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Time to initiation of disease-modifying drugs after a live birth in women with multiple sclerosis

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INTRODUCTION

- Multiple sclerosis (MS) affects three times as many women as men,[1] and the clinical onset is often during the period of life during which patients are having children.[2]
- MS is more commonly diagnosed in women of childbearing age than in any other group.[3]
- More evidence to support decision making in women with MS of childbearing age is needed.[4]
- A better understanding of the 'real-world' disease-modifying drug (DMD) treatment patterns in women with MS and pregnancy is essential in order to improve available clinical support, healthcare services, and quality of life for women with MS of childbearing age.[5]
- Administrative healthcare claims databases enable the assessment of DMD treatment patterns in patients with MS in a real-world setting reflective of clinical practice in a large number of patients.[6,7]

OBJECTIVE

- To evaluate the time to initiation of DMDs after a live birth in women with MS using US administrative claims data.

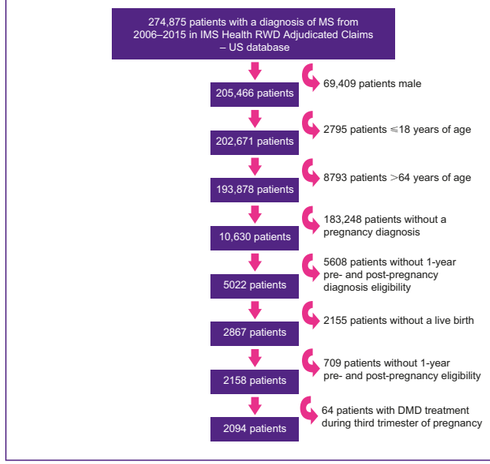
METHODS

- A retrospective analysis of women with MS (International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] code: 340.xx) in the IMS Health Real World Data (RWD) Adjudicated Claims – US database was conducted.
  - The IMS Health RWD Adjudicated Claims – US database includes complete, adjudicated plan-level data comprising a full inventory of a patient's prescriptions, inpatient hospital claims, and outpatient medical claims.
  - The database consists primarily of commercial Preferred Provider Organization plans and can thus under-represent patients on Medicaid or Medicare relative to patients on commercial plans.
  - The database includes ~150 million patients with a medical benefit, and a subset of 95 million patients with both medical and pharmacy benefits.
- Patients were required to have at least one encounter with a diagnosis of MS (ICD-9-CM code: 340.xx) from January 1, 2006 to June 30, 2015.
  - The date of the first MS encounter was the index date.
  - Included patients were required to be female, between the ages of 18 and 64 as of the index date, and have at least one encounter with a diagnosis of pregnancy or a pregnancy-related procedure from the index date to June 30, 2014.
  - The date of the live birth procedure was used to estimate the date of conception and the pregnancy periods (as per Knox 2014).[8]
- Continuous eligibility 1 year before conception and 1 year after the live birth were additional required inclusion criteria for this cohort.
- The proportion of women initiating a DMD within 1 year post-delivery was evaluated.
- For women who initiated a DMD, the time to first DMD (calculated as the time between the live birth and the date of first DMD prescription) was assessed.
- Results were summarized with means, medians, and standard deviations (SDs).

RESULTS

- There were 2094 women who met the eligibility criteria for this study, as illustrated in **Figure 1** and **Table 1**.
- Mean (SD) age was 30.3 (4.68) years (**Table 1**).
  - Most women had commercial health insurance (98.6%) and 32.3% of women were from the Midwest region, while 30.7% were from the South and 28.7% were from the Northeast.
- The proportion of women with a live birth initiating a DMD within 1 year was 28.5% (n=596).
  - For women initiating a DMD within 1 year, mean (SD) time from live birth to first DMD treatment was 119.0 (92.94) days; median time to first DMD was 93.5 days.
  - A total of 16.1% received a DMD <30 days after live birth; 18.6% initiated a DMD during the second month (**Figure 2**).
  - Approximately half initiated a DMD within 90 days (47.8%), and three-quarters initiated a DMD within 6 months (75.5%) (**Figure 3**).
- The proportion of patients initiating DMDs within 1 year after live birth increased with higher numbers of pre-pregnancy relapses (**Table 2**). Of those with 0 relapses, 24.5% (n=441) initiated a DMD within a year of live birth; of those with 1, 2, and ≥3 relapses, the proportions initiating a DMD within a year of live birth were 50.9% (n=108), 54.1% (n=33), and 60.9% (n=14), respectively.
  - The mean (SD) and median number of days until DMD initiation for those receiving treatment within 1 year for those with 0 relapses was 123.6 (96.02), median 99; for those with 1 relapse, 108.0 (84.38), median 80; for those with 2 relapses, 120.8 (83.63), median 98; and for those with ≥3 relapses, 55.6 (37.88), median 49.5 days.
  - Among patients treated with DMDs 1 year pre-pregnancy, 72.6% initiated DMD treatment within 1 year, while only 12.4% of those without DMD exposure 1 year pre-pregnancy initiated DMD treatment within 1 year.
    - However, patients tended to wait over 100 days after birth to initiate DMD treatment regardless of past use: the mean time to initiation was comparable between groups (mean [SD] 147.9 [103.59] days for those without DMD exposure pre-pregnancy vs 105.3 [84.21] days for those with DMD exposure pre-pregnancy; median 122 and 84 days, respectively).

Figure 1. Sample selection for the analysis of DMD initiation post-live birth in women who did not have a DMD claim in the third trimester



DMD, disease-modifying drug; **MS**, multiple sclerosis; **RWD**, real-world data.

Table 1. Baseline demographic and clinical characteristics of women with MS and a live birth and no DMD claim in the third trimester

Characteristic	
Age	
N	2094
Mean (SD)	30.3 (4.68)
Median	30
Age grouping, years, n (%)[a]	
18–24	219 (10.5)
25–29	705 (33.7)
30–34	787 (37.7)
35–39	326 (15.6)
40–44	52 (2.5)
≥45	1 (0.1)
Payer type, n (%)	
Commercial	2065 (98.6)
Medicaid	25 (1.2)
Medicare	4 (0.2)
Region, n (%)[b]	
Midwest	659 (32.3)
Northeast	585 (28.7)
South	625 (30.7)
West	169 (8.3)
CCI score pre-pregnancy diagnosis	
Mean (SD)	0.2 (0.59)
Median	0
Common comorbidities, n (%)	
Alcohol abuse	5 (0.2)
Anxiety	260 (12.4)
Arthritis	43 (2.1)
Chronic lung disease	114 (5.4)
Depression	209 (10.0)
Diabetes	56 (2.7)
Gastrointestinal disease	277 (13.2)
Hyperlipidemia	165 (7.9)
Hypertension	119 (5.7)
Thyroid disease	230 (11.0)

[a]n=2090.
[b]n=2038.
CCI, Charlson Comorbidity Index; **DMD**, disease-modifying drug; **MS**, multiple sclerosis; **SD**, standard deviation.

Figure 2. Time period initiating DMD treatment in the year after pregnancy for patients with MS and a live birth and no DMD treatment in the third trimester, among patients who initiated a DMD

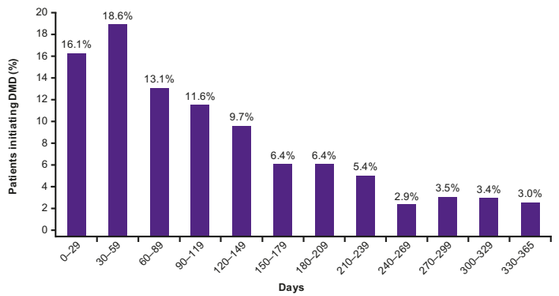


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Figure 3. Cumulative rate of DMD treatment in the year after pregnancy for patients with MS and a live birth and no DMD treatment in the third trimester, among patients who initiated a DMD

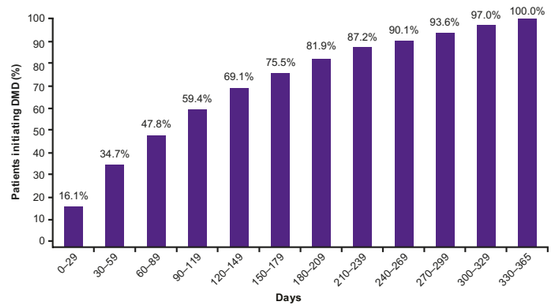

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Table 2. DMD initiation during the year after pregnancy in women with MS with a live birth and no DMD treatment in the third trimester, by number of pre-pregnancy relapses

	No. of relapses pre-pregnancy			
	0 (n=1798)	1 (n=212)	2 (n=61)	≥3 (n=23)
Patients initiating a DMD, n (%)	441 (24.5)	108 (50.9)	33 (54.1)	14 (60.9)
Mean (SD) time to initiation, days	123.6 (96.02)	108.0 (84.38)	121.0 (83.63)	55.6 (37.88)
Median time to initiation, days	99.0	80.0	98.0	49.5
Time to DMD initiation, days, n (%)				
0–29	69 (15.6)	19 (17.6)	0	5 (35.7)
30–59	83 (18.8)	18 (16.7)	1 (3.0)	3 (21.4)
60–89	51 (11.6)	21 (19.4)	3 (9.1)	3 (21.4)
90–119	51 (11.6)	9 (8.3)	7 (21.2)	2 (14.3)
120–149	40 (9.1)	15 (13.9)	3 (9.1)	1 (7.1)
150–179	29 (6.6)	7 (6.5)	2 (6.1)	0
180–209	29 (6.6)	5 (4.6)	2 (6.1)	0
210–239	25 (5.7)	5 (4.6)	4 (12.1)	0
240–269	14 (3.2)	2 (1.9)	2 (6.1)	0
270–299	18 (4.1)	2 (1.9)	1 (3.0)	0
300–329	16 (3.6)	3 (2.8)	1 (3.0)	0
330–365	16 (3.6)	2 (1.9)	7 (21.2)	0

DMD, disease-modifying drug; **MS**, multiple sclerosis; **SD**, standard deviation.

LIMITATIONS

- Claims data are not specifically collected for research purposes and missing information may limit the inferences that can be made from the data.
- The ICD-9-CM code for MS does not differentiate between different types of MS (eg, primary progressive MS, relapsing–remitting MS, or secondary progressive MS).
- Administrative claims databases provide information on patients with health insurance administered by regional health plans in the US and results may not be generalizable to patients who self-pay or patients without employer-sponsored commercial health insurance.

CONCLUSIONS

- **Less than one-third of women with MS and a live birth initiated a DMD within 1 year after delivery.**
- **Proportions of patients initiating DMDs within 1 year after live birth were higher among women with higher numbers of pre-pregnancy relapses.**
- **Women who had more pre-pregnancy relapses initiated DMDs sooner than those with no relapses in the pre-pregnancy period.**
- **More information regarding the 'real-world' DMD treatment patterns of women with MS and pregnancy is essential in order to improve available clinical support, healthcare services, and quality of life for women with MS of childbearing age.[5]**

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