

POPCORN - Measurement of the changes in hepatitis B immunization coverage in infants, and the acceptability thereof, before reimbursement, then during the three years after reimbursement of InfanrixHexa® in France, among the general population

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General

Identification

Detailed name	Measurement of the changes in hepatitis B immunization coverage in infants, and the acceptability thereof, before reimbursement, then during the three years after reimbursement of InfanrixHexa® in France, among the general population
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Sign or acronym	POPCORN
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	--
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General Aspects

Medical area	Infectious diseases
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Pathology (details)	Vaccine
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Keywords	infants, vaccine
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Scientific investigator(s) (Contact)

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Unit	Laboratoire GSK
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Collaborations

Funding

Funding status Private

Details Laboratoire GSK

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) Repeated cross-sectional studies (except case control studies)

Database recruitment is carried out by an intermediary A population file

Database recruitment is made on the basis of: Medication(s) taken

Database recruitment is carried out as part of an interventional study No

Additional information regarding sample selection. Set of patients aged 2 years or younger in the general French population. Study conducted in the general population that will cover samples of homes with children aged 27 months or less, selected via the quota method.

Database objective

Main objective Measure, in the general population, the variation in the proportion of infants (less than 27 months) vaccinated against hepatitis B according to the recommended plan between the initial measure and the measures repeated 1, 2 and 3 years after obtaining reimbursement of InfanrixHexa®

Inclusion criteria ? Child aged 12 to 15 months or 24 to 27 months included at the time of the study,
? For whom a parent or legal guardian accepts to respond to the interview,

? Resident of metropolitan France.

Population type

Age Infant (28 days to 2 years)
Early childhood (2 to 5 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) [1000-10 000[individuals

Details of the number of individuals 1200 every 4 years

Data

Database activity Data collection completed

Type of data collected Declarative data

Declarative data (detail) Face to face interview

Presence of a biobank No

Health parameters studied Health care consumption and services
Others

Care consumption (detail) Medicines consumption

Other (detail) Acceptability of a prevention measure by vaccination

Procedures

Data collection method	The interviews, face-to-face, will be conducted by survey takers who will have received training beforehand in the principles of sample surveys and in the specifics of this survey (in particular the vaccinal plan of the infant). They will go to the main domicile of the households. During the face-to-face interviews, the survey takers will perform the acceptability interviews with the parent in charge of the health of the children and then will proceed with taking information from the vaccinations booklet. In the event the vaccinations booklet is not accessible, the survey takers will suggest another time to return to the household. They will use the CAPI system (Computer Assisted Personal Interview) which allows for controlled key-entry of the data.
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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 (RICAI 2010) publication
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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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