Diphtheria, Tetanus, and Pertussis

DTaP/DT and Tdap/Td Vaccines

Chapters 7, 21, and 16
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 19\textsuperscript{th}–Early 20\textsuperscript{th} Century

1897
DIPHTHERIA EPIDEMIC

ALL THE FAMILY OF JOSEPH HYRUM AND JULIA ANN
KERSHAW CONSISTING OF EIGHT CHILDREN PASSED AWAY WITHIN A 17 DAY PERIOD.

KERSHAW

LYDIA

OCT. 24. 1878  JULY 25. 1880
HARRIET
SEPT. 24. 1880  MAR. 4. 1897
GEORGE
NOV. 25. 1882  MAR. 11. 1897
JOSEPH
NOV. 25. 1884  FEB. 27. 1897
WILLIAM
APR. 11. 1887  FEB. 27. 1897
EDMOND
SEPT. 14. 1889  FEB. 22. 1897

LILLIE

APR. 10. 1892  MAR. 6. 1897
FRANCIS
NOV. 6. 1894  MAR. 6. 1897
FREDERICK
APR. 5. 1896  MAR. 9. 1897
FERDINAND
FEB. 6. 1898  FEB. 6. 1898
JOHN
NOV. 18. 1900  SEPT. 10. 1902

...
Number of reported diphtheria cases -- United States, 1980-2015

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), stiffness of the neck, 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
  - 58,000 neonates died in 2010 worldwide
Notes from the Field: Tetanus in an Unvaccinated Child — Oregon, 2017

Weekly / March 8, 2019 / 68(9):231–232

- 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, 1900-2015

**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 195,000 deaths worldwide in 2008
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: 1922-2015*

*2015 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
Reported Pertussis Incidence by Age Group: 1990-2016*

*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</td>
</tr>
<tr>
<td>12 months and older</td>
<td>23</td>
</tr>
<tr>
<td>Total</td>
<td>82</td>
</tr>
</tbody>
</table>

<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!

Birth
DTaP
Tdap
Td
4

DTaP/DT Vaccine
## DTaP-Containing Vaccine Products

<table>
<thead>
<tr>
<th>Vaccine product</th>
<th>Age indications</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Single component vaccines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daptcel</td>
<td>6 weeks - 6 years</td>
<td>Approved for doses 1-5</td>
</tr>
<tr>
<td>Infanrix</td>
<td>6 weeks - 6 years</td>
<td>Approved for doses 1-5</td>
</tr>
<tr>
<td><strong>Combination vaccines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pediarix</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTaP, HepB, and IPV</td>
<td>6 weeks-6 years</td>
<td>Not approved for doses 4 or 5</td>
</tr>
<tr>
<td>Pentacel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTaP, IPV, and Hib</td>
<td>6 weeks–4 years</td>
<td>Not approved for 5th dose</td>
</tr>
<tr>
<td>Kinrix and Quadracel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTaP and IPV</td>
<td>4-6 years</td>
<td>Not approved for doses 1-4</td>
</tr>
<tr>
<td>Vaxelis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTaP, IPV, Hib, and HepB</td>
<td>6 weeks–4 years</td>
<td>3-dose series</td>
</tr>
<tr>
<td><strong>Vaccines without pertussis component</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No trade name</td>
<td>6 weeks–4 years</td>
<td>3- or 4-dose series</td>
</tr>
</tbody>
</table>
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)

Hib vaccine + DTaP-IPV diluent = Pentacel vaccine
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**
## Administer the Right Vaccine!

<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),</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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 years</td>
<td>3-dose series</td>
<td>IM</td>
</tr>
</tbody>
</table>

**Order, administer, and document the correct vaccine!**
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 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 c&lt;7 yrs)</td>
<td>1st dose</td>
<td>2nd dose</td>
<td>3rd dose</td>
<td>4th dose</td>
<td>5th dose</td>
<td>6th dose</td>
<td>7th dose</td>
<td>8th dose</td>
<td>9th dose</td>
<td>10th dose</td>
<td>11th dose</td>
<td>12th dose</td>
<td>13th dose</td>
<td>14th dose</td>
<td>15th dose</td>
<td>16th dose</td>
<td>17th dose</td>
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<td>----------------------------------------------</td>
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</tr>
</tbody>
</table>

## 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
  - Child is unlikely to return at 15 through 18 months of age
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:

- Pediatrix (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

- 4<sup>th</sup> or 5<sup>th</sup> 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 Former Contraindications – No Longer Applicable

- Temperature of 105°F (40.5°C) or higher within 48 hours with no other identifiable cause

- Collapse or shock-like state (hypotonic hypo-responsive episode) within 48 hours

- Persistent, inconsolable crying lasting 3 hours or more, occurring within 48 hours

- Convulsions with or without fever occurring within 3 days

- Family history of seizures, SIDS, adverse event after pertussis vaccination

- Stable neurological condition(s)
DTaP Adverse Reactions

- Local reactions (pain, redness, swelling) 20%–40%
- Temperature of 101° or higher 3%–5%
- 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
2

Tdap/Td Vaccine
# Tdap and Td Vaccines

<table>
<thead>
<tr>
<th>Vaccine product</th>
<th>Age indications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tdap vaccines</strong></td>
<td></td>
</tr>
<tr>
<td>Boostrix</td>
<td>10 years and older</td>
</tr>
<tr>
<td>Adacel</td>
<td>10–64 years</td>
</tr>
<tr>
<td><strong>Td vaccines</strong></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>
## ACIP Tdap/Td Vaccine Recommendations

### *Off-label recommendation: Adacel for persons 65 years of age and older*

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>19–21 years</th>
<th>22–26 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)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 dose Tdap, then Td booster every 10 yrs
Tdap Recommendations: Adolescent

- Routinely recommended at 11–12 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
Children who have not completed a primary series
- Tdap should be administered first
- If additional doses are needed, Td should be administered

Those who are 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 should be administered

Adolescents who received Tdap inadvertently or as part of the catch-up series between 7–10 years of age should be given the routine adolescent Tdap dose at 11–12 years of age

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

- 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.

*MMWR 66(41):1105–1108*
## 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(^#)</td>
<td>Younger than 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  
\(^\#\)Adjusted 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
ACIP recognizes the increasing burden of pertussis and the need for an effective strategy to reduce this burden.

A study evaluating additional doses of Tdap administered at either a 5- or 10-year interval suggested that the reduction in pertussis disease burden would be limited.

ACIP concluded that the data do not support a general recommendation for a routine second dose of Tdap, and that the public health impact of routinely recommending a second dose of Tdap would be limited.
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 immunizations 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
Tetanus Prophylaxis
<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></td>
<td></td>
<td>Yes</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, swelling)
  - 21– 66%

- Temp of 100.4°F or higher
  - 1.4%

- Adverse reactions occur at approximately the same rate as Td alone (without acellular pertussis vaccine)