PRALINE - Measurement of the changes in acceptability of hepatitis B immunization among general practitioners and open-care paediatricians

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General

Identification

Detailed name	Measurement of the changes in acceptability of hepatitis B immunization among general practitioners and open-care paediatricians
Sign or acronym	PRALINE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL

General Aspects

Medical area	Immunology Infectious diseases
Pathology (details)	acceptability of the Hepatitis B vaccination, measuring vaccinal practices
Keywords	vaccine, vaccination practice

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)	Not-repeated cross-sectional studies (except case control studies)
Database recruitment is carried out by an intermediary	A selection of health care professionals An administrative base or a register
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	For each measurement time, a national representative sample of French general practitioners (liberal) and pediatricians (liberal and mixed exercise) will be formed through simple random sampling within a sampling frame of the CEGEDIM type
Database objective	
Main objective	Measure, in general and pediatric practices, the change in the acceptability of the vaccination against Hepatitis B for children aged 27 months and younger before the reimbursement of InfanrixHexa®, then during the three following years in France
Inclusion criteria	? Children from the eligibility registry subjected to the vaccinal policy by the investigator. This criterion will be evaluated using the declarations of the doctors, via 2 questions: 1. ""Have you followed the child since birth? If yes: date of the 1st consultation of the child. If no: did you follow the child the first 6 months? » 2. ""Are you the doctor in charge of vaccinating this child since birth? »

Population type	
Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
Population covered	General population
Gender	Male Woman
Geography area	National
Detail of the geography area	France

Data collection

Dates	
Date of first collection (YYYY or MM/YYYY)	2009
Date of last collection (YYYY or MM/YYYY)	2012

Size of the database	
Size of the database (number of individuals)	[10 000-20 000[individuals
Details of the number of individuals	928 practitioners 13920 infants

Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures
Declarative data (detail)	Paper self-questionnaire Phone interview
Presence of a biobank	No
Health parameters studied	Others
Other (detail)	Vaccination practice

Procedures	
Data collection method	The investigating doctor will complete the two eligibility registries. If the vaccination booklet is not available on the day of consultation, the doctor will ask the child's parent to provide the vaccination booklet in the next few days and will then finish filling in the vaccination data in the registry. If the vaccination booklet is not available on the day of consultation, the key information on the vaccination of the child will be completed using the patient's dossier of the doctor, noting the absence of the vaccination booklet.The acceptability questionnaire (paper CRF) will be administered to participating doctors by a clinical research associate, by telephone, during the installation of the center.The data will be collected in the eligibility registry for all of the patients aged 12 to 15 months and 24 to 27 months spontaneously consulting the investigator over the duration of the study
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)	Abstract and publications
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only