

Massachusetts Department of Public Health Bureau of Infectious Disease and Laboratory Sciences





Adult Immunization Update

April 27, 2016
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Medical Director, Immunization Program
MA Department of Public Health







DPH 2016

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Presenter Disclosure Information

I, Susan Lett, have been asked to disclose any significant relationships with commercial entities that are either providing financial support for this program or whose products or services are mentioned during my presentations.

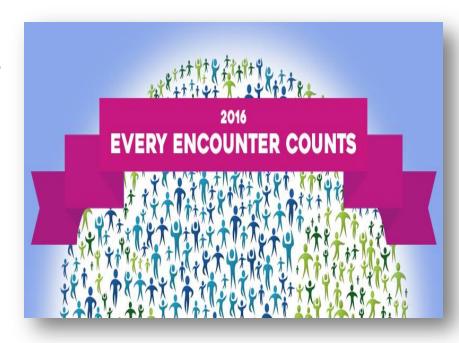
I have no relationships to disclose.

I will discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration.

But in accordance with ACIP recommendations.

Outline

- Recent Morbidity:
 Flu, Mumps, Meningitis
- Adult Immunization Rates
- Vaccine Administration Errors
- Adult Immunization Standards
- Special Initiatives
- MIIS



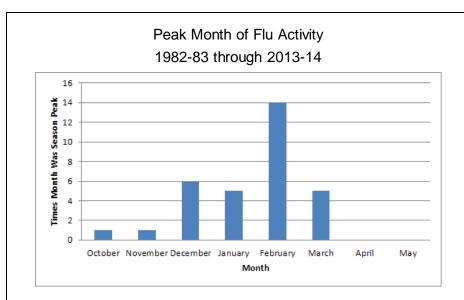
Recent Morbidity

- Flu
- Mumps
- Meningitis



2015-2016 Influenza Season National Summary

- Relatively mild season relative to other recent seasons
- Peak in early to mid March
 - One of the later peaks on record
- Influenza A (H1N1) predominated.
- Circulating strains appeared to be a good match with the vaccine
- Vaccine Efficacy Overall: 60%
 - 51 %: H1N1 viruses
 - 76 %: B viruses
 - 79 %: B/Yamagata
- Other respiratory pathogens circulated causing respiratory illness:
 - human rhino/entero, RSV, parainfluenza virus, human metapneumovirus, adenovirus, and human coronavirus.



*During 2008-2009, flu activity peaked twice because of the 2009 H1N1 pandemic. Activity in the United States peaked once in in February due to seasonal influenza activity and then again in the Spring (June), with the first wave of 2009 H1N1 viruses A second, larger peak of 2009 H1N1 activity occurred in October, the peak of the 2009-2010 season.

http://www.cdc.gov/flu/about/season/flu-season.htm

Not too late to get vaccinated!

www.cdc.gov/flu

Massachusetts Influenza-like Illness (ILI) as of 4/16/2016

5.0 4.5 2013-2014 2014-2015 2015-2016 2015-2016: 60 ILI Clusters (4/22/16) 4.0 2014-2015: 257 ILI Clusters (3/28/2015) 3.5 2013-2014: 100 ILI Clusters as of 4/29/14 % Influenza-like Illness* 2012-2013: 129 ILI Clusters 3.0 2011-2012: 52 ILI Clusters 2.5 MMWR Week 15 1.49% 2.0 April 10 - 16, 2016 1.5 1.0 0.0 21 23 25 27 29 31 MMWR Reporting Week

Figure 1: Percentage of ILI visits reported by sentinel provider sites

^{*}Influenza-like illness (ILI, defined by fever >100F and cough and/or sore throat), as reported by Massachusetts sentinel surveillance sites

Mumps Outbreak 2016

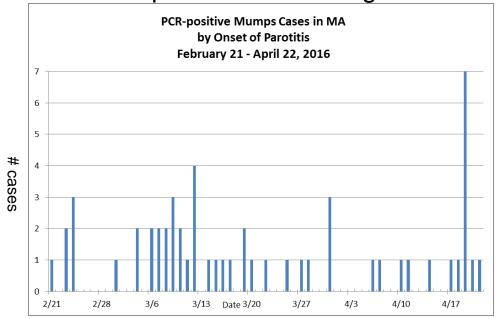
56 confirmed in MA (as of 4/22/16), all but one by PCR

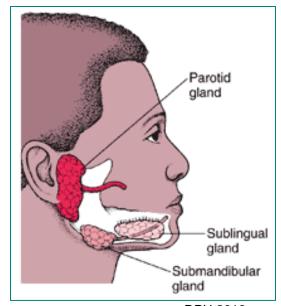
- 34 confirmed cases at Harvard
- Cases confirmed at seven other Boston-area universities
- Probable cases at two other universities
- 28 M/28 F
- Age range 15-50 Median age 21
- Majority with two MMR doses

patient is still in your office, to ensure collection of correct specimens and testing at MA PHL.

Call 617-983-6800 while

>300 suspect cases investigated since 2/15/2016





Challenges – Mumps Outbreak

- Many causes of parotitis (e.g., influenza)
- Asymptomatic and mildly ill may spread mumps
- Isolation of patients who feel well and/or have negative results – extremely important!
- Testing
 - Buccal swab in VTM for PCR soon after onset
 - False negative PCR results may occur (intermittent shedding)
 - IgM testing of limited value in vaccinated population
 - Acute/convalescent IgG titer comparison can rule in and rule out cases
- Social distancing in a college-age cohort
- Messaging when 2 doses only 88% effective (at best) in preventing mumps

Invasive Meningococcal Disease

- Five cases in two months among homeless people with ties to Boston – very unusual – 4 males/1 female
- Two deaths
- Antibiotic PEP to close contacts
- Two serogroup C; three serogroup Y
- Large vaccination campaign over 3,800 received vaccine to date
- Case-control interviews to determine risk factors







Immunization Rates





MA Receives 2015 Vaccination Coverage Awards

Outstanding Progress Towards Healthy People 2020 Goals



🦟 Adolescents Aged 13 – 17 Years

Based on 2014 NIS-Teen data 1 Tdap 93%, 1 MenACWY 92%, 1 HPV (females) 69%



Children Aged 19 – 35 months

– 4 DTaP, 3 Polio, 1 MMR, Hib full series, 3 HepB, 1 Var, 4 PCV, 1 HepA, and Rotavirus full series, based on 2014 NIS data.

Highest Coverage



Influenza Vaccination among Children Aged 6 Months – 17 Years

1 or more doses for the 2014-15 influenza season 76.1%



Highest Pneumococcal Vaccination Coverage among High-Risk Adults 18 - 64 Years

- 36.4%

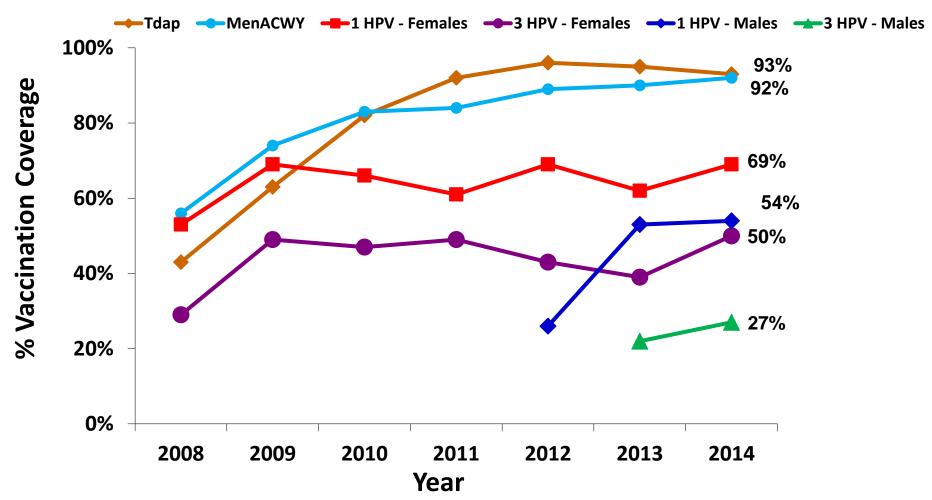
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Adult Vaccination Rates, MA and US, 2013-14

Vaccine/Group	MA 2013 ¹	MA 2014 ¹	US 2014 ²
Tdap <u>></u> 18 y/o	37%	41%	20%
Zoster ≥60 y/o	30%	39%	28%
HPV females 18-26 y/o (1+ doses)	61%	64%	40%
HPV females 18-26 y/o (3+ doses)	76%*	79%*	N/A
HPV males 18-26 y/o (1+ doses)	23%	38%	8%
HPV males 18-26 y/o (3+ doses)	30%*	N/A	N/A
Pneumococcal vaccine <u>></u> 65 y/o	70%	72%	61%

^{*}Percent of those who received at least 1 dose.

Adolescent Vaccination Coverage, Massachusetts, NIS 13-17 year Olds, 2008 – 2014



Note: For the purposes of comparability to 2014 estimates, 2013 estimates were revised by retrospectively applying the revised 2014 provider data definition to the 2013 NIS teen data and as a result, differ from those previously published.

MA Flu Vaccination Rates

	MA	MA	US
	2013-14	2014-15	2014-15
Everyone 6 mos+	53%*	#3 55%	47%*
Children 6 mos – 17 yrs	72%	#2 76%	59%
o Children 6 mos – 4 yrs	87%	81%	70%
o Children 5 – 12 yrs	72%	#3 78%	62%
o Adolescents 13 – 17 yrs	61%	#1 71%	47%
Adults 18 +	49%*	50%	44%*
o Adults 18 – 64 y/o	45%*	45%*	38%*
o Adults HR 18 – 64 y/o	58%	53%	48%
o Adults 50 – 64 y/o	51%	53%	47%*
o Adults 65+	64%*	67%	67%*

2014-15 National Immunization Survey (NIS) and Behavioral Risk Factor Surveillance System (BRFSS)

Seasonal Influenza Vaccination Rates, MA and US, ≥6 months of age, by Race/Ethnicity, 2014-2015 Season

	MA (n=11,895)	US (n=451,358)	MA Ranking
	% (CI)	% (CI)	Ranking
White	55% (±3)	49% (±0.5)	4
Black	56% (±10)	44% (±1.3)	9
Hispanic	58% (±7.5)	44% (±1.3)	7
Other	50% (±8.4)	48% (±1.7)	20

Pneumococcal Vaccination Rates, MA and US Adults 65+ years of age, by Race/Ethnicity, 2014

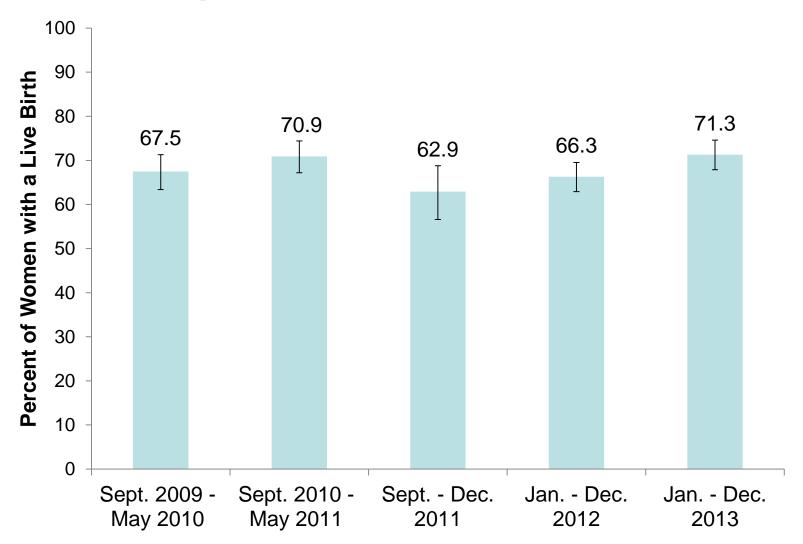
	MA	US	
	(n=4,977) ¹	(n=7,748) ²	
	% (CI)	% (CI)	
White	73% (±2)	65% (±1.6)	
Black	67% (±11)	50% (±4.4)	
Hispanic	59% (±14.6)	45% (±4.4)	

Immunization Rates in Pregnant Women, MA 2009-2013

Data from MA Pregnancy Risk Assessment Monitoring System (PRAMS)

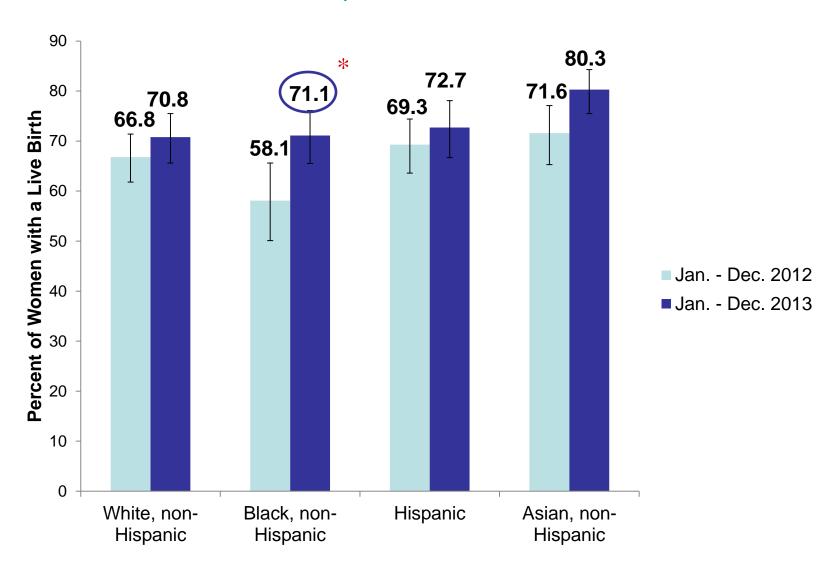


Influenza Vaccination Rates, MA Pregnant Women, 2009-2013



Source: MA PRAMS

Influenza Vaccination by Race/Ethnicity, MA Pregnant Women, 2012 vs. 2013



Source: MA PRAMS

Vaccine Administration Errors

- Employee Flu Clinic
- One & Only Campaign
- CDC Resources







Injection Safety Incident, NJ

- NJ business contracted with a health service company to provide influenza vaccine to its employees
- Plan was to use pre-filled syringes from manufacturer
- Instead nurse brought two 10-dose vials of flu vaccine to vaccinate 67 patients
 - Stored in her home refrigerator, with no temp. monitoring
 - Reported using 2 syringes to vaccinate all patients
 - Between each patient wiped syringe with alcohol and changed to new needle

<u>Impact</u>

- Public health and private sector worked together on investigation and notification of employees to:
 - Be screened for hepatitis B, hepatitis C and HIV
 - Receive HepB vaccine if indicated
 - Be revaccinated with influenza vaccine
- Nurse had to surrender her license
- CDC developed new materials

One & Only Campaign: Injection Safety Guidelines

- Follow proper infection control practices and maintain aseptic technique during the preparation and administration of injected medications
- Never administer medications from the same syringe to more than one patient, even if the needle is changed
- **Rx for Safe Injections** in Healthcare 1 Needle 1 Syringe +1 Time **O** Infections Injection safety, or safe injection practices, are practices intended to prevent transmission of infectious diseases. Patients and healthcare providers must both insist on nothing less than One Needle, One Syringe, Only One Time for each and every injection. For more information, please visit: www.ONEandONLYcampaign.org The One & Only Campaign is a public health
- Never enter a vial with a used syringe or needle
- Do not use medications packaged as a single-dose or singleuse for more than one patient
- Whenever possible and appropriate, limit use of multi-dose vials

CDC &Safe Injection Practices Coalition http://www.cdc.gov/injectionsafety/1anOnly.html

CDC Resource Page



Injection Safety http://wwwn.cdc.gov/pubs/CDCInfoOnDemand.aspx

ction Safety Dangerous

http://maic.jsi.com/resources/injection-safety-article-and-related resources/

CDC At-A-Glance Resource Guide

- Immunization service providers and business retaining their services should ensure staff adhere to CDC guidelines.
- New Guide includes links to info about:
 - Infection prevention
 - Vaccine administration and safety
 - ACIP Gen Imm Recs
 - · Skills checklists
 - Standing Orders
 - Vaccine storage and handling practices
 - Reporting to:
 - VAERs
 - Institute for Safe Medication Practices (ISMP)
 - VPD epidemiology

AT-A-GLANCE RESOURCE GUIDE VACCINE ADMINISTRATION AND STORAGE AND HANDLING

IMMUNIZATION AND VACCINES (GENERAL)

General Recommendations on Immunization - Recommendations of the Advisory Committee on Immunization Practices (ACIP) Guidance about vaccination and vaccines for health care providers. www.cdc.gov/mmwr/preview/mmwr/tml/refoozat.htm

Epidemiology and Prevention of Vaccine-Preventable Diseases (the Pink Book), 13th Edition: Course Textbook (2015)

Comprehensive information on routinely used vaccines and the diseases they prevent. www.cdc.gov/vaccines/pubs/ pinkbook/index.html

The Pink Book Webinar Series

One-hour webinars with CDC experts exploring chapters of the Pink Book. www.cdc.gov/vaccines/ed/webinar-epv/index.html

"You Call the Shots" Online Training Modules

A series of training modules for health care providers on vaccine recommendations with self-tests to assess learning. CE credit available. www.cdc.gov/vaccines/ed/youcalltheshots.htm

Vaccine Safety

Safety information about specific vaccines and answers to commonly asked questions.

www.cdc.gov/vaccinesafety/index.html

Vaccine Information Statements (VIS) Statements required by law to inform patients about the benefits and risks of a vaccine they are receiving. www.cdc.gov/vaccines/hcp/vis/

VACCINE STORAGE AND HANDLING

- Epidemiology and Prevention of Vaccine-Preventable Diseases (the Pink Book): Storage and Handling Chapter www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html
- Vaccine Storage and Handling Guidelines and Recommendations
 Resources on vaccine storage and handling recommendations and guidelines. http://www.cdc.gov/vaccines/recs/storage/default.htm
- Vaccine Storage and Handling Toolkit

Comprehensive guidance for health care providers on vaccine storage and handling recommendations and best practices. www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

"Keys to Storing and Handling Your Vaccine Supply" Training Video This training outlines vaccine storage and handling best practices, and provides helpful tips for preventing errors and preserving vaccine supply and integrity. www2.cdc.gov/vaccines/ed/shvideo/_

VACCINE ADMINISTRATION

Skills Checklist for Immunization

A self-assessment tool from the Immunization Action Coalition for health care staff who administer vaccines. www.immunize.org/catg.d/p7010.pdf

 Epidemiology and Prevention of Vaccine-Preventable Diseases (the Pink Book): Vaccine Administration Chapter

www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html

Vaccine Administration Guidelines and Recommendations

CDC resources include information on vaccine dosage, route, and site; vaccines with diluents; sample vaccine records; recommendations for emergency situations; managing vaccine reactions; and vaccine indications. www.cdc.gov/vaccines/recs/vac-admin/default.htm

► Injection Safety

vaccination.

Information for health care providers about safe injection practices. www.cdc.gov/injectionsafety/providers.html

- Using Standing Orders for Administering Vaccines: What You Should Know The Immunization Action Coalition provides standing orders for ACIPrecommended vaccines and an overview about the use of standing orders for
- www.immunize.org/standing-orders/

December 2015 08249278-K



http://www.cdc.gov/vaccines/recs/downloads/vacc-admin-storage-guide.pdf



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

Adult Immunization Practice Standards

- Call to action for healthcare professionals for evidence-based activities
 - 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/



MA Special Initiatives







Tools that Help Improve Immunization Rates

- Partnerships
- Tools to address vaccine confidence
- 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
 - MIIS







Immunization Neighborhood

Collaboration, Coordination, and Communication:

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





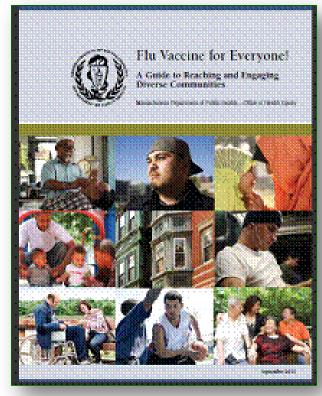


Collaboration with the Office of Health Equity

(OHE)

Immunization Program has a long history of collaboration with OHE and the Office of Emergency Preparedness to offer assistance and resources to public health agencies to help reduce immunization disparities in their communities

http://www.mass.gov/eohhs



http://www.mass.gov/eohhs/docs/dph/cdc/flu/vaccine-admin-diverse-communities.pdf

HPV Communication Strategies

- Talk about HPV vaccination as cancer prevention! Cancer prevention is important to parents so remind them that certain HPV types cause not only cervical cancer but anal, penile, vaginal, vulvar, and oropharyngeal cancers as well.
- Recommend the HPV vaccine the same way and on the same day as other vaccines.
- Example:
 - "Now that your child is 11, they are due for three shots that are really important for all kids their age: HPV, meningococcal, and Tdap. I recommend giving these at the end of the visit today."



New MDPH resource found at http://mcaap.org/immunization
-hpv/

Innovative Opportunity for OB-GYNs to Improve Their Immunization Programs

- American College of Obstetricians and Gynecologists (ACOG) 3 year grant to increase immunization rates for <u>all</u> women in CA and MA
- MA Chapter of ACOG is looking for practices to participate:
 - Learn about innovative ways to improve immunization rates
 - Be recognized as leader on the state and national level
- Eligibility requirements for participation includes the following:
 - ACOG membership
 - EHR system that can be used to track data requirements such as immunization rates
 - Serve both adult obstetrical and adult gynecology patients
 - Willingness to participate in state health department's immunization registry
- For more information, visit
 www.immunizationforwomen.org/projects



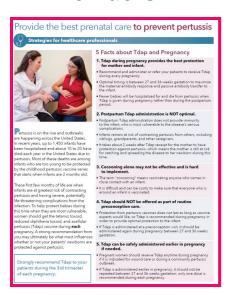




"Born with Protection" MATERNAL Tdap CAMPAIGN

Tdap is recommended with **every** pregnancy during the 3rd trimester

Providers



An infant's 1st dose of Tdap is the one you give his/her mother during pregnancy

Patients



Fact Sheets:

Providers: http://www.cdc.gov/pertussis/downloads/fs-protecting-before-birth.pdf
Mothers: http://www.cdc.gov/pertussis/downloads/fs-hcp-provide-prenatal-care.pdf

Standing Orders

- Protocol enabling assessment of vaccination status and vaccine administration w/o direct physician order
 - Provider offices
 - Health departments
 - Schools & their health centers
 - Pharmacies
 - Commercial vaccinators



 Facilitates adolescents and adults beginning vaccination in one venue and finishing in another

Strong evidence from over 34 studies with a median increase in immunization coverage from 24-27 percentage points.

Standing Orders in MA

- Licensed registered and practical nurses and can administer vaccines using standing orders (BORN Advisory Ruling No. 9804, updated 9-9-15)
 - http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/nursing/nursingpractice/advisory-rulings/administration-of-immunizing-agents.html
- Pharmacists (and interns under supervision of a pharmacist) can administer vaccines to adults using standing orders written by a physician (105 CMR 700.004(B)(6)(c)1)
 - http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/alerts/policy-2015-01.pdf

IAC model standing orders available at:

http://www.immunize.org/standing-orders/

MDPH model standing orders available at:

www.mass.gov/dph/imm



Project to Increase the Use of Standing Orders

- This workshop is a one-stop shop to help you easily implement standing orders in your practice.
- Using standing orders for adult immunizations can help your practice be a leader in quality adult care.

Interactive workshop led by nationally recognized expert speakers

L.J Tan, MS, PhD, Chief Strategy Officer, Immunization Action Coalition

William Atkinson, MD, MPH, Associate Director for Immunization Education, Immunization Action Coalition

Alexandra Stewart, JD, Associate Professor, George Washington University

The Westin Copley Place
June 6, 2016
10:00 am - 2:30 pm
Lunch included

REGISTER ONLINE TODAY!

Don't delay. Space is limited.

www.StandingOrders.org

HealthMap Vaccine Finder

 HealthMap Vaccine Finder assists the public with locating <u>influenza and other adult vaccination</u> <u>services</u> in their communities.

HealthMap Vaccine Finder:

http://flushot.healthmap.org/

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



Flu Clinic Website MA Health Officers Association







Affordable Care Act & 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





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
 - 10 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
 - 178 public sector providers across the state participate, representing 214 out of 351 towns in MA
- > \$2 million reimbursed to communities last flu season

Submit Insurance Form Public Clinics CHCF Submits Claim After Date Entry Health Plans

Distributes payments

Send payment explanation



Vaccinations Across the Lifespan

MIIS



RAPID EXPANSION OF THE MIIS SINCE 2011!

2014

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

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

2016

- Total Sites: 1649
- Total Patients:4,819,805
- Total Shots:33,996,056

2015

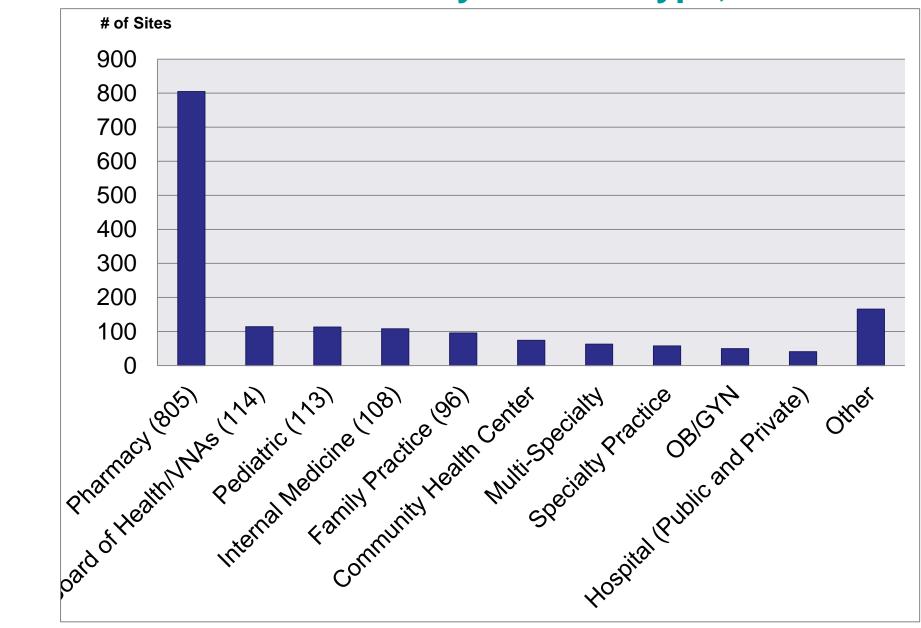
- Total Sites: 1121
- Total Patients: 4,427,623
- Total Shots:33,334,571



2011

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

Number of Sites by Practice Type, MIIS



MIIS Enhancements to Come...

Late Spring

- Vaccine Recall
- Returns/Storage & Handling
- Flu ceiling/Flu Ordering
- Temperature Log Work List
- Transfer Vaccines Report
- System Usage Dashboard

Late Summer

- School Module
- Coverage Reports
- Roster Entry





DPH 2016

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)



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EXTRAS

Vaccine Strain Selection for 2016-2017 Seasons

For 2016-17, WHO recommended a new H3N2 component.

The B components switched places, from IIV3 to IIV4, compared to the 2015-16 Northern Hemisphere vaccine:

2016-2017 2015-2016 A/California/7/2009 A/California/7/2009 (H1N1)pdm09-(H1N1)pdm09-like virus like virus A/Hong Kong/4801/2014 (H3N2)- A/Switzerland/9715293/2013 like virus (H3N2)-like virus B/Brisbane/60/2008-like virus B/Phuket/3073/2013-like virus (Victoria lineage) (Yamagata lineage) for quadrivalent vaccines, for quadrivalent vaccines, B/Phuket/3073/2013-like virus B/Brisbane/60/2008-like virus

(Yamagata lineage)

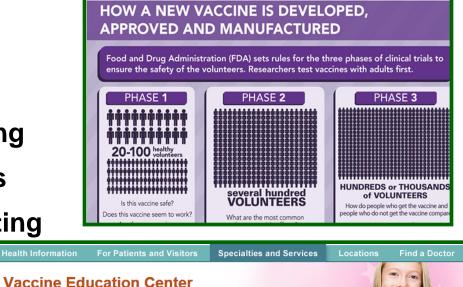
WHO: http://www.who.int/influenza/vaccines/virus/recommendations/2016_17_north/en

(Victoria lineage)

MDPH Vaccine Safety and Confidence Website

- Identifies the most helpful and reliable sources of information.
- Sections:
 - Information for Providers
 - Information for Parents
 - Vaccine Approval and Monitoring
 - Vaccine Information Statements
 - Vaccine Adverse Events Reporting System
 - Vaccine Administration Error Reporting





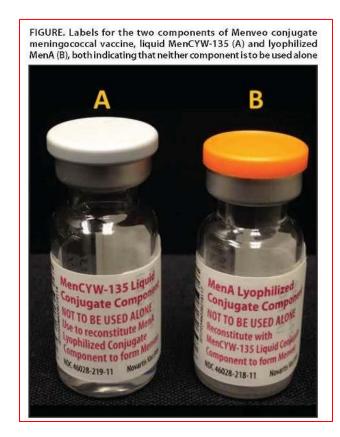
http://www.mass.gov/eohhs/gov/departments/dph/programs/id/immunizati on/vaccine-safety.html

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Menveo Administration Errors

CDC. MMWR 2016;65:161-162.

http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6506.pdf



Menveo Administration Errors March 2010 – September 2015

Morbidity and Mortality Washly Earnest

Notes from the Field

Administration Error Involving a Meningococcal Conjugate Vaccine — United States, March 1, 2010–September 22, 2015

John R. Su, MD²; Elaine R. Miller, MPH²; Jonathus Duffy, MD²; Bethany M. Baer, MD²; Maria V, Cano, MD²

Menveo (GlaxoSmithKline, previously Novartis AG) is a conjugate vaccine that was recommended in October 2010 for routine use in adolescents (preferably aged 11 or 12 years, with a booster at 16 years), and among persons aged 2 through 54 years with certain immunosuppressive conditions, to prevent invasive meningococcal disease caused by Neineria meningitidis serogroups A, C, Y, and W-135 (1). These recommendations have since been updated (2). Menveo is supplied in two vials that must be combined before administration The MenA lyophilized (freeze-dried) component must be reconstituted with the MenCYW-135 liquid component (Figure). To administer the vaccine, the liquid component is drawn into a syringe, and used to reconstitute the lyophilized component. The resulting solution is administered by intramuscular injection. Failure to prepare Menveo as directed by the manufacturer's instructions can lead to lack of protection against the intended pathogens (N. moningitidis ecogroups A, C, Y, and/or W-135) (3). Recently, an immunization provider administered only the lyophilized component of Menveo, subsequently administered a properly prepared dose of Menveo to the same patient, and asked CDC if this practice was safe. This question prompted CDC to search the Vaccine Adverse Event Reporting System (VAERS) database for reports during March 1, 2010-September 22, 2015, of only one component of Menveo being administered. Additionally, to more broadly identify disproportional reporting of adverse events in general following Menveo immunization compared with other vaccines in VAERS (including errors in vaccine preparation and administration), the Food and Drug Administration performed data mining with empiric Bayesian methods (4).

There were 390 reports of administration of only one component of Menwes to a total of 407 recipients. A total of 296 f6699 recipients received only the liquid MenCVW-135 component, and 138 recipients received only the lyophilized MenA component, reconstituted in sterlle water, saline, a different liquid vaccine (heparitis B vaccine in two cases, and different liquid vaccine (heparitis B vaccine in two cases, and dipheteris-team-asseclidar perturbated [DTAP] vaccine in one case), or an unspecified dilutent. Six reports described distinstration of only the liquid MenCVW-135 component to a total of 21 recipients, and one described administration of only the liquid MenCVW-135 component to a total of 21 recipients, and

FIGURE. Labels for the two components of Menveo conjugate meningococcal vaccine, liquid MenCYW-135 (A) and tyophilized MenA (B), both indicating that neither component is to be used alone



component to two recipients. Among 344 recipients whose sex was reported, 160 (51%) were made. The median age of 293 recipients with known age was 15 years (range 3–0-65 years). St?/we were aged 11–20 years. Among all 407 recipients, 346 (85%) operienced no adverse events the terported adverse events included redoness, fever, and pain. Medical Dictionary for Regulatory Activities (MedIDRA) preferred serum² that were reported at least wice as frequently as expected for Merwor (compared with all other vascines) were all associated with administration of only one commonent of Merwor.

Vaccination providers should follow the instructions provided with Menveo (including vaccine labeling, packaging, and product insert) regarding proper administration. Vaccines

MedDEA, durqu'/www.maddra.org/how-no-une/unport-do-cumentations english) provides a randandizad costobaley of mediald ineminology to facilitate sharing of regularory information. MedDEA terms are hierarchical, from very specific low-level seams that are grouped into: "preferred neums," to broad groups of seams regarding copies options. For this analysis, preferred neums were the root appropriate level of specificity for data minung.

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- Menveo is supplied in two vials that must be combined before administration.
- The MenA lyophilized (freeze-dried) component must be reconstituted with the MenCYW-135 liquid component.
- To administer, the liquid component is drawn into a syringe, and used to reconstitute the lyophilized component.
- The resulting solution is administered by intramuscular injection.

VAERS REPORTS (3/1/2010 - 9/22/2015)

390 reports of <u>only one component administered</u> to 407 recipients (which is twice as high as expected)

- 66% received only the liquid MenCYW-135 portion
- 34% received only the lyophilized MenA component reconstituted a variety of ways (including with other liquid vaccines)
- No adverse events were identified

CDC. MMWR 2016;65:161-162.

Recommendations to Avoid Menveo Administration Errors

- Providers should follow instructions that come with Menveo (including vaccine labeling, packaging, and product insert) regarding proper administration.
- Vaccines requiring reconstitution should only be reconstituted with the specific diluent supplied by the manufacturer for that vaccine.
- A recipient who receives an improperly prepared dose of Menveo should receive a repeat dose of MCV prepared according to manufacturer instructions; this repeat dose can be administered at any time.
- However, because serogroup A meningococcal disease is rare in the United States, patients only receiving the liquid MenCYW-135 component of Menveo might not need revaccination, unless international travel is anticipated (especially travel to Africa).

CDC. MMWR 2016;65:161-162.

Vaccines with Diluents: How to Use Them

Be sure to reconstitute the following vaccines correctly before administering them! Reconstitution means that the lyophilized (freeze-dried) vaccine powder or wafer in one vial must be reconstituted (mixed) with the diluent (liquid) in another.

- Only use the diluent provided by the manufacturer for that vaccine as indicated on the chart.
- ALWAYS check the expiration date on the diluent and vaccine.
 NEVER use expired diluent or vaccine.

Vaccine product name	Manufacturer	Lyophilized vaccine (powder)	Liquid diluent (may contain vaccine)	Time allowed between reconstitution and use, as stated in package insert°	Diluent storage environment
ActHIB (Hib)	Sanofi Pasteur	Hib	0.4% sodium chloride	24 hrs	Refrigerator
Hiberix (Hib)	GlaxoSmithKline	Hib	0.9% sodium chloride	24 hrs	Refrigerator or room temp
Imovax (RAB _{HDCV})	Sanofi Pasteur	Rabies virus	Sterile water	Immediately [†]	Refrigerator
M-M-R II (MMR)	Merck	MMR	Sterile water	8 hrs	Refrigerator or room temp
MenHibrix (Hib-MenCY)	GlaxoSmithKline	Hib-MenCY	0.9% sodium chloride	Immediately [†]	Refrigerator or room temp
Menomune (MPSV4)	Sanofi Pasteur	MPSV4	Distilled water	Single-dose vial: Immediately† Multidose vial: 35 days	Refrigerator
Menveo (MCV4)	Novartis	MenA	MenCWY	8 hrs	Refrigerator
Pentacel (DTaP-IPV/Hib)	Sanofi Pasteur	Hib	DTaP-IPV	Immediately†	Refrigerator
ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Refrigerator or room temp
RabAvert (RAB _{PCECV})	Novartis	Rabies virus	Sterile water	Immediately†	Refrigerator
Rotarix (RV1)‡	GlaxoSmithKline	RV1	Sterile water, calcium carbonate, and xanthan	24 hrs	Refrigerator or room temp
Varivax (VAR)	Merck	VAR	Sterile water	30 min	Refrigerator or room temp

http://www.immunize.org/catg.d/p3040.pdf