

EVISA - Cross-Sectional Study on Adverse Events Linked to Ambulatory Care

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General

Identification

Detailed name Cross-Sectional Study on Adverse Events Linked to Ambulatory Care

Sign or acronym EVISA

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation ---

General Aspects

Medical area Emergency medicine

Keywords iatrogenesis, treatment-related adverse event, medical accidents and incidents, outpatient care, patient safety, nosocomial, health safety, risk

Scientific investigator(s) (Contact)

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Organization Comité de Coordination de l'Évaluation Clinique et de la Qualité en Aquitaine

Collaborations

Funding

Funding status

Public

Details

Directorate for Research, Studies, Evaluation and Statistics (DREES).

Governance of the database

Sponsor(s) or organisation(s) responsible

Directions Régionales des Affaires Sanitaires et Sociales (DRASS) Aquitaine

Organisation status

Public

Sponsor(s) or organisation(s) responsible

OMEDIT-Agence régionale de l'hospitalisation Aquitaine

Organisation status

Public

Additional contact

Main features

Type of database

Type of database

Study databases

Study databases (details)

Not-repeated cross-sectional studies (except case control studies)

Database recruitment is carried out by an intermediary

A selection of health institutions and services

Database recruitment is carried out as part of an interventional study

No

Additional information regarding sample selection.

Patient sample was formed from random selection with two stratification levels, in order to reflect diversity within institutions and disciplines (medicine, surgery), and elements where patient recruitment differs.

Database objective

Main objective

To estimate the frequency, severity and preventability of adverse events linked to ambulatory care, as well as investigate the context and contributing factors on the occurrence of these events and to estimate the hospital treatment

costs.

Inclusion criteria

- Male and female;
- Patients hospitalised in medical and surgical departments in short-stay healthcare institutions.

Population type

Age

- Adulthood (19 to 24 years)
- Adulthood (25 to 44 years)
- Adulthood (45 to 64 years)

Population covered

Sick population

Gender

- Male
- Woman

Geography area

National

Detail of the geography area

Metropolitan France (7 hospitals).

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)

2008

Size of the database

Size of the database (number of individuals)

< 500 individuals

Details of the number of individuals

47

Data

Database activity

Data collection completed

Type of data collected

Declarative data

Declarative data (detail)

Paper self-questionnaire

Details of collected declarative data

Detection and confirmation questionnaires developed from British Review Forms.

Presence of a biobank

No

Health parameters studied

- Health event/morbidity
- Health event/mortality

Procedures

Data collection method	Adverse events were detected by a physician in the surveyed department from a detection questionnaire.
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Classifications used	Data quality control was carried out in three stages:
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Quality procedure(s) used	<ul style="list-style-type: none">- The CCECQA (Coordination Committee for Clinical Evaluation and Quality in Aquitaine) carried out checks in institutions to verify proper data collection conduct, adherence to the method, as well as the completeness and quality of collected data.- Researchers and research associates coded questionnaires and checked for completeness and consistency.- All questionnaires were reviewed by CCECQA methodologists. Problematic records (unclear; inconsistent; complex clinical situation; episodes, causes or impact of an unusual event, etc.) were reviewed by a case review committee and, if required, by field experts.
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Participant monitoring	No
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Links to administrative sources	No
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Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge.
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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