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Introduction

The French Multiple Sclerosis Registry (OFSEP) is a cohort of persons 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.

Objectives

To evaluate OFSEP population coverage and representativeness in France.

Methods

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

Persons with MS or related disorders (Neuromyelitis Optica Spectrum Disorder [NMOSD]) are followed longitudinally by their neurologist involved in the OFSEP network, who collects clinical data in a computerized medical file, EDMUS. Since June 2013, this collection is standardized, including demographic and socioeconomic characteristics and disease and therapeutic description. Since April 2016, serious adverse events are also collected. A standardized imaging protocol has been developed and is currently

disseminated in MRI centres; raw data are stored in a centralized national facility, Shanoir. Biological samples are collected in six 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, when the national database is updated, the OFSEP National Coordinating Centre (NCC) provides a quality report to all centers, with a list of incoherent data entries, which enables processing advice to be proposed. The NCC also provides a number of tools for the centers: information documents, data quality indicators and their evolution over time, training sessions and audits. Finally, 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.

Population coverage

Incidence and prevalence rates of MS (and NMOSD) have been estimated previously^{1,2} based on data from the French national health insurance database (SNIIRAM) and the National hospital discharge database (PMSI) in metropolitan regions (including Corsica).

Using these results, prevalence of MS for the 2012-16 period was calculated by subtracting the number of prevalent cases expected in 2016 and the number of expected deaths obtained from the National institute of statistics and economic studies (Insee) mortality tables and the 5-year age structure of MS cases.

OFSEP coverage and 95% confidence intervals by administrative regions were obtained by dividing the number of cases observed in the OFSEP database and the estimated number of prevalent cases.

1. Foulon S et al. Prevalence and mortality of patients with multiple sclerosis in France in 2012: a study based on French health insurance data. *J Neurol.* 2017.

2. Fromont A et al. National estimate of multiple sclerosis incidence in France (2001–2007). *Multiple Sclerosis Journal.* 2012.

Results in 2017 June

Collection of data and samples

On 15 June 2017, clinical data from 41 centers, representing all French referral centers and MS networks, sometimes both, were aggregated. There were 60,053 patients files; 54% of the patients have been seen since June 2013, with collection of the standardized minimal dataset. Biological samples were collected in 13 centers for 682 patients sampled (see e-poster eP1612). Standardized MRIs were produced by 17 MRIs centers and 6,018 sequences from 442 patients were available (see e-poster eP1555).

Population coverage

Data is censored at 31 December 2016 to evaluate the coverage of the population by OFSEP. At this date, 55,915 living patients were identified in the database. Their main characteristics are presented in the table below.

	RRMS	SPMS	PPMS	NMOSD	Total
N	37,549	10,558	6,654	1,154	55,915
% female	75.0%	69.2%	57.5%	70.5%	71.8%
Age at disease onset (y)	31 ± 10	32 ± 10	42 ± 11	36 ± 16	33 ± 11
Disease duration (y)	11 ± 11	23 ± 10	13 ± 9	8 ± 8	13 ± 10
Number of EDSS	7 ± 9	11 ± 11	7 ± 8	5 ± 6	7 ± 9
Time between 2 EDSS (y)	0.9 ± 1.5	1.0 ± 1.8	1.0 ± 1.7	0.8 ± 1.5	0.9 ± 1.6

Evolution of selected quality indicators between 2014 and 2017

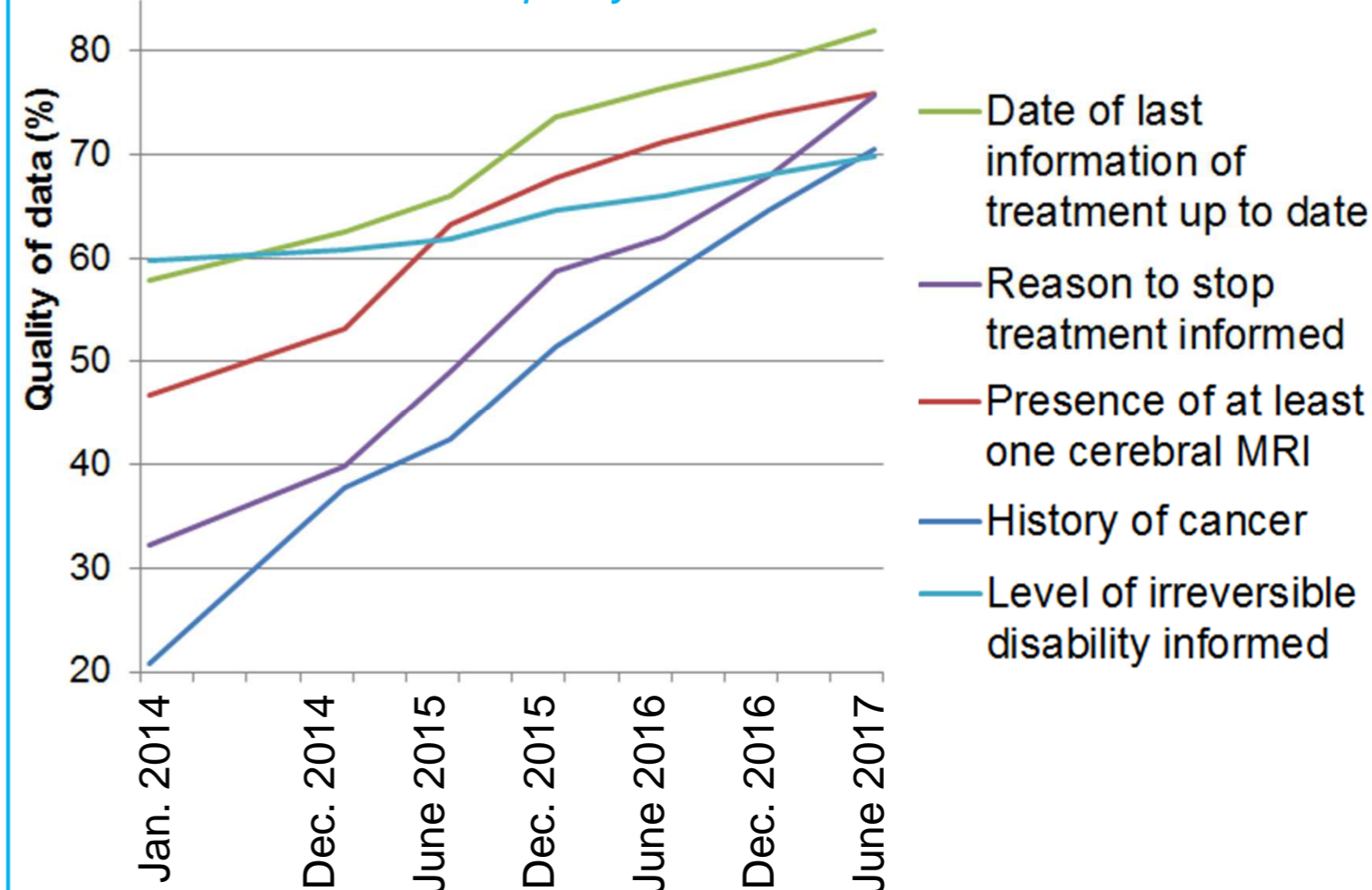


Figure A - Percentage of cover of MS patients by OFSEP in 2016

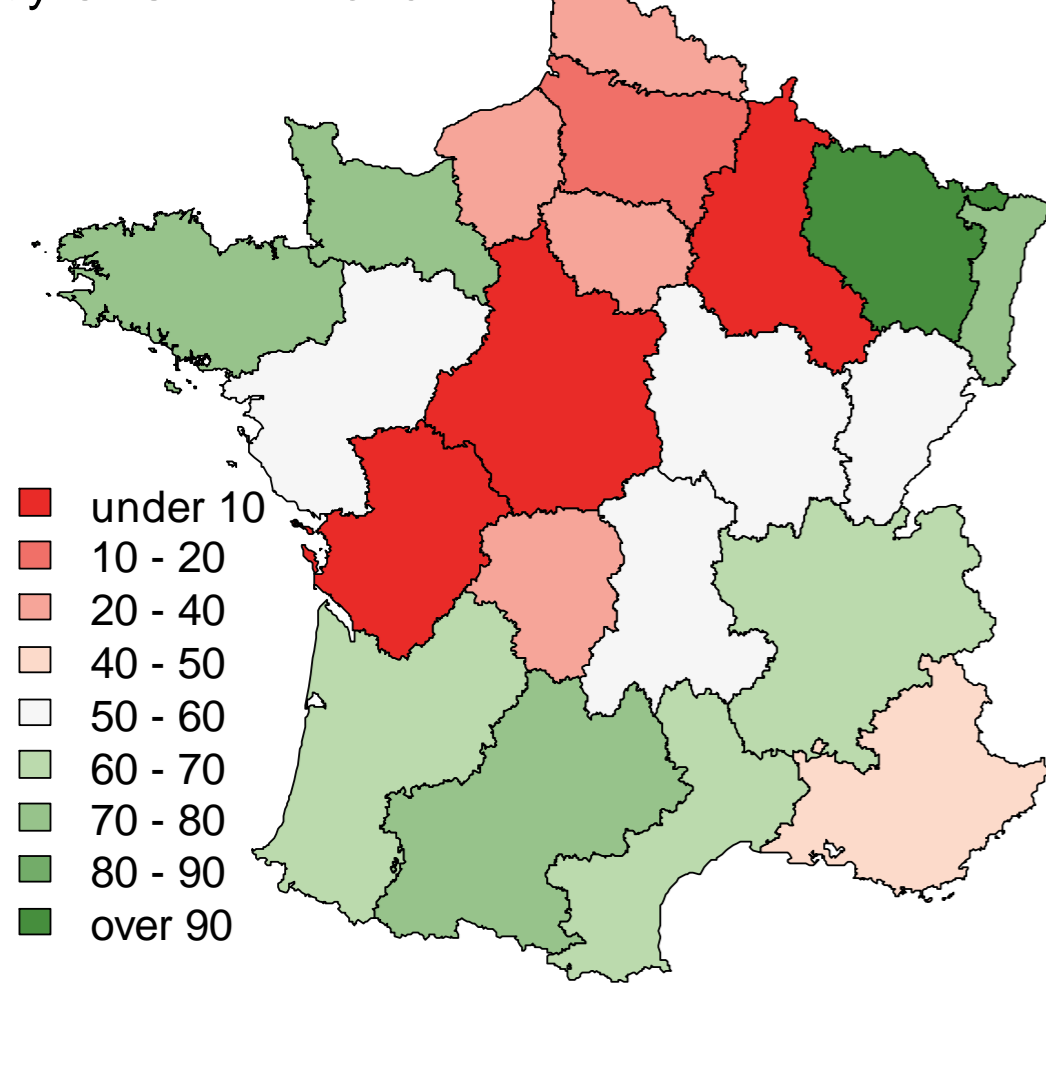
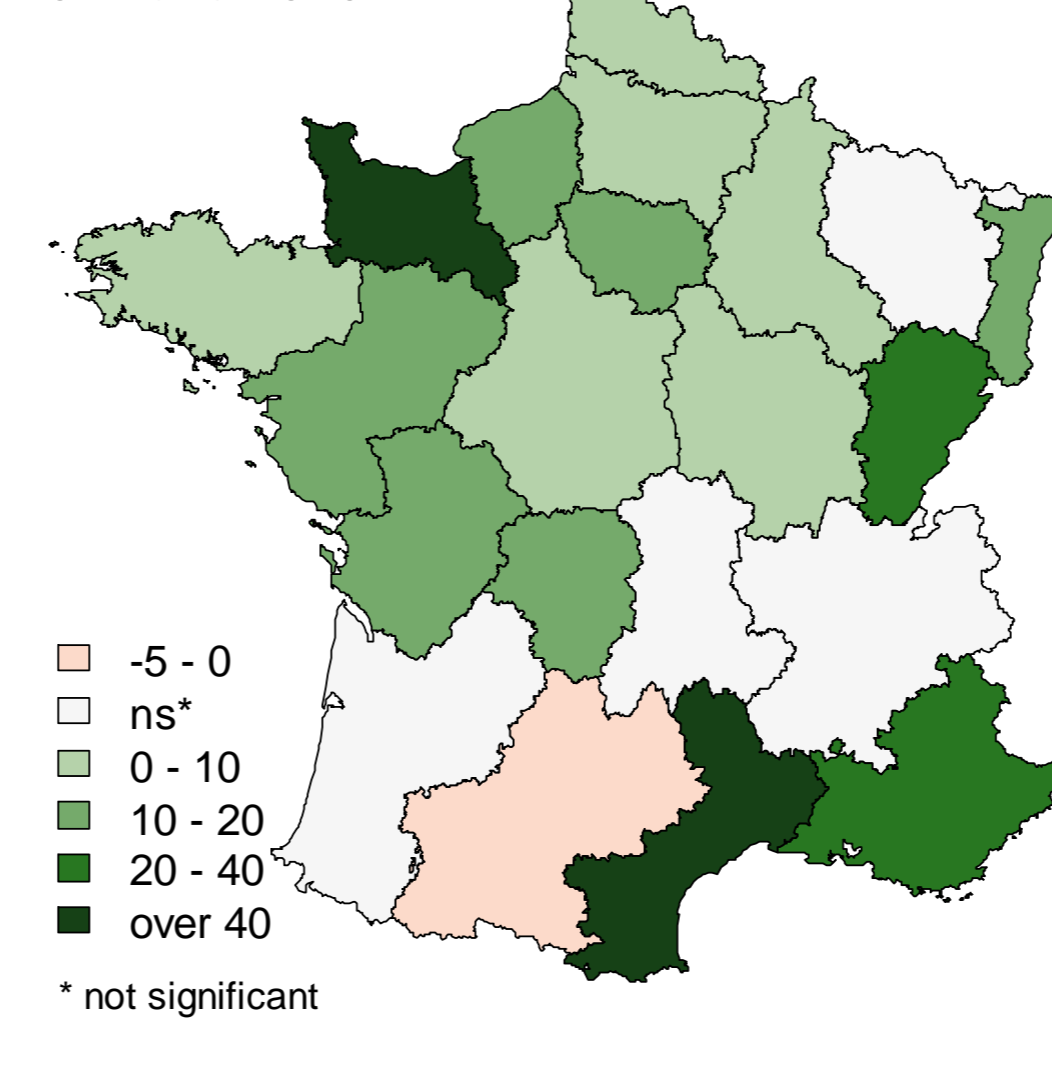


Figure B - Variation of cover of patients between 2012 and 2016



The coverage of MS patients in 2016 was 46.3% [95%CI 44.8-47.8] at the national level.

Major differences were observed between regions (Fig. A), from 3% to 96% (median=53%). The coverage was the most important in the North-East (especially in Lorraine, the only exhaustive MS registry in France), the North-West, the South-West and the Rhône-Alpes region. Inversely the coverage was lower in center, in the North and in the PACA region. In 2012, the coverage was 36.6% [35.7-37.7] (median=27%). At the national level the coverage increased by 9.7% between 2012 and 2016.

The large majority of region increased their coverage (Fig. B) but in an heterogeneous way (median by region=9% [IQR 3-15]).

Conclusion

Over the last five years, OFSEP has extended the quality of its data due to the overall strategy implemented. In the same time, the representativeness of patients increased but not homogeneously across the regions. This was mainly due to the historical territorial organization of care and participation of center to the OFSEP ancestor. The future perspective is to follow and reinforce the current strategy of data collection, especially around the 23 recently certified MS experts centers in France. OFSEP's objective is to continue to increase quality of data and better characterize its population to facilitate clinical and epidemiological research.

Data and samples collected by OFSEP are open to physicians and researchers, public and private entities, in France and abroad (visit EDMUS-OFSEP stand both D86 for more details).

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