

# Using real-life patient records to help identify predictors of future exacerbation risk (Asthma risk predictors)

**First published:** 14/11/2013

**Last updated:** 01/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS4869

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### Study ID

26292


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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### Study description

Background: Increased understanding of exacerbation patterns and the individual and clusters of risk factors associated with them could help to define 'frequent exacerbators' more meaningfully (e.g. as a persistent group of patients at the high end of the control continuum, or a dynamic group population made up of patients experiencing disease phases during which their exacerbation risk is elevated due to specific triggers). Improved understanding of the relationships between patient characteristics and frequent exacerbation risk will help to inform the development of new assessment tools, treatment strategies and interventions aimed at reducing the significant morbidity (and cost) associated with asthma exacerbations. This study aims to identify patient characteristics recorded within routine primary care datasets that are associated with increased risk of frequent asthma exacerbations, with the ultimate goal of:

1. Characterising the frequent exacerbator subgroup of asthma patients
2. Identifying individual risk factors associated with increased future exacerbation risk
3. Exploring clusters of risk factors associated with increased risk of future exacerbation risk.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions












#### Research in Real Life

**First published:** 01/02/2024

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## Networks

### Respiratory Effectiveness Group (REG)

-  Belgium
-  Denmark
-  France
-  Germany
-  Greece
-  Hungary
-  Italy
-  Netherlands
-  Spain
-  Sweden
-  United Kingdom

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Network

ENCePP partner

## Contact details

### Study institution contact

Kathryn Richardson [dprice@opri.sg](mailto:dprice@opri.sg)

**Study contact**

[dprice@opri.sg](mailto:dprice@opri.sg)

**Primary lead investigator**

Kathryn Richardson

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 08/10/2013

Actual: 02/12/2013

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**Study start date**

Planned: 06/01/2014

Actual: 06/01/2014

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**Date of final study report**

Planned: 30/04/2014

Actual: 31/12/2014

## Sources of funding

- Other

## More details on funding

Respiratory Effectiveness Group (REG), Research in Real Life Ltd

# Study protocol

[Asthma risk characterisation\\_REG study proposal\\_12Nov13.pdf](#) (1.8 MB)

## Regulatory

**Was the study required by a regulatory body?**

No

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

Not applicable

## Methodological aspects

### Study type

#### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

**Main study objective:**

To identify patient characteristics recorded within routine primary care datasets that are associated with increased risk of frequent asthma exacerbations with a view to building a risk assessment model to "Score" patients in terms of their future exacerbation risk.

## Study Design

**Non-interventional study design**

Cohort

Cross-sectional

## Study drug and medical condition

**Medical condition to be studied**

Asthma

## Population studied

**Short description of the study population**

Patients aged 12-80 years who have physician diagnosed asthma and  $\geq 3$  years of continuous medical records.

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**Age groups**

- Adolescents (12 to < 18 years)

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
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## **Special population of interest**

Other

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## **Special population of interest, other**

Asthma patients

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## **Estimated number of subjects**

50000

# Study design details

## **Outcomes**

Co-primary outcomes: • Moderate-to-severe exacerbations: based on the ATS/ERS taskforce definition, any of:(i) Asthma-related: a. Hospitalisations (inpatient admissions) OR b. A&E attendance OR(ii) Use of acute oral steroids • Clinical exacerbations: As above, but including asthma-related out-patient-department attendance and antibiotics for lower respiratory tract infections. Disaggregate components of exacerbation definitions: • Oral steroid prescriptions • Hospitalisations for asthma or lower respiratory conditions • A&E attendance for asthma or lower respiratory conditions • Antibiotic prescriptions for lower respiratory tract infections (LRTIs)

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## **Data analysis plan**

Phase 1. Autocorrelation plots will be examined to assess seasonality and time-dependent relationships in the rate of exacerbations as described in the

methods section. Phase 2 & 3. Univariate (phase 2) and multivariate (phase 3) associations will be estimated using: (i) Negative binomial regression models: will be used to determine predictors of future risk in terms of severe exacerbation rates over subsequent 1 & 2 yrs. (ii) Ordinal logistic regression models: will be used when annual exacerbations are categorised 0, 1 and  $\geq 2$ . (iii) Logistic regression models: will be used when severe exacerbations is defined as a binary outcome. Here, population attributable risks will be estimated to provide an estimation of the proportion of "frequent exacerbation" trait that is explained by each statistically significant factor in the multivariate models. Phase 4. Hierarchical multi-level modelling will be used to estimate associations with exacerbation rates.

## 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), other**

Optimum Patient Care Research Database (OPCRD)

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### **Data sources (types)**

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

### **Data sources (types), other**

Prospective patient-based data collection, The Optimum Patient Care Research Database (OPCRD). OPCRD contains all records from primary care practices in the UK who subscribe to the Optimum Patient Care (OPC) respiratory review. The dataset consists of both routine primary care electronic patient records + patient-reported questionnaire data (for a subset of patients who completed disease-specific questionnaires as part of the review).

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

## **Data characterisation conducted**

Unknown