# Evaluation of Current Implementation of BTS/NICE Clinical Quality Standards In Community Acquired Pneumonia (CAP): A UK retrospective follow-up study

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## Administrative details

#### **PURI**

https://redirect.ema.europa.eu/resource/28668

#### **EU PAS number**

**EUPAS28667** 

#### Study ID

28668

## **DARWIN EU® study**

No

Study countries		
United Kingdom		

## **Study description**

CRB65 scores have been recommended for assessing the severity of CAP and thereby determining clinical management, but it is not known how frequently these scores are used in primary care. This protocol aims to assess the use of CRB65 scores in UK primay care from 2009 to 206 using electronic medical records.

## **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**

Launders Naomi

Study contact

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## **Primary lead investigator**

Winchester Chris

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Actual: 05/01/2018

## Study start date

Actual: 16/07/2018

## Data analysis start date

Actual: 23/07/2018

## Date of final study report

Actual: 06/02/2019

# Sources of funding

Other

# More details on funding

Respiratory Effectiveness Group

# Study protocol

REG\_NICE Standards CAP Protocol\_v2\_Final.pdf(265.64 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 assess the degree to which CRB65 scores are utilised in primary care in the UK

# Study Design

## Non-interventional study design

Cross-sectional

# Study drug and medical condition

#### Medical condition to be studied

Community acquired infection

# Population studied

## Short description of the study population

The patient must meet the following criteria:

- Have a diagnostic (Read) code for Community Acquired Pneumonia (CAP) CAP
- Diagnosed with CAP between 1 January 2009 and 31 December 2016
- Have a minimum of 56 days continuous EMR:
- o ≥28 days immediately preceding the index date
- o ≥28 days immediately following the index date
- Aged 18 years or older at index date

## 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

Community Acquired Pneumonia (CAP) patients

#### **Estimated number of subjects**

3747

# Study design details

#### **Outcomes**

Primary outcomes are the proportion of CAP actively managed in primary care, the percentage of actively managed cases with CRB65 score recorded on the day of CAP diagnosis, and key characteristics of CAP management in primary care. Secondary outcomes are antibiotic prescription and duration on day of diagnosis, completeness of recording of components of CRB65 and annual trends in CRB65 reporting.

## **Data analysis plan**

This is a descriptive observational study. The number of patients/observations and percentage per category, mean plus standard deviation and median plus inter-quantile range will be given, as appropriate. Statistical tests (e.g. F-tests, t-tests, chi-squared tests) and models (e.g. linear models) will be used, as appropriate.

# Data management

## Data sources

#### Data source(s)

Optimum Patient Care Research Database

#### Data source(s), other

Optimum Patient Care Research Database (OPCRD)

#### 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