

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
Sign or acronym	POPCORN
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	--
General Aspects	
Medical area	Infectious diseases
Pathology (details)	Vaccine
Keywords	infants, vaccine
Scientific investigator(s) (Contact)	
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Unit	Laboratoire GSK
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 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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