Tdap Vaccination Strategies for Adolescents and Adults, Including Health Care Personnel

TDAP VACCINATION





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The Promising Approaches for Implementing or Improving Tdap Vaccination Programs for Health Care Personnel and Adolescent and Adult Patients Project staff are solely responsible for the content of this monograph. The findings and conclusions in this report are those of the authors and do not necessarily represent the position of the Centers for Disease Control and Prevention or any of the other collaborating organizations.

Many of the examples included come from self-reported strategies and data submitted to this project by health care organizations, as well as published literature. The examples included herein are intended to aid health care organizations in their efforts to improve Tdap immunization rates. We have worked to ensure that this monograph contains useful information, but it is not intended to be a comprehensive source of all relevant information. In addition, because the information contained herein is derived from many sources, The Joint Commission and its collaborating organizations are not responsible for any claims or losses arising from the use of, or from any errors or omissions in, this monograph.

The CDC-referenced information in this monograph is current at the point of the monograph's publication, but the CDC Web site should always be checked to ensure that the reader has the most up-to-date information.

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INTRODUCTION

Summary of Key Points

- Pertussis, or whooping cough, is on the rise. Rates have increased over the past two decades, primarily in adolescents and adults who have waning immunity from previous pertussis vaccinations or infection.
- Infants who are too young to be vaccinated bear the burden of severe pertussis disease.
- Most pertussis-related deaths occur in infants < 4 months of age.
- Adolescents and adults play a significant role in transmission of pertussis to vulnerable infants at home, in the community, and in health care and day care settings.

Pertussis: The Problem

Many American adults are not getting vaccines they need, putting them at risk of developing and spreading preventable infections. Adults may not realize that some of the vaccines they received in childhood will not protect them throughout their lives or that newer vaccines have been developed since they were first immunized.¹ In addition, some adults simply were never vaccinated.

These common circumstances create public health problems that have far-reaching consequences. Consider, for example, pertussis, or whooping cough, a highly contagious disease that can be prevented with a vaccine. An infectious disease of the upper respiratory tract characterized by coughing spasms (or paroxysms) and often followed by an inspiratory "whoop" or vomiting,² pertussis is the most common vaccine-preventable childhood disease3 and the least wellcontrolled bacterial vaccine-preventable disease.⁴ Experts estimate that up to 3.3 million cases of pertussis in adults and adolescents occur annually in the United States.³ Pertussis outbreaks occur in workplaces, schools, and households,5 resulting in substantial physical, economic, and social costs. For example, children miss school; parents lose time from work, either to care for ill children or because they are ill; and pertussis among health care personnel puts vulnerable patients at risk and disrupts health care delivery when caregivers are ill.6 Text Box I-1 on page viii provides a brief look at pertussis.

The widespread use of whole-cell pertussis vaccines in the mid-1940s led to dramatic declines in pertussis in the

Text Box I-1. Pertussis in Brief

Pertussis symptoms can last for several weeks. All infants less than 6 months of age and any infant who has not yet received three doses of pertussiscontaining vaccine are especially vulnerable to pertussis infection¹ and often require hospitalization for supportive care for coughing spasms and feeding difficulties.² Adolescents and adults with pertussis generally have mild symptoms that do not require hospitalization, but these populations are an important source of transmission of pertussis to infants.

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United States, but rates began to increase in the early 1980s.⁷ Despite the fact that more than 80% of children ages 19–35 months received all four diphtheria, tetanus, and acellular pertussis (DTaP) doses between 1994 and 2003,⁸ pertussis in adolescents and adults has increased because immunity wanes over time. A total of 103,940 cases of pertussis were reported to the Centers for Disease Control and Prevention's (CDC's) National Notifiable Diseases Surveillance System between 2000 and 2006, with 27% of the cases occurring in people ages 15 to 39.⁹ Difficult to recognize clinically, pertussis is often not even considered as a diagnostic possibility in adolescents and adults. Adding to the challenges of identifying the disease is the poor standardization of current laboratory diagnostics.

Even though vaccination rates in young children are high,¹⁰ the increasing number of adolescents and adults with pertussis infections leaves infants vulnerable.⁹ Infants less than 4 months of age, who are too young to be directly protected by vaccination, bear the burden of serious pertussis infection. Infants who are less than 1 year old typically have the most severe pertussis, often requiring hospitalization for respiratory or other complications, and most pertussisrelated deaths occur in this population.⁹ Parents, including new mothers, with pertussis are the identified source of pertussis in more than 25% of pertussis cases in infants.⁹

The following statistics demonstrate the changes seen in pertussis in recent decades:

- In 1976 the United States recorded the lowest-ever number of pertussis cases—1,010. That figure climbed to 25,827 cases in 2004, the highest number of cases since 1959.⁴
- There has been a disproportionate increase in reported pertussis cases in adolescents and adults since 1990.¹¹
- Americans older than age 10 accounted for 56% of reported pertussis cases between 2001 and 2003,¹² more than double the rate from 1990 to 1993.⁷

Adding to the concern about the increase in pertussis cases is health care–associated pertussis. Health care personnel may acquire pertussis from and spread it to the community, and they are at risk of contracting pertussis in the health care organizations where they work and unwittingly transmitting the disease to patients, coworkers, and visitors. The spread of pertussis has occurred in many health care organizations, including hospitals, ambulatory care facilities, emergency departments, and long term care settings.⁴

"It is time for health care personnel and the public to be proactive and not let even one child die from disease that can be prevented by vaccination."¹³ —Loretta Fauerbach, M.S., C.I.C., Director of Infection Control for Shands Hospital, University of Florida

This monograph intends to address issues that may hinder adolescent and adult Tdap vaccination and explores strategies to implement or enhance Tdap programs and improve Tdap vaccination rates among adolescents and adults.

Pertussis Prevention

The strategy most likely to control the spread of pertussis is pre-exposure vaccination.^{4,6,9,14,15} The 2005 licensing of two

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new tetanus toxoid, reduced diphtheria, and acelluar pertussis (Tdap) vaccines provided a special formulation for adolescents and adults that elicits an immune response similar to that achieved by the pediatric acellular vaccines.¹⁶ The Tdap vaccine differs from those given to infants in that it is administered as a single dose and has a lower concentration of pertussis antigens.⁵ The two Tdap vaccines licensed in the United States are ADACEL® (sanofi pasteur, Swiftwater, Pennsylvania) for use in persons ages 11 to 64¹⁶ and BOOSTRIX® (GlaxoSmithKline Biologicals, Rixensart, Belgium) for persons ages 10 to 64.¹⁷ Both vaccines are licensed for single-dose administration.

In 2006 the CDC's Advisory Committee on Immunization Practices (ACIP) released two recommendations concerning the one-time administration of Tdap: one directed at adolescents⁶ and one directed at adults, including health care personnel.⁴ Tdap has replaced the previously recommended tetanus toxoid (Td) booster at 11–12 years of age and for older adolescents and adults as a single replacement for those who need a Td booster. A third recommendation, published in 2008, focused on pregnant and postpartum women and their infants.⁹

For children, there are two combination vaccines available to prevent diphtheria and tetanus (*see* Text Box I-2 on page x for resources on these two diseases) and two that also prevent pertussis. Two of these vaccines (DTaP and DT) are given to children younger than age 7, and two (Tdap and Td) are given to children 10 years and older and adults. Children should receive five doses of DTaP by age 6; DT does not contain pertussis and is used for children who are not able to tolerate pertussis vaccine.¹⁸ Td is the adolescent and adult tetanus and diphtheria vaccine that is given as a booster every 10 years, or after exposure to tetanus.

The CDC recommendations for routine Tdap vaccinations seek to reduce morbidity among adolescents and adults, maintain the standard of care for tetanus and diphtheria prevention, and reduce the transmission of pertussis to infants and in health care settings. The primary objective of replacing a single dose of Td with Tdap in adolescents and adults is to protect the vaccinated individuals against pertussis; the secondary objective is to reduce the reservoir of pertussis in the population at large, which could result in decreasing exposure of individuals at increased risk for com-

Decoding the Vaccines

The initials used in the various vaccines for children and adults are as follows:

- *T* is the tetanus component.
- D is the diphtheria component.
- P is the pertussis component.
- Uppercase letters denote full-strength doses.
- Lowercase d and p denote reduced doses of diphtheria and pertussis (for example, DTaP has a higher antigen content of diphtheria and pertussis than Tdap).
- The *a* in DTaP and Tdap stands for *acellular*, which means only part of the pertussis organism is in the vaccine.

Source: Adapted from Centers for Disease Control and Prevention: Vaccines and Immunizations: *Pertussis* (*Whooping Cough*) Vaccination. http://www.cdc.gov/vaccines/ vpd-vac/pertussis/default.htm (accessed Jul. 12, 2010).

plicated pertussis infection, including infants.⁴ Pertussis is also the focus of several goals of Healthy People 2010 (*see* Sidebar I-1 on page xi).

Overview of CDC Recommendations for the Use of Tdap

Tdap vaccinations for adults and adolescents are designed to reduce pertussis in these populations, as well as prevent transmission of the disease to infants. Statements and recommendations published by the ACIP recommend the use of a one-time dose of Tdap vaccine in the following instances:

- Adolescents (ages 11–18)⁶
 - Routine Tdap booster at age 11–12, or at the earliest opportunity for those ages 13–18, or
 - To replace next Td booster, if indicated for wound management and not previously given
 - For pregnant adolescents, in the immediate postpartum period, if not previously given
- Adults (ages 19–64)⁴
 - To replace next decennial Td or if indicated for wound management
 - Adults who anticipate contact with an infant aged
 12 months (both for personal protection and to

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Text Box I-2. Information on Tetanus and Diphtheria

The focus of this monograph is on pertussis and approaches for implementing or improving Tdap vaccination programs for health care personnel and adolescent and adult patients. Information specific to tetanus and diphtheria can be found at the following CDC or Immunization Action Coalition Web sites:

- Tetanus and tetanus vaccine information: http://www.cdc.gov/vaccines/vpd-vac/tetanus/ default.htm or http://www.immunize.org/tetanus/
- Diphtheria and diphtheria vaccine information: http://www.cdc.gov/vaccines/vpd-vac/diphtheria/ default.htm or http://www.immunize.org/ diphtheria/

reduce the risk for transmitting *B. pertussis* to the infant)

- Health care personnel
- For pregnant adults, in the immediate postpartum period if not previously given
- Women of childbearing age, including pregnant and postpartum patients⁹
 - At a routine health assessment before conception to prevent the morbidity of pertussis that could occur during pregnancy
 - In the immediate postpartum period, if not previously given
 - Those who anticipate contact with an infant aged < 12 months

Appendix I-1, beginning on page xiii contains a table that summarizes these ACIP recommendations.

It is important to note that, at the October 2010 meeting of the ACIP, some important changes to the previously published ACIP recommendations were approved¹⁹:

- For adults ages 65 years and older, a single dose of Tdap vaccine may be given in place of a tetanus and diphtheria toxoids (Td) vaccine, in persons who have not received Tdap.
- Adults ages 65 years and older who have or anticipate having close contact with an infant less than 12 months

For a glossary of terms used in this monograph, see Appendix I-2, beginning on page xv.

of age should receive a single dose of Tdap to protect against pertussis and reduce the likelihood of transmission of pertussis to infants less than 12 months of age.

- Children ages 7–10 years who are not fully immunized against pertussis and for whom no contraindication to pertussis vaccines exists should receive a single dose of Tdap to provide protection against pertussis. If additional doses of tetanus and diphtheria toxoid– containing vaccines are needed, then children ages 7–10 years should be vaccinated according to catch-up guidance.
- Tdap can be administered regardless of the interval since the last tetanus- or diphtheria-containing vaccine.

A Search for Solutions

In March 2010 The Joint Commission launched the Promising Approaches for Implementing or Improving Tdap Vaccination Programs for Health Care Personnel and Adolescent and Adult Patients Project. The project began with an open call to health care organizations to submit strategies that have been useful in implementing or enhancing Tdap vaccination programs. Organizations were invited to share their strategies for Tdap vaccination in the following populations:

- Health care personnel
- Adolescent and adult patients, for routine wound care
- Adolescent and adult patients in contact with infants

The Joint Commission received a total of 82 submissions, representing ambulatory care centers, hospitals, and health systems in 39 states. Most organizations submitted a program description related to one identified population; a few submitted two or three program descriptions. An editorial review panel, which included a representative from each of the collaborating organizations, helped project staff identify criteria for evaluating the submitted approaches. Each submission was reviewed for completeness by a master'sprepared nurse who is also certified in infection control (C.I.C.); additional materials were collected, as needed, from the submitting organizations. Twenty-three submis-

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Sidebar I-1. Healthy People 2010 Goals

Managed by the Office of Disease Prevention and Health Promotion (U.S. Department of Health and Human Services), Healthy People 2010 is a national set of health care objectives. Several goals of the campaign focus on pertussis, including the following¹:

- Reducing pertussis in children less than 7 years of age from 3,417 cases to 2,000 cases per year. (The 3,417 figure represents a baseline established in 1998.)
- Achieving and maintaining four-dose vaccination coverage with DTaP vaccine in young children at 90% (84% in baseline year).

The Healthy People 2010 Midcourse Review noted that reported cases of pertussis in children younger than age 7 had actually increased to 3,719 cases in 2003, heading the wrong way from the target of 2,000 cases per year and exceeding the baseline count from 1998. It was unclear, though, whether the figures represented an actual increase in the circulation and transmission of *Bordetella pertussis* or whether the numbers reflected increased recognition, diagnosis, and reporting of the disease. Vaccination coverage with four doses of DTaP vaccine in young children, however, moved toward the target of 90%.^{2,3} Failure to reach the Healthy People 2010 objectives underscores the difficulties of case recognition and confirmation, as well as difficulties in substantially reducing the burden of pertussis in the setting of high childhood vaccination coverage.

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sions advanced to the Editorial Review Panel, and 17 were ultimately selected to be highlighted in this educational monograph intended to help health care organizations develop or improve their Tdap vaccination programs. Appendix I-3 on page xx lists the organizations whose submissions were selected.

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Content of the Monograph

The chapters that follow provide more detailed information:

- Chapter 1 reviews the epidemiology of pertussis, diagnostic issues, immunity to pertussis, and treatment and postexposure prophylaxis for pertussis. The morbidity and mortality associated with the disease, as well as the economic burden of pertussis, are reviewed.
- Chapter 2 provides information on pertussis vaccines and vaccinations, including the Tdap vaccines licensed

for use in adolescents and adults in 2005. Cost–benefit and cost-effectiveness issues and vaccine efficacy and safety are also covered in this chapter.

- Chapter 3 focuses on pertussis in health care personnel, the impact of institutional exposure incidents and outbreaks, cost-benefit issues of effective Tdap vaccination programs, and the parallel between influenza vaccination program strategies and Tdap programs. This chapter describes strategies for implementing or enhancing Tdap vaccination programs for health care personnel, with specific examples of how health care organizations have applied these strategies.
- Chapter 4 reviews issues related to pertussis in adolescents and adults, standards for vaccination practices in these populations, and strategies to improve Tdap vaccination coverage. Also included are examples of how health care organizations have implemented or enhanced their Tdap vaccination programs using the strategies described.

- Chapter 5 explores the concept of "cocooning" vulnerable infants from pertussis by providing Tdap vaccinations for individuals such as mothers, fathers, other family members, and caregivers who come into close contact with infants. Strategies for implementing cocooning vaccination programs are discussed, with frontline examples provided by health care organizations.
- Chapter 6 presents an overview of the many available resources related to pertussis and pertussis vaccination of health care personnel and adolescent and adult patients.

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Appendix I-1

Summary of recommendations of the Advisory Committee on Immunization Practices (ACIP) for vaccination to prevent pertussis, tetanus, and diphtheria among adults and adolescents,* with recommended intervals for vaccination from the most recent tetanus and diphtheria toxoid–containing vaccine[†]—United States, 2006–2008

Setting	March 2006 Adolescents (ages 11–18 yrs)	December 2006 Adults (ages 19–64 yrs)	May 2008 Women of childbearing age, including pregnant and postpartum women
Routine*	Tdap at age 11–12 yrs; Tdap catch-up ages 11–18 yrs [‡]	Tdap to replace the next decen- nial Td [§] ; ideally, women will receive Tdap before becoming pregnant	Tdap to replace the next decennial Td [§] ; Tdap is encouraged during preconception wellness visits
Special Situations*	-		
Pregnant women			
Interval < 10 yrs	Tdap as soon as feasible in the postpartum period [‡]	Tdap postpartum before leaving hospital or birthing center; interval as short as 2 yrs [§]	Tdap postpartum before leaving hospital or birthing center; interval as short as 2 yrs ^{s⊯}
Interval ≥ 10 yrs	Td recommended during pregnancy	Td recommended during pregnancy	 Td recommended during pregnancy,[#] or Tdap-postpartum before leaving hospital or birthing center instead of Td during pregnancy, if sufficient tetanus and diphtheria protection is likely until delivery
Nonpregnant adults and adolescents who anticipate having, or will have contact with an infant aged < 12 mos	Tdap at age 11–12 yrs; Tdap catch-up ages 11–18 yrs [‡]	Tdap, ideally administered at least 2 wks before contact with the infant; interval as short as 2 yrs suggested [§]	Tdap, ideally administered at least 2 wks before contact with the infant; interval as short as 2 yrs suggested [§]
Increased risk for pertussis or its complications, e.g., health care personnel with direct patient contact and persons in settings with a pertussis outbreak	Tdap ages 11–18 yrs⁺	Tdap; interval as short as 2 yrs [§]	Tdap postpartum before leaving hospital or birthing center; interval as short as 2 yrs ^{si#} ; pregnant women should be advised of symptoms of pertussis and the benefits of treatment and early prophy- laxis for household contacts exposed to pertussis
Increased risk for diphtheria	Tdap, when indicated [‡]	Tdap to replace the next Td when indicated*	Td for urgent protection during preg- nancy [#] ; Tdap postpartum before leaving hospital or birthing center
Tetanus wound manage- ment	Tdap instead of Td when indicated**	Tdap instead of Td when indicated**	Td when indicated for pregnant women***
No tetanus and diphtheria toxoids vaccination, or vacci- nation history incomplete or unknown	1 dose Tdap, followed by Td ≥ 4 wks later and dose 2 Td 6–12 mos later	1 dose Tdap, followed by Td ≥ 4 wks later and dose 2 Td 6–12 mos later	1 dose Td during pregnancy followed by dose 2 Td \ge 4 wks later [#] and dose 3 as Tdap 6–12 mos later (postpartum)

* ACIP recommends routine vaccination with tetanus and diphtheria toxoids every 10 years to boost tetanus and diphtheria protection. In 2006 ACIP recommended that adults and adolescents who have not been vaccinated previously with tetanus and reduced diphtheria toxoids and acellular pertussis (Tdap), including persons with a history of pertussis, receive a dose of Tdap to boost pertussis protection in addition to tetanus and diphtheria protection. Tdap is licensed for single-dose administration. In persons who have received Tdap, tetanus and reduced diphtheria toxoids (Td) vaccine should be administered when subsequent decennial booster vaccination is indicated for tetanus or diphtheria protection.

(footnotes continued on page xiv)

xiii

Tdap Vaccination Strategies for Adolescents and Adults, Including Health Care Personnel:

Strategies from Research and Practice

Appendix I-1, continued

[†] For adults and adolescents, tetanus and diphtheria toxoid–containing vaccines include tetanus toxoid (TT), Tdap, and Td; for infants and children, tetanus toxoid and diphtheria toxoid–containing vaccines include pediatric diphtheria and tetanus toxoids and whole-cell pertussis (DTP), pediatric diphtheria and tetanus toxoids and acellular pertussis, inactivated poliovirus and hepatitis B (DTaP-IPV-Hep B), and pediatric diphtheria and tetanus toxoids (DT).

⁺ During 2000–2006, U.S. adolescents aged 10–19 years had the highest incidence of reported pertussis outside of infancy (CDC, unpublished data, 2008). For this reason, a catch-up dose of Tdap is recommended for adolescents aged 11–18 years to add protection against pertussis if they have received Td but not Tdap. For catch-up Tdap, an interval of at least 5 years from the most recent tetanus and/or diphtheria toxoid–containing vaccine is encouraged to reduce the risk for local and systemic reactions that could result when concentration of tetanus and/or diphtheria antitoxin is high. An interval less than 5 years after Td may be used, particularly when the benefit of providing pertussis protection is likely to be increased. Adolescents who have received a childhood series of pediatric DTP or DTaP and Td or Tdap are protected against tetanus and diphtheria.

[§] A shorter interval may be used.

^{II} Limited evidence informs the risk of local and systemic reactions after Tdap at intervals of < 2 years. Higher rates of local and systemic reactions and more severe reactions can occur with high preexisting serum titers of tetanus or diphtheria antitoxin. Providers may choose to administer Tdap in postpartum women who received a tetanus toxoid– and/or diphtheria toxoid–containing vaccine (e.g., Td or TT) less than 2 years previously if the women have no history of serious adverse reaction after the most recent dose of tetanus toxoid– and/or diphtheria toxoid–containing vaccine.

[#] In special situations, a dose of Tdap might be warranted during pregnancy. Health care providers who choose to administer Tdap to pregnant women should discuss with the women the lack of evidence of safety and effectiveness for the mother, fetus, pregnancy outcome, and effectiveness of transplacental maternal antibodies to provide early pertussis protection to the infant. These women should be informed that no study has examined the effectiveness of transplacental pertussis antibodies induced by Tdap on the adequacy of the infant immune response to pediatric DTaP and conjugate vaccines containing tetanus toxoid or diphtheria toxoid. Because adverse outcomes of pregnancy are most common in the first trimester, vaccinating these pregnant women with Tdap during the second or third trimester is preferred to minimize the perception of an association of Tdap with an adverse outcome, unless vaccine is needed urgently.

** A Td booster might be recommended for wound management if ≥ 5 years have elapsed since the previous Td. Persons who have completed the 3-dose primary tetanus vaccination series and have received a tetanus toxoid–containing vaccine within the preceding 5 years are protected against tetanus and do not require a tetanus toxoid–containing vaccine as part of wound management.

Sources: Broder K.R., et al., Centers for Disease Control and Prevention: Preventing tetanus, diphtheria, and pertussis among adolescents: Use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccines. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep* 55:1–34, Mar. 24, 2006; Kretsinger K., et al., Centers for Disease Control and Prevention: Preventing tetanus, diphtheria, and pertussis among adults: Use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccines. 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 Morb Mortal Wkly Rep* 55:1–37, Dec. 15, 2006; and Murphy T.V., et al., Centers for Disease Control and Prevention: Prevention of pertussis, tetanus, and diphtheria among pregnant and postpartum women and their infants. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep* 57:1–51, May 30, 2008.

Appendix I-2 Glossary of Key Terms Used in This Monograph

Term	Definition
Acute encephalopathy1*	Acute illness of the brain characterized by a decreased level of consciousness (excluding tempo- rary drowsiness after a seizure), occurring with or without seizures.
Apnea ^{1*}	Transient cessation of respiration that can occur spontaneously or after a coughing spasm.
Catarrhal phase ^{2*}	The initial phase of pertussis, which lasts 1–2 weeks. This phase is characterized by an insidious onset similar to a mild respiratory illness that produces cold-like symptoms (i.e., watery nasal discharge, frequent cough and sneezing with injection of the conjunctiva). The cough is short, hacking, and isolated (unlike the paroxysmal cough) and is commonly present both day and night.
Cell-mediated immunity ^{3*}	Resistance of a host to a specific agent largely related to specific T-lymphocyte activity.
Cocoon strategy ^{4*}	A method of reducing pertussis transmission to newborns by which household members (including parents and siblings) and other caregivers (e.g., day care staff, health care personnel) are vaccinated. This strategy results in herd immunity and reduces, but does not eliminate, the risk of infants becoming infected with pertussis.
Cohorting⁵	The practice of grouping patients infected or colonized with the same infectious agent together to confine their care to one area and prevent contact with susceptible patients.
Cold-like symptoms1*	Conjunctival infection (redness of the eyes) and/or coryza (runny nose).
Convalescent phase ^{2*}	The third and final phase of pertussis, which usually lasts 2–6 weeks and is associated with grad- ual recovery, though symptoms can last for more than 6 months.
Cyanosis ^{1*}	Paleness or blueness of the skin, most noticeable on the lips and tongue, that occurs after cough- ing paroxysms and apnea.
Droplet Precautions ^{6*}	Control measure intended to prevent transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions. Elements include a single-patient room, separation from others by > 3 feet, and curtain drawn between patient beds (especially important for patients in multibed rooms). Health care personnel wear a mask (a respirator is not necessary) for close contact with infectious patients. Patients on Droplet Precautions who must be transported outside of the room should wear a mask if tolerated and follow Respiratory Hygiene/Cough Etiquette.
DT versus Td ^{7*}	Vaccines that contain tetanus and diphtheria toxoids but do not contain the pertussis component. DT is used as a substitute for children who cannot tolerate the DTaP vaccine. Td is a tetanus– diphtheria vaccine given to adolescents and adults as a booster shot every 10 years, or after an exposure to tetanus under some circumstances. Uppercase letters denote full-strength dose levels, while lowercase letters denote reduced dose levels.
DTaP ^{1*}	A pertussis vaccine for children younger than 7 years that contains acellular pertussis antigens in combination with diphtheria and tetanus toxoids. The Advisory Committee on Immunization Practices (ACIP) recommends a four-dose primary series of DTaP, administered at 2, 4, 6, and 15–18 months of age, followed by a fifth booster dose given at 4–6 years.

*Adapted from original source

(continued)

Term	Definition
DTP ^{8*}	A whole-cell pertussis vaccine that became available in the 1920s. In 1997 the Advisory Committee on Immunization Practices (ACIP) recommended that DTP be replaced by pediatric DTaP for the five-dose vaccination schedule (at ages 2, 4, 6, and 15–18 months and 4–6 years). Pediatric DTP has not been available in the United States since 2002.
Effectiveness ^{9*}	The prevention of illness in immunized populations.
Efficacy ^{9*}	The prevention of illness among persons immunized in clinical trials.
Endemic ¹⁰	The continual, low-level presence of disease in a community.
Epidemic ¹⁰	The occurrence of disease within a specific geographic area or population that is in excess of what is normally expected.
Epidemiologically linked case ^{1*}	A case in which the patient has or has had contact with one or more persons who have or have had the disease, and transmission of the agent by the usual modes of transmission is plausible. In general, a case may be considered epidemiologically linked to a laboratory-confirmed case if at least one case in the chain of transmission is laboratory confirmed.
Face mask ¹¹	A loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment.
Health care–associated infection (HAI) ^{6*}	An infection that develops in a patient who is cared for in any setting where health care is delivered (for example, acute care hospital, chronic care facility, ambulatory clinic, dialysis center, surgical center, home) and is related to receiving health care (that is, was not incubating or present at the time health care was provided). In ambulatory and home settings, HAI would apply to any infection that is associated with a medical or surgical intervention.
Health care personnel (HCP) ^{12*}	Defined broadly, all paid and unpaid persons working in health care settings who have the potential for exposure to patients and/or infectious materials. The full range of HCP work in a variety of settings, including acute care hospitals, long term care facilities, skilled nursing facilities, rehabilitation centers, physicians' offices, urgent care centers, outpatient clinics, home health care agencies, and emergency medical services. Some HCP provide direct patient care. Others, such as housekeepers, maintenance staff, vendors, volunteers, and outside contractors, have jobs that may put them into close contact with patients or the patient environment.
Herd immunity ^{13*}	The immunity of a group or community. The resistance of a group to invasion and spread of an infectious agent, based on the resistance to infection of a high proportion of individual members of the group.
Humoral immunity ^{3*}	Resistance of a host to a specific agent through the presence of specific immunoglobulins (antibod- ies) in surface body fluids or circulating in noncellular components of blood. Antibodies are pro- duced by B lymphocytes and are also recognized to be under the influence of T-lymphocyte functions.
Immunization information systems (IISs) ¹⁴	Formerly known as immunization registries, confidential, computerized information systems that collect and consolidate vaccination data from multiple health care providers, generate reminder and recall notifications, and assess vaccination coverage within a defined geographic area.

*Adapted from original source

(continued)

Term	Definition
Immunocompromised ^{1*}	Having either decreased or absent ability to mount an antibody and/or cell-mediated immune response to infectious agents.
Immunogenicity ^{3*}	An agent's (microorganism's) intrinsic ability to trigger specific immunity in a host.
Incubation period1*	The period of time from being exposed to an infectious agent to onset of symptoms of disease.
Index case ^{3*}	The first case to be recognized in a series of transmissions of an agent in a host population.
Infection preventionist ¹⁵	A person whose primary training is either in nursing, medical technology, microbiology, or epidemi- ology and who has acquired special training in infection prevention and control. Responsibilities may include collection, analysis, and feedback of infection data and trends to health care providers consultation on infection risk assessment, prevention, and control strategies; performance of edu- cation and training activities; implementation of evidence-based infection control practices or prac- tices mandated by regulatory and licensing agencies; application of epidemiologic principles to improve patient outcomes; evaluation of new products or procedures on patient outcomes; over- sight of employee health services related to infection prevention; implementation of preparedness plans; communication within the health care setting, with local and state health departments, and with the community at large concerning infection control issues; and participation in research. Certification in infection control (C.I.C.) is available through the Certification Board of Infection Control and Epidemiology (known as Infection Control Professionals prior to July 10, 2008).
Medical home ¹⁶	A health care setting that facilitates a partnership between patients and their personal physician that is facilitated by registries, information technology, exchange of health information, and other means to ensure that patients receive indicated care in a culturally appropriate and understandable manner.
Outbreak ^{13*}	Synonymous with epidemic, the occurrence of more cases of disease than expected in a given area or among a specific group of people over a particular period of time.
Pandemic ¹⁰	An epidemic occurring over a very large area.
Paroxysmal cough ^{1*}	Uncontrollable coughing spells in which one cough follows the next, without a break for breath.
Paroxysmal phase ^{2*}	The second phase of pertussis that lasts 2–6 weeks, with intermittent intense coughing (parox- ysms) that alternate with periods of normal respiratory rate and the individual appearing to be rela- tively well. The paroxysms are characterized by spasms of coughing and choking, with posttussive vomiting and inspiratory whoop. Infants and young children in particular appear very ill, and hospi- talization is often required to treat them. This is the stage at which pertussis may be suspected.
Polymerase chain reaction (PCR) ^{1*}	A rapid testing technique for amplification of DNA, with results available within 2–24 hours.
Posttussive vomiting ^{1*}	Vomiting following coughing paroxysms.
Presenteeism ^{17*}	The problem of lost productivity that occurs when employees are present at the work site but, because of illness or other medical condition, are not fully functioning.

*Adapted from original source

(continued)



Term	Definition	
Recall system ^{18*}	A system that sends messages to patients, parents, and providers, stating that recommended immu- nizations are past due.	
Reminder system ^{18*}	A system that sends messages to patients, parents, and providers, stating that recommended immu- nizations are due soon.	
Reportable disease ¹⁹	A disease for which there are legal requirements for reporting and notification to public health authori- ties. In the United States, requirements for reporting diseases are mandated by state laws or regula- tions, and the list of reportable diseases in each state differs.	
Respiratory Hygiene/ Cough Etiquette [®] *	Control measures used to contain respiratory secretions and prevent droplet and fomite transmission of respiratory pathogens. The elements include (1) education of health care personnel, patients, and visitors; (2) posted signs, in language(s) appropriate to the population served, that contain instructions to patients and others accompanying the patient; (3) source control measures, such as covering the mouth/nose with a tissue when coughing and prompt disposal of used tissues or using surgical masks on the coughing person when tolerated and appropriate; (4) hand hygiene after contact with respiratory secretions; and (5) separation of persons with respiratory infections, ideally by > 3 feet, in common waiting areas when possible. Covering coughs and sneezes and placing masks on coughing patients are proven methods of source containment that prevent infected persons from dispersing respiratory secretions into the air.	
Sensitivity ^{3*}	The ratio of the number of patients reported to have had an infection divided by the number of patients who actually had an infection.	
Specificity ^{3*}	The ratio of the number of patients who were reported not to have an infection divided by the number of patients who actually did not have an infection.	
Standard Precautions ^{12*}	A group of infection prevention practices that apply to all patients, regardless of suspected or con- firmed diagnosis or presumed infection status. Standard Precautions are based on the principle that blood, body fluids, secretions, excretions except sweat, nonintact skin, and mucous membranes may contain transmissible infectious agents. Standard Precautions include hand hygiene and the use of gloves, gowns, masks, eye protection, or face shields (depending on the anticipated exposure). Also equipment or items in the patient environment likely to have been contaminated with infectious mate als must be handled in a manner to prevent transmission of infectious agents (for example, wear gloves for handling, contain heavily soiled equipment, properly clean and disinfect or sterilize reusable equipment before use on another patient).	
Standing orders ^{20*}	Written protocols that authorize nonphysician medical personnel to administer vaccinations to persons who meet certain criteria (for example, underlying condition, age) in accordance with an institution- or physician-approved protocol without a physician's examination or direct physician involvement.	
Tdap ^{1*}	A pertussis vaccine for adolescents and adults that contains acellular pertussis antigens in combination with diphtheria and tetanus toxoids. The Advisory Committee on Immunization Practices (ACIP) recommends the replacement of a single Td booster with a dose of Tdap for adolescents (ages 11–18) and adults (ages 19–64) who have not previously received Tdap.	
Whoop ^{1*}	A high-pitched noise that occurs when breathing in after a coughing spasm.	

*Adapted from original source

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Appendix I-3

Submitting Organizations Highlighted in the Monograph

Submitting Organization	Health Care Organization Contact
Bartlett Regional Hospital	Infection Control/Employee Health
Juneau, Alaska	Phone: 907-796-8413
Bloomington Hospital	Special Care Nursery
Bloomington, Indiana	Phone: 812-353-9443
Center for Vaccine Awareness and Research, Texas Children's Hospital Houston, Texas	Pediatric Infectious Diseases Phone: 832-824-1780
Charleston Area Medical Center	Infection Prevention/Employee Health
Charleston, West Virginia	Phone: 304-388-4259
Columbia Basin Health Association	Quality Department
Othello, Washington	Phone: 509-488-5256
Edward Hospital and Health Services	Infection Control
Naperville, Illinois	Phone: 630-527-3060
Houston Northwest Medical Center	Occupational Health
Houston, Texas	Phone: 281-397-2718
Intermountain Healthcare	Corporate Employee Health
Salt Lake City, Utah	Phone: 801-442-2297
Johnson City Medical Center Mountain State Health Alliance—Washington County Johnson City, Tennessee	Team Member Health Phone: 423-431-5831
Lakeland Regional Medical Center	Employee Health Services
Lakeland, Florida	Phone: 863-687-1138
Mary Rutan Hospital	Infection Prevention/Employee Health
Bellefontaine, Ohio	Phone: 937-651-6710
Michigan State University/ Kalamazoo Center for Medical Studies Kalamazoo, Michigan	Nursing Services/Quality Improvement Phone: 269-337-6313
Ohio State University	Student Health Services
Columbus, Ohio	Phone: 614-247-4340
Otsego Memorial Hospital	Infection Prevention/Employee Health
Gaylord, Michigan	Phone: 989-731-2235
Rochester General Medical Group	Penn Fair Pediatric Group
Rochester, New York	Phone: 585-922-0460
Stormont-Vail HealthCare	Employee Health
Topeka, Kansas	Phone: 785-534-5928
Summa Health System, Akron City Hospital and St. Thomas Hospital Akron, Ohio	Infection Prevention Phone: 330-379-5099

CHAPTER 1

Pertussis Disease

Summary of Key Points

- In the pre-vaccination era, classical pertussis was primarily a childhood disease.
- With widespread childhood vaccination, increases in pertussis have shifted to adults and adolescents.
- Protection conferred by both pertussis vaccination and infection wane over time, lasting 5 to 10 years.
- Adults and adolescents who have asymptomatic disease or cough illnesses are often not recognized as having pertussis.
- Adults and adolescents play a significant role in the transmission of pertussis to infants who have not yet been vaccinated or have not completed the vaccination series.
- Pertussis rates among nonimmune exposed household contacts have been as high as 80% to 90%.

What Is Pertussis?

Pertussis is an acute, highly infectious bacterial illness of the respiratory tract, commonly known as whooping cough. The history of pertussis goes back to 1540 in England, with the first outbreak reported in 1578 in Paris.¹ Early names for the disease varied by region. In the British Isles, the disease was

known as "the kink," a Scottish term that means "fit" or "paroxysm."¹ In northern Europe, *kindhoest*, a Teutonic word that means "child's cough," was used.¹ The Chinese term for the disease, *bai ri ke*, means "100-day cough."² Thomas Sydenham first described the illness in 1679 and gave it the name *pertussis*, which means "violent cough."¹ It was not until 1906 that Gengou and Bordet first isolated the causative organism, *Bordetella pertussis*, in the laboratory.³

In the pre-vaccination era, pertussis outbreaks followed a cyclic pattern, with peaks of disease every three to five years.⁴ The overall incidence of pertussis declined dramatically after a vaccination became available in the mid-1940s, but the cyclic pattern has not changed.⁵ Unlike other infectious diseases, such as measles, that have seen incidence and circulation reduced through vaccination,⁶ the circulation of *Bordetella pertussis* has continued. Recent data suggest that the circulation of *B. pertussis* is occurring in adolescents and adults who have asymptomatic diseases or cough illnesses that often are not recognized as pertussis.⁶⁷ The cyclic nature of the disease has been highlighted recently in California, where pertussis cases increased sharply in 2010, with the last peak in 2005.⁸

Epidemiology of Pertussis

Pertussis is a human disease with no distinct seasonal pattern, though it may increase in summer and fall.³ The disease is caused by the fastidious gram-negative coccobacillus *Bordetella pertussis* and requires special media for isolation in a laboratory.^{5,9} (*See* Text Box 1-1, on page 3.) It is transmitted from person to person via large respiratory droplets that occur during coughing or sneezing. Attack rates among nonimmune exposed household contacts have been as high as 80% to 90%. Pertussis can initially be similar to other respiratory illnesses, including the common cold and diseases caused by *Bordetella parapertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae*, adenovirus, influenza virus, and coronavirus.⁵

The incubation period for pertussis averages 7 to 10 days but can range from 5 to 21 days. The three phases of classic pertussis are as follows (*see* Figure 1-1 on page 4)⁵:

- The catarrhal phase lasts one to two weeks, with an insidious onset similar to a mild respiratory illness that produces cold-like symptoms such as a watery nasal discharge and frequent cough and sneezing, with injection of the conjunctiva; the cough is short, hacking, and isolated—unlike the paroxysmal cough—and is commonly present both day and night. Fever is not common in any phase of the illness unless secondary infection occurs. This nonspecific presentation often leads to misdiagnosis.
- The **paroxysmal phase** lasts two to six weeks, with intermittent intense coughing (paroxysms) that alternate with periods of a normal respiratory rate and the individual appearing to be relatively well. The paroxysms, however, are characterized by spasms of coughing and choking, with posttussive vomiting and inspiratory whoop. Infants and young children in particular appear very ill, and hospitalization is often required. This is the stage at which pertussis may be suspected.
- The **convalescent phase** usually lasts two to six weeks, with gradual recovery, though symptoms can last for more than six months.

Pertussis is highly communicable in the catarrhal stage and for at least the first two weeks of the paroxysmal cough stage. Without antibiotics, communicability gradually decreases and becomes negligible in approximately three weeks, though the spasmodic cough and whoop may persist.⁹ Infants, however, can remain infectious for six weeks or longer without treatment.⁵ When treated with macrolide antibiotics such as erythromycin, clarithromycin, or azithromycin in the catarrhal phase, individuals are no longer contagious after five days of treatment.⁹ Older children and adults with previous pertussis vaccination or infection are usually infectious for three weeks or less.⁵

Pertussis Cases in the United States

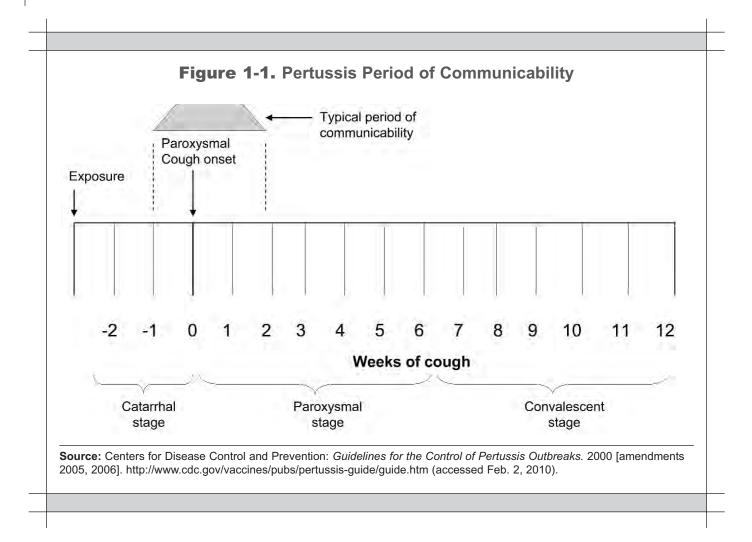
More than 200,000 cases of pertussis were reported in the United States each year (average incidence of approximately 150/100,000 population) between 1922 and 1940 (see Figure 1-2 on page 5). Following the introduction of universal childhood vaccination, the incidence of pertussis dropped, with 15,000 cases (approximately 8 per 100,000 population) reported in 1960.³ Aside from the typical cyclic activity, the fewest reported cases on record was 1,010 in 1976.¹⁰ The numbers then began rising, peaking at 25,827 cases in 2004¹⁰ before dropping back the next year.¹¹ In 2008, however, there were 13,278 reported cases, up from 2007's total, with infants less than 6 months of age continuing to have the highest number of reported cases. Adolescents and adults accounted for almost half the reported cases in 2008.12 Appendix 1-1, beginning on page 17, provides a brief historical overview of reported pertussis cases.

The illness is often nonspecific in adolescents and adults and can vary from asymptomatic infection to mild, atypical respiratory illness, to the classic whooping syndrome.⁵ Researchers for the Adult Pertussis Trial (APERT) Study Group estimated that, in persons ages 15 and older, there are approximately five asymptomatic pertussis cases for every symptomatic case.¹³ Data from a recent study suggest that 16% of infections in infants are the result of transmission of asymptomatic disease.¹⁴ Even though the disease may be milder in older individuals, this population can spread the disease to other susceptible individuals, including unimmunized or incompletely immunized infants.3 In a Canadian study, a source was identified in 60% to 70% of adults and adolescents with pertussis: Among adults (18 to 39 years), the source was a person in the household in 25% to 44% of the cases and a person at school or work in 17% to 25% of the cases; among adolescents (12 to 17 years), the source was a person in the household in 9% of the cases and a contact at work or school in 51% of the cases.¹⁵

	Text Box 1-1. Pertussis at a Glance
Clinical features	Highly communicable, vaccine-preventable disease that lasts many weeks and is typically mani- fested in children with paroxysmal spasms of severe coughing, whooping, and posttussive vomiting.
Etiologic agent	Bordetella pertussis, a gram-negative coccobacillus.
Incidence	Pertussis results in high morbidity and mortality in many countries every year. In the United States, 5,000–7,000 cases are reported annually, and the incidence has increased steadily since the 1980s. The incidence in 2007 was 3.6/100,000 when 10,454 cases of pertussis were reported. More than 17,000 cases were reported in 2009. Recent localized outbreaks have occurred in California (a seven-fold increase in 2010 over the number of cases reported in 2009) and Michigan (an increase in reported cases that began in 2008 and continued into 2010).
Complications	Major complications are most common among infants and young children and include hypoxia, apnea, pneumonia, seizures, encephalopathy, and malnutrition. More than half of infants younger than 1 year who become ill with pertussis must be hospitalized. Most deaths occur among unvaccinated children or children too young to be vaccinated.
Transmission	Transmission occurs through direct contact with discharges from respiratory mucous membranes of infected persons.
Risk groups	Children who are too young to be fully vaccinated and those who have not completed the primary vaccination series are at highest risk for severe illness. Like measles, pertussis is highly contagious, with up to 90% of susceptible household contacts developing clinical disease following exposure to an index case. Adolescents and adults become susceptible when immunity wanes but can receive one booster shot of the new combination vaccine (called Tdap).
Surveillance	National reporting through the National Notifiable Diseases Surveillance System throughout the United States.
Trends	Pertussis is an endemic illness. In the United States, epidemics occur every three to five years. The most recent epidemic occurred in 2005 (25,616 reported cases). Overall increase in cases since 1990, with disproportionate increase in adolescents and adults.
Source: Centers for D 2010).	isease Control and Prevention: Pertussis (Whooping Cough). http://www.cdc.gov/pertussis/index.html (accessed Aug. 31,

A reportable disease in the United States since 1922,¹⁰ pertussis cases are reported to local and state health departments by physicians, laboratories, infection preventionists, and other health care professionals. State health departments report probable and confirmed cases of pertussis to the Centers for Disease Control and Prevention (CDC) via the passive National Notifiable Disease Surveillance System. In 1979 the Supplemental Pertussis Surveillance System was introduced to monitor national trends over time by collecting additional information on the epidemiology of pertussis, its health impact, and vaccine and antibiotic efficacy and usage.¹⁶ See Text Box 1-2 on page 6 for the case definition of pertussis. The number of pertussis cases reported by states varies widely (*see* Figure 1-3 on page 7). States that report higher proportions of cases in adults and adolescents also report greater numbers of cases overall.¹⁷ Consider the example of Massachusetts: The state had a pertussis incidence in adolescents and adults in 1994 that was approximately 13 times greater than that of the rest of the United States, but it had no comparable difference in pertussis rates among young children.¹⁸ And, more recently, the state reported 1,812 cases among youths ages 10 to 19. This means that, despite having only 2% of the total U.S. population of 10- to 19-year-olds, Massachusetts accounted for 19% of all reported pertussis

Tdap Vaccination Strategies for Adolescents and Adults, Including Health Care Personnel: Strategies from Research and Practice

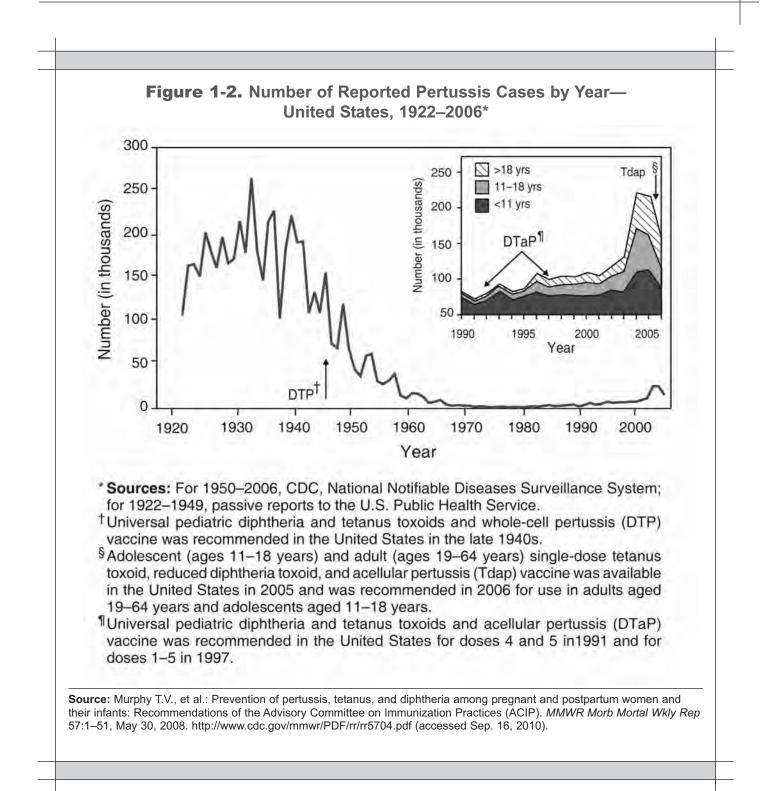


cases for this age group in the United States during that time period. Eight other states reported an average annual incidence of < 1 case per 100,000 persons ages 10 to 19 during the same period, and the median state average incidence for this age group was 3.7 per 100,000 population.¹⁹ The large number of cases reported in Massachusetts is due, in part, to the development and availability of a serologic test for confirmation of pertussis in those ages 11 and older and enhanced pertussis surveillance among students in middle and high schools.¹⁹

It is unclear how much the increase in reported cases of pertussis in adolescents and adults reflects a definite change in the burden of the disease, but better recognition, diagnosis, and reporting in persons ages 10 to 19 has likely contributed to the number of cases.¹⁹ Other reasons for increasing numbers of cases include the following⁶:

- Genetic changes in *B. pertussis* that make the vaccines less effective
- Decreased potency of the vaccine
- Waning vaccine-induced immunity
- Heightened awareness of pertussis
- Availability of better laboratory tests in some parts of the United States

Of these five possible causes, it is believed that waning vaccine-induced immunity due to vaccines that were less immunogenic in the 1980s (prior to the introduction of and universal use of DTaP vaccines) and greater awareness of



Text Box 1-2. Pertussis Case Definition

The Centers for Disease Control and Prevention (CDC) and the Council of State and Territorial Epidemiologists (CSTE) offer the following case definition for pertussis:

Clinical Case Definition

A cough illness lasting at least 2 weeks with one of the following: paroxysms of coughing, inspiratory "whoop," or posttussive vomiting, and without other apparent cause (as reported by a health care professional)

Laboratory Criteria for Diagnosis

Isolation of *Bordetella pertussis* from a clinical specimen or positive polymerase chain reaction (PCR) assay for *B. per*tussis

Case Classification*

Confirmed:

- 1. An acute cough illness of any duration associated with B. pertussis isolation
- 2. A case that meets the clinical case definition and is confirmed by PCR
 - or
- 3. A case that meets the clinical definition and is epidemiologically linked directly to a case confirmed by either culture or PCR

Probable:

 A case that meets the clinical case definition, is not laboratory confirmed by culture or PCR, and is not epidemiologically linked directly to a laboratory-confirmed case

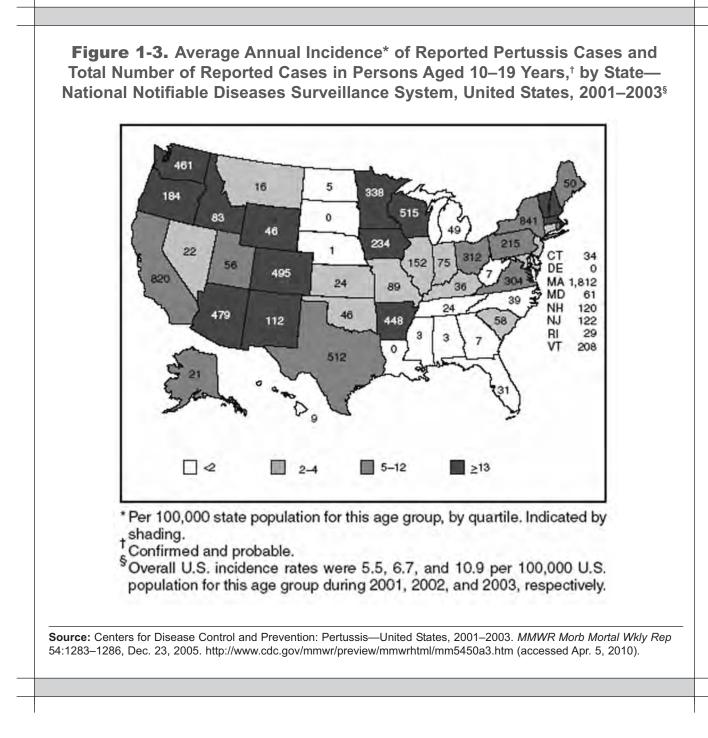
* Both probable and confirmed cases should be reported to the National Notifiable Diseases Surveillance System.

Sources: Centers for Disease Control and Prevention: *Guidelines for the Control of Pertussis Outbreaks*. 2000 [amendments 2005, 2006]. http://www.cdc.gov/vaccines/pubs/pertussis-guide/guide.htm (accessed Aug. 31, 2010); Council of State and Territorial Epidemiologists: *CSTE Position Statement 1997-ID-9: Public Health Surveillance, Control, and Prevention of Pertussis*. 1997. http://www.cste.org/ps/pssearch/1997/1997-id-09.htm. (accessed Nov. 14, 2010).

pertussis are responsible for rising numbers of pertussis cases.^{6,20} Güriş et al. analyzed pertussis surveillance data sent to the CDC from 1990 to1996, attributing the substantial increase in the number of reported cases in individuals ages 10 years and older to improved diagnosis and increased awareness of the disease in adolescents and adults.¹⁷

Although statistics show increased rates of pertussis, the actual number of cases in adolescents and adults continues to be substantially underreported. Some of those who contract the illness do not seek medical care; some patients may be misdiagnosed because pertussis can resemble other conditions; and other cases may go unreported because of a lack of available diagnostic tests.^{10,21,22} A population-based active

surveillance study conducted in 1995 and 1996 estimated the pertussis incidence rate at 507 per 100,000 population ages 10 to 49, demonstrating that only a fraction of cases among older persons (approximately 1% to 2%) are captured by passive surveillance.¹⁹ More recent research based on prospective studies with active surveillance estimated the annual incidence rate among persons older than age 15 at approximately 370 to 450 cases per 100,000 person years, or approximately 1 million cases of pertussis each year in the United States in this age group.²³ This variability in the reported incidence of pertussis and estimates based on active surveillance supports the contention that the disease often goes undiagnosed and is underreported in most of the United States.



Diagnostic Issues

Effective pertussis treatment and control measures are highly dependent on early diagnosis, but the disease remains poorly recognized by clinicians. A number of studies have examined why and how pertussis goes unnoticed and are summarized in the following:

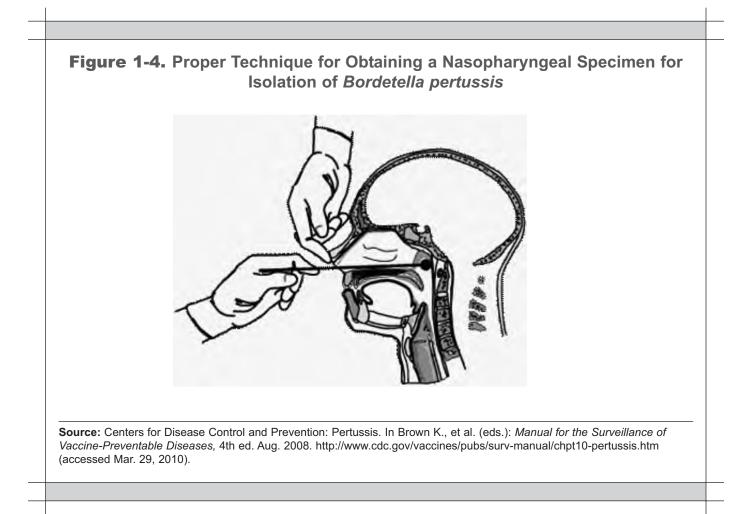
- Deeks et al. studied Canadian children who met the World Health Organization (WHO) or Canadian public health surveillance case definition for pertussis, and found that physicians considered a diagnosis of pertussis in 24% to 26% of children, made a diagnosis of pertussis in 12% to 14% of the patients and reported the case to health officials in 6% of the cases. Of particular concern in this study was the low number of pertussis cases that were diagnosed even when children had classical symptoms of the disease and after practitioners had received written communications regarding the resurgence of pertussis in the region. These researchers found significant associations $(p \le .05)$ between pertussis diagnosis and a history of pertussis exposure, the presence of four pertussis-related symptoms (paroxysmal cough, whoop, posttussive vomiting, and apnea), a cough for ≥ 5 weeks, and a physician consult in a hospital setting.²⁴
- Dworkin wrote of his personal experiences as a CDC epidemic intelligence service officer. He was board certified by the American Board of Internal Medicine and Infectious Diseases and held a master's degree in public health. Yet, when approached by a frustrated nurse who wanted help to convince a local physician to test or treat an adult with a chronic cough for pertussis, Dworkin's first reaction was surprise that adults could get pertussis. The experience provided a vivid illustration of how physician myths about pertussis and lack of knowledge about the disease hinder the recognition of the illness.²⁵
- A national survey of family practice and general pediatricians regarding the diagnosis and testing practices for pertussis in adolescents found that 16% of respondents did not test adolescents for pertussis. A similar proportion indicated that they likely would not be able to recognize pertussis symptoms in adolescents. Barriers to testing included delays in receiving test results (52%), specimen collection inconvenience (29%), lack of testing supplies (29%), lack of familiarity with testing protocols (28%), and cost (22%).²⁶

Diagnostic Tests

Health care professionals can choose from among four currently available diagnostic tests for pertussis. Each of these tests has certain limitations,⁵ and many laboratories are not equipped to diagnose *B. pertussis* infection.²⁷ The only pertussis tests that are accepted to meet the pertussis case definition established by the CDC and the Council of State and Territorial Epidemiologists (CSTE) (*see* Text Box 1-2) are culture and polymerase chain reaction (PCR) (when the clinical case definition is also met). Other diagnostic tests include direct fluorescent antibody testing and serologic antibody testing.²⁷ A number of factors can affect the sensitivity, specificity, and interpretation of diagnostic tests for pertussis (*see* Table 1-1 on page 10 for a summary of the issues associated with the various diagnostic tests).⁵

The following is an overview of the four diagnostic tests:

- ٠ Culture to isolate *B. pertussis* is considered the "gold standard" for laboratory diagnosis of pertussis.²⁸ Culture is necessary to identify the organism early in the course of disease and to test for antimicrobial susceptibility, if indicated.5 Culture requires specimens that contain nasopharyngeal cells (not the throat or anterior nose) obtained via aspiration or nasopharyngeal specimen⁵ using Dacron or calcium alginate swabs²⁸ (see Figure 1-4 on page 9 for a diagram of the technique). Cotton or rayon swabs should not be used because they contain fatty acids that are toxic to *B. pertussis.*²⁷ Specimens must be placed immediately in special transport media (Regan-Lowe) so as not to dry, and they must be promptly transported to the laboratory.²⁸ Modified Regan-Lowe agar is also the preferred growth medium.²⁷
- Isolation of the organism by culture is 100% specific, but sensitivity of culture early in pertussis varies between 30% and 60%. Outside infancy, *B. pertussis* yield declines to 1% to 3%.⁵ Infants tested after short symptom duration have the highest culture sensitivity, while adults tested after longer symptom duration have the lowest sensitivity.²⁹ Culture can be negative if the specimen is taken more than three weeks after onset of cough, in persons who have been vaccinated previously, if antimicrobial therapy has been started, or if the specimen is not handled properly.²⁸ The organism can be isolated as early as 72 hours after plating but requires up to



two weeks to definitively call the result negative.⁵ The primary reasons for failure to grow the organism are lack of fresh media and sample contamination.²⁷ It is important to note that a negative culture does not exclude the diagnosis of pertussis.²⁸

Polymerase chain reaction (PCR), or DNA amplification, to detect *B. pertussis* has been available for nearly 20 years, but currently there is no U.S. Food and Drug Administration (FDA)–licensed PCR test kit. The accuracy, analytical sensitivity, and quality control associated with PCR–based *B. pertussis* tests vary among laboratories.⁵ PCR was added to the CSTE pertussis case definition in 1997.⁴ PCR testing for identification of pertussis cases is rapidly evolving and has advantages over culture: It is more sensitive than conventional culture (70% to 99%),²⁹ and positive results can be obtained even when

the organism can no longer be cultured, such as when the patient has been on antibiotics.²⁷ It is, however, less specific than culture (86% to 100%).29 PCR results can be available in as little as 2–24 hours.²⁹ Edelman et al. studied the utility of PCR testing in culture-proven pertussis in nonvaccinated patients and found that, on the seventh day of erythromycin treatment, 56% of the PCR tests were positive when all cultures were negative.³⁰ As with culture, PCR results are affected by the technique used to collect the specimen; Dacron or rayon swabs should be used, as calcium alginate swabs inhibit PCR, and aspirate specimens require treatment with a mucolytic agent to remove or deactivate PCR-inhibiting substances.²⁷ Another issue that bears mentioning is the use of single-target PCR tests versus a two-target PCR test. In respiratory disease outbreaks, positive results with

Diagnostic Test	Test Description	Sensitivity of Test	Specificity of Test	Comments
Culture	Nasopharyngeal specimen, using Dacron or calcium alginate swab or nasopharyngeal aspi- rate; requires special transport media	30%–60%	100%	Considered the "gold standard" for laboratory diagnosis. Requires 5- to 10-day incubation. Included in the Council of State and Territorial Epidemiologists (CSTE) pertussis case definition.
Polymerase chain reaction (PCR)	Nasopharyngeal specimen, using Dacron swab or aspirate	70%–99%	86%–100%	Calcium alginate swabs must not be used to collect specimen. Added to the CSTE pertussis case definition in 1997. Rapid test turn- around, in 2–24 hours.
Direct fluorescent antibody (DFA)	Test performed on nasopharyn- geal secretions	10%–50%	Variable	No longer recommended by the Centers for Disease Control and Prevention (CDC) for pertussis diagnosis.
Serology	Test performed on paired sera specimens, collected during the acute and convalescent periods	Has not been clinically validated	Has not been clinically validated	Serologic testing for pertussis has been validated for use only in Massachusetts. Not an accepted confirmatory test outside the CDC or Massachusetts.

a single PCR assay have led to false diagnoses of pertussis, demonstrating the importance of using a two-target PCR assay to improve the diagnosis of the disease.^{29,31} Despite the advantages associated with PCR, efforts to culture the organism should be made. Recovery of the organism permits detection of strain variations, antibiotic resistance patterns, and other organism characteristics that would not be identified by PCR alone.²⁷ The CDC specifically recommends that PCR be used alongside culture.⁴ It also should be noted that both false-negative and falsepositive results have been reported with PCR assays, and reports of respiratory illness outbreaks have been mistakenly attributed to pertussis when PCR assays were solely relied upon, resulting in unnecessary investigation and treatment, as well as chemoprophylaxis of contacts.⁵ Falsepositive PCR may result from contamination with DNA at the point of specimen collection or within the laboratory performing the testing. In addition, use of a nonspecific, single-target PCR may detect related specimens of the genus *Bordetella*.³²

• Direct fluorescent antibody (DFA) testing of nasopharyngeal secretions has been used to diagnose pertussis for approximately four decades. The test's sensitivity ranges from 10% to 50%, much lower than culture,⁵ and the CDC no longer recommends DFA testing for pertussis.²⁷ Reasons for its use include the ability to yield positive results when cultures are negative (due to antibiotic use), low cost, and availability of results within hours.²⁷ DFA testing is not considered confirmatory because the tests also have variable specificity⁴ due to cross-reactivity with normal flora of the upper respiratory tract.²⁷ Cases that are DFA–positive but not culture- or PCR–positive that meet the case definition for pertussis would be considered probable cases.

Serologic antibody testing is not an accepted confirmatory criteria for reporting purposes, except in Massachusetts, where an assay for anyone age 11 and older has been clinically validated for use.4 Cases that meet the clinical case definition of pertussis that are serologically positive but not PCR- or culture-positive would be considered probable cases.⁴ Serology focuses on a significant variation (typically a four-fold increase) in titers for pertussis antigens between acute (< 2 weeks after onset of cough) and convalescent sera (> 4 weeks after the acute sample). Pertussis serology assays using commercial test kits are widely available and in use but are not licensed by the FDA for routine diagnostic use in the United States. The performance of individual assays should be evaluated in the population in which the assays are used in order to determine their sensitivity and specificity for detecting recent infection. Although results usually become available too late in the course of illness to be clinically useful,⁵ confirming the diagnosis remains important in clinical medicine and for public health surveillance and disease control efforts. Single-sample serology tests for antipertussis toxin have been developed for use at least two weeks after onset of symptoms.³¹ An assay developed jointly by the CDC and the FDA is currently under clinical validation.

Another test, pulsed-field gel electrophoresis (PFGE), is a type of DNA fingerprinting that can be useful on *B. pertussis* isolates to track transmission, such as during a community outbreak, but it is not done as part of routine surveillance or diagnosis.⁴

Health care personnel should check with their laboratory prior to collecting patient specimens for pertussis tests to ensure the availability of the proper swabs, media, specimen collection instructions, and test ordering information for the selected diagnostic test.

CDC Review of Diagnostic Tests

The CDC is currently conducting a diagnostic validation study to assess the clinical accuracy of several pertussis diagnostic tests in an effort to ensure that standardized laboratory tests are available for both public health interventions and routine testing.²⁶ The study was still under way at the writing of this monograph, but two reports describing the diagnostic tests under clinical review have been published by the CDC:

- Tatti et al. describe the two-target, real-time PCR assays they developed that are both sensitive and specific and would permit identification of relevant *Bordetella* species for public health interventions and outbreak efforts.²⁹ The assays and the interpretation criteria are being further validated using serologic and culture assays in a prospective clinical trial.
- Menzies et al. describe the enzyme-linked immunosorbent assay (ELISA) they developed for the detection of antipertussis IgG as a user-friendly kit for the diagnosis of pertussis in its later phases.³³ This test is also being evaluated in prospective clinical trials; when they have been completed and diagnostic thresholds have been established, this assay could also become available for wide-scale public health use.

Immunity to Pertussis

The mechanisms of pertussis protection are not completely understood, although most adults and adolescents have been exposed to *B. pertussis*, pertussis antigen–containing vaccines, or both.⁵ Overall, the protection conferred by both *B. pertussis* infection and pertussis vaccines lasts 5 to 10 years. After this period, individuals are susceptible to infection or reinfection.⁵

Studies in animals and humans show that protection against pertussis appears to be the result of both cellmediated (host macrophages and other cells) and humoral (acquired immunity, protective antibodies present) immunity.⁵ When administered a vaccine containing pertussis antigens, an individual will have a booster response, with a measurable rise in antibodies detected seven days after vaccination. These antibody concentrations peak at about two weeks after the booster dose and decline rapidly in the initial months following vaccination, after which the rate of decline slows.⁵ Infant protection against pertussis and the role of transplacental antibody is unclear. In the prevaccine era, observers concluded that infants are susceptible to pertussis from the day of birth, with the possible exception of an infant whose mother was ill with pertussis during pregnancy.⁵ Retrospective surveys of pregnant women after early vaccine trials, however, suggested some degree of protection against pertussis in the first six months of life, when high levels of transplacental antibodies were present.⁵

Morbidity and Mortality Associated with Pertussis

The most frequent complication of pertussis is pneumonia. Pertussis can also lead to encephalopathy, seizures, and even death.²⁸ For infants, pertussis is a serious risk. Consider the following:

- Pneumonia occurred in 11.8% of pertussis cases among infants under 6 months of age but in only 5.2% of all reported cases.³
- Most hospitalizations for pertussis occur in infants less than 6 months old.¹⁹
- Of the 100 pertussis-related deaths reported to CDC during 2000–2004, 90% were among infants less than 4 months of age.²²
- In 2005, 38 of 39 pertussis-related deaths reported to the CDC occurred among infants younger than 6 months of age.⁴
- A study of pertussis deaths during the 1990s suggested that infants born at gestational age less than 37 weeks and Hispanic infants comprised a larger proportion of pertussis deaths than would be expected based on population estimates.⁵

Pertussis infection in adolescents and adults can range from mild cough to classic pertussis; asymptomatic infections can also occur.²² Adolescents with pertussis commonly experience a prolonged cough illness, occasionally associated with complications such as difficulty sleeping, posttussive vomiting, weight loss, pneumonia, or rib fracture. Complications and hospitalizations related to pertussis have been reported to occur in up to 2% of adolescents.

A prolonged cough is common in adults, with the majority coughing for three weeks or longer and some coughing for months. In addition to pneumonia, which is seen in 5% of cases, complications in adults include rib fracture (4% of cases) and hospitalization (up to 3% of cases). Urinary incontinence, cough syncope, pneumothorax, inguinal hernia, subconjunctival hemorrhage, and herniated lumbar disc have also been reported. Neurological complications attributed to adult pertussis have also been described, including pertussis encephalopathy, exacerbation of migraines, and loss of memory or concentration. Adults with pulmonary or cardiac disease may be at risk of poor outcomes from severe coughing or cough syncope, but it is unclear whether adults with comorbid conditions are at increased risk for having pertussis or its complications.⁵

Costs of Pertussis

Although studies have varied in design and the various costs considered in each, pertussis infection comes at a significant cost.¹⁰ Adolescents with pertussis often make several visits for medical care and frequently miss work or school, which can result in parents or caretakers missing work as well.²² When pertussis is not considered, adults may undergo extensive evaluations by providers trying to make a diagnosis. The societal costs of pertussis in adolescents and adults in the United States are estimated at between \$150 and \$980 million annually.³⁴

Table 1-2 on page 13 shows some of the direct and indirect costs associated with pertussis, but researchers have found that many other pertussis cost analyses underestimate or ignore the indirect costs.²⁰ It has been estimated that indirect costs account for 88% of the total costs related to pertussis in individuals over age 10.³⁵

One study of the costs of pertussis in families found that average medical costs were \$2,822 for infants, \$308 for children, \$254 for adolescents, and \$181 for adults. In all, the average financial cost to each of the families studied was \$2,115, with work-related costs accounting for more than 60% of the total.³⁶ Another study of adolescent and adult cases found that the mean medical cost was \$242 for adolescents and \$326 for adults (in 2002 U.S. dollars), with antibiotics and physician visits ringing up the greatest costs.³⁴ Not included in the medical costs was the mean cost of antibiotics to treat contacts, which averaged \$242 for adolescent cases and \$225 for adult cases. Including these would have doubled the cost for adolescents to \$484 and brought the total for adults to \$551. The total average cost of pertussis in adolescents (medical and nonmedical costs)

Societal Costs Associated with	n Pertussis Illness
Direct Costs	Indirect Costs
Physician visits	• Work disability
 Emergency department visits 	Caregiver support
 Diagnostic tests, such as chest x-rays and laboratory tests 	Child care
Antibiotics	Premature death (infants)
• Nonprescription drugs, such as cough medicine and inhalers	Transportation time
Hospital care	Time for emergency department or physician visits

was \$397 per case; for adults the total was \$773 per case. If the cost of antimicrobials to treat contacts and the cost of personal time were included, the societal cost could be as high as \$1,952 per adult case.³⁴

Treatment and Postexposure Prophylaxis

Pertussis is an endemic disease in the United States, and outbreaks are relatively common. The primary goal of pertussis outbreak control efforts is to decrease morbidity and mortality among infants; a secondary goal is to decrease morbidity across all ages.³⁷ Health care personnel (HCP), who are at greater risk of acquiring pertussis than the general adult population, can spread the disease to other HCP, patients, or both, putting children without immunity or patients with weakened immune systems at high risk for pertussis.³⁸ Even before adult susceptibility to pertussis was recognized, health care–associated outbreaks among adults were well documented.^{39–41}

Vaccination is the most effective strategy for preventing the morbidity associated with pertussis, but antibiotics can be used both to treat *B. pertussis* infections and for postexposure prophylaxis of individuals who have been exposed to a case of pertussis. Although antibiotic treatment generally does not modify the course of the illness after the onset of cough, it is recommended to prevent the spread of the disease by eradicating *B. pertussis* from the nasopharynx of both symptomatic and asymptomatic infected individuals.¹⁰

When given early in the course of the illness (such as during the catarrhal stage), antibiotics can reduce the severity and duration of symptoms and decrease the period of communicability. Without antibiotics, 80% to 90% of individuals will spontaneously clear the organism from their nasopharynx, although unvaccinated and untreated infants can remain culture-positive for six weeks or longer.⁴²

A decision to administer postexposure prophylaxis should take into consideration the intensity of the exposure and the infectiousness of the individual, as well as the potential consequences in the exposed individual or contacts such as infants. The CDC defines a close contact of a patient with pertussis as a person who had face-to-face exposure within 3 feet of a symptomatic patient. Respiratory droplets (particles larger than 5 µm) are generated during coughing, sneezing, or talking, as well as during the performance of certain procedures, such as bronchoscopy or suctioning. These particles can be propelled through the air for up to 3 feet. Close contacts also can include individuals who come into direct contact with respiratory, oral, or nasal secretions from a symptomatic patient (for example, via cough or sneeze, by sharing food and eating utensils, by performing mouth-to-mouth resuscitation, or by performing a

medical examination of the mouth, nose, or throat); or who have shared the same confined space in close proximity with a symptomatic patient for an hour or more. Some close contacts are at high risk for acquiring severe disease following exposure to pertussis. These contacts include infants under age 1 and persons with immunodeficiency conditions or other underlying medical conditions, such as chronic lung disease, respiratory insufficiency, or cystic fibrosis. The CDC recommends postexposure prophylaxis with an appropriate antimicrobial agent for close contacts of patients and to persons who are at high risk for having severe or complicated pertussis.⁴²

When making decisions about postexposure prophylaxis, it is also important to weigh the risks of possible adverse drug reactions against the benefits of reducing the risk for pertussis and its complications.⁴²

Types of Antibiotics

The macrolide antibiotic erythromycin has been the antibiotic of choice for the treatment and prophylaxis of pertussis, but erythromycin has gastrointestinal side effects that can result in poor adherence to the prescribed treatment regimen. In the past decade, two additional macrolide antibiotics—azithromycin and clarithromycin—have also been determined to be effective in the treatment and postexposure prophylaxis of pertussis. The first-line antibiotics and the duration of treatment of pertussis and of postexposure are as follows:

- Erythromycin, 14-day course of treatment
- Azithromycin, 5-day course of treatment
- Clarithromycin, 7-day course of treatment

Alternatively, a 14-day course of trimethoprimsulfamethoxazole can be used for individuals 2 months of age and older.⁴² (*See* Table 1-3, page 15, for detailed information regarding drug choices and dosing information for infants, children, and adults.)

The macrolide antibiotics roxithromycin and telithromycin also have demonstrated in vitro activity against *B. pertussis*, but there are no published data regarding the clinical effectiveness of these antibiotics.⁴²

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		Alternate Agent*		
Age Group	Azithromycin	Erythromycin	Clarithromycin	TMP-SMZ
< 1 month	Recommended agent 10 mg/kg per day in a single dose for 5 days (only lim- ited safety data available)	Not preferred. Erythromycin is associated with infantile hypertrophic pyloric steno- sis. Use if azithromycin is unavailable; 40–50 mg/kg per day in 4 divided doses for 14 days	Not recommended (safety data unavailable)	Contraindicated for infants aged < 12 months (risk for kernicterus)
1–5 months	10 mg/kg per day in a sin- gle dose for 5 days	40–50 mg/kg per day in 4 divided doses for 14 days	15 mg/kg per day in 2 divided doses for 7 days	Contraindicated at age < 2 months. For infants aged \geq 2 months, TMP 8 mg/kg per day, SMZ 40 mg/kg per day in 2 divided doses for 14 days
Infants aged ≥ 6 months and children	10 mg/kg in a single dose on day 1 then 5 mg/kg per day (maximum: 500 mg) on days 2–5	40–50 mg/kg per day (max- imum: 2 g per day) in 4 divided doses for 14 days	15 mg/kg per day in 2 divided doses (maximum: 1 g per day) for 7 days	TMP 8 mg/kg per day, SMZ 40 mg/kg per day in 2 divided doses for 14 days
Adults	500 mg in a single dose on day 1 then 250 mg per day on days 2–5	2 g per day in 4 divided doses for 14 days	1 g per day in 2 divided doses for 7 days	TMP 320 mg/kg per day, SMZ 1,600 mg/kg per day in 2 divided doses for 14 days

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Appendix 1-1 Brief Historical Overview of Reported Pertussis Cases

Year/Time Frame	Reported Cases	Incidence per 100,000 Population*	Pertussis- Related Deaths	Comments
Prevaccination era (1934–1943)	Annual average: 200,752 cases ¹	150 ^{t2}	4,0341	Whole-cell pertussis vaccines became available in the 1920s, but they were not routinely recommended for children until the 1940s, after they were combined with diphtheria and tetanus toxoids (DTP). ¹
1960	15,000 ³	8†3		The number of reported cases of pertussis dropped dra- matically after universal childhood pertussis vaccination was introduced. ¹
1970	Fewer than 5,000 ³			
1976	1,010 ¹	< 11		Lowest number of reported cases since pertussis vacci- nations began in late 1940.1
1980–1989	Annual average: 2,800 (range: 1,248 in 1981 to 4,195 in 1986) ⁴	Annual average: 1 ³	77 ⁵	61 deaths (76% of all deaths) occurred in infants. ^{±5}
1990–1999	Annual average: 5,676 (range: 2,719 in 1991 to 7,796 in 1996) ⁶	Annual average: 2.26	1035	The increase in reported pertussis cases first noted in the 1980s continued in the 1990s. 1996 had the highest number of reported cases since 1967. ⁷ Infant deaths increased by 52% compared to the 1980s, with a total of 93 deaths in the 1990s. ⁵
2000	7,8676	2.96	128	Approximately one-quarter of all pertussis-related deaths in 2000 occurred in infants. ⁴
2002	9,771°	3.5 ⁶	186	Highest number of reported cases since 1964.9
2004	25,8276	8.96	166	Highest number of reported cases since 1959. Adolescents and adults account for 67% of reported cases. ¹
2006	15,6326	5.36	16	First marked decline in number of reported cases since Tdap was licensed, but likely due to the cyclical nature of pertussis. ¹⁰
2007	10,454 ⁶	3.5 ⁶		Reported cases of pertussis continued to decline after peaking in 2004–2005. Infants had the highest pertussis rate at almost 70/100,0000 population. ¹¹ Deaths related to pertussis not available. ⁶
2008	13,278	4.4°		Infants < 6 months of age continue to have the highest reported rate of pertussis at almost 80/100,000 popula- tion. ⁶ Deaths related to pertussis not available. ⁶

 * Incidence rounded to the nearest tenth; † approximated; ‡ Infant: child less than 12 months of age

(continued)

Appendix 1-1, continued

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CHAPTER 2

Pertussis Vaccines and the Prevention of Pertussis Transmission

Summary of Key Points

- 1. In 2005 the Food and Drug Administration (FDA) licensed new tetanus, diphtheria, and pertussis (Tdap) vaccines for use in adolescents and adults.
- 2. Tdap vaccination of adolescents and adults can reduce the risk of pertussis to vulnerable infants.
- 3. Pertussis vaccines are safe and highly effective in preventing pertussis in adults and adolescents.
- 4. The Centers for Disease Control and Prevention (CDC) has recommended that Tdap replace one decennial tetanus and diphtheria (Td) booster vaccination, or a dose of Td needed for wound care, for individuals ages 11 to 64.
- 5. At the October 2010 meeting of the Advisory Committee on Immunization Practices (ACIP), the recommendation for administering Tdap was extended to those age 65 years and older (especially those in contact with infants less than 12 months of age) and children ages 7–10 who are not completely protected from pertussis or who have an unknown vaccination status.
- 6. Tdap vaccination coverage in adolescents is approximately 55% and approximately 6% in adults, according to the most recent figures available.

- 7. The three diseases Tdap prevents are much more likely to result in severe sequelae than is getting the vaccine.
- 8. Vaccination against pertussis has been shown to be costeffective.

Pertussis vaccines currently available in the United States are acellular pertussis antigens in combination with diphtheria and tetanus toxoids (DTaP, combination vaccines, and Tdap).¹ Vaccines containing the whole-cell pertussis component (DTP) are no longer recommended in the United States, although they are used in many countries. Vaccines with lower amounts of diphtheria toxoid (abbreviated with a lowercase *d*), are formulated for use in persons ages 7 and older. None of the pertussis-containing vaccines used in the United States contain thimerosal preservative.¹ Text Box 2-1, page 20, explains the various letters used to name pertussis vaccines.

Vaccine History

Soon after identifying the pertussis bacterium in the early 1900s, medical researchers began working to develop a vaccine to protect people from this potentially devastating disease. The Council on Pharmacy and Chemistry of the American Medical Association endorsed pertussis vaccination in 1944.²

Text Box 2-1. Decoding the Vaccines

The initials used in the various vaccines for children and adults are as follows:

- *T* is the tetanus component.
- D is the diphtheria component.
- P is the pertussis component.
- Uppercase letters denote full-strength doses.
- Lowercase d and p denote reduced doses of diphtheria and pertussis (for example, DTaP has a higher antigen content of diphtheria and pertussis than Tdap).
- The *a* in DTaP and Tdap stands for *acellular*, which means only part of the pertussis organism is in the vaccine.

Source: Adapted from Centers for Disease Control and Prevention: Vaccines and Immunizations: *Pertussis (Whooping Cough) Vaccination.* http://www.cdc.gov/vaccines/ vpd-vac/pertussis/default.htm (accessed Jul. 12, 2010).

The following provides a brief historical overview of the development of pertussis-containing vaccines and related events:

- 1906: Bordet and Gengou isolate the pertussis bacterium.³
- 1914: The first pertussis vaccine is licensed as a suspension of inactivated *Bordetella pertussis* cells, prepared with killed microorganisms.⁴ These vaccines were not routinely recommended for children until the 1940s, when the vaccines were combined with diphtheria and tetanus toxoid.¹
- 1949: Diphtheria and tetanus toxoids and whole-cell pertussis (DTP) is licensed.⁵
- **1950–1980:** Reported cases of pertussis decline (*see* Figure 1-2 on page 5 in Chapter 1).¹
- Mid-1960s: Most states require all children to be DTP vaccinated prior to entering school.⁶
- 1986: Congress enacts the National Childhood Vaccine Injury Act (NCVIA) of 1986. The Department of Health and Human Services (DHHS) establishes the Vaccine Adverse Event Reporting System (VAERS), coadministered by the FDA and the CDC, to accept reports of all suspected adverse events, in all age groups, after the administration of any U.S.–licensed vaccine.

October 2010: Important Changes to ACIP Recommendations

It is important to note that, at the October 2010 meeting of the ACIP, some important changes to the previously published ACIP recommendations were approved:

- For adults ages 65 years and older, a single dose of Tdap vaccine may be given in place of a tetanus and diphtheria toxoids (Td) vaccine, in persons who have not received Tdap.
- 2. Adults ages 65 years and older who have or anticipate having close contact with an infant age less than 12 months should receive a single dose of Tdap to protect against pertussis and reduce the likelihood of transmission of pertussis to infants age less than 12 months.
- 3. Tdap can be administered regardless of the interval since the last tetanus- or diphtheria-containing vaccine.
- 4. Children ages 7 through 10 years who are not fully immunized against pertussis and for whom no contraindication to pertussis vaccines* exists should receive a single dose of Tdap to provide protection against pertussis. If additional doses of tetanus and diphtheria toxoid–containing vaccines are needed, then children ages 7 through 10 years should be vaccinated according to catch-up guidance.

* Fully immunized is defined as 5 doses of DTaP or 4 doses of DTaP if the fourth dose was administered on or after the fourth birthday.

Source: Centers for Disease Control and Prevention: Updated recommendations for use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine from the Advisory Committee on Immunization Practices, 2010. *MMWR Morb Mortal Wkly Rep* 60:13-15, Jan. 14, 2011.

The act requires health care providers and vaccine manufacturers to report specific adverse events following the administration of polio, pertussis, diphtheria, and tetanus vaccine, measles, mumps, and rubella (and any combinations thereof) to the DHHS.⁵ In addition, the NCVIA establishes the National Vaccine Injury Compensation Program to compensate individuals injured by vaccines on a "no-fault" basis. The NCVIA

Pertussis-Containing Vaccines for Children	Brand	Licensed Date and Use
DTaP	INFANRIX® DAPTACEL® Tripedia®	First licensed in 1991; used for all childhood doses
DTaP+Hib	TriHiBit®	Used for the fourth dose only
DTaP+IPV+HepB	PEDIARIX®	Used for the first three doses
DTaP+IPV+Hib	PENTACEL™	Approved in 2008; used for primary four-dose series
DTaP+IPV	KINRIX™	Approved in 2008; used for booster dose at 4–6 years
Pertussis-Containing Vaccines for Adolescents and Adults	Brand	Licensed Date
Tdap	ADACEL® BOOSTRIX®	First available in 2005
Other Vaccines	Brand	Licensed Date
Pertussis only		Not available in the United States
DT/Td	DECAVAC™ TENIVAC™	Do not contain pertussis; DT used for primary series when pertussis vaccination was not desired; Td used in persons aged ≥ 7 years

Source: Centers for Disease Control and Prevention: Pertussis: In Brown K., et al. (eds.): *Manual for the Surveillance of Vaccine-Preventable Diseases*, 4th ed. Aug. 2008. http://www.cdc.gov/vaccines/pubs/surv-manual/chpt10-pertussis.htm (accessed Mar. 29, 2010).

further establishes a committee from the Institute of Medicine to evaluate vaccine adverse events.⁷

- 1991: Pediatric acellular pertussis (DTaP) vaccines, less reactogenic than the earlier DTP vaccines, are licensed.⁵
- 1997: The ACIP recommends DTaP vaccines for all five doses in the vaccination schedule because local reactions, fever, and other systemic events are found to occur substantially less often after DTaP administration than after administration of whole-cell DTP.¹
- 2005: An acellular pertussis vaccine combined with the adult formulation of tetanus and diphtheria (Tdap: BOOSTRIX® by GSK) is licensed for use as an active booster in persons ages 10 to 18. This product is the first licensed acellular pertussis–containing vaccine with an indication for adolescents.⁵ The FDA also licenses a

second Tdap vaccine (ADACEL® by sanofi pasteur) for use in persons ages 11–64.⁵

 2008: The FDA approves expanded use of the BOOSTRIX Tdap vaccine for those ages 10 to 64.⁵

Table 2-1, above, provides a list of pertussis vaccines by brand name and date licensed, and Table 2-2 on page 22 shows the recommended vaccination schedules for children, adolescents, and adults.

A New Approach: Tdap Vaccines

The introduction of two Tdap vaccines in the United States has changed pertussis-prevention efforts for adolescents and adults, replacing a single dose of Td. The pertussis component of Tdap is similar to pediatric DTaP but contains a

AGE	Birth	2 months	4 months	6 months	12–18 months	4–6 years	11–12 years	13–18 years	19–64 years	> 65
)TaP ¹		X	X	Х	X ³	Х				
۲dap ²							X	X4	X ⁵	
Td										X6
Tdap: first This dose If Tdap no Tdap sho	may be adn ot received p uld replace	2005; used ninistered as previously a single dos	l for adoleso s early as ag	cents and a je 12 month	ood. dults in plac s, provided t 64 years who	that at least	6 months h	ave elapsed	since the th	
Tdap: firsi This dose If Tdap no Tdap shoi oost with	t licensed in may be adn ot received p	2005; used ninistered as previously. a single dos years.	l for adoleso s early as ag	cents and a je 12 month	dults in plac s, provided t	that at least	6 months h	ave elapsed	since the th	

reduced quantity of some pertussis antigens; the tetanus and diphtheria components in Tdap are similar to those of the licensed adult formulations of Td. There is no preparation of a vaccine containing pertussis antigens alone that is licensed in the United States, although acellular pertussis formulations are available in Australia, Canada, and several European countries.⁸ The antibody response to a single dose of Tdap vaccine has been similar to the response to three doses of DTaP in infants; this is referred to as "bridging," in which the new vaccines are presumed to have clinical efficacy similar to that of DTaP because a similar level of antibody production occurred.⁹

Although children ages 19 to 35 months in the United States are vaccinated at a rate of more than 90% for three or more doses of pertussis-containing vaccine,¹⁰ Tdap vaccination rates for adolescents and adults fall far short of that figure. The latest Tdap vaccination rate for adolescents stands at 55.6%,¹¹ and the rate for adults ages 19 to 64 is only 5.9%.¹² It is important to note, however, that the Tdap vaccine has been available for use only since 2005, and rates for both adolescents and adults have increased.¹¹⁻¹⁴ The primary objective of vaccinating adolescents and adults with Tdap is to protect against pertussis while maintaining the standard of care for protection against tetanus and diphtheria.^{1,8} A secondary objective of adolescent and adult Tdap vaccination is to reduce the reservoir of pertussis within the U.S. population at large and potentially reduce the incidence of pertussis in other age groups, including infants who are at the highest risk for complications and may not be old enough to be vaccinated.^{1,8} In addition, vaccinating adults is designed to reduce the cost and disruption of pertussis in health care facilities and other institutional settings.¹ More than 20 medical societies support the CDC recommendations to vaccinate adolescents and adults with pertussis-containing vaccine (*see* Table 2-3 on page 23).

Universal, Targeted Tdap Vaccination

The previously published ACIP recommendations include both universal and targeted one-time administration of Tdap vaccine for adolescents and adults.^{1,8,15} The recommendations include the following:

 American Academy of Allergy, 	Asthma and	 American College of Physicians
Immunology		- American Gastroenterological Association
- American Academy of Family	Physicians	- American Society of Clinical Oncology
- American Academy of Pediatr	cs	- American Society of Hematology
- American Association for the S	Study of Liver	- American Society of Nephrology
Diseases		- American Thoracic Society
- American Association of Clinic	al Endocrinologists	- The Endocrine Society
- American College of Allergy, A	sthma and	- Infectious Diseases Society of America
Immunology		- Society for Adolescent Medicine
- American College of Cardiolog	JY	- The Society for Healthcare Epidemiology of America
- American College of Chest Ph	ysicians	 Society of General Internal Medicine
- American College of Gastroen	terology	 Society of Hospital Medicine
- American College of Obstetric	ians and	
Gynecologists		

Routine (universal) vaccination

- Adolescents (at age 11 to 12 years) or at the earliest opportunity for those ages 13 to 18 years
- Adults (ages 19 to 64), to replace one decennial Td or Td needed for wound care

Targeted Tdap vaccination (if not previously received)

- Adolescent and adult women, preferably before becoming pregnant
- Adolescent and adult women, in the immediate postpartum period
- Adolescents and adults, ideally at least two weeks before contact with an infant (cocoon strategy)
- Health care personnel (HCP) with direct patient contact
- Persons in settings with a pertussis outbreak

It is important to note that, at the October 2010 meeting of the ACIP, some important changes to the previously published ACIP recommendations were approved¹⁶:

- 1. For adults ages 65 years and older, a single dose of Tdap vaccine may be given in place of a tetanus and diphtheria toxoids (Td) vaccine in persons who have not received Tdap.
- 2. Adults ages 65 years and older who have or anticipate having close contact with an infant age less than 12 months should receive a single dose of Tdap to protect against pertussis and reduce the likelihood of transmission of pertussis to infants age less than 12 months.
- 3. Tdap can be administered regardless of the interval since the last tetanus- or diphtheria-containing vaccine.

Strategy	Potential Predicted Impact
Routine adolescent vaccination at age 12	Vaccinating adolescents could initially have a large impact on the number of annual pertussis cases but likely not a sustained impact. It would have no effect on pertussis incidence in adults.
Adolescent vaccination plus cocoon vaccination of household contacts of newborns	Similar pattern as above, except resurgence in cases among adults would likely be lower. The greatest impact would be among young children.
Adolescent vaccination plus cocoon vaccination and a single dose for adults	Initially would have little impact but would prevent resur- gence of cases that could occur in the routine adoles- cent vaccination at age 12 strategy.
Adolescent vaccination plus cocoon vaccination and a single dose for adults and routine adult vaccination every 10 years	This strategy would likely lead to large reductions in per- tussis rates and permit a sustained control of pertussis in all age groups.

Table 2-4. Evaluation of Proposed Pertussis Vaccination Strategies

4. Children ages 7 through 10 years who are not fully immunized against pertussis and for whom no contraindication to pertussis vaccines exists should receive a single dose of Tdap to provide protection against pertussis. If additional doses of tetanus and diphtheria toxoid–containing vaccines are needed, then children ages 7 through 10 years should be vaccinated according to catch-up guidance.

After using computer models to assess the impact of pertussis vaccination strategies for adolescents and adults in the United States,¹⁷ researchers have concluded that using the combined CDC–recommended approach of universal adolescent pertussis vaccination along with targeted vaccination of close contact of infants and a single booster vaccination for all adults is supported.¹⁸ Table 2-4, above, provides an evaluation of strategies and conclusions.

The Cost Benefits and Cost-Effectiveness of Tdap

The cost savings associated with Tdap vaccination of adults have been studied by numerous researchers, with cost–benefit and cost-effectiveness conclusions varying widely.¹⁵ Adjusting for discrepancies in the various models, Lee et al. estimated that adult Tdap vaccination programs would be cost-effective when the incidence of pertussis exceeds 120 cases per 100,000 population, using a benchmark of \$50,000 per qualityadjusted life-year saved.¹⁹ Lee et al. further modeled various vaccination strategies in a German population and concluded that a Tdap vaccination program in adults ages 20 to 64 would be cost-effective and possibly cost-saving if the incidence of pertussis is higher than 200 cases per 100,000 adults.²⁰ Using a model that simulated both the epidemiologic and economic impacts of various vaccination strategies on the control of pertussis, Coudeville et al. concluded the following⁴:

- Without adolescent and adult vaccination, the incidence of pertussis would double in 20 years.
- Vaccinating adults in addition to conducting the childhood and adolescent pertussis vaccination programs could be economically viable and also provide considerable health benefits.
- Vaccinating parents of newborns (cocoon strategy) with a single booster for adults at age 40 appears to be the most cost-effective strategy, although a routine decennial vaccination would likely have similar costs and reduction in pertussis incidence.

A review by Purdy et al. of the literature between 1966 and 2003 for the incidence of pertussis and related compli-

cations, pertussis transmission among household members, the associated morbidity in persons with preexisting lung disease, and the direct and indirect costs of pertussis identified that, as with influenza, most of the costs associated with pertussis are due to the indirect costs, such as lost social and work productivity. They concluded that vaccinating adolescents would be the most economical strategy as well as the easiest to implement because Tdap vaccination in this age group would replace the already-established Td booster that is routinely given; this is also the age group with the highest incidence of pertussis. They estimate that vaccinating this age group could potentially prevent 0.4 to 1.8 million cases of pertussis and save \$0.3 to \$1.6 billion over a 10-year period. A one-time adult Tdap booster vaccination would likely result in significant economic and health benefits but would be more difficult to implement.²¹

Researchers in one study estimate that the cost of vaccinating all adolescents (\$203,404) exceeds the cost of preventing pertussis in adolescents (\$6,347), but the cost of preventing pertussis in infants (\$328,128) and children (\$5,887) makes vaccination of adolescents cost-effective.²²

More recently, Westra et al. estimated the costeffectiveness of three pertussis vaccination strategies for possible inclusion in the Dutch national immunization program.²³ The three strategies studied are as follows:

- Vaccination of infants at birth
- Vaccination of parents immediately after the birth of their infant (cocooning)
- Vaccination of the mother in the third trimester of pregnancy

Both cocooning and maternal vaccination were found to be effective in reducing pertussis among infants, as well as cost-effective from both payer and societal perspectives. Cocooning was the most expensive strategy to implement but resulted in the highest number of quality-adjusted lifeyears gained. At-birth vaccination was found to be highly unfavorable from both payer and societal perspectives.²³

Tdap Vaccine Efficacy

Unlike with tetanus and diphtheria, there are no wellaccepted laboratory or serologic correlates of protection for pertussis.¹ The Vaccines and Related Biological Products Advisory Committee (VRBPAC) found that clinical endpoint efficacy studies of acellular pertussis vaccines were not required for Tdap licensure for adolescents or adults. The VRBPAC determined that the efficacy (the prevention of illness among persons immunized in clinical trials) could be inferred in these age groups using a serologic "bridge," or comparison, to infants vaccinated with the pediatric DTaP vaccine during pertussis clinical endpoint efficacy trials. The immune response of adolescents and adults to the vaccine pertussis antigens after a single dose of Tdap was compared with the immune response of infants after three doses of pediatric DTaP; the antibody response of adolescent and adults to Tdap was determined to be noninferior to the antibody response of infants to three doses of DTaP.²⁴

The Adult Pertussis Trial (APERT), sponsored by the National Institutes of Health, demonstrated acellular pertussis vaccines to be safe and their efficacy in preventing pertussis in adults and adolescents to be 92%.²⁵ A recent report showed that the efficacy of Tdap in preventing pertussis during a school outbreak among children through grade 12 was 65%.²⁶ Disease clustered in students in grades 6 through 12; only 12% of the 11-year-olds had received Tdap. Unvaccinated students were three times more likely to develop pertussis than were those who were vaccinated.²⁶

Tdap Safety

The safety of a single dose of Tdap in adults and adolescents is well supported, but more research is needed on the safety of repeat Tdap doses.^{27–29} The safety and efficacy of using Tdap in pregnant women has not been established, and Tdap is not recommended for use in pregnant women in any country.¹⁵ Tdap is safe and recommended for women immediately postpartum.¹⁵

A related safety issue concerns accidental mix-ups between the adult Tdap and pediatric DTaP products, due to the similar names and abbreviations.³⁰ DTaP contains more antigen, which is necessary for initial vaccinations, meaning an adult who receives DTaP instead of Tdap would receive a higher amount of antigen that may cause arm soreness. An infant or a child who receives Tdap instead of DTaP would receive a lesser amount of antigen and may not produce an adequate protective response to the vaccination. Most of these mix-ups occur in physicians' offices, ambulatory care clinics, or hospitals where vaccines are selected from stock supplies or when vaccines are stored in the wrong area of the medication refrigerator.³¹ Both manufacturers of the vaccines have responded to these concerns by changing the color of the product labels or

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vial caps to differentiate them more clearly, and they have added statements on the front panel of product cartons to identify the vaccines as adolescent/adult preparation or pediatric preparation.

To avoid mix-ups and improve patient safety, the following practices should be used to deliver DTaP and Tdap vaccines³¹:

- Separate adolescent/adult and pediatric products in storage areas.
- Encourage prescribers to use the brand name, not the vaccine abbreviation.
- Provide the vaccine information statement (VIS), which includes age requirements, to each vaccinee.
- Have at least two clinicians compare the selected product to a picture of the two products, as a reference.
- Just prior to administration, document the vaccine and its lot number on a vaccine log; this may allow for recognition of a different lot number format and alert the clinician to a possible mix-up in products.

Adverse Reactions to Tdap

There is always a small risk of serious reaction to any medication, including vaccines, but such reactions are estimated to happen only once in a million doses.³² It is important to keep in mind, however, that the three diseases Tdap prevents (tetanus, diphtheria, and pertussis) are much more likely to result in severe sequelae than is getting the vaccine.

The vaccine is, however, *contraindicated* in the following circumstances¹:

- A life-threatening allergic reaction to any component of DTP, DTaP, DT, or Td, including latex allergy. Information about latex in vaccine packaging is available from the CDC, at http://www.cdc.gov/vaccines/pubs/ pinkbook/downloads/appendices/B/latex-table.pdf.
- Anyone who has had long or multiple seizures or who had a coma within seven days of a dose of DTP or DTaP, unless a cause unrelated to the vaccine was found.

The following are *precautions* for Tdap administration. A *precaution* is a condition that might increase an individual's risk for a serious adverse reaction:¹

 A history of Guillain–Barré syndrome ≤ 6 weeks after a previous dose of a tetanus toxoid–containing vaccine is a precaution for Tdap administration

- Tdap vaccine should be deferred in the following situations:
 - A moderate to severe acute illness, with or without fever, until resolved
 - An unstable neurologic condition, such as acute encephalopathy or a cerebrovascular event.
 Progressive but stable neurological disorders, such as dementia, are not considered a contraindication.
 - Arthus reactions. This hypersensitivity reaction is a rare event that can occur after vaccination. Arthus reaction is a local vasculitis that occurs in a setting of high circulating antibody concentration and high local concentration of vaccine antigens. Severe pain, swelling, induration, edema, and hemorrhage, and occasionally local necrosis, have been noted. This vaccine-related arthus reaction usually resolves without consequence. Signs and symptoms of this reaction occur within 4 to 12 hours after vaccination, compared with anaphylaxis (immediate type I hypersensitivity reaction), which has onset within minutes after vaccination. The ACIP recommends that persons who experience an arthus reaction after administration of a tetanus toxoid-containing vaccine not receive Td or other tetanus toxoid-containing vaccine more frequently than every 10 years, even for tetanus prophylaxis as part of wound management.¹

Individuals who have these precautions to vaccination with Tdap should be evaluated by a vaccine provider to determine the risks for, and benefits of, administering Tdap.

The following is a list of conditions that are *not contraindications* or *precautions* to Tdap:¹

- History of extensive limb swelling (ELS). This reaction has been reported following the fourth or fifth dose of pediatric DTaP. It is not disabling and often is not brought to the attention of medical providers; it typically resolves without complication within four to seven days.
- Stable neurologic disorders, including well-controlled seizures, a history of seizure disorder that has resolved, and cerebral palsy
- Brachial neuritis
- Immunosuppression
- Breastfeeding
- A minor illness
- Use of antimicrobials

Common mild reactions that have been reported after Tdap vaccinations include injection site pain, redness, or swelling; mild fever (100.4°F or greater); headache; tiredness; nausea, vomiting, diarrhea, or stomach ache; and, uncommonly, chills, body aches, sore joints, swollen glands, or rash.³²

Interval Between Td and Tdap

New recommendations from the ACIP endorse Tdap vaccination in eligible age groups without consideration of the time since the last tetanus- or diphtheria-containing vaccine.¹⁶ The ACIP decision to remove mention of minimal intervals is supported by a number of studies which suggest that brief intervals are acceptably safe, and the decision is intended to eliminate confusion among health care providers. Consider the following research related to intervals between Td and Tdap:

- Three Canadian studies of children and adolescents evaluated the safety of Tdap at an interval of less than 5 years after Td or after pediatric DTP or DTaP.^{33–35} The largest study—of 7,001 students ages 7 to 19—assessed adverse event rates at yearly intervals (from 2 to 9 years); there was no increase in local reactions among students who had received the most recent of five childhood DTP or DTaP doses, or a Td dose, > 2 years before Tdap, compared with > 10 years before Tdap.³³ The other Canadian studies showed similar safety when Tdap was administered at an interval of < 5 years after the previous tetanus toxoid– and diphtheria toxoid–containing vaccine.^{34,35}
- Adverse reactions after Tdap (ADACEL®) administered < 2 years from the most recent Td were evaluated in a retrospective survey of 4,524 HCP who received Tdap during an outbreak of pertussis-like illness in New Hampshire in 2006.³⁶ Of the 2,676 people (59%) responding to the survey, the rates of redness, swelling, or pain of moderate to severe intensity, subjective fever, and medical visits were no higher among respondents with an interval of < 2 years between administration of Td and that of Tdap. Three serious adverse events were reported among adults who received Tdap at an interval > 2 years after the most recent dose of Td, but causality was not evaluated.
- Sandora et al. studied the impact of shorter intervals between Td and Tdap on adverse reactions in 207 hospital personnel. The researchers noted that pain at the injection site became less common as the number of years increased since the last Td vaccination. Intervals studied were less than 5 years, from 5 to 10 years, and at

least 10 years. Female HCP had three times more local adverse reactions than male HCP, and younger HCP had an increased risk for systemic reactions.³⁷

Simultaneous Vaccination with Tdap and Other Vaccines

If two or more vaccines are indicated, the CDC recommends that both be given during the same visit.^{1,8} There is no evidence that simultaneous administration of vaccines reduces vaccine effectiveness or increases the risk of adverse events. In the case of Tdap, the vaccine can be safely administered in conjunction with other vaccines, such as seasonal influenza, hepatitis B, and pneumococcal vaccines. Simultaneous administration of Tdap and tetravalent meningococcal conjugate vaccine ([MCV4] Menactra[®], sanofi pasteur) to adolescents is preferred when both Tdap and MCV4 are indicated, even though MCV4 contains some diphtheria toxoid.⁸ Any time simultaneous vaccinations are given, each vaccine should be administered at a different anatomic site using a separate syringe.^{1,8}

The Future

Monitoring the impact of Tdap on pertussis disease trends and its safety are important to future efforts to increase vaccination rates. The CDC is currently supporting active pertussis surveillance in Massachusetts and Minnesota to evaluate the burden of pertussis and the impact of the Tdap vaccination strategies.⁸ Ongoing monitoring for changes in the incidence of pertussis and physician uptake of Tdap will be of interest, with additional research necessary to achieve the following goals^{1,8}:

- Define and evaluate immunologic correlates of protection for pertussis.
- Establish the safety and immunogenicity of Tdap for pregnant women.
- Develop improved diagnostics for pertussis.
- Evaluate the effectiveness of deferring postexposure pertussis prophylaxis among pertussis-exposed HCP who have recently received Tdap.
- Determine the effectiveness and safety of repeated doses of Tdap.
- Identify methods to enhance Tdap coverage and delivery.

Vaccine research is also needed for pregnant women and their infants. The reader is referred to Chapter 5 for the review of research needs for these populations.

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CHAPTER 3

Heath Care Personnel and Pertussis

Summary of Key Points

- Health care personnel (HCP) are at greater risk of acquiring pertussis than the general population.
- HCP with pertussis may go unrecognized, resulting in transmission of the disease to patients, coworkers, and visitors.
- Transmission of pertussis in health care facilities is disruptive and costly.
- The Centers for Disease Control and Prevention (CDC) recommends that HCP working in hospitals and ambulatory care settings who have direct patient contact should receive a single dose of Tdap as soon as feasible.
- Targeting Tdap vaccinations for HCP who anticipate close contact with infants or children could decrease the morbidity and mortality of pertussis among infants and can be a useful strategy if Tdap vaccination of all or most HCP is not possible.
- Tdap vaccination coverage of HCP in 2008 was approximately 16%.
- Tdap vaccinations for HCP can be cost-beneficial by preventing transmission of pertussis and outbreaks.
- Health care facilities should use strategies that have been successful in other hospital campaigns, such as those

used to enhance influenza vaccination, to optimize Tdap vaccination in HCP.

• No matter what strategies are chosen to begin or enhance an HCP Tdap vaccination program, the goal should be to improve vaccination rates over time; only through measurement is it possible to determine whether performance is improving, staying the same, or getting worse.

Health Care Personnel and Pertussis

The high rates of pertussis in the United States present a significant challenge to infection preventionists and employee health staff who are at the front lines in recognizing and managing exposures to, and transmission of, pertussis in health care organizations.¹ Lane et al. surveyed infection preventionists from pediatric hospitals, finding that 90% reported HCP exposures to pertussis over a fiveyear period.² Appendix 3-1, beginning on page 55, summarizes several exposure incidents and outbreaks in health care settings, as reported in the literature. Text Box 3-1 on page 32 provides a detailed definition of health care personnel.

The spread of pertussis has been documented in various health care settings, including outpatient clinics, hospitals and emergency departments, and nursing homes and long term care facilities.³⁻¹⁷ The original source of pertussis can be a patient, visitor, family member, or HCP with either health care- or community-acquired pertussis, but HCP are at greater risk of acquiring pertussis than the general adult population.^{15,18} Because the symptoms of early pertussis in adolescents and adults are nonspecific and may be indistinguishable from those of other respiratory infections, HCP with pertussis may go unrecognized; this can result in exposing other HCP, patients, and visitors to pertussis. Even when symptoms of pertussis are more specific, medical professionals may not consider pertussis as a diagnosis. For example, Bryant et al. described a nurse working in a hospital nursery who had classic signs of pertussis, including multiple medical care visits for a cough illness that included paroxysms, whoop, posttussive vomiting, and a spontaneous pneumothorax.¹⁰ Pertussis was not considered until the disease was diagnosed in an infant who had been in the nurse's care in the previous month and three other nurses had also become infected.

Text Box 3-1. Defining Health Care Personnel

For the purpose of this monograph, the term health care personnel (HCP) is defined broadly as all paid and unpaid persons working in health care settings who have the potential for exposure to patients and/or infectious materials. The full range of HCP work in a variety of settings, including acute care hospitals, long term care facilities, skilled nursing facilities, rehabilitation centers, physicians' offices, urgent care centers, outpatient clinics, home health care agencies, and emergency medical services. Some HCP provide direct patient care. Others, such as housekeepers, maintenance staff, vendors, volunteers, and outside contractors, have jobs that may put them into close contact with patients or the patient environment.¹⁹ Even HCP who do not come into close contact with patients are likely to have some contact with HCP who do-for example, by passing them in a hallway or eating in the same cafeteria with them.

Transmission of pertussis among HCP and/or patients places children without immunity and patients with weakened immune systems at high risk for severe pertussis. Health care–associated outbreaks among adults have been well documented, even before adult susceptibility to pertussis was recognized.^{4,20,21} Outbreaks of pertussis in health care organizations related to infected HCP continue to be reported¹⁰; they often result from failure to recognize pertussis in infants or children, failure to recognize and treat pertussis in HCP, and failure to institute control measures in a timely manner.¹ Daskalaki et al. evaluated several exposure incidents in a children's medical center and determined that, in 17 of 28 instances, pertussis was not suspected in children who had the disease, resulting in inadequate infection prevention and 355 HCP exposures.²²

The availability of the adult and adolescent pertussiscontaining vaccine (Tdap) since 2005 may provide an opportunity to reduce, if not eliminate, the disruption and human and financial costs associated with health care–associated pertussis. This chapter examines various factors and strategies that can be used to develop or enhance Tdap vaccination programs for health care personnel, as identified in the literature and from health care organizations participating in The Joint Commission project Promising Approaches for Implementing or Improving Tdap Vaccination Programs for Health Care Personnel and Adolescent and Adult Patients.

In 2006 the CDC's Advisory Committee on Immunization Practices (ACIP) and the Healthcare

"Health care workers often [mistakenly] think they're immune. They've been working in this setting for a long time, have been around sick people, and [wrongly] think they have natural defenses."²³

—Pascale Wortley, M.D., M.P.H., Chief, Health Services Research and Evaluation Branch, National Center for Immunization and Respiratory Diseases, CDC Infection Control Practices Advisory Committee (HICPAC) identified HCP with direct patient contact who work in hospitals or ambulatory care settings as a priority group to receive a single dose of Tdap as soon as feasible if they have not previously received Tdap.¹⁸ The primary objective of replacing a dose of Td with Tdap is to protect the vaccinated adult from pertussis. The secondary objective is to accomplish the following¹⁸:

- Reduce the reservoir of pertussis in the population at large, potentially reducing exposure of individuals at increased risk for complicated pertussis infections, such as infants.
- Reduce costs and disruptions caused by pertussis in health care organizations and other institutional settings.

It should be noted that, at the October 2010 meeting of the ACIP, it was agreed that any reference to time intervals between receiving a tetanus- or diphtheria-containing vaccine and Tdap should be removed from the Tdap recommendations, thus eliminating a barrier to HCP Tdap vaccination.²⁴

The Infectious Diseases Society of America (IDSA) guideline for immunization of infants, children, adolescents, and adults weighed in on vaccinations for HCP in 2009, recommending the following²⁵:

- HCP should receive an annual influenza vaccination and a booster dose of Tdap, as well as boosters for measles, mumps, and rubella; hepatitis B vaccination should be given to HCP at risk for occupational exposure to bloodborne pathogens, as per the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard.
- 2. Annual immunization coverage assessments should be conducted to ensure that HCP working in hospitals, clinics, and offices are immunized appropriately with all recommended vaccines.

The IDSA guideline notes that pertussis now ranks as one of the most common infectious diseases resulting in HCP exposures that require evaluation by occupational health services.²⁵ Weber and Rutala found pertussis to be the third most common infectious disease HCP are exposed to, just behind varicella and tuberculosis.¹

Impact of Institutional Exposure Incidents and Outbreaks

Expenses associated with pertussis exposures and outbreaks include the cost of diagnostic tests, antimicrobial prophy-

laxis for exposed individuals, treatment for individuals who have developed pertussis, and lost productivity and wages for HCP who are furloughed or ill. Costs also include time expended by employee health staff and public health authorities investigating the contacts of an index case and following up with exposed individuals. Other costs are more difficult to capture, including those associated with overall disruption of patient care, cost of travel for HCP seeking medical care, educational efforts by infection preventionists and employee health staff, and the occurrence of other health care-associated events that might have been prevented if the infection preventionist's time had not been diverted.²² Several researchers have attempted to quantify these costs, and many are summarized in Appendix 3-2, beginning on page 58, although costs associated with pertussis outbreaks vary depending on the extent of the outbreak, the setting or geographic location in which it occurs, diagnostic tests used to identify or confirm pertussis, and antimicrobials used for treatment or prophylaxis.²⁶

Pertussis Containment

The CDC has provided detailed information regarding the prevention and control of pertussis, including those that involve health care organizations.^{27–31} Infection prevention and control measures recommended to contain pertussis include the following:

- Identifying all persons such as HCP, patients, visitors, and so forth exposed to pertussis
- Droplet Precautions along with Standard Precautions for all confirmed or suspected pertussis patients
- Antimicrobial treatment of all patients and HCP with pertussis (*see* Table 3-1 on page 34 for the CDC's recommended treatment and postexposure prophylaxis)
- Postexposure antimicrobial prophylaxis for all asymptomatic persons in close contact with infected individuals, regardless of immunization history (*see* Table 3-1 for the CDC's recommended treatment and postexposure prophylaxis)
- Furloughs for HCP with known or suspected pertussis during the first five days of antimicrobial therapy, pending results of diagnostic testing

One standardized management protocol for HCP and patients exposed to pertussis, based on experience with 49 pertussis exposures over an eight-year period, includes a checklist for infection preventionists (for example, verify the diagnosis, determine the length of the exposure incident,

		Primary Agents		Alternate Agent*
Age Group	Azithromycin	Erythromycin	Clarithromycin	TMP-SMZ
< 1 month	Recommended agent 10 mg/kg per day in a single dose for 5 days (only lim- ited safety data available)	Not preferred. Erythromycin is associated with infantile hypertrophic pyloric steno- sis. Use if azithromycin is unavailable; 40–50 mg/kg per day in 4 divided doses for 14 days	Not recommended (safety data unavailable)	Contraindicated for infants aged < 12 months (risk for kernicterus)
I–5 months	10 mg/kg per day in a sin- gle dose for 5 days	40–50 mg/kg per day in 4 divided doses for 14 days	15 mg/kg per day in 2 divided doses for 7 days	Contraindicated at age < 2 months. For infants aged ≥ 2 months, TMP 8 mg/kg per day, SMZ 40 mg/kg per day in 2 divided doses for 14 days
nfants aged ≥ 6 months and children	10 mg/kg in a single dose on day 1 then 5 mg/kg per day (maximum: 500 mg) on days 2–5	40–50 mg/kg per day (max- imum: 2 g per day) in 4 divided doses for 14 days	15 mg/kg per day in 2 divided doses (maximum: 1 g per day) for 7 days	TMP 8 mg/kg per day, SMZ 40 mg/kg per day in 2 divided doses for 14 days
Adults	500 mg in a single dose on day 1 then 250 mg per day on days 2–5	2 g per day in 4 divided doses for 14 days	1 g per day in 2 divided doses for 7 days	TMP 320 mg/kg per day, SMZ 1,600 mg/kg per day in 2 divided doses for 14 days

and identify patients and HCP potentially exposed to pertussis); a standardized form letter to be sent to exposed departments; guidelines for physicians should one of their patients be exposed to pertussis; and guidelines for employee health staff to follow for exposed HCP.³²

Even with effective control measures, one or more cycles of transmission can occur before pertussis is recognized, resulting in continued exposures and secondary cases of pertussis.¹⁸ Outbreak-related secondary cases have been reported in the literature, ranging in number from none up to almost 80 per index case.¹⁸

One area that needs more study is the management of HCP who have previously received Tdap and who are subse-

quently exposed to pertussis. The CDC's guideline for the control of pertussis in health care settings was published in 2000, prior to the availability of Tdap vaccine for adolescents and adults.²⁸ The CDC stated in the 2006 recommendations that more information is needed regarding the following¹⁸:

- The effectiveness of Tdap in preventing pertussis in vaccinated HCP
- How long the protection lasts
- The effectiveness of the vaccine in preventing the transmission of pertussis from vaccinated HCP to patients and other HCP

The CDC recommends that, until further studies clarify the optimal management of previously vaccinated HCP exposed to pertussis, or a consensus of experts is developed,

vaccinated HCP who have unprotected exposure to pertussis should receive postexposure prophylaxis.¹⁸

An alternative approach to furloughs of previously vaccinated HCP is for health care facilities to develop a strategy for managing exposed, vaccinated HCP based on whether the patient population is at risk for severe pertussis. For example, daily monitoring of exposed, vaccinated HCP for early symptoms of pertussis would facilitate prompt assessment, treatment, and furloughing of staff if symptoms are noted. This approach has been successful in monitoring HCP who have been vaccinated and exposed to varicella^{33,34} and for monitoring the site of HCP's smallpox vaccination.35,36 The CDC also notes that additional research is needed to determine the usefulness of this approach as a control strategy. Recently, Goins et al. sought to determine whether close symptom monitoring of exposed Tdap-vaccinated HCP was as beneficial as routine postexposure antibiotic prophylaxis. They studied HCP with direct patient contact who had been vaccinated with Tdap and were subsequently exposed to patients with pertussis in their tertiary care pediatric hospital. Exposed HCP were randomized to receive no prophylaxis or routine antibiotic prophylaxis. At the writing of this monograph, complete analysis of this study is pending.³⁷

Nonvaccine Infection Prevention and Control Measures in Health Care Settings

In addition to Standard Precautions, the CDC recommends Droplet Precautions when HCP care for patients suspected or confirmed to have pertussis. Droplet Precautions include wearing a mask when within 3 feet of the patient and practicing good hand hygiene.³¹ Droplet Precautions should continue for five days after effective treatment for pertussis is started; if antimicrobial therapy is not initiated, the precautions should continue for three weeks from the onset of cough. A single-patient room is preferred; cohorting of patients who have, or have been exposed to, pertussis is acceptable. Calugar et al., however, noted that many staff at a Pennsylvania tertiary care hospital did not wear masks when caring for patients with cough illnesses; when the researchers evaluated perceptions surrounding HCP mask use, they found that almost half of the HCP surveyed perceived obstacles to mask use, including the feeling that it was a barrier to communication and that wearing the mask was uncomfortable and/or a burden.³⁸

The CDC also recommends that HCP working in outpatient settings ask coughing patients to wear a surgical mask or cover their coughs with tissues to prevent transmission of any respiratory infection. Such precautions should begin at the point of initial patient encounter. Signs in languages appropriate to the population served can be posted at the reception or registration desk or the entrance to facilities, requesting that the patient or an individual accompanying the patient promptly inform the receptionist if there are symptoms of a respiratory infection such as cough, flu-like illness, or increased production of respiratory secretions. Hand hygiene after contact with respiratory secretions is also emphasized. It is important to keep in mind that patients with pertussis are often afebrile, so absence of a fever does not exclude pertussis.

This strategy, known as Respiratory Hygiene/Cough Etiquette, evolved from the 2003 SARS outbreaks and should be incorporated into infection control practices as a component of Standard Precautions. The strategy is targeted at patients and accompanying family members and friends with undiagnosed transmissible diseases, including pertussis.³¹ Compliance with Respiratory Hygiene/Cough Etiquette can be difficult to achieve with all individuals, especially infants and young children and individuals having difficulty breathing; in such situations, it is important that HCP protect themselves by using a mask.

Visitors have also been identified as a source of pertussis in health care settings,^{5,21} and visitor screening can be especially important during community outbreaks of pertussis and for high-risk-patient units. Effective methods for screening visitors, however, have not been studied. Screening can be active, such as using a questionnaire, or passive, including posting restrictions at entrances. Family members visiting pediatric patients with pertussis may need to be screened for history of exposure as well as signs and symptoms of pertussis. Potentially infectious visitors should be excluded until they receive appropriate medical screening, diagnosis, or treatment. If exclusion is not considered to be in the best interest of the patient or family, the symptomatic visitor should wear a mask while in the health care setting, especially in public waiting areas and the cafeteria, and remain in the patient's room to avoid exposing others.³¹

In addition, HCP with pertussis should be excluded from work from the beginning of the catarrhal stage through the third week after onset of cough, or until five days after the start of effective antimicrobial therapy. Asymptomatic personnel exposed to pertussis who receive appropriate postexposure antimicrobial prophylaxis do not need work restrictions.²⁷ However, HCP who have had close contact with pertussis cases who have appropriately followed Standard and Droplet Precautions, including wearing a mask, do not require prophylaxis.²⁸

Barriers to Pertussis Control Measures

Researchers have identified a number of challenges to successful implementation of pertussis control measures for HCP, including the following:

- Delayed identification of infected individuals:
 - Underrecognition of pertussis in adults has been described previously in this monograph. Leekha et al. also point to the reluctance of HCP to report mild cough illnesses to employee health services, which can result in HCP working when they are most infectious.³⁹ Even when staff report to health care providers, the providers may not be aware that classic pertussis symptoms may not be present in adults, or the appropriate specimen may not be collected.
- Difficulties associated with contact tracing:
 - Bryant et al. noted that identifying all staff potentially exposed to a patient case of pertussis can be difficult because not all caregivers document their contact with patients.¹⁰ For example, HCP not specifically assigned to a patient may assist in that patient's care. Screening for exposed staff by reviewing work schedules may give only a partial picture of HCP who have been exposed. Consider, too, non-caregivers such as housekeeping staff, dietary personnel, volunteers, and so forth who have reason to be in patient rooms but do not document interactions in a patient's medical record. Bryant et al. also found that duration of exposure did not correlate with transmission, as some caregivers who had prolonged exposure to a patient with pertussis did not develop pertussis.¹⁰
- Inconsistent organizational policies:
 - Lane et al. found that hospitals had policies that included resident physicians and medical students regarding measles but did not include hospital-based, community, or private physicians.²
 - Leekha et al. reported that their organization's policy required staff to use the first two days of sick time as paid time off; sick time could not be used until the

third day an employee was ill.³⁹ Policies that require use of paid time off for a period of time before sick time can be accessed may discourage HCP from taking sick time.

- Because fever is not a common component of pertussis infection, policies that exclude from work only HCP with febrile respiratory illness fail to effectively identify HCP with pertussis.¹⁰
- Poor adherence to antimicrobial compliance:
- Although newer macrolides, such as azithromycin, have a lower incidence of adverse effects than erythromycin, none is without potential side effects, usually gastrointestinal upset. Refusal to take or complete treatment or prophylaxis can result in additional pertussis spread. Giugliani et al. found that, even with azithromycin, about one-third of HCP had at least one adverse reaction, 8% discontinued treatment, and 11% refused treatment.⁴⁰ Martinez et al. reported similar findings, with 35% of HCP given azithromycin reporting adverse effects and 5% discontinuing the medication prematurely.⁴¹
- Staff working when ill:
 - Pascual et al. reported that surgical staff members were reluctant to miss work when ill.¹¹ Staff believed their absence would place a burden on other HCP and potentially result in cancellation or rescheduling of surgical patients. This practice, known as presenteeism, refers to the opposite of absenteeism. It is the problem of lost productivity that occurs when employees are present at the work site but, because of illness or other medical condition, are not fully functioning.⁴²

The Cost–Benefit of Effective Programs

Vaccinating HCP could be cost-beneficial if health care facilities prevent transmission of pertussis infections and outbreaks. The CDC constructed a model to estimate the cost of vaccinating HCP and calculated the net return from preventing health care–transmitted pertussis in hospitals, using probabilistic methods and a hypothetical cohort of 1,000 HCP followed for 10 years. Baseline assumptions were determined from data in the literature.¹⁸ The following are some of the estimates derived from this model:

- The annual rate of pertussis among HCP, based on reported serosurveys, was 7%; 40% of these infections were assumed to be symptomatic.
- The ratio of exposures identified per infected HCP was estimated to be 9.

- The cost of infection prevention measures per exposed person was estimated to be \$231.
- The cost of vaccine was estimated to be \$30 per dose.

For each year, the number of health care–associated exposures requiring investigation and control activities was calculated for two scenarios: with and without a pertussis vaccination program for HCP with direct patient contact. The model estimated that, with a Tdap vaccination program in place, health care organizations would realize a net savings of \$95,000: \$2.38 would be saved in control measures for every \$1 spent on the vaccination program.

Overall, financial and operational costs associated with Tdap vaccination programs are offset by reductions in the costs associated with the investigation and control for HCP pertussis exposures as well as enhanced HCP and patient safety.¹⁸

Parallels Between HCP Influenza Vaccinations Programs and Tdap Vaccination Programs

The CDC recommends that health care facilities use strategies that have been successful in other hospital vaccination campaigns, including influenza vaccinations, to optimize Tdap vaccinations in HCP.¹⁸ A review of the literature regarding influenza vaccination of HCP reveals agreement among many that there is no "one size fits all" approach when it comes to strategies to improve rates. Strategies chosen and how those strategies are implemented should be based on an understanding of HCP knowledge of and concerns about the vaccine.⁴³⁻⁴⁸

Knowledge, Attitudes, and Beliefs

Misconceptions and beliefs can result in poor vaccine uptake. Common reasons for declining influenza vaccination include the perception that vaccination is not necessary, lack of vaccine efficacy, and concern about adverse events⁴³; reasons commonly given for accepting influenza vaccine are self-protection and protection of patients.^{49–51} Recent studies regarding HCP knowledge, attitudes, and beliefs surrounding pertussis and pertussis vaccination seem to parallel those noted in the influenza literature, including those briefly summarized here:

 Goins et al. surveyed HCP at a tertiary care academic medical center and found that intent to receive Tdap was associated with the following four factors⁵²:

- Awareness of the CDC's recommendation for HCP Tdap vaccination
- HCP belief that they could transmit pertussis to patients and family
- Physician recommendation for vaccination

• Coworker encouragement to be vaccinated Overall, only 13% of HCP surveyed intended to get Tdap. Concerns regarding the risk of transmission of pertussis were the most frequently cited reasons for receiving Tdap. Those who expressed disinterest in the vaccination believed that a recommendation was lacking and had misconceptions about pertussis and Tdap. Employment as a nurse and the presence of children in the HCP's home were negatively associated with intent to be vaccinated.

- To identify reasons for not taking the vaccination, Calderon et al. reviewed pertussis vaccination declination forms received from HCP at a teaching hospital during their pertussis vaccination campaign. They found that many HCP were not aware that they were at risk for pertussis.⁵³
- Wicker et al. conducted a survey at a children's university hospital regarding pertussis vaccination, with the following findings⁵⁴:
 - The reasons most often given for not accepting pertussis vaccination were doubt about being at risk for the disease (81%), belief that pertussis was not a serious disease (27%), fear about adverse effects (20%), and fear that the vaccine might cause pertussis (17%).
 - Misconceptions about pertussis vaccination were common, especially among nursing staff.
 - The reasons most often given for accepting pertussis vaccination were self-protection (91%) and protection for patients (81%).
- 4. Top et al. used a questionnaire to assess HCP knowledge, attitudes, and beliefs regarding pertussis vaccination at a pediatric and maternity tertiary care center. Key findings from their study include the following⁵⁵:
 - Attitudes about pertussis vaccination varied widely by occupation; HCP who were knowledgeable about pertussis and reported a high level of patient contact were less likely to be vaccinated than those with less patient contact and pertussis knowledge.
 - Vaccine safety and efficacy were common areas where HCP knowledge was lacking; concern regarding vaccine adverse effects was commonly given as a reason for declining the vaccine.

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- More than two-thirds indicated a lack of willingness to pay for the vaccination themselves.
- Only 25% of respondents correctly identified parents and other adult members of the family as the most common source of pertussis in infants.

Pertussis vaccination at a free vaccine clinic was offered to respondents following completion of the survey. Of 529 employees who completed the survey, 76% expressed a willingness to be vaccinated, but only 15% actually went to the free clinic to get the vaccination.⁵⁵

Learning from Other HCP Vaccination Programs

To achieve optimal Tdap coverage among personnel in health care settings, the CDC recommends that health care facilities use strategies that have enhanced HCP participation in other hospital vaccination campaigns.¹⁸ Strategies recommended by the CDC to enhance HCP *influenza* vaccination programs include the following⁵⁶:

- Educating HCP
- Offering influenza vaccine to all eligible HCP
- Providing free vaccine at the work site, using strategies that have been demonstrated to increase influenza vaccination, such as the following:
 - Using vaccination clinics
 - Using mobile carts
 - Ensuring access to vaccination during all work shifts
 - Using organizational leaders as supportive role models
- Obtaining signed declinations from HCP who have nonmedical reasons for declining the vaccine
- Tracking vaccination coverage rates by ward, unit, and occupation
- Using HCP influenza vaccination levels as a measure of an organization's patient safety program

Similarly, the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the National Foundation for Infectious Diseases (NFID) support the use of multifaceted influenza vaccination programs that include the elements listed here.^{57–60}

A national study of 50 hospitals by Talbot et al. to identify factors associated with increased influenza vaccination rates in HCP found that the median influenza vaccination rate of the surveyed hospitals was 55% (range, 25.6%–80.6%).⁵⁸ Strategies associated with improving vaccination rates included the following:

- Reporting vaccination rates to administrators or the board of trustees
- Any form of visible support by leadership
- · Providing the vaccine on weekends
- Use of train-the-trainer programs
- Sending a letter to HCP, emphasizing the importance of the vaccination

The study showed variation between facilities in the types of HCP included in influenza vaccination programs as well as the content of declination forms (where used). In addition, vaccination rates did not vary significantly in facilities that used declinations for HCP who refused influenza vaccinations.

In general, multifaceted campaigns are more successful than those employing a single approach.^{56,61–64} Talbot suggests using a "bundled" strategic approach to promoting influenza vaccination, an approach similar to those used in campaigns to prevent health care–associated infections.⁶⁵ Such an approach might include the following elements:

- Free vaccinations
- Easy access to vaccinations
- Leaders emphasizing the importance of vaccinations
- Use of informed declinations
- HCP education that stresses patient safety as a reason for accepting vaccination.

Several studies show increasing levels of success in influenza vaccination campaigns are associated with the progressive addition of various strategies.⁶⁶⁻⁶⁸

"As with other vaccines that improve the safety and health of health care workers and their patients, every effort must be made to increase Tdap vaccination coverage of this important population"⁶⁹

—Thomas Talbot, M.D., M.P.H., Assistant Professor of Medicine and Preventive Medicine, Chief Hospital Epidemiologist, Vanderbilt University School of Medicine

Improving Pertussis Vaccination Rates in HCP—Implementing a Hospital or Ambulatory Care Tdap Program

Tdap vaccination rates among HCP are low. The CDC analyzed data from the National Health Interview Survey (NHIS) of 2008 and found the self-reported Tdap vaccination rate among HCP to be 15.9%; 60.3% of those HCP who had received a tetanus vaccination between 2005 (the year Tdap was licensed for use) and 2008 reported receiving Tdap.⁷⁰

Even though HCP Tdap vaccination rates are low, there is a great opportunity to test strategies to raise rates. It is hoped that health care organizations can achieve Tdap vaccination rates that are better than those historically seen with influenza vaccination-because Tdap is intended to replace a routine Td booster vaccination, and there are few concerns about adverse reactions associated with Tdap vaccines. This section draws on several strategies for enhancing HCP vaccination programs, both as reported in the literature (for influenza and Tdap) and from health care organizations participating in The Joint Commission's open call for the project Promising Approaches for Implementing or Improving Tdap Vaccination Programs for Health Care Personnel and Adolescent and Adult Patients. These strategies can be useful whether the facility is just starting a Tdap vaccination program for HCP, expanding its scope to provide the vaccine to more HCP, or making another push to encourage staff to be vaccinated.

Leadership Support

The importance of leadership involvement in and support of, vaccination campaigns and programs to promote them cannot be overstated. The CDC has identified many responsibilities for health care organization administrators in efforts to prevent the transmission of infectious agents among HCP and patients in any setting where health care is delivered, including the following³¹:

- Preventing transmission of infectious agents, which should be incorporated into the objectives of the organization's patient and occupational safety programs
- Making prevention of transmission of infections an organizational priority
- Providing the human and fiscal resources necessary for infection prevention efforts relative to HCP immunization, postexposure evaluation and care, and the evaluation and management of HCP with communicable illnesses.

Organizational leaders can ensure that policies are in place, barriers to access are reduced or eliminated, and a culture exists in which vaccination is not only encouraged but expected for patient and HCP safety.^{47,49,57,58,64} Talbot et al. identified any form of leadership support (*see* Text Box 3-2 on page 40 for examples of leadership support) to be significantly associated with higher influenza vaccination rates in HCP, including the sending of a letter to HCP by leadership emphasizing the importance of the vaccination.⁵⁸

Getting Started

Health care facilities may choose to use a tiered approach as they implement their Tdap vaccination programs, initially focusing on HCP in settings that have contact with infants aged < 12 months, pregnant women, and other at-risk patient populations.¹⁸ Giving priority to vaccinating HCP at the greatest risk for pertussis transmission to high-risk populations is a practical strategy that can be used in settings such as emergency departments, ambulatory care centers, newborn and pediatric units or offices, and birthing centers, obstetrician offices, or postpartum units. It is important to keep in mind, however, that any staff who are in patient care areas could develop pertussis and transmit it to patients or other HCP. Housekeepers, therapists, social workers, volunteers, students, and various administrative staff may come in contact with patients and should therefore be considered for vaccination.¹⁸ Ptak et al. described how the use of an HCP symptom screening tool at the entrance of units with infants during a pertussis outbreak led to a surprising realization about the large number of non-patient care staff from many different departments who entered the units.⁷¹ (See Text Box 3-3 on page 40 for examples of two Tdap vaccination programs that have expanded over time.)

Assigned Responsibility

Talbot identified involvement of a multidisciplinary team in the development and promotion of HCP influenza vaccination programs as helpful in ensuring a well-supported and successful program.⁶⁵ Even in smaller facilities, there should be an individual or a group in charge of the program.⁶⁴ Consider Fedson's study of an influenza vaccination program for medical residents in the General Medicine Clinic at the University of Virginia Health Services Center.⁷² Beginning in 1986, the responsibility for vaccinating residents during the weekly halfday outpatient clinic sessions was assigned to all nursing staff; vaccination rates rose from 24% in 1986 to 75% in 1988. In 1989, when this responsibility shifted to one nurse, the rates

Text Box 3-2. Organization Leaders Support Tdap Vaccination Program

Leadership support comes in many forms. Following are three examples of organizations whose leaders emphasized the importance of improving Tdap vaccination rates for HCP:

- Stormont-Vail HealthCare, located in Topeka, Kansas, is an integrated health care system composed primarily of a 586bed acute care center and a 190-member physician group. Tdap vaccination is offered to all HCP when they begin employment, sustain an injury in which Td is indicated, and upon request. Senior leaders, recognizing the importance of the vaccination, include Tdap vaccination as part of a list of employee benefits, along with paid time off, medical and dental insurance, pharmacy discounts, and free parking. Job candidates are made aware of the vaccination during the interview process, at the preemployment health screen, and again during orientation.
- Houston Northwest Medical Center in Houston, Texas, is an acute care hospital with almost 500 beds and 3,000 HCP. The
 hospital initially began giving Tdap vaccinations to staff potentially in contact with infants aged < 12 months, and it
 expanded the program to all staff soon after. The hospital's leadership developed and supports a policy requiring Tdap
 vaccination as a condition of employment, and the organization has vaccinated 99.5% of age-eligible employees.
- Mary Rutan Hospital in Bellefontaine, Ohio, is a 110-bed general medical and surgical facility that began a Tdap vaccination program in 2006 when there were cases of pertussis in the community. The hospital's leaders made Tdap vaccination a priority for all staff. Staff education focuses on the dangers associated with pertussis, the rationale behind adults getting the vaccination, and the important role HCP play in protecting patients, coworkers, and family members by getting the vaccination. Although the vaccination is not mandatory, 641 of the hospital's 715 HCP were vaccinated by spring 2010. The organization's infection preventionist says almost no one has refused the vaccination, unless they have already received it.

Text Box 3-3. Starting Tdap Vaccination Programs

Examples of facilities that have expanded their initial Tdap vaccination programs over time include the following:

- Bloomington Hospital is a 255-bed acute-care hospital with almost 3,000 HCP in Bloomington, Indiana. It began its Tdap vaccination program in 2007, requiring the vaccination for staff who work in the hospital's defined high-risk areas (for example, labor and delivery; mother-baby unit; special care nursery; pediatrics and the emergency department, including ambulance personnel; laboratory staff; clinics that see children). This policy resulted in vaccinating 160 (about 5%) HCP. Later in 2007, the program began including all hospital staff and newly hired staff. As of June 2010, the hospital had vaccinated 75% of staff. The organization also requires contracted staff, including the photographer who enters the nursery, to receive Tdap vaccine.
- Johnson City Medical Center in Johnson City, Tennessee, is a 488-bed regional tertiary referral center for the Mountain States Health Alliance that provides care to individuals in 20 counties in Tennessee, Virginia, Kentucky, and North Carolina. The medical center began a Tdap vaccination program in 2008 by targeting direct caregivers in contact with infants < 12 months of age. The program expanded to all HCP with patient contact in 2009. As of June 2010, the organization had vaccinated 1,995 (78%) of 2,555 staff.

increased to 93%, then to 94% in 1990, and 99% in 1991. When this nurse and the clinic director were absent in 1992 and 1993, their impact on the vaccination program became apparent when rates fell to 82% and 63%, respectively.⁷²

Occupational health staff often have responsibility for screening new hires and providing Tdap when new staff begin employment. Tdap vaccination screening and vaccination can be performed along with other preemployment requirements; such screening is a useful way to expand a Tdap–vaccinated workforce. As Tdap vaccination coverage in the general population improves, more and more HCP will likely have already received a dose of the vaccine.

Text Box 3-4, right, includes an example of an organization that used a multidisciplinary team to guide the development and implementation of its HCP Tdap program.

HCP Education

Education to reduce misinformation and misconceptions about disease and vaccination has been associated with HCP acceptance of the influenza vaccine.^{73–75} While it is generally agreed that education is a key component of a vaccination campaign or program, education alone is likely not enough to enhance HCP vaccination rates.⁶¹ Education is likely to require more extensive planning and more time to implement than any other component of a vaccination program.⁴⁷ For example, both the content of the education and the dissemination approach will need to be determined. Will presentations be live or shown via video/DVD? Will there be online selflearning modules? Will printed materials be part of the education?

The CDC recommends that HCP receive job- or taskspecific education and training on preventing the spread of infectious agents in health care settings during orientation, with updated information provided periodically during ongoing education programs.³¹ The CDC further recommends a system to ensure that HCP employed by outside agencies have met education and training requirements.

The CDC recommends that the following basic information be provided to HCP as part of any educational influenza vaccination effort⁵⁶:

- The benefits of vaccination
- The potential impact and severity of influenza illness for HCP and their patients

Text Box 3-4. Multidisciplinary Team Approach

Bloomington Hospital in Bloomington, Indiana, has found success with a multidisciplinary Tdap immunization committee. Vaccination rates went from 5% at the start of the program in 2007 to 75% as of June 2010. The multidisciplinary committee includes the executive director for women and children services; the clinical directors for pediatrics, special care nursery, mother-baby, and labor and delivery services; the educators for the center for women and children; the maternal child nurse specialist; the employee health nurse; a county health nurse; the director of community health services; and the infection preventionist. The executive director for women's and children's services has been a strong supporter of the program from its beginning, stressing the importance of the vaccination.

- The epidemiology of influenza and its modes of transmission, diagnosis, and treatment
- Nonvaccine infection control strategies, such as antiviral medications, isolation precautions, and so on

Some authors believe vaccination education should cover additional subjects, such as the safety and efficacy of the vaccine.^{57,76} A SHEA position paper states that the ethical responsibility of HCP to protect themselves as well as their patients and coworkers should be emphasized.⁵⁷

Goins et al. recommend that educational efforts related to pertussis and pertussis vaccination emphasize the need for repeat vaccination due to waning pertussis protection in adults, the risk of health care–associated pertussis and potential spread to others, and the CDC's recommendations for HCP Tdap vaccination.⁵² Top et al. suggest that educational efforts emphasizing how pertussis vaccination can prevent outbreaks and that offer the vaccine at no charge may help improve vaccine uptake in HCP.⁵⁵ Wicker et al. recognize the importance of providing education to HCP to clear misconceptions about pertussis vaccination, stress the seriousness of pertussis illness and the risk of HCP

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contracting pertussis themselves, and highlighting the efficacy of pertussis vaccine.⁵⁴

It is important that education be offered at times and locations convenient to staff. For example, Calderon et al. offered eighteen 20-minute educational sessions for HCP on pertussis and pertussis vaccination over a three-week period, on all shifts and on weekends in order to reach as many staff as possible. In addition, managers agreed in advance to allow the staff to attend one of the sessions during regular work hours.⁵³

Other suggestions for promoting Tdap vaccination through education include the following:

- Emphasize that, unlike influenza vaccinations that must be given each year because new strains of influenza virus circulate each year, Tdap is currently recommended to be given only once.
- Explain that the one-time dose of Tdap replaces a recommended decennial tetanus booster vaccination.
- Point out the three-for-one benefit: One vaccination provides protection not only for tetanus but also for diphtheria and pertussis.

Getting the Message Out

Simply having the Tdap vaccine available is usually not enough, by itself, to entice HCP to accept vaccination. Whether the organization is just starting a Tdap program, expanding its scope, or attempting to vaccinate greater numbers of staff, it is important to be sure plans are clearly advertised (*see* Text Box 3-5 on page 43 for examples). HCP need to know when and where education will be offered or is available, when and where vaccinations will be provided, and the importance of getting the vaccination. Promoting vaccinations to HCP can take many forms and can take place in many venues, including the following⁶⁴:

- E-mail notices and reminders, which quickly provide information to large numbers of HCP
- Employee newsletters, which may take more time to develop than e-mail messages but can reach HCP who do not have access to e-mail. For influenza campaigns, the NFID has recommended publishing a series of articles, starting with announcements of the upcoming influenza campaign and the importance of the vaccinations, followed by regular updates on acceptance rates, reminders of when and how to get the vaccine, and any policy-related issues, such as deadlines for either accepting or declining the vaccine.

- Posters that deliver educational messages about the importance of the vaccinations and that advertise vaccination times and locations
- Screen savers that remind staff to get their vaccinations
- Messages delivered in person at staff meetings or health fairs
- Stickers worn by HCP, indicating that they have received the vaccination

A letter from organizational leadership to HCP stressing the importance of vaccination can also boost uptake of the vaccine. $^{\rm 58}$

Convenience and Accessibility

Approaches to increase HCP coverage rates through easy and convenient vaccination include the following:

- Offering vaccinations at various times and locations and ensuring that staff on all shifts have access to vaccinations. Talbot et al. found that providing vaccinations on weekends is significantly associated with improved influenza vaccination of HCP.⁵⁸ Vaccinations can be offered in common areas, such as building entrances or cafeterias, when meetings are taking place, or at shift changes. Offering the vaccination in preestablished vaccination clinics, either by appointment or on a "walk-in" basis, can also be useful.
- Ensuring a quick, streamlined process. Some organizations establish designated "vaccine days" during which the vaccine is offered to all staff.⁶⁷ Kimura et al. found that holding one or more vaccine days, combined with an educational program, improved vaccine acceptance by HCP in several long term care facilities in California in 2002.⁷⁷
- Using mobile carts to take the vaccine and associated supplies to units or departments to vaccinate HCP during their work shifts. This is not only convenient for staff but also offers an opportunity for face-to-face interaction with staff.^{54,56,67}

Examples of organizations that have made Tdap vaccinations convenient for staff are highlighted in Text Box 3-6 on page 45.

Train-the-Trainer Programs

Using a train-the-trainer approach permits expansion of the number of staff who receive training on the procedures associated with vaccine administration and then deliver the vac-

Text Box 3-5. Organizations Develop Tdap Program Communication Strategies

Several organizations participating in the open call for this project have developed communication strategies for marketing and advertising their Tdap vaccination programs, including the following:

- Columbia Basin Health Association in Othello, Washington, includes three ambulatory centers that provide medical, dental, vision, and eye care to residents across three counties. With the assistance and support of the marketing director, the nursing supervisor organized the first "double shot day" for staff to receive both influenza and Tdap vaccinations. A week before the event, the supervisor began advertising the day and educating staff about influenza, pertussis, and the vaccinations. An e-mail flyer (see Figure 3-1 on page 44) to all staff announced the date, time, and locations for the vaccinations. "Freaky Flu Facts" and "Provoking Pertussis Particulars" in the flyer offered a lighthearted approach to communicating key messages about the two diseases and the vaccinations.
- Otsego Memorial Hospital in Gaylord, Michigan, an 80-bed facility employing nearly 600 HCP, began its Tdap vaccination program in 2007. The employee health nurse, who is also the organization's infection preventionist, modeled the Tdap program after the hospital's influenza program. She used multiple communication strategies to advertise the availability of Tdap vaccinations, including weekly newsletters, paycheck stuffers, bulletin board announcements, table tents, and posters. She also advertises Tdap vaccinations during the annual Employee Health and Wellness Day, where other immunizations are offered to staff, along with nutrition, exercise and cholesterol resources, and massages. Offering Tdap to all staff in all departments, the organization has been able to vaccinate 61% of their HCP as of June 2010.

cinations to staff. The occupational or employee health staff serve as key resources in this training. The additional trained staff can enhance the delivery of vaccine by decentralizing the process, providing vaccine across all shifts and on weekends, and permitting one-on-one education for those they vaccinate. The trained staff may use mobile carts to deliver vaccine to HCP during work hours, or they may be recruited to help administer vaccines during health fairs, other safety- or health-related activities, or during meetings.

Free Vaccinations

Organizations make clear the value of immunization programs when they offer free vaccines to HCP.⁶⁴ Providing free vaccines removes a significant barrier to vaccination and is supported by the CDC and others.^{56,57,59} Top et al. found that two-thirds of HCP working in a pediatric and maternity tertiary care center were unwilling to pay for pertussis vaccinations,⁵⁵ while another study saw vaccination rates increase from 42% to 78% when the organization switched from offering a vaccine at cost to offering it at no cost.⁴⁶

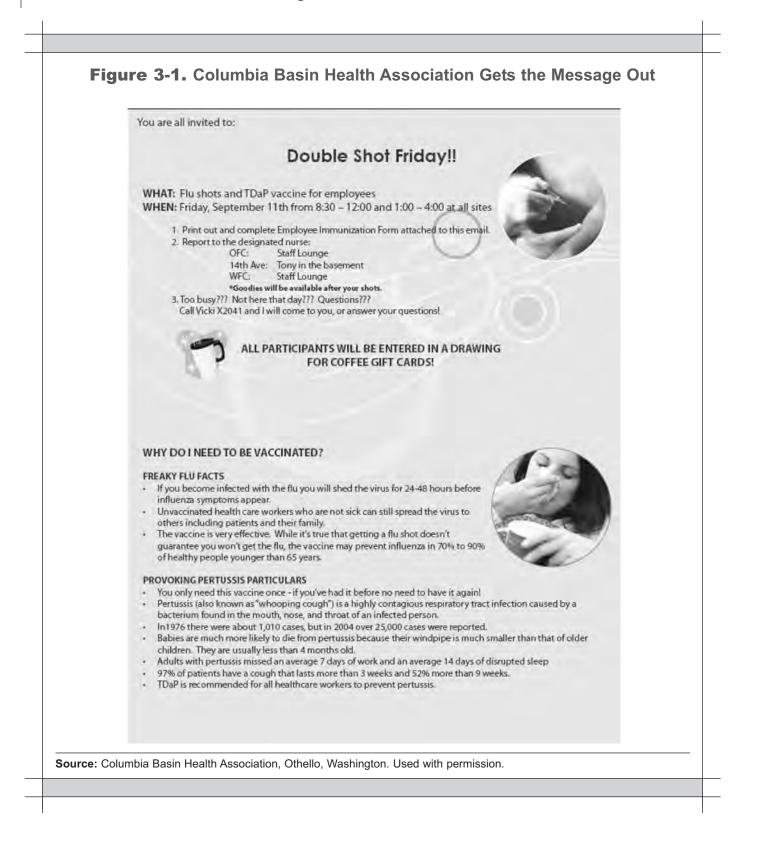
Role Models and Physician Champions

The CDC advocates the vaccination of senior medical staff or opinion leaders to improve vaccination rates in HCP.⁵⁶ SHEA and the NFID also recommend visible vaccination of leaders as a means of encouraging vaccination of HCP.^{57,64} Nafzinger and Herwaldt surveyed the attitudes of internal medicine residents at two Iowa hospitals about their reasons for accepting or declining the influenza vaccine; they found that faculty, especially infectious disease physicians, appeared to increase vaccine acceptance among residents by establishing a social norm.⁷⁵ One organization that has enlisted the help of physicians to persuade HCP to receive Tdap vaccinations is described in Text Box 3-7 on page 45.

Policies

When health care organizations create written vaccination policy statements, they affirm a commitment to improving coverage rates among HCP. Some researchers have looked at the usefulness of HCP influenza policies. The literature, however, contains little about which policies or combination of policies should be implemented to improve vaccination rates.

Adal et al. recommend work-release policies encouraging HCP not to work until they recover from influenza illness.⁷⁸ Gazmararian et al. point out that having a policy does not necessarily mean it has been well implemented and suggest



Text Box 3-6. Making Vaccinations Convenient and Accessible

The following examples show how two organizations take Tdap vaccines directly to staff in order to improve acceptance rates:

- Johnson City Medical Center in Johnson City, Tennessee, a 488-bed regional tertiary referral center for the Mountain States Health Alliance health care system, began a Tdap vaccination program by offering vaccinations to all HCP with patient contact. The organization provides Tdap vaccinations to staff by taking the vaccinations to work areas and during staff meetings, a strategy that has resulted in 78% of targeted staff being vaccinated.
- Intermountain Healthcare is a nonprofit system headquartered in Salt Lake City. The system includes more than 20 hospitals, 8 ambulatory surgical centers, and more than 150 medical clinics, as well as home care and hospice services that serve the medical needs of Utah and southern Idaho. Although Tdap has been offered to all HCP since 2006, a new policy regarding all immunizations (including Tdap) was put into place in 2010. All staff must either accept any needed vaccinations or sign a declination form. The organization uses roving carts to take vaccines to staff in their units/departments, offers flexible clinic hours on all shifts, and arranges prescheduled appointments at times convenient to staff. Tdap vaccinations increased from 22% in 2006 to 84% as of April 2010.

that organizations monitor the influence of policies over time to determine which ones seem to improve vaccination rates.⁷⁹ Researchers in North Carolina studied 268 health care organizations of various types throughout the state, surveying a sample of hospitals, long term care facilities, home health agencies, assisted living facilities, and dialysis centers. They found that only 38% of those surveyed reported having formal written policies pertaining to employee influenza vaccination; dialysis centers and assisted living facilities were less likely to have such policies than others (26% and 14%, respectively).⁶² Lindley et al. note that hospitals that include vaccination plans in written policies are more likely to measure vaccination rates than hospitals that do not have written policies.⁸⁰

Incentives

Incentives that have been offered to HCP who accept influenza vaccination include nominal gifts, such as notepads or pens; drawing for prizes; coupons for coffee or ice cream; candy; T-shirts; buttons or stickers that could be placed on name badges indicating that the HCP was vaccinated; and financial incentives such a discounts on benefits, consideration of vaccination status during merit increases, or decisions about granting time off.⁴³ Calderon et al. offered incentives during a hospital pertussis vaccination campaign, including such rewards as a pizza party for departments with the highest staff vaccination rate and gift certificates for randomly selected HCP who attended educational sessions.⁵³ Various levels of success, however, have been reported using

Text Box 3-7. Using Physician Champions

Akron City Hospital and St. Thomas Hospital in Akron, Ohio, are part of the Summa Health System. With a combined total of almost 600 beds and 10,000 HCP, they asked infectious disease and other physician leaders to help educate and encourage staff to take the vaccine. They were especially helpful in talking with the more reluctant staff and in areas that had low Tdap vaccination rates.

incentives to increase HCP vaccination rates.^{67,81} Anikeeva et al. suggest that incentives may play a role when coupled with education and minor sanctions.⁸²

Linking Vaccinations to a Required Activity

Organizations may be able to vaccinate greater numbers of HCP by offering administration at the same time as annual influenza campaigns or tuberculin skin tetsing.⁴⁷ For example, Steiner et al. describe how they gave influenza vaccinations to 62% of their 5,400 HCP, with two-thirds of the vaccinations administered when required tuberculosis screenings for all HCP were taking place.⁸³ Sampathkumar et al. gave Tdap vaccinations to staff during annual influenza vaccination campaigns and found that the

employee influenza vaccination rates were not negatively affected by adding Tdap to the vaccination clinics; in fact, the employees appreciated the opportunity to receive both vaccines simultaneously.84 Vaccinating HCP might also take place in conjunction with other annual mandatory requirements, such as reviews of various safety and infection control topics.⁷⁶ Schmid et al. found requiring occupational health checks for medical students who were about to begin clinical duties to be an important opportunity to assess the students' immunization status and to recommend and administer vaccinations if needed.⁸⁵ Tdap vaccinations can be incorporated into the preemployment health assessment along with the review and administration of other vaccines. Such "one-stop shopping" permits convenient access to vaccinations for HCP and demonstrates a respect for staff members' time. Text Box 3-8, right, provides examples of how two facilities used this approach.

Mandating Vaccinations

Mandatory pertussis vaccination for HCP has been suggested as a method to achieve high vaccine coverage. Calderon et al. undertook a comprehensive HCP pertussis vaccination campaign in their teaching hospital that included much publicity and education of staff, but fewer than one-third of the eligible staff accepted Tdap vaccinations.53 Many HCP declined the vaccination for unfounded or irrational reasons, including fear of adverse effects from the vaccination and fear of needles. The authors concluded that voluntary vaccination by HCP is not likely to achieve vaccination rates at a level that would protect patients, whereas a federal recommendation for HCP pertussis vaccination would likely be more effective in reaching protective levels.53 Poland et al. similarly state that, with the heightened awareness of quality of care and patient safety, the time has come to federally mandate that HCP with patient contact be vaccinated against vaccine-preventable diseases that pose a risk to patients and other HCP unless a contraindication or religious objection exists.86

By 2009, more than 30 health care organizations in 17 states mandated influenza vaccination programs for HCP. Some permitted declinations, but unvaccinated HCP were often subject to other requirements, particularly during influenza season, such as wearing a mask while working, being limited to working in non-patient care areas, taking a leave of absence, or possibly being subject to termination.⁸⁷

Text Box 3-8. Linking Vaccinations to Required Activities

- Bartlett Regional Hospital, a 51-bed hospital in Juneau, Alaska, provides Tdap vaccinations when new staff complete a preemployment health assessment. The organization also routinely assesses the need for and, when indicated, offers Tdap vaccinations as part of the annual employee health assessment. If it has been two years or more since an individual received Td, then Tdap is offered. This process allows the employee health staff to vaccinate those who may not have received the vaccine on preemployment due to pregnancy or recent receipt of Td vaccine.
- The employee health nurse at Otsego Memorial Hospital in Gaylord, Michigan, has been offering Tdap vaccinations to newly hired staff at the 80bed facility since 2007. She has found that staff almost never refuse Tdap during the preemployment health review.

In the spring of 2010, the CDC reported on the interim results of HCP influenza vaccination rates for the 2009–2010 influenza season (a season that included a recommendation for HCP to receive two influenza vaccines: pandemic influenza A [H1N1] and seasonal influenza vaccines).⁸⁸ The report notes that HCP who were required by their employer to receive influenza vaccinations were more likely to be vaccinated than HCP not subject to such a requirement. (Note: Information regarding the moral, ethical, and legal implications of mandatory vaccination programs is discussed elsewhere.⁴³)

Variations on mandatory programs have been described in the influenza literature, including the following three:

• Declination program without consequences: HCP either receive the vaccination each year or sign a written declination form, but no penalties are associated with not signing the form. For example, in a study of a large Georgia health care system, Ribner et al. note that employees were required to sign a form either consenting to an influenza vaccination, documenting any medical contraindications to it, or declining the vaccination.

Each week, supervisors received an updated list of the HCP who had not completed one of the sections of the form, but no formal disciplinary action was identified for failing to participate.⁸⁹

Declination program with consequences: HCP either receive the vaccination each year or sign a written declination, with penalties or disincentives associated with not signing the form. Penalties and disincentives include removal of HCP from work schedules until they comply, negative annual performance reviews, or ineligibility for bonus payouts. Palmore et al. implemented a mandatory influenza program for staff who had patient contact.90 All such staff were required to accept the vaccination or sign a declination. The policy was widely advertisedwith posters, flyers, and e-mails-all emphasizing patient safety as the goal of the new policy. The policy specified that those who neither accepted the vaccination nor formally declined it would be required to appear before the Medical Executive Committee (MEC) to explain their reason(s) for not following the policy. All HCP accepted the vaccination, and no HCP had to appear before the MEC.

Text Box 3-9 at right describes two organizations that require Tdap vaccination but allow HCP to decline the vaccination in writing.

 Mandatory program: All HCP receive the vaccine. Signed declinations or requests for accommodation are allowed only for HCP who have a medical contraindication or religious objection, and adherence to policy is a condition of employment. For example, Babcock et al. describe how they made annual influenza vaccinations a condition of employment in 2008.⁹¹ Overall, they achieved a vaccination rate of 98.4% among almost 26,000 HCP. A small number of HCP received religious or medical exemptions. HCP who were neither exempted nor vaccinated by mid-December 2008 were not scheduled for work, and employment was terminated for those still not vaccinated by mid-January 2009.

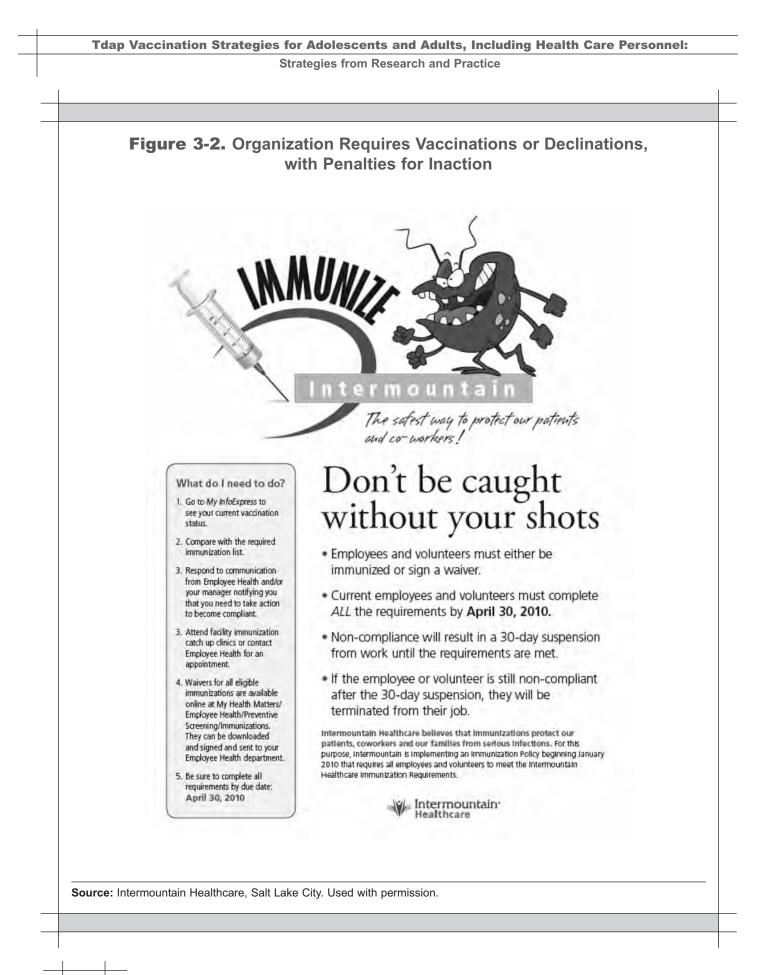
Text Box 3-10 on page 49 includes examples of organizations that mandate Tdap vaccinations, with medical contraindications or religious objections the only accepted reasons for not receiving the vaccine.

Text-Box 3-9. Tdap Vaccinations Required but Declinations Allowed

- Intermountain Healthcare in Salt Lake City has more than 32,000 HCP under one corporate employee health program, and all staff who are eligible to receive Tdap are required to either accept the vaccination or sign a declination form, regardless of whether they enter patient care facilities. Those who refuse the vaccination and refuse to sign a declination form are suspended from work without pay for a period of up to 30 days and are terminated for continued inaction. This policy was maintained in early 2010 when Intermountain rolled out a systemwide policy on all immunization requirements (see Figure 3-2, page 48). Corporate employee health staff now produce monthly compliance reports for managers with the names of employees, by facility, who face suspension or termination for not adhering to the policy.
- Lakeland Regional Medical Center in Lakeland, Florida, offers Tdap vaccinations to all HCP and requires the vaccine for HCP working in designated high-risk departments, including mother–baby units, newborn nursery, pediatrics, respiratory care, and radiology. Tdap vaccines also are mandatory for some operating room staff. Staff in those areas who refuse the vaccination must consult with the human resources department and find a non–high-risk position within 30 days or risk termination. To date, 100% of staff working in high-risk areas have accepted Tdap vaccination. New staff and staff who wish to transfer to one of the high-risk areas must be vaccinated prior to assignment.

Declination Statements

Declination statements designed to capture reasons for declining can provide useful information on HCP attitudes, beliefs, and misconceptions about pertussis or the vaccine. Such data can point to the need for additional education.⁹² Having reluctant HCP read a declination form may cause them to reflect on their decision and perhaps lead them to participate.⁹³ Limited data, however, are available regarding



the effectiveness of using declination statements as a strategy for improving vaccination rates among HCP.^{94,95} Such statements can capture those declining because they have received the vaccination elsewhere, which should be included when calculating vaccination rates (*see* "Measuring Vaccination Rates and Providing Feedback" beginning below). Talbot et al. noted in a revised position paper on influenza vaccination of HCP that the use of declination statements should not be considered a frontline method for increasing vaccination rates.⁹⁵

Talbot identified the following aspects of influenza declination forms that can influence their effectiveness in promoting vaccination as a patient safety measure and dispelling misconceptions about vaccination⁶⁵:

- Having a statement stressing that the HCP has received education regarding the rationale for the vaccination and that declining the vaccination puts patients at risk. This has a greater impact than a simple "yes or no" declination form.
- Having consequences for failure to sign the declination form
- Having a statement about the organization leaders' expectations and the importance they place on vaccination

APIC's influenza position paper states that informed declination statements for HCP refusing for reasons other than medical should be required, and information from declination statements should be used to develop improvement strategies.⁹⁶ Managing such statements, however, can be resource intensive; consideration should be given to who will track them and how.

Measuring Vaccination Rates and Providing Feedback

No matter what strategies are chosen to begin or enhance an HCP Tdap vaccination program, the goal should be to improve vaccination rates over time. Measurement is required to determine whether performance is improving, getting worse, or staying the same. Some organizations that require HCP to either receive a vaccination or sign a declination statement determine their "rate of participation," or the percentage of all staff who did one or the other. Although a 100% participation rate may be the policy, the goal should always be to increase the percentage of HCP accepting the vaccination and decrease the percentage declining it.

Text Box 3-10. Organizations Require Tdap Vaccinations with Limited Reasons for Nonacceptance

- Charleston Area Medical Center in Charleston, West Virginia, requires Tdap vaccination for all HCP with patient contact. The regional referral center with almost 900 beds and 7,000 employees modeled its Tdap vaccination program after its mandatory influenza vaccination program. (For the 2009-2010 influenza season, 99.6% of the organization's staff received influenza vaccinations.) Staff reporting a history of an allergic reaction to a component of the vaccine that is not formally documented by a health care provider are sent to an allergist for evaluation, at the organization's expense; the allergist gives the vaccination, if deemed appropriate. Staff eligible for the vaccination who refuse Tdap are given a few days off without pay to evaluate their decision of refusal; so far, all who have been suspended have returned and received the vaccination. Leadership supports the program, and the human resources department enforces the policy.
- Michigan State University/Kalamazoo Center for Medical Studies requires Tdap and influenza vaccination for employment. Approximately 400 clinical and nonclinical staff with patient contact are affected by the policy. The Tdap requirement is also written into all contracts involving nonemployee clinical staff. Declination statements are allowed only for specific reasons, such as pregnancy, age > 64, or allergy to a component of the vaccine. Newly hired staff must be vaccinated in order to work at the center. To date, the organization has vaccinated 99% of Tdap-eligible staff. A double-check is done each year, during annual tuberculin skin testing, in case there was a legitimate time-limited reason that the vaccination was previously not administered.

HCP who have received vaccinations in venues outside the formal organization program, such as in physicians' offices, local pharmacies, and so forth, should be captured and included with the number of HCP who received the vaccination within the organization's program. Capturing all HCP who have been vaccinated, regardless of where they were vaccinated, provides a more accurate picture of the number and percentage of HCP who are protected.^{57,97} For example, Bearman et al. found that 64% of medical house staff who had not received influenza vaccination through their organization had received it elsewhere; when the number of house staff vaccinated elsewhere was combined with the number who had received it in their organization, the vaccination acceptance rate rose from 48% to a true rate of 75%.⁹⁸

Because it can vary dramatically by specialty, vaccination coverage should be stratified by occupational groups or by department or unit, in order to target appropriate interventions for those with lower vaccination rates.^{56,99,100} Contraindications to vaccination and vaccine declinations should also be measured and reported separately, as should vaccinations received at the facility and elsewhere.¹⁰⁰ Lindley et al. conducted a national survey in 2006 of more than 500 hospital infection preventionists regarding policies and practices for the provision of influenza vaccine and the measurement and reporting of influenza vaccination rates. The researchers found that only 69% of the hospitals measured vaccination rates, whereas 92% tracked the number of vaccine doses given.⁸⁰ They further noted the following about the hospitals that did measure vaccination rates⁸⁰:

- Most measured their own staff vaccination rates, but only about half of them tracked vaccinations by type of staff or unit/department.
- Only about half measured contract staff, volunteers, or credentialed medical staff coverage.
- Fewer than one-third measured vaccination rates in students or residents.

If the goal of a vaccination program is to provide a safer environment for patients, all staff who come in contact with patients should be included in the denominator when determining vaccination coverage rates for HCP such as employed, contracted, volunteer staff, students, and so forth.

The CDC has recommended that health care facilities monitor HCP influenza vaccination coverage and provide

feedback of ward-, unit-, and specialty-specific rates to staff and administration.⁵⁶ The NFID also highlighted the role of feedback in improving influenza vaccination rates, noting the important influence of facts and figures on HCP perception of vaccination rates.⁶⁴ Other researchers have similarly seen the impact of feedback in improving HCP influenza vaccination rates.^{63,101}

Appendix 3-3, beginning on page 60, contains a case study highlighting how Intermountain Healthcare, headquartered in Salt Lake City, used many of the strategies presented in this chapter to attain a Tdap vaccination rate of 84% as of early 2010. The organization offers Tdap vaccinations to all HCP in all departments/units of its many hospitals and other facilities.

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Appendix 3-1 Examples of Pertussis Exposure Incidents and Outbreaks in Health Care Settings

Reference	Setting/ Time Frame	Source of Exposure	Exposed/ Infected Individuals	Summary
Addiss D.G., et al.: A per- tussis outbreak in a Wisconsin nursing home. <i>J Infect Dis</i> 164:704–710, Oct. 1991.	Nursing home in Wisconsin 1985	Undetermined	Residents HCP	Over one-third of the 105 residents were seropositive for pertussis, including 4 who were culture-positive for <i>B. pertussis</i> . Age range for the culture-positive residents was 52–81 years; cough in those patients interrupted their sleep and lasted 43–54 days. Seven HCP also developed pertussis; they were excluded from working for 5 days and were treated with erythromycin for 14 days. It was unclear how pertussis was initially introduced into the nursing home, but HCP were not believed to have been an important source of the infection. Several asymptomatic cases were identified in residents. Mass administration of erythromycin to residents appears to have been important in terminating the outbreak.
Alexander E.M., et al.: Pertussis outbreak on a neonatal unit: Identification of a health- care worker as the likely source. <i>J Hosp Infect</i> 69:131–134, Jun. 2008.	Hospital neonatal unit in London 2004	Likely a nursery nurse	Infants	The index case was a premature infant born at 25 weeks gesta- tion who developed cough, increased respiratory secretion, and apnea at 47 weeks of age while in the special care nursery. The infant had received 2 doses of pertussis vaccine prior to onset of symptoms. Another 2-month-old infant temporally associated with the first infant also developed pertussis. Both infants required mechanical ventilation. Several HCP working in the unit and other infants were also exposed, partly due to the delay in diagnosing the first infant. Twenty-seven infants were given a 7-day course of erythromycin for chemoprophylaxis. Contact tracing of medical, nursing and physiotherapy staff identified 120 exposed HCP, all of whom were given clarithromycin for 7 days. Only HCP with signifi- cant cough were furloughed for 5 days. A nursery nurse was iden- tified as the likely source of infection for the 2 infants; she had a severe cough illness for 4 weeks, beginning 2 weeks prior to onset of infection in the first infant.
Baggett H.C., et al.: Two nosocomial pertussis out- breaks and their associ- ated costs—King County, Washington, 2004. <i>Infect</i> <i>Control Hosp Epidemiol</i> 28:537–543, May 2007.	Tertiary care hospital in Washington 2004	Emergency department physician	Patients HCP Visitors	The emergency department physician, who was 37 weeks preg- nant, experienced paroxysmal cough with posttussive emesis for over a month. Hospital staff identified 388 HCP, 265 patients, and 85 visitors who had been potentially exposed to pertussis; the majority were evaluated in a temporary pertussis clinic and pre- scribed antimicrobials for treatment or prophylaxis of pertussis. HCP with any respiratory symptoms were furloughed for 5 days; those without symptoms were given antimicrobials if 21 days or less had passed since exposure but not furloughed. One asymp- tomatic HCP who was pregnant and had multiple allergies was furloughed for 21 days and not given antibiotics.
	Pediatric hospi- tal in Washington 2004	Respiratory therapist	Patients HCP Visitors	The respiratory therapist, who worked in the pediatric intensive care unit, had a 3-week history of paroxysmal cough before reporting to Occupational Health for evaluation. Three nurses who had worked with the therapist in the unit also developed pertus- sis. In all, 417 HCP, 120 patients, and 200 visitors were identified who had potentially been exposed to one of the infected HCP. Most of the HCP received antimicrobials for treatment or prophy- laxis; those with any symptoms were also furloughed. Approximately 20% of the exposed patients and visitors were given antimicrobials at the hospital's expense; the remaining patients and visitors were referred to their physicians for care.

(continued)

Appendix 3-1, continued

			Exposed/	
Reference	Setting/ Time Frame	Source of Exposure	Infected Individuals	Summary
Bassinet L., et al.: Nosocomial pertussis out- break among adult patients and healthcare workers. <i>Infect Control</i> <i>Hosp Epidemiol</i> 25:995–997, Nov. 2004.	General hospi- tal in France 2000–2001	Nurse officer	Patients HCP	A nurse officer transmitted pertussis to other HCP, who then transmitted it to other HCP (14) and patients (2). In all, 89 individ- uals with cough were examined: 77 HCP and 12 hospitalized patients. There was no concurrent outbreak of pertussis in the community. After the confirmation of the first case, HCP were evaluated and received antimicrobials for treatment or prophylaxis of pertussis.
Baugh V., McCarthy N.: Outbreak of <i>Bordetella</i> <i>pertussis</i> among oncology nurse specialists. <i>Occup</i> <i>Med</i> (Lond) 60:401–405, Aug. 2010.	Hospital and associated out- patient clinic in the United Kingdom 2009	Likely a former patient	Patients HCP	The first HCP identified as having pertussis, a nurse who worked in the outpatient oncology department, had been ill with a persist- ent cough, inspiratory whoop, posttussive vomiting, and periods of apnea for over 5 weeks before pertussis was diagnosed. Four HCP who shared an office with her also became ill, an attack-rate approaching that of household contacts to a case of pertussis. Pertussis spread throughout the hospital, with HCP and patients on 7 different wards became infected. Ultimately a 71-year-old patient who had received treatment in the outpatient oncology department, diagnosed with pertussis about 2 weeks prior to the first HCP case, was identified as the probable initial source of pertussis.
Calugar A., et al.: Nosocomial pertussis: Costs of an outbreak and benefits of vaccinating health care workers. <i>Clin</i> <i>Infect Dis</i> 42:981–988, Apr. 2006.	Tertiary hospi- tal setting with adult and pedi- atric beds 2003	Infant with pertussis	Patients HCP Student nurses Family members Residents of a facility for the mentally impaired	The infant's diagnosis was confirmed 16 days after admission. Seventeen cases of pertussis occurred in HCP exposed to the infant for 1 day, resulting in the identification of 307 exposed close contacts (patients, friends, and family members). III HCP were furloughed for 5 days and were treated for 5 days with azithromycin. Over 300 close contacts (other HCP, family mem- bers, patients, residents of a facility for the mentally impaired and student nurses residing in a dormitory) were offered azithromycin prophylaxis. The hospital distributed information about the expo- sures through media briefs, letters, and press conferences and set up a dedicated telephone hotline to answer questions.
Christie C.D., et al.: Containment of pertussis in the regional pediatric hospital during the Greater Cincinnati epi- demic of 1993. <i>Infect</i> <i>Control Hosp Epidemiol</i> 16:556–563, Oct. 1995.	Tertiary care university hos- pital serving Ohio, Kentucky, and Indiana 1993	Community contact likely	HCP 1 patient	During a communitywide outbreak of pertussis, the hospital eval- uated 206 HCP with respiratory infections; 87 met the clinical or lab criteria for pertussis. Seventy-nine HCP were furloughed for 5 days and treated with erythromycin, and 8 were not (diagnosed > 3 weeks after onset of paroxysmal cough). Prophylaxis was offered to 622 HCP who had been exposed to pertussis cases. Patients on a tracheostomy unit were also offered prophylaxis, as HCP had worked on the unit while symptomatically ill with pertus- sis. Only one nosocomial case of pertussis was identified in a patient. The hospital employed multiple, concurrent measures to limit the spread of pertussis, including hospitalwide education on pertussis (most HCP were unaware of adult pertussis), mass erythromycin prophylaxis, requiring persons from the community to don masks when coming into the test referral center, hospital- wide visitor restrictions for those 14 years and younger and for those with respiratory symptoms, and excluding symptomatic chil- dren from a temporary child care service. Containment costs were considerable.

(continued)

Reference	Setting/ Time Frame	Source of Exposure	Exposed/ Infected Individuals	Summary
Pascual F.B., et al.: Outbreak of pertussis among healthcare workers in a hospital surgical unit. <i>Infect Control Hosp</i> <i>Epidemiol</i> 27:546–552, Jun. 2006.	Community hospital 1999	Nurse anesthetist	НСР	The outbreak was first recognized in the surgical services of the hospital, when the index case, a nurse anesthetist, was identified (paroxysmal cough, posttussive vomiting, and periods of apnea that led to a loss of consciousness). Twelve of 53 surgical staff (11 other HCP and 1 surgeon from private practices) also developed pertussis. Of the 146 patients who received surgical care over the course of the 3-month outbreak, none was identified as having developed pertussis. The hospital actively sought to contain the outbreak by providing frequent updates to HCP, alerting HCP to contact the infection control department if they developed a cough illness, providing antimicrobial prophylaxis to exposed HCP, meeting with the local news media and briefing the medical community in the region on pertussis.
Centers for Disease Control and Prevention: Hospital-acquired pertus- sis among newborns— Texas, 2004. <i>MMWR</i> <i>Morb Mort Wkly Rep</i> 57: 600–603, Jun. 2008.	General hospital in Texas 2004	Nursery worker	Infants	Staff at a children's hospital cared for 6 infants with pertussis who had been born in the same general hospital over a 12-day period in June 2004. Further investigation identified 11 infants who were part of the outbreak related to an HCP at the general hospital. The HCP had worked in the newborn nursery from mid-June until mid-July with symptoms of pertussis, during which time she cared for 113 infants, for an attack rate of 9.7%. No additional cases occurred in either the general hospital or the children's hospital. The HCP with pertussis was furloughed and received antimicrobial therapy, with no new cases in infants during September and October 2004.

Appendix 3-1, continued

Abbreviations: HCP: health care personnel; lab: laboratory

Appendix 3-2

Examples of Pertussis Exposures and Outbreaks in Health Care Settings and Associated Costs

Reference	Setting/ Time Frame	Summary of Outbreak	Description of Costs
Baggett H.C., et al.: Two noso- comial pertussis outbreaks and their associated costs—King County, Washington, 2004. <i>Infect Control Hosp Epidemiol</i> 28:537–543, May 2007.	500-bed tertiary care hospital in Washington 2004	In both outbreaks, the source was HCP who had delayed diagnoses and contin- ued to provide care (1 emergency depart- ment physician, 1 respiratory therapist). Transmission of pertussis to coworkers and community contacts occurred. Costs not included in the estimates included those associated with lab tests performed	 Direct costs for personnel time, lab, and medical costs: \$195,342 Indirect costs (staff furloughs): \$68,015 Total cost per pertussis case: \$43,893 (6 cases) Total cost per person exposed to a case: \$357 (738 exposures)
	250-bed pedi- atric hospital in Washington 2004	by the health department, overhead, and costs to affected patients, visitors, and HCP.	 Direct costs: \$71,130 Indirect costs: \$50,000 Total cost per pertussis case: \$30,282 (4 cases) Total cost per person exposed to a case: \$164 (737 exposures)
Calugar A., et al.: Nosocomial pertussis: Costs of an outbreak and benefits of vaccinating health care workers. <i>Clin Infect Dis</i> 42:981–988, Apr. 2006	Tertiary care hospital with adult and pedi- atric beds 2003	Seventeen cases of symptomatic pertus- sis occurred among HCP exposed for a day to an infant later confirmed to have pertussis. A total of 307 close contacts to the 17 ill HCP were also identified (patients, family members, and friends). Not included in the cost analysis were other potential expenses, such as liability insurance premiums and revenue losses related to the outbreak.	 Total direct and indirect costs for hospital: \$74,870 Direct costs for lab tests, treatment, and postexposure prophylaxis, labor hours, information dissemination: \$63,670 Indirect costs (staff furloughs): \$11,200 Total direct and indirect costs to the 17 HCP: \$6,409 Total all costs: over \$81,000
Christie C.D., et al.: Containment of pertussis in the regional pediatric hospital dur- ing the Greater Cincinnati epi- demic of 1993. <i>Infect Control</i> <i>Hosp Epidemiol</i> 16:556–563, Oct. 1995.	361-bed tertiary care university hospital serving Ohio, Kentucky, and Indiana 1993	Communitywide pertussis outbreak in Ohio in 1993 resulted in pertussis diagno- sis in 102 hospitalized children from the community and 87 adult HCP. Only 1 nosocomial case occurred, but contain- ment costs were considerable.	 Direct costs to control pertussis in patients, visitors, and HCP was \$85,400, which included: Paid 5-day furloughs for 79 HCP 622 prescriptions for erythromycin and trimethoprim-sulfa methoxazole for HCP 179 cultures and DFA tests Employee health staff time Child care for 488 siblings of patients Security staff to monitor the elevators Education Signs and posters
Leekha S., Thompson R.L., Sampathkumar P.: Epidemiology and control of pertussis outbreaks in a tertiary care center and the resource consumption associated with these outbreaks. <i>Infect Control</i> <i>Hosp Epidemiol</i> 30:467–473, May 2009.	2,036-bed terti- ary care center in Minnesota 2005	 Two separate outbreaks: First was community based Second was hospital based, with more than half the cases occurring in HCP. An estimated 510 patients were potentially exposed to HCP with pertussis, though there were no documented instances of transmission from HCP to patients. 	 Total HCP costs associated with the hospital- based outbreak was \$236,284, which included: 513 HCP requiring evaluation and testing for pertussis 513 PCR tests 687 courses of antimicrobial treatment or prophylaxis (several HCP had more than 1 exposure) 320 missed work days

(continued)

Appendix 3-2, continued

Reference	Setting/ Time Frame	Summary of Outbreak	Description of Costs
Toy D., et al. <i>Pertussis</i> <i>Outbreak Among Healthcare</i> <i>Workers: Tdap Too Little, Too</i> <i>Late.</i> Paper presented at the Annual Educational Conference of the Association for Professionals in Infection Control and Epidemiology, Fort Lauderdale, Florida, Jun. 2009.	3-campus VA health care sys- tem providing inpatient and outpatient care 2008	Three MDs working in the same outpa- tient clinic developed confirmed pertussis. A total of 656 HCP and 215 patients were screened and offered prophylaxis. No patients developed pertussis related to the outbreak.	 Total cost of the outbreak: almost \$17,000, which included: Lost 51 days of lost work time by HCP (\$15,243) Lab tests (\$1,600) Medication (\$112) Additionally, employee health staff and infection preventionists worked 110 overtime hours. The authors noted that it would have cost the organization \$74.85 to vaccinate the 3 index cases, which would have prevented the outbreak.
Ward A., et al.: Health and eco- nomic consequences of an out- break of pertussis among healthcare workers in a hospital in France. <i>Infect Control Hosp</i> <i>Epidemiol</i> 26:288–292, Mar. 2005.	600-bed general hospital in France November 2000–March 2001	Initially, 3 HCP developed confirmed per- tussis transmitted from another coworker. There was no community outbreak at the time. Ultimately 17 confirmed cases were identified (15 other HCP and 2 family members). Many others with cough symp- toms were also evaluated as part of the screening process.	 Total cost of the outbreak to diagnose, treat, and provide prophylaxis, along with lost productivity of staff, was 46,661 euros. Of that: 42% was due to productivity losses 58% was for direct costs, which included: 32% for diagnostic tests 31% for hospitalization of 4 patients (all immunocompromised) 12% for treatment of household contacts 11% for antimicrobials 9% for physician care
Zivna I., et al.: Impact of Bordetella pertussis exposures on a Massachusetts tertiary care medical system. Infect Control Hosp Epidemiol 28:708–7112, Jun. 2007.	Academic tertiary care medical center and affili- ated ambulatory care setting in Massachusetts October 2003–September 2004	Over the 12-month period there were 20 primary and 3 secondary lab-confirmed pertussis cases. Two primary cases and 1 secondary case occurred among HCP. Over the course of the outbreak 353 HCP were screened, due to their close contact with lab-confirmed cases. Ultimately, 287 HCP received treatment or prophylaxis for pertussis.	 High and low estimates of time expended in the screening and management of exposed patients and HCP were determined. Total costs were estimated to be \$85,066–\$98,456, which included: Direct costs: Treatment and prophylaxis: \$13,416 Personnel time: \$19,500–\$31,190 Indirect costs for lost time from work: \$51,300–\$52,300

Abbreviations: DFA: direct fluorescent antibody; HCP: health care personnel; lab: laboratory; PCR: polymerase chain reaction

Appendix 3-3 Case Study: Organization with Multifaceted Tdap Program

Intermountain Healthcare is a nonprofit system headquartered in Salt Lake City, Utah. The system includes more than 20 hospitals, 8 ambulatory surgical centers, more than 150 medical clinics, and home care and hospice providers, serving the medical needs of Utah and southern Idaho.

Intermountain Healthcare began planning its Tdap immunization program in 2006, following the publication of the ACIP recommendations for adult Tdap vaccination, which included recommendations for health care personnel. The organization's corporate Employee Health (EH) department worked with the corporate adult immunization team to determine how Tdap would be administered to more than 24,000 employees. A tiered approach was developed to offer vaccination to all employees over a two-year period. First, Tdap vaccinations were offered to high-risk staff, such as those working in the neonatal intensive care unit (NICU staff), women and children's staff, and emergency department staff. Tdap was then rolled out to more employees, until all direct-patient care groups had an opportunity to be immunized. By 2008 all staff at each Intermountain facility were being offered Tdap vaccinations, with a vaccination rate of 55%.

In March 2009 the EH team met with senior leadership and key stakeholders such as human resources (HR), infection prevention (IP), risk management, medical directors, and senior operations leadership to seek input and approval for a policy on all vaccination requirements, including Tdap vaccination. The organization ultimately decided that the immunization policy should cover all employees, believing that, while some employees never enter a facility that houses patients, every employee probably works with someone who does. The policy specified the roles and responsibilities of all Intermountain staff, now numbering more than 32,000. Consequences were clearly stated and included a 30-day unpaid suspension if the policy was not followed. At the end of 30 days, if the employee had not been immunized or signed a declination statement, employment could be terminated. (Some departments, however, could choose not to accept declinations if they serve a vulnerable population.) Other workers, such as students or vendors, are expected to be compliant

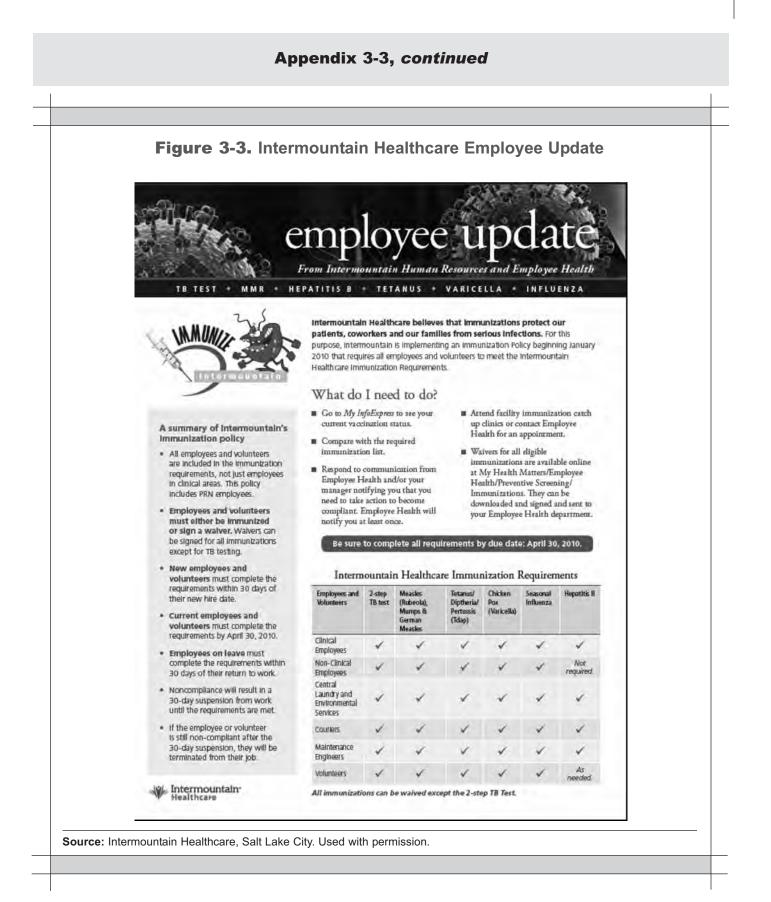
when they start their duties, and the vaccination requirements are specified in contracts. Licensed independent practitioners are required to sign a one-time attestation at the time of credentialing or recredentialing. Staff who choose to sign a declination statement acknowledge that, in the event of an outbreak or exposure incident, they could be furloughed without pay (though they can use earned paid time off) for the duration of the outbreak or period of communicability.

The plan was supported by the CEO, corporate chief medical officer, and council of nursing officers, all of whom communicated that support to other senior leaders and direct reports. EH and HR are responsible for program oversight, with EH running compliance reports and HR providing the reports to the appropriate manager and working with manager as part of any disciplinary action.

The campaign kicked off in January 2010, with a deadline of April 30, 2010, for completion of all immunization requirements. The campaign was designed to encourage immunization, using the theme "Immunize Intermountain" (see Figure 3-3, "Intermountain Healthcare Employee Update," page 61). All vaccinations were offered at no cost to employees. Education for employees, managers, physicians, and volunteers focused heavily on protecting patients, families, and coworkers. A Web site was developed on the corporate intranet to house information about the immunization requirements, immunization and declination forms, and consequences for not completing the requirements by the deadline. Education materials, questions and answers, information on roles and responsibilities, and clinic schedules were also available on the Web site. Forms could be submitted electronically, and EH e-mail addresses and fax numbers were available for quick reference by staff.

Senior leaders at each facility were held accountable for progress, and facility contacts were assigned responsibility for the program at their respective facilities. These contacts helped organize immunization clinics, delivered reports to managers and notices to employees, and helped with facility-specific communications and scheduling of appointments. Each facility utilized strategies appropriate to its

60



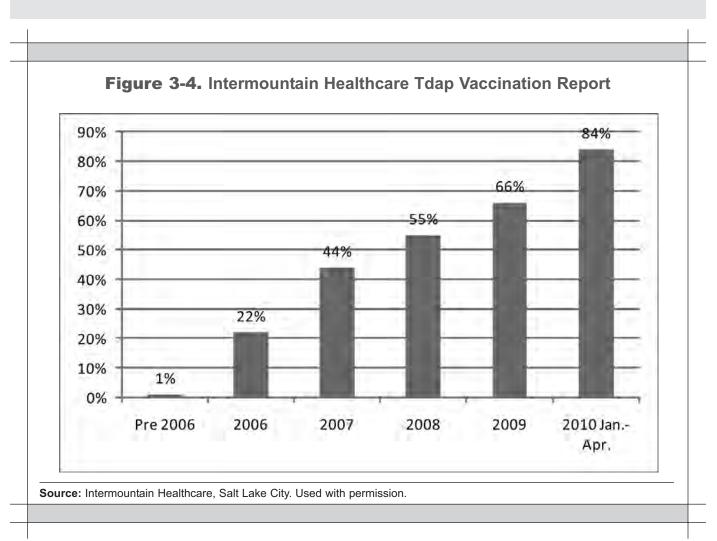
Appendix 3-3, continued

setting to enhance delivery of Tdap to staff, including the following:

- Fliers on main traffic doors, in elevators, in break rooms, on time clocks, in various department locations, and in cafeterias (*see* Text Box 3-9, page 47, and Figure 3-2, page 48)
- Flexible clinic hours, offered on all shifts
- · Mass immunization clinics, offered on all shifts
- Flexible locations for receiving vaccinations (such as during department meetings)
- Train-the-trainer vaccination programs
- Roving carts that go from department to department to vaccinate staff
- Overhead speaker reminders during clinic times
- Electronic reminders from leadership on the organizations intranet
- Electronic newsletters on the intranet
- Hard copies of facility newsletters, available for pickup in various locations
- · E-mail blasts with specific clinic locations and times
- Personal e-mails from EH to employees with specific information about their vaccination needs
- Reports to department managers with names of noncompliant employees
- Announcements and reminders during department meetings
- Notification of prescheduled individual appointment times that are endorsed by supervisors
- Rewards for positive health care personnel response with "free jeans Fridays" or pizza parties

According to the corporate employee health coordinator, Tdap immunization has been the hottest ticket in the immunization efforts, as many employees did not realize their childhood immunity to pertussis did not carry over into adulthood. Because they already understood the need for a decennial Td, most staff accepted the Tdap vaccination without hesitation. Tdap rates improved from 22% of ageeligible employees vaccinated in 2006 to 84% of age-eligible employees vaccinated by April 30, 2010 (*see* Figure 3-4, page 63). Some employees temporarily waived Tdap vaccination due to pregnancy or recent tetanus (Td) vaccination; the organization anticipates that vaccination rates will approach the 90% goal over a 12- to 18-month period as staff who declined for pregnancy or recent Td vaccination reasons are vaccinated.

Ongoing efforts to sustain the Tdap vaccination program include vaccinations at the time of hire, requests from staff at any time (including those who have previously waived immunization), and annually in association with various training or competency requirements. In 2010, corporate EH planned to request that each facility EH nurse proactively conduct a quarterly review of vaccination records, to identify staff who previously signed declinations for Tdap. EH nurses would then contact those employees to determine their eligibility for Tdap and offer the vaccination.



Appendix 3-3, continued

 Tdap Vaccination Strategies for Adolescents and Adults, Including Health Care Personnel:

 Strategies from Research and Practice

CHAPTER 4

Routine Use of Tetanus, Diphtheria, Acellular Pertussis (Tdap) Vaccinations in Adolescents and Adults

Summary of Key Points

- Tdap vaccinations for adolescents and adults are important to stem the up to 3.3 million cases of pertussis each year that can put infants at risk for the disease.
- Barriers to vaccination exist in adolescents and adults.
- Strategies have been recommended to overcome these challenges and improve vaccination coverage in adults, including use of standing orders, reminder/recall systems, review of patients' vaccination status at each office visit, and assessments of provider vaccination coverage levels.
- Immunization information systems (IISs, formerly known as immunization registries) are another tool that can increase and sustain vaccination coverage, prevent duplicate vaccinations, and reduce staff time in locating vaccination records or certificates; their use has been recommended wherever possible.

Pertussis in Adolescents and Adults

Up to 3.3 million cases of pertussis occur each year in adolescents and adults in the United States.¹ The incidence of pertussis in adolescents is second only to that in infants under age 1.² Pertussis can result in outbreaks involving both adolescents and adults, which are common in the community, middle schools and high schools, and the workplace.^{2,3} Although Tdap vaccination could stem the number of cases in these populations, there are significant barriers. In fact, as this chapter and the monograph as a whole make clear, implementing universal adult Tdap vaccination is expected to be difficult; adolescents have a routine point in time for evaluation of their vaccination status, but this is not the case for most adults.

Even though the disease may be milder in these individuals, infected adolescents and adults can spread pertussis to other susceptible individuals, including unimmunized or incompletely immunized infants.⁴ Pertussis is often nonspecific in adolescents and adults and can vary from asymptomatic infection to mild, atypical respiratory illness, to the classic whooping syndrome.⁵ The level of immunity at the time an individual is exposed to pertussis affects the clinical outcome.⁶ Researchers for the Adult Pertussis Trial (APERT) Study Group estimated that, in persons ages 15 and older, there are approximately five asymptomatic pertussis cases for every symptomatic case.⁷ Data also suggest that 16% of infections in infants are the result of transmission of asymptomatic disease.⁸

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Pertussis Features, Complications

A cough lasting 3 or more weeks is a common feature of pertussis in adolescents and adults, as are difficulty sleeping and breathing.^{2,3} Cherry estimated that approximately 13% to 20% of prolonged cough illnesses in adolescents and adults are due to pertussis.1 Lee et al. found that more than one-third of adolescents and nearly two-thirds of adults were still coughing 100 days into their illness.9 Pneumonia is a complication in up to 5% of adults and 2% of adolescents with pertussis. Weight loss occurs in about one-third of pertussis cases; rib fractures, loss of consciousness, and seizures have been reported to occur less often in both age groups. Up to 2% of adolescents, 3% of adults, and up to 12% of adults over age 65 have been hospitalized for pertussis. In addition, adolescents and adults with pertussis often make repeated visits for medical care and can undergo extensive medical evaluations by providers seeking to diagnose their illness.^{2,3} Deaths in the 10- to 64-year age group due to pertussis are rare.2.3 The various features and complications associated with pertussis are listed in Table 4-1, page 67.

Immunity to Pertussis

The mechanisms of pertussis protection are not completely understood. Most adults and adolescents have been exposed to *Bordetella pertussis*, pertussis antigen–containing vaccines, or both. When a vaccine containing pertussis antigens is administered, there is an expected booster response. A measurable rise in antibodies can be detected seven days after vaccination. These antibody concentrations peak at about two weeks after the booster dose and decline rapidly in the initial months following vaccination, after which the rate of decline slows.⁵ Overall, the protection conferred by both pertussis infection and pertussis vaccines lasts 5 to 10 years.⁵ This is important to keep in mind, as the declining immunity after infection or vaccination leaves individuals susceptible to infection or reinfection.⁵

Tdap Vaccine and Vaccination

The 2005 licensure of two Tdap vaccines (ADACEL[®] [sanofi pasteur] and BOOSTRIX[®] [GlaxoSmithKline]) provides significant new opportunities to reduce the morbidity associated with pertussis in the United States. The primary objective of adolescent and adult Tdap vaccination is to provide protection against pertussis while maintaining the standard of care for protection against tetanus and diphtheria. A secondary objective of Tdap vaccination in the 10- to 64year age group is to reduce the reservoir of pertussis in the U.S. population and potentially the incidence of pertussis in other age groups, including infants who have the highest risk for complications from pertussis; it is unknown at this time the extent to which the secondary objective can be achieved through Tdap vaccination.^{2,3} A related objective of adult vaccination, reducing costs and disruption of pertussis in health care facilities and other institutional settings,³ is discussed in Chapter 3.

Statements and recommendations by the Centers for Disease Control and Prevention's (CDC's) Advisory Committee for Immunization Practices (ACIP) have been published regarding the one-time dose of Tdap vaccine for the following:

- Adolescents (ages 11 to 18)²:
 - A routine Tdap booster at age 11–12,* or catch-up between ages 11 and 18, to replace one Td booster vaccination
 - Or, if not previously given:
 - To replace the next Td booster, if indicated for wound management
 - For those who have, or anticipate having, contact with an infant aged < 12 months (both for personal protection and to reduce the risk for transmitting pertussis to the infant) (*see* Chapter 5)
 - In the immediate postpartum period for pregnant adolescent (*see* Chapter 5).
- Adults (ages 19 to 64)³:
 - To replace next decennial Td or, if indicated for wound management

Or, if not previously given:

- For those who have, or anticipate having, contact with an infant aged < 12 months (both for personal protection and to reduce the risk for transmitting pertussis to the infant) (*see* Chapter 5)
- In the immediate postpartum period for pregnant adults (*see* Chapter 5).

* While BOOSTRIX[®] is licensed for use in adolescents ages 10–18, the ACIP preferred age for Tdap vaccination is 11–12 years.²

Clinical feature/complication	Adolescents Ages 10–18 ¹	Adults Ages 19–64 ²
Paroxysmal cough	74%-100%	82–99%
Difficulty sleeping	77%	84%
Difficulty breathing	72%	86%
Posttussive vomiting	49%–71%	27%–62%
Whoop	31%–67%	33%–82%
Weight loss	33%	33%
Apnea	27%-86%	32%-85%
Urinary incontinence	3%	28%-34%
Pneumonia	2%	0.6%–5%
Hospitalization	0.8%–2%	2%–12%
Rib Fracture	1%	1%–4%
Loss of consciousness	1%	3%–6%
Seizure	0.2%-0.3%	0.2%-0.6%

Table 4-1. Clinical Features and Complication in Adolescents and Adults with Pertussis

References:

1. Adapted from Broder K.R., et al.: Preventing tetanus, diphtheria, and pertussis among adolescents: Use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 55:1–34, Mar. 24, 2006. http://www.cdc.gov/mmwr/PDF/rr/rr5503.pdf (accessed Feb. 16, 2010).

2. Adapted from Kretsinger K., et al.: 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 Recomm Rep* 55:1–37, Dec. 15, 2006. http://www.cdc.gov/mmwr/PDF/rr/rr5517.pdf (accessed Sep. 16, 2010).

It is important to note that, at the October 2010 meeting of the ACIP, some important changes to the previously published ACIP recommendations were approved¹⁰:

- For adults ages 65 years and older, a single dose of Tdap vaccine may be given in place of a tetanus and diphtheria toxoids (Td) vaccine, in persons who have not received Tdap.
- Adults ages 65 years and older who have or anticipate having close contact with an infant younger than 12

months should receive a single dose of Tdap to protect against pertussis and reduce the likelihood of transmission of pertussis to infants younger than 12 months.

 Children ages 7 through 10 years who are not fully immunized against pertussis and for whom no contraindication to pertussis vaccines exists should receive a single dose of Tdap to provide protection against pertussis. If additional doses of tetanus and diphtheria toxoid– containing vaccines are needed, then children ages 7 through 10 years should be vaccinated according to catch-up guidance.

Tdap can be administered regardless of the interval since the last tetanus- or diphtheria-containing vaccine.

The recommended DTaP vaccination schedule for children and the Td/Tdap vaccination schedule for adolescents and adults can be found in Chapter 1.

Economic Considerations

Various evaluations have found that Tdap vaccinations of adolescents and adults are cost-beneficial, with two economic studies in the United States identifying a one-time dose of Tdap during adolescence as a cost-effective strategy.^{11,12} Both studies identified a single dose of Tdap to be the most costeffective strategy, as Tdap vaccination in this age group would replace the already established Td booster that is routinely given; this is also the age group with the highest incidence of pertussis. Purdy et al. estimate that vaccinating this age group could potentially prevent 0.4–1.8 million cases of pertussis and save \$0.3–\$1.6 billion over a 10-year period.¹²

Economic studies further estimate that an adult vaccination program would likely prevent about 44% of pertussis cases over a 10-year period.^{13,14} Lee et al. found the combined medical and nonmedical costs associated with pertussis in adults can average almost \$800 per case patient and often results in missing almost 10 days of work.⁹

Tdap Reimbursement and Workers' Compensation

Hospitals have noted that some workers' compensation insurers do not reimburse for Tdap vaccine when administered in the course of treating a wound. By regulation, workers' compensation insurers are limited to paying for medical care related to treatment of an injury or disease related to the workplace. Because the acellular pertussis component of the Tdap vaccine is preventive, some workers' compensation insurers may determine that paying for the vaccine is beyond the scope of care that they are required to provide. However, Tdap is recommended by the ACIP to replace Td, so some states have included Tdap on their fee schedule. At the writing of this monograph, 25 state agencies have added Tdap to their fee schedules, thus providing the insurers the option of covering Tdap even though it has a preventive aspect. The determination of what services are compensated is made by the workers' compensation insurer and the provider. In general, the state workers' compensation agencies have no formal coverage determination process. Some states' agencies have suggested that providers work with the workers' compensation insurers to make a case for using Tdap vaccine in the treatment of workplace-related wounds.¹⁵

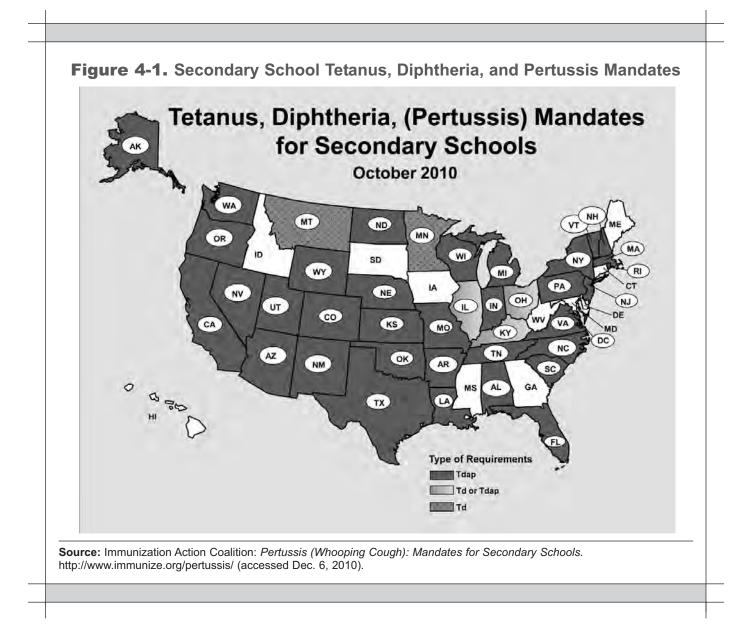
Barriers and Special Challenges to Vaccination

Barriers to vaccination can be found among health care providers and delivery systems at all levels of the private and public sectors.¹⁶ Differences exist in the barriers for adolescents and adults, so each will be examined individually.

Adolescents

The most recent information from the CDC shows Tdap vaccination rates among adolescents to be approximately 56%.¹⁷ Oster et al. surveyed family physicians and pediatricians regarding vaccination of adolescents, reporting that older adolescents are less likely to be assessed for immunization status and given indicated vaccinations than adolescents in the 11-to-13 age range.¹⁸ This finding is particularly troubling because immunity from prior pertussis infection or vaccination begins to wane in older children and adolescents, leaving them vulnerable to the disease and at risk of transmitting pertussis to infants.

Researchers have also found gaps in physician practices when compared to ACIP recommendations. For example, Tdap and MCV4 vaccine are recommended during the same medical visit,² but a study by Dempsey et al. demonstrates that some physicians will not coadminister the vaccines, indicating that they would wait one month between the two vaccines or would wait an unspecified period of time.19 In addition, pediatricians are more likely to recommend Tdap in place of a Td booster to their adolescent patients than are family practitioners. Davis et al. surveyed family physicians and pediatricians, asking if they thought pertussis was a serious enough disease to warrant giving Tdap, rather than Td, to adolescents; approximately 57% of the nearly 300 respondents agreed or strongly agreed that the disease warranted giving the vaccine.²⁰ These researchers also identified the need to educate physicians about the importance of integrating Tdap with other vaccines that are indicated for adolescents, especially among family practitioners.



Adults

The Tdap vaccination rate in adults ages 19–64 was only 5.9% in 2008.²¹ Although adolescents may receive a Tdap vaccination as part of state mandates for secondary schools (*see* Figure 4-1, above) or on the recommendation of a physician at a regular checkup, the only existing strategy to administer Tdap to adults on a broad scale is to wait for them to present to receive an updated Td and administer Tdap in its place.¹⁷ Clinicians, however, can be a barrier to adult vaccination despite the CDC's position that "every visit of an adult to a health care provider should be regarded as an opportunity to assess the patient's vaccination status and, if indicated, to provide protection against tetanus, diphtheria and

pertussis."^{3(p.17)} National survey data in the United States indicate that only 68% of internists and family physicians who see adult patients for outpatient primary care routinely administer Td for health maintenance when indicated.³ Johnson et al. found in their survey of 100 physician practices that physicians are less inclined to discuss immunizations during sick visits than during well-care visits or annual exams.²² Furthermore, while most physicians said they recommend tetanus vaccination to their patients, only 60% referred to official guidelines for information about adult vaccination, leading to concerns that some physicians may not be following recommended vaccination practices.²² In a joint statement regarding adult immunization practices by physicians, the American College of Physicians (ACP) and the Infectious Diseases Society of America (IDSA) note that primary care settings are the most appropriate and convenient settings within which to provide adult vaccinations because they serve as the medical home. The ACP and IDSA also recognize, however, that many patients with chronic diseases routinely visit subspecialists, who may be the source of vaccination administration or referral.²³ The bottom line: Physicians should either provide all needed vaccinations or refer the patient to someone who will.

Given that mandates for adult immunization are not likely, ongoing awareness campaigns and education of adults will be important in arming consumers with the information they need in order to ask their practitioners about vaccines. Ongoing education and awareness efforts are also needed to encourage practitioners to routinely evaluate their patients' vaccination status. This will require the commitment of all providers who care for patients across the health care system.¹⁶

A 2009 survey by the National Foundation for Infectious Diseases (NFID) further makes clear the crucial role physicians play in increasing vaccination rates for adult patients. Eighty-seven percent of the respondents said they would likely accept vaccinations if recommended by their physician.²⁴ The NFID, in its "Call to Action" on routine adult care and immunizations, advocated that adult immunization must become a fundamental aspect of routine patient care.¹⁶ A 2009 IDSA survey of membership in clinical practice found that approximately two-thirds of respondents were obtaining immunization histories from their patients, but only one-third were administering vaccines when indicated; two-thirds felt that infectious disease specialists should administer all ACIP–recommended vaccinations.²⁵

Davis et al. conducted a survey of family physicians and general internists regarding their attitudes and practices surrounding Td boosters, experience with pertussis, and attitudes about the Tdap vaccine, finding that 81% would recommend Tdap to their adult patients.²⁶ They also found a positive physician attitude toward Tdap vaccination of their adult patients when they stocked and administered Td booster vaccinations in their practices. The respondents further identified the following major barriers²⁶:

 Recordkeeping and knowing which patients need a Td booster (51%)

- Being too busy or having other priorities during patient visits (42%)
- Patient refusal or reluctance (42%)

Concerns less frequently cited included reimbursement or insurance issues (24%), vaccine supply (11%), and preferring to limit Td boosters to wound management (5%).²⁶

Except for influenza vaccination, the U.S. health care system has not focused on developing the infrastructure needed to achieve higher vaccination levels in adults.¹⁶ In a comparison of the successes in childhood immunization with the abysmal state of adult immunization, one study found the following²⁷:

- Childhood vaccination levels are at record highs, and vaccine-preventable diseases are at, or near, record lows; immunization levels among adults are low, including those for older adults and including the recommended pneumococcal and influenza vaccines (both at < 70%). Even though both vaccines have been recommended for more than 30 years, both pneumonia and influenza remain leading causes of death in older Americans.
- Ethnic and racial disparities have been greatly reduced among children but persist among adults.
- The Vaccines for Children program offers free vaccines to all uninsured children and those who are Medicaid eligible, Alaska Natives, or American Indian. There is no such corresponding program for adults, and, while most private insurance plans cover adult vaccinations, approximately 14% of adults younger than age 65 are uninsured.
- "Well child care" is a significant part of practices that provide care to children, but "well adult care" is not a major part of the care provided by practitioners caring for adults.

Trust for America's Health, a nonprofit organization working to make disease prevention a national priority, identified the following barriers to adult vaccination in general²⁸:

- No formal structure or system exists to ensure that adults have access to needed vaccines, except for some subgroups, such as adults serving in the military, attending colleges or universities, or working in health care settings where vaccine requirements often exist.
- Many adults change doctors and health plans frequently, and many do not have regular health examinations, which makes it difficult for physicians to track vaccinations and recommend needed vaccines to patients
- With many adults lacking health insurance coverage, cost can be a deterrent to vaccination.

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"We've had significant improvement in getting children immunized . . . but it's an embarrassment that we have done so poorly with adults."²⁸
 —Congressman Henry A. Waxman, Chairman of the House Energy and Commerce Committee

Johnson et al. conducted a survey of 2,000 people in 2006 to better understand why so many adults fail to receive recommended vaccinations. They identified the following reasons specific to tetanus (Td) vaccinations²²:

- False assumptions, such as healthy people do not need tetanus vaccinations or need them only when injured
- No physician recommendation for the vaccination or no regular physician contact
- Concerns about side effects or vaccine effectiveness
- Vaccination was not covered by insurance or cost too much
- Belief that the vaccine could cause the disease
- Fear of needles
- Concern that the vaccination might worsen a current condition or interact with medications

An NFID consumer awareness survey in 2007 found the following attitudes among adults¹²:

- 40% of respondents felt they did not need vaccines because they had had them as a child.
- 34% said they were not concerned about becoming ill with vaccine-preventable diseases.
- 32% said they were not concerned about spreading an infectious disease to family, friends, or coworkers.
- 25% did not think vaccine-preventable disease are serious or life threatening.

A 2009 NFID study of adults ages 18 and older found knowledge about vaccine-preventable diseases and awareness of available vaccines to be markedly low in young adults between the ages of 18 to 26.²⁴ Low awareness and knowl-edge often lead to lower vaccination rates, and this age group within the adult population may require focused strategies to encourage vaccination.

Standards for Vaccination Practices

The ACIP's general recommendations regarding vaccination cover topics such as timing and spacing of immunologics; contraindications and precautions; vaccine administration; storage and handling of immunologics; vaccination records and vaccination programs; and reporting adverse events after vaccination.²⁹ The recommendations contain a provision that physicians should follow established vaccination standards for children, adolescents, and adults.^{30,31}

The 2006 CDC general recommendations contain a summary of recommendations for improving vaccination coverage, based on a review of the literature by the CDC–appointed Task Force on Community Preventive Services in 1999.^{29,32} The Task Force's Web site, The Community Guide, at http://www.thecommunityguide.org/vaccines/universally/index.html, should be accessed for the most current information and recommendations. Table 4-2 on page 72 contains an overview of the task force's recommended interventions and recommendations for the implementation of the various interventions; a more detailed review of the task force's findings can be found elsewhere.³³

In addition, the IDSA issued guidelines in 2009 regarding immunization programs contain suggested strategies to improve vaccination coverage.³⁴ Table 4-3 on pages 73–74 summarizes the strategies identified in the IDSA guideline, along with the two publications on vaccination standards referenced in CDC's 2006 guideline. Each of the strategies found in Table 4-3 will be explored in this chapter.

Strategies to Improve Tdap Vaccination Coverage

The CDC Task Force on Community Preventive Services recommends a number of specific interventions to increase vaccination coverage in children, adolescents, and adults.^{33,35} As with health care personnel (HCP) vaccination programs, multifaceted adult and adolescent programs are more likely to be successful than are those employing one or only a few strategies.^{33,35,36} The following sections address the task force's recommendations related to standing orders, reminder and recall systems, expanded access to vaccinations, patient education, handheld vaccination records, review of patient vaccination status, assessment of patients for contraindications and precautions, provider performance assessment, and immunization information systems.

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Table 4-2. Overview of Recommendations for Interventions to ImproveCoverage of Vaccines Recommended for Routine Use Among Children,
Adolescents, and Adults

Intervention	Recommendation	
Interventions that increase community demand for immunization:		
Client reminder or recall systems	Strongly recommended	
 Multicomponent interventions, including education 	Strongly recommended	
 School, day care, and college-entry requirements 	Recommended	
Community education alone	Insufficient evidence*	
Clinic-based education	Insufficient evidence	
 Patient or family incentives or sanctions 	Insufficient evidence	
Client-held medical records	Insufficient evidence	
Interventions that enhance access to vaccination:		
 Reducing out-of-pocket costs 	Strongly recommended	
Enhancing access through the Women, Infants and Children	Recommended	
(WIC) program		
 Home visits, outreach, and case management 	Recommended	
 Enhancing access at day care centers 	Insufficient evidence	
 Enhancing access at schools 	Recommended	
 Enhancing access in health care settings 	Recommended as part of multicomponent	
	interventions only	
Interventions that target providers:		
Reminder or recall systems	Strongly recommended	
Assessment and feedback	Strongly recommended	
Standing orders	Strongly recommended	
Provider education alone	Insufficient evidence	

*A determination that evidence is insufficient does not imply ineffectiveness. Rather, it identifies areas of uncertainty regarding an intervention that requires more research.

Source: Adapted from Kroger A.T., et al.: General recommendations on immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 55:1–48, Dec. 1, 2006. http://www.cdc.gov/mmwr/ preview/mmwrhtml/rr5515a1.htm (accessed Jul. 20, 2010).

Strategy	Standards for Child and Adolescent Immunization Practices, 2003 ¹	Standards for Adult Immunization, 2003 ²	Immunization Programs for Infants, Children, Adolescents, and Adults: Clinical Practice Guidelines by the IDSA, 2009 ³
Standing orders		Standing orders are employed for vaccinations.	Standing orders for vaccinations should be established in clinics, hospitals, and nursing homes.
Reminder systems	Systems are used to remind par- ents/guardians, patients, and HCP when vaccinations are due	Systems are used to remind patients and HCP when vaccina- tions are due and to recall those	Systems are used to remind par- ents/guardians, patients, and HC when vaccinations are due and to
Recall systems	and to recall those who are overdue.	who are overdue.	recall those who are overdue.
Expanded access to vaccinations	HCP should seek advice from parents/guardians and parents to identify ways to make vaccination easier; barriers (e.g., requiring a well-care visit or long waiting periods in the office) should be	Providers should remove barri- ers to receiving vaccines (e.g., requiring a physical examination before vaccination or an addi- tional visit to receive it, long waiting periods, etc.).	Vaccination services should be easy to access using express services such as vaccination clin ics and expanded hours of serv- ice.
	minimized, and vaccination-only visits should be available.	Patient-oriented and community- based approaches are employed to reach target populations.	Vaccination should be integrated into routine health care services offered in clinics and offices.
			Providers should support use of community-based settings to vac cinate target populations that hav limited access to immunization providers (e.g., schools, childcar settings, hospitals, etc.).
Patient education	Parents/guardians and patients are educated about the benefits and risks of vaccination in appro- priate and understandable lan- guage.	Patients are educated about benefits and risks in easy-to- understand language. Vaccine Information Statements	Providers should educate parents and patients about risks, benefits and safety of vaccines in approp ate and understandable language
	Vaccine Information Statements (VISs) are given to each vaccine recipient.	(VISs) are available to give to each vaccine recipient.	Vaccine Information Statements (VISs) are given to each vaccine recipient or his or her parent.
Handheld vaccination records	HCP should ensure that each patient has a handheld vaccina- tion record and that he or she knows to bring it to each visit so it can be updated.	HCP should ensure that each patient has a handheld vaccina- tion record and that he or she knows to bring it to each visit so it can be updated.	Patients should be provided with accurate vaccination records that include dates and places of vacc nation and should be reminded of the importance of bringing their handheld vaccination record to each health care visit.
Review patient immu- nization status at each visit.	Providers should review the health and vaccination status of patients at each encounter to determine which vaccines are indicated.	Providers should routinely review the vaccination status of all new patients and on an annual basis thereafter.	The immunization status of patients should be reviewed at each visit.

Strategy	Standards for Child and Adolescent Immunization Practices, 2003 ¹	Standards for Adult Immunization, 2003²	Immunization Programs for Infants, Children, Adolescents, and Adults: Clinical Practice Guidelines by the IDSA, 2009 ³
Assess patients for valid contraindica- tions.	Providers should assess for and follow only those contraindica- tions that are medically accepted.	Providers should refer to current ACIP recommendations for valid and invalid vaccination con- traindications; failure to differen- tiate between valid and invalid contraindications can result in needless deferral of indicated vaccinations.	Providers should determine and follow valid vaccine precautions and contraindications for vaccina- tions that are given.
Performance assess- ment and feedback for providers	Office- or clinic-based patient record reviews and vaccination coverage assessments are per- formed annually.	Provider practices should con- duct regular assessments of immunization coverage rates (optimally done annually).	Provider practices should conduct regular assessments of immuniza- tion coverage rates.
Immunization infor- mation systems (IISs)	All patients' vaccinations should be reported to local or state immunization registries, where available. (Note: The American Academy of Pediatrics published recommendations in 2010 ⁴ that updated recommendations for provider and patient participation in IISs whenever possible, as a strategy to enhance vaccination coverage.)		Vaccine administration information should be entered into immuniza- tion information systems (i.e., immunization registries).

HCP: health care personnel

References:

1. Adapted from National Vaccine Advisory Committee: Standards for child and adolescent immunization practices. *Pediatrics* 112:958–963, Oct. 2003. Erratum in *Pediatrics* 113:184, Jan. 2004.

2. Adapted from Poland G.A., et al.: Standards for adult immunization practices. Am J Prev Med 25:144–150, Aug. 2003.

3. Adapted from Pickering L.K., et al.: Immunization programs for infants, children, adolescents, and adults: Clinical practice guidelines by the Infectious Diseases Society of America. *Clin Infect Dis* 49:817–840, Sep. 15, 2009. Erratum in *Clin Infect Dis* 49:1465, Nov. 1, 2009.

4. Hammer L.D., et al.: Increasing immunization coverage. *Pediatrics* 125:1295–1304, Jun. 2010.

Standing Orders

The task force strongly recommends the use of standing orders,^{33,35} which are written protocols that authorize nonphysician medical personnel to administer vaccinations to persons who meet certain criteria (for example, underlying condition or age), where permitted by law, in accordance with an institution- or physician-approved protocol without a physician's examination or direct physician involvement.³⁷ Several studies suggest that standing orders programs improve vaccination coverage among patients more than other strategies, when used alone or in combination with other strategies.37 In one hospital that began a standing orders program for pneumococcal vaccination for persons over age 65, the vaccination rate increased from 0% in the control group to 78%.38 In another study, pharmacists increased pneumococcal vaccination rates in one nursing facility from 4.2% to 94% and from 1.9% to 83% in another facility; rates at a control facility increased only from 0.9% to 4.0%.39

Standing orders can be used in a variety of settings, including inpatient and outpatient facilities, emergency departments, pharmacies, home health agencies, long term care facilities, and adult workplaces. Successful standing orders programs are relatively easy to implement but should be administered with the oversight of a team or committee (or an "immunization leader" in a smaller practice) that develops protocols for the following³⁷:

- The process for identifying persons who are eligible for vaccination, based on age and vaccination status or the presence of a medical condition that puts them at high risk
- How patients or their guardians are informed about the risks and benefits associated with a vaccine and documenting the delivery of that information
- How patient refusals or medical contraindications should be recorded
- How vaccine administration, and any adverse events postvaccination, should be recorded
- The process for documenting vaccine administration both for the patient and the primary care provider

Standing orders protocols should also specify that individuals who will be administering vaccines are properly trained to screen patients for contraindications to vaccination, administer the vaccines, and monitor patients for adverse events. In addi"Many doctors are not vaccine-savvy with respect to adults, and we need to educate them. Practices should have 'standing orders,' so that every patient who comes in is screened and asked questions about immunization and then receives the vaccines if they are needed."²⁸ —William Schaffner, M.D.,

Vanderbilt University School of Medicine, Department of Preventive Medicine

tion, staff administering vaccines should know how to report any adverse events to the national Vaccine Adverse Events Reporting System (VAERS). The Vaccine Information Statement for Tdap from the CDC can be useful in educating patients and for risk/benefit counseling before giving the vaccine; the tool is available on the CDC Web site, at http://www.cdc.gov/vaccines/pubs/vis/default.htm.⁴⁰

Appendix 4-1 on page 84 contains a sample standing order form for adult Td/Tdap, and Appendix 4-2 on page 85 contains a sample standing order form for children over age 7. Both forms are available on the Immunization Action Coalition Web site (at http://immunize.org). *See* Text Box 4-1 on page 76 for examples of how organizations that participated in this Joint Commission project incorporated standing orders into their practices.

A strategy that takes standing orders one step further is to provide only a supply of Tdap in the patient care area. If Td is needed, a special request/order is sent to the pharmacy to obtain it. Text Box 4-2 on page 76 provides an example of how one organization implemented such a strategy.

Reminder and Recall Systems

Patient and provider reminder and recall systems have been found to increase vaccination rates.³³ Supported by the ACIP and recommended by the CDC task force for use in all age groups, these systems can be implemented in a variety of settings.

Text Box 4-1. Organizations Use Standing Orders

- Bloomington Hospital is a 255-bed acute-care hospital in Bloomington, Indiana. The organization implemented standing orders for Tdap for any patient over age 10 and under age 65 in its emergency department in 2008. In January 2010, 100% of eligible patients seen for wound care received Tdap instead of Td.
- Michigan State University/Kalamazoo Center for Medical Studies is a university-based ambulatory care center with four primary care clinics, six specialty clinics, and many subspecialty clinics and on-site ancillary services in Kalamazoo, Michigan. The organization implemented the "Immunize Now!" vaccination campaign in 2006. Using standing orders and electronic health records, nurses assess each adolescent and adult patient seen for Tdap vaccination. Based on the center's approved standing order, nurses then administer the vaccine to patients meeting eligibility criteria. Contraindications to Tdap or patient declinations to receive the vaccine must be clearly documented in the patient's medical record; any patient record lacking such documentation is considered a missed vaccination opportunity that is documented and evaluated through the organization's quality improvement process. As of mid-2010, the organization had achieved vaccination rates of 91% in the adolescent (ages 10–16) population and 83% in the adult (ages 18 to 64) population.
- Ohio State University Student Health Services in Columbus, Ohio, developed standing orders for students that permit
 nurses to give Tdap rather than Td to those needing a Td booster. All of the approximately 1,400 professional health
 students at the university undergo a required review of their vaccination status before their clinical rotations, and Tdap
 vaccination status assessment is part of that evaluation process. They further strengthened their Tdap vaccination
 coverage rates by working with the health professionals' colleges to include Tdap in their admission requirements.
 While many in the university's total student body of 50,000 have received Tdap prior to coming to the school, the student health services has administered more than 2,000 doses of Tdap since 2006.

Text Box 4-2. Preferential Stocking of Tdap

Bartlett Regional Hospital, a 51-bed hospital in Juneau, Alaska, has a focused Tdap vaccination program for adolescent and adult patients. The main objective of the program is to provide Tdap to any patient coming to the emergency department for wound care, unless Tdap has been given previously or the patient is not eligible to receive the vaccine (for exapmle, because a contraindication exists, or the patient is over age 64). The emergency department does not stock Td. If a patient is ineligible for Tdap but eligible for Td, the staff obtains Td from the hospital's pharmacy. Now, all adolescent and adult patients receiving wound care in the emergency department are assured of receiving the needed vaccination. Patient reminder and recall systems send messages to patients or their parents to let them know that specific immunizations are due soon (reminders) or past due (recall).⁴ Reminders/recalls can be mailed or communicated by phone; auto-dialer systems are available to expedite phone calls. The messages can vary in their level of specificity and personalization and degree of automation. Similarly, provider reminder/ recall systems alert the HCP that a patient's vaccines are due or overdue. Such reminder/recall methods have been shown to improve vaccination coverage rates when used both alone and in combination with other strategies.⁴¹ Other forms of reminder systems include the following:

- 1. Computer-generated programs, using software that can be programmed to determine dates that vaccinations are due or past due and then printing reminder messages for patients with visits the next day. These systems can be effective, efficient, and inexpensive once the system is in place
- 2. Chart labels, such as a colorful sticker on the chart, or a comprehensive checklist of preventive services that includes vaccinations, are inexpensive and efficient;

"I get a card from my veterinarian when it's time to bring my dog and cat in for their shots. Why don't I get a card from my doctor when it's time for me to get mine?"²⁸ —Gregory A. Poland, M.D., Director, Mayo Clinic Vaccine Group

reminders that require some form of acknowledgement (even a simple check mark by the provider) are even more effective. Alternatively, an "immunization due" note can be stamped on, or attached to, the patient's chart.

Providers can design and implement their own reminder/recall systems, based on their own needs and the resources in the practice or setting. Whatever method(s) is used, reminder/recall systems can and should become routine provider practices. They can reduce missed vaccination opportunities, especially when combined with other strategies.⁴ Text Box 4-3, at right, describes one organization's successful use of a recall system.⁴²

Expanded Access to Vaccination

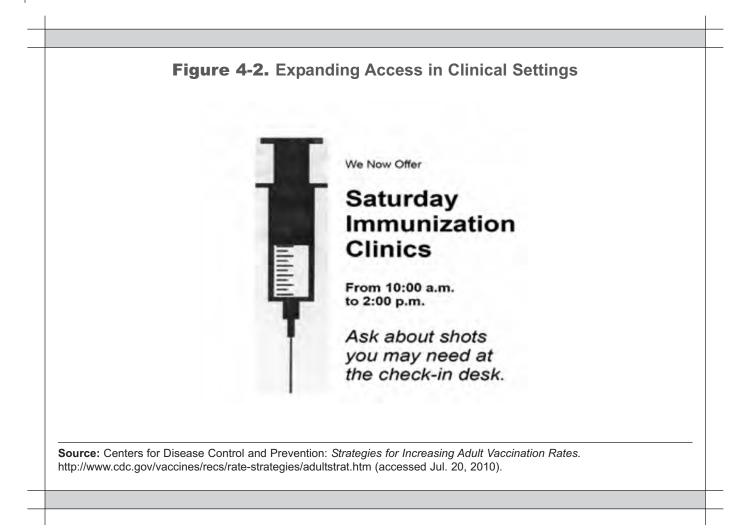
Expanding access to vaccinations is a strategy for increasing vaccination coverage in a variety of health care settings, including private practices, managed care settings, urgent care facilities, emergency departments, and hospitals. Providers should remove barriers to vaccination access, such as a requirement for a physical examination before vaccinations, long waiting periods, and additional visits in order to receive the vaccination.^{30,31,34} In addition, providers should incorporate vaccinations into routine care visits that are offered in clinics and private practices.³⁴ Expanding patient access to vaccination can also include strategies such as reducing the distance traveled to receive vaccinations; delivering vaccinations in settings not previously used; increasing or making the hours more convenient; and reducing barriers by incorporating "drop-in" (no appointment) clinics or express tract vaccinations. Recognizing that adolescents are the least likely pediatric population to have routine preventive care, Davis et al. underscore the importance of administering vaccinations in a variety of settings beyond that of the

Text Box 4-3. Improving Adolescent Vaccination Rates with a Telephone Recall System

Concern about low adolescent vaccination rates led Northeast Valley Health Corporation, a federally qualified health center with 12 licensed clinics in Los Angeles County, California, to implement a recall system for adolescents in need of Td/Tdap. The system was based on the health center's prior childhood vaccination program, which successfully used case managers to improve vaccination coverage among patients 24 to 35 months of age. The clinics began mailing postcards to adolescents one month prior to their 13th birthday if Td/Tdap had not been administered. When the postcards did not improve Td/Tdap vaccination rates, the health center implemented a more aggressive recall system, using trained case managers to call the parents/guardians of adolescent patients who had not received a recent Td/Tdap booster. A script for use by the case managers helps to ensure consistency in communications. During the calls, the case managers explain to parents that Tdap is a new vaccine available for their child, encourage the scheduling of a well-visit examination, and remind them to bring their child's record of prior vaccinations to the next office visit. This more aggressive recall system resulted in substantial improvement in vaccination rates: as of October 2007, the overall coverage for Td or Tdap increased to 81.1%.

primary care provider office.²⁰ When combined with other strategies, such as patient reminder/recall systems, expanding access has been very effective in increasing vaccination coverage⁴¹ and has been recommended by the CDC.^{33,35} Figure 4-2, page 78, contains an example of how expanded access to vaccinations can be communicated to patients.

Vaccinations in nontraditional settings can also be useful in efforts to enhance vaccine update. Such settings can include schools, child-care centers, churches or synagogues, or



pharmacies and can make delivery of vaccinations to children, adolescents, and adults more convenient. This strategy can be especially helpful in reaching target groups with limited access to providers. When community-based settings are used to deliver vaccinations, the same standards of care apply for screening, administering, and documenting vaccinations that apply to the traditional settings.³⁴

Patient Education

Patients and parents need to be educated about the risks, benefits, and safety of vaccination in language that is culturally appropriate and easy to understand. The Immunize.org Web site, http://www.immunize.org, offers educational information for patients on many vaccines, including pertussis vaccines. The CDC's Vaccine Information Statements (VISs) also provides patient information and is available both for individual and multiple vaccine combinations. The National Childhood Vaccine Injury Act of 1986 requires the use of VISs whenever most vaccines are administered. Providers should be sure they have and use the most current VISs, which can be downloaded from the Web sites of the Immunization Action Coalition, at http://www.immunize.org/vis,⁴³ or from the CDC, at http://www.cdc.gov/vaccines/pubs/vis/default.htm⁴⁰; many of the VISs on the former Web site are also available in Spanish and other languages. In addition, the Immunization Action Coalition's Web page "The Facts About Using VISs" provides information for health care personnel who may have misconceptions about the use of VISs.⁴⁴

Handheld Vaccination Records

Patients and parents should have a handheld (paper) vaccination record that indicates which vaccinations have been received. This record should be brought to each provider visit and updated with each vaccination. This strategy encourages patients and parents to be proactive in ensuring that they or their children are fully immunized.^{30,31}

Reviewing Patient Vaccination Status at Each Visit

Providers should review each patient's vaccination status when new patients are initially seen and annually thereafter to determine which vaccines are indicated.^{30,31,34} The assessment should include determining whether the patient has medical, lifestyle, or occupational risk factors for which certain vaccines are indicated. All assessment findings should be documented in the patient's medical record.³¹

Assess Patients for Valid Contraindications and Precautions

It is important that providers differentiate between valid and invalid contraindications for vaccinations, as failure to do so can result in needless deferral of indicated vaccinations. (*See* Table 4-4 on page 80 for valid contraindications and precautions for Tdap, as well as some of the invalid reasons for deferring this vaccination.) In general, a prior anaphylactic reaction to a vaccine or a component of the vaccine is a contraindication to administration.²⁹ Immunization standards state that providers should refer to current ACIP recommendations for valid and invalid contraindications.^{30,31} For example, a valid contraindication for Tdap is a patient history of coma or prolonged seizures not attributable to an identifiable cause within seven days of administration of a vaccine containing pertussis components.³⁰

A *precaution* is a condition in the vaccine recipient that might result in an adverse reaction. While a person might have a more serious reaction to the vaccine, the risk is less than expected with a contraindication. A precaution does not preclude vaccination; most precautions are temporary, permitting the vaccination to be given at a later date.²⁹ An example of a valid precaution for Tdap is a moderate or severe acute illness with or without fever.

Performance Assessment and Feedback for Providers

Most providers do not have an accurate perception of their own vaccination coverage rates,⁴ making regular assessment (audit) and feedback of vaccination coverage levels an important strategy for increasing vaccination rates.^{30,31,34,45} Assessment, along with feedback, creates awareness that is needed in order for vaccination coverage rates to improve. This strategy involves retrospective assessment of provider performance in delivering one or more vaccinations to the patient population, through review of patient records, followed by reviewing the results of the assessment with the providers. Performance can then be compared to a goal or standard, serving as an incentive for providers to do better. Another provider incentive is comparing his or her coverage rates against those of others in a given practice or setting. Ideally, assessment and feedback should be done at least annually, to identify suboptimal coverage levels and implement strategies to address them.^{4,31}

Vaccination coverage assessment and feedback can be implemented in various inpatient and ambulatory care settings, including private or group practices, urgent care settings or emergency departments, hospitals, and other settings. The process can be completed either by staff in the practice/facility, by an outside organization, or by state or local health departments. The CDC offers a free, downloadable software tool, the Comprehensive Clinic Assessment Software Application (CoCASA), to analyze vaccination coverage rates in any setting where vaccinations are provided and to identify the patient population in need of vaccination.⁴⁶ The program is part of the Assessment, Feedback, Incentives, and Exchange (AFIX) methodology for improving vaccination coverage levels and standards of health care delivery.⁴⁷ The AFIX acronym stands for the following:

- Assessment of the provider's vaccination coverage levels and immunization practices
- Feedback of results to the provider along with recommended strategies to improve coverage levels
- *I*ncentives to recognize and reward improved performance
- Exchange of health care information and resources necessary to facilitate improvement

More information about CoCASA is available at http://www.cdc.gov/vaccines/programs/cocasa/default.htm; more information about AFIX is available at http://www.cdc.gov/vaccines/programs/afix/default.htm.

Text Box 4-4 on page 81 contains an example of how an ambulatory care organization that participated in this Joint Commission project assessed its adolescent Tdap vaccination program.

Valid Contraindications	Valid Precautions	Invalid Reasons for Deferring
 Severe allergic reaction (e.g., anaphylaxis) after a previous vaccine dose or to a vaccine component Encephalopathy (i.e., coma, decreased level of con- sciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administra- tion of previous dose of DTP, DTaP, or Tdap 	 Moderate or severe acute ill- ness with or without fever Guillain–Barré syndrome < 6 weeks after a previous dose of tetanus toxoid–containing vaccine Progressive or unstable neu- rological disorder, uncon- trolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized History of arthus-type hyper- sensitivity reactions following a previous dose of tetanus toxoid–containing vaccine. Defer vaccination until at least 10 years have elapsed since the last tetanus toxoid– containing vaccine. 	 Invalid reasons in general (applicable for any vaccine, including Tdap): Mild acute illness with or without fever Mild to moderate local reaction (e.g., swelling, redness, soreness); low-grade or moderate fever after previous dose Lack of previous physical examination in well-appearing person Current antimicrobial therapy Convalescent phase of an illness Recent exposure to an infectious disease History of penicillin allergy or other nonvaccine allergies, relatives with allergies, receiving allergen extract immunotherapy Invalid reasons specific to Tdap: Temperature > 104° F (> 40.5° C) for < 48 hours after vaccination with a previous dose of DTP or DTaP Collapse or shock-like state < 48 hours after receiving a previous dose of DTP/DTaP Seizure < 3 days after receiving a previous dose of DTP/DTaP Persistent, inconsolable crying in an infant lasting > 3 hours within 48 hours after receiving a previous dose of DTP/DTaP History of extensive limb swelling after DTP/DTaP/Td that is not an arthus-type reaction Stable neurologic disorder Brachial neuritis Latex allergy that is not anaphylactic Breastfeeding Immunosuppression

Table 4-4. Contraindications and Precautions for Tdap

Source: Adapted from Kroger A.T., et al.: General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep.* 55:1–48, Dec. 1, 2006. http://www.cdc.gov/mmwr/PDF/rr/rr5515.pdf (accessed Jul. 5, 2010).

Text Box 4-4. Medical Group Practice Assesses Tdap Vaccination Coverage

Rochester General Medical Group in Rochester, New York, is a large medical practice with several offices. The practice recently began a Tdap immunization quality initiative that will require each office to annually review 100 records for 12-year-old patients to check for documentation that Tdap has been given. The physician submitter for this Joint Commission project noted that his office had a 100% Tdap vaccination rate in its 12-year-old patient population in 2010.

Immunization Information Systems

Immunization information systems (IISs, previously known as immunization registries) are confidential, computerized information systems that collect and consolidate vaccination data from multiple health care providers, generate reminder and recall notifications, and assess vaccination coverage within a defined geographic area.⁴⁸ Such systems have been recommended for use whenever possible as a critical tool that can increase and sustain vaccination coverage.^{30,31} A fully operational IIS also can prevent duplicate vaccinations, reduce vaccine waste, limit missed appointments, and reduce staff time required to locate vaccination records or certificates (*see* Text Box 4-5, above, for an example of how one organization has used an IIS to streamline the vaccination process). The use of IISs in the United States has continued to grow, as the following statistics demonstrate⁴⁸:

- In 2008 75% of all U.S. children younger than 6 years of age were registered in an IIS, up from 65% in 2006.
- More than 80% of IISs surveyed in 2008 also had the capacity to track vaccinations for persons of all ages, up from 70% in 2006.

The CDC is continuing to look for ways to include more adolescent and adult vaccination data in IISs. The American Academy of Pediatrics also endorses the development and implementation of IISs, recognizing the importance of bidirectional flow of vaccination information, which permits providers to not only enter vaccination data

Text Box 4-5. Ambulatory Organization Uses IIS

Michigan State University/Kalamazoo Center for Medical Studies in Kalamazoo, Michigan, utilizes the state's IIS to facilitate vaccination assessment and vaccine administration. The nurses in this ambulatory care facility routinely assess each patient at every visit for needed vaccinations, including Tdap. At each patient visit, the nurses access the state's immunization information system that contains vaccination documentation for Michigan children, adolescents, and adults. Nurses then print and review the record; document what vaccinations are needed; administer Tdap as indicated; and document its administration in the electronic medical record and the IIS.

but also retrieve patient-specific vaccination histories.⁴⁹ Presently, many IISs are not compatible with existing electronic health records (EHRs); the CDC is working to implement national standards that would enhance the interoperability of data exchanges between EHRs in provider offices and IISs.⁴⁸

Areas for Future Research

Ongoing efforts to further delineate the impact of adolescent and adult Tdap vaccination involves close monitoring of pertussis disease trends and vaccine safety; to that end, the CDC has established and supports active surveillance sites in Minnesota and Massachusetts.^{2,3} Further research is needed to evaluate and define the following:

- Physician uptake of Tdap over time
- · Immunologic correlates of pertussis protection
- Improved diagnostic tests for pertussis
- Methods to enhance coverage and delivery of Tdap
- The safety and effectiveness of repeated doses of Tdap

In the adolescent population, the safety and immunogenicity of both simultaneous and nonsimultaneous administration of MCV4 and Tdap needs further study; in addition, the risk factors for and prevalence of extensive limb swelling in adolescents who receive Tdap and who

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were vaccinated with five doses of pediatric DTaP series needs further study.² For adults, further research is needed to establish the following:

- The safety and immunogenicity of Tdap among pregnant women and their infants
- The effectiveness of deferring antibiotic prophylaxis in recently vaccinated HCP exposed to pertussis

In summary, this chapter has reviewed the recommendations for routine use of Tdap in adolescent and adults, barriers to vaccination in each age group, and strategies for enhancing Tdap vaccination coverage. The next chapter will review the use of Tdap vaccination in adolescents and adults in contact with infants, a practice that has come to be known as "cocooning."

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Appendix 4-1

(Available at http://www.immunize.org/catg.d/p3078.pdf; accessed July 21, 2010)

Standing Orders for Administering Tetanus-Diphtheria Toxoids & Pertussis Vaccine (Td/Tdap) to Adults

Purpose: To reduce morbidity and mortality from tetanus, diphtheria, and (where indicated) pertussis by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate adults who meet the criteria below.

Procedure

- Identify adults in need of vaccination against tetanus, diphtheria, and (where indicated) pertussis based on the following criteria:

 lack of documentation of at least 3 doses of tetanus- and diphtheria-containing toxoids
 - b. younger than age 65 years with no history of pertussis-containing vaccine given since age 10 years
 - c. completion of a 3-dose primary series of tetanus- and diphtheria-containing toxoids with receipt of the last dose being 10 years ago or longer
 - recent deep and dirty wound (e.g., contaminated with dirt, feces, saliva) and lack of evidence of having received tetanus toxoid-containing vaccine in the previous 5 years
- Screen all patients for contraindications and precautions to tetanus and diphtheria toxoids (Td) and, if applicable, pertussis vaccine (Tdap):
 - a. Contraindications:
 - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of Td or to a Td or Tdap component. For a list of
 vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - for Tdap only, a history of encephalopathy within 7 days following DTP/DTaP given before age 7 years

b. Precautions:

- · history of Guillain-Barré syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine
- history of an Arthus reaction following a previous dose of tetanus-containing and/or diphtheria-containing vaccine, including meningococcal conjugate vaccine
- · an unstable neurologic condition
- · moderate or severe acute illness with or without fever
- Note: Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester.
- 3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
- 4. Administer 0.5 mL Td (or Tdap, if appropriate) vaccine intramuscularly (22-25g, 1-11/2" needle) in the deltoid muscle.
- 5. Provide subsequent doses of Td (a one-time dose of Tdap may be substituted for Td if younger than 65 years) to adults as follows:
 - a. to complete the primary 3-dose schedule: observe a minimum interval of 4 weeks between the first and second doses, and 6 months between the second and third doses.
 - b. to boost after primary schedule is complete: observe a 10-year interval since previous dose of Td/Tdap; if protection against pertussis is needed, intervals as short as 2 years or less can be observed for parents and caregivers of infants younger than age 12 months, healthcare workers having direct patient contact, and adults in a pertussis outbreak setting.
 - c. In pregnancy, when indicated, give Td or Tdap in 2nd or 3rd trimester. If not administered during pregnancy, give Tdap in immediate postpartum period.
- 6. Document each patient's vaccine administration information and follow up in the following places:
 - a. Medical chart: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.
- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
- Report all adverse reactions to Td and Tdap vaccines to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967, VAERS report forms are available at www.vaers.hhs.gov.

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Appendix 4-2

(Available at http://www.immunize.org/catg.d/p3078a.pdf; accessed July 21, 2010).

Standing Orders for Administering Td/Tdap to Children Ages 7 Years and Older

Purpose: To reduce morbidity and mortality from tetanus, diphtheria, and (if indicated) pertussis by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and teens who meet the criteria below.

Procedure

- Identify children and teens ages 7 years and older in need of vaccination against diphtheria, tetanus, and (if indicated)
 pertussis based on the following criteria:
 - a. lack of documentation of at least 3 doses of diphtheria, tetanus, and (if indicated) pertussis vaccine
 - b. lack of history of pertussis-containing vaccine given since age 10 years
 - c. completion of a 3-dose primary series of diphtheria and tetanus toxoid-containing vaccine with receipt of the last dose being 10 years ago or longer.
- 2. Screen all patients for contraindications and precautions to Td or Tdap:

a. Contraindications:

- a history of a serious reaction (e.g., anaphylaxis) after a previous dose of Td or to a Td or Tdap component. For a list of
 vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
- for Tdap only, a history of encephalopathy within 7 days following DTP/DTaP given before age 7 years; give Td instead
 Precentions:

b. Precautions:

- · history of Guillain-Barré syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine
- for Tdap only, a progressive neurologic disorder
- history of an Arthus reaction following a previous dose of tetanus-containing and/or diphtheria-containing vaccine, including meningococcal conjugate vaccine
- · moderate or severe acute illness with or without fever

Note: Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester.

3. Provide all patients (parent/legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.

4. Administer 0.5 mL Td (or a one-time dose of Tdap, if indicated) intramuscularly (22-25g, 1-11/2" needle) in the deltoid muscle.

- 5. Schedule vaccination as follows:
 - a. For children and teens ages 7 years and older who have not received a primary series of at least 3 doses of tetanus and diphtheria toxoid-containing vaccines, give one dose at the earliest opportunity and then schedule subsequent doses by observing minimum intervals of 4 weeks between the first and second doses, and 6 months between the second and third doses. Children ages 7–9 years should receive Td only. A one-time dose of Tdap may be substituted for any dose of Td if child is age 10 years or older.
 - b. Provide a routine booster of Tdap at age 11-12 years if at least 5 years have elapsed since previous dose of Td.
 - c. If an adolescent 11-18 years received Td instead of Tdap as a booster, give Tdap with an interval of 5 years since prior Td. If immediate protection against pertussis is needed (e.g., pertussis outbreak), an interval as short as 2 years or less can be observed. Give further boosters as Td every 10 years.
 - d, In pregnancy, when indicated, give Td or Tdap in 2nd or 3rd trimester. If not administered during pregnancy, give Tdap in immediate postpartum period.
- 6. Document each patient's vaccine administration information and follow up in the following places:
 - a. Medical chart: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.
- Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
- Report all adverse reactions to Td and Tdap vaccines to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

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 Tdap Vaccination Strategies for Adolescents and Adults, Including Health Care Personnel:

 Strategies from Research and Practice

CHAPTER 5

Vaccination of Adolescents and Adults in Contact with Infants

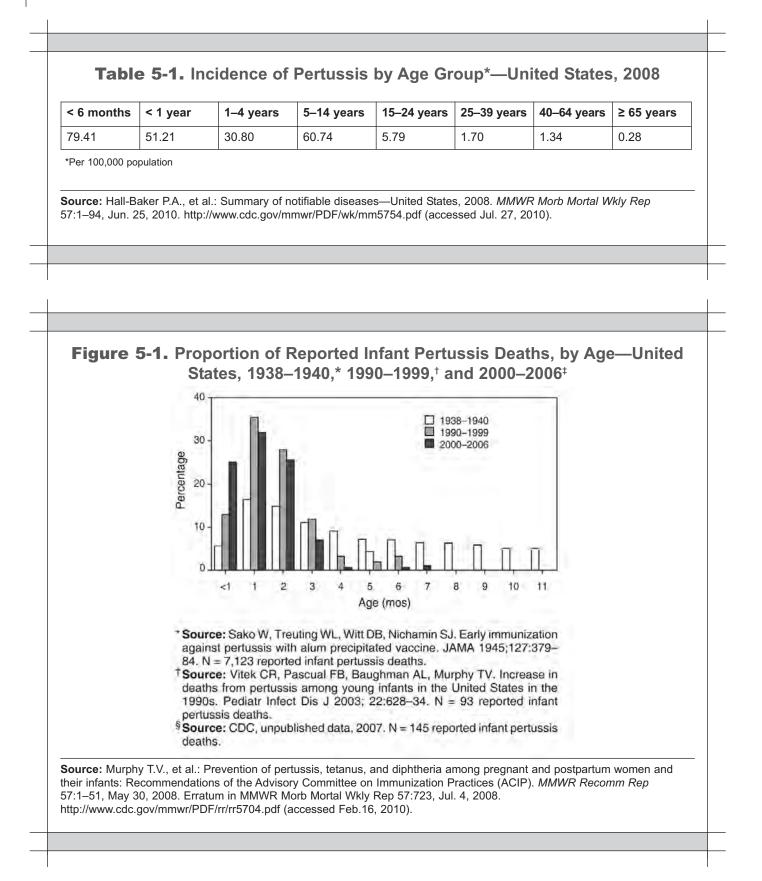
Summary of Key Points

- Parents and other household contacts are frequent sources of pertussis for infants.
- The most effective strategy to ensure that women are protected from pertussis is to give adolescent and adult women of childbearing age a one-time dose of Tdap prior to conception.
- Although not recommended, pregnancy is not a contraindication for Tdap, but the risks and benefits of the vaccination should be explained to the patient before offering the vaccination.
- Postpartum Tdap programs are a useful means of enhancing Tdap vaccinations and "cocooning" the infant from pertussis from the mother and others who will be in contact with the infant.
- Postpartum programs that also deliver Tdap to fathers and other household contacts further protect the infant from pertussis and expand the protective cocoon.

Adolescents and adults are a significant source of pertussis for infants less than 12 months of age. Although placental transfer of pertussis antibodies does occur, Healy et al. found the levels to be low and that they declined rapidly, thereby providing little to no protection for infants in early infancy.¹ Infants are not protected against pertussis until they have received three doses of DTaP in the first year of life (recommended for them at ages 2, 4, and 6 months).² This makes infants under 6 months of age especially vulnerable to pertussis and at the greatest risk for severe disease and death. Infants in this age group also continue to have the highest reported rate of pertussis.² Table 5-1 on page 88 shows the incidence of pertussis by age group, and Figure 5-1 on page 88 provides information about the proportion of infant deaths.

Parents, including new mothers, with pertussis are the source of infection for their infants in more than 25% of cases.² Bisgard et al. reviewed data from four states participating in the Enhanced Pertussis Surveillance (EPS) program from 1999 to 2002. These found that, when a source was identified, family members or relatives were the suspected source of pertussis for 75% of the infants ages 0 through 3 months and 73% of those ages 4 to 11 months.³ Of interest is the percentage of cases in which the source could not be identified—more than 50%—likely because the source had a mild or unrecognized pertussis infection³ (*see* Table 5-2 on page 89). Other researchers have also

Tdap Vaccination Strategies for Adolescents and Adults, Including Health Care Personnel: Strategies from Research and Practice



identified the important role household contacts play in transmission of pertussis to infants, including the following:

- Elliott et al. studied infant hospitalizations in Australia, finding 140 infants with pertussis; the most common source of infection (approximately 70%) was an adult, with parents accounting for 50% of reported contacts.⁴
- When Wendelboe et al. conducted an international, multicenter study of laboratory-confirmed infant pertussis cases and their household and nonhousehold contacts, household contacts were the identified sources for 76% to 83% of the infant pertussis cases.⁵ Identified contacts, broken down as to the source of infection, were as follows:
 - Parents: 55%
 - Siblings: 16%
 - Aunts/uncles: 10%
 - Friends/cousins: 10%
 - Grandparents: 6%
 - Part-time caregivers: 2%
- de Greeff et al. conducted a prospective study in the Netherlands to identify who introduced pertussis into the households of infants hospitalized for pertussis. In 96 households, the most likely source of infection in the infant was a sibling (41%), the mother (38%), or the father (17%).⁶

The findings from these researchers underscore why it is important for adolescents and adults who anticipate contact with an infant under age 12 months to receive Tdap vaccinations, preferably 2 weeks or more prior to anticipated contact with an infant.²

Tdap Vaccination of Adolescents and Adults in Contact with Infants

Recent data from the Centers for Disease Control and Prevention (CDC) estimate that approximately half of adults who received a tetanus vaccination during 2005 to 2008 received Tdap, but Tdap vaccination coverage among adults with infant contact was only 5%.⁷ Despite these low compliance rates, Tdap vaccination of adolescents and adults has been recommended in the United States since 2006 to reduce the burden of pertussis among those vaccinated and to help prevent transmission of the disease to infants.^{8,9} In 2008 the CDC further recommended that pregnant women who were not previously vaccinated with Tdap receive Tdap before discharge from the hospital or birthing center.² All three Tdap recommendations (*see*

Table 5-2. Reported Source ofPertussis Among Infants Aged< 12 Months, 1999–2002</td>

Source	Number (%)
Mother	84 (32)
Father	39 (15)
Grandparent	22 (8)
Sibling	52 (20)
Other	67 (25)
Total	264 (100)

Source: Adapted from Bisgard K.M., et al.: Infant pertussis: Who was the source? *Pediatr Infect Dis J* 23:985–989, Nov. 2004.

Appendix I-1, beginning on page xiii) encourage targeted vaccination of adolescents and adults in contact with infants younger than 12 months of age, as follows:

- For adolescents (ages 11 to 18) and adults (aged 19–64) who have not previously received the vaccine⁸:
 - For those who have, or anticipate having, contact with an infant aged < 12 months (both for personal protection and to reduce the risk for transmitting pertussis to the infant)
 - In the immediate postpartum period for pregnant adolescents
- Pregnant women who have not been previously vaccinated with Tdap²:
 - Should receive Tdap in the immediate postpartum period before discharge from the hospital or birthing center
 - Should receive Td during pregnancy for tetanus, diphtheria protection, when indicated, or defer Td vaccine indicated in pregnancy to substitute Tdap vaccine in the immediate postpartum period if the woman likely has sufficient protection to tetanus and diphtheria

It is important to note that, at the October 2010 meeting of the CDC's Advisory Committee on Immunization



Practices (ACIP), some important changes to the previously published ACIP recommendations were approved¹⁰:

- 1. For adults ages 65 years and older, a single dose of Tdap vaccine may be given in place of a tetanus and diphtheria toxoids (Td) vaccine in persons who have not received Tdap.
- 2. Adults ages 65 years and older who have or anticipate having close contact with an infant age less than 12 months should receive a single dose of Tdap to protect against pertussis and reduce the likelihood of transmission of pertussis to infants age less than 12 months.
- 3. Tdap can be administered regardless of the interval since the last tetanus- or diphtheria-containing vaccine.
- 4. Children ages 7 through 10 years who are not fully immunized against pertussis and for whom no contraindication to pertussis vaccines exists should receive a single dose of Tdap to provide protection against pertussis. If additional doses of tetanus and diphtheria toxoid–containing vaccines are needed, then children ages 7 through 10 years should be vaccinated according to catch-up guidance.

The strategy of administering Tdap vaccinations to individuals who are likely to serve as a source of pertussis infection to an infant too young to be fully protected against pertussis is known as "cocooning."^{2,11} This includes vaccinating mothers, fathers, siblings, grandparents, and other caregivers in contact with the infant. This strategy results in herd immunity, which is the resistance of a group to invasion and spread of an infectious agent due to the resistance to infection of a high proportion of individuals within the group. The strategy reduces, but does not eliminate, the risk of infants becoming infected with pertussis.¹¹

Because new mothers have frequently been identified as the source of their infant's pertussis, the strategy of immunizing women prior to pregnancy or during or in the immediate postpartum period will be reviewed first. Following that discussion, the expanded strategy of immunizing others who are likely to have infant contact will be reviewed. The description of the various approaches to cocooning and how health care organizations have employed these strategies demonstrate the following themes discussed in Chapter 4 and in other areas of this monograph:

• The use of a multifaceted approach: Multifaceted programs for adults and adolescents are more likely to be successful than those employing one or a few strategies, and the CDC's Task Force on Community Preventive Services and others have recommended this approach to improve vaccination coverage in both clinic-based and community-based settings.¹²

- The role of champions: It's important to identify a physician or nurse to be key advocates of and role models for the vaccination program. The CDC has advocated the vaccination of senior medical staff or opinion leaders to improve vaccination rates in members under their leadership.¹³
- The use of standing orders: Standing orders are written orders that authorize nonphysician medical personnel to administer vaccinations in accordance with an institutionor physician-approved protocol without a physician's examination or direct physician involvement.¹⁴ Several studies suggest that standing orders programs improve vaccination coverage among patients more than other strategies, when used alone or in combination with other strategies.¹⁴
- The importance of educating HCP about pertussis, Tdap vaccinations, and the cocoon theory: Health care personnel (HCP) play a key role in providing support and enthusiasm for the program. Without such support, the success of a program is jeopardized.
- The importance of education for the postpartum patient and her family: Patients and parents need to be educated about the risks, benefits, and safety of vaccination in language that is culturally appropriate and easy to understand. The Vaccine Information Statement (VIS) is a helpful source of information and is available both for individual and multiple vaccine combinations. VISs are patient education sheets developed by the CDC (available at http://www.cdc.gov/vaccines/pubs/vis/default.htm).
- Removing barriers to vaccination whenever possible: Expanding patient access to vaccination can include practices such as reducing the distance traveled to receive vaccinations; increasing or making the hours more convenient; delivering vaccinations in settings not previously used; or reducing barriers by incorporating "drop-in" (no appointment) clinics or express-lane vaccinations.

Tdap Vaccination of Women

Gerbie and Tan note that, even though there is growing awareness of the importance of preventing pertussis through Tdap vaccination, educational programs for obstetricians and gynecologists are needed.¹⁵ For example, Power et al. found that approximately 79% of obstetrician/gynecologists stock and administer at least some vaccines but that Tdap was stocked by fewer than 30% of the practices.¹⁶ In a national survey of

obstetricians, 78% indicated that they would recommend Tdap vaccination of postpartum women prior to discharge, but most thought that pediatricians, adult primary care providers, and public health providers also share a responsibility for promoting Tdap for adults, including fathers and close relatives, who may be in contact with an infant.¹⁷

Preconception Tdap

The most effective strategy to ensure that women are protected from pertussis, as well as tetanus and diphtheria, is to give adolescent and adult women of childbearing age a one-time dose of Tdap during a routine wellness visit.² Any physician practice that sees women could provide this vaccination, and a recent pilot study on providing human papillomavirus (HPV) and Tdap to nonpregnant and postpartum women found obstetrician/gynecologist offices to be ideal venues for offering these vaccinations.¹⁸ Tdap, which had not been offered to women in these settings previously, was accepted by almost 600 of 1,000 women in the pilot study. Researchers concluded that both HPV and Tdap vaccination programs could be implemented in obstetrician/gynecologist offices with relative ease, providing another important component to preventive care.¹⁸

Tdap at Prenatal Visits

Prenatal visits provide an opportunity to review vaccination histories for Td, tetanus toxoid (TT), or Tdap and any adverse reactions to the vaccines. The ACIP has developed criteria for safely deferring Td booster vaccinations until after delivery, meaning that Tdap can be substituted for Td for most women after delivery.²

It should be noted that, while pregnancy is not a contraindication for receiving Tdap, the CDC's ACIP recommends that providers weigh the theoretical risks and benefits of the vaccine before choosing to administer Tdap to a pregnant women.² (See Table 5-3 on page 92 for a summary of the ACIPs recommendations for Td and Tdap vaccination of pregnant women.) In August 2009, the American College of Obstetricians and Gynecologists (ACOG) updated its 2003 committee opinion on tetanus and diphtheria vaccination and pregnancy, supporting the 2008 ACIP recommendations. ACOG indicated that, while preconception vaccination is preferred to vaccinating during pregnancy in order to avoid unnecessary exposure to the fetus, Tdap may be considered for administration in the second or third trimester for pregnant women who need tetanus or diphtheria protection during pregnancy.19

In special situations in which pregnant women are at increased risk for tetanus, diphtheria, or pertussis, the ACIP recognizes that providers may elect to give Tdap during pregnancy, though data to inform this decision are scarce.² If Tdap is given to a pregnant woman, she should be advised of the following:

- There are currently no data to confirm the safety and immunogenicity of Tdap in pregnant women.
- The potential for early protection of the infant against pertussis by transplacental maternal antibodies is unknown.
- There could be an adverse effect of maternal antibodies on the ability of the infant to mount an adequate response to antigens in pediatric DTaP or conjugate vaccines containing tetanus toxoid or diphtheria toxoid.

The woman should also be advised of the benefit of Tdap vaccination: the reduced risk of contracting or transmitting tetanus, diphtheria, and pertussis.² ACOG's committee opinion supports Tdap administration during the second or third trimester to add protection against pertussis.¹⁹ The American Academy of Pediatrics also recommends that pregnant adolescents be considered for Tdap vaccination, just as nonpregnant teens would be; for pregnant teens, the preferable timing for vaccination is during the second or third trimester.²⁰

Even if a decision is made to wait until after delivery to administer Tdap, prenatal visits offer an important opportunity to discuss the risks of pertussis for newborns and the importance of receiving Tdap before discharge from the hospital or birthing center. In addition, pregnant women should be monitored throughout pregnancy for respiratory illness suggestive of pertussis or exposure to pertussis and prescribed a macrolide antimicrobial for treatment of pertussis or prophylaxis against it.²

The ACIP has also said that there is no evidence to demonstrate whether Tdap, when given during pregnancy, provides transplacental antibodies that protect infants against pertussis. Nor is there any evidence at this time that Tdap–induced transplacental maternal antibody will have a negative impact on an infant's immune response to routine pediatric DTaP or to conjugate vaccines containing tetanus toxoid or diphtheria toxoid.²

No prelicensure studies of the use of Tdap in pregnant women were conducted, but both Tdap manufacturers have

Td Recommendations	Tdap Recommendations
Pregnant women should receive Td vaccine if indi-	Pregnancy is not a contraindication for use of Tdap.
cated. Previously vaccinated pregnant women who have	Data on safety, immunogenicity, and the outcomes of
not received a Td vaccination within the past 10 years	pregnancy are not available for pregnant women who
should receive a booster dose.	receive Tdap. When Tdap is administered during preg-
	nancy, transplacental maternal antibodies might protect
Pregnant women who have not received three doses of	the infant against pertussis in early life. They also could
a vaccine containing tetanus and diphtheria toxoids	interfere with the infant's immune response to infant
should complete a series of three vaccinations. Two	doses of DTaP and leave the infant less well protected
doses of Td should be administered during pregnancy to	against pertussis.
ensure protection against maternal and neonatal	
tetanus. The preferred schedule in pregnant women is	The Advisory Committee on Immunization Practices
two doses of Td separated by four weeks and a dose of	(ACIP) recommends Td when tetanus and diphtheria
Tdap six months after the second dose (postpartum).	protection is required during pregnancy. In some situa-
Health care providers can choose to substitute a single	tions,* health care providers can choose to administer
dose of Tdap for a dose of Td during pregnancy.	Tdap instead of Td to add protection against pertussis.
	When Td or Tdap is administered during pregnancy, the
Although no evidence exists that tetanus and diphtheria	second or third trimester is preferred.
toxoids are teratogenic, waiting until the second	
trimester of pregnancy to administer Td is a reasonable	Providers who choose to administer Tdap to pregnant
precaution for minimizing any concern about the theoret-	women should discuss the lack of data with the pregnant
ical possibility of such reactions.	women and are encouraged to report Tdap administra-
	tions, regardless of the trimester, to the appropriate man-
	ufacturer's pregnancy registry: for BOOSTRIX, [®] to
	GlaxoSmithKline Biologicals, at 888-452-9622, and for
	ADACEL®, to sanofi pasteur, at 800-822-2463.

Source: Centers for Disease Control and Prevention: Guidelines for Vaccinating Pregnant Women. http://www.cdc.gov/vaccines/pubs/preg-guide.htm (accessed Jul. 27, 2010).

established registries to solicit voluntary reports of Tdap administration to pregnant women. The ACIP has recommended that all women vaccinated with Tdap during pregnancy be reported to the registry. At the writing of this monograph, two clinical trials were in the process of recruiting participants for testing maternal Tdap immunization. The trials focused on the following areas²¹:

- Tdap vaccination of women in their third trimester of pregnancy and whether passive protection is provided to the infant, either transplacentally or through breast milk. This study will also evaluate the safety of Tdap in pregnancy.
- The safety of vaccinating pregnant women in the third trimester as well as the safety of maternal vaccination in infants. In addition, this study will evaluate the effect of maternal vaccination on the infants' immune responses when vaccinated with DTaP.

Postpartum Tdap

For women who have not received a dose of Tdap previously, including those who are breastfeeding, Tdap in the immediate postpartum period boosts protection against pertussis, as well as tetanus and diphtheria.² Elevated levels of pertussis antibodies in vaccine recipients are likely within one to two weeks of the vaccination.² In hospitals and birthing centers, HCP can implement protocols to facilitate Tdap vaccination of postpartum women before their discharge. Standing orders for Tdap have been used successfully in this population and have been recommended by the ACIP and others as a strategy most likely to enhance vaccination coverage in general.^{12,14,22} If Tdap cannot be given at or before discharge, the dose should be given as soon as possible thereafter.

Despite national recommendations that women receive Tdap in the immediate postpartum period, substantial efforts are necessary to overcome challenges to implementing a postpartum Tdap vaccination program. The experience of some researchers in this area is offered in the following brief summaries:

• Healy et al. identified several challenges based on their own experience in implementing a Tdap program at Ben Taub General Hospital in Houston, Texas.²³ The hospital cares for a predominantly Hispanic, underinsured, and

medically underserved population. This population was likely to have received little information about pertussis or Tdap vaccination recommendations or to have access to the vaccine. Staff challenges included the following:

- Many HCP lack awareness that immunity to pertussis, either from childhood vaccination or natural infection, wanes after 5 to 10 years.
- Obstetrical care providers needed to be aware of the ACIP immunization recommendations, as well as order, stock, and administer the vaccinations, and educate mothers about pertussis and the vaccination.
- Time, effort, and costs are associated with the above challenges.
- Access to accurate immunization records of potential vaccinees can be problematic.

The researchers offered strategies they found useful in overcoming some of the barriers, including the following:

- Provide intensive education, adapting educational strategies to the target audience. For example, smallgroup discussions worked well with nurses and translators, but physicians responded better to lecture-style education. All must understand the rationale behind postpartum Tdap vaccination and have an opportunity to ask questions and have their concerns addressed.
- The implementation of standing orders ensured that most women were offered Tdap.
- Postpartum nurses should incorporate education about pertussis and Tdap vaccination into the routine postpartum information provided to patients, making them key vaccine advocates.
- Accessing immunization information systems (IISs) or registries (where available) can facilitate identification of women not previously given Tdap.
- In the first 25 months of the Tdap vaccination program at Texas Children's Hospital, 8,334 (75%) of the women who delivered at the hospital received Tdap prior to being discharged. Another 6% who were not administered Tdap during their hospital stay had previously received the vaccine—many at this hospital following the birth of a previous baby.²⁴ The experiences of this health care organization with a largely Hispanic population is of special note, given a 2010 pertussis outbreak in California, during which all of the pertussis-related

deaths occurred in otherwise healthy Hispanic infants under 2 months of age.²⁵ For unknown reasons, the Hispanic population is disproportionately represented in pertussis incidence and mortality rates.²

- Fowler et al. began implementing a postpartum Tdap vaccination program in 2006 at the Medical University of South Carolina in Charleston, focusing on implementing standing orders for postpartum Tdap administration.²⁶ This primary goal was achieved by the following actions:
 - Identifying a physician champion, who provided educational sessions for the nursing staff
 - Identifying key steps in the implementation process, such as obtaining vaccine supply, obtaining approval for standing orders through committees, educating and training staff, and obtaining VISs in English and Spanish.

Through the use of a survey, these researchers also captured postpartum patients' knowledge and beliefs about the vaccine, thereby identifying a need to target highly educated women who, overall, were less receptive to vaccine uptake.

- Mouzoon et al. implemented an office-based influenza vaccination program for pregnant women in a large obstetrics and gynecology practice, using strategies that might translate well into postpartum Tdap vaccination programs²⁷:
- The researchers first established baseline influenza vaccination rates for each physician's pregnant population (using billing data) and provided feedback to each physician. They identified a physician champion who encouraged nurse assessments of patients' vaccination status and promoted influenza vaccination of patients at every opportunity. Vaccination rates and educational updates were provided to all staff on a quarterly basis.
- Standing orders for influenza vaccine administration were revised and reinforced through staff training.
- Obstetric nurses were educated about influenza and trained to provide the vaccinations; they were also encouraged to identify and complete vaccinations for eligible patients.

Influenza vaccination rates increased over the baseline of 2.5% to 21.1% in 2003–2004; 30.6% in 2004–2005; 32.5% in 2005–2006; 40.5% in 2006–2007; and 46.5% in 2007–2008. The researchers found wide variability in vaccination rates by provider, suggesting that physician education and feedback are essential to increasing vaccine

uptake. The study also identified the importance of having the necessary equipment and protocols in place, along with appropriate budgeting and billing practices.²⁷

Text Box 5-1 on page 95 contains an example of how one hospital used a multidisciplinary approach to implement its program.

As discussed previously, getting the support and buy-in of staff is key to the success of a postpartum Tdap vaccination program. Text Box 5-2 on page 95 describes an organization which ensured that staff are educated and engaged in the vaccination program.

Tdap Vaccination for Others with Infant Contact

Mothers are not the only ones who can transmit pertussis to infants. Tdap vaccinations for fathers, siblings, grandparents, and other caregivers are an important component of creating a protective "cocoon" for infants. Expanding Tdap vaccination to this inclusive group of contacts can present new challenges, with their disparate nature making them difficult to target.²⁸ Examples of research related to vaccine delivery strategies for others in close contact with infants include the following:

Walter et al. studied the impact of providing Tdap vaccinations to parents who were bringing their newborn to a pediatric office during the first month of life. A study coordinator provided written information about the project as well as the Tdap VIS. The coordinator reviewed information and obtained informed consent before a clinic nurse administered the vaccine. Of the 160 parents eligible, 82 (51.2%) accepted the vaccination. Although almost 60% accepted the vaccination when it was first offered, more than 40% accepted it on a subsequent office visit during the infant's first month of life, pointing to the importance of offering the vaccine to parents more than once. The vaccine was provided at no charge, and no insurance reimbursement was sought to cover the cost of the vaccine or its administration. The authors recommend that, prior to implementing a program of this nature, practices consider how vaccines will be ordered and stocked, review the billing and registration processes, and determine how proof of vaccination will be provided to the vaccinated parents. They also recognize that additional strategies to achieve cocooning through Tdap vaccination of fathers need to be identified.29

Text Box 5-1. Using a Multidisciplinary Approach to Implement a Hospital Postpartum Tdap Program

Edward Hospital and Health Services in Naperville, Illinois, delivers approximately 3,500 newborns annually. The organization's July 2009 launch of a Tdap vaccination program for postpartum women required the cooperation and support of many individuals and departments, including the following:

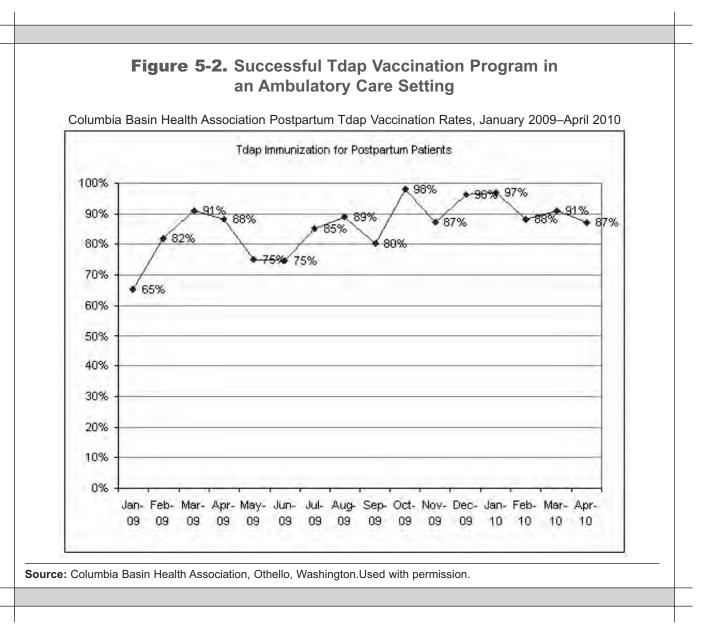
- With the support of the medical director for infection control, who worked with physicians in the obstetrics department, standing orders for Tdap vaccine were drafted, approved, and put into routine use in the obstetrical department.
- Working with the information technology department, the clinical leader of the mother/baby unit made changes in the computer documentation program to incorporate prompts for nurses to educate patients about the vaccine and offer it prior to discharge. A prompt to remind the nurse to administer the vaccine was added to the discharge assessment.
- The information technology department helped develop an online consent form that was tied to the pertussis education material; when the consent form printed, educational materials automatically printed.
- Because many postpartum patients also need measles, mumps, and rubella (MMR) vaccine, hepatitis B vaccine, and perhaps RhoGam or influenza vaccine prior to discharge, the pharmacy department developed a protocol for administering multiple injections.

During the same year the program launched, the hospital admitted two infants who were believed to have been infected with pertussis by mothers and/or siblings. Those two cases strengthened the conviction of staff that Tdap vaccination was important for their postpartum patients. Since the implementation of the postpartum Tdap program, approximately 40% of eligible women have accepted the vaccination. Fathers and other family members are also educated about pertussis and encouraged to get Tdap vaccine at an immediate care facility or from their private physician prior to the infant's discharge.

Text Box 5-2. Supportive HCP Are Important to Program Success

Although Columbia Basin Health Association in Othello, Washington, offers Tdap in lieu of Td to eligible adults at all well exams at its three ambulatory centers across three counties, the organization wanted to be sure the vaccine was provided to the eligible postpartum patients. In addition to the education on pertussis and the benefits of Tdap vaccinations that staff provide to eligible patients, the organization implemented a standing orders program by using an order form from the Immunization Action Coalition Web site (*see* Appendix 4-1 on page 84). When new mothers come to the clinics two to six weeks after delivery, the nurse reviews Tdap vaccination status, provides education if Tdap is indicated, and administers the vaccine if indicated and accepted by the patient. Tdap vaccination rates are tracked on a monthly basis and are also part of an incentive program for the nurses. If a nurse meets the goal of administering Tdap vaccinations to 90% or more of the eligible postpartum patients he or she sees in a given month, a \$20 bonus is awarded. The postpartum Tdap vaccination is one of 10 measures that the organization tracks, so a maximum bonus of \$200 per month per nurse is possible. Before implementing the standing orders and incentive program in January 2009, the postpartum Tdap vaccination rate was 2.4%. Since the program was implemented, monthly Tdap vaccination rates have climbed to an average of 85% (*see* Figure 5-2 on page 96).

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• Healy et al. began giving Tdap to postpartum patients in 2008 and expanded the program the next year to include family members of newborn infants.²³ The hospital customized a location on the postpartum unit where family members consented to the vaccination as per ACIP recommendations and as required by Texas law and were vaccinated with Tdap. Funding for this second phase of the Tdap program was provided through a grant and was supported with more than 17,000 doses of donated vaccine from a Tdap manufacturer; physician time is donated. An average of 2 family members per infant receive Tdap, although as many as 10 in one family have

been vaccinated; two-thirds of those vaccinated have been fathers of the newborn. $^{\rm 24}$

 Dylag and Shah evaluated the feasibility of providing Tdap to parents in a tertiary care, Level III neonatal intensive care unit (NICU).³⁰ Over a four-month period, all parents of admitted NICU patients were informed of the risks and benefits of Tdap via an informational letter at the infant's bedside. All staff were educated about pertussis and its serious and potentially life-threatening consequences and were encouraged to reinforce the benefits of the vaccination with the parents. The NICU provided vaccinations 20 hours per day at no charge. During the study period, 598 parents had infants admitted to the NICU and 495 (82.8%) were offered the vaccine. Overall, 430 parents (86.9%) accepted the vaccination.³⁰

- Shah et al. also support this approach, suggesting that the NICU is a logical venue to provide Tdap vaccinations for parents and other close contacts, given the family-centered nature of NICU programs and the interest NICU staff have in taking all possible steps to ensure the safety and well-being of their patients.²⁸ Limited access to vaccination, a potential deterrent to adult vaccination, is reduced by the 24/7 availability of trained medical staff. Further, they recognize that referring parents and others elsewhere to get vaccinations can be inconvenient and may fail to increase vaccine uptake.
- Although not directly related to Tdap, the successful influenza vaccination program developed by Burke et al. used the cocooning strategy to protect infants while in the nursery and postdischarge.³¹ The influenza vaccine was provided at no cost to family members, caregivers, and others who shared a residence with the newborns. Citing other researchers who have had success with influenza vaccination for families with NICU infants^{32,33} and recognizing the program's potential for positive outcomes, as well as its alignment with the organization's mission, hospital administrators funded the program. Identified problems were quickly resolved by two of the nursery's nurse champions, who made rounds each day to see every patient, taking the vaccination to the bedside and making it available to visiting family members. Education was provided to hospital staff and families regarding the benefits of the vaccination. By the end of influenza season, 185 potential infant contacts had been vaccinated, many of whom likely would not have otherwise received the vaccination. Based on this successful program, the hospital is planning to expand the influenza program to a year-round effort to provide Tdap to infant contacts.

Text Box 5-3 at right provides an example of how one ambulatory care organization that participated in this Joint Commission project successfully provides Tdap vaccinations to family members at the mother's first postpartum visit.

Areas for Future Research

Outside of efforts to eliminate neonatal tetanus and influenza in pregnant women, limited attention has been focused on the

Text Box 5-3. Maximizing the Pertussis Cocoon for Infants

Michigan State University/Kalamazoo Center for Medical Studies (MSU/KCMS) is a university-based ambulatory care center with four primary care clinics, six specialty clinics, many subspecialty clinics, and onsite ancillary services. Most women bring their families with them to their first postpartum visit, and the clinics use this as an opportunity to provide education on pertussis and the benefits of Tdap vaccinations. Since 2006, new mothers have been offered Tdap if they have not previously received the vaccination. Family members who are not patients at the clinics are either referred to their own physicians or given a recommendation to get the vaccination at the on-site pharmacy. When the order is written for patients, it generates an order that automatically prints in the on-site pharmacy. Because families walk past the pharmacy on their way out of the clinics, it is convenient for family members to have the pharmacist give them the vaccination before they leave. If a family member fails to get the vaccination, the pharmacist sends that information back to the clinics, which permits care managers to proactively follow up with family members to encourage them to get the vaccination. As of July 2010, 91% of all eligible adolescents and 83% of all eligible adults seen at their clinics had received Tdap. Information about vaccinations administered is routinely documented in the immunization information system (IIS) for the state.

vaccination of pregnant women as an approach to preventing disease in women and their infants during the first months of life.² Vaccine trials have traditionally been limited, due to concerns about liability from adverse outcomes that might be temporally related to vaccination. It would be beneficial, however, to better understand the following²:

- The safety of Tdap vaccine for pregnant women and their fetuses, as well as pregnancy outcomes
- Timing of vaccination and its effect on the immunogenicity of Tdap vaccine in pregnant women and transplacental maternal antibodies

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- The degree and duration of protection provided in transplacental maternal antibodies against pertussis in early infancy
- The effects of transplacental maternal antibodies (induced by pertussis, DTP, DTaP, and/or Tdap) on infant responses to active immunization with pediatric DTaP and conjugate vaccines that contain tetanus toxoid or diphtheria toxoid

Studies are also needed to determine the safety and any benefits of accelerated infant pertussis vaccination schedules or dosing (for example, pertussis vaccination starting at birth or employing acellular vaccines that do not contain diphtheria toxoid and tetanus toxoid), to better understand the range of options available to protect women and infants. The most effective and practical approaches to reducing the morbidity and mortality of pertussis will be determined by studying infant vaccination strategies independently or in conjunction with those of pregnant women.²

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CHAPTER 6

Guidelines and Other Resources Related to Pertussis, Pertussis Vaccination, and Strategies to Enhance Tdap Vaccination Rates

Summary of Key Points

- Many recognized health care leaders encourage health care organizations to use the resources described in this chapter to inform their Tdap vaccination program improvement efforts.
- Although these groups may have differences of opinion on certain aspects of organizational vaccination programs, they all recognize the importance of vaccinating adolescents and adults against pertussis.
- A more comprehensive list of resources, along with resources available from other organizations, appears in Appendix 6-1, beginning on page 104.

An overview of the guidelines, recommendations, and resources available related to pertussis disease and the tetanus, diphtheria, and acellular pertussis (Tdap) vaccine is useful for health care organizations implementing or seeking to improve Tdap uptake among both patients and health care personnel (HCP). A brief synopsis of the organizations that collaborated with The Joint Commission on this project, and of pertussis-related information from these and other sources, is provided in this chapter. These organizations include the Centers for Disease Control and Prevention (CDC), the National Foundation for Infectious Diseases (NFID), the Society for Healthcare Epidemiology of America (SHEA), and the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC). A more comprehensive list of resources, along with resources available from other organizations, is provided in Appendix 6-1.

The Centers for Disease Control and Prevention

The following two CDC committees have key roles in immunization guidance and infection prevention and control practice guidance:

• The Advisory Committee on Immunization Practices (ACIP) consists of 15 experts in fields associated with immunization. The ACIP provides advice and guidance to the secretary of the U.S. Department of Health and Human Services (HHS), the assistant secretary for HHS, and the CDC on the control of vaccine-preventable diseases. The role of the ACIP is to provide recommendations that will lead to a reduction in the incidence of vaccine-preventable diseases in the United States and an increase in the safe use of vaccines and related biological products. The committee develops recommendations for routine administration of vaccines to children and adults in the civilian population; specific ages for vaccine administration, the number of doses that should be given, and the dosing interval; and vaccination precautions and contraindications. The ACIP is the only entity in the federal government that makes such recommendations.

• The Healthcare Infection Control Practices Advisory Committee (HICPAC) is a federal advisory committee made up of 14 external infection prevention and control experts who provide advice and guidance to the CDC and the secretary of HHS. The committee advises on the practice of health care infection prevention and control and strategies for surveillance of health care–associated infections in U.S. health care facilities. One of the primary functions of HICPAC is to issue recommendations for preventing and controlling health care–associated infections in the form of guidelines, resolutions, and informal communications.

The CDC has many pertussis- and Tdap–related resources and guidelines for both the general public and HCP, including the following:

- A pertussis Web site that has information related to the epidemiology of the disease, clinical signs and symptoms, risk factors, transmission, complications, and vaccination (available at http://www.cdc.gov/vaccines/ vpd-vac/pertussis/default.htm)
- The ACIP recommendations on pertussis immunization are available at the following locations:
 - For adults: "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" is available at http://www.cdc.gov/mmwr/preview/mmwrhtml/ rr5517a1.htm?s_cid=rr5517a1_e.
 - For adolescents: "Preventing Tetanus, Diphtheria, and Pertussis Among Adolescents: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)" is

available at http://www.cdc.gov/mmwr/preview/ mmwrhtml/rr5503a1.htm.

 For pregnant and postpartum patients and their infants: "Prevention of Pertussis, Tetanus, and Diphtheria Among Pregnant and Postpartum Women and Their Infants: Recommendations of the Advisory Council on Immunization Practices (ACIP)" is available at http://www.cdc.gov/mmwr/ preview/mmwrhtml/rr5704a1.htm.

Important changes to these three recommendations were made at the October 2010 meeting of the ACIP and were published in the January 14, 2011 *MMWR*, available at http://www.cdc.gov/mmwr/PDF/wk/mm6001.pdf.

 A Web site with recommendations and guidelines for improving adult vaccination rates is available at http://www.cdc.gov/vaccines/recs/rate-strategies/ adultstrat.htm.

Many additional pertussis and pertussis vaccination resources are available from the CDC (*see* Appendix 6-1).

National Foundation for Infectious Diseases

The NFID is a nonprofit organization whose mission includes education of the public and HCP regarding infectious diseases. As a liaison member to the ACIP, the NFID supported the recommendations for Tdap vaccination. The resources related to vaccination include the following:

- A Web siteproviding information related to diphtheria, tetanus, and pertussis, available at http://www.nfid.org/pertussis/
- Press releases announcing the NFID's support of the CDC's recommendations regarding Tdap vaccination of HCP, adolescents, and adults, available at http://www.nfid.org/pertussis/media.html
- Publications related to immunization regarding increasing compliance, best practices, and raising awareness, available at http://www.nfid.org/publications/. Examples of available publications include the following:
 - "Adolescent Vaccination: Bridging from a Strong Childhood to a Healthy Adulthood"
 - "Saving Lives: Integrating Vaccines for Adults into Routine Care"
- A Web site (http://www.adultvaccination.org) specific to adult vaccination, sponsored by GlaxoSmithKline; sanofi pasteur; Merck & Co., Inc.; and Wyeth Pharmaceuticals.

The site features information on vaccine-preventable diseases, and it includes a public service announcement about the impact of pertussis.

Society for Healthcare Epidemiology of America

SHEA exists to advance the application of the science of health care epidemiology. Strengthened by active membership in all branches of medicine, public health, and health care epidemiology, the society offers multiple resources related to pertussis and the use of Tdap.

As a liaison member to the ACIP and HICPAC, SHEA supported the recommendations regarding the administration of Tdap to HCP. SHEA publications include articles specific to pertussis and vaccination against pertussis in the monthly journal *Infection Control & Hospital Epidemiology*, available at http://www.journals.uchicago.edu/toc/iche/current (enter the search term "pertussis").

Association for Professionals in Infection Control and Epidemiology, Inc.

APIC is an organization leading the way in improving health and patient safety by reducing risks for infection and other adverse outcomes. APIC, also a liaison to HICPAC, has links to various resources about pertussis, pertussis vaccination, and related infection prevention and control practices, available using the search feature on APIC's home page, at http://www.apic.org; enter search term "pertussis."



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Appendix 6-1

Examples of Professional Health Care Organizations and Agencies with Pertussis and Pertussis Vaccination Resources

					Age Group the source Addres		Specialty Populations the Resource Addresses			
Organization Name	Description	Examples of Resources	For More Information (All Web sites accessed July 14, 2010)	0–9 Child	10–18 Adolescent	19–64 Adult	НСР	Parents	Pregnant Women	
American Academy of Pediatrics (AAP)	Not-for-profit corpo- ration organized for scientific and educa- tional purposes. The AAP's mission is to promote the optimal health and well-being of infants, children, adolescents, and	The AAP provides immuniza- tion and vaccination safety information and schedules. The organization supports the ACIP recommendations that adolescents receive a one-time dose of Tdap vac- cine instead of Td.	AAP home page: http://www.aap.org AAP pertussis information and vaccine recommendations: http://www.aap.org/immunization/ illnesses/dtp/pertussis.html	x	х		x	x		
	young adults.	The AAP also supports the HealthyChildren.org Web site, designed for parents	http://www.aap.org/immunization/ about/chapterinitiatives.html	X	Х	Х	Х	Х	х	
		and caregivers. Vaccine and other health information and guidance are available on the Web site.	Healthy Children home page: http://www.healthychildren.org	Х	Х			х	Х	
		The AAP publishes the Red Book® in print and online. The information is practice focused, and current clinical guidelines are presented on 200 common childhood con- ditions, including pertussis. Immunization schedules are downloadable from the Red Book® Web site. Additional forms are available through an online subscription.	The Red Book [®] is available at http://aapredbook.aappublications.org	X	X	X	X	X	X	

					Age Group the source Addres		Specialty Populations the Resource Addresses		
Organization Name•	Description	Examples of Resources	For More Information (All Web sites accessed July 14, 2010)	0–9 Child	10–18 Adolescent	19–64 Adult	НСР	Parents	Pregnant Women
Association for Professionals in Infection Control and Epidemiology (APIC)	Professional organi- zation that repre- sents professionals practicing infection prevention, control, and epidemiology globally. APIC's mis- sion is to promote zero tolerance for health care-associ- ated infections (HAIs) and to ensure that appropriate standards and measures are established.	APIC provides professional certification, continuing edu- cation, and policy recom- mendations related to the reduction of HAIs. In addi- tion, APIC supports research related to infection prevention initiatives. Membership is not required to browse APIC's listserv, which includes discussion threads regarding pertussis and pertussis vaccination. Access "APICList" on the home page to get to the listserv. APIC has links to various resources about pertussis, pertussis vaccination, and related infection prevention and control activities. Use the "search" feature on APIC's home page.	APIC home page: http://www.apic.org		x	x	x		

(continued)

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					Age Group the source Addres			ialty Popu source Ad	ations the dresses
Organization Name	Description	Examples of Resources	For More Information (All Web sites accessed July 14, 2010)	0–9 Child	10–18 Adolescent	19–64 Adult	НСР	Parents	Pregnant Women
Centers for Disease Control and Prevention (CDC)	Federal government agency/public health. The CDC's mission is to promote health and quality of life by preventing and con- trolling disease, injury, and disability.	The CDC develops and posts general information, resources, and guidelines on vaccination for both the gen- eral public and HCP. The CDC has published three recommendations regarding Tdap [refer also to Appendix I-1]:	CDC home page: http://www.cdc.gov/ CDC Vaccine Administration: http://www.cdc.gov/vaccines/recs/ vac-admin/default.htm	x	x	х	x	x	x
		2006 adolescent Tdap. recommendations: Preventing tetanus, diphthe- ria, and pertussis among adolescents: Use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP). <i>MMWR Recomm</i> <i>Rep</i> 55:1–34, Mar. 24, 2006.	Adolescent recommendations available at http://www.cdc.gov/mmwr/PDF/rr/ rr5503.pdf		X				X
		2006 adult recommendations: Preventing tetanus, diphthe- ria, and pertussis among adults: Use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vac- cine: 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-	Adult recommendations available at http://www.cdc.gov/mmwr/PDF/rr/ rr5517.pdf			X	X	X	X

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					Age Group the source Addres			ialty Popul source Ade	ations the dresses
Organization Name	Description	Examples of Resources	For More Information (All Web sites accessed July 14, 2010)	0–9 Child	10–18 Adolescent	19–64 Adult	НСР	Parents	Pregnant Women
CDC, continued		care personnel. <i>MMWR</i> <i>Recomm Rep</i> 55:1–37, Dec. 15, 2006.							
		2008 pregnant/postpartum women and their infants rec- ommendations: Prevention of pertussis, tetanus, and diph- theria among pregnant and postpartum women and their infants: Recommendations of the Advisory Committee on Immunization Practices (ACIP). <i>MMWR Recomm</i> <i>Rep</i> 57:1–51, May 30, 2008. Erratum in <i>MMWR Morb</i> <i>Mortal Wkly Rep</i> 57:723, Jul. 4, 2008.	Pregnant/postpartum women and their infants recommendations available at http://www.cdc.gov/mmwr/PDF/rr/ rr5704.pdf		X	X		X	X
		The ACIP made important revisions to the above three recommendations at the October 2010 meeting.	2010 ACIP updated Tdap recommendations available at http://www.cdc.gov/mmwr/PDF/wk/ mm6001.pdf						
		Information regarding pertus- sis disease, DTaP and Tdap, vaccine safety, clinical infor- mation for HCP, additional references, provider educa- tion, and materials for patients are available on this site.	Vaccines & Immunizations, pertussis vaccination Web page: http://www.cdc.gov/vaccines/vpd-vac/ pertussis/default.htm	X	Х	x	Х	×	x
		Under "Recommendations and Guidelines" on the per- tussis vaccination page, strategies for improving adult vaccination rates are available.	Strategies for improving adult vaccina- tion rates: http://www.cdc.gov/vaccines/ recs/rate-strategies/adultstrat.htm			X		x	x

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				Re	Age Group the source Addres			ialty Popul source Ad	ations the dresses
Organization Name	Description	Examples of Resources	For More Information (All Web sites accessed July 14, 2010)	0–9 Child	10–18 Adolescent	19–64 Adult	НСР	Parents	Pregnant Women
CDC, continued		A self-study education pro- gram, "Adult Immunization 2010," is available for HCP (Webcast released June 15, 2010).	Self-study program available at http://www.cdc.gov/vaccines/ed/ adultimupdate/default.htm			X	X		
		The CDC oversees the National Center for Health Statistics (NCHS) program that conducts and publishes the annual National Health Interview Survey (NHIS). Survey results are publicly available and are used to monitor the overall health of the U.S. population, including the incidence of pertussis.	Annual National Health Interview Survey (NHIS) results: http://www.cdc.gov/nchs/index.htm	X	X	X	X	X	Х
		The CDC's NCHS works with the National Center for Immunizations and Respiratory Diseases (NCIRD) to conduct and pub- lish an annual National Immunization Survey (NIS). Survey results, which are publicly available, are used to monitor the vaccination rates for children, adoles- cents, and adults.	National Immunization Survey (NIS) results (by state): http://www.cdc.gov/ vaccines/stats-surv/imz-coverage.htm	X	X	X	X	X	X
		The NCIRD publishes the <i>Epidemiology and Prevention</i> of Vaccine-Preventable <i>Diseases</i> (The Pink Book). The Pink Book provides vaccine-preventable disease information that HCP can download for free or purchase online. The Pink Book	Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book): http://www.cdc.gov/vaccines/pubs/ pinkbook/pink-chapters.htm	x	X	x	x	X	X

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			-		Age Group the source Addres			ialty Popul source Ad	ations the dresses
Organization Name	Description	Examples of Resources	For More Information (All Web sites accessed July 14, 2010)	0–9 Child	10–18 Adolescent	19–64 Adult	НСР	Parents	Pregnant Women
CDC, continued		includes clinical information (e.g., diagnosis and medical manage- ment) as well as vaccination safety information. Chapter 14 of the Pink Book is specific to per- tussis and pertussis vaccination.							
		Manual for the Surveillance of Vaccine-Preventable Diseases also includes a chapter specific to pertussis (Chapter 10). The chapter covers case identification and definition, laboratory testing, and vaccination.	Manual for the Surveillance of Vaccine-Preventable Diseases: http://cdc.gov/vaccines/pubs/ surv-manual/default.htm	X	Х	X	X	X	X
CDC Advisory Committee on Immunization Practices (ACIP)	Federal government advisory committee.	The ACIP provides advice intended to reduce the incidence of vaccine-preventable diseases in the United States and increase the safe administration of vac- cines. All published ACIP recom- mendations on immunization, including DTaP and Tdap, can be accessed from this site.	CDC ACIP home page: http://www.cdc.gov/vaccines/recs/ acip/default.htm	x	Х	X	x	X	X
CDC Healthcare Infection Control Practices Advisory Committee (HICPAC)	Federal government advisory committee.	HICPAC provides advice regard- ing the practice of health care infection prevention and control, strategies for surveillance, and prevention and control of health care–associated infections in U.S. health care facilities. HICPAC issues guidelines, resolutions, and informal communications intended for HCP.	CDC HICPAC home page: http://www.cdc.gov/hicpac/	x	Х	x	X		

(continued)

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				Age Group the Resource Addresses			Specialty Populations the Resource Addresses		
Organization Name	Description	Examples of Resources	For More Information (All Web sites accessed July 14, 2010)	0–9 Child	10–18 Adolescent	19–64 Adult	НСР	Parents	Pregnant Women
GlaxoSmith Kline (GSK)	For-profit pharma- ceutical corporation. GSK's mission is to improve the quality of life by enabling people to do more, feel better, and live longer. Manufactures the BOOSTRIX [®] (Tdap) vaccine.	GSK develops and manufac- tures medicines and vac- cines. GSK provides BOOSTRIX® (Tdap vaccine) information that includes dosing, schedule, and safety- related issues. GSK supports a Web site to educate the general public.	GSK home page: http://www.gsk.com http://Helppreventwhoopingcough.com	x	x x	x		х	X
Health and Human Services (HHS) Healthy People 2020 Initiative	Sponsored by the U.S. Department of Health and Human Services (HHS) a national health pro- motion and disease prevention initiative.	Healthy People 2020 is a continuation of the Healthy People 2010 initiative. The initiative identifies significant preventable threats to health and establishes national goals to reduce them.	Healthy People home page: http://www.healthypeople.gov/About/ Healthy People 2020 home page: http://www.healthypeople.gov/hp2020	х	х	х			

		Description Examples of Resources		Re	Age Group the source Addres		Specialty Populations the Resource Addresses			
Organization Name	Description		For More Information (All Web sites accessed July 14, 2010)	0–9 Child	10–18 Adolescent	19–64 Adult	НСР	Parents	Pregnant Women	
Immunization Action Coalition (IAC)	A not-for-profit coali- tion of public health professionals. The IAC seeks to increase immuniza- tion rates and pre- vent disease by providing educational materials for HCP.	The IAC publishes free downloadable educational materials for HCP, including handouts, photos, videos, and PowerPoint presenta- tions. Data collection tem- plates are available for clinical documentation. Pertussis Vaccine Information Statements (VISs) published in the United States in several dif- ferent languages can be accessed, as can the "Ask the Experts" page, in which CDC experts answer ques- tions regarding diphtheria, tetanus, and pertussis dis- ease and vaccinations.	IAC's home page: http://www.immunize.org	X	X	X	X	X	X	
		The IAC also supports two user-friendly Web sites designed for both the general	Directory of Immunization Coalitions: http://www.izcoalitions.org	х	Х	х	х	х	Х	
		public and HCP. One Web site facilitates searches for other coalitions, and the sec- ond provides educational information across the lifes- pan.	Vaccineinformation.org home page: http://www.vaccineinformation.org	X	X	X	Х	X	X	

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				Re	Age Group the source Addres			ialty Popul source Ad	ations the dresses
Organization Name	Description	Examples of Resources	For More Information (All Web sites accessed July 14, 2010)	0–9 Child	10–18 Adolescent	19–64 Adult	НСР	Parents	Pregnant Women
Infectious Diseases Society of America (IDSA)	Professional organi- zation composed of physicians, researchers, and other HCP. IDSA's purpose is to improve the health of individuals, commu- nities, and society by promoting excellence	The IDSA Web site provides clinical practice guidelines regarding antimicrobial use, infections both by organism and organ system, immu- nization, travel medicine, hand hygiene, and preven- tion and treatment of catheter-related infections.	IDSA home page: http://www.idsociety.org/content.aspx IDSA Immunization policy: http://www.idsociety.org/ immunizationpolicy.htm						
	in patient care, edu- cation, research, public health, and prevention related to infectious diseases.	The IDSA publishes journals and other publications such as advocacy materials, guidelines, pharmaceutical recalls, and fact sheets related to vaccine safety. The Policy Blueprint to Strengthen Adult and Adolescent Immunization is available at this Web site.	Policy Blueprint: http://www.idsociety.org/ adultimmunization.htm	X	X	X	×	X	X
		The IDSA, in cooperation with the Robert Wood Johnson Foundation and Trust for America's Health (TFAH), created a brief on adult immunization. It includes recommendations for pertussis vaccinations, as well as other vaccine- preventable diseases.	Adult Immunization: Shots to Save Lives: http://healthyamericans.org/ assets/files/TFAH2010AdultImmnzBrief 13.pdf			x	X		
IDSA Emerging Infections Network (IDSA EIN)	Cooperative agree- ment program. Service provided by Immunizations for Public Health (I4PH), a Texas-based non- profit corporation that	The IDSA EIN is a provider- based emerging infections sentinel network. Membership is required to browse the network's listserv. Resources available to mem- bers include presentations, publications, conferences,	IDSA EIN home page: http://ein.idsociety.org	X	X	X	X	X	X

		For More Information	Age Group the Resource Addresses			Specialty Populations the Resource Addresses			
Description	Examples of Resources	For More Information (All Web sites accessed July 14, 2010)	0–9 Child	10–18 Adolescent	19–64 Adult	НСР	Parents	Pregnant Women	
is composed of 10 health care profes- sional organizations, including IDSA.	and announcements. The IDSA EIN assists the CDC as well as other public health authorities with surveillance for emerging infectious diseases and related phenomena.								
IDSA is a founding partner of NNii. NNii's mission is to provide current	NNii publishes current vac- cine and immunization infor- mation intended for HCPs, the media, and parents.	NNii home page: http://www.immunizationinfo.org NNii pertussis information:	x x	x x	x	x x	x	x x	
evidence-based information related to vaccines and	Some of the information that can be downloaded for free includes the following:	http://www.immunizationinfo.org/ vaccines/pertussis-whooping-cough							
immunization.	 Information about pertussis and the benefits of vaccination Information on specific populations (e.g., pregnant women) 	Vaccines for Pregnant Women: http://www.immunizationinfo.org/issues/ general/vaccines-pregnant-women		X	X			X	
	is composed of 10 health care profes- sional organizations, including IDSA. IDSA is a founding partner of NNii. NNii's mission is to provide current evidence-based information related to vaccines and	 is composed of 10 health care professional organizations, including IDSA. IDSA is a founding partner of NNii. IDSA is a founding partner of NNii. INii's mission is to provide current evidence-based information related to vaccines and immunization. Information about pertus- sis and the benefits of vaccination Information on specific populations (e.g., pregnant 	DescriptionExamples of Resources(All Web sites accessed July 14, 2010)is composed of 10 health care profes- sional organizations, including IDSA.and announcements. The IDSA EIN assists the CDC as well as other public health authorities with surveillance for emerging infectious diseases and related phenomena.NNii home page: http://www.immunizationinfo.orgIDSA is a founding partner of NNii. NNii's mission is to provide current evidence-based information related to vaccines and immunization.NNii publishes current vac- cine and immunization infor- mation intended for HCPs, the media, and parents. Some of the information that can be downloaded for free includes the following: • Information about pertus- sis and the benefits of vaccination • Information on specific populations (e.g., pregnantNNii Web sites accessed July 14, 2010)Vaccines-pregnant-womeninformation on specific populations (e.g., pregnantNNii Web sites accessed July 14, 2010)	DescriptionExamples of ResourcesFor More Information (All Web sites accessed July 14, 2010)0–9 Childis composed of 10 health care profes- sional organizations, including IDSA.and announcements	DescriptionExamples of ResourcesFor More Information (All Web sites accessed July 14, 2010)0-9 Child10-18 Adolescentis composed of 10 health care profes- sional organizations, including IDSA.and announcements.The IDSA EIN assists the CDC as well as other public health authorities with surveillance for emerging infectious diseases and related phenomena.NNii home page: http://www.immunizationinfo.orgXXIDSA is a founding partner of NNii.NNii publishes current vac- cine and immunization infor- mation intended for HCPs, the media, and parents.NNii home page: http://www.immunizationinfo.org/ vaccines/pertussis-whooping-coughXXNNii pertussis information: vaccines and immunization.Information about pertus- sis and the benefits of vaccination • Information on specific populations (e.g., pregnantNNii publishes. provide current vaccines-pregnant-womenX	DescriptionExamples of ResourcesFor More Information (All Web sites accessed July 14, 2010)0-9 Child10-18 Adolescent19-64 Adultis composed of 10 health care profes- sional organizations, including IDSA.and announcements.The IDSA EIN assists the CDC as well as other public health authorities with surveillance for emerging infectious diseases and related phenomena.NNii publishes current vac- cine and immunization infor- mation intended for HCPs, the media, and parents.NNii home page: http://www.immunizationinfo.orgXXXNNii publishes current evidence-based information related to vaccines and immunization.NNii publishes current vac- cine and immunization infor- mation intended for HCPs, the media, and parents. Some of the information that can be downloaded for free includes the following: • Information about pertus- sis and the benefits of vaccination • Information appecific populations (e.g., pregnantNNii home page: Nii pertussis-information: Nii pertussis-whooping-coughXXXVaccines for Pregnant Women: http://www.immunizationinfo.org/ such and the benefits of vaccination • Information appecific populations (e.g., pregnantVaccines-pregnant-womenXXX	DescriptionExamples of ResourcesFor More Information (All Web sites accessed July 14, 2010)Resource AddressesReDescriptionand announcements. The IDSA EIN assists the CDC as well as other public health care profes- sional organizations, including IDSA.and announcements. The IDSA EIN assists the CDC as well as other public health authorities with surveillance for emerging infectious diseases and related phenomena.NNii home page: http://www.immunizationinfo.orgXXXXIDSA is a founding partner of NNii. NNii s mission is to provide current evidence-based information related to vaccines and immunization.NNii home page: http://www.immunizationinfo.org/ vaccines/pertussis-whooping-coughXXXXNNii publishe current evidence-based information related to vaccination information on specific populations (e.g., pregnantNNii home page: http://www.immunizationinfo.org/ vaccines/pertussis-whooping-coughXXXXVaccines for Pregnant Women: http://www.immunizationinfo.org/ vaccines/pertussis-whooping-coughXXXX	DescriptionResource AddresserResource AddresserDescriptionExamples of ResourcesFor More Information (All Web sites accessed July 14, 2010)0-910-1819-64MCParentsis composed of 10 health care profes- sional organizations, including IDSA.and announcements. The IDSA EIN assists the CDC as well as other public health authorities with surveillance for emerging infectious diseases and related phenomena.and announcementsImage: Compose of NNii. 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CHAPTER 6: GUIDELINES AND OTHER RESOURCES

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	Description	Examples of Resources	For More Information (All Web sites accessed July 14, 2010)	Age Group the Resource Addresses			Specialty Populations the Resource Addresses		
Organization Name				0–9 Child	10–18 Adolescent	19–64 Adult	НСР	Parents	Pregnant Women
National Foundation for Infectious Diseases (NFID)	Charitable organiza- tion. NFID provides education to health care professionals and the public about the causes, treatment, and pre- vention of infectious	The NFID is an educational foundation that supports research and training in infectious diseases. Information is available regarding pertussis and per- tussis vaccination	NFID home page: http://www.nfid.org/ Pertussis, Tetanus & Diphtheria: http://www.nfid.org/pertussis/	Х	х	Х	х	x	
	diseases.	The NFID publishes educa- tional materials for HCP and the general public, as well as tools that promote vaccina-	Adolescent vaccination, Call to Action: http://www.nfid.org/pdf/publications/ adolescentvacc.pdf		Х	х		X	
		tion. The materials available include fact sheets and handouts pertaining to per- tussis vaccinations for ado- lescents and adults.	Adult vaccination, Call to Action: http://www.nfid.org/pdf/publications/ adultimmcta.pdf			X			
		The NFID supports the AdultVaccination.org Web site, designed for the general public and caregivers. Adult vaccine and other health information and guidance are available on the Web site.	Adult vaccination information: http://www.adultvaccination.org			X	X	X	
		Also, the NFID supports the adolescentvaccination.org Web site, designed for the general public and care- givers. Adolescent vaccine and other health information and guidance are available on the Web site.	Adolescent vaccination information: http://www.adolescentvaccination.org/		X			X	

Tdap Vaccination Strategies for Adolescents and Adults, Including Health Care Personnel: Strategies from Research and Practice

Organization Name	Description	Examples of Resources	For More Information (All Web sites accessed July 14, 2010)	Age Group the Resource Addresses			Specialty Populations the Resource Addresses		
				0–9 Child	10–18 Adolescent	19–64 Adult	НСР	Parents	Pregnant Women
sanofi pasteur	For-profit pharma- ceutical corporation. sanofi pasteur is the vaccines division of sanofi-aventis Group, devoted entirely to the development of human vaccines. Manufacturers the ADACEL [®] (Tdap) vaccine.	 sanofi pasteur provides information and education for the general public and HCP, including the etiology, symptomatology, and epidemiology of various vaccine-preventable diseases, including pertussis, as well as vaccine safety information. sanofi pasteur hosts two Web sites: The Vaccine Manager Web site provides HCP with online disease-specific educational tools that can be customized. Materials specific to pertussis and vaccination schedules for all patient populations are available with a free online 	sanofi pasteur home page: http://www.sanofipasteur.com Vaccine Manager Web site: http://www.vaccinemanager.com	x	x	x	x	x	X
		 subscription. The Silence the Sounds of Pertussis Web site is designed for parents and the general public. This Web site provides an audio of a pertussis cough and pertussis fact sheets that can be downloaded for free. 	Silence the Sounds of Pertussis: http://www.soundsofpertussis.com/	x	X	x		x	x

(continued)

				Age Group the Resource Addresses			Specialty Populations the Resource Addresses		
Organization Name	Description	Examples of Resources	For More Information (All Web sites accessed July 14, 2010)	0–9 Child	10–18 Adolescent	19–64 Adult	НСР	Parents	Pregnant Women
Society for Healthcare Epidemiology of America (SHEA)	Professional organi- zation. SHEA's mission is to prevent and control infections in healthcare settings.	SHEA strives to maintain the best quality of patient care and health care worker safety in all health care settings.	SHEA home page: http://www.shea-online.org						
	Settings.	SHEA's professional publica- tion <i>Infection Control and</i> <i>Hospital Epidemiology</i> (ICHE) has published exten- sively on the prevention and control of infections and infectious diseases, including pertussis (enter the search term "pertussis").	ICHE web site: http://www.journals.uchicago.edu/loi/iche				x		
World Health Organization (WHO)	Intergovernmental agency with 193 member countries. The WHO provides leadership related to world health issues and produces health guidelines and stan-	The WHO seeks to improve worldwide vaccination rates by providing education and establishing guidelines for the public and HCP regard- ing vaccine-preventable diseases.	WHO home page: http://www.who.int/en/						
	dards that address countries' public health issues.	 The WHO publishes pertussis epidemiologic information and provides global perspectives that includes the following: The location of pertussis outbreaks Data and surveillance standards Vaccine safety issues 	WHO pertussis Web site (information available in several languages): www.who.int/topics/pertussis/en	X	X	X			

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