# Breathlessness Rapid Evaluation and THErapy (BREATHE)

**First published:** 27/02/2024

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Study   Ongoing

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/1000000018

**EU PAS number**

EUPAS1000000018

**Study ID**

1000000018

**DARWIN EU® study**

No

**Study countries**

☐ Australia

☐ United Kingdom

**Study description**

To develop an algorithm to predict the probability of different conditions relating to breathlessness based on demographic, presenting symptoms, observations, diagnostic test results and treatments. The aim of the algorithm is to optimise assessment pathway based on evidence and reduce the time taken for a patient to receive an accurate diagnosis of conditions causing their presenting breathlessness.

**Study status**

Ongoing

# Research institutions and networks

# Institutions

The George Institute for Global Health, UNSW Sydney

# Networks

Optimum Patient Care (OPC) Network

☐ United Kingdom (Northern Ireland)

**First published:** 26/09/2015

**Last updated:** 14/08/2024

Network    ENCePP partner

# Contact details

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# Study timelines

**Date when funding contract was signed**

Planned: 01/04/2023

Actual: 01/04/2023

**Study start date**

Planned: 01/12/2023

Actual: 26/01/2024

**Date of final study report**

Planned: 30/09/2024

# Sources of funding

- Other public funding (e.g. hospital or university)

## More details on funding

Australian Government Medical Research Future Fund (MRFF)

## Regulatory

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

No

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

Non-EU RMP only

# 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

Validation of study variables (exposure outcome covariate)

**Data collection methods:**

Secondary use of data

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**Study design:**

Predictive modelling study.

**Main study objective:**

To develop an algorithm to predict the probability of different conditions relating to breathlessness based on demographic, presenting symptoms, observations, diagnostic test results and treatments.

# Study Design

**Non-interventional study design**

Cohort

# Study drug and medical condition

**Medical condition to be studied**

Dyspnoea

Chronic obstructive pulmonary disease

Asthma

Interstitial lung disease

Ejection fraction decreased

Anxiety disorder

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**Additional medical condition(s)**

Heart Failure; Breathing Pattern Disorder; Dysfunctional Breathing; Obesity

# Population studied

**Short description of the study population**

People aged 18 years and over, presenting at General Practices with either breathlessness or a diagnosis of a condition that may present with breathlessness in the UK and Australia.

**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)

**Estimated number of subjects**

7000000

# Study design details

**Outcomes**

Upon reception of the data, a refined list of outcomes will be constructed based on sample size and prevalence within the data population. Causes of breathlessness to be modelled include:

1. Asthma

2. Chronic obstructive pulmonary disease

3. Lung cancer

4. Heart attack

5. Heart failure

6. Pneumonia

7. Pulmonary thrombo-embolism

8. COVID-19

9. Dysfunctional breathing

10. Deconditioning

11. Anxiety

## Data analysis plan

A Bayesian Network (BN) predictive model will be developed. The model development has three steps.

1. Structure learning: Structured learning will take place for the total data set in an expert informed iterative manner.

(i) a directed acyclic graph (DAG) model will be developed based on expert knowledge

(ii) a data driven DAG will be developed using different available BN algorithms Iterations between the expert driven and data driven DAGs will continue until a simple but biologically plausible form is developed.

Multiple BN algorithms will be explored including:

• constraint-based

• score-based and

• hybrid learning

2. Parameter learning: A conditional probability table will be calculated for each symptom in the model. Conditional probabilities of the presence or absence of each symptom will be calculated, based on the presence or absence of all other variables that the symptom is directly or indirectly connected within the DAG.

3. Validation and assessment of the algorithm: The algorithm will be validated:

(i) Internally by using 10-fold cross-validation

(ii) Externally by training the algorithm with data from one country and validate it on the data from another country. For instance, train the algorithm using Australian data (from NPS Medicine Insight) and validate it using Vietnamese data (VCAPS-1).

4. Then, the predictive performance of the algorithm will be assessed through discrimination using Area Under the ROC Curve

**Summary results**

The result would be a Bayesian Network predictive model to incorporate into a breathlessness electronic decision support system for primary care.

# Data management

# 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

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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**

No