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
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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.
Classifications used	Data quality control was carried out in three stages:
Quality procedure(s) used	- 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.
Participant monitoring	No
Links to administrative sources	No

Promotion and access

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