Observatoire Français de la Sclérose en Plaques : an update

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Introduction

The French Multiple Sclerosis Registry (OFSEP) is a French national cohort of people with multiple sclerosis (MS) and related disorders. The OFSEP project aims at collecting data in a routine clinical setting, to foster clinical, basic and translational research in MS.

Objective

To update the OFSEP description.

Methods

Data collection (see www.ofsep.org for details)

Patients with a **MS** diagnosis according to the latest criteria, or present radiologically and clinically isolated syndromes (**RIS** and **CIS**) suggestive of MS, or a neuromyelitis optica spectrum disorder (**NMOSD**) are included.

Neurologists involved in the OFSEP network follow them up longitudinally and collect **clinical data** in a computerized medical file, EDMUS. This collection has been standardized since June 2013, including demographic and socioeconomic characteristics and disease and therapeutic description. In addition, serious adverse events have been collected since January 2017. A **standardized imaging protocol** is used by MRI centres and **raw data** are stored in a centralized national facility, Shanoir. **Biological samples** (blood and urine, mandatory; cerebrospinal fluid and stool, optionally) are collected in specific subgroups of patients and stored in certified biobanks.

An early and constant concern for quality

OFSEP has implemented a strategy to ensure and improve the **quality of the data and samples** collected.

- To help avoiding missing data, a pre-filled minimal clinical form can be automatically extracted from EDMUS before each visit.
- The EDMUS software has an integrated data verification tool to identify missing or incoherent data.
- Twice a year, a quality report and evolution of quality indicators over time is provided to all centers.
- Twice a year, a list of incoherent data entries is sent to all centers.
- The OFSEP management team provides centers with information documents and sets up training sessions and audits.
- Since 2016, the annual funding distributed by OFSEP to the centers is taking into account not only the number of cases, but also some selected quality indicators.

Results in 2018 June

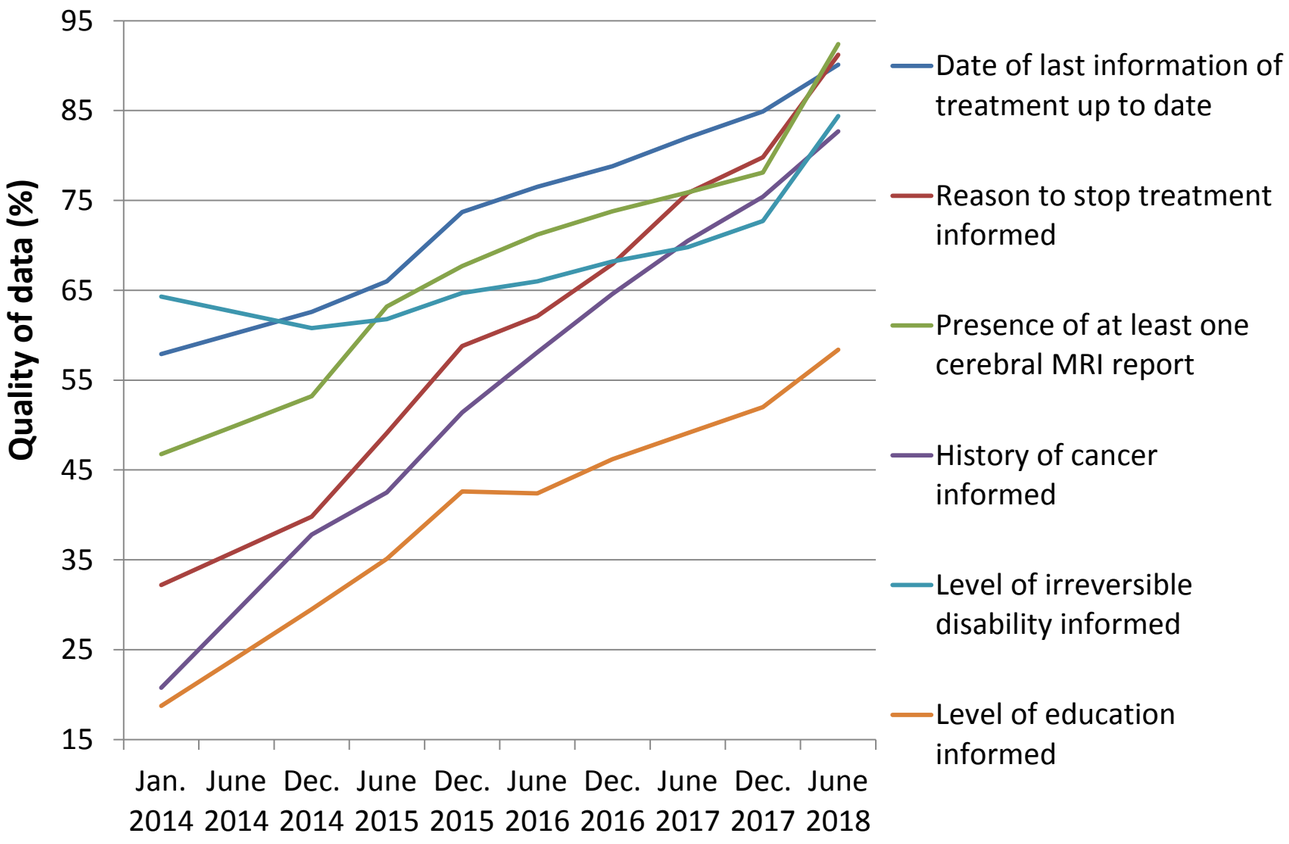
Population description

On June 15th 2018, clinical data from 36 centers, representing all French MS expert centers and networks, were aggregated.
There were **61,235 patients files**; 61% of the patients have been seen since June 2013, with collection of the standardized minimal dataset.
The main patients characteristics sorted by clinical manifestation are presented in the table below; 273 patients were confirmed RIS but 169 without any clinical manifestation at last clinical assessment.

	CIS	RRMS	SPMS	PPMS	NMOSD
N	**4,819**	**35,126**	**12,157**	**7,703**	**1,216**
% female	71%	75%	67%	56%	70%
Age at disease onset (y)	36 ± 11	31 ± 10	32 ± 10	42 ± 11	36 ± 16
Disease duration (y)	5 ± 7	12 ± 9	23 ± 11	14 ± 9	8 ± 8
Number of EDSS	2 ± 3	7 ± 9	11 ± 11	7 ± 8	5 ± 6
Time between 2 EDSS (y)	1.2 ± 2.1	0.9 ± 1.5	1.0 ± 1.9	1.0 ± 1.7	0.9 ± 1.6

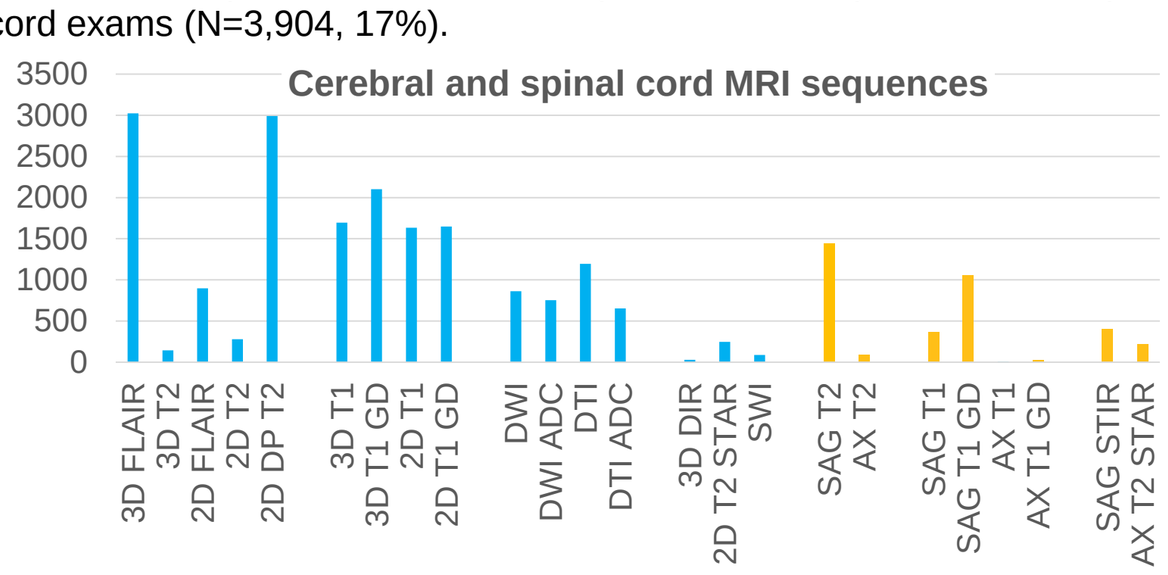
Evolution of selected quality indicators

The completeness of the data continually increases with time.



MRI raw data

Standardized MRIs were produced by 28 imaging centers; 22,841 sequences from 2,721 studies performed in 1,140 patients were available. Most of the sequences were cerebral (N=18,937, 83%), others were spinal cord exams (N=3,904, 17%).



There were respectively 409 (38%) and 107 (20%) patients with cerebral and spinal cord sequences at several temporal points.

Cerebral MRI	N patients 1 time point	2 time points	≥ 3 time points	Total
RIS	2	1	3	6
CIS	47	18	7	72
RRMS	469	197	126	792
SPMS	71	23	8	102
PPMS	64	13	5	82
NMOSD	18	5	3	26

Spinal cord MRI	N patients 1 time point	2 time points	≥ 3 time points	Total
RIS	2	2	1	5
CIS	30	4	0	34
RRMS	301	48	26	375
SPMS	44	7	4	55
PPMS	44	7	1	52
NMOSD	16	4	3	23

Biological samples

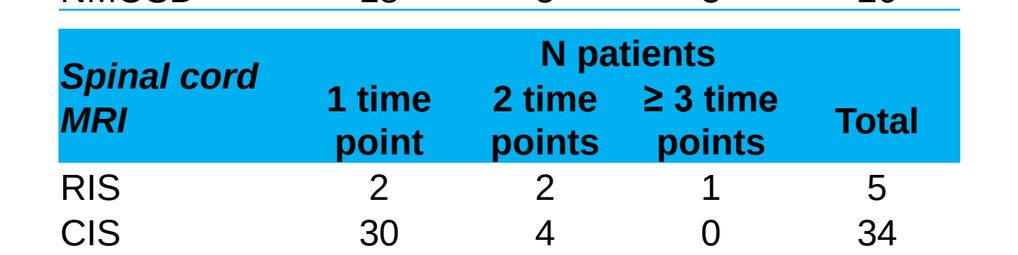
Biological samples were collected in 13 centers and 920 patients were sampled. They were available in eight subpopulations of patients, mostly not treated. Currently, about 400 new samples are being collected each year.

	N	Blood*	Urine	CSF**	Stool
RIS	69	69 (100%)	66 (96%)	33 (48%)	1 (1%)
CIS	402	402 (100%)	379 (94%)	271 (67%)	6 (1%)
RRMS	49	49 (100%)	49 (100%)	30 (61%)	4 (8%)
SPMS	9	9 (100%)	7 (78%)	4 (44%)	0 (0%)
PPMS	155	155 (100%)	140 (90%)	97 (63%)	6 (4%)
NMOSD	218	218 (100%)	181 (83%)	17 (8%)	2 (1%)
ADEM	13	13 (100%)	10 (77%)	3 (23%)	0 (0%)
PML	5	5 (100%)	4 (80%)	1 (20%)	0 (0%)

* Serum, EDTA plasma, DNA, PBMC (Peripheral Blood Mononuclear Cells)
** Cerebrospinal fluid, CSF cells

Conclusion

Over the last 7 years, OFSEP has improved his data quality and extended the number of patients followed and the amount of variables collected.
The ultimate goal of OFSEP is to answer questions about causes and mechanisms of MS, treatments effectiveness, prognostic factors of disease progression (see eP1359 for details on OFSEP HD cohort), etc.
Data and samples are open to physicians and researchers, public and private entities, in France and abroad, after an evaluation by the scientific committee and a validation by the steering committee (visit OFSEP at stand C30 for more details).



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