Considerations for Tdap Revaccination

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For the
ACIP Pertussis Vaccines Work Group

Advisory Committee on Immunization Practices
February 20, 2013

National Center for Immunization & Respiratory Diseases
Division of Bacterial Diseases

WG Review and Considerations: Tdap revaccination of the general population

- **Current Tdap policy and objectives**
- **Epidemiology of pertussis and status of vaccination program**
- **Summary of Tdap vaccine performance**
  - Antibody persistence
  - Effectiveness/duration of protection
  - Revaccination
    - Safety
    - Immunogenicity
- **Revaccination options**
  - Framework for decision and cost-effectiveness analysis
- **Programmatic feasibility and acceptability**

Current ACIP Recommendations for Tdap

- **A single Tdap dose**
  - Adolescents aged 11 through 18 years, preferred 11 or 12 years
  - Adults aged 19 years and older
  - Further guidance will be forthcoming on timing of revaccination in persons who have received Tdap previously
- **Pregnant women are recommended Tdap with every pregnancy**
- **Decennial Td booster for those who have received 1 Tdap**
  - 5 years for wound management

Adacel licensed for ages 11 through 64 years, Boostrix licensed for ages 11 years and older

Objectives of Pertussis Vaccination Policy

- **Primary**
  - To protect vaccinated persons against pertussis
- **Secondary**
  - To reduce the reservoir of pertussis in the population at large, and thereby potentially:

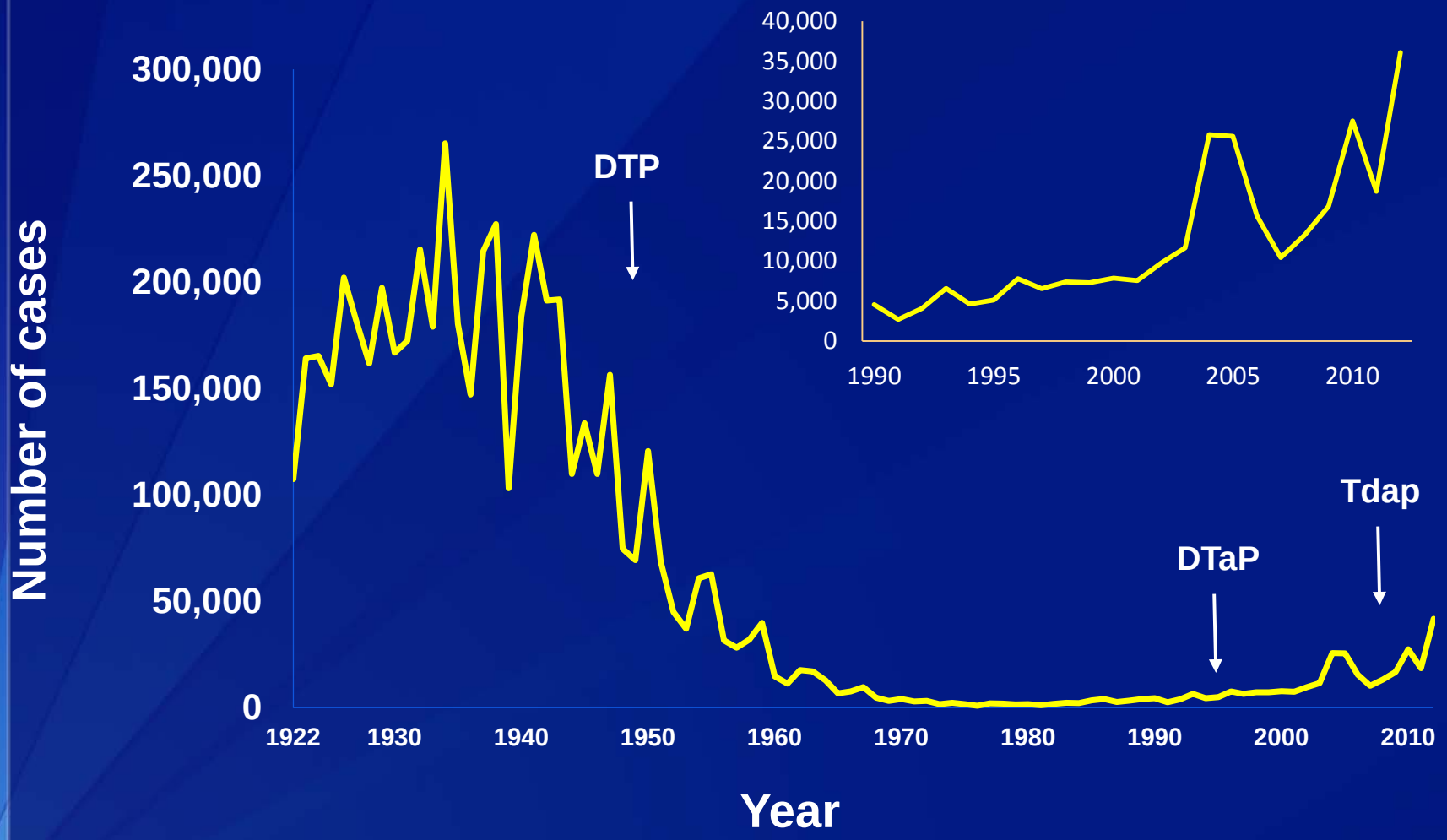
    1) decrease exposure of persons at increased risk for complicated infection (e.g., infants), and

    2) reduce the cost and disruption of pertussis in health-care facilities and other institutional settings

CDC. Preventing tetanus, diphtheria, and pertussis among adults: use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP) and recommendation of ACIP, supported by the Healthcare Infection Control Practices Advisory Committee (HICPAC), for use of Tdap among health-care personnel. MMWR 2006;55(No. RR-17).

PERTUSSIS EPIDEMIOLOGY AND VACCINATION

Reported NNDSS pertussis cases: 1922-2012*



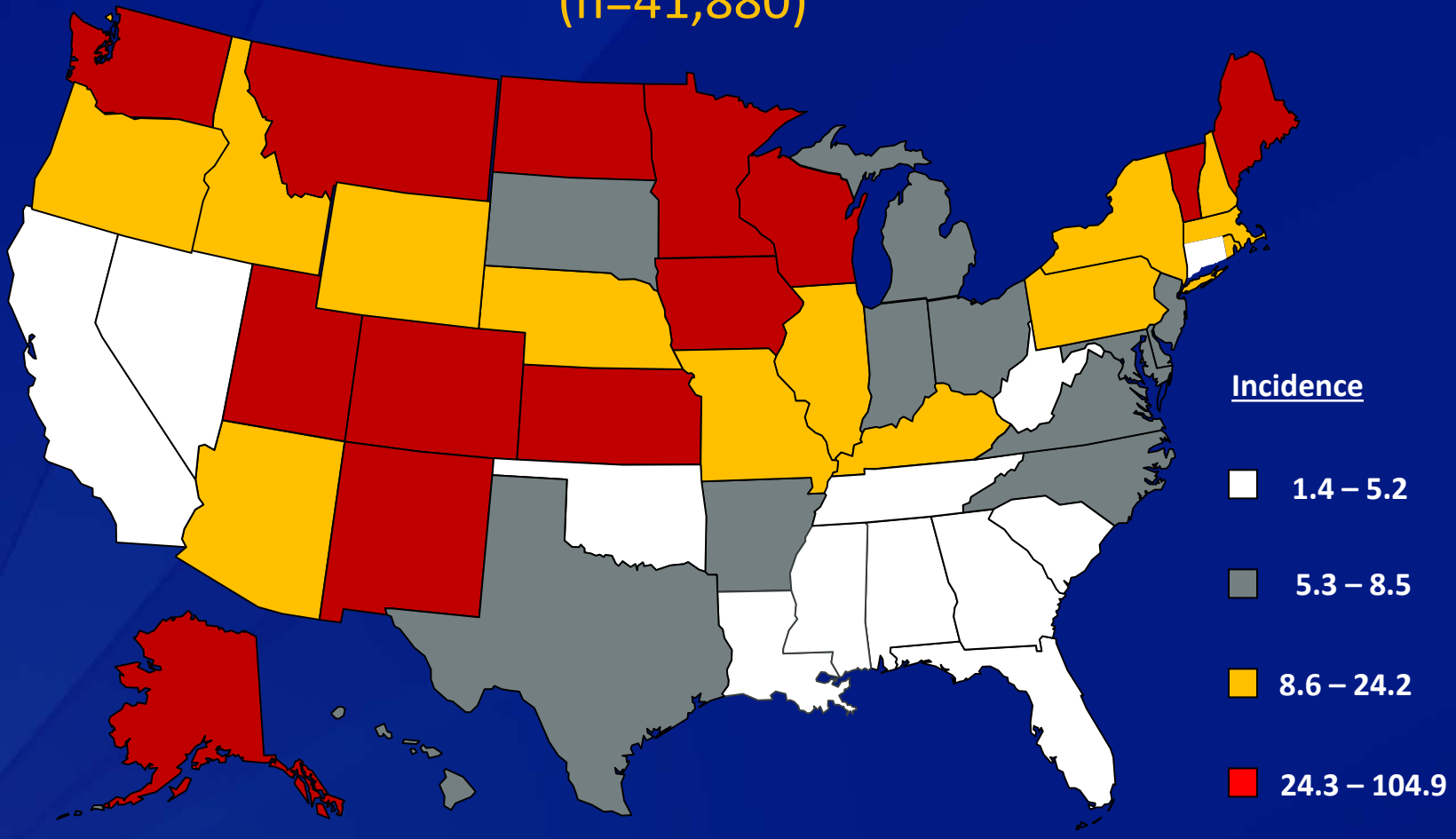
*2011 data are provisional; 2012 data are provisional.

SOURCE: CDC, National Notifiable Diseases Surveillance System and Supplemental Pertussis Surveillance System and 1922-1949, passive reports to the Public Health Service

Annual Incidence by State, 2012*

2012 incidence = 13.4

(n=41,880)

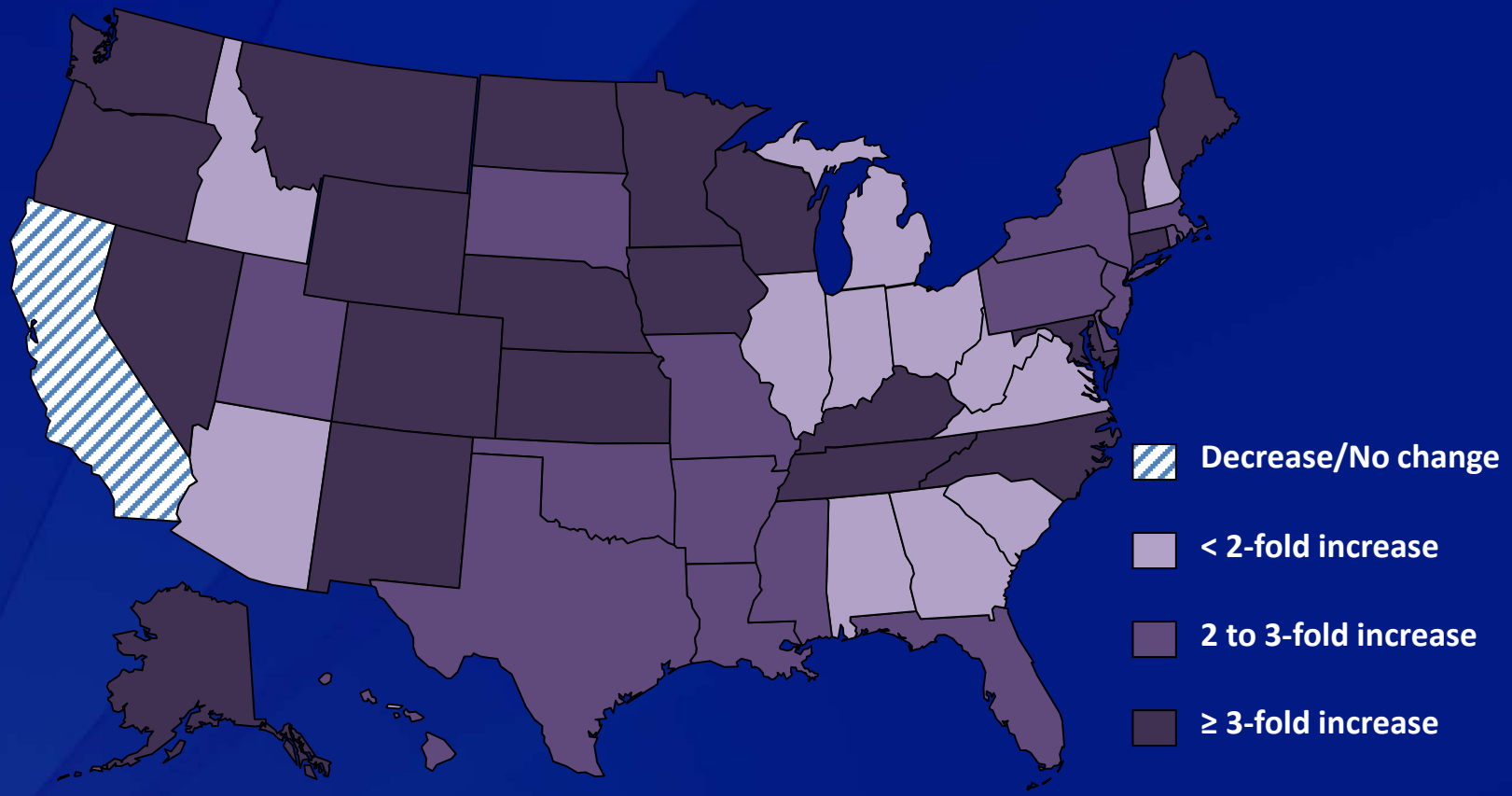


*2012 data are provisional.

Source : CDC National Notifiable Disease Surveillance System, 2012

2011 Census data used for population estimates; Incidence is per 100,000 population

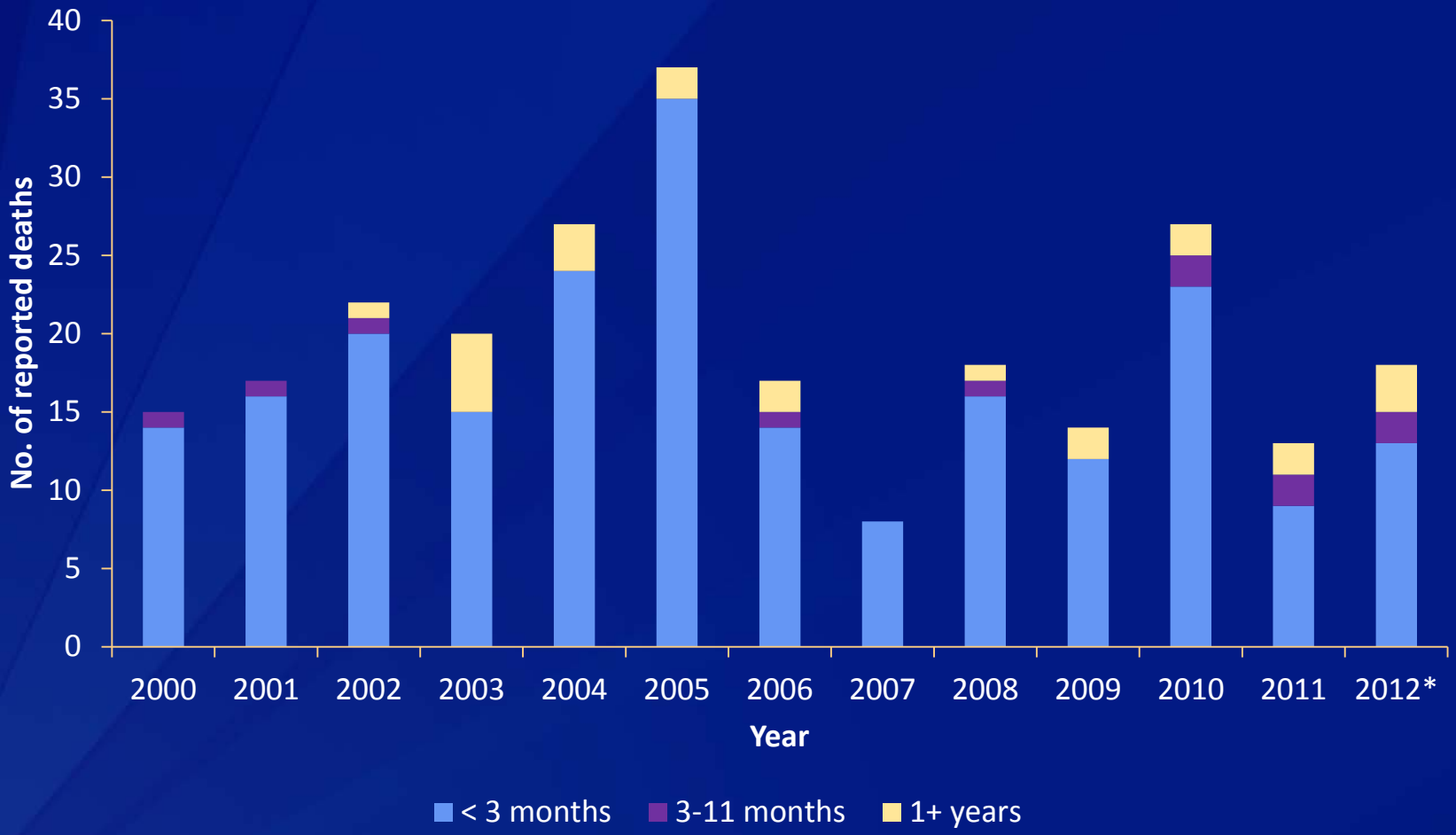
Changes in Pertussis Reporting by State from 2011 to 2012* †



*Data for 2012 are provisional.

†Cases reported through Week 52 in 2011 were compared with cases reported through Week 52 in 2012; fold-changes were calculated for each state.

Pertussis deaths by age group, 2000-2012*



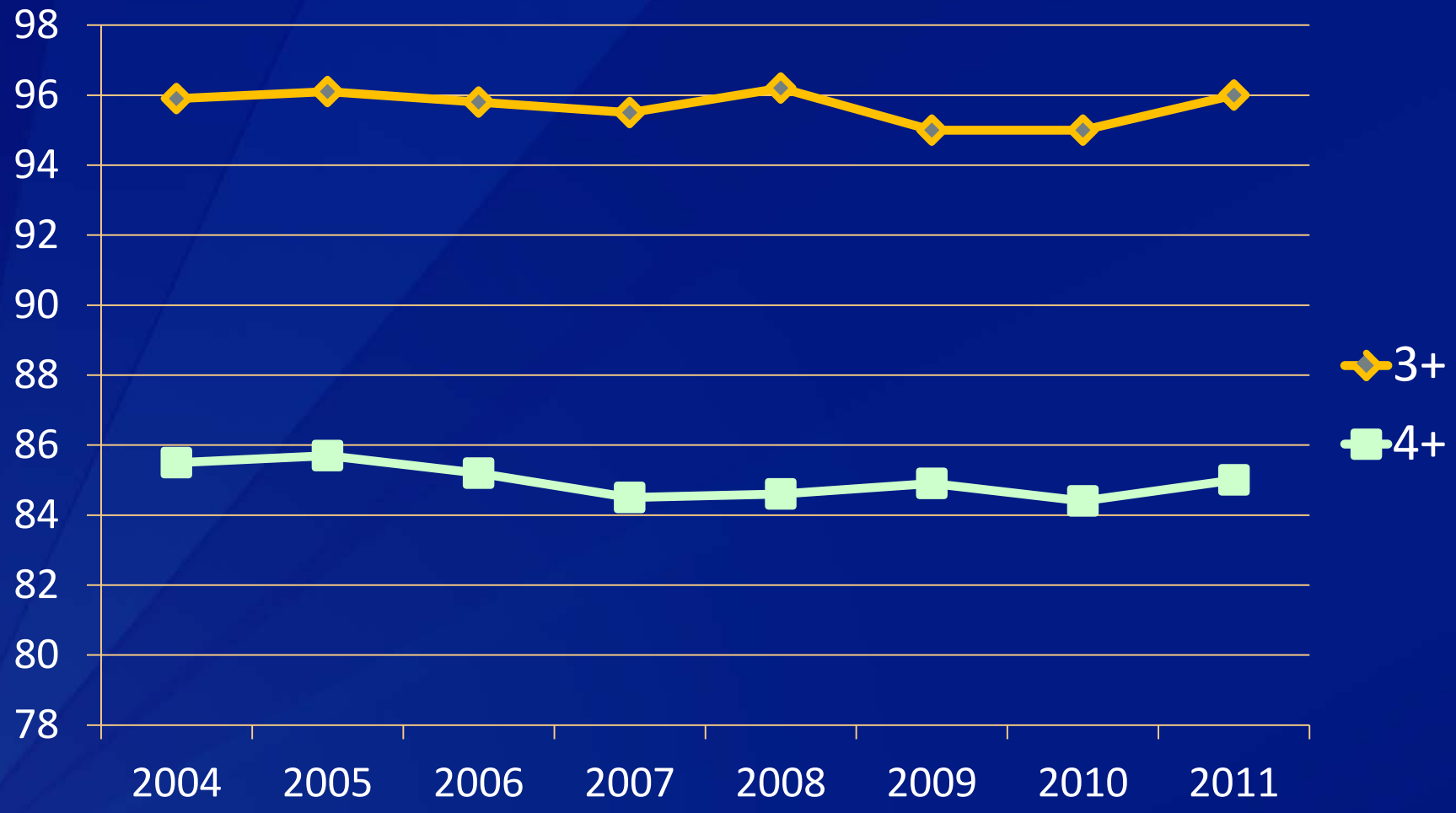
*2012 data are provisional.

Source: CDC. National Notifiable Diseases Surveillance System, 2012.

Pertussis Immunization in the US

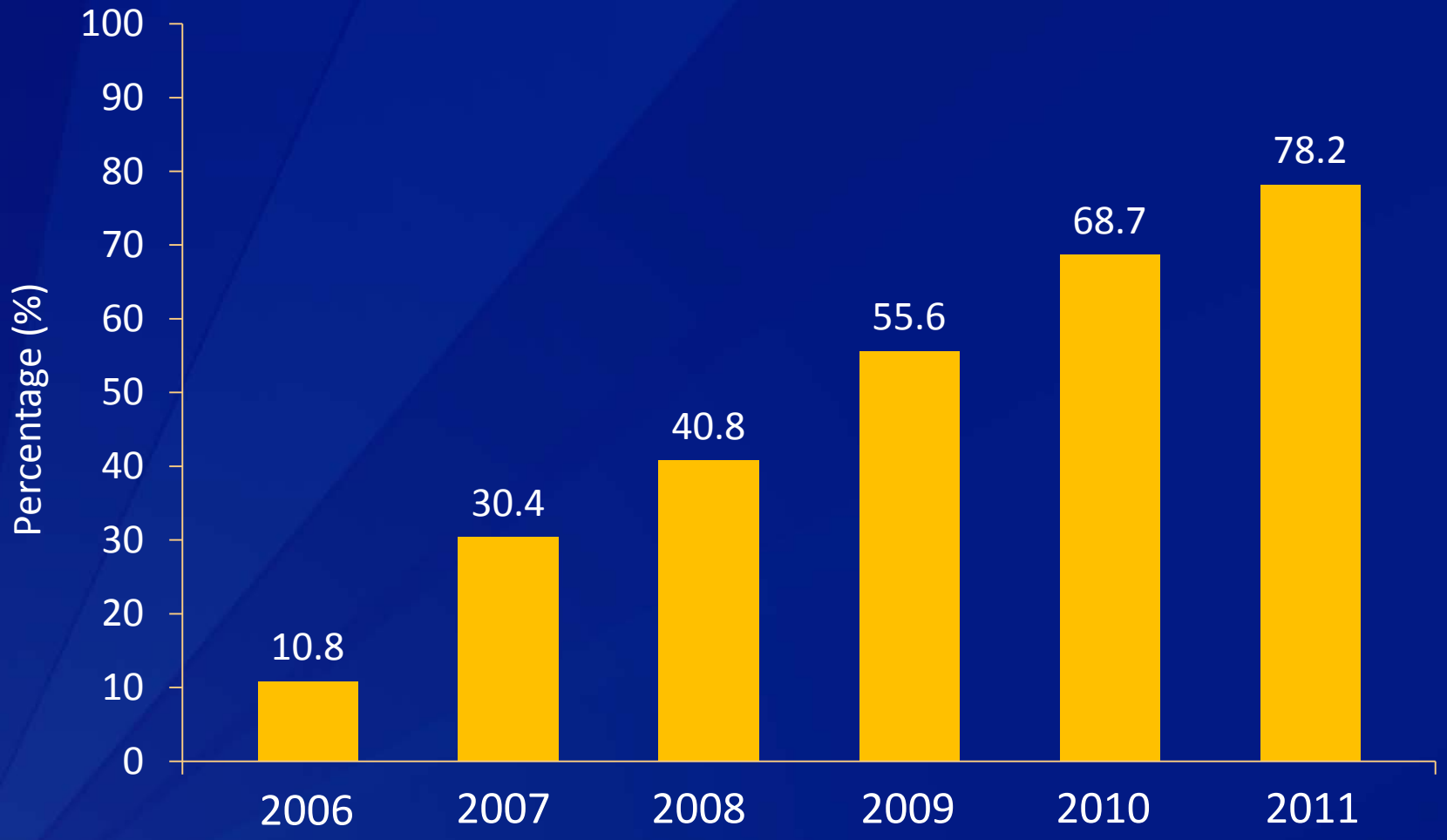
- Whole-cell vaccines/DTwP (1940s)
- DTaP (1990s)
  - Infants at 2, 4, 6 months (1997)
  - Toddlers at 15-18 months (1992)
  - Pre-school at 4-6 years (1992)
- Tdap
  - Adolescents at 11-12 years (2005)
  - Adults who have not received (2005)

High DTaP coverage among children aged 19 through 35 months — 2004–2011



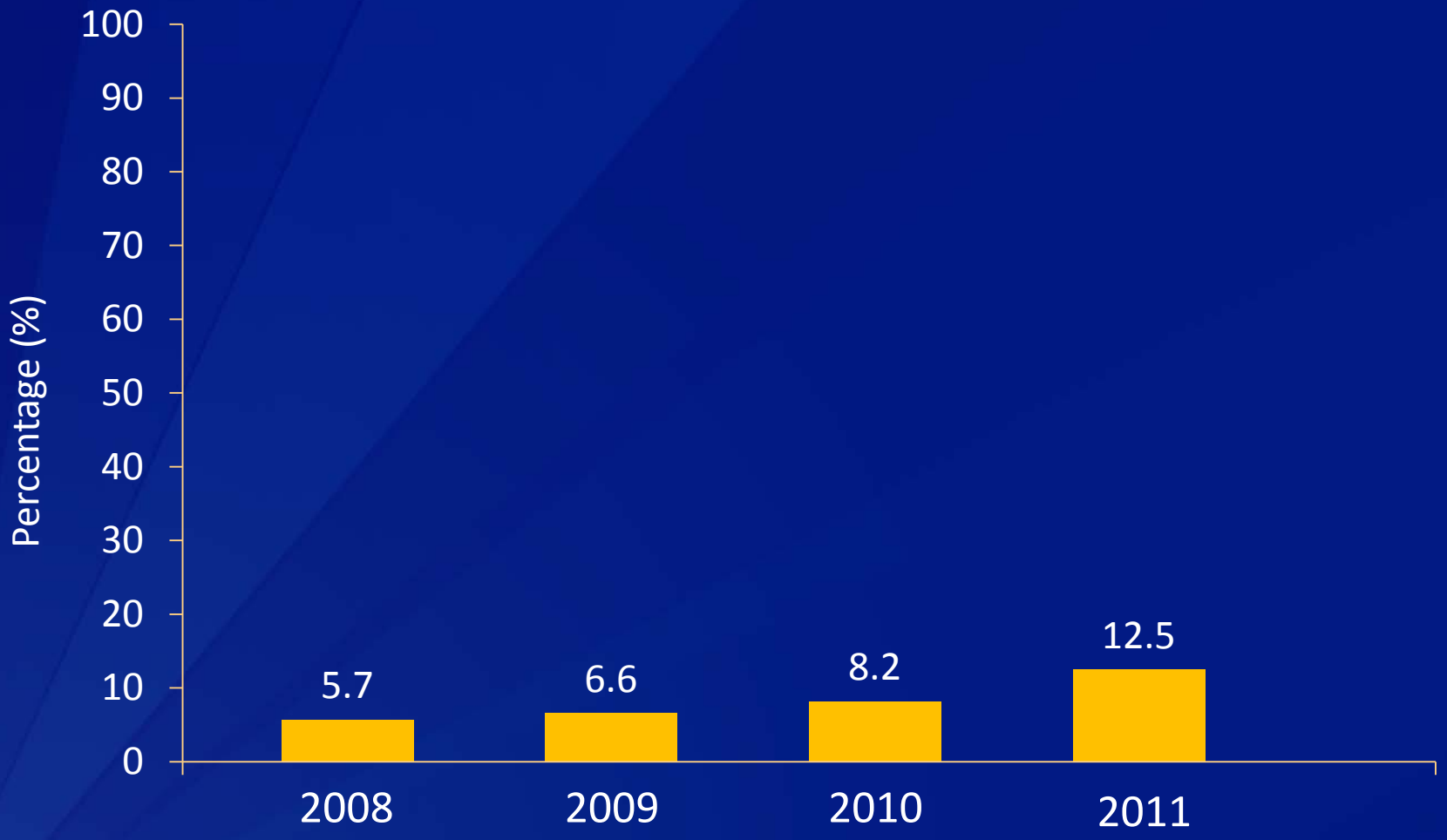
CDC National Immunization Survey

Increasing Tdap coverage among adolescents aged 13–17 years — 2006–2011



CDC. National, State, and Local Area Vaccination Coverage Among Adolescents Aged 33-17 Years - United States, 2008. MMWR 2008;58(36);997-1001.
CDC. Vaccination Coverage Among Adolescents Aged 13-17 Years – United States, 2007. MMWR 2008;57(40)1100-1103.
CDC. Vaccination Coverage Among Adolescents Aged 13-17 Years– United States, 2006. MMWR 2007;56(34) 885-888.
CDC. National, State, and Local Area Vaccination Coverage among Adolescents Aged 13-17 Years - United States, 2009 MMWR 2010 ;59(32);1018-1023.

Tdap coverage among adults aged 19–64 years, 2008 – 2011, NHIS



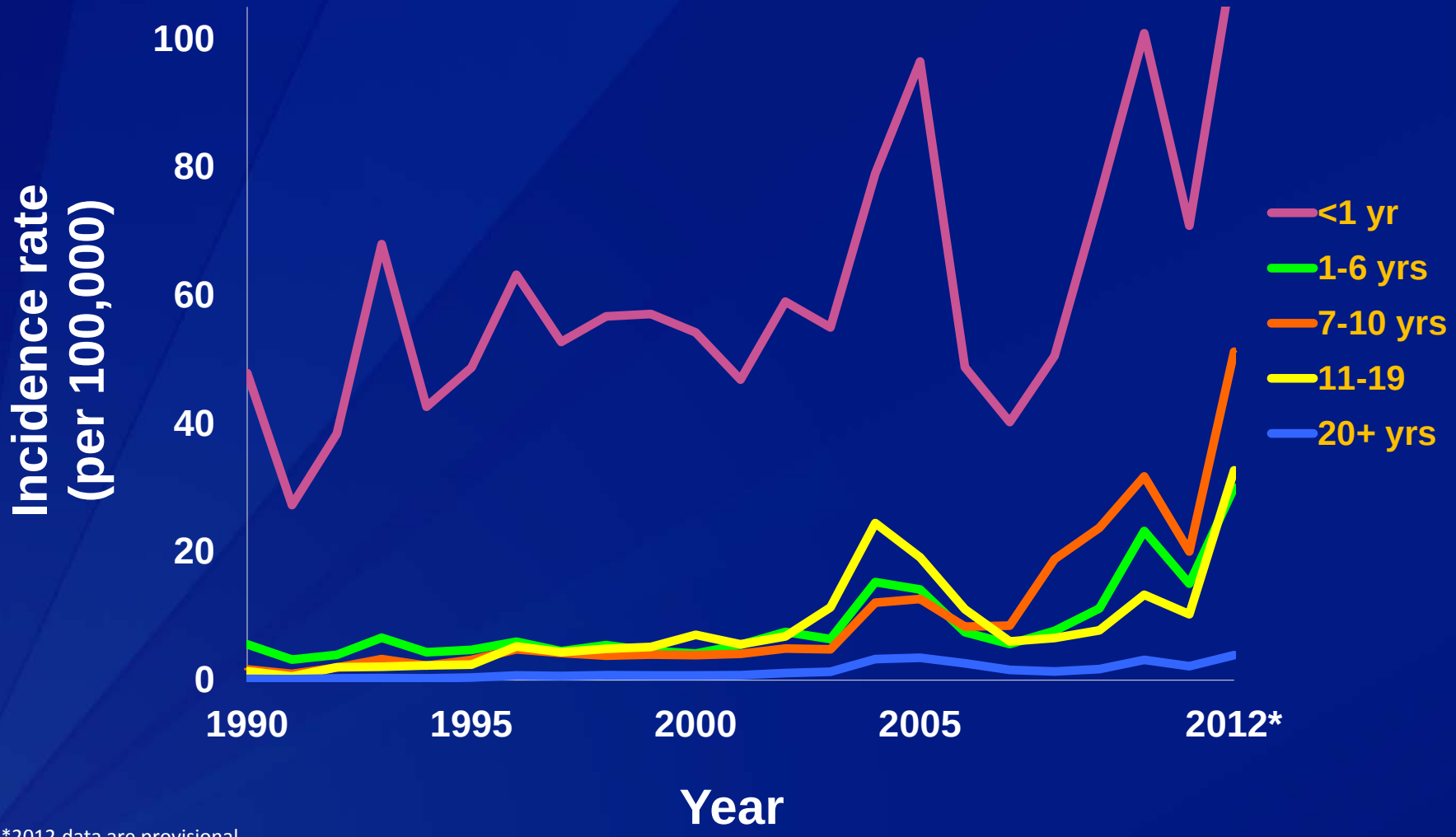
CDC. Tetanus and Pertussis Vaccination Coverage Among Adults Aged ≥18 Years --- United States, 1999 and 2008. MMWR 59(40);1302-1306
CDC. Adult Vaccination Coverage — United States, 2010. MMWR 61(04);66-72
CDC. Noninfluenza Vaccination Coverage Among Adults — United States, 2011. MMWR 62(04);66-72

Self-reported tetanus vaccination coverage among persons aged ≥19 years, 2009, NHIS

	Tetanus vaccination within preceding 10 yrs (2009)		
	No. in sample†§	Vaccination coverage	
		%	95% CI
Total	26,050	**61.3**	60.4-62.2
Age group (yrs)			
19--24	2,353	**66.4**	63.8-69.0
25--49	12,025	**62.3**	61.0-63.5
50--64	6,540	**62.8**	61.3-64.3
65--74	2,765	**58.3**	56.0-60.6
75+	2,367	**46.0**	43.5-48.5

CDC. 2009 Adult Vaccination Coverage, NHIS. http://www.cdc.gov/vaccines/stats-surv/nhis/2009-nhis.htm

Reported pertussis incidence by age group: 1990-2012*



*2012 data are provisional.

SOURCE: CDC, National Notifiable Diseases Surveillance System and Supplemental Pertussis Surveillance System

Absence of Indirect Effects of Tdap

Mean incidence of reported pertussis among infants

	1990-2003 (pre-peak)	2006-2012 (post-peak)	p-value
Mean incidence (per 100,000)	52.1	73.3	0.10

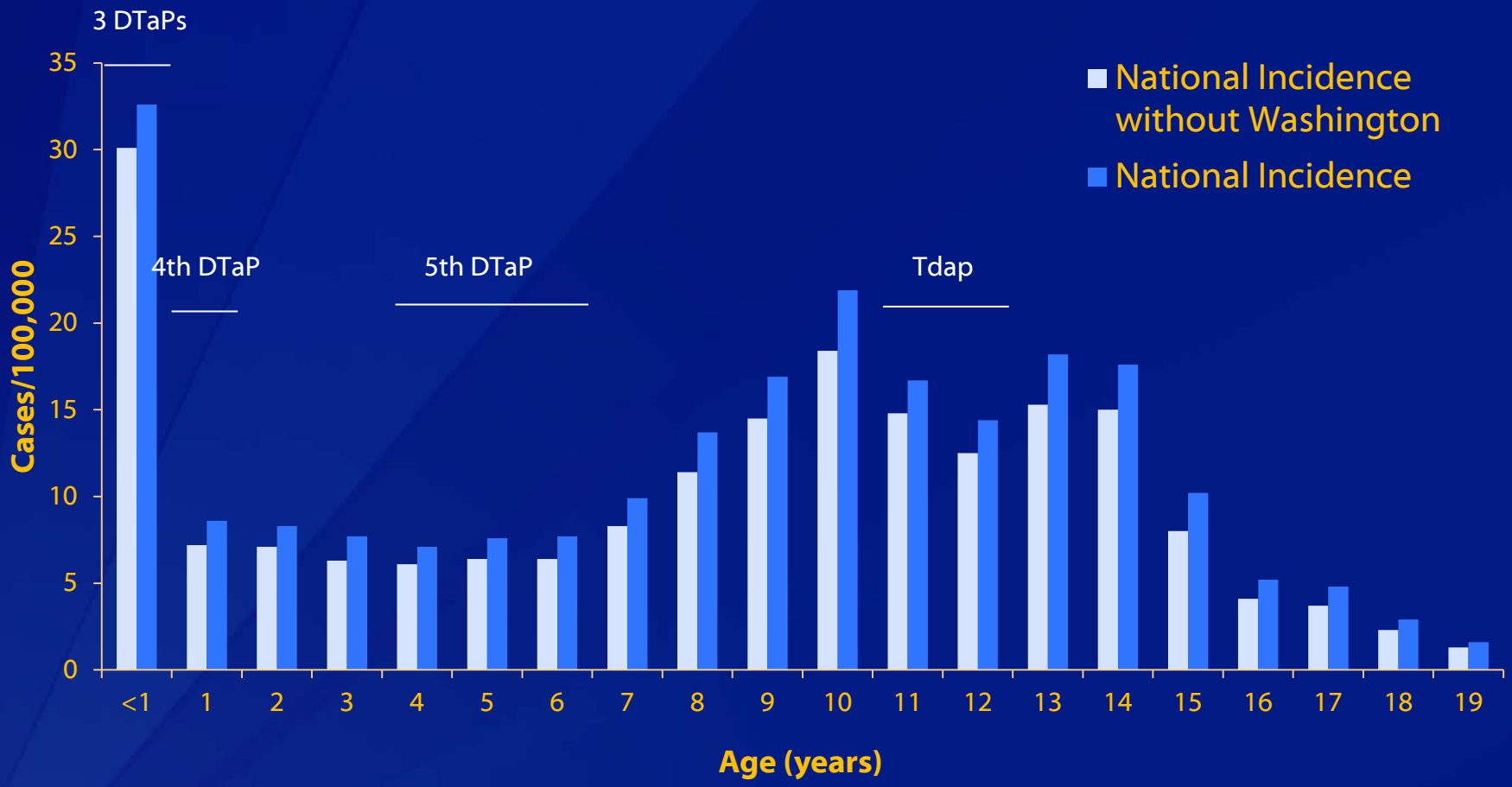
DTaP VE and Duration of Protection Estimates—California, 2010[1]

Model *	Case (n)	Control (n)	VE, %	95% CI
Overall VE, All Ages				
0 dose	53	19	Ref	--
5 doses	629	1,997	88.7	79.4 – 93.8
Time since 5th dose				
0 doses	53	19	Ref	--
< 12 months	19	354	98.1	96.1 – 99.1
12 – 23 months	51	391	95.3	91.2 – 97.5
24 – 35 months	79	366	92.3	86.6 – 95.5
36 – 47 months	108	304	87.3	76.2 – 93.2
48 – 59 months	141	294	82.8	68.7 – 90.6
60+ months	231	288	71.2	45.8 – 84.8

[1]JAMA. 2012;308:2126-2132.

*Accounting for clustering by county and provider

Pertussis rates by age — United States, 2012



CDC. MMWR 2012;61(28);517-522.

Summary and Working Hypothesis

- **Pertussis incidence has increased since 1980s**
- **Resurgence of childhood disease despite high DTaP coverage**
  - Excellent initial vaccine effectiveness
  - Moderate and immediate waning of immunity
- **Re-emergence of adolescent disease despite Tdap**
  - Tdap boost in DTaP recipients may wane quickly
- **Switch to aP vaccines is changing pertussis epidemiology**
  - i.e. a problem of susceptibility *despite* vaccination

Tdap ANTIBODY PERSISTENCE

Tdap antibody persistence
Published studies

			Subjects (n)		Mean age (yrs) (range)	
Country	**Vaccine**	**Post-Tdap (yrs)**	**Tdap**	**Control***	**Tdap**	**Control***
U.S.	Boostrix	3	937	449	44.8 (21-67)	45.3 (22-67)
Canada	Adacel	1	¶	¶	¶	¶
		3				
		5				
		10				
Finland	Boostrix	3	264	30	14.6 (14.0-15.9)	same as Tdap
		5	267	36	16.6 (15.8 – 17.9)	
		10	75	7	21.1 ± 0.31	
Australia	Boostrix	1-3	310	77	39.8 (20-69)	41.2 (22-57)
		5	240	64	45.2 (25-74)	47.0 (28-62)
		10	153	35	50.3 ± 9.74	same as Tdap

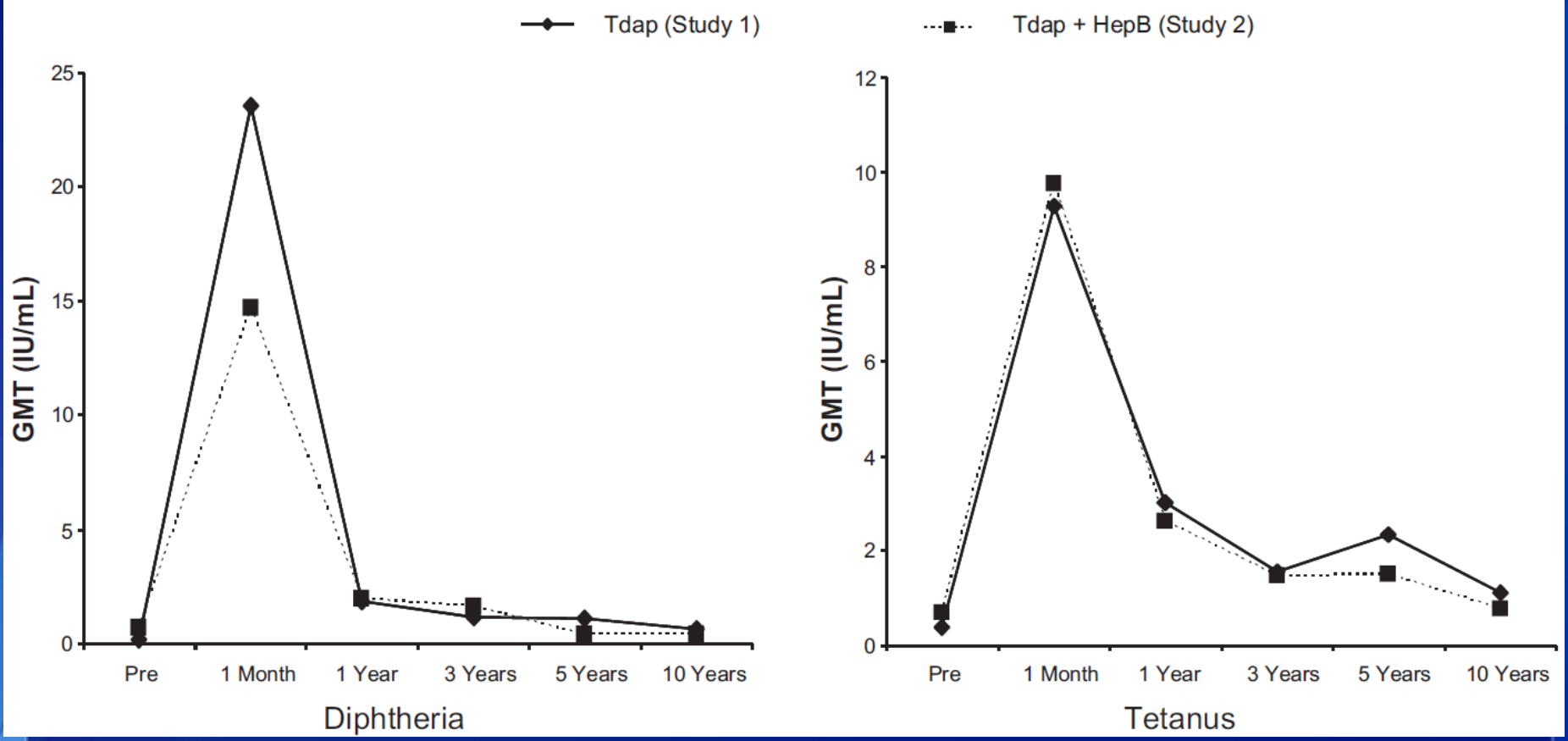
* Control vaccines: US – Adacel; Finland and Australia – Td + aP

¶ Summary of 3 studies: Study 1 - 11 – 54 yrs (3 lots of Tdap); Study 2 –11-13 yrs (Tdap + Hep B); Study 3 – 19-60 yrs (Td vs. Tdap)

US: Weston et al (2011); Canada: Barreto et al (2007), Tomovici et al (2012); Finland: Edelman et al (2004), Edelman et al (2007), Mertsola et al (2010); Australia: McIntyre et al (2004), McIntyre et al (2009), Booy et al (2010)

Diphtheria and tetanus antitoxin GMC up to 10 years after Tdap (Adacel)

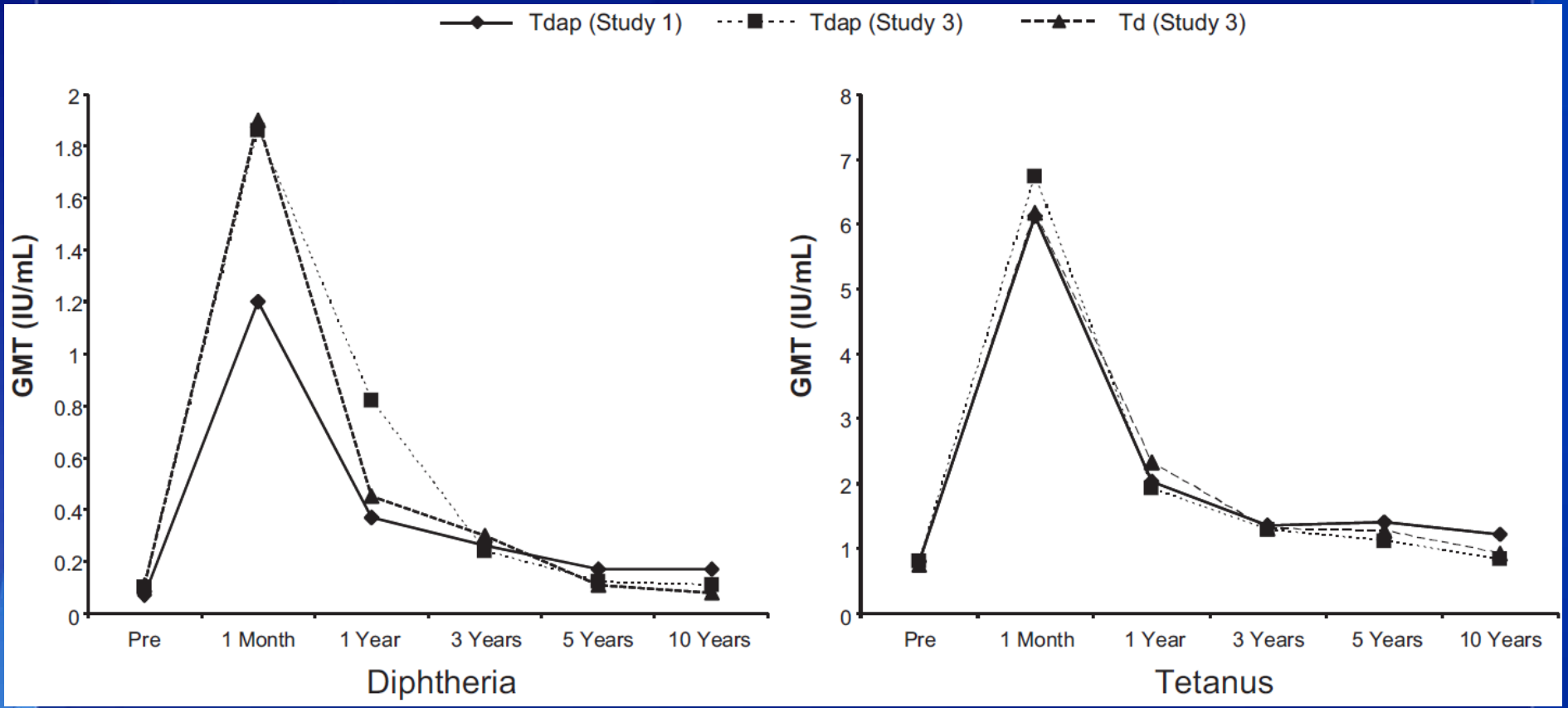
Adolescents (n=324)



Tomovici 2012

Diphtheria and tetanus antitoxin GMC up to 10 years after Tdap (Adacel)

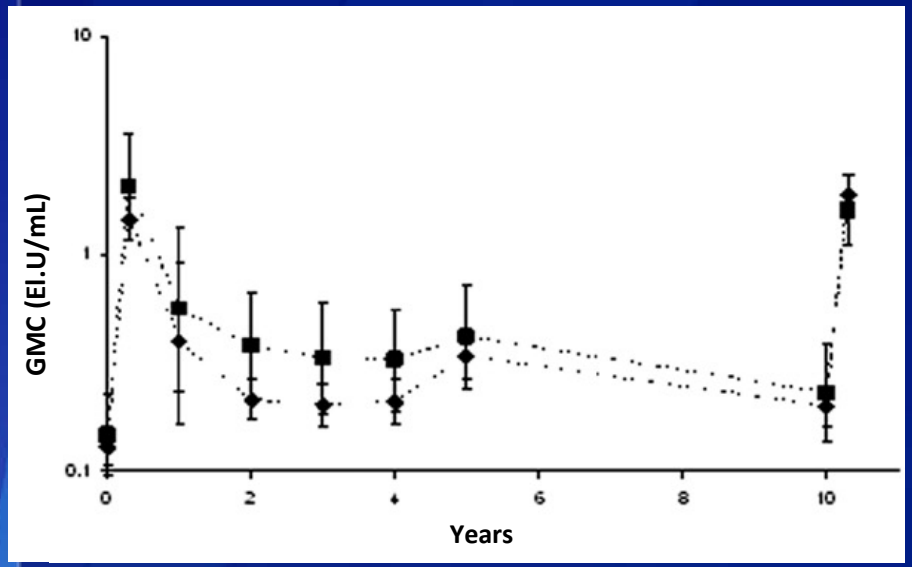
Adults (n=644)



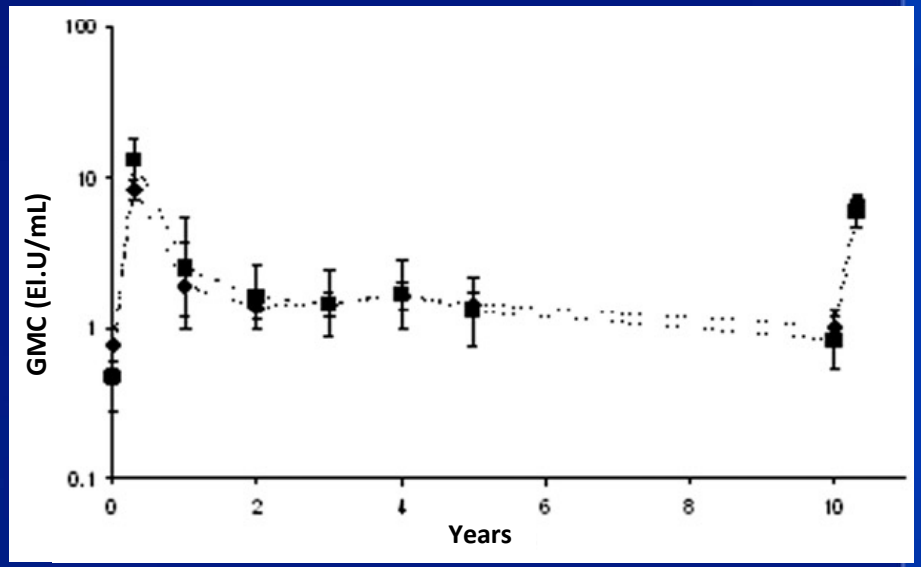
Tomovici 2012

Diphtheria and Tetanus: Antibody GMCs over 10 years before and after 1st Tdap and 1month after repeat Tdap booster (Boostrix)

Adults (n=164)



Diphtheria



Tetanus

Footnote: diamonds = Tdap group; squares = Td + aP group; Error bars = 95% CIs.

Booy 2010

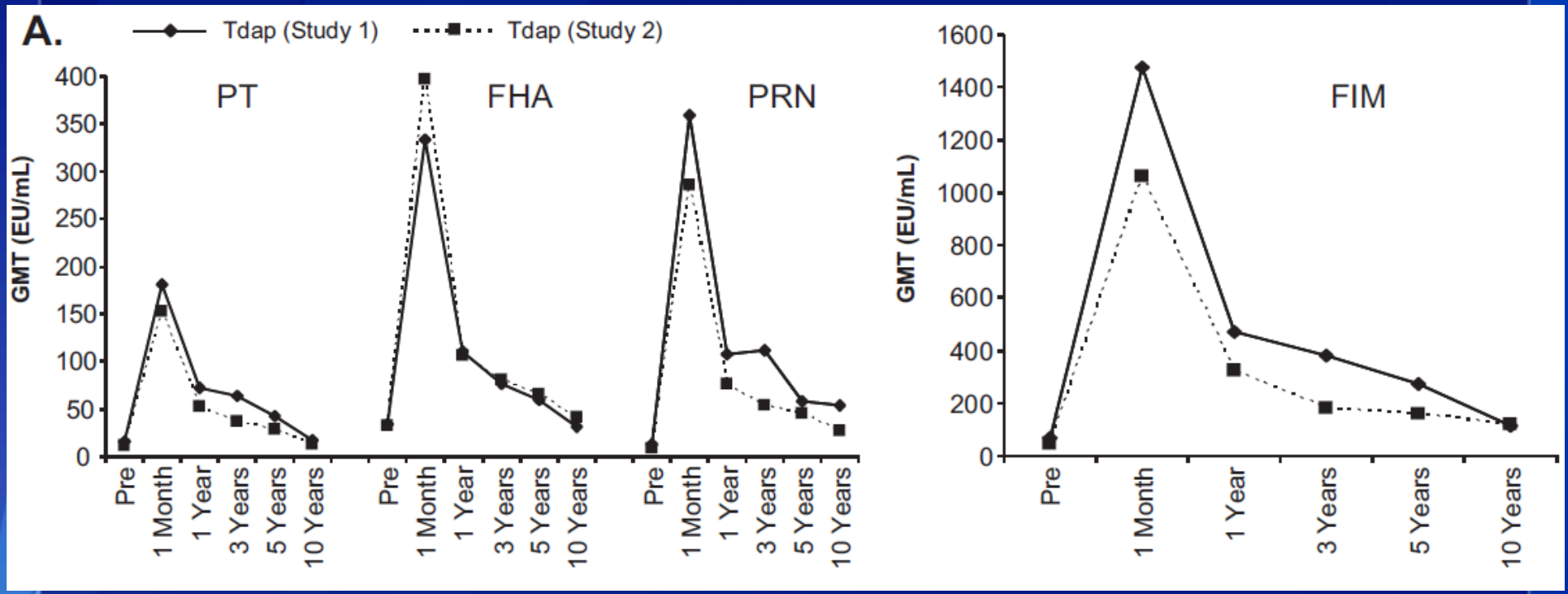
Summary: Persistence of antibodies post-Tdap Tetanus and Diphtheria

- **Diphtheria**
  - High levels of seroprotection* (>90%) at 3-5 years
  - >80% seroprotection at 10 years
  - Generally, adolescents > adults
  - Comparable to Td
- **Tetanus**
  - Very high levels of seroprotection persisting to 10 years
  - Comparable to Td

*Seroprotection for diphtheria and tetanus defined as ≥0.1 IU/mL by ELISA and/or Vero cell assay (0.016 IU/mL)

Pertussis antigens GMC up to 10 years after Tdap (Adacel)

Adolescents (n=324)

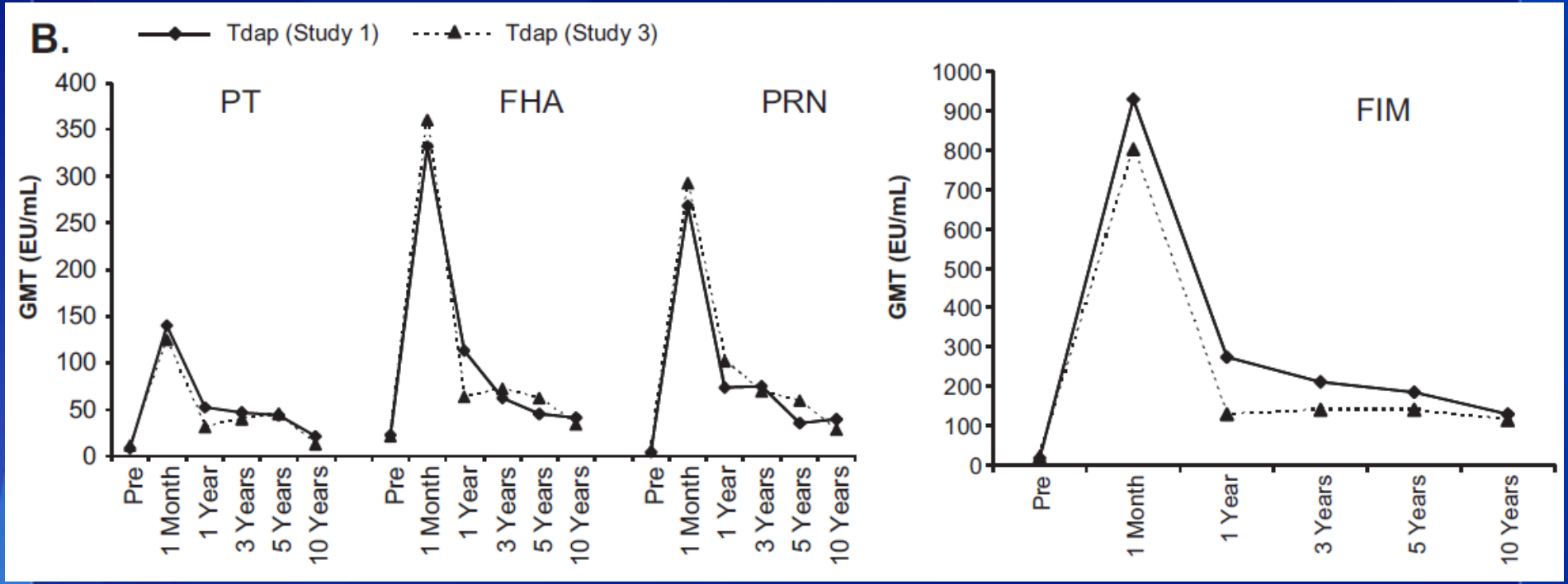


PT: pertussis toxin; FHA: filamentous hemagglutinin; PRN: pertactin; FIM: fimbriae types 2&3

Tomovici 2012

Pertussis antigens GMC up to 10 years after Tdap (Adacel)

Adults (n=644)

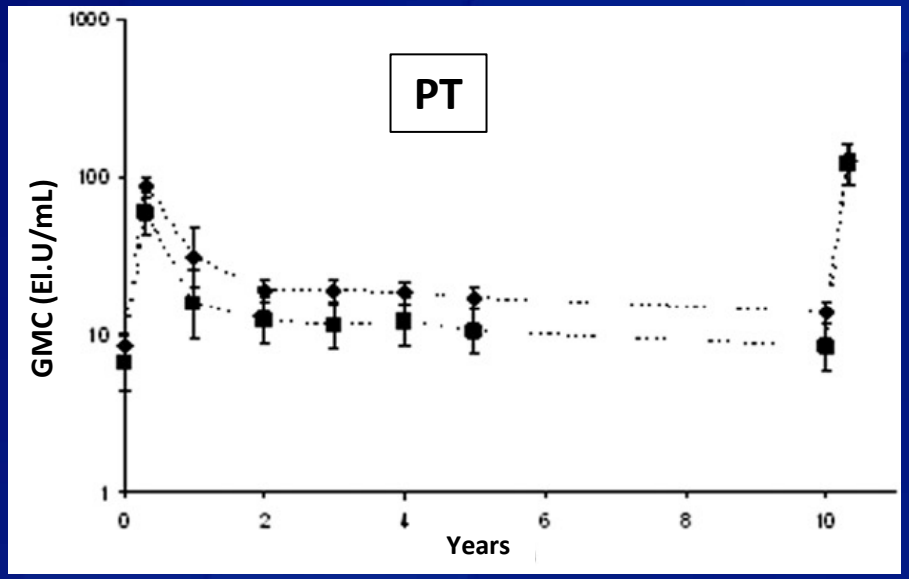


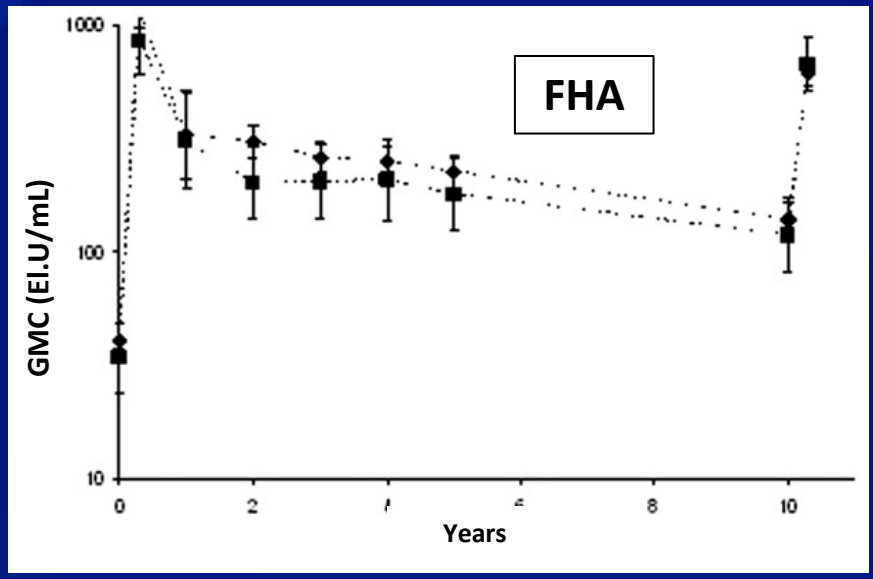
PT: pertussis toxin; FHA: filamentous hemagglutinin; PRN: pertactin; FIM: fimbriae types 2&3

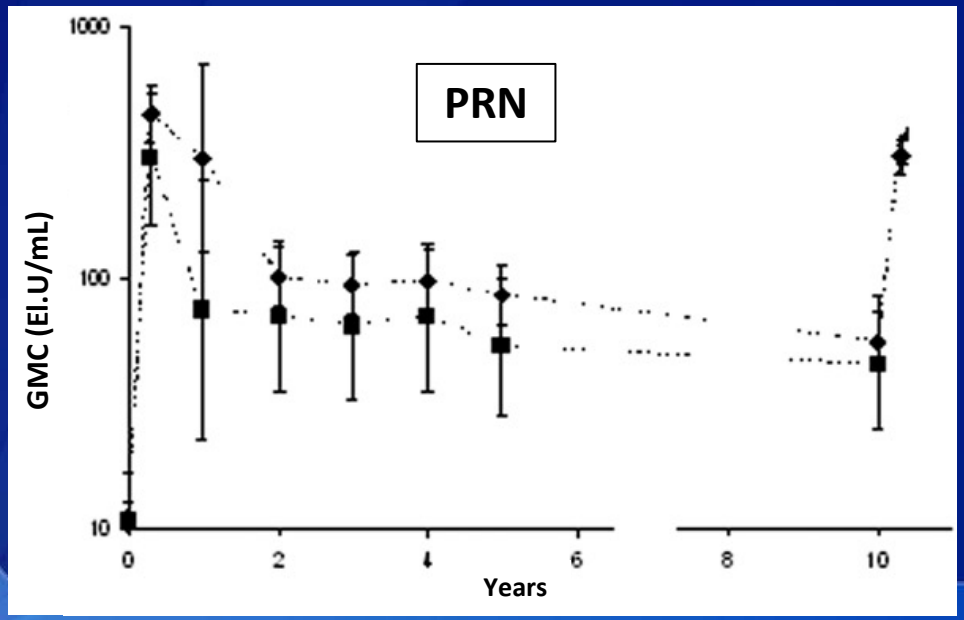
Tomovici 2012

Pertussis: Antibody GMCs over 10 years before and after 1st Tdap and one month after decennial Tdap (Boostrix)

Adults (n=164)







Diamonds = Tdap group

Squares = Td + ap group

Error bars = 95% CIs

Booy 2010

Persistence of antibodies post-Tdap Pertussis

- **Post-vaccination:**
  - Rapid decline in first 1-2 years
  - Slower decline over 5-10 years
  - Antibody levels generally higher than pre-vaccination, but close to pre-vaccination at 10 years

- **Antibody contributes to protection, but no defined level(s) of antibody correlates absolutely with protection**

Persistence of antibodies post-Tdap
WG conclusions

- Reassured that protection against tetanus and diphtheria would persist for 5 to 10 years
- Concern regarding decay of pertussis antibody by 5 years
- Difficulty in reconciling antibody response and persistence with vaccine effectiveness data

TDAP VACCINE EFFECTIVENESS

Tdap Vaccine Effectiveness Studies

Author	Year	Country	Age Range	Study Design	VE (Confidence Interval)
Pichichero	2005	US	11-64	Immunogenicity	85-89*
Ward	2005	US	15-65	Randomized Clinical Trial	92 (32-99)
Rank	2009	Australia	12-19	Screening	78 (61-88)
Wei	2010	St. Croix	11-18	Cohort	66 (-36-91)
CDC	2011	US	11-17	Case-Control	72 (38-87)
CDC	2012	US	11-19	Cohort	69 (38-86)
CDC	2012	US	11-14	Case-control	66 (52-76)

*Gustafsson et al. NEJM 1996; 334: 349-55.
*Schmitt et al. JAMA 1996; 275: 37-41.
Pichichero et al. JAMA 2005; 293: 3003-11.
Ward JI et al. N Engl J Med. 2005 Oct 13;353(15):1555-63.
CDC unpublished data.
Rank C, et al. Pediatr Infect Dis J. 2009 Feb;28(2):152-3.
Wei SC, et al. CID 2010; 51(3):315-321.
Skoff et al. NIC 2011, Washington, DC.
Terranella et al. EIS Conference 2012, Atlanta.

Adult Pertussis Trial (APERT)
United States

- **Vaccine: 3-component acellular pertussis***
- **Design: randomized controlled trial**
  - July 1997-December 1999
  - 2781 subjects (aged 15-65 years)
    - No history on primary series, but would have received DTwP
- **VE=92% (95% CI: 32-99)**
  - One vaccinated, 9 unvaccinated cases

* 8 µg pertussis toxin, 8 µg filamentous hemagglutinin, 2.5 µg pertactin without diphtheria or tetanus toxoids

Ward JI et al. N Engl J Med. 2005 Oct 13;353(15):1555-63.

Field evaluation of Tdap
New South Wales, Australia

- **Mass Tdap vaccination program**
  - 3-component Tdap
  - May - December 2004
- **Design: screening method**
  - 272,000 high school students (aged 12-19 years)
    - No history on primary series, but would have received DTwP
  - Coverage data from school records
  - Notified pertussis cases with onset January 1 -December 31, 2005
- **VE = 78.0% (95%CI: 60.7-87.6)**
  - 167 cases (26% vaccinated), PPV 56%

Rank C, et al. Pediatr Infect Dis J. 2009 Feb;28(2):152-3.

Field evaluation of Tdap
St. Croix, US Virgin Islands

- **Pertussis school outbreak**
  - Nursery - 12th grade
  - September - December 2007
- **Design: cohort study**
  - 266 students aged ≥11 years
    - 98% had received ≥4 childhood doses, would have received some DTwP
    - 12% had received Tdap
- **VE = 65.6% (95% CI: -35.8-91.3)**
  - 2 cases among 33 vaccinated, 41 cases among 233 unvaccinated

Wei SC, et al. CID 2010; 51(3):315-321

Summary of Tdap Effectiveness

- Tdap effectiveness 66 – 78% in field observational studies
- Preliminary data suggest effectiveness wanes within 3-4 years among acellular recipients
- Vaccine effectiveness data consistent with current epidemiology
- No evidence of herd immunity

Tdap REVACCINATION

Tdap revaccination - Published clinical trials

5 years after previous Tdap

Country	Product	Previously received (n)	N	Mean age (yrs)	Author
Germany	Boostrix (Tdap-IPV)	Tdap-IPV Tdap + IPV	415	11.4 ± 0.94* (range: 9 to 13)	Knuf *et al* (2010)
Canada & US	Adacel	Tdap	545	31.7 (range: 15 to 69)	Halperin *et al* (2011)

* Received first Tdap at age 4-8 years (replaced 5th DTaP dose)

10 years after previous Tdap

Country	Product	Previously received (n)	N	Mean age (yrs)	Author
Finland	Boostrix	Tdap (75) DT + ap (7)	82	21.1 ± 0.31	Mertsola *et al* (2010)
Australia	Boostrix	Tdap (153) DT + ap (35)	164	50.3 ± 9.74	Booy *et al* (2010)
Canada	Adacel	Tdap Tdap-IPV	342	31.2 (range: 21 to 70)	Halperin *et al* (2012)

Tdap revaccination U.S. clinical trials

- **GSK study of Boostrix in young adults administered 10 years after previous Tdap boosting**
  - Study starts in 1Q 2013 and report in 2014
- **Sanofi Pasteur – Adacel in adults administered 9-11 years after previous Tdap**
  - Study completed and presented to WG (2013)

Tdap revaccination 5- and 10-years after first Tdap

SAFETY

Summary of adverse events: 2nd Tdap 5 years after previous dose

	Injection site (%)			Systemic (%)				Serious AEs
	Pain	Erythema	Swelling	Myalgia	Headache	Malaise	Fever	
Adacel - 1 to 14 days post-vaccination (Halperin 2011)								
1st Tdap (n=532)	73.8	19.2	16.2	27.7	39.7	n/a	4.4	
2nd Tdap (n=539)	87.6	28.6	25.6	61.0	53.2	38.2	6.5	7*
Boostrix-IPV - 1 to 4 days post-vaccination (Knuf 2010)								
1st Tdap-IPV¶ (n=351)	54.4	52.1	46.4	n/a	n/a	n/a	14.5	
2nd Tdap-IPV (n=351)	73.2	48.1	40.2§	n/a	n/a	n/a	4.0	0

* Deemed to be unrelated to vaccination

¶ 1st Tdap at age 4-8 years (replaced 5th DTaP dose)

§ 2 large injection site swellings reported (0.6%)

Summary of adverse events: 2nd Tdap 10 years after previous dose

	Injection site (%)			Systemic (%)				
	Pain	Erythema	Swelling	Myalgia	Headache	Malaise	Fever	Serious AEs
Boostrix - Within 4 days of vaccination (Booy 2010)								
1st Tdap (n=164)	67.1	34.8	16.5	n/a	12.8	11.0*	9.1	
Repeat (n=164)	69.5	35.4	32.3¶	n/a	9.1	11.6*	2.4	0
Adacel - Within 7 days of vaccination (Halperin 2012)								
Naïve† (n=407)	84.4	29.7	23.3	53.5	37.6	29.0		
Repeat (n=361)	87.8	23.1	20.5	60.1	40.6	29.4		4§

* Reported fatigue
¶ 3 large injection site swellings
† Control group received 1st dose of Tdap
§ Considered unrelated to vaccination

Tdap revaccination
Safety: WG conclusions

- **Local reactions common, systemic reactions less common**
  - Mild to moderate and self-limited
  - Frequency generally comparable to first Tdap
- **Serious AEs rare, not related to vaccine**
- **Data from US trials would not differ significantly from data collected from other countries**
- **Observational studies support Tdap with intervals <5 years**

Tdap revaccination 5- and 10-years after first Tdap

IMMUNOGENICITY

Tetanus and diphtheria GMC concentration before and after 1st and 2nd dose of Tdap (Adacel) after 5-year interval

Table 2
Geometric mean concentrations and fold antibody rise before and after a first dose and second dose of Tdap after a 5-year interval.

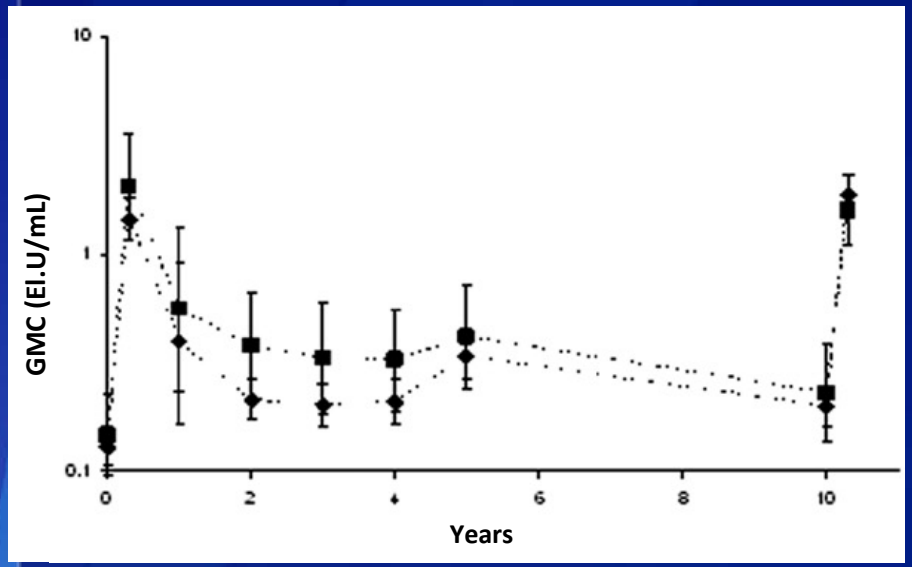
		Previous studies		Current study	
		Prevaccination	Postvaccination	Prevaccination	Postvaccination
Tetanus (IU/mL)	*N*	451	451	445	451
	GMC (95% CI)	0.643 (0.566; 0.731)	9.59 (8.67; 10.6)	1.41 (1.27; 1.56)	9.62 (9.06; 10.2)
	Fold-rise (95% CI)		14.9 (13.2; 16.7)		6.89 (6.13; 7.75)
Diphtheria (IU/mL)[a]	*N*	64	64	64	64
	GMC (95% CI)	0.415 (0.307; 0.560)	9.39 (7.85; 11.2)	4.45 (2.77; 7.15)	8.70 (6.59; 11.5)
	Fold-rise (95% CI)		22.6 (16.9; 30.2)		1.96 (1.48; 2.59)
Diphtheria (IU/mL)[b]	*N*	379	379	379	379
	GMC (95% CI)	0.089 (0.073; 0.109)	1.57 (1.27; 1.94)	0.133 (0.110; 0.162)	2.17 (1.84; 2.56)
	Fold-rise (95% CI)		16.2 (14.1; 18.8)		15.4 (13.5; 17.5)

[a] Diphtheria with intervening quadrivalent meningococcal vaccine.
[b] Diphtheria without intervening quadrivalent meningococcal vaccine.

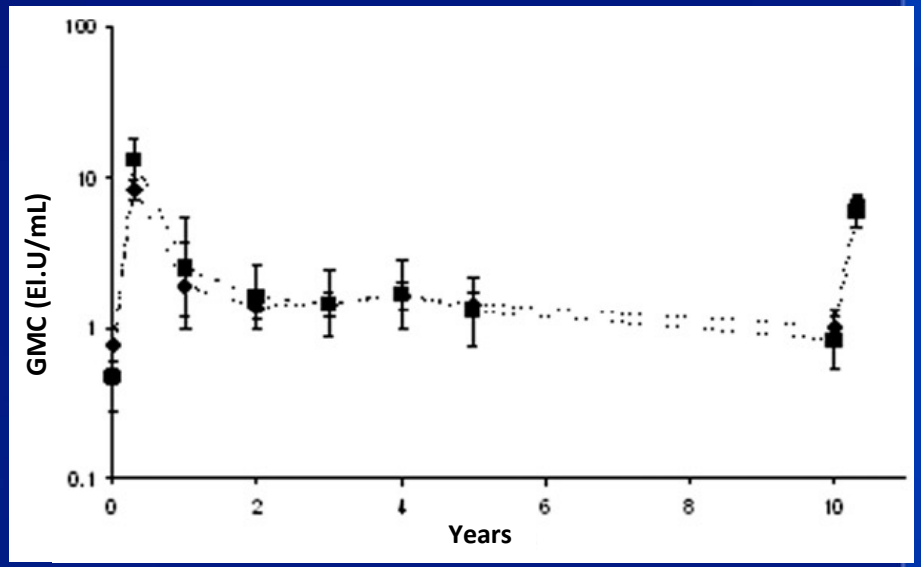
Halperin 2011

Diphtheria and Tetanus: Antibody GMCs over 10 years before and after 1st Tdap and 1month after repeat Tdap booster (Boostrix)

Adults (n=164)



Diphtheria



Tetanus

Footnote: diamonds = Tdap group; squares = Td + aP group; Error bars = 95% CIs.

Booy 2010

Response to Tdap booster dose Tetanus and Diphtheria

- Responses to tetanus and diphtheria robust at 5 and 10 years
- Very high levels of seroprotection

Pertussis GMC concentration before and after 1st and 2nd dose of Tdap (Adacel) after 5-year interval

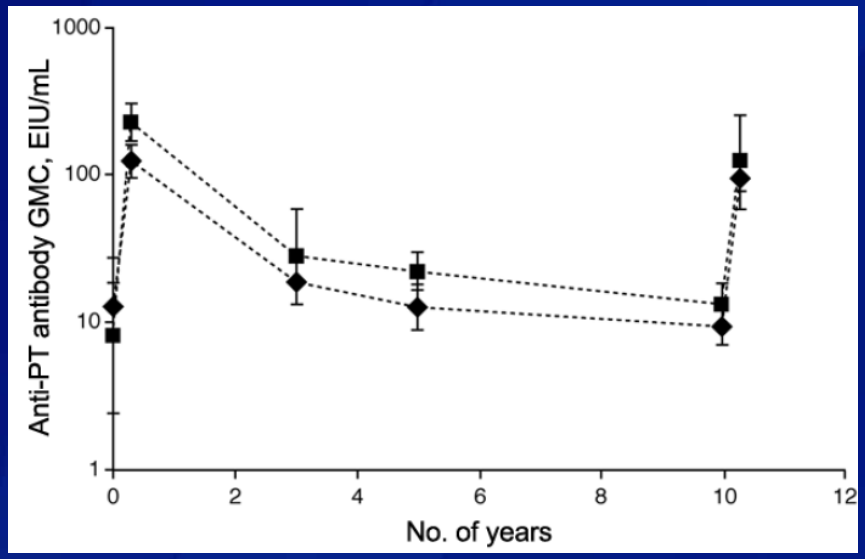
Table 2
Geometric mean concentrations and fold antibody rise before and after a first dose and second dose of Tdap after a 5-year interval.

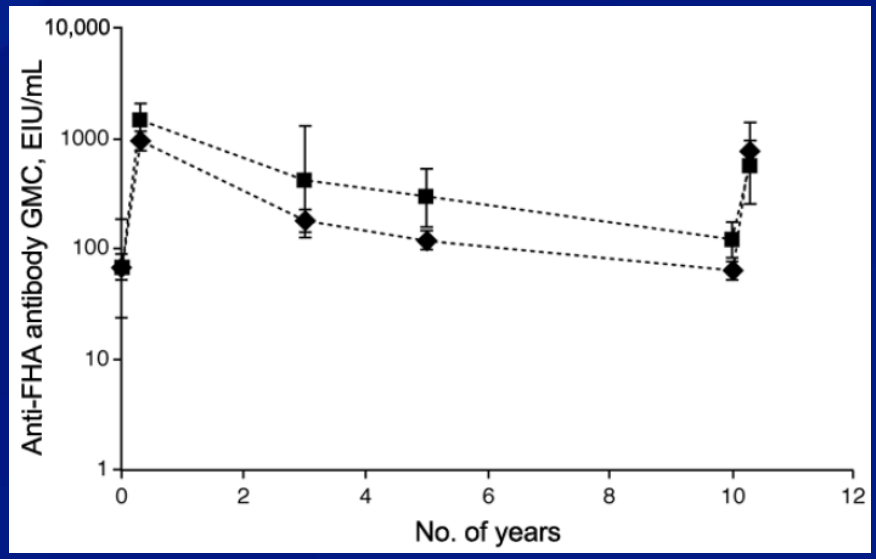
		Previous studies		Current study	
		Prevaccination	Postvaccination	Prevaccination	Postvaccination
PT (EU/mL)	*N*	451	449	381	425
	GMC (95% CI)	12.7 (11.3; 14.3)	243 (220; 270)	21.3 (19.4; 23.5)	104 (97.0; 112)
	Fold-rise (95% CI)		16.0 (14.3; 17.8)		4.91 (4.59; 5.24)
FHA (EU/mL)	*N*	451	450	450	450
	GMC (95% CI)	17.4 (15.6; 19.3)	241 (223; 261)	34.6 (31.9; 37.5)	201 (189; 215)
	Fold-rise (95% CI)		13.4 (12.1; 14.8)		5.81 (5.41; 6.24)
PRN (EU/mL)	*N*	451	450	451	451
	GMC (95% CI)	7.58 (6.75; 8.52)	271 (237; 309)	37.3 (32.7; 42.6)	218 (201; 236)
	Fold-rise (95% CI)		30.5 (27.3; 34.2)		5.60 (5.03; 6.24)
Fimbriae (EU/mL)	*N*	451	450	445	450
	GMC (95% CI)	32.7 (29.2; 36.6)	1337 (1169; 1529)	165 (145; 187)	749 (697; 806)
	Fold-rise (95% CI)		32.4 (28.1; 37.2)		4.50 (3.99; 5.09)

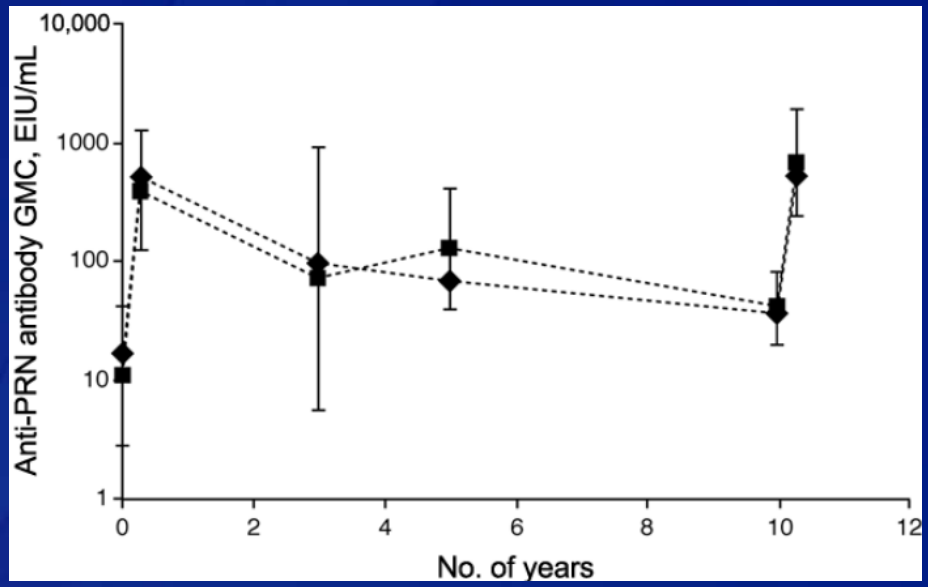
Halperin 2011

Pertussis: GMCs up to 10 years after 1st Tdap and 2nd Tdap after 10-year interval (Boostrix)

Young adults (n=75)







Diamonds: Tdap

Squares: Td + aP 1 month later

Vertical lines: 95% CI

Mertsola 2010.

Response to Tdap booster dose Pertussis

- Robust responses to all pertussis antibodies
- 2nd Tdap antibody response similar to 1st Tdap
- Antibody levels similar in cohorts boosted after 5 or 10 years[1]

[1]Halperin 2012

WG Conclusions on Tdap Revaccination Interval

- **Clinical trials support safety of 5- and 10-year intervals**
  - Shorter intervals supported by observational data
- **Immunogenic with intervals of 5- and 10-years**
  - 10-year interval probably sufficient for tetanus and diphtheria
- **Overall effectiveness and waning of protection will likely influence the impact of revaccination strategies**

- **Data available for second dose, not subsequent doses**
- **Considering “off-label” recommendation**

Tdap revaccination

FRAMEWORK FOR DECISION AND COST-EFFECTIVENESS ANALYSIS

Rationale and Objective

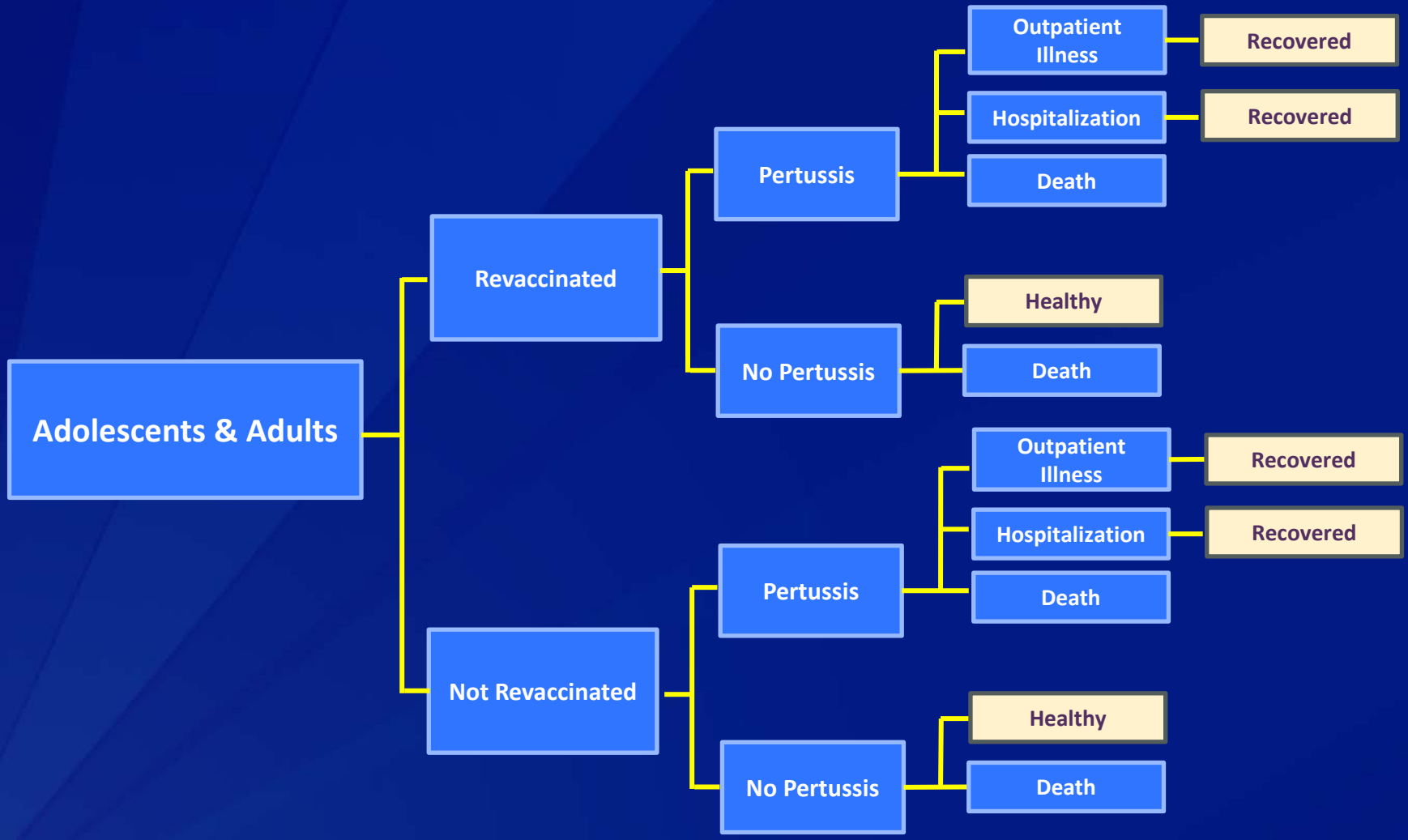
- **Rationale for decision and cost effectiveness analysis**
  - Incidence of pertussis in adolescents and adults increasing
  - Program implemented beginning in 2006
  - Duration of Tdap vaccine may be short among acellular recipients

- **Objective**
  - To evaluate the cost effectiveness and preventable burden of disease by different scenarios of revaccination of Tdap for healthy adolescents and adults

Decision and Cost-effectiveness Model

- **Strategy:**
  - revaccination vs. no revaccination
- **Cohort population: 11 year-old birth cohort**
- **Analytic horizon: life expectancy for 11-12 y.o. (68 years)**
- **Outcomes:**
  - Cases, outpatient visits, hospitalizations, death
  - Perspective: health system (direct cost) and societal (indirect costs)
  - Quality Adjusted Life Years (QALY's)

Decision Analytic Model

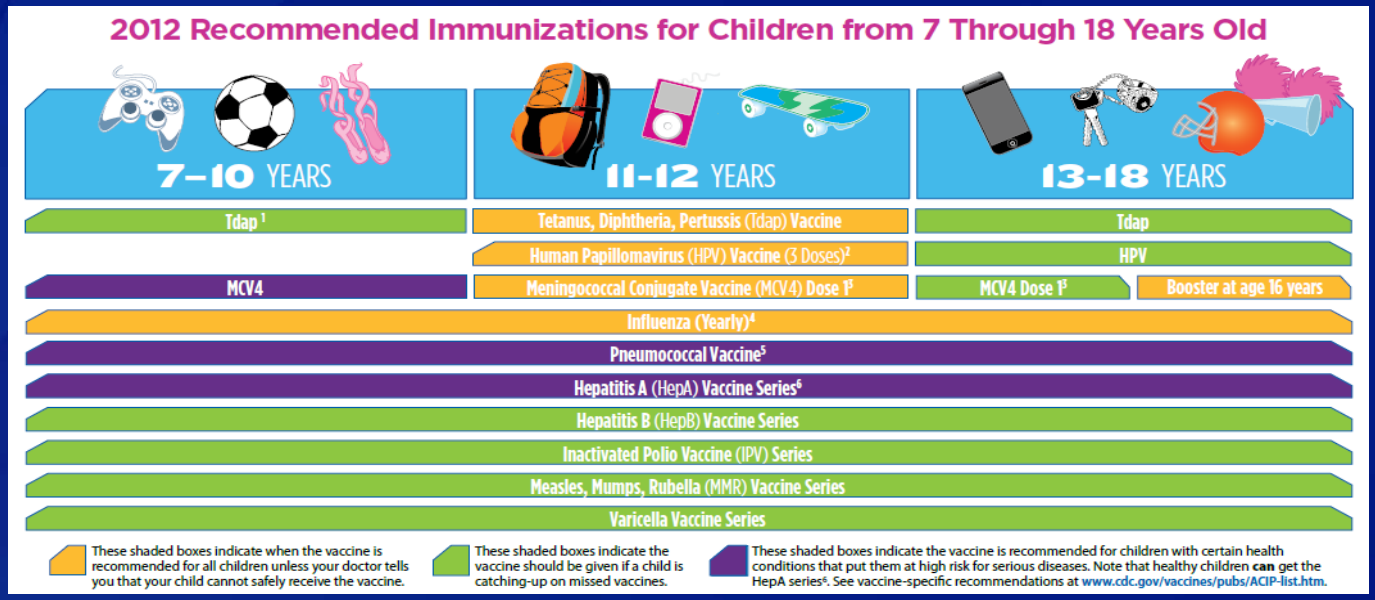


Key Vaccine Parameters of the Model

- **Incidence rates by age (or age group)**
- **Vaccine Effectiveness**
- **Waning immunity**
- **Vaccine Coverage**
- **Revaccination rate**
- **Infection rate of non vaccinated**
- **Pertussis patient's probability of visiting outpatient clinic and hospitalization**
- **Case fatality rate**
- **Natural death rate of each age**
- **Cost**
  - Direct medical cost of cases (inpatient & outpatient)
  - Indirect cost (wage loss and productivity loss)
  - Revaccination program cost

Considerations for Tdap revaccination schedule: Current recommendation/practices

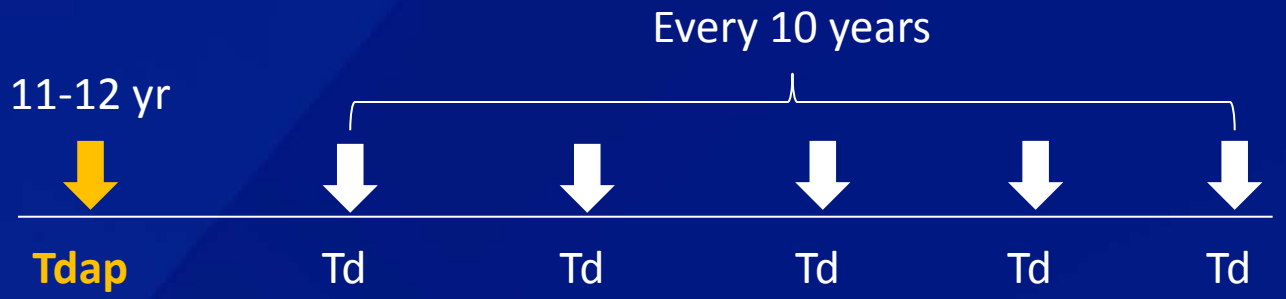
- Tdap for every pregnancy
- Decennial Td
- Adolescent platform
  - 11-12 years
  - 16 years (MCV4 booster)



Source: http://www.cdc.gov/vaccines/who/teens/downloads/parent-version-schedule-7-18yrs.pdf

Revaccination Scenario #1

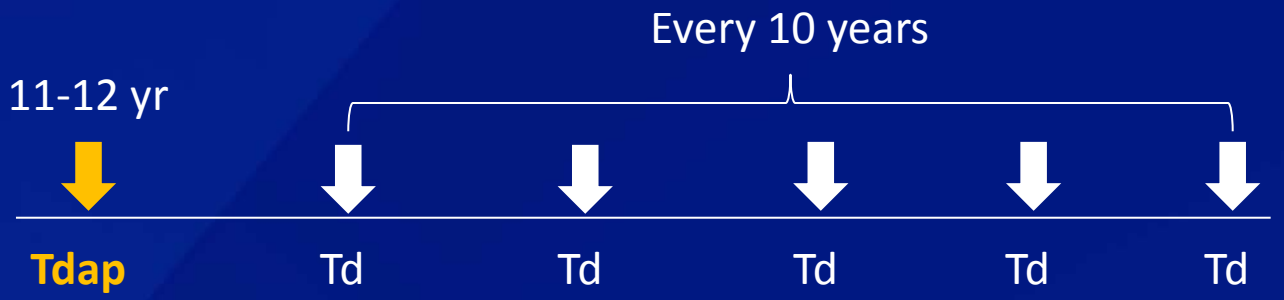
Current recommended schedule



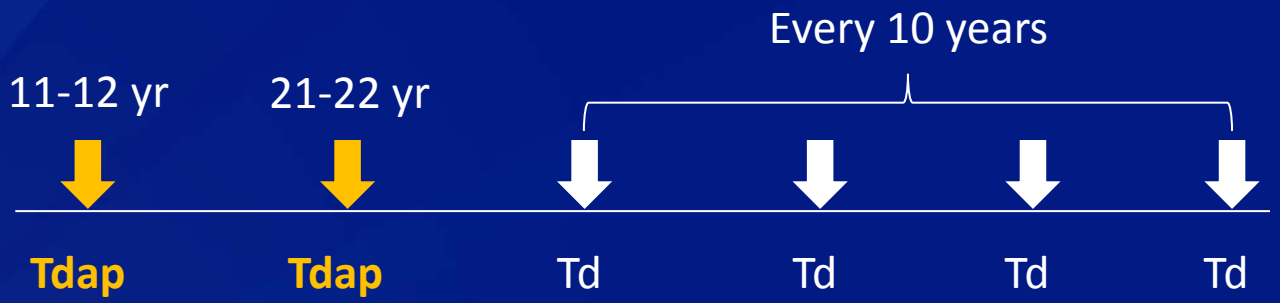
Decennial Tdap

Revaccination Scenario #2

Current recommended schedule

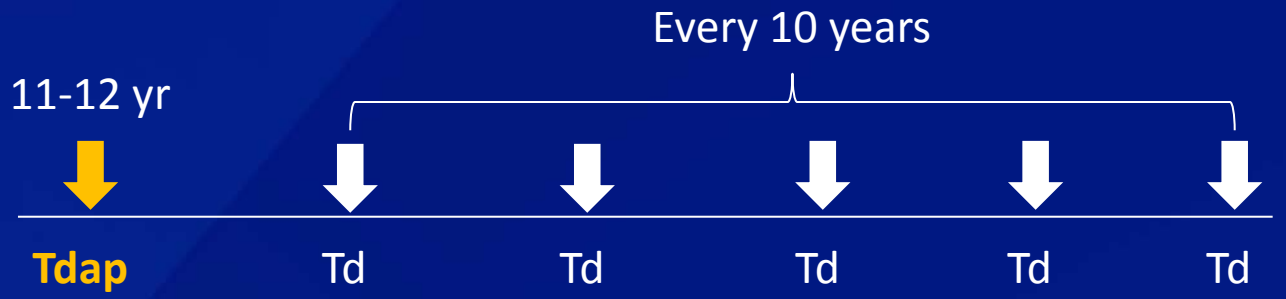


Replace 1st Td with Tdap



Revaccination Scenario #3

Current recommended schedule



2nd adolescent Tdap

Next steps for WG

- **To be completed for June 2013**
  - Tdap vaccine effectiveness and duration studies
  - Decision and cost effectiveness analysis
  - GRADE (question yet to be determined)

- **Consideration of “at-risk” populations**
  - Healthcare workers
  - Cocooning and post-partum
  - Under-vaccinated children aged 7-10 years

Final thoughts…

- **Pertussis vaccines protect**
- **Resurgence of pertussis expected to continue**
- **Goal is to prevent infant morbidity and mortality, but also limit burden of pertussis**
  - High coverage in adolescents can be achieved
  - Attaining high coverage among adults remains a challenge
- **No evidence yet of a strong “herd effect”**

Maximizing the Vaccination Program

Expanding the Evidence for New Vaccines

THANK YOU

Discussion Questions

- Are we considering appropriate strategies?
- Should we consider additional strategies?
- What additional data would you like to see?