

Real-World Cost-Consequence Analysis of an Integrated Chronic Disease Management Program in Saskatchewan, Canada

Health Services Insights
Volume 17: 1–14
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DOI: 10.1177/11786329231224621



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ABSTRACT: An integrated disease management program otherwise called a clinical pathway was recently implemented in Saskatchewan, Canada for patients living with chronic obstructive pulmonary disease (COPD). This study compared the real-world costs and consequences of the COPD clinical pathway program with 2 control treatment programs. The study comprised adult COPD patients in Regina (clinical pathway group, N = 759) matched on propensity scores to 2 independent control groups of similar adults in (1) Regina (historical controls, N = 759) and (2) Saskatoon (contemporaneous controls, N = 759). The study measures included patient-level healthcare costs and acute COPD exacerbation outcomes, both tracked in population-based administrative health data over a one-year follow-up period. Analyses included Cox proportional hazards models and differences in means between groups. The bias-corrected and accelerated bootstrap method was used to calculate 95% confidence intervals (CI). The COPD pathway patients had lower risks of moderate (hazard ratio [HR] = 0.57, 95% CI [0.40–0.83]) and severe (HR = 0.43, 95% CI [0.28–0.66]) exacerbations compared to the historical control group, but similar risks compared with the contemporaneous control group. The COPD pathway patients experienced fewer episodes of exacerbations compared with the historical control group (mean difference = –0.30, 95% CI [–0.40, –0.20]) and the contemporaneous control group (mean difference = –0.12, 95% CI [–0.20, –0.03]). Average annual healthcare costs in Canadian dollars were marginally higher among patients in the COPD clinical pathway (mean = \$10549, standard deviation [SD] = \$18 149) than those in the contemporaneous control group (\$8841, SD = \$17 120), but comparable to the historical control group (\$10677, SD = \$21 201). The COPD pathway provides better outcomes at about the same costs when compared to the historical controls, but only slightly better outcomes and at a marginally higher cost when compared to the contemporaneous controls.

KEYWORDS: Clinical pathway, COPD exacerbations, healthcare costs, administrative health data

RECEIVED: July 26, 2023. **ACCEPTED:** November 28, 2023.

TYPE: Original Research

FUNDING: The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The study was supported through the funding by the Saskatchewan Health Research Foundation (SHRF) and Saskatchewan Centre for Patient-Oriented Research (SCPOR) (Sprout Grant # 5190). The funders played no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and the decision to submit the manuscript for publication.

DECLARATION OF CONFLICTING INTEREST: The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr. Marciniuk has undertaken consulting with Alberta Health Services, Health Canada, Ontario Ministry of Health and Long-Term Care, Saskatchewan Health Authority, and Yukon Health and Social Services. He has provided research advisory and received

research funding (managed and held by University of Saskatchewan) from AstraZeneca, Boehringer Ingelheim, Canadian Institutes of Health Research, GlaxoSmithKline, Grifols, Lung Saskatchewan, Novartis, Sanofi, Saskatchewan Health Research Foundation, and Schering-Plough. Dr. Marciniuk is an employee of the University of Saskatchewan, is a Board Member of the Saskatchewan Health Research Foundation and serves as Deputy Editor, CHEST Journal. Dr. Penz reports grants from Saskatchewan Health Research Foundation SPROUT grant, during the conduct of the study; grants and personal fees from Astra Zeneca, grants and personal fees from GlaxoSmithKline, grants and personal fees from Sanofi, personal fees from COVIS Pharma, personal fees from Boehringer Ingelheim, outside the submitted work; and she is the Co-Chair of the Canadian Thoracic Society COPD Assembly. She is the Co-Chair of the ACTonCOPD National Steering Committee. All other authors have no conflicts to disclose.

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Background

Healthcare policymakers and providers usually require credible economic evaluation evidence to make decisions on the adoption, implementation, and/or expansion of complex healthcare interventions.¹ Complex healthcare interventions such as integrated disease management (IDM) programs, which are patient-centered and multi-disciplinary approaches to chronic disease management with a focus on health education and self-management tailored to all aspects of the disease presentation and progression,² are being implemented in various jurisdictions across the world. For example, the province of Saskatchewan (population of 1.18 million in 2021) in Canada has implemented clinical pathways (a type of IDM program) for 12 common and resource-intensive health conditions, including prostate cancer,

chronic pain, multiple sclerosis, acute stroke, and more recently, chronic obstructive pulmonary disease (COPD). Since the uptake of clinical pathways in 2009, there has not been a rigorous economic evaluation of these interventions in the province.^{3,4} This study explores the economic evaluation of the COPD clinical pathway. This clinical pathway was prioritized because COPD is the third leading cause of death globally^{5,6}; and in Canada, accounts for the highest hospital admissions rate among the major chronic diseases and incurs the most expensive hospital cost (about \$753.3M in 2016–2017).⁷ Thus, cost-effective disease management programs will present huge benefits to patients and the overall healthcare system.

Previous economic evaluations of COPD clinical pathways used different names for the intervention, including integrated



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care pathway,⁸ person-centered care,⁹ integrated disease management program,^{10,11} or respiratory coordinated care program.¹² These studies were mostly cost-effectiveness analysis,^{10,13} budget impact analysis,⁸ or cost-minimization analysis,^{12,14} with the commonest effects being quality-adjusted life years (QALYs),^{9,10,15} 90-day mortality,¹⁶ exercise tolerance,^{14,17} and frequency of exacerbations.¹³ Whereas the majority of the studies found COPD clinical pathways to be cost-effective regarding the outcomes of QALYs^{9,10,15} and hospital readmissions,^{12,18} a minority found clinical pathways not to be cost-effective in relation to the outcomes of exacerbations¹³ or 90-day mortality.¹⁶

Our review of the pertinent literature underscored the dearth of economic evaluation methods primed for resource allocation decisions regarding COPD clinical pathways. Conventional cost-effectiveness analysis and cost-utility analysis, which are very common in the literature, usually report summary measures such as incremental cost-effectiveness ratios (ICERs) and incremental cost-utility ratios (ICURs). However, decision-makers may find it difficult to interpret ICERs and ICURs,¹⁹ and may not often consider these when making resource allocation decisions.²⁰ In addition, clinical pathways are designed to have impacts on multiple patient outcomes; hence cost-utility analysis which normally considers 1 main outcome such as QALY may present limited utility for evaluating such interventions.²¹

A cost-consequences analysis, a different type of economic evaluation, could be more suitable for evaluating COPD clinical pathways because it considers disaggregated cost information, captures a range of different outcomes, and presents the results in tabular format.²¹ These characteristics make cost-consequences analysis transparent and easily understandable, and gives flexibility to decision-makers to select the components most relevant to their resource allocation decisions.²⁰ The objective of this study was to use cost-consequence analysis to evaluate the impacts of real-world implementation of the COPD clinical pathway in Saskatchewan, allowing for multiple patient outcomes to be considered simultaneously.

Methods

Study setting and intervention

The majority of individuals residing in Saskatchewan receive universal health coverage, including coverage for emergency department [ED], hospital, and physician visits. There are a few exceptions such as members of the Canadian Armed Forces and individuals with refugee/asylum status, who receive universal healthcare coverage from the federal government. The province also provides supplemental prescription drug coverage for eligible individuals over age 65 years and for those with limited incomes.

As previously described in Kuwornu et al,²² the COPD clinical pathway was implemented at the Regina area of the Saskatchewan Health Authority (SHA) in September 2017.^{3,4}

The COPD clinical pathway was designed to complement and align with an existing *LiveWELL* COPD program, the latter targeted at patients with more advanced COPD residing mostly at the Saskatoon area of the SHA.²³ The COPD clinical pathway relies on collaborations between care providers, including local primary care providers, respirologists, respiratory therapists, pharmacists, and nurses to provide coordinated patient navigation through the healthcare system. The goals of the clinical pathway were to increase quality of care and reduce healthcare utilization.³ After COPD diagnosis, both pharmacologic and non-pharmacologic therapies were administered to patients, and on a case-by-case basis items such as oxygen therapy, self-management with COPD Action Plan (developed by a patient and their healthcare provider), medication management, vaccinations, and pulmonary rehabilitation were also provided. The pulmonary rehabilitation program offers supervised aerobic exercise training and COPD education aimed at relieving symptoms, slowing disease progression, improving quality of life, and decreasing hospital and doctor visits, outcomes previously documented to improve with participation in pulmonary rehabilitation.²⁴ The details of the care components included in the COPD clinical pathway are shown in Table 1. Further details on the development and implementation of the COPD clinical pathway were previously published.³

Patients were recruited into the pathway from various sources, including respirologists, acute care nurse navigators, respiratory therapists, internal medicine physicians, family physicians, and intermediate care paramedics.²² Only patients who provided consent for their records to be linked with other administrative health data were included in the study.

Data sources

Saskatchewan population-based administrative health data was used for the study, including hospital discharge abstracts, ED records, physician billing claims, outpatient prescription drug dispensation records, and population health coverage registration files.²² These data sets contain every encounter with care providers in the healthcare sectors listed regardless of who pays for the service. The data sets were deterministically linked together using an anonymized personal health identification number to create a longitudinal healthcare utilization record across the continuum of care for everyone included in the study. The data sets were accessed and analyzed at the secure data laboratory of the Saskatchewan Health Quality Council (HQC). Ethics approval for the research was received from the Saskatchewan Health Authority Research Ethics Board (REB-20-69).

Intervention and control groups

Adult individuals (35+ years) diagnosed with COPD and recruited into the COPD clinical pathway program between April 1, 2018, and March 31, 2019 in Regina were included in

Table 1. COPD clinical pathways program key care elements.

KEY CARE ELEMENT	DETAILS
Prevention	Prevention activities such as physical activity, smoking cessation, vaccinations, etc. that are aimed at reducing the risk of COPD and related complications.
Targeted Screening	Screening to identify individuals at risk using screening posters (both print and electronic) designed for COPD. If high clinical suspicion, individuals are referred for spirometry testing.
Lung Function Testing	Spirometry (mandatory for diagnosis). Testing must meet acceptability and reproducibility criteria per guidelines
Diagnosis	Post bronchodilator FEV ₁ /FVC < 0.7. In some instances, FEV ₁ /FVC < lower limit of normal may be used. If additional investigations are required, referral to a specialist is considered.
Clinical Management	Medications, patient self-management (the patient being able to understand and recognize COPD exacerbations and have a COPD Action Plan), pulmonary rehabilitation, and oxygen therapy.

Abbreviations: COPD, chronic obstructive pulmonary disease; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity.

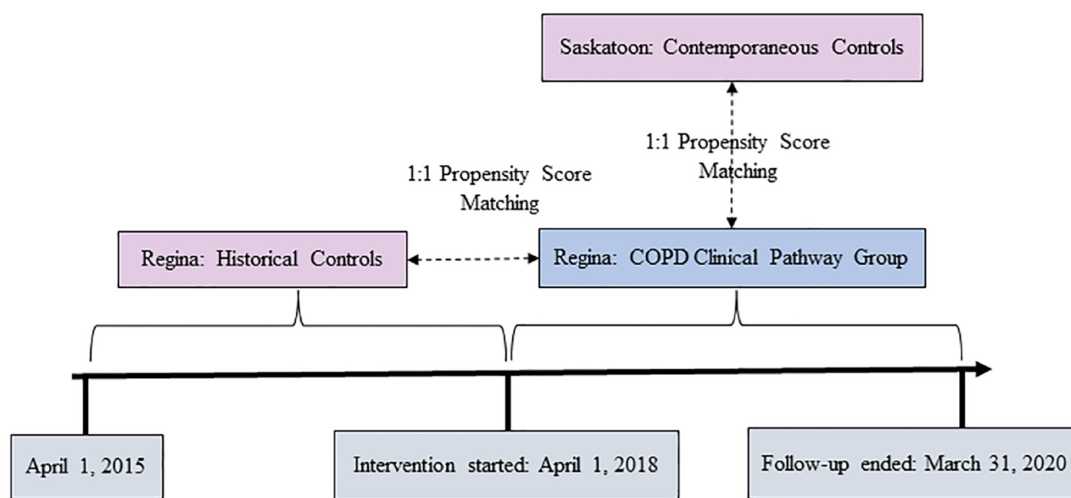


Figure 1. Selection of study control groups.

Abbreviations: COPD, chronic obstructive pulmonary disease.

*One-to-one matching on the propensity scores with the nearest neighbor matching algorithm without replacement was used to form matched pairs of treated and untreated individuals.

the intervention group.²² The study used 2 control groups (Figure 1), with the first control group (ie, contemporaneous control group) being individuals diagnosed with COPD and lived in Saskatoon between April 1, 2018, and March 31, 2019. The second control group (ie, historical control group) included individuals who were diagnosed with COPD and lived in Regina between April 1, 2015, and March 31, 2016, prior to the implementation of the COPD clinical pathway in the city. Both the intervention and the control groups met the criteria of a validated case definition for COPD²⁵: (1) a hospital discharge abstract and/or physician visit with a diagnosis of COPD. Cases were identified using the International Classification of Diseases, 10th Revision, Canada (ICD-10-CA) codes J41, J42, J43 or J44 in the hospital discharge abstracts or ICD-9 codes 491, 492 or 496 in the physician billing claims.²²

Saskatoon and Regina are the 2 largest cities in Saskatchewan (more than 200 000 population in each city), accounting for close to half of the provincial population. Thus, COPD patients

who lived in Saskatoon were appropriate controls for the intervention group in Regina. COPD patients in Saskatoon had access to a range of programs, including the *LiveWELL* COPD program during the study period. Consequently, some of the patients in the contemporaneous control group may not be treated under “usual care.” The historical control group comprised patients who resided in Regina before the COPD clinical pathway was implemented in that city. These patients may be considered to have received “usual care” since there were no specialized intervention programs targeted at them during this period.²² The selection of these control groups allowed for assessing the cost-consequence of the clinical pathway when compared to (1) patients under usual care (historical controls) and (2) patients possibly under other effective programs of care (contemporaneous controls). For non-randomized studies, the use of more than one control group has been recommended over single control group.²⁶

The date patients were recruited into the clinical pathway was the index date for the intervention group. The earliest

hospitalization or physician visit date for COPD diagnosis was the index date for patients in the control groups.

Outcome measures

Different measures of acute exacerbation of COPD were included in the cost-consequence analysis. Acute COPD exacerbation was selected because it negatively affects patients' quality of life, increases the risk of death, and contributes significantly to costly inpatient hospital care.²⁷ Acute exacerbations of COPD are periods in the natural course of the disease characterized by worsening of a patient's baseline symptoms, such as dyspnea, cough, and/or sputum production. We used healthcare-related events to define the level of exacerbation severity, which may not always align with clinical definitions of exacerbation severity.²⁸ Specifically, ICD-10-CA codes J41, J42, J43, J44 were used to identify severe exacerbations of COPD (ie, those requiring inpatient hospital admission) and moderate exacerbations of COPD (ie, those requiring ED visit/admission), whilst ICD-9 codes 491, 492, 496 were used to identify mild exacerbations of COPD (ie, those requiring physician visits).²⁸ The ICD-10-CA codes must be in the most responsible diagnosis field, or a diagnosis of an acute lower respiratory tract infection in the most responsible diagnosis field and a diagnosis of other COPD (ICD-10-CA code J44) in the second diagnosis field. The ICD-9 codes must be accompanied by outpatient dispensation of any drugs, within 2 days of the physician visit, used to treat acute exacerbations of COPD, including antibiotics, systemic corticosteroids, short-acting beta agonists (SABAs), and SABAs combined with anticholinergics.²⁸

The measures of acute exacerbations include (1) risk of exacerbation (measured by hazard ratios), (2) frequency of exacerbations (measured by the number of exacerbations), (3) durations of exacerbations (measured by the lengths of stay in ED or inpatient hospital), and (4) episodes of exacerbations. Episodes of exacerbations were measured using a method we previously published.²⁸ All instances of encounters with physicians, drug dispensations, EDs, and inpatient hospitalizations for COPD exacerbations were clustered together as an episode provided each contact was within 30 days. Encounters that were more than 30 days apart were considered separate episodes of COPD exacerbations. Measuring episodes is important because exacerbations often require contact with several different healthcare providers and services. For example, during an exacerbation, a patient may receive treatment in an ED and later be admitted to inpatient hospital care. Upon discharge, the same patient may also receive follow-up care from their primary care provider or a specialist physician and might require additional medications. The episode of COPD exacerbation measure would group all these contiguous cares together as a single episode provided there were no gaps of more than 30 days between 2 adjacent encounters.

For completeness, we also included the time to first ED visit/admission for any health condition during the follow-up period and the time to first inpatient hospital admission for any health condition during the follow-up period.

All outcomes were measured for every individual using a uniform period of 1 year following their index date.

Healthcare and intervention costs

Following similar methods in Kuwornu et al,²² all healthcare costs were calculated from the perspective of a single public payer (ie, the Saskatchewan Ministry of Health), excluding individual out-of-pocket expenditures such as copayments. Healthcare costs were calculated for inpatient hospital admissions, ED visits/admissions, specialist physician visits, general practitioner visits, and medication drugs in the one-year period following the index date. Hospital costs were estimated using a standard methodology developed by the Canadian Institute for Health Information for all Canadian provinces, which uses the product of resource intensity weights and provincial cost of a standard hospital stay to estimate cost of inpatient hospital stays at the patient level.²⁹ For the ED cost component, average costs per ED visit/admission were obtained from the Ministry of Health and applied to ED visits/admissions during the follow-up period. The cost of a physician visit was the amount billed by the physician to the Saskatchewan Ministry of Health. Costs were calculated separately for COPD exacerbation-related reasons and for all health reasons. Costs were adjusted for inflation using the health and personal care items of the Saskatchewan consumer price index³⁰ and expressed in 2020 constant Canadian dollars. The methods we used to estimate healthcare costs were applied in previous studies using Saskatchewan administrative health data.^{28,31}

All the direct costs of developing, implementing, and maintaining the intervention program were allocated to patients in the COPD clinical pathway. These costs comprised of patient recruitment, equipment, personnel, and facility rentals (see Table A1 in the appendix for details). These costs were added to the total healthcare costs of patient who were enrolled in the clinical pathway.

Patient and disease characteristics

Sex (male or female) and age group in years (35-45, 46-55, 56-65, 66-75, 76+) were the main demographic characteristics included in the study. We also included the patient's disease characteristics, which were estimated using a list of the 20 most prevalent health conditions included in the Charlson et al comorbidity index calculated for our cohort.³² These health conditions included diseases such as congestive heart failure, depression, and diabetes. These health conditions were defined based on diagnoses in the hospital discharge abstract and the physician billing claims data. The demographic variables were

defined as of the index date, whilst the comorbid conditions were defined from the three-year period before the index date.

Statistical analysis

Propensity score matching was used to control for confounding and minimize the risk of bias in our analyses. Individuals in the COPD clinical pathway group were separately matched to individuals in the (1) contemporaneous control group and (2) historical control group on their propensity scores, using one-to-one matching with the nearest neighbor matching algorithm without replacement.²² Standardized mean difference (SMD) was used to ascertain balance between groups, with SMD values of 0.1 and lower indicating balance. All the listed demographic and disease characteristics were included in the propensity score models. Variables that had residual confounding after matching were controlled for in the subsequent analyses.

Several statistical analyses were conducted for the cost-consequence analysis. Kaplan-Meier curves were used to summarize the time to first severe COPD exacerbation, time to first moderate COPD exacerbation, and time to first ED or inpatient hospital admission for any health condition. Cox proportional hazards regression models were used to estimate the hazards (ie, risk) of severe COPD exacerbation, moderate COPD exacerbation, and ED or inpatient hospital admission for any health condition. We calculated means (95% confidence intervals) and differences between means (95% confidence intervals) for the number and durations of severe, moderate, and mild COPD exacerbations. Also, we calculated means (95% confidence intervals) and differences between means (95% confidence intervals) for healthcare costs associated with COPD exacerbations and total healthcare costs. The 95% confidence intervals for the differences in means were calculated using the bias-corrected and accelerated (BCa) bootstrapping method with 3000 replications. All statistical analyses were performed using R (version 4.1.0, R Foundation for Statistical Computing, Vienna, Austria). Statistical significance was determined by a *P*-value of < .05.

Results

A total of 759 individuals who met the study requirements were included in the COPD clinical pathway group of the study. All individuals in the COPD clinical pathway group were successfully matched to comparable individuals in the contemporaneous control group (*N*=759) and historical control group (*N*=759) (Figure 2). A total of 2277 individuals diagnosed with COPD, from the 3 study groups, were included in the analysis with (mean [SD] age, 63 [14] years; 1286 females [56.5%]). Close to 20 out of the 22 covariates were balanced between the study groups because their SMDs after matching were less than or equal to 0.1 (Table 2).

The time until patients experienced the first moderate or severe COPD exacerbation is shown in Figure 3. There were

no statistically significant differences between the COPD clinical pathway group and the contemporaneous control group in terms of the time to first moderate or severe COPD exacerbations. However, in the comparison between the COPD clinical pathway group and the historical control group, the clinical pathway group took a longer time before experiencing the first moderate or severe COPD exacerbation in the one-year follow-up period (Figure 3).

Whilst the time until first ED visit/admission for any health condition is not different between the COPD clinical pathway group and the contemporaneous control group, the clinical pathway group took longer to visit or be admitted to ED for any health condition compared to the historical control group (Figure 4). There was no statistically significant difference between the COPD clinical pathway group and the historical control group for the time to first hospital inpatient admission for any health condition, but the contemporaneous control group took longer to be admitted to hospital for any health condition compared with the clinical pathway group (Figure 4).

Patients in the COPD clinical pathway group at any point during the one-year follow-up period were 33% more likely to experience hospital inpatient admissions for any health condition compared to patients in the contemporaneous control group (HR, 1.33; 95% CI, 1.12-1.59) (Table 3). Compared to patients in the historical control group, patients in the COPD clinical pathway group at any point during the follow-up period were less likely to experience severe COPD exacerbation (57% less), moderate COPD exacerbation (43% less), and ED visit/admission for any condition (18% less) (Table 3).

Patients in the COPD clinical pathway group experienced about the same number of severe exacerbations (mean difference = 0.00, 95% CI [-0.03, 0.04]) and moderate exacerbations (mean difference = -0.04, 95% CI [-0.11, 0.02]), but shorter time of moderate exacerbations (mean difference = -0.08, 95% CI [-0.18, 0.00]) and fewer episodes of exacerbations (mean difference = -0.12, 95% CI [-0.20, -0.03]) compared to patients in the contemporaneous control group (Table 4). Compared to patients in the historical control group, the patients in the COPD clinical pathway group experienced better outcomes on all frequency measures of exacerbations (Table 4). Regarding exacerbation-related healthcare costs, patients in the COPD clinical pathway group incurred similar inpatient hospital, ED, GP, and specialist costs compared to patients in the contemporaneous control group, but consistently lower costs compared to patients in the historical control group (Table 4).

The average annualized cost per patient for developing and implementing the COPD clinical pathway program was \$1485 (Table 5), whilst the average total annual healthcare cost per patient in the clinical pathway program was \$10 549 (inclusive of the program development and implementation costs). Thus, the COPD clinical pathway program development and implementation cost constituted about 14% of the annual total healthcare costs of patients enrolled in the program. Some of the COPD clinical pathway program cost items such as spiro

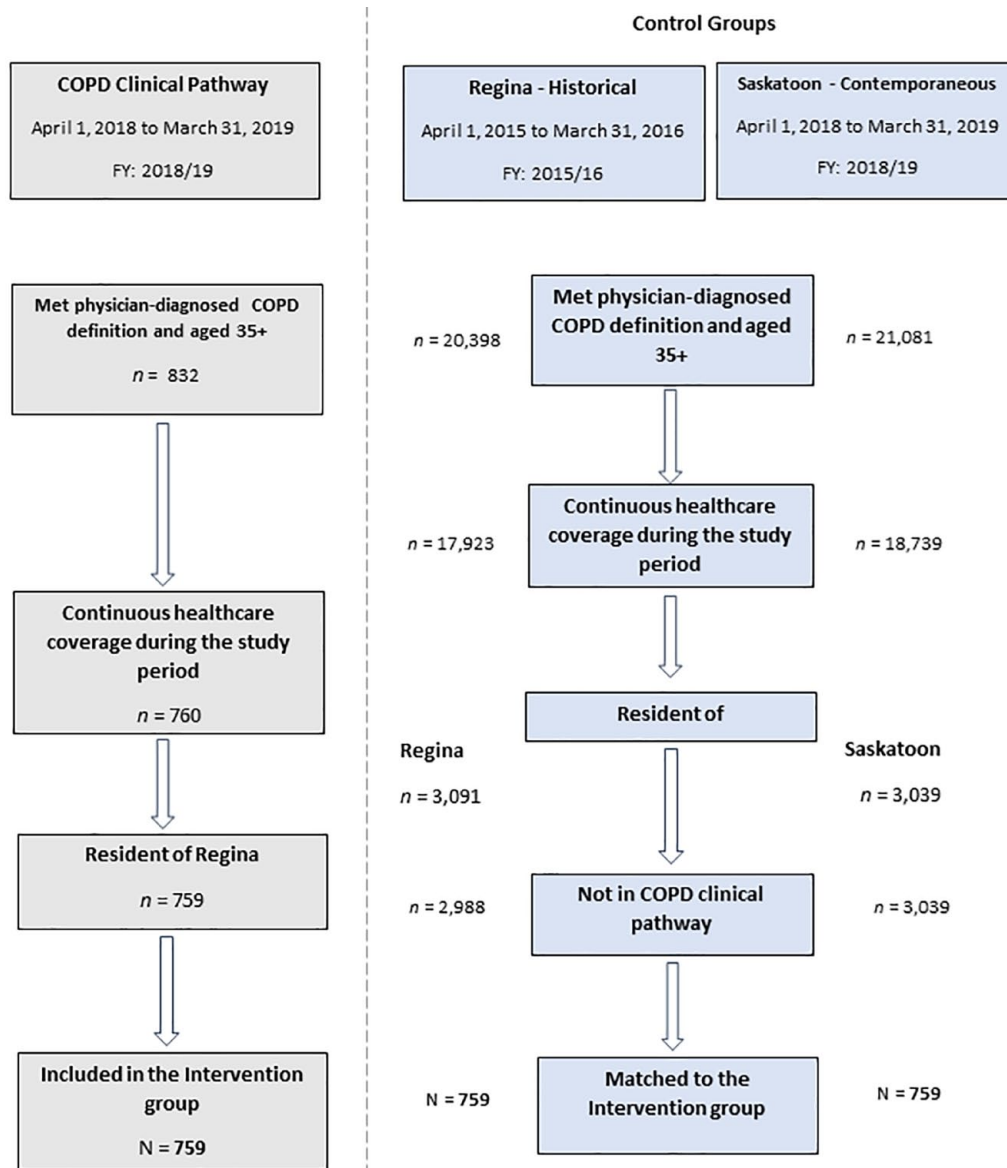


Figure 2. Study cohort flow diagram.

Abbreviations: COPD, chronic obstructive pulmonary disease; FY, Fiscal year.

kits (8 years) and portable concentrators (5 years) may last for several years. Only an annual depreciation portion of the acquisition cost was included in the program cost calculations. For example, although the 10 new spiro kits were acquired at the price of \$73 183, only \$9148 annual depreciation cost was added to the annual program cost calculation since the equipment are expected to last for about 8 years. Also, some of the cost item such as respiratory educators and sat monitors are variable, so may increase as more patients are enrolled in the COPD clinical pathway program. Further details of the program costing are presented in the appendix Table A1.

Discussion

This cost-consequence analysis provided a comprehensive comparison between the enrollees of a COPD clinical pathway and 2 independent control groups. The contemporaneous

control group comprised patients possibly under other effective programs of care whilst the historical control group comprised patients under usual care.

Individuals in the COPD clinical pathway and the contemporaneous control group had similar numbers of severe COPD exacerbations, and about the same durations of time until they experienced the first moderate or severe COPD exacerbations. The COPD clinical pathway group had a shorter duration of moderate exacerbations, fewer overall episodes of exacerbations, and incurred about the same exacerbation-related inpatient hospital costs but marginally higher total healthcare costs compared to individuals in the contemporaneous control group. Overall, the average annualized cost of developing and maintaining the COPD clinical pathway comprised about 14% of the total annual healthcare cost of patients in the program.

Table 2. Comparison of baseline characteristics between COPD clinical pathway and control subjects in the unmatched and matched samples.

VARIABLE	COPD PATHWAY GROUP (N=759)	CONTEMPORANEOUS CONTROL GROUP			HISTORICAL CONTROL GROUP				
		UNMATCHED (N=3038)	UNMATCHED SMD	MATCHED (N=759)	MATCHED SMD ^a	UNMATCHED (N=2988)	UNMATCHED SMD	MATCHED (N=759)	MATCHED SMD ^a
Age (%)			0.36		0.05		0.32		0.18
35-45	12.1	4.6		12.6		5.7		17.1	
46-55	14.4	11.9		15.5		12.8		16.6	
56-65	30.6	26.7		29.5		25.7		25.7	
66-75	23.7	27.9		24.4		27.3		23.2	
76+	19.2	28.9		17.9		28.5		17.4	
Female	56.0	49.7	0.13	56.9	0.02	52.4	0.07	56.5	0.01
Comorbid Health Conditions									
Cardiac Arrhythmia	3.3	2.1	0.08	4.2	0.05	3.9	0.04	3.4	0.01
Congestive Heart Failure	7.4	7.7	0.01	9.2	0.07	9.5	0.08	8.2	0.03
Coagulopathy	2.4	2.2	0.01	3.2	0.05	3.4	0.06	2.0	0.03
Deficiency Anemia	2.6	0.7	0.15	2.1	0.04	2.1	0.04	3.2	0.03
Depression	10.7	9.3	0.04	9.9	0.03	9.8	0.03	12.8	0.07
Diabetes Complicated	3.4	4.1	0.04	4.5	0.05	4.9	0.07	3.7	0.01
Diabetes Uncomplicated	6.5	3.3	0.15	7.2	0.03	6.1	0.02	8.2	0.07
Drug Abuse	2.1	2.8	0.04	1.6	0.04	3.3	0.08	2.0	0.01
Fluid and Electrolyte Disorder	3.7	2.7	0.05	4.2	0.03	4.8	0.05	3.7	<0.01
Hypertension Uncomplicated	37.0	32.0	0.11	43.1	0.12	38.4	0.03	39.3	0.05
Hypothyroidism	5.0	7.5	0.10	3.8	0.06	6.1	0.05	5.0	<0.01
Liver Disease	1.2	0.9	0.03	1.2	<0.01	1.1	0.01	1.2	<0.01
Other Neurological Disorder	1.6	1.3	0.03	2.0	0.03	1.6	0.01	1.3	0.02

(Continued)

Table 2. (Continued)

VARIABLE	COPD PATHWAY GROUP (N=759)	CONTEMPORANEOUS CONTROL GROUP			HISTORICAL CONTROL GROUP				
		UNMATCHED (N=3038)	UNMATCHED SMD	MATCHED (N=759)	MATCHED SMD ^a	UNMATCHED (N=2988)	UNMATCHED SMD	MATCHED (N=759)	MATCHED SMD ^a
	(%)								
Pulmonary Circulation Disorder	1.8	5.2	0.18	2.0	0.01	4.4	0.15	2.4	0.04
Peripheral Vascular Disorder	1.6	1.4	0.01	2.1	0.04	1.6	0.01	2.1	0.04
Psychosis	2.0	5.1	0.17	1.6	0.03	4.3	0.13	2.2	0.02
Renal Failure	4.3	3.1	0.07	6.3	0.09	5.8	0.07	4.3	<0.01
Rheumatoid Arthritis/ Collagen Vascular Disease	2.2	4.5	0.12	2.1	0.01	2.8	0.04	1.7	0.04
Solid Tumor without Metastasis	4.2	5.3	0.05	3.6	0.03	5.7	0.07	2.9	0.07
Valvular Disease	2.4	2.6	0.02	3.3	0.06	3.0	0.04	2.5	0.01

Abbreviation: COPD, chronic obstructive pulmonary disease.

^aOne-to-one matching on the propensity scores with the nearest neighbor matching algorithm without replacement was used to form matched pairs of treated and untreated individuals. Standardized mean difference (SMD) was used to ascertain balance between groups, with SMD values of 0.1 or lower indicating balance.

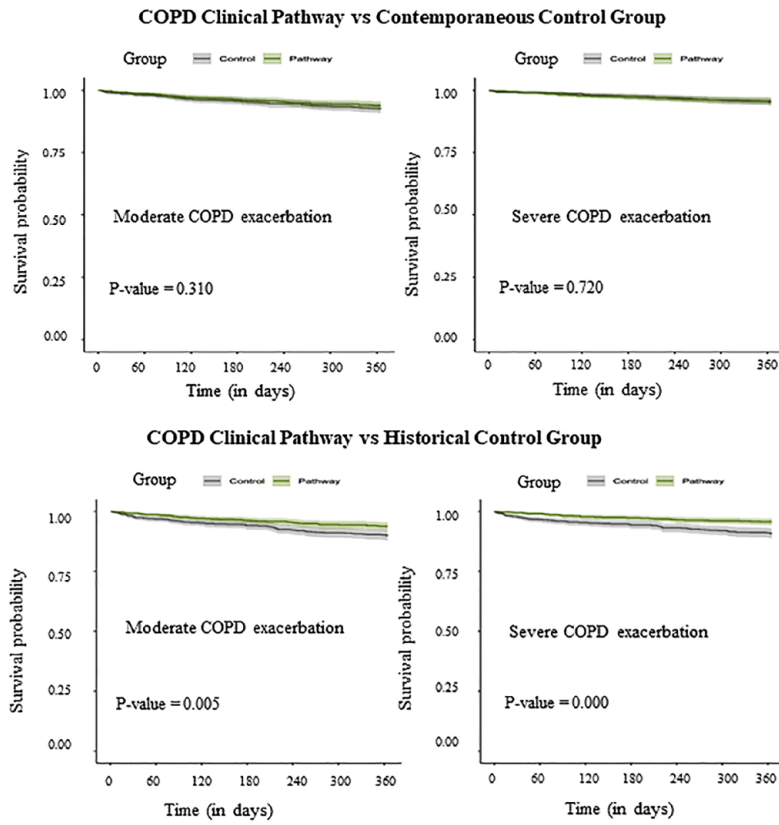


Figure 3. Time-to-first moderate and severe COPD exacerbations, by study comparison group. Abbreviation: COPD, chronic obstructive pulmonary disease.

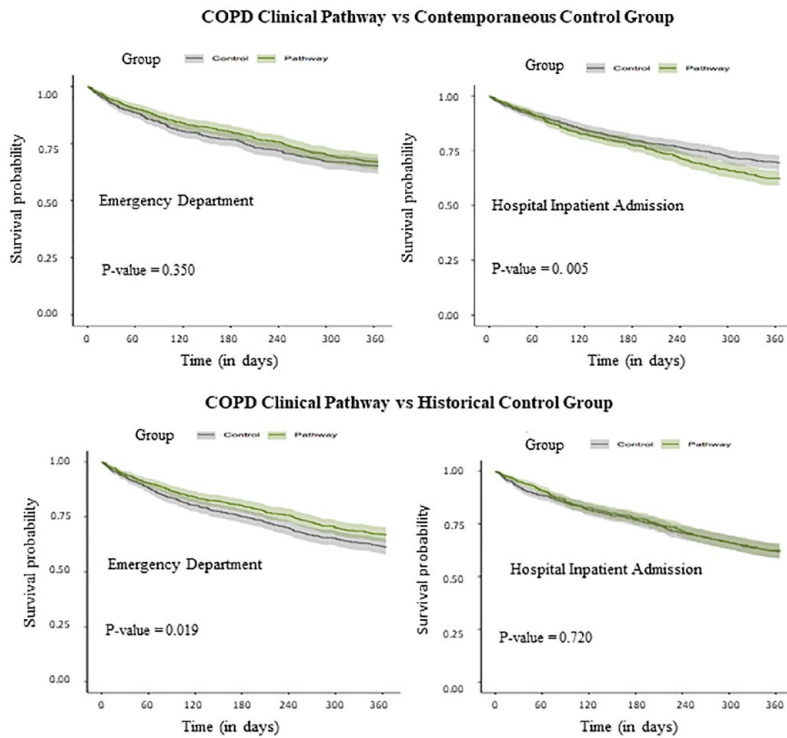


Figure 4. Time-to-first emergency department and hospital inpatient admission for any health condition, by study comparison group. Abbreviation: COPD, chronic obstructive pulmonary disease.

Table 3. Hazard ratios for moderate and severe COPD exacerbations, and hospital inpatient admissions and ED visits for any health condition, by study comparison group.

	HR (95% CI)	P-VALUE
COPD clinical pathway vs Contemporaneous control group		
Severe COPD exacerbation	0.95 (0.58-1.54)	.800
Moderate COPD exacerbation	0.86 (0.58-1.27)	.400
Hospital inpatient admission for any condition	1.33 (1.12-1.59)	.001
ED visit for any condition	0.95 (0.80-1.13)	.600
COPD clinical pathway vs Historical control group		
Severe COPD exacerbation	0.43 (0.28-0.66)	<.001
Moderate COPD exacerbation	0.57 (0.40-0.83)	.003
Hospital inpatient admission for any condition	0.98 (0.83-1.16)	.800
ED visit for any condition	0.82 (0.69-0.98)	.030

Abbreviations: CI, confidence interval; COPD, chronic obstructive pulmonary disease; ED, emergency department; HR, hazard ratio.

In the second comparison, where individuals in the COPD clinical pathway group were compared to those in the historical control group, the results were even better for the pathway group. The COPD clinical pathway group had lower risks of moderate and severe COPD exacerbations and consequently stayed longer before experiencing the first moderate or severe COPD exacerbations compared to the historical control group. Similarly, the COPD clinical pathway group had fewer moderate and severe COPD exacerbations, shorter durations of moderate and severe COPD exacerbations, and incurred lower exacerbation-related healthcare costs compared to the historical control group. Although there are methodological challenges with the historical comparison, such as the differences being observed could have been caused by changes in care delivery over time other than the implementation of the COPD clinical pathway, we believe this comparison answers a substantive question. The COPD clinical pathway decision-makers wanted to know how outcomes and costs have changed for COPD patients in Regina since the introduction of the clinical pathway. Care delivery in general may have changed in the city between the 2 periods, but the clinical pathway was the only targeted intervention toward COPD patients over the period.

To our knowledge, this is the first study to use cost-consequence analysis to evaluate the real-world implementation of a COPD clinical pathway program. Consequently, previous studies are not directly comparable to the current one. Most

previous studies that conducted economic evaluations of COPD clinical pathways used different approaches such as cost-effectiveness analysis,^{10,13} budget impact analysis,⁸ and cost minimization analysis.^{12,14} The few studies that used cost-consequence approach to evaluate interventions for COPD patients focused on different types of interventions/programs other than integrated care programs. Two studies conducted cost-consequence analyses of treating COPD patients according to global and national guidelines compared to real-life clinical practice in 4 countries, including the US, Belgium, Germany, and Sweden³³ and in the UK³⁴ and found that re-allocating patients from current clinical practice to treatment according to published recommendations would provide clinical benefits and result in substantial cost savings.

Strengths and limitations

The study used 2 control groups to conduct a real-world cost-consequence analysis of a COPD clinical pathway program. The choice of the 2 control groups allowed for estimating the potential ranges of the differences in outcomes and costs of the COPD clinical pathway when compared to patients receiving care under usual practice and patients possibly receiving care under other effective programs.

Despite these strengths, the results of the study should be interpreted considering the following limitations. First, the study used a one-year follow-up period due to the recency of the COPD clinical pathway implementation and the lag between processing and release of the administrative health data sets. Because of this practical reality it is likely that some of the benefits of the intervention may accrue over longer period and become magnified with time.

Second, it is acknowledged that there are other important endpoints and outcomes associated with optimal management of COPD. While frequency and duration of acute COPD exacerbations negatively impact patients' quality of life and increase risk of mortality, and are critical to consider, there are other patient-centered symptoms such as shortness of breath and activity limitation that are also important to individual patients. These latter endpoints were not included in our study because they were not routinely collected in the administrative health databases we used in the study. Similarly, a common limitation of studies that use population-based administrative health data is the inability to include all potential confounders such as smoking status, physical activity, body mass index, and spirometry testing results (ie, FEV₁/FVC).²² Unfortunately, these variables were not routinely collected in the data sources we used, thus could not be included in our study. Notwithstanding, we controlled for a comprehensive list of comorbid conditions that may have differential impacts on health outcomes and healthcare costs.

Finally, we used simple average costs for ED costs. This did not take acuity or complexity of patients' conditions into

Table 4. Clinical outcomes and healthcare costs during the one-year follow-up period, by study comparison group.

	CONTEMPORANEOUS COMPARISON			HISTORICAL COMPARISON		
	COPD CLINICAL PATHWAY MEAN (95% CI)	CONTEMPORANEOUS CONTROL GROUP MEAN (95% CI)	MEAN DIFFERENCE (95% CI) ^a	COPD CLINICAL PATHWAY MEAN (95% CI)	HISTORICAL CONTROL GROUP MEAN (95% CI)	MEAN DIFFERENCE (95% CI) ^a
	CLINICAL OUTCOMES			CLINICAL OUTCOMES		
Number of COPD exacerbations						
Severe	0.07 (0.04-0.10)	0.07 (0.04-0.09)	0.00 (-0.03 - 0.04)	0.07 (0.04-0.10)	0.16 (0.11-0.20)	-0.08 (-0.14 - -0.04)
Moderate	0.10 (0.07-0.14)	0.15 (0.09-0.20)	-0.04 (-0.11 - 0.02)	0.10 (0.07-0.14)	0.19 (0.14-0.24)	-0.09 (-0.15 - -0.03)
Mild	0.42 (0.32-0.52)	0.50 (0.42-0.59)	-0.08 (-0.20 - 0.05)	0.42 (0.32-0.52)	0.71 (0.59-0.82)	-0.28 (-0.43 - -0.12)
Duration of COPD exacerbations						
Severe	0.54 (0.32-0.76)	0.71 (0.43-1.00)	-0.18 (-0.56 - 0.16)	0.54 (0.32-0.76)	1.78 (1.24-2.32)	-1.25 (-1.97 - -0.76)
Moderate	0.13 (0.08-0.18)	0.20 (0.13-0.28)	-0.08 (-0.18 - 0.00)	0.13 (0.08-0.18)	0.28 (0.21-0.35)	-0.16 (-0.24 - -0.08)
Episodes of COPD exacerbations						
Number	0.34 (0.28-0.41)	0.46 (0.40-0.53)	-0.12 (-0.20 - -0.03)	0.34 (0.28-0.41)	0.64 (0.57-0.72)	-0.30 (-0.40 - -0.20)
Duration	2.87 (1.71-4.03)	2.69 (1.93-3.45)	0.18 (-0.06 - 1.80)	2.87 (1.71-4.03)	4.79 (3.56-6.02)	-1.92 (-3.56 - -0.08)
Healthcare Costs (CAD\$, 2020 constant dollars)						
Cost of COPD exacerbations						
Hospitalizations	\$518 (308-728)	\$602 (332-872)	-\$58 (-469-239)	\$518 (308-728)	\$1568 (958-2177)	-\$1049 (-1878 - -557)
ED visits	\$41 (26-57)	\$58 (37-78)	-\$16 (-45-7)	\$41 (26-57)	\$75 (55-95)	-\$33 (-59 - -8)
GP visits	\$52 (43-60)	\$61 (52-70)	-\$9 (-21-4)	\$52 (43-60)	\$75 (61-88)	-\$23 (-39 - -7)
Specialist visits	\$52 (40-63)	\$62 (49-76)	-\$10 (-29-5)	\$52 (40-63)	\$118 (97-140)	-\$66 (-94 - -44)
Medication drugs	\$27 (23-32)	\$29 (25-34)	-\$2 (-8-4)	\$27 (23-32)	\$35 (30-40)	\$8 (-14 - -1)
Total healthcare costs (all health conditions)	\$10,549 (9255-11841)	\$8841 (7620-10060)	\$ 1707 (-135-3459)	\$10,549 (9255-11,841)	\$10,677 (9166-12,188)	-\$128 (-2078-1771)

Abbreviations: CAD\$, Canadian dollars; CI, confidence interval; COPD, chronic obstructive pulmonary disease; ED, emergency department; GP, general practitioner.
^aThe 95% CIs associated with the differences in group means were calculated using the bias-corrected and accelerated (BCa) bootstrapping method with 3000 replications.

Table 5. Cost of developing and maintaining COPD clinical pathway, annualized.

ITEM	COSTS (CAD\$, 2020 CONSTANT DOLLARS)
Patient recruitment	\$58 241
Personnel	\$1 331 045
Equipment & Materials	\$99 422
Facility Rental & Transportation	\$10 160
Total annual cost	\$1 498 870
Patients served	1009
Annual cost per patient	\$1485

Abbreviations: CAD\$, Canadian dollars; COPD, chronic obstructive pulmonary disease.

account. However, hospitalization, which was the major component, was based on a standard methodology developed by the CIHI to reflect variations in resource utilization.

Conclusion

Patients enrolled in the clinical pathway had lower risks and frequencies of moderate and severe COPD exacerbations and incurred similar average annual healthcare costs when compared to patients in the historical control group. Patients in the clinical pathway had about the same risks of moderate and severe exacerbations, but marginally higher average annual healthcare costs when compared to patients in the contemporaneous control group. The COPD clinical pathway provides more clinical benefits at comparable costs when compared to patients under usual care, but only slightly better clinical benefits and at a marginally higher cost when compared to patients possibly under other effective programs of care.

Acknowledgements

The author is also grateful to Beliz Acan Osman for providing technical expertise in the use of administrative health data housed at the Saskatchewan Health Quality Council. This study is based in part on de-identified data provided by the Saskatchewan Ministry of Health, eHealth Saskatchewan, and Saskatchewan Health Authority. The interpretations and conclusions contained herein do not necessarily represent those of the Government of Saskatchewan, Saskatchewan Ministry of Health, eHealth Saskatchewan, or Saskatchewan Health Authority

Author Contributions

All authors have made substantial contributions to the conceptualization and design of the study; or the acquisition of data, analysis of data, or interpretation of results. All authors have substantially contributed to drafting the manuscript or revising it critically for important intellectual content. All authors have given their approval for the final version to be published in this journal.

Data Access

All data used for this study are stored in a de-identified database in a secure environment at the Saskatchewan Health Quality Council. The data sets are not publicly available but can be accessed through an approval process instituted by the data custodians.

Ethics Standards

The study protocol was reviewed and approved by the Saskatchewan Health Authority Research Ethics Board (REB-20-69).

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Appendix

Table A1. COPD care pathway program cost.

RESOURCE/ITEM	COST	NOTES ON COST CALCULATION
Patient Recruitment		
Diagnostic testing—Spirometry	\$41 318.55	Cost of full (\$40.95) spirometry test per patient ^a
Recruitment materials (posters, VBI cards, etc.)	\$399.09	VBI cards—\$195.50 + COPD posters—\$203.59
Spirometry Interpretation Training	\$16 523.91	Funded by a mix of public and private sector partners
Personnel^b		
Respiratory Educator	\$513 534.11	4 FTEs @ \$39.674 per hour and 1 FTE @ \$42.848 per hour.
Social workers	\$634.34	14 * 1 hour lecture @ \$45.31
Clerical/administrative	\$226 262.40	CUPE Office Administrative Assistant @ \$22.20 per hour.
CDPM manager	\$114 653.88	OOS pay band 5 step 6.
Exercise therapist	\$162 023.50	0.5 FTE @ \$44.595 per hour and 1 FTE @ \$41.291 per hour.
Dietitian	\$132 975.02	1 FTE @ \$52.188 per hour.
LPNs	\$92 976.52	1 FTE @ \$36.49 per hour.
Pharmacist	\$871.21	14 * 1-hour lecture @ \$62.229
FIM leader	\$585.94	14 * 1-hour lecture training all staff over 2 d sessions
Smoking Cessation Counsellor	\$871.21	14 * 1-hour lecture @ \$62.229
Mental Health Counsellors	\$1214.36	28 * 1-hour lecture @ \$43.37
Patients & Family Advisors (PFAs)	\$437.54	50 h between 12 PFAs
SHC RN	\$35 712.77	
SHC Paramedic	\$23 668.12	
Certified Respiratory Educator Course	\$24 625.00	17*\$625 (COPD) +6*\$1875 (CRE) +5*\$550 (Spirotrec)
Equipment & Materials		
Spiro kits	\$9147.88	10 new equipment @ \$73 183.00 (flow sensors, calibration syringes, software and online support, network software, offline mode software) depreciated over 8 years ^c

(Continued)

Table A1. (Continued)

RESOURCE/ITEM	COST	NOTES ON COST CALCULATION
Exercise bands	\$11 300.70	
Projectors	\$5306.00	
Sat monitors	\$62000.00	1000 sat monitors given to patients who have oxygen concerns
Portable concentrators	\$6963.47	8 portable concentrators with power cartridge and desktop chargers @ \$34 817.36, depreciate over 5 years ^d
High flow pressure regulators	\$1080.00	12 high flow pressure regulators @ \$90 each
Blood pressure cuffs	\$679.40	8 BP (\$69.95*8) @ \$559.60 and 4 CI cuffs (\$29.95*4) @ \$119.80
Bosch kits	\$517.32	
Dollys	\$359.97	3 dollys (3*\$119.99)
In check flowmeters plus mouth pieces	\$1780.00	
Bluetooth speakers for rehab	\$287.30	
Facility Rental & Transportation		
Facility rental—Fieldhouse	\$8460.69	Cost of space rented for COPD rehab program
Transportation provided to patients	\$1700.00	Round trip taxi vouchers provided to patients in need of transportation
Total annual cost	\$1 498 870.20	
Patients served	1009	
Annual cost per patient	\$1485.50	

^aPayment Schedule for Insured Services Provided by a Physician. Available at <https://www.ehealthsask.ca/services/resources/Resources/physician-payment-schedule-oct-17.pdf>

^bAll salaries are marked up with a 22.5% for benefits and other costs to the employer. Collective Agreement available at https://www.saho.ca/__media_downloads/HSAS-SAHO-Collective-Bargaining-Agreement-April-2018-to-March-2024-2021-05-25.pdf.

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