EVADEF - Medico-Economic Evaluation of Automatic Implantable Defibrillator

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Last update : 09/05/2017 | Version : 2 | ID : 60142

General	
Identification	
Detailed name	Medico-Economic Evaluation of Automatic Implantable Defibrillator
Sign or acronym	EVADEF
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL
General Aspects	
Medical area	Cardiology
Keywords	psychological impact, Complications, death
Scientific investigator(s) (Contact)	
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Collaborations	
Funding	
Funding status	Public
Details	Ministère de la Santé (Soutien aux innovations diagnostiques et thérapeutiques coûteuses - STIC).
Governance of the database	
Sponsor(s) or organisation(s) responsible	Société Française de Cardiologie
Organisation status	Private
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
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.	Prospective. Inclusion cut-off date: 01/06/2005.
Database objective	
Main objective	To assess the cost of automatic implantable defibrillator usage in France. Secondary objective: - Complications associated with automatic implantable defibrillators; - To investigate cause- specific mortality in patients with automatic implantable defibrillators; - The psychological impact of automatic implantable defibrillators; - Incidence of appropriate and inappropriate therapies.
Inclusion criteria	All patients who received an automatic implantable defibrillator

Population type	
Age	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	22 centres throughout France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	06/2003
Date of last collection (YYYY or MM/YYYY)	2005
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	2418
Data	
Database activity	Data collection completed
Type of data collected	Declarative data
Declarative data (detail)	Paper self-questionnaire Face to face interview
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Data collection method	- Self-administered questionnaire: manual input

	from a paper questionnaire Interviews: input from a paper questionnaire Clinical examinations: handwritten Biological analysis: handwritten.
Participant monitoring	Yes
Details on monitoring of participants	Every 2 years
Links to administrative sources	No

Promotion and access	
Promotion	
Link to the document	http://tinyurl.com/Hal-EVADEF
Description	List of publications in HAL
Link to the document	<u>http://www.ncbi.nlm.nih.gov/pubmed/?</u> <u>term=%28Marijon+E[author]+OR+Le+Heuzey+JY[</u> <u>author]%29+AND+evadef</u>
Description	List of publications in Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Data may not be used by academic teams
Access to aggregated data	Access on specific project only
Access to individual data	No access