# A prediction model for future exacerbation risk in children

**First published:** 24/02/2017

**Last updated:** 08/08/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS17985

**Study ID**

31045

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

Asthma attacks in children are common and result in considerable morbidity and occasionally mortality. Additionally, childhood asthma attacks may adversely affect their education, their parents economic productivity and

always incur costs to the healthcare system. Remarkably little is understood about factors which predict childhood asthma attacks and much of what is known is derived from relatively small clinical trials in countries other than the UK and the results may not be generalisable. The present analysis will use routinely acquired data collected in primary care in the UK to identify factors associated with asthma attacks in children. Predictive variables will include demographics (the child's age and sex), asthma characteristics (severity, control and past attacks) and physiological measurements (obesity, lung function and blood eosinophil count). Blood and airway eosinophilia are both risk factors for asthma attacks in adults and whilst the latter would be preferable, this is not routinely collected whereas blood eosinophil count is often measured and is used in this analysis.

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**Study status**

Finalised

## Research institutions and networks

### 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

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Study contact

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### Primary lead investigator

Steve Turner

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 03/02/2017

Actual: 03/02/2014

### Study start date

Planned: 24/02/2017

Actual: 24/02/2014

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**Date of final study report**

Planned: 28/04/2017

Actual: 23/09/2014

## Sources of funding

- Other

## More details on funding

Respiratory Effectiveness Group

## Study protocol

REG Study Protocol_Future Risk of Asthma Exacerbations_FINAL.pdf (434.4 KB)

## 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:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The aim of this study is to create a tool to predict which paediatric patients are at risk of future exacerbation.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Asthma

## Population studied

**Short description of the study population**

Patients with following criteria were included:

• Valid blood eosinophil count expressed as a numeric value ≤5000 blood eosinophils/µl, recorded at least 1 year prior to the end of available data

• Aged 5-12 years at date of last valid blood eosinophil count

• An asthma diagnosis (at any time)

• 2 years of continuous data (one year pre/ one year post date of last valid blood eosinophil count).

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**Age groups**

- Children (2 to < 12 years)
- Adolescents (12 to < 18 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**

5.000

## Study design details

**Outcomes**

1. Exacerbations:An exacerbation is defined as the occurance of the following: • Respiratory-related hospital attendance / admission AND/OR• Respiratory-related A&E attendance AND/OR• An acute oral corticosteroids course, 2. Blood

eosinophil count3. Percent Predicted Peak Flow 4. Number of GP consults for lower respiratory tract infections5. Acute oral steroid usage6. Hospital in-patient admissions

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**Data analysis plan**

Univariable logistic regression models will be used to identify baseline measures of disease severity, patient demographics and comorbidities predictive of future exacerbations. The dichotomous variable indicating an exacerbation during the outcome period (YES/NO) will be used as the dependent variable with each measure of disease severity, patient demographic and comorbidity as an explanatory variable. Those variables which show an association ($p < 0.05$) with future exacerbation will be entered into a multivariable model and step-wise reduced to produce a final list of non-collinear predictors of one or more future exacerbations. Results will be presented as odds ratios (OR) with 95% confidence intervals (95% CI).

# 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)**

Clinical Practice Research Datalink

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**

Unknown