# Evaluation of vaccination error cases with fatal outcome reported to EudraVigilance

**First published:** 15/08/2018

**Last updated:** 02/02/2019

Study Planned

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/27849

**EU PAS number**

EUPAS25265

**Study ID**

27849

**DARWIN EU® study**

No

**Study countries**

☐ Netherlands

**Study description**

This study will be a case-series analysis with the aim to review ICSRs reporting vaccination errors with fatal outcome as reported in EudraVigilance. Causality of the vaccine with regards to the fatal outcome will be assessed using the WHO tool for causality assessment of AEFI. The case review will be performed by two independent reviewers, who will also estimate the contribution of the vaccination error to the fatal outcome.

**Study status**

Planned

# Research institutions and networks

## Institutions

### Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

**First published:** 03/11/2022

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Institution | Educational Institution | ENCePP partner

### Medicines Evaluation Board Utrecht, Netherlands

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Christina Hoeve

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/12/2015

**Study start date**

Planned: 01/01/2001

**Date of final study report**

Planned: 30/06/2019

## Sources of funding

- Other

## More details on funding

Erasmus Medical Center

## Study protocol

Study protocol_Fatal vaccination errors_v3.2_20180815.pdf(673.3 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 type:**

Non-interventional study

**Scope of the study:**

Other

**If ‘other’, further details on the scope of the study**

Case review of spontaneous reporting data

**Main study objective:**

This study aims to review cases in Eudravigilance between 1 January 2001 and 31 December 2016 reporting vaccination errors with fatal outcome.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Case-series

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J07A) BACTERIAL VACCINES

BACTERIAL VACCINES

(J07B) VIRAL VACCINES

VIRAL VACCINES

(J07C) BACTERIAL AND VIRAL VACCINES, COMBINED

BACTERIAL AND VIRAL VACCINES, COMBINED

## Population studied

**Age groups**

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

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)

Adults (85 years and over)

**Estimated number of subjects**

0

## Study design details

**Outcomes**

Death

**Data analysis plan**

Cases are identified from EudraVigilance using the Standard MedDRA Query for medication errors in combination with a reported vaccine and a fatal outcome. All cases received between 1 January 2001 and 31 December 2016 are included for the analysis. A causality assessement for death will be performed by two independednt reviewers using the AEFI causality assessment form of the WHO and an estimation of the impact of the error will be performed.

# Data management

## Data sources

**Data source(s), other**

EudraVigilance

**Data sources (types)**

Spontaneous reports of suspected adverse drug reactions

## 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