- Paris Registry of Congenital Malformations

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General

Identification

Detailed name	Paris Registry of Congenital Malformations
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	97010

General Aspects

Medical area	Rare diseases
Others (details)	congenital malformation, chromosomal defects, genetic syndromes
Keywords	congenital defects prenatal diagnosis

Scientific investigator(s) (Contact)

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Organization	Inserm

Collaborations

Funding

Funding status	Public
Details	Institut de veille sanitaire - InVS Institut national de

	la santé et de la recherche médicale - INSERM

Governance of the database

Sponsor(s) or organisation(s) responsible	InVS
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Inserm
Organisation status	Public

Additional contact

Main features

Type of database

Type of database	Morbidity registers
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.	Selection of subjects having the required inclusion criteria Several sources are used to identify cases: - AP-HP maternity wards - Private non-profit maternity wards - Clinics operating for profit (maternity wards) - Paris DDASS - Neonatology services - Versatile intensive care services - Pediatric SMUR (mobile emergency units) - Cytogenics services - Foetopathology services

Database objective

Main objective	1. Provide epidemiological surveillance of congenital defects in the Parisian population, with the objective of an alert faced with any teratogens from the environment (e.g.: medication, industrial accident), and this, on a local, national and international scale. In the event of an abnormal change in the frequency of a defect, additional investigations are conducted, with a search for special risk factors, and also recording or recruiting bias that can result

	in a false alarm. 2. Assess in the population the impact of the health initiatives: - Evaluating the prenatal screening of malformations is a basic objective of the registry, and this even more so as this screening has developed substantially in France since the 1980s. - Evaluating preventive initiatives is also important, and especially that of the impact of the primary prevention policy of neural tube defects by periconceptional folic acid supplementation, implemented in France starting in the year 2000. 3. Conduct studies in collaboration with specialized clinical services, in particular for assessing in the population the future of children who carry certain incapacitating malformations. 4. Contribute to etiological research, in particular within the framework of collaborative and multi-center studies. This can entail case/control studies or cohorts set up for particular research questions.
Inclusion criteria	The Registry includes the cases of chromosomal anomalies and structural birth defects among live births, and the still-born (22 weeks of amenorrhea or more), as well as pregnancy terminations for fetal anomalies regardless of the gestational age at termination.
Population type	
Age	Newborns (birth to 28 days)
Population covered	Sick population
Gender	Male Woman
Geography area	Regional
French regions covered by the database	Île-de-France
Detail of the geography area	Paris and Petite Couronne (92, 93, 94)
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	1981
Date of last collection (YYYY or	2011

MM/YYYY)

Size of the database

Size of the database (number of individuals)	Greater than 20 000 individuals
Details of the number of individuals	1981-2008: more than 34 000 cases 2008 : 1409 cases

Data

Database activity	Data collection completed
Type of data collected	Clinical data Administrative data
Clinical data (detail)	Direct physical measures
Administrative data (detail)	Identification data: - Date of birth - Place of birth - Postal code (place of residence) Socio-demographic data: - Sex of the child - Age of the mother - Geographical origin of the parents - Parental occupation
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality

Procedures

Data collection method	active
Participant monitoring	No
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	http://www.u953.idf.inserm.fr/page.asp?page

Access

Terms of data access (charter for data provision, format of data, availability delay)	publications, reports, summaries - access to anonymous data is possible with a study protocol after approval by the Registry team and Inserm Unit 953
Access to aggregated data	Access on specific project only

Access to individual data	Access on specific project only