Protocol to Increase Administration of Herpes Zoster Vaccine in a Long-Term Care Facility

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Abstract
Although the herpes zoster (HZ) vaccine to decrease the incidence of Shingles was licensed for use in 2008, little coverage for HZ vaccination has occurred and stands nationally at 16%. At a targeted nursing home and assisted living facility, a protocol for including HZ along with state-mandated vaccinations was devised and used in screening incoming residents. Baseline data from chart reviews (n=122) showed that despite treatments given for the infection in the preceding 12 months, no vaccinations had occurred. During a 6-month implementation period, all new residents meeting eligibility criteria were offered the HZ vaccination. In this period, four residents agreed to the vaccination. In a pre to post implementation survey, all clinical providers (n = 9) indicated they had been (1) or would (8) would recommend the HZ vaccination.

Keywords
herpes zoster vaccine, vaccination initiative, long term care
Introduction

A vaccine for reducing the risk for developing herpes zoster (HZ) was approved by the US Food and Drug Administration (FDA) and licensed for use in 2006. In 2008, the Advisory Committee on Immunization Practices (ACIP) recommended administering the vaccine to adults aged 60 years and older (Hales, Harpaz, Ortega-Sanchez, & Bialek, 2014; Tseng et al., 2011). Care providers were hopeful that use of the vaccine would occur and thus, decrease the incidence of HZ and post-herpetic neuralgia that, in turn, would reduce the cost of managing HZ. This has not been the case. According to the Centers for Disease Control and Prevention (CDC), the vaccination coverage level for the age group of 60 and over is 15.8%, as compared to 54.4% for pneumonia and 68% for influenza in the same age group (Centers for Disease Control and Prevention [CDC], 2014).

Problem Identification

The project’s principal investigator, a Nurse Practitioner at a facility for assisted-living and long-term care, noticed that the existing vaccination protocols at the facility did not include HZ vaccination. The on-site pharmacy did not store the vaccine as there was no call for it. Despite the incidence of reported cases of HZ in the facility, patients were not offered the HZ vaccine. Screening for specific vaccines was limited to state-mandated vaccines, such as for pneumonia and influenza. While providers generally agreed on the need to follow national guidelines in managing chronic conditions, there seemed to be a disconnect in applying national recommendations for the prevention of HZ. In general, both providers and residents seemed to not be aware of the availability and benefits of the vaccine.

Background and Significance of HZ and the HZ Vaccine

Approximately 1 million episodes of HZ occur annually, and half of all cases occur in men and women 60 years old or older (CDC, 2014). One-third of persons who have had a varicella zoster virus infection (Chicken Pox) will develop HZ during their lifetime (Chua & Chen, 2010). The incidence of Herpes Zoster in long-term care facilities is a problem because the pain of HZ and of post-herpetic neuralgia is debilitating and often long lasting. Herpes zoster, caused by reactivation of the varicella zoster virus dormant in the dorsal root ganglia of people who had contracted the virus, increases with age, mainly as a result of declining immunity (Harpaz, Ortega-Sanchez, & Seward, 2008; Watkins, 2010).

Efficacy of the vaccine was demonstrated in the pre-licensing trials. Oxman et al. (2005) reported that in two large-scale randomized controlled trials (the Zoster Efficacy and Safety Trial and the Shingles Prevention Study), a live vaccine that increases varicella-specific immunity in immunocompetent persons proved to be partially effective (51% in the Shingles Prevention Study) in preventing HZ in older adults. Tseng et al. (2011) in a retrospective cohort study, matched persons with and without vaccination in a sample of older community dwelling adult persons and found similar results. The authors reported 6.4 incidences per 1000 for vaccinated persons 60 and older vs. 13 per 1000 for unvaccinated persons.

Although state mandates may require that long-term care residents be screened for and offered vaccination for pneumonia and influenza, vaccination for herpes zoster is not usually on state-mandated rosters. However, despite the cost-effectiveness of clinical preventive services, the percentage of older adults who are up to date with core services is low (Department of Health and Human Services, 2010). Less than half of adults 65 years and older, and 25% of adults 50-64 years old, report being up to date with coverage (Shenson, Adams, Bolen & Anderson, 2011).

Purpose of the HZ Vaccine Initiative

The HZ vaccination initiative was conducted to determine whether a systematic approach would increase the number of residents vaccinated against HZ in a long-term care and assisted living facility. The goal was to ultimately decrease the incidence of HZ. To achieve a systematic approach, an overall
design for developing, implementing, and evaluating the initiative was developed. In the pre-project development phase, presentations were made to key stakeholders, staff, and residents to introduce the initiative and gain support. Once approval was obtained, awareness and educational sessions were developed. Before project implementation, a protocol for HZ screening and administration was devised. Baseline information was collected from resident medical records to determine both the number of residents who had been vaccinated and the number of incidences occurring in the previous 12 months.

The HZ vaccine initiative sought to increase awareness among providers, staff, and residents about the availability, accessibility, safety, and efficacy of the HZ vaccine; to identify barriers to protocol implementation; and to identify partners necessary to accomplish project aims. In addition, the initiative aimed to develop an algorithm that would aid providers and staff in screening persons for vaccinations and standardize a protocol for administering the vaccination. The intent was to screen all incoming or new admittances to the facility for HZ during the 6-month implementation period. Therefore, the initiative was limited to screening and vaccination of incoming residents only.

**Methods**

**Context**

The setting for the HZ vaccine project was a 200-resident nursing home and assisted living facility in a large southwestern city. The facility’s Medical Director, Administrator, Director of Nursing, and Assistant Director of Nursing were involved in planning, developing, and then implementing the HZ initiative. The facility’s clinical staff included two physicians and seven nurse practitioners who served to meet the residents’ medical needs. The clinicians provided clinical care to minimize unnecessary patient isolation, hospitalizations, and emergency room visits.

**Vaccine Availability and Reimbursement**

Because the on-site pharmacy does not stock HZ vaccine, a partnering arrangement was made with a neighboring facility for delivery of the vaccine at call. Payment options included out-of-pocket, private insurance, or Medicaid or Medicare. Insurance usually covered the cost of the HZ vaccine for residents in the acute and rehabilitation phase of the facility, whereas the vaccine cost for residents in the long-term facility were through Medicaid or Medicare part D for qualifying patients. When a resident or patient agreed to receive the vaccine, the pharmacy was updated to as to his or her insurance carrier.

**Intervention**

The intervention was a 6-month period following a 3-month planning phase. During the 3-month pre-implementation phase, the initiative staff developed project components, which included education materials, a screening algorithm and vaccination protocol, vaccination forms, and a standing order for clinicians to order the HZ vaccine at need. The intervention was limited to intake of new admittances to the facility. Persons joining both the nursing home and assisted living components of the facility during the 6 month implementation period were screened for HZ. This resulted in a corresponding low number of vaccinations in the 6 month period (n = 4) as few residents were admitted during the time frame and not all admittances qualified for vaccination.

**Education**

A 30-minute educational training program was presented on a monthly basis for 3 months prior to screening persons newly admitted to the facility for HZ. Sessions were open to nurses, medication aides, nursing assistants, clinical providers, and residents. PowerPoint presentations provided basic knowledge about the incidence of HZ, costs to the facility in managing HZ, payment options, and vaccine availability, cost, side effects, benefits, and administration schedule. Merck & Co, licensee of
ZOSTAVAX® (live HZ vaccine), provided an online module that focused on clinical aspects of the vaccine, such as prescribing, dosing, and ensuring patient safety.

Clinical providers (7 NPs and 2 physicians) completed a survey prior to and at the end of the 6-month implementation period. The survey was based on a similar form for influenza (Nexøe, Kragstrup, & Søgaard, 2009). The providers (n = 9) and other nursing staff (n= 12) also completed a test before and after the training to obtain a pre- to post-test difference in scores.

**Screening Algorithm**

On patient admission to the facility, the admission director screens the resident and/or caregiver to determine whether the patient was vaccinated for HZ, tuberculosis, pneumonia, and influenza. The Yes-No paths were as follows:

**Question:** Has resident been vaccinated for HZ?

**Path 1** if Yes for HZ. Screen for state-mandated vaccines.

- If Yes, notate record.
- If No, refer to vaccination protocol and inform pharmacy.

**Path 2** if No for HZ. Screen for state-mandated vaccines

- If Yes for state-mandated, notate record.
- If No, go to HZ protocol and follow up with state-mandated vaccination protocol.

**HZ Vaccination Protocol**

A protocol for guiding clinicians through the process of patient evaluation and HZ vaccine administration was developed in consultation with the facility administration, pharmacy, and nursing staff (See Appendix A). Steps of the HZ protocol accomplished in the implementation phase of the initiative are as follows:

1. The admitting nurse determines the patient’s eligibility for HZ vaccination payment.
2. The clinical provider (nurse practitioner or physician) assesses the patient to ascertain if patient is immunocompetent and for contraindications to taking the HZ vaccine. The provider makes the final decision to vaccinate or not.
3. If the clinical provider recommends HZ vaccination, the standing order for the vaccine goes into effect.
   a. The partnering pharmacy is notified.
   b. The pharmacy delivers the HZ vaccine to the facility.
4. The nurse obtains permission and a vaccination consent form the patient or legally responsible party.
5. The nurse vaccinates the patient.

**Evaluation**

Prior to attending the educational components, clinical providers (n = 9) completed a survey to determine their comfort level with recommending the HZ vaccine. One item of the 6-item questionnaire asked respondents to rate their knowledge about the use of the vaccine and another asked what
limitation kept them from routinely ordering the vaccination. The clinicians’ initial responses constituted baseline information. The survey was repeated 6 months later. The initiation team completed a baseline review of vaccination records in patient charts to determine the number of residents who had been vaccinated for HZ (n = 52 charts for long-term care residents and n = 70 charts for residents in assisted living). Noted also were the number of residents treated for HZ in the prior 12 months. This chart review was repeated at 3 months and 6 months after the rollout of the HZ vaccine protocol.

**Initiative Approval and Ethical Considerations**

The project’s research protocol was submitted to the Institutional Review Board of the project manager’s university for review and was granted approval as a quality improvement initiative. Approval was also obtained from the facility’s administrators, who ensured that no conflicts of interest existed. Protection of the patients’ identities was maintained and assured. Because the vaccine used is FDA approved, the measures applied were within the expected standard of care. Each resident or his or her responsible party or guardian gave consent for vaccination when requested for administration. The vaccine manufacturer’s support for the project was limited to educational posters and on-line materials for the clinicians. The facility or project coordinator received no monetary gains from Merck & Co. or the partnering pharmacy.

**Results**

Nine clinicians (7 nurse practitioners and 2 physicians) participated in the HZ initiative. Survey results are reported in Appendix A. Prior to the educational component of the program, 2 of the 9 providers reported they had recommended the vaccine. After the 6-month implementation period, the number increased to 8. That incidences were occurring was evident. Participants reported that they had managed treatment of 8 patients with shingles before the initiative and an additional 2 (total of 10) during the 6-month period. Whereas the providers’ comfort level increased markedly, from 2 “most comfortable” to 8, they felt restricted in their effectiveness in providing HZ vaccination. Eight of the clinicians reported that lack of facility support was the chief limiting factor. Reasons at baseline identified for not recommending the vaccine were the high cost of vaccine and insurance coverage issues (44%) and lack of awareness of the vaccine (22%). However, all participants at 6 months rated themselves as “most knowledgeable” of the vaccine, and cost and lack of awareness were not given as barriers to prescribing the vaccination.

During the 6 month period, all persons admitted to the facility were screened for HZ vaccination. The providers followed the steps of the HZ protocol and offered the vaccine accordingly. Four persons, all new residents in assisted living, met the vaccination criterion and agreed to the vaccination. The increase from baseline is shown in Figure 1.
The percentage of increase in pre- and posttest analysis (n = 21) showed a significant increase. Whereas 51% of test respondents answered correctly on the pretest, 83% answered correctly on the posttest. This showed a 32% pre- to posttest difference in knowledge of HV and the vaccine.

**Discussion**

**Changes in Processes of Care at Facility**

Prior to the HZ initiative, the HZ vaccination status of the residents was not included on the standard patient intake and screening form. A review of resident charts (total n=122) showed that no vaccinations had been given in the previous 12 months, although incidences of shingles had occurred. To support the initiative, the NH facility implemented standing orders for the HZ vaccine for immunocompetent residents who met the vaccine administration criteria. The HZ vaccine standing orders empowered the nursing staff (including registered nurses and licensed vocational nurses) to make the decision to vaccinate based on the developed HZ vaccine criteria and HZ protocol guidelines. To facilitate the process, patient intake and screening forms were redesigned to include HZ vaccine on the list of vaccines offered by the facility.

The facility did not store the HZ vaccine on premises. The HZ vaccine had not previously been offered, and the on-site pharmacy did not have the conditions for maintaining potency at the required low temperatures. This issue was addressed through partnering with a pharmacy close to the nursing home facility that could provide expedient access to the vaccine when required.

**Screening Implementation**

After the implementation of the HZ Vaccine initiative, screening for HZ vaccine coverage for newly admitted residents increased from no screening of residents for prior HZ vaccine coverage to 100% screening. All residents admitted to the facility were screened for prior HZ vaccination and offered the HZ vaccine. Because the baseline for comparative purposes derived from chart reviews was 0%, any vaccination that occurred represented an improvement. The intent was that as HZ screening commenced and facility administrators and clinical staff became more aware of the need for decreasing the incidence of shingles in the facility’s residents, the percentage of vaccination would increase. Of note is that not
all residents would or did meet eligibility criteria due to suppressed immune systems and ongoing treatments (e.g. chemotherapy, HIV antiviral therapy).

The role of education in increasing staff awareness of HZ and the vaccine was profound. The proof was seen in the providers’ willingness to recommend vaccination after 6 months and a 32% increase in providers’ knowledge of HZ and the vaccine from baseline. Because admittance protocols were not following national guidelines for the prevention of HZ, the implementation of a screening and vaccination protocol was of value to the facility. Ongoing education brought an awareness of national guidelines that refocused the providers’ attention and consequently improved the health outcomes of the facility’s residents.

A success measure of the HZ vaccine initiative was that the clinical practice group, members of which also practiced in other long-term care facilities, wanted to implement the HZ vaccine initiative at those other facilities. This raises the expectation that replicating this initiative in similar facilities can reduce HZ occurrence and lower costs associated with managing the disease. Future efforts should be geared toward changing Medicare policy on vaccination to mandate that the HZ vaccine be offered in long-term care facilities.

Conclusion

Herpes Zoster remains a common infection in the U.S. despite the availability of an effective and safe vaccine. The HZ vaccination initiative in one targeted institution increased awareness among providers, staff, and patients about HZ vaccine availability, accessibility, safety, efficacy, and cost. Not offering the vaccine can potentially cause a financial burden for the healthcare system and decreased quality of health and well-being for patients. Concerted efforts on the part of clinical providers, facility administrators, pharmacists, and nurse practitioners to update protocols and recommend vaccination at time of resident admittance to the facility can result in decreased incidence of herpes zoster and improved quality of care for long-term care residents.

References


Appendix A: Provider Comfort Level with Herpes Zoster Vaccine

<table>
<thead>
<tr>
<th>PROVIDER QUESTIONS</th>
<th>BASELINE</th>
<th>6 MONTHS POST-IMPLEMENTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you ordered Zostavax for any of your residents/patients in the last year? Y/N</td>
<td>Yes = 2</td>
<td>Yes = 6</td>
</tr>
<tr>
<td></td>
<td>No = 7</td>
<td>No = 2</td>
</tr>
<tr>
<td></td>
<td>No response = 1</td>
<td></td>
</tr>
<tr>
<td>Have managed any patient with herpes zoster (shingles) in the last 3 months Y/N</td>
<td>Yes = 5</td>
<td>Yes = 5</td>
</tr>
<tr>
<td></td>
<td>No = 4</td>
<td>No = 4</td>
</tr>
<tr>
<td>If Yes, how many?</td>
<td>Total patients treated for HZ = 8</td>
<td>Total patients treated for HZ =10</td>
</tr>
<tr>
<td>How comfortable are you recommending Zostavax to your patients? On a scale of 1-5 where 1 is least comfortable and 5 is most comfortable</td>
<td>Least comfortable</td>
<td>Least comfortable</td>
</tr>
<tr>
<td>1 = 2</td>
<td>1 = 0</td>
<td></td>
</tr>
<tr>
<td>2 = 3</td>
<td>2 = 0</td>
<td></td>
</tr>
<tr>
<td>3 = 1</td>
<td>3 = 0</td>
<td></td>
</tr>
<tr>
<td>4 = 1</td>
<td>4 = 1</td>
<td></td>
</tr>
<tr>
<td>5 = 2</td>
<td>5 = 8</td>
<td></td>
</tr>
<tr>
<td>Most comfortable</td>
<td>Most comfortable</td>
<td></td>
</tr>
<tr>
<td>What limitation if any bars you from ordering Zostavax routinely as you do Pneumovax or flu vaccines? Describe briefly</td>
<td>No limitations n = 1</td>
<td>No limitations n = 1</td>
</tr>
<tr>
<td></td>
<td>Costs n = 4</td>
<td>Costs n = 0</td>
</tr>
<tr>
<td></td>
<td>Lack of information n = 2</td>
<td>Lack of information n = 0</td>
</tr>
<tr>
<td></td>
<td>Lack of facility support n = 1</td>
<td>Lack of facility support n = 8</td>
</tr>
<tr>
<td></td>
<td>No response n = 1</td>
<td>No response n = 0</td>
</tr>
</tbody>
</table>
Appendix B: HZ Vaccination Protocol

Has resident been vaccinated for Herpes zoster?

Patient has no contraindications to Zostavax including immunosuppression, HIV, Recent Chemotherapy, Steroid therapy or Allergy to vaccines?

Nurse offers vaccine to resident & resident or responsible party signs consent form

If yes, Screen for other Mandated Vaccines (Pneumovax, & Influenza)

Verify Insurance coverage for Zostavax

Notify partnering Pharmacy to avail vaccine

Vaccinate, monitor and report any adverse effects to clinical provider

Yes