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September 2014



BioMarketing Insight Newsletter

Creating Markets and Marketing
Strategies

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter. Last month I covered "How Gluten Increases Glucose Levels and Can Cause Neurological and Cardiac Diseases." If you missed last month's article, click [here](#) to read it. This month I will discuss my experience with shingles and the things you need to know.

Read on to learn more about this topic and other current news. On the right are quick links to the topics covered in this month's newsletter. The next newsletter will be published on October 15th.

We encourage you to share this newsletter with your colleagues by using the social media icons at the top left, or by simply forwarding the newsletter via email.

Please email [me](#), Regina Au, if you have any questions, comments, or suggestions.

Sincerely,
Regina Au
Principal, Strategic Marketing Consultant
[BioMarketing Insight](#)

In This Issue

[My Experience with Shingles](#)

[Closing Thoughts](#)

[Developing a Product?](#)

[New Technology - "Gene therapy creates 'biological pacemaker' cells for the heart"](#)

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[Previous Newsletters](#)

My Experience with Shingles

The Disease

For those unfamiliar, [shingles](#) is an infection caused by the varicella zoster virus (VZV), better known as the chicken pox virus. If you had chicken pox as a child, you carry the virus and it remains in the nerve cells of your body after the infection clears and it can be reactivated years later, causing shingles. No one knows why the VZV reactivates, but for some reason our immune systems harbor the dormant virus. When the immune system is either not working properly or is compromised, the shingles virus may be reactivated. VZV is classified under the category of Herpes Virus. However, [herpes zoster](#) is not caused by the same virus that causes genital herpes, a sexually transmitted disease.

According to the Centers for Disease Control, it is estimated that 1 million cases of shingles occur each year in this country and about 1 out of every 3 people in the United States will develop shingles in their lifetime. The risk of shingles increases as you get older and approximately half of all cases occur in men and women 60 years old or older. Anyone who has had chickenpox may develop shingles at any age, even children. I know of two people who had shingles, one at age 25 and the other at age 36. Also, you can contract shingles more than once; one of those people had it 5 times and the other had it twice.

Those at [higher risk](#) of developing shingles are:

- people who have medical conditions that keep their immune systems from working properly, such as those who have cancers such as leukemia and lymphoma, and human immunodeficiency virus (HIV), and
- people who receive immunosuppressive drugs, such as steroids and drugs given after organ transplantation.

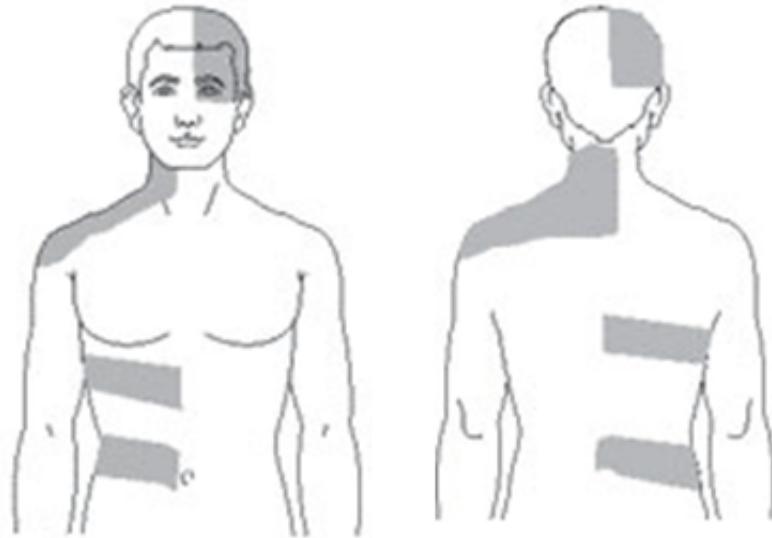


Shingles on the face.
Source: CDC

Signs & Symptoms

Shingles causes a [painful rash](#) that develops on one side of the face or body. The rash forms blisters that typically scab over in 7 to 10 days and clear up within 2 to 4 weeks.

Before the rash develops, people often have pain, itching, or tingling in the area where the rash will develop. This may happen anywhere from 1 to 5 days before the rash appears.



Source: CDC

Most commonly, the rash occurs in a single stripe around either the left or the right side of the body. In other cases, the rash occurs on one side of the face. In rare cases (usually among people with weakened immune systems), the rash may be more widespread and look similar to a chickenpox rash. Shingles can affect the eye and cause loss of vision.

Other symptoms of shingles can include:

- Fever
- Headache
- Chills
- Upset stomach

My first symptom was shooting pain on the top of my scalp or right side of my head, that radiated throughout my body. At first I thought I strained a neck muscle, since I was using the foam roll to loosen my neck muscles. Then the pain started around my ear and jaw line to the point that my face was swollen. I tried taking Aleve to relieve the pain and also using an ice pack several times a day to get the swelling down, but neither helped. Needless to say, I could not sleep due to the pain.

Then a rash or 3 large bumps appeared on my face, near my hairline. I couldn't figure out how I had injured myself, or what I came in contact with to get the rash. I did not connect the pain and the rash as the onset of shingles, since I had never experienced or seen shingles before. When the rash didn't get better by day two 2, I began to worry. Just my luck this was happening over the 4th of July holiday weekend! But I decided it wasn't an emergency and I waited until Monday to call my PCPs office. The redness from the rash started to spread down my face.

I talked to the Nurse Practitioner (NP) and as soon as I said rash, she said shingles and asked me to come into the office that day. She and my PCP confirmed the shingles diagnosis and wanted me to see an ophthalmologist right away, because the shingles (three lesions under my eyelid and in my eyelid) had spread down to my eye and they were worried that the virus might affect my cornea and possibly cause blindness.

The NP prescribed an antiviral drug, valacyclovir HCL (Valtrex), for 10 days to inactivate the virus and stop it from spreading. She also prescribed gabapentin (Neurontin) for the nerve pain. I got the generic version of both drugs. Gabapentin is used to prevent and control seizures, but it is also used to relieve nerve pain following shingles in adults, according to the prescribing information.

When I couldn't get an appointment with an ophthalmologist at Massachusetts Eye and Ear Hospital, I saw an optometrist. The optometrist said everything looked fine so far, but wanted me to come back in 2-3 days for an update. In the meantime, the optometrist prescribed an eye drop and an ointment to keep the eye moist. I was told the antiviral medication was the only thing that would

inactivate the virus and that prescribing steroids could do more harm than good.

I went back to see another optometrist since the first one was not available, but by that time the rash was getting worse and my eyelid was so swollen it was half shut and I had to have someone drive me to my appointment. Thank goodness my eye was not affected by the virus, but I nevertheless had a follow-up in two weeks.

If this experience wasn't bad enough, I developed new lesions under my eye and had yet another course of antiviral treatment for seven days.

Even with the gabapentin, I still experienced pain; sharp pain, tingling pain and burning on my face as the rash and migrated further down my face and to the back of my scalp on the right side. I never knew I had so many nerves in my face. The rash followed the same path as the pain. I developed a tolerance to the gabapentin and I had to increase the dosage. Gabapentin causes drowsiness, so if I wasn't in pain, I was sleeping every time I took the gabapentin three times a day.

The rash lasted three weeks before the redness started to subside. I still have scarring or dark marks from where the lesions were and I have postherpetic neuralgia (PHN), pain from the shingles nine weeks later. The pain has lessened and isn't as frequent as it was initially, but the pain still reminds me that I had shingles. Postherpetic neuralgia is common after having shingles and the duration varies from individual to individual. In some people, [PHN](#) can persist for years.

Shingles Vaccine

I highly recommend that if you've had chicken pox, get the shingles vaccine Zostavax®. You don't want to go through what I experienced. The vaccine is a live attenuated (weaker) virus that builds up your immune system and keeps the virus dormant. The CDC recommends that anyone over the age of 60 should get the vaccine because the older you are, the more severe the experience.

[Zostavax](#) reduces the overall risk of shingles by 51% for those 60+ years old and the risk of post-herpetic neuralgia by 67%. The vaccine is most effective in people 60-69 years old, but also provides some protection for older age groups.

Zostavax is approved and indicated for those who are [50 and older](#). There were two separate clinical trials. In the Zostavax Efficacy and Safety Trial (ZEST), a placebo-controlled, double-blind clinical trial in which 22,439 subjects 50 to 59 years of age were randomized to receive a single dose of either Zostavax (n=11,211) or placebo (n=11,228), [Zostavax](#) significantly reduced the risk of developing zoster by 69.8% (95% CI [54.1, 80.6%]).

The efficacy of Zostavax was evaluated in the Shingles Prevention Study ([SPS](#)), a placebo-controlled, double-blind clinical trial in which 38,546 subjects 60 years of age or older were randomized to receive a single dose of either Zostavax (n=19,270) or placebo (n=19,276). The efficacy was overall 51%; 64% for age 60-69, 41% for age 70-79 and 18% for those 80+. Due to this study, the CDC recommends those 60+ years of age get the vaccine, noting that the efficacy is best in the 60-69 year old age group.

My understanding is that you can still get shingles with the vaccine, but it would be a milder case. The vaccine also had the greatest reduction in the incidence of [postherpetic neuralgia](#) with the 70-79 age group at 55%, followed by the 80-89 age group at 26% and the 60-69 age group at 5% for an overall reduction of 39%.

Reimbursement

All [Medicare Part D](#) (prescription) plans cover the shingles vaccine. Depending on the plan, there may be a co -pay, or one pays a portion of the total cost.

You would need to check with your insurance company as to whether or not they cover the vaccine. At CVS, where they are pushing the vaccine, my pharmacist mentioned that depending on the insurance plan, people have paid anywhere from \$0 up to \$208 to get the vaccine.

[Top](#)

Closing Thoughts

I highly recommend anyone who has had chicken pox to get the vaccine. A bout with shingles is not pleasant and I would not want anyone to experience it. While the vaccine doesn't protect you 100%, the severity would be less and the incidence of postherpetic pain would also be reduced in the age groups indicated. If you believe that your immune system is better equipped to keep the zoster virus at bay the younger you are, then I have to believe that the efficacy of the vaccine makes it useful in those less than 50 years of age.

Many people believe that stress reactivates the dormant shingles virus. While stress does play a role in the functioning of our immune systems, particularly if one is under constant stress for an extended period of time, there are other factors that can contribute:

1. Eating wheat products (gluten). Gluten (gliadin) triggers the protein zonulin that leads to intestinal permeability that in turns activates our immune system (innate immunity) which leads to inflammation and symptoms (from immune cells) for those who don't have Celiacs Disease. This can cause food sensitivity to gluten and other foods that passes through the intestinal wall.
2. Our gut microbiome, the composition of the bacteria in our gut, is the key factor impacting intestinal physiology, where microbiome helps the intestinal immune function to maturity, according to Dr. Alessio Fasano who discovered the protein zonulin. Our microbiome affects how our genes are expressed.
3. Environmental factors, such as toxic chemicals and radiation.
4. Lifestyle choices, such as lack of sleep and exercise, poor diet, excessive alcohol use and smoking.
5. Co-morbidity and the medications we take for them.
6. Our genes and bad luck.



We really don't know what causes shingles, but there must be a tipping point and stress could be the hand on the scale that fatigues our immune system, leading it to unleash the shingles virus.

Here are the lessons I learned:

1. Get the shingles vaccine to significantly reduce your risk of contracting shingles, even though the vaccine is primarily indicated for 50+ year olds. You can get shingles at any age. Check your insurance.
2. Should you experience unexplained pain, shooting pain or tingling pain with or without a rash, don't wait, go to your primary care physician to get it checked out yesterday and start on an antiviral medication. This is the only strategy to inactivate the virus and prevent it from spreading.
3. Even if you've had shingles, get the vaccine anyway, since you can get shingles more than once. There is a resting period post - shingles, to give your immune system a rest before you get the vaccine. Healthcare professionals recommend that you wait anywhere from 2- 6 months post -shingles.
4. If you do have shingles with active lesions you are contagious, but only with direct contact of the lesions with people who have not had chicken pox. This is particularly so with pregnant women.
5. If you have shingles on your face and near your eyes, go to a cornea specialist (ophthalmologist) and not an optometrist. The optometrist is not trained in cornea disease. In the case of an emergency such as mine, the first visit could be an optometrist, but all subsequent visits should be with the specialist. If the optometrist does not refer you after the first visit, have your primary care specialist refer you.

It can happen to anyone, and the best offense is a good defense, so be prepared.

[Top](#)

Developing a Product?



If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, email [me](#) for an appointment. For successful commercial adoption of your product, email [me](#) for an appointment.

[Top](#)

New Technology - "Gene therapy creates 'biological pacemaker' cells for the heart"

Using gene therapy, researchers have injected a human gene into a pig's pumping heart chamber with heart block in reprogramming the heart muscle cells into cells that emits electrical impulses to pump the heart. Cardiologists at Cedars-Sinai Heart Institute in Los Angeles have created "biological pacemaker" cells that can restore normal heart rate in pigs.

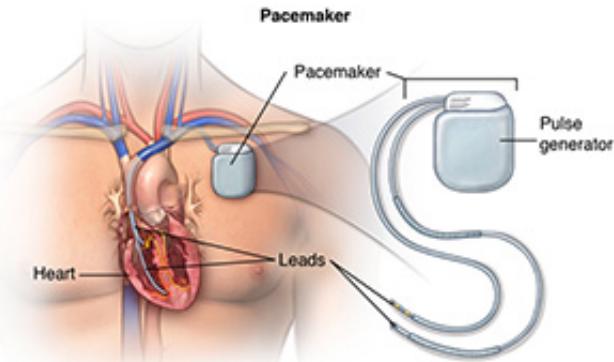
"This development heralds a new era of gene therapy where genes are used not only to correct a deficiency disorder but actually to convert one type of cell into another to treat disease," Dr. Eduardo Marbán, director of the Cedars-Sinai Heart Institute and leader of the research team, told reporters.

Dr. Eugenio Cingolani, director of the institute's Cardiogenetics-Familial Arrhythmia Clinic, said "if all goes well" in further animal studies examining the procedure's long-term effectiveness and safety, "we hope to be able to begin trials in humans within three years."

They developed this therapy as an alternative to metal pacemakers that need to be changed regularly, that fail or can't be used due to infections related to the device as well as for fetuses in the womb with heart block.

To read the full article in *Reuters*, click [here](#).

[Top](#)



Source: John Hopkins Medical Health Library.

About BioMarketing Insight

We help companies de-risk their product development process by conducting the business due diligence to ensure that it is the right product for the right market and the market opportunity for the product meets the business goals of the company. We can then develop marketing strategies to drive adoption for the product.

[Top](#)

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