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Leigh Gault

Casie Brown

Mackinzie Lee

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RECOMBINANT ZOSTER VACCINE (SHINGRIX) KNOWLEDGE AND PRACTICES OF PRIMARY CARE PROVIDERS IN MISSISSIPPI

by

Leigh Gault

Casie Brown

Mackinzie Lee

Kimberly Word

Clinical Research Project
Submitted in Partial Fulfillment of the Requirements for the
Degree of Master of Science in Nursing, College of Nursing
and Health Sciences
Mississippi University for Women

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Graduate Committee Approval

The Graduate Committee of Leigh Gault, Casie Brown,

Mackinzie Lee, and Kimberly Word

hereby approves this research project as meeting partial

fulfillment of the requirements for the Degree of

Master of Science in Nursing

Date_______________________ Approved [signature]
Committee Chair

Approved [signature]
Committee Member

Approved [signature]
Committee Member

Approved:
[signature]
Director of Graduate Studies

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DEDICATION

First and foremost, I would like to thank God for the opportunity to advance my education that fulfills a dream to become a nurse practitioner. May my hands be His healing hands to those that come under my care. I would like to dedicate this research to my husband, Brian, for his unlimited love, encouragement, and support through this year. Without him, there would be no dream fulfilled. I would also like to thank both my daughters and stepdaughters for granting patience and understanding towards my need to study…a lot. A special thanks to my parents and sister, for their support has been invaluable through my education journey.

Leigh Gault

I would like to dedicate my research to my family. Without the love and support you have given this would not be possible. To my husband, Justin, words cannot begin to describe how thankful I am for you. Your endless love and continuous encouragement over the past year has been a strong hold for me. You have given of yourself in so many ways to provide for our family in my absence. Together we have made this dream come true. I love you. To my children, you are my most precious gifts from God. My love for you is never ending. I am thankful for the encouragement and patience you sweet young souls have given me daily. Each of you have stepped up to the plate in different ways to help your dad and I keep life moving. I am forever grateful and thankful for each of you. Lilly, Bennett, Emma, and Mitchell, momma loves you bunches. To Nan, Pap, Dana, MeMe, Johnny Rabbit and extended family, thank you. You have stepped in and been whoever you were needed to be, and you have done whatever was needed, and for that I

am thankful. The Word family would not have survived without your love, prayers, and support. Last but not least, I would like to thank God for all he has done. He has walked with me from day one, picked me up when I was down, gone before me, and provided a way for me. I am thankful for the opportunity He set before me. As I begin my practice, I pray I will be the hands and feet of Jesus every day. When they see me, may they see you, Lord.

Kimberly Word

Thanks, honor and praise to the Almighty God for allowing me the opportunity to be a part of an amazing movement to further my skills and advance my career as a family nurse practitioner. To my supportive husband, Nigel, thanks for your presence, support, love, and constant encouragement throughout this journey and life. To our children Briana (Jarrid), Brittany (Tyrone), Ajasia, Demarquis, Morgan, Madison, and Alicia, and our grandchildren Collin, Skylar, Allyson, Samuel, Tyreke, and Amelia, you guys have been my driving forces and my reasons for never giving up. God truly blessed me when he placed you all in my life. To my loving parents Calvin and Dorothy Hoskins and my darling siblings Yolanda, Shaquella, Dana, Brandon, and Calvin Jr., I am truly thankful for your help, love, and support. We never could have made it through without you guys. And most of all, to my late Grandmother, Rebecca, you were my muse. Your passing during this journey was truly hard to deal with, but I refuse to give up. Your love abides in my heart, and I will continue to make you proud. Growing up in the Mississippi Delta, I learned early on about the healthcare disparities that plagued my childhood community. My goal is to make a difference and one day return and give back by improving

healthcare opportunities for those who need it. That is a promise I made to my family and friends that remain there, and I am beyond excited about what is to come.

Mackinzie Lee

I would like to first thank God for blessing me throughout this journey on becoming a nurse practitioner. I am truly blessed and forever grateful to be fulfilling my calling in life. I truly enjoy helping and taking care of others. To my husband, I would like to thank you for your support every step of the way. You have been my backbone throughout this journey, and I thank you for supporting me while I accomplish my dreams. To my son, I love you unconditionally and I am thinking of you in all that I do. To my parents and my siblings, I thank you for your limitless support and love along the way. Without you all, I wouldn't be where I am today. Your love and support have helped me tremendously along the way and I am forever grateful for each of you. I will always keep God first in all that I do as I begin this new journey.

Casie Brown

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RECOMBINANT ZOSTER VACCINE (SHINGRIX) KNOWLEDGE AND PRACTICES OF PRIMARY CARE PROVIDERS IN MISSISSIPPI

Leigh Gault, RN, BSN

Casie Brown, RN, BSN

Mackinzie Lee, RN, BSN

Kimberly Word, RN, BSN

Mississippi University for Women, 2019

Supervising Professor: Dr. Alena Lester, DNP, FNP-C, ONP-C

Abstract

Herpes Zoster (shingles) is a preventable disease that affects 1 in 3 people over their lifetime. A severely painful complication called post-herpetic neuralgia (PHN) occurs in up to 20% of people affected with shingles. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommends and prefers a recombinant zoster vaccine (Shingrix) with a greater than 90% efficacy rate for preventing shingles for immunocompetent adults aged 50 years and older. The purpose of this study was to determine the knowledge and practices of the ACIP's Shingrix recommendations in the practices of Mississippi primary care providers. The researchers conducted a descriptive, quantitative study using a convenience sampling of 54 primary care providers from multiple clinics within Mississippi via a voluntary, anonymous online and emailed survey. A self-developed worksheet was utilized for data collection analysis.

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CHAPTER I

Dimension of the Problem

Herpes zoster (HZ or shingles) is a localized eruption of painful blisters along dermatomal lines. It is caused by a latent varicella zoster virus (VZV). Following childhood chickenpox, VZV lives dormant within the nerves of the host's body for years. The virus can be reactivated spontaneously or by a condition that decreases the body's immune system. Potential triggers for reactivation include increasing age, trauma, surgery, immunosuppressant therapies, emotional or physical stress, and malignancies (Lecrenier et al., 2018). The most important risk factors for viral reactivation are immunosenescence (age-dependent decrease in the immune response) and immunodeficiency (caused by disease or medication). HZ incidence in 50-59 years of age is approximately 5 cases per 1000 persons per year. It increases to 10 cases per 1000 persons per year in persons aged 60 years and older and represents half of all HZ cases. Estimates show that individuals aged 85 years or older have a 50% chance of having HZ during their lifetime (Lal et al., 2018). This population, along with the immunocompromised groups, also are at higher risk for developing the most severe HZ complications (Famuyiro, Smith, & Raji, 2018).

HZ, although painful, is usually a self-limiting disease with treatment targeting symptom relief. However, HZ has multiple complications. The most common complication follows a blistering rash and manifests as long-term neuropathic pain called post-herpetic neuralgia (PHN). PHN occurs in up to 20% of patients and in more than 30% of those who are 80 years of age and older. The pain can be refractory and difficult to treat (Lecrenier et al., 2018).

Statement of Problem

Approximately one million HZ cases are reported in the United States (US) with 1 in 3 older adults developing HZ at some point in their lifetime. Previous researchers have found that an astonishing 99% of all adults aged 40 years and older have serological evidence of VZV infection and are at risk of developing HZ. Though the varicella vaccination has been available, HZ incidence has been increasing over the last decades for reasons unknown. An increase in HZ incidence is expected to continue due to the compounding effect of aging populations and longer life spans. In 2017, researchers projected the costs of HZ in the population of 65 years and older at $4.47 billion if the HZ incidence is not slowed (Famuyiro et al., 2018).

Initially, HZ appears to be an uncomplicated, yet painful rash, but the infection can trend toward debilitating illness and significant decrease in the quality of life. HZ complications contribute substantially to the country's health economic burden (Lecrenier et al., 2018). In a 2016 cost analysis for HZ and other vaccine-preventable diseases, researchers found that approximately 9% ($782 million) of the annual US economic burden of under vaccination could be attributed to HZ (Famuyiro et al., 2018).

Statement of Purpose

The purpose of this study was to determine Mississippi primary care providers' (PCP) knowledge and practices of the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommendations for administering the Shingrix vaccine to immunocompetent adults aged 50 years and older. Immunizations are among the most successful public health achievements for prevention of diseases. The CDC reported the most recent national results (2016) of the National

Health Interview Survey (NHIS) for HZ vaccination rates, influenza vaccination rates, and pneumococcal vaccination rates in adults aged 60 years and older. Herpes coverage was 33.4%, influenza coverage 70.4%, and pneumococcal coverage 66.9% (Centers for Disease Control and Prevention [CDC], 2018b). "Vaccination acceptance is affected by a variety of factors, with the single most commonly cited determinant of successful vaccination being provider recommendation" (Bonville, Domachowske, Cibula, & Suryadevara, 2017, p. 2645).

Yaqub, Castle-Clark, Sevdalis, and Chataway (2014) performed a literature review regarding the general population and PCP attitudes concerning vaccination. Previous researchers have discovered several limiting factors that affected the PCP's attitudes such as lack of time, lack of awareness of national guidelines, lack of knowledge about vaccines, and personal reservations about recommending specific vaccinations (Yaqub, Castle-Clark, Sevdalis, & Chataway, 2014). Even though most PCPs agree that ACIP recommendations are important, one study evaluated the attitudes and practices of physicians in the state of New York and found that HZ vaccination was found to be less of a clinical priority than influenza and pneumococcal vaccination (Tsui et al., 2018).

Lu, O'Halloran, Williams, and Harpaz (2017) analyzed the results of the 2014 Behavioral Risk Factor Surveillance System. This system assessed national and state level adherence to the shingles vaccination administration following the United States Food and Drug Administration (FDA) approval of the shingles vaccine (Zostavax) in 2006. The researchers found that among national and state levels regarding shingles vaccination in adults aged 60 years and older, Mississippi ranked lowest at 17.8% (Lu, O'Halloran, Williams, & Harpaz, 2017).

Significance of Study

Efforts at alleviating HZ and its associated complications are ongoing. Prevention by vaccination is the most cost-effective option (Famuyiro et al., 2018). Since 2006, a live-attenuated zoster vaccine (ZVL or Zostavax) has been the only HZ vaccine available to prevent shingles, with a moderate efficacy rate of 51.3% in adults 60 years and older and 37.6% in adults aged 70 years and older. Zostavax's efficacy rate for PHN prevention is 66.5% in adults aged 60 years and older. Zostavax's efficacy for HZ prevention and PHN substantially decreases in the first year, and then tapers to nonsignificant levels after 6 years. In October 2017, the FDA approved a 2-dose subunit adjuvanted recombinant zoster vaccine (RZV, HZ/su, or Shingrix) for use in immunocompetent adults aged 50 years and older. Following FDA approval, the ACIP reviewed HZ epidemiology and the evidence for the efficacy, safety, and programmatic factors for RZV and ZVL. "The majority of ACIP members voted to recommend RZV preferentially" (Dooling et al., 2018, p. 106).

The recombinant zoster vaccine's efficacy for prevention of HZ is 96.6% in adults aged 50-59 years, 97.4% in adults aged 60-69 years, and 91.3% in adults aged 70 years and older. Clinical trials showed the vaccine's efficacy in the first year was 97.6% and was 84.7% or higher for the remaining 3 years of the study in persons aged ≥70 years. Vaccination efficacy for PHN was 91.2% in adults aged 50 years and older and 88.8% in adults aged 70 years and older. Within the clinical trials, solicited adverse events (AE) such as injection site pain, myalgia, and fatigue were reported in 16.5% of vaccine participants compared to 3.1% of placebo recipients. Rates of serious AE were similar in the RZV and placebo groups (Dooling et al., 2018).

HZ infection is a significant illness that negatively affects a patient both physically, socially, and economically, more so if it progresses towards severe complications that could require intensive treatment such as hospitalization. It is also a significant financial burden to the US economy. A 2011 savings estimation for cost per case of prevented HZ was $3,330 and the cost per case of prevented PHN was estimated to be $6,405 (Evans, 2010). Considering 7 years of inflation, calculating the increased index value with the past cost results in an estimated increase for cost per case of prevented HZ as $4,063 and the cost per case of prevented PHN as $7,814 (U.S Department of Labor, Bureau of Labor Statistics, 2010).

Knowledge and appropriate practice of the ACIP's recommendation for Shingrix vaccination could decrease the burden of disease to the patient and to the nation. The current research project was useful in identifying possible factors that are barriers to knowledge and practice of the ACIP's recommendations for RVZ vaccination in adults aged 50 years and older, which could be met with continued education, in-services, and workshops. Improving PCP knowledge and practices related to RZV recommendations could improve patient health outcomes and decrease costs for individuals, providers, and the US economy.

Theoretical Framework

Nola J. Pender's Health Promotion Model (HPM) was used to guide this research study. Theoretical models of nursing can be used not only to assist in understanding the behaviors of patients, but also in understanding the behaviors or practices of PCPs. Pender's HPM will be influential in this research study by revealing factors contributing to PCPs' health promoting practices.

The goal of the current study was aimed at evaluation of PCPs' practice regarding their knowledge and practice of ACIP guidelines that can result in increased health status for an individual and decreased costs in healthcare. HPM is a foundational model in changing practices and promoting healthy behavior and choices. Health promotion can lead to healthy behavior, increased health status and decreased cost in healthcare. This model provides a useful theoretical framework for research aimed toward improving health and detecting health promoting behaviors (Heydari & Khorashadizadeh, 2014).

Pender's HPM focuses on helping individuals achieve a higher level of wellness and identify factors influencing or hindering healthy behavior. PCPs are encouraged to provide resources to help individuals achieve behavior changes to promote wellness. The goal of the HPM is not only preventing illness through behavioral changes, but to identify and educate PCPs and individuals on interventions that promote health (Khoshnood, Rayyani, & Tirgari, 2018).

Major determinants of health promotion and quality of life practices are identified by the HPM as cognitive and perceptual factors. The promotion of health is motivated by the desire of one to enhance wellness and actualize human potential. Pender claims individuals are motivated to engage in behaviors or practices that promote health by biopsychological processes. There are fourteen theoretical assertions from the HPM. This research study considered four of the fourteen assertions as follows: (a) perceived benefits of action; (b) perceived barriers of action; (c) perceived self-efficacy; and (d) activity-related affect (Alligood, 2018).

Perceived benefits of action are defined as the anticipated positive outcomes arising from health promoting practice. Perceived barriers to action are defined as

anticipated, real, and personal cost or hinderance associated with the health promoting practice. Perceived self-efficacy is defined as the discernment of one's capability to organize and conduct a health promoting practice. Activity-related affect describes one's positive or negative feelings before, during, and after the health promoting practice regarding the practice itself. There is a correlation among these four assertions. Activity-related affect influences the perceived self-efficacy, and increased self-efficacy influences a further positive affect. Also, perceived self-efficacy influences perceived barriers to action, meaning a higher self-efficacy lowers the perception of barriers associated with the health promoting practice (Alligood, 2018).

Pender's HPM can be used to assist PCPs in recognizing perceived benefits and barriers of adherence to the ACIP guidelines regarding HZ vaccination. It can also assist PCPs in determining one's self-efficacy and activity-related affect. Utilizing Pender's HPM, the research study intends to make adherence to the ACIP guidelines appear beneficial to the PCP and the patient. Evaluation of the PCP activity-related affect regarding the guidelines and vaccination has the potential to increase the PCP self-efficacy of adherence, and in turn can decrease the perception of any barriers to the guidelines and vaccination increasing adherence. Highlighting or exposing the activity-related affect and self-efficacy of Mississippi PCPs has the potential to impact current practices and healthy promotion for individuals within the state.

Research Questions

The current research study was based on the following questions for the scope of this study:

1. Are Mississippi primary care providers knowledgeable about the Advisory

Committee on Immunization Practice's Shingrix recommendations for patients age 50 years and older?

2. What are the Shingrix practices of Mississippi primary care providers?

Definition of Terms

For the purposes of this study, the following terms were defined with theoretical and operational definitions, respectively:

Primary Care Providers.

Theoretical: Licensed medical personnel, such as a physician (M.D. – Medical Doctor or D.O. – Doctor of Osteopathic Medicine), nurse practitioner, or physician assistants allowed under state law, who provide and coordinate a range of health care services for patients ("Primary Care Provider," n.d.)

Operational: Physicians, nurse practitioners, or physician assistants that practiced within the state of Mississippi, provided care to patients aged 50 years and older, and responded to the survey.

Advisory Committee on Immunization Practices (ACIP).

Theoretical: ACIP is a group of fifteen voting members responsible for making vaccine recommendations (CDC, 2018a).

Operational: ACIP meets three times a year at the Centers for Disease Control and Prevention in Atlanta, Georgia to review scientific data and vote on vaccine recommendations.

Shingrix.

Theoretical: A new shingles 2-dose recombinant vaccine, licensed by the Food and Drug Administration and recommended for healthy adults 50 years and older that provides strong protection against shingles and PHN (CDC, 2018c).

Operational: The vaccine, Shingrix, prescribed by the surveyed Mississippi primary care providers within our study to prevent the risk of shingles and PHN in adults aged 50 years and older in their practice.

Assumptions

The current researchers made three assumptions about the study. These assumptions are listed as follows:

1. The responders to the research survey are willing participants.
2. Primary care providers will respond to the survey questions with honesty about their awareness and adherence to their practices regarding the Shingrix vaccination.
3. Primary care providers' awareness and adherence to the current Shingrix recommendations will vary.

Limitations of Study

A major limitation of this study was a small sample size due to lack of survey response. This study relied on PCPs' self-reporting instead of a calculated measurement from chart reviews that impartially document the PCPs' practices or observed practices. Another limitation was the inability to generalize results based on the sample participants not being representative of all providers collected at a single point in time due to the study being restricted to Mississippi and PCPs.

CHAPTER II

Literature Review

The review of literature was performed to determine the awareness and adherence of PCPs to the CDC guidelines for vaccinating immunocompetent adults aged 50 years and older with the 2-dose recombinant HZ vaccine Shingrix. This following review of literature will discuss pertinent topics, such as the conceptual framework related to Pender's HPM and a review of related literature. The review of related literature is further divided into sections that include vaccine effectiveness, cost effectiveness, and barriers to adherence. The sections of vaccine effectiveness and cost effectiveness support the importance of PCPs' awareness and adherence to the CDC's recommendation and preference for the newer HZ/su vaccine. The barriers section identifies areas that can be targeted for increased adherence to the recommendation.

Vaccine Effectiveness

Lal et al. (2018) performed a randomized, open-label, multicenter study for assessing the immunogenicity, reactogenicity, and safety of HZ/su administered at 2-, 6- and 12-month intervals after an initial dose to adults aged 50 years and older. Previous results in the phase III clinical trials for HZ/su showed the administration of two doses at 2 months apart resulted in reduced risk with an efficacy of HZ prevention at 97.2% in adults aged 50 years and older and 91.3% in adults aged 70 years and older. Assessing the response to 6-and 12-month interval dosing could provide more flexibility to both health-care providers and patients for completing the 2-dose schedule. The researchers posed two hypotheses. The first hypothesis was that the post-dose 2 at the 6-month and 12-month intervals would be as immunogenic as post-dose 2 at the 2-month dosing

interval. The second hypothesis was that the HZ/su vaccine would be safe with expected, common side effects or AE.

Between March 12, 2013 and April 8, 2015 within the US and Estonia, 354 adults aged 50 years and older were randomized 1:1:1 in an open-label study across three age strata (50-59 years, 60-69 years and ≥70 years) to receive two HZ/su doses 2-, 6-, or 12-months apart. The participants were comprised mainly of Caucasian/European heritage females with the mean age of 64.5, 64.0, and 64.1 years in Gr 0-2, Gr 0-6, and Gr 0-12 respectively at dose 1. Adults age 50 years and older were included in the study but excluded if any investigational or non-registered product had been consumed, if any live or non-replicating vaccination had been administered or planned to be, had a history of HZ, had received previous vaccination for varicella or HZ, or had a reactive history or hypersensitivity to components of the vaccine. Other exclusionary factors were administration of immunosuppressants or other immune-modifying drugs 6 months before the initial dose, as well as a condition from disease or therapy that suppressed the immune system. Risk of pregnancy of female participants had to be ruled out by a negative pregnancy test on the day of vaccination, fulfilling contraceptive requirements to protocol specificity, or inability to bear children (Lal et al., 2018).

Lal et al. (2018) concluded that immune responses at the 0- and 6-month schedule were non-inferior to the 0- and 2- month schedule based on blood samples measured at these time points and their resulting statistical significance. This comparable immunogenicity at the 6-month dosing interval allows for dosing flexibility with the HZ/su vaccination schedule. In turn, researchers pose this flexibility could increase vaccination compliance by aligning with routine physician visits instead of non-routine

visits. Along with immune efficacy, researchers reported the HZ/su has an acceptable safety profile for all dosing intervals. The safety/reactogenicity assessment revealed the most common AEs were injection site pruritis (2.5% in Gr 0-2), erythema (2.5% in Gr 0-6), and injection site pruritis and arthralgia (1.7% in Gr 0-12). Serious AEs occurred in very few participants and were not related to the vaccine (Lal et al., 2018).

Dooling et al. (2018) analyzed a report summarizing recommendations presented by the ACIP concerning uses of the HZ vaccines. The researchers identified two vaccines to prevent HZ: RZV (Shingrix), a 2-dose subunit vaccine approved for use in adults ≥50 years of age, and ZVL (Zostavax), a 1-dose live attenuated strain of VZV licensed for use in immunocompetent adults ≥60 years of age. The ACIP recommends use of RZV in immunocompetent adults aged ≥50 years of age, whereas recommendations for use of ZVL is in immunocompetent adults aged ≥60 years of age.

Dooling et al. (2018) sought to determine the differences in effectiveness between RZV and ZVL when used to vaccinate immunocompetent adults ≥50 years of age against the HZ virus. Currently, ZVL is recommended for adults >/=60 years of age who are immunocompetent. The ACIP was presented with three proposed recommendations at the October 2017 meeting that were ultimately approved by its 15 voting members. These recommendations were as follows: (a) 14 to 1 favoring RZV recommended for immunocompetent adults ≥50 years of age; (b) 12 to 3 favoring RZV recommended for immunocompetent adults who were previously vaccinated with ZVL; and (c) 8 to 7 favoring RZV preference to ZVL.

The ACIP Herpes Zoster Vaccines Work Groups deemed the outcomes of prevention of HZ and PHN as critical, while outcomes deemed important included

duration of protection and reactogenicity. Outcomes comparing no vaccination to RZV and ZVL were addressed. No direct comparison between the two vaccines were conducted (Dooling et al., 2018).

A two-part, phase III multicenter clinical trial, involving the enrollment of >30,000 participants was conducted. The participants randomly received RZV or a saline placebo. Target groups were individuals from two different age groups, adults 50 years of age and older and adults 70 years of age and older. The Zoster Efficacy Study documented a median follow-up time of 3.2-3.7 years, yielding the following efficacy rates: (a) prevention of HZ—96.6% for those 50-59 years of age and 97.4% for those 60-69 years of age; (b) vaccine efficacy—84.7%-97.6% for those ≥70 years of age; this includes the first year after activation and the remaining 3 years of the study; and (c) prevention of PHN—91.2% for those ≥50 years of age and 88% for those ≥70 years of age (Dooling et al., 2018).

Dooling et al. (2018) also addressed how RZV is more cost effective compared to ZVL, with separate studies conducted by the CDC and GlaxoSmithKline to support this notion. However, a study conducted by Merck suggests ZVL is more cost effective. GlaxoSmithKline sponsored eight studies related to serious AE that concluded similar overall rates for RZV and placebo groups. Pain, myalgia, and fatigue were the most common solicited adverse reactions. Concurrently, the performance of ZVL was evaluated using two randomized clinical trials and seven observational studies for participants ≥50 years of age. A randomized clinical trial and a modeled control group were used to evaluate the duration of protection. This study was conducted following an 11-year period. Results concluded a substantial decrease in effectiveness one year after

receiving ZVL. This decrease continued and proved no longer statistically significant 9-11 years after vaccination.

Although RZV has been licensed for all persons ≥50 years of age, Dooling et al. (2018) identified that some populations should not receive RZV. Those persons excluded or not evaluated in this study include ones who are receiving moderate to high doses of immunotherapy or those who presently have an immunocompromising illness, persons who are VZV seronegative, and pregnant or lactating women. There are ongoing studies for these populations, therefore, caution should be used to ensure the patient's safety and well-being are not further compromised. Longitudinal and observational studies will be used to assess long and short-term effectiveness of RZV. The CDC will monitor coverage of RZV, adherence to the 2-dose schedule, and AE following immunizations. GlaxoSmithKline will conduct studies to monitor post-marketing safety monitoring due to the high reactogenicity and immunogenicity of RZV (Dooling et al., 2018).

James, Chahine, Sucher, and Hanna (2018) performed a literature search through PubMed summarizing the review of the immunogenicity, efficacy, and safety data for HZ/su and recommendations by ACIP for its use. Two vaccines are currently available for the prevention of HZ, Zostavx and Shingrix. Zostavax, approved by the FDA in May 2006, is a live, attenuated vaccine approved for use in all eligible persons 60 years and older, regardless of zoster history. HZ/Su, approved by the FDA in 2017, is an inactive recombinant subunit vaccine comprising varicella zoster vaccine glycoprotein E (gE) that is reconstituted at the time of use with AS01B adjuvant suspension. It is approved for use in the prevention of HZ in adults 50 years and older.

James et al. (2018) desired for HZ/su to be included in both hospital and community pharmacy formularies, as well as to supersede the previous recommendation of vaccination with ZVL. This literature search sought to determine efficacy in HZ/su vaccine. HZ/Su has shown to have more beneficial effects in comparison to ZVL. A reduction in PHN is one of the benefits of HZ/su versus ZVL. PHN is a painful complication of the shingles virus, which can have long-lasting effects.

James et al. (2018) performed a review of five different studies. The first was a randomized, open-label study of HZ/su in patients aged 50-70 years who had no previous vaccination. Evidence from this study shows cellular and humoral immune response rates were higher and remained elevated with HZ/su after 42 months. Two other randomized, observer-blind studies were conducted on immunocompromised persons. These individuals were not previously vaccinated with, nor had known exposure to VZV or were HIV positive. Compared with saline placebo, those who received HZ/su had higher cellular and humoral immune responses that remained elevated for at least one year. A third randomized, observer-blind study tested adjuvanted and unadjuvanted HZ/su in immunocompetent persons older than 60 years of age. Immune response results were higher for adjuvanted HZ/su compared with the unadjuvanted HZ/su.

Finally, a randomized, double-blind placebo-controlled study was conducted. Patients would receive either two intramuscular doses of HZ/su or placebo separated by 2 months. Cases of patients aged 70 years and older developing PHN were also identified during this study. The researchers concluded that HZ/su produced a significant reduction in the risk of HZ and PHN in adults aged 70 years and older. The researchers highlighted the long-term protection when immunized with the Shingrix vaccine. Both physicians

and pharmacists can counsel and give clients information about the Shingrix vaccine, which aids in making a more informed decision about vaccination (James et al., 2018).

Shingrix is the preferred vaccine for the prevention of the HZ virus based on recommendations from the ACIP. Raedler (2018) analyzed a report of the phase clinical trials that ultimately encouraged the approval of the Shingrix vaccine by the FDA. Shingrix is an adjuvanted zoster vaccine recombinant approved for the prevention of the HZ infection. These two studies, the ZOE-50 study and the ZOE-70 study, are analyzed in this report. The researcher identified the effectiveness of Shingrix against the HZ infection. HZ, also referred to as shingles, is caused by the VZV and presents as a painful outbreak seen on the face and body. Affecting approximately 1 million people each year, shingles poses an increased risk to those with weakened immune systems (Raedler, 2018).

The ZOE-50 study was performed in 18 countries, consisting of thousands of participants aged 50 and older. These participants were divided into 3 age-groups: (a) 50-59 years, (b) 60-69 years, and (c) ≥70 years (Raedler, 2018). In more than 97% of the participants, Shingrix was proven effective compared to a placebo, and a significant reduction in PHN was also observed. In the ZOE-70 study, participants were divided into 2 groups: (1) 70-79 years, and (2) ≥80 years. A significant reduction risk of HZ for approximately 90% of these participants was observed compared to a placebo. In both clinical trials, participants received 2 doses of either Shingrix or placebo (Raedler, 2018).

Raedler (2018) concluded that Shingrix is effective in the prevention of herpes zoster in those aged ≥50 years of age. It also provides protection against PHN pain. Previous researcher concluded there is no data to determine risk with Shingrix if

administered to pregnant women. No information is available to determine effectiveness in persons <18 years of age. However, the ACIP does recommend its use for healthy individuals aged ≥50 years of age, as well as individuals previously vaccinated by Zostavax, a 1-dose live attenuated vaccine also approved for the prevention of HZ.

Cost Effectiveness

Le and Rothberg (2018) compared the cost-effectiveness of the adjuvanted herpes zoster subunit vaccine (HZ/su) to the live attenuated herpes zoster vaccine (ZVL). The HZ/su was developed to address ZVL's shortcomings, particularly its complete waning of efficacy after 10 years. The ACIP would have to choose the preferred vaccine, because insurance plans would require a recommendation for coverage. The ACIP previously examined the cost-effectiveness of the two vaccines using models developed by the manufacturers of the HZ/su and the ZVL. Both models showed HZ/su to be cost saving compared to ZVL. The authors used an independent model without pharmaceutical funding. Examining cost-effectiveness can also aid PCPs and patients in their choice of vaccine with the best value.

Le and Rothberg (2018) used a Markov decision model with transition probabilities using data from PubMed and an updated previous study and conducted the study from a societal perspective. The researchers extracted data from these sources that were from participants groups that consisted of less than 100 to more than 30,000. The number was dependent on the variable being assessed. Participants in this study were immunocompetent adults 60 years or older. The study lasted from July 1 to July 31, 2017. The primary outcomes and measures were total costs and quality-adjusted life-years (QALYs). To assess costs and QALY's, the researcher's variables for model inputs were

epidemiology inputs, vaccine efficacy and AE inputs, efficacy function for PHN incidence, and utility and cost inputs.

Le and Rothberg (2018) looked at the cost-effectiveness for three groups: (a) no vaccination; (b) vaccination with ZVL; and (c) vaccination with HZ/su. Within these groups, the researchers further subdivided them into age groups due to the varying cost-effectiveness of ZVL at vaccination age. The three age groups were 60-year-olds, 70-year-olds, and 80-year-olds. The researchers concluded that "HZ/su was more effective and less expensive than ZVL for adults 60 years and older." (Le and Rothberg, 2018, p. 256). The projected cost of HZ/su was $280 per series ($140 per dose), making it less than ZVL's current price of $213 per dose for adults 60 years or older with a high cost-effectiveness at $50,000 per QALY for 60-year-olds.

Due to HZ/su's superior efficacy and cost-effectiveness, Le and Rothberg (2018) declared that the ACIP should recommend a preference for HZ/su over ZVL. The researchers for this study, also identified HZ/su's single dose efficacy and its potential to mitigate low adherence rates. HZ/su is a 2-dose vaccine, which can create a barrier to vaccination adherence. The researchers reported cost-effectiveness, even if 95% of patients only received the first dose. The researchers suggested that future studies should be aimed at examining the effectiveness and the waning rate of a single dose, and that better define efficacy duration, serious reactions, and adherence rates to measure precise ICER estimates for HZ/su's cost-effectiveness compared to ZVL. The researchers stated that the results of these future studies would not change their conclusions. If no preference is expressed, the researchers stated that avoidable cases of HZ and PHN will occur among vaccinated pts when a more effective vaccine could have been received.

Without the ACIP's recommendation, physicians, patients, or insurers could be steered into choosing a vaccine with less value and effectiveness.

Practice Barriers

O'Donnell, Shurpin, and Janotha (2018) performed a two-phase study for the purpose of determining nurse practitioner (NP) barriers to the use of herpes zoster vaccine (HZV) and implementing the results to develop and evaluate the outcomes of an educational program. Although it is recommended by the CDC for immunocompetent adults 50 years of age and older and its efficacy has been demonstrated, HZV usage continues to be low. According to the CDC and multiple other studies reviewed by O'Donnell et al. (2018), 99% of people over age 50 in the US have serologic evidence of varicella virus and reactivation. Reactivation results in HZ, a virus that travels on a nerve root causing a painful rash. The complication of HZ, PHN, occurs 18% of the time. PHN is damage to the nerve tissue causing disabling pain long after the rash is resolved. After the age of 50, due to the natural decline in immunogenicity of aging, HZ incidence increases with as many as 3% requiring hospitalization. Studies reviewed also reveal concerns of cost for the patient and provider, safety, and lack of knowledge regarding HZV continue to present as barriers.

O'Donnell et al. (2018) discovered in Phase I, 50% of the patients were eligible for HZV, and more than 50% of the surveyed NPs gave 0-9 HZV in the previous twelve months. The three main barriers identified in Phase I were up-front HZV purchasing cost (46%), concern for patient cost (39%), and concerns of reimbursement issues (29%). Phase II revealed a statistical difference in scores of the pretest and posttest regarding NP understanding on HZV. The results of this two-phase study confirmed NPs face similar

barriers as physicians regarding approving the HZV as recommended by the CDC. The primary barrier is identified as a lack of knowledge in multiple areas concerning the HZV. The study contributed additional evidence to the need of continued education and distribution of information on HZV to healthcare providers (HCP). The documented increase in provider knowledge following the educational program gave further evidence to the lack of knowledge regarding HZV and the benefits of education.

Tsui et al. (2018) performed a cross-sectional online survey for evaluating the knowledge, attitudes, and practices for the HZ vaccine of providers within five of the NYU Langone Health (NYULH) clinics. Because HZ infects 1 in 3 people in their lifetime, and 1.2 million cases develop each year, the researchers cited the organizations that recommend vaccination against HZ for individuals aged 50 years and older: the American Academy of Ophthalmology (in 2016), the American Dermatological Association (in 2017), and the FDA (in 2011). The researchers stated that the CDC has maintained its recommendation for HZ vaccination in the 60 years and older population. However, since the researcher's study, the CDC has expanded its recommendation to include the 50 years and older age group. Vaccination provides protection from infection and its potential complications, yet vaccination rates remain lower compared to the annual influenza vaccine or pneumococcal vaccine.

The researchers previously studied the variables via survey in 2011 before interventions, such as education, availability, and electronic health record alerts were introduced into the clinics. A one-year follow-up survey after intervention implementation showed an increase in physician knowledge and vaccine administration. The researchers desired to investigate again the current knowledge, attitudes, and practice

patterns of HZ vaccination in context of the previously stated interventions, the FDA approval of 50-years and older age expansion for HZ vaccination, great HZ vaccination availability, television commercial advertising, and the consistency of the HZ vaccination's safety and efficacy (Tsui et al., 2018).

The inherent questions within this study are included: (a) Are NYULH physicians aware of the CDC and FDA HZ vaccination recommendations?; (b) Are NYULH physicians adhering to current HZ vaccination recommendations?; (c) What are NYULH physician's attitudes towards the HZ vaccine?; and (d) Are NYULH physician's attitudes barriers to HZ vaccination? (Tsui et al., 2018). To answer these research questions, a cross-sectional online survey was distributed through email to 530 faculty members across five different practice settings of the Division of General Internal Medicine and Clinical Innovation at NYULH. The study was conducted from February 2017 to March 2017 (Tsui et al., 2018).

Tsui et al. (2018) reported a total response rate of 26% (138/530) across the 5 clinics. Among the responders, over 95% were aware of the CDC's recommendation for the HZ vaccine for individuals age 65 or 70 years, including if they are on medications for heart disease, diabetes, or hypertension. Even a history of HZ is permissible within the CDC's recommendation. Comparatively, only 63% were aware of the FDA's approval for immunocompetent individuals 50 years and older to receive the HZ vaccine. Of the self-reported practice patterns, 43% of the patients 60 years and older were reported as receiving the HZ vaccine. Only 11% of patients 50 years to 59 years had received the HZ vaccine. In contrast, 72% of patients received the pneumococcal vaccine and 67% of patients received the influenza vaccines ($P < 0.001$, respectively). Physician

reported cost of the vaccine was a primary barrier. A high percentage of physicians (91%, 121/133) recommended HZ vaccination for immunocompetent patients age 60 years and older. Only 76% of responders agreed that the HZ vaccine was clinically important compared to the 94% for pneumococcal vaccination importance and the 93% for influenza vaccination importance. Over half of physicians believed that patients age 60 years and older should receive the HZ vaccine. However, only 36% of physicians believed that patients 50 years and older should receive the HZ vaccine.

Chaudhry et al. (2013) conducted a study at four clinical sites in the Rochester area that employed 45 general internists, 40 family doctors, 96 internal medicine residents and 20 family medicine residents, and provides primary care to 140,000 patients. When Chaudhry et al. (2013) began their implementation of the clinical decision support system, the workflow for addressing the preventive services for patients began with the licensed practical nurses, who showed the patient to his or her room, checked vital signs and medications, and checked the necessity of age-specific preventive services. The researchers developed a web-based application that used GE Web services and a MSQweb.net platform to retrieve patient vital statistics, weight and body mass index, age, demographic information, prior diagnoses, allergies and previous services. This method included a rules-based application in which national guidelines for age-specific criteria were applied to the individual patient's biostatistics. The application would alert the provider if a need for the vaccination was indicated; if the patient accepted the provider's recommendation for vaccination, the nurse vaccinated the patient at the end of the visit (Chaudhry et al., 2013).

Chaudhry et al. (2013) used billing information to calculate the number of HZ vaccinations administered in the Primary Care Internal Medicine and Family Medicine clinics. In a one-year time span, rates started at 63 and increased to 117 vaccinations after a one-month period of clinical support software implementation, which was a 53.8% increase in vaccination adherence. At the time of their study, there were no other practice improvement initiatives underway at any of the practices related to the HZ vaccine. The two most proven methods reported in the literature are a provider recommendation for immunization and protocols that allow nurses and allied health staff to screen the patients and vaccinate them, if indicated. The approach of nursing staff providing the vaccination has been proven to be the most beneficial.

Chaudhry et al. (2013) sought to determine the reason for decreased implementation of preventive services in the US, with up to 50% of patients not receiving age-specific, preventative services, or care for their chronic conditions. The researchers reported a study of attitudes of primary care doctors toward vaccination and perceived barriers and found that 22% believed that their eligible patients did not need the vaccine. Further exploration for why PCPs did not believe their patients were eligible was not addressed, but provider beliefs are known to play an important role in whether patients receive vaccinations. PCPs lack of knowledge could have been a contributing factor. Our current study will seek to determine Mississippi PCP's awareness of the recommendations of RSV for adults aged 50 years and older.

Chaudhry et al. (2013) sought to determine the utilization of HZ vaccine before and after the implementation of a web-based clinical decision support software solution in a primary care practice. HZ is a localized neurocutaneous eruption of blisters caused

by reactivation of the VZV. The cost of care for HZ and its complications is estimated as $1.1 billion. The CDC ACIP recommends one-time dose of the vaccine for adults aged 60 years or older. The 2017 recommendation from the CDC is that adults 50 years of age and older receive the new vaccination, Shingrix. This vaccination is administered in two doses, within 2 to 6 months after the first dose. Despite the recommendation, utilization of the vaccine is very low. One method to increase the practice of preventive services such as vaccinations is with a computerized clinical decision support system. The researchers found that the HZ vaccination rate increased significantly after the implementation of such a system.

Elkin et al. (2011) surveyed general internal medical physicians (GIM) from October to December 2011 before interventions and one year later to increase the use of HZ vaccine by studying the knowledge, attitudes, practices and perceived obstacles of physicians after interventions to overcome barriers. The researchers hypothesized that by introducing interventions that influenced GIM physicians' knowledge and attitudes in relation on the HZ vaccine, there would be a change in provider practices to increase the use of the HZ vaccine in eligible patients.

Following analysis, the researchers found the average monthly HZ vaccine usage in the New York University pharmacy increased 156% in the 10 months between the two surveys when compared with the 3 months prior to the baseline survey and interventions. Of the physicians that participated in both surveys, they were statistically more likely to know there were greater than 1,000,000 cases of HZ annually in the US and to report physician education regarding the severity of HZ. Significant differences in physician attitudes and practices remained the same among the four different provider sites in both

surveys. The Bellevue Hospital and Gouverneur Healthcare Services (B/G) and voluntary practice services (Vol) were more likely to report cost as a barrier. B/G expressed greater difficulty with order and administration of the HZ vaccine, due to no available formulary for the vaccine, which resulted in B/G physicians responding that less than 10% of their patients received the HZ vaccine. As with the prior SPS, four years later the efficacy remains, but the reduction of illness decreased to 50.1% from 61%. Among eligible patients, improving HZ vaccination rates remained a clinical priority (Elkin et al., 2011).

Elkin et al. (2011) were able to improve awareness of the underutilization of the HZ, despite the continued support of its efficacy and safety. Simple interventions like a nurse present at the pharmacy to administer the vaccine and nurse-initiated prompting may increase the usage of the HZ vaccine and physician recommendation for the vaccine.

CHAPTER III

Methodology

The purpose of the current research was to determine PCP knowledge and practices of the ACIP's recommendations for the Shingrix vaccination in patients 50 years and older. Shingrix is the ACIP's preferred vaccination to prevent the occurrence of shingles and its potential consequences, such as PHN. Shingles affects one in three persons within their lifetime. Following this section, this chapter will discuss the design, setting, population and sample, methodology, and data analysis used to conduct the research.

Design of the Study

The researchers utilized a descriptive, quantitative survey design to evaluate PCP knowledge and practices of the ACIP's recommendation for administering the HZ vaccination in people 50 years of age and older. Data for this research project was collected from 54 healthcare providers via surveys provided through the electronic database Survey Monkey, digital surveys through email and social media, and written, hand-delivered surveys to qualifying participants. This research was utilized to show results from a nonexperimental study that described aspects of Mississippi PCP knowledge and practices regarding the Shingrix vaccination. This design study was most appropriate given the time constraints for collecting data, the accessibility of participants responding, and the likelihood of obtaining quality information that cannot be extracted from a compliance audit (e.g. perceived barriers and attitudes). The online and written survey allowed the researchers to access and receive responses from PCPs across Mississippi instead of a localized area within Mississippi.

Setting for the Research Project

The research study was conducted in multiple primary care clinics located throughout Mississippi. Surveys were distributed to physicians, nurse practitioners, and physician assistants utilizing Survey Monkey's online application, email, social media, and hand delivered paper surveys. For social media utilization and email, the links to the survey were posted to various professional closed-member group sites for physicians, nurse practitioners, and physician assistants or emailed to physicians, nurse practitioners, and physician assistants to reduce the possibility of unqualified subjects completing the survey. The hand delivered paper surveys were distributed in sealable envelopes by the four members of the researcher group conducting the study to ensure privacy.

Population and Sample

The population for the research were PCPs from Mississippi. The population included the following disciplines: medical doctors, physician assistants, doctors of osteopathy, and nurse practitioners. The sample population of Mississippi PCPs was 54. The researchers utilized a convenience sampling by email distribution and messaging online via social media, and hand-delivered written surveys.

Methods of Data Collection

Permission to conduct the study was obtained from the Institutional Review Board at Mississippi University for Women prior to ignition of research. Humans subject were used when asking PCPs in Mississippi to complete a questionnaire regarding the individual's current practices regarding the ACIP's recommendation for the Shingrix vaccine for adults aged 50 years and older. During data collection for the research study, anonymity was maintained via non-traceable Survey Monkey technology and sealable

envelopes with a return address. No personal patient information was collected on the questionnaire or data collection forms, nor was data saved on computer hard drives. Upon compiling data for analysis, data was stored on a single jump drive that was locked in a researcher's filing safe.

On completion of the research study, the jump drive containing all collected data was destroyed. The Survey Monkey account was deleted, and the data maintained on the site was removed according to the website policy. The researchers utilized Survey Monkey to host the survey and maintain the data collected for the duration of the research study. The survey consisted of researcher developed questions (see Appendix). The researchers gathered data regarding PCP self-reported practices related to knowledge and practices of the ACIP's recommendations. The survey contained multiple choice questions. On the survey, questions 1-6 requested demographic data and questions 7-16 were related to ACIP recommendations, Shingrix vaccination, and adherence. The question and answer options for each question were developed and selected based on current literature regarding PCP knowledge and practice to ACIP recommendations or guidelines. The questionnaire did not undergo psychometric testing but faced validity based on a panel of expert researchers.

Methods of Data Analysis

Data was compiled following the conclusion of the survey. The data collected from the surveys represented the nominal measurements from the multiple-choice format questions. Parameters were calculated for each question and displayed as a percentage. These percentages were used to assess the sample population's knowledge and practice of the ACIP's recommendations for the Shingrix vaccination in adults aged 50 years and

older. The demographic data obtained was used to help identify any trends that may exist in Mississippi PCPs' Shingrix practices. Findings to research questions were reported using descriptive statistics and percentages.

CHAPTER IV

Presentation of the Findings

Data collected from the survey are presented in this chapter with respect to the research questions in Chapter I. This information will be informative in identifying the practices and knowledge of PCPs in Mississippi concerning the Shingrix vaccine.

HZ is a preventable disease that affects 1 in 3 people over their lifetime. A severely painful complication called PHN occurs in up to 20% of people affected with shingles. The CDC ACIP recommends, and prefers a recombinant zoster vaccine (Shingrix) with a greater than 90% efficacy rate for preventing shingles for immunocompetent adults aged 50 years and older. The researcher's main objectives were to determine Mississippi PCPs' knowledge and practices of the CDC ACIP recommendations for administering the Shingrix vaccine to immunocompetent adults aged 50 years and older.

The results of this study were collected from an online survey via social media and hand-delivered written surveys. Survey questions addressed the demographic data regarding participant's age, years of experience, gender, title, type of community served, type of insurance accepted, and electronic health record (EHR) prompting for zoster vaccination. Questions also addressed PCP's knowledge and practice of ACIP's most recent Shingrix recommendations and administration parameters, knowledge of Shingrix's effectiveness at decreasing incidence of shingles and peripheral herpetic neuralgia, and importance of the Shingrix vaccine compared to the flu and pneumonia vaccines. Shingrix's cost-effectiveness and efficacy compared to Zostavax was surveyed,

along with self-reported barriers to recommending the Shingrix vaccine. The presentation of the findings includes the profile of the study participants and the statistical results.

Profile of Study Participants

A total of 54 PCPs from multiple clinics within Mississippi via a voluntary, anonymous online survey and hand-delivered written survey responded to the survey. Demographics of the respondents and their representative clinics are shown in Table 1. Most of the respondents were advanced practice nurses totaling 88.9% ($n = 48$). Of the remaining respondents surveyed, 9.3% ($n = 5$) were MDs, while 1.9% ($n = 1$) of the respondents were DOs. There were no PA respondents noted.

Most participants were of the female gender totaling 87% ($n = 47$). The majority of the respondents were 30-44 years of age at 59.3% ($n = 32$). The remaining age groups of 45-59 years of age totaled 24.1% ($n = 13$), 20-29 years of age totaled 11.1% ($n = 6$), and 60+ years of age totaled 5.6% ($n = 3$).

Respondents with less than five years of experience totaled the highest at 38.9% ($n = 21$). Respondents with 20-29 years of experience totaled next highest at 25.9% ($n = 14$). Respondents with experience of 5-10 years and 10-19 years totaled equally at 16.7% ($n = 9$) and 16.7% ($n = 9$). Most respondents practice in rural clinics 70.4% ($n = 38$). The remaining respondents totaled at 18.5% ($n = 10$) urban clinics and at 11.1% ($n = 6$) suburban clinics.

Most respondents accepted federal and state insurance totaling at 40.7% ($n = 22$). The remaining respondents that accepted both federal/state and private insurance totaled at 31.5% ($n = 17$), while 22.2% ($n = 12$) of the respondents only accepted private insurance. Lastly, 5.6% ($n = 3$) of the respondents accepted no insurance.

Table 1

Demographics of Survey Respondents (N=54)

	Number of Respondents	% of Respondents
Title		
NP	48	88.9
MD	5	9.3
DO	1	1.9
Gender		
Female	47	87.0
Male	7	13.0
Age		
20-29 years	6	11.1
30-44 years	32	59.3
45-59 years	13	24.1
60+ years	3	5.6
Experience		
<5 years	21	38.9
5-10 years	9	16.7
10-19 years	9	16.7
20-29 years	14	25.9
Location		
Rural	38	70.4
Suburban	6	11.1
Urban	10	18.5
Insurance Accepted		
None	3	5.6
Private	12	22.2
Federal/State	22	40.7
Both	17	31.5

Statistical Results

As mentioned in Chapter 1, the researchers posed the following two questions:

1. Are Mississippi primary care providers knowledgeable about the Advisory Committee on Immunization Practices' Shingrix recommendations for patients age 50 years and older?
2. What are the Shingrix practices of Mississippi primary care providers?

In order to answer the research questions, a 17-question survey was distributed via voluntary, anonymous online social media link and hand-delivered written surveys. The results are presented in the following sections.

Question 1: Are Mississippi primary care providers knowledgeable about the Advisory Committee on Immunization Practices' Shingrix recommendations for patients age 50 years and older?

Question 8 of the survey was used to analyze this question. Respondents were asked, "*Are you aware of the ACIP's recommendations from October 2017 to recommend Shingrix as the preferred vaccine to immunocompetent adults aged 50 years and older?"* Of the 54 respondents, 85.2% answered "Yes," indicating that they were aware of the ACIP's recommendations. The awareness rates were highest for those practitioners with more experience, as shown in Table 2. There was no statistical difference in awareness rates based on title, gender, age, location, or insurance.

Table 2

ACIP Recommendation Awareness by Years of Experience

Experience	N	% of Yes Reponses
<5 years	21	71.4%
5-10 years	9	77.8%
10-19 years	9	100.0%
20-29 years	14	100.0%
Overall	53[1]	85.2%

[1]Note: Only 53 respondents answered the awareness question.

Question 2: What are the Shingrix practices of Mississippi primary care providers?

Question 9 on the survey addressed practices of PCPs' Shingrix recommendations. Respondents were asked to rate their agreement to the statement, *"I*

recommend the Herpes Zoster subunit (Shingrix) to immunocompetent adults aged 50 years and older." Of the 54 respondents, 20.4% reported "Always," 37.0% reported "More than 50%," 27.8% reported "Less than 50%," and 13.0% reported "None." There was no statistically significant difference in respondent ratings based on title, gender, age, years of experience, location, or insurance.

Question 7 on the survey addressed HER prompting. Respondents were asked, *"Is there prompting in your EHR for recommending the Zoster vaccine to patients?"* Of the 54 respondents, 18.5% reported "Yes," and 81.5% reported, "No." There was no statistically significant difference in responses based on title, gender, age, years of experience, location, or insurance.

Question 10 on the survey addressed exclusionary criteria for Shingrix administration. Respondents were given a list of possible criteria; the most commonly selected response was "Pregnant or lactating women (70.4%)." The second-most commonly selected response was "Immunocompromising illness (63.0%)," followed by "Persons taking moderate to high doses of immunotherapy (50.0%)," and "Persons who are VZV seronegative (35.2%)."

Other Findings

Questions 11, 12, 13, 14, 15, and 16 addressed the Shingrix vaccine and the ACIP recommendations. Respondents were asked to rate their level of agreement with the six statements. Table 3 shows the frequency of responses for the six statements. The most common response on the first the items was "Strongly Agree." The most common response on the last three items was "Neither Agree nor Disagree."

Table 3

Frequency of Responses to Vaccine and ACIP Recommendation Statements (N=54)

Statement	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
Shingrix vaccine is effective at decreasing the incidence of peripheral herpetic neuralgia.	0.0%	0.0%	16.7%	38.9%	**44.4%**
Shingrix vaccine is effective at decreasing incidence of shingles.	0.0%	0.0%	5.6%	38.9%	**55.6%**
The Shingrix vaccine is comparatively important to the flu and pneumo vaccine for the health of patients aged 50 years and older.	0.0%	1.9%	11.1%	33.3%	**53.7%**
The ACIP and the CDC's vaccination recommendations are important to adhere to in the health promotion and disease prevention of patients.	0.0%	5.6%	**48.1%**	25.9%	20.4%
The recombinant Shingrix vaccine is more cost-effective than the live-attenuated Zostavax vaccine.	0.0%	5.6%	**48.1%**	25.9%	20.4%
Shingrix's efficacy is better than Zostavax.	0.0%	1.9%	**44.4%**	22.2%	31.5%

Question 17 addressed barriers for not recommending the Shingrix vaccine to immunocompetent patients age 50 years and older. Respondents were asked to rank-order seven possible barriers for not recommending the Shingrix vaccine. The rating of "1" designated the most important barrier. Table 4 shows the results of the ranking. The most important barrier ranked was "Cost to patient" by 25 respondents (46.3%) and received the lowest average rank (2.10). The order of important of the other barriers, by average rank, were "Uncertainty about eligibility (3.27)," "Lack of time (3.29)," "Side effects (4.04)," "Injection site reactions (5.25)," and "Other (6.00)."

Table 4

Barrier Ranking Results

Barrier	1	2	3	4	5	6	7	Average Rank
Lack of time	12	9	6	7	4	8	2	3.29
Cost to patient	25	11	8	4	3	0	1	2.10
Uncertainty about eligibility	5	11	15	8	5	4	1	3.27
2-dose scheduling	3	9	7	15	9	4	1	3.71
Side effects	3	6	9	7	22	2	2	4.04
Injection site reactions	1	4	3	5	6	28	6	5.25
Other	1	1	3	3	1	2	25	6.00

CHAPTER V

Summary and Conclusions

As the incidence of HZ increases, the goal of prevention is essential. The goal of this research study was to determine if Mississippi PCPs are knowledgeable of the ACIP Shingrix recommendations for patients age 50 years and older, and the Shingrix practices of Mississippi PCPs. The current research study surveyed a sample of 54 PCPs from multiple clinics in Mississippi to determine if Mississippi PCPs adhere to the CDC's ACIP's recommendations for administering the Shingrix vaccine to immunocompetent adults aged 50 years and older.

Related research studies, previously reviewed in Chapter II, indicated that the HZVs are effective in the prevention of HZ and PHN. The articles focused on barriers to providing vaccines, the knowledge of vaccines, and the effects of vaccines. As this study focused on Mississippi PCPs knowledge of recommendations and practices, the results of prior related research assisted in the development of the research survey and provided confirmation of findings. These studies will be referenced further in the summary of findings section.

The data analysis summary, discussion of the findings, and the limitations of this research study are presented in this chapter. In conclusion, an interpretation of the results, implications to support further education, and additional recommendations for future research will be discussed.

Summary of the Findings

Demographic data revealed that the majority of the 54 respondents were nurse practitioners in Mississippi. The other participants identified their provider type as MD or

DO. All surveys were sent to PCPs in MS, indicating that the findings are reflective of practices among family care.

The results of the survey indicated that 85.2% of the respondents were aware of the ACIP's recommendations. The rate of awareness was significantly different based on years of experience of PCPs. The awareness rates were highest for those PCPs with more experience. There was no statistically significant difference in awareness rates based on title, gender, age, location, or insurance.

When investigating the recommendation of the Shingrix vaccine to immunocompetent adults aged 50 years and older, there was no majority leading in recommendations. Of those surveyed, 20.4% reported they always recommend the vaccine, 37.0% reported recommending greater than 50% of the time, 27.8% reported recommending the vaccine less than 50% of the time, and 13.0% reported never recommending the vaccine. In comparison with previous studies, the findings were similar. Although PCPs were aware of the recommendations of the CDC, ACIP, or FDA for administering the HZV, the rates of actual recommendation remain low. In review of previous literature and the current research finding, there seemed to be common barriers for lack of recommendation including; vaccination cost, lack of PCP time, and a lack of knowledge regarding the HZV.

The researchers also sought to determine if PCP used EHRs to prompt them to recommend the zoster vaccine to patients. Of the respondents, the larger amount reported that they are not prompted by their EHR to recommend the HZV. It is not clear why HZV prompting is not standard in EHR. However, as revealed by previous studies, the addition of this simple prompt to EHRs would increase the number of HZV recommendations,

possibly increasing the number of HZVs administered and decreasing the incidence of HZ and PHN.

Furthermore, the researchers investigated through the survey PCPs' exclusionary criteria for administering the vaccine, their level of agreement with statements regarding the Shingrix vaccine and ACIP's recommendation, and barriers to recommending the vaccine. The most selected exclusionary criteria were pregnant and lactating women, followed by persons with immunocompromising illness, then those receiving moderate to high doses of immunotherapy, and finally persons who are VZV seronegative. Researchers found that the surveyed PCPs strongly agree with the effectiveness of Shingrix vaccine decreasing the incidence of shingles and PHN. They also strongly agree that Shingrix vaccine is comparatively important as the flu and pneumococcal vaccine in patients aged 50 years and older. However, the majority of the surveyed PCPs neither agreed nor disagreed with the importance of adhering to the vaccination's recommendation by CDC and ACIP for health promotion and prevention. Nor did they agree or disagree regarding the cost-effectiveness and efficacy of the vaccines when comparing Shingrix to the other shingles vaccine Zostavax. When evaluating the importance of barriers to recommending the Shingrix vaccine, it was discovered that the most important barrier was the cost to the patient followed by uncertainty of eligibility, lack of time, 2-dose scheduling, side effects, and injection site reactions.

Discussion of Findings

The CDC ACIP recommendations suggest the administration of Shingrix vaccine to immunocompromised adults aged 50 years and older. The researchers concluded that roughly 85% of Mississippi PCPs surveyed were knowledgeable about these

recommendations. In contrast, Mississippi PCPs had a low compliance of 20.4% for consistently offering the Shingrix vaccine. Several barriers were also presented and rated by the Mississippi PCPs that were surveyed.

Health promotion can lead to healthy behavior, increased health status and decreased cost in healthcare. Researchers found that when utilizing Pender's HPM, PCPs can prevent or predict events that may interfere with health promoting behavior. Pender's HPM has been shown to be a workable model in the intervention development, prevention of unhealthy choices, changing practices and promoting healthy activity (Heydari & Khorashadizadeh, 2014). Although research showed that health promotion and disease prevention is essential, research revealed that Mississippi PCPs in this study neither agreed or disagreed with the importance of vaccination recommendations of the ACIP and the CDC for health promotion and disease prevention.

In review of the practices of PCP with EHR prompting, Chaudhry et al. (2013) sought to study utilization of HZ vaccine before and after the implementation of a web-based clinical decision support software solution in a primary care practice when the CDC ACIP was recommending a one-time dose of the vaccine for adults aged 60 years or older. In October 2017 recommendations from the CDC were changed for adults 50 years of age and older to receive the new vaccination, Shingrix. This vaccination is administered in two doses, within 2 to 6 months after the first dose. Despite the recommendation, utilization of the vaccine is very low. One method to increase the practice of preventive services such as vaccinations is with a computerized clinical decision support system. Chaudhry et al. (2013) found that the HZ vaccination rate increased significantly after the implementation of such a system. Our study found that

only 18.5% of the 54 responders EHR prompted them to recommend the Zoster vaccine. With implementation of EHR prompting for Zoster vaccination for Mississippi PCPs there could be an increase in administering the Zoster vaccine, thereby decreasing the incidence of shingles and PHN.

Despite recommendations from the CDC and ACIP to provide HZV, there remains multiple barriers. O'Donnell et al. (2018) performed a study revealing that although zoster vaccination was recommended by the CDC for immunocompetent adults 50 years of age and older, and its efficacy has been demonstrated, HZV usage continued to be low. The studies further revealed concerns of cost for the patient and provider, safety, and lack of knowledge regarding HZV, with the primary barrier identified as a lack of knowledge in multiple areas concerning the HZV. These findings were inconsistent with the results of the current research, which identified cost as the primary barrier that hindered the PCPs compliance with ACIPs recommendations.

In addition, Tsui et al. (2018), performed a survey to evaluate the knowledge, attitudes, and practices for the HZ vaccine of providers within five clinics of the NYU Langone Health (NYULH) clinics. While the majority of the respondents were aware of the HZV recommendations according to the CDC for ages 65-70 years, there was a comparatively fewer amount aware of the FDA's approval of the HZV at the age of 50. Physician attitudes regarding barriers showed that cost of the vaccine was the top reported barrier. The researchers also reported that a considerably large number of responders agreed that the HZ vaccine was comparatively important to the pneumococcal and influenza vaccination. When compared to the current study, these findings varied in consistency. While the PCP in the study lacked knowledge of recommendations at age

50, the respondents in the current study were found to be knowledgeable of the recommendation at age 50. The referenced study revealed that the responders strongly agreed that the Shingrix vaccine is comparatively important to the flu and pneumococcal vaccine in patients aged 50 years and older, as did those in the current study. Finally, both studies reveal cost to the patient as the most important barrier to recommending HZV.

Limitations of the Study

The researchers assert that one of the limitations of this study was a small sample size due to lack of survey responses. There was also a time constraint. The survey was opened for a limited time of approximately 2 months. This study relied on PCPs' self-reporting instead of a calculated measurement from chart reviews that impartially document the PCP practices or observed practices. Another limitation was the inability to generalize results based on the sample participants not being representative of all providers collected at a single point in time due to the study being restricted to Mississippi and PCP. There was also the limitation of the majority of the respondents being female nurse practitioners from rural areas, thus limiting the types of providers surveyed.

Conclusion

The goal of the current research was to determine if Mississippi PCPs were knowledgeable about the CDC ACIP Shingrix recommendations for patients aged 50 years of age and older. The current research also sought to determine if Mississippi PCPs are adhering to ACIP's Shingrix recommendations for patients aged 50 years and older. According to the results, the researchers determined Mississippi PCPs' knowledge of

CDC guidelines were sufficient. Of the 54 respondents, the results indicated that 85.2% were knowledgeable. Additionally, response rates varied regarding Mississippi PCPs' adherence to recommending the vaccine to patients aged 50 years and older. Of the 54 respondents, only 20.4% reported always recommending the Shingrix vaccine to immunocompetent adults aged 50 years and older, with 13% reporting not recommending at all.

The results of the survey indicated that the most common barrier for not recommending was cost to the patient. While this study does not determine if Mississippi PCPs are aware of the actual cost to the patient, or if their assumptions of the cost is the reason for the decrease in recommending this vaccine, this finding does indicate a significant need for further education of the Shingrix vaccine. If patients were better educated on the benefits of the Shingrix vaccine and the potential side effects of the HZ vaccine, cost may not be an issue for the patient.

Implications

According to the CDC recommendations, the Shingrix vaccine is recommended for use in immunocompetent adults aged 50 years and older. This study concluded Mississippi PCPs possess an increase in knowledge of the Shingrix vaccine, yet they have decreased compliance in regard to recommending Shingrix to their patients. The researchers inferred that Mississippi PCPs need additional education on the benefits of Shingrix vaccine as well as the potential painful, long-term side effects of HZ. With further education, Mississippi PCPs could further understand the efficacy of Shingrix vaccine, which could improve the overall health and well-being of their patients. This study was guided by Nola Pender's HPM which, in summary, focuses on identifying

factors that could influence or hinder health. Mississippi PCPs should educate their patients on the HZ virus and the beneficial aspects of receiving Shingrix vaccine to either prevent the HZ virus or minimize or eliminate its side effects.

Recommendations

Based on the outcomes of this study, the following recommendations are made for practice:

1. Construct a visual education model to display to Mississippi PCPs and to patients about the harmful effects of HZ virus, including the possible long-term effects of PHN.
2. Construct an additional education model to demonstrate the benefits of Shingrix vaccine.
3. Develop a program to prompt Mississippi PCPs to screen all potential patients for the Shingrix vaccine.
4. Develop a quick reference guide of co-pays for common insurance carriers to determine the cost to the patient for the Shingrix vaccine.

Summary

The current researchers, as reported in Chapter V, revealed that Mississippi PCPs are deficient in compliance of the CDC ACIP recommendations of Shingrix vaccine to immunocompetent adults aged 50 years and older, yet a vast majority of the Mississippi PCPs surveyed possessed the knowledge of the Shingrix vaccine. The researchers also determined cost of the vaccine as the primary barrier to Mississippi PCPs recommending Shingrix to patients. An increase in patient education about the potential long-term side

effects of HZ and the benefits of Shingrix vaccine could break the barrier of cost, thus leading to an increase of the number of patients preferring and receiving vaccination.

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APPENDIX

Awareness and Adherence to ACIP's Shingrix Recommendation Worksheet Among Mississippi Primary Care Providers

1. What is your title?
   - MD
   - DO
   - NP
   - PA
2. Gender
   - Male
   - Female
3. What is your age?
   - 20-29 years
   - 30-44 years
   - 45-59 years
   - 60+ years
4. How many years of experience?
   - <5 years
   - 5-10 years
   - 10-19 years
   - 20-29 years
   - >30 years

5. What type of community do you serve?

- Rural
- Suburban
- Urban

6. What type of insurance do you accept?

- Private
- Federal or State
- None

7. I recommend the Herpes Zoster subunit (Shingrix) to immunocompetent adults aged 50 years and older.

- Always
- More than 50%
- Less than 50%
- None (If not, please specify)

8. Are you aware of the ACIP's recommendations from October 2017 to recommend Shingrix as the preferred vaccine to immunocompetent adults aged 50 years and older?

- Yes
- No

9. Which of the following are the exclusionary criteria for Shingrix? Select all that apply.

- Persons taking moderate to high doses of immunotherapy
- Persons who are VZV seronegative
- Persons who presently have an immunocompromising illness
- Pregnant or lactating women

10. Is there prompting in your EHR for recommending the zoster vaccine to patients?
    - Yes
    - No
11. Shingrix vaccine is effective at decreasing incidence of shingles.
    - Strongly agree
    - Agree
    - Disagree
    - Strongly disagree
12. Shingrix vaccine is effective at decreasing the incidence of peripheral herpetic neuralgia.
    - Strongly agree
    - Agree
    - Disagree
    - Strongly disagree
13. The Shingrix vaccine is comparatively important to the flu and pneumococcal vaccine for the health of patients aged 50 years and older.
    - Strongly agree
    - Agree
    - Disagree
    - Strongly disagree
14. The ACIP and the CDC's vaccination recommendations are important to adhere to in the health promotion and disease prevention of patients.
    - Strongly agree

- Agree
- Disagree
- Strongly agree

15. The recombinant Shingrix vaccine is more cost-effective than the live-attenuated Zostavax vaccine.
    - Strongly agree
    - Agree
    - Disagree
    - Strongly agree
16. Shingrix's efficacy is better than Zostavax.
    - Strongly agree
    - Agree
    - Disagree
    - Strongly agree
17. Rate the following barriers in order of importance (1 being the most important) for not recommending Shingrix.
    - Lack of time due to other priority tasks for each patient visit
    - Cost to patient
    - Hesitant to vaccinate due to uncertainty about patient's eligibility to receive vaccination.
    - Hesitant to vaccinate due to Shingrix's 2-dose scheduling
    - Hesitant to vaccinate due to Shingrix's potential side effects
    - Hesitant to vaccinate due to injection site reactions

- Other barriers [Please comment]