

Complementary use of administrative and clinical data in studying disease-modifying therapies in MS in France in 2010-2015

J. Roux^{1,2}, R. Casey^{3,4,5,6}, S. Vukusic^{3,4,5,6}, E. Leray^{1,2}, on behalf of OFSEP investigators



¹ Univ Rennes, EHESP, REPERES (Pharmacoepidemiology and health services research) - EA 7449, F-35000 Rennes, France

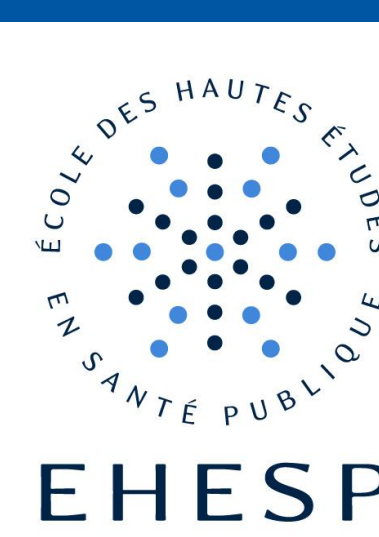
² INSERM CIC-P 1414, University Hospital of Rennes, F-35000 Rennes, France

³ Université de Lyon, Université Claude Bernard Lyon 1, F-69000 Lyon, France

⁴ Hospices Civils de Lyon, Service de Neurologie, sclérose en plaques, pathologies de la myéline et neuro-inflammation, F-69677 Bron, France

⁵ Observatoire Français de la Sclérose en Plaques, Centre de Recherche en Neurosciences de Lyon, INSERM 1028 et CNRS UMR 5292, F-69003 Lyon, France

⁶ EUGENE DEVIC EDMUS Foundation against multiple sclerosis, state-approved foundation, F-69677 Bron, France



Introduction

- **Wide range of disease-modifying therapies (DMTs)** in France over 2010-2015
 - 11 MS-specific DMTs
 - 6 injectable DMTs (5 β -interferons (of which peg-interferon- β), glatiramer acetate)
 - 2 in-hospital infusions (natalizumab, mitoxantrone)
 - 3 oral DMTs (fingolimod, teriflunomide, dimethyl fumarate)
 - 6 off-label drugs (azathioprine, methotrexate, mycophenolate mofetil, alemtuzumab, cyclophosphamide, rituximab)
- Two main types of data sources to study utilization of DMTs
- **Clinical series:** strong quality but potential recruitment bias
 - OFSEP database (“*Observatoire Français de la Sclérose en Plaques*”)
- **Administrative data:** exhaustiveness but no clinical data
 - French National Health Data System (SNDS-“*Système National des Données de Santé*”)

Methods

- **OFSEP cohort** (extraction date: December 2016)
 - All PwMS seen at least once in 2010-2015 in one of the 41 inclusion centers across France
 - Data completed by neurologists - Clinical trials included
 - DMTs available: 11 MS-specific and 6 off-label drugs
 - Exact start and end dates of each DMT
- **SNDS cohort** (extraction date: October 2017)
 - All PwMS identified using a validated algorithm over 2010-2015 across France (Foulon 2017) with at least one reimbursement of care over 2010-2015
 - Data issued from health insurance reimbursements
 - DMTs available: 10 MS-specific (mitoxantrone missing) and 3 off-label drugs (alemtuzumab, cyclophosphamide and rituximab missing)
 - Only delivery dates of each DMT

Follow-up period: From the earliest of January 1st, 2010 or MS diagnosis (in the OFSEP) / identification date (in the SNDS) until the earliest of last clinical visit (in the OFSEP only), death or December 31st, 2015

Outcomes: Monthly proportion of PwMS receiving each DMT and individual sequences of DMTs

Objective

To describe the use of DMTs in real-life settings of persons with MS (PwMS) in France over 2010-2015 period by using two different data sources: the OFSEP database and the SNDS

Results

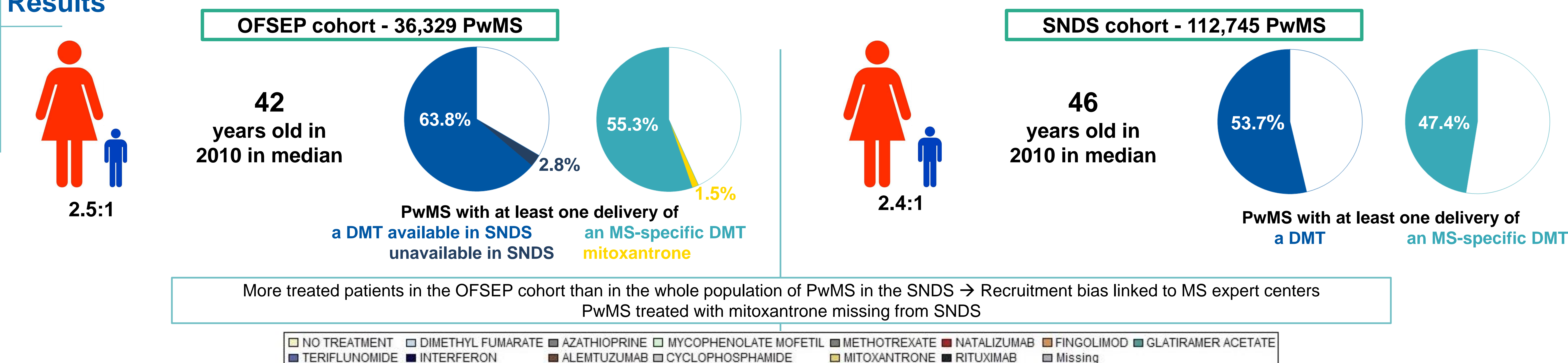


Figure 1 Distribution of DMTs use in France over 2010-2015 in the OFSEP cohort

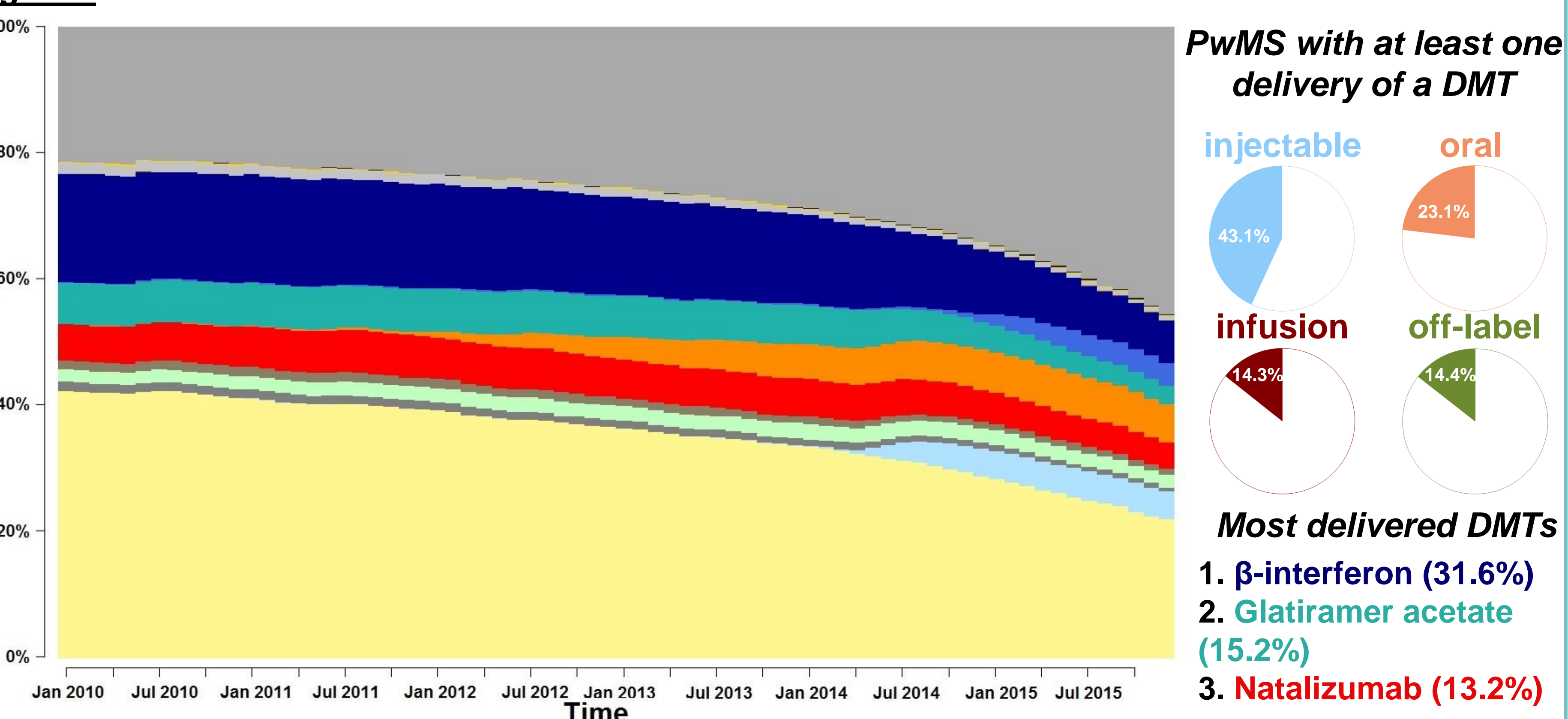
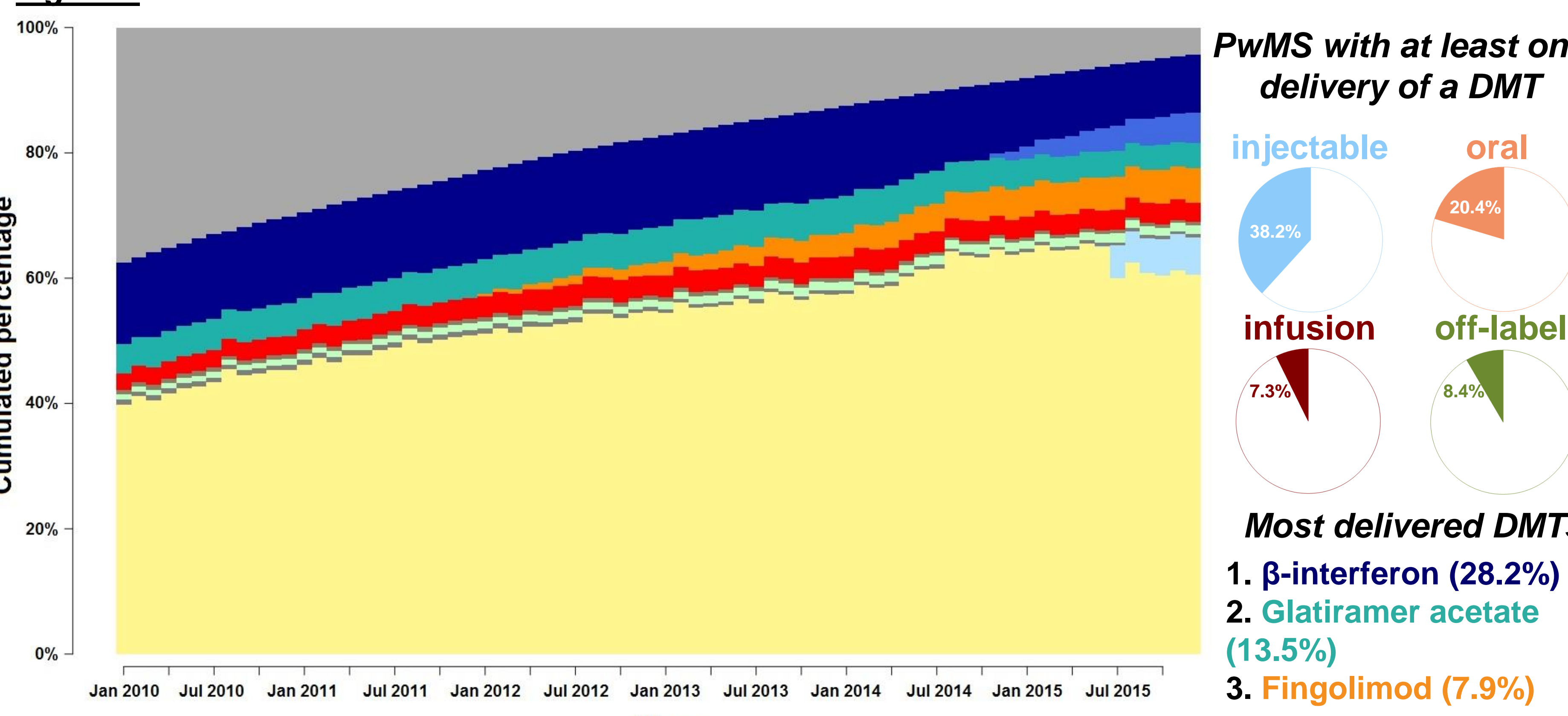


Figure 2 Distribution of DMTs use in France over 2010-2015 in the SNDS cohort



Higher number of missing values in the OFSEP cohort due to the availability of data linked to last clinical follow-up
Clinical trials available in the OFSEP cohort → longer follow-up of newly introduced DMTs, especially oral one
Over-representation of PwMS with at least one delivery of either an infusion DMT, an injectable DMT or off-label one in the OFSEP cohort

Figure 3 Observed individual sequences of DMTs over 2010-2015 in the OFSEP cohort

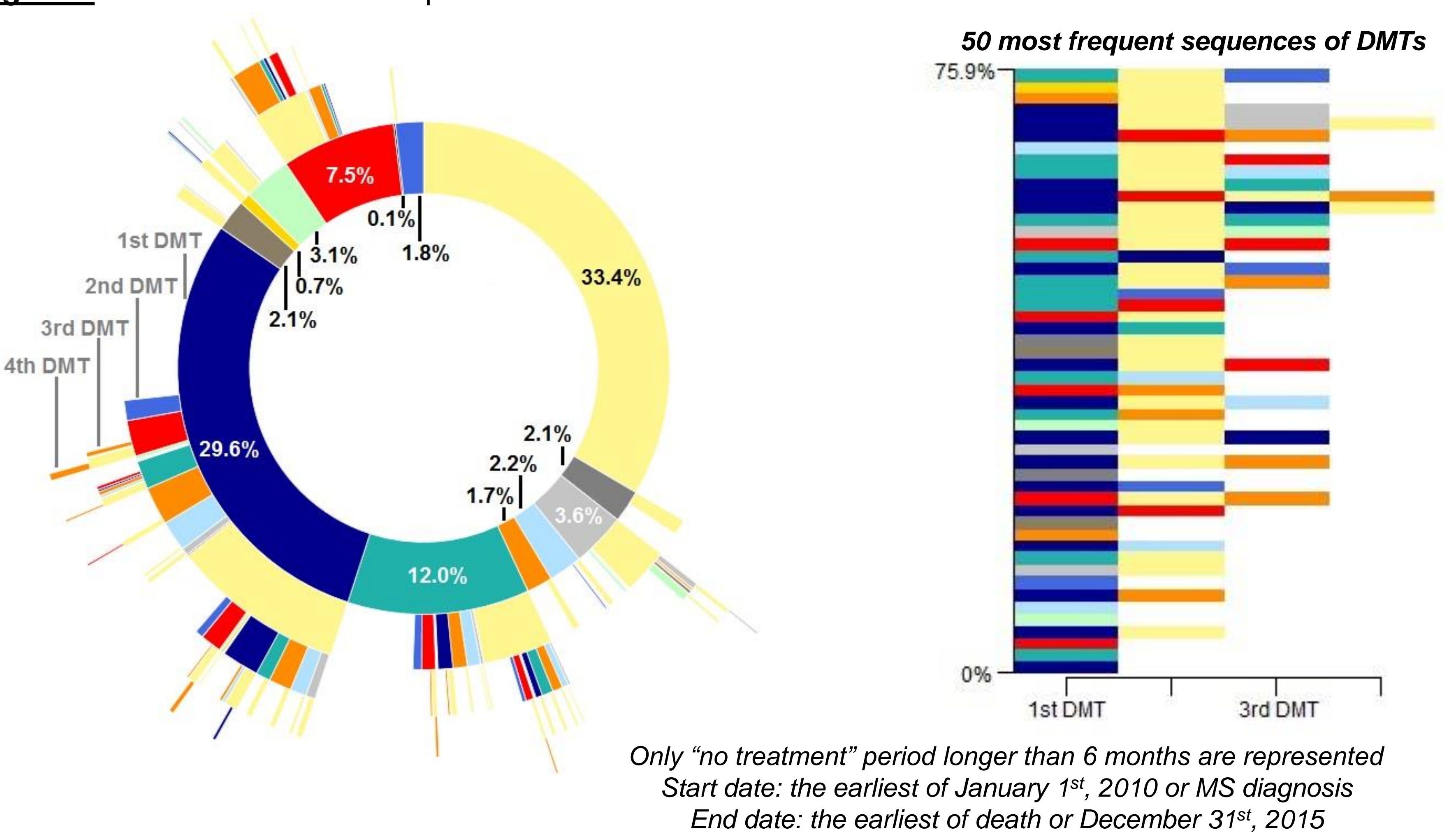
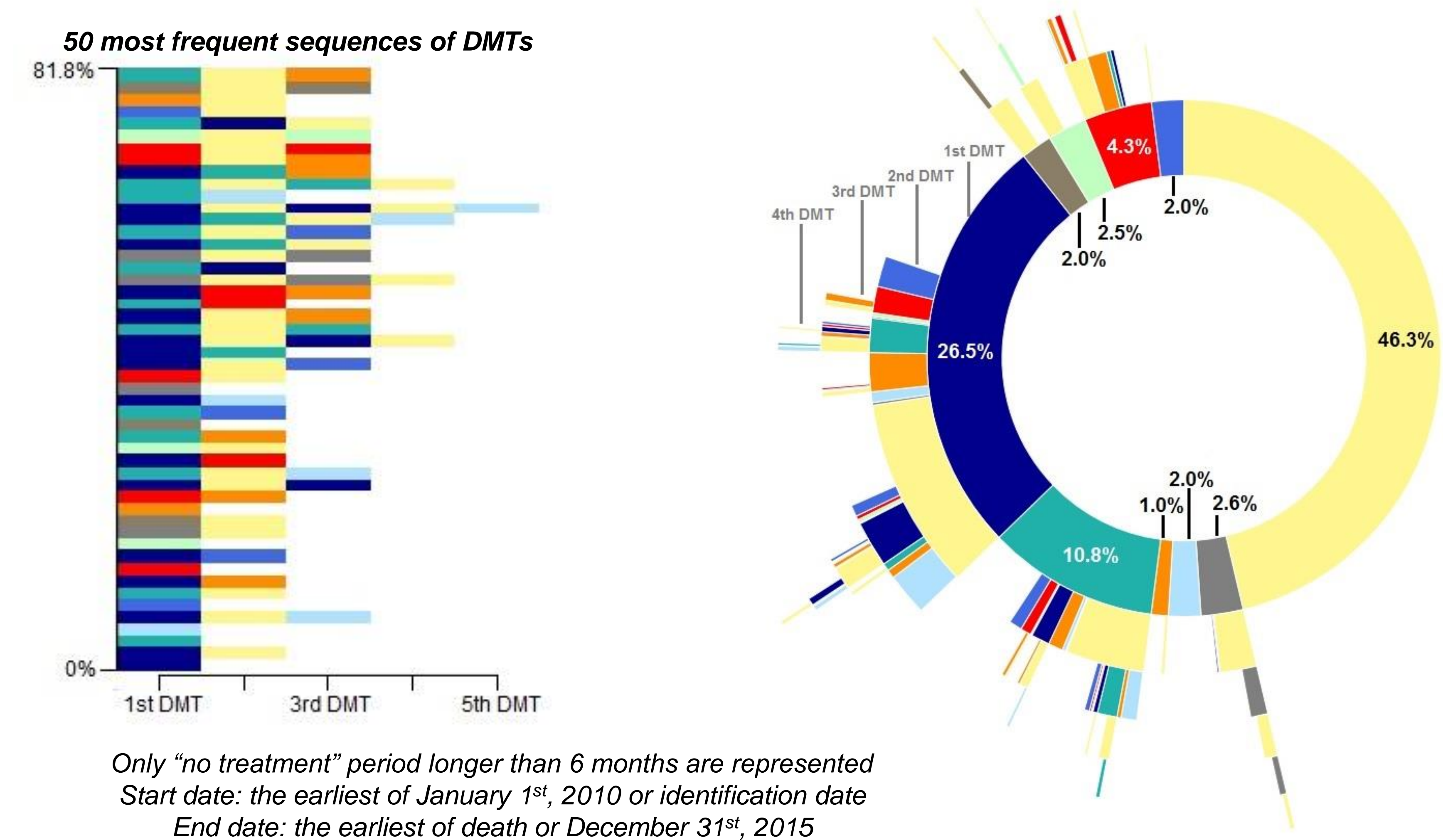


Figure 4 Observed individual sequences of DMTs over 2010-2015 in the SNDS cohort



Wide variety of DMTs in both databases
Longer sequences of DMTs in SNDS → Lack of exact start and end dates of each treatment contrary to the OFSEP cohort

Discussion

- Use of administrative data highlighted the **recruitment bias of the OFSEP cohort**
- **Over-representation of treated PwMS in the OFSEP cohort**, probably linked to recruitment based on MS centers
- **Linkage of both databases** would give opportunity to study MS care practices in France on an exhaustive population-based dataset
- Period 2010-2015: **too early to study prescription of oral DMTs**

Literature

Foulon S, Maura G, Dalichamp M, Alla F, Debouerie M, Moreau T, 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;264(6):1185–92.