

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

Head :Leclerc-Zwirn Christel, Laboratoire GSK

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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)

Name of the director Leclerc-Zwirn

Surname Christel

Phone +33 (0)1 39 17 86 96

Email christel.c.leclerc-zwirn@gsk.com

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)
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Population covered	General population
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Gender	Male Woman
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Geography area	National
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Detail of the geography area	France
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2009
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Date of last collection (YYYY or MM/YYYY)	2012
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Size of the database

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

Database activity	Data collection completed
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Type of data collected	Clinical data Declarative data
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Clinical data (detail)	Direct physical measures
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Declarative data (detail)	Paper self-questionnaire Phone interview
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Presence of a biobank	No
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Health parameters studied	Others
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Other (detail)	Vaccination practice
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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
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Participant monitoring	No
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Links to administrative sources	No
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Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Abstract and publications
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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