# A description of the UK NHS hospital resource use and patient quality of life associated with hospitalisations for recurrent Clostridium difficile infection

**First published:** 25/04/2014

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Study Ongoing

## Administrative details

**EU PAS number**

EUPAS6413

**Study ID**

6414

**DARWIN EU® study**

No

**Study countries**

☐ United Kingdom

**Study description**

A multi-centre, non-interventional study to describe UK hospital resource use and quality of life (QoL) associated with hospitalisations for recurrent Clostridium difficile infection (CDI). Primary objective: to describe the cost of hospital resource use of patients with a CDI recurrence. Secondary objectives: to determine the number of days hospitalised for CDI recurrence, the cost of hospital resource between CDI episodes and to describe QoL of patients hospitalised for CDI. The study has two parts: 1) Retrospective collection of clinical/resource use data from medical records of patients who have had a first CDI episode and are hospitalised with a recurrence within 12 weeks of end of treatment of first episode (cases) or have not had a recurrence within 12 weeks (matched controls). 2) Prospective assessment of health-related QoL of patients hospitalised for CDI, through patient-completion of the EQ5D-3L questionnaire, with recording of demographic details from medical records.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Merck Sharp & Dohme LLC

United States

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

**Last updated:** 08/07/2025

**Institution** **Pharmaceutical company**

## Royal Free Hospital

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

**Last updated:** 01/02/2024

Institution

Leeds General Infirmary Leeds, UK, The Royal Free Hospital London, UK, Glasgow Royal Infirmary Glasgow, UK, Royal Sussex County Hospital Brighton, UK, Sunderland Royal Hospital Sunderland, UK, Manchester Royal Infirmary Manchester, UK

# Contact details


**Study institution contact**

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**Primary lead investigator**

Mark Wilcox

Primary lead investigator

# Study timelines

**Date when funding contract was signed**
Actual: 13/11/2012

**Study start date**
Actual: 23/09/2013

**Data analysis start date**
Planned: 30/06/2014

**Date of final study report**
Planned: 31/08/2014

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

# Regulatory

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

No

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Main study objective:**

To describe the cost of hospital resource use of patients with a recurrence of CDI

## Study Design

**Non-interventional study design**

Case-control

## Study drug and medical condition

**Medical condition to be studied**

Clostridium difficile infection

## Population studied

**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**

180

## Study design details

**Outcomes**

Difference in total hospital resource (£) (including prescribing, infection control measures, diagnostic tests, supplementary nutrition, multidisciplinary team review, stay per ward/side room) between patients with and without recurrent CDI hospitalisation and stratified for patients with a mild/moderate recurrence of CDI and for those with a severe recurrence of CDI. Difference in no. days hospitalised between patients with (cases) and without (controls) CDI recurrence, stratified by severity of recurrence, total hospital resource (£) for the period between first and recurrent CDI, stratified by severity of recurrence, mean EQ5D score for patients with CDI hospitalisations, overall and stratified by age/disease severity, patient/disease characteristics.

**Data analysis plan**

This study is designed to be descriptive of recurrent CDI overall and not to detect differences between different treatment regimens for CDI, although descriptive sub-group analyses will be conducted according to patient and disease characteristics. Both distributions and descriptive statistics of both central tendency (medians and arithmetic or geometric means) and dispersion (standard deviation, interquartile range) will be presented for quantitative variables. Nominal variables will be described with frequencies, percentages and modes, while ordinal variables will also have medians and interquartile ranges described.

## 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 sources (types)**

Other

**Data sources (types), other**

Prospective patient-based data collection, Retrospective data collection from patients’ routine hospital medical records

# 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