SPRIK - General practitioner/paediatrician-based surveillance to estimate the disease burden of rotavirus gastroenteritis in children <5 years of age in France

Head :Leclerc-Zwirn Christel, Laboratoire GSK

Last update : 01/01/2018 | Version : 1 | ID : 161

General	
Identification	
Detailed name	General practitioner/paediatrician-based surveillance to estimate the disease burden of rotavirus gastroenteritis in children <5 years of age in France
Sign or acronym	SPRIK
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL 770334
General Aspects	
Medical area	Infectious diseases
Keywords	general practice, rotavirus
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 institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Any child under the age of 5 years from the monitored population who spontaneously consulted an investigating center for a acute gastroenteritis (defined as the appearance of diarrhea in the 14 previous days) was included in a registry and the study was proposed to the parents of the child or to the child's legal tutors
Database objective	
Main objective	Estimate the incidence of RVGE leading to a consultation of a general practitioner or pediatrician in a monitored population of children under the age of 5 years.
Inclusion criteria	? Any child under the age of 5 years from the monitored population who spontaneously consults an investigating center for a acute gastroenteritis
Population type	
Age	Infant (28 days to 2 years) Early childhood (2 to 5 years)
Population covered	Sick population
Gender	Male

Geography areaInternationalDetail of the geography areaEuropeanData collectionEuropeanDatesDate of first collection (YYY or MMYYYY)2005Date of last collection (YYY or MMYYYY)2008Date of last collection (YYY or MMYYYY)2008Size of the database[1000-10 000[individualsSize of the database (number of individuals)1463Database activityData collection completedDatabase activityData collection completedType of data collectedClinical data Biological dataClinical data (detail)Direct physical measures Medical registrationPesence of a biobankNoHealth parameters studiedHealth event/morbidity Health care consumption and servicesCare consumption (detail)Hospitalization Medicines consumptionProceduresEligibility questionnaire; verification of the eligibility criterion, characteristics of the episode		Woman
Data collectionDatesDate of first collection (YYY or MMYYYY)2005Date of last collection (YYY or MMYYYY)2008Size of the database2008Size of the database (number of Individuals)1400-10 000[individualsDetails of the number of Individuals1463Data base activityData collection completedType of data collectedClinical data Biological dataClinical data (detail)Direct physical measures Medical registrationDeclarative data (detail)Stool sample. Analysis of the presence of rotavirus Health parameters studiedHealth parameters studiedHealth event/morbidity Health care consumption and servicesCare consumption (detail)Displaitization Medicines consumptionProceduresLingibility questionnaire: verification of the eligibility	Geography area	International
DatesDate of first collection (YYY or MM/YYY)2005Date of last collection (YYY or MM/YYY)2008Size of the database2008Size of the database (number of individuals)1403-000[individualsDetails of the number of ndividuals1463Data of the number of petails of the number of individualsData collection completedData base activityData collection completedType of data collectedClinical data Declarative data Biological dataClinical data (detail)Direct physical measures Medical registrationPoecharative data (detail)Stool sample. Analysis of the presence of rotavirus Phone interviewRiological data (detail)NoHealth parameters studiedHealth event/morbidity Health care consumption and servicesCare consumption (detail)Hospitalization Medicines consumptionPoecduresLingibility questionnaire: verification of the eligibility	Detail of the geography area	European
Date of first collection (YYYY or MMYYYY)2005Date of last collection (YYYY or MMYYYY)2008Size of the database1000-10 000[individualsSize of the database (number of Individuals)1463Details of the number of ndividuals1463Data of the number of IndividualsData collection completedDatabase activityData collection completedType of data collectedClinical data Declarative data Biological dataClinical data (detail)Direct physical measures Medical registrationPesence of a biobankNoHealth parameters studiedHealth event/morbidity Health care consumption and servicesCare consumption (detail)Biospitalization Medicines consumptionPata collection methodEligibility questionnaire: verification of the eligibility	Data collection	
MM/YYYY)Date of last collection (YYYY or MM/YYYY)2008Size of the database1000-10 000[individualsSize of the database (number of individuals)1463Details of the number of individuals1463DataData collection completedDatabase activityData collection completedType of data collected Declarative data Biological dataClinical data Declarative data Biological dataClinical data (detail)Direct physical measures Medical registrationPesence of a biobankNoHealth parameters studied Medicines consumption and servicesCare consumption (detail)Hospitalization Medicines consumptionProceduresLigibility questionnaire: verification of the eligibility	Dates	
MMYYYYY) Size of the database Size of the database (number of individuals) Details of the number of individuals Details of the number of individuals Data Data Data Data collection completed Type of data collected Direct physical measures Medical registration Declarative data (detail) Direct physical measures Medical registration Posence of a biobank No Health parameters studied Health care consumption (detail) Pospitalization Medicines consumption and services Procedures Data collection method	•	2005
Size of the database (number of individuals)[1000-10 000[individuals]Details of the number of ndividuals1463DataDataDataData collection completedType of data collectedClinical data Declarative data Biological dataClinical data (detail)Direct physical measures Medical registrationDeclarative data (detail)Stool sample. Analysis of the presence of rotavirus Presence of a biobankHealth parameters studiedHealth event/morbidity Health care consumption and servicesCare consumption (detail)Sospitalization Medicines consumptionData collection methodEligibility questionnaire: verification of the eligibility		2008
individuals)Details of the number of individuals1463DataDataDatabase activityData collection completedType of data collectedClinical data Declarative data Biological dataClinical data (detail)Direct physical measures Medical registrationDeclarative data (detail)Paper self-questionnaire Phone interviewBiological data (detail)Stool sample. Analysis of the presence of rotavirus Presence of a biobankNoHealth event/morbidity Health care consumption and servicesCare consumption (detail)Hospitalization Medicines consumptionProceduresEligibility questionnaire: verification of the eligibility	Size of the database	
individuals Data Database activity Data collection completed Type of data collected Clinical data Declarative data Biological data Clinical data (detail) Direct physical measures Medical registration Declarative data (detail) Paper self-questionnaire Phone interview Biological data (detail) Stool sample. Analysis of the presence of rotavirus Presence of a biobank Health parameters studied Health event/morbidity Health care consumption and services Care consumption (detail) Hospitalization Medicines consumption and services Procedures Data collection method	•	[1000-10 000[individuals
Data base activityData collection completedType of data collectedClinical data Declarative data Biological dataClinical data (detail)Direct physical measures Medical registrationDeclarative data (detail)Paper self-questionnaire Phone interviewBiological data (detail)Stool sample. Analysis of the presence of rotavirus Presence of a biobankNoHealth parameters studiedHealth event/morbidity Health care consumption and servicesCare consumption (detail)Hospitalization Medicines consumptionProceduresEligibility questionnaire: verification of the eligibility		1463
Type of data collectedClinical data Declarative data Biological dataClinical data (detail)Direct physical measures Medical registrationDeclarative data (detail)Paper self-questionnaire Phone interviewBiological data (detail)Stool sample. Analysis of the presence of rotavirus Presence of a biobankNoHealth parameters studiedHealth event/morbidity Health care consumption and servicesCare consumption (detail)Hospitalization Medicines consumptionProceduresEligibility questionnaire: verification of the eligibility	Data	
Declarative data Biological dataClinical data (detail)Direct physical measures Medical registrationDeclarative data (detail)Paper self-questionnaire Phone interviewBiological data (detail)Stool sample. Analysis of the presence of rotavirus NoPresence of a biobankNoHealth parameters studiedHealth event/morbidity Health care consumption and servicesCare consumption (detail)Hospitalization Medicines consumptionProceduresEligibility questionnaire: verification of the eligibility	Database activity	Data collection completed
Medical registrationDeclarative data (detail)Paper self-questionnaire Phone interviewBiological data (detail)Stool sample. Analysis of the presence of rotavirus NoPresence of a biobankNoHealth parameters studiedHealth event/morbidity Health care consumption and servicesCare consumption (detail)Hospitalization Medicines consumptionProceduresEligibility questionnaire: verification of the eligibility	Type of data collected	Declarative data
Phone interviewBiological data (detail)Stool sample. Analysis of the presence of rotavirusPresence of a biobankNoHealth parameters studiedHealth event/morbidity Health care consumption and servicesCare consumption (detail)Hospitalization Medicines consumptionProceduresEligibility questionnaire: verification of the eligibility	Clinical data (detail)	
Presence of a biobankNoHealth parameters studiedHealth event/morbidity Health care consumption and servicesCare consumption (detail)Hospitalization Medicines consumptionProceduresEligibility questionnaire: verification of the eligibility	Declarative data (detail)	
Health parameters studiedHealth event/morbidity Health care consumption and servicesCare consumption (detail)Hospitalization Medicines consumptionProceduresEligibility questionnaire: verification of the eligibility	Biological data (detail)	Stool sample. Analysis of the presence of rotavirus
Health care consumption and servicesCare consumption (detail)Hospitalization Medicines consumptionProceduresEligibility questionnaire: verification of the eligibility	Presence of a biobank	No
Medicines consumption Procedures Data collection method Eligibility questionnaire: verification of the eligibility	Health parameters studied	
Data collection method Eligibility questionnaire: verification of the eligibility	Care consumption (detail)	
	Procedures	
	Data collection method	Eligibility questionnaire: verification of the eligibility criterion, characteristics of the episode

	ofgastroenteritis on the day of consultation Inclusion questionnaire: results of the samples with the Rotastrip® test, characteristic of thepatients included, diagnosis and care during the consultation, information on the childrenliving in the same household, antecedents and history of the children included, economicquestionnaire and characteristics of the episode of gastroenteritis before the consultation Telephone questionnaire: medical evaluation of the patients over the 14 days following theconsultation at the doctor's, information on the other children in the household suffering fromgastroenteritis, economic questionnaire Laboratory results: confirmation of the presence of rotavirus, genotyping of the samples
Participant monitoring	Yes
Details on monitoring of participants	14 days after release from the hospital
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.biomedcentral.com/1471-2431/12/58
Access	
Terms of data access (charter for data provision, format of data, availability delay)	abstract (RICAI 2008), publication in progress
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only