Immunization Update

IHS California Providers' Best Practices and GPRA Measures Conference

Disclosures

- Speakers have no financial conflict of interest with any of the vaccine products that we will be discussing today.
- Any discussion of off-label use will be for educational purposes only.

Overview

- **New Vaccines and ACIP Recommendations**
  - Meningococcal Vaccines
    - Reminder: MenACWY (MCV4) recommendations
    - Meningococcal serogroup B vaccines
  - 9-valent HPV vaccine
- **Update on recommended intervals between PCV13 and PPSV23 for adults 65 years and older**
- **Other ACIP Recommendations**
- **Resources**

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Meningococcal Disease

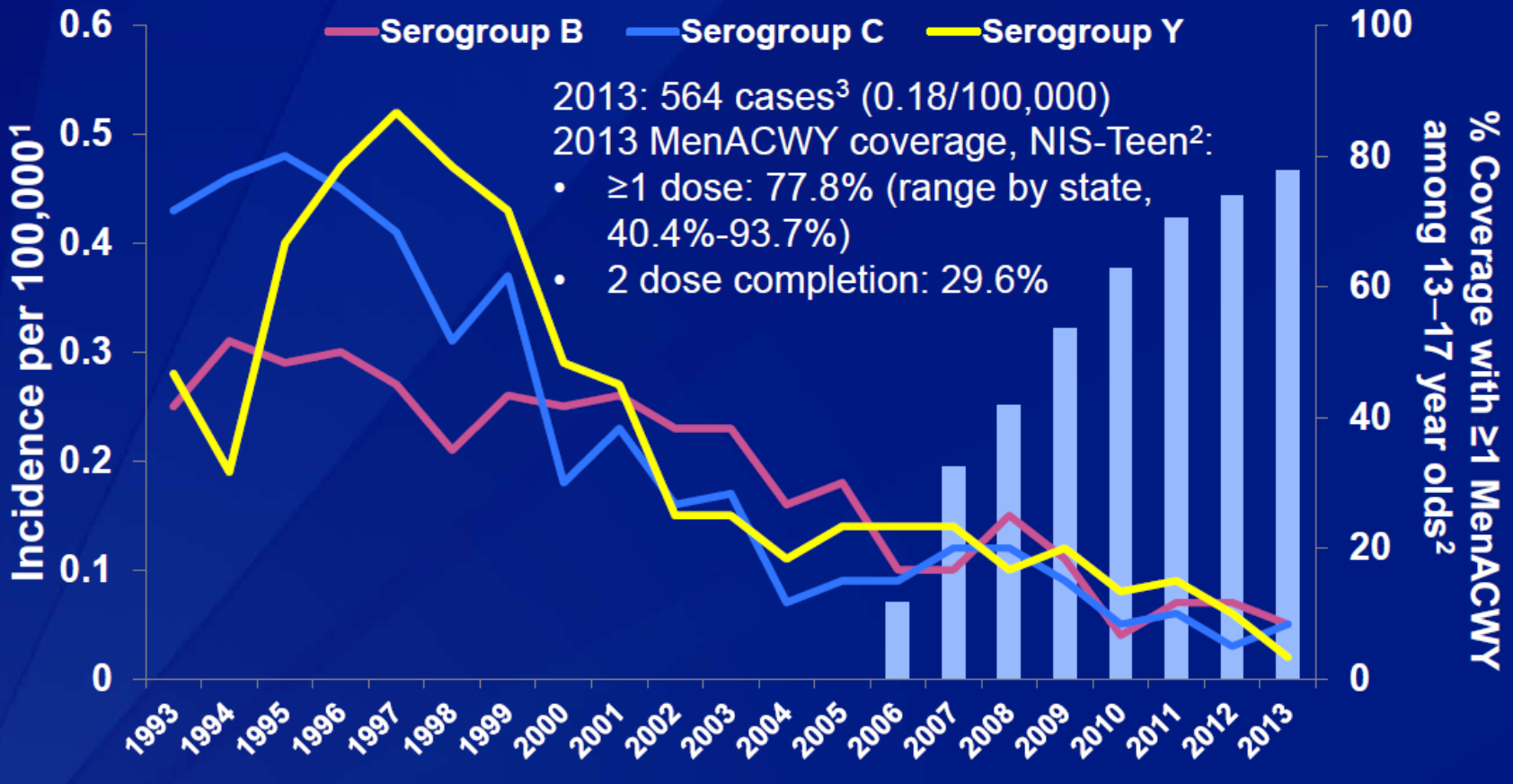
Meningococcal Disease

- **Bacterial disease caused *by Neisseria meningitidis***
- **Transmitted through direct contact with large-droplet respiratory tract secretions from patients or asymptomatic carriers.**
- **Incubation period: 3-4 days (range of 2-10 days)**
- **Abrupt onset fever, meningeal symptoms, hypotension, and rash**
- **Clinical presentation:**
  - Meningitis
  - Bacteremia/Sepsis
  - Pneumonia

Complications

- **Case fatality rate of 10-15%, even with appropriate antibiotics**
  - Meningococcemia - 40% case fatality rate
- **Permanent sequelae in 20% of survivors**
  - Hearing loss, neurologic damage, or loss of limb(s)

Meningococcal Incidence in All Ages by Serogroup and Adolescent MenACWY Vaccine Coverage, 1993–2013



[1]Source: Active Bacterial Core surveillance (ABCs) cases from 1993-2013 estimated to the U.S. population with 18% correction for nonculture confirmed cases. In 2010, estimated case counts from ABCs were lower than cases reported to the National Notifiable Diseases Surveillance System (NNDSS) and might not be representative.

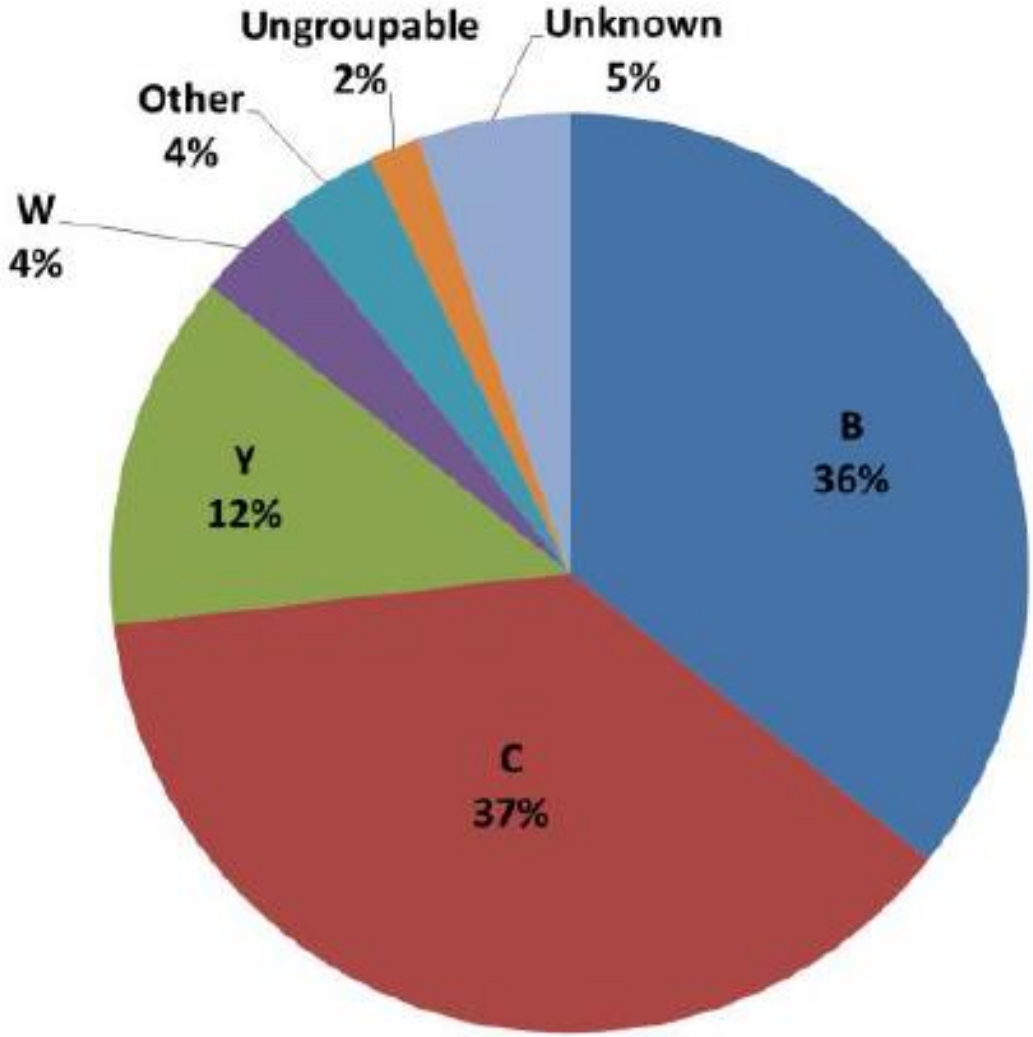
[2]National Immunization Survey-Teen; 2006-2013.

[3]NNDSS 2013 final case count

Meningococcal Serogroups

- Classified based on structure of the polysaccharide capsule
- Thirteen antigenically and chemically distinct polysaccharide capsules have been described
- Some strains do not have a capsule and are not groupable
- Almost all invasive disease is caused by one of five serogroups (A, B, C, W and Y)

Figure 4. Invasive meningococcal disease cases by serogroup -- California, 2014



http://www.cdph.ca.gov/programs/immunize/Documents/VPD-DiseaseSummary2014.pdf

Meningococcal Conjugate Vaccines for Adolescents and Adults

- **MenACWY (MCV4)**
  - Meningococcal capsular polysaccharide is conjugated to a protein carrier, resulting in stronger immune responses to the polysaccharide
    - Primary
    - Anamnestic (memory) at re-exposure

Vaccine	Conjugate Protein	Age Licensure
Menactra®	Diphtheria toxoid	9 months through 55 years
Menveo®	CRM197 (nontoxic form of diphtheria toxin)	2 months through 55 years

ACIP Recommendations: Quadrivalent Meningococcal Conjugate Vaccines

- **Routinely recommended for all adolescents**
  - Dose 1 at age 11-12 years of age
  - Booster at age 16 years

- **Protects against serogroups A, C, Y, and W-135**

Note: adolescents aged 11 through 18 years who are HIV+ should receive a 2-dose primary series with at least 8 weeks between doses

http://www.cdc.gov/mmwr/pdf/rr/rr6202.pdf

Recommended for Persons 2 Months and Older at High-Risk for Meningococcal Disease

- Persons who have persistent complement component deficiencies (including inherited or chronic deficiencies in C3, C5-C9, properdin, factor H, or factor D or taking eculizumab [Soliris®])
- Persons who have anatomic or functional asplenia, including sickle cell disease
- Persons identified to be at increased risk because of a meningococcal disease outbreak attributable to the vaccine serogroup
- Persons who travel to or reside in countries in which meningococcal disease is hyperendemic or epidemic, including countries in the African meningitis belt or the Hajj

Additional ACIP High-Risk Groups in Adults (MenACWY)

- First-year college students who are living in residence halls if did not receive a dose on or after their 16th birthday
- Microbiologists routinely exposed to isolates of *Neisseria meningitidis*
- Military recruits

Meningococcal Conjugate Vaccine (MenACWY) Boosters for Those Who Remain at High-Risk

- **Primary series received before age 7 years**
  - 1st booster in 3 years
  - Boosters every 5 years thereafter.
- **Primary series received after 7th birthday**
  - Boosters every 5 years.

http://www.cdc.gov/mmwr/pdf/rr/rr6202.pdf

Conjugate Meningococcal Vaccines: Primary Series Schedule for High-Risk Children

Vaccine	Age Indications/Schedule
Menveo® Serogroups A, C, Y, W-135	2 months through 55 years • 2 through 6 months: 2, 4, 6, and 12 months • 7 through 23 months: Give 2 doses, 2nd dose at least 12 weeks after 1st dose and after the first birthday • 24 months through 18 yrs: 2 doses at least 8 wks apart
Menactra® Serogroups A, C, Y, W-135	9 months through 55 years • 9 through 23 months*: 2 doses at least 12 wks apart • 24 months through 18 yrs: 2 doses at least 8 wks apart
MenHibrix® Serogroups C and Y only	6 weeks through 18 months • 2, 4, 6, and 12-15 months • 1st dose at/after 12 mos: 2 doses at least 8 wks apart

*If Menactra ® is administered to a child with asplenia (including sickle cell disease), do not administer Menactra ® until 2 years of age and at least 4 weeks after the completion of all PCV13 doses.

Men B Vaccine

History of MenB Vaccines

- **Capsular polysaccharide vaccines for MenB have been unsuccessful because its structure is antigenically similar to proteins in human neural tissue**
  - Poor immunogenicity
  - Potential of autoantibody generation
- **Research has focused on conserved outer membrane proteins and other vaccine targets**

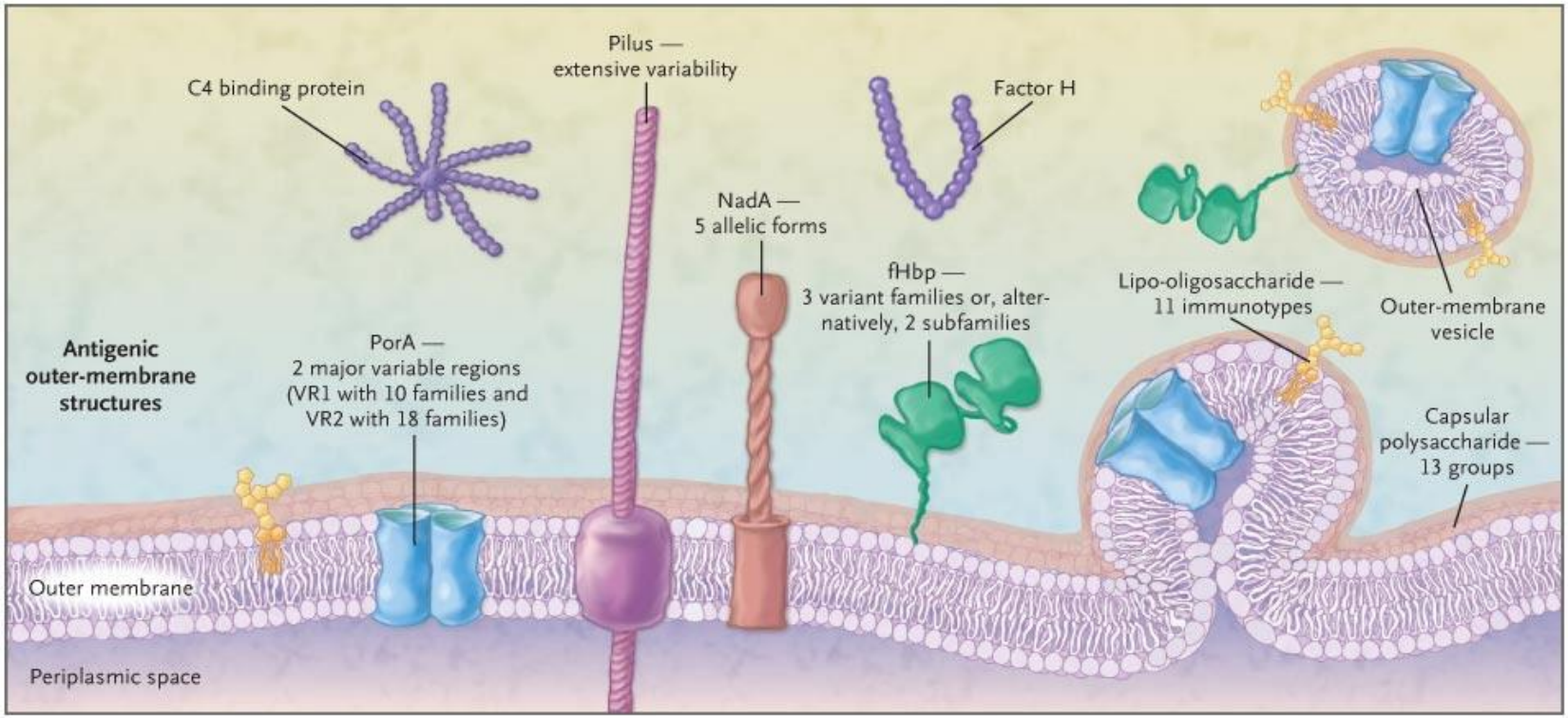
Findlow, 2016.

First Successful MenB Vaccines

- **First MenB vaccine incorporated outer membrane vesicles (OMVs) from local outbreak strains in response to clonal epidemics**
  - Norway, Cuba, Chile, and New Zealand
- **Showed efficacy in all age groups**
- **Protection generally specific to the clonal outbreak strain**
  - Need for broader coverage

Findlow, 2016.

Structure of Meningococcal Outer Membrane, Showing Variability of Outer-Membrane Proteins and Capsule Used in Vaccines and Interaction with Complement.



Tan LK et al. N Engl J Med 2010;362:1511-1520.

The NEW ENGLAND JOURNAL of MEDICINE

Licensed Serogroup B Meningococcal (Men B) Vaccines--Trumenba® (Wyeth/Pfizer)—MenB-FHbp

- **Licensed October 2014**
- **Licensed for persons 10 through 25 years of age**
- **Proteins: Two FHbp (subfamily A and B)**
- **3 dose series (0, 2, 6 month schedule)**

  2 dose series (0, 6 month schedule) – April 2016
- **Adverse events:**
  - Most common solicited adverse reactions observed in the 7 days after receipt were pain at the injection site (≥85%), fatigue (≥40%), HA (≥35%), myalgia (≥30%), and chills (≥15%).

Licensed Serogroup B Meningococcal (Men B) Vaccines--Bexsero® (Novartis/GSK)—Men B-4C

- Licensed January 2015
- Licensed for persons 10 through 25 years of age
- Proteins: NadA, NHBA, fHbP, OMV (PorA)
- 2 dose series (0, 1-6 month schedule)
- Tip caps of prefilled syringes contain natural latex
- Adverse events:
  - The most common solicited adverse events were pain at the injection site (≥83%), myalgia (≥48%), erythema (≥45%), fatigue (≥35%), headache (≥33%), induration (≥28%), nausea (≥18%), and arthralgia (≥13%).

Work Group Interpretation: Burden of Disease

- **Incidence of disease has declined for all meningococcal serogroups, including serogroup B**
  - Currently at a stable low in disease incidence
- **Approximately 55–65 cases of serogroup B meningococcal disease occur in adolescents and young adults each year**
  - The majority of those cases occur in older adolescents and young adults aged 16–24 years
- **Approximately 40-70% of serogroup B cases in 18–23 year olds occur in college students**
  - Incidence in college and non-college students is similar

MacNeil, ACIP Meeting, June 2015.

Work Group Interpretation: Immunogenicity

- **Immunogenicity suggests short term efficacy**
- **Evidence of waning antibody levels within 6 months post dose 3 for MenB-FHbp**
  - Appears to stabilize 6-48 months post dose 3
- **Modest waning in antibody observed through 24 months post dose 2 for MenB-4C**
  - Data from Chilean adolescents with higher baseline bactericidal antibodies compared to U.S. adolescents
- **Proportion of vaccinees who develop bactericidal antibodies may vary with each outbreak or circulating strain**

MacNeil, ACIP meeting, June 2015

Safety Summary

- **MenB vaccines are more reactogenic than other vaccines given during adolescence**
- **Majority of local & systemic reactions are mild to moderate in severity and transient**
  - Most common AE was pain at injection site
- **SAE rare and similar between vaccine recipients and controls in clinical trials**
- **Safety data not currently available in groups at increased risk**

MacNeil, ACIP meeting, February 2015

MenB Vaccines - Summary

- **Current data suggest Men B vaccines will protect against the majority (but not all) of currently circulating sergroup B strains).**
  - Ongoing studies to understand breadth of coverage.
- **Data based on immune response predict efficacy in most individuals in the short term but no data on clinical effectiveness or duration of protection against clinical disease (rare outcome).**
- **Awaiting additional data on impact of vaccines on nasopharyngeal carriage and herd protection**
- **Current low prevalence of disease**
- **Continued review of safety of these vaccines post licensure**

Meningogoccal Serogroup B Vaccine

- **A serogroup B meningococcal (MenB) vaccine series may be administered to adolescents and young adults 16 through 23 years of age to provide short term protection against most strains of serogroup B meningococcal disease.**
  - The preferred age for MenB vaccination is 16 through 18 years of age.

http://www.cdc.gov/mmwr/pdf/wk/mm6441.pdf#page=11

Additional Guidance

- **MenB should be administered as either**
  - a 2-dose series of MenB-4C (Bexsero®) or
  - a 3-dose series of MenB-FHbp (Trumenba) ®
- **The same vaccine product should be used for all doses in a series. The two vaccines are NOT interchangeable.**

Meningococcal Serogroup B Vaccine ACIP Recommendations

- **Recommended for persons aged 10 years and older at increased risk for meningococcal disease, including:**
  - Persons with persistent complement component deficiency (including persons taking eculizumab (Soliris®)
  - Persons with anatomic or functional asplenia, including sickle cell disease
  - Microbiologists routinely exposed to isolates of *Neisseria meningitidis*
  - Persons identified to be at increased risk because of a serogroup B meningococcal disease outbreak.

http://www.cdc.gov/mmwr/pdf/wk/mm6422.pdf#page=8

Summary: Licensed Meningococcal Vaccines

Trade name	Type of Vaccine	Meningococcal Serogroups Covered
Menactra®	Conjugate MenACWY	A, C, W, Y
Menveo®	Conjugate MenACWY	A, C, W, Y
MenHibrix®	Conjugate HibMenCY	C, Y (and *Haemophilus influenzae* type b [Hib])
Menomune®	Polysaccharide	A, C, W, Y
Bexsero®	Recombinant MenB	B
Trumenba®	Recombinant MenB	B

Common Questions

I have a 16 year old coming in today. Can I give both the meningococcal conjugate vaccine (MenACWY) and a MenB vaccine at the same visit?

- Yes, you can give a booster of MenACWY and the first dose in the series of MenB vaccine (Bexsero®, Trumenba®) at the same visit but at a different anatomic site, if feasible. The booster dose of meningococcal conjugate vaccine (Menactra®, Menveo®) is recommended at age 16 years. Men B vaccines may be given to all 16-23 year olds. Make sure to make a follow-up appointment for remaining doses of MenB vaccine in the series.

Can someone finish a series started with one brand of MenB vaccine and complete the series with the other MenB vaccine?

- No. The two MenB vaccines are not interchangeable. The vaccine series should be completed using the same MenB vaccine brand.

Can I offer VFC supplies of MenB vaccine series to all my 16-18 year old VFC patients? Or just those with high-risk conditions?

- Yes, any VFC-eligible person 16 through 18 years of age (not only those at high risk) may be vaccinated with VFC supplies of MenB vaccine to provide short-term protection against most strains of MenB disease.
- Recent outbreaks in California and other states reflect the ongoing, unpredictable risk of MenB disease to adolescents and young adults, including college students.

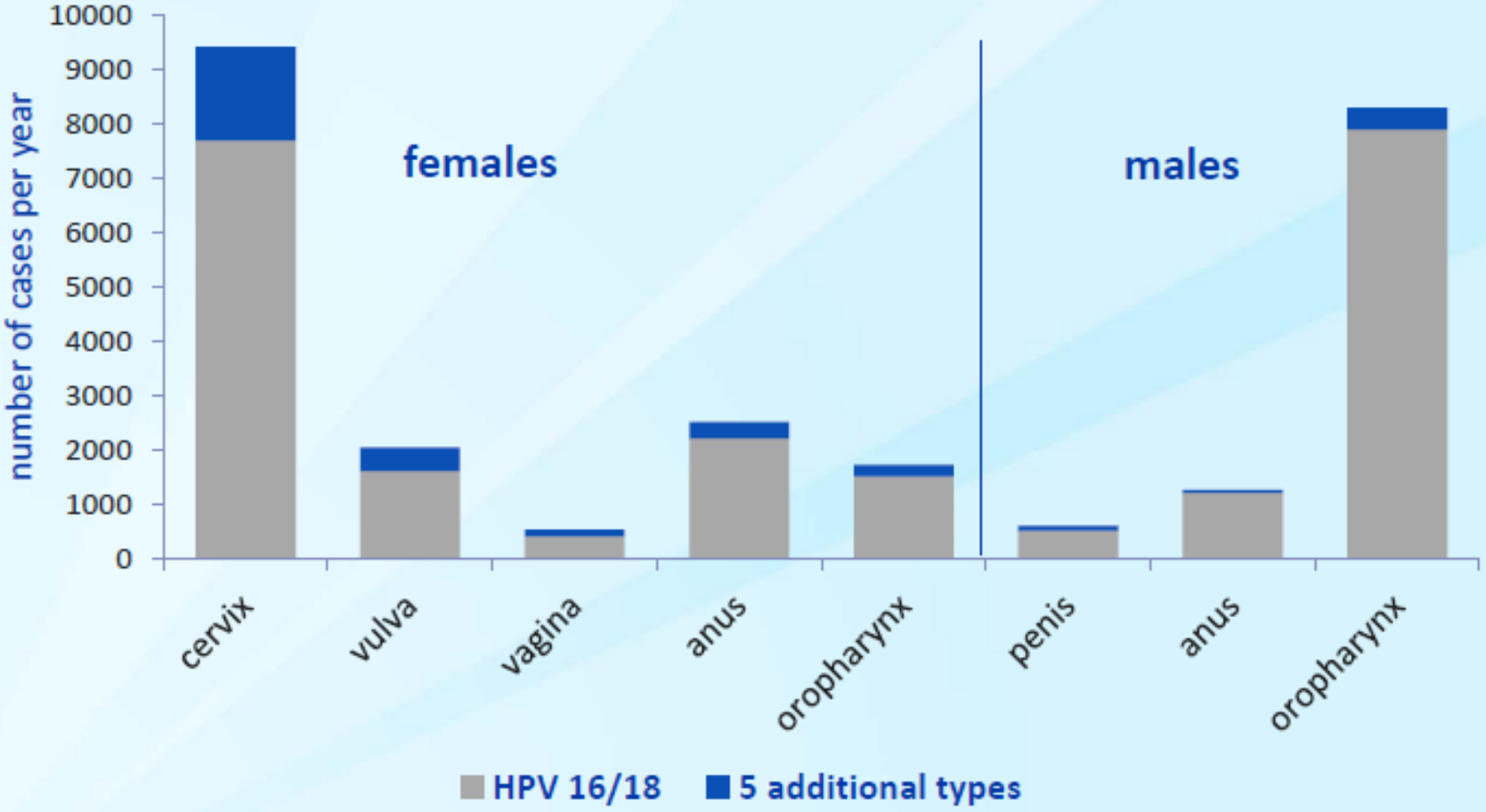
9-Valent HPV Vaccine

9-Valent HPV Vaccine, Gardasil® 9

- Initially licensed December 2014 and since December 2015 with an expanded age indication for boys (to include ages 16 through 26 years)
- Indicated for both females and males ages 9 through 26 years
- Contains VLPs for HPV 6, 11, 16, 18, 31, 33, 45, 52, and 58 (5 additional high risk HPV types compared to quadrivalent Gardasil®).
- 3 dose series
- 0, 1-2, 6 month schedule

www.fda.gov

Estimated annual number of cancers attributable to HPV 16/18 and 5 additional HPV types in 9-valent vaccine, U.S.*



*Based on years 2006-2010 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6349a11.htm and data from Saraiya et al. JNCI 2015;107

HPV-Associated Cancers

- **In the U.S. ~64% of invasive HPV-associated cancers are attributable to HPV16 or 18 (~21,300 cases annually)**
  - 65% for females
  - 63% for males
- **10% are attributable to the additional 5 types in Gardasil 9 (HPV 31, 33, 45, 52, and 58) (~3400 cases annually).**
  - 14% for females
  - 4% for males

http://www.cdc.gov/mmwr/pdf/wk/mm6411.pdf

Protocol 001: Efficacy Against HPV 31/33/45/52/58 [1 of 2]
(Cervical/Vulvar/Vaginal Disease, Persistent Infection)
Per Protocol Efficacy Population

Endpoint	9vHPV Vaccine No. of cases/n	qHPV Vaccine No. of cases/n	Efficacy (95% CI)
≥CIN2, VIN2/3, VaIN2/3	**1** / 6016	**30** / 6017	**96.7% (80.9, 99.8)**
All CIN, VIN, VaIN	**3** / 6016	**103** / 6017	**97.1% (91.8, 99.2)**
6-month persistent infection	**35** / 5939	**810** / 5953	**96.0% (94.4, 97.2)**

Presentation by Luxembourg, ACIP Meeting, October 2014.

Summary of 9-Valent HPV Vaccine Studies

- **Non-inferior anti-HPV 6, 11, 16, and 18 vs. the quadrivalent HPV vaccine and similar protection against disease.**
- **~97% protection against HPV 31, 33, 45, 52, and 58-related disease**
- **Non inferior immunogenicity**
  - Boys and girls vs. young women
  - Young men vs. young women
- **Generally well tolerated; AE profile similar to HPV4 vaccine**
  - More injection site reactions (typically mild – moderate intensity)
  - >15,000 subjects received HPV9 vaccine
- **Generally well tolerated and highly immunogenic in prior HPV4 recipients**

Adapted from presentation by Luxembourg, ACIP Meeting, October 2014.

ACIP HPV Vaccine Recommendations

- **ACIP recommends routine HPV vaccination at age 11 or 12 years. The vaccination series can be started beginning at age 9 years.***
- **Also recommended for females ages 13 through 26 years and for males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series. Males aged 22 through 26 years may be vaccinated.****

* Recommend starting at age 9 years for children with any history of sexual abuse or assault.

**Vaccination is also recommended for men who have sex with men or for immunocompromised persons (including those with HIV) aged 22 through 26 years if not vaccinated previously

http://www.cdc.gov/mmwr/pdf/wk/mm6411.pdf
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm

HPV Vaccine Schedule

- **HPV2, HPV4, and HPV9 are each administered in a 3-dose schedule.**
- **ACIP Recommended Schedule:**
  - 0, 1-2 months, 6 months
  - Recommended schedule is preferred
- **Catch-Up Immunization Minimum Intervals**
  - Dose 1 and 2: 4 weeks
  - Dose 2 and 3: 12 weeks
  - Dose 1 and 3: 24 weeks

http://www.cdc.gov/mmwr/pdf/wk/mm6411.pdf

HPV Vaccine FAQs

Is there a MAXIMUM interval?

- **No, if the vaccine schedule is interrupted, the vaccine series does NOT need to be restarted.**

- **Continue the series where it was interrupted. No need to repeat prior doses given in the past.**

http//www.cdc.gov/mmwr/pdf/wk/mm6411.pdf

If a series was started with quadrivalent HPV vaccine or bivalent HPV vaccine, can it be completed with 9-valent HPV vaccine?

- Yes, ACIP recommendations state that 9-valent HPV may be used to continue or complete a series started with a different HPV vaccine product.

Is additional vaccination with 9-valent HPV vaccine recommended for persons who have completed a 3 dose series of either quadrivalent or bivalent HPV vaccine?

- There is no ACIP recommendation for routine additional 9-valent HPV vaccination of person who previously completed a quadrivalent or bivalent vaccination series.

Co-Administration

- **Should be given at the same visit when other adolescent immunizations are provided**
  - Tdap
  - MenACWY conjugate vaccine

Additional Key Points

- **Start HPV vaccine series with other preteen vaccines**
- **Preventive vaccine—don't wait until sexually active**
  - Best immune response in early adolescence
- **Stress cancer prevention**
- **Encourage follow-up appointments to complete series before leaving office**

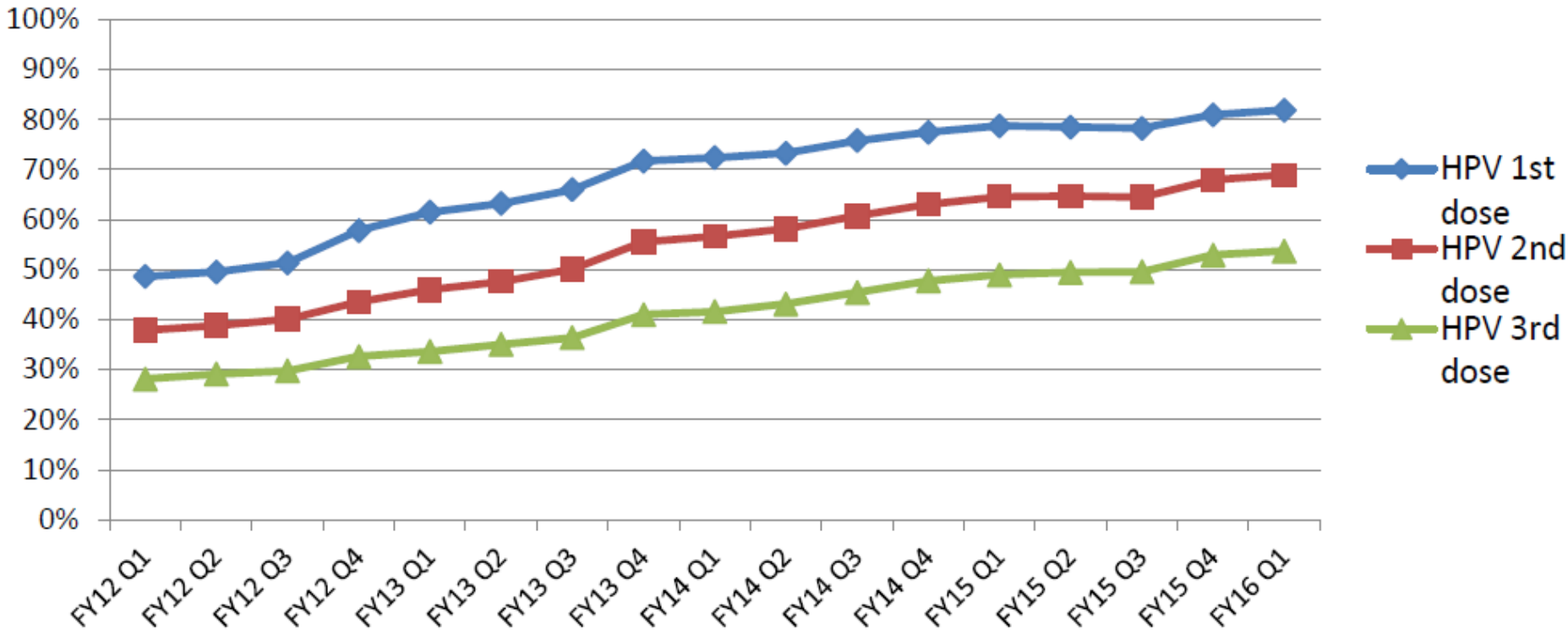
Est. Vaccination Coverage, 13-17 Yr Olds, National Immunization Survey-Teen, U.S. and California, 2014, and Ca Tribal 2016

Vaccine	HP 2020*	U.S.	California	California Tribal (Q1 2016)
1 Tdap	80%	87.6% (±0.9)	87.7% (±4.6)	83.5%
1 MCV4	80%	79.3% (±1.1)	79.3% (±5.7)	73.5%
1 HPV (female)	-	60.0% (±1.9)	69.2% (±9.4)	65.4%
2 HPV (female)	-	50.3% (±1.9)	61.5% (±9.8)	52.2%
3 HPV (female)	80%	39.7% (±1.9)	47.7% (±9.8)	38.1%
1 HPV (male)	-	41.7% (±1.8)	52.1% (±9.3)	61.2%
2 HPV (male)	-	31.4% (±1.7)	41.2% (±9.2)	44.1%
3 HPV (male)	80%	21.6% (±1.6)	31.1% (±8.9)	28.9%
≥ 2 MMR	90%	90.7% (±0.8)	91.4% (±3.4)	84.3%
≥ 3 Hep B	90%	91.4% (±0.7)	92.6% (±3.4)	85.4%
≥ 2 VAR/Dis	-	85.0% (±0.9)	81.7% (±5.7)	78.9%

* 13-15 year olds

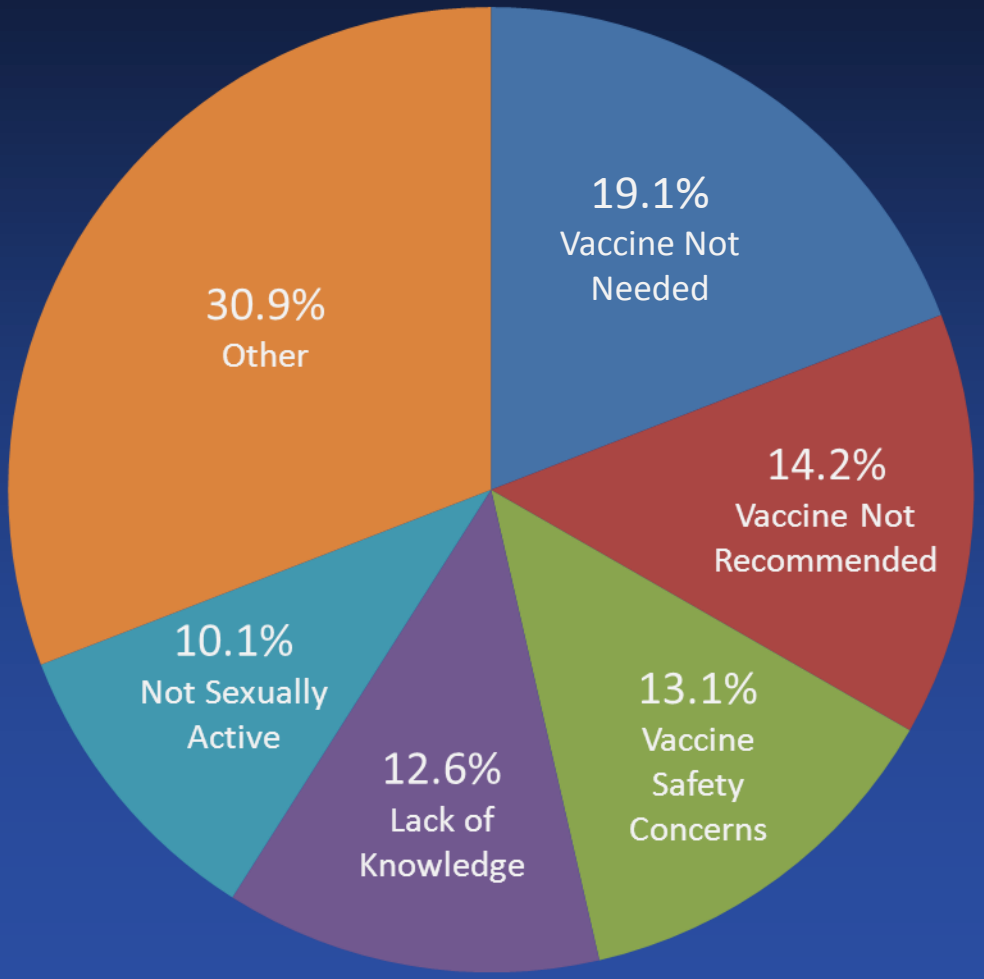
http://www.cdc.gov/vaccines/stats-surv/default.htm

HPV Coverage for 13 - 17 year olds
FY12 Q1 - FY16 Q1



https://www.ihs.gov/epi/documents/vaccine/reports/Adolescentgraph.pdf

Reasons Cited by Parents to Not Vaccinate Daughters against HPV, 2012



Source: CDC MMWR http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6229a4.htm

Measures to Improve Initiation of HPV Series at age 11-12 years

- **Strong provider message**
- **Offer immunization at every opportunity**
  - Use of information systems to know you patients' status: CAIR, EMR, etc.
  - Part of preteen bundle: Tdap, MCV4, catch-up doses
- **Inform families - tailor level of detail**
- **Emphasize cancer prevention**
  - Answering questions on
    - Growing and extensive safety record
    - Efficacy against infection, warts, CIN
    - Does not encourage sexual activity

ACIP Recommendation for PCV13 for all Adults 65 Years and Older

- **ACIP vote on August 13, 2014 to recommend PCV13 for persons 65 years and older.**
- **ACIP voted to harmonize the intervals between PCV13 and PPSV23 doses in June 2015 (published in MMWR September 4, 2015).**
- **Routine use of 13-valent, pneumococcal conjugate vaccine (PCV13, Prevnar 13®) in addition to PPSV23 (PNEUMOVAX® 23) for adults 65 years of age and older.**

http://www.cdc.gov/mmwr/pdf/wk/mm6337.pdf
http://www.cdc.gov/mmwr/pdf/wk/mm6434.pdf

Modifications to Medicare Part B (Physician) Coverage of Pneumococcal Vaccinations

- IMPLEMENTATION DATE: February 2, 2015
- EFFECTIVE DATE: September 19, 2014
  - Previously, pneumococcal vaccine was covered once in a beneficiary's lifetime, with revaccinations covered for those at highest risk if 5 years have passed since the last vaccination, or if the beneficiary's vaccination history was unknown.
  - New coverage: An initial pneumococcal vaccine may be administered to beneficiaries who have never received a pneumococcal vaccine under Medicare Part B. A different, second pneumococcal vaccine may be administered 1 year after the first vaccine was administered (i.e., 11 full months have passed).

http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R3159CP.html

ACIP Recommendations for PCV13 and PPSV23 for Adults 65 Years and Older

- **Both PCV13 and PPSV23 should be administered routinely in series to all adults aged 65 years and older.**
  - Do NOT administer together at the same visit.

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

Pneumococcal vaccine naïve persons aged 65 years and older

- **Adults aged 65 years and older who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown should receive a dose of PCV13 first, followed by a dose of PPSV23.**
- **For immunocompetent adults 65 years and older, the dose of PPSV23 should be given at least 1 year after a dose of PCV13.**
  - If PPSV23 cannot be given during this time window, the dose of PPSV23 should be given during the next visit.
- **For those with immunocompromising conditions, functional or anatomic asplenia, CSF leaks or cochlear implants, PPSV23 can be given at least 8 weeks after PCV13.**

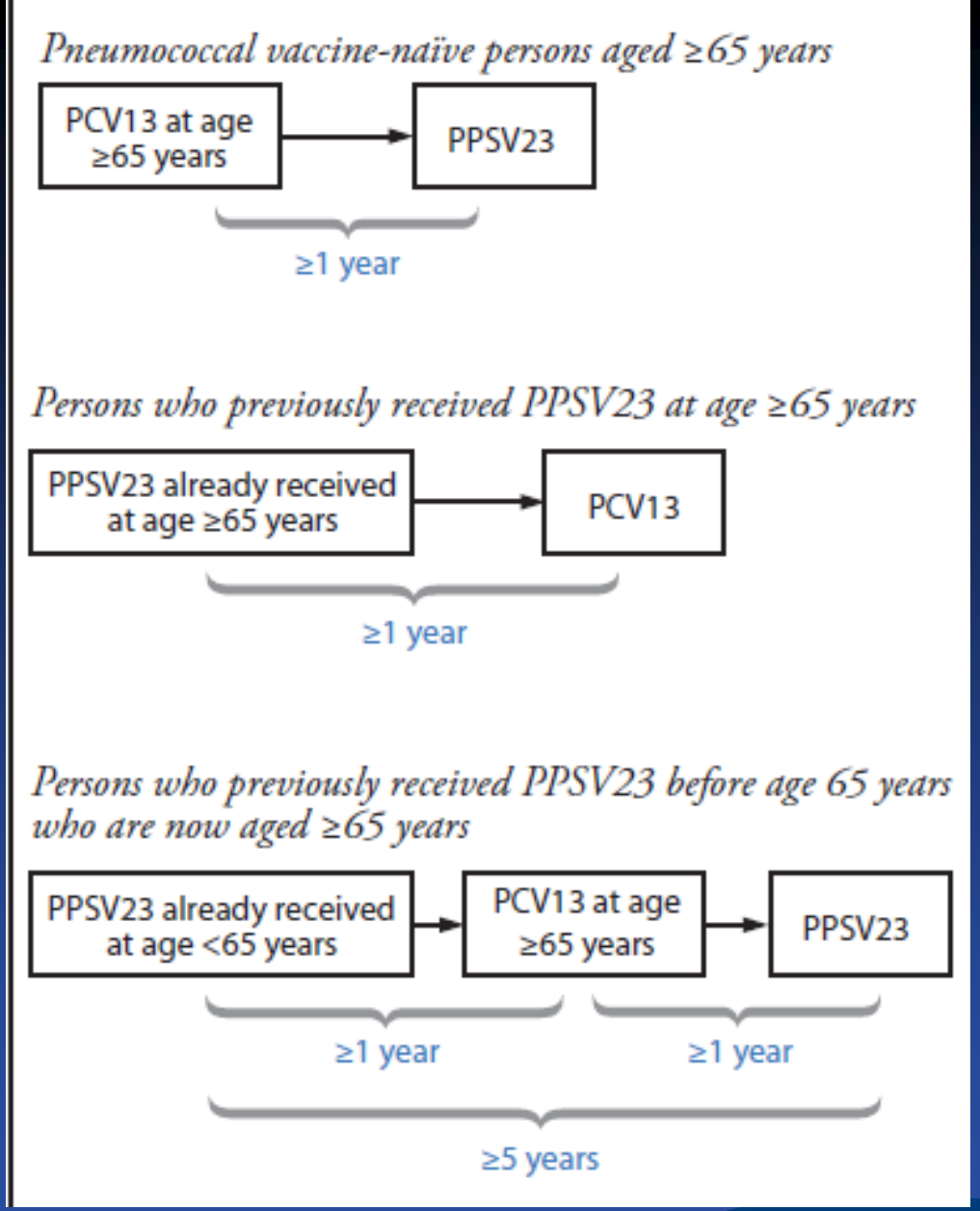
http://www.cdc.gov/mmwr/pdf/wk/mm6337.pdf

Adults 65 Years and Older who had a Previous Vaccination with PPSV23

- **Adults aged 65 years of age and older who have previously received 1 or more doses of PPSV23 also should receive a dose of PCV13, if they have not yet received it.**
  - A dose of PCV13 should be given at least 1 year after receipt of the most recent PPSV23 dose.
  - If the prior dose of PPSV23 was given prior to age 65 years, another dose of PPSV23 is indicated.
    - This subsequent PPSV23 dose should be given at least 1 year after PCV13 for immunocompetent adults and at least 5 years after the most recent dose of PPSV23. A shorter interval may be used for certain high risk persons, as previously described.

http://www.cdc.gov/mmwr/pdf/wk/mm6337.pdf
http://www.cdc.gov/mmwr/pdf/wk/mm6434.pdf#page=16

Sequential Administration and Recommended Intervals for PCV13 and PPSV23 for Immunocompetent Adults Aged 65 Years and Older



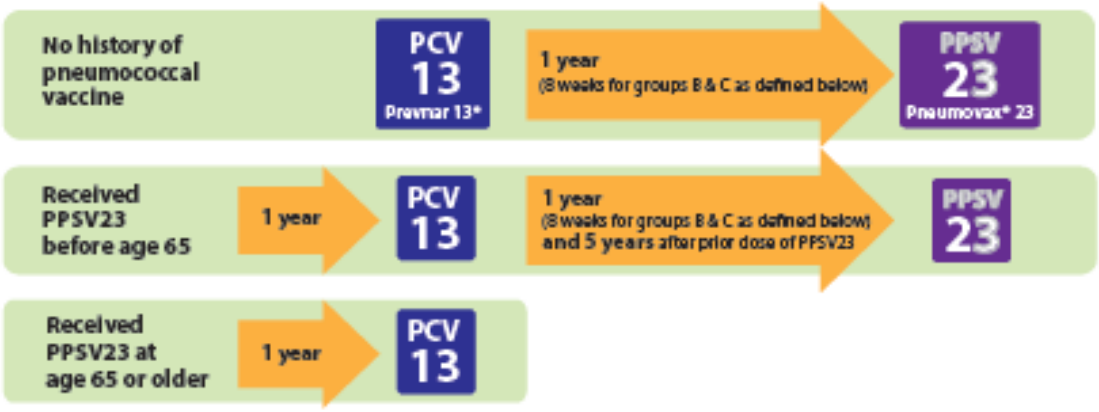
http://www.cdc.gov/mmwr/pdf/wk/mm6434.pdf#page=16

Pneumococcal Vaccine Timing–For Adults

DO NOT administer PCV13 and PPSV23 at the same visit.

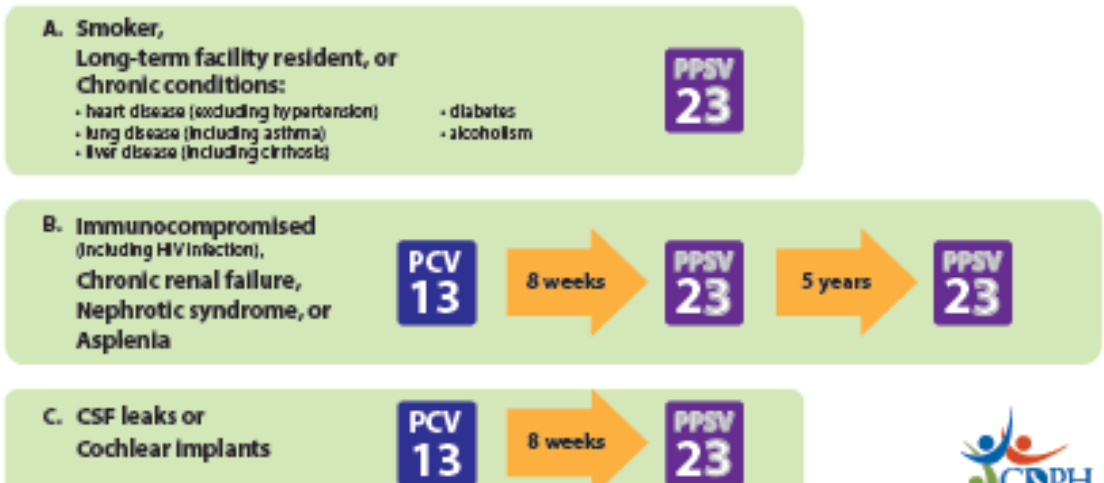
Age 65 Years or Older

- If PCV13 was given before age 65 years, no additional PCV13 is needed.



Age 19-64 Years With Underlying Condition(s)

- Prior doses count towards doses recommended below and do not need to be repeated.
- If PPSV23 given previously – wait one year before giving PCV13
  – for group B, wait at least five years before giving a second dose of PPSV23.
- No more than two doses of PPSV23 recommended before 65th birthday and one dose thereafter.



http://eziz.org/assets/docs/IMM-1152.pdf

Pneumococcal Vaccine Timing–For Children

Ages 2-59 Months

Standard

Age:	2 months	4 months	6 months	12–15 months
	PCV 13 Prevnar 13®	PCV 13	PCV 13	PCV 13

- Catch-up: 1–4 doses depending on age and timing of past doses.
  1–2 doses for children ages 60 through 71 months with underlying conditions listed below.

Ages 2-18 Years With Underlying Condition(s)

- DO NOT administer PCV13 and PPSV23 at the same visit.
- Complete all recommended doses of PCV13 before giving PPSV23.
- Prior doses count towards doses recommended below and do not need to be repeated.
- If PCV13 series completed previously, or at least 1 dose given at age 6 years or older, no additional PCV13 needed.
- If PPSV23 given previously – wait at least 8 weeks before giving PCV13.
  – for group B, wait at least five years before giving a second dose of PPSV23.
- No more than two doses of PPSV23 recommended before age 65 years.

A. Chronic conditions:

- Diabetes
- Heart Disease (particularly failure or cyanotic disease)
- Lung disease (excluding asthma, unless immunocompromised by prolonged high-dose oral corticosteroids – see below)

PPSV 23 Pneumovax® 23

B. Immunocompromised (including HIV infection or immunosuppressive treatments), **Hemoglobinopathy** (including sickle cell disease), **Asplenia, Chronic renal failure, or Nephrotic syndrome**

PCV 13 → 8 weeks → PPSV 23 → 5 years → PPSV 23

C. CSF leaks or Cochlear Implants

PCV 13 → 8 weeks → PPSV 23

CDPH

For further details, see: www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html

California Department of Public Health, Immunization Branch, www.EZIZ.org

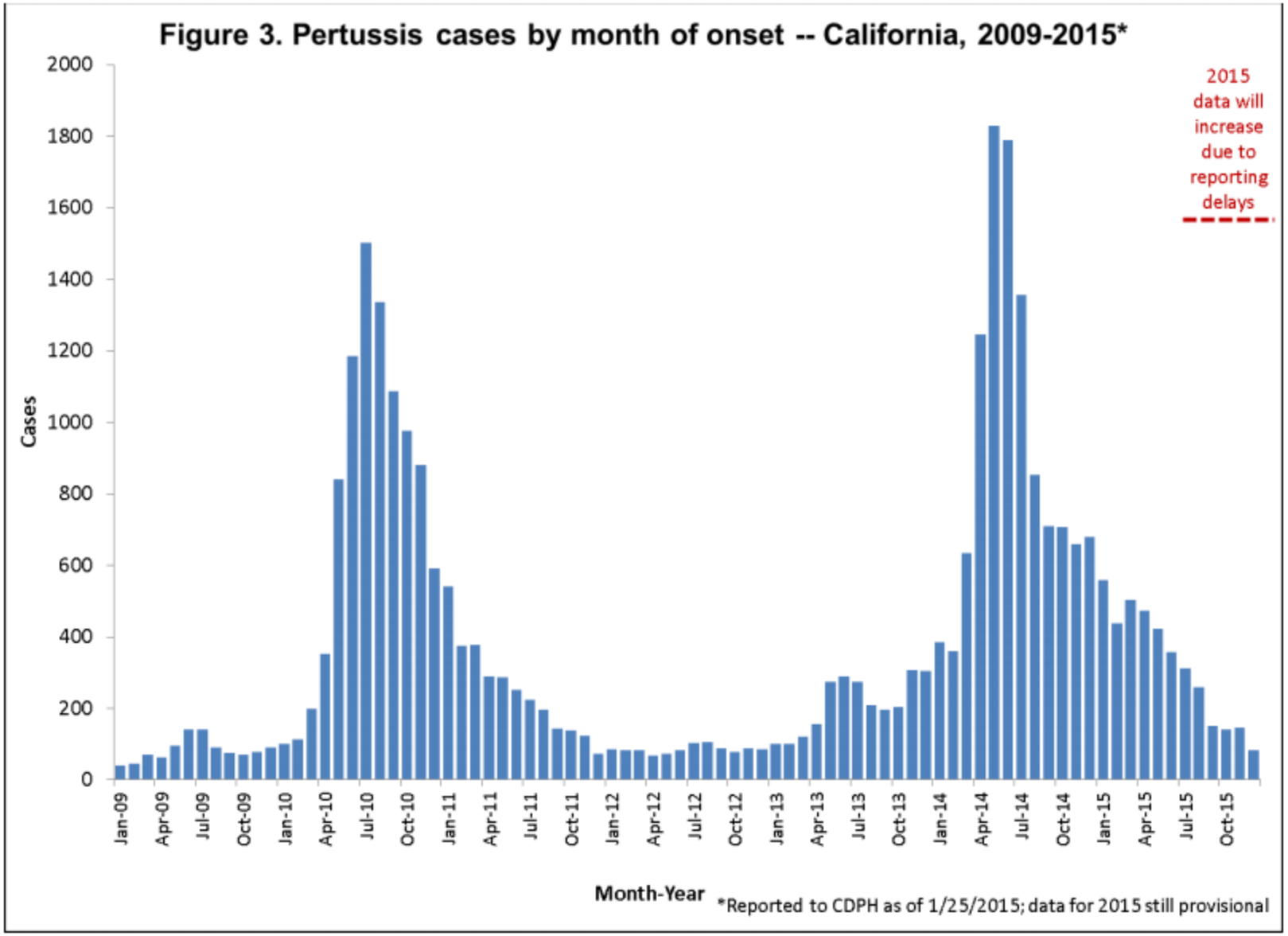
http://eziz.org/assets/docs/IMM-1159.pdf/

CDPH

Robert Schechter, MD

Immunization Branch,
California Department of Public Health

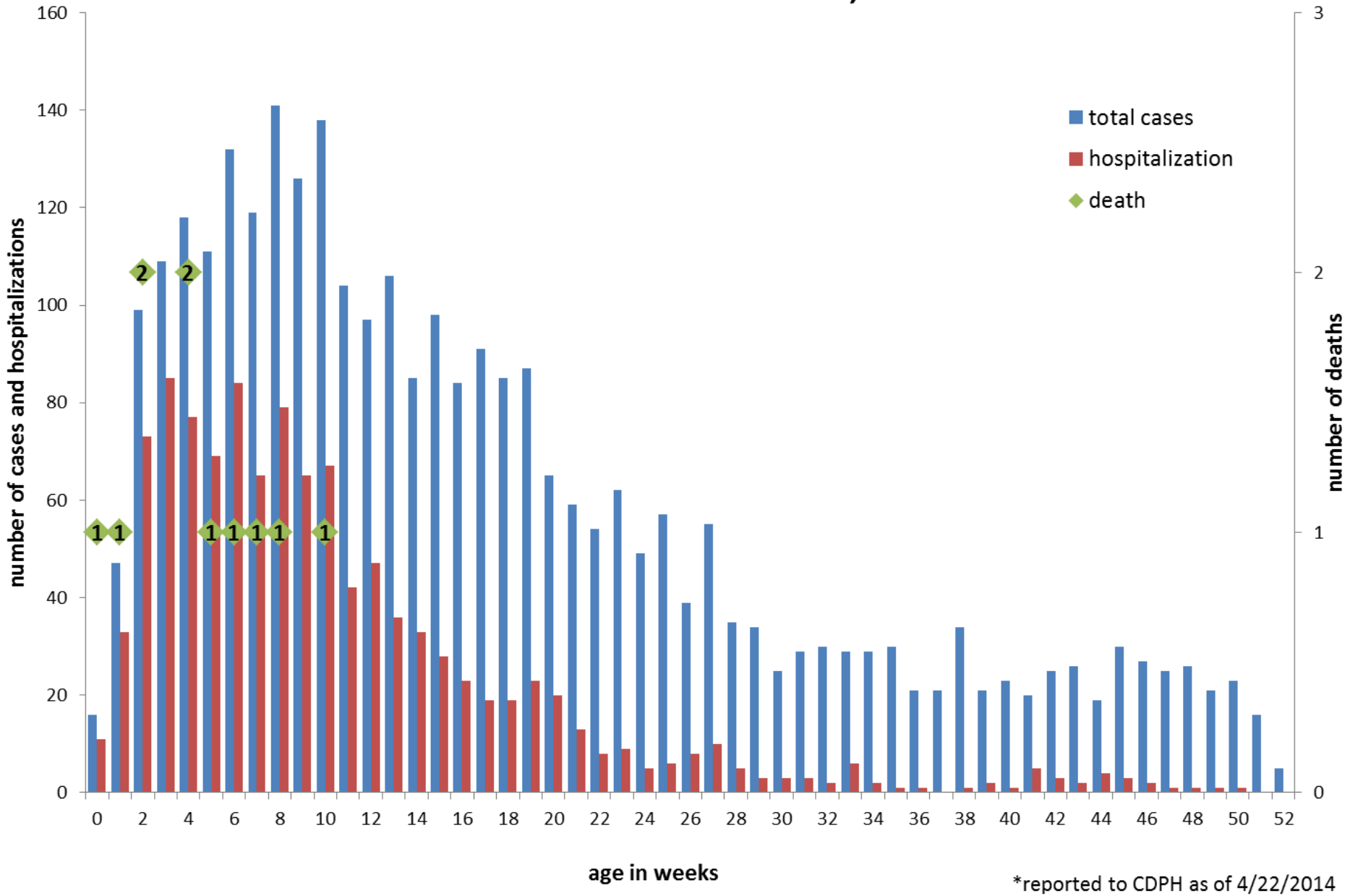
Tdap Vaccine in Third Trimester of Each Pregnancy



www.cdph.ca.gov/programs/immunize/Documents/Pertussis%20report%201-25-2016.pdf

Prepared by the California Department of Public Health, Immunization Branch

Pertussis cases, hospitalizations and deaths in infants, by age in weeks at time of disease onset -- California, 2010-2014*



*reported to CDPH as of 4/22/2014

ACOG and ACIP Recommendations

- Tdap should be administered during each pregnancy, irrespective of the patient's prior history of receiving Tdap.
- To maximize maternal antibody response and passive antibody transfer to the infant, optimal timing for Tdap administration is between 27 and 36 weeks gestation.

http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Update-on-Immunization-and-Pregnancy-Tetanus-Diphtheria-and-Pertussis-Vaccination
http://www.cdc.gov/mmwr/pdf/wk/mm6207.pdf

Key Steps to Protect Young Infants

- **Immunize at each pregnancy (3rd trim.)**
  - Don't forget prenatal influenza vaccine too!
- **Prompt immunization of infants**
  - Consider DTaP at 6 weeks if mom didn't get prenatal Tdap

- (Immunize close contacts of infants
  - Continue routine immunization of children, adolescents, adults)

California School and Pre-K Immunization Requirements

Child Care Only	☐ *Haemophilus influenzae* type b (Hib meningitis)
Child Care and K-12th Grade	☐ DTaP (Diphtheria, Tetanus, Pertussis [whooping cough]) ☐ Hepatitis B ☐ MMR (Measles, Mumps, Rubella) ☐ Polio ☐ Varicella (Chickenpox)
7th Grade Advancement (or admission at 7-12th Grade)	☐ Tdap (Tetanus, reduced Diphtheria, Pertussis [whooping cough])

Categories of Unimmunized Students

- Medical Exemptions
  - Require documentation from licensed physician
- Personal Beliefs Exemptions (PBEs)
  - Assembly Bill 2109: Process modified 2014-15
  - Senate Bill 277, 2015: Option removed, 2016 -
- Conditional Entrants
  - Children whose missing shots due later in year
- Unimmunized children may be excluded from school or child care by local health officer when they may have been exposed to disease

2014-15 Disney Outbreak Continuing Role by Unvaccinated

Table 2. Vaccination status among confirmed cases with known vaccination status

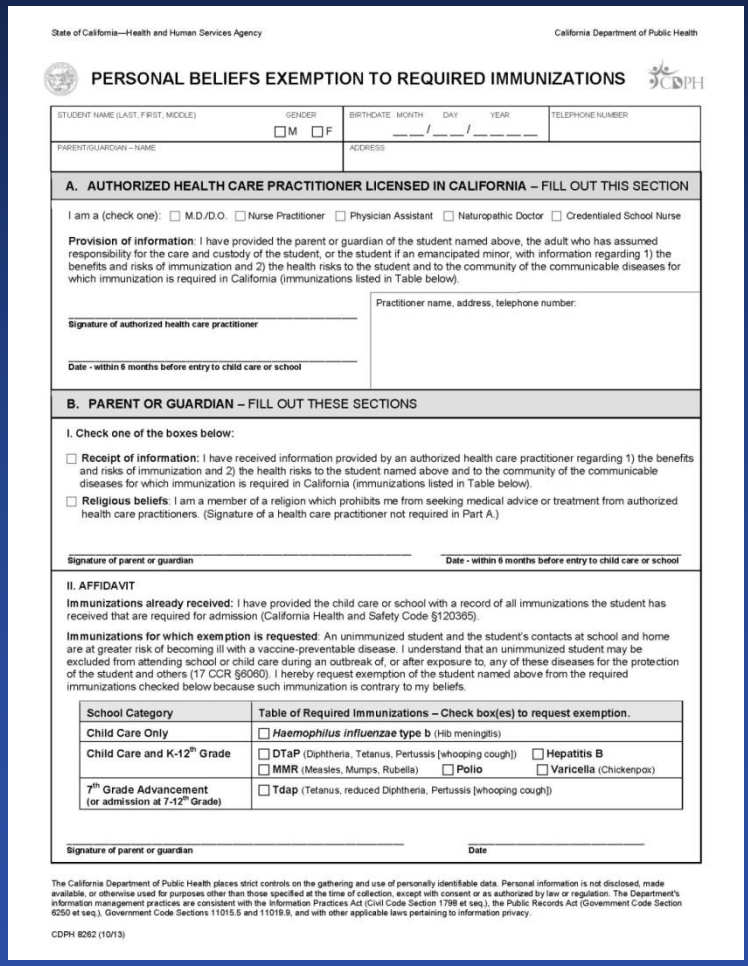
	Total	%
Unvaccinated	40	77%
Vaccinated		
1 dose	4	8%
2 doses	7	13%
3 doses	1	2%
Total	52	

Table 3. Reason for not being vaccinated among unvaccinated cases

Reasons for not being vaccinated*	Total	Percent
Missed dose	1	3%
PBE	26	76%
Too Young	7	21%
Total	34	

Revised PBE Procedure
AB 2109 - Effective 2014-15

1. Practitioner shares information
2. Practitioner documentation
3. Parent documentation
4. School files documentation



State of California—Health and Human Services Agency — California Department of Public Health

PERSONAL BELIEFS EXEMPTION TO REQUIRED IMMUNIZATIONS

STUDENT NAME (LAST, FIRST, MIDDLE) | GENDER ☐M ☐F | BIRTHDATE MONTH DAY YEAR ___/___/____ | TELEPHONE NUMBER

PARENT/GUARDIAN – NAME | ADDRESS

A. AUTHORIZED HEALTH CARE PRACTITIONER LICENSED IN CALIFORNIA – FILL OUT THIS SECTION

I am a (check one): ☐ M.D./D.O. ☐ Nurse Practitioner ☐ Physician Assistant ☐ Naturopathic Doctor ☐ Credentialed School Nurse

Provision of information: I have provided the parent or guardian of the student named above, the adult who has assumed responsibility for the care and custody of the student, or the student if an emancipated minor, with information regarding 1) the benefits and risks of immunization and 2) the health risks to the student and to the community of the communicable diseases for which immunization is required in California (immunizations listed in Table below).

Signature of authorized health care practitioner

Date - within 6 months before entry to child care or school

Practitioner name, address, telephone number:

B. PARENT OR GUARDIAN – FILL OUT THESE SECTIONS

I. Check one of the boxes below:

☐ **Receipt of information:** I have received information provided by an authorized health care practitioner regarding 1) the benefits and risks of immunization and 2) the health risks to the student named above and to the community of the communicable diseases for which immunization is required in California (immunizations listed in Table below).

☐ **Religious beliefs**: I am a member of a religion which prohibits me from seeking medical advice or treatment from authorized health care practitioners. (Signature of a health care practitioner not required in Part A.)

Signature of parent or guardian — Date - within 6 months before entry to child care or school

II. AFFIDAVIT

Immunizations already received: I have provided the child care or school with a record of all immunizations the student has received that are required for admission (California Health and Safety Code §120365).

Immunizations for which exemption is requested: An unimmunized student and the student's contacts at school and home are at greater risk of becoming ill with a vaccine-preventable disease. I understand that an unimmunized student may be excluded from attending school or child care during an outbreak of, or after exposure to, any of these diseases for the protection of the student and others (17 CCR §6060). I hereby request exemption of the student named above from the required immunizations checked below because such immunization is contrary to my beliefs.

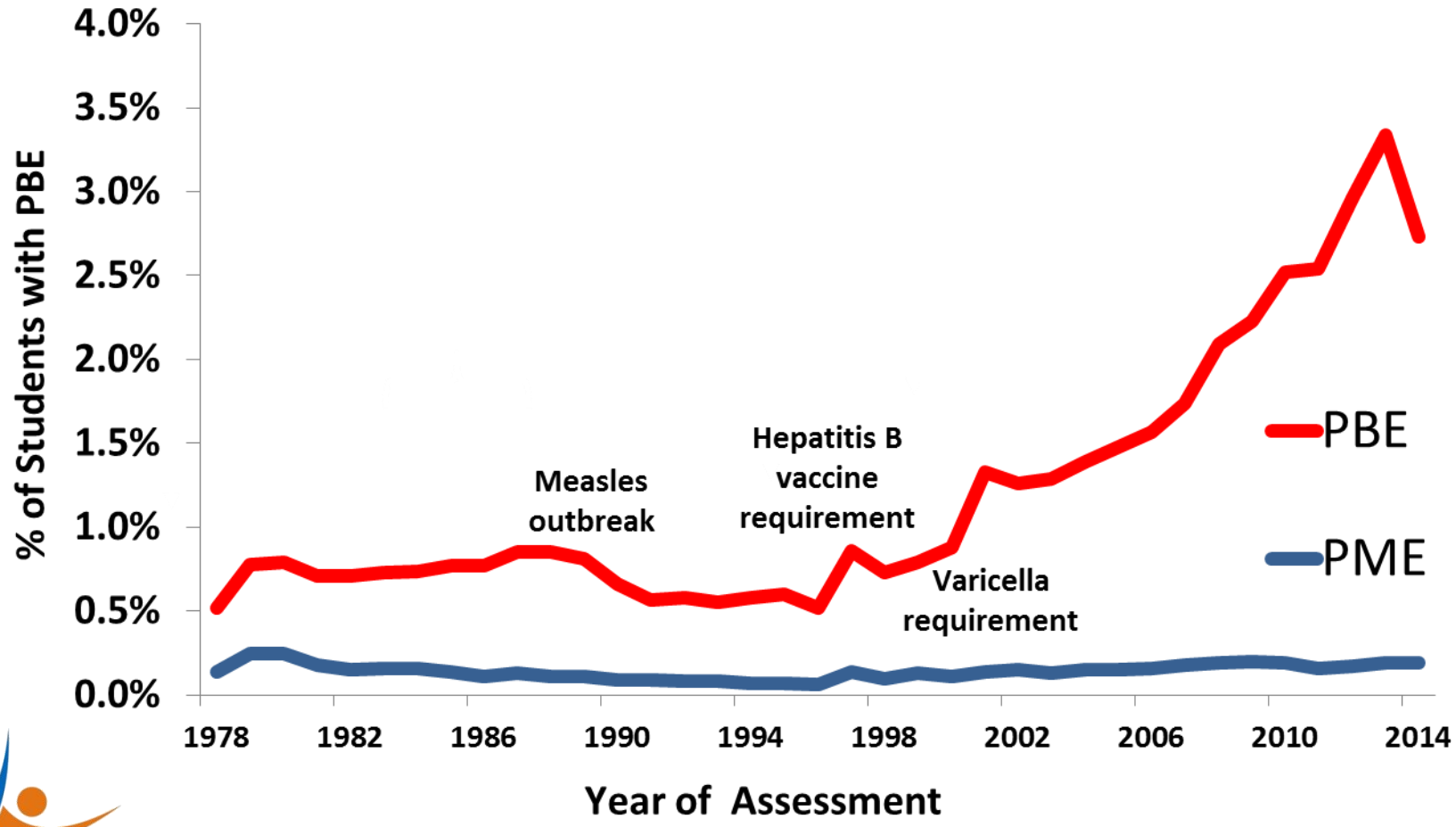
School Category	Table of Required Immunizations – Check box(es) to request exemption.
Child Care Only	☐ ***Haemophilus influenzae* type b** (Hib meningitis)
Child Care and K-12th Grade	☐ **DTaP** (Diphtheria, Tetanus, Pertussis [whooping cough]) ☐ **Hepatitis B** ☐ **MMR** (Measles, Mumps, Rubella) ☐ **Polio** ☐ **Varicella** (Chickenpox)
7th Grade Advancement (or admission at 7-12th Grade)	☐ **Tdap** (Tetanus, reduced Diphtheria, Pertussis [whooping cough])

Signature of parent or guardian — Date

The California Department of Public Health places strict controls on the gathering and use of personally identifiable data. Personal information is not disclosed, made available, or otherwise used for purposes other than those specified at the time of collection, except with consent or as authorized by law or regulation. The Department's information management practices are consistent with the Information Practices Act (Civil Code Section 1798 et seq.), the Public Records Act (Government Code Section 6250 et seq.), Government Code Sections 11015.5 and 11019.9, and with other applicable laws pertaining to information privacy.

CDPH 8262 (10/13)

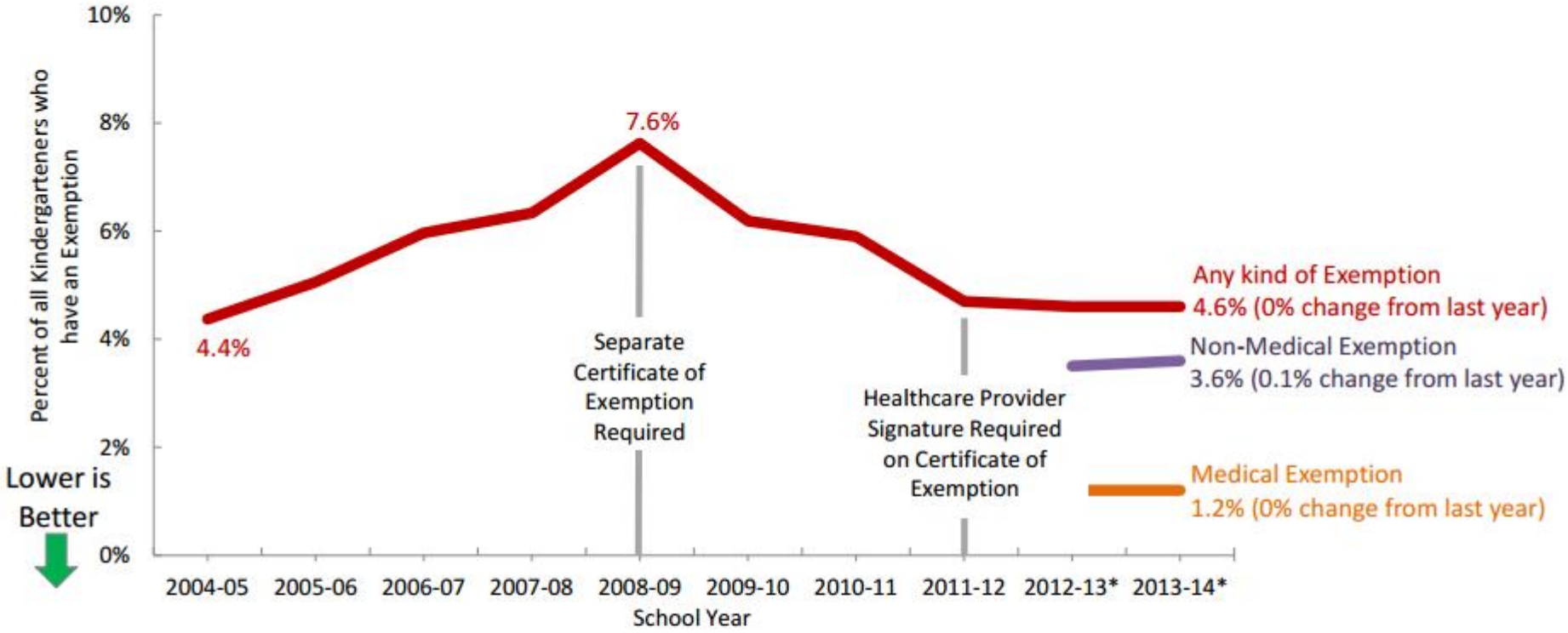
Permanent Medical (PME) and Personal Beliefs (PBE) Exemptions Among Kindergarten Students in California, 1978-79 to 2014-15 School Years



CDPH California Department of PublicHealth

Percent of Kindergarteners Exempt for Required Vaccines in School Year 2013-14

About the same number of kindergarten students have exemptions to school-entry vaccine requirements this year compared to last year. Students with exemptions are more at risk of getting and spreading vaccine-preventable diseases.



- **Any Exemption:** The student has a documented exemption to any kindergarten entry vaccine requirement. Students are counted only once here.
- **Medical Exemption:** The student has a documented medical condition which contraindicates getting a required vaccine. Students can have medical as well as non-medical exemptions to school entry vaccine requirements so can be counted in both categories.
- **Non-Medical Exemption:** Parent opts their child out of required vaccines due to personal beliefs, religious beliefs, or religious membership. Students can have non-medical as well as medical exemptions to school entry vaccine requirements so can be counted in both categories.
- Medical vs. Non-Medical exemptions for kindergartners is measured separately starting in school year 2012-13.
- The 2013-14 results are based on public and private school reports for 78,924 kindergarteners out of total kindergarten enrollment of 81,530.
- *Data for school years 2012-13 and 2013-14 is weighted to account for the number of schools that reported.

Washington State Department of Health

For persons with disabilities, this document is available on request in other formats. To submit a request, please call 1-800-525-0127 (TDD/TTY call 711).

DOH 348-324
June 2014

SB 277 – Effective 2016
No new personal belief exemptions

ShotsforSchool

Child Care | K-12 | 7TH Grade | College | Laws

► SB277 FAQs

- Immunization Laws
- Exemptions
- ► SB277 FAQs
- ► Personal Beliefs Exemption FAQs
- Conditional Admission FAQs
- Handbook, Records, & Materials

ShotsForSchool > Immunization Laws > ► SB277 FAQs

Senate Bill 277 Frequently Asked Questions

These FAQs were last updated on 11/13/2015 (this included edits to question 13).
This content is considered current until any future update is made.

Print file in English (PDF) | Spanish (PDF) | Russian (PDF)

Immunization Requirements for 2015

1. In 2015 and future years, which vaccines are required to enter child care or school in California?
2. In the summer or fall of 2015, are there any changes to the immunization requirements for children entering child care or school?

New law (SB277) for 2016 and future years

3. In 2016, what are the changes to the immunization requirements for children entering child care or school?
4. When does the law take effect?
5. Where can I review the new law?
6. Which facilities are affected by the new law in 2016 and future years?

FAQ - Are personal beliefs exemptions filed during or after 2016 valid?

No. Personal beliefs exemptions are no longer an option for the vaccines that are currently required for entry into school or child care in California.

No distinction is made between exemptions based on religious beliefs versus other personal beliefs.

FAQ – Do personal beliefs exemptions, including those based on religious beliefs, filed in California before 2016 remain valid in later years?

A PBE filed before January 1, 2016 at:

- A child-care facility remains valid until the child first enters the span between Transitional Kindergarten through 6th grade.
- Entry to any grade from Transitional Kindergarten/Kindergarten through 6th grade remains valid until the child completes 6th grade.
- Entry to any grade from 7th through 12th remains valid through 12th grade.

FAQ, continued – Do personal beliefs exemptions, including those based on religious beliefs, filed in California before 2016 remain valid in later years?

PBEs filed in 2014 or 2015 are only valid when signed (by a parent/guardian and typically an authorized health care provider) no more than 6 months prior to first entry into school or child care or a new grade span.

Therefore, PBEs filed in 2015 are invalid for children first entering child care or school in California in the fall of 2016.

FAQ - What are the requirements for students entering a home-based private school or independent study program and do not receive classroom-based instruction?

Students entering:

- A home-based private school or
- An independent study program and do not receive classroom-based instruction

were subject to immunization requirements for entry during 2015 but not in 2016 or future years.

Parents or guardians must provide records to the schools of any required immunizations received by these students.

FAQ -What will happen in future years when children with a prior personal beliefs exemption enter their next grade span in primary or secondary school (typically TK/Kindergarten or 7th grade)?

Children with a valid personal beliefs exemption filed before 2016 who enter a new grade span will have to

- meet all age-appropriate immunization requirements for admission into primary or secondary school (K-12th grade) or
- be enrolled in an independent study program and do not receive classroom-based instruction or in a home-based private school.

FAQ –What happens when children with a prior personal beliefs exemption enter 7th grade?

All immunization requirements for age and grade will need to be met before entering 7th grade.

In order to begin 7th grade, children who had a valid personal beliefs exemption filed before 2016 upon entry between TK/Kindergarten and 6th grade need to meet all requirements for children 7-17 years old…(e.g., polio, measles, rubella, chickenpox and primary series for diphtheria, tetanus, and pertussis), including the 7th grade requirements for Tdap and 2 doses of measles.

FAQ –What happens when children with a prior personal beliefs exemption enter 7th grade?

Added responsibilities for middle schools for tracking children with expired PBEs, many of whom will become conditional entrants

Table 2: Conditional Admission Immunization Schedule

Vaccine	Dose	Time Intervals
Polio[1]	1st dose	Before admission
	2nd dose	As early as 6 weeks but no later than 10 weeks after the 1st dose. Before admission if 10 or more weeks have elapsed since the 1st dose at the time of admission.
	3rd dose	As early as 6 weeks but no later than 12 months after the 2nd dose. Before admission if 12 or more months have elapsed since the 2nd dose at the time of admission.
	4th dose (Required only for entry to kindergarten level or above)	Age 4-6 years: If the 3rd dose was given before the 4th birthday one more dose is required before admission. Age 7-17 years: If the 3rd dose was given before the 2nd birthday, one more dose is required before admission.
Diphtheria, Tetanus, and Pertussis FOR PUPILS UNDER AGE 7 YEARS:	1st dose	Before admission.
	2nd dose	As early as 4 weeks but no later than 8 weeks after the 1st dose. Before admission if 8 or more weeks have elapsed since the 1st dose at the time of admission.

FAQ - What's required for a medical exemption to a required immunization?

- A parent or guardian must submit a written statement from a licensed physician (M.D. or D.O.) which states:

- That the physical condition or medical circumstances of the child are such that the required immunization(s) is not indicated.
- Which vaccines are being exempted.
- Whether the medical exemption is permanent or temporary.
- The expiration date, if the exemption is temporary.

FAQ – Does CDPH have a standardized form for medical exemptions?

No, but a standardized form that includes all minimum required elements will shortly become available to medical providers from AAP-CA and AAFP.

FAQ - May other practitioners, besides licensed physicians (M.D.s and D.O.s), provide a medical exemption to a required immunization?

No. Only a licensed Medical Doctor (MD) or Doctor of Osteopathic Medicine (DO) may provide a medical exemption.

In contrast, the other categories of licensed or credentialed practitioners in California previously authorized through 2015 to sign requests for personal beliefs exemptions (e.g., Nurse Practitioner, Physician Assistant, Naturopathic Doctor, or School Nurse) may not provide medical exemptions.

External Resources for Providers

immunizeca.org

October 28, 2015

New School Rules: What Providers and Parents Need to Know

This webinar was focused on SB 277 which goes into effect January 1, 2016 and removes the personal belief exemption from school vaccination requirements. The presentation consisted of an overview of the law and how it will impact schools and medical practices, an explanation of medical exemptions for vaccines, and resources for educating parents and providers.

Archived Recording
Download Presentation
Frequently Asked Questions – special thanks to the California Medical Association

Featured Presenters

- ***Randy Bergen, MD***, Pediatric Infectious Diseases, Kaiser Permanente Northern California

External Resources for Providers

cdc.gov

Chart of Contraindications and Precautions to Commonly Used Vaccines

For Childhood Vaccines

The contents of this page were excerpted from the ACIP General Recommendations (January 28, 2011) and include corrections detailed in errata dated July 29, 2011 and any changes to recommendations as of January 2014.

Consult the main contraindications page for links to other contraindications and precautions materials.

Printer-friendly version of this chart [2 pages]
Source: Immunization Action Coalition

Also see Conditions Commonly Misperceived as Contraindications to Vaccination
Also available Contraindications and precautions for ADULTS only

Guide to Contraindications[1] and Precautions[1] to Commonly Used Vaccines[*,†]		
Vaccine	**Contraindications[1]**	**Precautions[1]**
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component	• Moderate or severe acute illness with or without fever • Infant weighing less than 2000 grams (4 lbs, 6.4 oz)[2]
Rotavirus (RV5 [RotaTeq], RV1 [Rotarix])	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • Severe combined immunodeficiency (SCID) • History of intussusception	• Moderate or severe acute illness with or without fever • Altered immunocompetence other than SCID • Chronic gastrointestinal disease[3] • Spina bifida or bladder exstrophy[3]
Diphtheria, tetanus, pertussis (DTaP) **Tetanus,**	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component • For pertussis-containing vaccines: encephalopathy (e.g., coma, decreased level of consciousness,	• Moderate or severe acute illness with or without fever • Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus

External Resources for Providers

cdc.gov

Conditions Commonly Misperceived as Contraindications to Vaccination

Recommendations and Guidelines

Clinicians or other health care providers might misperceive certain conditions or circumstances as valid contraindications or precautions to vaccination when they actually do not preclude vaccination. These misperceptions result in missed opportunities to administer recommended vaccines (ref 1). Among the most common conditions mistakenly considered to be contraindications are diarrhea, minor upper respiratory tract illnesses (including otitis media) with or without fever, mild to moderate local reactions to a previous dose of vaccine, current antimicrobial therapy, and being in the convalescent phase of an acute illness.

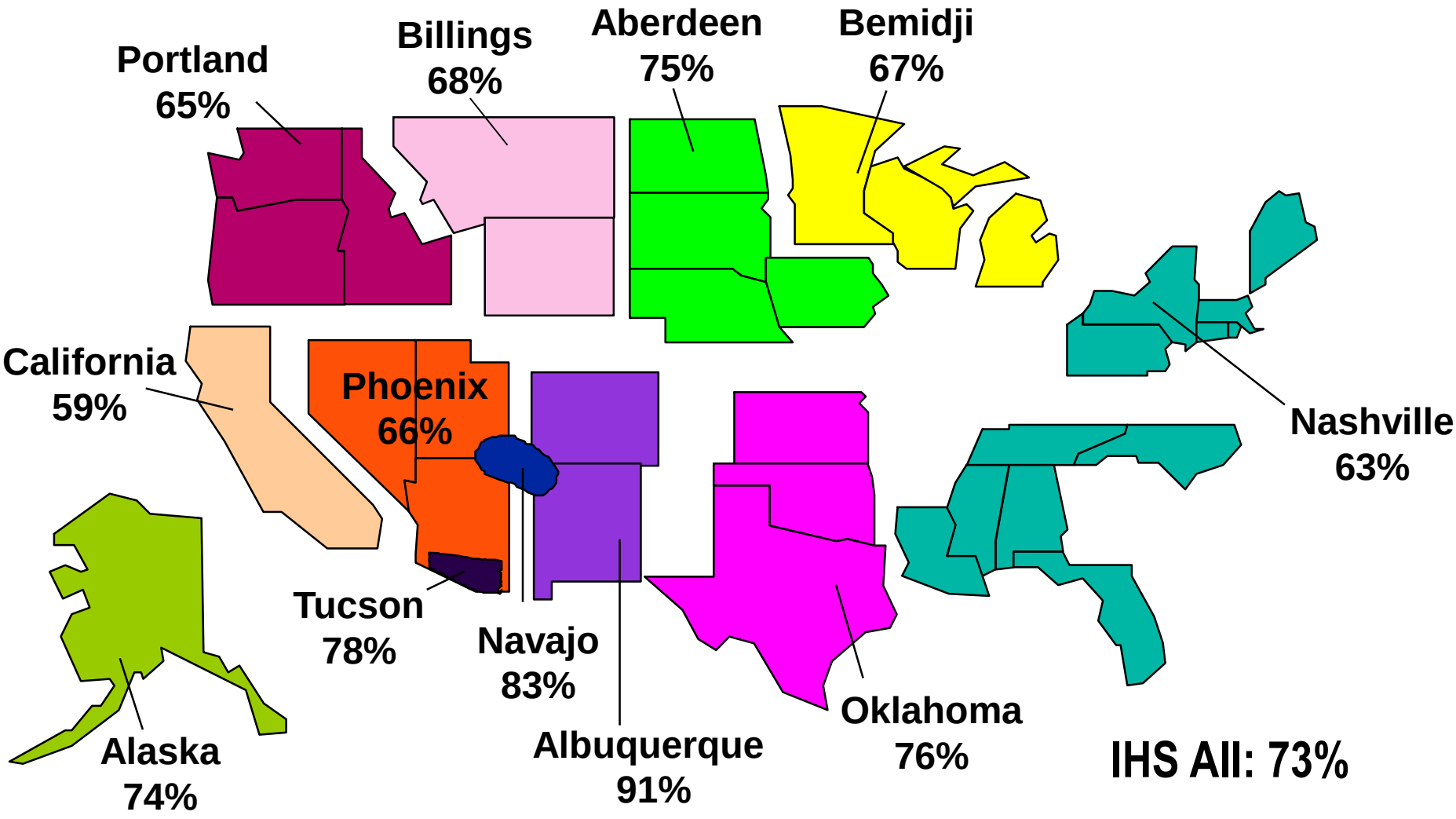
NOTE: The contents of this page were excerpted from the ACIP General Recommendations (January 28, 2011) and include corrections detailed in errata dated July 29, 2011 and any changes to recommendations as of October 2013.

TIP: Consult the main contraindications page for links to other contraindications and precautions materials.

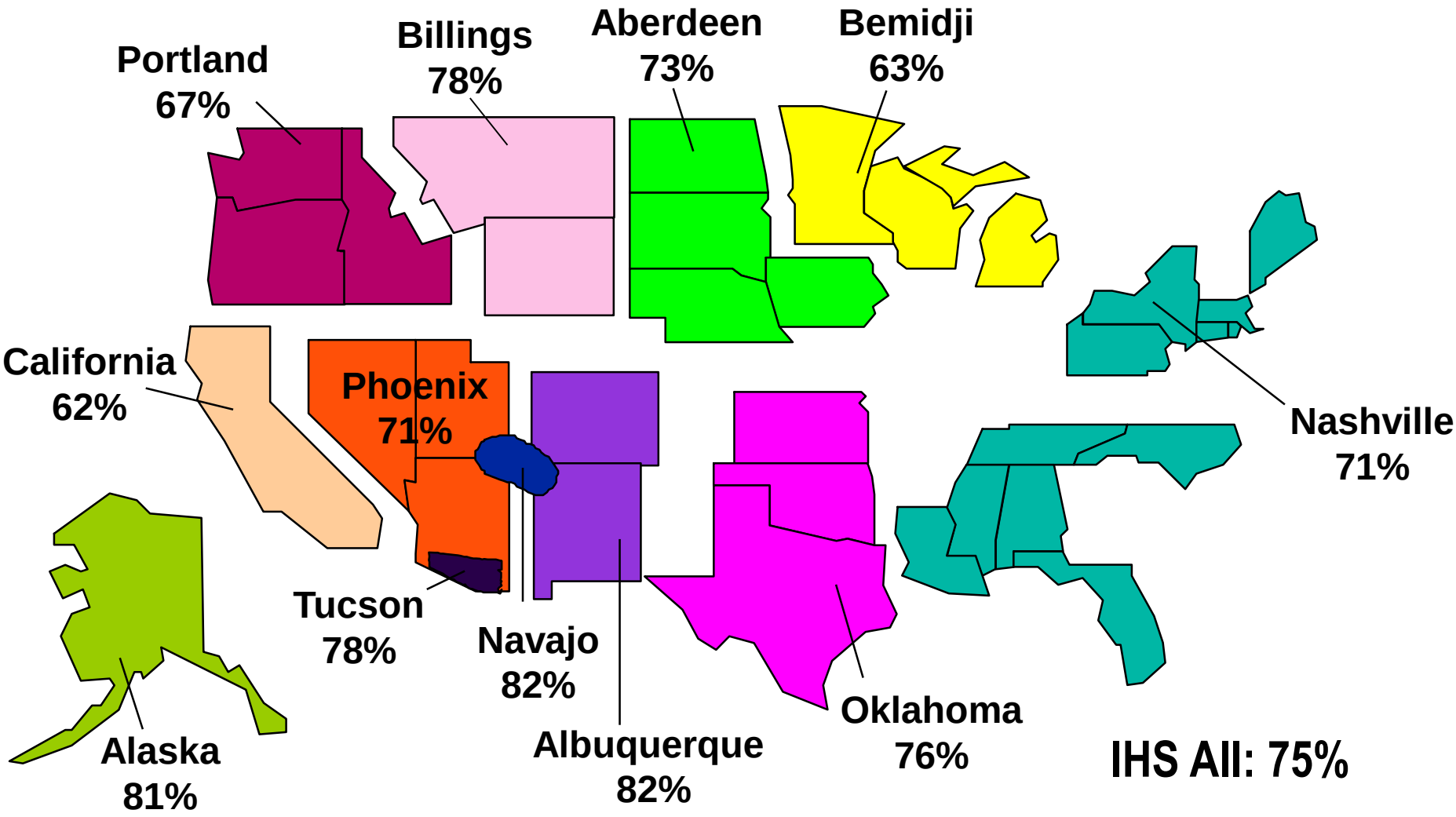
Quick Guide to Conditions Commonly Misperceived as Contraindications to Vaccination	
Vaccine	**Conditions commonly misperceived as contraindications (i.e., vaccination may be administered under these conditions)**
general for all vaccines, including DTaP, pediatric DT, adult Td, adolescent-adult Tdap, IPV, MMR, Hib, hepatitis A, hepatitis B, varicella, rotavirus, PCV, TIV, LAIV, PPSV, MCV4, MPSV4, HPV, and herpes zoster	• Mild acute illness with or without fever • Mild-to-moderate local reaction (i.e., swelling, redness, soreness); low-grade or moderate fever after previous dose • Lack of previous physical examination in well-appearing person • Current antimicrobial therapy**1** • Convalescent phase of illness • Preterm birth (hepatitis B vaccine is an exception in certain circumstances)**2** • Recent exposure to an infectious disease • History of penicillin allergy, other nonvaccine allergies, relatives with allergies, or receiving allergen extract immunotherapy
DTaP	• Fever of <105°F (<40.5°C), fussiness or mild drowsiness after a previous dose of DTP/DTaP • Family history of seizures

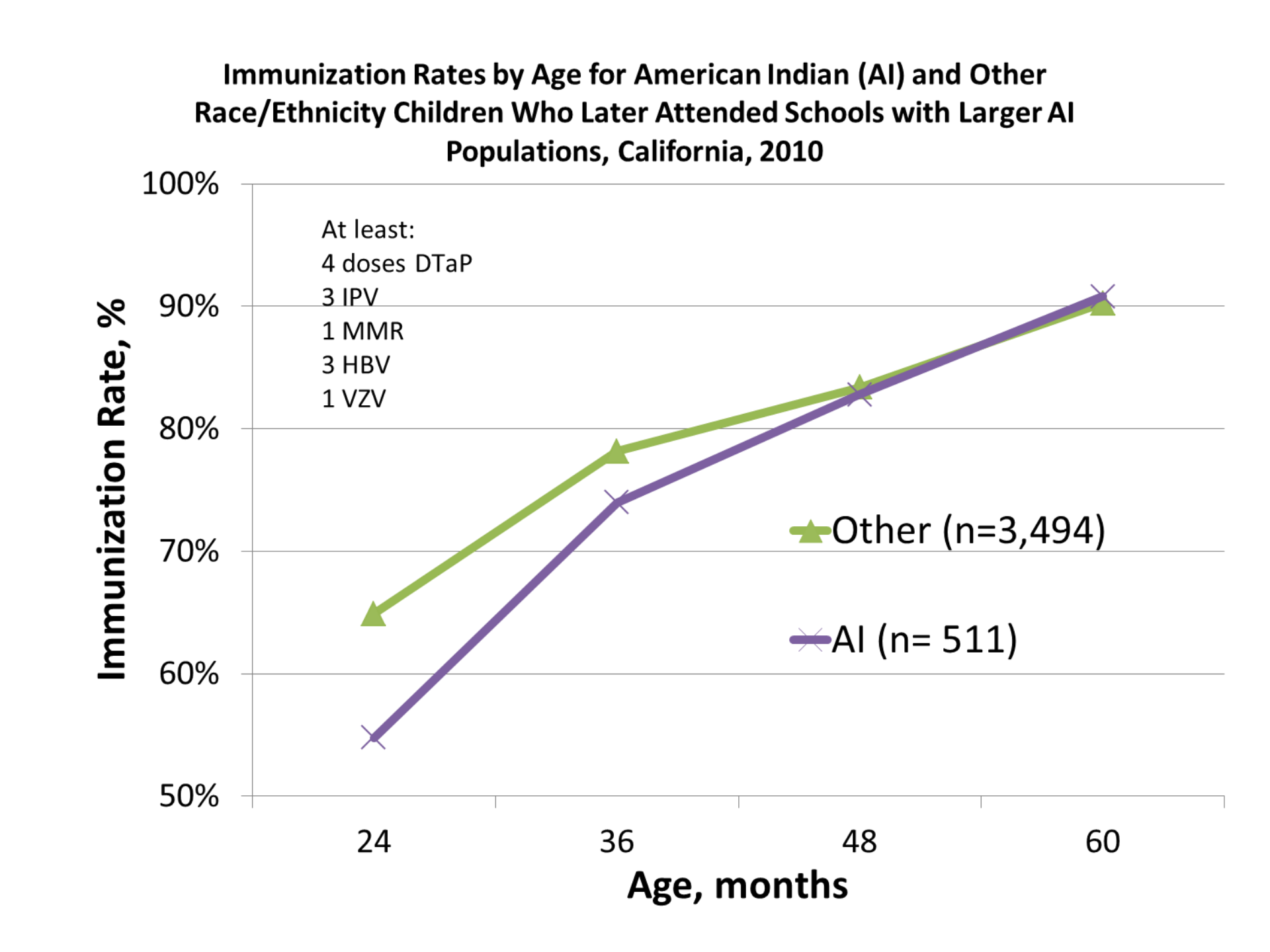
Using CAIR
to help keep patients up-to-date

Indian Health Service FY 2015
4313314 Coverage for 2 year olds



Indian Health Service FY 2013
4313314 Coverage for 2 year olds




Immunization Rates by Age for American Indian (AI) and Other Race/Ethnicity Children Who Later Attended Schools with Larger AI Populations, California, 2010
100%
90%
80%
70%
60%
50%
Immunization Rate, %
At least:
4 doses DTaP
3 IPV
1 MMR
3 HBV
1 VZV
Other (n=3,494)
AI (n= 511)
24
36
48
60
Age, months

California Tribal and Urban Health Programs contributing to CAIR

- Data Exchange from RPMS or different EHR
  - Active 8
  - Coming soon 11
- Several other programs entering data into CAIR manually or looking up records

- CAIR can help reduce
  - Fragmentation - Records from multiple providers are combined to increase completeness
  - Delays: Reminder/Recall abilities
- http://cairweb.org/

Thank you for immunizing!