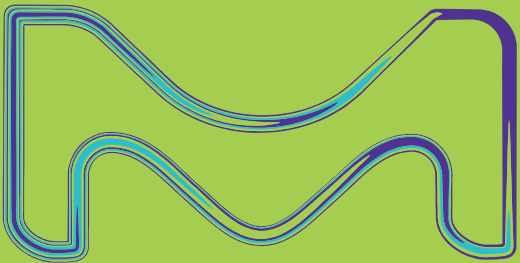


The biopharma business of Merck KGaA, Darmstadt, Germany operates as EMD Serono in the U.S. and Canada.

Maternal Health

Multiple Sclerosis

Terrie Livingston, PharmD
Head of Patient Outcomes & Solutions
North America Medical Affairs



**EMD
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MS is often diagnosed in women who are of childbearing age

Average age of onset of MS in the US¹

Younger



Older

33 years old



Some women may delay conception due to disease-related pregnancy concerns (eg, disease stability, societal attitudes, treatment discontinuation)^{2,3}

Pregnancy is a key consideration in treatment decisions for women with MS who are of childbearing age^{4,5}

MS, multiple sclerosis

1. Multiple Sclerosis International Federation. <https://www.msif.org/about-us/who-we-are-and-what-we-do/advocacy/atlas/> [Accessed March 4, 2019]; 2. Houtchens MK et al. Neurology 2018;91:e1559–69; 3. Kaisey M et al. Neurol Clin Pract 2018;8:142–7; 4. Amato MP, Portaccio E. CNS Drugs 2015;29:207–20; 5. Riñón A et al. Patient Prefer Adherence 2011;5:629–43



Prevalence of pregnancy in women with MS has increased from 2006–2014



The difference in linear trends between groups was statistically significant ($p < 0.0001$)^a

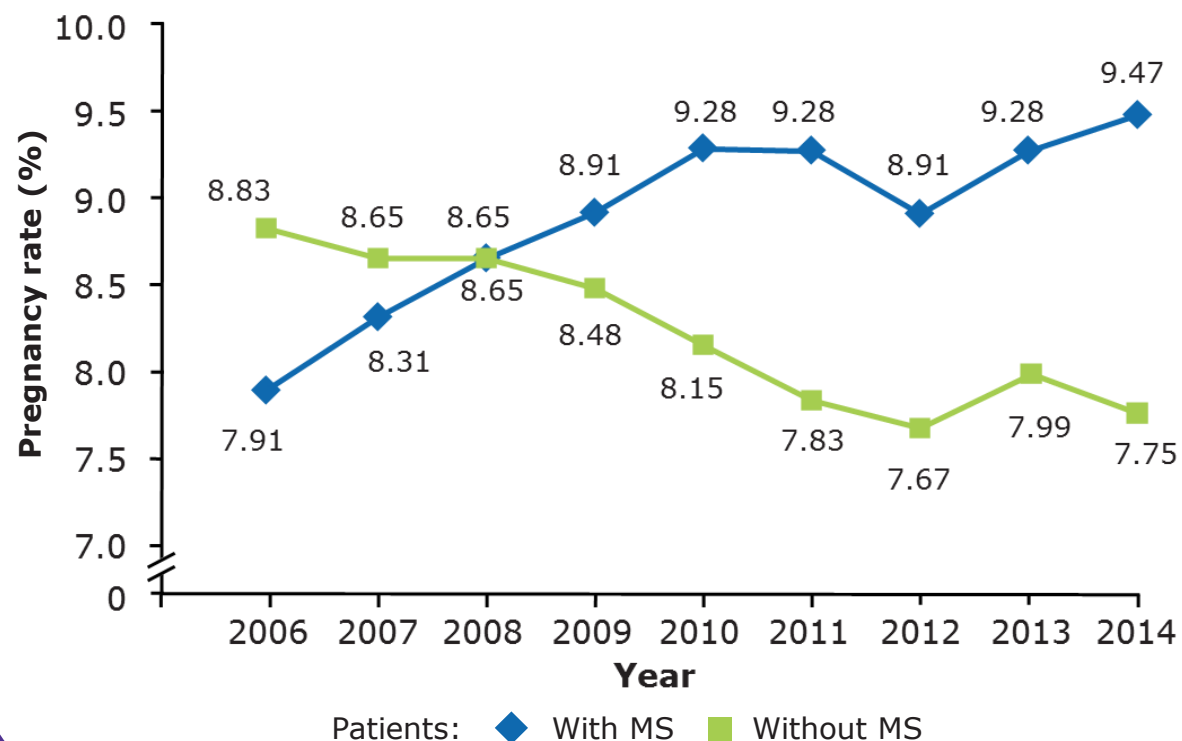


In recent years, women with MS have had pregnancy rates at least as high as women without MS



This trend may reflect a change in perceptions regarding pregnancy risks in this patient population

Adjusted proportion of women with and without MS and with a pregnancy, by year^a



Number of women with MS ranged from 36,361 to 58,218; number of women without MS ranged from 735,974 to 1,144,868. Observed in US women with MS in a retrospective administrative claims database study using IQVIA™ Real-World Data Adjudicated Claims data. ^aResults were adjusted for age, region, payer type, and comorbidity (using Charlson Comorbidity Index). Model assumptions were age = 30 years, region = Midwest, payer = commercial, and Charlson Comorbidity Index score = 0.25 (assumptions approximated the median values). After adjusting results, when comparing women with and without MS, the difference in linear trend was 0.17% increase and 0.15% decrease in per annum pregnancy rates, respectively. MS, multiple sclerosis
Houtchens MK et al. Neurology 2018;91:e1559–69



Effects of pregnancy on MS

Annualized relapse rate in the year before pregnancy and during pregnancy in women with MS (n=2158)^{1,a}

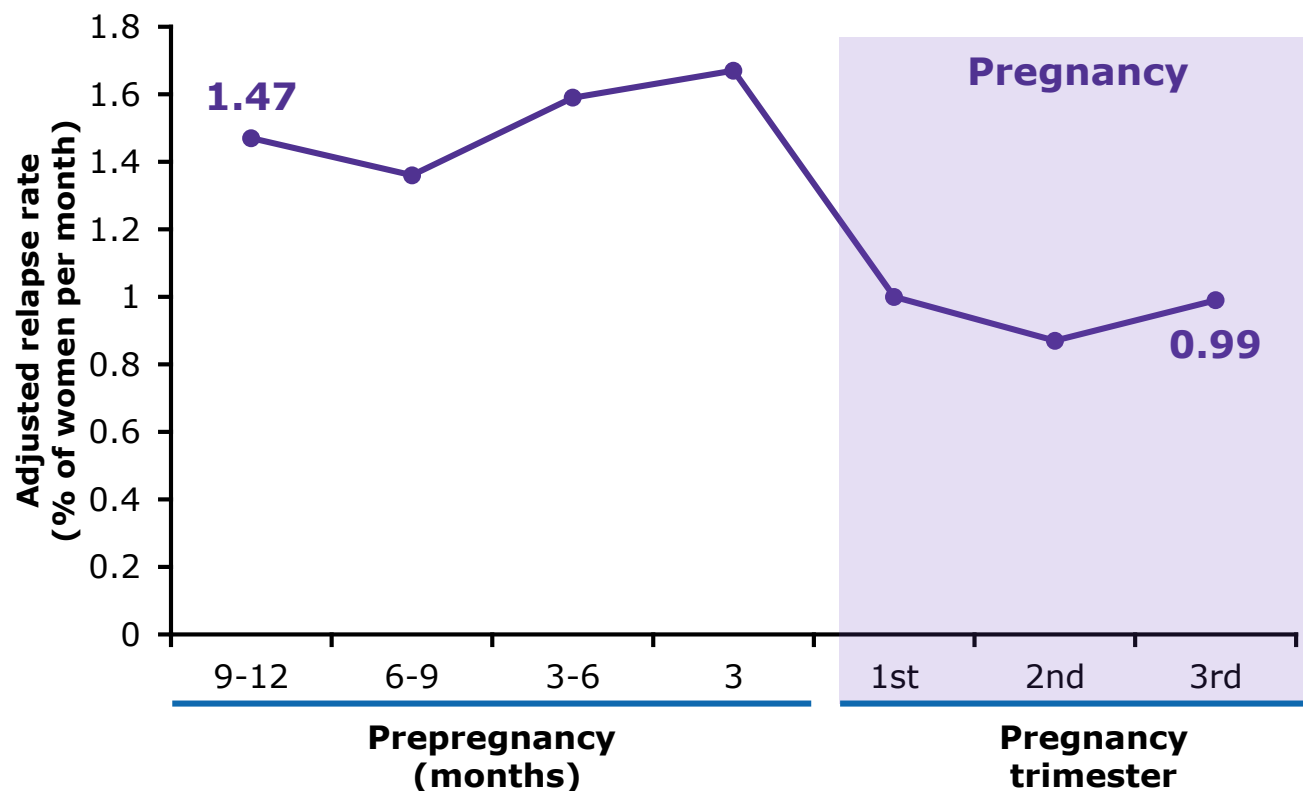


Figure from Houtchens MK et al. Neurology 2018;91:e1570-8

Pregnancy is an immunotolerant state; clinical and MRI disease activity is suppressed²

Pregnancy is associated with a decreased risk of relapse, compared with the prepregnancy period^{1,3,4}

There is no consistent evidence associating pregnancy with worsened long-term disability⁵

80% of patients with MS suffer from fatigue,⁶ which can worsen during pregnancy⁷

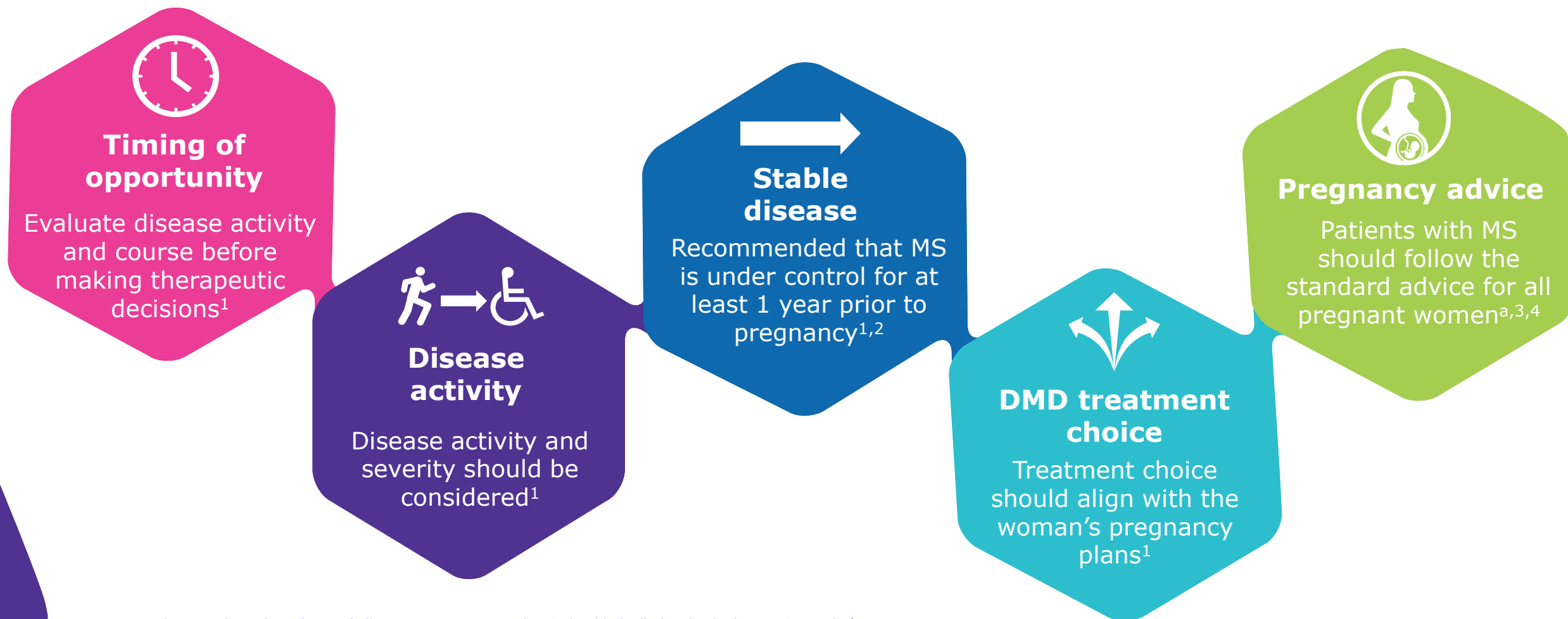
^aBased on data collected from the IQVIA™ Real-World Data Adjudicated Claims PharMetrics Plus Database ("PharMetrics Database") – 2006–2015

MRI, magnetic resonance imaging; MS, multiple sclerosis

1. Houtchens MK et al. Neurology 2018;91:e1570-8; 2. Coyle P. Ther Adv Neurol Disord 2016;9:198-210; 3. Confavreux C et al. N Engl J Med 1998;339:285-91; 4. Vukusic S et al. Brain 2004;127:1353-60; 5. McKay KA et al. Neurotoxicology 2017;61:189-212; 6. Veauthier C et al. EPMA J 2016;7:25; 7. Frago YD et al. Neurol Ther 2018;7:207-32



Considerations for pregnancy planning in MS



^aThe neurological condition of all pregnant patients with MS should ideally be checked every 3 months¹

DMD, disease-modifying drug; MS, multiple sclerosis

1. Amato MP et al. Neurol Sci 2017;38:1849–58; 2. Hughes SE et al. Mult Scler 2014;20:739–46; 3. Fragoso YD et al. Neurol Ther 2018;7:207–32; 4. Dobson R et al. Pract Neurol 2019;19:106–14



MS and Pregnancy

Questions to Ask Your Doctor.

Planning Ahead

- What medicines are okay to take pre-pregnancy?
- Is the medication I am currently taking (or my spouse is currently taking) okay if I am thinking of getting pregnant? Should I consider discontinuing therapy? If so, when should I stop taking it?
- Are there medications that are safe to take while pregnant? What are the benefits and risks for me and my baby if I continue taking medication?
- Are there any treatments for MS-related sexual dysfunction?

Before Conceiving

- Is my MS well-controlled? Can I do anything to control my MS before I start trying to conceive?
- Do my partner or I need to stop taking certain MS medications prior to trying to conceive?
- How will I manage any relapses before, during, or immediately after pregnancy?
- Would undergoing in-vitro fertilization (IVF) or other assisted reproductive treatment increase my risk for relapse?

Pregnancy

- How frequently should I visit the doctor?
- What type of medical team will I need in place during my pregnancy?
- How can I help make sure my neurologist, primary care physician, and OB/GYN work together with me to ensure a healthy pregnancy?
- Will MS make it difficult for me to give birth vaginally due to mobility issues or other MS symptoms?
- Under what circumstances would you recommend a patient with MS have a cesarean section (C-section)?
- Does the medication I'm taking put me or my baby at risk for any complications such as low birth weight or infection?
- Is it safe for my baby if I relapse?

Postpartum

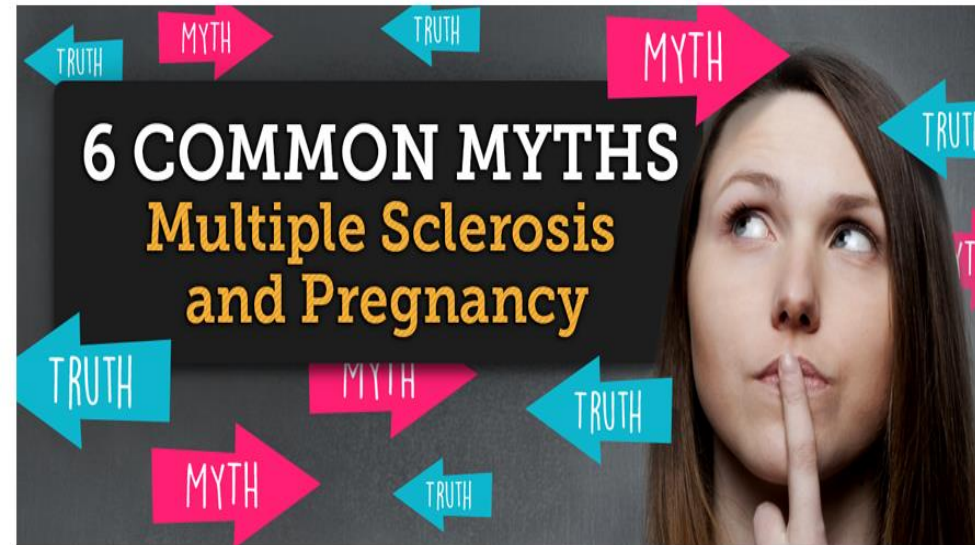
- Can I breastfeed? What if I can't? Would timing the medication affect breastfeeding?
- What should I tell my child?
- Would occupational therapy be helpful?
- How will I manage any relapses?



THINKING ABOUT STARTING A FAMILY
While Living With Multiple Sclerosis (MS)?

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What to
Expect:
**MS and
Pregnancy**

Family Planning
Resource Center



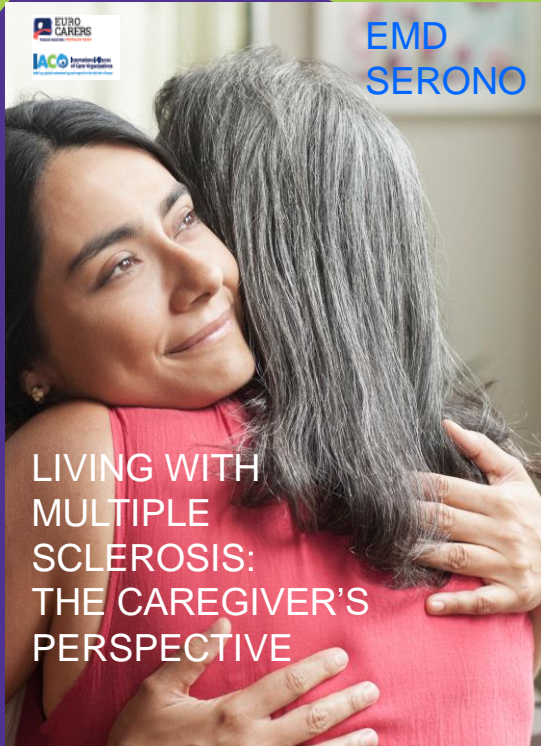


COMPANY / CORPORATE RESPONSIBILITY

HEALTHY WOMEN, HEALTHY ECONOMIES



SPHARZ



EMD
SERONO

LIVING WITH
MULTIPLE
SCLEROSIS:
THE CAREGIVER'S
PERSPECTIVE

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