OFSEP - French registry on Multiple Sclerosis

Head :Vukusic Sandra, Service de Neurologie A, Centre de Coordination et Fondation EDMUS contre la Sclérose en PlaquesInserm U1028

Last update : 02/17/2020 | Version : 7 | ID : 3138

General

Identification

Detailed name	French registry on Multiple Sclerosis
Sign or acronym	OFSEP
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL 914066v2

General Aspects

Medical area	Neurology
Pathology (details)	Multiple sclerosis
Keywords	Pharmacoepidemiology

Scientific investigator(s) (Contact)

Name of the director	Vukusic
Surname	Sandra
Address	Hôpital Neurologique Pierre Wertheimer - 59 boulevard Pinel - 69677 BRON cedex
Phone	+33 (0)4 72 68 13 10
Email	sandra.vukusic@chu-lyon.fr
Unit	Service de Neurologie A, Centre de Coordination et Fondation EDMUS contre la Sclérose en PlaquesInserm U1028
Organization	Université Claude Bernard Lyon 1, Hospices Civils de Lyon, Fondation Eugène Devic

Collaborations

Participation in projects, networks and consortia	Yes
Details	Projet Big MS Data gathering European registers

Funding

Funding status	Public
Details	ANR "Investissements d'avenir"

Governance of the database

Sponsor(s) or organisation(s) responsible	Université Claude Bernard Lyon 1
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Hospices Civils de Lyon (HCL)
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Fondation Eugène Devic EDMUS
Organisation status	Private
Presence of scientific or steering committees	Yes

Additional contact

Name of the contact	Casey
Surname	Romain
Address	Hôpital Neurologique Pierre Wertheimer - 59 boulevard Pinel - 69677 BRON cedex
Phone	04 72 12 96 41
Email	romain.casey@chu-lyon.fr
Unit	OFSEP
Organization	Fondation EDMUS

Main features

Type of database

Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health care professionals A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Cohort open to all French neurologists willing to participate. The medical care of French MS patients is provided by two specialized, complementary and closely interconnected networks : the 28 university hospital neurology departments (expert centres) and the 18 regional health care networks dedicated to MS. This organization ensures a dense and homogeneous nationwide coverage.

Database objective

Main objective	- Maintain and develop the national cohort of MS patients (currently more than 40,000 patients) registered at the EDMUS format (database that can be used as an electronic medical record, specifically designed to process the data of MS patients) and enrich the clinical data currently available with biological samples, MRI data and socio-economic data. - Provide a continuously updated "photograph" of MS in France, thus allowing a better understanding of the personal, professional and social consequences of the disease, and of the effect of disease modifying treatments (DMTs) in MS care in France. It is ideally suited for nationwide epidemiological studies on MS. - Maintain and develop existing nested cohorts ("historical" Lyon cohort on the natural history of MS, KIDMUS cohort on MS with childhood onset, TYSEDMUS cohort on patients treated with Tysabri, etc.) and implement new ones, addressing specific issues such as pharmaco-epidemiology of recently introduced DMTs and their cost effectiveness. To develop the new OFSEP-HD cohort
Inclusion criteria	MS patients treated by any neurologist involved in the OFSEP project

Population type

Age	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
Pathology	G35 - Multiple sclerosis
Gender	Male Woman
Geography area	National
Detail of the geography area	Metropolitan France and French overseas departments and territories

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	1992

Size of the database

Size of the database (number of individuals)	Greater than 20 000 individuals
Details of the number of individuals	62 000

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data Biological data Administrative data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Neurological episodes, handicap scale, MRI (results and pictures), disease modifying treatments, medical history, etc.
Declarative data (detail)	Face to face interview

Paraclinical data (detail)	1. Results of additional tests for the diagnosis and during routine follow-up (brain and spinal cord MRI, evoked potentials...) registered in the EDMUS software. 2. Electronic storage of brain and spinal cord images on the Shanoir Platform (http://shanoir.org). A common and feasible brain and spinal cord acquisition protocol has been defined by the MRI Work Group and the major MRI manufacturers have agreed to provide the dedicated collection of sequences as an ?OFSEP box? with every software upgrade or new MRI machine in order to guarantee the standardisation of data.
Biological data (detail)	1. Results of additional tests for the diagnosis and during routine follow-up (lumbar puncture, blood tests...) registered in the EDMUS software. 2. Biological samples (blood, cerebrospinal fluid, urine...) stored in specific (REFGENSEP for genetics) or generic ("MS collection") Biological Ressources Centres. Treatment and conservation of biological samples have been standardised. The groups of patients to be followed are defined according to research projects.
Administrative data (detail)	Medico-economic data : 1. Places of birth and residence 2. Domestic status (lives alone/with spouse or partner/with another family member/in health institution) 3. Education level.
Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Plasma Fluids (saliva, urine, amniotic fluid, ?) Cell lines DNA DNAc/RNAm Others
Details of biobank content	- Minimum samples : serum, plasma EDTA, DNA, PBMC, urine. - Additional samples : cerebrospinal fluid and feces
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception Others
Care consumption (detail)	Hospitalization

	Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	1/ Clinical data. Data are collected using the EDMUS software. According to the physician's convenience, medical data can be restricted to minimum data (specified by the community of EDMUS users) or be comprehensive, thus constituting a real electronic medical record. Clinical symptoms are deliberately described from a functional angle first, then from an objective examination angle if necessary. This ensures a homogeneous integration of information, either restrospective or prospective, from the patients, their family circle, their GP or neurologist. Only crude data are also deliberately recorded in the system. All inferred data, such as the level of diagnostic ascertainment or classification of disease course (recurring-remitting, secondary progressive, primary progressive) are automatically generated with algorithms integrated in the software. This approach has many advantages : time-saving, uniform classification, automatic update of classifications each time new data are entered in a patient's record. Changes in the classifications that may be decided by the medical and scientific community can also be taken into consideration by changing the algorithms. Data can be entered directly using the software or using the standardized form called "OFSEP minimal data". 2/ MRI. MRI (realized according to OFSEP standard during the clinical follow-up of the patient) are uploaded on Shanoir platform from PACS or CD of patients. 3/ Biological samples. Biological samples are collected during clinical follow-up of patients. They are stored locally by CBR participating to the OFSEP project.
Participant monitoring	Yes
Details on monitoring of participants	Inclusion of a patient in the OFSEP cohort does not mean any change in his/her routine follow-up. Data are collected during the visits and hospitalizations required for the patient's follow-up, usually at least twice a year for patients receiving an immuno-active treatment, once a year for other patients. Additional tests may be done according to clinical requirements. The samples stored in the biological ressources centers are surpluses from these routine tests. However, in the OFSEP project, a minimum clinical, biological and MR follow-up will be recommended for all patients in the cohort. For

	nested cohorts (particularly for the monitoring of immuno-active treatments), a specific follow-up included in the routine follow-up will be proposed.
Links to administrative sources	Yes
Linked administrative sources (detail)	CNAM-TS systematic agreement for the interconnection with individual reimbursement data collected by health insurance systems(SNIIR-AM). Definition of practical and regulatory terms on going.

Promotion and access

Promotion

Link to the document	OFSEP_Dissemination des résultats_2019-09-04_VF.pdf
Link to the document	http://www.hal.inserm.fr/OFSEP
Description	List of publications in HAL
Link to the document	http://tinyurl.com/Publi-Pubmed-OFSEP
Description	List of publications in Pubmed
Link to the document	OFSEP_Access to a powerful epidemiological tool_V1.0_2019-07-19.pdf

Access

Presence of document that lists variables and coding procedures	Yes
Terms of data access (charter for data provision, format of data, availability delay)	Access to the OFSEP cohort data is made available to outer institutions (academic or industrial, public or private, French or foreign). Requests should be made to the OFSEP National Coordination Centre (request form available on the OFSEP web site http://www.ofsep.org/en/data-access or on request at contact@ofsep.org). Projects are assessed by the OFSEP Scientific Committee and the National Coordination Centre on the basis of their scientific rationale, quality of the protocol and feasibility. Compliance with good practices, ethical aspects and compliance with the current regulations will also be taken into consideration. Decisions are approved by the OFSEP Steering Committee. A signed data transfer agreement between OFSEP and the applicant is required before any transfer of data.
Access to aggregated data	Access on specific project only

Access to individual data	Access on specific project only