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### Evaluation of a Refill-Associated Clinical Service in a Health System Specialty Pharmacy

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## Background

### Pharmacist intervention and medication adherence

- Patients receiving specialty medications often require close monitoring and frequent follow-up to ensure patient safety and adequate outcomes.<sup>1</sup>
- Pharmacist interventions are shown to improve medication adherence, which has a significant impact on patient outcomes.<sup>2</sup>

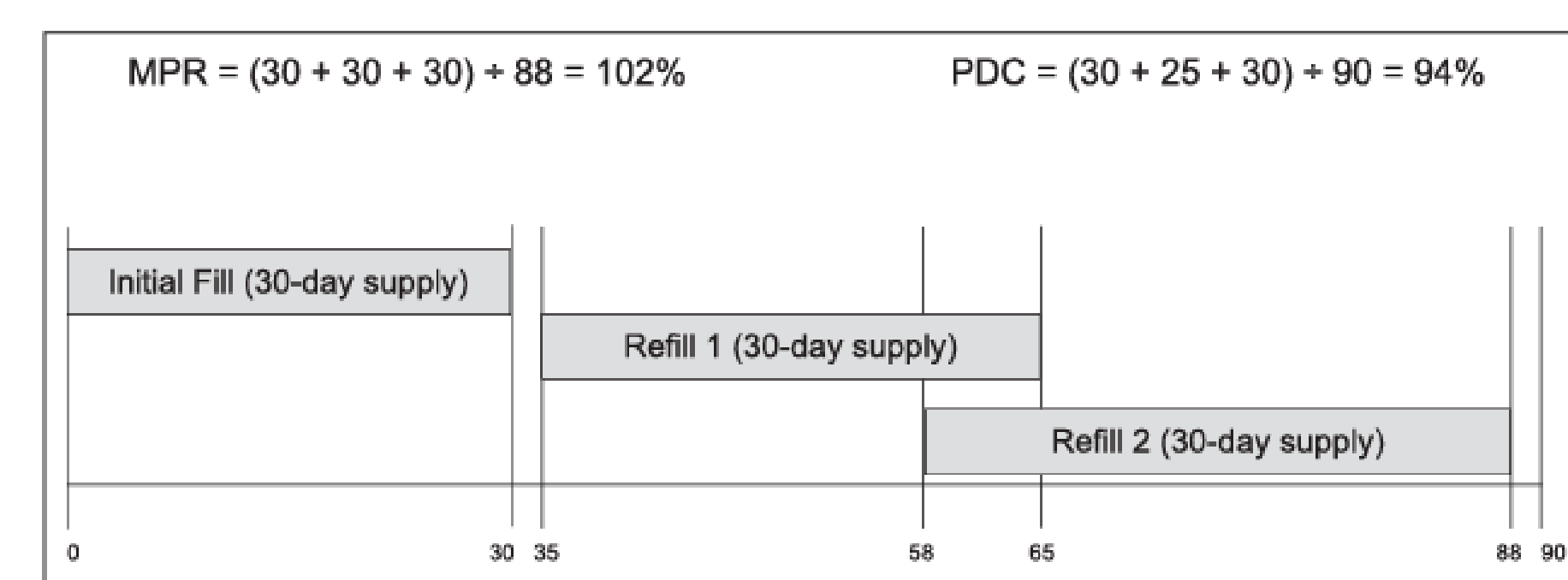
### Implementation of refill-associated clinical questions

- The Health System Specialty Pharmacy (HSSP) provides a specialty medication patient management service (SMMS) to assess clinical outcomes and patient safety.
- In June 2022, as part of the SMMS program, the HSSP implemented refill-associated clinical questions to assess adherence, efficacy, safety, and other relevant health status changes.
- Any changes, concerns, or questions are triaged to a clinical pharmacist for review and appropriate patient/provider follow-up.

### How to measure medication adherence

- Medication proportion of days covered (PDC) is one of the common metrics used to assess adherence. Unlike medication possession ratio (MPR), which can often overestimate adherence, PDC offers a more conservative approach to estimate the adherence.<sup>3</sup>

$$MPR = \frac{\text{sum of days supply}}{\text{total days in period}} \times 100, PDC = \frac{\text{total days covered}}{\text{total days in period}} \times 100$$



Loucks J, et al. *Am J Health Syst Pharm.* 2022;79(6):492-496.

## Purpose

To evaluate the impact of a refill-associated clinical question implementation on medication adherence and pharmacist interventions in a HSSP setting.

## Endpoints

### Primary endpoints

- Change in average PDC and proportion of patients with PDC ≥ 0.80 in pre- and post-implementation among SMMS-enrolled patients
- Change in number of interventions from pre- to post-implementation among SMMS-enrolled patients

### Secondary endpoints

- Difference in average PDC between patients enrolled in SMMS and patients who are not enrolled in SMMS before the implementation
- Average PDC based on age group, disease state, and payor type among SMMS-enrolled patients

## Methods

### Study design

- Retrospective quasi-experimental cohort study
- Pre-implementation: Jan 1, 2022 - Jun 30, 2022
- Post-implementation: Jul 1, 2022 - Dec 31, 2022

### Inclusion criteria

- Adults ≥ 18 years old
- Patients with at least 3-month fill history at HSSP during study period

### Exclusion criteria

- Patients filing only as-needed medications

## Baseline Characteristics

Characteristic	SMMS Opt-In		SMMS Opt-Out	
	Pre-Implementation (N = 3,344)	Post-Implementation (N = 3,531)	Pre-Implementation (N = 2,225)	Post-Implementation (N = 2,338)
Age (years)				
Range	18 to 97	18 to 97	18 to 95	18 to 95
Mean – no. ± SD	52 ± 15	51 ± 14	51 ± 14	50 ± 14
Sex – no. (%)				
Male	1,323 (40)	1,425 (40)	913 (41)	954 (41)
Female	2,021 (60)	2,106 (60)	1,312 (59)	1,392 (59)
Disease state – no. (%)				
Autoimmune	2,127 (63.6)	2,258 (63.9)	1,255 (56.4)	1,255 (53.7)
Cardiovascular/Lipid-lowering	143 (4.3)	136 (3.9)	37 (1.7)	33 (1.4)
Growth hormone	28 (0.8)	27 (0.8)	24 (1.1)	24 (1.0)
Hepatitis B	48 (1.4)	52 (1.5)	58 (2.6)	5 (2.3)
Hepatitis C	52 (1.6)	26 (0.7)	19 (0.9)	28 (1.2)
HIV	36 (1.1)	42 (1.2)	36 (1.6)	28 (1.2)
Multiple sclerosis	233 (7.0)	240 (6.8)	293 (13.2)	292 (12.5)
Oral oncology	448 (13.4)	491 (13.9)	157 (7.1)	178 (7.6)
Osteoporosis	30 (0.9)	37 (1.0)	6 (0.3)	11 (0.5)
Pulmonary arterial hypertension	24 (0.7)	21 (0.6)	8 (0.4)	8 (0.3)
Respiratory/Related conditions	94 (2.8)	117 (3.3)	187 (8.4)	213 (9.1)
Transplant	64 (1.9)	63 (1.8)	23 (1.0)	27 (1.2)
Other	19 (0.0)	21 (0.0)	120 (5.4)	188 (8.0)
Payor type – no. (%)				
Commercial	2,071 (61.9)	2,329 (66.0)	1,238 (55.7)	1,367 (58.5)
Medicaid	998 (29.8)	905 (25.6)	788 (35.4)	764 (32.7)
Medicare	275 (8.2)	297 (8.4)	201 (8.9)	207 (8.9)

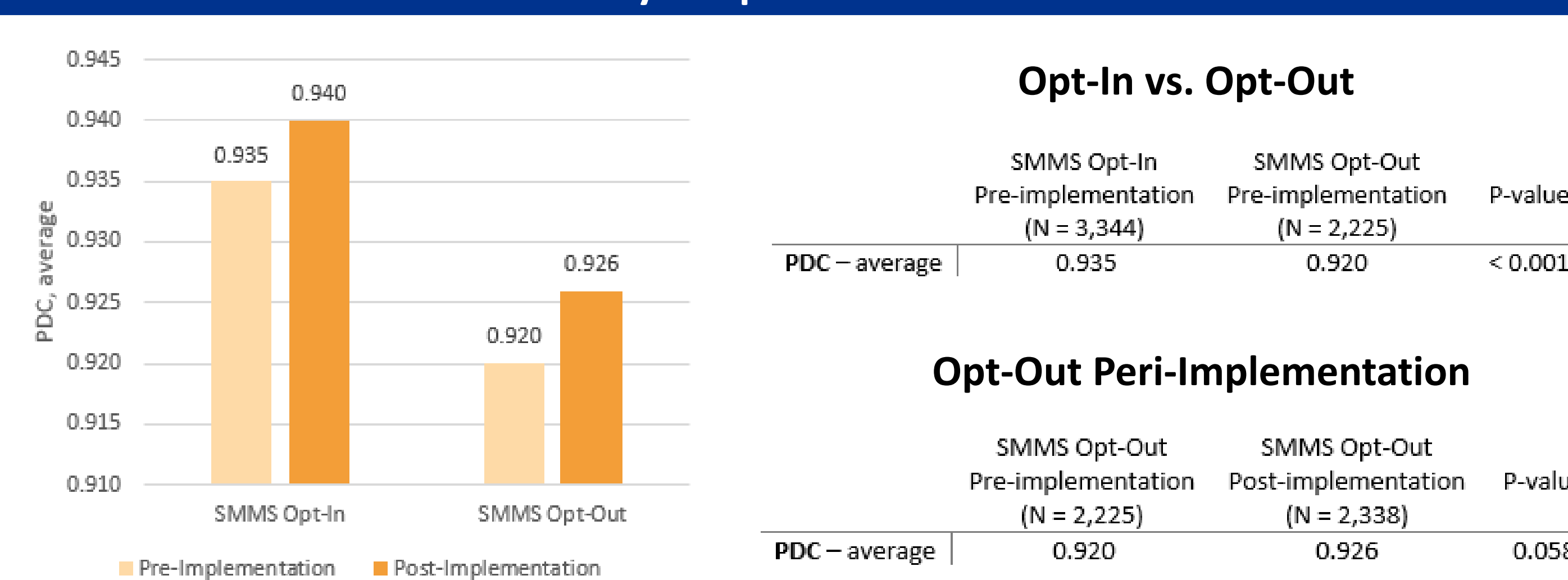
## Primary Endpoints

Variable	Pre-implementation (N = 3,344)	Post-implementation (N = 3,531)	Statistics
PDC – average	0.935	0.940	P = 0.010
PDC ≥ 0.8 – no. (%)	3,046 (91.1)	3,274 (92.7)	↑ 1.8%

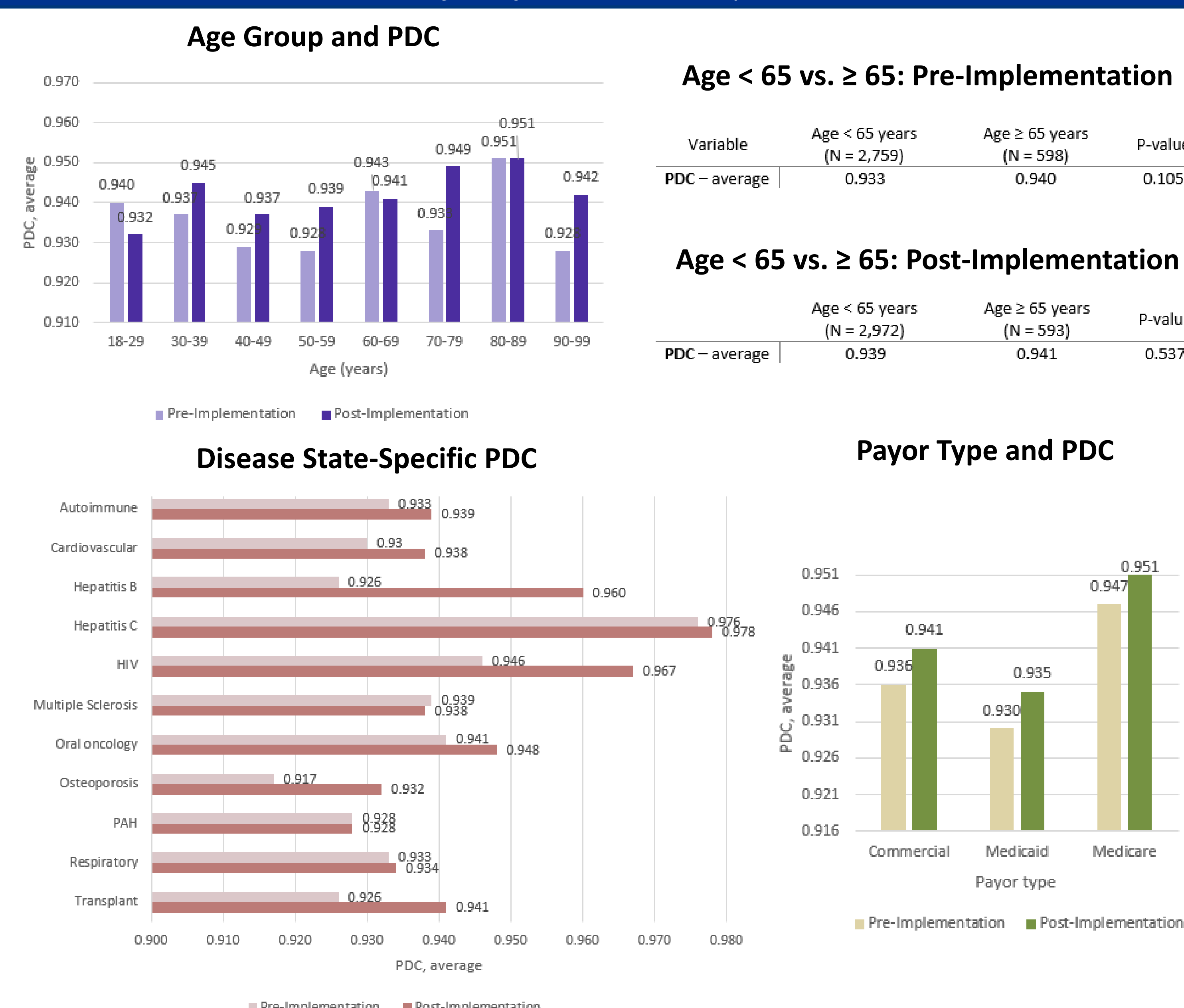
  

Intervention type – no. (%)	Pre-implementation (N = 3,344)	Post-implementation (N = 3,531)	% Increase
Adherence Issue	109 (3.3)	268 (7.6)	130%
Efficacy Concerns/Recommendations	11 (0.3)	107 (3.0)	900%
Side effect Management/Identification	27 (0.8)	129 (3.7)	363%
Patient Education	289 (8.6)	461 (13.1)	52%
All interventions – no. (%)	983 (29.4)	2,193 (62.1)	111%

## Secondary Endpoints: SMMS Enrollment



## Secondary Endpoints: Patient-Specific Factors



## Results & Discussion

### Baseline characteristics

- Baseline characteristics were evenly distributed between the pre-implementation and post-implementation groups for the Opt-In population.
- Autoimmune diseases is the most common disease state managed at the HSSP, followed by oncology.
- The majority of the patients have commercial plan or Medicaid, and less than 10% have Medicare.

### Primary endpoints

- After implementation of refill-associated clinical questions in the SMMS, PDC scores improved significantly (P = 0.010).
- An adherence rate ≥ 80% is expected to provide optimal efficacy in many disease states.<sup>2,4</sup> After the implementation, the proportion of patients with PDC ≥ 0.8 increased by 1.8%.
- Number of pharmacist interventions doubled after the implementation.

### Secondary endpoints

- The patients who are enrolled in SMMS showed better adherence than the patients who were not enrolled.
- There were no distinct PDC patterns demonstrated between age groups, and no statistical significance was found between PDC of age groups of < 65 and ≥ 65 years, using the common Medicare age cut-off.
- Medication adherence is especially crucial for HIV, hepatitis B, and hepatitis C medications. These disease states showed higher PDC than most other disease states, especially post-implementation.<sup>4-6</sup>
- Medicaid patients had a lower adherence compared to patients with Medicare or commercial insurance.

### Limitations

- Retrospective design can lead to potential patient-specific confounders.
- Statistical significance was not defined for the secondary endpoints regarding patient-specific factors.
- PDC improvement in the Opt-Out population after the implementation suggests a possibility of maturation bias or other confounders.

## Conclusion

- The data from this study shows the positive impact of SMMS and its refill-associated clinical questions on specialty medication adherence and pharmacist interventions, which have been linked to improved patient outcomes.<sup>2</sup>
- The low adherence rate of Medicaid patients could be attributed to lack of resources, social support, poorer health literacy, and barriers to healthcare access that Medicaid patients can experience.<sup>7</sup>

### Future directions

- The result of this study encourages the continuation and expansion of refill-associated clinical questions at HSSP.
- Impact of patient-specific factors on adherence requires further investigation to determine the causal relationship.

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