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A matched-groups study evaluating the implementation of an Integrated Care Pathway Programme for Chronic Obstructive Pulmonary Disease in JurongHealth: study protocol

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5 **Programme for Chronic Obstructive Pulmonary Disease in JurongHealth: study protocol**
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ABSTRACT

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a principal cause of death and hospitalisation in Singapore. The chronic disease imposes a cost of USD\$9.9 million per year on the country's healthcare system. Gaps remain at both the primary care level and acute level in managing or right-siting of patients. In response to these gaps, JurongHealth has launched a COPD-Integrated Care Pathway (ICP) programme to provide comprehensive care for COPD patients. The programme has been designed to identify patients at high risk for early intervention. For the diagnosed patients, the programme aims to reduce morbidity, improve their quality of life and delay or prevent disease progression in an economically effective manner.

Methods and analysis

This is a prospective, pre-post, matched-groups study. Patients are enrolled into the COPD-ICP programme if they are seen in JurongHealth institutions and meet a set of inclusion/exclusion criteria. For this study, COPD patients seen in another public healthcare cluster will act as the control group database. The COPD-ICP programme classifies each enrolled patient based on the Patient Group Classification from the updated GOLD. It is hypothesized that the COPD-ICP

1
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3 programme will result in better clinical outcomes, reduced health utilisation and costs, and
4
5 improved quality of life for the programme patients. Hence, the primary objective is to evaluate
6
7 both the impact and economic-effectiveness of the COPD-ICP programme in terms of clinical
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9 outcomes (mortality, 30-day readmission rate) and health services utilisation and costs.
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14 15 **Ethics and dissemination**

16
17 This study has received ethical approval from the NHG Domain Specific Review Board (DSRB
18
19 Ref: 2013/01200). This study protocol describes the implementation and proposed evaluation of
20
21 the COPD-ICP programme. Results of the study will be reported through journal publications
22
23 and healthcare conferences. This study also enables the COPD-ICP team to identify areas in the
24
25 programme which requires a change of implementation approach.
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32 **Keywords**

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35 Chronic Obstructive Pulmonary Disease, Integrated Care Pathway, Evaluation, Healthcare
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37 Utilisation, Propensity Score Matching, Health Economics, Respiratory Medicine
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BACKGROUND

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of chronic disease morbidity and mortality worldwide. The disease is a global health problem with a worldwide prevalence of 10.1%.[1] In Singapore, there are about 60,000 cases of COPD which constitute about one-fifth of all deaths. Moreover, COPD is the seventh principal cause of death and the seventh most common condition for hospitalisation.[2] The disease places a large financial burden on health-care systems and society. A study conducted measured that the mean cost was approximately USD\$9.9 million per year in Singapore, with inpatient admission being the major cost driver, contributing an average of USD\$7.2 million per year.[3] The disease also accounts for high average length of stay (ALOS) and 30-day readmission rate.

Many of the patients who experienced repeated exacerbations are seen in the acute setting in Singapore. However, they can be appropriately managed at the secondary and/or primary care level, thereby freeing up tertiary resources for more advanced treatments, such as lung transplants and lung volume reduction surgeries. For patients discharged from the acute setting, more can be done to streamline and coordinate their care at the primary care levels. Early diagnosis and intervention efforts for at-risk individuals are also insufficient in the primary care setting as many GP clinics do not offer spirometry services. Furthermore, COPD patients in the community experience poor quality of life due to the lack of convenient access to pulmonary rehabilitation.

In response to the need for an economically-effective care model and to enhance care outcome, Jurong Health Services (JurongHealth) has launched a Ministry of Health (MOH) funded COPD-Integrated Care Pathway (COPD-ICP) programme in April 2012 that coordinates care across

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2
3 different healthcare settings. It aims to provide comprehensive care for COPD patients at
4
5 different stages of the disease, involving primary, hospital-based, community-based and
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7 palliative care. Similar to a Danish COPD early intervention project,[4] the programme
8
9 envisages the coordinating of care across different sites from primary care to homes and the
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11 hospital. The objectives of the programme are to:
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16 1. Reduce COPD prevalence in the western population through effective prevention efforts
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18 in the community
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21 2. Reduce morbidity and improve the quality of life of COPD patients
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24 3. Delay or prevent disease progression of COPD patients through early interventions

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26 The programme adopts a coordinated and multi-disciplinary approach to the management of the
27
28 patients' medical conditions. Dedicated case managers work with JurongHealth's multi-
29
30 disciplinary team of doctors, nurses, respiratory technologists, pharmacists, physiotherapists and
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32 medical social workers to develop a customised care plan for each patient, empower patients
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34 towards self-management through education and help coordinate referrals and patients'
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36 appointments across care sites.
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40 41 **Objective**

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44 This study is designed to evaluate the effect of the COPD-ICP programme on the following
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46 primary outcome measures: 1) Health services utilisation and cost; 2) 1-year mortality rate; 3)
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48 30-day readmission rate. The impact on the care costs for COPD patients will also be
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50 investigated via economic-effectiveness analysis.
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55 The secondary aims of this study include looking at the recommended care compliance and
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57 quality of life. Patients' perception of the extent to which the service is congruent with five of the
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3 care elements within the Chronic Care Model – Health System, Delivery System Design,
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5 Decision Support, Self-Management Support and Community will also be evaluated.
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8 9 **Methods/Design**

10 11 Design

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15 A prospective, pre-post, matched-groups design will be implemented for this study. Such a
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17 design will be utilised instead of the randomised controlled trial design as the COPD-ICP
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19 programme has been implemented in JurongHealth for almost two years. Care resources may
20
21 also be unnecessarily stretched if two care programmes (usual care and COPD-ICP) were run
22
23 concurrently. In order to strengthen the evidence obtained from this study, a matched control
24
25 group will also be formed from non-enrolees using methods described in later sections. Patients
26
27 for this control group will be sourced from another healthcare cluster in Singapore. Primary
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29 outcome measures will then be compared between programme patients and this control group.
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34 35 Study Setting

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38 The setting for this study is Alexandra Hospital, an acute care hospital in Singapore managed by
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40 JurongHealth. The hospital provides a range of clinical services mainly for the population in the
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42 south-western region of Singapore. Since April 2012, the COPD-ICP programme has been used
43
44 as the care model for all COPD patients seen in JurongHealth. For the purpose of this study
45
46 evaluation, COPD patients seen at National Healthcare Group (NHG) and National Healthcare
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48 Group Polyclinics (NHGP) institutions will act as the control group database. The study period
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50 will also be fixed from Apr 2012 to Jul 2013.
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55 56 Inclusion and exclusion criteria

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3 Patients are enrolled into the programme if they are 40 years old and above; are current or ex-
4 smokers; present with persistent (>3 months) or recurrent respiratory complaints compatible with
5 COPD; have spirometry reading of FEV₁ / FVC < 70%; and showed no increase in FEV₁ > 15%
6 above baseline value or >200 mL after bronchodilator administration.[5-6] Patients were
7 excluded if they have illnesses other than COPD that was likely to result in death within 2 years;
8 Bronchial asthma, Bronchiectasis, Active Pulmonary Tuberculosis, and uncontrolled heart
9 diseases such as unstable angina, heart failure refractory to treatment (New York Heart
10 Association class III or IV).[5, 7] Patients who have been enrolled into other care programmes
11 (such as The Airways Programme, TAP) are also excluded.
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25 Intervention

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28 The COPD-ICP programme classifies each patient enrolled into the programme based on the
29 Patient Group Classification from updated GOLD guidelines (see Figure 1).[5-6] This
30 programme has a customised set of interventions and right-siting plans for patients in each of the
31 four groups. Group A patients exhibit less symptoms and can be managed at the primary care
32 setting in this programme. Group B patients exhibit more symptoms and present an opportunity
33 to be managed well by primary care doctors to move into Group A with appropriate drug therapy
34 in this programme.[8-12] Group C patients exhibit less symptoms but have a more severe airflow
35 limitation. Patients belonging to this group are currently admitted to the hospital due to
36 exacerbations but those with stabilised conditions can be managed at the Specialist Outpatient
37 Clinics (SOCs) at 6 monthly interval. Group D patients exhibit more symptoms and are the target
38 of Advance Care Planning (ACP) and home care service in this programme.[13-14]
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There are 6 recommended care elements for Group A and Group B patients, namely; smoking cessation, patient education, drug optimisation, influenza vaccination, Body Mass Index (BMI) assessment and COPD Assessment Test (CAT) score measurement.[15-16] There are two additional ones recommended for the COPD patients classified into Group C and D category, namely; home oxygen whenever relevant and ACP when patients are ready for the conversation (Table 1 and 2).

Table 1: Key care elements for Group A, B, C and D COPD patients

Key Care Elements	At-risk	Group A	Group B	Group C	Group D	In exacerbation
		Low risk, less symptoms	Low risk, more symptoms	High risk, less symptoms	High risk, more symptoms	
1. Smoking prevention	√					
2. Smoking cessation	√	√	√	√	√	
3. Differential diagnosis	√					
4. Spirometric diagnosis	√	18-24monthly or when clinician suspects patient grouping has changed				
5. Patient education		√	√	√	√	
6. Drug optimisation		√	√	√	√	√
7. Influenza vaccination (yearly)		Only for Elderly (≥ 65 years old) & those		√	√	√
8. BMI assessment (yearly)		√	√	√	√	
9. COPD Assessment tool (CAT)		6-12monthly	6-12monthly	6-12monthly	3-4monthly	
10. Acute NIV (Invasive/Non-invasive)						√
11. Supported Restructured Hospital/Emergency Department discharge						√
12. Home Oxygen				√	√	
13. Advance care planning				√	√	

Table 2: Care elements recommended at each care site

	GP	POLYCLINIC	JURONG MEDICAL CENTRE	REGIONAL HOSPITAL	COMMUNITY HOSPITAL	HOSPICE	HOME
Care provision	Primary Care		Ambulatory & Community Care	Acute Care	Sub-acute and Rehab care	End-of-life care	Self-management
Management							
1. Smoking prevention			√				
2. Smoking cessation			√	√			
3. Differential diagnosis	√	√	√	√			
4. Spirometric diagnosis		√	√	√			
5. Patient education	√	√	√	√	√		
6. Drug optimization	√	√	√	√	√		
7. Influenza vaccination (yearly)	√	√	√	√	√		
8. BMI assessment (yearly)	√	√	√	√	√		
9. COPD Assessment tool (CAT)	√	√	√	√	√		
10. Acute NIV (Invasive/Non-invasive)				√			
11. Supported Restructured Hospital/Emergency Department discharge				√	√		
12. Home Oxygen						√	√
13. Advance care planning			√	√	√		

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3 In order to reduce the risk of deterioration in disease condition, five standards of care along the
4 care continuum model has been adopted for the programme. This involves collaboration with
5 healthcare providers from different care settings to close the current gaps in service provision
6 (Table 3). Training courses have also been organised to upgrade GPs' and polyclinic doctors'
7 knowledge in managing COPD patients. The sessions are also an avenue for the primary care
8 physicians to obtain specialist advice if necessary. With a reduction in deterioration incidences,
9 resources at the acute hospital level will be conserved while the prognosis of patients will be
10 improved.
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Table 3 Five Standards of care with care continuum model

1. Prevention of COPD

24 Primary and secondary prevention strategies will be implemented. Primary prevention strategies such as social
25 marketing campaigns and lifestyle modifications targeting the general population can help reduce smoking
26 incidence rates. Common secondary prevention strategies, such as patient education and smoking cessation
27 counseling can minimise the impact of the disease.
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2. Early Diagnosis

31 Many patients are not detected in the early stages of the disease because GP clinics, in Singapore, typically do
32 not offer spirometry tests which measure lung function. By providing access to spirometry tests in the community,
33 JurongHealth will be able to identify patients at risk of developing COPD or in the mild stage of COPD and provide
34 timely secondary prevention and early intervention.
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3. Management of stable COPD patients

37 Coordinated management planning and care that is based in the primary care setting should include pulmonary
38 rehabilitation for COPD patients. Pulmonary rehabilitation has been shown to improve patients' exercise capacity,
39 health related quality of life, and reduce healthcare service utilisation.
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4. Treatment and support during acute exacerbations

42 There should be access to appropriate levels of COPD care in the community, with referral access for the more
43 severe patients at the hospitals when needed.
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5. Care and support at end of life

47 Palliative care management is to be provided by the intermediate and long term care (ILTC) providers, in the
48 community where possible, for patients with end stage disease.
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Study Outcomes

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3 The primary outcome measures are at the system level. They include 1) health services
4 utilisation and cost; 2) 1-year mortality rate; 3) 30-day readmission rate.
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10 11 12 Healthcare utilisation and cost

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15 Hospital costs will be estimated by multiplying the diagnosis-related group (DRG) cost per
16 patient day by the inpatient length of stay (LOS). DRG average cost estimates include
17 manpower, room, procedure, medication and allocated fixed costs. The average cost by DRG
18 will be provided by the finance department. Direct medical costs for emergency department
19 (ED), specialist and primary care visits will be derived by multiplying the standardised unit cost
20 by the number of visits to each level of care. For primary care visits, costs per visit estimates for
21 both acute and chronic conditions will be used. Unit cost estimates include manpower,
22 medication and allocated fixed cost which will be obtained from the finance department.[17] The
23 administrative cost of operating the COPD-ICP programme will be derived from its financial
24 statement.
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40 1-year mortality rate

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43 The 1-year mortality rate for each enrolment group refers to the proportion of patients who died
44 (all causes) before the 1-year post-baseline time point.
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48 30-day readmission rate

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51 The proportion of patients who were discharged from either an NHG or JurongHealth institution
52 and re-admitted (all causes) to the same hospital within 30 days of their discharge date.
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3 In addition, the following measure will be used to gauge the level of achievement of the study's
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5 secondary aims.
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8 9 CAT score

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11 This is an eight-question health survey used to measure COPD control in individuals. Scores
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13 range from 0 to 40 and lower scores indicate better control. The quality of life of the patients is
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15 measured using the CAT at baseline and during their follow-up visits within the first year of
16
17 enrolment. It is used to measure the impact of COPD on a patient's wellbeing and daily life. A
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19 CAT score difference of 2 or more (or $\geq 10\%$) suggests clinically significant changes in the
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21 quality of life.[18] The CAT score difference is taken as the difference between the baseline and
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23 the best reading within 1 year. This outcome is only available for programme enrolees.
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29 Patient Assessment of Care for Chronic Conditions (PACIC) score

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31 This is a twenty-question survey used to measure the patients' perception on the congruency of
32
33 the service to five aspects of the Chronic Care Model.[19] These aspects have been widely
34
35 recognised as the key to improving quality and experience of chronic disease care.[20]
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44 **Data collection**

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46 The parameters and outcomes of interest for which data shall be collected have been summarised
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48 in Table 4. The three main sources of data are
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52 1. Chronic Disease Management System (CDMS): Source of SOC/clinic visit information
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54 for both enrolees and non-enrolees.
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2. Patient Case Management (PCM) system database: Case managers capture entered data on the 6 recommended key care elements (Table 1) common among the four patient groups.
 3. NHG administrative databases: Source of data for healthcare utilisation cost.

Table 4 Overall of assessments used in COPD-ICP implementation study

Domain	Type of assessment/outcomes	Pre-ICP implementation	Post-ICP implementation	ICP concurrent controls in CDMD
Baseline demographics	Age, race, gender, nationality, postal code	x	x	x
Disease	Disease Type, Disease duration	x	x	x
Social-economics	Medisave, Medifund, Medical social worker referral	x	x	x
Programme management	Programme enrolment date	x(baseline)	-	-
Quality of life	CAT score	x(baseline)	x	-
Smoking history	Smoking status, no of year smoke	x	x	x
Key care elements	Refer to table 1	x(baseline)	x	
Medication use		x	x	x
Comorbidities & Complication	Asthma	x	x	x
	Depression			
	Congestive heart failure	x	x	x
	Diabetes	x	x	x
	Hypertension	x	x	x
	Renal failure	x	x	x
	Stroke	x	x	x
	Dyslipidemia			
	Obesity			
	Others	x	x	x
COPD-related Health service utilisation	Hospitalisation	x	x	x
Number of encounters	Emergency department attendance	x	x	x
	Specialist outpatient visit	x	x	x
	Primary care visit	x	x	x
COPD-related Cost	Direct cost	x	x	x
	Indirect cost	x	x	
Mortality	Rate of mortality	x	x	x
Qualitative measures	Patient assessment of chronic illness care	x	x	
	Integrated team monitoring and assessment tool	x	x	

COPD patients will be identified based on the International Classification of Diseases Tenth Revision (ICD-10-AM) diagnostic codes (J40.xx and J47.xx). All data will be collected for the COPD-ICP enrollees over 1 year pre-enrolment and 1 year follow up post-enrolment (3 monthly interval) and over a 1-year period for non-enrolees. They include patient demographics and socio-economic indicators (Age, race, gender, nationality, postal code, Medisave/Medifund, Medical social worker referral); programme enrolment date; smoking history; medication; comorbidities; severity of COPD (GOLD classification) and quality of life assessment (CAT

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3 score). The Patient Assessment of Care for Chronic Conditions (PACIC) survey will be
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5 administered during baseline and every follow-up visit.
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10 11 12 **Sample size**

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15 Using a mean CAT scores difference of 2.1 as the threshold for clinical significance, standard
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17 deviation of 6.9 (approximated from routinely collected data) and ratio between groups of 1, a
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19 sample size of 115 patients in each group will be needed for statistical comparisons to be made at
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21 90% power. Hence, 200 enrolees (to account for missing data) will be sampled from amongst
22
23 those who were enrolled into the programme during the study period and their matching controls
24
25 will be drawn from the control group database who have at least one visit to NHG or NHGP
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27 institutions during the study period.
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32 33 **Statistical Analysis**

34 35 36 **Propensity Score Matching**

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39 Since patients are enrolled into the programme based on the institution which they were seen in,
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41 there is likely to be imbalance in baseline characteristics between enrolees and non-enrolees.
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43 Matching will be performed via propensity scores.[21] These scores will be derived from a
44
45 multivariate logistic regression with programme enrolment as the dependent variable and the
46
47 following covariates: age, gender, race, hospital, ward class, number of hospitalisation or
48
49 emergency attendances in the past year, comorbid conditions and use of medication.
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54 Patient baseline characteristics from both enrolee and the matched-control groups will be
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56 described with mean and standard deviation for continuous variables and number and percentage
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3 for categorical variables. Differences between COPD-ICP enrolees and non-enrolees will be
4 compared using chi-square statistics for categorical variables and Wilcoxon rank sum tests for
5 continuous variables.
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10 Comparing the primary outcomes

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13 Healthcare utilisation & cost will be compared using a gamma regression while mortality and 30-
14 day readmission will be compared with a logistic regression.[22] Since certain unmeasured
15 clinical characteristics may influence whether a patient is enrolled into the programme and their
16 outcome directly, there is a need to reduce systematic bias from these unmeasured risk factors.
17 Hence, the direct distance between the postal code of patients' residential address and Alexandra
18 Hospital's postal code will be used as an instrumental variable for programme enrolment in each
19 of the regression models.[23] This variable is considered to be a good instrument for programme
20 enrolment as it should generally be uncorrelated with most clinical outcomes but is correlated
21 with whether the patient is enrolled into the programme (patients with longer direct distances
22 from Alexandra Hospital are more likely to be seen in NHG/NHGP institution).
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39 CAT score comparison

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42 To evaluate the quality of life improvement of the COPD patients using CAT score as the
43 outcome, the change in CAT score over the 1-year post-enrolment time frame will be examined
44 using longitudinal modelling.
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49 PACIC score

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53 To evaluate the congruency of the COPD-ICP programme to the CCM, the average PACIC score
54 for programme enrolees will be computed and benchmarked with PACIC results of other
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3 integrated care programmes in present literature that have showed substantial congruency to the
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5 CCM.
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11 Economic-effectiveness Analysis

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13 To assess the economic effectiveness of the COPD-ICP to the hospital, a Markov model will be
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15 developed to simulate patient movement between patient classifications.[24] Specific parameters
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17 (cost incurred and transition probabilities) of the model will be estimated from the data. The five-
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19 year healthcare utilisation cost and mortality rate of each programme arm will be computed.
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21 Probability sensitivity analysis will also be used to assess the robustness of analysis results.[25]
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28 Software

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31 All analyses will be conducted using Stata version 12 and Treeage Pro 2011.
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38 Discussion

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41 In designing the COPD-ICP programme, three key principles have been adopted: right-siting,
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43 integration and patient-centredness. It also involves the five standards of care: COPD prevention,
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45 early diagnosis, management of stable COPD patients, treatment and support during acute
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47 exacerbations, together with care and support at end of life. The model of care concept plan is
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49 drafted with reference to various evidence-based guidelines such as the GOLD standard,
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51 American College of Physicians guideline on diagnosis and management of stable chronic
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53 COPD and MOH COPD Clinical Practice Guidelines (2006).[26–27]
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Potential shown in COPD-ICP programme

This programme serves to close current service gaps to provide comprehensive integrated care along the care continuum in the following ways. Training for primary care physicians in the management of COPD has the potential to enhance care standards at their care setting. A multi-disciplinary care team comprising of the clinician, case manager, coordinator and other relevant allied health members have been shown to improve clinical outcomes and life expectancy of COPD patients. Patients admitted for exacerbations are contacted within 48 hours from discharge to reinforce patient education and to increase their confidence in self-managing of their own condition. Lastly, the case manager plays the role of the liaison between step-down care partners, primary care physicians and patients. This can potentially lower the risk of readmission and reduce the frequency of exacerbation. From an international perspective, similar integrated care models around the world have also showed similar positive results.[28-29] These evidences further support JurongHealth to launch and maintain the COPD-ICP programme.

Benefits of study evaluation

The rationale behind this programme evaluation stems from the motivation to bolster support for the programme. In this evaluation, two outcomes – 30-day re-admission rate and CAT score will be used by the team to identify any care gaps, so as to improve the COPD-ICP programme. In addition, two other outcomes measure – healthcare utilisation cost and mortality rate are indicators used to assess the practicality of sustaining the programme. This study can also potentially add to the mounting evidence in support of integrated care in healthcare literature.

Strengths of study design

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3 This study design has several strengths. The PACIC survey will be used assess patients'
4 experience of care which they received. This is in line with the organisation's aim to deliver
5 patient-centred care.
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11 The choice of the matched-control group patients using propensity scores will replicate the
12 balance in baseline characteristics between compared cohorts achieved through randomisation.
13 This will in turn reduce the effect of selection bias due to the lack of randomisation.[30] This
14 step will be vital for making valid conclusions from the economic effectiveness analysis. By
15 introducing direct distance between residential address and Alexandra Hospital as an instrument
16 variable for programme status, systematic bias introduced by unmeasured baseline characteristics
17 will also be attenuated.
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28 By looking at several outcomes (economic-effectiveness, clinical outcomes, patients'
29 experience), this study also allows the COPD-ICP team to identify areas in the programme which
30 requires a change of implementation approach.
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36 Limitations of the study

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39 The study design may have some limitations. Firstly, the data collection process does not account
40 for both enrolees and non-enrolees who choose to have their follow-up medical appointments at
41 non-NHG/NHGP/JurongHealth institutions. Such non-compliance may potentially skew results.
42 In addition, the assumption that direct distance is uncorrelated with unmeasured confounders
43 may not be true. It is still unclear whether direct distance is correlated with household income
44 which influences both outcome (more resources to control disease) and baseline characteristics.
45 However, these limitations affect the evaluation of the programme only but not the quality of
46 care provided at any institution.
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3 As a whole, the COPD-ICP programme serves to equip primary care partners with the adequate
4 knowledge and skills for managing stable COPD patients and to right-site patients in order to
5 provide excellent and appropriate care while optimising available healthcare resources. We
6 believe that this evaluation study can provide an evidence-based assessment of the impact and
7 economic-effectiveness of the COPD-ICP programme. The lessons learnt from this study may
8 also be extended to the evaluations of other ICP programmes that JurongHealth is implementing
9 in the near future.
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20 **Ethics and Dissemination**

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22 This study has received ethical approval from the NHG Domain Specific Review Board (DSRB
23 Ref: 2013/01200).
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29 Confidentiality

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31 Names and National Registration Identity Card (NRIC) number of patients will be removed and
32 replaced with unique study IDs after merging of datasets. The link between these study IDs and
33 the NRIC number it represents will only be known to the principal investigator of the study.
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40 Data Access

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42 Access rights to the data will be given to the Clinical Analytics team in JurongHealth, the project
43 manager and the clinician lead of the COPD-ICP programme.
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50 **Abbreviations**

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52 COPD: Chronic Obstructive Pulmonary Disease; ICP: Integrated Care Pathway; TAP: The
53 Airways Programme; SOC: Specialist Outpatient Clinics; ACP: Advance Care Planning; CAT:
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3 COPD Assessment Test; PACIC: Chronic Assessment of Chronic Illness Care; GLM:
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5 Generalised Linear Model; MOH: Ministry of Health, Singapore; NHG DSRB: National
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8 Healthcare Group Domain Specific Review Board;
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11 12 13 14 **Authors' contributions**

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16
17 Ms Christine Wu Xia contributed to study design, data analysis method and writing up of
18 manuscript. Mr See Chor Kian participated as the project manager of this programme and
19 contributed to the write-up of the manuscript. Mr Yu Weichang contributed to statistical
20 methods and writing up of manuscript. Ms Lynette Kwek Siang Lim participated in the
21 implementation of the model of care and inputs into the manuscript. Dr Gerald Chua Seng Wee
22 is the clinician lead of this programme and participated in the design of the COPD model of care.
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25 All the authors read and approved the final manuscript.
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38
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40 Development Programme (HSDP) grant number MH 36: 18/95.
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48 **Competing interests**

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50 The authors declare that they have no competing interests.
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2
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10
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12
13 constitute the project team that contributed to the whole implementation of this programme, in
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19 Operations), Dr Muhammad Rahizan, Mr Lim Kian Chong and Ms Koh Ang Hong (all
20
21 physiotherapists), Mr Timothy Chua and Ms Krutika Menon (both Social Workers), Ms Kimmy
22
23 Liew (Head, Pharmacy), Mr Ong Chee Chong (Spirometry Technologist), Dr Thomas Soo
24
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26
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30
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STROBE Checklist

Section	Subsection	Item No.	Recommendation	Checked? (Y/N)	Remarks
Title and abstract		1a	Indicate the study's design with a commonly used term in the title or the abstract	Y	
		1b	Provide in the abstract an informative and balanced summary of what was done and what was found	Y	
Introduction	Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Y	
	Objectives	3	State specific objectives, including any prespecified hypotheses	Y	
Methods	Study design	4	Present key elements of study design early in the paper	Y	
	Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Y	
	Participants	6a	<i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Y	
		6b	<i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed	Y	Based on propensity scores
	Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Y	
	Data sources/measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment	Y	

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			methods if there is more than one group		
	Bias	9	Describe any efforts to address potential sources of bias	Y	
	Study size	10	Explain how the study size was arrived at	Y	
	Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Y	
	Statistical methods	12a	Describe all statistical methods, including those used to control for confounding	Y	
		12b	Describe any methods used to examine subgroups and interactions	N	No basis for studying interactions
		12c	Explain how missing data were addressed	N	
		12d	<i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed	N	The follow-up period is one-year and hence loss to follow-up (excl. death) rates will be low.
		12e	Describe any sensitivity analyses	Y	
Results	Participants	13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N	This is a study protocol. Hence, no results have been obtained.
		13b	Give reasons for non-participation at each stage	N	
		13c	Consider use of a flow diagram	N	
		14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N	
		14b	Indicate number of participants with missing data for each variable of interest	N	

		14c	<i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N	
	Outcome data	15	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	N	
	Main results	16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N	
		16b	Report category boundaries when continuous variables were categorized	N	
		16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N	
	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N	
Discussion	Key results	18	Summarise key results with reference to study objectives	N	No results obtained yet.
	Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Y	
	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	N	No results obtained yet.
	Generalisability	21	Discuss the generalisability (external validity) of the study results	Y	

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Other information	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Y	
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For peer review only

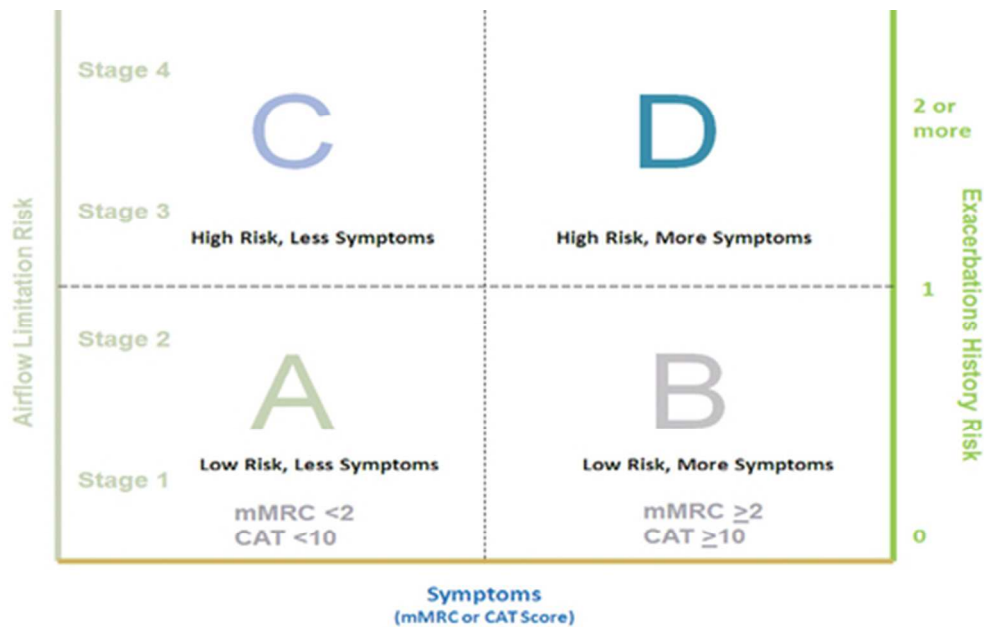


Figure 1: COPD GOLD Classifications
42x26mm (300 x 300 DPI)

Review only

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BMJ Open

A matched-group study protocol to evaluate the implementation of an Integrated Care Pathway Programme for Chronic Obstructive Pulmonary Disease in Singapore

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2014-005655.R1
Article Type:	Protocol
Date Submitted by the Author:	11-Sep-2014
Complete List of Authors:	Wu, Christine; JurongHealth, Medical Affairs Tan, Woan Shin; National Healthcare Group, Health Services & Outcomes Research See, Ryan; JurongHealth, Clinical Operations Department Yu, Weichang; JurongHealth, Medical Affairs Kwek, Lynette; JurongHealth, Clinical Operations Toh, Matthias; National Healthcare Group, Information Management Chee, Thong Gan; JurongHealth, Clinical Operations Department Chua, Gerald; JurongHealth, Medicine
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Respiratory medicine, Public health, Health economics
Keywords:	Chronic airways disease < THORACIC MEDICINE, HEALTH ECONOMICS, RESPIRATORY MEDICINE (see Thoracic Medicine)

SCHOLARONE™
Manuscripts

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3 **A matched-group study protocol to evaluate the implementation of an Integrated Care**
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5 **Pathway Programme for Chronic Obstructive Pulmonary Disease in Singapore**
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52 **Keywords**
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54 Chronic Obstructive Pulmonary Disease, Integrated Care Pathway, Evaluation, Propensity Score
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56 Matching
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ABSTRACT

Introduction

The treatment of chronic obstructive pulmonary disease (COPD) involves different care providers across care sites. This fragmentation of care increases the morbidity and mortality burden, as well as acute health services use. The COPD-Integrated Care Pathway (ICP) was designed and implemented to integrate the care across different sites from primary care to acute hospital and home. It aims to reduce the prevalence of COPD among the population in her catchment, reduce risk of hospital admissions, delay or prevent the progression of the disease and reduce mortality rate by adopting a coordinated and multi-disciplinary approach to the management of the patients' medical conditions. This study on the COPD-ICP programme is undertaken to determine the impact on processes of care, clinical outcomes, and acute care utilisation.

Methods and analysis

This will be a retrospective, pre-post, matched-groups study to evaluate the effectiveness of COPD-ICP programme in improving clinical outcomes and reducing healthcare costs. Programme enrolees (intervention group) and non-enrolees (comparator group) will be matched using propensity scores. Administratively, we set 30% as our target for proportion admission difference between programme and non-programme patients. A sample size of 56 patients in each group will be needed for statistical comparisons to be made at 90% power. Adherence with recommended care elements will be measured at baseline and quarterly during one year follow-up. Risk of COPD-related hospitalisations as primary outcome, healthcare costs, disease

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3 progression, and one-year mortality during one-year follow-up will be compared between the
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5 groups using generalised linear regression models.
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8 **Ethics and dissemination**

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10 This protocol describes the implementation and proposed evaluation of the COPD-ICP
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12 programme. The described study has received ethical approval from the NHG Domain Specific
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14 Review Board (DSRB Ref: 2013/01200). Results of the study will be reported through peer-
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16 review publications and healthcare conferences presentation.
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19 **Key message**

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- 23 ■ This study aims to evaluate the effectiveness of the programme in improving adherence with
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25 recommended processes of care, and lowering COPD-related hospitalisation and inpatient
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27 costs.
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 - 29 ■ This study will also compare the one-year mortality rate and disease progression rate
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31 between enrollees and non-enrollees. This study will use CAT score to measure COPD control
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33 in patients and Patient Assessment of Chronic Illness Care (PACIC) score to measure
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35 patients' experience of care congruent to the Chronic Care Model.
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42 **Strengths and limitation of this study**

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- 45 ■ This study will use a retrospective, pre-post, matched-groups design to evaluate the
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47 effectiveness of the programme in terms of adherence with processes of care, clinical
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49 outcomes, healthcare costs, and quality of life. It is envisioned that through this study, the
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51 COPD-ICP team will be able to identify potential gaps in the programme implementation and
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53 design, and implement necessary changes to improve care. This is in line with the
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55 organisation's aim to deliver patient-centred care.
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- This study will use propensity score matching to reduce selection bias due to the lack of randomisation.

9 **BACKGROUND**

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Chronic Obstructive Pulmonary Disease (COPD) is a major cause of chronic disease morbidity and mortality worldwide. The disease is a global health problem with a worldwide prevalence of 10.1%.^[1] In Singapore, COPD is the seventh principal cause of death and the seventh most common condition for hospitalisation.^[2] COPD patients with complications spent 8.5 days or 69% longer in hospital and accounted for the high 30-day readmission rate.^[3-4] The COPD 30-day readmission in JurongHealth is around 30% which is higher than the all-cause national 30-day readmission rate of 11.6% and other condition-specific readmission rates.^[5]

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The GOLD international standards for COPD advise spirometry for the gold standard for accurate and repeatable measurement of lung function.^[6] However, in Singapore, most solo general practice (GP) clinics do not offer spirometer services necessary for early diagnosis of COPD and for the staging of COPD severity to enable appropriate disease management. Patients with COPD in the community experience poor quality of life due to lack of convenient access to pulmonary rehabilitation.^[7] Therefore, most patients are diagnosed in the acute care setting and those who experienced repeated exacerbations also obtain care in the specialist outpatient settings.

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In response to the need for a cost-effective care model, JurongHealth launched a COPD Integrated Care Pathway (COPD-ICP) programme in April 2012. This was funded by the Singapore Ministry of Health (MOH). The programme seeks to coordinate care across different

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3 healthcare settings. It aims to provide comprehensive care for patients with COPD at different
4 stages of the disease, involving primary, hospital-based, community-based, and palliative care.
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9 Similar to other COPD integrated care programmes,[8] the programme envisages coordination of
10 care across different sites from primary to home and hospital care. The objectives of the
11 programme are to:
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17 1. Reduce the prevalence of COPD among the population residing in the Western part of
18 Singapore (catchment area of JurongHealth).
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21 2. Reduce risk of hospital admissions and healthcare costs.
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24 3. Delay or prevent the deterioration of disease condition of COPD patients.
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27 4. Reduce mortality of patients with COPD.
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30 The programme adopts a coordinated and multi-disciplinary approach to the management of the
31 patients' medical conditions. Case managers work with JurongHealth's multi-disciplinary team
32 of doctors, nurses, respiratory technologists, pharmacists, physiotherapists and medical social
33 workers to develop a customised care plan for each patient, empower patients towards self-
34 management through education, and help coordinate referrals and patients' appointments across
35 care sites.
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44 The current scope of our study will focus on the evaluation of the hospital-based segment of the
45 ICP programme. We will use propensity-score matching method to select a suitable comparator
46 group. Specifically, the aim of our study will be to assess whether the intervention group
47 compared to comparator group has 1) better adherence to the recommended processes of care; 2)
48 lower risk of COPD-related hospitalisation as our primary outcome; 3) lower overall healthcare
49 and COPD-related inpatient costs; 4) slower disease progression; and 5) lower one-year mortality
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3 rate. We will use PACIC score to measure patients' experience of chronic care delivery in
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5 congruence to the Chronic Care Model (CCM).[9] In addition, we will also use CAT score to
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8 measure COPD control and hence the quality of life of patients with COPD. Our study will focus
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10 on the second, third and fourth objectives of the programme as written above.
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12 13 **METHODS/DESIGN**

14 15 **The Regional Healthcare System**

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18 In Singapore, public healthcare is provided by six regional healthcare systems (RHSs):
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20 Alexandra Health, Eastern Health Alliance, National Healthcare Group (NHG), National
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22 University Health System (NUHS), JurongHealth, and Singapore Health Services (SHS).
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24 Together, these RHSs provide 80% of all acute care service. The government primary care
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26 clinics under NHG and SHS provide approximately 20% of primary care services consumed.
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34 35 **Target Patient**

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37 Figure 1 shows the inclusion and exclusion criteria for patients' enrolment into the COPD-ICP
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39 programme.[10-11] We will exclude patients who have medical conditions other than COPD that
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41 are likely to result in death within the next two years.
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47 We classify each patient enrolled into the programme based on the Patient Group Classification
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49 from updated GOLD guidelines (Figure 2).[10-11]
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52 53 **Intervention**

Table 1 shows the recommended key care elements for each group of patients. Various healthcare team members are responsible for administering the respective key care elements (Table 2).

With the implementation of the programme, care plans are designed to cater to each patient's disease severity. Patients are followed up by case managers regularly to ensure that the care elements as mentioned above are strictly adhered to. Case managers will also call the patient 48 hours post discharge to reinforce patient education and drugs optimisation, where they play a pivotal role in linking patients to community resources. Hence, with the coordination by case managers, the programme has made care delivery a more seamless and integrated process as compared to when such an initiative is absent.

Table 1: Key care elements for Group A, B, C and D patients

Key Care Elements	At risk	Group A	Group B	Group C	Group D	In exacerbation
		Low risk, less symptoms	Low risk, more symptoms	High risk, less symptoms	High risk, more symptoms	
1. Smoking prevention	√					
2. Smoking cessation	√	√	√	√	√	
3. Differential diagnosis	√					
4. Spirometric diagnosis	√	18-24 monthly or when clinician suspects patient grouping has changed				
5. Patient education		√	√	√	√	
6. Drug optimization		√	√	√	√	√
7. Influenza Vaccination (yearly)		Only for Elderly (>=65 years old) & those who have concomitant	√	√	√	
8. BMI assessment (yearly)		√	√	√	√	
9. COPD Assessment Tool (CAT)		6-12 monthly	6-12 monthly	6-12 monthly	3-4 monthly	
10. Acute NIV (Invasive/Non-invasive)						√
11. Supported Restructured Hospital/Emergency Department discharge						√
12. Home Oxygen				√	√	
13. Advanced care planning				√	√	

Table 2: Care elements administered by the various healthcare team members

Key Care Elements	Doctor	Case Manager	ICP Coordinator	Spirometry Techologist	Pharmacist	Physiotherapist	Medical Social Worker
1. Smoking prevention	√	√			√		
2. Smoking cessation	√	√			√	√	
3. Differential diagnosis	√	√					
4. Spirometric diagnosis	√	√		√			
5. Patient education	√	√			√		
6. Drug optimization	√	√			√		
7. Influenza Vaccination	√	√					
8. BMI assessment	√	√				√	
9. CAT	√	√	√			√	
10. Acute NIV	√	√					
11. Supported RH/ED discharge	√	√	√				√
12. Home O ₂	√	√					
13. Advance care planning	√	√					√

Evaluation Design

A retrospective pre-post, matched-groups design will be implemented for this study. Such a design will be utilised instead of the randomised controlled trial design as the COPD-ICP programme has been implemented in JurongHealth for almost two years. Care resources may also be unnecessarily stretched if two care programmes (usual care and COPD-ICP) were run concurrently.

The study cohort will include individuals diagnosed with COPD who had at least one Specialist Outpatient Visit (SOC) record in COPD Registry from Apr 2012 to Dec 2013. For our study, we

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2
3 will use the same inclusion and exclusion selection criteria as those for the COPD-ICP
4 programme enrolment (Figure 1). Patients with COPD will be identified based on the
5 International Classification of Diseases Tenth Revision (ICD-10-AM) diagnostic codes (J40.xx
6 and J47.xx).
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12 Patients in the intervention group will be sampled from programme patients in the COPD
13 registry who received care from JurongHealth from Apr 2012 to Dec 2013. A comparator group
14 will be formed from non-enrolees using matching method described in later sections. Patients for
15 the comparator group will be sampled from non-programme patients in the COPD registry who
16 received care from non-JurongHealth institutions from Apr 2012 to Dec 2013. All data will be
17 collected over one-year pre-enrolment and one-year follow up post-enrolment (three-month
18 interval) for enrolees, and over one-year period for non-enrolees. The outcomes will be
19 compared between enrolees and non-enrolees (Figure 1).
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33 **Sample size**

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36 Administratively, we set 30% as our target for proportion admission difference between
37 programme and non-programme patients. Thus, a sample size of 51 patients in each group will
38 be needed for statistical comparisons to be made at 90% power. Hence, 56 enrolees (to account
39 for 10% missing data) will be sampled from amongst those who were enrolled into the
40 programme during the study period and their matching group will be drawn from the comparator
41 group COPD management registry.
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51 **Data Sources and Data**

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54 The three main sources of data are (1) COPD Registry: patient demographics; clinical
55 information and outcome variables for both enrolees and non-enrolees; (2) Patient Case
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Management (PCM) system database: Case managers capture entered data on all recommended key care elements (Table 1) common among the four patient groups; and (3) Health System administrative databases: healthcare utilisation cost. Data for one-year mortality rate will be captured from National Registry of Diseases Office (NDRO).

Covariates include patient demographics and socio-economic indicators (Age, race, gender, nationality, Medisave/Medifund and Medical social worker referral); programme enrolment date; smoking history; medication; comorbidities; severity of COPD (GOLD classification) and CAT score.

The parameters and outcomes of interest for which data shall be collected have been summarised in Table 3.

Table 3 Overall of assessments used in COPD-ICP implementation study

Domain	Type of assessment/outcomes	Pre-ICP implementation	Post-ICP implementation	concurrent comparator group in COPD disease management registry
Baseline demographics	Age, race, gender, nationality, postal code	✓	✓	✓
Disease	Disease Type, Disease duration	✓	✓	✓
Social-economics	Medisave, Medifund, Medical social worker referral	✓	✓	✓
Programme management	Programme enrolment date	✓(baseline)	X	x
Quality of life	CAT score	✓(baseline)	✓	x
Smoking history	Smoking status, no of year smoke	✓	✓	✓
Key care elements	Refer to table 1	✓(baseline)	✓	✓
Disease Severity (based on medication use)	Refer to the 2011 GOLD guidelines summaryⁱ [12]	✓	✓	✓
Comorbidities & Complication	Asthma	✓	✓	✓
	Depression	✓	✓	✓
	Congestive heart failure	✓	✓	✓
	Diabetes	✓	✓	✓
	Hypertension	✓	✓	✓
	CKD stage 3-5	✓	✓	✓
	Stroke	✓	✓	✓

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3				
4		Dyslipidaemia	✓	✓
5		Obesity	✓	✓
6		Others	✓	✓
7	COPD-related Health service utilisation	Hospitalisation, Average length of stay	✓	✓
8				
9	Number of encounters	Emergency department attendance	✓	✓
10		Specialist outpatient visit	✓	✓
11		Primary care visit	✓	✓
12	COPD-related Cost (DRG)	Direct cost	✓	✓
13		Indirect cost	✓	✓
14				
15	Mortality	Rate of mortality	✓	✓
16	Qualitative measures	Patient assessment of chronic illness care	✓	✓
17				x

Study Outcomes

Hospital admissions and Healthcare costs

The primary outcome of this study is hospital admission. Hospital admission refers to inpatient episodes at acute care hospital managed by three regional health clusters (JurongHealth, NHG, and NUHS). Total annual healthcare costs refer to the cost of resources utilised at the primary care clinics, emergency departments, specialist outpatient clinics, and inpatient wards of these regional health clusters. To define specific COPD-related hospitalisations and inpatient costs, we have adopted the COPD-related hospitalisation ICD-10-codes used in Jiang *et al.* 2005.[12]

Disease progression and one-year mortality rate

Different medications are used during different disease progression stages.[10] Due to the absence of GOLD guidelines in measuring disease progression, we will utilise medication usage to determine the disease progression of patients with COPD. This will be compared between the intervention group and the comparator group. One-year mortality rate is defined as the proportion of patients who died (all causes) during one-year follow up for both intervention and comparator groups.

Adherence with recommended processes of care and PACIC score

We will monitor the adherence with the recommended key care elements for Group A, B, C and D patients (Table 1) at baseline and three-month interval. In addition, we will use PACIC score to measure patients' experience of chronic care delivery. PACIC score is a 20-question survey used to measure patients' perception on the congruency of the service to the Chronic Care Model (CCM).[9] CCM is a guideline which recognises six aspects as key to improving quality of chronic disease management.[9,13] The score obtained from PACIC assessment tool will allow us to assess if the COPD-ICP programme is aligned with CCM.

Quality of life

As there is no locally validated tool to measure quality of life in patients with COPD and the COPD-specific version of St. George's Respiratory Questionnaire is too long to administer, we will use CAT score, which is an eight-question health survey, to measure COPD control in individuals.[14] Scores range from 0 to 40 and lower scores indicate better control. Due to its strong correlation with the COPD-specific version of the St. George's Respiratory Questionnaire, it has been used as an alternative tool for assessing quality of life of patients with COPD.[14, 15-18] Enrolees' CAT score will be measured at baseline and during their follow-up visits within the first year of enrolment. A CAT score difference of 2 or more (or $\geq 10\%$) suggests clinically significant changes in the quality of life.[19] The CAT score difference is taken as the difference between the baseline and the best reading within 1 year. This outcome is only available for programme enrolees as CAT score is not routinely collected for non-enrolees.

Statistical Analysis

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3 Key recommended processes of care (Table 1) will be monitored quarterly to track the adherence
4 and progress of the COPD-ICP programme. Patient baseline characteristics from both enrolees
5 and non-enrolees will be described with mean and standard deviation for continuous variables
6 and number and percentage for categorical variables. Differences between COPD-ICP enrolees
7 and non-enrolees will be compared using chi-square statistics for categorical variables and
8 Wilcoxon rank sum tests for continuous variables.
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11 Since patients are enrolled into the programme based on the institution which they were seen in,
12 there is likely to be imbalance in baseline characteristics between enrolees and non-enrolees.
13 Hence, we will use propensity score matching to balance the baseline characteristics across
14 enrolees and non-enrolees.[20] We will start off with estimating the propensity score, which is
15 the conditional probability of each patient enrolling into the programme given their baseline
16 characteristics, by using multivariate logistic regression.[20] Covariates to be included in the
17 regression are: age, gender, race, hospital, subsidy term, the number of hospitalisation or
18 emergency attendances in the past year, number and severity of comorbid conditions and COPD
19 severity based on medication use. We will then form pairs of enrolee and non-enrolee by using
20 the caliper matching method, within a range of 0.2 of the standard deviation of propensity
21 score.[21]
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45 **Hospital admissions, healthcare costs and mortality**

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47 We will compare healthcare costs using generalised linear model with log link and gamma
48 distribution. For odds of hospital admission and one-year mortality, we will compare using
49 logistic regression.[22]
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55 **CAT score comparison**

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3 To evaluate the quality of life improvement of the patients with COPD using CAT score as the
4 outcome, the change in CAT score over the 1-year post-enrolment time frame will be examined.
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8 A paired-sample *t*-test will be used to compare baseline CAT score and the best achieved CAT
9 score over the 1-year time frame.
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12 13 **PACIC score**

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16 To evaluate patients' perception on the programme's congruency with CCM, the average PACIC
17 score for programme enrollees will be computed and benchmarked with PACIC results of other
18 integrated care programmes in present literature that have showed substantial congruency to the
19 CCM. At present, recommended cut-offs for CCM concordance is set at ≥ 3.5 in a study with
20 veterans and at ≥ 4 in another study with older adults at risk of high healthcare costs.[23-24].
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29 **Software**

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32 All analyses will be conducted using Stata version 12.
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36 **DISCUSSION**

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39 In designing the COPD-ICP programme, three key principles have been adopted: right-siting,
40 integration and patient-centeredness. It also involves the five standards of care: COPD
41 prevention, early diagnosis, management of stable patients with COPD, treatment and support
42 during acute exacerbations, and care and support at end of life. The model of care concept plan is
43 drafted with reference to various evidence-based guidelines such as the GOLD standard,
44 American College of Physicians guideline on diagnosis and management of stable chronic
45 COPD, and MOH COPD Clinical Practice Guidelines (2006).[25-26]
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3 This programme serves to close current service gaps to provide comprehensive integrated care
4 along the care continuum in the following ways. Training for primary care physicians in the
5 management of COPD has the potential to enhance care standards at their care setting. A multi-
6 disciplinary care team comprising of the clinician, case manager, coordinator and other relevant
7 allied health members have been shown to improve clinical outcomes and life expectancy of
8 patients with COPD.[27] Patients admitted for exacerbations are contacted within 48 hours from
9 discharge to reinforce patient education and to increase their confidence in self-managing their
10 own condition. Lastly, the case manager plays the role of the liaison between step-down care
11 partners, primary care physicians and patients. This may lower the risk of readmission and
12 reduce the frequency of exacerbation. From an international perspective, similar integrated care
13 models around the world have also showed similar positive results.[28-29] These evidences
14 further support JurongHealth in launching and maintaining the COPD-ICP programme.
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32 The rationale behind this programme evaluation stems from the motivation to bolster support for
33 the programme and to identify care gaps for improvement. As such, adherence with processes of
34 care and outcomes such as risk of hospitalisation, CAT score and PACIC score will be used by
35 the team to identify any care gaps, so as to improve the COPD-ICP programme. In addition,
36 healthcare costs, disease progression and one-year mortality rate will also be used to assess the
37 practicality of sustaining the programme. Furthermore, this study can also potentially add to the
38 mounting evidence in support of integrated care in healthcare literature.
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49 This study protocol has several strengths. The PACIC survey will be used to assess patients'
50 experience of the congruency of care to CCM. This is in line with the organisation's aim to
51 deliver patient-centred care.
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3 The choice of the matched group patients using propensity scores will replicate the balance in
4 baseline characteristics between compared cohorts achieved through randomisation. This will in
5 turn reduce the effect of selection bias due to the lack of randomisation.[21] This step will be
6 vital for making valid conclusions from the economic effectiveness analysis.
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13 This study protocol is limited in several areas. Firstly, even though we will use propensity score
14 matching to reduce the selection bias due to non-randomisation, there might be unmeasured
15 confounders which can affect our results. Secondly, the data collection process will only account
16 for both enrolees and non-enrolees who choose to have their follow-up medical appointments at
17 JurongHealth, NHG and NUHS. Due to non-captive nature of the healthcare system in
18 Singapore, patients in Singapore are free to choose healthcare providers outside these clusters on
19 an episodic basis. Hence, such exclusion might lead to underestimation. However, these
20 limitations affect the evaluation of the programme only but not the quality of care provided at
21 any institution.
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36 In conclusion, the COPD-ICP programme serves to equip primary care partners with the
37 adequate knowledge and skills for managing stable patients with COPD and to right-site patients
38 in order to provide excellent and appropriate care while optimising available healthcare
39 resources. With the support from case managers, the programme does so by discharging patients
40 to primary care doctors so that the clinically stable patients can be managed without the need to
41 see a specialist if not clinically necessary. We believe that this evaluation study can provide an
42 evidence-based assessment of the impact and effectiveness of the COPD-ICP programme. The
43 lessons learnt from this study will be fed back to the COPD-ICP programme team and be useful
44 in informing the design evaluations of other ICP programmes nationally.
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ETHICS AND DISSEMINATION

This protocol describes the implementation and proposed evaluation of the COPD-ICP programme. The described study has received ethical approval from the NHG Domain Specific Review Board (DSRB Ref: 2013/01200). Results of the study will be reported through peer-review publication and healthcare conferences presentation.

CONFIDENTIALITY

Names and National Registration Identity Card (NRIC) number of patients will be removed and replaced with unique study IDs after merging of datasets. The link between these study IDs and the NRIC number it represents will only be known to the principal investigator of the study.

DATA ACCESS

Access rights to the data will be given to the Clinical Analytics team in JurongHealth, the project manager and the clinician lead of the COPD-ICP programme.

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AUTHORS' CONTRIBUTIONS

Ms Christine Wu Xia contributed to study design, data analysis method and writing up of manuscript. Miss Tan Woan Shin contributed to study design, statistical analysis and the critical revision of the manuscript for important intellectual content. Mr See Chor Kian participated as the project manager of this programme and contributed to the write-up of the manuscript. Mr Yu Weichang contributed to statistical methods and manuscript review. Ms Lynette Kwek Siang Lim participated in the implementation of the model of care and inputs into the manuscript. Dr Matthias Toh contributed to study design and manuscript review. Dr Gerald Chua Seng Wee and Ms Chee Thong Gan are the clinician lead and operational lead of this programme and

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3 participated in the design of the COPD model of care. All the authors read and approved the final
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5 manuscript.
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12
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17 18 **COMPETING INTERESTS**

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20 The authors declare that they have no competing interests.
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A matched-group study protocol to evaluate the implementation of an Integrated Care Pathway Programme for Chronic Obstructive Pulmonary Disease in Singapore

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ABSTRACT

Introduction

The treatment of chronic obstructive pulmonary disease (COPD) involves different care providers across care sites. This fragmentation of care increases the morbidity and mortality burden, as well as acute health services use. The COPD-Integrated Care Pathway (ICP) was designed and implemented to integrate the care across different sites from primary care to acute hospital and home. It aims to reduce the prevalence of COPD among the population in her catchment, reduce risk of hospital admissions, delay or prevent the progression of the disease and reduce mortality rate by adopting a coordinated and multi-disciplinary approach to the management of the patients' medical conditions. This study on the COPD-ICP programme is undertaken to determine the impact on processes of care, clinical outcomes, and acute care utilisation.

Methods and analysis

This will be a retrospective, pre-post, matched-groups study to evaluate the effectiveness of COPD-ICP programme in improving clinical outcomes and reducing healthcare costs. Programme enrolees (intervention group) and non-enrolees (comparator group) will be matched using propensity scores. Administratively, we set 30% as our target for proportion admission difference between programme and non-programme patients. A sample size of 56 patients in each group will be needed for statistical comparisons to be made at 90% power. Adherence with recommended care elements will be measured at baseline and quarterly during one year follow-up. Risk of COPD-related hospitalisations as primary outcome, healthcare costs, disease progression, and one-year mortality during one-year follow-up will be compared between the groups using generalised linear regression models.

Ethics and dissemination

This protocol describes the implementation and proposed evaluation of the COPD-ICP programme. The described study has received ethical approval from the NHG Domain Specific Review Board (DSRB Ref: 2013/01200). Results of the study will be reported through peer-review publications and healthcare conferences presentation.

Keywords

Chronic Obstructive Pulmonary Disease, Integrated Care Pathway, Evaluation, Propensity Score Matching

Key message

- This study aims to evaluate the effectiveness of the programme in improving adherence with recommended processes of care, and lowering COPD-related hospitalisation and inpatient costs.
- This study will also compare the one-year mortality rate and disease progression rate between enrolees and non-enrolees. This study will use CAT score to measure COPD control in patients and Patient Assessment of Chronic Illness Care (PACIC) score to measure patients' experience of care congruent to the Chronic Care Model.

Strengths and limitation of this study

- This study will use a retrospective, pre-post, matched-groups design to evaluate the effectiveness of the programme in terms of adherence with processes of care, clinical outcomes, healthcare costs, and quality of life. It is envisioned that through this study, the COPD-ICP team will be able to identify potential gaps in the programme implementation and

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3 design, and implement necessary changes to improve care. This is in line with the
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5 organisation's aim to deliver patient-centred care.
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- This study will use propensity score matching to reduce selection bias due to the lack of randomisation.

BACKGROUND

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of chronic disease morbidity and mortality worldwide. The disease is a global health problem with a worldwide prevalence of 10.1%.^[1] In Singapore, COPD is the seventh principal cause of death and the seventh most common condition for hospitalisation.^[2] COPD patients with complications spent 8.5 days or 69% longer in hospital and accounted for the high 30-day readmission rate.^[3-4] The COPD 30-day readmission in JurongHealth is around 30% which is higher than the all-cause national 30-day readmission rate of 11.6% and other condition-specific readmission rates.^[5]

The GOLD international standards for COPD advise spirometry for the gold standard for accurate and repeatable measurement of lung function.^[6] However, in Singapore, most solo general practice (GP) clinics do not offer spirometer services necessary for early diagnosis of COPD and for the staging of COPD severity to enable appropriate disease management. Patients with COPD in the community experience poor quality of life due to lack of convenient access to pulmonary rehabilitation.^[7] Therefore, most patients are diagnosed in the acute care setting and those who experienced repeated exacerbations also obtain care in the specialist outpatient settings.

In response to the need for a cost-effective care model, JurongHealth launched a COPD Integrated Care Pathway (COPD-ICP) programme in April 2012. This was funded by the

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3 Singapore Ministry of Health (MOH). The programme seeks to coordinate care across different
4 healthcare settings. It aims to provide comprehensive care for patients with COPD at different
5 stages of the disease, involving primary, hospital-based, community-based, and palliative care.
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11 Similar to other COPD integrated care programmes,[8] the programme envisages coordination of
12 care across different sites from primary to home and hospital care. The objectives of the
13 programme are to:
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- 18 1. Reduce the prevalence of COPD among the population residing in the Western part of
19 Singapore (catchment area of JurongHealth).
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- 22 2. Reduce risk of hospital admissions and healthcare costs.
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- 25 3. Delay or prevent the deterioration of disease condition of COPD patients.
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- 28 4. Reduce mortality of patients with COPD.
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32 The programme adopts a coordinated and multi-disciplinary approach to the management of the
33 patients' medical conditions. Case managers work with JurongHealth's multi-disciplinary team
34 of doctors, nurses, respiratory technologists, pharmacists, physiotherapists and medical social
35 workers to develop a customised care plan for each patient, empower patients towards self-
36 management through education, and help coordinate referrals and patients' appointments across
37 care sites.
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47 The current scope of our study will focus on the evaluation of the hospital-based segment of the
48 ICP programme. We will use propensity-score matching method to select a suitable comparator
49 group. Specifically, the aim of our study will be to assess whether the intervention group
50 compared to comparator group has 1) better adherence to the recommended processes of care; 2)
51 lower risk of COPD-related hospitalisation as our primary outcome; 3) lower overall healthcare
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3 and COPD-related inpatient costs; 4) slower disease progression; and 5) lower one-year mortality
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5 rate. We will use PACIC score to measure patients' experience of chronic care delivery in
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7 congruence to the Chronic Care Model (CCM).[9] In addition, we will also use CAT score to
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9 measure COPD control and hence the quality of life of patients with COPD. Our study will focus
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11 on the second, third and fourth objectives of the programme as written above.
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15 16 **METHODS/DESIGN**

17 18 19 **The Regional Healthcare System**

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22 In Singapore, public healthcare is provided by six regional healthcare systems (RHSs):
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24 Alexandra Health, Eastern Health Alliance, National Healthcare Group (NHG), National
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26 University Health System (NUHS), JurongHealth, and Singapore Health Services (SHS).
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28 Together, these RHSs provide 80% of all acute care service. The government primary care
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30 clinics under NHG and SHS provide approximately 20% of primary care services consumed.
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37 **Target Patient**

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40 Figure 1 shows the inclusion and exclusion criteria for patients' enrolment into the COPD-ICP
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42 programme.[10-11] We will exclude patients who have medical conditions other than COPD that
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44 are likely to result in death within the next two years.
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48 We classify each patient enrolled into the programme based on the Patient Group Classification
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50 from updated GOLD guidelines (Figure 2).[10-11]
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53 **Intervention**

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Table 1 shows the recommended key care elements for each group of patients. Various healthcare team members are responsible for administering the respective key care elements (Table 2).

With the implementation of the programme, care plans are designed to cater to each patient's disease severity. Patients are followed up by case managers regularly to ensure that the care elements as mentioned above are strictly adhered to. Case managers will also call the patient 48 hours post discharge to reinforce patient education and drugs optimisation, where they play a pivotal role in linking patients to community resources. Hence, with the coordination by case managers, the programme has made care delivery a more seamless and integrated process as compared to when such an initiative is absent.

Table 1: Key care elements for Group A, B, C and D patients

Key Care Elements	At risk	Group A	Group B	Group C	Group D	In exacerbation
		Low risk, less symptoms	Low risk, more symptoms	High risk, less symptoms	High risk, more symptoms	
1. Smoking prevention	√					
2. Smoking cessation	√	√	√	√	√	
3. Differential diagnosis	√					
4. Spirometric diagnosis	√	18-24 monthly or when clinician suspects patient grouping has changed				
5. Patient education		√	√	√	√	
6. Drug optimization		√	√	√	√	√
7. Influenza Vaccination (yearly)		Only for Elderly (>=65 years old) & those who have concomitant	√	√	√	
8. BMI assessment (yearly)		√	√	√	√	
9. COPD Assessment Tool (CAT)		6-12 monthly	6-12 monthly	6-12 monthly	3-4 monthly	
10. Acute NIV (Invasive/Non-invasive)						√
11. Supported Restructured Hospital/Emergency Department discharge						√
12. Home Oxygen				√	√	
13. Advanced care planning				√	√	

Table 2: Care elements administered by the various healthcare team members

Key Care Elements	Doctor	Case Manager	ICP Coordinator	Spirometry Technologist	Pharmacist	Physiotherapist	Medical Social Worker
1. Smoking prevention	√	√			√		
2. Smoking cessation	√	√			√	√	
3. Differential diagnosis	√	√					
4. Spirometric diagnosis	√	√		√			
5. Patient education	√	√			√		
6. Drug optimization	√	√			√		
7. Influenza Vaccination	√	√					
8. BMI assessment	√	√				√	
9. CAT	√	√	√			√	
10. Acute NIV	√	√					
11. Supported RH/ED discharge	√	√	√				√
12. Home O ₂	√	√					
13. Advance care planning	√	√					√

Evaluation Design

A retrospective pre-post, matched-groups design will be implemented for this study. Such a design will be utilised instead of the randomised controlled trial design as the COPD-ICP programme has been implemented in JurongHealth for almost two years. Care resources may also be unnecessarily stretched if two care programmes (usual care and COPD-ICP) were run concurrently.

The study cohort will include individuals diagnosed with COPD who had at least one Specialist Outpatient Visit (SOC) record in COPD Registry from Apr 2012 to Dec 2013. For our study, we will use the same inclusion and exclusion selection criteria as those for the COPD-ICP programme enrolment (Figure 1). Patients with COPD will be identified based on the

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3 International Classification of Diseases Tenth Revision (ICD-10-AM) diagnostic codes (J40.xx
4 and J47.xx).
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9 Patients in the intervention group will be sampled from programme patients in the COPD
10 registry who received care from JurongHealth from Apr 2012 to Dec 2013. A comparator group
11 will be formed from non-enrolees using matching method described in later sections. Patients for
12 the comparator group will be sampled from non-programme patients in the COPD registry who
13 received care from non-JurongHealth institutions from Apr 2012 to Dec 2013. All data will be
14 collected over one-year pre-enrolment and one-year follow up post-enrolment (three-month
15 interval) for enrolees, and over one-year period for non-enrolees. The outcomes will be
16 compared between enrolees and non-enrolees (Figure 1).
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28 **Sample size**

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30 Administratively, we set 30% as our target for proportion admission difference between
31 programme and non-programme patients. Thus, a sample size of 51 patients in each group will
32 be needed for statistical comparisons to be made at 90% power. Hence, 56 enrolees (to account
33 for 10% missing data) will be sampled from amongst those who were enrolled into the
34 programme during the study period and their matching group will be drawn from the comparator
35 group COPD management registry.
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47 **Data Sources and Data**

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49 The three main sources of data are (1) COPD Registry: patient demographics; clinical
50 information and outcome variables for both enrolees and non-enrolees; (2) Patient Case
51 Management (PCM) system database: Case managers capture entered data on all recommended
52 key care elements (Table 1) common among the four patient groups; and (3) Health System
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administrative databases: healthcare utilisation cost. Data for one-year mortality rate will be captured from National Registry of Diseases Office (NDRO).

Covariates include patient demographics and socio-economic indicators (Age, race, gender, nationality, Medisave/Medifund and Medical social worker referral); programme enrolment date; smoking history; medication; comorbidities; severity of COPD (GOLD classification) and CAT score.

The parameters and outcomes of interest for which data shall be collected have been summarised in Table 3.

Table 3 Overall of assessments used in COPD-ICP implementation study

Domain	Type of assessment/outcomes	Pre-ICP implementation	Post-ICP implementation	concurrent comparator group in COPD disease management registry
Baseline demographics	Age, race, gender, nationality, postal code	✓	✓	✓
Disease	Disease Type, Disease duration	✓	✓	✓
Social-economics	Medisave, Medifund, Medical social worker referral	✓	✓	✓
Programme management	Programme enrolment date	✓ (baseline)	X	x
Quality of life	CAT score	✓ (baseline)	✓	x
Smoking history	Smoking status, no of year smoke	✓	✓	✓
Key care elements	Refer to table 1	✓ (baseline)	✓	✓
Disease Severity (based on medication use)	Refer to the 2011 GOLD guidelines summaryⁱ [12]	✓	✓	✓
Comorbidities & Complication	Asthma	✓	✓	✓
	Depression	✓	✓	✓
	Congestive heart failure	✓	✓	✓
	Diabetes	✓	✓	✓
	Hypertension	✓	✓	✓
	CKD stage 3-5	✓	✓	✓
	Stroke	✓	✓	✓
	Dyslipidaemia	✓	✓	✓
	Obesity	✓	✓	✓
Others	✓	✓	✓	
COPD-related Health service utilisation	Hospitalisation, Average length of stay	✓	✓	✓

Number of encounters	Emergency department attendance	✓	✓	✓
	Specialist outpatient visit	✓	✓	✓
	Primary care visit	✓	✓	✓
COPD-related Cost (DRG)	Direct cost	✓	✓	✓
	Indirect cost	✓	✓	✓
Mortality	Rate of mortality	✓	✓	✓
Qualitative measures	Patient assessment of chronic illness care	✓	✓	x

Study Outcomes

Hospital admissions and Healthcare costs

The primary outcome of this study is hospital admission. Hospital admission refers to inpatient episodes at acute care hospital managed by three regional health clusters (JurongHealth, NHG, and NUHS). Total annual healthcare costs refer to the cost of resources utilised at the primary care clinics, emergency departments, specialist outpatient clinics, and inpatient wards of these regional health clusters. To define specific COPD-related hospitalisations and inpatient costs, we have adopted the COPD-related hospitalisation ICD-10-codes used in Jiang *et al.* 2005.[12]

Disease progression and one-year mortality rate

Different medications are used during different disease progression stages.[10] Due to the absence of GOLD guidelines in measuring disease progression, we will utilise medication usage to determine the disease progression of patients with COPD. This will be compared between the intervention group and the comparator group. One-year mortality rate is defined as the proportion of patients who died (all causes) during one-year follow up for both intervention and comparator groups.

Adherence with recommended processes of care and PACIC score

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3 We will monitor the adherence with the recommended key care elements for Group A, B, C and
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5 D patients (Table 1) at baseline and three-month interval. In addition, we will use PACIC score
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7 to measure patients' experience of chronic care delivery. PACIC score is a 20-question survey
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9 used to measure patients' perception on the congruency of the service to the Chronic Care Model
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11 (CCM).[9] CCM is a guideline which recognises six aspects as key to improving quality of
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13 chronic disease management.[9,13] The score obtained from PACIC assessment tool will allow
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15 us to assess if the COPD-ICP programme is aligned with CCM.
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20 21 Quality of life

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24 As there is no locally validated tool to measure quality of life in patients with COPD and the
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26 COPD-specific version of St. George's Respiratory Questionnaire is too long to administer, we
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28 will use CAT score, which is an eight-question health survey, to measure COPD control in
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30 individuals.[14] Scores range from 0 to 40 and lower scores indicate better control. Due to its
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32 strong correlation with the COPD-specific version of the St. George's Respiratory Questionnaire,
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34 it has been used as an alternative tool for assessing quality of life of patients with COPD.[14, 15-
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36 18] Enrolees' CAT score will be measured at baseline and during their follow-up visits within
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38 the first year of enrolment. A CAT score difference of 2 or more (or $\geq 10\%$) suggests clinically
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40 significant changes in the quality of life.[19] The CAT score difference is taken as the difference
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42 between the baseline and the best reading within 1 year. This outcome is only available for
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44 programme enrolees as CAT score is not routinely collected for non-enrolees.
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50 51 Statistical Analysis

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54 Key recommended processes of care (Table 1) will be monitored quarterly to track the adherence
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56 and progress of the COPD-ICP programme. Patient baseline characteristics from both enrolees
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3 and non-enrolees will be described with mean and standard deviation for continuous variables
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5 and number and percentage for categorical variables. Differences between COPD-ICP enrolees
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7 and non-enrolees will be compared using chi-square statistics for categorical variables and
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9 Wilcoxon rank sum tests for continuous variables.
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13 Since patients are enrolled into the programme based on the institution which they were seen in,
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15 there is likely to be imbalance in baseline characteristics between enrolees and non-enrolees.
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17 Hence, we will use propensity score matching to balance the baseline characteristics across
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19 enrolees and non-enrolees.[20] We will start off with estimating the propensity score, which is
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21 the conditional probability of each patient enrolling into the programme given their baseline
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23 characteristics, by using multivariate logistic regression.[20] Covariates to be included in the
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25 regression are: age, gender, race, hospital, subsidy term, the number of hospitalisation or
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27 emergency attendances in the past year, number and severity of comorbid conditions and COPD
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29 severity based on medication use. We will then form pairs of enrolee and non-enrolee by using
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31 the caliper matching method, within a range of 0.2 of the standard deviation of propensity
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33 score.[21]
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40 **Hospital admissions, healthcare costs and mortality**

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42 We will compare healthcare costs using generalised linear model with log link and gamma
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44 distribution. For odds of hospital admission and one-year mortality, we will compare using
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46 logistic regression.[22]
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50 **CAT score comparison**

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52 To evaluate the quality of life improvement of the patients with COPD using CAT score as the
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54 outcome, the change in CAT score over the 1-year post-enrolment time frame will be examined.
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3 A paired-sample *t*-test will be used to compare baseline CAT score and the best achieved CAT
4 score over the 1-year time frame.
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8 9 **PACIC score**

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11 To evaluate patients' perception on the programme's congruency with CCM, the average PACIC
12 score for programme enrolees will be computed and benchmarked with PACIC results of other
13 integrated care programmes in present literature that have showed substantial congruency to the
14 CCM. At present, recommended cut-offs for CCM concordance is set at ≥ 3.5 in a study with
15 veterans and at ≥ 4 in another study with older adults at risk of high healthcare costs.[23-24].
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24 25 **Software**

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28 All analyses will be conducted using Stata version 12.
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31 32 **DISCUSSION**

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34 In designing the COPD-ICP programme, three key principles have been adopted: right-siting,
35 integration and patient-centeredness. It also involves the five standards of care: COPD
36 prevention, early diagnosis, management of stable patients with COPD, treatment and support
37 during acute exacerbations, and care and support at end of life. The model of care concept plan is
38 drafted with reference to various evidence-based guidelines such as the GOLD standard,
39 American College of Physicians guideline on diagnosis and management of stable chronic
40 COPD, and MOH COPD Clinical Practice Guidelines (2006).[25-26]
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52 This programme serves to close current service gaps to provide comprehensive integrated care
53 along the care continuum in the following ways. Training for primary care physicians in the
54 management of COPD has the potential to enhance care standards at their care setting. A multi-
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3 disciplinary care team comprising of the clinician, case manager, coordinator and other relevant
4 allied health members have been shown to improve clinical outcomes and life expectancy of
5 patients with COPD.[27] Patients admitted for exacerbations are contacted within 48 hours from
6 discharge to reinforce patient education and to increase their confidence in self-managing their
7 own condition. Lastly, the case manager plays the role of the liaison between step-down care
8 partners, primary care physicians and patients. This may lower the risk of readmission and
9 reduce the frequency of exacerbation. From an international perspective, similar integrated care
10 models around the world have also showed similar positive results.[28-29] These evidences
11 further support JurongHealth in launching and maintaining the COPD-ICP programme.
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25 The rationale behind this programme evaluation stems from the motivation to bolster support for
26 the programme and to identify care gaps for improvement. As such, adherence with processes of
27 care and outcomes such as risk of hospitalisation, CAT score and PACIC score will be used by
28 the team to identify any care gaps, so as to improve the COPD-ICP programme. In addition,
29 healthcare costs, disease progression and one-year mortality rate will also be used to assess the
30 practicality of sustaining the programme. Furthermore, this study can also potentially add to the
31 mounting evidence in support of integrated care in healthcare literature.
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43 This study protocol has several strengths. The PACIC survey will be used to assess patients'
44 experience of the congruency of care to CCM. This is in line with the organisation's aim to
45 deliver patient-centred care.
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50 The choice of the matched group patients using propensity scores will replicate the balance in
51 baseline characteristics between compared cohorts achieved through randomisation. This will in
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3 turn reduce the effect of selection bias due to the lack of randomisation.[21] This step will be
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5 vital for making valid conclusions from the economic effectiveness analysis.
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9 This study protocol is limited in several areas. Firstly, even though we will use propensity score
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11 matching to reduce the selection bias due to non-randomisation, there might be unmeasured
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13 confounders which can affect our results. Secondly, the data collection process will only account
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15 for both enrolees and non-enrolees who choose to have their follow-up medical appointments at
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17 JurongHealth, NHG and NUHS. Due to non-captive nature of the healthcare system in
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19 Singapore, patients in Singapore are free to choose healthcare providers outside these clusters on
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21 an episodic basis. Hence, such exclusion might lead to underestimation. However, these
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23 limitations affect the evaluation of the programme only but not the quality of care provided at
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25 any institution.
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31 In conclusion, the COPD-ICP programme serves to equip primary care partners with the
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33 adequate knowledge and skills for managing stable patients with COPD and to right-site patients
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35 in order to provide excellent and appropriate care while optimising available healthcare
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37 resources. With the support from case managers, the programme does so by discharging patients
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39 to primary care doctors so that the clinically stable patients can be managed without the need to
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41 see a specialist if not clinically necessary. We believe that this evaluation study can provide an
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43 evidence-based assessment of the impact and effectiveness of the COPD-ICP programme. The
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45 lessons learnt from this study will be fed back to the COPD-ICP programme team and be useful
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47 in informing the design evaluations of other ICP programmes nationally.
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52 53 **ETHICS AND DISSEMINATION** 54 55 56 57 58 59 60

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This protocol describes the implementation and proposed evaluation of the COPD-ICP programme. The described study has received ethical approval from the NHG Domain Specific Review Board (DSRB Ref: 2013/01200). Results of the study will be reported through peer-review publication and healthcare conferences presentation.

CONFIDENTIALITY

Names and National Registration Identity Card (NRIC) number of patients will be removed and replaced with unique study IDs after merging of datasets. The link between these study IDs and the NRIC number it represents will only be known to the principal investigator of the study.

DATA ACCESS

Access rights to the data will be given to the Clinical Analytics team in JurongHealth, the project manager and the clinician lead of the COPD-ICP programme.

AUTHORS' CONTRIBUTIONS

Ms Christine Wu Xia contributed to study design, data analysis method and writing up of manuscript. Miss Tan Woan Shin contributed to study design, statistical analysis and the critical revision of the manuscript for important intellectual content. Mr See Chor Kian participated as the project manager of this programme and contributed to the write-up of the manuscript. Mr Yu Weichang contributed to statistical methods and manuscript review. Ms Lynette Kwek Siang Lim participated in the implementation of the model of care and inputs into the manuscript. Dr Matthias Toh contributed to study design and manuscript review. Dr Gerald Chua Seng Wee and Ms Chee Thong Gan are the clinician lead and operational lead of this programme and

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3 participated in the design of the COPD model of care. All the authors read and approved the final
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5 manuscript.
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10
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17 18 **COMPETING INTERESTS**

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20 The authors declare that they have no competing interests.
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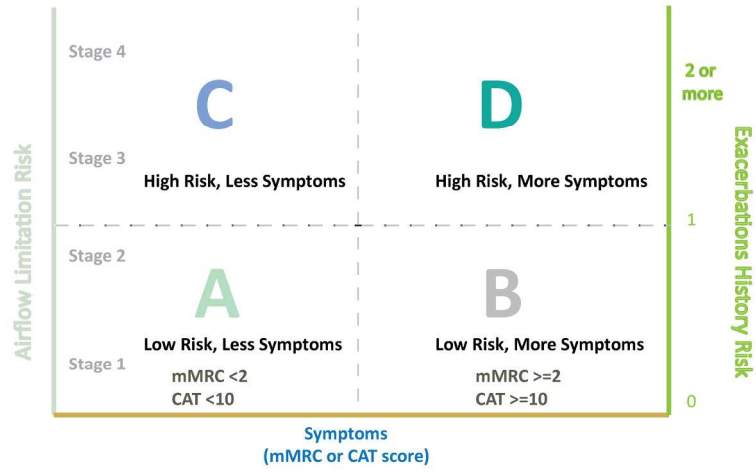
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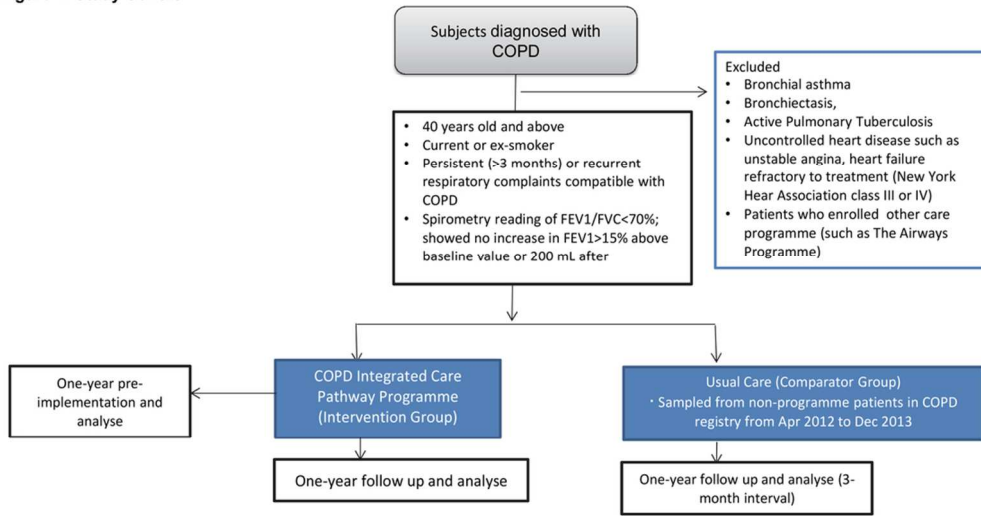
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Figure 1: Study Cohort



94x51mm (300 x 300 DPI)

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STROBE Checklist

Section	Subsection	Item No.	Recommendation	Checked? (Y/N)	Remarks
Title and abstract		1a	Indicate the study's design with a commonly used term in the title or the abstract	Y	
		1b	Provide in the abstract an informative and balanced summary of what was done and what was found	Y	
Introduction	Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Y	
	Objectives	3	State specific objectives, including any prespecified hypotheses	Y	
Methods	Study design	4	Present key elements of study design early in the paper	Y	
	Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Y	
	Participants	6a	<i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Y	
		6b	<i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed	Y	Based on propensity scores
	Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Y	
	Data sources/measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment	Y	

			methods if there is more than one group		
	Bias	9	Describe any efforts to address potential sources of bias	Y	
	Study size	10	Explain how the study size was arrived at	Y	
	Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Y	
	Statistical methods	12a	Describe all statistical methods, including those used to control for confounding	Y	
		12b	Describe any methods used to examine subgroups and interactions	N	No basis for studying interactions
		12c	Explain how missing data were addressed	N	
		12d	<i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed	N	The follow-up period is one-year and hence loss to follow-up (excl. death) rates will be low.
		12e	Describe any sensitivity analyses	Y	
Results	Participants	13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N	This is a study protocol. Hence, no results have been obtained.
		13b	Give reasons for non-participation at each stage	N	
		13c	Consider use of a flow diagram	N	
		14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N	
		14b	Indicate number of participants with missing data for each variable of interest	N	

		14c	<i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N	
	Outcome data	15	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	N	
	Main results	16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N	
		16b	Report category boundaries when continuous variables were categorized	N	
		16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N	
	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N	
Discussion	Key results	18	Summarise key results with reference to study objectives	N	No results obtained yet.
	Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Y	
	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	N	No results obtained yet.
	Generalisability	21	Discuss the generalisability (external validity) of the study results	Y	

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Other information	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Y	
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BMJ Open

A matched-group study protocol to evaluate the implementation of an Integrated Care Pathway Programme for Chronic Obstructive Pulmonary Disease in Singapore

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2014-005655.R2
Article Type:	Protocol
Date Submitted by the Author:	17-Oct-2014
Complete List of Authors:	Wu, Christine; JurongHealth, Medical Affairs Tan, Woan Shin; National Healthcare Group, Health Services & Outcomes Research See, Ryan; JurongHealth, Clinical Operations Department Yu, Weichang; JurongHealth, Medical Affairs Kwek, Lynette; JurongHealth, Clinical Operations Toh, Matthias; National Healthcare Group, Information Management Chee, Thong Gan; JurongHealth, Clinical Operations Department Chua, Gerald; JurongHealth, Medicine
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Respiratory medicine, Public health, Health economics
Keywords:	Chronic airways disease < THORACIC MEDICINE, HEALTH ECONOMICS, RESPIRATORY MEDICINE (see Thoracic Medicine)

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	Data sources/measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment	Y	

			methods if there is more than one group		
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	Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Y	
	Statistical methods	12a	Describe all statistical methods, including those used to control for confounding	Y	
		12b	Describe any methods used to examine subgroups and interactions	N	No basis for studying interactions
		12c	Explain how missing data were addressed	N	
		12d	<i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed	N	The follow-up period is one-year and hence loss to follow-up (excl. death) rates will be low.
		12e	Describe any sensitivity analyses	Y	
Results	Participants	13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N	This is a study protocol. Hence, no results have been obtained.
		13b	Give reasons for non-participation at each stage	N	
		13c	Consider use of a flow diagram	N	
		14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N	
		14b	Indicate number of participants with missing data for each variable of interest	N	

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		14c	<i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N	
	Outcome data	15	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	N	
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Other information	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Y	
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3 **A matched-group study protocol to evaluate the implementation of an Integrated Care**
4 **Pathway Programme for Chronic Obstructive Pulmonary Disease in Singapore**
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ABSTRACT

Introduction

The treatment of chronic obstructive pulmonary disease (COPD) involves different care providers across care sites. This fragmentation of care increases the morbidity and mortality burden, as well as acute health services use. The COPD-Integrated Care Pathway (ICP) was designed and implemented to integrate the care across different sites from primary care to acute hospital and home. It aims to reduce the prevalence of COPD among the population in the catchment, reduce risk of hospital admissions, delay or prevent the progression of the disease and reduce mortality rate by adopting a coordinated and multi-disciplinary approach to the management of the patients' medical conditions. This study on the COPD-ICP programme is undertaken to determine the impact on processes of care, clinical outcomes, and acute care utilisation.

Methods and analysis

This will be a retrospective, pre-post, matched-groups study to evaluate the effectiveness of COPD-ICP programme in improving clinical outcomes and reducing healthcare costs. Programme enrolees (intervention group) and non-enrolees (comparator group) will be matched using propensity scores. Administratively, we set 30% as our target for proportion admission difference between programme and non-programme patients. A sample size of 62 patients in each group will be needed for statistical comparisons to be made at 90% power. Adherence with recommended care elements will be measured at baseline and quarterly during one year follow-up. Risk of COPD-related hospitalisations as primary outcome, healthcare costs, disease progression, and one-year mortality during one-year follow-up will be compared between the groups using generalised linear regression models.

Ethics and dissemination

This protocol describes the implementation and proposed evaluation of the COPD-ICP programme. The described study has received ethical approval from the NHG Domain Specific Review Board (DSRB Ref: 2013/01200). Results of the study will be reported through peer-review publications and healthcare conferences presentation.

Keywords

Chronic Obstructive Pulmonary Disease, Integrated Care Pathway, Evaluation, Propensity Score Matching

Key message

- This study aims to evaluate the effectiveness of the programme in improving adherence with recommended processes of care, and lowering COPD-related hospitalisation and inpatient costs.
- This study will also compare the one-year mortality rate and disease progression rate between enrolees and non-enrolees. This study will use CAT score to measure COPD control in patients and Patient Assessment of Chronic Illness Care (PACIC) score to measure patients' experience of care congruent to the Chronic Care Model.

Strengths and limitation of this study

- This study will use a retrospective, pre-post, matched-groups design to evaluate the effectiveness of the programme in terms of adherence with processes of care, clinical outcomes, healthcare costs, and quality of life. It is envisioned that through this study, the COPD-ICP team will be able to identify potential gaps in the programme implementation and

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2
3 design, and implement necessary changes to improve care. This is in line with the
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5 organisation's aim to deliver patient-centred care.
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- This study will use propensity score matching to reduce selection bias due to the lack of randomisation.

14 BACKGROUND

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Chronic Obstructive Pulmonary Disease (COPD) is a major cause of chronic disease morbidity and mortality worldwide. The disease is a global health problem with a worldwide prevalence of 10.1%.[1] In Singapore, COPD is the seventh principal cause of death and the seventh most common condition for hospitalisation.[2] COPD patients with complications spent 7.7 days or 79% longer in hospital than COPD patients without complications.[3] The COPD 30-day readmission in JurongHealth is around 30% which is higher than the all-cause national 30-day readmission rate of 11.6% and other condition-specific readmission rates.[4]

The GOLD international standards for COPD advise spirometry for the gold standard for accurate and repeatable measurement of lung function.[5] However, in Singapore, most solo general practice (GP) clinics do not offer spirometer services necessary for early diagnosis of COPD and for the staging of COPD severity to enable appropriate disease management. Patients with COPD in the community experience poor quality of life due to lack of convenient access to pulmonary rehabilitation.[6] Therefore, most patients are diagnosed in the acute care setting and those who experienced repeated exacerbations also obtain care in the specialist outpatient settings.

In response to the need for a cost-effective care model, JurongHealth launched a COPD Integrated Care Pathway (COPD-ICP) programme in April 2012. This was funded by the

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3 Singapore Ministry of Health (MOH). The programme seeks to coordinate care across different
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5 healthcare settings. It aims to provide comprehensive care for patients with COPD at different
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7 stages of the disease, involving primary, hospital-based, community-based, and palliative care.
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11 Similar to other COPD integrated care programmes,[7] the programme envisages coordination of
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13 care across different sites from primary to home and hospital care. The objectives of the
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15 programme are to:
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19 1. Reduce the prevalence of COPD among the population residing in the Western part of
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21 Singapore (catchment area of JurongHealth).
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24 2. Reduce risk of hospital admissions and healthcare costs.
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27 3. Delay or prevent the deterioration of disease condition of COPD patients.
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30 4. Reduce mortality of patients with COPD.
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32 The programme adopts a coordinated and multi-disciplinary approach to the management of the
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34 patients' medical conditions. Case managers work with JurongHealth's multi-disciplinary team
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36 of doctors, nurses, respiratory technologists, pharmacists, physiotherapists and medical social
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38 workers to develop a customised care plan for each patient, empower patients towards self-
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40 management through education, and help coordinate referrals and patients' appointments across
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42 care sites.
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46 The current scope of our study will focus on the evaluation of the hospital-based segment of the
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48 ICP programme. We will use propensity-score matching method to select a suitable comparator
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50 group. Specifically, the aim of our study will be to assess whether the intervention group
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52 compared to comparator group has 1) primary outcome: lower risk of COPD-related
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54 hospitalisation; and 2) secondary outcomes: better adherence to the recommended processes of
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3 care, lower overall healthcare and COPD-related inpatient costs, slower disease progression, and
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5 lower one-year mortality rate. We will use PACIC score to measure patients' experience of
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7 chronic care delivery in congruence to the Chronic Care Model (CCM).[8] In addition, we will
8
9 also use CAT score to measure COPD control and hence the quality of life of patients with
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11 COPD.
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14 15 16 **METHODS/DESIGN**

17 18 19 **The Regional Healthcare System**

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22 In Singapore, public healthcare is provided by six regional healthcare systems (RHSs):
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24 Alexandra Health, Eastern Health Alliance, National Healthcare Group (NHG), National
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26 University Health System (NUHS), JurongHealth, and Singapore Health Services (SHS).
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28 Together, these RHSs provide 80% of all acute care service. The government primary care
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30 clinics under NHG and SHS provide approximately 20% of primary care services consumed.
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37 38 39 **Target Patient**

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41 Figure 1 shows the inclusion and exclusion criteria for patients' enrolment into the COPD-ICP
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43 programme.[9-10] We will exclude patients who have medical conditions other than COPD that
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45 are likely to result in death within the next two years.
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49 We classify each patient enrolled into the programme based on the Patient Group Classification
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51 from updated GOLD guidelines (Figure 2).[9-10]
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53 54 55 **Intervention**

Table 1 shows the recommended key care elements for each group of patients. Various healthcare team members are responsible for administering the respective key care elements (Table 2).

With the implementation of the programme, care plans are designed to cater to each patient's disease severity. Patients are followed up by case managers regularly to ensure that the care elements as mentioned above are strictly adhered to. Case managers will also call the patient 48 hours post discharge to reinforce patient education and drugs optimisation, where they play a pivotal role in linking patients to community resources. Hence, with the coordination by case managers, the programme has made care delivery a more seamless and integrated process as compared to when such an initiative is absent.

Table 1: Key care elements for Group A, B, C and D patients

Key Care Elements	At-risk	Group A	Group B	Group C	Group D	In exacerbation
		Low risk, less symptoms	Low risk, more symptoms	High risk, less symptoms	High risk, more symptoms	
1. Smoking prevention	✓					
2. Smoking cessation	✓	✓	✓	✓	✓	
3. Differential diagnosis	✓					
4. Spirometric diagnosis	✓	18-24 monthly or when clinician suspects patient grouping has changed				
5. Patient education		✓	✓	✓	✓	
6. Drug optimisation		✓	✓	✓	✓	✓
7. Influenza vaccination (yearly)		Only for Elderly (>= 65 years old) & those who have concomitant	✓	✓	✓	
8. BMI assessment (yearly)		✓	✓	✓	✓	
9. COPD Assessment tool (CAT)		6-12 monthly	6-12 monthly	6-12 monthly	3-4 monthly	
10. Acute NIV (Invasive/Non-invasive)						✓
11. Supported Restructured Hospital/Emergency Department discharge						✓
12. Home Oxygen				✓	✓	
13. Advance care planning				✓	✓	

Table 2: Care elements administered by the various healthcare team members

Key Care Elements	Doctor	Case Manager	ICP Coordinator	Spirometry Technologist	Pharmacist	Physiotherapist	Medical Social Worker
1. Smoking prevention	✓	✓			✓		
2. Smoking cessation	✓	✓			✓	✓	
3. Differential diagnosis	✓	✓					
4. Spirometric diagnosis	✓	✓		✓			
5. Patient education	✓	✓			✓		
6. Drug optimisation	✓	✓			✓		
7. Influenza Vaccination	✓	✓					
8. BMI assessment	✓	✓				✓	
9. CAT	✓	✓	✓			✓	
10. Acute NIV	✓	✓					
11. Supported RH/ED discharge	✓	✓	✓				✓
12. Home Oxygen	✓	✓					
13. Advance care planning	✓	✓					✓

Evaluation Design

A retrospective pre-post, matched-groups design will be implemented for this study. Such a design will be utilised instead of the randomised controlled trial design as the COPD-ICP programme has been implemented in JurongHealth for almost two years. Care resources may also be unnecessarily stretched if two care programmes (usual care and COPD-ICP) were run concurrently.

The study cohort will include individuals diagnosed with COPD who had at least one Specialist Outpatient Visit (SOC) record in COPD Registry from Apr 2012 to Dec 2013. For our study, we will use the same inclusion and exclusion selection criteria as those for the COPD-ICP

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3 programme enrolment (Figure 1). Patients with COPD will be identified based on the
4 International Classification of Diseases Tenth Revision (ICD-10-AM) diagnostic codes (J40.xx
5 and J47.xx).
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11 Patients in the intervention group will be sampled from programme patients in the COPD
12 registry who received care from JurongHealth from Apr 2012 to Dec 2013. A comparator group
13 will be formed from non-enrolees using matching method described in later sections. Patients for
14 the comparator group will be sampled from non-programme patients in the COPD registry who
15 received care from non-JurongHealth institutions from Apr 2012 to Dec 2013. All data will be
16 collected over one-year pre-enrolment and one-year follow up post-enrolment (three-month
17 interval) for enrolees, and over one-year period for non-enrolees. The outcomes will be
18 compared between enrolees and non-enrolees (Figure 1).
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30 31 **Sample size**

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34 Administratively, we set 30% as our target for proportion admission difference between
35 programme and non-programme patients. Thus, a sample size of 56 patients in each group will
36 be needed for statistical comparisons to be made at 90% power. Hence, 62 enrolees (to account
37 for 10% missing data) will be sampled from amongst those who were enrolled into the
38 programme during the study period and their matching group will be drawn from the comparator
39 group COPD management registry.
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49 50 **Data Sources and Data**

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52 The three main sources of data are (1) COPD Registry: patient demographics; clinical
53 information and outcome variables for both enrolees and non-enrolees; (2) Patient Case
54 Management (PCM) system database: Case managers capture entered data on all recommended
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key care elements (Table 1) common among the four patient groups; and (3) Health System administrative databases: healthcare utilisation cost. Data for one-year mortality rate will be captured from National Registry of Diseases Office (NDRO).

Covariates include patient demographics and socio-economic indicators (Age, race, gender, nationality, Medisave/Medifund and Medical social worker referral); programme enrolment date; smoking history; medication; comorbidities; severity of COPD (GOLD classification) and CAT score.

The parameters and outcomes of interest for which data shall be collected have been summarised in Table 3.

Table 3 Overall of assessments used in COPD-ICP implementation study

Domain	Type of assessment/outcomes	Pre-ICP implementation	Post-ICP implementation	Concurrent comparator group in COPD disease management registry
Baseline demographics	Age, race, gender, nationality, postal code	✓	✓	✓
Disease	Disease Type, Disease duration	✓	✓	✓
Social-economics	Medisave, Medifund, Medical social worker referral	✓	✓	✓
Programme management	Programme enrolment date	✓(baseline)	x	x
Quality of life	CAT score	✓(baseline)	✓	x
Smoking history	Smoking status, no. of years of smoking	✓	✓	✓
Key care elements	Refer to Table 1	✓(baseline)	✓	✓
Disease Severity (based on medication use)	Refer to the 2011 GOLD guidelines summary [9]	✓	✓	✓
Comorbidities & Complication	Asthma	✓	✓	✓
	Depression	✓	✓	✓
	Congestive heart failure	✓	✓	✓
	Diabetes	✓	✓	✓
	Hypertension	✓	✓	✓
	CKD stage 3-5	✓	✓	✓
	Stroke	✓	✓	✓
	Dyslipidaemia	✓	✓	✓
	Obesity	✓	✓	✓
Others	✓	✓	✓	

COPD-related Health service utilisation	Hospitalisation, Average length of stay	✓	✓	✓
Number of encounters	Emergency department attendance	✓	✓	✓
	Specialist outpatient visit	✓	✓	✓
	Primary care visit	✓	✓	✓
COPD-related Cost (DRG)	Direct cost	✓	✓	✓
	Indirect cost	✓	✓	✓
Mortality	Rate of mortality	✓	✓	✓
Qualitative measures	Patient assessment of chronic illness care	✓	✓	x

Study Outcomes

Hospital admissions and Healthcare costs

The primary outcome of this study is hospital admission. Hospital admission refers to inpatient episodes at acute care hospital managed by three regional health clusters (JurongHealth, NHG, and NUHS). Total annual healthcare costs refer to the cost of resources utilised at the primary care clinics, emergency departments, specialist outpatient clinics, and inpatient wards of these regional health clusters. To define specific COPD-related hospitalisations and inpatient costs, we have adopted the COPD-related hospitalisation ICD-10-codes used in Jiang *et al.* 2005.[11]

Disease progression and one-year mortality rate

Different medications are used during different disease progression stages.[9] Due to the absence of GOLD guidelines in measuring disease progression, we will utilise medication usage to determine the disease progression of patients with COPD. This will be compared between the intervention group and the comparator group. One-year mortality rate is defined as the proportion of patients who died (all causes) during one-year follow up for both intervention and comparator groups.

Adherence with recommended processes of care and PACIC score

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3 We will use all-or-none care bundle to monitor adherence with the recommended key care
4 elements for Group A, B, C and D patients (Table 1) at baseline and three-month interval. All-or-
5 none care bundle is a process indicator which measures the percentage of patients who adhere
6 with all of the recommended key care elements according to each patient group.[12] In addition,
7 we will use PACIC score to measure patients' experience of chronic care delivery. PACIC score
8 is a 20-question survey used to measure patients' perception on the congruency of the service to
9 the Chronic Care Model (CCM).[8] CCM is a guideline which recognises six aspects as key to
10 improving quality of chronic disease management.[8,13] The score obtained from PACIC
11 assessment tool will allow us to assess if the COPD-ICP programme is aligned with CCM.
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24 25 26 Quality of life

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28 As there is no locally validated tool to measure quality of life in patients with COPD and the
29 COPD-specific version of St. George's Respiratory Questionnaire is too long to administer, we
30 will use CAT score, which is an eight-question health survey, to measure COPD control in
31 individuals.[14] Scores range from 0 to 40 and lower scores indicate better control. Due to its
32 strong correlation with the COPD-specific version of the St. George's Respiratory Questionnaire,
33 it has been used as an alternative tool for assessing quality of life of patients with COPD.[14, 15-
34 18] Enrolees' CAT score will be measured at baseline and during their follow-up visits within
35 the first year of enrolment. A CAT score difference of 2 or more (or $\geq 10\%$) suggests clinically
36 significant changes in the quality of life.[19] The CAT score difference is taken as the difference
37 between the baseline and the best reading within 1 year. This outcome is only available for
38 programme enrolees as CAT score is not routinely collected for non-enrolees.
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55 56 **Statistical Analysis**

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3 Key recommended processes of care (Table 1) will be monitored quarterly to track the adherence
4 and progress of the COPD-ICP programme. Patient baseline characteristics from both enrolees
5 and non-enrolees will be described with mean and standard deviation for continuous variables
6 and number and percentage for categorical variables. Differences between COPD-ICP enrolees
7 and non-enrolees will be compared using chi-square statistics for categorical variables and
8 Wilcoxon rank sum tests for continuous variables.
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18 Since patients are enrolled into the programme based on the institution which they were seen in,
19 there is likely to be imbalance in baseline characteristics between enrolees and non-enrolees.
20 Hence, we will use propensity score matching to balance the baseline characteristics across
21 enrolees and non-enrolees.[20] We will start off with estimating the propensity score, which is
22 the conditional probability of each patient enrolling into the programme given their baseline
23 characteristics, by using multivariate logistic regression.[20] Covariates to be included in the
24 regression are: age, gender, race, hospital, subsidy term, the number of hospitalisation or
25 emergency attendances in the past year, number and severity of comorbid conditions and COPD
26 severity based on medication use. We will then form pairs of enrolee and non-enrolee by using
27 the caliper matching method, within a range of 0.2 of the standard deviation of propensity
28 score.[21]
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45 **Hospital admissions, healthcare costs and mortality**

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48 We will compare healthcare costs using generalised linear model with log link and gamma
49 distribution. For odds of hospital admission and one-year mortality, we will compare using
50 logistic regression.[22]
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55 **CAT score comparison**

To evaluate the quality of life improvement of the patients with COPD using CAT score as the outcome, the change in CAT score over the 1-year post-enrolment time frame will be examined.

A paired-sample *t*-test will be used to compare baseline CAT score and the best achieved CAT score over the 1-year time frame.

PACIC score

To evaluate patients' perception on the programme's congruency with CCM, the average PACIC score for programme enrollees will be computed and benchmarked with PACIC results of other integrated care programmes in present literature that have showed substantial congruency to the CCM. At present, recommended cut-offs for CCM concordance is set at ≥ 3.5 in a study with veterans and at ≥ 4 in another study with older adults at risk of high healthcare costs.[23-24].

Software

All analyses will be conducted using Stata version 12.

DISCUSSION

In designing the COPD-ICP programme, three key principles have been adopted: right-siting, integration and patient-centeredness. It also involves the five standards of care: COPD prevention, early diagnosis, management of stable patients with COPD, treatment and support during acute exacerbations, and care and support at end of life. The model of care concept plan is drafted with reference to various evidence-based guidelines such as the GOLD standard, American College of Physicians guideline on diagnosis and management of stable chronic COPD, and MOH COPD Clinical Practice Guidelines (2006).[25-26]

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3 This programme serves to close current service gaps to provide comprehensive integrated care
4 along the care continuum in the following ways. Training for primary care physicians in the
5 management of COPD has the potential to enhance care standards at their care setting. A multi-
6 disciplinary care team comprising of the clinician, case manager, coordinator and other relevant
7 allied health members have been shown to improve clinical outcomes and life expectancy of
8 patients with COPD.[27] Patients admitted for exacerbations are contacted within 48 hours from
9 discharge to reinforce patient education and to increase their confidence in self-managing their
10 own condition. Lastly, the case manager plays the role of the liaison between step-down care
11 partners, primary care physicians and patients. This may lower the risk of readmission and
12 reduce the frequency of exacerbation. From an international perspective, similar integrated care
13 models around the world have also showed similar positive results.[28-29] These evidences
14 further support JurongHealth in launching and maintaining the COPD-ICP programme.
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32 The rationale behind this programme evaluation stems from the motivation to bolster support for
33 the programme and to identify care gaps for improvement. As such, adherence with processes of
34 care and outcomes such as risk of hospitalisation, CAT score and PACIC score will be used by
35 the team to identify any care gaps, so as to improve the COPD-ICP programme. In addition,
36 healthcare costs, disease progression and one-year mortality rate will also be used to assess the
37 practicality of sustaining the programme. Furthermore, this study can also potentially add to the
38 mounting evidence in support of integrated care in healthcare literature.
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49 This study protocol has several strengths. The PACIC survey will be used to assess patients'
50 experience of the congruency of care to CCM. This is in line with the organisation's aim to
51 deliver patient-centred care.
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3 The choice of the matched group patients using propensity scores will replicate the balance in
4 baseline characteristics between compared cohorts achieved through randomisation. This will in
5 turn reduce the effect of selection bias due to the lack of randomisation.[21] This step will be
6 vital for making valid conclusions from the economic effectiveness analysis.
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13 This study protocol is limited in several areas. Firstly, even though we will use propensity score
14 matching to reduce the selection bias due to non-randomisation, there might be unmeasured
15 confounders which can affect our results. Secondly, the data collection process will only account
16 for both enrolees and non-enrolees who choose to have their follow-up medical appointments at
17 JurongHealth, NHG and NUHS. Due to non-captive nature of the healthcare system in
18 Singapore, patients in Singapore are free to choose healthcare providers outside these clusters on
19 an episodic basis. Hence, such exclusion might lead to underestimation. However, these
20 limitations affect the evaluation of the programme only but not the quality of care provided at
21 any institution.
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35 In conclusion, the COPD-ICP programme aims to equip primary care partners with the adequate
36 knowledge and skills for managing stable patients with COPD and to right-site patients in order
37 to provide excellent and appropriate care while optimising available healthcare resources. With
38 the support from case managers, the programme does so by discharging patients to primary care
39 doctors so that the clinically stable patients can be managed without the need to see a specialist if
40 not clinically necessary. We believe that this evaluation study can provide an evidence-based
41 assessment of the impact and effectiveness of the COPD-ICP programme. The lessons learnt
42 from this study will be fed back to the COPD-ICP programme team and be useful in informing
43 the design evaluations of other ICP programmes nationally.
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ETHICS AND DISSEMINATION

This protocol describes the implementation and proposed evaluation of the COPD-ICP programme. The described study has received ethical approval from the NHG Domain Specific Review Board (DSRB Ref: 2013/01200). Results of the study will be reported through peer-review publication and healthcare conferences presentation.

CONFIDENTIALITY

Names and National Registration Identity Card (NRIC) number of patients will be removed and replaced with unique study IDs after merging of datasets. The link between these study IDs and the NRIC number it represents will only be known to the principal investigator of the study.

DATA ACCESS

Access rights to the data will be given to the Clinical Analytics team in JurongHealth, the project manager and the clinician lead of the COPD-ICP programme.

AUTHORS' CONTRIBUTIONS

Ms Christine Wu Xia contributed to study design, data analysis method and writing up of manuscript. Miss Tan Woan Shin contributed to study design, statistical analysis and the critical revision of the manuscript for important intellectual content. Mr See Chor Kian participated as the project manager of this programme and contributed to the write-up of the manuscript. Mr Yu Weichang contributed to statistical methods and manuscript review. Ms Lynette Kwek Siang Lim participated in the implementation of the model of care and inputs into the manuscript. Dr Matthias Toh contributed to study design and manuscript review. Dr Gerald Chua Seng Wee and Ms Chee Thong Gan are the clinician lead and operational lead of this programme and

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3 participated in the design of the COPD model of care. All the authors read and approved the final
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5 manuscript.
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10
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12
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17 18 **COMPETING INTERESTS**

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20 The authors declare that they have no competing interests.
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FIGURE LEGENDS

Figure 1: Identification of the study cohort

Figure 2: Patient classification based on symptoms and risk of exacerbations from GOLD guidelines.[9-10] Symptoms of COPD are assessed using mMRC or CAT score. Patient's risk of exacerbations is assessed based on the patient's stage of airflow limitation and/or number of exacerbations that the patient has had over previous 12 months.

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3 **A matched-group study protocol to evaluate the implementation of an Integrated Care**
4 **Pathway Programme for Chronic Obstructive Pulmonary Disease in Singapore**
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ABSTRACT

Introduction

The treatment of chronic obstructive pulmonary disease (COPD) involves different care providers across care sites. This fragmentation of care increases the morbidity and mortality burden, as well as acute health services use. The COPD-Integrated Care Pathway (ICP) was designed and implemented to integrate the care across different sites from primary care to acute hospital and home. It aims to reduce the prevalence of COPD among the population in the catchment, reduce risk of hospital admissions, delay or prevent the progression of the disease and reduce mortality rate by adopting a coordinated and multi-disciplinary approach to the management of the patients' medical conditions. This study on the COPD-ICP programme is undertaken to determine the impact on processes of care, clinical outcomes, and acute care utilisation.

Methods and analysis

This will be a retrospective, pre-post, matched-groups study to evaluate the effectiveness of COPD-ICP programme in improving clinical outcomes and reducing healthcare costs. Programme enrolees (intervention group) and non-enrolees (comparator group) will be matched using propensity scores. Administratively, we set 30% as our target for proportion admission difference between programme and non-programme patients. A sample size of 62 patients in each group will be needed for statistical comparisons to be made at 90% power. Adherence with recommended care elements will be measured at baseline and quarterly during one year follow-up. Risk of COPD-related hospitalisations as primary outcome, healthcare costs, disease progression, and one-year mortality during one-year follow-up will be compared between the groups using generalised linear regression models.

Ethics and dissemination

This protocol describes the implementation and proposed evaluation of the COPD-ICP programme. The described study has received ethical approval from the NHG Domain Specific Review Board (DSRB Ref: 2013/01200). Results of the study will be reported through peer-review publications and healthcare conferences presentation.

Keywords

Chronic Obstructive Pulmonary Disease, Integrated Care Pathway, Evaluation, Propensity Score Matching

Key message

- This study aims to evaluate the effectiveness of the programme in improving adherence with recommended processes of care, and lowering COPD-related hospitalisation and inpatient costs.
- This study will also compare the one-year mortality rate and disease progression rate between enrolees and non-enrolees. This study will use CAT score to measure COPD control in patients and Patient Assessment of Chronic Illness Care (PACIC) score to measure patients' experience of care congruent to the Chronic Care Model.

Strengths and limitation of this study

- This study will use a retrospective, pre-post, matched-groups design to evaluate the effectiveness of the programme in terms of adherence with processes of care, clinical outcomes, healthcare costs, and quality of life. It is envisioned that through this study, the COPD-ICP team will be able to identify potential gaps in the programme implementation and

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3 design, and implement necessary changes to improve care. This is in line with the
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5 organisation's aim to deliver patient-centred care.
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- 8 ■ This study will use propensity score matching to reduce selection bias due to the lack of
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10 randomisation.
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12 13 **BACKGROUND**

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17 Chronic Obstructive Pulmonary Disease (COPD) is a major cause of chronic disease morbidity
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19 and mortality worldwide. The disease is a global health problem with a worldwide prevalence of
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21 10.1%.^[1] In Singapore, COPD is the seventh principal cause of death and the seventh most
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23 common condition for hospitalisation.^[2] COPD patients with complications spent 7.7 days or
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25 79% longer in hospital than COPD patients without complications.^[3] The COPD 30-day
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27 readmission in JurongHealth is around 30% which is higher than the all-cause national 30-day
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29 readmission rate of 11.6% and other condition-specific readmission rates.^[4]
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34 The GOLD international standards for COPD advise spirometry for the gold standard for
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36 accurate and repeatable measurement of lung function.^[5] However, in Singapore, most solo
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38 general practice (GP) clinics do not offer spirometer services necessary for early diagnosis of
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40 COPD and for the staging of COPD severity to enable appropriate disease management. Patients
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42 with COPD in the community experience poor quality of life due to lack of convenient access to
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44 pulmonary rehabilitation.^[6] Therefore, most patients are diagnosed in the acute care setting and
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46 those who experienced repeated exacerbations also obtain care in the specialist outpatient
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48 settings.
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54 In response to the need for a cost-effective care model, JurongHealth launched a COPD
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56 Integrated Care Pathway (COPD-ICP) programme in April 2012. This was funded by the
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3 Singapore Ministry of Health (MOH). The programme seeks to coordinate care across different
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5 healthcare settings. It aims to provide comprehensive care for patients with COPD at different
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7 stages of the disease, involving primary, hospital-based, community-based, and palliative care.
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11 Similar to other COPD integrated care programmes,[7] the programme envisages coordination of
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13 care across different sites from primary to home and hospital care. The objectives of the
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15 programme are to:
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19 1. Reduce the prevalence of COPD among the population residing in the Western part of
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21 Singapore (catchment area of JurongHealth).
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24 2. Reduce risk of hospital admissions and healthcare costs.
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27 3. Delay or prevent the deterioration of disease condition of COPD patients.
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30 4. Reduce mortality of patients with COPD.
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32 The programme adopts a coordinated and multi-disciplinary approach to the management of the
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34 patients' medical conditions. Case managers work with JurongHealth's multi-disciplinary team
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36 of doctors, nurses, respiratory technologists, pharmacists, physiotherapists and medical social
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38 workers to develop a customised care plan for each patient, empower patients towards self-
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40 management through education, and help coordinate referrals and patients' appointments across
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42 care sites.
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46 The current scope of our study will focus on the evaluation of the hospital-based segment of the
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48 ICP programme. We will use propensity-score matching method to select a suitable comparator
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50 group. Specifically, the aim of our study will be to assess whether the intervention group
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52 compared to comparator group has 1) primary outcome: lower risk of COPD-related
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54 hospitalisation; and 2) secondary outcomes: better adherence to the recommended processes of
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3 care, lower overall healthcare and COPD-related inpatient costs, slower disease progression, and
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5 lower one-year mortality rate. We will use PACIC score to measure patients' experience of
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7 chronic care delivery in congruence to the Chronic Care Model (CCM).[8] In addition, we will
8
9 also use CAT score to measure COPD control and hence the quality of life of patients with
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11 COPD.
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14 15 16 **METHODS/DESIGN**

17 18 19 **The Regional Healthcare System**

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22 In Singapore, public healthcare is provided by six regional healthcare systems (RHSs):
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24 Alexandra Health, Eastern Health Alliance, National Healthcare Group (NHG), National
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26 University Health System (NUHS), JurongHealth, and Singapore Health Services (SHS).
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28 Together, these RHSs provide 80% of all acute care service. The government primary care
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30 clinics under NHG and SHS provide approximately 20% of primary care services consumed.
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37 38 39 **Target Patient**

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41 Figure 1 shows the inclusion and exclusion criteria for patients' enrolment into the COPD-ICP
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43 programme.[9-10] We will exclude patients who have medical conditions other than COPD that
44
45 are likely to result in death within the next two years.
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49 We classify each patient enrolled into the programme based on the Patient Group Classification
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51 from updated GOLD guidelines (Figure 2).[9-10]
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53 54 55 **Intervention**

Table 1 shows the recommended key care elements for each group of patients. Various healthcare team members are responsible for administering the respective key care elements (Table 2).

With the implementation of the programme, care plans are designed to cater to each patient's disease severity. Patients are followed up by case managers regularly to ensure that the care elements as mentioned above are strictly adhered to. Case managers will also call the patient 48 hours post discharge to reinforce patient education and drugs optimisation, where they play a pivotal role in linking patients to community resources. Hence, with the coordination by case managers, the programme has made care delivery a more seamless and integrated process as compared to when such an initiative is absent.

Table 1: Key care elements for Group A, B, C and D patients

Key Care Elements	At-risk	Group A	Group B	Group C	Group D	In exacerbation
		Low risk, less symptoms	Low risk, more symptoms	High risk, less symptoms	High risk, more symptoms	
1. Smoking prevention	✓					
2. Smoking cessation	✓	✓	✓	✓	✓	
3. Differential diagnosis	✓					
4. Spirometric diagnosis	✓	18-24 monthly or when clinician suspects patient grouping has changed				
5. Patient education		✓	✓	✓	✓	
6. Drug optimisation		✓	✓	✓	✓	✓
7. Influenza vaccination (yearly)		Only for Elderly (>= 65 years old) & those who have concomitant	✓	✓	✓	
8. BMI assessment (yearly)		✓	✓	✓	✓	
9. COPD Assessment tool (CAT)		6-12 monthly	6-12 monthly	6-12 monthly	3-4 monthly	
10. Acute NIV (Invasive/Non-invasive)						✓
11. Supported Restructured Hospital/Emergency Department discharge						✓
12. Home Oxygen				✓	✓	
13. Advance care planning				✓	✓	

Table 2: Care elements administered by the various healthcare team members

Key Care Elements	Doctor	Case Manager	ICP Coordinator	Spirometry Technologist	Pharmacist	Physiotherapist	Medical Social Worker
1. Smoking prevention	✓	✓			✓		
2. Smoking cessation	✓	✓			✓	✓	
3. Differential diagnosis	✓	✓					
4. Spirometric diagnosis	✓	✓		✓			
5. Patient education	✓	✓			✓		
6. Drug optimisation	✓	✓			✓		
7. Influenza Vaccination	✓	✓					
8. BMI assessment	✓	✓				✓	
9. CAT	✓	✓	✓			✓	
10. Acute NIV	✓	✓					
11. Supported RH/ED discharge	✓	✓	✓				✓
12. Home Oxygen	✓	✓					
13. Advance care planning	✓	✓					✓

Evaluation Design

A retrospective pre-post, matched-groups design will be implemented for this study. Such a design will be utilised instead of the randomised controlled trial design as the COPD-ICP programme has been implemented in JurongHealth for almost two years. Care resources may also be unnecessarily stretched if two care programmes (usual care and COPD-ICP) were run concurrently.

The study cohort will include individuals diagnosed with COPD who had at least one Specialist Outpatient Visit (SOC) record in COPD Registry from Apr 2012 to Dec 2013. For our study, we will use the same inclusion and exclusion selection criteria as those for the COPD-ICP

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3 programme enrolment (Figure 1). Patients with COPD will be identified based on the
4 International Classification of Diseases Tenth Revision (ICD-10-AM) diagnostic codes (J40.xx
5 and J47.xx).
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11 Patients in the intervention group will be sampled from programme patients in the COPD
12 registry who received care from JurongHealth from Apr 2012 to Dec 2013. A comparator group
13 will be formed from non-enrolees using matching method described in later sections. Patients for
14 the comparator group will be sampled from non-programme patients in the COPD registry who
15 received care from non-JurongHealth institutions from Apr 2012 to Dec 2013. All data will be
16 collected over one-year pre-enrolment and one-year follow up post-enrolment (three-month
17 interval) for enrolees, and over one-year period for non-enrolees. The outcomes will be
18 compared between enrolees and non-enrolees (Figure 1).
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30 31 **Sample size**

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33 Administratively, we set 30% as our target for proportion admission difference between
34 programme and non-programme patients. Thus, a sample size of 56 patients in each group will
35 be needed for statistical comparisons to be made at 90% power. Hence, 62 enrolees (to account
36 for 10% missing data) will be sampled from amongst those who were enrolled into the
37 programme during the study period and their matching group will be drawn from the comparator
38 group COPD management registry.
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49 50 **Data Sources and Data**

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52 The three main sources of data are (1) COPD Registry: patient demographics; clinical
53 information and outcome variables for both enrolees and non-enrolees; (2) Patient Case
54 Management (PCM) system database: Case managers capture entered data on all recommended
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key care elements (Table 1) common among the four patient groups; and (3) Health System administrative databases: healthcare utilisation cost. Data for one-year mortality rate will be captured from National Registry of Diseases Office (NDRO).

Covariates include patient demographics and socio-economic indicators (Age, race, gender, nationality, Medisave/Medifund and Medical social worker referral); programme enrolment date; smoking history; medication; comorbidities; severity of COPD (GOLD classification) and CAT score.

The parameters and outcomes of interest for which data shall be collected have been summarised in Table 3.

Table 3 Overall of assessments used in COPD-ICP implementation study

Domain	Type of assessment/outcomes	Pre-ICP implementation	Post-ICP implementation	Concurrent comparator group in COPD disease management registry
Baseline demographics	Age, race, gender, nationality, postal code	✓	✓	✓
Disease	Disease Type, Disease duration	✓	✓	✓
Social-economics	Medisave, Medifund, Medical social worker referral	✓	✓	✓
Programme management	Programme enrolment date	✓(baseline)	x	x
Quality of life	CAT score	✓(baseline)	✓	x
Smoking history	Smoking status, no. of years of smoking	✓	✓	✓
Key care elements	Refer to Table 1	✓(baseline)	✓	✓
Disease Severity (based on medication use)	Refer to the 2011 GOLD guidelines summary [9]	✓	✓	✓
Comorbidities & Complication	Asthma	✓	✓	✓
	Depression	✓	✓	✓
	Congestive heart failure	✓	✓	✓
	Diabetes	✓	✓	✓
	Hypertension	✓	✓	✓
	CKD stage 3-5	✓	✓	✓
	Stroke	✓	✓	✓
	Dyslipidaemia	✓	✓	✓
	Obesity	✓	✓	✓
Others	✓	✓	✓	

COPD-related Health service utilisation	Hospitalisation, Average length of stay	✓	✓	✓
Number of encounters	Emergency department attendance	✓	✓	✓
	Specialist outpatient visit	✓	✓	✓
	Primary care visit	✓	✓	✓
COPD-related Cost (DRG)	Direct cost	✓	✓	✓
	Indirect cost	✓	✓	✓
Mortality	Rate of mortality	✓	✓	✓
Qualitative measures	Patient assessment of chronic illness care	✓	✓	x

Study Outcomes

Hospital admissions and Healthcare costs

The primary outcome of this study is hospital admission. Hospital admission refers to inpatient episodes at acute care hospital managed by three regional health clusters (JurongHealth, NHG, and NUHS). Total annual healthcare costs refer to the cost of resources utilised at the primary care clinics, emergency departments, specialist outpatient clinics, and inpatient wards of these regional health clusters. To define specific COPD-related hospitalisations and inpatient costs, we have adopted the COPD-related hospitalisation ICD-10-codes used in Jiang *et al.* 2005.[11]

Disease progression and one-year mortality rate

Different medications are used during different disease progression stages.[9] Due to the absence of GOLD guidelines in measuring disease progression, we will utilise medication usage to determine the disease progression of patients with COPD. This will be compared between the intervention group and the comparator group. One-year mortality rate is defined as the proportion of patients who died (all causes) during one-year follow up for both intervention and comparator groups.

Adherence with recommended processes of care and PACIC score

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3 We will use all-or-none care bundle to monitor adherence with the recommended key care
4 elements for Group A, B, C and D patients (Table 1) at baseline and three-month interval. All-or-
5 none care bundle is a process indicator which measures the percentage of patients who adhere
6 with all of the recommended key care elements according to each patient group.[12] In addition,
7 we will use PACIC score to measure patients' experience of chronic care delivery. PACIC score
8 is a 20-question survey used to measure patients' perception on the congruency of the service to
9 the Chronic Care Model (CCM).[8] CCM is a guideline which recognises six aspects as key to
10 improving quality of chronic disease management.[8,13] The score obtained from PACIC
11 assessment tool will allow us to assess if the COPD-ICP programme is aligned with CCM.
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24 25 26 Quality of life

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28 As there is no locally validated tool to measure quality of life in patients with COPD and the
29 COPD-specific version of St. George's Respiratory Questionnaire is too long to administer, we
30 will use CAT score, which is an eight-question health survey, to measure COPD control in
31 individuals.[14] Scores range from 0 to 40 and lower scores indicate better control. Due to its
32 strong correlation with the COPD-specific version of the St. George's Respiratory Questionnaire,
33 it has been used as an alternative tool for assessing quality of life of patients with COPD.[14, 15-
34 18] Enrolees' CAT score will be measured at baseline and during their follow-up visits within
35 the first year of enrolment. A CAT score difference of 2 or more (or $\geq 10\%$) suggests clinically
36 significant changes in the quality of life.[19] The CAT score difference is taken as the difference
37 between the baseline and the best reading within 1 year. This outcome is only available for
38 programme enrolees as CAT score is not routinely collected for non-enrolees.
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54 55 56 **Statistical Analysis**

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3 Key recommended processes of care (Table 1) will be monitored quarterly to track the adherence
4 and progress of the COPD-ICP programme. Patient baseline characteristics from both enrolees
5 and non-enrolees will be described with mean and standard deviation for continuous variables
6 and number and percentage for categorical variables. Differences between COPD-ICP enrolees
7 and non-enrolees will be compared using chi-square statistics for categorical variables and
8 Wilcoxon rank sum tests for continuous variables.
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18 Since patients are enrolled into the programme based on the institution which they were seen in,
19 there is likely to be imbalance in baseline characteristics between enrolees and non-enrolees.
20 Hence, we will use propensity score matching to balance the baseline characteristics across
21 enrolees and non-enrolees.[20] We will start off with estimating the propensity score, which is
22 the conditional probability of each patient enrolling into the programme given their baseline
23 characteristics, by using multivariate logistic regression.[20] Covariates to be included in the
24 regression are: age, gender, race, hospital, subsidy term, the number of hospitalisation or
25 emergency attendances in the past year, number and severity of comorbid conditions and COPD
26 severity based on medication use. We will then form pairs of enrolee and non-enrolee by using
27 the caliper matching method, within a range of 0.2 of the standard deviation of propensity
28 score.[21]
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45 **Hospital admissions, healthcare costs and mortality**

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48 We will compare healthcare costs using generalised linear model with log link and gamma
49 distribution. For odds of hospital admission and one-year mortality, we will compare using
50 logistic regression.[22]
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55 **CAT score comparison**

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3 To evaluate the quality of life improvement of the patients with COPD using CAT score as the
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5 outcome, the change in CAT score over the 1-year post-enrolment time frame will be examined.
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8 A paired-sample *t*-test will be used to compare baseline CAT score and the best achieved CAT
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10 score over the 1-year time frame.
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12 13 **PACIC score**

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16 To evaluate patients' perception on the programme's congruency with CCM, the average PACIC
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18 score for programme enrollees will be computed and benchmarked with PACIC results of other
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20 integrated care programmes in present literature that have showed substantial congruency to the
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22 CCM. At present, recommended cut-offs for CCM concordance is set at ≥ 3.5 in a study with
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24 veterans and at ≥ 4 in another study with older adults at risk of high healthcare costs.[23-24].
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29 30 **Software**

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32 All analyses will be conducted using Stata version 12.
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36 37 **DISCUSSION**

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39 In designing the COPD-ICP programme, three key principles have been adopted: right-siting,
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41 integration and patient-centeredness. It also involves the five standards of care: COPD
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43 prevention, early diagnosis, management of stable patients with COPD, treatment and support
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45 during acute exacerbations, and care and support at end of life. The model of care concept plan is
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47 drafted with reference to various evidence-based guidelines such as the GOLD standard,
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49 American College of Physicians guideline on diagnosis and management of stable chronic
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51 COPD, and MOH COPD Clinical Practice Guidelines (2006).[25-26]
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3 This programme serves to close current service gaps to provide comprehensive integrated care
4 along the care continuum in the following ways. Training for primary care physicians in the
5 management of COPD has the potential to enhance care standards at their care setting. A multi-
6 disciplinary care team comprising of the clinician, case manager, coordinator and other relevant
7 allied health members have been shown to improve clinical outcomes and life expectancy of
8 patients with COPD.[27] Patients admitted for exacerbations are contacted within 48 hours from
9 discharge to reinforce patient education and to increase their confidence in self-managing their
10 own condition. Lastly, the case manager plays the role of the liaison between step-down care
11 partners, primary care physicians and patients. This may lower the risk of readmission and
12 reduce the frequency of exacerbation. From an international perspective, similar integrated care
13 models around the world have also showed similar positive results.[28-29] These evidences
14 further support JurongHealth in launching and maintaining the COPD-ICP programme.
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32 The rationale behind this programme evaluation stems from the motivation to bolster support for
33 the programme and to identify care gaps for improvement. As such, adherence with processes of
34 care and outcomes such as risk of hospitalisation, CAT score and PACIC score will be used by
35 the team to identify any care gaps, so as to improve the COPD-ICP programme. In addition,
36 healthcare costs, disease progression and one-year mortality rate will also be used to assess the
37 practicality of sustaining the programme. Furthermore, this study can also potentially add to the
38 mounting evidence in support of integrated care in healthcare literature.
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49 This study protocol has several strengths. The PACIC survey will be used to assess patients'
50 experience of the congruency of care to CCM. This is in line with the organisation's aim to
51 deliver patient-centred care.
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3 The choice of the matched group patients using propensity scores will replicate the balance in
4 baseline characteristics between compared cohorts achieved through randomisation. This will in
5 turn reduce the effect of selection bias due to the lack of randomisation.[21] This step will be
6 vital for making valid conclusions from the economic effectiveness analysis.
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13 This study protocol is limited in several areas. Firstly, even though we will use propensity score
14 matching to reduce the selection bias due to non-randomisation, there might be unmeasured
15 confounders which can affect our results. Secondly, the data collection process will only account
16 for both enrolees and non-enrolees who choose to have their follow-up medical appointments at
17 JurongHealth, NHG and NUHS. Due to non-captive nature of the healthcare system in
18 Singapore, patients in Singapore are free to choose healthcare providers outside these clusters on
19 an episodic basis. Hence, such exclusion might lead to underestimation. However, these
20 limitations affect the evaluation of the programme only but not the quality of care provided at
21 any institution.
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35 In conclusion, the COPD-ICP programme aims to equip primary care partners with the adequate
36 knowledge and skills for managing stable patients with COPD and to right-site patients in order
37 to provide excellent and appropriate care while optimising available healthcare resources. With
38 the support from case managers, the programme does so by discharging patients to primary care
39 doctors so that the clinically stable patients can be managed without the need to see a specialist if
40 not clinically necessary. We believe that this evaluation study can provide an evidence-based
41 assessment of the impact and effectiveness of the COPD-ICP programme. The lessons learnt
42 from this study will be fed back to the COPD-ICP programme team and be useful in informing
43 the design evaluations of other ICP programmes nationally.
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ETHICS AND DISSEMINATION

This protocol describes the implementation and proposed evaluation of the COPD-ICP programme. The described study has received ethical approval from the NHG Domain Specific Review Board (DSRB Ref: 2013/01200). Results of the study will be reported through peer-review publication and healthcare conferences presentation.

CONFIDENTIALITY

Names and National Registration Identity Card (NRIC) number of patients will be removed and replaced with unique study IDs after merging of datasets. The link between these study IDs and the NRIC number it represents will only be known to the principal investigator of the study.

DATA ACCESS

Access rights to the data will be given to the Clinical Analytics team in JurongHealth, the project manager and the clinician lead of the COPD-ICP programme.

AUTHORS' CONTRIBUTIONS

Ms Christine Wu Xia contributed to study design, data analysis method and writing up of manuscript. Miss Tan Woan Shin contributed to study design, statistical analysis and the critical revision of the manuscript for important intellectual content. Mr See Chor Kian participated as the project manager of this programme and contributed to the write-up of the manuscript. Mr Yu Weichang contributed to statistical methods and manuscript review. Ms Lynette Kwek Siang Lim participated in the implementation of the model of care and inputs into the manuscript. Dr Matthias Toh contributed to study design and manuscript review. Dr Gerald Chua Seng Wee and Ms Chee Thong Gan are the clinician lead and operational lead of this programme and

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3 participated in the design of the COPD model of care. All the authors read and approved the final
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5 manuscript.
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17 18 **COMPETING INTERESTS**

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20 The authors declare that they have no competing interests.
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41 Mr Lim Kian Chong and Ms Koh Ang Hong (all physiotherapists), Mr Timothy Chua and Ms
42
43 Krutika Menon (both Social Workers), Ms Kimmy Liew (Head, Pharmacy), Mr Ong Chee
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FIGURE LEGENDS

Figure 1: Identification of the study cohort

Figure 2: Patient classification based on symptoms and risk of exacerbations from GOLD guidelines.[9-10] Symptoms of COPD are assessed using mMRC or CAT score. Patient's risk of exacerbations is assessed based on the patient's stage of airflow limitation and/or number of exacerbations that the patient has had over previous 12 months.

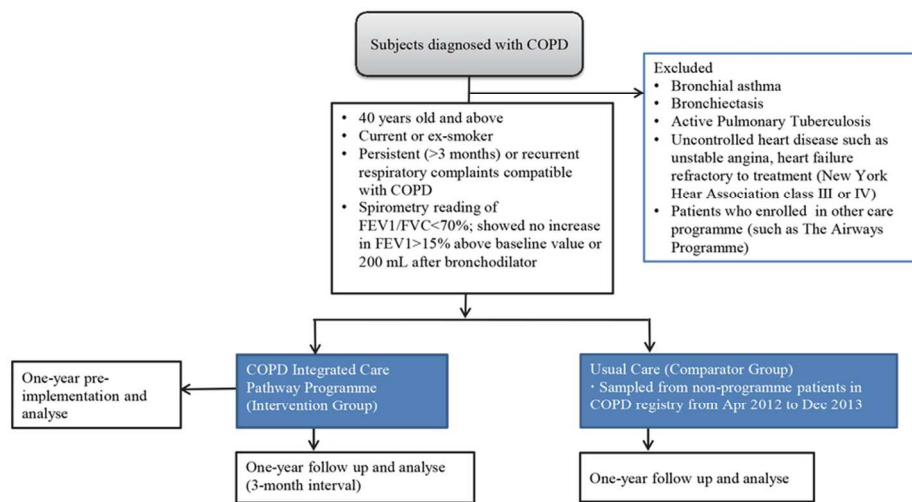
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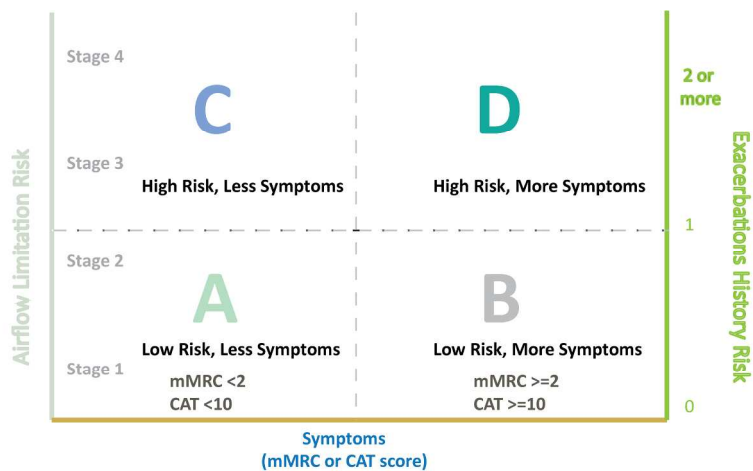
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Identification of study cohort
89x46mm (300 x 300 DPI)

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Patient classification based on symptoms and risk of exacerbations from GOLD guidelines.[9-10] Symptoms of COPD are assessed using mMRC or CAT score. Patient’s risk of exacerbations is assessed based on the patient’s stage of airflow limitation and/or number of exacerbations that the patient has had over previous 12 months.

194x266mm (300 x 300 DPI)