting for more than 70% of COPD-related costs incurred from emergency visits and hospitalisations.[11] From a societal perspective, there are substantial indirect costs associated with disability, premature mortality and lost production (such as home-based care provided by family members) from COPD. The annual economic burden of COPD is estimated to be €48.4 billion across the EU, including total direct and indirect costs.[12]

1.3 Integrated Care Programme

In line with current objectives for health system reform in Ireland,[13-15] the Health Service Executive (HSE) is developing four Integrated Care Programmes that aim to introduce a model of care in which patients are treated at the lowest level of complexity that is safe, timely, efficient and as close to home as possible.[10, 16, 17] As part of this reform, an Integrated Care Programme for Prevention and Management of Chronic Disease (which focuses on a number of chronic diseases including diabetes, asthma and COPD) is being introduced on a phased basis.

Under the Programme, better care to people with chronic diseases will be achieved through the provision of a continuum of preventative, management and support services to patients with these conditions. This model of care, which includes easy access to diagnostics and specialist supports in the community in addition to close co-ordination with hospital services, will enable people to understand and care for their own condition in collaboration with their primary care team so that they can access the care they need, when they need it and in the most appropriate way for their circumstances, be it at home, in the community or in hospital.

Community healthcare services are currently delivered across nine Community Healthcare Organisations (CHOs), supported by the recruitment of 65 additional posts (including therapy and nursing) in 2020. As part of the ongoing reform, community healthcare services will be provided through primary care teams and Community Healthcare Networks (CHNs), through which specialist multi-disciplinary teams engage and interact with services at the CHN level with the aim of caring for more people in the community, bridging and linking the care pathways between acute and community services.

Under the Sláintecare Community Enhancement Fund, €10 million has been allocated in 2020 (rising to €60m in 2021) to enhancing community care and supporting the delivery of reform initiatives.[18] This includes a commitment to recruiting up to 1,000 new community frontline staff in order to support the shift in care from the acute sector to the community sector.

Furthermore, the expansion of services in CHN learning sites is considered a priority. In 2020, the community-based GP-led Chronic Disease Management Programme targets 45,000 General Medical Services (GMS) clients aged 75 years and over with a chronic disease (diabetes, asthma, COPD and cardiovascular disease). By 2023, full roll-out aims to benefit over 430,000 GMS patients through provision of routine community-based care.

In September 2020, the HSE's Winter Plan 2020/21 announced the allocation of an additional €600 million to support hospital and community care, including additional funding for CHNs and Community Specialist Teams.[19] Cost estimates for the expansion of COPD healthcare interventions are presented in this report in accordance with the national health technology assessment (HTA) guidelines and National Clinical Effectiveness Committee (NCEC) guidance,[2, 20, 21] but it is highlighted that funding has already been secured for the initial two years of the guideline's implementation plan under the HSE's Winter Plan and the HSE acute hospital budget.[22]

2. Methods

The purpose of this analysis is to estimate the resource and financial consequences for the Irish healthcare system of implementing the clinical recommendations outlined in the *Management of COPD in adults* guideline. The budget impact analysis (BIA) also estimates the costs incurred during the initial implementation phase of the guideline recommendations.

The analysis was conducted in accordance with the HIQA guidelines for budget impact analysis and economic evaluation in Ireland, using the Excel 2013 and R Studio (version 4.0.0) software packages.[20, 21] All costs from previous economic evaluations presented in this BIA have been adjusted in line with these national guidelines.

2.1 Study perspective

In line with national guidelines, costs and benefits were assessed from the perspective of the publicly-funded health and social care system, the Health Service Executive (HSE).[20, 21] Accordingly, only direct medical costs were included. Indirect costs such as decreased productivity associated with morbidity, treatment or death, or out-of pocket expenses incurred by patients, for example, travel costs incurred by patients attending pulmonary rehabilitation sessions, were excluded from the analysis.

2.2 Time horizon

The time horizon represents the timeframe over which resource use is planned. In accordance with national guidelines, the annual budget impact was estimated over a five-year period.[20, 21]

2.3 Rationale for included interventions

The BIA aims to estimate the financial consequences (in terms of costs and or cost savings) that result from changes to the standard clinical pathway following implementation of the clinical guideline. Accordingly, the BIA's comparator comprises the current standard practice, but this can be difficult to define in the context of clinical guidelines given that the rationale for the guideline may in part be due to variation in clinical practice. Under such circumstances, it may be reasonable to restrict the description of current practice to those practices that are most commonly used.

From a resourcing perspective, the key changes arising from the implementation of the *Management of COPD in Adults* guideline were the expansion of existing services and implementation of Community Healthcare Networks to improve capacity to deliver pulmonary rehabilitation, COPD outreach services, oxygen assessment clinics and community diagnostics. These recommendations, presented in Appendix 1 and outlined below, were

prioritised by the Guideline Development Group (GDG) due to insufficient service capacity in the current system to address the needs of COPD patients.

Recommendation 14 entails the provision of pulmonary rehabilitation to all patients with stable COPD with exercise limitation and the provision of pulmonary rehabilitation to patients who have recently been hospitalised for an acute exacerbation of COPD. Expanding the current provision of pulmonary rehabilitation programmes (PRPs) will require investment in additional staff and resources.

Recommendation 19 proposes tracking the decline of FEV^1 in stable COPD patients by performing spirometry at least every two years. In line with the Sláintecare Community Enhancement Fund which aims to establish Community Healthcare Network (CHN) Sites to inform the development and provision of a multi-disciplinary model of service,[18] the guideline's implementation plan requires the recruitment of staff to expand diagnostics in the community. Therefore, implementation of this recommendation will require investment in additional staff and resources.

Recommendation 25 outlines involvement of the COPD outreach team at the earliest possible time (within 72 hours) of a hospital admission for a COPD exacerbation. The current insufficient capacity to deliver outreach services means that investment in staffing is required to deliver this recommendation.

Recommendation 28 states that patients discharged home from hospital on oxygen therapy should be evaluated for the need for long-term oxygen therapy (LTOT) 60–90 days after discharge and that LTOT should not be continued for patients that do not meet the criteria. There are currently insufficient oxygen assessment clinics to meet the demand for this recommendation. Therefore, investment will be required to expand access to oxygen assessment clinics.

The clinical pathway for the management of COPD before and after implementation of the recommendations was identified through consultation with the GDG and review of national literature (such as policy documents and models of care). The rationale for inclusion and exclusion of individual recommendations is outlined in Appendix 1. The included interventions and proposed implementation plan are described in Section 3. The international evidence underpinning the cost-effectiveness of these interventions is summarised in Section 3 and detailed in the accompanying systematic review of cost-effectiveness.

2.4 Rationale for excluded interventions

Whether or not a recommendation represented a change to routine clinical practice was identified through discussion with the GDG. It was also informed by a review of national literature (such as policy documents and models of care) and data sources relating to the care

of adults with COPD in Ireland.

No changes to standard practice arising from implementation of the guideline recommendations were identified for the following areas: ongoing pharmacological management of COPD (short and long acting bronchodilators, inhaled corticosteroids, theophyllines, prophylactic use of macrolide antibiotics, antioxidants and mucolytics and leukotriene antagonists, smoking cessation); non-pharmacological management of COPD (smoking cessation, oxygen therapy, nutritional support, lung volume reduction surgery, lung transplantation, role of palliative care); or management of exacerbations in COPD (bronchodilator therapy, steroids, antibiotics, non-invasive ventilation, respiratory physiotherapy and theophyllines).

For the pharmacological management of COPD, the use of roflumilast and alpha-1 anti-trypsin augmentation therapy would represent a change to standard practice. However, these recommendations are conditional upon reimbursement by the HSE. As reimbursement decisions include explicit consideration of the budget impact of the proposed therapies, these pharmacological interventions have not been considered within this BIA. However, it is acknowledged that any decision by the HSE in relation to their reimbursement would have ongoing financial consequences for the budget impact of this guideline.

Recommendation 4 entails expanding practice to ensure that all patients that have commenced treatment on an inhaler device are provided with instructions and a demonstration of proper inhalation technique. This will also involve increased incorporation of inhalation technique evaluation into clinical practice. The implications of this recommendation, from a resourcing perspective, relate mainly to time considerations of the physician and or other healthcare professionals. As this represents the current minimum standard of care, any additional resources associated with this recommendation have been excluded from this BIA.[9]

Recommendations 12 and 13, which advise on provision of the pneumococcal and influenza vaccinations, are already implemented under national immunisation guidelines and, therefore, represent established practice within the Irish healthcare system.[23, 24] For these recommendations, the aim of the GDG is to support awareness.

Finally, recommendation 29 entails expanding access to pathways, bundles and checklists for all patients admitted with an acute exacerbation of COPD. While admission and discharge bundles are provided to some patients admitted acutely, there is variation in practice. Improved awareness of the benefits of admission and discharge pathways and bundles is required for this recommendation to be implemented, but it is not expected to have resource implications.

2.5 Target population

As COPD has a slow and insidious onset with initial asymptomatic loss of lung function, many patients are not diagnosed until damage is advanced and classic symptoms of cough and dyspnoea occur.[25] In light of this and an ageing population, it is suspected that there is a large and rising segment of the Irish population that remains undiagnosed. Applying the results of the international cross-sectional Burden of Obstructive Lung Disease (BOLD) study, it is estimated that there are up to 500,000 people with COPD in Ireland.[10, 26-28] This estimate accounts for up to 10% of the Irish population: it represents all people with COPD of all stages of severity, including those that are not yet diagnosed. However, there is a lot of uncertainty surrounding the application of international prevalence estimates due to differences in genetic, behavioural and demographic factors that may influence prevalence.

The costs of implementing the guideline recommendations will be driven largely by the resources required to expand current service provision of pulmonary rehabilitation, COPD outreach and oxygen assessment clinics. Each of these services should be offered to COPD patients following hospitalisation according to clear referral criteria that are outlined in Sections 3 to 5. This guideline recommends the provision of PRPs to stable patients with exercise limitation. However, as patient-level data on COPD prevalence in Ireland is currently unavailable, implementation focuses on delivering PRPs to COPD patients that have been hospitalised. Not all of these patients will have the physical capacity to undertake a PRP and some patients may have attended a PRP in previous years (repeat attendance is not recommended). Therefore, the number of patients hospitalised due to a COPD exacerbation is assumed as a proxy of the target population.

Data from the Hospital In-patient Enquiry scheme (HIPE) in 2014 indicated that there were 16,147 admissions with a principal diagnosis of COPD, representing 11,080 unique patients.[29] Assuming that this represents the cohort admitted to hospital due to exacerbation of their COPD, and implementation of recommendations in relation to pulmonary rehabilitation, COPD outreach and oxygen assessment clinics is restricted only to those hospitalised, the target population requiring these services is considerably less than the estimated total COPD population of 500,000. To estimate the number of hospitalised COPD patients (which is predicted to increase annually) over the BIA's five year time horizon, a generalised linear model (GLM), based on HIPE data and described in Section 4.3, was used.

2.6 Sensitivity analysis

Two types of uncertainty are relevant to a BIA: structural and parameter.

Structural uncertainty relates to the assumptions underpinning the modelling framework. Any estimate of costs and uncertainty is conditional upon the structural assumptions of the model. If the model fails to accurately represent how the introduction of new interventions

and restrictions for use will occur, then there can be little expectation of an accurate result even if the true value of all input parameters is known. Such uncertainty is not easily incorporated into economic models. Therefore, the assumptions underpinning this BIA were documented in a protocol that was reviewed by the GDG and endorsed by the Chair.

Parameter uncertainty relates to the input values used in the BIA and was addressed by undertaking univariate and probabilistic sensitivity analysis. A univariate sensitivity analysis, in which each parameter is assigned an upper and lower limit based on available empirical evidence, shows how influential each parameter is by itself and how sensitive the results are to fluctuations in each input value. It was used to identify the key model inputs contributing most to the level of uncertainty in the estimated budget impact. The 95% confidence intervals (representing the lower and upper limits) are presented alongside the model inputs in Section 4.1.

In a probabilistic sensitivity analysis, probability distributions are assigned to each parameter and a random sample is drawn simultaneously from the plausible range of each parameter. These random samples were drawn repeatedly in a Monte Carlo simulation (where the model was run 10,000 times) with different sets of inputs simulated. The mean value and variance across the model replications were then recorded and presented. The statistical distribution assigned to each parameter was based on published recommendations for economic evaluation in health care.[20, 21, 30] The probability distributions are presented alongside the model inputs in Section 4.1.

2.7 Quality assurance

The BIA was developed in accordance with national HTA guidelines[20, 21] and quality assured in accordance with the HRB-CICER quality assurance framework. All model inputs and outputs were reviewed by a second economic modeller to ensure accuracy. The structure and assumptions underpinning the model were reviewed by a second economic modeller to ensure that these were reasonable and appropriate based on the evidence synthesis process. A quality assurance checklist was applied to the BIA by a second economic modeller to test the robustness of the analysis. The clinical and implementation assumptions underpinning the model were described in a protocol which was agreed with the Chair of the GDG and the Programme Manager of the National Clinical Programme for Respiratory Diseases (COPD and Asthma) prior to conduct of the analysis.

3. Summary of included interventions

3.1 Description of pulmonary rehabilitation

3.1.1 Background

Acute exacerbations of COPD lead to significant decline in muscle function and ability to participate in physical activity.[31] Patients with severe COPD suffer from progressively restricted mobility and encounter increasing difficulty in performing activities of daily living. Physical activity is a strong predictor of mortality in COPD patients, and increased activity is associated with better physical function, cognitive status and survival.[12] Pulmonary rehabilitation is advocated as an evidence-based, multidisciplinary and comprehensive intervention for COPD patients that are symptomatic and whose ability to perform daily life activities has decreased.

Cochrane reviews by McCarthy et al.[32] and Puhan et al.[31] found that pulmonary rehabilitation can:

- improve HRQoL and exercise capacity
- reduce the number of hospital admissions
- reduce mortality (although not statistically significant) following an acute exacerbation of COPD
- reduce perceived sensation of dyspnoea
- reduce anxiety and depression associated with COPD.

McCarthy et al. highlighted that the way in which pulmonary rehabilitation is delivered, in terms of programme curriculum (more extensive programmes are associated with greater improvements), and levels of motivation of patients can be important factors contributing to the effectiveness of the programme.[32] However, a systematic review published by Wuytack et al.[33] in 2018 found that there was no clinical difference in the effectiveness of PRPs delivered in different treatment settings. Therefore, health services should consider the local circumstance and barriers and tailor the delivery of PRPs to best suit the local context, available resources and patients' needs.

3.1.2 Description of pulmonary rehabilitation

Pulmonary rehabilitation is a comprehensive intervention based on patient-tailored therapies that include exercise training, education and behaviour change. These are designed to improve the physical and psychological condition of people with COPD and to encourage long-term adherence to health-enhancing behaviours.[33] The aim of pulmonary rehabilitation is to reduce symptoms, promote autonomy, increase participation in activities of daily living and improve health-related quality of life (HRQoL) by focusing on aspects of COPD that are

common among patients.[32] By achieving these objectives, pulmonary rehabilitation can help to optimise healthcare resources by reducing healthcare costs such as hospitalisations and emergency department (ED) attendances associated with COPD.[34]

Referral to a pulmonary rehabilitation programme (PRP) is based on a thorough patient assessment (including review of respiratory history, co-morbidities and other factors that may affect participation) and should be at the discretion of the healthcare service provider.[34] The selection criteria for pulmonary rehabilitation are presented in Table 3.1.1.1.

Table 3.1.1.1: Selection criteria for pulmonary rehabilitation[34]

Inclusion criteria	Exclusion criteria
✓ Confirmed diagnosis of respiratory disease by spirometry ✓ Functionally limited by dyspnoea despite optimal therapy ✓ Motivated to participate and change lifestyle ✓ Ability to exercise independently without supervision ✓ Ability to travel to venue	✓ Uncontrolled cardiovascular conditions limiting participation in an exercise programme ✓ Significant orthopaedic or neurological conditions that reduce mobility or cooperation with physical training

The educational component of pulmonary rehabilitation is focused on collaborative self-management and implementing behavioural change by:

- providing information regarding COPD
- building self-management competencies (such as goal setting, problem solving and decision making) and developing action plans
- modifying nutritional intake and discouraging bad health behaviours (such as smoking)
- encouraging medication adherence and exercise
- demonstrating effective breathing techniques and energy-saving strategies.[32]

The exercise component of pulmonary rehabilitation can:

- improve muscle function resulting in improved exercise tolerance
- increase inspiratory volume (maximum lung inhalation) and decrease dynamic hyperinflation (when inhalation begins before the lung has reached capacity) which reduces dyspnoea.[32]

The structure of a PRP may vary depending on the culture, resources and healthcare system, but is typically delivered in a group setting. The optimal duration of programmes, number of sessions offered per week and type of staff required to deliver PRPs are unclear,[32] but a

minimum programme duration of at least eight weeks and a minimum of 20 sessions is recommended by the 2018 draft model of care developed by the National Programme for COPD.[34, 35] This also recommends class sizes of 12 patients to facilitate safe patient-centred care. To achieve staff to patient ratios of 1:8 for exercise training and 1:16 for education sessions, it recommends that two members of staff are present for exercise sessions with one senior staff member present at all times.[34] Exercise sessions are provided at a minimum of three times per week and up to a maximum of five times per week, but this may include one unsupervised home session. It is recommended that exercise sessions last at least 30 minutes.

An Irish review of the optimal setting for pulmonary rehabilitation identified community-based programmes as the preferred setting (compared with hospital-based programmes); however, there is no formal requirement for pulmonary rehabilitation and setting selection should be made on a case-by-case basis.[33, 34]

The design and implementation of a PRP requires an appropriately trained multidisciplinary team and administrative support that will enable organisational management of the programme alongside patient referral, collection of outcome measures and audit. Ideally, the multidisciplinary team will include a consultant respiratory physician, a dietitian, a general practitioner (GP), an occupational therapist, a pharmacist, a respiratory nurse, a respiratory physiologist, a respiratory physiotherapist, a palliative care professional, a psychologist, a smoking cessation officer, a social worker and a speech and language therapist. However, at a minimum a PRP should comprise one full-time respiratory physiotherapist and one full-time respiratory nurse specialist or physiotherapist assistant. A full description of each role can be found in the model of care.[10, 34]

The role of the dietitian in a PRP comprises delivery of the nutritional education component (approximately one hour per cycle), provision of individualised tailored nutrition interventions as required and provision of education and training to other healthcare professionals on the use of nutrition screening tools and the role of nutrition in optimising pulmonary rehabilitation.

The consultant respiratory physician has overall responsibility for the care of patients with COPD in the community (while participating in a PRP) and hospital settings. Within a PRP, the consultant may be involved in the prescription of oxygen therapy, non-invasive ventilation, smoking cessation measures and referral to palliative care services as appropriate. During the programme, the consultant may deliver an educational talk to participants and provide advice to other referrers (such as other physicians, nurses and physiotherapists). Overall, it is estimated that the consultant will provide approximately one hour of input per week during a PRP including on-going clinical oversight. That is, a total of eight hours of input across an eight-week programme.

3.1.3 Description of current approach to pulmonary rehabilitation in Ireland

The National Needs Assessment for Pulmonary Rehabilitation Services was carried out in 2016 to collect information regarding the gap between the need for and provision of pulmonary rehabilitation in Ireland.[29] Key information for this BIA is reported below.

Needs assessment:

- Data from the Hospital In-patient Enquiry scheme (HIPE) in 2014 indicated that there were 16,147 admissions with a principal diagnosis of COPD, thought to represent 11,080 unique patients (of which 11,052 were resident in the Republic of Ireland).
- In 2015, 1,211 COPD patients accessed a PRP. This represents 11% of the total estimated need for patients admitted with an acute exacerbation of COPD in 2014. Pulmonary rehabilitation is recommended for all patients admitted to hospital as a result of an acute exacerbation of COPD according to the inclusion criteria presented in Table 3.2.1.[34]

Provision, capacity and participant dropout of PRPs:

- There were 29 PRPs operating in Ireland in 2015. However, one centre was in the initial stages of setting up the service so data were only available for 28 centres.
- There were five counties without access to a PRP (Laois, Meath, Roscommon, Wexford and Wicklow).
- The number of pulmonary rehabilitation centres in each hospital group ranged from four to six, with the annual capacity ranging from 175 to 242 participants per hospital group and 8 to 120 participants per programme. The mean annual capacity per centre was 46 participants and the median was 40.
- Eight of the 28 centres were unable to deliver the planned number of PRPs due to staff absence (illness or maternity leave), staff commitments to other duties or a lack of available facilities.
- Only one centre was able to offer a place on a PRP within one month of hospital discharge to patients admitted with an acute exacerbation of COPD. Eight centres could offer a place within one to three months, and 11 centres were unable to offer a place within three months from time of discharge. The remaining centres reported that waiting times varied.
- Detailed data on patient throughput for 2015 was available for 25 of the 28 centres, totalling 915 patients. Of these 915 patients, 231 (25%) commenced but did not complete pulmonary rehabilitation. This dropout rate ranged from 5–49%. Reasons for dropping out included illness or readmission, lack of motivation, transport issues, family reasons, lack of benefit found from the programme and a dislike of group activities.

Duration and structure of PRPs:

- The duration of PRPs was eight weeks in 26 of the 28 centres that provided data.
- The average class size was 9.6 patients per PRP (ranging from six to 15; with a mode of eight). However, one PRP would accept up to 20 participants depending on resource availability while another accepted up to 30 participants for educational modules.
- For education sessions, the ratio was 1:8 (range 1:4 to 1:30) and staff could be any member of the multidisciplinary team. Nineteen centres provided eight weeks of education (range 4–8 weeks), with session duration ranging from 30 minutes to 2.5 hours. The average duration of a session was one hour. All centres provided education in a face-to-face format, and 25 centres provided additional written information. Ten centres used online material for education and five centres used other aids (such as DVDs and CDs).
- The most common staff to patient ratio for exercise sessions was 1:5 (range 1:3 to 1:10), which operated on a format of a 2:10 staff to patient ratio. Staff members for exercise sessions were physiotherapists and or nurses. All centres offered two supervised exercise sessions per week (assumed duration of one hour per session, but this was not specified in the report).

3.1.4 Summary of proposed implementation

As part of the Sláintecare reform and HSE Integrated Care Programme (ICP), Community Healthcare Networks (CHNs) have been identified as the core unit of healthcare service provision and co-ordination within the community. The CHNs ensure alignment of service provision for integrated care across care domains, including general practice chronic disease management, general practice with Specialist Support, Specialist Ambulatory Care and Hospital Inpatient Specialist Care. Nationally, there are 96 geographically-based CHNs, each of which will deliver healthcare services to a population of approximately 50,000. Under the guideline implementation plan, the Guideline Development Group (GDG) proposes that an additional 32 (11 in year one and 21 in year two) PRP teams are established in Ireland, with each PRP team delivering services across three CHNs with the aim of addressing a significant proportion of the currently unmet need for pulmonary rehabilitation in Ireland.

Each PRP team will comprise a full-time respiratory specialist physiotherapist as a coordinator, a full-time physiotherapist, a full-time respiratory nurse and a part-time (0.5 whole time equivalent (WTE)) administrator. The appointment of these teams is subject to securing funding in the Health Service Executive (HSE) national estimates process in the year prior to team appointment. A fully resourced PRP team has capacity to cover up to 132 patients per annum.[9]

In addition, support will be required from existing personnel within the healthcare system to deliver each PRP. This will include support from:

- a respiratory consultant
- a dietitian
- a pharmacist
- a psychologist
- an occupational therapist (OT)
- a speech and language therapist (SLT).

Over the duration of an eight week programme, a dietitian, a pharmacist, a psychologist, an OT and an SLT each deliver educational talks lasting approximately one hour. A respiratory consultant provides approximately one day of input (including educational talks and on-going clinical oversight) per team per week across pulmonary rehabilitation, COPD outreach and oxygen assessment.

3.2 Description of COPD outreach

3.2.1 Background

Hospital admissions for exacerbations of COPD are significant cost drivers for the management of COPD. The opportunity to treat suitable patients in the community instead of in hospital is attractive from an economic and organisational perspective.[36] COPD outreach delivered in the community by a respiratory health worker can benefit patients by encouraging self-management behaviour with education about pulmonary disease, medication (such as inhaler technique), coping strategies and permits greater surveillance of patient deterioration. The desired outcome of COPD outreach is to maintain the patient's optimal respiratory state and reduce hospital admissions.[6] According to the COPD outreach model of care, outreach services involve no costly management choices and consume minimal financial or human resources.[37] However, a successful outreach programme requires adherence to practices and policies and a drive by the outreach team to deliver high-quality care to COPD patients.

A 2017 Cochrane review comparing early supported discharge with acute hospital inpatient care (n=5 studies) concluded that there was insufficient information to determine the effect on mortality and readmission in trials recruiting participants with COPD due to the variable effects reported.[38] A retrospective review by Lawlor et al. compared COPD patients' data for the year prior to and following the receipt of an early discharge programme in St James's Hospital in Ireland between 2002 and 2005.[39] They found that patients experienced fewer ED presentations (dropping from 2.1 to 1.36 per patient), hospital readmissions (dropping from 1.88 to 1.16 per patient) and fewer acute exacerbations of COPD when comparing the data for the year prior to and the year following receipt of an early discharge programme. However, these findings were at risk of bias owing to the observational study design and the inclusion criteria (which required patients to have good mobility, social support and

performance status without significant co-morbidities).

3.2.2 Description of COPD outreach

The core objective of a COPD outreach service is to deliver a high-quality, professional, holistic patient-focused service in the patient's home environment that attempts to improve the patient's quality of life, coping strategies and social functioning skills.[37] One of the key benefits of an outreach service is that it bridges the gap between hospital and community by providing a safe transition home that enables the patient to recuperate in their own environment with family support. COPD outreach provides an early supported discharge (frequently referred to as a hospital at home programme) for patients who present with an uncomplicated acute exacerbation of COPD. An outreach service facilitates patients to be discharged within 72 hours of presentation to hospital under the care of the outreach team for approximately two weeks.

During the two weeks of supported discharge, the patient is visited at home and their progress is monitored by the outreach team. A home visit comprises a thorough assessment of spirometry, inhaler technique and quality of life, as well as offering support with new equipment (such as oxygen and nebulisers), education on COPD and medication, instructions on self-management and early intervention strategies. Overall, the potential benefits of an outreach service can be summarised as follows:

- improved adherence to prescribed treatments because of improved self-management education and supervision
- reduced primary care utilisation as a result of reduced re-exacerbations
- fewer emergency department (ED) presentations and hospital admissions due to COPD exacerbations and reduced length of stay.[37]

Table 3.2.2.1 presents the selection criteria for patients to whom COPD outreach is applicable following hospital admission.

Table 3.2.2.1: Selection criteria for COPD outreach[37]

Inclusion criteria	Exclusion criteria
FEV1 <80% predicted	Suspected malignancy
FEV1/FVC<70% predicted	Pneumothorax, pneumonia
MMSE >7	Uncontrolled LVF
Systolic BP >100mmHg	Acute ECG changes
ABGs pH>7.35, pO2 > 7.3kPa, pCO2<8kPa (on room air unless on oxygen therapy)	Requires full-time care
Total WCC 4-20*10/l· 0-72hrs of presenting to hospital	Insufficient home care
Access to telephone	Requires IV therapy
Adequate social support	Type 1 diabetes

Key: ABG – arterial blood gas; BP – blood pressure; ECG – electrocardiogram; FEV – forced expired volume; FVC – forced vital capacity; IV – intravenous; kPa – kilopascal; LVF – left ventricular failure; MMSE – mini mental state examination; WCC – white cell count.

3.2.3 Description of current approach for COPD outreach

The model currently implemented in Ireland is based on that used in the UK where a "Hospital at Home'' Programme is offered to a select group of COPD patients, that would otherwise require acute inpatient care, within 72 hours of admission.[10] Outreach programmes are consultant-led and driven by a field team (comprising a specialist respiratory nurse and respiratory specialist physiotherapist) in collaboration with a multidisciplinary team across Primary and Secondary care.

Once enrolled, eligible patients remain under the care of the lead consultant for the first 14 days following discharge, at which point they revert back to the care of their GP with appropriate and timely discharge documentation to enable them to do so. During the first three days, a member of the outreach visits each patient daily, again at 14 days with a final visit at six weeks following discharge from hospital to check on progress.

During each visit a clinical assessment is performed which includes assessment of vital signs, chest auscultation, questions on symptom perception and quality of life. The patient also receives education on medication management, disease management and vaccinations. If necessary, patients will receive oral antibiotics (with or without) steroids, nebulised bronchodilators and a nebuliser. There are currently 14 sites in Ireland where a COPD outreach service is in place.

3.2.4 Summary of proposed implementation

Expansion in the provision of COPD outreach services in Ireland is proposed under this guideline's implementation plan. The Guideline Development Group (GDG) has proposed that

an additional 15 COPD outreach teams are established across a two year timeframe (subject to securing funding in the HSE national estimates process), resulting in a total of 29 sites. Expansion of COPD outreach will entail the establishment of four sites in year one and 11 sites in year two.

The resourcing of a COPD outreach service requires one full-time respiratory specialist physiotherapist and one full-time respiratory nurse specialist. In addition, support will be required from existing personnel within the healthcare system to deliver COPD outreach. This will include one half day of administrative support per week, and approximately one day of input per week from a respiratory consultant across pulmonary rehabilitation, COPD outreach and oxygen assessment clinics.

3.3 Oxygen assessment clinics

3.3.1 Background

COPD causes lung damage that restricts the lungs' capacity to absorb oxygen, thus impairing physical function and causing an oxygen deficiency (that is, hypoxemia). Oxygen therapy delivers a supplemental supply of oxygen into the body that helps to relieve COPD symptoms, and can help to decrease fatigue, breathlessness and improve mental health and sleep quality. Long-term oxygen therapy (LTOT), more common during the later stages of disease, means that patients require oxygen for 15 to 24 hours every day due to hypoxemia. In such cases, oxygen can be transported by a portable delivery unit, which allows the individual to participate in their activities of daily living.

A 2005 Cochrane review, which evaluated the effect of domiciliary oxygen therapy on survival in patients with COPD and hypoxemia,[(40)] found that LTOT improved survival in a selected group of COPD patients with severe hypoxemia. In 2016, a randomised controlled trial (RCT) by the Long-Term Oxygen Treatment Trial Research Group found no significant effect on survival, time to first COPD exacerbation, time to first hospitalisation, rate of hospitalisations, the rate of COPD exacerbations, HRQoL, depression, anxiety, or functional status in COPD patients with moderate resting desaturation or moderate exercise induced desaturation.[(41)] Therefore, LTOT should only be prescribed in carefully selected COPD patients with severe hypoxaemia, as per the recommendations of this guideline.

3.3.2 Description of oxygen assessment clinics

To determine whether or not a patient will benefit from LTOT, a patient is referred by their GP or a specialist (following an admission for an acute exacerbation) for a hospital-based outpatient assessment (that is, an oxygen assessment clinic). In stable COPD patients, LTOT can be administered for long periods during the day and night or as ambulatory oxygen (either as part of LTOT or on its own to facilitate exercise). Patients discharged home following

hospitalisation on oxygen therapy should be evaluated for the need to remain on long term oxygen therapy 60 to 90 days after discharge.[10] The procedure for referral and formal assessment of patients for LTOT is described in the Irish guidelines on LTOT in adults 2015.[42]

The duration of a patient's oxygen assessment is generally between 30 and 90 minutes depending on the complexity of the assessment. LTOT should not be continued if patients do not meet the following selection criteria:

- PaO_2 (pressure of arterial oxygen) at or below 7.3 kPa (55 mmHg) or SaO_2 (saturation of arterial oxygen) at or below 88%, with or without hypercapnia confirmed twice over a three week period
- PaO_2 between 7.3 kPa (55 mmHg) and 8.0 kPa (60 mmHg), or SaO_2 of 88% if there is evidence of pulmonary hypertension, peripheral oedema suggesting congestive cardiac failure, or polycythemia (haematocrit > 55%).[4]

Currently, there are oxygen assessment clinics operating across 16 hospital sites in Ireland. At the time of writing, baseline data were not available for the number of patients currently receiving LTOT in Ireland nor for the number of patients that have undergone oxygen assessment.

3.3.3 Summary of proposed implementation

Under the guideline implementation plan, the Guideline Development Group (GDG) proposes that a further 32 sites are established within a two year timeframe, resulting in a total of 48 sites to facilitate oxygen assessment for people with COPD. This will entail the establishment of an additional 11 sites in year one and 21 sites in year two (subject to securing funding in the HSE national estimates process). It is anticipated that the resourcing of oxygen assessment clinics will be provided by healthcare personnel recruited to deliver integrated care and through the restructuring of existing resources within the healthcare system. Support from existing personnel will include one half day of administrative support per week, and approximately one day of input per week from a respiratory consultant across pulmonary rehabilitation, COPD outreach and oxygen assessment.

3.4 Specialist teams to support Community Enhancement Fund plan

3.4.1 Background

Under the Sláintecare Community Enhancement Fund, €10 million has been allocated in 2020 (rising to €60m in 2021) to enhancing community care and supporting the delivery of reform initiatives.[18] The Fund plan includes a commitment to recruiting up to 1,000 new community frontline staff in order to support the shift in care from the acute sector to the community sector. Furthermore, the expansion of services in Community Healthcare Network (CHN)

learning sites is considered a priority. By 2023, full roll-out aims to benefit over 430,000 GMS patients through provision of routine community-based care. It is intended that the CHNs will be complemented by Community Specialist Teams.

3.4.2 Description of community specialist team to support CHNs

Under the Integrated Care Programme for Prevention and Management of Chronic Disease, the Community Specialist Team (i.e. Community Hub) will provide specialist support to GPs in managing patients with chronic disease in the community. Specialist support (at Levels 1 and 2 in the Chronic Disease Model) will include the provision of diagnostics, structured education programmes and community-based rehabilitation services. Each Community Hub will be directly linked to a local acute hospital, facilitating specialist support outside of the hospital setting.

In the case of COPD, the establishment of Community Specialist Teams will include a spirometry service that integrates community diagnostic services with each local hospital Pulmonary Function Laboratory. It is anticipated that better access to diagnostics and specialist support within the community will enhance the delivery of care to people with COPD or at-risk of developing COPD, and facilitate coordination of care.

3.4.3 Summary of proposed implementation

Under the Community Enhancement Fund plan, a model of care will be established which enables the specialist multidisciplinary team to engage and interact with services at CHN level, in terms of diagnosis and ongoing care of GMS patients. CHNs have been identified as the core unit of healthcare service provision and co-ordination within the community in order to ensure greater alignment of service provision for integrated care across care domains. As part of the model of care, a number of specialist community facing teams will support network teams in addressing the needs of older people and those with chronic disease, bridging and linking the care pathways between acute and community services.

The guideline's implementation plan proposes that additional posts for community-based spirometry will be sought to support the Community Enhancement Fund plan. The spirometry posts comprise 32 specialist teams (one per every three CHNs) that will be established over a two-year timeframe to support CHN Sites, entailing the establishment of 11 new teams in year one and 21 new teams in year two. Each specialist team will comprise one full-time technician, one full-time administrator and one part-time (0.25 WTE) Chief II Officer, resourced through recruitment of new personnel. The role of the technician will be to perform specialist tests supported by an administrator, under the oversight of a Chief II Officer.

4. Economic model inputs

The Guideline Development Group (GDG) developed an implementation plan based on the additional resources required to implement recommendations that will involve a change to current standard practice (listed in Appendix 1). The budget impact analysis (BIA) estimated the financial implications of the guideline based on this implementation plan. All resources were identified with costs assigned based on the year in which they would accrue to the health system. The costs are categorised according to three main headings:

- staff costs (including recruitment and opportunity costs)
- miscellaneous costs (such as equipment and transport costs)
- cost savings (such as reduced healthcare utilisation)

Unit costs for the analysis were expressed in 2020 Irish euro (apart from diagnosis related group costs which were expressed in 2019 euro due to unavailability of data for the full year 2020). All costs were derived according to the HIQA guidelines for budget impact analysis and economic evaluation in Ireland.[20, 21] The unit costs are presented in Sections 4.1 to 4. 3 according to the categories listed above.

4.1 Staff costs

4.1.1 Recruitment costs

Under the guideline implementation plan, it is proposed (subject to securing funding in the Health Service Executive (HSE) national estimates process in the year prior to team appointment) that:

- 32 new pulmonary rehabilitation programme (PRP) teams are established (comprising recruitment of one full-time respiratory specialist physiotherapist as a coordinator, one full-time physiotherapist, one full-time respiratory nurse and one part-time (0.5 WTE) administrator per team)
- 15 new COPD outreach services are established (comprising recruitment of one full-time respiratory specialist physiotherapist and one full-time respiratory nurse specialist per team)
- 32 new community specialist teams (comprising one full-time technician, one full-time administrator and one part-time Chief II Officer) will be established over a two-year timeframe to support Community Healthcare Network (CHN) Learning Sites.

The unit costs and whole-time equivalent (WTE) for the recruitment of additional staff are presented in Table 4.1.1.

Table 4.1.1: Unit costs for recruitment of additional staff

Description	Grade	WTE (per team)	Unit cost (per annum)*	LCI	UCI	Distribution	Source(s)
Pulmonary rehabilitation							
Respiratory specialist physiotherapist	Clinical specialist physiotherapist	1	€90,262	€81,857	€99,071	Gamma	[43]
Physiotherapist	Physiotherapist	1	€64,719	€55,730	€74,370	Gamma	[43]
Respiratory clinical nurse specialist	Clinical nurse specialist (general)	1	€76,751	€68,607	€85,344	Gamma	[43]
Administrator	Clerical officer, grade IV	0.5	€52,705	€38,303	€69,371	Gamma	[43]
COPD outreach							
Respiratory specialist physiotherapist	Clinical specialist physiotherapist	1	€90,262	€81,857	€99,071	Gamma	[43]
Respiratory clinical nurse specialist	Clinical nurse specialist (general)	1	€76,751	€68,607	€85,344	Gamma	[43]
CHN specialist team							
Technician	ECG Technician, Chief I	1	€62,252	€54,321	€70,715	Gamma	[43]
Chief II Officer	Respiratory physiologist, Chief II	0.25	€84,477	€67,797	€102,965	Gamma	[43]
Administrator	Clerical officer, grade IV	1	€52,705	€38,303	€69,371	Gamma	[43]

Key: CHN – community healthcare network; COPD – chronic obstructive pulmonary disease; ECG – electrocardiogram; LCI – lower 95% confidence interval; UCI – 95% upper confidence interval; WTE – whole time equivalent.

*Salaries are based on mid-point of scale adjusted for pension, pay related social insurance (PRSI) and overheads (such as office space, heating and lighting) as per HIQA guidelines.[20, 21] Non-parametric bootstrapping (n=10,000 bootstraps), based on random sampling of the relevant HSE salary scales,[43] was undertaken to estimate salary uncertainty.

4.1.2 Opportunity costs (delivery by existing staff)

As outlined in Section 3, support will also be required from existing personnel within the healthcare system to expand the provision and delivery of PRPs, COPD outreach and oxygen assessment clinics. These labour requirements will be fulfilled by existing personnel already employed in the HSE, and thus are estimated as opportunity costs. In this instance, the opportunity cost refers to the time spent supporting the delivery of PRPs, outreach or oxygen assessment clinics in place of delivering their usual duties. The unit costs for estimating these opportunity costs are presented in Table 4.1.2.

Table 4.1.2: Unit costs for estimation of staff opportunity costs

Description	Grade	Time input (per week)	Unit cost (per hour)*	LCI	UCI	Distribution	Source(s)
Pulmonary rehabilitation							
Respiratory consultant	Consultant	1 day x 0.4 WTE**	€185	€168	€204	Gamma	(44)
Dietitian	Senior dietitian	1 hour	€53	€47	€58	Gamma	(43)
Pharmacist	Senior pharmacist	1 hour	€62	€56	€66	Gamma	(43)
Psychologist	Clinical psychologist	1 hour	€62	€42	€83	Gamma	(43)
Occupational therapist	Clinical specialist OT	1 hour	€58	€52	€62	Gamma	(43)
SLT	Clinical specialist SLT	1 hour	€58	€52	€62	Gamma	(43)
COPD outreach							
Respiratory consultant	Consultant	1 day x 0.3 WTE**	€185	€168	€204	Gamma	(44)
Administration	Clerical officer	Half day	€29	€20	€37	Gamma	(43)
Oxygen assessment clinics							
Respiratory consultant	Consultant	1 day x 0.3 WTE**	€185	€168	€204	Gamma	(44)
Administration	Clerical officer	Half day	€29	€20	€37	Gamma	(43)

Key: LCI – lower 95% confidence interval; UCI – 95% upper confidence interval; OT – occupational therapist; SLT – speech and language therapist; WTE – whole time equivalent.

*Salaries are based on mid-point of scale adjusted for pension, pay related social insurance (PRSI) and overheads (such as office space, lighting and heating) as per HIQA guidelines.[20, 21] Non-parametric bootstrapping (n=10,000 bootstraps), based on random sampling of the relevant HSE salary scales,[43] was undertaken to estimate salary uncertainty.

** It is assumed that one day of consultant time will be required across the delivery of pulmonary rehabilitation, COPD outreach and oxygen assessment clinics.

4.2 Miscellaneous costs

The set-up of a centre for delivering PRPs requires a one-off purchase of equipment. This includes dumbbells, ankle weights, an exercise step, a stopwatch, cones and a vital signs monitor with finger probe. Consistent with national guidelines for conducting BIA,[21] depreciation of equipment is calculated on a straight-line basis of 10% per annum.

As those involved in the delivery of outreach must travel to patients' homes, travel costs for the outreach team are estimated. The transport were estimated by application of the HSE allowance rates to the average mileage covered by three outreach teams (including urban and rural teams) in 2017. These costs are presented in Table 4.2.1.

Table 4.2.1: Inputs for estimating miscellaneous costs

Description	Details	Unit cost	LCI	UCI	Distribution	Source(s)
PRP equipment*	Purchase cost per PRP centre	€950	€781**	€1,156**	Lognormal	[9]
Equipment depreciation	10% annual reductions	€95	NA	NA	NA	[21]
Outreach team mileage	Annual mileage per team (km)	7,136	5,708	8,563	Normal	[45] [9]
Mileage allowance	Reimbursement rate per km	€0.29	€0.27	€0.31	Gamma	[45]

Key: LCI – lower 95% confidence interval; UCI – 95% upper confidence interval; PRP – pulmonary rehabilitation programme.

* Cost excludes purchase of oxygen and a defibrillator. These will be required where not already available.

** An arbitrary standard deviation of 10% was used to estimate the 95% confidence interval due to data unavailability.

The following costs were excluded from this BIA:

- Rental costs from hiring real estate (such as community facilities) for the delivery of services, as it is expected that services will be provided within existing facilities.
- The opportunity cost from the use of existing facilities are not currently known.
- Staff subsistence costs associated with the delivery of COPD outreach. Subsistence costs were excluded as it is intended that staff will deliver outreach within a limited distance of the hospital vicinity, where possible. Therefore, staff are unlikely to be eligible for subsistence allowances.
- Staff training costs. Under the implementation plan, additional training will not be required for recruited or existing personnel involved in the delivery of pulmonary rehabilitation, COPD outreach or oxygen assessment.

4.3 Cost offsets and savings

4.3.1 Reduction in rehospitalisation following PRP completion

Recurrence of acute exacerbations of COPD is associated with increased healthcare utilisation (such as hospital admission and ED attendance).[46] It is estimated that 20% of patients hospitalised with an acute exacerbation of COPD are readmitted within 30 days with a third readmitted within 90 days of discharge.[47] A 2016 Cochrane review of randomised control trials (RCTs) by Puhan et al.[31] investigated the effectiveness of pulmonary rehabilitation on the prevention of hospital readmission. Their meta-analysis estimated an odds ratio (OR) of 0.44 (95% Confidence Interval: 0.21–0.91) at 12 months follow-up. That is, patients who completed a PRP following hospitalisation were 0.44 times as likely to be readmitted to hospital as patients that received usual care. This OR was recalculated, by reproducing the random effects meta-analysis, as a risk ratio (RR) of 0.66. To estimate potential cost savings from a reduction in rehospitalisation through the expansion of access to pulmonary rehabilitation a number of additional parameters were required (see Table 4.3.1) how these were estimated is outlined below.

Based on the pulmonary rehabilitation needs assessment,[29] there were 16,147 COPD hospital admissions representing 11,052 patients in 2014, giving an average rehospitalisation rate of 0.46 per individual admitted in 2014. HIPE data on the total number of COPD hospitalisations and COPD patients hospitalised (using the number of unique hospitalisations (that is, those that were not re-admitted) was used as a proxy for the annual number of COPD patients hospitalised) from 2007 up to 2019.[48] As the data comprise annual mean estimates with a clear linear trend, a generalised linear (GLM) model approach was considered appropriate to estimate both the overall number of COPD hospitalisations and the annual number of COPD patients hospitalised over the BIA's five year time horizon. These GLMs modelled the number of hospitalisations and patients hospitalised as count data using a Poisson link function and error distribution, and included year and data from the Central Statistics Office (CSO) on projections of the over 65 population[8] as explanatory variables. The estimated GLM coefficients (that is, the change in the response of the dependent variable associated with a change in an explanatory variable, while holding all other explanatory variables constant) were then simulated from a multivariate normal distribution to account for imprecision in the model projections. These were used to estimate the annual COPD hospitalisations and COPD patients hospitalised to calculate a baseline rehospitalisation rate for each year of the BIA.

The number of patients that complete a PRP is a function of the annual capacity of a PRP, adjusted for the number of patients that do not complete the PRP. The pulmonary rehabilitation model of care recommends class sizes of 12 patients per PRP, with up to 132 patients attending PRPs per centre per annum.[34] Based on the findings of the pulmonary rehabilitation needs assessment,[29] patient dropout in PRPs in Ireland ranged from 5% to 49%, with a mean of 25%. As PRPs are operated concurrently (with effort made to replace

patients that drop out), a replacement rate of 50% was assumed.

To estimate potential cost savings from a reduction in rehospitalisations, the average cost of a hospital admission for COPD in Ireland was estimated. In line with the methods used in the pulmonary rehabilitation needs assessment,[29] the International Statistical Classification of Diseases and Related Health Problems (ICD) codes J40 to J44 were used to identify the average number of COPD inpatient admissions between 2015-2019 in the HIPE database. An average cost for an acute exacerbation of COPD per admission was calculated based on the weighted average cost for the applicable diagnosis related groups (DRGs) per patient in 2019.

Applying this estimate to the cost of hospitalisation enabled the calculation of the incremental savings from the prevention of hospitalisation. This saving was assumed to accrue for each patient that successfully completed a PRP one year after completion of the programme. Savings were not estimated to occur beyond one year as there is no high-quality evidence of a sustained effect and the current guideline does not recommend repeat PRPs. The parameters used to estimate cost savings from the avoidance of rehospitalisation following PRP completion are presented in Table 4.3.1.

Table 4.3.1: Input parameters for estimating cost savings from a reduction in rehospitalisation following PRP attendance

Description	Mean	LCI	UCI	Distribution	Source(s)
COPD hospitalisations*	17,503	17,022	17,984	Normal	[8, 48]
COPD patients hospitalised*	12,600	12,123	13,078	Normal	[8, 48]
RR of rehospitalisation following PRP	0.66	0.45	0.99	Lognormal	[31]
Participants per PRP	12	NA	NA	NA	[34]
Dropout rate	0.25	0.22	0.28	Binomial	[29]
Replacement rate	0.5	0	1	Uniform	Assumption
Cost per hospitalisation (ICD-codes J40 to J44)	€4,402	€3,618**	€5,355**	Lognormal	[48]

Key: COPD – chronic obstructive pulmonary disease; ICD – International Statistical Classification of Diseases and Related Health Problems; PRP – pulmonary rehabilitation programme; RR – risk ratio.

* Unadjusted average annual estimate over next five years. The number of COPD hospitalisations and patients hospitalised were simulated directly from the GLM outputs.

** An arbitrary standard deviation of 10% was used to estimate the 95% confidence interval.

4.3.2 COPD outreach – cost offsets from reduced length of stay

Expansion of COPD outreach is likely to release hospital capacity for inpatient care as a greater number of COPD patients will be discharged from hospital, to receive care in their home environment, within 72 hours of admission. The release of hospital capacity was estimated in terms of cost offsets attributable to the HSE from a reduced length of stay in hospital by COPD

patients. The median length of stay for COPD patients admitted to inpatient care from 2015 to 2019 was four days. The cost offset was based on the difference in average DRG costs between a hospital admission lasting three days versus four days.

The number of COPD patients that are likely to receive outreach care was estimated using 2017 national hospital data (n=13 hospitals) provided to the COPD clinical programme.[9] These data included the number of eligible patients that were reviewed for potential inclusion in a COPD outreach programme. To estimate the eligible population on a national level per hospital, each hospital was assigned a weight based on its sample size and a simulation exercise using a sampling with replacement method was conducted, with the mean and standard deviation of the estimates recorded. A random effects meta-analysis of hospital level data was then undertaken to estimate the mean uptake rate of COPD outreach.

The parameters used to estimate the cost offsets to the HSE from the reduction in length of stay for COPD patients that receive outreach care are presented in Table 4.3.2.

Table 4.3.2: Input parameters for calculation of cost offsets for COPD outreach

Description	Mean	LCI	UCI	Distribution	Source(s)
Cost offset per patient	€120	€99	€146	Lognormal	[48]
Eligible population per hospital*	642	559	725	Normal	[9]
Uptake rate**	0.17	0.12	0.23	Beta	[9]

Key: COPD – chronic obstructive pulmonary disease; LCI – lower 95% confidence interval limit; HIPE – Hospital Inpatient Enquiry Scheme; ICD – International Statistical Classification of Diseases and Related Health Problems; UCI – upper 95% confidence interval limit.

* Based on sampling with replacement in simulation of 2017 hospital data.[9]

** Based on random effects meta-analysis of 2017 hospital data. A subgroup of three hospitals with established COPD outreach programmes were used for the mean and 95% confidence interval.

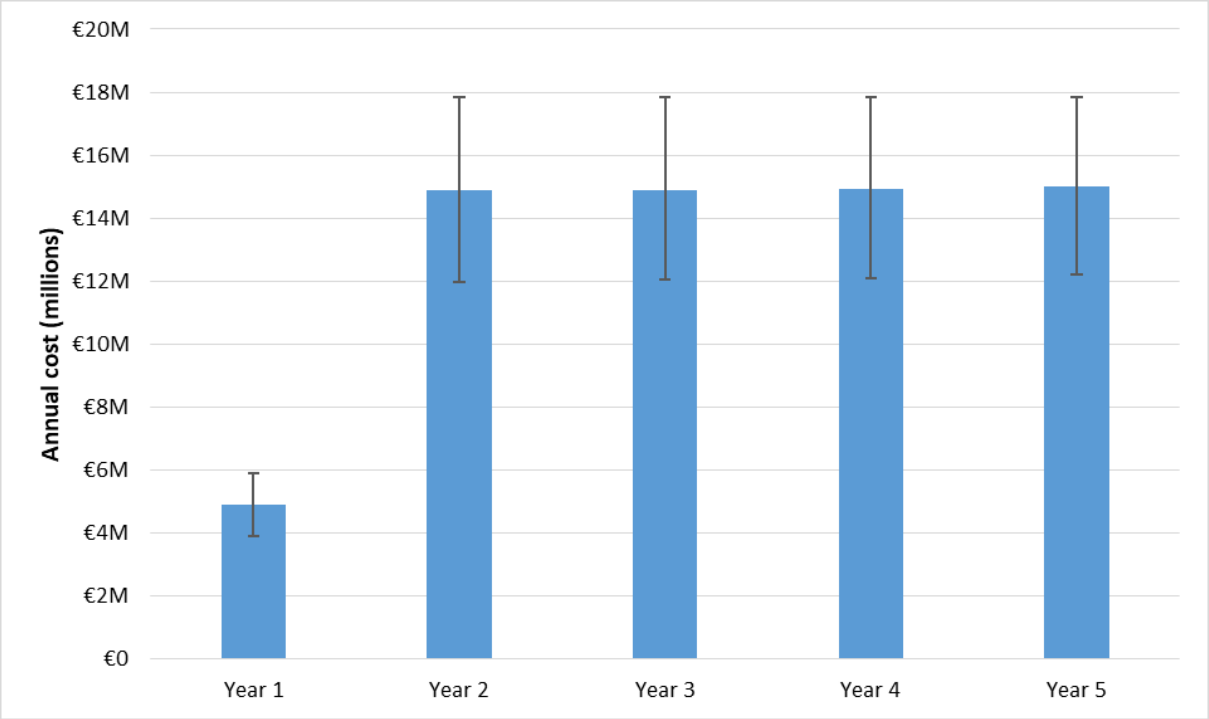
5. Results

Results of the budget impact analysis (BIA) are presented in this section, but it should be noted that funding for the initial two years of the implementation plan has already been allocated to the HSE Integrated Care Programme Prevention and Management of Chronic Disease to support the implementation of this guideline under the HSE Winter Plan 2020/21 and Acute Hospitals budget.[9, 19]

5.1 Overall budget impact

Overall, the incremental net cost of the COPD guideline was estimated at €65 (95% CI: 52.2-77.3) million over five years. This estimate includes the net costs of setting up 32 pulmonary rehabilitation programmes (PRP) teams (and the offset of cost savings due to prevention of hospital admissions), 15 COPD outreach services (and the cost offsets from the release of hospital capacity), 15 oxygen assessment clinics and 32 specialist teams to support Community Healthcare Network (CHN) learning sites. In accordance with the proposed implementation plan, the budget impact stabilises from year two onward (given that all additional interventions are established and new staff recruited). A graphical summary of the incremental cost per year is illustrated in Figure 5.1.1.

Figure 5.1.1: Incremental budget impact (in millions) across a five year time horizon*



* Error bars represent the 95% confidence intervals estimated in the probabilistic sensitivity analysis.

5.2 Budget impact according to health intervention

The annual costs applicable to resourcing each intervention (that is, pulmonary rehabilitation, outreach, oxygen assessment clinics and CHN specialist teams) are summarised in Table 5.2.1. In descending order, the largest budget impact was estimated from the expansion of PRP teams, recruitment of specialist teams to support CHNs, expansion of COPD outreach and expansion of oxygen assessment clinics. However, it should be noted that the cost estimates for the expansion of oxygen assessment clinics include only the resourcing costs of existing HSE staff and assumes that the operation of the clinics will be synergised alongside delivery of PRPs. Therefore, the full recruitment cost of expansion is incurred as part of the expansion of PRP teams. The estimated salary costs are discussed further in Section 5.3.

The incremental budget impact includes the estimated cost savings from rehospitalisations avoided by patients that successfully complete a PRP, and the cost offsets from the release of hospital capacity for patients that receive COPD outreach. These estimates are discussed in more detail in Section 5.4.

Table 5.2.1: Summary of incremental budget impact per year (in millions)

Intervention	Year 1 (95% CI)	Year 2 (95% CI)	Year 3 (95% CI)	Year 4 (95% CI)	Year 5 (95% CI)	Total (95% CI)
PRP teams	€2.4 (1.7-3.2)	€7.1 (5.0-9.2)	€7.1 (5.1-9.2)	€7.1 (5.1-9.2)	€7.2 (5.2-9.2)	€31.0 (22.1-39.9)
COPD outreach	€0.7 (0.7-0.8)	€2.7 (2.5-2.9)	€2.7 (2.5-2.9)	€2.7 (2.5-2.9)	€2.7 (2.5-2.9)	€11.5 (10.6-12.3)
Oxygen clinics	€0.3 (0.2-0.3)	€0.7 (0.7-.8)	€0.7 (0.7-.8)	€0.7 (0.7-.8)	€0.7 (0.7-0.8)	€3.2 (2.9-3.6)
Specialist teams (CHNs)	€1.5 (1.3-1.7)	€4.4 (3.8-5.0)	€4.4 (3.8-5.0)	€4.4 (3.8-5.0)	€4.4 (3.8-5.0)	€18.9 (16.6-21.5)
Total	**€4.9 (3.9-5.9)**	**€14.9 (12.0-17.9)**	**€14.9 (12.1-17.8)**	**€14.9 (12.1-17.8)**	**€15.0 (12.2-17.8)**	**€64.6 (52.2-77.3)**

Key: CHN – community healthcare network; CI – confidence interval; COPD – chronic obstructive pulmonary disease; PRP – pulmonary rehabilitation programme.

5.3 Gross (staff) costs

Staff costs represent the vast majority (approximately 99%) of the gross costs estimated in this BIA. Across the five year time horizon, recruitment and opportunity costs were estimated at €65.5 (95% CI: €61.2 to €70.0) million and €8.6 (95% CI: €7.8 to €9.4) million, respectively. The large recruitment costs, which represent upfront investment, is a direct consequence of the resource requirements for additional staff to expand COPD healthcare access outlined in the guideline implementation plan. The total estimated gross staff costs across the five year time horizon is presented in Table 5.3.1.

As per the guideline's implementation plan, the gross costs stabilise from year two onward (given that all additional interventions are established and new staff recruited). It is clear from the annual gross costs that the estimated budget impact is primarily driven by the salary costs of new staff.

Table 5.3.2: Total gross costs (in millions) across five year time horizon

Intervention	Year 1 (95% CI)	Year 2 (95% CI)	Year 3 (95% CI)	Year 4 (95% CI)	Year 5 (95% CI)	Total (95% CI)	% of all gross costs
Recruitment costs	€5.0 (4.7-5.4)	€15.1 (14.1-16.2)	€15.1 (14.1-16.2)	€15.1 (14.1-16.2)	€15.1 (14.1-16.2)	€65.5 (61.2-70.0)	88.2% (87.5-88.7%)
Opportunity costs	€0.7 (0.6-0.7)	€2.0 (1.8-2.2)	€2.0 (1.8-2.2)	€2.0 (1.8-2.2)	€2.0 (1.8-2.2)	€8.6 (7.8-9.4)	11.6% (11.2-11.9%)
Total gross costs	€5.7 (5.3-6.0)	€17.2 (16.1-18.2)	€17.1 (16.1-18.2)	€17.1 (16.1-18.2)	€17.1 (16.1-18.2)	€74.3 (69.9-78.9)	100%

Key: CI – confidence interval.

5.4 Cost savings and offsets

In the BIA, cost savings were estimated from the potential avoidance of rehospitalisation for COPD patients that successfully completed a PRP. Over the five year time horizon, it was estimated that a total of 20,662 (95% CI: 17,406 to 23,501) patients would accept a place on a PRP. However, with a drop-out rate of 25% it was estimated that 4,632 (95% CI: 4,131 to 5,153) would not complete the PRP. Therefore, patient throughput was estimated at 16,030 (95% CI: 13,275 to 18,348). Following the establishment of all 32 PRP teams in year two of the time horizon, national PRP throughput from newly established PRP teams was estimated at approximately 3,700 patients per annum at an average cost per patient (that completed the PRP) of approximately €1,950.

Over the five year time horizon, cost savings accruing from rehospitalisation avoidance was estimated at €8.8 (95% CI: 0.03 to 17.0) million. These cost savings, from the prevention of hospital admission from an exacerbation of COPD, were assumed to occur for patients that completed PRPs in the year following completion. It was conservatively assumed that these cost savings do not continue to accrue to patients beyond one year.

In addition, cost offsets were estimated from the release of hospital capacity from patients receiving outreach. Over the five year time horizon, it was estimated that 6,974 (95% CI: 4,752 to 9,604) patients would receive COPD outreach following hospitalisation. It was estimated that this would lead to a total cost offset of €0.8 (95% CI: 0.5 to 1.2) million across the five year time horizon. Following the establishment of all 15 outreach teams in year two, it was estimated that an additional 1,637 would receive outreach per annum.

5.5 Univariate sensitivity analysis

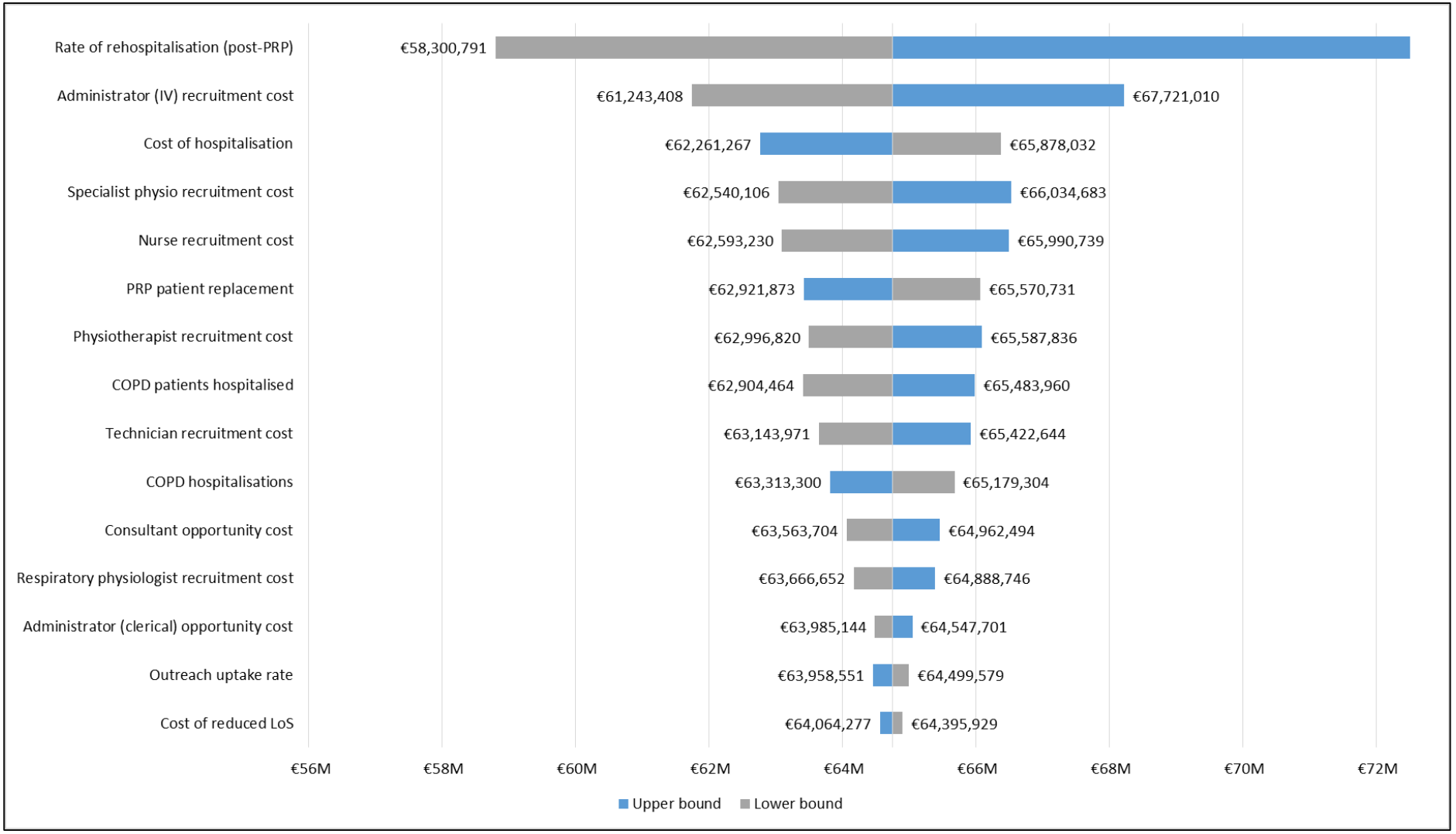
Through investigation of the univariate sensitivity analysis results, whereby all of the BIA parameters were fixed at their plausible lower and upper bounds, the 15 most influential parameters were identified. For the remaining parameters, the univariate sensitivity analysis did not vary the overall budget impact by more than 0.5%. In rank order, the most influential parameters were:

- the risk of rehospitalisation following participation in a PRP
- administrator (grade IV) recruitment cost
- the cost of an inpatient admission for COPD
- respiratory specialist physiotherapist recruitment cost
- respiratory nurse specialist recruitment cost
- replacement rate for patients that drop-out of a PRP
- physiotherapist recruitment cost
- the number of COPD patients hospitalised per annum
- technician recruitment cost
- the number of COPD hospitalisations per annum
- consultant opportunity cost
- respiratory physiologist recruitment cost
- clerical support for administration cost
- patient uptake of COPD outreach
- cost saving from reduced length of stay for patients that receive outreach.

The most influential parameter was the risk of rehospitalisation following participation in a PRP (where changing the estimated value led to a 23% variation in the overall budget impact), a change in this risk will have a direct influence on the cost savings that accrue to the HSE. Similarly, the cost of a hospital admission (6% variation in budget impact), the annual number of hospitalisations (3%), the annual number of patients hospitalised (4%) and the PRP replacement rate for patients that drop-out (4%) are influential given that these inputs form the basis of the estimated cost savings. This is also the case for uptake rate of COPD outreach (1%) and the cost of reduced length of stay (1%) which are used to estimate the cost offsets accruing to the HSE from the release of hospital capacity. Aside from these parameters, variation in the salary costs of those recruited will also have a significant impact on the estimated budget impact given the resource requirements outlined in the implementation plan.

The results of the univariate sensitivity analysis are presented in Figure 5.5.1.

Figure 5.5.1: Tornado plot illustrating results of the univariate sensitivity analysis



Key: COPD – chronic obstructive pulmonary disease; LoS – length of stay; PRP pulmonary rehabilitation programme.

8. Discussion

Given the rising prevalence of chronic conditions in higher income countries, the economic and social burden associated with COPD (in terms of morbidity and healthcare utilisation) has become an increasingly important public health issue.[5, 6] In Ireland, outcomes for COPD patients have been poor in terms of hospital admissions and length of stay, with international estimates suggesting that Ireland has one of the highest rates of hospital admissions for exacerbations of COPD in the Organisation for Economic Co-operation and Development.[7, 28, 49] These outcomes may be a result of resourcing deficits and underinvestment in community care.

Based on the implementation plan of the national clinical guideline for the *Management of COPD*, the following changes to the clinical pathway were included in this budget impact analysis (BIA):

- expansion of access to pulmonary rehabilitation programmes (PRPs)
- expansion of access to COPD outreach
- expansion of access to oxygen assessment clinics
- recruitment of specialist teams to support Community Healthcare Network (CHN) Learning Sites.

The overall incremental budget impact was estimated at €64.6 million (95% CI: €52.2 million to €77.3 million) over a five year time horizon. Uncertainty surrounding the budget impact was assessed by univariate and probabilistic sensitivity analyses. The univariate sensitivity analysis identified the risk of rehospitalisation following participation in a PRP, the salary costs of recruited staff and the cost of a COPD hospitalisation as the most influential parameters in the BIA. Changes in the estimated values for these three parameters could result in significant changes to the incremental budget impact.

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. International estimates suggest that Ireland has the highest rate of hospital admissions for exacerbations of COPD in the Organisation for Economic Co-operation and Development (OECD) at 368 per 100,000 population compared with the OECD average of 190 in 2015.[50] Additionally, Ireland has one of the highest death rates for COPD in the EU. According to a 2016 OECD report, the age-standardised mortality rate for COPD in Ireland is estimated at 60.3 per 100,000 (third highest in Europe behind Hungary and Denmark) compared with the EU average of 34.9.[51] COPD accounted for almost 5% (1,554 deaths) of all deaths in those aged 15 and over in Ireland in 2017.[8]

Overall, it is estimated that total recruitment costs will be €65.5 (95% CI: €61.2 to €70.0) million over five years. This represents the total funding required to hire new staff but excludes potential savings that may accrue as a result of better patient outcomes (such as reduced healthcare utilisation). As noted, funding has been allocated to support expansion of a variety of healthcare interventions under the Integrated Care Programme for Prevention and Management of Chronic Disease.

The incremental net cost of expanding the provision of PRPs was estimated at €31.0 (95% CI: €22.1 to €39.9) million over five years. However, this cost should be interpreted in light of the significant currently unmet need for pulmonary rehabilitation in Ireland. The National Needs Assessment for Pulmonary Rehabilitation Services (carried out in 2016) estimated that, in 2015, the total provision of PRPs met only 11% (1,211 of the 11,052 patients admitted with an acute exacerbation of COPD) of the total need.[29] Following the establishment of all 32 PRP teams in year two of the time horizon, it was estimated that approximately 4,800 additional patients would be offered a place on a PRP per annum, indicating that there would still be a deficit (5,000 patients) of unmet need versus capacity.

Although the long-term effectiveness of pulmonary rehabilitation is not well established, randomised controlled trials (RCTs) have shown that it can be effective at relieving symptoms, preventing complications and exacerbations, improving health status, and reducing mortality in COPD patients.[32, 34] In this BIA, it was assumed that the completion of a PRP led to a reduced risk of hospitalisation in the year following completion, based on a previously published meta-analysis of RCTs.[31] Over the five year time horizon, cost savings accruing from rehospitalisation avoidance was estimated at €8.8 (95% CI: 0.03 to 17.1) million representing a reduction of 1,989 (95% CI: 8 to 3,741) rehospitalisations. However, there is uncertainty in the applicability of the risk reduction given that it is applied only to those who complete a PRP, but non-attenders and non-completers may be more likely to have higher rates of readmission. The univariate sensitivity analysis found that reduced risk of rehospitalisation was the most influential parameter in the BIA.

A dropout rate of 25% (that is, 75% of patients completed the PRP) was assumed based on the pulmonary rehabilitation national needs assessment.[29] In the UK, 62% (4,637 out of 7,476) of patients completed (defined as attendance at 75% of classes) PRPs in 2017.[52] UK audit data also demonstrated that outcomes (in terms of readmissions, length of stay and death rates) were less favourable for patients that attended fewer classes and or attended shorter programmes,[53] highlighting the importance of implementing comprehensive PRPs that abide by national guidelines in terms of programme duration and class frequency.

An additional cost of €3.2 (95% CI: €2.9 to €3.6) million was estimated for the expanded provision of oxygen assessment clinics. It was assumed that the running of these clinics would be synergised across the delivery of PRPs and that full-time resourcing will not be required.

Therefore, it is not anticipated that new staff will be required for delivery of oxygen assessment, and the estimated cost comprises only the opportunity costs of time dedicated by existing staff in the health system. It should also be noted that the estimated expansion is based on the guideline implementation plan (stipulating the set-up of 32 additional oxygen assessment clinics) which, due to a lack of available epidemiological data, was not informed by expected patient numbers.

Long-term oxygen therapy (LTOT) can significantly improve patient survival rates when appropriately prescribed.[54] However, people derive no clinical benefit from inappropriately prescribed LTOT.[55] Data for the costs and outcomes of COPD patients receiving LTOT in Ireland is scarce. However, anecdotally it is believed that expanded provision of oxygen assessment has the potential to ensure that inappropriate prescribing of LTOT is reduced. The potential benefits (such as improved capacity within the healthcare system), the cost implications of increased or decreased uptake of LTOT and or other new pharmaceutical technologies that may reduce admission rates were not explicitly accounted for in this BIA. However, findings from a service review in UK, where an annual cost of £13 million from inappropriate prescribing to people who do not require oxygen therapy (n=15,000) has been estimated with findings indicating that 20% of people with COPD would have benefitted from oxygen therapy were not prescribed it.[55] The total annual cost in England was approximately £120 million, but the annual spend was reduced by up to 20% in Primary Care Trusts (approximating to between £10 and £20 million savings per year if replicated across England) where an assessment service was introduced.[55] This trend in the UK, in terms of reduced expenditure from a reduction in inappropriate prescribing, may be generalisable to Ireland.

The net cost of expanding COPD outreach was estimated at €11.5 (95% CI: €10.6 to €12.3) million with a total reduction of 6,974 (95% CI: 4,752 to 9,604) bed days over five years. The evidence on the effectiveness of outreach (in terms of reducing mortality and readmission rates, and improving health-related quality of life (HRQoL)) is limited;[38] however, expanding outreach has the potential to free up hospital capacity by discharging patients earlier to be cared for in their home environment. In line with current objectives for reform within the Irish healthcare system,[56] the release of acute healthcare capacity is an important feature considering that Ireland had the joint highest acute hospital bed occupancy of countries captured by the World Health Organisation's analysis in 2015.[57] This was estimated at 93% which is comparably higher than other European countries such as Germany (83%), France (76%), Italy (77%), Spain (76%) and the UK (84%).[57]

Finally, the recruitment of specialist teams to support CHN Learning Sites was estimated at €18.9 (95% CI: €16.6 to €21.5) million. These estimates comprise the salary costs of funding the new posts proposed in the guideline implementation plan. These Community Specialist Teams will provide specialist support to GPs in managing patients with chronic disease in the

community, including the provision of diagnostics, structured education programmes and community-based rehabilitation services that integrate community diagnostic services with each local hospital Pulmonary Function Laboratory. It is anticipated that better access to diagnostics and specialist support within the community will enhance the delivery of care to people with COPD or at-risk of developing COPD, and facilitate coordination of care. However, as these teams will support the needs of older people and those with chronic disease, bridging and linking the care pathways between acute and community services, it is also acknowledged that they may have a role beyond that of supporting COPD patients exclusively. The estimated budget impact should be interpreted in light of this requirement.

In addition to those already outlined, there are a number of key limitations relevant to this BIA. Firstly, the generalised linear model (GLM) used to estimate the number of COPD hospitalisations and number of COPD patients hospitalised may have led to overly precise projections due to autocorrelation and over-fitting of observed data. Secondly, an arbitrary replacement rate of 0.5 for patients that drop-out from a PRP was used in the analysis. The univariate sensitivity analysis demonstrated that this replacement rate will have a strong influence on the estimated budget impact. An empirically-based replacement rate (that is one that is based on real-world data) would be more informative. Lastly, it should be noted that estimates of the cumulative effects on patient morbidity and HRQoL of healthcare interventions is beyond the scope of a BIA (which focuses on the financial implications of introducing or expanding delivery of health interventions). A cost-effectiveness analysis tailored to the Irish setting would be required to fully assess the relevant cost and health consequences.

8.1 Conclusion

The budget impact of the *Management of COPD* guideline is estimated at €64.6 million (95% CI: €52.2 million to €77.3 million) across a five-year period. This includes the estimated cost of expanding the provision of pulmonary rehabilitation, COPD outreach, oxygen assessment clinics and Community Healthcare Networks Learning sites in Ireland. The expansion of these services will be implemented over a two year time horizon at an estimated cost of €19.8 (95% CI: €15.9 to €23.8) million. Funding to support the expansion of these interventions has already been allocated to the Integrated Care Programme over the initial two-year time horizon.

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Appendix 1: List of clinical recommendations

Guideline Recommendations

Pharmacological Management of COPD		
Recommendation		**Grade of recommendation**
Recommendation 1 *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)** *(GOLD).*	***Grade A***
Recommendation 2 *Long acting bronchodilators*	**2.1** Long acting bronchodilators should be offered to patients with confirmed stable COPD who continue to have respiratory symptoms (e.g. dyspnoea or cough) ***(Grade A)*** *(GOLD).*	***Grade A***
	2.2 Inhaled long acting muscarinic antagonists (LAMAs) and long acting beta agonists (LABAs) both significantly improve lung function, breathlessness and reduce exacerbations **(Grade A)** *(GOLD).*	***Grade A***
	2.3 LAMAs have a greater impact on exacerbation frequency compared to LABAs **(Grade B)** *(GOLD).*	***Grade A***
	2.4 LABA/LAMA combination therapy has a more profound impact on FEV1 and symptoms than monotherapy **(Grade A)** *(GOLD).*	***Grade A***
	2.5 LAMA/LABA in combination has a greater impact on exacerbation frequency than monotherapy **(Grade B)** *(GOLD).*	***Grade B***

Recommendation 3 *Inhaled corticosteroids*	**3.1** Offering an inhaled corticosteroid (ICS) to patients with confirmed stable COPD as first line therapy is not routinely recommended ***(Grade A)*** ***(Department of Veteran Affairs3) (Implied in GOLD).***	***Grade A***
	3.2 Regular treatment with ICS increases the risk of pneumonia especially in those with severe disease **(Grade A)** ***(GOLD)***.	***Grade B***
	3.3 ICS should however be considered in patients with ACOS **(Expert Opinion) (Guideline Development Group)**.	***Expert Opinion***
	3.4 Stable state blood eosinophil levels may be used to influence whether or not ICS should be used. Patients with blood eosinophil's <0.1 x10^9 are deemed unlikely to benefit while those with levels >0.3x10^9 are most likely to benefit **(Grade B)** ***(GOLD).***	***Grade B***
	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)***.	***Grade A***
	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)***.	***Grade A***

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 **(Expert Opinion)** ***(Guideline Development Group)*** ***(GOLD).***	***Expert Opinion***
Recommendation 5 *Roflumilast*	**5.1** In selected patients with the chronic bronchitic phenotype of COPD with severe to very severe air flow obstruction and history of exacerbations, a phosphodiesterase-4 (PDE-4) inhibitor may be reasonable add on therapy with a LAMA and LABA and possibly ICS. Roflumilast is not approved for reimbursement under the community drug schemes ***(Grade A)*** ***(GOLD).***	***Grade A***
Recommendation 6 *Theophylline*	**6.1** In certain selected patients, the addition of a theophylline may be reasonable ***(Grade B)*** **(GOLD).**	***Grade B***

Recommendation 7 *Prophylactic use of Macrolide Antibiotics*	**7.1** In patients who have severe COPD with two treated exacerbations, 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)** ***(Guideline Development Group).***	***Grade A*** ***Expert Opinion***
Recommendation 8 *Antioxidants and mucolytics*	**8.1** The use of mucolytic and antioxidants in routine practice for management of patients with COPD is **not recommended** ***(GOLD).***	
Recommendation 9 *Leukotriene antagonists*	**9.1** A role for leukotriene receptor antagonists in the management of patients with COPD is **not recommended** ***(GOLD).***	
Recommendation 10 *Alpha One Anti-trypsin (AATD) Augmentation Therapy*	**10.1** It is recommended that AATD augmentation therapy might be considered in young patients who 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 in an Irish context following completion of a pharmacoeconomic evaluation, as	***Grade B***

	cost-effectiveness was not demonstrated.	

Non-Pharmacological Management of COPD		
Recommendation		**Grade**
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).*** At the moment, the effectiveness and safety of E. cigarettes as a smoking cessation aid remains uncertain.	***Grade A***
Recommendation 12 *Influenza vaccination*	**12.1** The provision of an annual influenza vaccination is recommended **(Grade A)** ***(GOLD).***	***Grade A***
Recommendation 13 *Pneumococcal vaccination*	**13.1** The provision of the pneumococcal vaccination is recommended **(Grade B)** ***(GOLD).***	***Grade B***

Recommendation 14 *Pulmonary rehabilitation*	**14.1** The provision of pulmonary rehabilitation to stable patients with exercise limitation despite pharmacological treatment is recommended **(Grade A)** ***(GOLD).*** **14.2** The provision of pulmonary rehabilitation to patients who have recently been hospitalised for an acute exacerbation of COPD is recommended **(Grade B)** ***(GOLD).***	***Grade A*** ***Grade B***
Recommendation 15 *Oxygen Therapy provision*	**15.1** The provision of long-term oxygen therapy to patients with chronic stable hypoxemia with a PaO_2 less than 7.3kPa 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).*** **15.2** The provision of oxygen for patients with moderate hypoxemia, nocturnal desaturation, or exercise-induced desaturation in patients with COPD is not routinely recommended **(Grade A)** ***(GOLD).***	***Grade A*** ***Grade A***
Recommendation 16 *Nutritional support*	**16.1** Nutritional support should be considered in all malnourished patients with COPD **(Grade B)** ***(GOLD).***	**Grade B**

Recommendation 17 *Lung volume reduction*	**17.1** Lung volume reduction surgery is recommended for carefully selected patients with upper lobe emphysema and low post rehabilitation exercise capacity **(Grade A)** ***(GOLD).*** **17.2** In selected patients, bullectomy can also be recommended **(Grade C)** ***(GOLD).*** **17.3** In selected patients with advanced emphysema, bronchoscopic interventions can reduce end-expiratory lung volume and improve exercise tolerance; health status and lung function at 6 to 12 months following treatment. Endobronchial valves (Grade A); Lung coils (Grade B); Vapour ablation **(Grade B)** ***(GOLD).***	***Grade A*** ***Grade C*** **Grade A/B**
Recommendation 18 *Lung transplantation*	**18.1** It is recommended that appropriately selected patients with very severe COPD be considered for lung transplantation surgery **(Grade C)** ***(GOLD).***	***Grade C***
Recommendation 19 *Monitoring of Spirometry*	**19.1** In stable, diagnosed COPD patients, FEV 1 can be tracked by spirometry every two years ***(Expert Opinion)*** ***(Guideline Development Group).***	***Expert Opinion***
Recommendation 20 *Role of Palliative Care*	**20.1** For advanced COPD care, patients should be referred to a palliative care specialist as appropriate ***(Expert Opinion)*** ***(Guideline Development Group).***	***Expert Opinion***
Management of Exacerbations in COPD		
Recommendation 21 *Bronchodilator therapy*	**21.1** The initiation of short acting acute bronchodilator therapy (salbutamol, ipratropium or combination) is recommended for patients with an	***Grade C***

	exacerbation of COPD **(Grade C)** (***GOLD*).**	
Recommendation 22 *Steroids*	**22.1** 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*).**	***Grade A***
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 Guideline Development Group).***	***Grade B***
Recommendation 24 *Non-invasive ventilation (NIV)*	**24.1** The use of non-invasive ventilation in patients with acute exacerbations of COPD who develop acute respiratory failure associated with respiratory acidosis is recommended i.e. a $PaCO_2$ greater than 6kPa and an arterial PH less than 7.35, which is persistent following rationalization of delivered oxygen therapy **(Grade A)** ***(GOLD).***	***Grade A***

Recommendation 25 *COPD Outreach service*	**25.1** The 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)*** **(Guideline Development Group).**	***Expert Opinion***
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)** ***(Guideline Development Group).***	***Expert Opinion***
Recommendation 27 *Theophylline*	**27.1** The use of theophylline in acute exacerbations of COPD is not recommended **(Grade B)** ***(GOLD).***	***Grade B***
Oxygen therapy prescribing and monitoring in COPD		
Recommendation 28 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_2) of 88-92% is suggested pending arterial blood gas results ***(Expert Opinion) (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 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 ***(Expert Opinion) (Guideline Development Group).*** **28.3** Routinely offering ambulatory LTOT for patients with chronic, stable	***Expert Opinion*** ***Expert Opinion*** ***Grade A***

	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_2 ≤92%) should be assessed for long term oxygen therapy **(Expert Opinion) Guideline Development Group.**	**Expert Opinion**
	28.5 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).***	**Grade A**
	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).***	**Grade A**
Pathways, Bundles and Checklists for Managing Acute Exacerbation of COPD		
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)** ***(Guideline Development Group).***	***Expert Opinion***

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