CVCR
Center for Value-Based Care Research

Cleveland Clinic

Value Added

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Shingles Vaccine: Is it time for a booster?

Herpes Zoster, better known as Shingles, is an important cause of morbidity in the elderly. Zoster causes a painful rash and in a minority of patients, the pain can last for years. For almost a decade, we have been vaccinating patients to prevent Shingles, but new data published in the past 2 years raises questions about the duration of immunity. Dr. Phuc Le has been studying the Zoster vaccine for the past several years. In this issue, she shares insights, based on her research, about how best to protect patients from the harms of Shingles.

Why did you choose to study the Zoster vaccine?

Immunization against Shingles with the zoster vaccine is known to be a cost-effective disease prevention measure. For older adults, vaccination is critical to prevent the substantial morbidity associated with shingles and post-herpetic neuralgia, a painful condition that can last for years. In 2008, the Advisory Committee on Immunization Practices (ACIP) recommended a single dose of the live attenuated herpes zoster vaccine (HZV) for persons aged 60 years or older. This recommendation was based on the inclusion criteria for the Shingles Prevention Study, a large randomized trial that demonstrated the vaccine's effectiveness. However, recent long-term follow-up data showed that the efficacy of HZV disappears by 10 years. Because the incidence of herpes zoster (HZ) and, especially, post-herpetic neuralgia increases with age, if patients get vaccinated in their 60s, they will be susceptible to the disease in their 70s or later when the incidence peeks. We wondered, if only one dose of vaccine will be administered, when is the best time to get it? In addition, a recent study of an HZV booster dose administered after 10 years showed safety and immunogenicity similar to that seen in patients vaccinated for the first time. This made us question whether a single-dose is really the best approach. Perhaps a booster would also be cost-effective. In that case, it might make sense to start early and then add a booster. We used a sophisticated computer simulation model to compare different vaccination schedules of HZV, including booster options, in persons aged ≥60 years.

What did you learn?

First of all, we found that booster strategies always beat single dose strategies at a very reasonable cost. That's an important point, because people who were vaccinated when the vaccine first came out are approaching the 10-year mark. Right now the ACIP only recommends a single dose, so insurance may not pay for a booster and the vaccine is expensive. We also found that the optimal schedule was to give the first dose when the patients were 70 years old (not 60, as is currently recommended) and then administer a booster 10 years later. Administering the first vaccination at age 60 years and then giving boosters at 70 years and again at 80 years provided the greatest benefit, but this option was too expensive, based on generally accepted standards of cost-effectiveness.

What surprised you the most?

Compliance with the booster is one of the most influential factors in our study. When we assessed the impact of vaccine price and compliance rate, it turned out that only the compliance rate mattered in determining the best vaccination schedule. The current compliance rate for a Tetanus booster (which also has a 10-year time frame) is only 60% in older adults. If a patient had at least a 68% chance of getting each booster, then it would be reasonable to begin vaccination at age 60 followed by 2 boosters 10 years apart. Therefore, if a booster is recommended, measures to increase compliance rate should be promoted.

What are next steps in your research on zoster vaccine?

There are many more questions on HZ vaccine that we want to answer. Although our study identified an optimal vaccination schedule for vaccine-naïve patients, we have about 28% of the 18 million persons aged ≥60 years already vaccinated. What should we do for these patients? Should they receive a booster, and if so, what is the optimal timing?

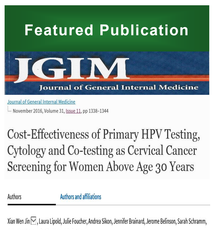
Another issue is that a new adjuvanted subunit herpes zoster vaccine (ASV) has been recently proven to be highly effective in patients aged 50 years or older. The introduction of this new vaccine may change practice because ASV is much more effective than HZV, especially for older patients. The ASV is not yet FDA approved, or priced, and its cost-effectiveness is unknown. However, any future data on the long-term efficacy of the ASV, or its price, would be useful for us to determine the best vaccine for use in both vaccine-naïve and vaccine-experienced patients.

How will your research impact clinical care at the Cleveland Clinic?

Our research shows that, contrary to current recommendations, a single dose of HZV is not enough to protect patients from HZ and complications, and it is not cost-effective to administer a single dose at age 60. Under the current situation, the best practice may be to wait to vaccinate until patients turn 70, and then administer a booster dose 10 years later. For patients who are already vaccinated, physicians may want to offer a booster if it has been 10 years past the initial dose, but patients will need to check to see if their insurance covers it. Once the ASV is available (assuming it will eventually get FDA approval), the optimal vaccination schedule for HZ will need to be revisited. Primary care physicians should be alert to changes in clinical practice so that the patients can enjoy the greatest benefit that HZ vaccine has to offer.

Click here to read the Editorial on this publication

Featured Publication



An Introduction to the CVCR's newest investigators

Elizabeth R. Pfoh, PhD, MPH began her position as Associate Staff at Cleveland Clinic's Medicine Institute in July 2016. Dr. Pfoh is a Health Services Researcher interested in understanding how best to deliver high quality outpatient care, particularly for complex patients. Prior to coming to Cleveland Clinic, Elizabeth was a General Internal Medicine postdoctoral fellow at Johns Hopkins School of Medicine. She received her PhD in Health Services Research and Policy from Johns Hopkins Bloomberg School of Public Health in 2014. In 2010, she received a MPH from Columbia Mailman School of Public Health where her focus was health promotion. Dr. Pfoh has published peer-reviewed papers on a variety of topics including patient safety, quality of medical care, and measuring long-term outcomes in ICU survivors.

Matthew A Pappas, MD, MPH was appointed as a Staff Physician and Research Investigator in the Cleveland Clinic's Medicine Institute in July of 2016. Dr. Pappas is a hospitalist and health services researcher whose goal is to make medicine simultaneously more personalized and more rigorously grounded in the best-available evidence. Prior to the Cleveland Clinic, Dr. Pappas was at the University of Michigan, where he completed medical school, residency, and was on faculty as a Clinical Lecturer. He also completed a health services research fellowship through the Ann Arbor VA, which followed the Robert Wood Johnson Foundation's Clinical Scholars Program curriculum. Dr. Pappas' published research has focused on the balance of benefits and harms for common decisions facing general internists and hospitalists.

Featured study-in-progress: *Individualizing Disease Prevention for Middle-Aged Adults*

Principal Investigator: Glen Taksler, PhD
Co-Investigators: Michael Rothberg, MD, MPH

Sometimes a routine visit to the doctor can seem like one long checklist: Have you gained or lost weight recently? How's your blood pressure? Let's go over your blood test results. It's time to schedule your colonoscopy.

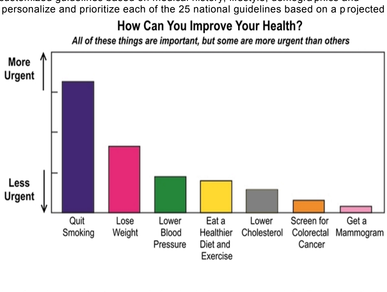
Actually, there really is a checklist. The U.S. Preventive Services Task Force, an independent group of national experts in prevention and evidence-based medicine, created a list of preventive care guidelines for healthcare providers to follow. These guidelines, however, can be difficult to implement, says Glen Taksler, PhD, a researcher and Assistant Professor of Medicine at Cleveland Clinic's Medicine Institute. "There are so many recommendations that it's impractical to try to do every recommended service for every patient, every time."

Helping Patients Prioritize their Care

Physicians rarely have time during an office visit to address all the recommended screenings and preventive guidelines. And patients may not feel motivated to follow through on these recommendations. But what if the checklist were created specifically for you – using your medical records, family history and lifestyle choices? Dr. Taksler has designed a computer program that uses information and health history from a patient's electronic medical record (EMR) to create customized guidelines based on medical history, lifestyle, demographics and family history. He also developed a mathematical model to personalize and prioritize each of the 25 national guidelines based on a projected gain in life expectancy if a particular patient followed each recommendation.

How Customization Works

Dr. Taksler thought that if doctors could combine recommended guidelines with the data collected in a patient's unique EMR, they would better know how to treat that patient. "What recommendations are most likely to help the patient live a longer, healthier life? It can help doctors and patients be more objective," he says. The program uses a bar graph format to show the patient's own health information and the impact of the health recommendations on health and life expectancy. "I'm showing what the U.S. guidelines would look like if they had been created *just for this patient*," Dr. Taksler says. Because the recommendations are intended to increase life expectancy, "none of these things is likely to do anything to impact a patient's health tomorrow, next week or even next year," Dr. Taksler says. "We're talking five, 10, 20 or even 30 years down the line."



From Theory to Practice

Dr. Taksler soon will begin a study with a small group of physicians focusing on patients coming in for physicals and wellness visits. For each patient, he'll create a graph using the individual's EMR data. After analyzing information from these sessions, Dr. Taksler can modify the program as needed. Michael Rothberg, MD, MPH, Vice Chair for Research at Cleveland Clinic's Medicine Institute, says he is looking forward to implementing Dr. Taksler's program in his own practice. In addition to helping prioritize his recommendations to his patients, he says it will help him spend his time more effectively. "Even if I understand the benefit of one intervention compared with another, it's impossible for me to know the relative benefit for this particular patient," Dr. Rothberg says. "It gives me a way to put a value on each of the interventions relative to each other and easily communicate it to my patient." It also helps patients prioritize. "If a patient who smokes is thinking about being screened for lung cancer or quitting smoking, then she can easily see that quitting smoking will have a much greater impact on her current and future health than the lung cancer screening," Dr. Rothberg says. "A bar graph printout will help patients say, 'Oh, now I get it. If I do this and this and this, I'll see the impact on my health.'"

A Gateway to Better Conversation

Eventually the program will be implemented at Cleveland Clinic family health centers for broader testing, and Dr. Taksler believes it has the potential to become the standard of care. The program, which will be compatible with all types of EMR systems, also can be adapted for use by other healthcare organizations. Currently a researcher must manually extract each patient's information from the medical record and enter it into the model. In a future version, the data will flow automatically from the EMR into the program, allowing for widespread implementation, but that will require additional funding. Dr. Taksler says his program is meant to be a gateway to a better conversation between patients and providers. "Being able to show patients what will happen if they take recommended steps to improve their health will create a better dialogue in a doctor's office."

Recent Publications

Content and Outcomes of Social Work Consultation for Patients with Diabetes in Primary Care. Rabovsky AJ, Rothberg MB, Rose SL, Brateanu A, Kou L, Misra-Hebert AD

Prostate Cancer Screening Practices in a Large, Integrated Health System: 2007-2014. Misra-Hebert AD, Hu B, Klein EA, Stephenson A, Taksler GB, Kattan MW, Rothberg MB.

Factors Associated with Routine Recommendation of Mammography for Women Aged 40-49: Provider Characteristics and Screening Influences. Martinez KA, Deshpande A, Ruff AL, Bolen SD, Teng K, Rothberg MB.

Development of an Ambulatory Clinical Pharmacy Prioritization Prediction Model for Patients With Diabetes. Lam SW, Russo-Alvarez G, Cristiani C, Rothberg MB.