2018 – 2019 Flu Recommendations and communication plans

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Immunization Program

Flu Recommendations

Some Things That are the Same for 2018-19

1) Groups Recommended for Vaccination

Groups Recommended for Vaccination

- **Routine annual influenza vaccination is recommended for all persons ≥6 months of age who do not have contraindications**
- **While vaccination is recommended for everyone in this age group, there are some for whom it is particularly important—**
  - People aged ≥6 months who are at high risk of complications and severe illness
  - Contacts and caregivers of these people, and of infants under age 6 months (because there is no vaccine approved for children this age)

Groups at Increased Risk for Influenza Complications and Severe Illness

- Children aged 6 through 59 months and adults aged ≥50 years (children under 6 months of age are also at high risk, but cannot be vaccinated);
- Persons with chronic pulmonary (including asthma) or cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus);
- Immunosuppressed persons;
- Women who are or will be pregnant during the influenza season;
- Children and adolescents (aged 6 months–18 years) who are receiving aspirin- or salicylate-containing medications (who might be at risk for Reye syndrome after influenza virus infection);
- Residents of nursing homes and other long-term care facilities;
- American Indians/Alaska Natives; and
- Persons who are extremely obese (BMI ≥40).

Some Things That are the Same for 2017-18

2) There are many influenza vaccines available

There are Still Many Different Vaccines

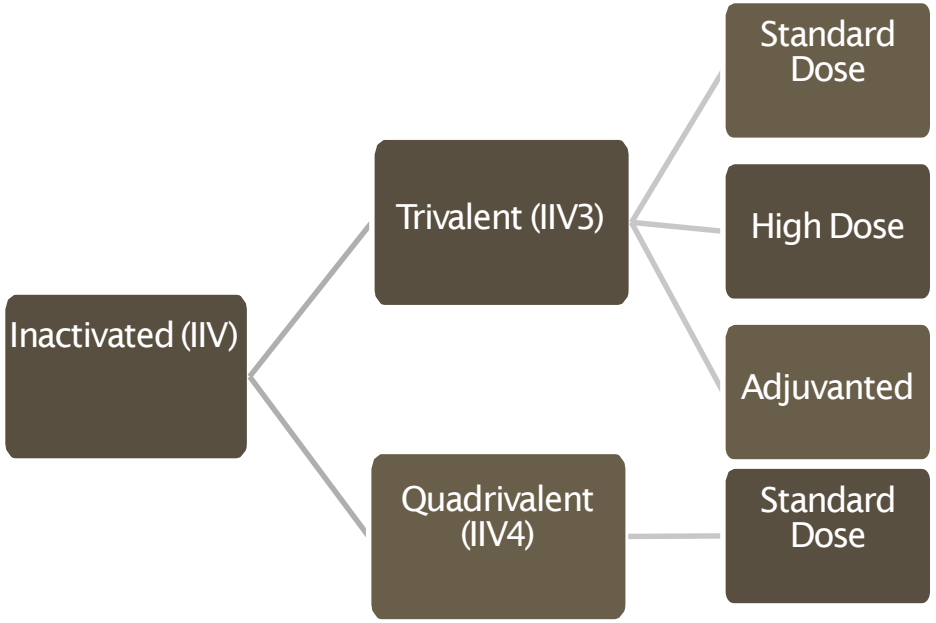
- 13 distinct products for 2017-18
- 10 expected for 2018-19 (still a lot)
- More than one available vaccine might be appropriate for any recipient
- ACIP/CDC express no preferences for any one influenza vaccine over another
- Vaccination should not be delayed in order to obtain a specific product.

Influenza Vaccine Products for the 2018–2019 Influenza Season

Manufacturer	Trade Name (vaccine abbreviation)[1]	How Supplied	Mercury Content (mcg Hg/0.5mL)	Age Range	Vaccine Product Billing Code[2]	
					CPT	Medicare
GlaxoSmithKline	Fluarix (IIV4)	0.5 mL (single-dose syringe)	0	6 months & older	90686	90686
ID Biomedical Corp. of Quebec, a subsidiary of GlaxoSmithKline	FluLaval (IIV4)	0.5 mL (single-dose syringe)	0	6 months & older	90686	90686
		5.0 mL (multi-dose vial)	<25	6 months & older	90688	90688
MedImmune	FluMist (LAIV4)	0.2 mL (single-use nasal spray)	0	2 through 49 years	90672	90672
Protein Sciences Corporation, a Sanofi company	Flublok (RIV4)	0.5 mL (single-dose syringe)	0	18 years & older	90682	90682
Sanofi Pasteur, Inc.	Fluzone (IIV4)	0.25 mL (single-dose syringe)	0	6 through 35 months	90685	90685
		0.5 mL (single-dose syringe)	0	3 years & older	90686	90686
		0.5 mL (single-dose vial)	0	3 years & older	90686	90686
		5.0 mL (multi-dose vial)	25	6 through 35 months	90687	90687
		5.0 mL (multi-dose vial)	25	3 years & older	90688	90688
	Fluzone High-Dose (IIV3-HD)	0.5 mL (single-dose syringe)	0	65 years & older	90662	90662
Seqirus	Afluria (IIV3)	0.5 mL (single-dose syringe)	0	5 years & older[3]	90656	90656
		5.0 mL (multi-dose vial)	24.5		90658	Q2035
	Afluria (IIV4)	0.5 mL (single-dose syringe)	0	5 years & older[3]	90686	90686
		5.0 mL (multi-dose vial)	24.5		90688	90688
	Fluad (aIIV3)	0.5 mL (single-dose syringe)	0	65 years & older	90653	90653
	Flucelvax (ccIIV4)	0.5 mL (single-dose syringe)	0	4 years & older	90674	90674
		5.0 mL (multi-dose vial)	25		90756	90756

http://www.immunize.org/catg.d/p4072.pdf

Influenza Vaccine Options, 2018-2019



- Many brands
- Some with age indication down to 6 months (dose volume varies)
- High dose and adjuvanted are ≥ 65 yrs
- Intramuscular (jet injector option for one)

Recombinant (RIV4) — Quadrivalent

- ≥ 18 years
- Intramuscular

Live Attenuated (LAIV4) — Quadrivalent

- 2 – 49 years
- Intranasal

National Influenza Vaccine Supply 2018-19 Season

- Manufacturers have projected they will provide as many as 163 million to
  - 168 million doses of influenza vaccine.
    - More than 80% will be quadrivalent.
      - Remaining will be trivalent including high dose and adjuvanted vaccines,
      - and one brand of standard does inactivated vaccine.
    - More than 80% thimerosal free
      - Only multidose vials contain thimerosal
    - ~85% egg based
      - Remaining will be produced using cell based and recombinant technology.
- For more information on seasonal influenza vaccine supply and distribution. https://www.cdc.gov/flu/about/qa/index.htm

Timing of Vaccination

- Vaccine should be offered by the end of October.
- Continue to offer vaccine as long as influenza is circulating and unexpired vaccine is available.
- Optimally, vaccination should occur before the onset of influenza activity in a community.
  - Specific start time cannot be predicted.
  - Balance concern for possible waning of vaccine induced immunity, unpredictable timing of the influenza season and programmatic considerations (e.g., missed opportunities, shorter vaccination window).
- Revaccination later in the season of persons who have already been fully vaccinated is not recommended.

Quadrivalent vs. Trivalent

- **IIV3, HD-IIV3, aIIV3**
  - Contain an A(H1N1) virus, an A(H3N2) virus, and a B virus (from one lineage)
- **IIV4, RIV4, LAIV4:**
  - Contain an A(H1N1) virus, an A(H3N2) virus, and 2 B viruses (one from each lineage)
  - Designed to provide broader protection by representing both B lineages
- **No preference expressed for trivalent or quadrivalent**

High-Dose vs. Standard-Dose (IIVs Only)

- **SD-IIV3 and 4:**
  - Contain 15µg of HA total per virus (45µg total for trivalents and 60µg total for quadrivalents)

- **HD-IIV3 (Fluzone High-Dose):**
  - Licensed for ages ≥65 years
  - Contain 60µg of HA total per virus (180µg total).
  - Observed to provide stronger immune response in persons aged ≥65 years
  - In several studies, HD-IIV3 demonstrated better efficacy/effectiveness compared with SD-IIV3 in this age group, including one large (nearly 32,000 participants) two- season randomized trial

- **No preference expressed for HD-IIV3 or SD-IIVs**

Unadjuvanted or Adjuvanted (IIVs Only)

- **Currently licensed U.S. influenza vaccines are unadjuvanted, except for:**

- **aIIV3 (Fluad):**
  - Licensed for ages ≥65 years
  - Contains MF59, an oil-in-water adjuvant
  - Intended to provide better immune response
  - Non-inferior immune response compared with unadjuvanted SD-IIV3 in pre-licensure studies
  - Better effectiveness compared with unadjuvanted, SD-IIV3 in an analysis from a small observational study (n=227)

- **No preference expressed for adjuvanted vs. unadjuvanted vaccines**

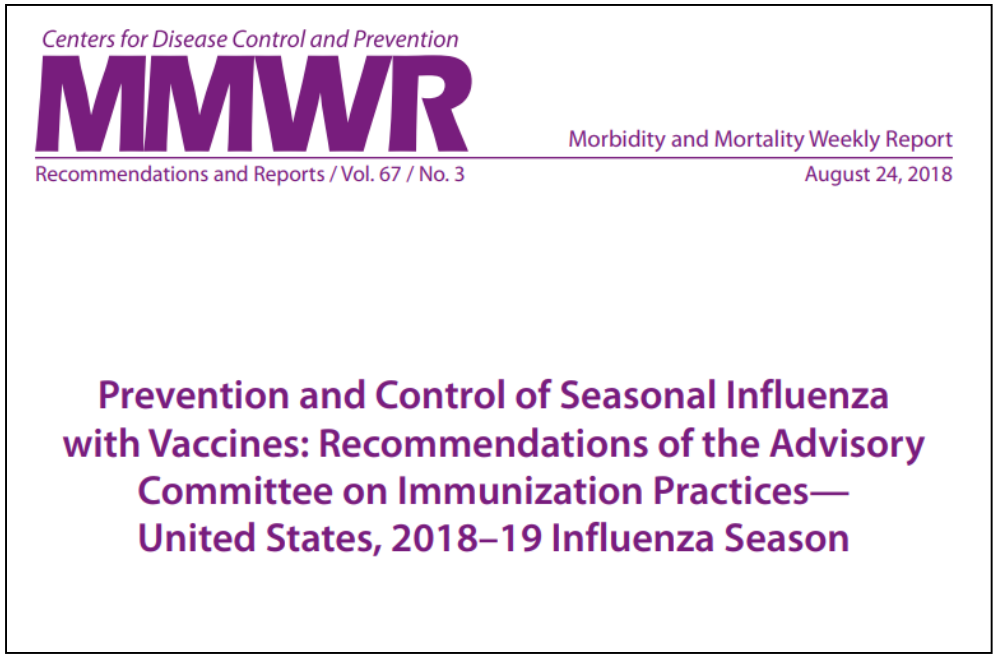
- The immunogenicity and safety of the simultaneous or sequential administration of two vaccines containing novel adjuvants (e.g., Fluad, Shingrix, Heplisav-B) has not yet been evaluated. Selection of a nonajuvanted influenza vaccine (if available) may be considered in situations where influenza vaccine and another vaccine which contain a novel adjuvant are to be administered at the same time.

Egg-Based vs. non Egg-Based

- **For most influenza vaccines, viruses are propagated in eggs. Two exceptions:**
  - **ccIIV4 (Flucelvax):**
    - Viruses are propagated in canine kidney cells rather than eggs
    - However, one of the four initial viruses supplied to the manufacturer is egg- derived (for 2018-19, the H1N1 is still egg-derived), so not considered egg-free
  - **RIV4 (Flublok):**
    - Licensed for ages ≥18 years
    - HA is produced without viruses, in an insect cell line
    - Considered egg-free
    - Better efficacy compared to an SD-IIV4 in a single-season randomized trial of
      - ~8,600 participants aged ≥50 years
  - **No preference expressed for egg-based vs. non-egg-based vaccines**
  - **Egg allergic persons can receive egg-based vaccines**

2018-19 ACIP Influenza Statement—Updates

- **Principal changes and updates for 2018-19**
  - Influenza vaccine composition for 2018-19
  - LAIV4 an option for 2018-19
  - Vaccines for egg-allergic persons
  - Two labeling changes for existing vaccines



https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6703a1-H.pdf

Key Updates for 2018-19

1) Composition of U.S. influenza Vaccines for 2018-19

2018-19 Influenza Vaccine Composition

- **Trivalent vaccines:**
  - an A/Michigan/45/2015 (H1N1)pdm09-like virus;
  - an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus; and
  - a B/Colorado/06/2017-like virus (Victoria lineage).

- **Quadrivalent vaccines:**
  - The above three viruses, and
  - a B/Phuket/3073/2013-like virus (Yamagata lineage).

LAIV4 Recommendations for 2018-19

- **Can choose any licensed, appropriate vaccine (IIV, RIV4, or LAIV4)**
  - LAIV had not been recommended for 2016-17 or 2017-18
    - Low effectiveness against influenza A(H1N1)pdm09 among children aged 2 through 17 yrs during 2013-14 and 2015-16
    - Thought due to poor fitness of the H1N1pdm09 virus in the vaccine
  - In February 2018, ACIP reviewed additional data
    - Two analyses of previous seasons' data from observational studies:
    - Manufacturer data on shedding and immunogenicity of LAIV
      - New H1N1pdm09 virus showing better fitness
  - For 2018-19, LAIV4 is an option for those for whom it is appropriate
    - No U.S. VE data yet on new formulation with the new H1N1pdm09

LAIV4 Recommendations for 2018-19

- Difference in ACIP and American Academy of Pediatrics (AAP) and American Academy of Family Physicians (AAFP) recommendations:
  - **ACIP** makes no preferential recommendations for any one vaccine type when more than one is appropriate;
  - **AAP** recommends IIV as the primary choice for children;
  - **AAFP** recommends IIV as the primary choice for nonpregnant patients ages 2-49

Recommendations share the same principle that influenza vaccination is an important preventive strategy!

Who Shouldn't Receive LAIV4 (Contraindications)

- **Persons aged <2 years or >49 years**
- **Labeled contraindications in package insert:**
  - History of severe allergic reaction to any vaccine component* or to a previous dose of influenza vaccine (like other flu vaccines)
    - Note though that ACIP recommends vaccination of persons with egg allergy
  - Concomitant aspirin- or salicylate-containing therapy in children or adolescents (risk of Reye syndrome)
- **In addition, ACIP recommends LAIV not be used for**
  - Pregnant women
  - Immunocompromised persons
  - Children <5 with asthma or wheezing
  - Caregivers and contacts of persons requirement a protected environment
  - Persons who have received influenza antivirals within previous 48 hours

Precautions to use of LAIV4

- **Similar to other influenza vaccines:**
  - Moderate of severe illness with or without fever
  - Guillain-Barré syndrome within 6 weeks following a previous dose of influenza vaccine
- **Additional precautions specific to LAIV4**
  - Asthma in persons aged 5 and older
  - Other medical conditions that predispose to increased risk of severe influenza illness

Key Updates for 2018-19

3) Influenza vaccination and persons with a history of egg allergy

Influenza Vaccination of Persons with Egg Allergy

- **Mostly unchanged from last few seasons**
  - Main change is that LAIV4 is an option
- **Egg allergic persons can receive any licensed, recommended vaccine that is otherwise appropriate (IIV, RIV4, or LAIV4)**
  - However, RIV not licensed for persons under 18 years of age
- **For persons with a history of severe allergic reaction to egg (i.e., any symptom other than hives)**
  - "The selected vaccine should be administered in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic conditions."
- **No specific post-vaccination observation period recommended**
  - However, per the ACIP General Best Practices guidelines, providers should consider observing all recipients of any vaccine for 15 minutes to avoid injury due to syncope

Key Updates for 2017-18

4) Labeling changes for Afluria Quadrivalent and Fluarix Quadrivalent

Afluria Quadrivalent

- **Standard-dose IIV4 (Seqirus)**
- **Licensed in August 2016,**
  - Initially for persons aged ≥18 years
  - In August 2017, age indication expanded to persons aged **≥5 years**
- **Trivalent formulation of Afluria also available this season**
- **Afluria (IIV3 and IIV4) can be administered via jet injector (the Pharmajet Stratis), but only for those aged 18 through 64 years**
  - No other jet injector licensed
  - Those outside 18 through 64 years of age: needle and syringe
  - Afluria (IIV3 and IIV4) are licensed for ≥5 years

Fluarix Quadrivalent

- Standard-dose IIV4 (GSK)
- Previously licensed for ages ≥3 years; since January 2018 licensed for ≥6 months
  - One of three IIVs approved for children 6 through 35 months of age
- Dose volume is same for everyone 6 months and older (0.5mL)

INFLUENZA VACCINE DOSING INFORMATION FOR 6- 35 MONTH-OLDS

- **Two potential points of confusion**
  - **Three licensed products, but the dose volumes differ:**
    - Fluarix Quadrivalent: 0.5mL
    - FluLaval Quadrivalent: 0.5 mL
    - Fluzone Quadrivalent: 0.25 mL
  - ***Dose volume* is distinct from *number of doses* needed:**
    - A child aged 6 months through 8 years who needs 2 doses—
    - (for example, if a first-time vaccinee)—
    - and who gets 0.5mL FluLaval Quadrivalent for a first dose—
    - *Still* needs a second dose of influenza vaccine, ≥4 weeks later

Summary

- **Still a good number of different influenza vaccines available**
  - Age indications differ
- **No preferences for any one product over another**
- **LAIV4 is an option for those for whom it is appropriate for 2018-19**
  - Not recommended for some groups
  - Can be given to egg-allergic recipients of otherwise appropriate
- **Now three different IIVs available for 6-35 month olds**
  - But dose volumes differ!

Communication Plans

Seasonal Influenza Vaccination Rates in Massachusetts by Age, 2017-18 Influenza Season, July 2017– May 2018

	MA	US	Ranking
Children 6 mos – 17 years	**74% (+1.9%)**	**58% (-1.1%)***	**2 (RI)**
• **Children 6 mos – 4 years**	**76% (-6.5%)**	**68% (-2.2%)***	**7**
• **Children 5 – 12 years**	**74% (+2.8%)**	**60% (-0.4%)**	**3 (RI, CT)**
• **Children 13 – 17 years**	**72% (+7.9%)**	**47% (-1.4%)**	**1**

NIS – Flu
Parentheses denote percent-point difference in coverage from the 2016-17 influenza season
*Statistically significant

CDC's Flu Communication Objectives

- Provide clear, consistent, and timely scientific, technical and programmatic information and communication resources to partners in support of their flu prevention and control activities
- Increase the number of healthcare providers making a strong flu vaccine recommendation
- Support healthcare providers that are already making flu vaccine recommendations to patients across the lifespan

CDC Plans for 2018-19 Flu Season

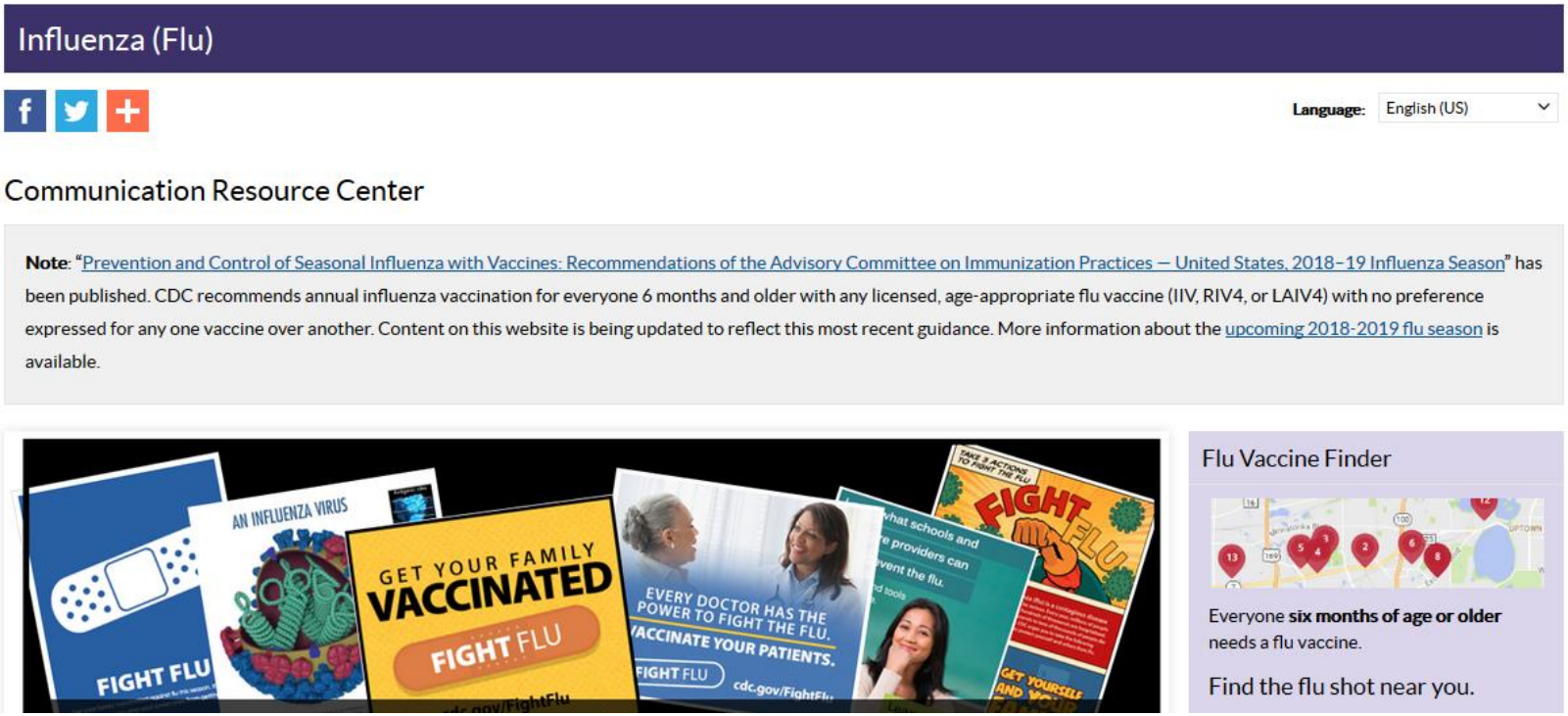
External Communication Activities

- Seasonal Flu Vaccination Campaign Kick-off: September 27
- National Influenza Vaccination Week: December 2-8
- Focus on reaching healthcare professionals
  - Fight Flu material updated and online
  - Website live with updated recommendations
  - Pilot new approaches, including "How I Recommend" videos
  - Continue to support flu messages and materials across CDC lifespan immunization campaigns
- Continue partner engagement, media relations strategies, and response to clinician and consumer inquiries

Communication Research

- Patient interviews to improve HCP vaccine recommendations
- Maternal clinician encounter observations during upcoming flu seasor
- Adult survey on health disparities

CDC Resources



https://www.cdc.gov/flu/resource-center/index.htm

CDC Resources Continued

Key Messages for the Public

- Flu season is coming. And, as we saw last season, it can be very serious – even deadly.
- Getting an annual flu vaccine is the single best way to protect yourself and your loved ones.
- You may get sick even if you get vaccinated. But the vaccine has many benefits.
- The flu vaccine can:
  - Save children's lives
  - Reduce the risk of hospitalizations
  - Be an important part of managing a chronic health condition, like heart disease or diabetes
  - Help you get back on your feet sooner if you do get sick
- There are many different flu vaccine options. *Talk to your healthcare provider about which vaccine is right for you.*

General HCP Outreach

- Ongoing social and digital media using CDC's Twitter, CDC's Flu Twitter, Facebook, LinkedIn, and Pinterest channels targeting clinicians of all types
- Paid media campaign reaching general HCPs through trade organizations (American Medical Association (AMA) and American Nurses Association (ANA)), LinkedIn, and ad networks
- Fight Flu Toolkit for all HCPs includes appointment reminder email template for practices to customize based on patient population, with information for high-risk groups, such as older adults, pregnant women, young children, and adults with chronic medical conditions
- Medscape Expert Commentary sharing the official influenza vaccination recommendations for the 2018 – 2019 flu season and including information on the importance of a HCP vaccination recommendation

Lifespan Campaign - Messages

6 months and older

Children 6 months-11 years | Teens & Young Adults | Pregnant Women | Adults w/ Chronic Conditions | Adults (Otherwise Healthy) | Aging Adults 50-64 | Older Adults 65+ | Health Care Providers

The flu vaccine saves lives in children.

The flu vaccine protects you and your baby.

The flu vaccine is an important part of managing your chronic disease.

The flu vaccine is part of your healthy lifestyle.

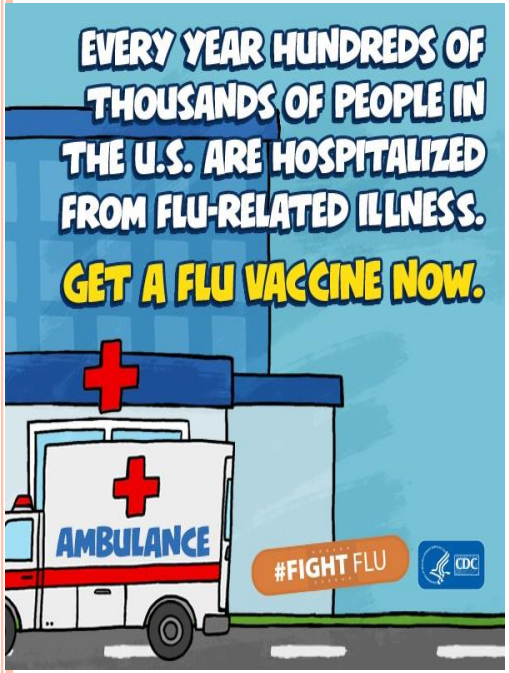
Lifespan Campaign - Tactics

Children 6 months-11 years	Teens & Young Adults	Pregnant Women	Adults w/ Chronic Conditions	Adults (Otherwise Healthy)	Aging Adults 50-64	Older Adults 65+	Health Care Providers
Print material for parents, schools, and HCPs	College health center material	Print materials for moms, families	Diabetes Infographic	Workplace/ Business toolkit	Targeted print material	Targeted print material	Recommendation materials
Ready Wrigley Activity book	Digital Media	Digital ads	Digital Media	Digital Media	External media placement	Vaccine option info	Inter-agency partnerships
Cooperative Agreement (AAP)	Infographics	Infographics	Partnerships with diabetes organizations	Infographics	Sandwich generation messaging	Audience profiles (HCP and Consumer)	Professional organization partnerships
Audience profiles (HCP and Consumer)		Digital Media	Targeted print materials	Messaging to caregivers	Audience profiles (HCP and Consumer)		Medscape Commentaries
		Contributed articles	Contributed articles	Print materials	Digital Media		"How I Recommend" Videos
		Paid Media	Paid media				
		Cooperative Agreement					

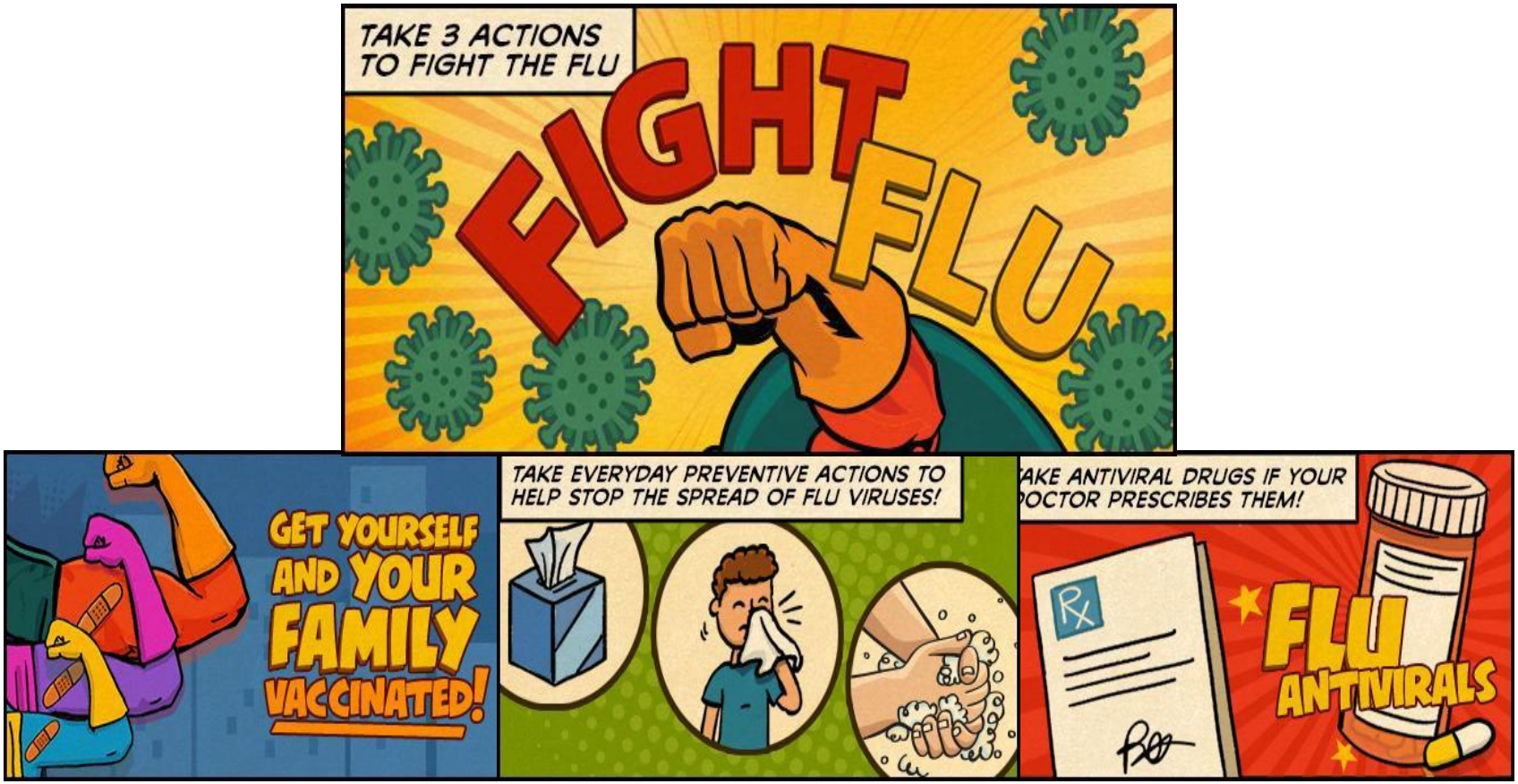
Lifespan Campaign - Material Examples

6 months and older

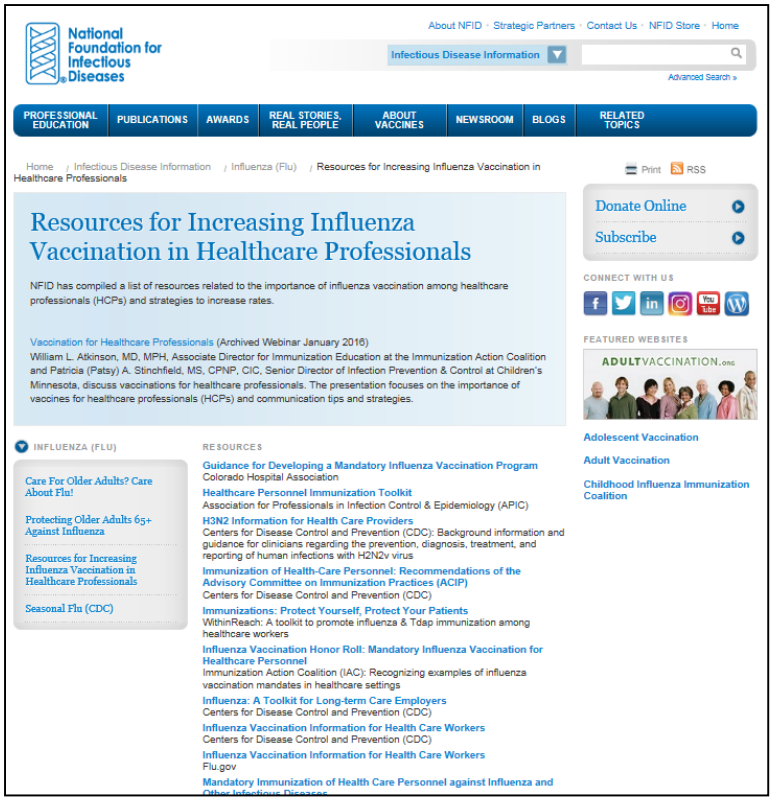
- General
- Health Care Providers
- Adults w/ Chronic Conditions
- Pregnant Women



Take 3 Messaging



National Foundation for Infectious Diseases



http://www.nfid.org/idinfo/influenza/increasing-influenza-vaccination-in-hcps

MDPH Resources

Please visit our Flu Website (www.mass.gov/flu) for what's new during the 2018-2019 flu season and additional MDPH resources.

- Sample Standing Orders*
  - Sample Standing Orders for IIV vaccine
  - Sample Standing Orders for LAIV vaccine
- Screening/Consent Form*
  - Screening/Consent form for IIV vaccine
  - Screening/Consent form for LAIV vaccine
  - Screening/Consent form for IIV and LAIV vaccine
- Flu Highlights for 2018-2019, which is geared towards a general public audience that you can use in discussions with your patients
- Control of Influenza and Pneumococcal Disease in Long-Term Care Facilities discusses specific recommendations for long-term care residents and staff as well as other vaccines applicable to this population

*These resources are based on the recommendations of the Advisory Committee on Immunization Practices (ACIP).

MDPH 2018-2019 Flu Highlights

Highlights for the 2018-2019 Flu Season

The 2017-2018 flu season was very severe. Here are some highlights for what you need to know this flu season to stay healthy.

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https://www.mass.gov/info-details/highlights-for-the-2018-2019-flu-season

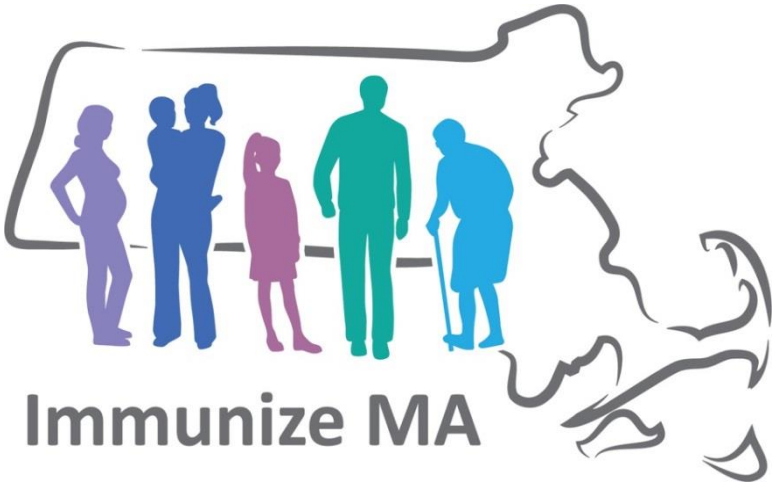
Overall Flu Summary

- During the 2017-2018 influenza season, the United States had **record breaking levels of influenza illness**. Hospitalizations were of high severity in all age groups and geographically widespread for an extended period. Last season, deaths in children (180) were the highest reported during a regular influenza season.
- Flu vaccine offers the best protection against flu-related illness, hospitalization, and death. During the 2016–2017 season, **vaccination prevented an estimated 5.3 million illnesses, 2.6 million medical visits, and 85,000 influenza-associated hospitalizations**. When more people get vaccinated against the flu, less flu can spread through the community.

Other MDPH News

- HPV Information Sheet
  - Highlights HPV-associated cancers
  - Shows HPV vaccination rates
- Vaccine Confidence Project
  - Target areas of the state that have higher school exemption rates

Questions?



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