

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.	<p>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.</p> <p>? Doctors interested in the study can identify themselves on the Internet website and confirm their participation agreement.</p> <p>A random drawing will then be done to recruit the necessary number of participating doctors.</p> <p>? 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.</p>
Database objective	
Main objective	Describe in general practice the care for AOM in children aged 0 to 6 years in France.
Inclusion criteria	<p>? Child aged 0 to 6 years</p> <p>? Child with an episode of AOM diagnosed by a doctor</p> <p>? Parent(s)/tutor(s) who accept the inclusion of the child in the study</p>
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