OMA - Evaluation of the management of acute otitis media in children aged ? 6 years in France

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General

Identification

Detailed name	Evaluation of the management of acute otitis media in children aged ? 6 years in France
Sign or acronym	OMA
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 770 334

General Aspects

Medical area	Infectious diseases
Others (details)	Acute otitis media
Keywords	epidemiology, care

Scientific investigator(s) (Contact)

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Unit	Laboratoire GSK

Collaborations

Funding

Funding status	Private
Details	GSK laboratory

Governance of the database

Sponsor(s) or organisation(s) responsible	Laboratoire GSK
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 care professionals A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Sending of an email presenting the study to all GPs and pediatricians in the Thalès network offering them to participate in the study. The Thalès network to date has 1,200 general practitioners and 100 pediatricians. ? Doctors interested in the study can identify themselves on the Internet website and confirm their participation agreement. A random drawing will then be done to recruit the necessary number of participating doctors. ? 1st phase: For a period of 15 days, the first children (3 on the average) consulting for an episode of AOM will be included in the study and will be followed.

Database objective

Main objective	Describe in general practice the care for AOM in children aged 0 to 6 years in France.
Inclusion criteria	? Child aged 0 to 6 years ? Child with an episode of AOM diagnosed by a doctor ? Parent(s)/tutor(s) who accept the inclusion of the child in the study

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)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2008
Date of last collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	439
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire
Presence of a biobank	No
Health parameters studied	Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	

Data collection method	Medical questionnaire, parent questionnaire, follow-up questionnaire
Participant monitoring	Yes
Details on monitoring of participants	Each child will be followed for 2 weeks (medical follow-up questionnaire and parent questionnaire). In the case of a relapse appearing in the week following the AOM episode, a follow-up questionnaire will be completed.
Links to administrative sources	No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Publications in progress
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only