TV-115-082620-06

SYLLABUS AND COURSE GUIDE

Giving Shingles Immunization Your Best Shot: Implementing a Shingles Vaccination Protocol in Your Practice

A Free, 90-Minute Live and OnDemand Activity
Premiere Date: Wednesday, August 26, 2020
6:30 PM - 8:00 PM ET (live)
Credit Expiration Date: Thursday, August 26, 2021

https://www.cmeoutfitters.com/ShinglesVax

#ShinglesVax

LIVE FACULTY: Anthony Cunningham, MD, MBBS and Iris Gorfinkel, MD, CM
MODERATOR: William Schaffner, MD

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INFORMATION FOR PARTICIPANTS

Statement of Need

Shingles, or herpes zoster, is a common secondary infection for older patients. Almost all individuals over the age of 50 are latently infected with varicella zoster virus (VZV) and therefore are at risk of developing shingles with reactivation of latent VZV. Individuals who develop shingles often experience debilitating postherpetic neuralgia (PHN), secondary skin infections, eye problems, or neurologic conditions including an increased risk of stroke.

Despite the existence of vaccines, the number of people vaccinated for shingles remains low. In large part, this is due to the majority of individuals being unaware that a vaccine exists, as clinicians often fail to initiate discussion about it.

This CME Outfitters Live and OnDemand webcast will focus on the burden imposed by shingles, improving uptake of vaccination and series completion for shingles through patient education, and applying real-world strategies to implement shingles immunization protocols.

Learning Objectives

At the end of this CME/CE activity, participants should be able to:

- Identify the primary risk factors and clinical and quality of life (QoL) complications imposed by shingles.
- More frequently and effectively educate eligible patients about shingles vaccination to improve uptake of vaccination and series completion for shingles.
- Apply real-world strategies to implement shingles immunization that consider safety and efficacy of available therapies, storage and administration, and pharmacy-based vaccination.

The following learning objectives pertain only to those requesting CNE or CPE credit:

- Identify the primary risk factors and clinical and QoL complications imposed by shingles.
- Explain ways to educate eligible patients about shingles vaccination to improve uptake of vaccination and series completion for shingles.
- Summarize real-world strategies to implement shingles immunization that consider safety and efficacy of available therapies, storage and administration, and pharmacy-based vaccination.

Target Audience

Physicians, PAs, nurse practitioners, nurses, and pharmacists

Financial Support

This educational activity is supported by an educational grant from GlaxoSmithKline.

CREDIT INFORMATION

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CNE Credit (Nurses)

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Universal Activity Number: Live: 0376-0000-20-110-L01-P; Enduring: 0376-0000-20-110-H01-P
Type: knowledge-based

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Learning Formats: Live activity; Enduring material

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This activity counts towards MIPS Improvement Activity requirements under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Clinicians should submit their improvement activities by attestation via the CMS Quality Payment Program website.

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FACULTY BIOS & DISCLOSURES

William Schaffner, MD (Moderator)

Dr. William Schaffner is Professor of Preventive Medicine in the Department of Health Policy and Professor of Infectious Diseases at the Vanderbilt University School of Medicine, Nashville, Tennessee.

Dr. Schaffner's primary focus has been the prevention of infectious diseases. He is a strong proponent of collaboration between academic medical centers and public health institutions. He has worked extensively on the effective use of vaccines and has been a member of expert advisory committees that establish national vaccine policy.

Dr. Schaffner is committed to the communication of disease prevention with the general public and regards this as a teaching opportunity. He is often invited to comment on communicable disease issues on local and national media, translating research and public health events into language that the public can understand.

After graduating from Yale in 1957, Schaffner attended the University of Freiburg, Germany as a Fulbright Scholar. He graduated from Cornell University Medical College in 1962 and completed residency training and a Fellowship in Infectious Diseases at Vanderbilt. He was commissioned in the U.S. Public Health Service as an Epidemic Intelligence Service Officer with the Centers for Disease Control and Prevention (CDC) for two years. He returned to Vanderbilt after that tour of duty and established a long collaboration with the Tennessee Department of Health and the CDC.

Anthony Cunningham, MD, MBBS

Dr. Cunningham stepped down as Executive Director of The Westmead Institute for Medical Research after 23 years (1996-2019) and now continues as Director of the Institute's Centre for Virus Research and Professor, Faculty of Medicine and Health in the University of Sydney. He is also Director of the Australian Centre for HIV and Hepatitis Virology Research (ACH2), which is funded directly by the Australian Government, as well as the NSW/ACT State Branch Chair, The Australian Academy of Health and Medical Sciences.

He is a clinician scientist who trained in infectious diseases and virology research at the University of Melbourne and as a postdoctoral fellow in infectious diseases at Stanford University. His longstanding research is in herpesvirus and HIV immunology relevant to vaccine development, culminating in lead international roles in the pivotal trials of a vaccine candidate for herpes simplex and a highly efficacious vaccine for herpes zoster. He has published extensively in most aspects of immunization for herpes zoster and more broadly on immunization in general. He is currently investigating the mechanism of action of adjuvants to counteract declining immunity and vaccine efficacy in ageing populations.

Iris Gorfinkel, MD, CM

Dr. Gorfinkel is a family physician and Founder/Principal Investigator of PrimeHealth Clinical Research. She has participated in over 60 clinical trials and has a special interest in vaccination research. She helped co-author seminal papers on shingles vaccination and is on the advisory board for GlaxoSmithKline. Additionally, Dr. Gorfinkel is active in-patient advocacy and produces a regular medical radio column on CBC Radio One.

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Dr. Schaffner has no disclosures to report.

Dr. Cunningham reports he is on the advisory committee for GlaxoSmithKline.

Dr. Gorfinkel reports she receives research support from GlaxoSmithKline and Merck & Co., Inc. She is on the advisory committee and consultant for GlaxoSmithKline.

Kashemi D. Rorie, PhD (planning committee) has no disclosures to report.

Jeffrey Helfand, DO (peer reviewer) has no disclosures to report.

Mae Ochoa, RPh (peer reviewer) has no disclosures to report.

Evan Luberger (planning committee) has no disclosures to report.

Jan Perez (planning committee) has no disclosures to report.

Sharon Tordoff (planning committee) has no disclosures to report.

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Learning Objective 1

Identify the primary risk factors and clinical and quality of life (QoL) complications imposed by shingles.

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Learning Objective 2

More frequently and effectively educate eligible patients about shingles vaccination to improve uptake of vaccination and series completion for shingles.

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Learning Objective 3

Apply real-world strategies to implement shingles immunization that consider safety and efficacy of available therapies, storage and administration, and pharmacy-based vaccination.

Risk Factors for Herpes Zoster (HZ)

- Increasing Age
  - Less opportunity for boosting?
    - Less frequent exposure to varicella cases
    - Less frequent contact with multiple ill children
- Decline in cell-mediated immunity
  - Immunosenescence
  - Cell-mediated immunosuppressive disorders
  - Haematological malignancies
  - Immunosuppressive drugs
  - HIV: 12-17-fold increased risk
- Gender: Increased risk in females
- Race: Risk in African Americans less than half that of Whites
- Trauma or surgery in the affected dermatone
- Early varicella (in utero, infancy): Increased risk of pediatric zoster

Thomas SL, Hall AJ. *Lancet Infect Dis.* 2004;4(1):26-33.; Liesegang TJ. *Curr Opin Ophthalmol.* 2004;15:531-536.; Donahue JG, et al. *Arch Intern Med.* 1995;155(15):1605-1609.

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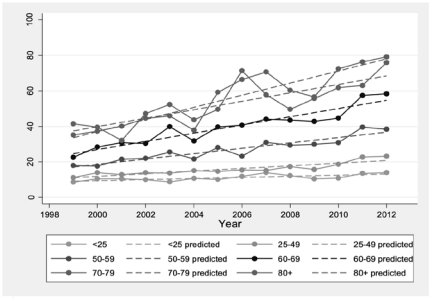
Complications of Herpes Zoster

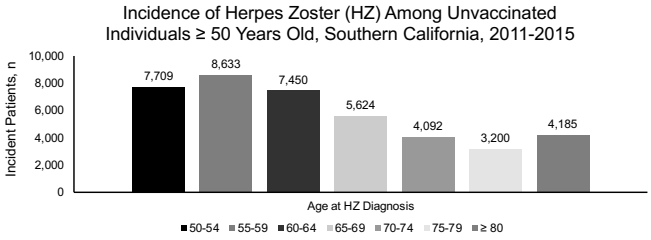
An Animated Tour

Incidence of Herpes Zoster is Increasing Globally: Trend in HZ ED Visits, New South Wales



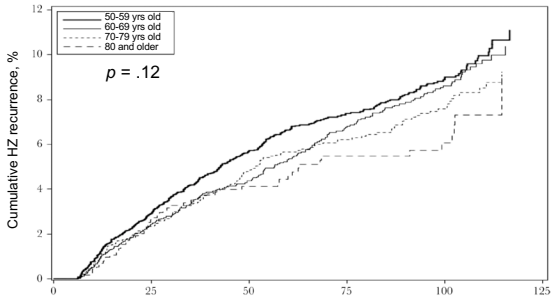
ED = Emergency department
MacIntyre R, et al. Plos One. 2015;10(6):e0129872.

Herpes Zoster: Incidence



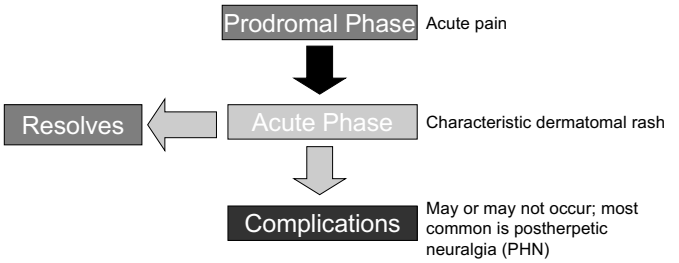
Tseng HF, et al. *J Infect Dis.* 2020;222(5):798-806.

Cumulative Incidence of HZ in an Immunocompetent, Unvaccinated Population ≥ 50 years, Southern California



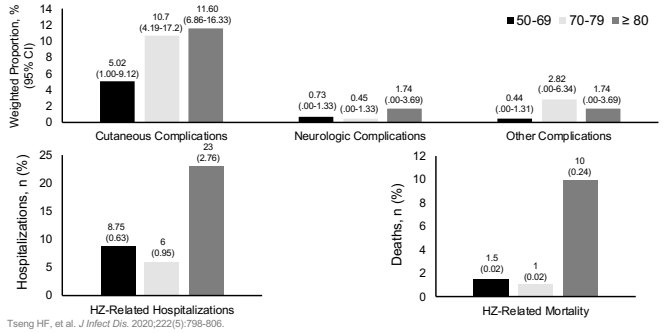
Tseng HF, et al. *J Infect Dis.* 2020;222(5):798-806.

Clinical Manifestations of Zoster



Oxman MN. *Varicella-Zoster Virus: Virology and Clinical Management.* 1st ed. 2000.
Kovac H, Lal H, Cunningham AL, et al. *Vaccine.* 2018;36(12):1537-1541.

Impact of HZ Among Unvaccinated Individuals ≥ 50 Years Old, Southern California, 2011-2015



Tseng HF, et al. *J Infect Dis.* 2020;222(5):798-806.

Herpes Zoster-Associated Pain

- May persist, appear, change character[1]
- Origin not only from ganglionitis, but also from skin necrosis[2]
- Persisting pain is from ganglionic damage and misinterpretation of normal skin sensations as being painful (allodynia)[3]
- Pain for > 90 days after rash onset is defined as PHN[1]

1. Cukic V. *Med Arch.* 2016;70(1):72-75.
2. Sewell GS, et al. *Am J Med.* 2000;108(6):520-521.;
3. Sampathkumar P, et al. *May Clin Proc.* 2009;84(3):274-280.

Risk Factors for

- Age, particularly increasing age
- Gender (women)
- Severe immunosuppressive conditions (e.g., leukemia, lymphoma)
- Autoimmune conditions (e.g., rheumatoid arthritis)
- Severe shingles
- Severe acute pain
- Asthma
- Diabetes
- Presence of a prodrome – symptoms preceding the rash by approximately 1-4 days

Forbers J, et al. *Neurology.* 2016;87(1):94–102.; Zagaria MAE. *US Pharm.* 2011;36(5):24-26.

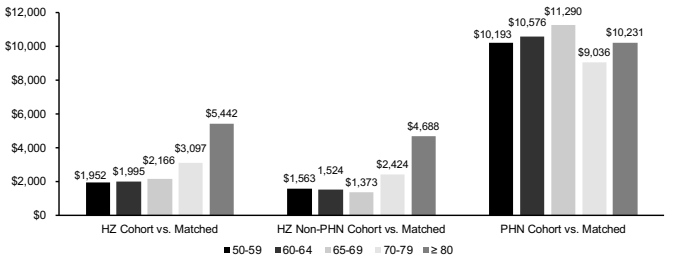
Impact of Postherpetic Neuralgia on Quality of Life in Older Adults

Physical	Psychological
• Chronic fatigue • Anorexia • Weight loss • Physical inactivity • Insomnia	• Depression • Difficulty concentrating • Potential caregiver burden
Social	**Functional**

• Decreased social gatherings
• Change in social role
	• Interfere with basic and instrumental activities of daily living
	  • Dressing, bathing, eating, mobility
	  • Traveling, cooking, housework, shopping

Schmader KE. *Clin Infect Dis.* 2001;32(10):1481-1486.

Economic Burden of HZ: Annual Incremental Health Care Costs by Age and Cohort

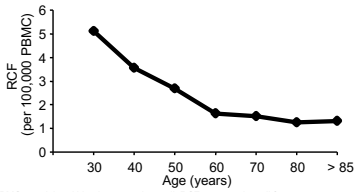


HZ Cohort n = 142,519; Matched Non-HZ Cohort n = 357,907; PHN Cohort n = 9,470; Matched Non-HZ Cohort n = 23,303

Meyers JL, et al. *Hum Vaccin Immunother.* 2017;13(8):1861-1872.

Rationale for an HZ Vaccine

- The frequency and severity of zoster increase with age
- T cell responses to varicella-zoster vaccine (VZV) decline with aging, while antibody does not



The basis for two hypotheses:

1. The fall in T cell responses to VZV with age to below a threshold permits clinical reactivation of latent VZV
2. Increasing the T cell responses to VZV in older people will prevent OR attenuate herpes zoster

PBMC = peripheral blood mononuclear cell; RCF = responder cell frequency
Weinberg A, et al *J Infect Dis.* 2010;201(7):1024-1030.

Advisory Committee on Immunization Practices (ACIP) Recommendation for HZ Vaccines

RZV is recommended for:

1. Prevention of HZ and related complications for immunocompetent adults aged 50 years and older
2. Prevention of HZ and related complications for immunocompetent adults who previously received zoster vaccine live

RZV is preferred over ZVL for the prevention of HZ and related complications

RZV = recombinant zoster vaccine; ZVL = live attenuated zoster vaccine
Dooling KL, et al. *MMWR.* 2018;67(3).

Efficacy Rates of ZVL and RZV in Preventing HZ and PHN

Preventive Efficacy (Age, y)	ZVL, %	RZV, %
Herpes zoster (50-59)	70	96.6
Herpes zoster (60-69)	64	97.4
Herpes zoster (> 70)	38	97.9
Postherpetic neuralgia (> 50)	65.7	91.2
Postherpetic neuralgia (> 70)	66.8	88.8

*ZVL is no longer be sold in the United States starting July 1, 2020. Some pharmacies and clinics may still have ZVL in stock. This vaccine is safe and may be used until the supply expires (before or by November 18, 2020).

Ilyas S, et al. *Open Forum Infectious Diseases.* 2020;7(7):ofaa274.

Efficacy of RZV: Age Groups ≥ 50 Years of Age

Pre-specified, pooled analyses from ZOE-50

Age (years)	RZV HZ cases (n)	Placebo HZ cases (n)	VE_{HZ} (95% CI)*
≥ 50[1]	6 (7,344)	210 (7,415)	**97.2%** (93.7, 99.0)
≥ 60[2]	3 (3,852)	123 (3,890)	**97.6%** (92.7, 99.6)
≥ 70[1]	1 (1,711)	48 (1,724)	**97.9%** (87.9, 100)

Included 7344 randomized subjects ≥ 50 years of age, who received a second dose of the vaccine and did not develop a confirmed case of HZ within 1 month after the second dose. n = number of subjects within each age group. Mean follow-up 3.8 years
*$p < .001$ for all comparisons. Two-sided exact p-value conditional to number of cases.

CI = confidence interval; VE = vaccine efficacy

1. Lal H, *et al. N Engl J Med* 2015;372:2087–2096; 2. McElhaney JE, et al. *Open Forum Infect Dis.* 2016;3(1):127.

Efficacy of RZV: Age Groups ≥ 70 Years of Age

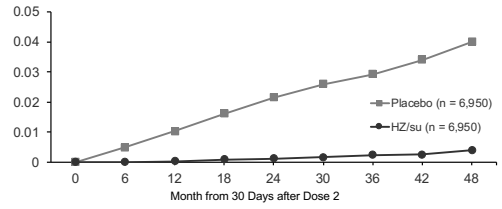
Age (years)	RZV HZ cases (n)	Placebo HZ cases (n)	VE (95% CI*)
			HZ
70–79	19 (6,468)	216 (6,554)	**91.3%** (86.0, 94.9)
≥ 80	6 (1,782)	68 (1,792)	**91.4%** (80.2, 97.0)
			PHN
≥ 70	4 (8,250)	36 (8,346)	**88.8%** (68.7, 97.1)
≥ 50	4 (13,881)	46 (14,035)	**91.2%** (75.9, 97.7)

Pooled data from ZOE-50 (subjects ≥ 50 years) of age and ZOE-70 (subjects ≥ 70 years of age). Included 16,596 randomized subjects ≥ 50 year of age, without immunocompromise, who received a second dose of the vaccine and did not develop a confirmed case of shingles within 1 month after the second dose. Mean follow-up 3.8 years
*$p < .0001$ for all comparisons; n = number of subjects within each age group.

Cunningham AL, et al. *N Engl J Med.* 2016;375:1019-1032.

RZV (ZOE-70): Risk of Development of HZ after Vaccination

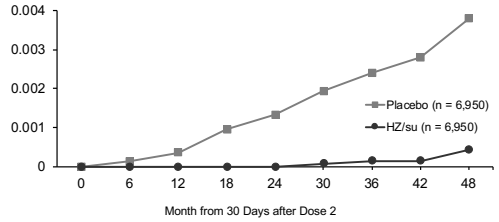
Modified Vaccinated Cohort in ZOE-50 and ZOE-70:
HZ Incidence in Participants ≥ 70 Years of Age



HZ/su = he
Cunningham AL, et al. *N Engl J Med.* 2016;375;1019-1032.

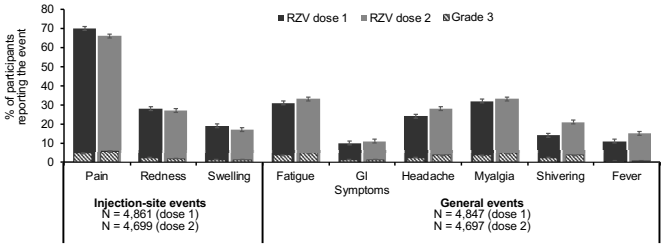
RZV (ZOE-70): Risk of Development of PHN after Vaccination

Modified Vaccinated Cohort in ZOE-50 and ZOE-70:
PHN Incidence in Participants ≥ 50 Years of Age (n = 13,900)



HZ/su = her,
Cunningham AL, et al. *N Engl J Med.* 2016;375;1019-1032.

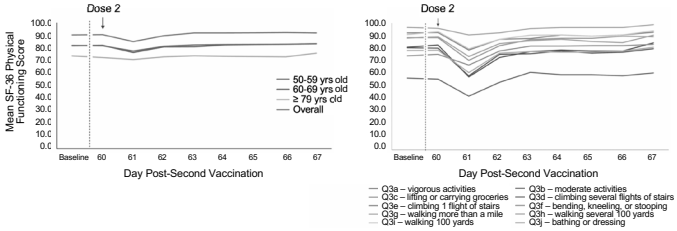
RZV: Local and General Reactogenicity



- Reactogenicity to RZV generally lasts only 2-3 days after immunization
- All general reactogenicity symptoms could be confused with early COVID-19 but cough does not occur

Colindres R, et al. *Human Vacc Immunother.* 2020 Apr 29. [Epub ahead of print].

RZV: Reactogenicity After Two Doses on Physical Functioning and Quality of Life



Schmader KE, et al. *J Gerontol A Biol Sci Med Sci*. 2020 Jun 12;glaa127. [Epub ahead of print].

RZV in Subjects with Multiple Morbidities

- Conditions with an increased risk of HZ
  - Systemic lupus erythematosus
  - Rheumatoid arthritis
  - Inflammatory bowel disease
  - Chronic obstructive pulmonary disease/asthma
  - Chronic kidney disease/renal failure
  - Hypertension, diabetes mellitus (type I)
  - Spinal disc herniation/osteoarthritis
- No difference in vaccine efficacy in any of these conditions and even in multiple conditions, up to 6 (~frailty)
- Efficacy and reactogenicity not affected by frailty

Oostvogels L, et al. *Hum Vacc Immunother.* 2019;15(12):2865-2872.; Curran D, et al, *J Am Geriatr Soc.* In Press.

Pharmacy-Based Vaccination for HZ

- 73% of community pharmacies now offer immunization services
  - All states allow pharmacists to administer flu vaccines
  - HZ vaccination certification varies by state
- Critical component to ease accessibility
- Primary care physician collaboration is important

Guo A, et al. *Vaccine*. 2019;37(37):5509-5512.; Ecarnot F, et al. *BMC Public Health*. 2019;19:1698.

3 Major Errors for Missing the Mark

- Missing the second injection
- Errors in preparation and reconstitution
- Inappropriate injection site
  - Both injections must be intramuscular

Tavares-Da-Silva F, et al. *Vaccine*. 2020;38(18):3489-3500.

Recommending Vaccine

- Make a firm, positive vaccine recommendation:
  - DO: "Our records don't show that you've received a shingles vaccine. We need to take care of that for you today while you are here."

  Vs.
  - DON'T: "Would you like to get your shingles vaccine while you are here?"

Working with Vaccine Hesitation

1. Do not dismiss them from your practice
- Set aside extra time to counsel vaccine-hesitant patients
- Be non-judgemental and non-confrontational
- Discuss the benefits and risks
- Validate patient concerns and correct misconceptions
- Promise that you're there to help if needed

2. Use presumptive language
3. Frame your language optimally
4. Be proactive in preventing the pain of vaccinations

Recalling Patients for Vaccines Dosed in a Series

- Give the patient an appointment card/tangible reminder with a specific date to return to clinic for 2nd dose before they leave the office/pharmacy
  - If the patient fails to make appointment, call the patient to rebook
- Set up automated reminders in electronic health records (EHR) for both patient and provider
- Use recall reminders (e.g., telephone, text, email) one or more days prior to the date to return

CDC. (IQIP) Immunization Quality Improvement for Providers. 2020. www.cdc.gov/vaccines/programs/afix/site-visit-answers.html.

Recalling Patients for Vaccines Dosed in a Series

- Assess dose completion of series-dosed vaccines at each patient encounter
- Offer vaccines in the late afternoon, evening, and on weekends
- Partner with other providers to complete series (e.g., family medicine office administers dose 1; pharmacist administers dose 2)
- Designate an immunization champion within your practice

CDC. (IQIP) Immunization Quality Improvement for Providers. 2020. www.cdc.gov/vaccines/programs/afix/site-visit-answers.html.

Takeaway Messages

- Ask about vaccine status
- Discuss hesitancy and refusal
- Implement reminders to ensure 2nd dose

Vaccination turns a common disease into a rare event

To Ask a Question

Please click on the *Ask Question* tab and type your question. Please include the faculty member's name if the question is specifically for them.

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AFTER THE SHOW

Questions & Answers

To Receive Credit

To receive CME/CE credit click on the *Request Credit* tab to complete the post-test and evaluation online.

Be sure to fill in your **ABIM ID number** and **DOB** (MM/DD) on the evaluation so we can submit your credit to ABIM.

Participants can print their certificate or statement of credit immediately.

CME for MIPS Improvement Activity

How to Claim this Activity as a CME for MIPS Improvement Activity

- Complete activity post-test and evaluation at the link provided
- Over the next 90 days, actively work to incorporate improvements in your clinical practice from this presentation
- Complete the follow-up survey from CME Outfitters in approximately 3 months

CME Outfitters will send you confirmation of your participation to submit to CMS attesting to your completion of a CME for MIPS Improvement Activity

CME for MIPS
IMPROVEMENT ACTIVITY

Additional Resources

Visit **www.cmeoutfitters.com** for clinical information and certified educational activities

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CME CAST
Implementing a Shingles Protocol in Primary Care Settings

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TV-115-082620-06

Attendance Form for Groups

Please complete and FAX to **614.929.3600**

Activity Title and Faculty:

Giving Shingles Immunization Your Best Shot: Implementing a Shingles Vaccination Protocol in Your Practice

with William Schaffner, MD (Moderator); Anthony Cunningham, MD, MBBS; Iris Gorfinkel, MD, CM

Site/Institution Name: ______________________________

Practice Setting: ❑ Office-Based ❑ Hospital ❑ Clinic ❑ Managed Care ❑ Small Group Practice (less than 5) ❑ Large Group Practice (more than 5) ❑ Other: ______________________________

Address: ______________________________

City: ______________________________ State: ________ ZIP: ______________

Site Coordinator: ______________________________ Phone: ______________________________

Fax: ______________________________ Email: ______________________________

Completion Date: ____________ We participated in: ______________________________

Attendee Name (please print)	Please Circle Discipline						
______________________	MD	DO	PA	NP	RN	Pharm	Other: ____________
______________________	MD	DO	PA	NP	RN	Pharm	Other: ____________
______________________	MD	DO	PA	NP	RN	Pharm	Other: ____________
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______________________	MD	DO	PA	NP	RN	Pharm	Other: ____________
______________________	MD	DO	PA	NP	RN	Pharm	Other: ____________

Please FAX completed form to 614.929.3600 and use additional sheets as necessary.
Questions? Call 877.CME.PROS. Thank you for participating in this continuing education activity!