FCN - FranceCoag Network

Head :Goulet Véronique, Département des maladies chroniques et traumatismes

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General	
Identification	
Detailed name	FranceCoag Network
Sign or acronym	FCN
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL authorisation no.: 903272

General Aspects	
Medical area	Hematology Rare diseases
Pathology (details)	hereditary hemorrhagic diseases (except platelet disorders)
Health determinants	Genetic Geography Medicine
Keywords	haemophilia, von Willebrand disease, national registry, inhibitor, hereditary hemorrhagic diseases, replacement therapy; prophylaxis

Scientific investigator(s) (Contact)	

Name of the director	Goulet
Surname	Véronique
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Unit	Département des maladies chroniques et traumatismes

Collaborations	
Participation in projects, networks and consortia	Yes
Details	Participation in the World Federation of hemophilia (WFH)
Funding	
Funding status	Public
Details	Ministry of Health
Governance of the database	
Sponsor(s) or organisation(s) responsible	INVS - Institut de Veille Sanitaire
Organisation status	Public
Additional contact	
Main features	
Type of database	
Type of database	Morbidity registers
Type of database Study databases (details)	Morbidity registers Cohort study
Study databases (details) Additional information regarding	Cohort study
Study databases (details) Additional information regarding sample selection.	Cohort study
Study databases (details) Additional information regarding sample selection. Database objective	Cohort study None because of national registry. Four objectives: 1) Thorough knowledge of the epidemiological

- Type 1 von Willebrand disease (VWD) with VWF:Ag <30%; Type 2 with a VWF:RCo/VWF:Ag ratio <0.7 or VWF:CB/VWF:Ag <0.7 or FVIII:C/VWF:Ag < 0.5 or positive RIPA; Type 3 with VWF:Ag and VWF:RCo <5%:
- Afibrinogenemia (fibrinogen < 0.2 g / l);
- a deficiency in factor FII, FV, FVII, FX, FXIII <10%, FXI <20% or FV + FVIII <30%.

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Age Newborns (birth to 28 days)

Infant (28 days to 2 years)
Early childhood (2 to 5 years)
Childhood (6 to 13 years)
Adolescence (13 to 18 years)
Adulthood (19 to 24 years)
Adulthood (25 to 44 years)
Adulthood (45 to 64 years)
Elderly (65 to 79 years)

Great age (80 years and more)

Population covered Sick population

Gender Male Woman

Geography area National

Detail of the geography area Patients are included throughout the national

territory and monitored by 36 haemophilia

treatment centres (HTC).

Data collection

Dates

Date of first collection (YYYY or

1994

MM/YYYY)

Size of the database

Size of the database (number of individuals)

[1000-10 000] individuals

Details of the number of individuals

9,288 patients enrolled on 07/09/2015.

Data

Database activity Current data collection

Type of data collected Clinical data

	Paraclinical data Biological data
Clinical data (detail)	Medical registration
Paraclinical data (detail)	Score PedNet (joint score)
Biological data (detail)	Deficient factor base rate, inhibitor research assessment, etc.
Presence of a biobank	Yes
Contents of biobank	Serum Plasma Blood cells isolated
Details of biobank content	A Biobank was established between 1994 and 2002 and between 2008 and 2011. This includes blood samples (mononuclear cells, plasma, serum). The Biobank was stopped at the end of 2011.
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Others
Care consumption (detail)	Medicines consumption
Other (detail)	Genetics, ethnic origin
Procedures	
Data collection method	Data are gathered through electronic forms by clinicians following patients in 36 haemophilia treatment centres throughout the national territory.
Classifications used	Coding conventions specific to project.
Quality procedure(s) used	Data monitoring conducted by 3 clinical research associates. Data are checked: - at the coordination centre by automatically processing collected data after recording (missing data, outliers and inconsistent data) - in treatment centres against clinical files on 100% of forms: General cohort (on a selection of items); PUPS sub-cohort (all data).
Participant monitoring	Yes
Details on monitoring of participants	No follow-up schedule imposed by clinicians; No controlled treatment; No specific examination; Only one recommandation: patient's data sent on an annual (general cohort) or quarterly basis (PUPS sub-cohort = patients with severe hemophilia).

Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.francecoag.org/SiteWebPublic/html/documentsTele.html
Access	

Terms of data access (charter for data provision, format of data, availability delay) Access to operation results on the database through webFC, dedicated RFC computer application (http://www.francecoag.org). Database is accessible to all internal or external researchers interested in the project after submitting a project to 2 experts that is validated by members of the RFC Steering Committee.