CEMC-Auvergne - Registry of Congenital Malformations in Auvergne (Certified Registry 2012-2015)

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General

Identification

Detailed name	Registry of Congenital Malformations in Auvergne (Certified Registry 2012-2015)
Sign or acronym	CEMC-Auvergne
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	1387396

General Aspects

Medical area	Disability/handicap Pediatrics Rare diseases
Health determinants	Addictions Genetic Iatrogenic Lifestyle and behavior Medicine
Keywords	prenatal diagnosis

Scientific investigator(s) (Contact)

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Organization	CEMC-Auvergne

Collaborations	
Funding	
Funding status	Mixed
Details	Regional Health Agency - ARS - French Institute for Public Health Surveillance - InVS -French National Institute of Health and Medical Research - INSERM, private donations.
Governance of the database	
Sponsor(s) or organisation(s) responsible	CHU de Clermont-Ferrand
Organisation status	Public
Additional contact	
Main features	
Type of database	
Type of database	Morbidity registers
Additional information regarding sample selection.	Selection of subjects having the required inclusion criteria:- Public and private maternity wards in the Auvergne region- Multidisciplinary center for prenatal diagnosis- Medical and surgical pediatric departments- Cardiology departments- Maxillo-facial surgery- Pediatric urology- Public and private cytogenetics laboratories- Anatomopathology laboratory- Mother and child protection centers (PMIs)- Medical information departments (DIMs)
Database objective	
Main objective	The registry's primary objective is to conduct epidemiological surveillance of congenital malformations in Auvergne, with a role of sounding the alert when any environmental teratogenic agents become evident. With the development of prevention measures - particularly in the field of prenatal diagnosis - this surveillance-alert mission has gradually been extended to include an essential role in evaluating the impact of public health policies with regards to perinatal care on the population. The registry also helps to improve knowledge in the field of malformations by collaborating on studies with specialist clinical

	departments (particularly genetic and foetal medicine departments) and by being involved in the Multidisciplinary Center for Prenatal Diagnosis in Clermont-Ferrand (the registry's data provides food for thought from obstetricians on the meaning and action to take when certain malformations are observed during prenatal diagnosis). Lastly, the registry's data informs healthcare stakeholders and the public authorities about congenital malformations and chromosomal abnormalities.
Inclusion criteria	All malformed children are listed, whether stillborn or a live birth after a pregnancy of at least 22 weeks of amenorrhoea, or in the event of therapeutic abortion due to foetal malformation, regardless of term. For children who are born alive, the malformation diagnosis must have been made before the end of their first year of life (infants may be recorded up to 12 months after their birth). All types of malformation are included, whether these concern isolated or polymalformative syndromes, whether or not identified, with normal or abnormal karyotype. The only types to be excluded are inborn metabolic errors and minor malformations or deformations (snapping hips without real dislocation, deformed feet, small superficial naevi or angiomas less than 4cm2, inguinal hernia, umbilical hernia not requiring surgery, isolated persistent ductus arteriosus in premature infants weighing less than 2.5kg, hypertrophic pyloric stenosis, single umbilical artery, uni- or bilateral ectopic testis).
Population type	
Age	Newborns (birth to 28 days) Infant (28 days to 2 years)
Population covered	Sick population
Gender	Male Woman
Geography area	Regional
French regions covered by the database	Auvergne Rhône-Alpes
Detail of the geography area	Auvergne
Data collection	

Dates	
Date of first collection (YYYY or MM/YYYY)	1983
Size of the database	
Size of the database (number of individuals)	[10 000-20 000[individuals
Details of the number of individuals	10 145 patients (1983-2011)
Data	
Database activity	Current data collection
Type of data collected	Clinical data Paraclinical data Biological data Administrative data
Clinical data (detail)	Direct physical measures
Paraclinical data (detail)	MRI, scan, radiographies, ultrasounds (prenatal, foetal echocardiography, in post-natal stages: urinary tracts, cardio, etc.).
Biological data (detail)	cytogenetic examinations, maternal serum markers.
Administrative data (detail)	Identification data.
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Data collection method	primarily active +/- passive.
Classifications used	ICD 10, ATC.
Participant monitoring	Yes
Details on monitoring of participants	Vital status:The vital status is reported systematically when each case is being registered. The following are distinguished: - children who are alive when the report is made to the registry - therapeutic abortions before 22 weeks of amenorrhoea- therapeutic abortions after 22 weeks of amenorrhoea- fetal deaths in utero- infants who

	have died (in the first 8 days of life, between 8 and 28 days or after 28 days)
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://tinyurl.com/PUBMED-CEMC
Description	Liste des publications dans Pubmed
Link to the document	http://tinyurl.com/HAL-CEMC
Description	Liste des publications dans HAL
Access	
Terms of data access (charter for data provision, format of data, availability delay)	By request to the scientist in charge.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only