A Review of the 2016-2017 Flu Season: Guidelines, Costs, and Barriers

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Abstract

In the United States (US), about 50,000 influenza-related deaths occur annually (Centers for Medicaid and Medicare Services [CMS], 2014). The most important preventive measure for the influenza virus is for people to obtain the influenza vaccine (Varsha et al., 2014; Uyeki, 2014). Of note, the vaccine is often underutilized; however, the influenza vaccine is recommended as an annual part of preventive care for people who are >6 months of age (United States Government of Health and Human Services, 2015; Centers for Diseases Control and Prevention [CDC], 2016; World Health Organization [WHO], 2016). The under-vaccination of patients with the influenza vaccine is a profound issue, especially in rural communities, which is

defined as locations populated by fewer than 50,000 people (United States Census Bureau [U.S. Census Bureau], 2015). In West Virginia, for example, a state where 38% of the population resides in rural areas, people who were insured by Medicare and whose insurance records did not manifest that they received the influenza vaccine, possessed a 170% increased risk of death during the influenza season in comparison to those who did receive the influenza vaccine (Schade & McCombs, 2000). This literature review discusses the increased need for influenza vaccination in rural communities; reviews the 2016-2017 influenza season's guidelines and costs; and in preparation for the 2017-2018 influenza season, the need to overcome barriers that are associated with influenza vaccination.

Keywords: Rural, Influenza, Flu, Flu Shot, Flushot, Influenza Vaccine, Guidelines, Costs

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The influenza vaccine, which is colloquially referred to as the "flu shot," is recommended as an annual part of preventive care for people who are ≥6 months of age (United States Government of Health and Human Services, 2015; Centers for Diseases Control and Prevention [CDC], 2016a; World Health Organization [WHO], 2016). The under-vaccination of patients with the influenza vaccine is a profound issue, especially in rural communities (United States Census Bureau [U.S. Census Bureau], 2015). Generally, rural communities may be defined as locations populated by fewer than 50,000 people. Of note, a limitation exists within most reviews of literature and national data about rural communities because data are limited about counties populated by less than or equal to 10,000 people (Bennett, 2013; U.S. Census Bureau, 2015). The Behavioral Risk Factor Surveillance System (BRFSS), a national entity that monitors

the receipt of the influenza vaccine, does not gather data from rural counties populated with ≤10,000 people (Bennett, 2013). Keeping in mind these limitations, during the 2009-2010 influenza season, Galarce, Minsky, and Viswanath (2011) found that influenza vaccination uptake occurred in only 47% of the population residing in rural areas. From October to December of the 2015-2016 influenza season, only 20% of the patients who visited a rural Federally Qualified Health Center in the southeastern part of the United States, as determined by the center's former Director of Quality Improvement, received the influenza vaccine (J. Brown, personal interview, February 12, 2016).

In the United States (US), about 50,000 influenza-related deaths occur annually (Centers for Medicaid and Medicare Services [CMS], 2014). In West Virginia, for example, a state where 38% of the population resides in rural areas, people who were insured by Medicare and whose insurance records did not manifest that they received the influenza vaccine, possessed a 170% increased risk of death during the influenza season in comparison to those who did receive the influenza vaccine (Schade & McCombs, 2000). In preparation for the next flu season, this literature review discusses issues that impact rural communities and the guidelines, costs, and barriers that are associated with influenza vaccinations during the 2016-2017 influenza season.

Guidelines

The director for the CDC makes the ultimate determination about the governing guidelines for preventive influenza practices in the United States (US). This decision is based on recommendations from WHO and the Advisory Committee on Immunization Practices (ACIP), an organization composed of both medical and public health personnel responsible for US immunization recommendations. The official CDC influenza guidelines are published annually at some point in August in the *MMWR Morbidity Mortality Weekly Report.* Per CDC guidelines,

healthcare providers should recommend annual influenza vaccines to anyone who does not possess a contraindication for vaccination and is greater than or equal to six months of age from October each year until the government issues a notification that the flu season is over (Grohskopf et al., 2015; United States Government of Health and Human Services, 2015). The following list consists of groups that are considered a priority for the receipt of the annual influenza vaccination: pregnant women—recognized by the WHO for being at risk for developing serious complications if they were to become infected with influenza virus — children six to fifty-nine months of age, people greater than 65 years of age, individuals with chronic medical conditions, healthcare workers, and/or people who provide care for those who belong to priority influenza vaccination groups. These conditions include the following: people with pulmonary conditions, people with either suppressed or compromised immune systems, children from 6 months to 18 years of age who possess an increased risk of developing Reyes syndrome post influenza infection due to current adherence to an aspirin regimen, individuals residing in group facilities, people with a body mass index greater than 40, Native Americans and those of Alaskan descent, and people suffering from metabolic, renal, hepatic, and/or neurologic dysfunction (CDC, 2016a; WHO, 2016).

The composition of the strains of influenza viruses included in the annual influenza vaccine changes annually (WHO, 2016). The WHO performs year-round surveillance of influenza activity and makes recommendation for the strains to be included in the annual vaccine. The WHO (2016) recommended that the following influenza virus strains be included in the 2016-2017 trivalent influenza vaccines: A/California/7/2009 (H1N1)pdm09-like virus, A/Hong Kong/4801/2014 (H3N2)-like virus, and B/Brisbane/60/2008-like virus. In addition to these strains, WHO recommended that quadrivalent vaccines also contain B/Phuket/3073/2013-like

virus. Country-specific entities—e.g. the CDC in the United States—make the final determination about the inclusion/exclusion of influenza strains in the annual influenza vaccines. The Federal Drug Administration Vaccine and Biological Products Advisory Committee, the organization that makes the final determination about the composition of the annual influenza vaccine in the US, endorsed the WHO's recommended influenza strains for the 2016-2017 influenza season on March 4, 2016, noting that the same strains will be used for both the Northern and Southern Hemisphere influenza vaccines (Federal Drug Administration [FDA], 2016). An additional noteworthy recommendation occurred on June 22, 2016: the ACIP recommended to the CDC that the live attenuated vaccines not be used during the 2016-2017 influenza season; however , as of when this article was submitted for publication, the CDC had yet to make a final determination (CDC, 2016c).

Contraindications for the influenza vaccine consist of having a severe reaction to the influenza vaccine in the past, a current state of moderate to severe illness, and/or a history of Guillain-Barre (Grohskopf et al., 2015; ACIP, 2016). Allergies to eggs and/or latex are not contraindications for the receipt of the influenza vaccine; however, additional care needs to be made to discern which vaccine is best for this patient population. Also, specific guidelines govern the immunization of children, between the ages of six months and eight years of age, with the influenza vaccine. The ACIP is responsible for immunization recommendations in the US. As this article is a reflection of the 2016-2017 influenza season, minutes from the ACIP meeting on February 2016 refer to the 2015-2016 list of FDA approved influenza vaccines; therefore, vaccination recommendations in this article only pertain to those vaccines, which are presented in Table 1 using the table as published by Grohskopf et al. (2015) and ACIP (2016).

Table 1

Influenza vaccines – US, 2015 -2016 influenza season

Trade Name	Manufacturer	Presentation	Mercury µg/0.5 mL from thimerosal	Ovalbumin µg/0.5 mL	Age indications	Latex	Route
Inactivated influenza vaccine, quadrivalent (IIV4), standard dose. *Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
Fluarix Quadrivalent	GlaxoSmithKline	0.5 mL single-dose prefilled	—	≤0.05	≥3 yrs	No	IM†
FluLaval Quadrivalent	ID Biomedical Corp. of Quebec (distributed by GlaxoSmithKline)	5.0 mL multi-dose vial	<25	≤0.3	≥3 yrs	No	IM†
Fluzone Quadrivalent	Sanofi Pasteur	0.25 mL single-dose prefilled	—	§	6 through 35 mos	No	IM†
		0.5 mL single-dose	—	§	≥36 mos	No	IM†
		0.5 mL single-dose vial	—	§	≥36 mos	No	IM†
		5.0 mL multi-dose vial	25	§	≥6 mos	No	IM†
Fluzone Intradermal Quadrivalent	Sanofi Pasteur	0.1 mL single-dose prefilled microinjection system	—	§	18 through 64 yrs	No	ID**
Inactivated influenza vaccine, trivalent (IIV3), standard dose. *Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							

Trade Name	Manufacturer	Presentation	Mercury µg/0.5 mL from thimerosal	Ovalbumin µg/0.5 mL	Age indications	Latex	Route
Afluria	bioCSL	0.5 mL single-dose prefilled	—	<1	≥9 yrs††	No	IM†
		5.0 mL multi-dose vial	24.5	<1	≥9 yrs†† via needle;18 through 64 yrs via jet injector	No	IM†
Fluvirin	Novartis Vaccines and Diagnostics	0.5 mL single-dose prefilled syringe	≤1	≤1	≥4 yrs	Yes§§	IM†
		5.0 mL multi-dose vial	25	≤1	≥4 yrs	No	IM†
Fluzone	Sanofi Pasteur	5.0 mL multi-dose vial	25	§	≥6 mos	No	IM†
Inactivated influenza vaccine, cell-culture-based (ccIIV3), standard dose. *Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
Flucelvax	Novartis Vaccines and Diagnostics	0.5 mL single-dose prefilled syringe	—	¶¶	≥18 yrs	Yes§§	IM†
Inactivated influenza vaccine, trivalent (IIV3), high dose. *Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
Fluzone High-Dose***	Sanofi Pasteur	0.5 mL single-dose prefilled syringe	—	§	≥65 yrs	No	IM†

Trade Name	Manufacturer	Presentation	Mercury µg/0.5 mL from thimerosal	Ovalbumin µg/0.5 mL	Age indications	Latex	Route
Recombinant influenza vaccine, trivalent (RIV3), standard dose. *Contraindications*: Severe allergic reaction to any vaccine component. Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine.*							
Flublok	Protein Sciences	0.5 mL single-dose vial	—	0	≥18 yrs	No	IM†
Live attenuated influenza vaccine, quadrivalent (LAIV4)**** *Contraindications*: Severe allergic reaction to any vaccine component, including egg protein, or after previous dose of any influenza vaccine. Concomitant use of aspirin or aspirin-containing medications in children and adolescents. In addition, ACIP recommends LAIV4 not be used for pregnant women, immunosuppressed persons, persons with egg allergy, and children aged 2 through 4 years who have asthma or who have had a wheezing episode noted in the medical record within the past 12 months, or for whom parents report that a health care provider stated that they had wheezing or asthma within the last 12 months. LAIV4 should not be administered to persons who have taken influenza antiviral medications within the previous 48 hours. Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV4, or should avoid contact with such persons for 7 days after receipt. Precautions*: Moderate to severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine; asthma in persons aged 5 years and older; medical conditions which might predispose to higher risk for complications attributable to influenza.*							
FluMist Quadrivalent†††	MedImmune	0.2 mL single-dose prefilled intranasal sprayer	—	<0.24 (per 0.2 mL)	2 through 49 yrs	No	IN

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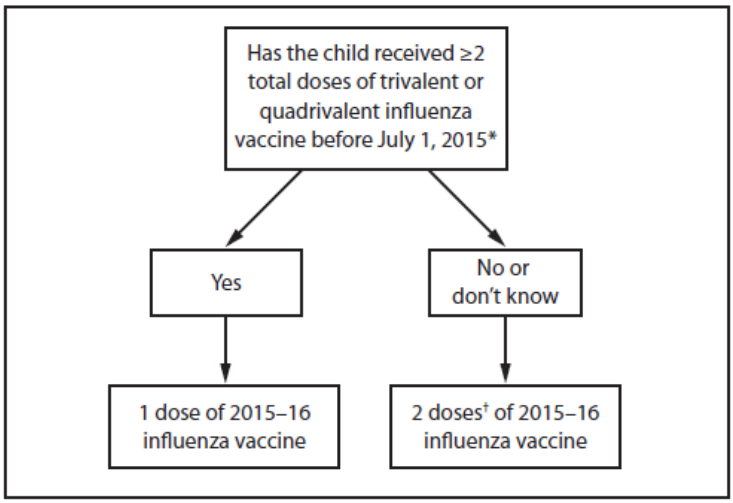
Table 1 Abbreviations: ACIP = Advisory Committee on Immunization Practices; ID = intradermal; IM = intramuscular; IN = intranasal.
* Immunization providers should check Food and Drug Administration-approved prescribing information for 2015–16 influenza vaccines for the most complete and updated information, including (but not limited to) indications, contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm.
† For adults and older children, the recommended site for intramuscular influenza vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh. Specific guidance regarding site and needle length for intramuscular administration may be found in the ACIP General Recommendations on Immunization, available at www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm.
§ Available upon request from Sanofi Pasteur (1–800–822–2463 or MIS.Emails@sanofipasteur.com).
¶ Quadrivalent inactivated influenza vaccine, intradermal: a 0.1-mL dose contains 9 µg of each vaccine antigen (36 µg total).
** The preferred injection site is over the deltoid muscle. Fluzone Intradermal Quadrivalent is administered using the delivery system included with the vaccine.
†† Age indication per package insert is ≥5 years; however, ACIP recommends Afluria not be used in children aged 6 months through 8 years because of increased risk of febrile reactions noted in this age group with bioCSL's 2010 Southern Hemisphere IIV3. If no other age-appropriate, licensed inactivated seasonal influenza vaccine is available for a child aged 5 through 8 years who has a medical condition that increases the child's risk for influenza complications, Afluria can be used; however, providers should discuss with the parents or caregivers the benefits and risks of influenza vaccination with Afluria before administering this vaccine. Afluria may be used in persons aged ≥9 years.
§§ Syringe tip cap may contain natural rubber latex.
¶¶ Information not included in package insert. Estimated to contain <50 femtograms (5x10-8 µg) of total egg protein (of which ovalbumin is a fraction) per 0.5 mL dose of Flucelvax.
*** Trivalent inactivated influenza vaccine, high-dose: a 0.5-mL dose contains 60 µg of each vaccine antigen (180 µg total)
****On June 22, 2016, the ACIP recommended to the CDC that the LAIV vaccine not be used during the 2016-2017 influenza season. During the time that this article was composed, the CDC had yet to make a determination (2016c).
††† FluMist is shipped refrigerated and stored in the refrigerator at 35°F–46°F (2°C–8°C) after arrival in the vaccination clinic. The dose is 0.2 mL divided equally betweeneach nostril. Health care providers should consult the medical record, when available, to identify children aged 2 through 4 years with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 2 through 4 years should be asked: "In the past 12 months, has a health care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing
episode noted in the medical record within the past 12 months should not receive FluMist.**** On June 22, 2016, the ACIP recommended to the CDC that the FluMist vaccine not be used during the 2016-2017 influenza season. The CDC has yet to make a final determination (CDC, 2016).

During the 2016-2017 influenza season, in the population who possessed an allergy to eggs, the severity of the allergy served as the determining factor for which influenza vaccine was used (ACIP, 2016). A mild egg allergy was defined as the development of uticaria post-ingestion/exposure to eggs. The occurrence of any other symptoms—e.g. urticaria and nausea/vomiting, angioedema, anaphylaxis, etc.—when exposed to eggs, was defined as a severe allergy. Based on this stratification, the following guidelines were implemented by the ACIP (2016) as a determinant about which vaccine should be used for people with egg allergies during the 2016-2017 influenza season. In individuals who possessed a mild egg allergy, providers could use any age and health appropriate influenza vaccine. People who possessed a severe egg allergy could use any age and health appropriate influenza vaccine; however, in this population, any vaccine other than the recombinant influenza vaccine was required to be administered in a medical facility staffed by a physician who specialized in the management of serious allergic reactions (ACIP, 2016). Additionally, everyone, regardless of allergy to eggs, was required to undergo observation for fifteen minutes after receiving the influenza vaccine. Per the implementation of these changes by the ACIP (2016), the algorithm that was used for the selection of an influenza vaccine during the 2015-2016 influenza season was no longer applicable during the 2016-2017 influenza season.

Specific guidelines, which are presented in Figure 1 using the same table from Grohskopf et al., (2015), governed influenza vaccine administration to children from six months of age to eight years of age who historically was never inoculated with the influenza vaccine. During the 2015-2016 season, among children who were six months through eight years of age, no preference existed for the use of either the trivalent or quadrivalent vaccine. If children were obtaining the vaccine for the first time, they received two doses, separated by approximately four

weeks (Grohskopf et al., 2015). The quantity of doses administered to children less than or equal to 8 years varies each year based on the strain(s) of the influenza virus that the vaccine protects against. Based on the ACIP's (2016) recommendations, the guidelines from the 2015-2016 influenza season roughly remained the same for the 2016-17 season. Children who received two doses of the influenza vaccine during the same influenza season prior to the most recent influenza season were only to receive one dose of the influenza vaccine during the subsequent season. In reference to the duration of immunity after vaccination, the quantity of antibodies in the body declines within six months after vaccination. In reference to the geriatric population, antibodies to the influenza vaccination decline at a more rapid rate than other age groups (Grohskopf et al., 2015). Sanofi developed the quadrivalent influenza vaccine to combat this decline. Additionally, the vaccine was deemed safe for use in pediatric populations greater than six months of age (Sanofi Pasteur, 2016).



* The two doses need not have been received during the same season or consecutive seasons.
† Doses should be administered ≥4 weeks apart.

FIGURE 1. Fused with implied permission—e.g. materials that are used from public domains are reproducible with reference to the source(s) of origin. Influenza vaccine dosing algorithm for children aged 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2015–16 influenza season from *MMWR Morbidity Mortality Weekly Report*, *64*(30), p.821

Cost

Table 2

Vaccines, Ages Appropriateness, and Cost.—Based on charts used by the CDC (2016b)

Vaccine	Brandname/ Tradename	Cost ($)/ Package of 10 Doses *Values were rounded to the closest number*	Manufacturer
Influenza (Age 6 months and older)	Fluzone® Quadrivalent	16.62	Sanofi Pasteur
Influenza (Age 6-35 months)	Fluzone® Quadrivalent Pediatric dose No Preservative	23.17	Sanofi Pasteur
Influenza (Age 36 months and older)	Fluzone® Quadrivalent No-Preservative	18.23 (average)* *Cost is based on how the vaccine is packaged.	Sanofi Pasteur
Influenza (Age 36 months and older)	Fluarix® Quadrivalent Preservative Free	16.82	GlaxoSmithKline
Influenza (Age 36 months and older)	FluLaval Quadrivalent	15.77	GlaxoSmithKline
Influenza (Age 4 years and older)	Fluvirin®	14.41	Novartis
Influenza Live, Intranasal (Age 2-49 years) ****On June 22, 2016, the ACIP recommended to the CDC that this vaccine not be used during the 2016-2017 influenza season. The CDC has yet to make a final determination (CDC, 2016c).	FluMist® Quadrivalent No Preservative	23.70	MedImmune
Influenza (Age 9 years and older)	Afluria® No Preservative	15.67	bioCSL
Influenza (Age 9 years and older)	Afluria®	14.41	bioCSL
Influenza (Age 18 years and older)	Flublok® No Preservative	35.75	Protein Sciences

Information presented in table with implied permission—e.g. materials that are used from public domains are reproducible with reference to the source(s) of origin. Centers for Disease Control and Prevention on July 5, 2016 (2016b)

Table 2, reflects influenza vaccination prices for providers as reported by manufacturers to the CDC (2016b). The prices were valid until February of 2017.

Costs for influenza vaccines at Publix®, as presented in Table 3, were applicable to locations that served dually as a grocery store and pharmacy. Such establishments are only located in the southeastern region of the United States—e.g. Alabama, Florida, Georgia, North Carolina, South Carolina, and Tennessee (Publix®, 2016). The descriptions used are based on the descriptions that are used by Publix® on their website. These descriptions do not contain manufacturer information.

Table 3

Costs for Influenza Vaccines at Publix ®

Influenza Vaccine	**Description of the Influenza Vaccine**	**Approved Population**	**Cost ($)**
Trivalent	Trivalent vaccines protect against two influenza A viruses and one influenza B virus	Recommended for everyone 6 months of age and older	30
Flucelvax (preservative-free & egg free)	A standard-dose trivalent shot containing virus grown in cell culture instead of eggs	Recommended for ages 18 years of age and older	38
Quadrivalent	Quadrivalent vaccines protect against two influenza A viruses and two influenza B viruses	Yearly vaccine for everyone 6 months of age and older	40
High Dose	Trivalent vaccine with a higher dose of antigen	ACIP recommended option for people 65 years of age and older	60

(CDC, 2015; Publix, 2016)

Walgreens, Walmart, and CVS offered three different types of influenza vaccines. The costs associated with those vaccines are presented in Table 4.

Table 4

Costs for Influenza Vaccines at Walmart®, CVS®, and Walgreens®

Influenza Vaccine	Description of the Influenza Vaccine	Approved Population	Walmart® Cost($)	CVS® Cost ($)	Walgreens® Cost ($)
Influenza	Seasonal	Recommended for everyone 2 years of age and older	25	31.99	31.99 * Price in Delaware: 35.99 (seasonal and preservative free)
Fluzone-High Dose	Trivalent vaccine with a higher dose of antigen	ACIP recommended option for people 65 years of age and older	48	54.99	59.99 * Price in Delaware: 63.99
Fluarix	Quadrivalent vaccines protect against two influenza A viruses and two influenza B viruses. Preservative free.	Yearly vaccine for everyone 3 years of age and older	24	36.99	39.99

(CVS, 2015;Walgreens, 2016;Walmart Pharmacist, conversation, June 28, 2016)

Barriers

The most important preventive measure for the influenza virus is for people to obtain the influenza vaccine (Verger et al., 2015; Uyeki, 2014); however, the vaccine is often underutilized. The following are potential barriers to obtaining the influenza vaccine: a) cost; b) providers fail to recommend the vaccine to patients; c) patients' perceived lack of access to vaccine; d) fear of injections; e) beliefs that influenza is not a serious illness, f) lack of time to obtain the vaccine due to other obligations; g) lack of transportation to sites where vaccines are administered; and h) concerns about the safety and efficacy of the vaccine (Beel, Rench, Montesinos, & Healy, 2014; Mayet, Al-Shaikh, Al-Mandeel, Alsaleh, & Hamad, 2017; Yuen & Tarrant, 2014). In preparation for the next flu season, healthcare providers need to work diligently to remove

barriers to the influenza vaccine by implementing evidence-based practices. For example, the provision of opportunities to obtain the influenza vaccine and vaccination education at medical visits results in the removal of several barriers (Stinchfield, 2008; Verger et al., 2015; Grohskopf et al., 2015; Chinnis, 2017).

Healthcare providers need to recognize that rural populations encounter numerous health disparities. Providers are members of a diverse interprofessional team; it is imperative that team members work with rural populations to ensure that they receive the best preventive care possible during the next influenza season. Healthcare providers are charged with the task to ensure that a flame is forever lit, sparking fervor to administer as many influenza vaccines as possible. With a rejuvenated spirit, healthcare providers need to recommit themselves to increasing influenza vaccine uptake during the 2017-2018 influenza season. This task begins now!

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