BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2014-005655
Article Type:	Protocol
Date Submitted by the Author:	08-May-2014
Complete List of Authors:	Wu, Christine; Alexandra Hospital, JurongHealth, Medical Affairs See, Ryan; Alexandra Hospital, JurongHealth, Clinical Operations Yu, Weichang; Alexandra Hospital, JurongHealth, Medical Affairs Kwek, Lynette; Alexandra Hospital, JurongHealth, Clinical Operations Chua, Gerald; Alexandra Hospital, 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)

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

Authors:

1. Christine Xia Wu : christine_wu@juronghealth.com.sg

Medical Affairs Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

2. Chor Kian See: ryan_see@juronghealth.com.sg

Clinical Operations Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

3. Yu Weichang: weichang_yu@juronghealth.com.sg (Corresponding Author)

Medical Affairs Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

+65-63706156

4. Lynette Kwek Siang Lin: lynette_kwek@juronghealth.com.sg

Clinical Operations Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

5. Gerald Seng Wee Chua: gerald_chua@juronghealth.com.sg

Medicine Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

Details of this manuscript

- 3498 words excluding title page, abstract, references, figures and tables.
- 4 tables and 1 figure
- 30 references

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

programme will result in better clinical outcomes, reduced health utilisation and costs, and improved quality of life for the programme patients. Hence, the primary objective is to evaluate both the impact and economic-effectiveness of the COPD-ICP programme in terms of clinical outcomes (mortality, 30-day readmission rate) and health services utilisation and costs.

Ethics and dissemination

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

Keywords

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

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

different healthcare settings. It aims to provide comprehensive care for COPD patients at different stages of the disease, involving primary, hospital-based, community-based and palliative care. Similar to a Danish COPD early intervention project,[4] the programme envisages the coordinating of care across different sites from primary care to homes and the hospital. The objectives of the programme are to:

1. Reduce COPD prevalence in the western population through effective prevention efforts in the community
2. Reduce morbidity and improve the quality of life of COPD patients
3. Delay or prevent disease progression of COPD patients through early interventions

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

Objective

This study is designed to evaluate the effect of the COPD-ICP programme on the following primary outcome measures: 1) Health services utilisation and cost; 2) 1-year mortality rate; 3) 30-day readmission rate. The impact on the care costs for COPD patients will also be investigated via economic-effectiveness analysis.

The secondary aims of this study include looking at the recommended care compliance and quality of life. Patients' perception of the extent to which the service is congruent with five of the

care elements within the Chronic Care Model – Health System, Delivery System Design, Decision Support, Self-Management Support and Community will also be evaluated.

Methods/Design

Design

A prospective, 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. In order to strengthen the evidence obtained from this study, a matched control group will also be formed from non-enrolees using methods described in later sections. Patients for this control group will be sourced from another healthcare cluster in Singapore. Primary outcome measures will then be compared between programme patients and this control group.

Study Setting

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

Inclusion and exclusion criteria

Patients are enrolled into the programme if they are 40 years old and above; are current or ex-smokers; present with persistent (>3 months) or recurrent respiratory complaints compatible with COPD; have spirometry reading of FEV_1 / FVC < 70%; and showed no increase in FEV_1 > 15% above baseline value or >200 mL after bronchodilator administration.[5-6] Patients were excluded if they have illnesses other than COPD that was likely to result in death within 2 years; Bronchial asthma, Bronchiectasis, Active Pulmonary Tuberculosis, and uncontrolled heart diseases such as unstable angina, heart failure refractory to treatment (New York Heart Association class III or IV).[5, 7] Patients who have been enrolled into other care programmes (such as The Airways Programme, TAP) are also excluded.

Intervention

The COPD-ICP programme classifies each patient enrolled into the programme based on the Patient Group Classification from updated GOLD guidelines (see Figure 1).[5-6] This programme has a customised set of interventions and right-siting plans for patients in each of the four groups. Group A patients exhibit less symptoms and can be managed at the primary care setting in this programme. Group B patients exhibit more symptoms and present an opportunity to be managed well by primary care doctors to move into Group A with appropriate drug therapy in this programme.[8-12] Group C patients exhibit less symptoms but have a more severe airflow limitation. Patients belonging to this group are currently admitted to the hospital due to exacerbations but those with stabilised conditions can be managed at the Specialist Outpatient Clinics (SOCs) at 6 monthly interval. Group D patients exhibit more symptoms and are the target of Advance Care Planning (ACP) and home care service in this programme.[13-14]

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 Restructed Hospital/Emergency Deparment discharge				√	√		
12. Home Oxygen						√	√
13. Advance care planning			√	√	√		

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

Table 3 Five Standards of care with care continuum model

1. Prevention of COPD Primary and secondary prevention strategies will be implemented. Primary prevention strategies such as social marketing campaigns and lifestyle modifications targeting the general population can help reduce smoking incidence rates. Common secondary prevention strategies, such as patient education and smoking cessation counseling can minimise the impact of the disease.
2. Early Diagnosis Many patients are not detected in the early stages of the disease because GP clinics, in Singapore, typically do not offer spirometry tests which measure lung function. By providing access to spirometry tests in the community, JurongHealth will be able to identify patients at risk of developing COPD or in the mild stage of COPD and provide timely secondary prevention and early intervention.
3. Management of stable COPD patients Coordinated management planning and care that is based in the primary care setting should include pulmonary rehabilitation for COPD patients. Pulmonary rehabilitation has been shown to improve patients' exercise capacity, health related quality of life, and reduce healthcare service utilisation.
4. Treatment and support during acute exacerbations There should be access to appropriate levels of COPD care in the community, with referral access for the more severe patients at the hospitals when needed.
5. Care and support at end of life Palliative care management is to be provided by the intermediate and long term care (ILTC) providers, in the community where possible, for patients with end stage disease.

Study Outcomes

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

Healthcare utilisation and cost

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

1-year mortality rate

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

30-day readmission rate

The proportion of patients who were discharged from either an NHG or JurongHealth institution and re-admitted (all causes) to the same hospital within 30 days of their discharge date.

In addition, the following measure will be used to gauge the level of achievement of the study's secondary aims.

CAT score

This is an eight-question health survey used to measure COPD control in individuals. Scores range from 0 to 40 and lower scores indicate better control. The quality of life of the patients is measured using the CAT at baseline and during their follow-up visits within the first year of enrolment. It is used to measure the impact of COPD on a patient's wellbeing and daily life. A CAT score difference of 2 or more (or ≥10%) suggests clinically significant changes in the quality of life.[18] 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.

Patient Assessment of Care for Chronic Conditions (PACIC) score

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

Data collection

The parameters and outcomes of interest for which data shall be collected have been summarised in Table 4. The three main sources of data are

1. Chronic Disease Management System (CDMS): Source of SOC/clinic visit information for both enrolees and non-enrolees.

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 enrolees 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

score). The Patient Assessment of Care for Chronic Conditions (PACIC) survey will be administered during baseline and every follow-up visit.

Sample size

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

Statistical Analysis

Propensity Score Matching

Since patients are enrolled into the programme based on the institution which they were seen in, there is likely to be imbalance in baseline characteristics between enrolees and non-enrolees. Matching will be performed via propensity scores.[21] These scores will be derived from a multivariate logistic regression with programme enrolment as the dependent variable and the following covariates: age, gender, race, hospital, ward class, number of hospitalisation or emergency attendances in the past year, comorbid conditions and use of medication.

Patient baseline characteristics from both enrolee and the matched-control groups will be described with mean and standard deviation for continuous variables and number and percentage

for categorical variables. Differences between COPD-ICP enrolees and non-enrolees will be compared using chi-square statistics for categorical variables and Wilcoxon rank sum tests for continuous variables.

Comparing the primary outcomes

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

CAT score comparison

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

PACIC score

To evaluate the congruency of the COPD-ICP programme to the CCM, the average PACIC score for programme enrolees will be computed and benchmarked with PACIC results of other

integrated care programmes in present literature that have showed substantial congruency to the CCM.

Economic-effectiveness Analysis

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

Software

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

Discussion

In designing the COPD-ICP programme, three key principles have been adopted: right-siting, integration and patient-centredness. It also involves the five standards of care: COPD prevention, early diagnosis, management of stable COPD patients, treatment and support during acute exacerbations, together with 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).[26–27]

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

This study design has several strengths. The PACIC survey will be used assess patients' experience of care which they received. This is in line with the organisation's aim to deliver patient-centred care.

The choice of the matched-control group patients using propensity scores will replicate the balance in baseline characteristics between compared cohorts achieved through randomisation. This will in turn reduce the effect of selection bias due to the lack of randomisation.[30] This step will be vital for making valid conclusions from the economic effectiveness analysis. By introducing direct distance between residential address and Alexandra Hospital as an instrument variable for programme status, systematic bias introduced by unmeasured baseline characteristics will also be attenuated.

By looking at several outcomes (economic-effectiveness, clinical outcomes, patients' experience), this study also allows the COPD-ICP team to identify areas in the programme which requires a change of implementation approach.

Limitations of the study

The study design may have some limitations. Firstly, the data collection process does not account for both enrolees and non-enrolees who choose to have their follow-up medical appointments at non-NHG/NHGP/JurongHealth institutions. Such non-compliance may potentially skew results. In addition, the assumption that direct distance is uncorrelated with unmeasured confounders may not be true. It is still unclear whether direct distance is correlated with household income which influences both outcome (more resources to control disease) and baseline characteristics. However, these limitations affect the evaluation of the programme only but not the quality of care provided at any institution.

As a whole, the COPD-ICP programme serves to equip primary care partners with the adequate knowledge and skills for managing stable COPD patients and to right-site patients in order to provide excellent and appropriate care while optimising available healthcare resources. We believe that this evaluation study can provide an evidence-based assessment of the impact and economic-effectiveness of the COPD-ICP programme. The lessons learnt from this study may also be extended to the evaluations of other ICP programmes that JurongHealth is implementing in the near future.

Ethics and Dissemination

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

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.

Abbreviations

COPD: Chronic Obstructive Pulmonary Disease; ICP: Integrated Care Pathway; TAP: The Airways Programme; SOC: Specialist Outpatient Clinics; ACP: Advance Care Planning; CAT:

COPD Assessment Test; PACIC: Chronic Assessment of Chronic Illness Care; GLM: Generalised Linear Model; MOH: Ministry of Health, Singapore; NHG DSRB: National Healthcare Group Domain Specific Review Board;

Authors' contributions

Ms Christine Wu Xia contributed to study design, data analysis method and writing up of manuscript. 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 writing up of manuscript. Ms Lynette Kwek Siang Lim participated in the implementation of the model of care and inputs into the manuscript. Dr Gerald Chua Seng Wee is the clinician lead of this programme and participated in the design of the COPD model of care. All the authors read and approved the final manuscript.

Funding Statement

This work was supported by Ministry of Health, Singapore (MOH) Health Services Development Programme (HSDP) grant number MH 36: 18/95.

Competing interests

The authors declare that they have no competing interests.

Acknowledgements

We would like to thank the Ministry of Health (MOH), Singapore for funding the implementation of this programme, Prof. Lim Tow Keang, Head Division of Respiratory and Critical Medicine at NUH for advising the team in the initial phase of implementation of this programme and Miss Tan Woan Shin, Principal Research Analyst, Health Services & Outcomes Research at NHG for advising the team on study design. Special thanks to the members that constitute the project team that contributed to the whole implementation of this programme, in particular Nurse Xu Meng and Bariah Rahman (both Case Managers), Ms Lynette Kwek, Ms Rubiah Bte Rahman Ms Huang Meixian and Ms Siti Mahfuzah Azman (all from Clinical Operations), Dr Muhammad Rahizan, Mr Lim Kian Chong and Ms Koh Ang Hong (all physiotherapists), Mr Timothy Chua and Ms Krutika Menon (both Social Workers), Ms Kimmy Liew (Head, Pharmacy), Mr Ong Chee Chong (Spirometry Technologist), Dr Thomas Soo (Clinical Director, JMC), Dr Hwang Chi Hong and Ms Joanna Chia (Medical Affairs Department). Special thanks to JurongHealth, Medical Affairs, and clinical analytics team (Medical Affairs Department). We would also like to thank Dr Frederick James Bloom Jr. (Geisinger Health Services) for his advice to the implementation strategy of this programme.

Reference

1. Buist AS, McBurnie MA, Vollmer WM, et al. International variation in the prevalence of COPD (The BOLD Study): a population-based prevalence study. Lancet 2007;370:741–50.
2. Ministry of Health, Singapore. Health Facts 2011. Singapore: Ministry of Health.
3. Teo WS, Tan WS, Chong WF, et. al. Economic burden of chronic obstructive pulmonary disease. *Respirology* 2012;17:120–26.

4. Lyngsø AM, Backer V, Gottlieb V, et al. Early detection of COPD in primary care -The Copenhagen COPD Screening Project. *BMC Public Health* 2010;10:524.
5. Global initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of COPD. *Proceedings of the Global Initiative for Chronic Obstructive Lung Disease*: Nov 2011; Shanghai.
6. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for diagnosis, management, and prevention of chronic obstructive pulmonary disease. *Proceedings of the Global Initiative for Chronic Obstructive Lung Disease*: 2005; Bethesda.
7. Singer PA, Robertson G, Roy DJ. Bioethics for clinicians: 6. Advance care planning. *CMAJ* 1996;155:1689–92.
8. Marcoa FD, Vergaa M, Santusa P, et al. The pharmacodynamics effects of single inhaled doses of formoterol, tiotropium and their combination in patients with COPD. *Pulm Pharmacol Ther* 2004;17:35–39.
9. Casaburi R, Mahler DA, Jones PW, et al. A long-term evaluation of once-daily inhaled tiotropium in chronic obstructive pulmonary disease. *Eur Respir J* 2002;19:217–24.
10. Van Noord JA, Aumann JL, Janssens E, et al. Comparison of tiotropium once daily, formoterol twice daily and both combined once daily in patients with COPD. *Eur Respir J* 2005;26:214–22.
11. Bourbeau J, Rouleau M, Boucher S. Randomised controlled trial of inhaled corticosteroids in patients with chronic obstructive pulmonary disease. *Thorax* 1998;53:477–82.
12. Ram FSF, Jardin JR, Atallah A. Efficacy of theophylline in people with stable chronic obstructive pulmonary disease: a systematic review and meta-analysis. *Respir Med* 2005;99:135–44.

13. Janssen DJ, Engelberg RA, Wouters EF, et al. Advance care planning for patients with COPD: past, present and future. *Patient Educ Couns* 2012;86:19–24.
14. Singer PA, Robertson G, Roy DJ. Bioethics for clinicians: 6. Advance care planning. *CMAJ* 1996;155:1689–92.
15. Ministry of Health, Singapore. COPD Clinical Practice Guidelines 4/2006. Singapore: Ministry of Health.
16. P. W. Jones, G. Harding, P. Berry, et al. Development and first validation of the COPD Assessment Test. *Eur Respir J* 2009;34: 648–54.
17. Bodenheimer T, Wagner EH, Grumbach K. Improving Primary Care for Patients with Chronic Illness. *JAMA* 2002;15:1909–14.
18. Kon SCK, Canavan JL, Jones SE, et. al. Minimum clinically important difference for the COPD Assessment Test: a prospective analysis. *Lancet Respir Med* 2014;2: 195–203.
19. Russell EG, Edward HW, Judith S, et. al. Development and Validation of the Patient Assessment of Chronic Illness Care (PACIC). *Med Care* 2005;43:436–44.
20. Bodenheimer T, Wagner EH, Grumbach K. Improving Primary Care for Patients with Chronic Illness. *JAMA* 2002;15:1909–14.
21. Robert MH, Dalal AA. Clinical and economic outcomes in an observational study of COPD maintenance therapies: multivariable regression versus propensity score matching. *Int J Chron Obstruct Pulmon Dis* 2012;7:221–33.
22. Pearson K. Contributions to the mathematical theory of evolution, II: Skew variation in homogeneous material. *Phil Trans R Soc A* 1895;186:343 – 414.
23. Cragg JG, Donald SG. Identifiability and specification in instrumental variable models. *Econometric Theory* 1993;9:222–40.

24. Briggs A, Sculpher M. An introduction to Markov Modelling for Economic Evaluation. *Pharmacoeconomics* 1998;13:397–409.

25. Gelman A, Carlin JB, Stern HS. Bayesian data analysis. London: Chapman & Hall; 1995.

26. Qaseem A, Wilt TJ, Weinberger SE, et. al. Diagnosis and Management of Stable Chronic Obstructive Pulmonary Disease: A Clinical Practice Guideline Update from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society. *Ann Intern Med* 2011;155:179-191.

27. MOH COPD Clinical Practice Guidelines 4/2006.

28. Thistlethwaite P. Integrating health and social care in Torbay. Improving care for Mrs Smith. *London: The King's Fund* 2011.

29. Asch SM, McGlynn EA, Hogan MM et. al. Comparison of care for patients in the Veterans Health Administration and patients in a national sample. *Ann Intern Med* 2004;141: 938 – 945.

30. Weldam SWM, Schuurmans MJ, Liu R, Lammers JJ. Evaluation of Quality of Life instruments for use in COPD care and research: A systematic review. *Int J Nurs Stud* 2013;50:688–707.

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	*Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Y	
		6b	*Cohort study*—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	*Cohort study*—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	*Cohort study*—Summarise follow-up time (eg, average and total amount)	N	
	Outcome data	15	*Cohort study*—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	

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	

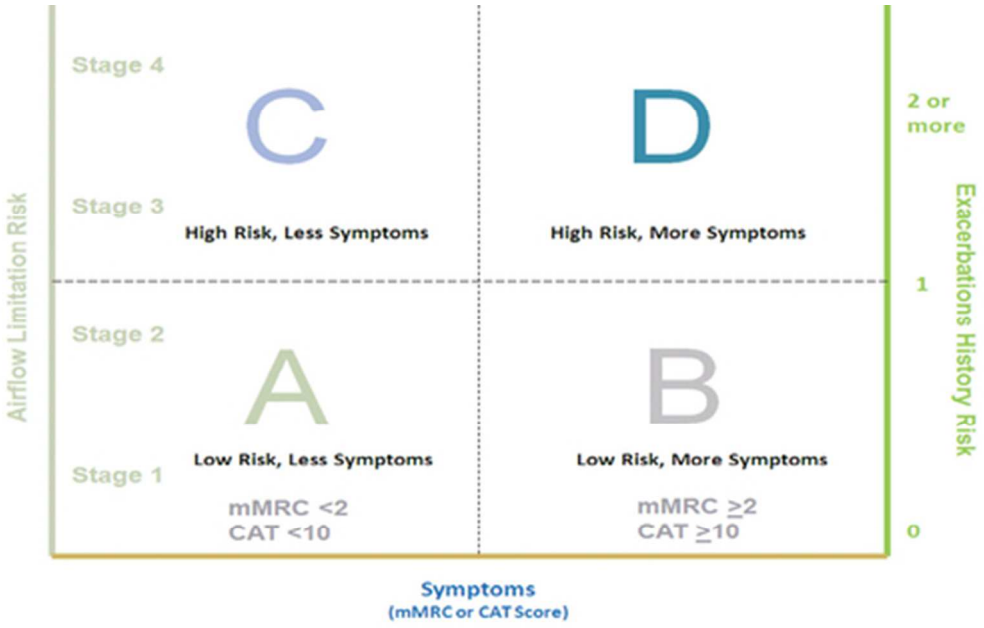


Figure 1: COPD GOLD Classifications
42x26mm (300 x 300 DPI)

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:	*BMJ Open*
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)

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

Authors:

1. Christine Xia Wu : christine_wu@juronghealth.com.sg

Medical Affairs Department, Alexandra Hospital, 378 Alexandra Road, Singapore 1599

2. Woan Shin Tan woan_shin_tan@nhg.com.sg

Health Services& Outcomes Research, National Healthcare Group

3. Ryan Kian See Chor: ryan_see@juronghealth.com.sg

Clinical Operations Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

4. Weichang Yu: weichang_yu@juronghealth.com.sg

Medical Affairs Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

5. Lynette Siang Lin Kwek: lynette_kwek@juronghealth.com.sg

Clinical Operations Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

6. Matthias PHS Toh: Matthias_toh@nhg.com.sg

Information Management, National Healthcare Group, 3 Fusionopolis Link, #04-08 Nexus@one-north, Singapore 138543

7. Thong Gan Chee: thong_gan_chee@juronghealth.com.sg

Clinical Operations Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

8. Gerald Seng Wee Chua: gerald_chua@juronghealth.com.sg

Medicine Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

Keywords

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

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.

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 design, and implement necessary changes to improve care. This is in line with the organisation's aim to deliver patient-centred care.

- 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 Singapore Ministry of Health (MOH). The programme seeks to coordinate care across different

healthcare settings. It aims to provide comprehensive care for patients with COPD at different stages of the disease, involving primary, hospital-based, community-based, and palliative care.

Similar to other COPD integrated care programmes,[8] the programme envisages coordination of care across different sites from primary to home and hospital care. The objectives of the programme are to:

1. Reduce the prevalence of COPD among the population residing in the Western part of Singapore (catchment area of JurongHealth).
2. Reduce risk of hospital admissions and healthcare costs.
3. Delay or prevent the deterioration of disease condition of COPD patients.
4. Reduce mortality of patients with COPD.

The programme adopts a coordinated and multi-disciplinary approach to the management of the patients' medical conditions. Case managers work with JurongHealth's multi-disciplinary team of doctors, nurses, respiratory technologists, pharmacists, physiotherapists and medical social workers to develop a customised care plan for each patient, empower patients towards self-management through education, and help coordinate referrals and patients' appointments across care sites.

The current scope of our study will focus on the evaluation of the hospital-based segment of the ICP programme. We will use propensity-score matching method to select a suitable comparator group. Specifically, the aim of our study will be to assess whether the intervention group compared to comparator group has 1) better adherence to the recommended processes of care; 2) lower risk of COPD-related hospitalisation as our primary outcome; 3) lower overall healthcare and COPD-related inpatient costs; 4) slower disease progression; and 5) lower one-year mortality

rate. We will use PACIC score to measure patients' experience of chronic care delivery in congruence to the Chronic Care Model (CCM).[9] In addition, we will also use CAT score to measure COPD control and hence the quality of life of patients with COPD. Our study will focus on the second, third and fourth objectives of the programme as written above.

METHODS/DESIGN

The Regional Healthcare System

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

Target Patient

Figure 1 shows the inclusion and exclusion criteria for patients' enrolment into the COPD-ICP programme.[10-11] We will exclude patients who have medical conditions other than COPD that are likely to result in death within the next two years.

We classify each patient enrolled into the programme based on the Patient Group Classification from updated GOLD guidelines (Figure 2).[10-11]

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

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 International Classification of Diseases Tenth Revision (ICD-10-AM) diagnostic codes (J40.xx and J47.xx).

Patients in the intervention group will be sampled from programme patients in the COPD registry who received care from JurongHealth from Apr 2012 to Dec 2013. A comparator group will be formed from non-enrolees using matching method described in later sections. Patients for the comparator group will be sampled from non-programme patients in the COPD registry who received care from non-JurongHealth institutions from Apr 2012 to Dec 2013. All data will be collected over one-year pre-enrolment and one-year follow up post-enrolment (three-month interval) for enrolees, and over one-year period for non-enrolees. The outcomes will be compared between enrolees and non-enrolees (Figure 1).

Sample size

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

Data Sources and Data

The three main sources of data are (1) COPD Registry: patient demographics; clinical information and outcome variables for both enrolees and non-enrolees; (2) Patient Case

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 summary[i] [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

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

Key recommended processes of care (Table 1) will be monitored quarterly to track the adherence and progress of the COPD-ICP programme. Patient baseline characteristics from both enrolees and non-enrolees will be described with mean and standard deviation for continuous variables and number and percentage for categorical variables. Differences between COPD-ICP enrolees and non-enrolees will be compared using chi-square statistics for categorical variables and Wilcoxon rank sum tests for continuous variables.

Since patients are enrolled into the programme based on the institution which they were seen in, there is likely to be imbalance in baseline characteristics between enrolees and non-enrolees. Hence, we will use propensity score matching to balance the baseline characteristics across enrolees and non-enrolees.[20] We will start off with estimating the propensity score, which is the conditional probability of each patient enrolling into the programme given their baseline characteristics, by using multivariate logistic regression.[20] Covariates to be included in the regression are: age, gender, race, hospital, subsidy term, the number of hospitalisation or emergency attendances in the past year, number and severity of comorbid conditions and COPD severity based on medication use. We will then form pairs of enrolee and non-enrolee by using the caliper matching method, within a range of 0.2 of the standard deviation of propensity score.[21]

Hospital admissions, healthcare costs and mortality

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

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 enrolees 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]

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 patients with COPD.[27] Patients admitted for exacerbations are contacted within 48 hours from discharge to reinforce patient education and to increase their confidence in self-managing their own condition. Lastly, the case manager plays the role of the liaison between step-down care partners, primary care physicians and patients. This may 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 in launching and maintaining the COPD-ICP programme.

The rationale behind this programme evaluation stems from the motivation to bolster support for the programme and to identify care gaps for improvement. As such, adherence with processes of care and outcomes such as risk of hospitalisation, CAT score and PACIC score will be used by the team to identify any care gaps, so as to improve the COPD-ICP programme. In addition, healthcare costs, disease progression and one-year mortality rate will also be used to assess the practicality of sustaining the programme. Furthermore, this study can also potentially add to the mounting evidence in support of integrated care in healthcare literature.

This study protocol has several strengths. The PACIC survey will be used to assess patients' experience of the congruency of care to CCM. This is in line with the organisation's aim to deliver patient-centred care.

The choice of the matched group patients using propensity scores will replicate the balance in baseline characteristics between compared cohorts achieved through randomisation. This will in turn reduce the effect of selection bias due to the lack of randomisation.[21] This step will be vital for making valid conclusions from the economic effectiveness analysis.

This study protocol is limited in several areas. Firstly, even though we will use propensity score matching to reduce the selection bias due to non-randomisation, there might be unmeasured confounders which can affect our results. Secondly, the data collection process will only account for both enrolees and non-enrolees who choose to have their follow-up medical appointments at JurongHealth, NHG and NUHS. Due to non-captive nature of the healthcare system in Singapore, patients in Singapore are free to choose healthcare providers outside these clusters on an episodic basis. Hence, such exclusion might lead to underestimation. However, these limitations affect the evaluation of the programme only but not the quality of care provided at any institution.

In conclusion, the COPD-ICP programme serves to equip primary care partners with the adequate knowledge and skills for managing stable patients with COPD and to right-site patients in order to provide excellent and appropriate care while optimising available healthcare resources. With the support from case managers, the programme does so by discharging patients to primary care doctors so that the clinically stable patients can be managed without the need to see a specialist if not clinically necessary. We believe that this evaluation study can provide an evidence-based assessment of the impact and effectiveness of the COPD-ICP programme. The lessons learnt from this study will be fed back to the COPD-ICP programme team and be useful in informing the design evaluations of other ICP programmes nationally.

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.

ACKNOWLEDGEMENTS

The authors would like to acknowledge Miss Lee Lin Jen and Thaung Yin Min (Information Management, NHG) for their advice and assistance in the study. The authors also wish to acknowledge the project team that contributed to the whole implementation of this programme, in particular Nurse Xu Meng and Bariah Rahman (both Case Managers), Ms Lynette Kwek, Ms Rubiah Bte Rahman Ms Huang Meixian and Ms Siti Mahfuzah Azman (all from Clinical Operations), Dr Muhammad Rahizan, Mr Lim Kian Chong and Ms Koh Ang Hong (all physiotherapists), Mr Timothy Chua and Ms Krutika Menon (both Social Workers), Ms Kimmy Liew (Head, Pharmacy), Mr Ong Chee Chong (Spirometry Technologist), Dr Thomas Soo (Clinical Director, JMC). We would also like to thank Dr Frederick James Bloom Jr. (Geisinger Health Services) for his advice to the implementation strategy of this programme. Special thanks to Dr Hwang Chi Hong and Ms Joanna Chia (Medical Affairs Department) for their support.

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

participated in the design of the COPD model of care. All the authors read and approved the final manuscript.

FUNDING STATEMENT

This work was supported by Ministry of Health (MOH), Singapore Health Services Development Programme (HSDP) grant number MH 36: 18/95.

COMPETING INTERESTS

The authors declare that they have no competing interests.

REFERENCE

1. Buist AS, McBurnie MA, Vollmer WM, et al. International variation in the prevalence of COPD (The BOLD Study): a population-based prevalence study. Lancet 2007;370:741–50.
2. Ministry of Health, Singapore. Health Facts 2011. Singapore: Ministry of Health.
3. Teo WS, Tan WS, Chong WF, et al. Economic burden of chronic obstructive pulmonary disease. *Respirology* 2012;17:120–26.
4. Sun Y, Heng BH, Lim TK. Outcomes of patients hospitalized for exacerbations of Chronic Obstructive Pulmonary Disease (COPD) in Singapore, 2000 – 2005. *ISPOR 12th Annual International Meeting* 2007, Arlington, Virginia, USA.
5. Lim E, Matthew N, Mok W, et al. Using hospital readmission rates to track the quality of care in public hospitals in Singapore [abstract]. *BMC Health Serv Res*. Published Online First: 19 October 2011. doi: 10.1186/1472-6963-11-S1-A16
6. Soriano JB, Zielinski J, Price D. Screening for and early detection of chronic obstructive pulmonary disease. Lancet 2009;374:721-32.
7. Spruit MA. Pulmonary Rehabilitation. *Eur Respir Rev,* 2014;23(131):55-63.
8. Kruis AL, Smidt N, Assendelft WJJ, et al. Integrated disease management interventions for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev*. Published Online First: 10 October 2013. doi: 10.1002/14651858.CD009437.pub2

9. Improving Chronic Illness Care. *The Chronic Care Model*. http://www.improvingchroniccare.org/index.php?p=Model_Elements&s=18. Accessed on: 19 June 2014.
10. Global initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of COPD. *Proceedings of the Global Initiative for Chronic Obstructive Lung Disease*: Nov 2011; Shanghai.
11. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for diagnosis, management, and prevention of chronic obstructive pulmonary disease. *Proceedings of the Global Initiative for Chronic Obstructive Lung Disease*: 2005; Bethesda.
12. Jiang JH, Andrews R, Stryer D, et al. Racial/Ethnic Disparities in Potentially Preventable Readmissions: The Case of Diabetes, Am J Public Health, 2005;95:1561-1567
13. Bodenheimer T, Wagner EH, Grumbach K. Improving Primary Care for Patients with Chronic Illness. *JAMA* 2002;15:1909–14.30.
14. Jones PW, Harding G, Berry P, et al. Development and first validation of the COPD Assessment Test. *Eur Respir J* 2009;34:648–54.
15. Jones PW, Quirk FH, Baveystock CM. The St. George's Respiratory Questionnaire. Resp Med 1991;85:25-31.
16. Weatherall M, Marsh S, Shirtcliffe P, et al. Quality of life measured by the St George's Respiratory Questionnaire and spirometry. *Eur Respir J* 2009;33:1025–30.
17. Li X, Zhou Y, Chen S, et al. Early intervention with tiotropium in Chinese patients with GOLD stages I-II chronic obstructive pulmonary disease (Tie-COPD): study protocol for a multicentre, double-blinded, randomised, controlled trial. *BMJ Open* 2014;4:e003991.

18. Weldam SWM, Schuurmans MJ, Liu R, et al. Evaluation of Quality of Life instruments for use in COPD care and research: A systematic review. *Int J Nurs Stud*2013;50;688-7027.
19. Kon SSC, Canavan JL, Jones SE, et. al. Minimum clinically important difference for the COPD Assessment Test: a prospective analysis. *Lancet Respir Med* 2014;2: 195–203.
20. Robert MH, Dalal AA. Clinical and economic outcomes in an observational study of COPD maintenance therapies: multivariable regression versus propensity score matching. *Int J Chron Obstruct Pulmon Dis* 2012;7:221–33.
21. Cochran WG, Rubin DB. Controlling bias in observational studies: a review. *Sankhya Ser A* 1973;35;417-46.
22. Nelder J, Wedderburn R. Generalized Linear Models. *J R Stat Soc Series B* 1972;135(3):370-84.
23. Jackson GL, Weinberg M, Hamilton NS, et al. Racial/ethnic and educational-level differences in diabetes care experiences in primary care. *Prim Care Diabetes* 2008;2(1):39-44.
24. Boyd CM, Reider L, Frey K, et al. The effects of guided care on the perceived quality of health care for multi-morbid older persons: 18-month outcomes from a cluster-randomized controlled trial. *J Gen Intern Med* 2010;25(3):235-42.
25. Ministry of Health, Singapore. COPD Clinical Practice Guidelines 4/2006. Singapore: Ministry of Health.
26. Qaseem A, Wilt TJ, Weinberger SE, et. al. Diagnosis and Management of Stable Chronic Obstructive Pulmonary Disease: A Clinical Practice Guideline Update from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society. *Ann Intern Med* 2011;155:179-191.

27. Eeden SF, Burns J. A multidisciplinary approach to the treatment and management of chronic obstructive pulmonary disease. BCMJ 2008;50(3):143-47.

28. Thistlethwaite P. Integrating health and social care in Torbay. Improving care for Mrs Smith. *London: The King's Fund* 2011.

29. Asch SM, McGlynn EA, Hogan MM et. al. Comparison of care for patients in the Veterans Health Administration and patients in a national sample. *Ann Intern Med* 2004;141: 938 – 945.

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

Authors:

1. Christine Xia Wu : christine_wu@juronghealth.com.sg

Medical Affairs Department, Alexandra Hospital, 378 Alexandra Road, Singapore 1599

2. Woan Shin Tan woan_shin_tan@nhg.com.sg

Health Services& Outcomes Research, National Healthcare Group

3. Ryan Kian See Chor: ryan_see@juronghealth.com.sg

Clinical Operations Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

4. Weichang Yu: weichang_yu@juronghealth.com.sg

Medical Affairs Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

5. Lynette Siang Lin Kwek: lynette_kwek@juronghealth.com.sg

Clinical Operations Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

6. Matthias PHS Toh: Matthias_toh@nhg.com.sg

Information Management, National Healthcare Group, 3 Fusionopolis Link, #04-08 Nexus@one-north, Singapore 138543

7. Thong Gan Chee: thong_gan_chee@juronghealth.com.sg

Clinical Operations Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

8. Gerald Seng Wee Chua: gerald_chua@juronghealth.com.sg

Medicine Department, Alexandra Hospital, 378 Alexandra Road, Singapore 159964

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

design, and implement necessary changes to improve care. This is in line with the organisation's aim to deliver patient-centred care.

- 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

Singapore Ministry of Health (MOH). The programme seeks to coordinate care across different healthcare settings. It aims to provide comprehensive care for patients with COPD at different stages of the disease, involving primary, hospital-based, community-based, and palliative care.

Similar to other COPD integrated care programmes,[8] the programme envisages coordination of care across different sites from primary to home and hospital care. The objectives of the programme are to:

1. Reduce the prevalence of COPD among the population residing in the Western part of Singapore (catchment area of JurongHealth).
2. Reduce risk of hospital admissions and healthcare costs.
3. Delay or prevent the deterioration of disease condition of COPD patients.
4. Reduce mortality of patients with COPD.

The programme adopts a coordinated and multi-disciplinary approach to the management of the patients' medical conditions. Case managers work with JurongHealth's multi-disciplinary team of doctors, nurses, respiratory technologists, pharmacists, physiotherapists and medical social workers to develop a customised care plan for each patient, empower patients towards self-management through education, and help coordinate referrals and patients' appointments across care sites.

The current scope of our study will focus on the evaluation of the hospital-based segment of the ICP programme. We will use propensity-score matching method to select a suitable comparator group. Specifically, the aim of our study will be to assess whether the intervention group compared to comparator group has 1) better adherence to the recommended processes of care; 2) lower risk of COPD-related hospitalisation as our primary outcome; 3) lower overall healthcare

and COPD-related inpatient costs; 4) slower disease progression; and 5) lower one-year mortality rate. We will use PACIC score to measure patients' experience of chronic care delivery in congruence to the Chronic Care Model (CCM).[9] In addition, we will also use CAT score to measure COPD control and hence the quality of life of patients with COPD. Our study will focus on the second, third and fourth objectives of the programme as written above.

METHODS/DESIGN

The Regional Healthcare System

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

Target Patient

Figure 1 shows the inclusion and exclusion criteria for patients' enrolment into the COPD-ICP programme.[10-11] We will exclude patients who have medical conditions other than COPD that are likely to result in death within the next two years.

We classify each patient enrolled into the programme based on the Patient Group Classification from updated GOLD guidelines (Figure 2).[10-11]

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 **Low risk, less symptoms**	Group B **Low risk, more symptoms**	Group C **High risk, less symptoms**	Group D **High risk, more symptoms**	**In exacerbation**
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 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

International Classification of Diseases Tenth Revision (ICD-10-AM) diagnostic codes (J40.xx and J47.xx).

Patients in the intervention group will be sampled from programme patients in the COPD registry who received care from JurongHealth from Apr 2012 to Dec 2013. A comparator group will be formed from non-enrolees using matching method described in later sections. Patients for the comparator group will be sampled from non-programme patients in the COPD registry who received care from non-JurongHealth institutions from Apr 2012 to Dec 2013. All data will be collected over one-year pre-enrolment and one-year follow up post-enrolment (three-month interval) for enrolees, and over one-year period for non-enrolees. The outcomes will be compared between enrolees and non-enrolees (Figure 1).

Sample size

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

Data Sources and Data

The three main sources of data are (1) COPD Registry: patient demographics; clinical information and outcome variables for both enrolees and non-enrolees; (2) Patient Case 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 summary[i] [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

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 ≥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

Key recommended processes of care (Table 1) will be monitored quarterly to track the adherence and progress of the COPD-ICP programme. Patient baseline characteristics from both enrolees

and non-enrolees will be described with mean and standard deviation for continuous variables and number and percentage for categorical variables. Differences between COPD-ICP enrolees and non-enrolees will be compared using chi-square statistics for categorical variables and Wilcoxon rank sum tests for continuous variables.

Since patients are enrolled into the programme based on the institution which they were seen in, there is likely to be imbalance in baseline characteristics between enrolees and non-enrolees. Hence, we will use propensity score matching to balance the baseline characteristics across enrolees and non-enrolees.[20] We will start off with estimating the propensity score, which is the conditional probability of each patient enrolling into the programme given their baseline characteristics, by using multivariate logistic regression.[20] Covariates to be included in the regression are: age, gender, race, hospital, subsidy term, the number of hospitalisation or emergency attendances in the past year, number and severity of comorbid conditions and COPD severity based on medication use. We will then form pairs of enrolee and non-enrolee by using the caliper matching method, within a range of 0.2 of the standard deviation of propensity score.[21]

Hospital admissions, healthcare costs and mortality

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

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 enrolees 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]

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 patients with COPD.[27] Patients admitted for exacerbations are contacted within 48 hours from discharge to reinforce patient education and to increase their confidence in self-managing their own condition. Lastly, the case manager plays the role of the liaison between step-down care partners, primary care physicians and patients. This may 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 in launching and maintaining the COPD-ICP programme.

The rationale behind this programme evaluation stems from the motivation to bolster support for the programme and to identify care gaps for improvement. As such, adherence with processes of care and outcomes such as risk of hospitalisation, CAT score and PACIC score will be used by the team to identify any care gaps, so as to improve the COPD-ICP programme. In addition, healthcare costs, disease progression and one-year mortality rate will also be used to assess the practicality of sustaining the programme. Furthermore, this study can also potentially add to the mounting evidence in support of integrated care in healthcare literature.

This study protocol has several strengths. The PACIC survey will be used to assess patients' experience of the congruency of care to CCM. This is in line with the organisation's aim to deliver patient-centred care.

The choice of the matched group patients using propensity scores will replicate the balance in baseline characteristics between compared cohorts achieved through randomisation. This will in

turn reduce the effect of selection bias due to the lack of randomisation.[21] This step will be vital for making valid conclusions from the economic effectiveness analysis.

This study protocol is limited in several areas. Firstly, even though we will use propensity score matching to reduce the selection bias due to non-randomisation, there might be unmeasured confounders which can affect our results. Secondly, the data collection process will only account for both enrolees and non-enrolees who choose to have their follow-up medical appointments at JurongHealth, NHG and NUHS. Due to non-captive nature of the healthcare system in Singapore, patients in Singapore are free to choose healthcare providers outside these clusters on an episodic basis. Hence, such exclusion might lead to underestimation. However, these limitations affect the evaluation of the programme only but not the quality of care provided at any institution.

In conclusion, the COPD-ICP programme serves to equip primary care partners with the adequate knowledge and skills for managing stable patients with COPD and to right-site patients in order to provide excellent and appropriate care while optimising available healthcare resources. With the support from case managers, the programme does so by discharging patients to primary care doctors so that the clinically stable patients can be managed without the need to see a specialist if not clinically necessary. We believe that this evaluation study can provide an evidence-based assessment of the impact and effectiveness of the COPD-ICP programme. The lessons learnt from this study will be fed back to the COPD-ICP programme team and be useful in informing the design evaluations of other ICP programmes nationally.

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

participated in the design of the COPD model of care. All the authors read and approved the final manuscript.

FUNDING STATEMENT

This work was supported by Ministry of Health (MOH), Singapore Health Services Development Programme (HSDP) grant number MH 36: 18/95.

COMPETING INTERESTS

The authors declare that they have no competing interests.

ACKNOWLEDGEMENTS

The authors would like to acknowledge Miss Lee Lin Jen and Thaung Yin Min (Information Management, NHG) for their advice and assistance in the study. The authors also wish to acknowledge the project team that contributed to the whole implementation of this programme, in particular Nurse Xu Meng and Bariah Rahman (both Case Managers), Ms Lynette Kwek, Ms Rubiah Bte Rahman Ms Huang Meixian and Ms Siti Mahfuzah Azman (all from Clinical Operations), Dr Muhammad Rahizan, Mr Lim Kian Chong and Ms Koh Ang Hong (all physiotherapists), Mr Timothy Chua and Ms Krutika Menon (both Social Workers), Ms Kimmy Liew (Head, Pharmacy), Mr Ong Chee Chong (Spirometry Technologist), Dr Thomas Soo (Clinical Director, JMC). We would also like to thank Dr Frederick James Bloom Jr. (Geisinger Health Services) for his advice to the implementation strategy of this programme. Special thanks to Dr Hwang Chi Hong and Ms Joanna Chia (Medical Affairs Department) for their support.

REFERENCE

1. Buist AS, McBurnie MA, Vollmer WM, et al. International variation in the prevalence of COPD (The BOLD Study): a population-based prevalence study. Lancet 2007;370:741–50.
2. Ministry of Health, Singapore. Health Facts 2011. Singapore: Ministry of Health.
3. Teo WS, Tan WS, Chong WF, et al. Economic burden of chronic obstructive pulmonary disease. *Respirology* 2012;17:120–26.
4. Sun Y, Heng BH, Lim TK. Outcomes of patients hospitalized for exacerbations of Chronic Obstructive Pulmonary Disease (COPD) in Singapore, 2000 – 2005. *ISPOR 12th Annual International Meeting* 2007, Arlington, Virginia, USA.
5. Lim E, Matthew N, Mok W, et al. Using hospital readmission rates to track the quality of care in public hospitals in Singapore [abstract]. *BMC Health Serv Res*. Published Online First: 19 October 2011. doi: 10.1186/1472-6963-11-S1-A16
6. Soriano JB, Zielinski J, Price D. Screening for and early detection of chronic obstructive pulmonary disease. Lancet 2009;374:721-32.
7. Spruit MA. Pulmonary Rehabilitation. *Eur Respir Rev,* 2014;23(131):55-63.
8. Kruis AL, Smidt N, Assendelft WJJ, et al. Integrated disease management interventions for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev*. Published Online First: 10 October 2013. doi: 10.1002/14651858.CD009437.pub2
9. Improving Chronic Illness Care. *The Chronic Care Model*. http://www.improvingchroniccare.org/index.php?p=Model_Elements&s=18. Accessed on: 19 June 2014.
10. Global initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of COPD. *Proceedings of the Global Initiative for Chronic Obstructive Lung Disease*: Nov 2011; Shanghai.

11. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for diagnosis, management, and prevention of chronic obstructive pulmonary disease. *Proceedings of the Global Initiative for Chronic Obstructive Lung Disease*: 2005; Bethesda.
12. Jiang JH, Andrews R, Stryer D, Friedman B. Racial/Ethnic Disparities in Potentially Preventable Readmissions: The Case of Diabetes, Am J Public Health, 2005;95:1561-1567
13. Bodenheimer T, Wagner EH, Grumbach K. Improving Primary Care for Patients with Chronic Illness. *JAMA* 2002;15:1909–14.30.
14. Jones PW, Harding G, Berry P, et al. Development and first validation of the COPD Assessment Test. *Eur Respir J* 2009;34:648–54.
15. Jones PW, Quirk FH, Baveystock CM. The St. George's Respiratory Questionnaire. Resp Med 1991;85:25-31.
16. Weatherall M, Marsh S, Shirtcliffe P, et al. Quality of life measured by the St George's Respiratory Questionnaire and spirometry. *Eur Respir J* 2009;33:1025–30.
17. Li X, Zhou Y, Chen S, et al. Early intervention with tiotropium in Chinese patients with GOLD stages I-II chronic obstructive pulmonary disease (Tie-COPD): study protocol for a multicentre, double-blinded, randomised, controlled trial. *BMJ Open* 2014;4:e003991.
18. Weldam SWM, Schuurmans MJ, Liu R, et al. Evaluation of Quality of Life instruments for use in COPD care and research: A systematic review. *Int J Nurs Stud*2013;50;688-7027.
19. Kon SSC, Canavan JL, Jones SE, et. al. Minimum clinically important difference for the COPD Assessment Test: a prospective analysis. *Lancet Respir Med* 2014;2: 195–203.
20. Robert MH, Dalal AA. Clinical and economic outcomes in an observational study of COPD maintenance therapies: multivariable regression versus propensity score matching. *Int J Chron Obstruct Pulmon Dis* 2012;7:221–33.

21. Cochran WG, Rubin DB. Controlling bias in observational studies: a review. *Sankhya Ser A* 1973;35;417-46.

22. Nelder J, Wedderburn R. Generalized Linear Models. *J R Stat Soc Series B* 1972;135(3):370-84.

23. Jackson GL, Weinberg M, Hamilton NS, et al. Racial/ethnic and educational-level differences in diabetes care experiences in primary care. *Prim Care Diabetes* 2008;2(1):39-44.

24. Boyd CM, Reider L, Frey K, et al. The effects of guided care on the perceived quality of health care for multi-morbid older persons: 18-month outcomes from a cluster-randomized controlled trial. *J Gen Intern Med* 2010;25(3):235-42.

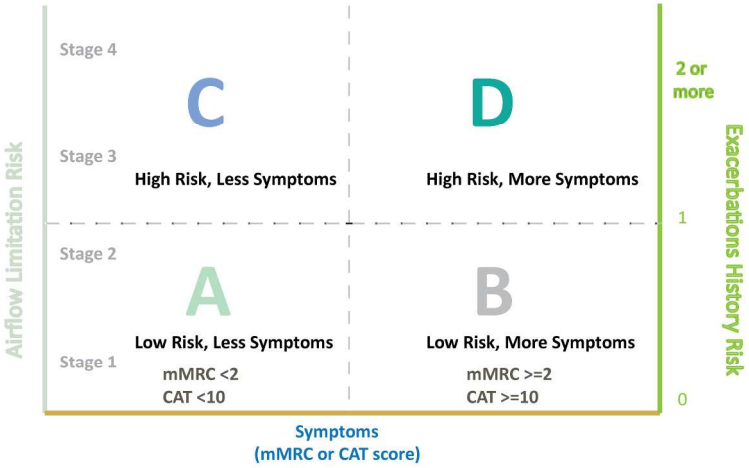
25. Ministry of Health, Singapore. COPD Clinical Practice Guidelines 4/2006. Singapore: Ministry of Health.

26. Qaseem A, Wilt TJ, Weinberger SE, et. al. Diagnosis and Management of Stable Chronic Obstructive Pulmonary Disease: A Clinical Practice Guideline Update from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society. *Ann Intern Med* 2011;155:179-191.

27. Eeden SF, Burns J. A multidisciplinary approach to the treatment and management of chronic obstructive pulmonary disease. BCMJ 2008;50(3):143-47.

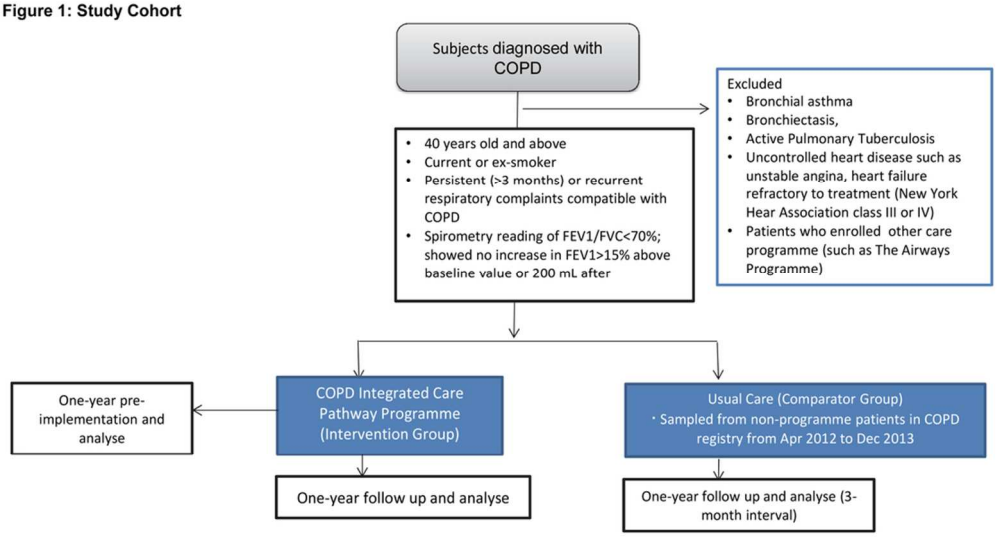
28. Thistlethwaite P. Integrating health and social care in Torbay. Improving care for Mrs Smith. *London: The King's Fund* 2011.

29. Asch SM, McGlynn EA, Hogan MM et. al. Comparison of care for patients in the Veterans Health Administration and patients in a national sample. *Ann Intern Med* 2004;141: 938 – 945.



194x266mm (300 x 300 DPI)

Figure 1: Study Cohort



94x51mm (300 x 300 DPI)

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	*Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Y	
		6b	*Cohort study*—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	*Cohort study*—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	*Cohort study*—Summarise follow-up time (eg, average and total amount)	N	
	Outcome data	15	*Cohort study*—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	

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	

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:	*BMJ Open*
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)

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	*Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Y	
		6b	*Cohort study*—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	*Cohort study*—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	*Cohort study*—Summarise follow-up time (eg, average and total amount)	N	
	Outcome data	15	*Cohort study*—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	

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	

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

Authors:

1. Christine Xia Wu : christine_wu@juronghealth.com.sg

Medical Affairs Department, JurongHealth, 378 Alexandra Road, Singapore 1599

2. Woan Shin Tan woan_shin_tan@nhg.com.sg

Health Services & Outcomes Research, National Healthcare Group, 3 Fusionopolis Link, #03-08 Nexus@one-north, Singapore 138543

3. Ryan Kian See Chor: ryan_see@juronghealth.com.sg

Clinical Operations Department, JurongHealth, 378 Alexandra Road, Singapore 159964

4. Weichang Yu: weichang_yu@juronghealth.com.sg

Medical Affairs Department, JurongHealth, 378 Alexandra Road, Singapore 159964

5. Lynette Siang Lin Kwek: lynette_kwek@juronghealth.com.sg

Clinical Operations Department, JurongHealth, 378 Alexandra Road, Singapore 159964

6. Matthias PHS Toh: Matthias_toh@nhg.com.sg

Information Management, National Healthcare Group, 3 Fusionopolis Link, #04-08 Nexus@one-north, Singapore 138543

7. Thong Gan Chee: thong_gan_chee@juronghealth.com.sg

Clinical Operations Department, JurongHealth, 378 Alexandra Road, Singapore 159964

8. Gerald Seng Wee Chua: gerald_chua@juronghealth.com.sg

Medicine Department, JurongHealth, 378 Alexandra Road, Singapore 159964

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

design, and implement necessary changes to improve care. This is in line with the organisation's aim to deliver patient-centred care.

- 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 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

Singapore Ministry of Health (MOH). The programme seeks to coordinate care across different healthcare settings. It aims to provide comprehensive care for patients with COPD at different stages of the disease, involving primary, hospital-based, community-based, and palliative care.

Similar to other COPD integrated care programmes,[7] the programme envisages coordination of care across different sites from primary to home and hospital care. The objectives of the programme are to:

1. Reduce the prevalence of COPD among the population residing in the Western part of Singapore (catchment area of JurongHealth).
2. Reduce risk of hospital admissions and healthcare costs.
3. Delay or prevent the deterioration of disease condition of COPD patients.
4. Reduce mortality of patients with COPD.

The programme adopts a coordinated and multi-disciplinary approach to the management of the patients' medical conditions. Case managers work with JurongHealth's multi-disciplinary team of doctors, nurses, respiratory technologists, pharmacists, physiotherapists and medical social workers to develop a customised care plan for each patient, empower patients towards self-management through education, and help coordinate referrals and patients' appointments across care sites.

The current scope of our study will focus on the evaluation of the hospital-based segment of the ICP programme. We will use propensity-score matching method to select a suitable comparator group. Specifically, the aim of our study will be to assess whether the intervention group compared to comparator group has 1) primary outcome: lower risk of COPD-related hospitalisation; and 2) secondary outcomes: better adherence to the recommended processes of

care, lower overall healthcare and COPD-related inpatient costs, slower disease progression, and lower one-year mortality rate. We will use PACIC score to measure patients' experience of chronic care delivery in congruence to the Chronic Care Model (CCM).[8] In addition, we will also use CAT score to measure COPD control and hence the quality of life of patients with COPD.

METHODS/DESIGN

The Regional Healthcare System

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

Target Patient

Figure 1 shows the inclusion and exclusion criteria for patients' enrolment into the COPD-ICP programme.[9-10] We will exclude patients who have medical conditions other than COPD that are likely to result in death within the next two years.

We classify each patient enrolled into the programme based on the Patient Group Classification from updated GOLD guidelines (Figure 2).[9-10]

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

programme enrolment (Figure 1). Patients with COPD will be identified based on the International Classification of Diseases Tenth Revision (ICD-10-AM) diagnostic codes (J40.xx and J47.xx).

Patients in the intervention group will be sampled from programme patients in the COPD registry who received care from JurongHealth from Apr 2012 to Dec 2013. A comparator group will be formed from non-enrolees using matching method described in later sections. Patients for the comparator group will be sampled from non-programme patients in the COPD registry who received care from non-JurongHealth institutions from Apr 2012 to Dec 2013. All data will be collected over one-year pre-enrolment and one-year follow up post-enrolment (three-month interval) for enrolees, and over one-year period for non-enrolees. The outcomes will be compared between enrolees and non-enrolees (Figure 1).

Sample size

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

Data Sources and Data

The three main sources of data are (1) COPD Registry: patient demographics; clinical information and outcome variables for both enrolees and non-enrolees; (2) Patient Case 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 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

We will use all-or-none care bundle to monitor adherence with the recommended key care elements for Group A, B, C and D patients (Table 1) at baseline and three-month interval. All-or-none care bundle is a process indicator which measures the percentage of patients who adhere with all of the recommended key care elements according to each patient group.[12] 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).[8] CCM is a guideline which recognises six aspects as key to improving quality of chronic disease management.[8,13] 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

Key recommended processes of care (Table 1) will be monitored quarterly to track the adherence and progress of the COPD-ICP programme. Patient baseline characteristics from both enrolees and non-enrolees will be described with mean and standard deviation for continuous variables and number and percentage for categorical variables. Differences between COPD-ICP enrolees and non-enrolees will be compared using chi-square statistics for categorical variables and Wilcoxon rank sum tests for continuous variables.

Since patients are enrolled into the programme based on the institution which they were seen in, there is likely to be imbalance in baseline characteristics between enrolees and non-enrolees. Hence, we will use propensity score matching to balance the baseline characteristics across enrolees and non-enrolees.[20] We will start off with estimating the propensity score, which is the conditional probability of each patient enrolling into the programme given their baseline characteristics, by using multivariate logistic regression.[20] Covariates to be included in the regression are: age, gender, race, hospital, subsidy term, the number of hospitalisation or emergency attendances in the past year, number and severity of comorbid conditions and COPD severity based on medication use. We will then form pairs of enrolee and non-enrolee by using the caliper matching method, within a range of 0.2 of the standard deviation of propensity score.[21]

Hospital admissions, healthcare costs and mortality

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

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 enrolees 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]

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 patients with COPD.[27] Patients admitted for exacerbations are contacted within 48 hours from discharge to reinforce patient education and to increase their confidence in self-managing their own condition. Lastly, the case manager plays the role of the liaison between step-down care partners, primary care physicians and patients. This may 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 in launching and maintaining the COPD-ICP programme.

The rationale behind this programme evaluation stems from the motivation to bolster support for the programme and to identify care gaps for improvement. As such, adherence with processes of care and outcomes such as risk of hospitalisation, CAT score and PACIC score will be used by the team to identify any care gaps, so as to improve the COPD-ICP programme. In addition, healthcare costs, disease progression and one-year mortality rate will also be used to assess the practicality of sustaining the programme. Furthermore, this study can also potentially add to the mounting evidence in support of integrated care in healthcare literature.

This study protocol has several strengths. The PACIC survey will be used to assess patients' experience of the congruency of care to CCM. This is in line with the organisation's aim to deliver patient-centred care.

The choice of the matched group patients using propensity scores will replicate the balance in baseline characteristics between compared cohorts achieved through randomisation. This will in turn reduce the effect of selection bias due to the lack of randomisation.[21] This step will be vital for making valid conclusions from the economic effectiveness analysis.

This study protocol is limited in several areas. Firstly, even though we will use propensity score matching to reduce the selection bias due to non-randomisation, there might be unmeasured confounders which can affect our results. Secondly, the data collection process will only account for both enrolees and non-enrolees who choose to have their follow-up medical appointments at JurongHealth, NHG and NUHS. Due to non-captive nature of the healthcare system in Singapore, patients in Singapore are free to choose healthcare providers outside these clusters on an episodic basis. Hence, such exclusion might lead to underestimation. However, these limitations affect the evaluation of the programme only but not the quality of care provided at any institution.

In conclusion, the COPD-ICP programme aims to equip primary care partners with the adequate knowledge and skills for managing stable patients with COPD and to right-site patients in order to provide excellent and appropriate care while optimising available healthcare resources. With the support from case managers, the programme does so by discharging patients to primary care doctors so that the clinically stable patients can be managed without the need to see a specialist if not clinically necessary. We believe that this evaluation study can provide an evidence-based assessment of the impact and effectiveness of the COPD-ICP programme. The lessons learnt from this study will be fed back to the COPD-ICP programme team and be useful in informing the design evaluations of other ICP programmes nationally.

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

participated in the design of the COPD model of care. All the authors read and approved the final manuscript.

FUNDING STATEMENT

This work was supported by Ministry of Health (MOH), Singapore Health Services Development Programme (HSDP) grant number MH 36: 18/95.

COMPETING INTERESTS

The authors declare that they have no competing interests.

ACKNOWLEDGEMENTS

The authors would like to acknowledge Miss Tan Ainie (Medical Affairs Department) for her assistance in statistical methods and manuscript review. The authors would also like to acknowledge Miss Lee Lin Jen and Thaung Yin Min (Information Management, NHG) for their advice and assistance in the study. The authors wish to acknowledge the project team that contributed to the whole implementation of this programme, in particular Nurse Xu Meng and Bariah Rahman (both Case Managers), Ms Lynette Kwek, Ms Rubiah Bte Rahman Ms Huang Meixian and Ms Siti Mahfuzah Azman (all from Clinical Operations), Dr Muhammad Rahizan, Mr Lim Kian Chong and Ms Koh Ang Hong (all physiotherapists), Mr Timothy Chua and Ms Krutika Menon (both Social Workers), Ms Kimmy Liew (Head, Pharmacy), Mr Ong Chee Chong (Spirometry Technologist), Dr Thomas Soo (Clinical Director, JMC). We would also like to thank Dr Frederick James Bloom Jr. (Geisinger Health Services) for his advice to the implementation strategy of this programme. Special thanks to Dr Hwang Chi Hong and Ms Joanna Chia (Medical Affairs Department) for their support.

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.

REFERENCE

1. Buist AS, McBurnie MA, Vollmer WM, et al. International variation in the prevalence of COPD (The BOLD Study): a population-based prevalence study. Lancet 2007;370:741–50.
2. Ministry of Health, Singapore. Health Facts 2011. Singapore: Ministry of Health.
3. Teo WS, Tan WS, Chong WF, et al. Economic burden of chronic obstructive pulmonary disease. *Respirology* 2012;17:120–26.
4. Lim E, Matthew N, Mok W, et al. Using hospital readmission rates to track the quality of care in public hospitals in Singapore [abstract]. *BMC Health Serv Res.* Published Online First: 19 October 2011. doi: 10.1186/1472-6963-11-S1-A16
5. Soriano JB, Zielinski J, Price D. Screening for and early detection of chronic obstructive pulmonary disease. Lancet 2009;374:721-32.
6. Spruit MA. Pulmonary Rehabilitation. *Eur Respir Rev,* 2014;23(131):55-63.
7. Kruis AL, Smidt N, Assendelft WJJ, et al. Integrated disease management interventions for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev.* Published Online First: 10 October 2013. doi: 10.1002/14651858.CD009437.pub2

8. Improving Chronic Illness Care. *The Chronic Care Model*. http://www.improvingchroniccare.org/index.php?p=Model_Elements&s=18. Accessed on: 19 June 2014.
9. Global initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of COPD. *Proceedings of the Global Initiative for Chronic Obstructive Lung Disease*: Nov 2011; Shanghai.
10. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for diagnosis, management, and prevention of chronic obstructive pulmonary disease. *Proceedings of the Global Initiative for Chronic Obstructive Lung Disease*: 2005; Bethesda.
11. Jiang JH, Andrews R, Stryer D, Friedman B. Racial/Ethnic Disparities in Potentially Preventable Readmissions: The Case of Diabetes, Am J Public Health, 2005;95:1561-1567
12. Nolan T, Berwick DM. All-or-None Measurement Raises the Bar on Performance. *JAMA* 2006;295:1168-70.
13. Bodenheimer T, Wagner EH, Grumbach K. Improving Primary Care for Patients with Chronic Illness. *JAMA* 2002;288:1775-79. .
14. Jones PW, Harding G, Berry P, et al. Development and first validation of the COPD Assessment Test. *Eur Respir J* 2009;34:648–54.
15. Jones PW, Quirk FH, Baveystock CM. The St. George's Respiratory Questionnaire. *Resp Med* 1991;85:25-31.
16. Weatherall M, Marsh S, Shirtcliffe P, et al. Quality of life measured by the St George's Respiratory Questionnaire and spirometry. *Eur Respir J* 2009;33:1025–30.

17. Li X, Zhou Y, Chen S, et al. Early intervention with tiotropium in Chinese patients with GOLD stages I-II chronic obstructive pulmonary disease (Tie-COPD): study protocol for a multicentre, double-blinded, randomised, controlled trial. *BMJ Open* 2014;4:e003991.
18. Weldam SWM, Schuurmans MJ, Liu R, et al. Evaluation of Quality of Life instruments for use in COPD care and research: A systematic review. *Int J Nurs Stud*2013;50;688-7027.
19. Kon SSC, Canavan JL, Jones SE, et. al. Minimum clinically important difference for the COPD Assessment Test: a prospective analysis. *Lancet Respir Med* 2014;2: 195–203.
20. Robert MH, Dalal AA. Clinical and economic outcomes in an observational study of COPD maintenance therapies: multivariable regression versus propensity score matching. *Int J Chron Obstruct Pulmon Dis* 2012;7:221–33.
21. Cochran WG, Rubin DB. Controlling bias in observational studies: a review. *Sankhya Ser A* 1973;35;417-46.
22. Nelder J, Wedderburn R. Generalized Linear Models. *J R Stat Soc Series B* 1972;135(3):370-84.
23. Jackson GL, Weinberg M, Hamilton NS, et al. Racial/ethnic and educational-level differences in diabetes care experiences in primary care. *Prim Care Diabetes* 2008;2(1):39-44.
24. Boyd CM, Reider L, Frey K, et al. The effects of guided care on the perceived quality of health care for multi-morbid older persons: 18-month outcomes from a cluster-randomized controlled trial. *J Gen Intern Med* 2010;25(3):235-42.
25. Ministry of Health, Singapore. COPD Clinical Practice Guidelines 4/2006. Singapore: Ministry of Health.

26. Qaseem A, Wilt TJ, Weinberger SE, et. al. Diagnosis and Management of Stable Chronic Obstructive Pulmonary Disease: A Clinical Practice Guideline Update from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society. *Ann Intern Med* 2011;155:179-191.
27. Eeden SF, Burns J. A multidisciplinary approach to the treatment and management of chronic obstructive pulmonary disease. BCMJ 2008;50(3):143-47.
28. Thistlethwaite P. Integrating health and social care in Torbay. Improving care for Mrs Smith. *London: The King's Fund* 2011.
29. Asch SM, McGlynn EA, Hogan MM et. al. Comparison of care for patients in the Veterans Health Administration and patients in a national sample. *Ann Intern Med* 2004;141: 938 – 945.

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

Authors:

1. Christine Xia Wu : christine_wu@juronghealth.com.sg

Medical Affairs Department, JurongHealth, 378 Alexandra Road, Singapore 1599

2. Woan Shin Tan woan_shin_tan@nhg.com.sg

Health Services & Outcomes Research, National Healthcare Group, 3 Fusionopolis Link, #03-08 Nexus@one-north, Singapore 138543

3. Ryan Kian See Chor: ryan_see@juronghealth.com.sg

Clinical Operations Department, JurongHealth, 378 Alexandra Road, Singapore 159964

4. Weichang Yu: weichang_yu@juronghealth.com.sg

Medical Affairs Department, JurongHealth, 378 Alexandra Road, Singapore 159964

5. Lynette Siang Lin Kwek: lynette_kwek@juronghealth.com.sg

Clinical Operations Department, JurongHealth, 378 Alexandra Road, Singapore 159964

6. Matthias PHS Toh: Matthias_toh@nhg.com.sg

Information Management, National Healthcare Group, 3 Fusionopolis Link, #04-08 Nexus@one-north, Singapore 138543

7. Thong Gan Chee: thong_gan_chee@juronghealth.com.sg

Clinical Operations Department, JurongHealth, 378 Alexandra Road, Singapore 159964

8. Gerald Seng Wee Chua: gerald_chua@juronghealth.com.sg

Medicine Department, JurongHealth, 378 Alexandra Road, Singapore 159964

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

design, and implement necessary changes to improve care. This is in line with the organisation's aim to deliver patient-centred care.

- 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 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

Singapore Ministry of Health (MOH). The programme seeks to coordinate care across different healthcare settings. It aims to provide comprehensive care for patients with COPD at different stages of the disease, involving primary, hospital-based, community-based, and palliative care.

Similar to other COPD integrated care programmes,[7] the programme envisages coordination of care across different sites from primary to home and hospital care. The objectives of the programme are to:

1. Reduce the prevalence of COPD among the population residing in the Western part of Singapore (catchment area of JurongHealth).
2. Reduce risk of hospital admissions and healthcare costs.
3. Delay or prevent the deterioration of disease condition of COPD patients.
4. Reduce mortality of patients with COPD.

The programme adopts a coordinated and multi-disciplinary approach to the management of the patients' medical conditions. Case managers work with JurongHealth's multi-disciplinary team of doctors, nurses, respiratory technologists, pharmacists, physiotherapists and medical social workers to develop a customised care plan for each patient, empower patients towards self-management through education, and help coordinate referrals and patients' appointments across care sites.

The current scope of our study will focus on the evaluation of the hospital-based segment of the ICP programme. We will use propensity-score matching method to select a suitable comparator group. Specifically, the aim of our study will be to assess whether the intervention group compared to comparator group has 1) primary outcome: lower risk of COPD-related hospitalisation; and 2) secondary outcomes: better adherence to the recommended processes of

care, lower overall healthcare and COPD-related inpatient costs, slower disease progression, and lower one-year mortality rate. We will use PACIC score to measure patients' experience of chronic care delivery in congruence to the Chronic Care Model (CCM).[8] In addition, we will also use CAT score to measure COPD control and hence the quality of life of patients with COPD.

METHODS/DESIGN

The Regional Healthcare System

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

Target Patient

Figure 1 shows the inclusion and exclusion criteria for patients' enrolment into the COPD-ICP programme.[9-10] We will exclude patients who have medical conditions other than COPD that are likely to result in death within the next two years.

We classify each patient enrolled into the programme based on the Patient Group Classification from updated GOLD guidelines (Figure 2).[9-10]

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

programme enrolment (Figure 1). Patients with COPD will be identified based on the International Classification of Diseases Tenth Revision (ICD-10-AM) diagnostic codes (J40.xx and J47.xx).

Patients in the intervention group will be sampled from programme patients in the COPD registry who received care from JurongHealth from Apr 2012 to Dec 2013. A comparator group will be formed from non-enrolees using matching method described in later sections. Patients for the comparator group will be sampled from non-programme patients in the COPD registry who received care from non-JurongHealth institutions from Apr 2012 to Dec 2013. All data will be collected over one-year pre-enrolment and one-year follow up post-enrolment (three-month interval) for enrolees, and over one-year period for non-enrolees. The outcomes will be compared between enrolees and non-enrolees (Figure 1).

Sample size

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

Data Sources and Data

The three main sources of data are (1) COPD Registry: patient demographics; clinical information and outcome variables for both enrolees and non-enrolees; (2) Patient Case 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 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

We will use all-or-none care bundle to monitor adherence with the recommended key care elements for Group A, B, C and D patients (Table 1) at baseline and three-month interval. All-or-none care bundle is a process indicator which measures the percentage of patients who adhere with all of the recommended key care elements according to each patient group.[12] 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).[8] CCM is a guideline which recognises six aspects as key to improving quality of chronic disease management.[8,13] 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

Key recommended processes of care (Table 1) will be monitored quarterly to track the adherence and progress of the COPD-ICP programme. Patient baseline characteristics from both enrolees and non-enrolees will be described with mean and standard deviation for continuous variables and number and percentage for categorical variables. Differences between COPD-ICP enrolees and non-enrolees will be compared using chi-square statistics for categorical variables and Wilcoxon rank sum tests for continuous variables.

Since patients are enrolled into the programme based on the institution which they were seen in, there is likely to be imbalance in baseline characteristics between enrolees and non-enrolees. Hence, we will use propensity score matching to balance the baseline characteristics across enrolees and non-enrolees.[20] We will start off with estimating the propensity score, which is the conditional probability of each patient enrolling into the programme given their baseline characteristics, by using multivariate logistic regression.[20] Covariates to be included in the regression are: age, gender, race, hospital, subsidy term, the number of hospitalisation or emergency attendances in the past year, number and severity of comorbid conditions and COPD severity based on medication use. We will then form pairs of enrolee and non-enrolee by using the caliper matching method, within a range of 0.2 of the standard deviation of propensity score.[21]

Hospital admissions, healthcare costs and mortality

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

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 enrolees 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]

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 patients with COPD.[27] Patients admitted for exacerbations are contacted within 48 hours from discharge to reinforce patient education and to increase their confidence in self-managing their own condition. Lastly, the case manager plays the role of the liaison between step-down care partners, primary care physicians and patients. This may 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 in launching and maintaining the COPD-ICP programme.

The rationale behind this programme evaluation stems from the motivation to bolster support for the programme and to identify care gaps for improvement. As such, adherence with processes of care and outcomes such as risk of hospitalisation, CAT score and PACIC score will be used by the team to identify any care gaps, so as to improve the COPD-ICP programme. In addition, healthcare costs, disease progression and one-year mortality rate will also be used to assess the practicality of sustaining the programme. Furthermore, this study can also potentially add to the mounting evidence in support of integrated care in healthcare literature.

This study protocol has several strengths. The PACIC survey will be used to assess patients' experience of the congruency of care to CCM. This is in line with the organisation's aim to deliver patient-centred care.

The choice of the matched group patients using propensity scores will replicate the balance in baseline characteristics between compared cohorts achieved through randomisation. This will in turn reduce the effect of selection bias due to the lack of randomisation.[21] This step will be vital for making valid conclusions from the economic effectiveness analysis.

This study protocol is limited in several areas. Firstly, even though we will use propensity score matching to reduce the selection bias due to non-randomisation, there might be unmeasured confounders which can affect our results. Secondly, the data collection process will only account for both enrolees and non-enrolees who choose to have their follow-up medical appointments at JurongHealth, NHG and NUHS. Due to non-captive nature of the healthcare system in Singapore, patients in Singapore are free to choose healthcare providers outside these clusters on an episodic basis. Hence, such exclusion might lead to underestimation. However, these limitations affect the evaluation of the programme only but not the quality of care provided at any institution.

In conclusion, the COPD-ICP programme aims to equip primary care partners with the adequate knowledge and skills for managing stable patients with COPD and to right-site patients in order to provide excellent and appropriate care while optimising available healthcare resources. With the support from case managers, the programme does so by discharging patients to primary care doctors so that the clinically stable patients can be managed without the need to see a specialist if not clinically necessary. We believe that this evaluation study can provide an evidence-based assessment of the impact and effectiveness of the COPD-ICP programme. The lessons learnt from this study will be fed back to the COPD-ICP programme team and be useful in informing the design evaluations of other ICP programmes nationally.

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

participated in the design of the COPD model of care. All the authors read and approved the final manuscript.

FUNDING STATEMENT

This work was supported by Ministry of Health (MOH), Singapore Health Services Development Programme (HSDP) grant number MH 36: 18/95.

COMPETING INTERESTS

The authors declare that they have no competing interests.

ACKNOWLEDGEMENTS

The authors would like to acknowledge Miss Tan Ainie (Medical Affairs Department) for her assistance in statistical methods and manuscript review. The authors would also like to acknowledge Miss Lee Lin Jen and Thaung Yin Min (Information Management, NHG) for their advice and assistance in the study. The authors wish to acknowledge the project team that contributed to the whole implementation of this programme, in particular Nurse Xu Meng and Bariah Rahman (both Case Managers), Ms Lynette Kwek, Ms Rubiah Bte Rahman Ms Huang Meixian and Ms Siti Mahfuzah Azman (all from Clinical Operations), Dr Muhammad Rahizan, Mr Lim Kian Chong and Ms Koh Ang Hong (all physiotherapists), Mr Timothy Chua and Ms Krutika Menon (both Social Workers), Ms Kimmy Liew (Head, Pharmacy), Mr Ong Chee Chong (Spirometry Technologist), Dr Thomas Soo (Clinical Director, JMC). We would also like to thank Dr Frederick James Bloom Jr. (Geisinger Health Services) for his advice to the implementation strategy of this programme. Special thanks to Dr Hwang Chi Hong and Ms Joanna Chia (Medical Affairs Department) for their support.

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.

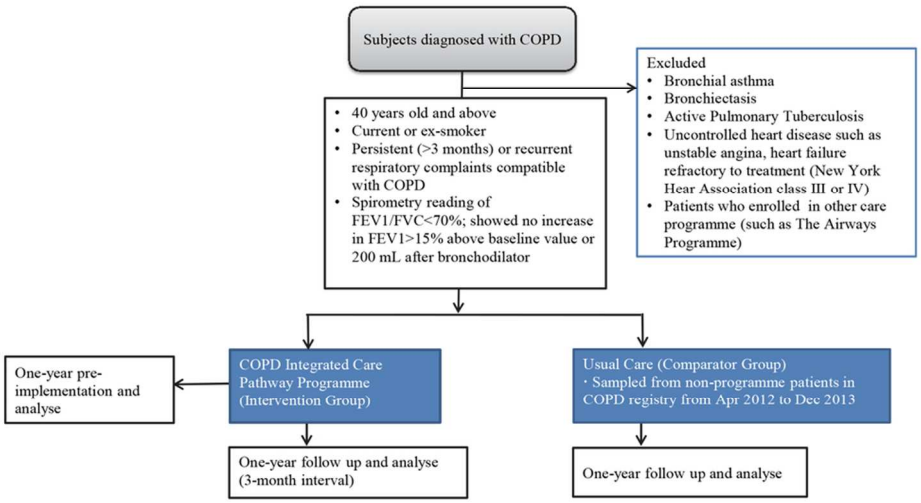
REFERENCE

1. Buist AS, McBurnie MA, Vollmer WM, et al. International variation in the prevalence of COPD (The BOLD Study): a population-based prevalence study. Lancet 2007;370:741–50.
2. Ministry of Health, Singapore. Health Facts 2011. Singapore: Ministry of Health.
3. Teo WS, Tan WS, Chong WF, et al. Economic burden of chronic obstructive pulmonary disease. *Respirology* 2012;17:120–26.
4. Lim E, Matthew N, Mok W, et al. Using hospital readmission rates to track the quality of care in public hospitals in Singapore [abstract]. *BMC Health Serv Res.* Published Online First: 19 October 2011. doi: 10.1186/1472-6963-11-S1-A16
5. Soriano JB, Zielinski J, Price D. Screening for and early detection of chronic obstructive pulmonary disease. Lancet 2009;374:721-32.
6. Spruit MA. Pulmonary Rehabilitation. *Eur Respir Rev,* 2014;23(131):55-63.
7. Kruis AL, Smidt N, Assendelft WJJ, et al. Integrated disease management interventions for patients with chronic obstructive pulmonary disease. *Cochrane Database Syst Rev.* Published Online First: 10 October 2013. doi: 10.1002/14651858.CD009437.pub2

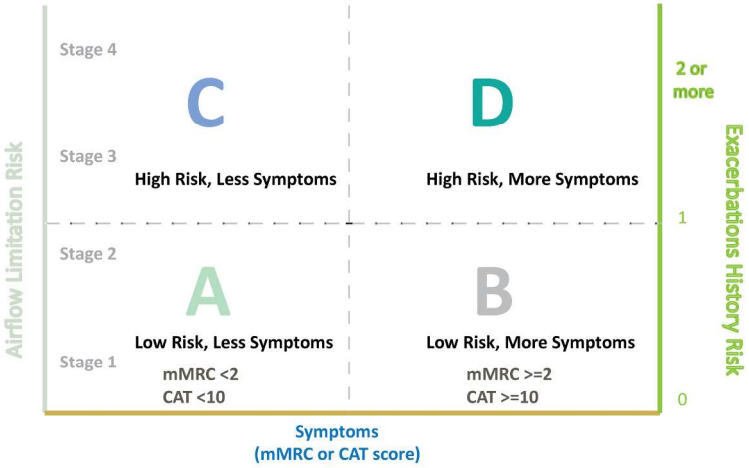
8. Improving Chronic Illness Care. *The Chronic Care Model*. http://www.improvingchroniccare.org/index.php?p=Model_Elements&s=18. Accessed on: 19 June 2014.
9. Global initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of COPD. *Proceedings of the Global Initiative for Chronic Obstructive Lung Disease*: Nov 2011; Shanghai.
10. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for diagnosis, management, and prevention of chronic obstructive pulmonary disease. *Proceedings of the Global Initiative for Chronic Obstructive Lung Disease*: 2005; Bethesda.
11. Jiang JH, Andrews R, Stryer D, Friedman B. Racial/Ethnic Disparities in Potentially Preventable Readmissions: The Case of Diabetes, Am J Public Health, 2005;95:1561-1567
12. Nolan T, Berwick DM. All-or-None Measurement Raises the Bar on Performance. *JAMA* 2006;295:1168-70.
13. Bodenheimer T, Wagner EH, Grumbach K. Improving Primary Care for Patients with Chronic Illness. *JAMA* 2002;288:1775-79. .
14. Jones PW, Harding G, Berry P, et al. Development and first validation of the COPD Assessment Test. *Eur Respir J* 2009;34:648–54.
15. Jones PW, Quirk FH, Baveystock CM. The St. George's Respiratory Questionnaire. *Resp Med* 1991;85:25-31.
16. Weatherall M, Marsh S, Shirtcliffe P, et al. Quality of life measured by the St George's Respiratory Questionnaire and spirometry. *Eur Respir J* 2009;33:1025–30.

17. Li X, Zhou Y, Chen S, et al. Early intervention with tiotropium in Chinese patients with GOLD stages I-II chronic obstructive pulmonary disease (Tie-COPD): study protocol for a multicentre, double-blinded, randomised, controlled trial. *BMJ Open* 2014;4:e003991.
18. Weldam SWM, Schuurmans MJ, Liu R, et al. Evaluation of Quality of Life instruments for use in COPD care and research: A systematic review. *Int J Nurs Stud*2013;50;688-7027.
19. Kon SSC, Canavan JL, Jones SE, et. al. Minimum clinically important difference for the COPD Assessment Test: a prospective analysis. *Lancet Respir Med* 2014;2: 195–203.
20. Robert MH, Dalal AA. Clinical and economic outcomes in an observational study of COPD maintenance therapies: multivariable regression versus propensity score matching. *Int J Chron Obstruct Pulmon Dis* 2012;7:221–33.
21. Cochran WG, Rubin DB. Controlling bias in observational studies: a review. *Sankhya Ser A* 1973;35;417-46.
22. Nelder J, Wedderburn R. Generalized Linear Models. *J R Stat Soc Series B* 1972;135(3):370-84.
23. Jackson GL, Weinberg M, Hamilton NS, et al. Racial/ethnic and educational-level differences in diabetes care experiences in primary care. *Prim Care Diabetes* 2008;2(1):39-44.
24. Boyd CM, Reider L, Frey K, et al. The effects of guided care on the perceived quality of health care for multi-morbid older persons: 18-month outcomes from a cluster-randomized controlled trial. *J Gen Intern Med* 2010;25(3):235-42.
25. Ministry of Health, Singapore. COPD Clinical Practice Guidelines 4/2006. Singapore: Ministry of Health.

26. Qaseem A, Wilt TJ, Weinberger SE, et. al. Diagnosis and Management of Stable Chronic Obstructive Pulmonary Disease: A Clinical Practice Guideline Update from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society. *Ann Intern Med* 2011;155:179-191.
27. Eeden SF, Burns J. A multidisciplinary approach to the treatment and management of chronic obstructive pulmonary disease. BCMJ 2008;50(3):143-47.
28. Thistlethwaite P. Integrating health and social care in Torbay. Improving care for Mrs Smith. *London: The King's Fund* 2011.
29. Asch SM, McGlynn EA, Hogan MM et. al. Comparison of care for patients in the Veterans Health Administration and patients in a national sample. *Ann Intern Med* 2004;141: 938 – 945.



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



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)