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Long-term Follow-up of Swedish Children Vaccinated With Acellular Pertussis Vaccines at 3, 5, and 12 Months of Age Indicates the Need for a Booster Dose at 5 to 7 Years of Age

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ABSTRACT

OBJECTIVES. The purpose of this work was to evaluate the long-term effectiveness of vaccination with acellular pertussis vaccines at 3, 5, and 12 months of age.

METHODS. Clinical follow-up of reported culture- and polymerase chain reaction–confirmed cases of pertussis was initiated during October 1997 in most of Sweden (except Gothenburg and environs). The study population included 90% of Swedish children born during 1996 or later (ie, who received diphtheria-tetanus-acellular pertussis vaccines at 3, 5, and 12 months of age) and children who had participated in a large pertussis vaccine trial in 1993–1996. Age-specific incidences were estimated using reported culture- or polymerase chain reaction–confirmed pertussis from October 1997 to September 2004 in areas covered by enhanced surveillance. In addition, annual overall and age-specific incidences of pertussis throughout Sweden before and after introduction of acellular pertussis vaccines were estimated.

RESULTS. The overall incidence of notified culture- and polymerase chain reaction–confirmed pertussis dropped from 113 to 150 per 100 000 during 1992–1995 to 11 to 16 per 100 000 during 2001–2004. In areas of enhanced surveillance, the incidence of pertussis was 31 per 100 000 person-years after 2 doses and 19 per 100 000 person-years after the third dose at 12 months of age. The age-specific incidence remained low for ~5 years after the third dose but increased in children aged 6 to 8 years, becoming 32 and 48 per 100 000 person-years, respectively. The highest incidence occurred among infants who were unvaccinated or had received only 1 dose of diphtheria-tetanus-acellular pertussis vaccine.

CONCLUSIONS. The increased incidence among 7- to 8-year-olds (ie, mainly acellular pertussis vaccine–vaccinated children) suggests waning of vaccine-induced protection from pertussis. Along with a concomitant increase in incidence among infants, most likely infected by older siblings, these data suggest a booster dose of acellular pertussis vaccine is warranted from 5 to 7 years of age.

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Key Words

acellular pertussis vaccines, surveillance, immunization schedule

Abbreviations

aP—acellular pertussis
DTaP—diphtheria-tetanus-acellular pertussis
PCR—polymerase chain reaction
WHO—World Health Organization
DTwP—diphtheria tetanus whole-cell pertussis
CI—confidence interval

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PREVIOUS CLINICAL STUDIES and field experiences in Sweden, Italy, and Germany have shown a marked reduction of pertussis for 5 to 6 years¹⁻⁴ after 3 or 4 doses of acellular pertussis (aP) vaccine. These vaccines were shown to effectively control endemic pertussis and reduce the peak in disease among 2- to 4-year-old children. However, control of pertussis among unvaccinated infants has not been fully achieved.⁴ This is consistent with several reports that severe pertussis in infants remains a problem in countries with longstanding vaccination programs against pertussis.⁵⁻¹⁰ Additional observations are needed to determine when diphtheria-tetanus-acellular pertussis (DTaP) vaccine-induced protection from pertussis wanes.

This report extends our previous observations⁴ until 8 years after the introduction of aP vaccines among infants in Sweden in 1996. The purpose of this work was to evaluate the long-term effectiveness of vaccination with aP vaccines at 3, 5, and 12 months of age.

METHODS

In a previous publication,⁴ the routine reporting of laboratory-confirmed pertussis in Sweden, covering the period from 1996 to September 2000, and the enhanced surveillance since October 1997 of children with a pertussis episode were described. The present report updates enhanced surveillance through September 2004 and, from the routine reporting system, overall and age-specific pertussis incidences through 2004. We did not seek informed consent from involved parents, because we only report public health data according to the Communicable Disease Act for which informed consent is not required. Briefly, materials and methods are provided here.

Routine Reporting

During the period 1980–1995, culture-confirmed pertussis was voluntarily reported from all of the bacteriologic laboratories with full personal identifiers. Pertussis was included in the new Communicable Disease Act in 1997. Since the autumn of 1997, all cases of pertussis confirmed by culture and by polymerase chain reaction (PCR) have been reported to the Swedish Institute for Infectious Disease Control through a computerized system. Clinical and immunization data are either incomplete or lacking in this routine reporting system.

Annual overall and age-specific incidences of pertussis in Sweden from 1986 to 1995 and from 1998 to 2004 were based on the total number of notified culture- or PCR-confirmed pertussis cases in the whole population and in each age group. To calculate incidences, we estimated person-time of follow-up from the annual mean population in 1-year classes for each year (data from Statistics Sweden, www.scb.se) and calculated age at episodes from the dates of birth and positive laboratory samples. Only the overall incidence of notified pertussis

could be estimated for 1996 and 1997, because during these years, legal restrictions prohibited combining information on dates of birth and positive laboratory findings.

Enhanced Surveillance

In October 1997, clinical follow-up of reported culture- and PCR-confirmed cases of pertussis was initiated for children born during 1996 or later (ie, who received DTaP vaccines at 3, 5, and 12 months of age) and children born from June 1993 to May 1994, who had participated in a large pertussis vaccine trial (1993–1996), which enrolled ~71% of the national birth cohort.¹¹ The present report does not include clinical data and vaccination histories for notified cases from the Gothenburg area (with 10% of the Swedish population), where pertussis surveillance was part of another clinical trial until 2001.¹ For the studied age groups, the clinical course and vaccination history of children with notified laboratory-confirmed pertussis were documented by telephone by study nurses according to the same procedures as in the large trial during 1993–1996. Parental permission was obtained to request medical charts as needed.

We used a primary case definition of culture-confirmed or PCR-confirmed *Bordetella pertussis* regardless of symptoms. Typical pertussis was defined as culture- or PCR-confirmed pertussis with ≥ 21 days of spasmodic cough, corresponding with the World Health Organization (WHO) pertussis case definition.¹²

Based on the number of notified pertussis cases during the study period October 1, 1997, to September 30, 2004, age-specific incidence rates of pertussis among children born January 1, 1996, or later and among children born 1993–1994 vaccinated in the 1993–1996 trial were estimated as described previously⁴; complete results are available in the “Seven-Year Report-Pertussis Surveillance in Sweden” (available at www.smittskyddsinstitutet.se).

Vaccines Used

During 1996 and 1997, a 3-component DTaP containing pertussis toxin, filamentous hemagglutinin, and pertactin (Infanrix from GlaxoSmithKline) was used throughout Sweden, except in the Gothenburg area. From 1998 onward, a 2-component aP (pertussis toxin and filamentous hemagglutinin) pentavalent vaccine (Pentavac from Sanofi Pasteur MSD) replaced this vaccine in several counties. Since 2000, the pentavalent vaccines Infanrix–Polio+Hib and Pentavac have been used throughout the country. To avoid potentially biased comparisons by virtue of vaccines used in different geographical areas at various times, our analysis is limited to aP vaccination irrespective of product.

This report also includes observations on confirmed pertussis among children born during 1993–1994 who participated in the pertussis vaccine trial from 1993–

1996.¹¹ Children in this trial were vaccinated with either 1 of 3 experimental DTaP vaccines or a diphtheria tetanus whole-cell pertussis (DTwP) vaccine from Evans (United Kingdom).

RESULTS

Enhanced Surveillance

During 7 years of follow-up from October 1997 to September 2004, there were 1293 cases of culture-confirmed pertussis among children born during 1996 or later. Most cases were reported in the youngest birth cohort in each calendar period. Of these, 516 were unvaccinated children, and 331 were ≤ 3 months of age. The incidence among unvaccinated children aged 0 to 2 months of age was 225 per 100 000 person-years (Table 1) compared with an average incidence of 337 per 100 000 person-years in that age group during the almost vaccine-free 10-year period of 1986 to 1995, before the introduction of aP-containing vaccines.⁴ Among children who had received only 1 dose of pertussis vaccine, incidence was 212 per 100 000 person-years compared with an average of 677 per 100 000 person-years in that age group from 1986 to 1995.⁴ A marked decline in reported incidence occurred after the second and third doses of pertussis vaccine. Between dose 2 and 3, the incidence was 31 per 100 000 person-years. In fully vaccinated children, incidence was 8 per 100 000 person-years among children ≤ 2 years of age (ie, within 1 year of the third dose of DTaP). Incidence gradually increased to 48 per 100 000 among the oldest group, aged 7 to 8 years. The incidence at 6 years old is similar to that at 5 to 12 months old (after the second dose of pertussis vaccine). From 7 years old on, incidence is even

higher, suggesting waning of protection by 6 to 7 years of age (Table 1).

During the 7-year follow-up period, there were 153 cases of culture-confirmed pertussis among participants in the 1993–1996 randomized, controlled pertussis vaccine trial¹¹ who had received trial doses at 3, 5, and 12 months of age (Table 2). These trial participants were between 3 and 11 years of age during the follow-up period. Their overall pertussis incidence (ie, regardless of vaccine group) was similar to that observed between doses 2 and 3 but higher than the overall incidence after dose 3 among children between 1 and 7 to 8 years of age in the enhanced surveillance cohort (Table 1), also indicating some waning of protection.

Lower point estimates of pertussis incidence were noted for children who had received the Evans DTWP vaccine and for DTaP recipients who had received a later booster dose of monovalent aP. The relative risk of confirmed pertussis was 1.67 (95% confidence interval [CI]: 1.10–2.56) for recipients of 3 doses of any acellular vaccine compared with 3 doses of DTWP. In contrast, children who had received 3 doses of a 2-component aP and a fourth dose of a 3-component aP vaccine had a lower risk (Table 2).

Routine Reporting

The overall annual incidence of culture- and PCR-confirmed *B pertussis* in the whole country was 89–150 per 100 000 person-years in the decade before introduction of aP vaccines in 1996. After a rapid drop from 1996 to 2000, the overall annual incidence has varied from 7 to 16 per 100 000 person-years from 2001 to 2004. The number of culture-confirmed cases per month showed a

TABLE 1 Number of Culture- or PCR-Confirmed Pertussis Cases and Incidence per 100 000 Person-Years in Unvaccinated Infants 0 to 2 Months of Age and Vaccinated Children by Age Group and Number of Doses Reported From October 1, 1997, to September 30, 2004, Among Children Born 1996 or Later in Areas Under Enhanced Surveillance

Vaccination Status	Person-Years of Follow-up	No. of Cases	Incidence per 100 000 Person-Years	95% CI ^a
Before dose 1				
Age 0–2 mo	147 260	331	225	201–249
Between doses 1 and 2				
Age 3–4 mo	97 920	208	212	184–241
Between doses 2 and 3				
Age 5–11 mo	354 615	110	31	25–37
After dose 3				
Age 1 y	602 040	51	8	6–11
Age 2 y	514 400	86	17	13–20
Age 3 y	432 540	83	19	15–23
Age 4 y	350 940	70	20	15–25
Age 5 y	269 340	59	22	16–27
Age 6 y	190 290	61	32	24–40
Age 7–8 y	102 815	49	48	34–61
All ages from 1 y	2 462 365	459	19	15–20

^a P values for differences between age-specific incidence estimates were not calculated because individual children may contribute to person-year estimates in several age groups.

TABLE 2 Number of Culture- or PCR-Confirmed Pertussis Cases and Incidence per 100 000 Person-Years of Follow-up Among Participants Who Had Followed the 3-, 5-, 12-Month Schedule in the 1993–1996 Randomized, Controlled Pertussis Vaccine Trial¹¹ Reported From October 1, 1997, to September 30, 2004, at 3 to 11 Years of Age

Trial Cohort (Vaccine)	No. of Children (Person-Years of Follow-up)	No. of Pertussis Cases	Incidence per 100 000 Person-Years (95% CI)	RR (95% CI)
3 doses of Evans DTwP	17 495 (122 465)	27	22 (14–30)	1.00
3 doses of CLL DTPa5	17 728 (124 096)	47	38 (27–49)	1.72 (1.06–2.74)
3 doses of Chiron DTPa3	17 739 (124 173)	44	35 (25–46)	1.61 (1.00–2.61)
3 doses of SB DTPa2	5542 (38 794)	15	39 (19–58)	1.75 (0.93–3.28)
3 doses of SB DTPa2 + 1 dose SB Pa3	12 122 (84 854)	20	24 (13–34)	1.07 (0.60–1.92)
Total	70 626 (494 382)	153	31 (26–36)	

Risks are given for acellular vaccine recipients relative to recipients of the British whole-cell vaccine, Evans DTwP. CLL indicates Connaught Laboratories Ltd, Canada; SB, Smith Kline Biologicals, Belgium; Pa5, 5-component; Pa3, 3-component, Pa2, 2-component acellular pertussis vaccine.

marked peak every third winter (1987–1988, 1990–1991, and 1993–1994; Fig 1), whereas only small undulations were observed during 2001–2004, 5 to 8 years after the introduction of aP vaccines.

The annual age-specific incidence rates from 1992 to 1995 before and 1998 to 2004 after introduction of DTaP-containing vaccines are shown in Fig 2. After the introduction of these vaccines, the age-specific incidence rates were markedly lower compared with before. The peak incidence in the pre-1996 era was between 1400 and 2000 per 100 000 person-years and occurred among 2- to 3-year-old children. In the vaccinated cohorts born after 1996, each age-specific annual pertussis incidence was <150 per 100 000 person-years beginning in 2001. The reduction of age-specific incidence is least marked below 1 year of age.

Cross-sectional population data suggest a shift in pertussis incidence from 2- to 4-year-old children during

the no-vaccination period to 5-year-olds in 2000, 6-year-olds in 2001, 7-year-olds in 2002, and 8-year-olds in 2003, corresponding with the youngest partially vaccinated cohorts, born 1994 and 1995. This trend was interrupted in 2004, when the highest incidence after infancy was observed among 8-year-old mainly immunized children, born 1995 and 1996 (Fig 3).

DISCUSSION

The enhanced pertussis surveillance program in Sweden was established to document the long-term effects of aP vaccines beyond their demonstrated efficacy in randomized, controlled trials.¹³ The routine passive reporting program for pertussis in Sweden is well established and was used in the nationwide pertussis trial in 1993–1996.¹¹ The vaccination status of children is well documented, and coverage of 3 doses of aP vaccine has been consistently high, >98% at 2 years of age, since

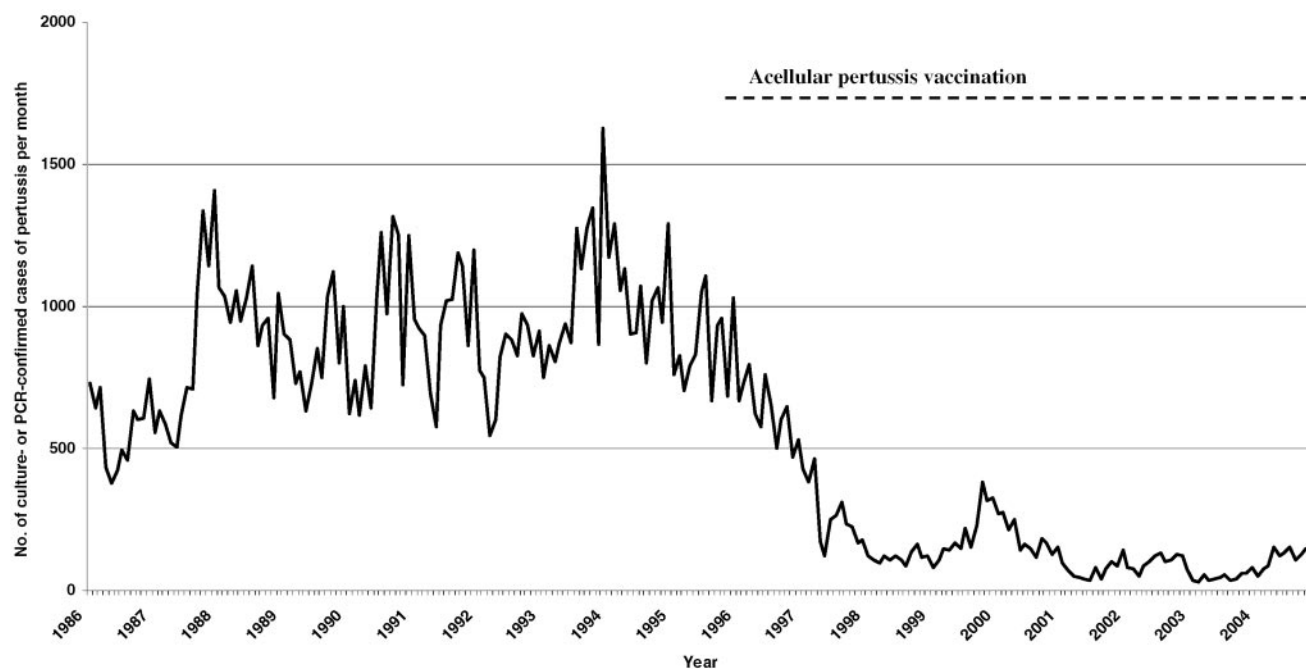


FIGURE 1

Number of culture- and PCR-confirmed pertussis cases in all of Sweden per month from January 1986 to December 2004. Source: www.smittskyddsinstitutet.se.

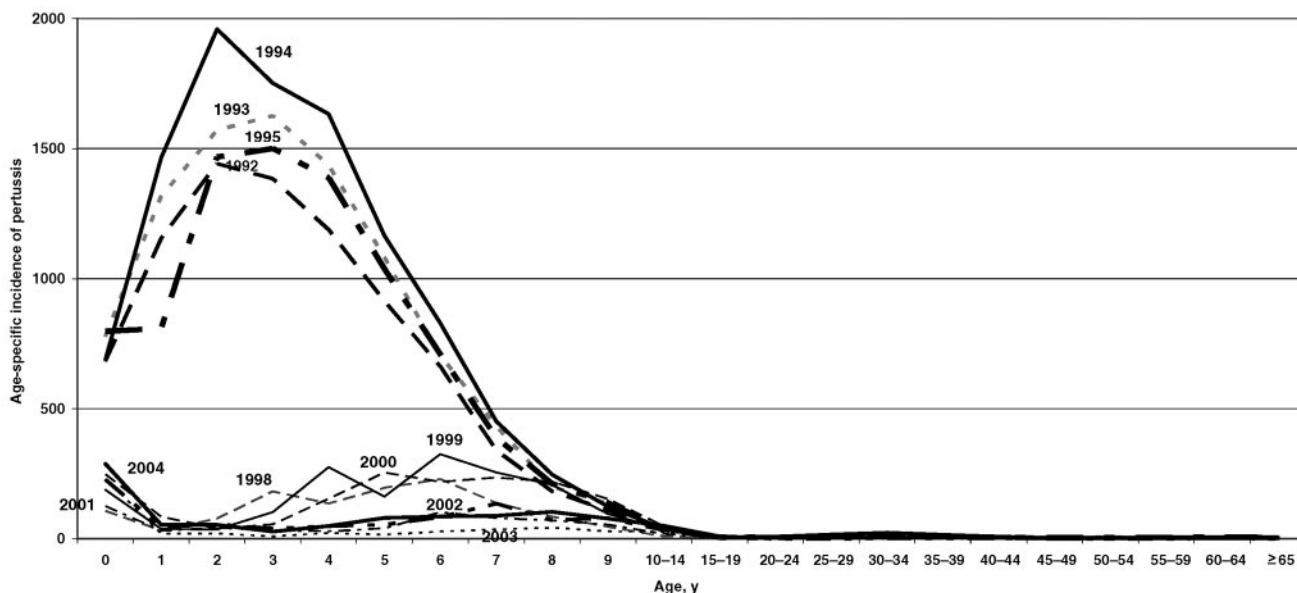


FIGURE 2 Annual age-specific incidences in all of Sweden preintroduction (1992–1994) and postintroduction (1998–2004) of DTaP in 1996. Source: www.smittskyddsinstitutet.se.

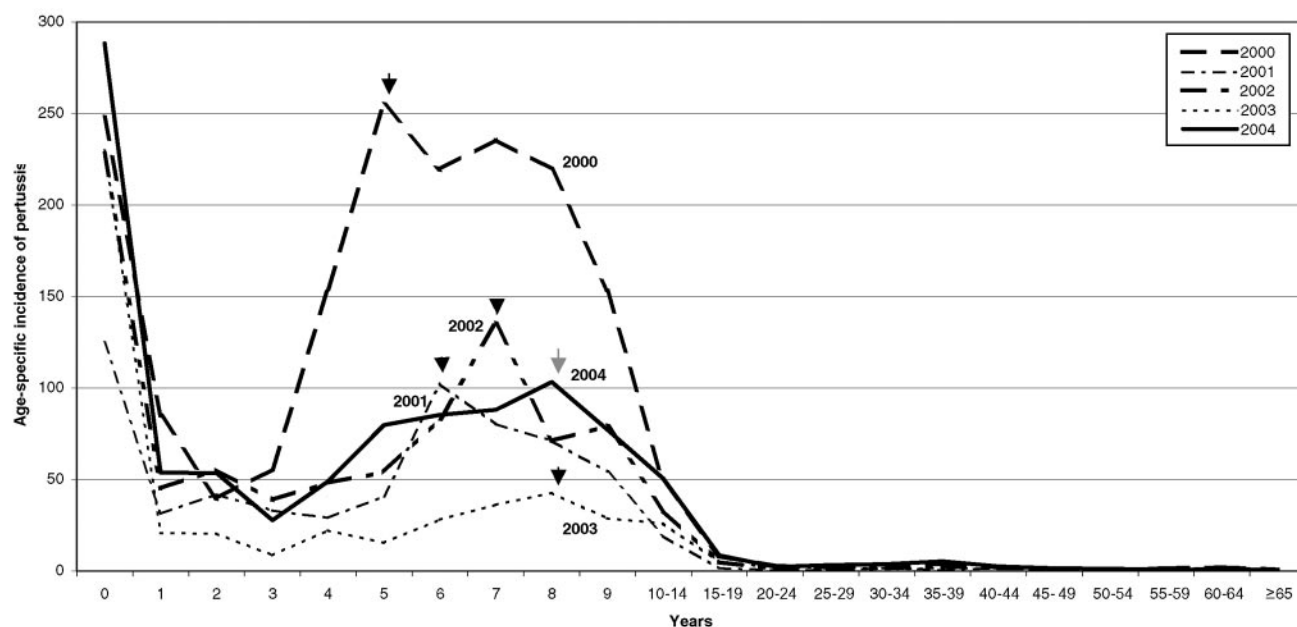


FIGURE 3 Enlarged detail of annual age-specific incidences for 2000 to 2004 postintroduction of DTaP. Arrows indicate peak incidence cohorts.

these vaccines were introduced in 1996. However, it should be noted that 90% of notified culture- or PCR-confirmed pertussis cases among unvaccinated children fulfilled the WHO-definition of ≥ 21 days of spasmodic cough, compared with 78% among children who had received ≥ 1 dose of pertussis vaccine ($P < .001$; data not shown). The relatively small difference between the proportion of cases meeting the WHO case definition among immunized and unimmunized children is not in accordance with observations during the randomized, con-

trolled trial of 1992–1995¹³ and suggests an underreporting of mild cases among immunized children.

Despite the limited and differential sensitivity of culture- and PCR-confirmed pertussis and potential heterogeneity in surveillance activities between subnational regions, the enhanced surveillance program with careful follow-up of identified cases provides valuable information to evaluate and support immunization policies. After introduction of the acellular vaccines in 1996, the overall incidence of reported pertussis in Sweden rapidly

decreased and has since 2000 stabilized at a low level corresponding with incidence in the late 1960s when an efficacious Swedish DTwP vaccine was used.¹⁴ We may conclude with confidence that the incidence of pertussis has dropped markedly from the second dose of DTaP at 5 months of age and that protection remains stable after the third dose at 12 months of age for ~5 or 6 years.

Point estimates of aggregated age-specific incidence of pertussis in the areas covered by enhanced surveillance and annual age-specific incidences of pertussis throughout Sweden indicate that protection has declined somewhat 6 to 7 years after the primary series. The rate of pertussis is then similar to that after 2 doses of aP vaccine. Data from the clinical trial follow-up (Table 2) covering a later period, 4 to 10 years after the primary series, also show higher average incidence of notified pertussis than during the first 5 to 6 years. Interestingly, long-term follow-up supports and extends the observation in clinical trials that an efficacious whole-cell vaccine is somewhat more protective than acellular vaccines, now also including the 5-component vaccine. Our data provide evidence that protection via aP vaccines wanes in a time frame similar to, or even more rapidly than, that observed for whole-cell vaccines.^{5,6} Sweden recently introduced a fourth dose of aP vaccine at 10 years of age, when the fourth dose of diphtheria tetanus vaccine was given in the Swedish immunization schedule.¹⁵ However, these observations suggest that 10 years of age might not be the optimal age for a booster after doses at 3, 5, and 12 months of age.

CONCLUSIONS

Data from the present 7 years of enhanced surveillance indicate a sizable reduction in the incidence of pertussis also among unvaccinated infants <3 months of age and perhaps even more among incompletely immunized infants <5 months of age, in parallel with decreasing incidence in older vaccinated age groups (Table 1 and Fig 2). However, almost half of the reported pertussis cases occurred among these young infants (www.smittskyddsinstitutet.se).

Our observations support the introduction of a booster dose of pertussis vaccines around school entry, already introduced in several countries,¹⁶ and suggested in Sweden at ~6 years of age.¹⁷ The rationale is not solely to reduce pertussis among school children, but to further decrease the risk of pertussis among young infants. To evaluate planned changes in the immunization program, surveillance focusing on the incidence of pertussis among school children, as well as rates of hospitalization and severe disease among infants, is warranted.⁷

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DO SCHOOL SYSTEMS AGGRAVATE DIFFERENCES IN NATURAL ABILITY?

“In our mobile societies, few of this month’s graduating high-school seniors have been with the same classmates for 12 years. But if you know such students, think back to the pupils who, at five years old, were pint-sized math whizzes and spelling champs. Now match those memories with the seniors at the top of their class. You’ll likely find a near-perfect match. That raises some disturbing questions. Why doesn’t 12 years of schooling raise the performance of kids who start out behind? Can you really tell which toddler is destined for Cal Tech? For as long as there has been a science of intelligence (roughly a century), prevailing opinion has held that children’s mental abilities are highly malleable, or ‘unstable.’ Cognition might improve when the brain reaches a developmental milestone, or when a child is bitten by the reading bug or suddenly masters logical thinking and problem solving. Some kids do bloom late, intellectually. Others start out fine but then, inexplicably, fall behind. But according to new studies, for the most part people’s mental abilities relative to others change very little from childhood through adulthood. Relative intelligence seems as resistant to change as relative nose sizes. One of the more striking findings comes from the longest follow-up study ever conducted in this field. On June 1, 1932, Scotland had all children born in 1921 and attending school—87,498 11-year-olds—take a 75-question test on analogies, reading, arithmetic and the like. The goal was to determine the distribution of intellectual ability. In 1998, scientists at the Universities of Edinburgh and Aberdeen tracked down 101 of those students, then 77 years old, and administered the same test. The correlation between scores 66 years apart was a striking .73. (A correlation of 1 would mean no change in rankings: a correlation of .73 is very high.) There is ‘remarkable stability in individual differences in human intelligence’ from childhood to old age, the scientists concluded in a 2000 paper. In the US, two long-running studies also show the durability of relative intelligence. The Early Childhood Longitudinal Study, launched in 1998, tested 22,782 children entering kindergarten. As in the Scottish study, individual differences in mental ability were clear and persistent. In math and reading, when the children were sorted into three groups by ability, ranking stayed mostly the same from kindergarten to the end of the first and third grades. Some gaps actually widened.”

Begley S. *Wall Street Journal.* June 2, 2006

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