Pharmacist Driven Shingrix® Follow-Up, a Randomized Controlled Trial

Michael D. Stapley, PharmD Candidate Class of 2020[1,2]; Sarah Nestlehut, PharmD[2]; Jonathan W. Magness, PharmD[2]

1. University of Utah College of Pharmacy
2. Magellan Rx Management • Scottsdale, AZ

AMCP Nexus 2019 | National Harbor, MD

Background

- Telephonic reminders have been shown to increase adherence to vaccines.[1] This study is the first-of-its-kind to leverage the unique pharmacy claims data available to a pharmacy benefit manager (PBM) in order to intervene with those patients who were at risk for non-adherence to the second dose of Shingrix® (recombinant herpes zoster vaccine [RZV]).
- **Hypothesis:** Pharmacist driven telephonic intervention within a prescription drug plan (PDP) will be an effective method for increasing completion of the RZV two-dose series.

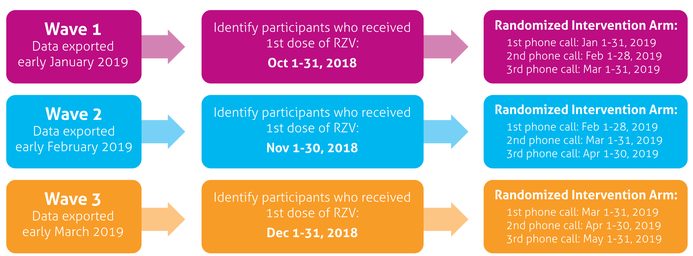
Objective

- To determine if pharmacy intern delivered telephonic outreach reminders to a randomized selection of Magellan Rx Medicare Part-D (PDP) participants who have only received one dose of RZV will improve adherence with its two-dose schedule within the Advisory Committee on Immunization Practices (ACIP) and Centers for Disease Control and Prevention (CDC)-specified timeline[2] compared to those who do not receive a telephonic outreach reminder.

Methods

Figure 1. Methods by which participants were identified and entered the study protocol

Final data exported July 2019 for final analysis



Low-Income Subsidy (LIS) status affects adherence to the Shingrix® vaccine series more than telephone call reminders.

Results

Table 1. Primary end point: Participants vaccinated within CDC/ACIP-specified timeframe for RZV (as tested via Chi-Square)

	Received 2nd dose (n)	Did not receive 2nd dose (n)	Improvement over control (%)	Relative Risk (95% CI)
Wave 1				
Intervention Arm	27	8	10	1.14 (0.86-1.51)
Control Arm	27	13		
Wave 2				
Intervention Arm	19	7	-1	0.99 (0.73-1.34)
Control Arm	28	10		
Wave 3				
Intervention Arm	9	6	-2	0.97 (0.59-1.59)
Control Arm	21	13		
Overall				
Intervention Arm	55	21	5	1.07 (0.88-1.29)
Control Arm	76	36		

CI = confidence interval; CDC = Centers for Disease Control and Prevention; ACIP = Advisory Committee on Immunization Practices; RZV = Recombinant Zoster Vaccine (aka "Shingrix")

Table 2. Exploratory Analysis: Participants vaccinated within CDC/ACIP-specified timeframe for RZV after receiving a phone call and receiving the Low-Income Subsidy (LIS) (as tested via Chi-Square)

	Received 2nd dose (n)	Did not receive 2nd dose (n)	Difference (%)	Relative Risk (95% CI)	P
Overall					
Receiving LIS	15	12	-26%	0.68 (0.47-0.98)	0.0375
Not receiving LIS	40	9			

CI = confidence interval; CDC = Centers for Disease Control and Prevention; ACIP = Advisory Committee on Immunization Practices; RZV = Recombinant Zoster Vaccine (aka "Shingrix"); LIS = Low-Income Subsidy

Results cont.

Table 3. Baseline Patient Characteristics of MRx PDP members who participated in the Pharmacist Driven Shingrix Follow-Up RCT, Mean [Standard Deviation] or n (%) (as tested via student's t-test and Chi-Square)

	Intervention (n = 76)	Control (n = 112)	P
Mean age, years [SD]	73 [8]	72 [9]	0.44
Female	64%	66%	0.82
LIS Recipient	36%	39%	0.60
CMS Region of Residence			
3 (NY)	33%	35%	0.72
5 (DC, DE, MD)	26%	24%	
7 (VA)	32%	36%	
28 (AZ)	9%	5%	

MRx PDP = Magellan Rx Part D Plan; RCT = Randomized Controlled Trial, LIS = Low-Income Subsidy

Table 4. Outcome* of telephone calls to participants within the Intervention Arm across all Waves, n (%)

	n (%)
1. Answered and had at least one live telephone call	34 (45%)
2. Voicemail was left	32 (42%)
3. Answered the call but was uninterested	4 (5%)
4. Never answered the call	3 (4%)
5. Wrong Number/No number/Disconnected until the Pharmacy answered	3 (4%)
TOTAL	76 (100%)

*Each participant is only counted once. Outcomes are listed in a hierarchical order (1=most impactful outcome).

Discussion/Conclusion

- The null hypothesis was unable to be rejected.
- For the LIS recipients in our population, a traditional telephonic outreach did not have significant influence on adherence.
- LIS-receiving members were less likely to be adherent to the RZV series.
- LIS-receiving members have been shown to have a lower health literacy, and this contributes to decreased adherence.[3-6]
- **There is a need for future research to address LIS recipients' Social Determinants of Health.**

References

1. Stilwell AM, Pavero C, Buxton J, Herrington G. Implementation of a pharmacist-driven immunization program designed to improve overall vaccination rates in indigent and uninsured patients. *Journal of the American Pharmacists Association : JAPhA.* 2017;57(4):520-525.
2. Dooling KL GA, Patel M, et al. Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines. *Morbidity and Mortality Weekly Report (MMWR).*67(3):103-108. https://www.cdc.gov/mmwr/volumes/67/wr/mm6703a5.htm. Accessed September 13, 2018.
3. Aruru MV, Salmon JW. Development of a medicare beneficiary comprehension test: assessing medicare part d beneficiaries' comprehension of their benefits. *Am Health Drug Benefits.* 2013;6(8):453-461.
4. Bauhoff S, Carman K, Wuppermann A. Low-Income Consumers' Lack Of Financial Literacy Could Impede Use Of ACA Coverage, Subsidies. 2013. https://www.healthaffairs.org/do/10.1377/hblog20130926.034158/full/.
5. The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy. Institute of Education Sciences; 2006. https://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2006483. Accessed September 15, 2019.
6. Quick Guide to Health Literacy. https://health.gov/communication/literacy/quickguide/factsbasic.htm. Accessed September 15, 2019.