MA Adult Immunization Update

April 14, 2015

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Presenter Disclosure Information

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Consultant	No relevant conflicts of interest to declare or relevant conflict
Grant Research/Support	No relevant conflicts of interest to declare or relevant conflict
Speaker's Bureau	No relevant conflicts of interest to declare or relevant conflict
Major Stockholder	No relevant conflicts of interest to declare or relevant conflict
Other Financial or Material Interest	No relevant conflicts of interest to declare or relevant conflict
Off Label Use of Vaccines	Will be discussed, but in accordance with current ACIP recommendations

20 Years of Adult Immunization Conferences

THANK YOU FOR ALL THAT YOU DO TO PROTECT MASSACHUSETTS FROM VACCINE PREVENTABLE DISEASES

Outline

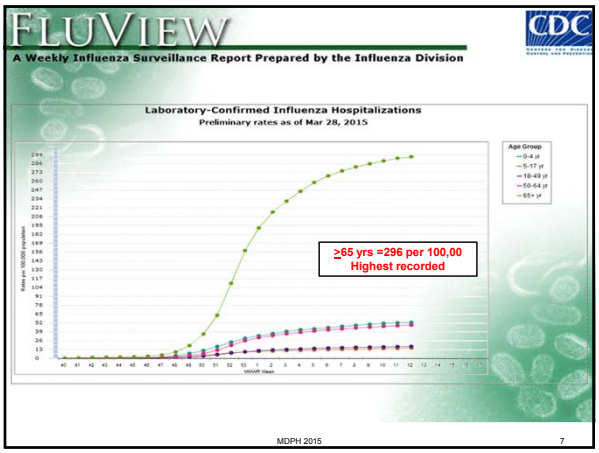
- Flu Season
- Historical Perspective
- 2015 Adult Immunization Schedule
- Pneumococcal Recommendations
- Adult Immunization Rates
- Adult Immunization Standards
- 9vHPV Vaccine Recommendations
- Meningococcal Serogroup B Vaccines

Influenza 2014-15 Season

Main Flu CDC Website
www.cdc.gov/flu

National Influenza Activity Summary 2014-2015 Season

- Relatively early sharp peak, similar to 2 seasons ago (2012-2013)
- Influenza A H3N2 is predominant strain and it is drifted.
  - About 70% of the H3N2 viruses are drifted compared the vaccine component (A/Texas). B viruses increasing at end of season. But most B viruses are like the vaccine strain.
  - H3N2 drift similar to that seen in the Southern Hemisphere over the summer, so they are changing that component of the vaccine for the next season to A/Switzerland.
  - Influenza A H3N2 strains are associated with more severe seasons. Hospitalizations in those >65 years hits a record high.
- Vaccine was not a good match and was only 18-23 percent effective.
- **Influenza vaccine still offers the best protection.**
- In the context of reduced vaccine effectiveness, the **use of antivirals** as a 2nd line of defense becomes even more important, particularly for **high risk**
- CDC Health Alert Network guidance for providers 12-3-14 and 1-6-15
- Unusual presentations of flu: parotitis (flu AH3) and rash (flu B strains)



CDC Antiviral Recommendations

All high risk patients with **suspected** or confirmed influenza should be treated **as soon as possible**, without waiting for confirmatory influenza testing:

- Hospitalized patients
- Patients with severe, complicated, or progressive illness
- Patients at high risk for complications from influenza (either outpatient or hospitalized)
- Antivirals might still be beneficial in patients with severe, complicated or progressive illness and in hospitalized patients **when started later**
- Phone triage lines facilitate antiviral prescriptions without testing and before an office visit

Have a high index of suspicion.
Early empiric treatment.

http://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm

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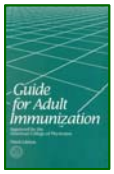


Looking Back and Looking Ahead

Routine Immunization of Adults, 1994 American College of Physicians

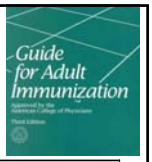
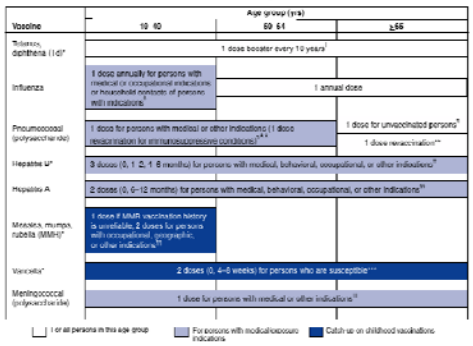


Table 1.1 **Routine Immunization of Adults**

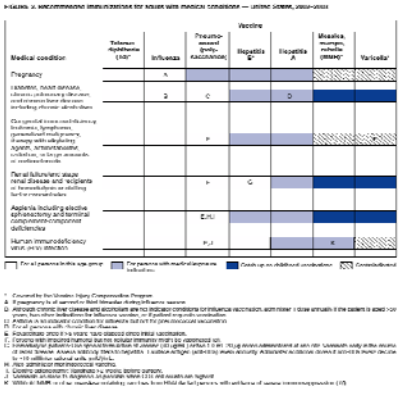
Vaccine	Recommendation
Pneumococcal	All adults age ≥ 65 years; all younger adults with risk factors. Reimmunization is recommended at age 65 if 6 or more years have passed since first pneumococcal immunization
Influenza	Yearly for all adults age ≥ 65 years; all younger adults with risk factors. Offer to other healthy younger adults.
Hepatitis B	Sexually active young adults; high-risk groups. Assess serological response in persons age ≥ 30 years.
Measles-mumps-rubella (MMR)	Adults born after 1956 without proof of immunity or documentation of previous immunization; two doses for special risk groups
Tetanus-diphtheria (Td)	Completion of primary (three-dose) immunization schedule followed by either Td boosters every 10 years, or a single mid-life (at age 50 years) booster for persons who have completed the full pediatric series, including the teenage/young adult booster

First ACIP Adult Immunization Schedule -- U.S., 2002-2003

FIGURE 1. Recommended adult immunization schedule — United States, 2002–2003



CDC. MMWR 2002;51:904-908 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5140a5.htm.



CDC. MMWR 2002;51:904-908 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5140a5.htm.

Factors Contributing to Low Immunization Rates in Adults Then

- Lingering doubt of both the public and health care providers about the efficacy and safety of vaccines
- Uncertainty about specific recommendations
- Liability concerns
- Inadequate reimbursement
- Poorly developed systems for immunization of adults

Why I Am Optimistic We Have Tools Now to More Effectively Address these Problems

- Partnerships
- Tools to address vaccine hesitancy
- National Vaccine Injury Compensation Program
- Evidence-based clinical guidance
- More vaccinators in more venues
  - Immunization Neighborhood
- Health care reform
  - Improves patient access and provider reimbursement
- Information technology
  - Consolidates records and shares information
  - Clinical decision support

Commissioner Monica Bharel!!
Dr. Bharel was Medical Director of Health Care for the Homeless prior to assuming leadership of MDPH.

Immunization Neighborhood

Collaboration, **C**oordination, and **C**ommunication:

Among immunization stakeholders dedicated to meeting the immunization needs of the patient and protecting the community from vaccine-preventable diseases.

Adapted from :

American Pharmacists Association

Immunization Neighborhood

Where are You?

Strategy to Address Immunization Needs

Meeting specific needs of targeted populations

Supporting the Neighborhood

- HIT
- Documentation
- Standards / Guidelines
- Consistent Messaging
- Scope of Authority
- Referral mechanisms

Adapted from :

American Pharmacists Association

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2015 Adult Immunization Schedule

MMWR 2015;64:91.

Annals of Internal Medicine 2015;64:214

Available at:

http://www.cdc.gov/vaccines/schedules/hcp/adult.html

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6404a4.htm?s_cid=mm6404a4_w

http://annals.org/article.aspx?articleid=2107750

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2015 Adult Immunization Schedule Changes from 2014

- **September 2014 pneumococcal vaccine recommendation**
  - Routine administration of 13-valent pneumococcal conjugate vaccine (PCV13) in series with 23-valent pneumococcal polysaccharide vaccine (PPSV23) for all (PCV13-naïve) adults aged 65 years or older
- **August 2014 influenza vaccine contraindications and precautions for live attenuated influenza vaccine (LAIV)**
  - Move "influenza antiviral use within the last 48 hours" from precautions to contraindications
  - Move asthma in those ≥5years and chronic lung diseases; cardiovascular, renal, and hepatic diseases; and diabetes and other conditions from contraindications to precautions
- **October 2014 approval by Food and Drug Administration to expand approved age for recombinant influenza vaccine (RIV)**
  - Adults aged 18 years or older (changed from 18 through 49 years) can receive RIV

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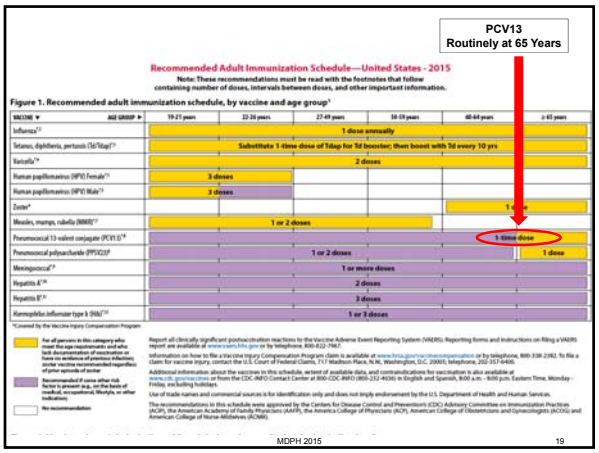
PCV13
Routinely at 65 Years
Recommended Adult Immunization Schedule—United States - 2015
Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.
Figure 1. Recommended adult immunization schedule, by vaccine and age group
1-time dose
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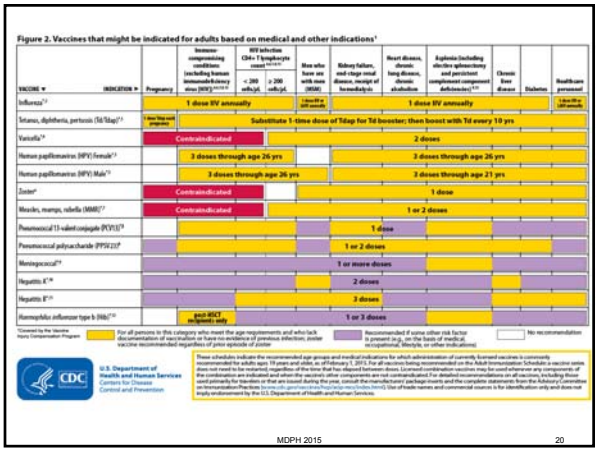
Figure 2. Vaccines that might be indicated for adults based on medical and other indications
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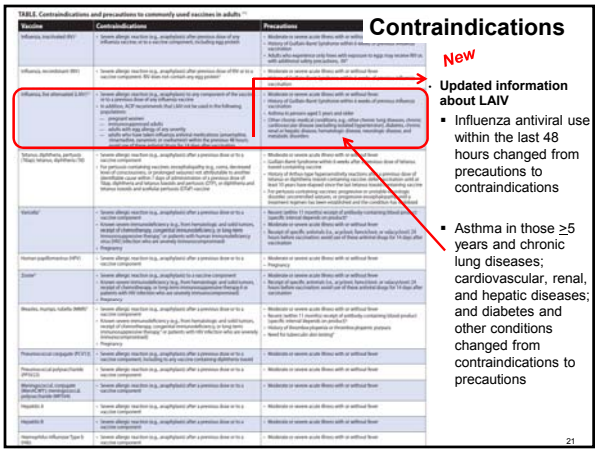
Contraindications
New
Updated information about LAIV
Influenza antiviral use within the last 48 hours changed from precautions to contraindications
Asthma in those ≥5 years and chronic lung diseases; cardiovascular, renal, and hepatic diseases; and diabetes and other conditions changed from contraindications to precautions
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"Born with Protection" MATERNAL Tdap CAMPAIGN

- Researched-based campaign
- Targeting pregnant women & prenatal healthcare providers
- English and Spanish materials available.

www.cdc.gov/pertussis/pregnant

Advisory Committee on Immunization Practices

PCV13 NOW RECOMMENDED FOR ALL ADULTS ≥65 YEARS IN SERIES WITH PPSV23

CDC. MMWR 2014;63:822.

http://www.cdc.gov/mmwr/pdf/wk/mm6337.pdf

CLINICAL GUIDELINE — Annals of Internal Medicine

Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older: United States, 2015*

David K. Kim, MD; Carolyn B. Bridges, MD; and Kathleen H. Harriman, PhD, MPH, RN on behalf of the Advisory Committee on Immunization Practices†

In October 2014, the Advisory Committee on Immunization Practices (ACIP) approved the Recommended Adult Immunization Schedule, United States, 2015. This schedule provides a summary of ACIP recommendations for the use of vaccines routinely recommended for adults in 2 figures (Figures 1 and 2), footnotes for each vaccine, and a table that describes primary contraindications and precautions for commonly used vaccines for adults (Table 1). Changes in the 2015 adult immunization schedule from the 2014 schedule include the September 2014 recommendation for routine administration of the 13-valent pneumococcal conjugate vaccine (PCV13) in series with the 23-valent pneumococcal polysaccharide vaccine (PPSV23) for all adults aged 65 years or older (1), the August 2014 revision on contraindications and precautions for the live attenuated influenza vaccine (LAIV) (2), and the October 2014 approval by the U.S. Food and Drug Administration

- The footnotes for pneumococcal vaccination have been revised to provide algorithmic, patient-based guidance for the health care provider to arrive at appropriate vaccination decisions for individual patients.
- The footnote for influenza vaccination has been updated to indicate that adults aged 18 years or older (changed from adults aged 18 through 49 years) can receive RIV. A list of updated available influenza vaccines can be found at www.cdc.gov/flu/protect/vaccine/vaccines.htm.
- Table 1, showing contraindications and precautions to commonly used vaccines in adults, has been revised to update the section on LAIV to reflect the changes in the ACIP recommendations for the 2014–2015 influenza season. These changes include moving "influenza antiviral use within the last 48 hours" from the precautions column to the contraindications col-

Pneumococcal Vaccination Recommendations for Adults - General Guidance

- One dose of PCV13 indicated for all adults; timing of PCV13 dependent on age and health conditions
- No additional doses of PPSV23 indicated for adults who received PPSV23 at or after age 65 years
- When both PCV13 and PPSV23 are indicated, administer PCV13 first (PCV13 and PPSV23 should not be administered during same visit)
- For adults with incomplete or unknown pneumococcal vaccination history, administer PCV13 and PPSV23 as indicated (but not during the same visit)
- Administer PPSV23 6-12 months after PCV13 for adults ≥65 years
  - Adults aged 19-64 years with immunocompromising conditions, anatomical or functional asplenia, or cerebrospinal fluid leak or cochlear implant -- PPSV23 ≥8 weeks after PCV13

ACIP. Annals of Int Med 2-3-15 MDPH 2015 25

Adults ≥65 years of age with no previous pneumococcal vaccine (PCV13 or PPSV23) or unknown vaccination history

- Administer PCV13 and PPSV23 in a series.
  Ideally give PCV13 first, followed by a dose of PPSV23 six to 12 months later
  - Minimum interval is 8 weeks
- The two vaccines should **not** be administered at the same visit
  - But do not need to be repeated if the interval is shorter or if given on the same day

Note: Adults who have previously received PCV13 at ≤64 years, not NOT need to receive another dose at ≥ 65 years.

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Adults ≥65 years of age with no previous pneumococcal vaccine (PCV13 or PPSV23) or unknown vaccination history

PCV13 (at ≥ 65 years) + **PPSV23**

6-12 months*

* Minimum interval between sequential administration of PCV13 and PPSV23 is 8 weeks. But do not need to repeat if interval shorter or if given on the same day .

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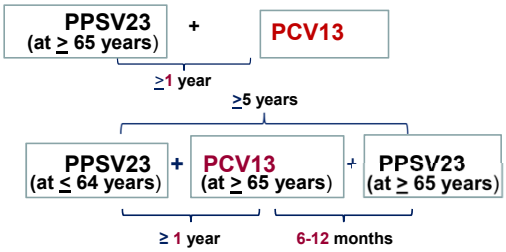
PCV13-naïve adults ≥65 years of age previously vaccinated with PPSV23

- Administer a dose of PCV13 at least 1 year after the receipt of the most recent PPSV23 dose
  - This is to avoid interference with immune response
  - But, PCV13 does not have to be repeated if interval is shorter
- For those for whom an additional dose of PPSV23 is indicated, administer it 6 to 12 months after PCV13 and at least 5 years after the most recent dose of PPSV23

PCV13-naïve adults ≥65 years of age previously vaccinated with PPSV23



* Minimum interval between sequential administration of PCV13 and PPSV23 is 8 weeks. But do not need to repeat if intervals shorter or given on the same day.

IAC Resources for Pneumococcal Vaccines

- Pneumococcal Vaccination Recommendations for Children and Adults by Age and/or Risk Factor
  - www.immunize.org/catg.d/p2019.pdf
- Recommendations for Pneumococcal Vaccines in Children and Teens
  - http://www.immunize.org/catg.d/p2016.pdf
- Pneumococcal Vaccines Ask the Experts **(Updated regularly)**
  - http://www.immunize.org/askexperts/experts_pneumococcal_vaccines.asp

CDC Pneumococcal Resources

- Main Pneumo Website
  www.cdc.gov/vaccines/vpd-vac/pneumo
- CDC Resources for Clinicians
  www.cdc.gov/pneumococcal/clinicians
- CDC Fact Sheet for Clinicians and Patients
  http://www.cdc.gov/vaccines/hcp/patient-ed/adults/downloads/fs-pneumo-hcp.pdf

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Medicare Part B Coverage for Pneumococcal Vaccines

(Effective Date: September 19,2014. Implementation Date: February 2, 2015)

New

- An initial pneumococcal vaccine may be administered to all beneficiaries who have never received a pneumococcal vaccine under Medicare Part B
- A 2nd pneumococcal vaccine may be administered 1 year after the first vaccination was administered (i.e., 11 full months have passed following the month in which the last pneumococcal vaccine was administered
  - Please note, the interval between the two different pneumococcal vaccines must be 11 months not 6 months as described in the ACIP recommendations
- Patients should check with their provider and plan to review the details of their coverage

Resources

MLN Matters CMS News Letter (MM9051): http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9051.pdf
CMS regulations and guidance for claims processing: http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R3159CP.html

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Immunization Rates

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Adult Vaccination Rates

Vaccine/Group	MA 2011	MA 2012	MA 2013	US 2013
Tdap ≥18 y/o	19%	21%	37%	17%
Zoster ≥60 y/o	17%	24%	30%	24%
HPV females 18-26 y/o (1+ doses)	55%	61%	61%	37%
HPV females 18-26 y/o (3+ doses)	78%*	79%*	76%*	N/A
HPV males 18-26 y/o (1+ doses)	6%	9%	23%	6%
HPV males 18-26 y/o (3+ doses)	N/A	N/A	30%*	N/A
Influenza vaccine ≥65 y/o	67%	64%	66%	65%
Pneumococcal vaccine ≥65 y/o	72%	70%	70%	62%

*Percent of those who received at least 1 dose.

Source: MA Data: BRFSS, US Data: NHIS Data collection methods changed in 2011.

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MA Flu Vaccination Rates

	MA 2012-13	MA 2013-14	US 2013-14
Everyone 6 mos+	**58%**	**53%***	**46%**
#2 **Children 6 mos – 17 yrs**	**75%**	**72%**	**59%**
○ Children 6 mos – 4 yrs	83%	87%	70%
○ Children 5 – 12 yrs	78%	72%	61%
○ Adolescents 13 – 17 yrs	67%	61%	46%
Adults 18 +	**53%**	**49%***	**42%**
○ Adults 18 – 64 y/o	49%	45%*	37%
○ Adults HR 18 – 64 y/o	58%	58%	46%
○ Adults 50 – 64 y/o	56%	51%	45%
○ Adults 65+	71%	64%*	65%

Source: 2013-14 National Immunization Survey (NIS) and Behavioral Risk Factor Surveillance System (BRFSS)

*Statistically significant

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Seasonal Influenza Vaccination Rates in MA in ≥6 months, by Race/Ethnicity 2013-2014 Season

	MA	US	Ranking*
White	53%	47%	7
Black	50%	42%	14
Hispanic	59%	44%	7
Other	49%	47%	17

*All confidence intervals overlap with #1.

Source: BRFSS and NIS

MDPH 2014

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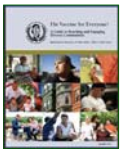
Work with the Office of Health Equity (OHE) on Immunization Equity Technical Assistance

- Immunization Program collaborates with OHE and Office of Emergency Preparedness to offer technical assistance and resources to public health agencies in order to reduce immunization disparities in their communities

New

- 10 agencies are part of 2015 effort: 5 CHCs and 5 BOHs



- Promoting MDPH-developed tools like: *"Flu Vaccine for Everyone! A Guide for Reaching and Engaging Diverse Communities"*

MDPH 2014

Standards for Adult Immunization Practice and Other Tools to Improve Coverage

Standards available at:
http://www.cdc.gov/vaccines/hcp/patient-ed/adults/index.html
or
http://www.publichealthreports.org

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Adult Immunization Opportunities

Adult patients low awareness of need for vaccines **BUT…**

- Healthcare providers believe immunizations important for adults **AND…**
- Adults are receptive to information about and getting vaccinated when recommended by healthcare provider
- Collaboration and communication are key
- All recommendations are evidence-based

References: 1. Hurley, et al. Annals of Internal Medicine, 2014.
2. Guide to community preventive services: www.thecommunityguide.org/vaccines/index.html
3. Adult non-influenza vaccine coverage: www.cdc.gov/mmwr.

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Adult Immunization Practice Standards

- **Call to action for healthcare professionals**
  - **Assess** immunization status of all patients in every clinical encounter.
  - Strongly **recommend** vaccines that patients need.
  - **Administer** needed vaccines or **refer** to a vaccinating provider and confirm receipt
  - **Document** vaccines received by patients, including entering immunizations into immunization registries.

Goal is to decrease missed opportunities!

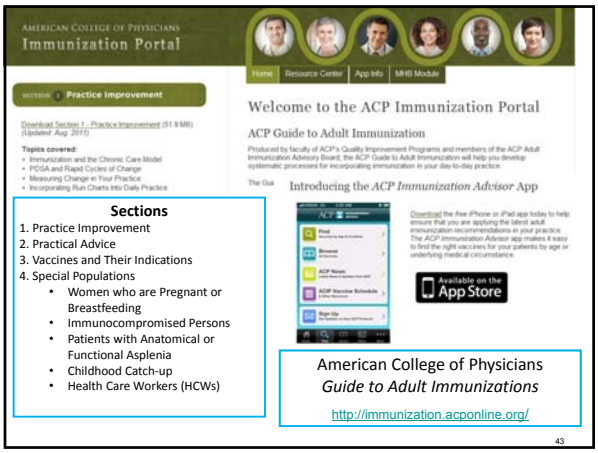
Immunization Information Systems (IIS) (Immunization Registries)

- **Increased use important for many reasons, including**
  - Consolidates immunization records
  - Coordination and communication among patients' multiple providers
  - Ensuring patients get the right vaccines at the right time
  - Potential for use in quality measures and coverage tracking
  - Increase preparedness for a pandemic vaccine response
- **Clinical decision support**

References: 1. Hurley, et al. Annals of Internal Medicine, 2014.
2. Guide to community preventive services: www.thecommunityguide.org/vaccines/index.html
3. Adult non-influenza vaccine coverage: www.cdc.gov/mmwr/preview/mmwrhtml/mm6305a4.htm.

ADULT IMMUNIZATION PRACTICE STANDARDS

http://www.cdc.gov/vaccines/hcp/patient-ed/adults/for-practice/standards/



Sections

1. Practice Improvement
2. Practical Advice
3. Vaccines and Their Indications
4. Special Populations
   - Women who are Pregnant or Breastfeeding
   - Immunocompromised Persons
   - Patients with Anatomical or Functional Asplenia
   - Childhood Catch-up
   - Health Care Workers (HCWs)

American College of Physicians
Guide to Adult Immunizations

http://immunization.acponline.org/

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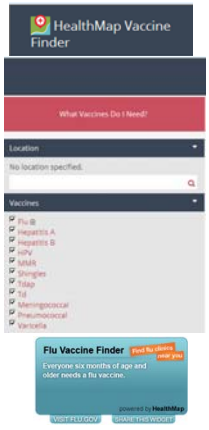
HealthMap Vaccine Finder

- HealthMap Vaccine Finder assists the public with locating influenza and other adult vaccination services in their communities.
  - It is a free, online service where users can search for locations that offer immunizations.
  - Its staff works with partners such as clinics, pharmacies, and health departments to provide accurate and up-to-date information about vaccination services.
  - There is a link to this site via the *Flu Vaccine Finder* widget on FLU.GOV
- MDPH urges providers and other agencies to post their clinics on HealthMap Vaccine Finder site.



HealthMap Vaccine Finder:

http://flushot.healthmap.org/

To register Your Clinic with HealthMap Go To:
https://flushot.healthmap.org/admin/signup/

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Flu Clinic Website
MA Health Officers Association (MHOA)

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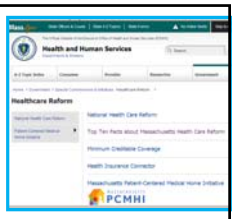
Healthcare Reform - MA

- Since 2006, 439,000 more individuals have health insurance
- MA enjoys highest rate of insurance coverage
- 99% of children and seniors are insured
  - young adults remain a challenge
- Racial and ethnic disparities in coverage reduced
- Community health centers play critical role in implementation, with 31% increase in patients during MA health care reform
  - 285 access sites representing 49 organizations
- One year after launch of ACA, more than 400,000 residents signed up for coverage
- Continued roll-out of healthcare reform nationally and in MA
  - integration and clarification about reimbursement



http://www.mass.gov/eohhs/gov/commissions-and-initiatives/healthcare-reform/
hthttp://www.massleague.org/

ACA and Clinical Preventive Services

- Under the ACA, 'nongrandfathered' private health plans **must provide coverage** for a range of preventive services without cost-sharing
  - those services rated as "A" (strongly recommended) and "B" (recommended) by the U.S. Preventive Services Task Force;
  - vaccinations recommended by ACIP;
  - services recommended under the Bright Futures guidelines developed by HRSA and the American Academy of Pediatrics for children from birth to age 21; and
  - women's preventive services recommended by HRSA based on an Institute of Medicine study committee

University of Massachusetts Medical School
Center for Health Care Financing
a Commonwealth Medicine center of distinction

MA Public Clinic Billing Project

- For 10% fee, CHCF at Commonwealth Medicine electronically bills the participating plans and distributes payments to public providers
  - 11 private health plans and MassHealth participate
- Cities and towns can bill contracted plans for the:
  - Administration of state-supplied flu vaccine to individuals ages 6 months and older
  - Cost of purchasing and administering all recommended vaccines to adults
  - 176 public sector providers across the state participate, representing 212 out of 351 towns in MA
- > $800,000 reimbursed to communities last flu season

http://commed.umassmed.edu/flureimbursement

Vaccinations Across the Lifespan

MIIS

System Usage

2011
- Total Sites: 9
- Total Patients: 3,902
- Total Shots: 69,505

2012
- Total Sites: 55
- Total Patients: 815,928
- Total Shots: 3,371,434

2013
- Total Sites: 341
- Total Patients: 1,539,629
- Total Shots: 7,303,293

2014
- Total Sites: 532
- Total Patients: 2,370,194
- Total Shots: 13,597,285

2015 (March)
- Total Sites: 644
- Total Patients: 2,379,826
- Total Shots: 14,512,998

Compliance Schedule

9/1/2015 Providers that do not use electronic health record systems and will enter data directly into the web interface

12/1/2015 Providers that administer more than 1,000 doses of vaccine per year that use electronic health record technology and will report immunization information through electronic data exchange

6/1/2016 Providers that administer less than 1,000 doses of vaccine per year that use electronic health record technology and will report immunizations through electronic data exchange

For more information or any questions:
MIIS Help Desk
Tel: (617) 983-4335
Email: miishelpdesk@state.ma.us
Website: www.contactmiis.info

GARDASIL 9
Human Papillomavirus
9-valent Vaccine, Recombinant

ACIP Recommendations for 9-Valent HPV Vaccine, February 2015

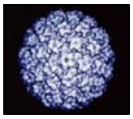
CDC. MMWR 2015;64:300 at:
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm?s_cid=mm6411a3_e

YOU ARE THE KEY TO CANCER PREVENTION

New

9-Valent HPV Vaccine Gardasil 9 (Merck)

HPV VLP



- VLP vaccine that targets 5 additional high risk types
  - 6, 11, 16, 18, **31, 33, 45, 52, 58**
- Licensed 12-10-14:
  - **3-dose schedule**
  - Females 9-26 years and males 9-15 years*
- At the time of the first 9vHPV application to FDA, trials in males 16-26 years had not been completed
- Immunogenicity data now are available for males 16-26 years, reviewed by ACIP and submitted to FDA

* ACIP has made an off-label recommendation for use in males through 26 years of age.

CDC. MMWR 2015;64:300
BLA – Biologics License Application
VLP – virus like particle

Package insert available at:
http://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf

Available HPV Vaccines

	Bivalent 2vHPV (Cervarix)	Quadrivalent 4vHPV (Gardasil)	9-valent 9vHPV (Gardasil 9)
L1 VLP types	16, 18	6, 11, 16, 18	6, 11, 16, 18, 31, 33, 45 ,52, 58
Manufacturer	GlaxoSmithKline	Merck	Merck
Adjuvant	AS04: 500 µg aluminum hydroxide 50 µg 3-*O*-desacyl-4'-monophosphoryl lipid A	AAHS: 225 µg amorphous aluminum hydroxyphosphate sulfate	AAHS: 500 µg amorphous aluminum hydroxyphosphate sulfate

L1, Major capsid protein; VLP, virus like particle

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Summary: attribution of HPV 16/18 and HPV 31/33/45/52/58, United States

- **HPV-associated cancers**
  - ~33,000 per year
  - 64% of cancers attributable to HPV 16/18
    - 66% of cervical cancer
    - Other cancers: range, 48% penile -80% anal
  - **10%** of cancers attributable to additional 5 types
    - 15% of cervical cancer
    - Other cancers: range, 4% oropharyngeal -18% vaginal
    - Differences by sex: **14% for females; 4% for males**
- **Cervical intraepithelial neoplasia grade 2 or higher lesions**
  - ~50% attributable to HPV 16/18
  - ~25% attributable to 5 additional types

% among all HPV-associated cancers

MMWR 2015;64:300-4 MMWR RR 2014; 63:1-30 Hariri et al. CEBP 2015

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9-valent HPV Vaccine Trials

- Efficacy
  - ~97% protection against HPV 31, 33, 45, 52, 58-related outcomes
  - Similar protection against HPV 6, 11, 16, 18-related disease
- Non-inferior immunogenicity
  - For HPV 6, 11, 16, 18 compared with 4vHPV in 16–26 and 9–15 years
  - For all 9 HPV vaccine types in adolescent females and males compared to adult females and in adult males compared to adult females
- Concomitant use
  - No impact on immunogenicity or safety administered concomitantly with MCV4 (Menactra) and Tdap (Adacel)
- Safety
  - Similar safety profile, but slightly higher injection site reactions

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426457.pd

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Implementation Considerations

- Will be a transition period. We will know more specifics about this soon.
- 4vHPV and 2vHPV protect against HPV types 16 and 18 which account for almost 70% of cervical and the majority of other HPV-related cancers
- 9vHPV include protects against and additional 10% percent of cancers
  - Main benefit is for females

DON'T WAIT -- VACCINATE
You may not be choosing between 4vHPV and 9vHPV;
but, between 4vHPV and nothing!

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ACIP Recommendations for HPV Vaccine

- **ACIP did NOT express a preference for 9vHPV9 vs. 2vHPV or 4vHPV for females or for 9vHPV vs. 4vHPV for males.**
- Routine vaccination at age 11 or 12 years (but, can be started at 9 years)
- Vaccination recommended through age 26 for females and through age 21 for males not previously vaccinated*
  - Vaccination recommended for men who have sex with men and immunocompromised men (including persons HIV-infected) through age 26*
- Vaccination of females is recommended with 2vHPV, 4vHPV (as long as this formulation is available), or 9vHPV
- Vaccination of males is recommended with 4vHPV (as long as this formulation is available) or 9vHPV
- If a provider does not know or have available the HPV product previously administered, or if in a setting transitioning to 9vHPV, **ANY** product can be used to complete the series.*

* ACIP off-label recommendation. MMWR 2015;64:300-4.

Summary: 9-valent HPV vaccine

- Licensed by FDA in December 2014
- Recommended by ACIP in February 2015
  - Began to be available from the manufacturer
- One of 3 HPV vaccines that can be used for routine vaccination of females and one of 2 for males
- Targets 5 additional high risk types
  - Overall 14% of HPV-associated cancers in females; 4% in males attributable to these 5 types
  - 15% of cervical cancers attributable to these 5 types

Main focus should be to increase HPV immunization coverage!

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Future ACIP Policy Considerations HPV Vaccines

- The ACIP will discuss issues related to 9vHPV for persons who have completed 3 doses of 4vHPV or 2vHPV at future meeting.
- 2-dose vs 3-dose schedules
- Stay tuned.

http://www.immunize.org/catg.d/p4251.pdf

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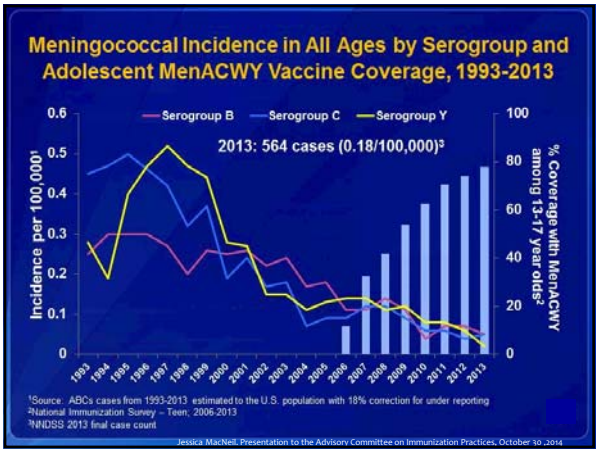
CDC "You Are the Key" Website

CDC
http://www.cdc.gov/vaccines/who/teens/for-hcp/hpv-resources.html

ACIP Meets and Makes Recommendations for the Two Newly Licensed Meningococcal Serogroup B Vaccines February 26, 2015

Recommendations, **not** yet published in the MMWR. When they are, they will be posted on the ACIP website at:
http://www.cdc.gov/vaccines/hcp/acip-recs/index.html

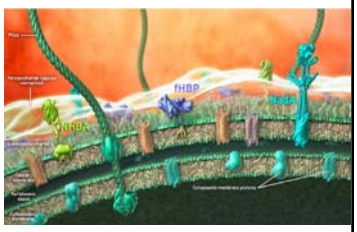


Groups at Increased Risk of Meningococcal B Disease

- High risk medical conditions:
  - Persistent complement component deficiencies
  - Functional or anatomic asplenia (including sickle cell)
- Microbiologists
- Outbreaks
  - Historically rare, causing 2-3% of all US meningococcal cases
  - 200-1,400 fold increased risk in students during serogroup B outbreaks
  - 6 serogroup B outbreaks 2006-2014
  - 2 serogroup B outbreaks to date in 2015
  - Sporadic cases of cases in college students

Meningococcal Serogroup B (MenB) Vaccines

- Two MenB vaccines are now licensed in the U.S. for persons 10–25* years of age:
  - Trumenba® (Pfizer) was licensed on 10/29/14
  - Bexsero® (Novartis) was licensed on 1/29/14



Vaccine 30S:B87,2012

- MenB vaccines are distinct from MenACWY conjugate vaccines because they are based on immunity to proteins rather than capsular polysaccharides

* ACIP has made an off-label recommendation for use in select groups ≥10 years.

Trumenba Package insert: http://labeling.pfizer.com/ShowLabeling.aspx?id=1796

Bexsero Package insert: http://novartisvaccines.com/us/downloads/Bexsero_PI.pdf

MenB-FHbp (Trumenba)

- **Composed of two factor H binding protein (fHbp) subtypes:**
  - **subfamily A/v2,3**
  - **subfamily B/v1**
- **3 dose series (0, 2, 6 mos.)**

MenB-4C (Bexsero)

- **Components:**
  - **Factor H binding protein (FHbp) subfamily B/v1**
  - **Neisserial adhesion A (NadA)**
  - **Neisserial heparin binding antigen (NhbA)**
  - **Outer membrane vesicles (OMV) containing Por A1.4**
- **2 dose series (0, 1-6 mos.)**

Same vaccine to be used to complete the series.

ACIP Recommends MenB Vaccine for Persons at Increased Risk and Outbreak Control

- The serogroup B meningococcal (MenB) vaccine series should be administered to persons aged **≥10 years*** at increased risk for meningococcal disease. (Category A) This includes:
  - Persons with persistent complement component deficiencies.[1]
  - Persons with anatomic or functional asplenia.[2]
  - Microbiologists routinely exposed to isolates of *Neisseria meningitidis.*
- MenB vaccine is also recommended for persons identified to be at increased risk because of a serogroup B meningococcal disease outbreak.

[1] Including inherited or chronic deficiencies in C3, C5-9 properdin factor D, factor H, or **taking eculizumab** (Soliris®). New
[2] Including sickle cell disease.
* ACIP an off-label recommendation (Meeting 2-26-15)

ACIP MenB Vaccines Future Considerations

- Recommendations for MenB vaccine for use in high risk groups expected to be published in MMWR soon.
- In June, the ACIP will discuss recommendations related to possible routine use in adolescents, college students or other groups; and possible "permissive" recommendations
- CDC will be issuing updated guidelines for use of MenB vaccines for outbreak control.

MDPH Immunization Program Contact Information

Immunization Program Main Number

For questions about immunization recommendations, disease reporting, etc.

- Phone: 617-983-6800
- Fax: 617-983-6840
- Website: www.mass.gov/dph/imm

MIIS Help Desk

- Phone: 617-983-4335
- Fax: 617-983-4301
- Email: miishelpdesk@state.ma.us
- Websites: www.contactmiis.info | www.mass.gov/dph/miis

MDPH Vaccine Unit

- Phone: 617-983-6828
- Fax: 617-983-6924
- Email: dph-vaccine-management@state.ma.us
- Website: www.mass.gov/dph/imm (click on Vaccine Management)

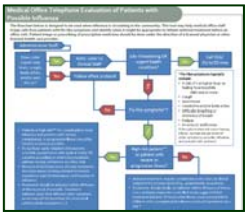
EXTRAS

CDC Influenza Treatment Guidelines

- Focus is on prevention of severe outcomes
  - Treatment of those with severe disease and persons at highest risk of severe influenza complications
  - No randomized control trials (RCTs) available
- Include observational studies and meta-analyses of antiviral effectiveness
  - Cochrane review did not consider data from observational studies
- Antiviral recommendations are common to ACIP, IDSA, AAP

http://www.cdc.gov/media/haveyouheard/stories/Influenza_antiviral2.html

High-Risk Outpatients and Early Treatment CDC Algorithm



- During influenza season, providers should advise high-risk patients to call promptly if they have symptoms of influenza
- Phone triage lines may be useful to enable high risk patients to discuss symptoms over the phone
- To facilitate early initiation of treatment, when feasible, an antiviral prescription can be provided without testing and before an office visit

Available at:
http://www.cdc.gov/flu/pdf/professionals/antivirals/antivirals-protocol-flowchart.pdf

Composition of the 2015-2016 Influenza Vaccines

- Trivalent vaccines will contain 2 new strains:
  - New · A/Switzerland/9715293/2013-like (H3N2) virus (replacing AH3N2/Texas-like)
  - A/California/7/2009-like ((H1N1)pdm09) virus (same as last year)
  - New · B/Phuket/3073/2013-like (B/Yamagata lineage) virus (replacing B/Massachusetts-like)

AND

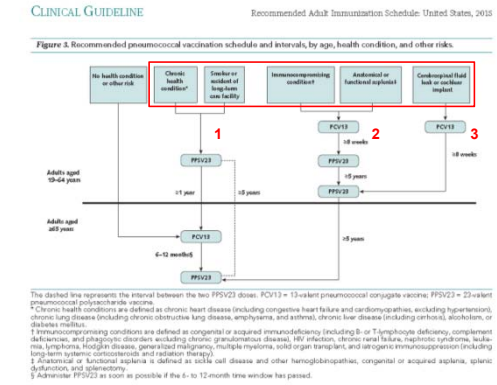
- Quadrivalent vaccines will also contain:
  - B/Brisbane/60/2008-like (B/Victoria lineage) virus same as last year).

Pneumococcal Vaccination Recommendations 2015 Adult Immunization Schedule

- **Adults ≥65 years**
  - Have not received PCV13 or PPSV23, or unknown history — PCV13 → PPSV23[1]
  - Have not received PCV13 but received PPSV23 at ≥65y — PCV13[3]
  - Have not received PCV13 but received ≥1 PPSV23 at <65y — PCV13[3] → PPSV23[1,4]
  - Have received PCV13 but not PPSV23 at <65y — PPSV23[1]
  - Have received PCV13 and ≥1 PPSV23 at <65y — PPSV23[1,4]
- **Adults 19–64 years immunocompromised, asplenia**
  - Have not received PCV13 or PPSV23, or unknown history — PCV13 → PPSV23[2] → PPSV23[4]
  - Have not received PCV13 but received 1 dose PPSV23 — PCV13[3] → PPSV23[2,4]
  - Have not received PCV13 but received 2 doses PSV23 — PCV13[3]
  - Have received PCV13 but not PPSV23 — PPSV23[2] → PPSV23[4]
  - Have received PCV13 and 1 dose PPSV23 — PPSV23[4]
- **Adults 19–64 years**
  - CSF leaks, cochlear implants — PCV13 → PPSV23[2]
  - Chronic health conditions, smoke cigarettes or reside in long-term facilities — PPSV23

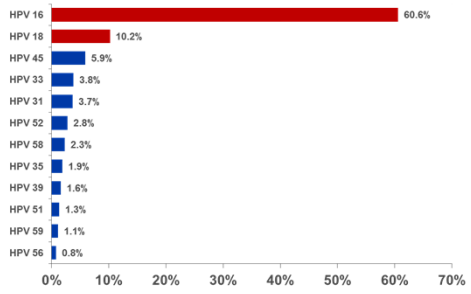
[1]6–12 mos after PCV13
[2]≥8 wks after PCV13
[3]≥1y after most recent PPSV23
[4]≥5y after most recent PPSV23

ACIP. Annals of Int Med 2-3-15



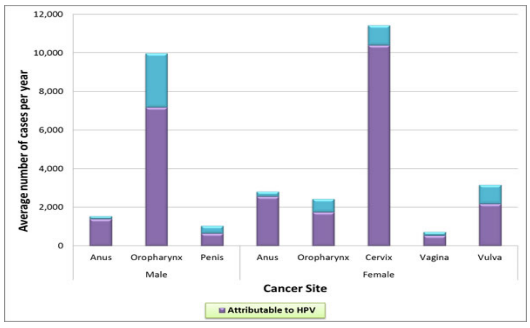
Annals of Int Med 2-3-15 MDPH 2015 76

Percentage of Cervical Cancers Attributed to High Risk HPV Types, Worldwide



de Sanjose et al. Lancet 2010 % of HPV positives and are based on the upper estimate attribution of multiple HPV types 77

Estimated Number of HPV-attributable Cancer Cases per year, United States



http://www.cdc.gov/cancer/hpv/statistics/cases.htm

Estimated percentages of cancers attributed to HPV in the U.S.

Cancer	HPV attributable % (95% CI)	HPV 16/18 attributable % (95% CI)	HPV 31/33/45/52/58 attributable % (95% CI)
Cervical	91 (88-92)	66 (63-69)	15 (12-17)
Vaginal	75 (63-84)	55 (43-67)	18 (11-30)
Vulvar	69 (62-75)	49 (41-56)	14 (10-20)
Penile	63 (52-73)	48 (37-59)	9 (4-17)
Anal			
Male	89 (77-95)	79 (66-88)	4 (1-13)
Female	92 (85-96)	80 (70-87)	11 (6-19)
Oropharyngeal			
Male	72 (68-76)	63 (59-68)	4 (3-7)
Female	63 (55-71)	51 (43-59)	9 (6-15)

Adapted from Saraiya, presented at AIN Conference, March 13–15, 2015, Atlanta, GA.

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Don't Wait: Vaccinate

- Providers don't realize how infrequently adolescents come for care
  - Vast majority of HPV vaccinations occur at preventive care visits
  - Minnesota study: 30% of 13-18 years had no preventive care visits in a 4-5 year period

http://www.immunize.org/catg.d/p4251.pdf

You may not be choosing between 4vHPV and 9vHPV;
but, between 4vHPV and nothing!

Nordin et al. Ann. Fam. Med. Nov 2010; 8(6): 511–516

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Invasive Meningococcal Disease

Estimated Average Annual Cases in Children and Adolescents During High and Low Incidence Years

	Age Group	1997-1999 "High Incidence Years"[1]	2010-2012 "Low Incidence Years"[2]
Serogroups B	<5 years	367	78-92
	11-24 years	161	48-56
	All ages	767	197-237
Serogroups C & Y	<5 years	335	39-46
	11-24 years	370	63-74
	All ages	1,490	321-386

MacNeil J. ACIP October 30, 2014

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Interim Outbreak Recommendations for Investigational MenB - 2014

Threshold for considering vaccination campaign with MenB (investigational) vaccine

- Population size <5,000: 2 or more case in 6 months
- Population size >5,000: 3 or more cases in 6 months

In addition

- Chemoprophylaxis of close contacts
- Testing of isolates: molecular genotyping
  - Determine if outbreak isolate covered by MenB vaccine(s)
  - Comparison of isolates from outbreak

Now that licensed MenB vaccines are licensed, CDC expects to be updating these guidelines later in the year.

Interim guidance for Control of serogroup B meningococcal disease outbreaks in organization settings. 2014. www.cdc/gov/meningococcal/outbreaks/vaccine-serogroupb.html