Pertussis Cocooning: The Concept, Experiences and Lessons Learned

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The Immunize Kansas Kids project is a unique partnership among the Kansas Department of Health and Environment, the Kansas Health Institute and dozens of stakeholder organizations. The goal is simple: to protect every Kansas child from vaccine-preventable diseases.

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EXECUTIVE SUMMARY

Pertussis (whooping cough) is a highly contagious respiratory illness caused by the bacteria *Bordetella pertussis*, which can cause serious disease in infants, children and adults. The condition typically begins with cold-like symptoms, and progresses to severe coughing that may continue for weeks or months. It can cause violent and rapid coughing until air is expelled from the lungs and the victim is forced to inhale with a loud "whooping" sound, from which the name "whooping cough" is derived. The persistent and violent coughing may lead to exhaustion and sometimes causes vomiting. Pertussis is spread through the inhalation of droplets expelled when an infected individual in close proximity coughs or sneezes. Pertussis is particularly dangerous for infants, especially those under six months of age. More than half of infants infected with pertussis require hospitalization, and about one in 100 infected infants die (CDC, June 15, 2012).

Despite long-standing pertussis immunization programs and high rates of vaccination coverage in the United States, the disease has remained poorly controlled. In 2010, a total of 27,550 cases of pertussis were reported in the United States; 3,350 of those cases occurred in infants younger than six months of age and resulted in 25 infant deaths. Infants are most often infected by older siblings, parents or caregivers who may be unaware that they have the disease. One approach to protecting vulnerable infants from pertussis infection until they reach the age where they can be fully immunized (6 months) has been to create a protected shield (a *cocoon*) around the infant and minimize the risk of infection by ensuring that all adults and family members in close contact with the infant are immunized against pertussis.

In 2006, pertussis cocooning was recommended for adoption in the United States by the Advisory Committee on Immunization Practices (ACIP). The recommendation was, at that time, based upon theory but there was little scientific evidence of the effectiveness of the approach. Since that time, a number of communities including several in Kansas have attempted implementation of the cocooning concept, with limited success. Most, if not all, have focused their immunization efforts on the postpartum hospitalization setting. These hospital-based programs have achieved relatively high rates of immunization among new mothers, but have had less success in immunizing fathers or caregivers. In 2006, when the cocooning concept was first

endorsed, immunization of pregnant women against pertussis was not recommended due to uncertainties about safety.

In the years since 2006, evolving research findings have cast doubt upon the effectiveness of cocooning alone as a strategy for preventing infant infection with pertussis, have expanded knowledge about the limited duration of immunity conferred by the newer acellular versions of pertussis vaccines, and have demonstrated the safety of administration of the Tdap vaccine to women during pregnancy. Maternal antibodies against pertussis have also been shown to be transferred to the fetus through placental transport, although the degree to which the maternal antibodies confer direct protection to an infant remains uncertain. ACIP recommendations on pertussis immunization practices have been updated and revised accordingly.

In December 2012, ACIP issued a provisional recommendation that Tdap vaccine be administered to all pregnant women during each pregnancy, preferably after 20 weeks of gestation. The extent to which this recent recommendation has been implemented in Kansas is unknown.

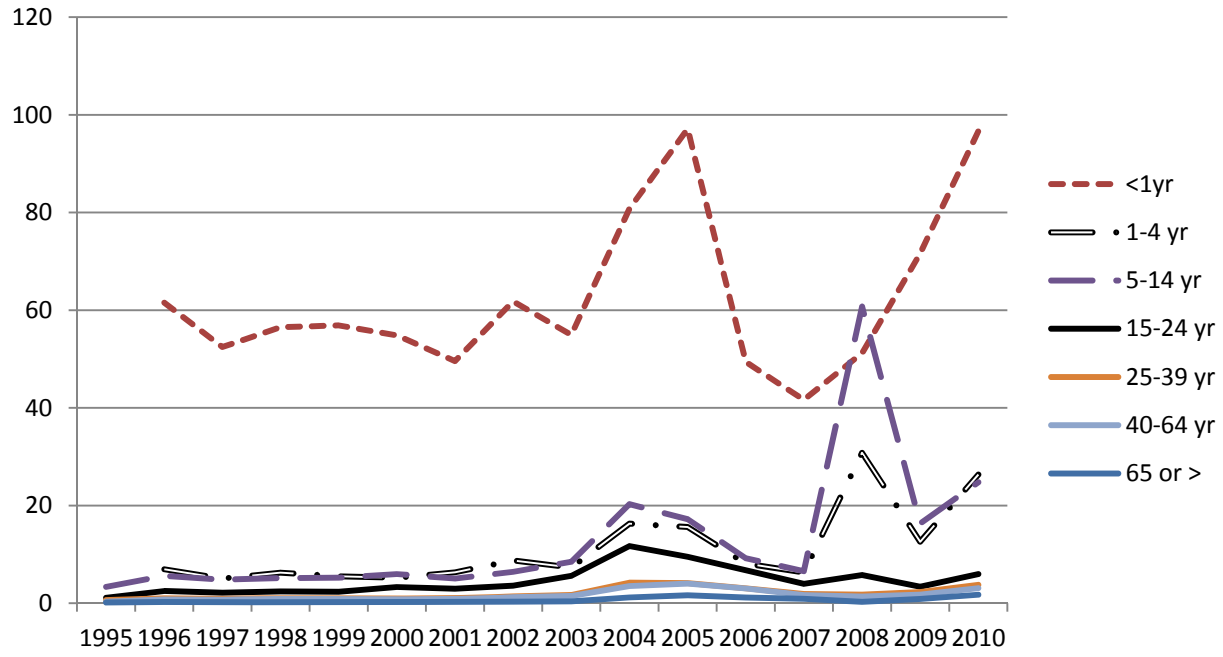
ACIP has also recommended that all adults age 19 years and older receive a single dose of Tdap. Because antibody response to Tdap immunization does not peak until approximately 14 days following receipt of the vaccine, waiting to immunize fathers and caregivers until after the birth of an infant may leave the infant vulnerable to pertussis exposure for a period of two weeks or longer. Re-focusing paternal and caregiver pertussis immunization efforts to the prenatal period would offer more time and increased number of opportunities to achieve immunization of the adults and could result in increased protection to newborn infants.

In summary, implementation of pertussis cocooning in the postpartum hospital setting has proven to be challenging, and experts have concluded that vaccination of women during each pregnancy offers the best opportunity to protect infants from pertussis. Ensuring that children and adolescents are fully immunized, and increasing the number of adults who have received Tdap immunization will also help to reduce the opportunities for infant exposure and infection.

BACKGROUND

Pertussis (whooping cough) is a highly contagious respiratory illness caused by the bacteria *Bordetella pertussis*, which can cause serious disease in infants, children and adults. The condition typically begins with cold-like symptoms and progresses to severe coughing that may continue for weeks or months. It can cause violent and rapid coughing until air is expelled from the lungs and the victim is forced to inhale with a loud "whooping" sound, from which the name "whooping cough" is derived. The persistent and violent coughing sometimes causes vomiting and may lead to exhaustion. Pertussis is spread when an infected person coughs or sneezes and a person in close proximity inhales the expelled droplets. Pertussis is particularly dangerous for infants under 6 months of age. More than half of infants infected with pertussis require hospitalization and about one in 100 infected infants die (CDC, June 15, 2012). In older children and adults, symptoms are sometimes mild and the illness may go undiagnosed.

Figure 1. **Pertussis Incidence, by Year and Age Group**



Source: Data from Centers for Disease Control and Prevention annual Summary of Notifiable Diseases reports.

Infants are most often infected by older siblings, parents or caregivers who may be unaware that they have the disease. Despite long-standing pertussis immunization programs and high rates

of vaccination coverage in the United States, the disease has remained poorly controlled (Figure 1, page 1). In 2010, a total of 27,550 cases of pertussis were reported in the U.S.; 3,350 of those cases occurred in infants younger than 6 months of age, and 25 of those infants died (CDC, June 15, 2012). One approach to protecting vulnerable infants from pertussis infection until they reach the age where they can be immunized has been to create a protected shield (a *cocoon*) around the infant and minimize the risk of infection by ensuring that all adults and family members in close contact with the infant are immunized against pertussis.

Two forms of pertussis vaccine are currently used in the U.S. Both combine acellular pertussis with tetanus and diphtheria antigens.[1] The first, abbreviated as DTaP, is used for active immunization of infants and young children and contains concentrations of the diphtheria and pertussis components three to five times higher than the booster formulation used for older children and adults, which is abbreviated as Tdap. Infants in the U.S. routinely receive pertussis vaccination through the DTaP series which is administered at 2, 4 and 6 months of age, with boosters at 15–18 months and at school entry. Infants are not fully protected from pertussis prior to completion of the primary DTaP series, and no pertussis vaccines are licensed for administration to infants younger than 2 months of age. Immunity of vaccinated children is known to wane over time, and in 2005 the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) called for vaccination of adolescents and adults with Tdap to improve population immunity. In October of 2010, ACIP recommendations were updated to include a single dose of Tdap for persons 11 to 18 years of age who had completed the childhood DTaP or DTP series (preferably at 11 to 12 years of age),

[1] Prior to 1979, whole-cell pertussis vaccines (DTP) were used to immunize infants and children in the United States. Local reactions, fever and other mild systemic reactions occurred following up to half of administered doses of whole-cell DTP, and concerns about safety led to the development of more purified (acellular) pertussis vaccines that are associated with lower frequency of adverse reactions. In 1997, ACIP and CDC recommended that infants be given acellular versions of pertussis vaccine for the primary immunization series. Whole-cell pertussis vaccines are no longer available in the United States, but remain in use in many other countries. Source: CDC Pinkbook – Pertussis Chapter (http://www.cdc.gov/vaccines/pubs/pinkbook/pert.html#vaccines), and MMWR 46(RR-7):1-25, 28 March 1997.

and for adults age 19 to 64 years of age (CDC, January 1, 2011). Table 1 summarizes current recommendations for pertussis immunization.

Table.1. **Current Pertussis Immunization Recommendations in the U.S., November 2012**

Vaccine Form	Population/ Age
DTaP – active immunization	Infants, 2 months
	Infants, 4 months
	Infants, 6 months
	Infants, 15–18 months
	Children, 4–6 years (at school entry)
Tdap - boosters	Adolescents, 11–12 years
	All adults (one time only, then Td booster every 10 years)
	Pregnant women, after 20 weeks gestation, during each pregnancy

Source: Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices.

The purpose of this study is to provide updated information about experiences to date with implementation of the pertussis cocooning strategy, both in Kansas and in other locations, as well as a summary of relevant research and evolving recommendations for reducing the disease burden of pertussis in the U.S. Toward that end, staff from the Kansas Health Institute (KHI) interviewed representatives of the Immunization Program and the Bureau of Epidemiology and Public Health at the Kansas Department of Health and Environment (KDHE) and from one local health department that has been actively involved in pertussis cocooning efforts about their experiences with pertussis cocooning in Kansas. KHI staff also gathered additional background information through searches of peer-reviewed literature and Internet sources.

HISTORY OF THE PERTUSSIS COCOON CONCEPT

Research has shown that where the source of infant pertussis infections could be identified, adult family members were the source in more than half of the cases (Bisgard, 2004). In an effort to provide infants with protection against pertussis until they are old enough to complete the DTaP vaccination series, the Global Pertussis Initiative recommended in 2001 that infant caregivers and other adults in close contact with infants be vaccinated with a Tdap booster, to provide a protective “cocoon” effect around the vulnerable infants. Although there was little

empirical evidence to support this approach, it was believed that by immunizing the adults in closest contact with the newborn, "herd immunity" around the newborn could be established and the risk of pertussis transmission to the infant could be effectively minimized. The cocoon strategy envisioned the immunization of parents, family members, caregivers and close contacts of newborns within the prenatal period or the first few weeks following birth. ACIP endorsed the pertussis cocooning concept and recommended implementation in the U.S. in 2006.

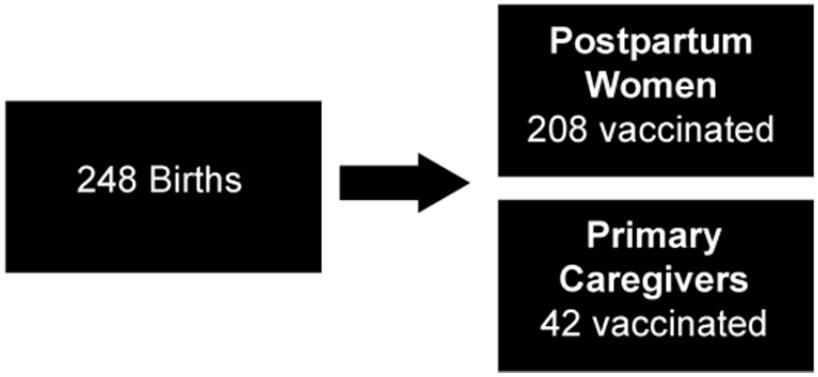
KDHE PERTUSSIS COCOON PILOT PROJECT, 2010

The first efforts to implement the pertussis cocoon concept in Kansas began in January 2010 when the Bureau of Epidemiology and Public Health within KDHE launched a pilot demonstration project in partnership with four community hospitals and three local health departments located in the same counties as the participating hospitals. At that time, KDHE had sufficient funds remaining from a federal grant to cover the cost of 800 doses of Tdap vaccine for the project. Four hospitals were selected for participation on the basis of the number of births per year, current participation in the Vaccines for Children (VFC)[2] program, geographic location within reasonable driving distance from the KDHE office in Topeka, and willingness to participate. The goals of the project were threefold: 1) to increase pertussis awareness through education of health care providers and families of newborns, 2) to immunize 80 percent of postpartum women delivering at the project hospitals, and 3) to immunize one primary caregiver (designated by the new mother) for each newborn infant. Presentations were provided to the participating hospitals and health departments in January of 2010, with the goal of having programs at all participating hospitals up and running by March. At that time, KDHE proposed that the hospitals implement standing orders for Tdap immunization of the new mothers prior to their discharge from the hospital. Additionally, the hospital staff would provide a voucher that the infant's father and/or caregivers could take to the local health department to redeem for a free

[2] The Vaccines for Children (VFC) program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. CDC purchases vaccines at a discount and distributes them to grantees — i.e., state health departments and certain local and territorial public health agencies — which in turn distribute them at no charge to those private physicians' offices and public health clinics registered as VFC providers. Source: *http://www.cdc.gov/vaccines/programs/vfc/index.html*

pertussis vaccination. Free Tdap vaccine was provided to the participating hospitals and health departments for use under the pilot program.

Figure 2. **Results of the Kansas Department of Health and Environment Pertussis Cocoon Pilot Project, January–June 2010**



KDHE evaluated preliminary results from the demonstration project in June of 2010. At that time, there had been 248 births at the participating hospitals. Of those 248 births, 208 mothers (83.9 percent) were vaccinated for pertussis prior to their discharge. Results of caregiver vaccination, however, were less positive with only 42 (16.9 percent) of primary caregivers vaccinated (Figure 2). Project managers recognized the need to refine their approach, and conducted further analysis and investigation of early results to identify barriers to implementation and opportunities for improvement. Feedback was provided to participating hospitals. A nurse from one of the participating hospitals made follow-up calls to fathers who had been provided with vouchers but had not completed the immunization process; referral to the health department rather than on-site caregiver immunization was identified as a barrier. A number of options were considered for increasing the caregiver immunization rates, including standing orders for family member vaccination by the hospital prior to mother/infant discharge. When one of the four participating hospitals began vaccinating caregivers at the hospital rather than referring them to the local health department for vaccination, caregiver vaccination rates immediately increased from approximately 30 percent in the first six months to 70 percent after the procedural change. One hospital opted to bypass the patient registration requirement for caregivers receiving Tdap vaccination, and recorded the patient consents and vaccine

administration in a logbook, but did not create an individual patient account or medical record for the caregiver. The hospital did not bill for the caregiver immunizations. The pilot project continued through the end of 2010, and then was discontinued when the supply of free vaccine was exhausted.

A number of lessons were learned during the pilot project. It quickly became apparent that having an immunization champion among the nursing staff was a key to success, and that broad buy-in from the hospital's labor and delivery unit, pharmacy, and infection control practitioner were also helpful. While three of the participating hospitals readily adopted and implemented standing orders for Tdap immunization of the mother prior to discharge, the fourth hospital, which was a member of a large multi-hospital corporate system, was not able to do so because of a requirement for system-wide approval and adoption. Although immunizing caregivers at the hospital offered clear advantages over the voucher and referral approach, the on-site immunization was challenging to implement because the caregivers had to be processed through the hospitals' admission systems as patients, and doctors' orders were necessary before hospital staff could vaccinate the caregivers. While the hospital which waived registration requirements for caregivers was successful in streamlining the process of caregiver immunization, this approach is probably not practical for widespread implementation because it would not allow the hospital to bill for the immunization service, and may be in violation of regulatory requirements that hospitals maintain a medical record for every patient evaluated or treated by the facility.

Reimbursement issues for hospital administration of Tdap to mothers and family members were also complicated. Once the supply of free vaccine was exhausted, hospitals that wanted to continue the program would then be faced with navigating a complex system of vaccine procurement and reimbursement to continue offering the immunization service. Potential reimbursement for immunization of new mothers was complicated by the fact that payment for labor, delivery and postpartum care is often bundled, and it was not clear whether a mechanism existed for additional reimbursement to cover the costs of vaccine and administration. Considering these challenges, interest from hospitals for continuing Tdap vaccination programs was low.

KDHE EXPANSION OF ADULT PERTUSSIS IMMUNIZATION PROGRAM, 2012

In 2012, KDHE staff had another opportunity to implement an expanded pertussis cocooning program. With several thousand doses of Tdap vaccine available through the federally sponsored Section 317 program,[3] all birthing hospitals in Kansas which currently participated in the VFC program (approximately 72) were offered the opportunity to receive free vaccine and participate in the newly expanded pertussis cocoon program. Initially, Tdap vaccine was offered to hospitals and health departments to be used in vaccinating new mothers and caregivers. With the supply of free vaccine, interest from hospitals and health departments increased, and approximately 17 hospitals signed on to the program. In September of 2012, the program was again expanded and vaccine was offered for adult infant caregiver immunization programs. To date, approximately 23,000 doses of vaccine have been distributed under this expansion program. It is hoped that through this effort, better adult coverage against pertussis will be achieved. Effective October 1, 2012, program funding was restricted to the provision of vaccine only for individuals with no other source of health insurance. Participants in this expanded immunization effort have been required to track and report their vaccine use to KDHE; at the time of this report these data have not yet been finalized and reviewed.

Members of the immunization staff from one health department that received vaccine through the expanded program were also interviewed as part of this study. The staff reported that they had first learned of the pertussis cocooning concept during a presentation by a Missouri health care provider, and they were eager to implement the concept in their county. Work and collaboration had already begun with local hospitals and health care professionals when KDHE offered the free Tdap vaccine, financed through the 317 program. The health department ordered what they estimated to be a one-year supply of vaccine for both the health department and the

[3] The Section 317 program is a discretionary federal grant program to all states, six cities, territories and protectorates which provides vaccines to underinsured children and adolescents not served by the Vaccines for Children (VFC) program, and as funding permits to uninsured and underinsured adults. The majority of Section 317 program funds are dedicated to routine childhood programs, with a smaller portion remaining for adolescent and adult immunization programs. The 317 program also provides immunization infrastructure which is crucial, especially when public health priorities can shift rapidly in the event of an outbreak of a vaccine-preventable disease or a bioterrorism event. Source: *www.cdc.gov/vaccines/programs/vfc/downloads/grant-317.pdf*

local hospitals, with the number of doses ordered being based upon the annual number of births in the county. The health department planned to work in partnership with the local hospitals, with hospitals administering Tdap vaccination to new mothers, and referring fathers or adult caregivers to the health department for immunizations. Unknown to health department staff, the collaborating hospitals also requested Tdap vaccine supplies from KDHE independently, leaving the county with a surplus of vaccine that would expire at the end of 2012. Several months into the program, participants were informed by KDHE staff that they would be required to pay for any unused vaccine that reached the expiration date. Given the pressure and potentially substantial cost of a large surplus of vaccine, combined with the simultaneous occurrence of a pertussis outbreak in a nearby community, the health department broadened its eligibility criteria for adult Tdap immunizations, and stepped up its outreach efforts. Remaining doses of Tdap vaccine were administered to adults in the broader community, including staff at childcare facilities, adults in nursing and assisted living facilities, participants at after-school fairs, adults at homeless shelters and through emergency feeding programs. At the time of our interview, all doses of Tdap received through the KDHE program had been administered.

SUCCESSES AND LESSONS LEARNED

Experiences both in Kansas and in other U.S. locations have shown that implementation of the pertussis cocooning concept in the postpartum hospital setting can be logistically complicated. Factors identified as key to success include having a hospital "champion" to promote the cocoon program, access to free vaccine, and hospital willingness to donate staff time to support the program (KDHE interview; Clark, 2011a). Hospitals incur additional costs (staff time required to explain and administer the vaccine and direct costs associated with vaccine and administration supplies) in immunizing postpartum mothers for which they may not be able to recover reimbursement under bundled payment systems. Immunization of infant caregivers is more challenging; for the hospital to offer the immunizations on-site, they must register the caregivers as hospital patients and receive doctors' orders for administration of the pertussis vaccines. To maximize caregiver immunization rates, immunization services would need to be available during the hours when family members are likely to visit, including evenings and weekends. Alternatively, when hospital staff refer family members and caregivers to either the local health department or their personal physician to obtain pertussis immunization, follow-up is

often poor. This has been the case even when the health department is located in close proximity to the hospital, and when coupons or vouchers for free immunization have been offered. Inaccurate or incomplete recall of adult vaccination history has also been cited as a barrier to successful implementation of the cocoon strategy (Healy, 2011). One researcher (Healy, 2011) concluded that, "although it is possible to achieve high Tdap vaccination rates for hospital-based cocooning, such a program requires a significant investment of resources to achieve its goals."

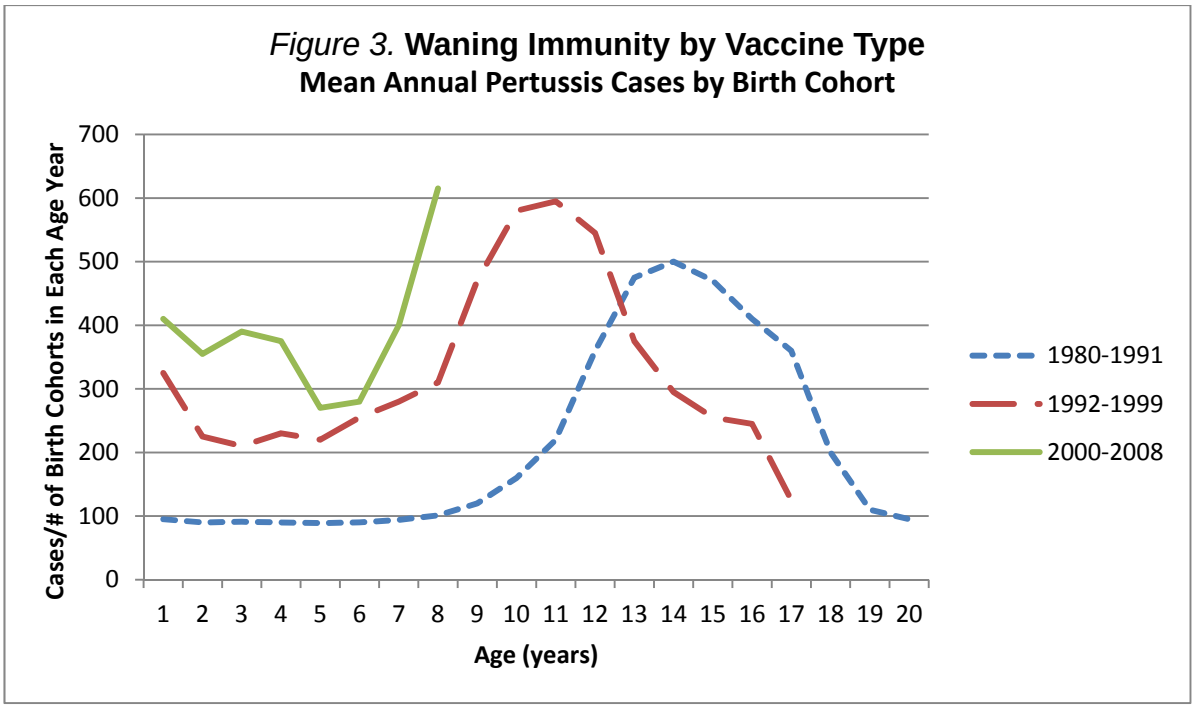
LIMITATIONS OF THE COCOONING APPROACH

To date, no rigorous evaluation has been published on the effectiveness of the pertussis cocooning concept in preventing infant pertussis infections. Researchers have estimated that cocooning alone is unlikely to reduce infant infection rates by more than about one-third (Scuffam & McIntyre, 2004). One significant limitation of postpartum implementation of the pertussis cocooning strategy is that the immune response to Tdap is known to peak approximately two weeks following vaccination. If the mother and other adult caregivers are not vaccinated until after the birth of the infant, there is a gap of two or more weeks where the newborn remains unprotected. Difficulties encountered in obtaining complete cocoon coverage (by vaccinating all adults in close contact with the infant) also leave the infant vulnerable to pertussis infection. An ecological study in Texas (Castagnini, 2012) found that immunizing only postpartum mothers with Tdap failed to reduce rates of pertussis illness in infants up to six months of age. Finally, cost-effectiveness analyses also have called into question the feasibility of relying upon the cocoon strategy to protect newborns from pertussis until they can be fully immunized and establish their own immunity. One recent analysis (Skowronski, 2012) estimated that more than one million parents would need to be vaccinated to prevent a single infant death from pertussis, and more than 10,000 parents would need to be vaccinated to prevent an infant hospitalization due to pertussis. The authors concluded that, "in the context of low pertussis incidence, the parental cocoon program is inefficient and resource intensive for the prevention of serious outcomes in early infancy." In Australia, the government recently curtailed a program that offered free pertussis vaccine to adults when the Pharmaceutical Benefits Advisory Committee concluded that there was insufficient evidence to support the benefit of pertussis cocooning (Bramwell, 2012). In 2011, ACIP concluded that, "cocooning alone is an insufficient strategy to prevent pertussis morbidity and mortality in newborn infants." At the same time, they

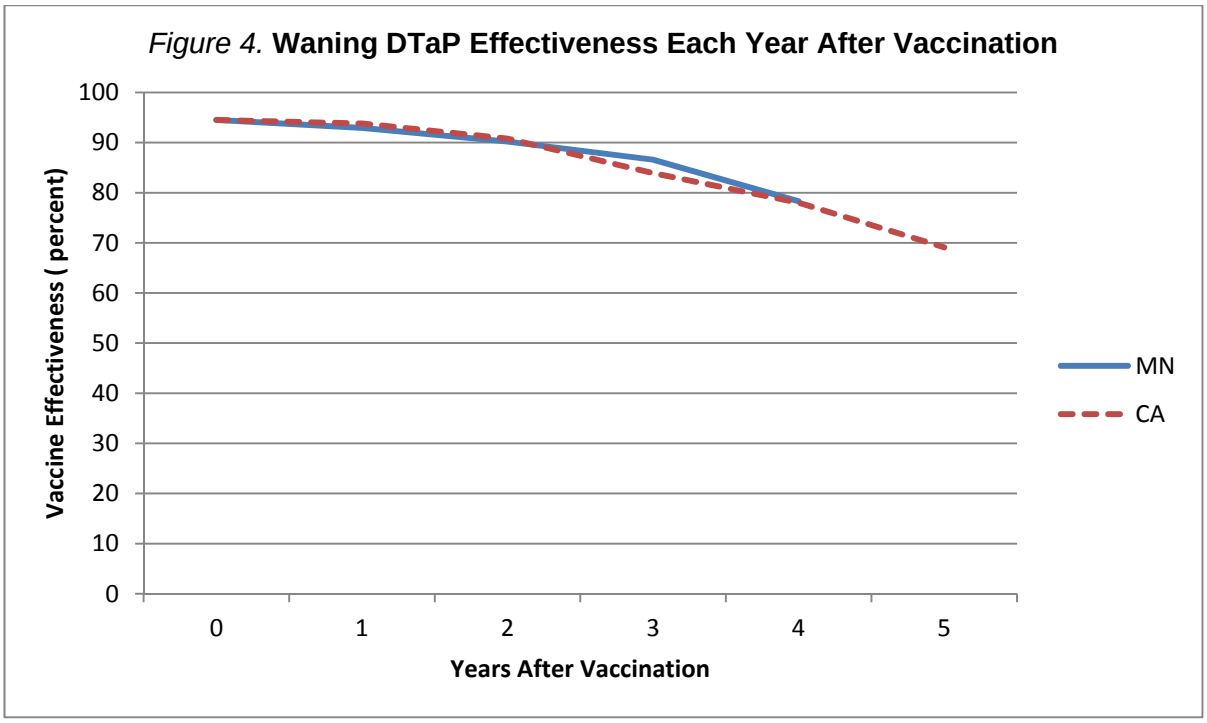
reaffirmed that cocooning is likely to provide indirect protection to infants and continued to recommend Tdap vaccination for unvaccinated persons who anticipate close contact with infants (CDC, October 21, 2011).

LIMITATIONS OF THE ACELLULAR PERTUSSIS AND TDAP VACCINES

The identification of effective immunization strategies for prevention of pertussis infection is complicated by uncertainty about the duration of immunity conferred by the Tdap vaccine. From the 1940s through the 1990s, Pertussis vaccines prepared from whole cell *Bordetella Pertussis* organisms were in use in the U.S. While these vaccines were regarded as effective, they also were associated with adverse effects which led to the development of safer acellular pertussis vaccines containing inactivated pertussis toxin. By the late 1990s, acellular pertussis vaccines were being used in the U.S. for all five early childhood doses and boosters. Despite high vaccine coverage rates in U.S. children, outbreaks of *B. pertussis* have continued to occur since the 1980s, leading some researchers to suggest that the immunity conferred by acellular vaccines may be of shorter duration than that from the earlier whole-cell vaccines (Witt, 2012; Clark 2011b; Klein, 2012) (Figure 3). It is widely recognized that pertussis immunity wanes somewhat as elapsed time since last vaccination increases, but the precise degree to which Tdap effectiveness declines remains unclear. One study conducted after an outbreak in California (Klein, 2012) found that the odds of a child becoming infected with pertussis increased by 42 percent per year for each year elapsed after the fifth dose of DTaP. Another study (Clark, 2011b) examined data from two states and found that Tdap vaccine effectiveness rates declined from 94.5 percent at the time of vaccination to 78 percent four years later (Figure 4). Faced with sporadic outbreaks of pertussis despite high vaccine childhood coverage rates, ACIP recommended in January 2010 that adolescents ages 11 – 18 and adults age 65 and older who anticipate having close contact with an infant receive an additional pertussis booster with Tdap vaccine.



Source: Clark T. (August 2011). Pertussis Epidemiology and Vaccination in the U.S.



Source: Clark T. (August 2011). Pertussis Epidemiology and Vaccination in the U.S.

POSSIBLE ALTERNATIVES AND OPPORTUNITIES

As the spread of pertussis has remained poorly controlled and research findings have contributed to a more complete understanding of the gaps in efforts to effectively immunize against infection, immunization recommendations have evolved (Table 2). When initial recommendations for the pertussis cocooning approach were developed, the safety of Tdap administration to pregnant women had not been fully evaluated and vaccination of pregnant women with Tdap was not recommended. Since that time, however, additional study has resulted in greater confidence in the safety and benefit of Tdap administration during pregnancy, and recommendations have been updated accordingly. In June of 2011, ACIP issued a recommendation that pregnant women who had not previously received Tdap should be vaccinated, preferably in the third or late second trimester of pregnancy (after 20 weeks gestation) (CDC, October 21, 2011). Vaccination in late pregnancy allows sufficient time for the pregnant woman's immunity to peak prior to delivery of the newborn; a mother vaccinated with Tdap vaccine during pregnancy will be protected at time of delivery and will be less likely to transmit pertussis to her newborn. Transplacental transfer of maternal pertussis antibodies from mother to infant may also provide the infant with protection against pertussis in early life, before beginning the primary DTaP series. There is evidence of efficient transplacental transfer of pertussis antibodies to infants, but the effectiveness of maternal antibodies in preventing infant pertussis is not yet known.

Table 2. **Evolving Tdap Recommendations in the U.S.**

Date	Recommendation
January 14, 2011 (MMWR)	• Children 7–10 years not fully vaccinated against pertussis and without contraindications should receive a single dose of Tdap • Adolescents 11–18 years who have completed childhood vaccination series should receive Tdap, preferably at 11–12 years • Adults age 65 and older who have or anticipate having close contact with an infant <12 months should receive a single dose of Tdap • Other adults age 65 years and older may be given single dose of Tdap
June 2011 (ACIP Recommendation)	• Women's health care providers should administer Tdap to pregnant women who have not previously received the vaccine, preferably after 20 weeks gestation
October 21, 2011 (MMWR)	• Women's health care providers should administer Tdap to pregnant women who have not previously received the vaccine, preferably after 20 weeks gestation • Adolescents and adults who have or anticipate having close contact

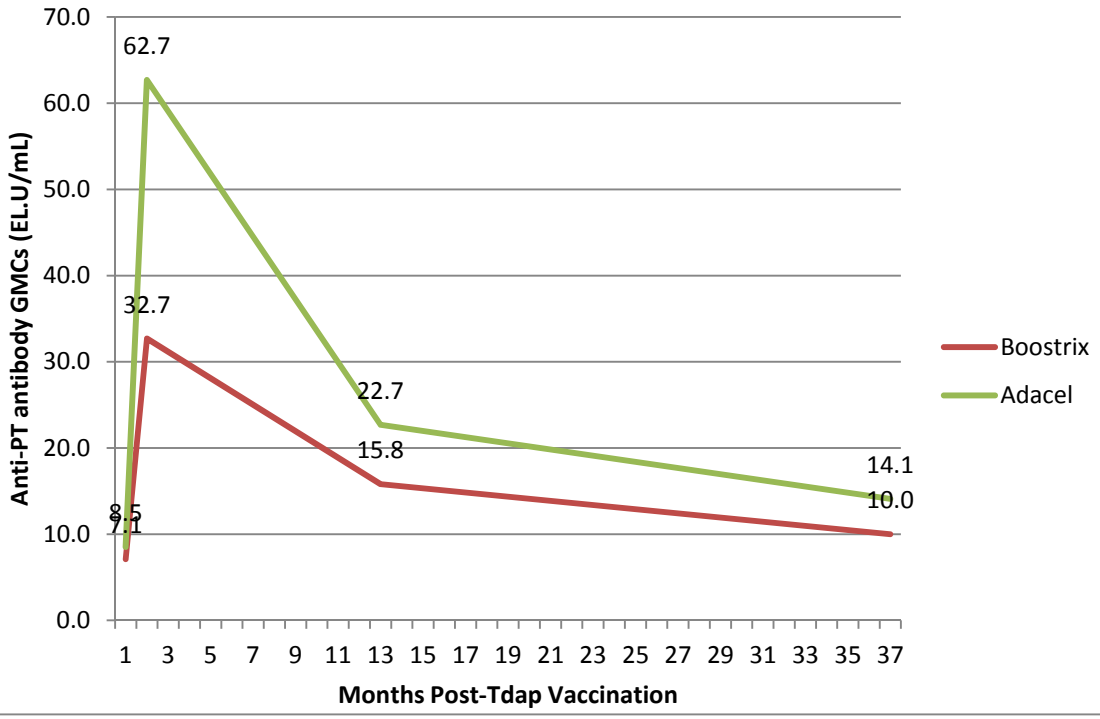
Table 2. **Evolving Tdap Recommendations in the U.S.**

Date	Recommendation
	with an infant <12 months should receive a single dose of Tdap if they have not previously received Tdap
March 2012 (ACOG Committee Opinion)	Women's health care providers should implement a Tdap vaccination program for pregnant women who previously have not received Tdap. Providers should administer Tdap during pregnancy, preferably after 20 weeks gestation
June 29, 2012 (MMWR)	Tdap administration recommended for all adults age 65 years and older. All adults age 19 years and older who have not yet received a dose of Tdap should receive a single dose
October 24, 2012 (CDC Media Advisory)	ACIP recommended that prenatal care providers administer a dose of Tdap to pregnant women during ***each pregnancy***, regardless of patient's prior Tdap history
December 6, 2012 (ACIP Provisional Recommendation)	Pregnant women who were not previously vaccinated with Tdap: 1) receive Tdap in the immediate postpartum period prior to discharge from the hospital or birthing center, 2) may receive Tdap at an interval as short as two years since the most recent Td vaccine, 3) receive Td during pregnancy for tetanus and diphtheria protection when indicated, or 4) defer the Td vaccine indicated during pregnancy to substitute Tdap vaccine in the immediate postpartum period

Some evidence suggests that fetal exposure to maternal pertussis antibodies may blunt the child's immune response to DTaP when the primary immunization series is begun. Although ACIP members acknowledged that this early exposure to maternal antibody could possibly interfere with the infant's own immune response to DTaP, they concluded that because the greatest risk to infants from pertussis is prior to 3 months of age, any protection that can be provided during that timeframe is critical and should be pursued. A decision analysis and cost effectiveness model developed by ACIP showed that Tdap vaccination during pregnancy would prevent more infant pertussis cases, hospitalizations and deaths compared with the postpartum dose. Two reasons were cited for this finding: 1) vaccination during pregnancy provides earlier immunity in the mother and protects the infant from birth, and 2) vaccination during late pregnancy likely provides direct protection to the infant through transfer of maternal antibodies to the infant (CDC, October 21, 2011). The American College of Obstetrics and Gynecology (ACOG) Committee on Obstetric Practice soon adopted the ACIP guidance and recommended to their members in March 2012 that women's healthcare providers should administer Tdap during pregnancy to women who had not previously received the vaccine, preferably after 20 weeks of

pregnancy. While this ACIP recommendation focused on the benefits to both mother and infant with the initial Tdap immunization, it was silent on two unanswered questions: 1) how long immunity could be expected to be sustained in the mother following the single Tdap vaccination, and 2) what, if anything, should be done during subsequent pregnancies where the infants might not receive the same benefit of transplacental antibody transfer as the mother's circulating antibody level waned following the initial peak response. Studies (Weston, 2011) have shown that antibody levels in response to Tdap peak rapidly within a few weeks of vaccination and then decline rapidly during the first year, but remain higher than pre-vaccination levels at 3 years following vaccination (Figure 5).

Figure 5. **Anti-PT Antibody Concentration Following Tdap**



Source: Weston et al. (November 03, 2011). Persistence of antibodies three years after booster vaccination of adults with combined acellular pertussis, diphtheria and tetanus toxoids vaccine. Vaccine, 29(47), 8483-8486.

On October 24, 2012, ACIP again revised their recommendation to say that all pregnant women should receive Tdap during *each* pregnancy, regardless of the patient's prior history of receiving Tdap. This most recent provisional recommendation does not become final until officially endorsed by the CDC. If adopted and successfully implemented, it would assure that the pregnant woman has established immunity to pertussis prior to delivery of the newborn, and

increase the likelihood that each infant born to mothers who received the Tdap booster during pregnancy would also receive the benefit of antibody transfer from the mother.

Although only limited discussion has been found in published literature, it would seem that similar logic should also be applied to shifting Tdap immunization of prospective infant caregivers and family members to the prenatal period. The prenatal period is likely to be a less hectic time for the family than immediately after the birth of a new baby, and could offer multiple opportunities for education about the need for Tdap immunization. Settings such as prenatal care visits, childbirth and parenting classes, and WIC Clinic appointments might offer venues for promotion of Tdap immunization. Focus on immunization of family members and caregivers prior to the birth of the baby would confer a higher level of protection to the infant by assuring that all individuals have had sufficient time to fully establish immunity before the baby is born.

CONCLUSIONS

Several years of experience with implementation of the postpartum pertussis cocooning strategy in hospitals have shown that approach to be challenging to implement, and caregiver vaccination rates achieved by the programs have been disappointing. With the recent change in ACIP recommendations to encourage Tdap vaccination of all pregnant women, it seems clear that the most direct and preferred route to protecting infants from pertussis is through prenatal Tdap vaccination of the mother. The CDC has concluded “Full implementation of cocooning has proven to be a challenge; vaccinating during pregnancy provides the best opportunity to protect infants from pertussis,” (CDC, June 15, 2012).

Consideration should also be given to shifting efforts for Tdap vaccination of family members and caregivers to the prenatal period where there are numerous educational opportunities for pregnant women and family members, more time to make the needed arrangements and obtain the vaccination, and time for vaccinated individuals to establish full immunity prior to the birth of the infant. Postpartum Tdap immunization efforts in the hospital setting are probably most appropriately reserved for periods of pertussis outbreaks in the community, or for those mothers

and family members who have slipped past immunization efforts in the prenatal period and remain unprotected against pertussis.

At the time of this paper, it is unknown to what extent the most recent recommendations for administering Tdap to all pregnant women have been disseminated or adopted in Kansas. Implementation of this strategy will require the active support of obstetrics and gynecology clinicians, who may be unfamiliar with vaccination administration and reimbursement practices. The Immunize Kansas Kids coalition and its participating partners could possibly promote adoption of this recommendation through educational outreach and the provision of informational materials to clinicians across the state. Similarly, immunization of fathers and caregivers prior to infant birth could be encouraged through educational outreach to healthcare providers and programs most likely to have contact with pregnant women and their family members. Possible venues could include WIC clinics, childbirth and parenting classes, and messaging through the Text 4 Baby program.

APPENDIX A: ABBREVIATIONS

ACIP ― Advisory Committee on Immunization Practices

ACOG ― American College of Obstetrics and Gynecology

CDC ― Centers for Disease Control and Prevention

DTaP ― Diphtheria, tetanus and acellular pertussis vaccine, for active immunization in infants and children ages birth – 5

GPI ― Global Pertussis Initiative

KDHE ― Kansas Department of Health and Environment

KHI ― Kansas Health Institute

Tdap ― Tetanus, diphtheria and acellular pertussis vaccine, for booster administration to adolescents and adults

VFC ― Vaccines for Children

WIC ― Special Supplemental Nutrition Program for Women, Infants and Children

APPENDIX B: REFERENCES

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