

Sustainability of the Achieving Clinical Audits with Electronic Records (ACAER) Asthma and COPD Quality Improvement Program on Patient Outcomes

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Study

Planned

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/1000000426>

EU PAS number

EUPAS1000000426

Study ID

1000000426

DARWIN EU® study

No

Study countries

☐ Australia

Study description

This project focuses on preventing high cost/high burden respiratory events through the harnessing, coordination, dissemination and scaling up of an evidence-based clinical audit model (ACAER Quality improvement program) into general practice. It aligns with national strategies for quality improvement in general practice, hence utilised current general practice infrastructure.

The real-world effectiveness and sustainability of the ACAER QI program in supporting primary care providers in quality improvement initiatives across asthma and COPD care was assessed. Impact was evaluated based on changes in maintenance treatment and exacerbation rates.

Study status

Planned

Research institutions and networks

Institutions

Optimum Patient Care Australia

☐ Australia

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Institution

Not-for-profit

Networks

Optimum Patient Care (OPC) Network

☐ United Kingdom (Northern Ireland)

First published: 26/09/2015

Last updated: 14/08/2024

Network

ENCePP partner

Respiratory Effectiveness Group (REG)

☐ Belgium

☐ Denmark

☐ France

☐ Germany

☐ Greece

☐ Hungary

☐ Italy

☐ Netherlands

☐ Spain

☐ Sweden

☐ United Kingdom

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Study timelines

Date when funding contract was signed

Planned: 18/11/2020

Study start date

Planned: 26/05/2021

Date of final study report

Planned: 08/01/2024

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Funding for this study was partially provided by Optimum Patient Care Australia and GlaxoSmithKline (GSK).

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Study design:

This was an observational cohort study that audited data from the Optimum Patient Care Research Database Australia (OPCRDA).

Main study objective:

The objective was to assess the real-world effectiveness and sustainability of the ACAER program in supporting primary care providers in quality improvement initiatives across asthma and COPD care. Impact was evaluated based on changes in maintenance treatment and exacerbation rates.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Asthma

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

The study population included individuals aged ≥ 12 years with a documented diagnosis of asthma or COPD, receiving asthma or COPD therapy and at high risk of exacerbation and hospitalization. Data were derived from routine primary care electronic medical records (EMR) within the Optimum Patient Care Research Database Australia (OPCRDA).

Age groups

Adolescents (12 to < 18 years)

Adult and elderly population (≥ 18 years)

Elderly (≥ 65 years)

Estimated number of subjects

14000

Study design details

Setting

For the purposes of our study, patient data was collected from primary care only, from 21 practices across 5 Australian states or territories, Queensland (8), New South Wales (9), Australian Capital Territory (1), Victoria (1) and South Australia (2) who participated in the ACAER asthma and COPD audit.

Individuals aged ≥ 12 years with a documented diagnosis of asthma or COPD and who had received asthma or COPD therapy in the last 2 years were selected to receive an intervention, which consisted of linked patient questionnaires that were completed as part of practice audits and quality improvement. Eligible patients were sent the questionnaire and then followed up via the OPCRDA utilizing their EMR data.

For inclusion in this evaluation period, patients were required to have clinical indicators associated with a high risk of exacerbation and hospitalization: one or more exacerbations in the 2 years prior to the index date (the date the questionnaire was sent). They were also required to be active patients at their original practice at the time of the 12-month review. Patients were defined as being 'active' if they had at least one documented primary care consultation in a given year, or subsequent year.

Outcomes

The primary study outcomes included the changes in maintenance inhaled asthma and COPD treatment and the rate of exacerbations. Exacerbation rate was calculated from exacerbations recorded in the EMR, and did not include those reported by the patient. Patients were followed up for exacerbations throughout the evaluation period, from 2018 to 2024. A change in therapy was defined as any change in asthma or COPD medication (ICS, LABA, LAMA and combinations), doses or device types (DPI, MDI) in the first 12 months post-intervention (i.e. from the index date) versus the most recent therapy received in the 12 months pre-intervention. Any changes in therapy in the 2-, 3-, 4- and 5-years post-intervention were also recorded.

Data analysis plan

Statistical analysis will be performed using Stata statistical software (version 15.1). The characteristics of the study population will be described by age, gender and body mass index (BMI), stratified by COPD, asthma and high-risk asthma status.

For both high-risk asthma and COPD patients, mean exacerbation rates (per

1000) pre- and post-intervention with confidence intervals will be described. Exacerbation rates (per 1000 population) will be plotted by month from 2018 to 2024 using fitted linear regression lines to evaluate trends pre- and post-intervention. As the intervention date varied between individuals, pre-intervention trend lines will be plotted from Jan 2018 to Sep 2019 and post-intervention trend lines from May 2021 to Sep 2024 when most patients (92% for both severe asthma and COPD cohorts) will have received the intervention. The analyses will be repeated to report the exacerbations by year. To assess whether the intervention had prompted a change in maintenance therapy, the proportion of patients that changed therapy (and exact binomial 95% confidence intervals) for each year post-intervention will be plotted, also stratifying by asthma/COPD status.

Summary results

7,512 patients with asthma and 6,526 COPD were evaluated in the program with EMR collection. A subset of 1,327 asthma patients and 629 COPD patients were classified as active and high-risk. Patient questionnaires and audit reports were sent out between 29 October 2019 and 21 September 2021, the intervention period. 58.4% of patients in the high-risk asthma population and 65.2% of patients in the high-risk COPD population had a maintenance therapy change in the first year post-intervention. Exacerbation rates fell after the intervention period in the high-risk asthma (66.2 to 29.6 per 1000) and COPD (118.8 to 89.8 per 1000) populations. High-risk asthma patients had increasing rates of exacerbations in the 2 years prior to the intervention period (linear trend: 1.86 exacerbations per 1000 per month [0.72,3.00]; $p=0.003$), which declined and remained stable after the intervention ($p=0.10$; up to 2024). Exacerbation rates for high-risk COPD patients were stable prior to the intervention period ($p=0.44$) but showed a marginal increase post-intervention (linear trend: 0.55 exacerbations per month [0.002,1.10]; $p=0.05$).

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database Australia (OPCRDA)

Data sources (types)

[Disease registry](#)

[Electronic healthcare records \(EHR\)](#)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown