Frequency of Alternative Immunization Schedule Use in a Metropolitan Area

WHAT'S KNOWN ON THIS SUBJECT: Parents are increasingly following alternative immunization schedules. Current studies suggest up to 21% of parents in the United States are intentionally delaying or refusing some or all of the recommended early-childhood vaccines.

WHAT THIS STUDY ADDS: This is the first study to use Immunization Information System data to quantify the proportion of children consistently delaying receipt of vaccines. Consistent-limiting children were found to have lower levels of recommended vaccines.

abstract

OBJECTIVES: Recent studies have described an increase in parental hesitancy regarding vaccines as well as increases in parental adoption of vaccine schedules that delay or limit receipt of recommended vaccines. This study quantifies potential prevalence and trends in alternative schedule compliance by measuring consistent shot-limiting in a metropolitan area of Oregon.

METHODS: Retrospective cohort analysis using the Oregon ALERT Immunization Information System to track children born between 2003 and 2009 in the Portland metropolitan area. Joinpoint regression was used to analyze prevalence trends in consistent shot-limiting during that time period. The 2007–2009 *Haemophilus influenzae* type b vaccine shortage and increased availability of combination vaccines were also examined for their effects on shot-limiting rates.

RESULTS: A total of 4502 of 97 711 (4.6%) children met the definition of consistent shot-limiters. The proportion of consistent shot-limiters in the population increased from 2.5% to 9.5% between 2006 and 2009. Compared with those with no or episodic limiting, consistent shot-limiters by 9 months of age had fewer injections (6.4 vs 10.4) but more visits when immunizations were administered (4.2 vs 3.3). However, only a small minority of shot-limiters closely adhered to published alternative schedules.

CONCLUSIONS: The percentage of children consistently receiving 2 or fewer vaccine injections per visit between birth and age 9 months increased threefold within a 2-year period, suggesting an increase in acceptance of non–Advisory Committee on Immunization Practices vaccine schedules in this geographic area. *Pediatrics* 2012;130:32–38

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KEY WORDS

immunization, immunization schedules, vaccine hesitancy, vaccines

ABBREVIATIONS

ACIP—Advisory Committee on Immunization Practices
CDC—Centers for Disease Control and Prevention
CI—confidence interval
DTaP—diphtheria-tetanus-acellular pertussis
HepB—hepatitis B
Hib—*Haemophilus influenzae* type b
IIS—Immunization Information System
MPC—monthly percentage change
RR—relative risk

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Since 1995, the Advisory Committee on Immunization Practices (ACIP) has provided a recommended schedule of childhood vaccines that is supported by the American Academy of Pediatrics, the American Academy of Family Physicians, and the Centers for Disease Control and Prevention (CDC). From 1995 to 2010, the number of antigens on the ACIP schedule recommended by age 2 years increased from 9 to 14.[1,2] As this number increased, so have parental concerns about the individual and cumulative effect of vaccines.[3] Overall, 21.8% of US parents have deliberately delayed or refused vaccines[4] for various reasons, including skepticism about the safety of vaccines,[5–8] fears that too many vaccines are given at young ages,[5,9,10] pain associated with multiple injections,[8] concerns about the effect of vaccines when a child is ill,[4] and questioning whether certain vaccines are necessary.[11] Also present is mistrust toward industries and governments associated with vaccination.[12] In response to these concerns, alternative vaccination schedules offering variations on the ACIP schedule while legitimizing parental worries have circulated widely through television, books, and Internet sources.[13]

Although alternative schedules emphasize individual parental choice, 3 common elements of alternative schedules include delaying receipt of some vaccines or doses, selective avoidance of others, and limiting the number of vaccinations received at any provider visit. Two commonly cited alternative schedules are those of Dr Stephanie Cave and Dr Robert Sears,[14,15] originally published in books in 2001 and 2007, respectively. Both of these schedules call for limiting the number of vaccinations received at 1 time, along with delaying or avoiding some vaccines. As such, both alternative schedules call for more visits in the first year of life compared with the ACIP schedule.

Oregon has documented an increase in exemption rates to school vaccination requirements,[16,17] prompting the question of whether parents in Oregon are adopting alternative vaccination schedules. The primary objective of this study was to assess potential prevalence and trends in alternative schedule compliance in a metropolitan area of Oregon, as measured by consistent "shot-limiting" in early childhood, where no more than 2 vaccine injections are received during any provider encounter.

METHODS

Sample

The study population included children born between July 2003 and October 2009 whose most recent residence was within the Oregon Sentinel Immunization Surveillance region. The Oregon sentinel region is part of a CDC-sponsored surveillance system across multiple US sites[18] and represents the core of the Portland metropolitan area. Immunization records for study children were extracted from the ALERT Immunization Information System (IIS). IIS are population-based data systems capturing immunization doses administered by participating providers within a given area. The ALERT IIS receives immunization records from 100% of public providers and 95% of private providers in the sentinel region (CDC IIS Annual Report, 2009[19]) and contains both immunization and demographic records. Encounters without immunizations are not reported to ALERT. To reduce biases due to record scattering, partial reporting, and unobserved mobility, participants were restricted to those with $\geq$2 reported immunization visits by 9 months of age. Children who moved out of the sentinel area before 9 months of age were excluded from the study, as were those with no reported vaccinations. Children who moved in before 9 months of age were included, provided they met other study requirements.

Definitions

The injectable vaccines included in this analysis were diphtheria-tetanus-acellular pertussis (DTaP), polio, hepatitis B (HepB), *Haemophilus influenzae* type b (Hib), and pneumococcal conjugate. For the definition of consistent shot-limiting, vaccine injections were counted rather than total antigens received. Seasonal influenza injections were included in the total per immunization visit but were not otherwise assessed. For this study, the sample was categorized into 3 groups: consistent shot-limiters, episodic limiters, and nonlimiters (Fig 1). Consistent shot-limiters were defined as those children having no more than 2 vaccine injections on all immunization visits from birth up to 9 months of age. This definition is based on a common feature among alternative schedules[14,15] to limit the number of vaccines received on a given visit.

Visits up to 9 months of age were selected to include the 2-, 4-, and 6-month well-child visits according to the ACIP schedule, where generally $>$2 vaccinations are due at each visit, along with a post–6-month period in which alternative schedules specify extra visits.

Alternative Vaccine Schedules

The ACIP schedule recommends immunization visits at ages 2, 4, and 6 months. In comparison, Dr Cave's 2007 schedule specifies a total of 5 visits at 4, 5, 6, 7, and 8 months, and Dr Sears' "Alternative Vaccine Schedule" suggests a total of 6 visits at 2, 3, 4, 5, 6, and 7 months. Both Dr Cave and Dr Sears specify avoidance of HepB vaccines in the first 2 years of life, unless the birth mother is HepB surface antigen positive. Other specifics of Dr Cave's schedule, reissued in 2007, include entirely avoiding the rotavirus vaccine and delaying the pneumococcal vaccine until the second year of life. According to Dr Sears' schedule, infants would receive all recommended

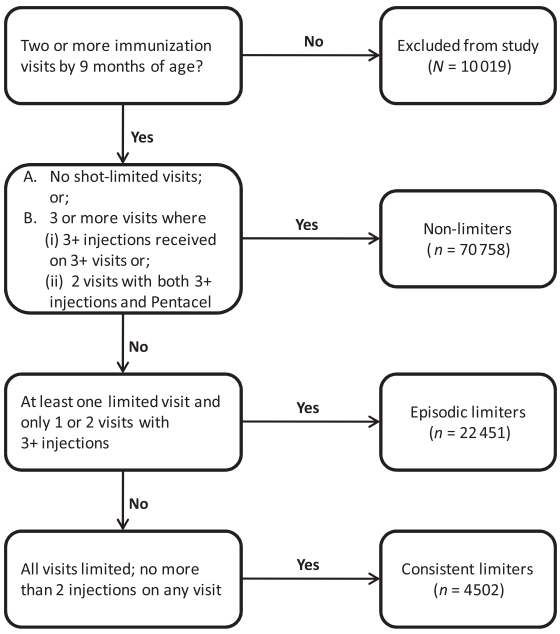

FIGURE 1
Shot-limiting classification system.

vaccines by 9 months of age except for the HepB and the polio vaccine.

Analysis

Trends in shot-limiting according to birth cohort were analyzed by using Joinpoint regression (Software from National Cancer Registry; Available at: http://surveillance.cancer.gov/joinpoint/). Joinpoint fits a set of line segments to trend data and detects points at which the fitted slopes significantly change between trend periods. In this study, data were grouped according to birth month cohorts, and the trend period unit of analysis was selected as monthly percentage change (MPC) instead of the more commonly used annual percentage change. Joinpoint regression produces estimates of the points in time at which rates or trends change, along with a temporal confidence interval (CI) about the trend change point.[20] In addition to Joinpoint regression, the proportions of consistent and episodic limiters were calculated by year.

Consistent shot-limiters were compared with those with nonlimiting or episodic limiting up to 9 months of age according to birth month cohorts for number of vaccinations, number of visits, and compliance with ACIP age-appropriate vaccination receipt. The percentage of shot-limiters compliant up to 9 months of age with the specifics of the 2 cited alternative schedules (those of Dr Cave and of Dr Sears) was also calculated.

The number of vaccine injections per visit was based on the count of immunization vaccine-administered codes per date of service (www2a.cdc.gov/nip/IIS/IISStandards/vaccines.asp?rpt=cpt). Consistent shot-limiters were identified by the number of vaccine injections received per visit on all visits between 24 and 274 days of age. Birth and early doses of HepB vaccine were included for the purpose of assessing age-appropriate vaccine receipt up to 9 months of age. Likelihood ratios and Fisher exact 95% CIs were calculated by using WINPEPI.[21]

To examine whether consistent shot-limiters use combination vaccines, uptake rates of 2 common DTaP-containing combination vaccines, Pediarix (licensed in 2002 [GlaxoSmithKline, Research Triangle Park, NC]) and Pentacel (licensed in 2008 [Sanofi Pasteur Inc, Swiftwater, PA]), were assessed. Pediarix contains DTaP, polio, and HepB components in a single injection. Pentacel includes DTaP, polio, and Hib. Both combination vaccines can be used as part of the ACIP vaccine recommendations at the 2-, 4-, and 6-month well-child visits. The impact of combination vaccines on patterns of limiting was also considered, as increases in the use of combination vaccines decrease the total number of injections needed per visit, although no combination presently on the US market allows for both ACIP schedule compliance and consistent receipt of $\leq$2 injections at each of 3 visits. The impact of the Hib vaccine shortage, from December 2007 through September 2009, was considered for its potential to reduce the number of vaccines received by children. Age-appropriate immunizations were also assessed at 19 months of age, per ACIP recommendations.

RESULTS

From July 2003 through October 2009, the Oregon ALERT IIS provided immunization records for 97 711 children in the sentinel region who met the analysis criteria. The average monthly birth cohort in the study population contained 1287 children. The average monthly birth cohort in the sentinel region during this period was 1394 children according to Oregon birth records. Overall, 9.3% of the initial study population was excluded; 51% had no immunization visits reported to ALERT, 30% had only 1, and 19% had $>$1 but failed to have $\geq$2 within the study age range. Overall, 4502 children, or 4.6% of the study population, met the definition of consistent shot-limiting. The rate of shot-limiting among birth cohorts varied from a low of 1.9% for the February 2006 cohort to a high of 11.6% for the October 2009 cohort.

Joinpoint regression analysis found 3 statistically distinct trends in shot-limiting

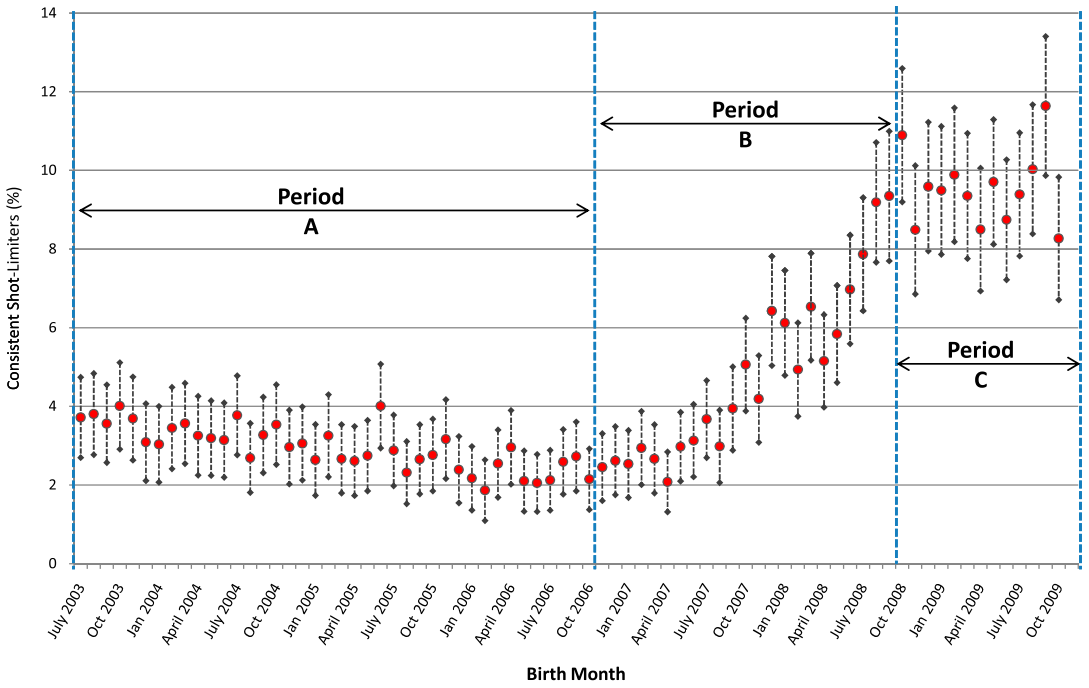

FIGURE 2

Consistent shot-limiting rates according to birth month, with distinct periods identified by using Joinpoint analysis as (A) mild decline from July of 2003 to October of 2006, (B) steep increase from November of 2006 to September of 2008, and (C) flat from October of 2008 to October of 2009. Results do not include those avoiding all immunizations.

rates according to birth month (Fig 2). The first trend represents a mild decline in shot-limiting rates, from 3.7% to 2.3%, for children born between July 2003 and November 2006, where the average MPC was −1.2% of the limiting rate (95% CI: −1.6% to −0.8% per month). The second trend period contained a rapid increase in rates starting with the November 2006 birth cohort and continuing through September 2008. During the second period, rates increased from 2.5% to 9.3%. In the second trend period, the MPC in limiting rate was 6.8% per month (95% CI: 5.9% to 7.7% per month). After September 2008, no discernable change in rates was detected (MPC rate: 0.1%; 95% CI: ±1.4% per month).

Joinpoint analysis was also used to determine temporal CIs for the beginnings and endings of each trend. For the period of rapid rate increase beginning with the November 2006 birth cohort, Joinpoint produced a 95% CI for the period's start as between August 2006 to March 2007. Similarly, the estimated 95% CI for the end of the period of rapid increase was from June 2008 through November 2008.

Yearly totals for consistent and episodic shot-limiters revealed increases across both categories, with a combined limiting rate increasing from 24.9% in 2004 to 39.6% in 2009 (Fig 3).

Up to 9 months of age, consistent shot-limiters received an average of 6.4 vaccination injections across 4.2 immunization visits (average of 1.5 injections per visit), compared with 10.4 vaccination injections across 3.2 immunization visits received by nonlimiters and episodic limiters (average of 3.2 injections per visit) ($P < .01$) (Fig 4).

The gap in immunizations between consistent shot-limiters and all others was significant for age-appropriate receipt of all vaccines by 9 months of age, with the greatest difference observed for the HepB primary vaccine series (28.0% series completion for consistent limiters versus 92.1% for nonlimiters and episodic limiters) and the smallest difference for the Hib series (54.3% series completion for consistent limiters versus 81.8% for nonlimiters and episodic limiters) (Table 1). At 9 months of age, the consistent limiters were substantially less likely to be caught up for any immunization series than nonlimiters or episodic limiters (average relative risk [RR]: 0.55). By 19 months of age, this risk was attenuated for those vaccinations that were due by 9 months (average RR: 0.72). However, the gap for vaccination due by 19 months remained unchanged (average RR: 0.54). In addition, at 19 months, consistent limiters were less likely on average to have received varicella, hepatitis A, or the measles-mumps-rubella vaccines (average RR: 0.48), which are only due after 1 year of age.

Consistent shot-limiters did not closely follow alternative schedules as specified by Dr Cave (0.9% [40 of 4502 consistent limiters across entire period])

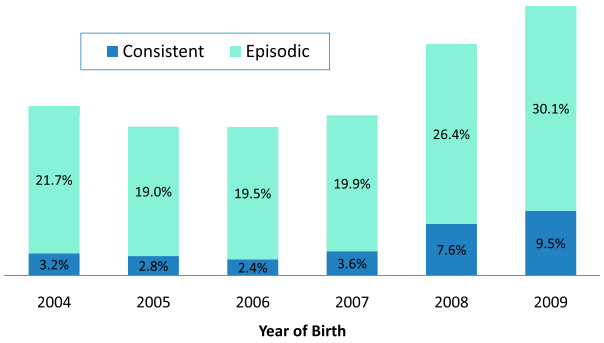

FIGURE 3
Consistent and episodic shot-limiters as a percentage of yearly birth cohort.

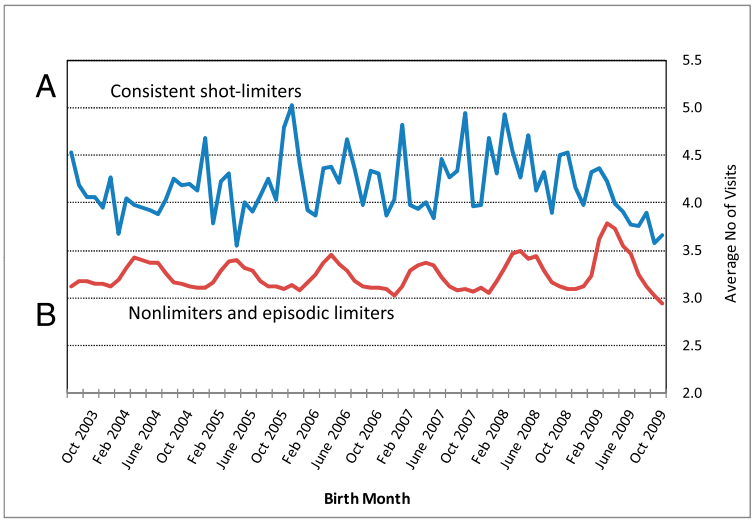

FIGURE 4
Average numbers of immunization visits according to birth month during the study period between (A) consistent shot-limiters and (B) nonlimiters and episodic limiters.

or Dr Sears (3.2% [81 of 2517 consistent shot-limiters after October 2007 schedule release]).

For children born in 2007, 42% of the doses of DTaP-containing vaccine given to nonlimiters and episodic limiters were Pediarix, whereas only 16% of the DTaP doses given to consistent shot-limiters were Pediarix. Among children born in 2009, 63% of the doses of DTaP-containing vaccine given to nonlimiters and episodic limiters and 54% of the doses given to consistent shot-limiters were Pentacel, which was introduced in 2008 (Fig 5). Substantial uptake of Pentacel did not occur until the majority of rate increases in consistent limiting had already occurred in 2007, and no relation was found between Pentacel uptake and changes in consistent shot-limiting. Hib receipt among consistent shot-limiters during the study period stayed relatively stable at all times, including periods of increased shot-limiting and during the Hib shortage of 2007–2009.

DISCUSSION

Our analysis found that an increasing percentage of children within the Oregon sentinel region experienced consistent shot-limiting between birth and 9 months of age, increasing to 10% by 2008. Consistent shot-limiters had more visits with providers compared with nonlimiters and episodic limiters but also had fewer vaccines, behaviors that are consistent with the ideas promulgated by authors of alternative schedules[15,16] and which distinguish them from those who may have delayed vaccinations because of illness or access barriers. Nonlimiting and episodic limiting birth cohorts had an annual cyclical increase in average number of shots, reflecting annual flu immunizations. This flu season effect was missing for consistent shot-limiters. Media attention regarding vaccine safety issues likely contributed to the observed increase in shot-limiting in 2007[22]; however, without knowing the motivations of parents who were defined as consistent shot-limiters, the extent of this impact cannot be determined.

This analysis has established that consistent, early childhood shot-limiting is a trackable behavior in the Portland area. We believe that the pattern of consistent shot-limiting is indicative of an increase in parental demand and provider accommodation for less than full compliance with the ACIP vaccination schedule. Although the identified pool of consistent shot-limiters is small, this group has translated their worries about vaccines into action and may represent the concerns of a larger proportion that may only episodically limit or delay, or who may have trouble finding accommodating providers.

This analysis also found that consistent shot-limiters had a low rate of exact compliance with 2 referenced alternative schedules (those of Dr Sears and Dr Caves), supporting the theory that there is variation in the way parents choose to apply alternative vaccination concepts or how providers offer vaccinations outside of ACIP recommendations. This finding may be because parents are unable to accommodate the extra visits needed to space out vaccinations according to alternative schedules or

TABLE 1 Age-Appropriate Immunizations by 9 Months of Age

Immunization	Consistent Limiters		Nonlimiters and Episodic Limiters	
	Rate, %	95% CI	Rate, %	95% CI
3 DTaP	64.1	62.4–65.7	89.3	89.0–89.6
2 Polio	63.6	61.9–65.2	97.4	97.2– 97.6
2 HepB	28.0	26.4–29.6	92.1	91.8–92.4
2/3 Hib[a]	54.3	52.6–56.1	81.8	81.4–82.2
3 Pneumococcal	27.4	48.6–52.1	75.0	74.5–75.4

Source: Oregon ALERT IIS.

[a] Two Hib vaccines if *Haemophilus b* conjugate vaccine used; otherwise, 3 Hib vaccines.

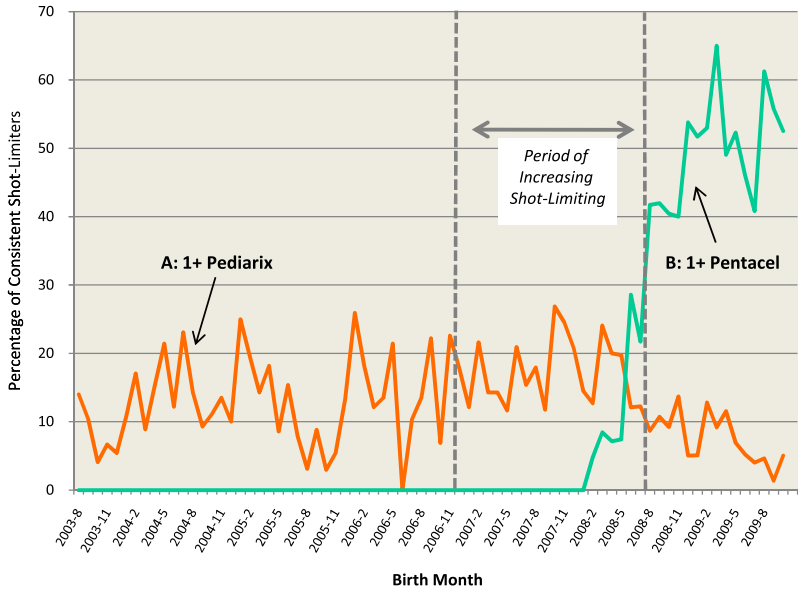

FIGURE 5

DTaP-containing combination vaccine usage rates among consistent shot-limiters according to birth month for (A) 1+ Pediarix and (B) 1+ Pentacel. Source: Oregon ALERT IIS.

because parents are customizing their own schedules. Individual provider decisions about how to accommodate parental concerns are likely equally influential; studies have shown that provider opinions are highly regarded by most parents.[8] However, providers may be incorporating some alternative vaccination standards such as shot-limiting in order not to further discourage vaccine-hesitant parents, and some providers may have their own concerns about specific vaccines.[23]

Delaying receipt of vaccines will unnecessarily increase the amount of time children are susceptible to vaccine-preventable diseases[9,24–26]; there are known risks to the child but no known benefits associated with use of alternative schedules. This analysis found consistent shot-limiters to be significantly less likely to have received each ACIP-recommended vaccine by 9 months of age and to stay behind by 19 months of age. These findings are consistent with 1 previous study that assessed up-to-date series completion among intentional delayers; age-appropriate immunization rates were also significantly lower at 19 months of age.[4]

The use of combination vaccines may have contributed to the observed rates of shot-limiting over time. For example, providers may have opted to use the Pentacel vaccine in 2008, when other Hib-containing vaccines were still in short supply, thereby minimizing the number of needed vaccines. However, even with combination vaccines, a child receiving no more than 2 injections at a time at the 2-, 4-, and 6-month well-child visits will receive fewer vaccines than are recommended by the ACIP. Also, the group defined as shot-limiting continued to have lower vaccination rates for all vaccines at 9 months of age, including those antigens contained in Pentacel, which further diminishes the likelihood that the increase in shot-limiting is an artifact of combination vaccine use. The challenges with availability of the Hib vaccine in 2007–2009 overlapped with the increase in shot-limiting observed in 2008; however, a review of Hib uptake from 2003 through 2009 revealed that patterns of Hib uptake among limiters and nonlimiters were consistent for the past 6 years, even during the shortage time period.

There are several limitations to this study. It represents a population with high exemption rates for school entry and may not be representative on a national scale. However, 1 recent national study reported that 13% of parents self-report following an alternative schedule,[27] which suggests that the findings reported here may be applicable outside of this study's geographic area. The strict definition of consistent shot-limiting used and the exclusion of parents entirely avoiding immunizations likely understate the degree of intentional delay. The role of providers in either allowing or discouraging shot-limiting was not examined, nor was the degree of clustering among accommodating providers. Bias may also have come from record scattering, partial reporting, or nonparticipation in ALERT. However, because ALERT receives immunization records from most Oregon administrative and payor sources in addition to providers, immunizations from nonparticipating providers are still likely to be captured. Most

ALERT records are submitted from electronic medical and health records or through billing services, reducing the chance of partial visit reporting and potential misidentification of a visit as shot-limiting.

CONCLUSIONS

Although <1% of parents choose not to immunize their children,[28] this study found an increase in the number of infants who are consistently out of compliance with the ACIP schedule. Infants who never receive >1 or 2 injections on any visit are potentially using alternative vaccination schedules. Parental decisions to delay or avoid certain vaccines may have an impact on susceptibility of the individual child to vaccine-preventable diseases as well as on the community in which they live. Continued research is needed to understand the true impact of delaying vaccine receipt on individual disease incidence, as well as community immunity.

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