EpiVac Pink Book Web-on-Demand Series

DTaP/Tdap-2020

Immunization Services Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Atlanta, GA
Learning Objectives

- For each vaccine-preventable disease, identify those for whom routine immunization is recommended.
- For each vaccine-preventable disease, describe characteristics of the vaccine used to prevent the disease.
- Describe an emerging immunization issue.
- Locate current immunization resources to increase knowledge of team’s role in program implementation for improved team performance.
- Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.
Today’s Agenda

EpiVac Pink Book Web-on-Demand Series: DTaP/Tdap-2020

Andrew Kroger, MD, MPH, Medical Officer, CDC/NCIRD
Continuing Education Information

- CE credit, go to: [www.cdc.gov/GetCE](http://www.cdc.gov/GetCE)
- Search course number: WD4344-080520
- CE credit expires: July 1, 2022
- CE instructions are available on the EpiVac Pink Book Web-on-Demand Series web page
- Questions and additional help with the online CE system, e-mail [CE@cdc.gov](mailto:CE@cdc.gov)
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Diphtheria, Tetanus, and Pertussis

DTaP/DT and Tdap/Td Vaccines

Pink Book Web-on-Demand Series 2020

Andrew Kroger, MD, MPH
Medical Officer/Medical Health Educator
Diphtheria Disease
Diphtheria

- A toxin-mediated disease caused by *Corynebacterium diphtheriae*
- Usually produces exudate and membrane involving pharynx and tonsils
- Complications attributable to toxin – severity generally related to extent of local disease
- Most complications are myocarditis and neuritis.
- Death in 5% to 10% of cases
Tonsillar diphtheria
Diphtheria Clinical Features

- Incubation period: 2–5 days (range: 1–10 days)
- May involve any mucous membrane
- Classified based on site of disease
  - Anterior nasal
  - Pharyngeal and tonsillar
  - Laryngeal
  - Cutaneous
  - Ocular
  - Genital
Diphtheria in the Late 19th–Early 20th Century
Number of Reported Diphtheria Cases -- United States, 1980 through 2015

Source: National Notifiable Diseases Surveillance System
Tetanus Disease
Tetanus

- A toxin-mediated disease caused by Clostridium tetani
- Anaerobic gram-positive, spore-forming bacteria
- Spores found in soil, animal feces
- Two exotoxins produced with growth of bacteria
  - Tetanospasmin responsible for clinical manifestations of tetanus
Tetanus Clinical Features

- Incubation period: 8 days (range: 3–21 days)
- Three clinical forms: local (uncommon), cephalic (rare), generalized (most common)
- Generalized tetanus: descending pattern of trismus (lockjaw), neck stiffness, difficulty swallowing, rigidity of abdominal muscles
  - Spasms continue for 3–4 weeks.
  - Complete recovery may take months.
- Neonatal tetanus
  - Generalized tetanus in newborn infant
  - Infant born without protective passive immunity
  - 39,000 neonates died in 2015 worldwide.
• Required 57 days of inpatient acute care, including 47 days in the intensive care unit
• The inpatient charges totaled $811,929 (excluding air transportation, inpatient rehabilitation, and ambulatory follow-up costs).
Annual Incidence* of and Deaths Due to Tetanus -- United States, 1900 through 2015

Sources: National Notifiable Diseases Surveillance System and passive reports to the Public Health Service
* Per 100,000 population
Pertussis Disease
Pertussis

- Acute infectious disease caused by *Bordetella pertussis*
- Outbreaks first described in 16th century
- *Bordetella pertussis* isolated in 1906
- Estimated 160,700 deaths worldwide in 2014
Pertussis Clinical Features

- Incubation period: 7–10 days (range: 4–21 days)
- Insidious onset, similar to the common cold with nonspecific cough
- Fever usually minimal throughout course of illness
- Catarrhal stage
  - 1–2 weeks
- Paroxysmal cough stage
  - 1–6 weeks
- Convalescence
  - Weeks to months
Reported NNDSS pertussis cases: 1922-2017

*2016 through 2017 data are provisional.
Reported Pertussis Incidence by Age Group: 1990 through 2016*

*2016 data are provisional.

Source: CDC, National Notifiable Diseases Surveillance System and Supplemental Pertussis Surveillance System
## Pertussis Deaths in the United States, 2012–2018

<table>
<thead>
<tr>
<th>Age at onset</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 12 months</td>
<td>59 (72%)</td>
</tr>
<tr>
<td>12 months and older</td>
<td>23 (28%)</td>
</tr>
<tr>
<td>Total</td>
<td>82</td>
</tr>
</tbody>
</table>

[https://www.cdc.gov/pertussis/surv-reporting.html](https://www.cdc.gov/pertussis/surv-reporting.html)
Why Adolescents and Adults Need Pertussis Vaccine

- 20,762 pertussis cases reported in the U.S. in 2015, 15,737 cases in 2016
  - >50% of cases in those 11 years and older
- Infection may be asymptomatic or may present as classic pertussis.
- Disease often milder than in infants and children
  - Persons with mild disease may transmit the infection.
- Older persons and household contacts often source of infection for infants and children
Pertussis Complications Among Adolescents and Adults

- Difficulty sleeping
- Urinary incontinence
- Pneumonia
- Rib fracture

Plus:
- Medical costs
- Missed school and work
- Impact on public health system
Vaccinate Throughout a Lifetime!

- DTaP
  - Birth

- Tdap

- Td
4

DTaP/DT Vaccine
## DTaP – containing Vaccine Products

<table>
<thead>
<tr>
<th>Product (mfr)</th>
<th>Component(s)</th>
<th>Use for ages</th>
<th>Use for DTaP doses</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daptacel (SP)</td>
<td>DTaP</td>
<td>6 wks thru 6 yrs</td>
<td>1 thru 5</td>
<td>IM</td>
</tr>
<tr>
<td>Infanrix (GSK)</td>
<td>DTaP</td>
<td>6 wks thru 6 yrs</td>
<td>1 thru 5</td>
<td>IM</td>
</tr>
<tr>
<td>Pediarix (GSK)</td>
<td>DTaP-HepB-IPV</td>
<td>6 wks thru 6 yrs</td>
<td>1 thru 3</td>
<td>IM</td>
</tr>
<tr>
<td>Pentacel (SP)</td>
<td>DTaP-IPV/Hib</td>
<td>6 wks thru 4 yrs</td>
<td>1 thru 4</td>
<td>IM</td>
</tr>
<tr>
<td>Kinrix (GSK), Quadracel (SP)</td>
<td>DTaP-IPV</td>
<td>4 thru 6 yrs</td>
<td>5</td>
<td>IM</td>
</tr>
<tr>
<td>Vaxelis (Merck)</td>
<td>Dtap-IPV-Hib-HepB</td>
<td>6 wks thru 4 yrs</td>
<td>3-dose series</td>
<td>IM</td>
</tr>
</tbody>
</table>

**Order, administer, and document the correct vaccine!**
DTaP-HepB-IPV (Pediarix)

- Components: DTaP, HepB, and IPV

- Licensed for:
  - Children 6 weeks through 6 years of age
  - Doses 1 through 3

- Not approved for doses 4 or 5

- Can be given to infants who received a birth dose of hepatitis B vaccine
  - Total of 4 doses of HepB vaccine
DTaP-IPV/Hib (Pentacel)

- **Components:** DTaP, IPV, and Hib

- **Licensed for:**
  - Children 6 weeks though 4 years of age
  - Doses 1 through 4

- **Not approved for the 5th dose of DTaP series or for children older than 5 years**
DTaP-IPV/Hib (Pentacel)

- Must be reconstituted (mixed) prior to administration
- Use ONLY the manufacturer-supplied vaccine diluent (DTaP-IPV)
DTaP-IPV (Kinrix and Quadracel)

- Components: DTaP and IPV

- Licensed for:
  - Children 4 through 6 years of age
  - Dose 5 only

- Do NOT use for doses 1 through 4 or for children younger than 4 years of age.
DTaP, IPV, Hib, HepB (Vaxelis)

- Components: DTaP, IPV, Hib, HepB

- Licensed for:
  - Children 6 weeks through 4 years
  - 3-dose series (2, 4, 6 months of age)

- Do NOT use for 4th or 5th doses.
Interchangeability of Different Brands of DTaP Vaccine

- Whenever feasible, the same DTaP vaccine should be used for all doses of the series.

- Limited data suggest that “mix and match” DTaP schedules do not adversely affect safety and immunogenicity.

- If the vaccine used for earlier doses is not known or not available, any brand may be used to complete the series.
# Primary DTaP Schedule

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Birth</th>
<th>1 mo</th>
<th>2 mos</th>
<th>4 mos</th>
<th>6 mos</th>
<th>9 mos</th>
<th>12 mos</th>
<th>15 mos</th>
<th>18 mos</th>
<th>19-23 mos</th>
<th>2-3 yrs</th>
<th>4-6 yrs</th>
<th>7-10 yrs</th>
<th>11-12 yrs</th>
<th>13-15 yrs</th>
<th>16 yrs</th>
<th>17-18 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria, tetanus, &amp; acellular pertussis (DTaP)</td>
<td></td>
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</tr>
</tbody>
</table>

**Minimum Interval to Next Dose**

<table>
<thead>
<tr>
<th>Dose</th>
<th>Routine Age</th>
<th>Minimum Interval to Next Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary 1</td>
<td>2 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Primary 2</td>
<td>4 months</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Primary 3</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Primary 4</td>
<td>15–18 months</td>
<td></td>
</tr>
</tbody>
</table>

Fourth DTaP Dose

- Routinely recommended at 15 through 18 months

- May be given earlier if:
  - Child is at least 12 months of age and
  - At least 6 months since DTaP dose 3 and
  - The child is unlikely to return at 15 through 18 months of age.
Fifth DTaP Dose

- Administer a 5th dose of DTaP when the 4th dose was given *before* age 4 years.

- All DTaP products are approved for use for the 5th dose except:
  - Pediarix (DTaP-HepB-IPV)
  - Pentacel (DTaP-IPV/Hib)
Diphtheria and Tetanus Toxoid
DT Vaccine

- Given as a 3- or 4-dose series

- DT should only be used for children with a true contraindication to pertussis vaccine.
Pediatric DT Schedule

- First dose of DT at younger than 1 year of age
  - Total of 4 doses

- First dose of DT at 1 year of age or older
  - Total of 3 doses

- 4th or 5th dose at school entry not needed if pertussis vaccine is not being administered
DTaP Contraindications

- Severe allergic reaction to vaccine component or following a prior dose

- Encephalopathy not due to another identifiable cause occurring within 7 days after vaccination
DTaP Precautions

- Moderate or severe acute illness

- Progressive or unstable neurologic disorder, including infantile spasms, uncontrolled seizures, or progressive encephalopathy

- Guillain-Barré syndrome <6 weeks after previous dose of tetanus-toxoid-containing vaccine

- History of Arthus-type hypersensitivity reactions after a previous dose of tetanus- or diphtheria-toxoid-containing vaccines
DTaP Adverse Reactions

- Local reactions (pain, redness, swelling) Up to 40%
- Fever Up to 27%
- More severe adverse reactions Not common
Adverse Reactions
Following the 4th and 5th DTaP Doses

- Local adverse reactions and fever increased.

- Reports of swelling of entire limb
  - Self-limited and resolves without sequelae

- Limb swelling after 4th dose NOT a contraindication to 5th dose
Tdap/Td Vaccine
# Tdap and Td Vaccines

<table>
<thead>
<tr>
<th>Vaccine product</th>
<th>Age indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tdap vaccines</td>
<td></td>
</tr>
<tr>
<td>Boostrix</td>
<td>10 years and older</td>
</tr>
<tr>
<td>Adacel</td>
<td>10 through 64 years</td>
</tr>
<tr>
<td>Td vaccines</td>
<td></td>
</tr>
<tr>
<td>TDVAX</td>
<td>7 years and older</td>
</tr>
<tr>
<td>TENIVAC</td>
<td>7 years and older</td>
</tr>
</tbody>
</table>
Clinical Considerations
### ACIP Tdap/Td Vaccine Recommendations

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Birth</th>
<th>1 mo</th>
<th>2 mos</th>
<th>4 mos</th>
<th>6 mos</th>
<th>9 mos</th>
<th>12 mos</th>
<th>15 mos</th>
<th>18 mos</th>
<th>19-23 mos</th>
<th>2-3 yrs</th>
<th>4-5 yrs</th>
<th>7-10 yrs</th>
<th>11-12 yrs</th>
<th>13-15 yrs</th>
<th>16 yrs</th>
<th>17-18 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetanus, diphtheria, &amp; acellular pertussis (Tdap: ≥7 yrs)</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Ages 19–26 years

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>19–26 years</th>
<th>27–49 years</th>
<th>50–64 years</th>
<th>≥65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetanus, diphtheria, pertussis (Tdap or Td)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 1 dose Tdap, then Td or Tdap booster every 10 years
**Tdap Recommendations: Adolescent**

- Routinely recommended at 11 or 12 years of age
- Catch up adolescents 13 years of age and older who were not vaccinated.
Tdap Recommendations: Adults

- Administer Tdap vaccine to persons 19 years of age and older who were NOT previously vaccinated and to those with unknown vaccination status.
  - Persons who were vaccinated with Tdap during adolescence (or at another time) = previously vaccinated, including:
    - Health care personnel
    - New fathers
    - Close contacts of newborns
    - Day care workers or babysitters
  - No additional doses are recommended.
Tdap Recommendations: Children 7 through 10 Years of Age*

- Children who have not completed a primary series
  - Tdap should be administered first.
  - If additional doses are needed, Td or Tdap should be administered.

- Those not fully immunized against pertussis (i.e., did not complete a series of pertussis-containing vaccine before their 7th birthday) should receive a single dose of Tdap.
  - If additional doses are needed, Td or Tdap should be administered.

- Adolescents who received Tdap inadvertently or as part of the catch-up series between 7 through 9 years of age should be given the routine adolescent Tdap dose at 11 or 12 years of age.

*Off-label ACIP recommendation

MMWR 67(2):1–44
Administer a dose of Tdap during each pregnancy, regardless of the patient's prior history of receiving the vaccine.

Tdap should be administered between 27 and 36 weeks’ gestation, although it may be given at any time during pregnancy.

- Currently available data suggest that vaccinating earlier in the 27- through 36-week time period will maximize passive antibody transfer to the infant.

*Off-label ACIP recommendation*  *MMWR* 67(2):1–44
Tdap and Pregnant Women

- Vaccination coverage for pregnant women:
  - 2010 and earlier: <1%
  - 2013: 28%
  - 2015: 53%

- 96% of Tdap vaccinations were administered in physicians’ offices or clinics.
## Maternal Tdap Vaccination Is Very Effective in Prevention of Infant Pertussis Infection

<table>
<thead>
<tr>
<th>Definitions</th>
<th>Vaccine effectiveness (95% confidence intervals)</th>
<th>Infant age at pertussis onset</th>
<th>Mother gestational age received Tdap</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>United Kingdom</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observational,(^1) screening method</td>
<td>91% (83–95%)</td>
<td>Younger than 3 months</td>
<td>At least 28 days before birth*</td>
</tr>
<tr>
<td>Case-Control,(^2) retrospective</td>
<td>91% (77–97%), unadjusted 93% (81–97%), adjusted(^a)</td>
<td>Younger than 2 months</td>
<td>Cases: 31.5 weeks (range, 28–38) Controls: 33 weeks (range, 26–38)</td>
</tr>
<tr>
<td><strong>United States</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohort,(^3) retrospective</td>
<td>85% (33–98%)</td>
<td>Younger than 2 months</td>
<td>27–36 weeks</td>
</tr>
<tr>
<td>Case-Control,(^4) retrospective</td>
<td>78% (44–91%)</td>
<td>Younger than 2 months</td>
<td>27–36 weeks</td>
</tr>
</tbody>
</table>

*2012 UK recommendation: Tdap between 28 and 38 weeks
AAdjusted for sex, geographical area, and birth period
ACIP Conclusions: Safety of Tdap for Every Pregnancy

- Data reassuring on 2 doses of Tdap

- Data and experience with tetanus toxoid vaccine suggest no excess risk of adverse events.
  - ~5% of women would receive 4 or more doses.

- CDC provides ongoing monitoring to address concerns about the safety of Tdap given during subsequent pregnancies.
Postpartum Women and Close Contacts of Infants

- Previously unvaccinated EVER or vaccination status unknown—administer Tdap

- Previously vaccinated persons—Tdap is NOT indicated
  - Including mothers, fathers, siblings, and grandparents
  - Any previous, documented dose counts.
Tdap for Persons Without History of DTP or DTaP

- All adolescents and adults should have documentation of having received a primary series of DTaP, DTP, DT, Tdap, or Td.

- Persons without documentation who have never been vaccinated or have unknown status should receive a 3-dose primary series.

- One dose should be Tdap, preferably the first.
Tdap for Persons Without History of DTP or DTaP

- Preferred schedule:
  
  - Dose 1  Tdap
  
  - Dose 2  Td at least 4 weeks after dose 1
  
  - Dose 3  Td at least 6 months after dose 2
  
  - Booster  Td every 10 years
Tdap and Health Care Personnel
Tdap and Health Care Personnel (HCP)

- Previously unvaccinated HCP should receive a single dose of Tdap as soon as feasible, regardless of time since last Td dose.

- After receipt of 1 dose of Tdap, health care personnel should receive routine Td booster doses according to the recommended schedule.

- Additional doses of Tdap are not recommended for previously vaccinated HCP.*

*Except pregnant women

MMWR 2006;55(RR-17):1–37
Knowledge Check

- A 21-year-old woman has a history of a complete series of DTaP vaccine and a dose of Tdap at 11 years of age. She is not pregnant. May she receive a dose of Tdap at her next well visit?

A) Yes

B) No
Answer

- A 21-year-old woman has a history of a complete series of DTaP vaccine and a dose of Tdap at 11 years of age. She is not pregnant. May she receive a dose of Tdap at her next well visit?
  - YES
Tetanus Prophylaxis
### TABLE 6. Guide to tetanus prophylaxis in routine wound management

<table>
<thead>
<tr>
<th>No. doses of adsorbed tetanus toxoid–containing vaccines</th>
<th>Clean and minor wound</th>
<th>All other wounds*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DTaP, Tdap, or Td†‡</td>
<td>TIG</td>
</tr>
<tr>
<td>Unknown or &lt;3</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>≥3</td>
<td>No†</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No**</td>
</tr>
</tbody>
</table>

**Abbreviations:** DTaP = diphtheria and tetanus toxoids and acellular pertussis vaccine; Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis; Td = tetanus and diphtheria toxoids; TIG = tetanus immune globulin.

* Such as, but not limited to, wounds contaminated with dirt, feces, soil, and saliva; puncture wounds; avulsions; and wounds resulting from missiles, crushing, burns, and frostbite.

† DTaP is recommended for children aged <7 years. Tdap is preferred to Td for persons aged ≥11 years who have not previously received Tdap. Persons aged ≥7 years who are not fully immunized against pertussis, tetanus or diphtheria should receive one dose of Tdap for wound management and as part of the catch-up series.

‡ Persons with HIV infection or severe immunodeficiency who have contaminated wounds should also receive TIG, regardless of their history of tetanus immunization.

§ Yes, if >10 years since the last tetanus toxoid–containing vaccine dose.

** Yes, if ≥25 years since the last tetanus toxoid–containing vaccine dose.
Tdap Contraindications

- Severe allergic reaction to vaccine component or following a prior dose
- Encephalopathy not due to another identifiable cause within 7 days of administration of a pertussis-containing vaccine
**Tdap Precautions**

- History of Guillain-Barré syndrome within 6 weeks after a prior dose of tetanus-toxoid-containing vaccine

- Progressive neurologic disorder until the condition has stabilized

- History of a severe local reaction (Arthus reaction) following a prior dose of a tetanus- and/or diphtheria-toxoid-containing vaccine

- Moderate or severe acute illness
Tdap/Td Adverse Reactions

- Local reactions (pain, redness, induration)
  - 21 to 66%

- Temp of 100.4°F or higher
  - 1.4% Tdap
  - 1.1% Td

- Adverse reactions occur at approximately the same rate as Td alone (without acellular pertussis vaccine).
Questions
Continuing Education Information

- CE credit, go to: www.cdc.gov/GetCE
- Search course number: WD4344-080520
- CE credit expires: July 1, 2022
- CE instructions are available on the EpiVac Pink Book Web-on-Demand Series web page
- Questions and additional help with the online CE system, e-mail CE@cdc.gov
E-mail Your Immunization Questions to Us

NIPINFO@cdc.gov

Write “Web-on-Demand–DTaP/Tdap” in the subject line
EpiVac Pink Book Web-on-Demand Resources

- Comprehensive list of resources for ALL sessions
- Located on the web page for this web-on-demand session at www.cdc.gov/vaccines/ed/webinar-epv/index.html
- Additional materials located on this webpage include:
  - DTaP/Tdap slide set
  - Web-on-demand questions and answers
  - Transcript of this session
  - Continuing education instructions
Thank You From Atlanta!