

# Development of zostavax



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Shingles vaccine, Zostavax, has been available since 2006, and is gaining in popularity among adults older than fifty years old. In order to alleviate any misconceptions of the vaccine or the disease process, a discussion of the disease, effectiveness of the vaccine, proper administration, safety precautions, complications, and immunity process will be highlighted by utilizing evidenced based studies and practices. It is through proper knowledge and patient education that the adverse effects of shingles, as well as other communicable diseases, can be prevented and provide a better quality of life for those at risk for shingles.

Shingles is a debilitating disease caused by the same virus that causes chickenpox and will affect one in three people (Hall, 2010). Chickenpox are caused by the varicella-zoster virus (VZV), and most commonly acquired during childhood (U. S. Department of Health and Human Services, Center for Disease Control and Prevention, 2012). One important point is that one cannot develop shingles unless they have had chickenpox or have received the chickenpox vaccine (Hall, 2010). Shingles is an exacerbation caused by the virus, which hides in the dorsal root ganglion of the central nervous system for years after infection of chickenpox or years after administration of the chickenpox vaccine. Some of the first symptoms of shingles are headache or sensitivity to light, or one may have flu like symptoms without a fever (American Pharmacists Association, 2009). The inflammation reaction of shingles takes place when the dormant virus has the opportunity to become active, commonly in adults over fifty years old with a weakened immune system (Hall, 2010). When active, the virus will travel down the nerve from the dorsal root ganglion and cause a reaction to take place on

the skin. The reaction is concentrated to the nerve root, also known as a dermatome, that is affected, which is presented by a distinctive irritating rash that begins at the midline of the back and follows the nerve root around the torso toward the front in a horizontal fashion. The rash has also been known to affect the face. The rash is usually unilateral, but in some cases the rash may be bilateral (DHHS, CDC, 2012). The rash associated with shingles is very painful and has an intense itching and tingling sensation, which is followed by clusters of blisters. The blisters are filled with fluid and then after some time burst and crust over. These blisters may leave scars on the skin, and may take two to four weeks to heal. The blisters are only contagious to people who have not had chickenpox or have not received the chickenpox vaccine, and one will only contract the chickenpox virus, not shingles (Hall, 2010).

When the shingles vaccine was first approved in 2006 by the Food and Drug Administration (FDA), it was intended for those sixty years old and above (Laustsen & Neilson, 2007). The potency of Zostavax is at least fourteen times greater than the chickenpox vaccine (DHHS, CDC, 2012). The effectiveness of the vaccine, Zostavax, was studied using eight different randomized controlled trials which included a total of 52, 269 participants (Gagliardi, Gomes, Torioni, & Soares, 2010). The study concluded that the vaccine was most effective in the sixty to sixty-nine year old age group, although this age group had the greatest number of side effects (Gagliardi et al., 2010). In a more recent study to determine the effectiveness in fifty to fifty-nine year olds, the use of Zostavax was shown to be effective (Schmader et al., 2012). The results of the study proved to be over seventy

percent effective in the fifty to fifty-nine age group (Schmader et al., 2012). The use of the Zostavax vaccine to reduce the effects of shingles on activities of daily living has also been proven to be effective for older adults (Singh & Subhashni, 2011). Due to this new study the age limit was changed to fifty years old and above. This change by the FDA proves that the vaccine is effective in preventing shingles in the aging population. Therefore proper education of adults fifty and older with regards to shingles should be a mainstay of intervention. Informing these adults of the serious consequences of not being vaccinated against shingles should also be incorporated into community education.

The administration of the shingles vaccine Zostavax is a simplistic procedure and starts with proper storage and handling. Zostavax must be stored or shipped at temperatures between -58°F to +5°F (DHHS, CDC, 2012). Before reconstitution, Zostavax is a live attenuated vaccine that is a solid white powder and is brought to room temperature prior to administration (APhA, 2009). The powder is reconstituted with sterile water and should be 0.65mL when diluted. When reconstituting, the use of sterile syringe and needle is required. Once the vaccine is mixed, it is only good for up to thirty minutes. The administration of the vaccine is done by withdrawing the entire contents of the mixed vial, which is 0.65mL, into a sterile syringe. Once the vaccine is drawn up into the syringe discard the needle use to puncture the seal and replace with a new sterile needle prior to administration. The entire contents of the syringe are to be injected subcutaneously by using a 1mL syringe with a 5/8" 23 gauge needle. The injection site suggested by the FDA is the posterolateral aspect of the upper arm using a 45° angle of entry. Prior to

entry of the skin, wipe the site with an alcohol swab and allow to dry. Inject the vaccine at a moderate pace, one to four seconds. After injection remove the needle, activate the safety device and discard in proper sharps container. Next, apply light pressure to the site using a sterile cotton ball to discourage bleeding and apply a bandage if needed or desired. Be sure to keep an eye on the patient for a minimum of fifteen minutes to observe for signs of an adverse reaction. The signs for an adverse reaction can be itching, redness, hives; swelling of the lips, face, or throat; shortness of breath or wheezing; abdominal cramping; or cardiovascular collapse. A request for water, indicating thirst, and difficulty breathing shortly after vaccination are the first hint from a patient that anaphylaxis may occur. Do not give the patient anything to drink, and instruct the patient to sit down. If anaphylaxis is occurring, immediately enact emergency protocols. The use of epinephrine is the first line treatment for acute anaphylaxis. The general dose is based on the patient's body weight, 0.01mg/kg up to a maximum dose of 0.5mg per dose. The dose of epinephrine may be repeated every five to twenty minutes, and is based on the patient's response (APhA, 2009).

Zostavax is classified as a live attenuated vaccine, which means that a "wild" virus is modified in a laboratory. During the modification process of the "wild" virus, it is weakened during the production process and therefore usually will not cause the disease. Once the vaccine is injected into the body, the live attenuated viruses must undergo replication in order to produce an immune response. The live vaccine has shown to be effective with one or two doses and have proven to be more effective than inactivated vaccines (APhA, 2009).

Zostavax is an artificial active immunity, in which the subject is exposed to the live weakened “ wild” pathogen. The exposure to the vaccine is artificial in nature, meaning the patient is injected with the weakened form of the virus to produce immunity. It is artificial active immunity that produces a prolonged effectiveness against shingles and also protects the patient against the disease without the risk of developing complications from having shingles. The immunity takes a couple of weeks to produce an antibody level sufficient enough to provide protection against shingles (APhA, 2009).

The immune response is a complex process. First the subject needs to be exposed to the antigen, in this case the varicella zoster virus. The exposure to the virus allows for replication of the virus in the body. Once the immune system detects the antigen(s), two types of acquired immune responses occur, the humoral and cell-mediated immune responses. Both immune responses usually occur at the same time and cause a cascade of immune responses in order to eliminate the antigen(s). Both immune responses are mediated by many types of lymphocytes. They are two dominant types of lymphocytes, the B lymphocytes and T lymphocytes. The B lymphocytes arise and mature in the bone marrow, while the T lymphocytes arise in the bone marrow and then circulate to the thymus where they mature. Both B and T cells circulate in the blood looking for any foreign antibodies, and if detected an immune response will be activated (APhA, 2009).

The humoral response is mediated by the B cells, which contain a unique receptor that is specific to only one antigen. When a B cell finds a matching antigen in the blood, it will bind to the antigen and activate the humoral immune response. This response functions by developing antigen-specific

antibodies, which are responsible for recognizing and neutralizing the specific antigen. When the humoral response is begun, the B cells proliferate and mature into plasma cells. It is these plasma cells that make millions of identical antibodies to the specific antigen in which was encountered. The newly formed antibodies are then released into the bloodstream to find and bind to the antigen, which forms an antigen-antibody complex. The antigen-antibody complexes are then cleared by the immune system by phagocytosis and the complement system. After the elimination of the antigens, some of the B cells remain in the immune system as memory B cells; the memory B cells are there to defend against a future invasion of the same antigen (APhA, 2009).

The cell mediated immune response involves the helper T cells, which are a type of T lymphocyte. The helper T cells do not directly bind to antigens; they are activated when they encounter infected cells that contain antigen fragments on the cells surface. The activated helper T cells secrete cytokines, which are chemical mediators that direct an immune response by recruiting additional immune cells to the area of infection. The cytokines signal helper T cells to perform many different functions. One of which the helper T cells stimulate additional B cells to activate antigen-specific antibodies; this will induce production of antibodies to fight the antigen. Next, the helper T cells will recruit macrophages and other immune cells to the area of infection which complements the destruction and elimination of the antigen. Finally the helper T cells can activate cytotoxic T cells, which can identify and kill infected cells. Once the antigen has been removed from the subject, the body will retain a certain number of B cells and T cells to “

remember” the antigen which results in immunologic memory. It is these remaining cells that can give a subject a specific immunity that can last from years to decades, or even a lifetime (APhA, 2009).

Since the introduction of Zostavax in 2006 the CDC is continuing to reach the at risk populations to help educate and vaccinate against shingles as well as other preventable communicable diseases. It is the proper knowledge and education of at risk populations, that we have seen an improvement in quality of life revolving around proper up-to-date vaccination. Through continued community education and proper placement of public and volunteer educators, the misconceptions of shingles and vaccination can be alleviated as long as up-to-date evidenced based healthcare information is provided to the at risk populations.