MAJOR ARTICLE

Implementation of Cocooning against Pertussis in a High-Risk Population

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Background. In 2006, the Advisory Committee on Immunization Practices recommended tetanus, diphtheria, acellular pertussis (Tdap) vaccination of all caregivers of infants aged <1 year ("cocooning") to prevent pertussis-related complications and deaths. We implemented cocooning in a predominantly Hispanic, medically underserved, uninsured population at a Houston hospital. Phase 1 (January 2008–January 2010) provided maternal postpartum Tdap vaccine; Phase 2 (June 2009–January 2010) also vaccinated infant contacts on-site.

Methods. Pertussis education was provided to health care personnel and mothers. Standing orders for maternal postpartum Tdap vaccination were initiated. Mothers were interviewed to ascertain the number of additional infant contacts eligible to receive Tdap vaccine. Consenting eligible contacts received Tdap vaccine as soon as possible after delivery.

Results. From 7 January 2008 through 31 January 2010, 8334 (75%) of 11,174 postpartum women received Tdap vaccine. During Phase 2, 2969 (86%) of 3455 postpartum women were vaccinated; another 197 (6%) had previously received Tdap vaccine. Mothers were Hispanic (91.4%), black (5.4%), white (0.8%), Asian (1.4%) and other (1.0%). A median of 3 (range, 1–11) other Tdap-eligible contacts per infant were identified, and a median of 2 (range, 0–10) contacts per infant received Tdap vaccine. Of 1860 contacts vaccinated, 1813 (98%) anticipated daily infant contact. A total of 1697 (91%) received Tdap vaccine before infant hospital discharge, and 144 (8%) received Tdap vaccine within 7 days after hospital discharge. Barriers to full cocooning included the need for extended vaccination hours, visiting restrictions because of pandemic H1N1 influenza, and inaccurate recall of vaccination history.

Conclusion. Although practical and logistical barriers exist, Tdap cocooning was well accepted by and successfully implemented in a high-risk population by using standing orders and providing vaccinations on-site.

Pertussis vaccination in the United States reduced annual pertussis-attributable morbidity and mortality by 92% and 99%, respectively [1]. Despite this fact, and despite pertussis vaccination rates in US children of 80%–95%, the annual incidence of pertussis has increased since the nadir of 1010 cases reported in 1976 [2, 3]. The Centers for Disease Control and Prevention (CDC) report that infants under 6 months of age, who are too young to have completed the primary vaccination series, have up to a 20-fold higher incidence of pertussis than does the general population (69.99 versus 3.62 cases per 100,000 population in 2007). Two-thirds of pertussis-infected infants in this age group are hospitalized [4]. Furthermore, pertussis-related deaths occur almost exclusively in young infants, the risk being inversely proportional to age and number of infant DTaP vaccine doses received [5–7]. Studies also demonstrate that 75% of infants are infected by a household contact or caregiver, most commonly their mother (33%) or father (16%) [8, 9]. Pertussis incidence and mortality are higher in infants of Hispanic ethnicity, for reasons that are not understood [6, 7, 10].

Since June 2006, in an effort to prevent pertussis in young infants, the Advisory Committee on Immunization Practices (ACIP) to the CDC has recommended that

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Tdap vaccine be administered to postpartum women before hospital discharge and to household and caregiver contacts of newborns and infants less than 1 year of age [11]. This targeted vaccination strategy, called cocooning—the only protection against pertussis available to young infants except vaccination during pregnancy—has not been widely implemented, largely because of a lack of necessary infrastructure, a need for education, reimbursement issues, and logistical barriers [12–14]. We initiated a phased implementation of Tdap cocooning in a predominantly Hispanic, medically underserved, and underinsured population in Houston, Texas. Phase 1 implemented maternal postpartum vaccination [13]. Phase 2 expanded the program to vaccinate household contacts of newborn infants on site. This report describes the implementation of both phases of this strategy through January 2010.

METHODS

Patient population. Ben Taub General Hospital is 1 of 2 public hospitals of the tax-supported Harris County Hospital District in Houston, Texas. Approximately 5000 live-born infants, predominantly Hispanic (>90%), are delivered there annually. Ben Taub General Hospital cares for a largely underinsured, medically underserved, predominantly Spanish-speaking population that is likely to have inadequate antenatal care and is unlikely to receive Tdap vaccine from other sources or to have knowledge about pertussis or Tdap vaccination recommendations.

Education for health care professionals (HCPs). Educational methods for HCPs have been previously described [13]. Briefly, the severity of pertussis illness in young infants and the rationale for cocooning were presented in obstetrical grand rounds and small group in-service sessions. In-service sessions targeted physicians, nurses, administrative staff, and hospital interpreters. Nursing personnel were particularly targeted because of their role as trusted advisors for new mothers and their potential to be powerful vaccine advocates. In-service sessions occurred at convenient times for day-shift and night-shift personnel to ensure optimal attendance. Education was performed at regular intervals for new personnel, to reinforce prior information, and provide updates. Physician directors and dedicated program nurses also were available to address any questions from hospital nurses and physicians.

Education for postpartum women and families. Posters advocating Tdap vaccination were displayed prominently in antenatal, labor and delivery, and postpartum areas. Program education was incorporated into antenatal, baby-care, and breastfeeding classes. Each postpartum woman received a pertussis information packet that contained bilingual information about pertussis infection, Tdap vaccination recommendations for adults (provided by the Texas Department of Health), and the Tdap vaccine information statement.

Nurses caring for postpartum women were available to answer questions about the program. This education was supplemented, whenever possible, by a visit from our program nurse, who provided additional education to mothers and any visiting household contacts or caregivers.

Phase 1: Tdap vaccination for postpartum women. Beginning in January 2008, a standing order for Tdap vaccination of all eligible and consenting postpartum women was initiated. Postpartum women were offered Tdap vaccine prior to hospital discharge unless there was a medical contraindication (eg, history of anaphylaxis or current unstable neurological condition) or the woman had previously received Tdap vaccine [11, 15]. During the period from January 2008 through May 2009, a 2-year minimum interval since receipt of a tetanus-containing vaccine (tetanus toxoid or tetanus-diphtheria toxoid) was observed [11]. In June 2009, the minimum interval was eliminated after the CDC issued updated guidelines [15]. Women who consented received Tdap vaccine on the day of hospital discharge, concomitant with rubella vaccine at a different site, if the latter was indicated. Vaccinated women were given a personal, updated vaccination record. When Tdap vaccine was not administered, hospital nurses documented the reason in the medical record.

Phase 2: Tdap vaccination of household contacts. Beginning in June 2009, postpartum women were interviewed Monday through Friday by the program nurse to ascertain the number of household contacts and the number of contacts eligible to receive Tdap vaccine by age and vaccination history. Supplemental education was provided to women and contacts as necessary. Contacts who desired vaccination were referred to The Cocoon Family Vaccine Center, a dedicated room for the program on the postpartum floor. Contacts who were unable to avail themselves of Tdap vaccination prior to maternal hospital discharge also were referred here by other HCPs and by the newborn follow-up outpatient clinic.

Tdap vaccine recipients completed a screening questionnaire adapted from those recommended by the CDC and Immunization Action Coalition (available at http://www.immunize.org/catg.d/p4065.pdf). This questionnaire recorded their personal demographic data and previous tetanus-containing vaccination history, screened for medical contraindications, and documented their consent for vaccination. Eligible, consenting contacts received Tdap vaccine as recommended [16]. Each vaccinated contact was provided with an updated vaccination record for future use. Tdap vaccination was documented for program records.

Where possible, for each infant, the number of contacts who received Tdap vaccine was compared with the number of contacts eligible to receive Tdap vaccine. An infant was classified as

being completely cocooned when it was confirmed that the mother and all eligible infant contacts had received Tdap vaccine (either through this program or through documentation of prior Tdap vaccination). Partial cocoons were expressed as a percentage of vaccinated versus eligible persons.

Identifying barriers. The program was assessed on a regular basis to determine Tdap uptake and identify areas for process improvement. Records were reviewed for demographic characteristics and to define reasons for not administering Tdap vaccine. The implementation of Phase 2 coincided with the 2009 H1N1 influenza pandemic, and the hospital instituted visiting restrictions in late September 2009 through the end of the study period. Only 1 named contact per postpartum woman was permitted to visit for the duration of the hospitalization. Other contacts were permitted to come to the clinic for vaccination but were not permitted to visit mother or baby. Tdap vaccine uptake before initiation of these restrictions was compared with uptake after restrictions were in place.

Financing could be a barrier to implementing cocooning; thus, the annual cost to the hospital of delivering this service (including overhead, personnel, and vaccine costs) was determined. Vaccine cost was determined from price lists available from the CDC (available at http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm). The number of Tdap vaccine-eligible individuals was calculated by multiplying the annual hospital birth rate by the median number of eligible persons per newborn, as determined by maternal interview.

Statistical analysis was performed using SPSS software, version 15.0 for Windows (SPSS). Statistical significance for dichotomous outcomes was determined by χ^2 and Fisher exact tests. Normally distributed data were assessed by means and the Student's *t* test; where positive or negative skewing of data occurred, statistical significance was assessed by medians and the Mann-Whitney *U* test.

RESULTS

Phase 1: Tdap vaccination of postpartum women. One-hundred and fifty HCPs completed in-service training, which was repeated at regular intervals. From 7 January 2008 through 31 January 2010, 8334 (75%) of 11,174 postpartum women (median age, 27 years; range, 11–47 years) received Tdap vaccine prior to hospital discharge. No serious adverse events were reported.

From 1 June 2009 through 31 January 2010, following elimination of the requirement for a 2-year minimum interval since receipt of prior tetanus-containing vaccine [15], 2969 (86%) of 3455 postpartum women received Tdap vaccine prior to discharge from the hospital (91% of those who reported themselves eligible). An additional 197 (6%) had documented prior Tdap vaccination; 172 of these had been vaccinated by our program following the birth of a previous infant. Vaccinated women during this interval had demographic characteristics that were similar to those of the overall cohort. Two-hundred and ninety-two (10%) were ⩽19 years of age. Women who had received Tdap vaccine during the current hospitalization or previously did not differ by age, but they did differ by ethnicity, when compared with women who had not received Tdap vaccine. The proportions of white and black women who refused Tdap vaccine were 3.1-fold and 2.1-fold greater, respectively, than those who did not ($P < .001$) (Table 1).

Phase 2: Tdap vaccination of household contacts and caregivers. Sixty-seven percent of postpartum women (2303 of 3445) were interviewed by the program nurse. Most women who were not interviewed delivered their infants and were discharged from the hospital on days on which the program nurse was not present (generally on the weekend). Maternal interviews identified that families had a median of 4 household contacts (range, 1–15 contacts), of whom a median of 3 contacts (range, 1–11 contacts) were eligible for Tdap vaccination (age range, 11–64 years; no prior Tdap vaccine; no medical contraindications). The median number of vaccinated contacts was 2 (range, 0–10 contacts). Overall, 1332 (58%) of the families of interviewed mothers had ⩾1 household contact (other than the mother) vaccinated with Tdap by this program.

The characteristics of 1860 infant contacts who received Tdap vaccine are summarized in Table 2. A total of 1697 (91%) were

Table 1. Characteristics of Women Vaccinated and Not Vaccinated with Tetanus, Diphtheria, Acellular Pertussis (Tdap) Vaccine at Hospital Discharge from 1 June 2009 through 31 January 2010

	No. (%) of women	
Variable	Vaccinated[a] (*n* = 3166)	Not Vaccinated (*n* = 279)
Ethnicity[b]		
Hispanic	2891 (91.3)	228 (81.7)
Black	167 (5.3)	31 (11)
Asian	47 (1.5)	5 (1.8)
White	27 (.8)	7 (2.5)
Other	34 (1.1)	8 (2.8)
Age group		
10–19 Years	314 (9.9)	32 (11.5)
20–24 Years	738 (23.3)	65 (23.3)
25–29 Years	918 (29)	71 (25.4)
30–34 Years	858 (27.1)	75 (26.9)
35–39 Years	249 (7.9)	25 (9)
⩾40 Years	89 (2.8)	11 (3.9)

NOTE. No minimum interval since previous tetanus-containing vaccine after 1 June 2009.

[a] A total of 2969 individuals received Tdap vaccine between 1 June 2009 and 31 January 2010; 197 had previously received Tdap vaccine

[b] $P < .001$.

vaccinated before or on the day of infant discharge from the hospital; an additional 144 (8%) were vaccinated on days 1–7 after infant hospital discharge. A total of 1813 contacts (98%) reported daily contact with the infant, and 63% anticipated that contact would exceed 12 h per day. One-thousand and eighteen (55%) could not remember when their last tetanus-containing vaccine was administered, even to within a 5-year interval. One patient reported feeling ill 48 h after Tdap vaccine administration; this was deemed to be unrelated to Tdap vaccination after the patient received a diagnosis of gastroenteritis from her physician.

Pertussis vaccination histories for each contact were obtained for 2268 (99%) of 2303 families. Following this program, a complete cocoon (vaccination of 100% of infant contacts) was achieved for 579 (26%) of the infants. Overall, the median percentage of each cocoon completed was 50% (range, 0%–100%).

Effect of the H1N1 pandemic. Following the institution of hospital visiting restrictions during the H1N1 pandemic, Tdap vaccination rates decreased. Among interviewed families, the proportion of fathers vaccinated decreased from 58% to 49% ($P < .001$); families with ⩾1 contact (other than the mother) vaccinated decreased from 64% to 53% ($P < .001$), and the proportion of families with a completed cocoon decreased from 28% to 23% ($P < .001$). The Tdap vaccine uptake rate among postpartum women increased from 89% to 94% during the same time period ($P = .002$).

Table 2. Characteristics of 1860 Contacts Vaccinated with Tetanus, Diphtheria, Acellular Pertussis (Tdap) Vaccine

Variable	Contacts
Age, median years (range)	30 (11–64)
Age group	
11–19 Years	140 (7.5)
20–29 Years	763 (41)
30–39 Years	633 (34)
40–49 Years	219 (11.8)
>50 Years	105 (5.7)
Ethnicity	
Hispanic	1757 (94.5)
Black	47 (2.5)
White	31 (1.7)
Asian	20 (1.1)
Other	5 (.2)
Relationship to infant	
Father	1219 (65.5)
Sibling	54 (3)
Grandmother	186 (10)
Grandfather	45 (2.4)
Aunt	174 (9.4)
Uncle	119 (6.4)
Great-grandparent	4 (.2)
Caregiver	43 (2.3)

NOTE. Data are no. (%) of contacts, unless otherwise indicated.

Estimate of annual cost. We estimated the cost per dose of Tdap vaccine administered as $40, considering the CDC contract cost per dose ($26.25) plus the cost of overhead, faculty, and nursing personnel required to administer the program. Assuming an annual birth rate of 5000 babies and 4 persons (mother and 3 Tdap vaccine–eligible contacts) vaccinated to complete a cocoon, the annual cost of this program was estimated at approximately $800 000.

DISCUSSION

This report is, to our knowledge, the first to document successful implementation of pertussis cocooning in a US hospital setting in a population at particular risk of transmitting life-threatening pertussis to young infants [3, 4, 7–10, 17]. Cocooning is difficult to implement [12–14, 18, 19]. Cocooning involves a new vaccination platform utilizing health care providers who may be relatively unfamiliar with the severity of pertussis illness in young infants and who, traditionally, have not provided vaccinations. It targets 2 populations, postpartum women and the contacts of newborn infants until 1 year of age, who have different educational needs and are governed by different state and legal requirements regarding vaccinations. Finally, there are significant financial constraints for hospitals and physicians.

We achieved overall Tdap vaccination rates in excess of 90% in postpartum women, which is the group who are most likely to infect young infants [8, 9, 15, 20]. Eliminating the minimum 2-year interval since receipt of prior tetanus-containing vaccine is the most important explanation for this increase from our previously reported 72% vaccination rate [13]. Our cohort has little access to health care outside of childhood and peripartum periods and is more likely to receive recommended tetanus-diphtheria toxoids (Td) booster vaccine during pregnancy, precluding them from receiving postpartum Tdap vaccine in prior years. This was exacerbated by inaccurate reports of Td vaccine receipt when other intramuscular agents were administered during pregnancy [13]. It also is likely that repeated education targeting HCPs, coupled with their increasing familiarity with the rationale for cocooning, enhanced their role as vaccination advocates. However, although postpartum vaccination is a necessary prerequisite for the "protective cocoon" around a newborn infant, it alone is unlikely to reduce infant infection rates by more than a third, if that [8, 9, 15]. Furthermore, the 14-day window required to develop a "protective" antibody response to pertussis [15] could allow maternal infection with subsequent infant transmission. The most significant limitation of focusing only on postpartum women is that household contacts also may infect infants [6, 8, 9, 20–23], especially in populations where large households are the rule.

Establishing a platform to vaccinate family and household contacts is particularly challenging. Ideally, this platform should deliver the service prior to the infant's birth, thus allowing time for protective immunity to develop before the infant's birth. In practice, this is unlikely to occur, given that preventative services often are not a priority for healthy adults. Delivering a service before the infant's discharge from hospital is a reasonable, if imperfect, compromise that will theoretically provide indirect protection to infants by age 14 days. A hospital-based program is likely to be superior to models that target pediatrician offices because it can vaccinate and protect contacts earlier. A hospital-based program also can theoretically immunize larger, more-diverse populations of contacts who may be more likely to visit the hospital than to attend well-child visits, and it provides a service for contacts before the demands of caring for a newborn infant take priority after hospital discharge [14].

A hospital program is subject to significant barriers, however. There are state-specific legal and logistical complexities when vaccinating individuals who are not hospital patients. There is the need to provide service during times when working families are visiting (eg, evenings and weekends). We achieved a remarkably good vaccination rate for a new platform (~60% for families who were interviewed by a program nurse). This personal intervention was superior to utilizing postpartum nursing personnel alone and was particularly effective for families who visited during cocoon clinic operating hours, compared with families who received clinic referrals. We have recently expanded our service, adding an additional program nurse on weekends to overcome this limitation; however, this increases program cost considerably.

Our program highlights some inherent limitations of current vaccination platforms and future cocooning strategies. We vaccinated significant numbers of adolescents, who are epidemiologically at high risk of transmitting pertussis but are more properly targeted by the adolescent platform [20, 24–26]. Furthermore, this age group, for whom school mandates have been established, is not affected by vaccine procurement costs, as older age groups are, because cost is covered by the Vaccines for Children program. The need for access to lifespan vaccination registries is also highlighted, because recall of vaccination history is notoriously unreliable. This will assume greater importance if recommendations for Tdap booster doses are made. The cost of Tdap vaccine procurement and administration is often viewed as prohibitive for hospitals and physicians, because this has not yet been bundled into maternity charges covered by Medicaid or by many insurance plans.

One attraction of a cocooning delivery model is the potential to immunize against infections that target very young infants in cases in which infant vaccination is not appropriate (eg, influenza). Our finding that the Tdap vaccine uptake rate among postpartum women increased during the 2009 H1N1 influenza pandemic, probably attributable in part to greater awareness of vaccinations in general, suggests that this approach could have synergy in preventing both infections. Ironically, the pandemic also negatively impacted our ability to cocoon against pertussis when infection control measures eliminated the very motivation (ie, visit to mother and infant) that allowed us to vaccinate a diverse group of household contacts.

Our study has some limitations. First, despite our best efforts to verify vaccination history, inaccurate reports of prior Tdap vaccination may have reduced our vaccination rates. However, program nurses were very proactive and administered Tdap vaccine when the vaccination history seemed doubtful, realizing that the benefit to contacts and infants exceeded the risk of greater injection site reactions. Second, we could have underestimated the number of cocoons completed, because additional contacts may have accessed no-cost or low-cost vaccines through public health clinics, as noted in our educational materials, especially during times when H1N1 vaccine also was available. Finally, publicity surrounding the importance of vaccinations that accompanied the 2009 H1N1 pandemic could have positively affected our cohort's acceptance of Tdap vaccine, although high acceptance rates have previously been reported in this population [13].

Cocooning alone is unlikely to completely prevent infant pertussis-related deaths, because the infant is vulnerable in the first few weeks of life. Augmenting cocooning with maternal vaccination in the third trimester of pregnancy could offer greater benefit. This approach was shown to be safe and effective with whole-cell vaccines many decades ago [27, 28]. Contemporary studies have demonstrated that pertussis antibodies are actively transported from mother to infant, the half-life of this antibody has been calculated, and high maternal antibodies did not interfere with infant response to acellular pertussis vaccines [29–33]. Maternal vaccination could be a potent weapon in reducing pertussis-related mortality and morbidity in early infancy, while allowing more time for vaccination of other contacts.

In summary, our study demonstrates 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. In addition to the costs and hospital HCP support outlined, our program utilizes the services of 2 physicians, 2 full-time program nurses, and administrative support that is not reimbursed by the hospital. Targeted educational initiatives need to be delivered and updated frequently to meet the specific needs of the target population. Ideally, the service should be delivered either before or as soon as possible after birth and not restricted to 8 am to 5 pm on Monday through Friday, but scheduled for the convenience of working contacts. A variety of vaccination providers should be used. It is only through the investment of time and finances and by using innovative models in a co-

operative fashion that a successful infant cocoon program can be achieved.

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