Twenty years of COPD primary care: Patterns of management of high-risk COPD and opportunities for optimising care in the United Kingdom 2000-2019: Study Protocol (CONQUEST UK Opportunity Analysis)

First published: 19/10/2021

Last updated: 21/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS43721

Study ID

48476

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

The main aim for this “Opportunity Analysis” is to assess the management of patients with modifiable high-risk COPD over 20 years in UK primary care and describe opportunities for treatment optimisation in line with the Quality Standards, over this period. The analysis will focus specifically on patients in whom this risk is modifiable, i.e. whose treatment can be optimised as described above. The objectives per quality standards are: 1. Assess whether undiagnosed patients who potentially have modifiable high-risk COPD are actively and promptly identified in UK primary care. 2. Assess whether modifiable high-risk patients with newly diagnosed COPD receive a proper assessment and quantification of future risk of exacerbations and cardiac events within 12 months of diagnosis. 3. Assess whether pharmaceutical and non-pharmacological therapy is provided to patients with modifiable high-risk COPD within 12 months of meeting criteria for modifiable high-risk COPD. 4. Assess whether modifiable high-risk patients diagnosed with COPD are followed up appropriately over a 12m period following baseline assessment 5. (Exploratory) To compare the management of COPD patients in different socio-demographic categories (including age and gender), using key selected indicators from each objective above (1-4). These objectives will be applied:- i) To all patients fitting criteria in years 2014-2019 combined, to assess current management, and ii) Separately in each year between 2000 and 2019 to assess changing trends in COPD management over time.

Study status

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2020

Actual: 01/07/2020

Study start date
Planned: 02/08/2020

Actual: 02/08/2020

Data analysis start date
Planned: 09/09/2021

Actual: 09/09/2021

Date of final study report
Planned: 30/06/2022

Actual: 30/06/2022

Sources of funding

- Non-for-profit organisation (e.g. charity)
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, Observational and Pragmatic Research Institute Pte Ltd

Study protocol

OPCG-1801_CONQUESTUK Opportunity Analysis Document_V0.9.4_20210520 FINAL.pdf (825.01 KB)

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:

Secondary use of data

Main study objective:

To describe real-world UK practice in COPD care over the period 2000-2019 in the light of carefully developed Quality Standards (QS), in patient populations with modifiable high-risk COPD which is either diagnosed or undiagnosed.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, longitudinal descriptive study

Study drug and medical condition

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

The study involved active (alive, have not left practice) patients aged 40 years or older diagnosed with COPD, undiagnosed patients with a smoking history that suggests potential COPD and patients who are at high- risk for future exacerbations identified between 2000 and 2019 from the Optimum Patient Care Research Database (OPCRD).

Inclusion criteria:

• Age 40 or older

• High risk criteria for exacerbation: 2 or more moderate or 1 or more severe exacerbation in the baseline period

Alive and no deregistration/leaving database. In addition, patients will be categorized as:

1. Undiagnosed patients with potential COPD

• Patients without a COPD diagnosis code ever in their electronic record prior to

the index date (1st January) in that year
• And Current or ex-smoker with either 10 years smoking duration or 10 pack years
2. Patients newly diagnosed with COPD since baseline
• Patients where the first record of a COPD diagnosis occurs within the 12-month baseline period (prior to the index date).
3. COPD already diagnosed
• Patients diagnosed with COPD at any point in their history before the baseline period preceding index date

Exclusion criteria:
• Patients with indicator of active asthma: a clinical asthma consultation code in 12m before index date • Patients with diagnoses suggesting conflicting morbidities requiring a more holistic complex management approach:
a) Other significant lung disease which is being actively managed
b) Active cancer (except non-invasive skin cancer)
• Undiagnosed patients only: No previous diagnostic assessment for COPD in the year prior to the baseline year. That is, patients with any of below recorded in the year prior to the start of the baseline period.
a) Spirometry performed - EMR codes (FEV1, FVC, FEV1/FVC)

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients with chronic obstructive pulmonary disease

Estimated number of subjects

49000

Study design details

Outcomes

Assessment of: active identification of undiagnosed patients with potential modifiable high-risk (MHR) COPD, disease & quantification of future risk in newly diagnosed patients, appropriate pharmacological and non-pharmacological therapy provision in newly-diagnosed patients and already-diagnosed patients, whether MHR COPD patients are followed up appropriately over a 12m period after index date. To examine associations of (2015-2019) quality of COPD care by patient types, using key indicators under QS objectives 1-4.

Data analysis plan

Descriptive analyses will be performed on the characteristics of high-risk patients and of medical management of COPD in each patients group (undiagnosed, newly-diagnosed, already diagnosed). All summary statistics will be presented as percentages with counts (categorical variables) and mean/medians with standard deviation/interquartile ranges for normally and non-normally distributed continuous variables respectively. The yearly trends in UK practice in COPD care over time will be described for a set of characteristics. Data illustrating current treatment practices (2000-2019) will be initially described in tables, and graphs will be produced to show the trends for key

outcomes longitudinally over the 20-year assessment period. We will develop univariate & multivariate linear & logistic regression models to calculate influence of patient and practice variables on study outcomes. These trends will be analysed to show whether the characteristics have shown to change over time.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Optimum Patient Care Research Database

Data sources (types)

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

No