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Shingles Vaccine: Identifying high risk groups in the IBD clinic setting

Crystal Barajas

University of San Diego, cbarajas@sandiego.edu

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“Shingles Vaccine: Identifying high risk groups in the IBD clinic setting”
UNIVERSITY OF SAN DIEGO
Hahn School of Nursing and Health Science

DOCTOR OF NURSING PRACTICE PORTFOLIO
by

Crystal Barajas, BSN, RN, PHN, DNPc

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Abstract

Title: Shingles Vaccine: Identifying high risk groups in the IBD clinic setting

Background: The Inflammatory Bowel Disease (IBD) population is an immunocompromised patient population who is at risk for Herpes Zoster (HZ) due to their medication regimen, which further compromises their immune system. It can be difficult for patients to receive appropriate preventative health maintenance measures due to patients' fears, primary care providers' lack of knowledge, and gastroenterologists not addressing what may be considered primary care topics. Furthermore, evidence demonstrates that IBD patients have low vaccination rates despite insurance coverage.

Purpose of Project: (a) To increase awareness of the importance of Shingrix in the Inflammatory Bowel Disease population (over 50 years old); (b) To increase Shingrix vaccination orders by 5% in a two-month period.

EBP Model/Frameworks: The ACE Star model was used to guide this project.

Evidenced-Based Interventions: A PowerPoint presentation will be utilized to educate IBD healthcare providers on the newest evidence regarding high risk groups for shingles and Shingrix. In addition, posters will be located in every patient room for patient education on Shingrix.

Evaluation/Results: No significant difference was found in vaccination rates between pre-and post-project implementation of patient posters and staff educational PowerPoint. Limitations included small patient sample size in post implementation.

Implication for Practice: Most insurance plans now cover Shingrix for patients aged 50 years and older. Spreading awareness of the importance of this vaccination will aid in increasing low numbers of vaccination rates in the IBD population.

Conclusion: The new Shingrix vaccine is not a live vaccine, therefore can be administered to immunocompromised patients, including those patients who have received the previous shingles vaccine, Zostavax. It is essential to assess health maintenance, including vaccines needed, at patients' initial visit.

Shingles Vaccine: Identifying High Risk Groups in the IBD Clinic Setting

Vaccination rates among the inflammatory bowel disease patient population continue to be low despite evidence exposing this population is at an increased risk for contracting illnesses due to the disease process and the treatment of immunosuppressive therapies (Gisbert & Chapparo, 2013). Historically, it has been advised to avoid live vaccines in this patient population, but now with the newly developed Shingrix vaccine, an attenuated vaccine, this adds to the list of recommended vaccines whether on or off immunosuppressive therapy. Another issue with the older version of the shingles vaccine, the Zostavax, was that it was recommended and covered by most insurances after the age of 60; this new vaccine, Shingrix, is recommended and covered by most insurances for patients over the age of 50. Regardless of whether the patient has received the Zostavax in the past, the Shingrix is recommended.

Background and Significance

The Inflammatory Bowel Disease (IBD) population is an immunocompromised patient population who is at further risk for Herpes Zoster (HZ) due to their treatment regimen. In a review article of previous research, it is hypothesized that the features of IBD, in combination with immunosuppressive therapy, could result in lower response rates of vaccinations, thus making it imperative to give vaccinations before implementing therapy if possible (Gisbert & Chapparo, 2013). Patients at highest risk for acquiring Herpes Zoster include those on triple immunosuppressive therapy including corticosteroids, disease-modifying antirheumatic drugs (DMARDs), and biologics. Studies show it can be difficult for patients to receive appropriate preventative health maintenance measures due to patients' fears, primary care providers' lack of knowledge, and gastroenterologists not addressing primary care topics (Reich, Wasan, & Farraye, 2016). Ways to close these gaps in care would be to assess health maintenance at an

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initial gastroenterologist visit and send primary care provider recommendations for vaccine administration. Furthermore, evidence demonstrates that IBD patients have low vaccination rates despite insurance coverage (Reich et al., 2016).

Purpose of Project

The purpose of this evidence-based project was to increase awareness of the importance of the Shingrix vaccine in the inflammatory bowel disease population, over the age of 50. The goal was to increase vaccination orders and recommendation rates for this high-risk group by 5% in a 2-month period. A PowerPoint presentation was utilized to educate IBD healthcare providers on the crucial information and literature findings. In addition, posters, which included side effects of the vaccine and pricing information, were located in every patient room for patient education. A chart review was completed on all patients over the age of 50, for the 2 months following PowerPoint and poster implementation, to check for number of recommendations and orders placed by healthcare providers in this inflammatory bowel disease center in the metropolitan area of San Diego, California.

Literature Review

While conducting this literature review, the databases Cochrane, CINAHL, and Pub Med were used. Key words such as: inflammatory bowel disease, IBD, Crohn's Disease, Ulcerative Colitis, Shingrix, Zostavax, inflammatory bowel disease plus shingles, inflammatory bowel disease plus vaccines, and immunosuppressive therapy were searched. As this evidence-based project progressed, more articles were found because the Shingrix vaccine has only been approved as of October 2017, therefore this topic is slowly surfacing new research findings and journal articles.

Studies such as one done in Korea (Soh et al., 2019), have looked at the risk of acquiring shingles in the inflammatory bowel disease patient population. The retrospective study looked at 30,100 patients with IBD and matched them by age and gender to 150,500 non-IBD patients. The information was gathered between 2010 to 2013 from patients in Korea. The results showed an increase risk was evident in patients with inflammatory bowel diseases, especially in those who were younger and were otherwise healthy without metabolic comorbidities (Soh et al., 2019).

In the collection of randomized controlled trial data by Colombel (2018), there was an increased risk of HZ for non-TNFi agents overall (abatacept, interleukin-1 receptor antagonist, abatacept, tocilizumab, ustekinumab, sifalimumab, and natalizumab data combined) when compared to TNFi agents (etanercept, adalimumab, Anbainuo, infliximab, certolizumab pegol, and golimumab data combined). Similarly, risks of HZ have been notable for Crohn's disease and ulcerative colitis patients receiving thiopurine therapy (Colombel et al., 2018). Furthermore, after biologics such as infliximab, adalimumab, or certolizumab pegol, or combination (both thiopurine and biologic) therapies were administered, a slight increase in risk of HZ were visualized for patients with ulcerative colitis in comparison to Crohn's disease. Additionally, in the meta-analysis from Colombel (2018), JAK inhibitors, as well as tofacitinib, have been associated with HZ risk in patients. It is hypothesized that the key inflammatory cytokines and the regulation of the immune response could put the patient at risk for HZ. In this same meta-analysis, a dose-dependent risk for HZ was observed with tofacitinib, with most cases being non-complicated, mild to moderate in severity, and manageable with antiviral medication. Therefore, tofacitinib can be safely continued after an event of shingles. In fact, most patients in the tofacitinib clinical programs were able to continue tofacitinib treatment during their shingles

event, with a small portion of patients temporarily discontinuing tofacitinib and resuming after antiviral therapy (Colombel, 2018).

In a meta-analysis inclusive of 57 studies out of 4,225 articles screened, Marra, Lo, Kalashnika, and Richardson (2016) looked at the correlation between the risk of HZ and immunosuppression therapy. Evidence showed an increased risk of shingles in immunocompromised patients taking biologics, particularly non-TNF- α blockers. An increased shingles risk was also seen in patients taking corticosteroids and nbDMARDs. Biologics and DMARDs are used as treatment for inflammatory bowel disease patients. Biological agents differ in their potency when targeting opportunistic infections, and investigating newer agents with different therapeutic actions than the traditional TNF- α inhibitors is essential.

A higher incidence of HZ cases were detected in patients who were on the medication tofacitinib for ulcerative colitis management (Winthrop et al., 2018). The authors observed that amongst older individuals, Asian patients, and those with prior TNFi use, who were taking 10mg of tofacitinib twice daily, and those with initial corticosteroid use, had higher incidences of HZ outbreaks. Age and prior TNFi failure were acknowledged as independent risk factors in ulcerative colitis patients who acquired HZ while using tofacitinib. Reports by Winthrop et al. (2016) and Winthrop et al. (2018) of patients taking tofacitinib and baricitinib for rheumatoid arthritis yielded a 1.5- to 2-fold increase in risk in HZ within some Asian countries compared with North American and European regions.

The higher incidences in Asia for patients taking JAK inhibitors is unknown (Winthrop et al., 2018). One possible reason for the increased risk of HZ in rheumatoid arthritis patients taking tofacitinib is from a genetic analysis that identified two single nucleotide polymorphisms (SNPs) that presented an increased risk within Japanese and Korean populations (Winthrop et al., 2018).

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The SNPs were intermittently present and were reflected in only a small percentage of the increased incidence noted with the patient sample. In this study, there was one case of encephalitis and nearly all prior reported cases with tofacitinib, and other JAK inhibitors have involved skin or ocular diseases only (Winthrop et al., 2016).

The mechanism of action by which tofacitinib or other JAK inhibitors increase the risk of HZ is unclear. In conclusion, with the data gathered by both Winthrop (2016; 2018) studies, the discussion points included the importance of vaccinations for HZ risk management and the benefits to all patients with immune-mediated diseases who receive treatment, principally those using JAK inhibitors. One recommendation concluded that when HZ occurs, antiviral therapy should be considered and tofacitinib temporarily stopped until resolution (Winthrop et al., 2018).

At the University of Manitoba, an IBD Epidemiology Database was used to identify cases of inflammatory bowel disease and controls from 1984 to 2016 who were diagnosed with Herpes Zoster before and after 2009, which was when the shingles vaccine was introduced (Nugent, Singh, Targownik, & Bernstein, 2018). The university wanted to look at the rates of vaccinations for HZ in patients older than age 50. They also investigated if there were any correlations among the patients that received the vaccinations. The data demonstrated the control patients were more likely to get the HZ vaccine than those with IBD. Patients newly diagnosed with IBD who were of higher socioeconomic status also had higher rates of the HZ vaccine. This systematic review also noted the incidence of having HZ infections in persons with chronic immune-mediated diseases receiving biologics was 60% to 70% more likely than controls (Nugent et al., 2018).

Studies such as the one by Hechter, Tartof, Jacobsen, Smith, & Tseng (2013) viewed data from Kaiser Permanente Southern California and looked at racial disparities and Herpes Zoster vaccine rates. The data revealed that within the sample size of 819,466 patients, coverage rate

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was higher in patients between that ages of 65 and 74 years and who were non-Hispanic White females. Coverage among non-Hispanic Whites and Asian/Pacific Islanders was similar and higher than the coverage for African-American/African and Hispanics (Hechter et al., 2013). The statistics on this study were collected to look at Herpes Zoster vaccination numbers and coverage regardless of the presence or absence of disease. These findings, therefore, are not specific to IBD, but important to keep in mind, since vaccination rates are already low in the IBD population and for African-Americans/Africans and Hispanics.

In a retrospective study, which included two cohorts of 67,920 participants total, the United States Department of Veterans Affairs healthcare system compared the overall risk of acquiring Herpes Zoster if patients were taking immunosuppressant therapy (Khan et al., 2018). Numbers were collected from patient records between January 1, 2000 and June 30, 2016. The results displayed that when compared to patients who did not have IBD, patients with ulcerative colitis (UC) and Crohn's disease (CD) had a significantly higher risk of Herpes Zoster infection. Additionally, IBD patients who were treated with 5-aminosalicylate acid (5-ASA) treatment alone also had an amplified risk of acquiring herpes zoster. When comparing the patients, who were treated with 5-ASA alone, there was also an increased risk for those patients on thiopurines or a combination therapy of thiopurines and TNF antagonists. TNF antagonist therapy alone did not demonstrate an increased risk of Herpes Zoster (Khan et al., 2018). Even more intriguing, this study exposed that vaccination rates nationwide for Herpes Zoster, in the IBD population without insurance constraints remained tremendously low.

Theoretical Model

For this evidenced-based project, the ACE Star Model of Knowledge Transformation (Stevens, 2013) was used to carry out implementation of a quality improvement project that was

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targeted at increasing Shingrix vaccination rates. There are five points on this model titled: discovery research, evidence summary, translation into guidelines, practice integration, and process/outcome evaluation. This model was chosen to guide this project due to its simplicity and for being applicable to evidence-based practice projects.

Under the first point, discovery research, a quality improvement project was discussed with the facility's nurse practitioner and medical director. A problem was identified which was the low Herpes Zoster vaccination rates in the immunocompromised population. The age range of 50 years and older was targeted because the Shingrix vaccine is approved for use in patients 50 years and older. This was also the step in which databases such as PubMed, CINAHL, and Cochrane were used to collect evidence on the importance of the shingles vaccine in the inflammatory bowel disease population.

The second point was the evidence summary, which included a literature review that was incorporated into the staff education PowerPoint slide deck. The literature was narrowed down to nine articles that included information from medications that caused immunosuppression, to pathology of the immunosuppressive disease, low vaccination rates in the IBD population, and racial disparities in vaccination numbers of the Herpes Zoster vaccine.

The third point was translation into guidelines. The Shingrix vaccination guidelines and recommendation of the Centers for Disease Control and Prevention (CDC) were used to guide the educational portion and recommendations listed in the staff educational PowerPoint. It was also recommended that after discussing the vaccine with patients, an order for the vaccine be placed or a recommendation note would be written in the patients' plan-of-care.

The fourth point was that of practice integration. On December 19, 2018, the project was piloted for a total of two months. The posters with vaccine information were placed in patient

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rooms and the staff education PowerPoint was sent via email for providers to read at their convenience in a one week period. Providers were then asked to send an email back stating they had reviewed the PowerPoint.

The final fifth point was the process/outcome evaluation. The project concluded on February 19, 2019. Data was collected on pre-and post-PowerPoint and poster implementation. The data collected included demographic information as well as pre-and post-orders and recommendation numbers of both Shingrix and Zostavax rates.

Practice Change Process

The nurse practitioner at the inflammatory bowel disease center at a large facility in San Diego, California was approached by the Doctor of Nursing Practice student regarding the needs of the facility. After further discussion, the student and nurse practitioner agreed on a change-of-practice plan that would be simple enough for providers to incorporate and an educational quality improvement project that would bring awareness to the latest research on the shingles vaccine which had been approved for patients aged 50 years and older, the year prior on October 2017.

Both the student and nurse practitioner presented their proposal to the medical director of gastroenterology and he approved both components of the project: emailing an educational PowerPoint presentation and posting information flyers in patient rooms to increase awareness of the importance of the shingles vaccine, thus encouraging the increase in numbers of Shingrix vaccination rates in this vulnerable population.

After the PowerPoint slide deck was emailed to staff in the inflammatory bowel disease department, data was collected for the two months prior to project implementation and two months post- project implementation. Data was collected on patients' demographics, if they were taking immunosuppressive therapy, if they had Zostavax in the past, and if they had any orders

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or recommendations placed in their charts for the Shingrix vaccine. The quality improvement evidence-based project goal was to increase awareness of the importance of Shingrix in the IBD population (over 50 years old) and increase vaccination rates for this high-risk group by 5% in a two-month period.

Cost/Benefit Analysis

Limited information was available on the cost benefit of the Shingrix vaccine for the United States at the time the literature review was completed. This is due to the relatively new information that continues to be studied and submitted for publication. One retrospective study from Canada showed that in 2011-2012, the average cost of an episode of Herpes Zoster was \$127.34 (Friesen, Chateau, Falk, Alessi-Severini, & Bugden, 2017). This price included pain medications and antivirals. For Herpes Zoster that led to post-herpetic neuralgia, the drug cost was approximately \$635, including again both antivirals and pain medications; with more spending on pain medications due to long term effects. It is estimated that the Shingrix vaccine costs approximately \$244 per dose in Canada. As future studies and data are collected in the United States, there will be better estimates of San Diego prices for episodes of Herpes Zoster, episodes leading to post-herpetic neuralgia and, cost benefit analyses specific to medical costs in this country. Today in San Diego, the Shingrix vaccine ranges from \$150 to \$190 per dose depending on which pharmacy is used and under which insurance plan. The complete series of this vaccine is two doses, therefore this project also emphasized for providers the importance of using the vaccine company as a resource for information on reimbursement forms as well as GoodRx.com when recommending the vaccine and ordering it for patients.

Results

The pre-implementation group consisted of 44 patients and the post-implementation group consisted of 25 patients. Of the 69 patients in total, 45% were female and 55% were male (Figure 1). The patient sample size was further broken down by age groups: 23 patients were in their 50s, 30 patients in their 60s, 11 patients in their 70s, and five patients in their 80s (Figure 2). When looking at how many patients were on immunosuppressive therapy at the time, 11% of the pre-implementation group were not on immunosuppressive therapy compared to the post-implementation group in which 16% of patients were not on immunosuppressive therapy (Figure 3). The remainder of the sample size was on immunosuppressive therapy, bringing the percentages to 88.6% in the pre-implementation group and 84% in the post-implementation group. Lastly, the data exposed order and recommendation rates in both the pre-and post-implementation rates to be 18.9% and 31.6% respectively (Figure 4). The second sample size, however, was not large enough to make the difference significant.

The patient sample size was acquired by counting all the patients over the age of 50 who were seen in the two months before implementing the educational PowerPoint and flyers in the patient rooms, and all the patients over 50 years old seen post-project implementation. None of the patients in the sample size were seen twice in those two time frames. Data was collected by manually reviewing the patients' charts and analyzing the orders placed, medication orders, immunization records, and the clinic visit note recommendations and plan of care. There was no significant difference in referral numbers pre-and post-implementation of this evidence-based quality improvement project when reviewing chi-square data.

Gender (N=69)

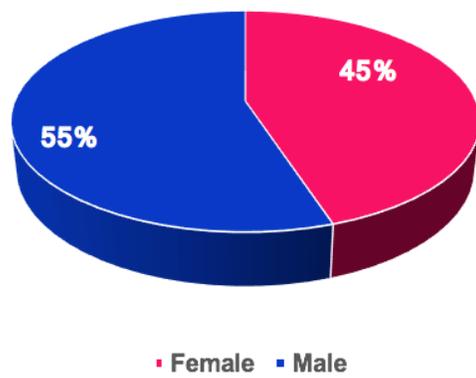


Figure 1. Gender of the Sample Size

Age of Sample

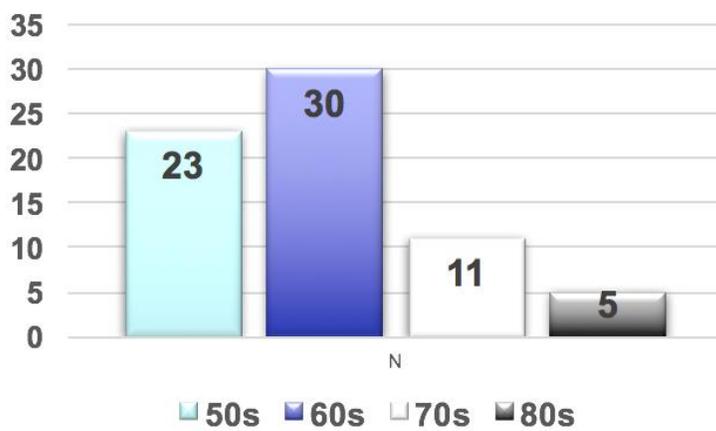


Figure 2. Age of the Sample Size

Patients on Immunosuppressive Therapy:

Groups:	Pre Implementation	Post Implementation
No	5	4
<u>Yes</u>	39	21
Grand Total	44	25

Figure 3. Patients on Immunosuppressive Therapy

Shingrix Ordered/Recommended

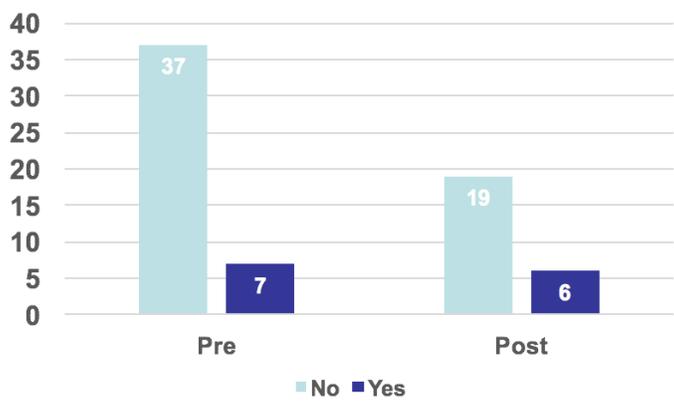


Figure 4. Number of Shingrix Orders and Recommendations Placed

Implications for Practice

Most insurance plans now cover Shingrix for patients aged 50 years and older. Spreading awareness of the importance of vaccination will aid in increasing our low numbers of vaccination rates in the IBD population who are especially vulnerable to acquiring the HZ infection. More importantly, HZ can be prevented, so it will be imperative to assess health maintenance, which includes vaccines needed at initial gastroenterology and primary care visits. As a healthcare provider, one can also refer the patient to a pharmacy to receive Shingrix or to their primary care

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provider and ask that the patient ensure their immunization records are up to date in the gastroenterology office. Another recommendation would be to ask patients if they have any questions or concerns about the vaccine when recommending it.

Discussion

When discussing the results and limitations with the medical director of the facility and University of San Diego faculty mentor, all concurred that low vaccination rates for Shingrix in the IBD population are a concern. Especially, because patients who had the older live shingles vaccine can and should get the newer shingles vaccine because of its higher efficacy rate in preventing Herpes Zoster.

Limitations to reaching the projected goal of significantly increasing Shingrix vaccination rates in this vulnerable population were that the provider whose schedule was being monitored for data collection changed in the last month, or halfway through project implementation. Another possible limitation could have been the providers viewing the PowerPoint on their own time instead of scheduling a group in-service meeting for everyone to get the information and lecture at the same time. An extension to this project would be to create an alert on the electronic medical record system, reminding providers to order the Shingrix vaccine for patients over the age of 50 years old. Another suggestion by the medical director of the inflammatory bowel disease center was to create a protocol for staff, including nursing staff, to assist with the adherence to Shingrix.

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