

PHARMACISTS AS ADVOCATES FOR THE ANNUAL INFLUENZA VACCINE

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This activity is supported by an educational grant from Sanofi Pasteur U.S.

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Educational Objectives

At the completion of this activity, the participant will be able to:

- Apply current recommendations from the Advisory Committee on Immunization Practices (2016-2017) regarding influenza vaccinations for various patient populations
- Differentiate between the various types of influenza vaccinations on the market
- Explore the role of the pharmacist in administering influenza vaccines and in increasing awareness regarding the importance of obtaining yearly influenza vaccine

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Understanding Immunizations

- Vaccines are among the most cost-effective clinical preventive services
- Childhood immunization programs provide a very high return on investment. For example, for each birth cohort, society:
 - Saves 33,000 lives
 - Prevents 14 million cases of disease
 - Reduces direct health care costs by \$9.9 billion
 - Saves \$33.4 billion in indirect costs

U.S. Department of Health and Human Services, <http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases>. Accessed March 5, 2017.

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Approximately 42,000 adults and 300 children in the United States die each year from vaccine-preventable diseases!*

*This includes influenza, but does not include deaths due to 2009 H1N1

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What is this?



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Influenza

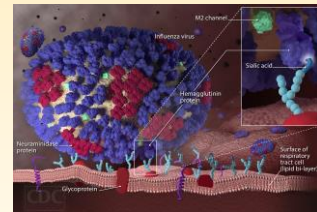
- A contagious respiratory illness
- Possible symptoms
 - Fever, cough, sore throat, muscle or body aches, fatigue
- Complications
 - Pneumonia, exacerbation of pulmonary and cardiac conditions

CDC. <https://www.cdc.gov/flu/about/diseases/complications.htm>. Accessed March 5, 2017.

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Influenza Virus



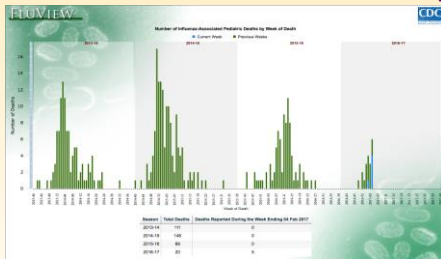
**A/California/7/2009(H1N1)
Type/Ori/Strain/Year/Virus Subtype**

Printed with permission from CDC. <https://www.cdc.gov/flu/images.htm>. Accessed March 5, 2017. CDC. <https://www.cdc.gov/flu/about/flu-virus-types.htm>. Accessed March 5, 2017.

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Influenza Associated Pediatric Mortality



Printed with permission from CDC. <http://gis.cdc.gov/GRASP/FluView/PedFLUDeath.html>. Accessed March 5, 2017.

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What's New With Influenza?

**Influenza-Like Illness (ILI) Activity Level Indicator Determined by Data Reported to ILINet
2016-17 Influenza Season Week 5 ending Feb 04, 2017**



Printed with permission from CDC. <https://www.cdc.gov/flu/weekly/>. Accessed March 5, 2017.

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Healthy People 2020 Objectives

| Category | 2020 Goal (%) |
|---|---------------|
| Increase the percentage of children aged 6 months through 17 years who are vaccinated annually against seasonal influenza | 70 |
| Increase the percentage of adults aged 18 and older who are vaccinated annually against seasonal influenza | 70 |
| Increase the percentage of health care personnel who are vaccinated annually against seasonal influenza | 90 |

U.S. Department of Health and Human Services. <http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives>. Accessed March 5, 2017.

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2015 Influenza Vaccination Rates Over the Past 12 months

- Children 6 months to 17 years: 49.6%
- Adults 18 to 49 years: 31.7%
- Adults 50 to 64 years: 48.1%
- Adults 65 years and over: 69.1%

CDC. <https://www.cdc.gov/vhcf/flustats/flu.htm>. Accessed March 5, 2017.

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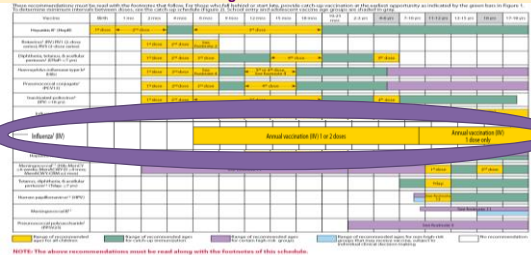
Immunization Schedule: Children and Adolescents Aged 18 Years and Younger

Recommended Immunization Schedule for Children and Adolescents Aged 18 Years and Younger – United States 2017



Printed with permission from CDC. <https://www.cdc.gov/vaccines/schedules/hcp/18-adolescent.html>. Accessed March 5, 2017.

Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger – United States 2017



Printed with permission from CDC. <https://www.cdc.gov/vaccines/schedules/hcp/18-adolescent.html>. Accessed March 5, 2017.

Vaccines that Might be Indicated for Children and Adolescents Aged 18 Years or Younger Based on Medical Infections

| DISEASE | VACCINE | Progression | When vaccination is indicated | When vaccination is not indicated | When vaccination is not indicated | When vaccination is not indicated | When vaccination is not indicated | When vaccination is not indicated | When vaccination is not indicated |
|-------------------------------------|-------------------------------------|-------------|-------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| Chlamydia | Chlamydia | | | | | | | | |
| Gonorrhea | Gonorrhea | | | | | | | | |
| Human immunodeficiency virus (HIV) | HIV | | | | | | | | |
| Herpes simplex virus type 1 (HSV-1) | Herpes simplex virus type 1 (HSV-1) | | | | | | | | |
| Herpes simplex virus type 2 (HSV-2) | Herpes simplex virus type 2 (HSV-2) | | | | | | | | |
| Human papillomavirus (HPV) | Human papillomavirus (HPV) | | | | | | | | |
| Measles | Measles | | | | | | | | |
| Mumps | Mumps | | | | | | | | |
| Poliovirus | Poliovirus | | | | | | | | |
| Scarlet fever | Scarlet fever | | | | | | | | |
| Strep throat | Strep throat | | | | | | | | |
| Tuberculosis | Tuberculosis | | | | | | | | |
| Whooping cough | Whooping cough | | | | | | | | |
| Yersinia enterocolitica | Yersinia enterocolitica | | | | | | | | |

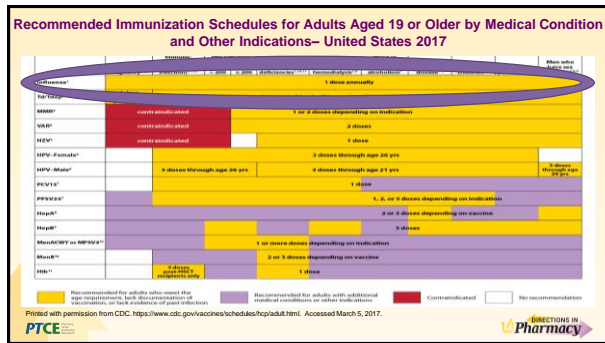
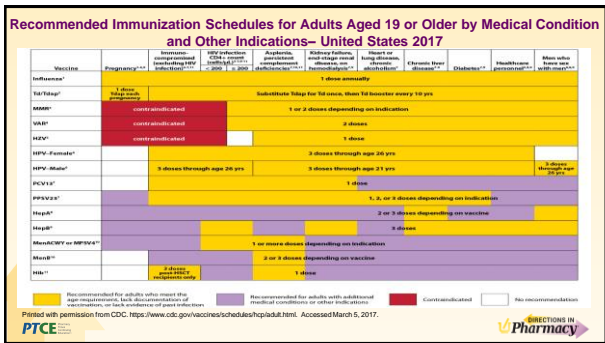
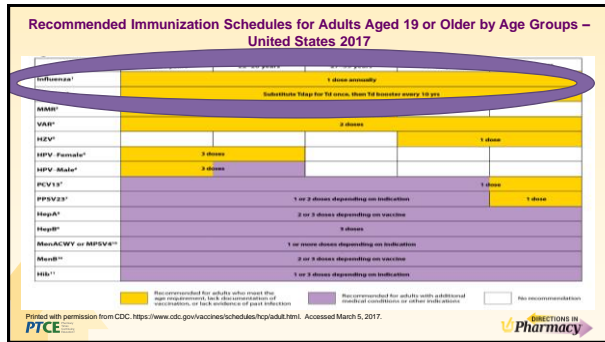
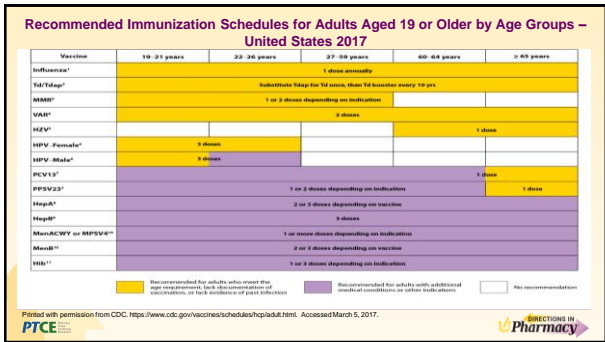
Printed with permission from CDC. <https://www.cdc.gov/vaccines/schedules/hcp/18-adolescent.html>. Accessed March 5, 2017.

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Printed with permission from CDC. <https://www.cdc.gov/vaccines/schedules/hcp/18-adolescent.html>. Accessed March 5, 2017.

Immunization Schedule: Adults 19 Years or Older



Footnotes. Recommended immunization schedule – United States, 2017

- Influenza vaccination**
 - All persons aged 6 months or older who do not have a contraindication should receive annual influenza vaccination with an age-appropriate formulation of inactivated influenza vaccine (IV) or recombinant influenza vaccine (RIV).
 - In addition to standard-dose IV, available options for adults in certain age groups include high-dose or adjuvanted IV for adults aged 65 years or older, and RIV for adults aged 18 through 64 years, and RIV for adults aged 18 years or older.
 - Recent live attenuated influenza vaccine (LAIV) should not be used during the 2016–2017 influenza season. A list of currently available influenza vaccines is available at www.cdc.gov/flu/professionals/vaccine/.
- Herpes zoster vaccination**
 - Adults aged 50 years or older should receive 2 doses of recombinant zoster vaccine (RZV) separated by at least 2 months.
 - Adults aged 60 years or older who have not received RZV should receive 2 doses of RZV separated by at least 2 months.
- Human papillomavirus vaccination**
 - Human papillomavirus (HPV) vaccination is recommended for all persons aged 11–12 years.
 - Persons aged 13–26 years who have not received HPV vaccination should receive HPV vaccination.
 - Persons aged 27–45 years who have not received HPV vaccination should receive HPV vaccination.
- Measles, mumps, and rubella vaccination**
 - Adults who have not received measles and rubella vaccine should receive 2 doses of measles, mumps, and rubella vaccine (MMR2) separated by at least 4 weeks.
 - Adults who have not received rubella vaccine should receive 1 dose of rubella vaccine.

Printed with permission from CDC. <https://www.cdc.gov/vaccines/schedules/hq/adult.html>. Accessed March 5, 2017.

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Printed with permission from CDC. <https://www.cdc.gov/vaccines/schedules/hq/adult.html>. Accessed March 5, 2017.

Influenza Recommendations

- Routine annual influenza vaccination is recommended for all persons aged ≥ 6 months who do not have contraindications

CDC: <https://www.cdc.gov/mmwr/volumes/65/nr0505a1.htm>. Accessed March 5, 2017.

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Types of Vaccines and Routes of Administration 2016-2017

- Inactivated influenza vaccine (IIV)
 - Egg-based and cell culture-based quadrivalent inactivated influenza vaccines (IIV4)
 - Egg-based quadrivalent inactivated influenza vaccine (IIV4)
 - Available in intramuscular (IIV3 or IIV 4), intradermal (IIV4), or high dose (IIV3)
 - Adjuvanted trivalent inactivated influenza vaccine (aIIV)
 - For people who are 18 through 64 years old, a jet injector can be used for delivery of one particular flu vaccine
- Live-attenuated influenza vaccine (LAIV4)
 - Available in intranasal
- Recombinant hemagglutinin influenza vaccine (RIV3)
 - Available as intramuscular

CDC: <https://www.cdc.gov/flu/protect/vaccine/vaccines.htm>. Accessed March 5, 2017

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Influenza Vaccines 2016-2017

| Trade Name | Vaccine Type | Age Indication |
|----------------------------|--------------|---------------------------------|
| Afluria | IIV3, IIV4 | ≥ 9 years, ≥ 18 years |
| Fluarix | IIV4 | ≥ 3 years |
| Flucevax | ccIIV4 | ≥ 4 years |
| FluLaval | IIV4 | ≥ 6 months |
| Fluvirin | IIV3 | ≥ 4 years |
| Fluzone 0.25 prefilled | IIV4 | 6-35 months |
| Fluzone 0.5 prefilled | IIV4 | ≥ 36 months |
| Fluzone 0.5 mL single dose | IIV4 | ≥ 36 months |
| Fluzone 5.0 mL multidose | IIV4 | ≥ 6 months |
| Fluzone intradermal | IIV4 | 18-64 years |
| Fluzone high dose | IIV3 | ≥ 65 years |
| Fluad | aIIV3 | ≥ 65 years |
| FluBlok | RIV3 | ≥ 18 years |
| FluMist | LAIV4 | 2-49 years |

aIIV3 = adjuvanted inactivated influenza vaccine, CC=cell culture based, IIV3 = inactivated influenza vaccine, trivalent; IIV4 = inactivated influenza vaccine, quadrivalent; RIV = recombinant influenza vaccine; LAV = live-attenuated influenza vaccine.
CDC: <https://www.cdc.gov/flu/protect/vaccine/vaccines.htm>. Accessed March 5, 2017.

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2016-2017 Strain

- A/California/7/2009 (H1N1) pdm09-like virus,
- A/Hong Kong/4801/2014 (H3N2)-like virus
- B/Brisbane/60/2008-like virus (B/Victoria lineage)
- Four component vaccines include B/Phuket/3073/2013-like virus (B/Yamagata lineage)

CDC: <https://www.cdc.gov/flu/about/season/flu-season-2016-2017.htm>. Accessed March 5, 2017.

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Intramuscular Dosing Recommendations

- 6 months up to and including 8 years of age
 - 2 doses if never been previously immunized with seasonal influenza vaccine (spaced 4 weeks apart minimum interval)
 - 1 dose only if previously immunized with seasonal influenza vaccine
- 9 years of age and older
 - 1 dose
- Dosing
 - 6 months to 35 months (0.25 mL)
 - ≥ 36 months (0.5 mL)



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Intradermal Quadrivalent Influenza Vaccine

- Novel microinjection system works by depositing vaccine antigen into dermal layer of skin
- IIV4
- Administered as a single 0.1 mL injection by the intradermal route
- Indicated for adults 18 through 64 years of age

Fluzone Intradermal Quadrivalent vaccine [Prescribing Information]. Swifthead, PA: Sanofi Pasteur Inc.; 2016.

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IIV High-Dose

- Contains 4 times the amount of influenza virus antigen compared to other inactivated influenza vaccines
- Indicated for patients age ≥ 65 years
- No preference expressed by ACIP for any IIV for use in persons aged ≥ 65 years

Fluzone Intradermal Quadrivalent vaccine [Prescribing Information]. Swifwater, PA: Sanofi Pasteur Inc.; 2016.; DiazGrandados CA, et al. *N Engl J Med*. 2014;371(7):635-45.

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Vaccine Compared With IIV in Elderly Adults

- 31,989 participants ≥ 65 years of age
- Trial spanned over 2 influenza seasons
 - 2011-2012 and 2012-2013
- Participants randomized 1:1 to receive 1 dose of IIV high-dose vaccine or IIV vaccine and followed for illness until the end of each season
- Primary objective
 - To compare the clinical efficacy of IIV high-dose vaccine to that of IIV vaccine in adults ≥ 65 years of age

Robertson, C. Efficacy of Fluzone High-Dose vaccine (letter). Sanofi Pasteur.; DiazGrandados CA, et al. *N Engl J Med*. 2014;371(7):635-45.

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High-dose Vaccine Compared With Standard Dose IIV in Elderly Adults

- Relative efficacy of IIV high-dose vaccine compared with IIV 2 years combined
 - Relative vaccine efficacy; efficacy of IIV high-dose vaccine compared with IIV 24.2%
 - 95% confidence interval was 9.7 to 36.5
 - Pre-specified lower limit required by FDA to demonstrate superior clinical benefit $> 9.1\%$

Fluzone High-Dose vaccine [Prescribing Information]. Swifwater, PA: Sanofi Pasteur Inc.; 2016.; DiazGrandados CA, et al. *N Engl J Med*. 2014;371(7):635-45.

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Medicare Data from 2012 to 2013

- Retrospective cohort study of U.S. Medicare beneficiaries
- Received high-dose or standard-dose inactivated influenza vaccines
- August 2012 and January 2013
- More than 929,000 recipients of high-dose vaccine and 1.6 million recipients of standard-dose vaccine
- Results indicate that the high-dose vaccine was:
 - 22% more effective than the standard-dose vaccine for the prevention of probable influenza infections
 - 22% more effective for the prevention of influenza-related hospital admissions

Izurrieta HS, et al. *Lancet Infect Dis*. 2015;15(3):299-300.

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Adjuvanted Inactivated Influenza Vaccine

- Standard-dose, three-component (trivalent) inactivated influenza vaccine that contains an adjuvant, MF59
- MF59 is an oil-in-water emulsion of squalene oil
- Indicated for patients aged ≥ 65 years
- New for 2016-2017 season
- No head-to-head trials with influenza high-dose
- No preference expressed by ACIP for any IIV for use in persons aged ≥ 65 years

CDC. <https://www.cdc.gov/flu/protect/vaccine/adjuvant.html>. Accessed March 5, 2017.; FLUAD [package insert]. Cambridge, MA: Seqirus; 2017.

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Influenza Vaccine with Jet Injector Device

- On August 14, 2014, the FDA approved use of one jet injector device
- 0.5 mL needle-free jet injector can be used in people 18 through 64 years of age
- Delivers an injectable liquid medication/vaccine by means of a narrow, precise fluid stream injection, which penetrates the skin in about 1/10 of a second
- Spring-operated, requiring no external power source
- Enhanced design features such as convenient one-hand jet syringe attachment, enhanced visibility, a smooth easy trigger force and no touch syringe ejection

CDC. <http://www.cdc.gov/flu/about/season/flu-season-2015-2016.html>. Accessed March 5, 2017.; PharmaJet. <http://pharmajet.com/product/>. Accessed March 5, 2017.

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Intranasal Influenza Vaccine

- Live vaccine
- For inhalation only
- Indicated for healthy patients aged 2 to 49 years old
- Passing the virus is rare
- Avoid in pregnancy

CDC. <https://www.cdc.gov/vaccines/hcp/ndis/statements/flu/iv.html>. Accessed March 5, 2017.

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LAIV Preferential Recommendation

- CDC's Advisory Committee on Immunization Practices (ACIP) voted that live attenuated influenza vaccine (LAIV), also known as the "nasal spray" flu vaccine, should **not** be used during the 2016-2017 flu season

CDC. <https://www.cdc.gov/media/releases/2016/s0224-iv-iv.html>. Accessed March 5, 2017.

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Recombinant Hemagglutinin Influenza Vaccine

- Trivalent influenza vaccine
- Approved for use in adults 18 years and older
- Produced differently and has a slightly shorter shelf-life than most influenza vaccines
- Contains no egg

Flublok [package insert]. Meriden, CT: Protein Sciences Corporation; 2013.

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Egg Allergy

- Recommendations for influenza vaccination of persons with egg allergy have been modified, including:
 - Removal of the recommendation that egg-allergic recipients should be observed for 30 minutes post vaccination
- A recommendation that persons with a history of severe allergic reaction to egg (i.e., any symptom other than hives) should be vaccinated in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices), under the supervision of a health care provider who is able to recognize and manage severe allergic conditions

CDC. <https://www.cdc.gov/flu/about/season/flu-season-2016-2017.htm>. Accessed March 5, 2017.

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Differences Between Vaccines

| Vaccine Type | Live or Inactivated | Age Indication | Administer with Other Chronic Diseases |
|---|---------------------|--------------------------------------|--|
| Inactivated Influenza Vaccine | Inactivated | ≥ 6 months depending on manufacturer | Yes |
| High-dose Inactivated Influenza Vaccine | Inactivated | ≥ 65 years | Yes |
| Adjuvanted Inactivated Influenza Vaccine | Inactivated | ≥ 65 years | Yes |
| Recombinant Hemagglutinin Influenza Vaccine | Inactivated | ≥ 18 years | Yes |
| Live-attenuated Influenza Vaccine | Live | 2-49 years | No |

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Contraindications to IIV Administration

- **Contraindications**
 - Severe (life-threatening) allergies
 - To eggs*
 - To any vaccine component
 - To a previous dose of influenza vaccine
- **Precautions**
 - Patients suffering from moderate or severe acute illness (with or without fever)
 - History of Guillain-Barré syndrome

* In package inserts only

CDC. <https://www.cdc.gov/vaccines/hcp/admin/contraindications-adults.html>. Accessed March 5, 2017.

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Factors Contributing to Unvaccinated Status

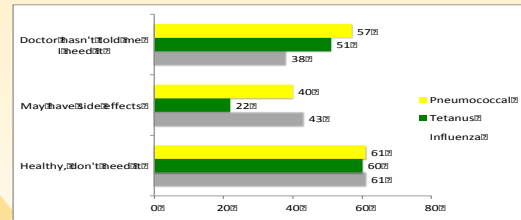
- Concern regarding adverse effects
- Lack of concern about significance of illness
- Feeling impervious to influenza
- Lack of provider directive

Van Essen GA, et al. Age Ageing. 1997;26(4):275-9.

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Reasons to Not Receive Vaccination

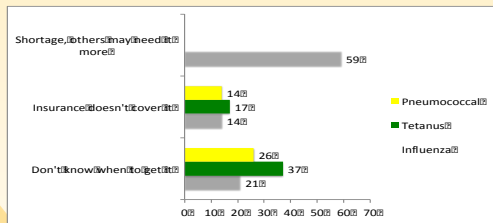


Adapted from Johnson DR, et al. Am J Med. 2008;121(7 Suppl 2):S28-35.

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Reasons to Not Receive Vaccination



Adapted from Johnson DR, et al. Am J Med. 2008;121(7 Suppl 2):S28-35.

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Community Pharmacist Administered Influenza Program

- 1502 surveys collected post vaccination
- 46% of participants stated convenience and accessibility were key factors in determining patient satisfaction
- 25% did not obtain annual vaccines, and 47% were classified as being at high risk for influenza complications

Papadargou J, et al. Canadian Pharmacist Journal. CJP. 2014;147(8):359-365.

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Role of the Pharmacist

- Increasing patient education about vaccines
- Expanding immunization services with standing orders
- Reminder and recall interventions
- Report to state immunization information systems
- Increasing provider education to avoid missed opportunities
- Reducing out-of-pocket costs for adults for other vaccines
- Expanding access

National Foundation for Infectious Diseases. A report on reaching underserved ethnic and minority populations to improve adolescent and adult immunization rates. Bethesda, MD: National Foundation for Infectious Disease, 2002.

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Conclusion

- Pharmacists are in a unique position to identify high-risk patients
- Pharmacists can improve adherence to immunization schedules by educating patients
- Pharmacists can assess adherence and identify barriers that may prevent patients from obtaining appropriate immunizations
- Pharmacists can help increase awareness regarding the importance of obtaining yearly influenza vaccine

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Continuing Professional Development Tips for Immunizations

- Reflect on additional knowledge and stay up-to-date to appropriately care for patients
- Ask patients about vaccination history
- Discuss barriers for vaccination with both physicians and patients

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Additional Resources

- Review the websites below and stay current on information
 - Center for Disease Control and Prevention
 - <https://www.cdc.gov/vaccines/default.htm>
 - Immunization Action Coalition
 - <http://immunize.org/>
 - American Pharmacists Association Immunization Center
 - www.pharmacist.com/immunization-center
 - Morbidity and Mortality Weekly Report (MMWR)
 - www.cdc.gov/mmwr

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