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, Shanor. Biological samples are collected in six specific subgroups of patients and stored in certified biobanks.

Results

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 incorrect 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 incorrect 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 taken 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 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 and incidence for the MS 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.

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 the number of cases observed in the OFSEP database and the estimated number of prevalent cases.

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 the 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]).

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

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

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

Disclosure

Dr. Debouverie has received consulting and teaching fees, travel grants and unconditional research support from Frohlich, Biogen, Genzyme, Merck Serono, Roche, Sanofi Aventis, and Teva Pharma. Dr. Confavreux has no conflicts of interest to declare.

Acknowledgments

This work has been supported by a grant provided by the French State and handled by the "Agence Nationale de la Recherche," within the framework of the "Investments for the Future" programme, under the reference ANR-10-COHO-002 Observatoire Français de la Sclérose en plaques (OFSEP). It also received support from the ARSEP Foundation and the Eugène Devic EDMUS Foundation against MS.