# - Paris Registry of Congenital Malformations

Head :Khoshnood Babak, U953

Last update : 01/16/2012 | Version : 1 | ID : 221

## 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)

| | |
|---|---|
| Name of the director | Khoshnood |
| Surname | Babak |
| Address | Inserm U953, Hôpital Saint Vincent de Paul, 75014 Paris |
| Phone | 01 42 34 55 87 |
| Email | babak.khoshnood@inserm.fr |
| Unit | U953 |
| 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<br>Several sources are used to identify cases:<br>- AP-HP maternity wards<br>- Private non-profit maternity wards<br>- Clinics operating for profit (maternity wards)<br>- Paris DDASS<br>- Neonatology services<br>- Versatile intensive care services<br>- Pediatric SMUR (mobile emergency units)<br>- Cytogenics services<br>- 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.<br>2. Assess in the population the impact of the health initiatives:<br>- 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.<br>- 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.<br>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.<br>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<br>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<br>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<br>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](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 |