ENEIS - National survey on serious adverse events in hospitals

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General

Identification

Detailed name	National survey on serious adverse events in hospitals
Sign or acronym	ENEIS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Cnil : 1328615 ; CNIS : label n°2009X706SA Thématiques générales

General Aspects

Medical area	Study of allergies
Health determinants	Iatrogenic Medicine
Keywords	serious adverse events, patient safety

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Public

Details	Ministère de la santé - DREES
Governance of the database	
Sponsor(s) or organisation(s) responsible	Direction de la recherche, des études, de l'évaluation et des statistiques (DREES)
Organisation status	Public
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	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.	Sampling plan: Three-tier sampling 1st tier: picking of observation dates (window of observation) 2nd tier: picking of beds 3nd tier: picking of stays or fractions of stays observed over the period of observation.
Database objective	
Main objective	The survey's primary objective is to estimate the incidence of serious adverse events observed in hospitals and their avoidable character - for events resulting from admission in medicine and surgery units of health institutions or arising in such units during hospitalization. The secondary objectives are: 1) estimate the severity and avoidable portion of such events; 2) describe the immediate care-related causes of such events arising.
Inclusion criteria	All patient stays present during the survey in shortstay medicine and surgery units
Population type	
Age	Newborns (birth to 28 days)

	Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years) Adolescence (13 to 18 years) Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	Metropolitan France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2004
Date of last collection (YYYY or MM/YYYY)	2009

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	The purpose is to compile a minimum sample of 800 stays or fractions of stays in each of the analytical areas defined below. The analysis is conducted according to two main criteria: 1) the type of care unit: surgery or medicine 2) the type of care institution: regional or university teaching hospitals (CHU/CHR), other public and private not-for-profit institutions, private profitmaking institutions. This makes six analytical strata. In total, around 8,000 stays make up the sample. The sample allows for national estimations to be made.

Data

Database activity	Data collection completed
Type of data collected	Clinical data Administrative data

Clinical data (detail)	Direct physical measures
Administrative data (detail)	admission date, discharge date, age
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality

Procedures

Data collection method	External survey takers to the health institution collected the data over two stages During one week, an investigating nurse comes every two or three days to detect patients likely to present an adverse event from a grid of 17 detection criteria. This detection is carried out with the care manager and on the basis of the patient's record. One or two weeks afterwards, an investigating physician comes to the unit to confirm or invalidate the presence of an adverse event for the patients detected. Moreover, this physician assesses the avoidable character of the events that have occurred during hospitalization. To do this, s/he meets the patient's attending physician, with whom s/he also consults the patient's record.
Participant monitoring	No
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	http://www.drees.sante.gouv.fr/l-enquete-nationale-sur-les-evenements-indesirables-lies,6507.html

Access

Terms of data access (charter for data provision, format of data, availability delay)	The anonymized database can be made available to researchers subject to a justified request (examination by a scientific committee). The participating institutions are given feedback concerning them in December of the collection year.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only