

Using Registry Data to Evaluate the 2004 Pneumococcal Conjugate Vaccine Shortage

Norma J. Allred, PhD, John M. Stevenson, MA, Maureen Kolasa, MPH, Diana L. Bartlett, MPH, Richard Schieber, MD, MPH, Kyle S. Enger, MPH, Abigail Shefer, MD

Background: The most recent pneumococcal conjugate vaccine (PCV7) shortage occurred between December 2003 and September 2004. To ensure vaccination of the highest-risk children, the Centers for Disease Control and Prevention recommended that providers delay administration of the third and fourth doses of vaccine to healthy children. We used Michigan Child Immunization Registry (MCIR) data collected from September 1, 2001 to November 30, 2004 to evaluate changes in PCV7 coverage.

Methods: Vaccination and demographic data from MCIR were reviewed for 420,733 children born between September 2001 and August 2004. Main outcome measures were the proportion of children who received the third dose of PCV7 by 7 months of age and the fourth dose of PCV7 by 16 months of age. Vaccine coverage for measles, mumps, and rubella vaccine (MMR) and diphtheria, tetanus, and acellular pertussis vaccine (DTaP) was used for comparison, as these vaccines were abundant during this time period and their administration schedule is the same as the third and fourth doses of PCV7, respectively. Data analysis was conducted in spring 2005.

Results: Coverage for the third dose of DTaP and the first dose of MMR remained steady, while PCV7 coverage for the third dose dropped from 29% to 11%, and the fourth dose dropped from 27% to 22% in the month following the recommendations to defer doses. Coverage returned close to pre-shortage levels shortly after the recommendations to resume the normal schedule. PCV7 coverage trends were similar for children seen in the private or public sector.

Conclusions: Registry data can be useful for evaluating vaccination coverage trends during a shortage. Our findings suggest that providers were compliant with recommendations to alter vaccine administration during the shortage.

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Introduction

The heptavalent pneumococcal conjugate vaccine (PCV7), which prevents disease in young children caused by *Streptococcus pneumoniae*, has experienced periods of short supply, with the most recent shortage lasting from December 2003 to September 2004.¹ To conserve vaccine supply for the highest-risk children and to provide healthy children with at least two doses of vaccine, the Centers for Disease Control and Prevention (CDC)^{2,3} published recommendations in February and March of 2004 requesting that providers temporarily withhold the third and fourth doses of PCV7 for healthy children.

Recommendations were published in July to resume the third dose and in September to resume the normal schedule.^{4,5} To assess changes in PCV7 administration, we examined vaccine coverage changes were examined during the 2004 vaccine shortage using immunization registry data.

Methods

The Michigan Childhood Immunization Registry (MCIR) collects vaccination data regularly from >90% of healthcare providers throughout the state.⁶ The study sample included data from all children born in Michigan between September 1, 2001 and August 31, 2004. Children were eligible for inclusion if they had at least one vaccination recorded in MCIR. Vaccination data were collected from September 1, 2001 through November 30, 2004.

Age-appropriate administration⁷ of the third and fourth doses of PCV7 was evaluated for children at 7 months and 16 months of age, respectively. PCV7 coverage was compared with coverage for vaccines that were not in short supply and given on the same schedule. PCV7 third-dose coverage was

From the National Immunization Program, Centers for Disease Control and Prevention (Allred, Stevenson, Kolasa, Bartlett, Schieber, Shefer), Atlanta, Georgia; and Michigan State Health Department (Enger), Lansing, Michigan

Address correspondence and reprint requests to: Norma J. Allred, MSN, PhD, National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Rd. NE, Mailstop E-52, Atlanta GA 30333. E-mail: nallred@cdc.gov.

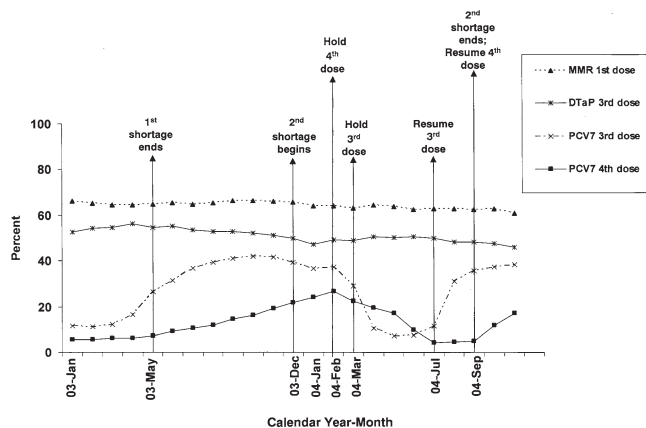


Figure 1. Pneumococcal conjugate vaccine coverage for third and fourth doses compared to nonshortage vaccines, January 2003–November 2004. MMR, measles, mumps, rubella vaccine; DTaP, diphtheria, tetanus, acellular pertussis vaccine; PCV7, pneumococcal conjugate vaccine.

compared with the proportion of children who received the third dose of diphtheria, tetanus, and acellular pertussis vaccine (DTaP) by 7 months of age. PCV7 fourth-dose coverage was compared with the proportion of children who received the first dose of measles, mumps, and rubella vaccine (MMR) by 16 months of age. Vaccine administration dates from MCIR were compared with the dates that the recommendations were announced to evaluate changes in vaccination coverage.

In addition to evaluating coverage trends by birth cohort, cohort members were classified as patients who received vaccines in pediatricians' or family physicians' offices or public clinics, to evaluate coverage differences by provider type. The provider of the most recent vaccination recorded in the registry was used to classify a child as a pediatric, family physician, or public provider patient. Children were classified by four different urban/rural categories by ZIP code to examine coverage based on geographic differences. Data analysis was conducted in spring 2005.

Results

The study sample included 420,733 children who had one or more vaccinations recorded in MCIR. Thirty-six percent of children had visits to both public and private providers, with 45% seen only by private providers and the remaining 14% seen only by public providers. For children visiting only private providers, <13% were seen by both a pediatrician and a family physician.

Figure 1 shows PCV7 coverage rates with doses three and four, given at 7 months and 16 months of age, compared with DTaP and MMR, respectively. Coverage for dose three of PCV7 dropped from 29% to 11% from March to April 2004, with coverage remaining around 7% until August, when it increased to 31% after the July recommendation was made to resume this dose. Coverage for its comparison vaccine, the third dose of DTaP, remained steady at about 52% between February and November.

Coverage for dose four of PCV7 decreased from a high of 27% in February to 22% in March with a low of 4% in July. An increase in coverage to 12% was seen in October after the September announcement to resume the fourth dose. Mean coverage for the first dose of MMR remained steady at 64% throughout the shortage period.

Figure 2 provides a comparison of coverage levels during the 2004 shortage period for PCV7 doses one through four. Coverage for doses one and two remained around 64% and 49%, respectively, compared to the declines seen for doses three and four. Coverage trends for PCV7 were similar regardless of provider type and urban/rural status of the child (data not shown).

Discussion

The MCIR data revealed that coverage with the third and fourth doses of PCV7 for young children declined with the CDC announcements in February and March 2004 to withhold these doses for healthy children. PCV7 coverage levels increased following the announcements to resume administration of the normal schedule. Coverage for the comparison vaccines, DTaP and MMR, remained constant, indicating that the observed declines in PCV7 coverage were due to factors other than access to care. Coverage trends for PCV7 were similar by practice specialty. Coverage rates used in this study to compare the antigens are for age-appropriate administration and are therefore lower than those reported in the National Immunization Survey, which measures coverage for vaccines received up to 36 months of age.

Interestingly, coverage with the third dose of PCV7 dropped slightly from February to March before the recommendation was made to withhold this dose. Providers may have been anticipating the upcoming recommendation to withhold the third dose based on experiences during the previous PCV7 vaccine short-

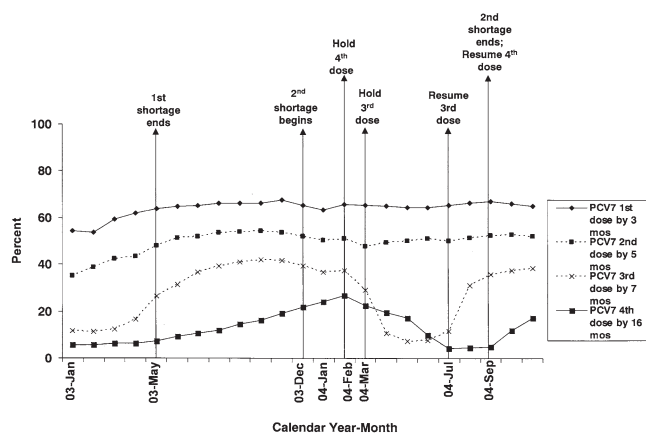


Figure 2. Pneumococcal conjugate vaccine (PCV) coverage for 3-, 5-, 7-, and 16-month-old children by dose number. PCV7, pneumococcal conjugate vaccine.

age⁸ or may have been voluntarily conserving vaccine. The sharper drop in coverage with the third dose of PCV7 compared to the fourth dose is due to the fact that children should receive the third dose at age 6 months, whereas the fourth dose can be given anytime between age 12 and 15 months. By the time the recommendations were made to hold the fourth dose, many 16-month-old children had already received the vaccination at an earlier age. Fourth-dose PCV7 coverage steadily declined from February until July 2004, when children who were aged 12 months in February would not be eligible for the dose and coverage was appropriately at its lowest point.

From this study, it is unclear whether the PCV7 vaccine coverage declines that corresponded with the dates of the announcements were due to providers' compliance or if other factors were involved. A number of recent studies have looked at the issue of provider compliance and practices during PCV7 vaccine shortages.^{9–11}

During the previous PCV7 vaccine shortage that lasted from August 2001 to May 2003, Freed et al.⁹ found that most providers ran out of vaccine before they could comply with recommendations to alter their schedule. They found that very few practices with adequate vaccine supply altered their administration schedule due to the shortage. Stokely et al.¹⁰ found that only 29% implemented recommendations announced during the 2001–2003 shortage. Broder et al.¹¹ surveyed pediatricians about the 2001–2003 PCV7 shortage, and found that while most were aware of the recommendations, those with more vaccine reported less adherence to the revised schedule. However, in a study of the 2004 PCV7 vaccine shortage, Bhatt et al. (A. Bhatt, CDC, personal communication, August 2004) found that >80% of surveyed immunization providers were deferring doses for healthy children. This is not surprising given that CDC guidelines to defer doses during the 2004 shortage were much simpler to interpret than those given during the 2001–2003 shortage.^{8,12} While data from the Bhatt survey, as well as the finding that vaccination coverage for the first and second doses of PCV7 remained steady, support the supposition that the declines in coverage observed with the MCIR data were due to provider adherence to the recommendations, we cannot be certain without having information on individual provider-level PCV7 vaccine supplies.

Limitations

While MCIR contains vaccination data on a large majority of Michigan children, as indicated by 91.6% of children aged 19 to 35 months in MCIR having at least two vaccinations recorded at the end of 2004, 8.4% of children have no vaccination data on record (unpublished data). Also, although vaccination records for

children in the registry may be incomplete, we feel that this would non-differentially bias estimates of vaccine coverage downward for all three vaccines evaluated. Therefore, the observed drop in PCV coverage when compared to the steady trends in coverage found for MMR and DTaP does not appear to be an artifact related to missing data. Approximately 80% of providers report vaccination data to the registry within 60 days. While some data may be missing in the November coverage estimates, it is unlikely that this small percentage would have a large effect.

Conclusions

Registries are a useful tool for evaluating vaccination coverage trends during a vaccine shortage if data are collected for almost all children in its catchment area. This information can provide near “real-time” data that could be useful to target specific providers to maximize use of resources at the state or local level. Using registries to identify and recall children who missed vaccines during a shortage is an especially valuable contribution that a registry can provide to increase coverage. Additionally, registries may be used for immunization reminder and recall messages to parents, accessing immunization histories during a national disaster such as Hurricane Katrina when records were lost, and facilitating coverage assessments for providers. Immunization registries can allow for more rapid immunization coverage assessments as compared to the National Immunization Survey where there is a 6-month lag between final data collection and availability of the data.

Declines in PCV7 third- and fourth-dose coverage did occur when CDC recommendations were announced. Additional information on vaccine supply at the individual-provider level would be needed to answer questions on provider compliance with vaccine administration recommendations.

The findings and conclusions in this report are those of the author(s) and do not necessarily reflect the views of the funding agency.

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References

1. Centers for Disease Control and Prevention. Notice to readers: limited supply of pneumococcal conjugate vaccine. *MMWR Recomm Rep* 2003;52:1234.
2. Centers for Disease Control and Prevention. Notice to readers: limited supply of pneumococcal conjugate vaccine: suspension of recommendation for fourth dose. *MMWR Recomm Rep* 2004;53:108–9.
3. Centers for Disease Control and Prevention. Notice to readers: limited supply of pneumococcal conjugate vaccine: suspension of recommendation of third and fourth dose. *MMWR Recomm Rep* 2004;53:177–8.
4. Centers for Disease Control and Prevention. Notice to readers: updated recommendations for use of pneumococcal conjugate vaccine: reinstatement of the third dose. *MMWR Recomm Rep* 2004;53:589–90.

5. Centers for Disease Control and Prevention. Notice to readers: pneumococcal conjugate vaccine shortage resolved. *MMWR Recomm Rep* 2004;53:851-2.
6. Centers for Disease Control and Prevention. Immunization information system progress—United States, 2003. *MMWR Recomm Rep* 2005;53:722-24.
7. Centers for Disease Control and Prevention. Preventing pneumococcal disease among infants and young children. Recommendations of the Advisory Committee on Immunization Practices. *MMWR Recomm Rep* 2000;49:1-38.
8. Centers for Disease Control and Prevention. Notice to readers: decreased availability of pneumococcal conjugate vaccine. *MMWR Recomm Rep* 2001;50:783-4.
9. Freed GL, Davis MM, Clark SJ. Variation in public and private supply of pneumococcal conjugate vaccine during a shortage. *JAMA* 2003;289:575-8.
10. Stokley S, Santoli JM, Willis B, Kelley V, Vargas-Rosales A, Rodewald L. Impact of vaccine shortages on immunization programs and providers. *Am J Prev Med* 2004;26:15-21.
11. Broder KR, Macneil A, Malone S, et al. Who's calling the shots? Pediatricians' adherence to the 2001-2003 pneumococcal conjugate vaccine shortage recommendations. *Pediatrics* 2005;115:1479-87.
12. Centers for Disease Control and Prevention. notice to readers: updated recommendations on the use of pneumococcal conjugate vaccine in a setting of vaccine shortage—Advisory Committee on Immunization Practices. *MMWR Recomm Rep* 2001;50:1140-2.