A non-interventional study of LAIV utilization to identify and characterize medication errors due to expired vaccine use in individuals 2-17 years of age in the CPRD

First published: 09/12/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11799

Study ID

28019

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This study is intended to provide data to identify and characterize the proportion of expired LAIV administrations during the past two influenza seasons (2013-2014, 2014-15) and to identify risk factors for this medication error. In addition, there is interest in quantifying the frequency distribution of days between expiration and vaccination date.

Study status

Finalised

Research institutions and networks

Institutions

Clinical Practice Research Datalink (CPRD)

United Kingdom

First published: 15/03/2010

Last updated: 17/01/2025

Institution **Laboratory/Research/Testing facility** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Robert Brody

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/11/2015

Actual: 06/11/2015

Study start date

Planned: 01/12/2015

Actual: 30/11/2015

Data analysis start date

Planned: 01/12/2015

Actual: 30/11/2015

Date of interim report, if expected

Actual: 30/12/2015

Date of final study report

Planned: 29/04/2016

Actual: 30/05/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

D2660R00002 CSP_05NOV2015.pdf(92.71 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:

Other

Study topic, other:

Medication errors, Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The overall aim for this study is to identify and characterize the proportion of LAIV administrations that used expired product during the two most recent influenza seasons and to identify risk factors that may be associated with administration of an expired dose of LAIV. In addition, there is interest in quantifying the frequency distribution of days between expiration and vaccination da

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective Database

Population studied

Short description of the study population

Children and adolescents who were administered LAIV from September 1 2013 to March 31 2014 and from September 1 2014 to March 31 2015, aged 2 through 17 years at the time of LAIV administration. All patients with LAIV administration during the influenza season with valid LAIV lot identifiers were included.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

134000

Study design details

Outcomes

To measure administrations of LAIV beyond the expiry date in individuals aged 2 through 17 years during the past two influenza seasons (September 2013 – March 2014 and September 2014 – March 2015) in the UK through use of the CPRD. To investigate risk factors that may be associated with administration of an expired dose of LAIV:• Time of administration: season and timing during the season• Population characteristics: age, gender, comorbidities, and region• Characteristics of physician practices in terms of size and geographic region To quantify the frequency distribution of days between dose expiration dates a

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Data analysis plan

The proportion of individuals receiving expired LAIV vaccine during each influenza season (September 2013 – March 2014 and September 2014 – March 2015) is defined as the number of children and adolescents receiving expired

vaccine during each season divided by the total number of children and adolescents with valid lot LAIV administrations during each influenza season. The proportion of individuals receiving expired vaccine and 95% CIs will be reported. Median intervals and measures of dispersion in days between vaccinations and vaccine expiration dates will also be described. With due attention to the seasonal time period of receiving an expired LAIV, the proportion of patients receiving expired LAIV as medication errors will be calculated by age group and by gender

Documents

Study publications

Caspard H, Wise RP, Steffey A, Brody RS. Incidence of live-attenuated influenza...

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

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

CPRD

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