

# Health system owned specialty pharmacy provided laboratory monitoring for patients with multiple sclerosis receiving sphingosine 1-phosphate receptor modulators

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## Background

- Sphingosine 1-phosphate modulators (S1P) are commonly dispensed by specialty pharmacies to treat Multiple Sclerosis (MS)<sup>1,2</sup>
- S1P agents place patients at risk for hepatotoxicity and immunosuppression  
→ requires additional monitoring to ensure patient safety
- Specialty pharmacists at Nebraska Medicine identified patients with MS were not receiving appropriate monitoring of S1P agents
- ❖ A laboratory monitoring protocol was created by specialty pharmacists for all patients on S1P agents from an affiliated MS Clinic, regardless of where the medication was dispensed. Pharmacists could order labs pursuant to protocol at Nebraska Medicine and outside facilities.

## Service Description

- **Specialty Pharmacists initiated discussions** with MS clinic providers to develop lab monitoring protocol and included pharmacists ordering labs on behalf of providers including:
  - Liver function tests (LFT)
  - complete blood counts w/ differential (CBC)
- Patients were included in the protocol after receiving a prescription from the MS clinic providers for any of the following S1P agents:
  - fingolimod, siponimod, ponesimod, or ozanimod

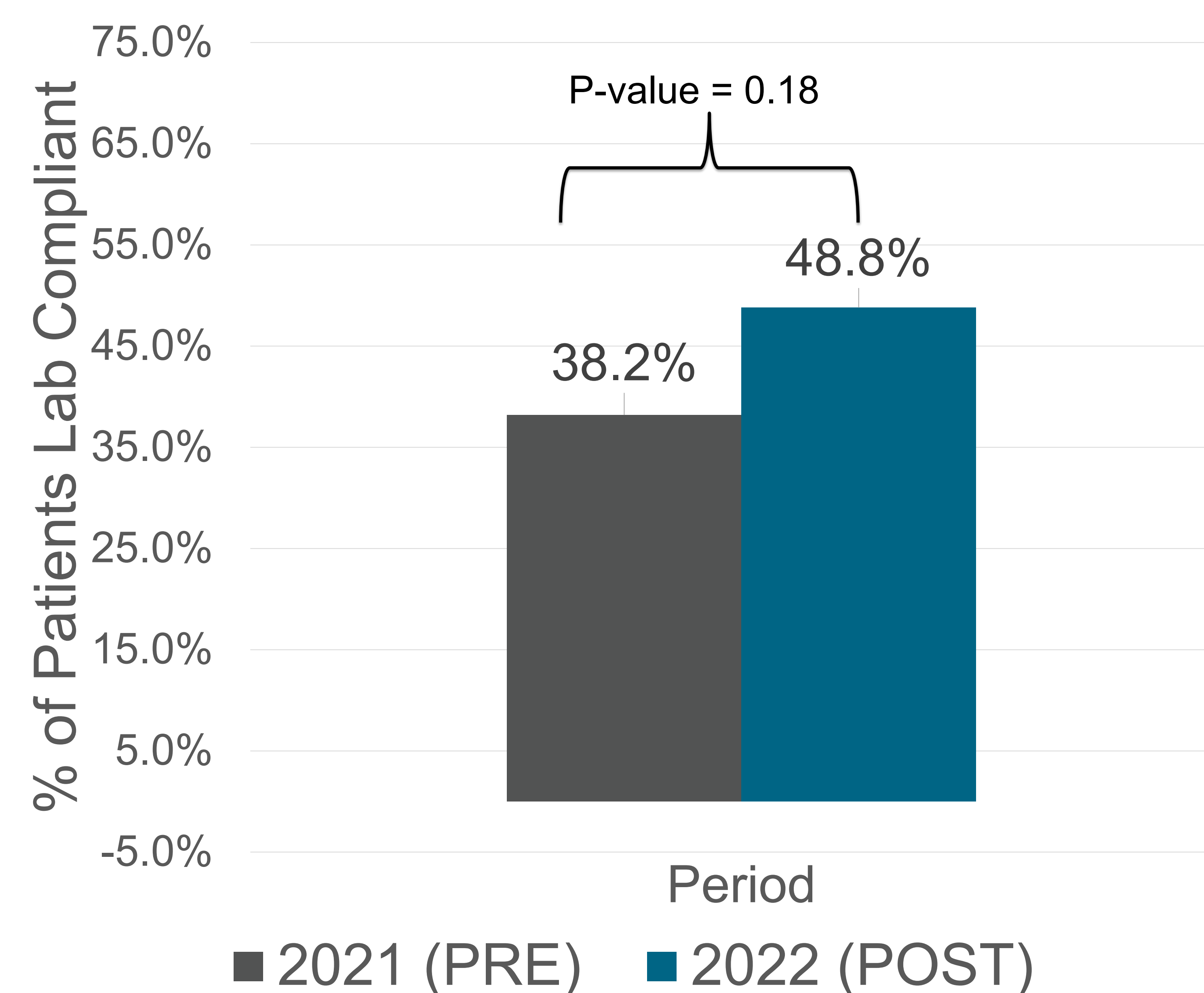
Workflow initiated on 1/1/2022:

1. MSOT queue orders were flagged to identify patients receiving S1P agents
2. Specialty pharmacist reviewed lab orders and results
3. Scheduled outreach assessment for next lab monitoring event to be evaluated, confirmed standing labs present
4. Patient contacted by pharmacist if labs were not performed on time or followed up with outside facility

## Evaluation and methods

- **One Year Pre/Post Quality Improvement Project**
  - 1/1/2021 to 12/31/2021, Pre-Period
  - 1/1/2022 to 12/31/2022, Post-Period
- Database query inclusion criteria during period (pre/post):
  - Patients with MS, 19 years or older
  - At least one MS clinic office visit
  - At least one prescription for S1P + look back in 2020
- Outcome defined in each period as:
  - Patients with labs at least every 6 months  
*Total Patients on S1P during year*
- Statistical analysis: Two-Proportion test on composite outcome, LFT only, and CBC only

## Results - Composite Outcome



**Figure 1: Composite outcome is defined as the completion of both LFT and CBC labs within at least every 6 months interval for all included patients compared by the pre period without the specialty pharmacist protocol and post period after. The 6-month lab compliance interval began at the first observed order within the year or look back period. Missing one lab interval led to patients failing the outcome in the year the interval due date was exceeded.**

## Results - Continued

Table One	2021	2022	p-value
Sample Size	76	82	
Composite	38.2%	48.8%	0.18
<b>CBC Only</b>	<b>44.0%</b>	<b>63.0%</b>	<b>0.018</b>
LFT Only	41.7%	55.4%	0.10

## Limitations

- New start versus chronic regimens not quantified
- Cannot ascertain if & when S1P may have been discontinued
- Small sample size limits power to detect significance
- Outside labs not quantified
- Patient and confounding factors not addressed

## Conclusion and Future Directions

- A numerically higher trend of composite and LFT lab compliance after pharmacist protocol was enacted
  - Statistically significantly higher proportion of CBC lab compliance
- Positive 1-year findings on program success were observed. Results strengthened by automated database query not requiring chart pulls being duplicated
- Future direction include quantifying new start S1P agents with more stringent lab monitoring requirements, evaluating patient characteristics, and clinical outcomes.

## References

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2. Darby S, Mazyck PJ. Evaluation of the impact of a clinical pharmacist on a specialty neurology clinic's adherence to recommended laboratory test monitoring. *J Manag Care Spec Pharm.* 2021;27(12):1664-1670. doi:10.18553/jmcp.2021.27.12.1664