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HERPES ZOSTER VACCINE TO THE HOMEBOUND ELDERLY:
PREVENTION, PROTECTION, AND ACCESS TO CARE

UNIVERSITY OF SAN DIEGO
Hahn School of Nursing and Health Science
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DOCTOR OF NURSING PRACTICE PORTFOLIO

by

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Description

As lifespans increase and the population of the United States ages, the incidence of herpes zoster (Hz), or shingles, will also rise.¹ With the natural aging process, a decrease in cellular-mediated immunity produces immunosenescence where the functions of the innate and adaptive immune systems diminish. After initial infection with the varicella zoster virus (VZV), or chickenpox, the virus will lie dormant in the dorsal root ganglion of the spinal cord. Similar to all of the three herpes virus strains, this latent state remains until a trigger reactivates the VZV that causes an Hz outbreak.² VZV can be a relatively mild disease whereas Hz tends to be a severe, unilateral, vesicular rash lasting 2 to 4 weeks, causing degrees of morbidity and mortality.³ For persons over 40 years of age in the United States, 99% have a positive serology of the VZV making them prone to develop Hz.⁴ The potential of developing shingles within one's lifetime is 1 in 3 for the United States;^{4,5} therefore, approximately 1 million new cases of Hz occur each year in the United States; this incidence increases with age. The incidence for 50- to 59-year-olds is 5 per 1,000 cases, while the incidence for 80-year-olds and older is 11 per 1,000 cases.⁶ In the United States, the aging population is projected to be greater than 70 million by the year 2030,⁷ all of whom are at high risk of developing Hz as well as experiencing potentially devastating complications.² To combat these high risks in the elderly, the 10-year goal of Healthy People 2020 is to increase adult-vaccination rates of persons 65 years and older by 10%.⁷

Of those who develop Hz, 10%-25% will develop peripheral herpetic neuralgia (PHN); the occurrence of PHN is 3 times higher in people 65 years or older.⁸ This condition is the most prevalent, painful, and long-lasting complication of Hz, consisting of severe neuropathic pain,

with only palliative treatment available.⁹ Since the risk of Hz increases with age as cell-mediated immunity declines, persons 80 years or older have a 25% to 50% chance of developing Hz¹⁰ and the presence of co-morbid diseases, stress, and depression contributes to a shingles outbreak.^{2,11} With the age-related decrease in immunity, any subsequent physiologic or emotional stressors can trigger reactivation of the virus creating the classic, unilateral, painful vesicular rash.¹²

The Shingles Prevention Study, a 5.5-year seminal study conducted by the Department of Veterans Affairs and completed in 2004, trialed the live attenuated Hz vaccine for the prevention of shingles and its complications.¹³ This study of 38,456 persons in 22 Veterans Affairs facilities provided the evidence to support Food and Drug Administration (FDA) approval for Merck's Zostavax® vaccine in May 2006 for the prevention of shingles.¹³ Zostavax® reportedly reduced the incidence of an Hz outbreak by 51% and lessen the development of PHN by 67%.¹⁴ Zostavax® was also shown to reduce the burden of illness by 61.1%, increase one's functional status by 66.2%, and enhance quality of life by 55%.¹⁰

The Centers for Disease Control and Prevention (CDC) reported that vaccination rates for adults in 2013 were unsatisfactorily low suggesting a public concern that was not adequately addressed at the local, state, and national levels.¹² Zostavax® had also been under-prescribed to minorities,⁵ with administration rates reported as low as 3.9%.² The FDA approval in 2006 recommended Zostavax® for persons over 60 years of age with a 24% uptake of the vaccine.⁴ In 2011, the uptake rate decreased to 15.8%.⁹ Then in 2011, the FDA recommended the age for Zostavax be extended to 50 years and older as the incidence in this age group (50 to 59-year-olds) was 5 persons per 1,000.^{14,15} In 2018, the CDC reported that 33% of eligible adults received the Hz vaccine.⁶ No data were available specifying immunizations rates for the Hz vaccine in California or San Diego County where the project was conducted.

One of the main causes of low immunizations rates is attributed to the lack of provider recommendation, albeit time constraints, knowledge deficits, or personal beliefs.¹⁶ The National Vaccine Advisory Committee recommends registering vaccinations in individual state's Immunization Information Systems (IIS) to document and track immunizations¹⁷ as a means to improve awareness and knowledge of required adult immunizations.

Another major barrier for obtaining the HZ vaccine was cost and reimbursement.¹⁸ Zostavax® is covered under Medicare Part D, a pharmacy benefit.⁹ In 2015, approximately 69% of the Medicare enrollees signed up for Medicare Part D.⁸ Clinicians were not able to administer the vaccine at the clinical appointment due to reimbursement concerns, hampering the ability to offer certain vaccinations.¹⁶ In 2014, the cost for Zostavax® in the United States ranged from \$123 to \$253.²⁰ During this 4-month project, from May 2017 to August 2017, the cost for the Zostavax® was between \$0 to \$245 under Medicare Part D coverage. The out-of-pocket payment quoted by one Rite Aid pharmacy in San Diego was \$319 (R. Cortez, personal communication, March 26, 2018), while Costco offered Zostavax® at \$230.74 for uninsured customers (K. Patel, personal communication, March 26, 2018). The administration of a vaccine could produce a fee of up to \$32 for the clinician.^{21,22}

Storage issues at the clinic were also seen as a barrier as the serum must be kept frozen with the reconstitute solution stored separately, then mixed prior to administration.¹⁴ These requirements make purchasing, stocking, and monitoring Zostavax® within the clinic cumbersome. To overcome this issue, patients obtained a prescription, picked up the vaccine from a pharmacy, and properly transported it back to the clinic for administration. Some pharmacies have registered and are capable of administering vaccines, thereby removing the final step.⁹ Nevertheless, this arduous method has been recognized as one of the barriers to

vaccination.¹⁶ Homebound populations have often been unable to procure the vaccine in this manner. Additionally, the homebound population tends to be elderly with multiple co-morbidities. Incidents of depression, a result of high levels of daily stress, can lead to lower immunity reserves. All of these issues increase susceptibility to a shingles outbreak, hence the need for H_z vaccination in this population.^{2,11} One technique to reduce these barriers is to provide Zostavax® through a provider with a home visit.¹⁷

Innovation

The purpose of this 4-month project was to increase the immunization rate of Zostavax® administration in the homebound population 60 years of age and older by having the vaccine delivered and administered at home under the Medicare Part D reimbursement plan. The practice setting was a primary-care mobile practice providing health care to homebound persons, mostly elderly, with multiple co-morbid diseases. Due to co-morbidities, these patients tended to have extenuating circumstances that produced stress and experienced some degree of depression. All of these compounding factors made them highly susceptible to a shingles outbreak and the development of PHN.

The low rate of adult vaccinations and high rate of protection achieved with Zostavax® were the main drivers for this project. An additional benefit was protection against potentially devastating complications, such as PHN. This project was also influenced by the Healthy People 2020 initiative that recognized low adult vaccination rates and set a goal to increase vaccinations in adults by 10%.⁷

The live attenuated H_z vaccine can reduce the incidence of a shingles outbreak by 70% in ages 50 to 59, 64% in ages 60 to 69 and 38% in ages 70 years and older.⁴ Additionally, the H_z vaccine reduces the occurrence of PHN by 66% in ages 60 years and older. Zostavax® can be

administered to those who have had a previous shingles outbreak^{2,4} or who are unsure of a previous chickenpox infection.⁵ Zostavax® remains effective for 7 to 11 years.²³ With these positive health benefits, providing the Hz vaccine to homebound patients at higher risk for a shingles outbreak is a vital preventative measure. Additionally, Hz vaccination is one of the four Grade A adult vaccines recommended by the U.S. Preventive Services Task Force.⁷ The clinic's EHR systems incorporated the IIS registry of California in July 2017, the second month of the project, which allowed previous and future vaccinations to be registered in the tracking system.

In 2013, the cost of Hz outbreaks in the United States for persons 50 years and older was reportedly \$5 billion (95% CI [\$3.8 billion, \$5.7 billion]), including both direct medical care and indirect costs associated with individual productivity.¹² In 2006 dollars, the cost of an individual Hz outbreak was estimated as high as \$467, including clinic visits and antiviral medications.²⁴ Additionally, costs associated with an Hz outbreak for other non-PHN related expenses were estimated between \$1,158 and \$11,255 for cutaneous, ophthalmic, or neuromuscular issues. Costs associated with PHN can be as high as \$5,387 per episode. If hospitalization is required, the charge adds up to \$7,206 in 2006 dollars. In the 12 years since then, these amounts have increased and do not completely reflect today's charges or fully capture personal costs, such as pain, depression, anxiety, chronic fatigue, social isolation, PHN complications, or other extensive problems such as eye involvement including permanent vision loss.²⁴

Model Description

This project was conducted through a private, home-based, primary care practice for 4 months, May 2017 through August 2017. To qualify for the Hz vaccination, patients were first identified as not having been vaccinated. Further inclusion criteria included: 60 years of age or older, Medicare Part D coverage, a functioning refrigerator/freezer, eligibility for service with a

delivering pharmacy, understanding and complying with the storage requirements, and agreeing to be vaccinated. Exclusion criteria included: immunocompromised status, a contraindication; or declining the vaccine. Eligibility would be evaluated with future assessments and offered again, if applicable.

Effectiveness

The project was successful in increasing Hz vaccination rates by 473% to eligible patients over a 4-month period during 2-day work weeks. The project suggested that provider recommendations were key as well as the highest predictor for patients receiving Zostavax®.⁸ Another deciding factor was monetary; the vaccine was covered by insurance or the amount of the co-payment was affordable.

Of the 24 identified patents that qualified for Zostavax®, 16 received the vaccine. Six declined due to coverage or co-payment concerns. Two were admitted into the hospital and were not at home for the duration for the project. Patients with Medicare Part D coverage were offered Zostavax® during a routine home appointment along with an explanation of Hz, prevalence, complications, vaccine's benefits, and storage requirements. An order was sent to a designated, delivering pharmacy where coverage was determined, then the vaccine and reconstitution were delivered. Upon arrival, the serum was promptly stored in the patient's freezer. The reconstitute was stored in the refrigerator to enhance ease in finding both vials for administration on a return visit. Once administered, the vaccination was documented in the patient's EHR chart including the administration data, and entry in the IIS registry. The International Classification of Diseases, 10th revision (ICD-10) was used in the patient's EHR, diagnostic code Z23, encounter for immunization.²⁵ Likewise, the Current Procedural Terminology (CPT) code 90736 for product

and CPT code 90471 for administration was used in the notes, all of which allowed for the payment of \$32 for the Zostavax® subcutaneous injection.²⁶

Evidence of Feasible Implementation

The purpose of this 4-month project was to increase the immunization rate of Zostavax® administration to the homebound population of 60 years and older by having the vaccine delivered and administered in the home under the Medicare Part D reimbursement plan. The project produced an increase of Zostavax® immunization of 473%, but the process had several limitations. One limitation was the requirement that the Zostavax® serum had to be maintained in a frozen state and was further complicated by ensuring Zostavax® was delivered prior to the follow-up administration appointment. Another limitation was whether the vaccine was covered by insurance or the size of the co-payment; patients readily declined if Zostavax® was not covered at a lowest co-payment cost of \$103.

A newer version of the Hz vaccine, Shingrix®, manufactured by GlaxoSmithKline, was approved by the FDA on October 20, 2017 for persons 50 years and older.⁶ Shingrix® is a recombinant, adjuvanted, inactivated form of the virus containing a lyophilized surface glycoprotein E (gE) antigen element of the varicella virus.²⁷ It does not require freezing as both the antigen and the suspension are refrigerated until time of reconstitution and administration. Shingrix® is reconstituted with its accompanying AS01_B suspension and is an intramuscular injection. It requires two separate doses, 2- to 6 months apart; therefore, it poses a risk of complicating its full potential with the second dose. In random control trials, Shingrix® was found to be 97.2% effective to persons 50 years and older (95% CI [93.7%, 99.0%]) and 85.1% effective in persons 70 years and older (95% CI [64.5%, 94.8%]), yielding a 91.3% efficacy in pooled analysis for persons 70 years and older (95% CI [86.9%, 94.5%]).²⁷ Zostavax® has been

shown to become less effective with age as the immune system continues to decline,⁴ but Shingrix® maintains its efficacy with aging.⁶ Increased provider recommendations with Shingrix® is anticipated as efficacy is enhanced for the higher-risk, elderly groups. Shingrix® can also be given to persons with or without known evidence of a VZV infection, those who have had a previous Hz outbreak, and immunocompetent persons. Shingrix® may also be given to persons with previous Zostavax® vaccinations if given at least 2 months afterwards.⁶ The major barriers of cost and coverage remain. Shingrix® is also a Medicare Part D pharmacy benefit. The stated cost is \$194.99 per injection when not covered by insurance, making the Shingrix® vaccination course as much as \$389.98 at Rite Aid in San Diego, CA (R. Cortez, personal communication, March 26, 2018). At Costco in San Diego, CA, the cost is \$159.82 per injection, totaling \$319.64 for the course without insurance benefit (K. Patel, personal communication, March 26, 2018). Although the cost of the Shingrix® course is slightly higher than the cost of one Zostavax®, Shingrix® appears to be more effective in aging populations, prevents more outbreaks, and should be favored over Zostavax.⁶ However, cost and coverage will continue to be a barrier. By using home care providers for access enabling the use of Medicare Part D coverage, vaccination and protection against shingles is possible for the homebound elderly population by eliminating 2 main barriers¹⁷. Utilizing home care providers for this growing high-risk population is a logical next-step, not only as shown in this project, but also for the complex variables in the homebound elderly by keeping them healthier and out of the hospital.

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