

Physician Perspectives Regarding Pneumococcal Conjugate Vaccine

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ABSTRACT. *Objectives.* Pneumococcal conjugate vaccine (PCV) was first licensed for routine administration to young children in February 2000. The objective of this study was to assess physician perspectives about the use of PCV, to ascertain which children were being given the vaccine soon after licensure, and to determine how the addition of PCV to the schedule of recommended childhood vaccines may affect the timing of other vaccinations.

Methods. A 30-item survey containing questions about the use of PCV was sent to all pediatricians and family physicians who provide primary care to young children in Monroe County (Rochester, NY) and Davidson County (Nashville, TN) in October 2000. As many as 3 subsequent mailings were sent to nonresponders. Descriptive and χ^2 statistical analyses and logistic regression were used to evaluate the responses.

Results. Response rates were 82% in Rochester and 78% in Nashville. Eighty-two percent of responding physicians, including 92% of pediatricians and 55% of family physicians, indicated that they were giving PCV to their patients at the time of the survey. Sixty percent noted that an initial lack of insurance reimbursement for the cost of the vaccine caused them to delay introducing PCV. Fifty-one percent delayed initially offering the vaccine to any of their patients because the Vaccines for Children (VFC) program did not begin to offer PCV until several months later. The vast majority routinely vaccinated healthy children who are younger than 2 years as well as older children who had defined chronic medical conditions that put them at high risk of invasive pneumococcal disease. Fewer than 15% were recalling patients for PCV, with most recall efforts focused on patients who had chronic medical conditions. When discussing PCV with parents, 78% of physicians primarily emphasized the vaccine's potential to decrease the risk of sepsis and/or meningitis, whereas smaller percentages primarily emphasized the vaccine's potential to decrease the risk of pneumonia or ear infections. Approximately 20% of physicians who gave PCV delayed other vaccinations (primarily varicella vaccine, hepatitis B vaccine, or polio vaccine) because of concern about administering 4 or more vaccines simultaneously. Similarly, 40% of physi-

cians indicated that they considered PCV to be more important than varicella vaccine or hepatitis B vaccine, whereas 26% percent considered PCV to be more important than polio vaccine.

Conclusions. PCV has been widely accepted by physicians in both Rochester and Nashville. However, many physicians delayed introducing the vaccine for reasons that were ultimately related to financial considerations. For privately insured patients, delays were related to when coverage for PCV was added to benefit packages. For patients who receive publicly purchased vaccine via the VFC program, delays were related to availability of the vaccine through the VFC program. In addition, after the introduction of PCV, some physicians began delaying the administration of other vaccines because of the need to give multiple vaccinations simultaneously. Although lack of insurance or VFC coverage and concerns about multiple simultaneous injections may somewhat delay the initial use of newly recommended vaccines, physicians rapidly begin to provide new vaccines that they believe to be beneficial once those vaccines are incorporated into existing payment mechanisms. *Pediatrics* 2002;110(6). URL: <http://www.pediatrics.org/cgi/content/full/110/6/e68>; *Pneumococcus, vaccine, vaccination, immunization.*

ABBREVIATIONS. PCV, pneumococcal conjugate vaccine; ACIP, Advisory Committee on Immunization Practices; CDC, Centers for Disease Control and Prevention; AAP, American Academy of Pediatrics; AAFP, American Academy of Family Physicians; VFC, Vaccines for Children; HiB, *Haemophilus influenzae* type B; OR, odds ratio; CI, confidence interval.

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S*treptococcus pneumoniae* is the primary cause of severe bacterial infections in US infants and young children.¹ It is also the primary bacterial cause of otitis media² and sinusitis.³ The incidence of invasive pneumococcal infections is highest in children who are younger than 2 years, decreasing steadily thereafter. It is estimated that *S pneumoniae* is responsible for 1400 cases of meningitis, 17 000 cases of bacteremia, 71 000 cases of pneumonia, and 5 million to 7 million cases of otitis media annually among US children who are younger than 5 years.⁴

The risk of invasive pneumococcal infection varies across population groups. Among those at highest risk are children who are younger than 5 years and have sickle cell disease, other types of functional or anatomic asplenia, human immunodeficiency virus infection or primary immunodeficiencies, or are receiving immunosuppressive therapy.⁵ In addition, healthy black, Native American, and Alaska native children who are younger than 5 years have an in-

creased risk of invasive pneumococcal infections.⁴ Finally, children who are younger than 5 years and in out-of-home care for >4 hours per week have a 2.29- to 3.28-fold increased risk of invasive pneumococcal infection.⁶

A 23-valent pneumococcal polysaccharide vaccine has been available in the United States for a number of years. However, in young children, the 23-valent vaccine has not been found to be immunogenic for many of the serotypes of pneumococci that commonly cause invasive infections.⁷ Studies have also noted that this vaccine has variable efficacy for children.^{8–12}

A heptavalent pneumococcal conjugate vaccine (PCV), Prevnar (Wyeth Lederle Vaccines, Pearl River, NY), was licensed by the US Food and Drug Administration on February 7, 2000, after prelicensure testing that demonstrated an efficacy of approximately 94% for prevention of invasive pneumococcal disease.¹³ Within days, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) released draft recommendations in conjunction with the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP) suggesting the routine use of PCV for all young children.^{5,14} On June 21, 2000, the ACIP formally added PCV to the pediatric immunization schedule and the Vaccines for Children (VFC) program. The VFC program then rapidly signed contracts with the vaccine manufacturer, state Medicaid programs quickly added PCV to their vaccine recommendations, and PCV first became available to children who qualified for VFC-supplied vaccines soon thereafter. This study was designed to measure physician acceptance of the recommendation to immunize young children with PCV and to assess the factors that affect the provision of the vaccine by physicians.

METHODS

After pilot testing for content validity and readability and approvals by the Research Subjects Review Board of the University of Rochester and the Investigational Review Boards of Vanderbilt University and the CDC, a survey about PCV was sent to all physicians who provide routine primary care services to young children in 2 communities: Monroe County, New York, and Davidson County, Tennessee. Monroe County includes the city of Rochester and a large surrounding suburban area and has a total population of 735 000. Davidson County includes the city of Nashville and has a total population of 530 000. The survey instrument was a 30-item questionnaire about physicians' PCV immunization practices and their opinions about the vaccine. It was sent to each physician up to 4 times between October 2000 and March 2001.

Physicians to whom the surveys were sent were assured that their responses would be confidential and that only aggregate results would be analyzed. Descriptive and χ^2 statistical analyses and logistic regression (to identify factors associated with early or late adoption of the PCV vaccine recommendation) were performed using SPSS software (SPSS Inc, Chicago, IL).

RESULTS

A total of 197 (82%) of the 240 eligible physicians in Rochester and 109 (78%) of the 140 eligible physicians in Nashville completed and returned the survey. The response rate was considerably higher for pediatricians than for family physicians in both communities (96% vs 58% in Rochester and 98% vs 51% in Nashville; $P < .01$). Table 1 lists some of the demographic characteristics of the responding physicians. Approximately three-fourths were pediatricians, most were men, and most practiced >30 hours per week. Almost all were board-certified or board-eligible, and the majority participated in the VFC program.

At the time of the survey—8 to 13 months after licensure and 4 to 9 months after initial ACIP, AAP, and AAFP recommendation of the vaccine—84% of responding Rochester primary care physicians and 77% of responding Nashville primary care physicians were offering PCV to at least some of their patients who were younger than 1 year. Among the physicians who were offering the vaccine, >90% in both communities recommended PCV for all of their patients who were younger than 1 year. Responding pediatricians were significantly more likely to indicate that they administered the vaccine than were responding family physicians (95% vs 54% among Rochester physicians, $P < .001$; 86% vs 56% among Nashville physicians, $P < .001$).

As noted in Fig 1, significant proportions of physicians in both Rochester and Nashville first began immunizing their privately insured patients with the vaccine by April or May of 2000, 2 to 3 months after the vaccine's licensure by the US Food and Drug Administration but before publication of the formal ACIP, AAP, and AAFP recommendations. However, children who were insured by traditional Medicaid or Medicaid managed care plans, who qualify to receive vaccine purchased through VFC, were generally not offered the vaccine until the third quarter of the year (when VFC-supplied vaccine became available).

The primary factors found to be associated with a delay in introducing PCV for infants younger than 1

TABLE 1. Demographic Characteristics of Responding Physicians

Characteristic	Rochester (<i>n</i> = 197; %)	Nashville (<i>n</i> = 109; %)	Both Communities Combined (<i>n</i> = 306; %)
Pediatrician	74	77	75
Family physician	26	23	25
Male	59	54	58
Practices <15 h/wk	7	9	8
Practices 15–30 h/wk	24	15	20
Practices >30 h/wk	69	76	72
Board-eligible or board-certified	99	97	99
Participates in the VFC program	85	75	81

Rochester

Nashville

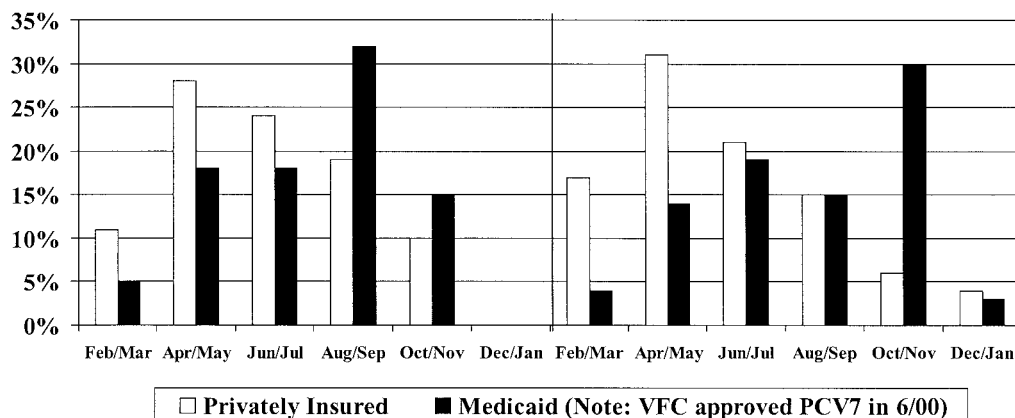


Fig 1. Month in 2000–2001 when physicians first gave PCV, by patient insurance.

year were related to the delay in initiation of insurance coverage after vaccine licensure (cited by 60% of respondents), the delay in vaccine supply through the VFC program (51% of respondents), the high cost of the vaccine for out-of-pocket payment (cited by 42%), and variation in insurance plan coverage for the vaccine (cited by 39%). Some physicians also noted that they delayed initially offering PCV to their privately insured patients until it was also available for their publicly insured patients through the VFC program. Other physicians offered PCV to all of their patients as soon as it became available, thereby absorbing the cost of providing the vaccine to their VFC-eligible patient population until it subsequently became available through VFC.

When data from both cities were combined, 86% of the responding physicians who noted that they provided PCV to infants younger than 1 year also reported that they offered it to all children 12 to 24 months of age; 93% of them also reported offering it to children who were 2 to 5 years of age and had chronic medical conditions (eg, sickle cell disease, human immunodeficiency virus infection, diabetes mellitus) that put them at high risk for invasive pneumococcal disease. In contrast, less than one third of these physicians also offered PCV to 2- to 5-year-old children who were at somewhat increased risk of pneumococcal infection because of their ethnicity (black) or out-of-home child care attendance. Thirty-nine percent of physicians who provided the vaccine to Rochester children and 66% of physicians who provided the vaccine to Nashville children nevertheless offered it to children who were 2 to 5 years of age and had a history of recurrent otitis media.

When asked about recalling patients for PCV vaccine, more than half of the responding physicians in Rochester and Nashville who offered PCV indicated that they were able to recall patients 0 to 5 years of age to their practice to receive immunizations, but only 9% of Rochester and 13% of Nashville physicians who had the capacity to do so were actually recalling any patients to receive PCV. Those who did recall patients to receive PCV were targeting children with chronic medical conditions for whom vaccination until age 5 is recommended.

Seventy-eight percent of responding physicians in both Rochester and Nashville indicated that, in discussing PCV with the parents of their patients, they primarily emphasized the vaccine's potential to decrease the risk of meningitis and sepsis, with far fewer physicians (9% in Rochester and 10% in Nashville) indicating that they primarily emphasized the prevention of either pneumonia or otitis media. Physicians who provided PCV were asked to rate the strength of their recommendation that healthy children receive PCV. Most responding physicians strongly recommended PCV, particularly for children younger than 1 year (Fig 2). Indeed, 90% of respondents either recommended PCV strongly or moderately strongly for infants younger than 1 year, whereas 72% recommended PCV either strongly or moderately strongly for children 12 to 24 months of age.

With the addition of PCV to the immunization schedule, physicians are often faced with the need to inject 4 or more immunizations at the same office visit. When the surveyed physicians were asked whether the need to administer 4 or more vaccines at once had changed their immunization practices (Table 2), >50% indicated that they gave all of the recommended vaccines at the same visit. Small percentages noted that they were more likely to offer hepatitis B vaccine at birth or had switched to the combined hepatitis B–*Haemophilus influenzae* type B (HiB) vaccine, whereas 20% changed their immunization schedule in ways that were not recommended by the ACIP (eg, by scheduling extra visits to provide certain immunizations, or by postponing hepatitis B, polio, or varicella vaccination). Physicians who were postponing immunizations were most likely to delay administering hepatitis B vaccine.

Surveyed physicians were asked how the rotavirus vaccine experience may have affected their adoption of the recommendations for the use of pneumococcal conjugate vaccine. Only 14% of those who completed the survey noted that they delayed initially offering PCV because of the well-publicized adverse reactions after licensure and initial use of rotavirus vaccine.

Surveyed physicians were asked to rate the rela-

Fig 2. Strength of physicians' recommendations for PCV (Rochester and Nashville data combined).

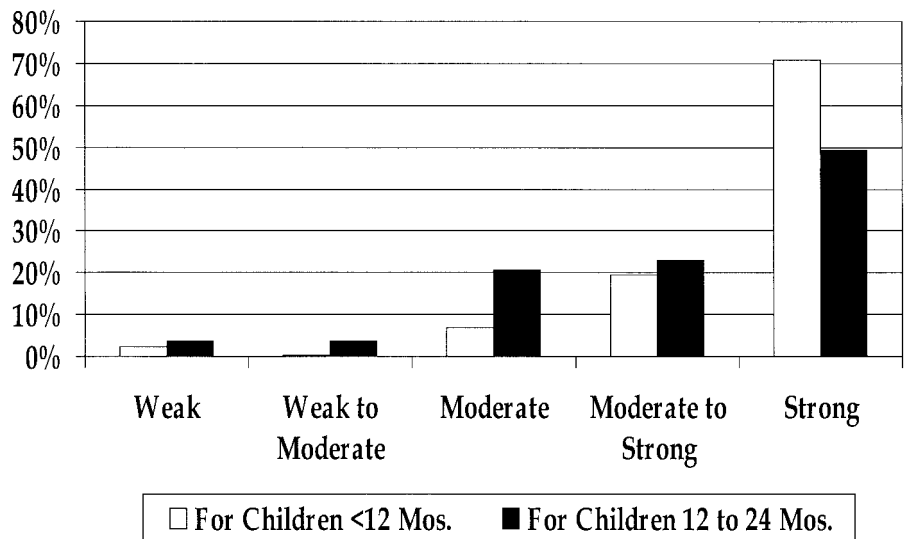


TABLE 2. Changes in Immunization Practices Resulting From the Need to Give ≥ 4 Vaccinations at Once

Change in Immunization Practice	Rochester (n = 164; %)	Nashville (n = 85; %)	Both Communities Combined (n = 249; %)
No change	54	58	55
More likely to give hepatitis B vaccine at birth and 1 month of age	1	11	4
Give more hepatitis B-HiB combination vaccine	13	19	15
Schedule extra visits for immunizations	4	9	6
Postpone hepatitis B vaccination	15	9	13
Postpone polio vaccination	4	1	3
Postpone varicella vaccination	4	-	3

tive importance of PCV in comparison to each of the other routine childhood vaccines given throughout the country. As noted in Fig 3, a majority of responding physicians rated PCV as being as or more important than each of the other routinely recommended vaccines (diphtheria-tetanus-acellular pertussis, polio, HiB, hepatitis B, measles-mumps-rubella, and varicella vaccine), whereas only approximately 30%

rated PCV as less important than diphtheria-tetanus-acellular pertussis, HiB, and measles-mumps-rubella vaccines.

Fifty-two percent of physicians who responded to the survey, including 60% of pediatricians and 26% of family physicians, reported that children in their practices had died or had severe sequelae as a result of invasive pneumococcal disease. These physicians

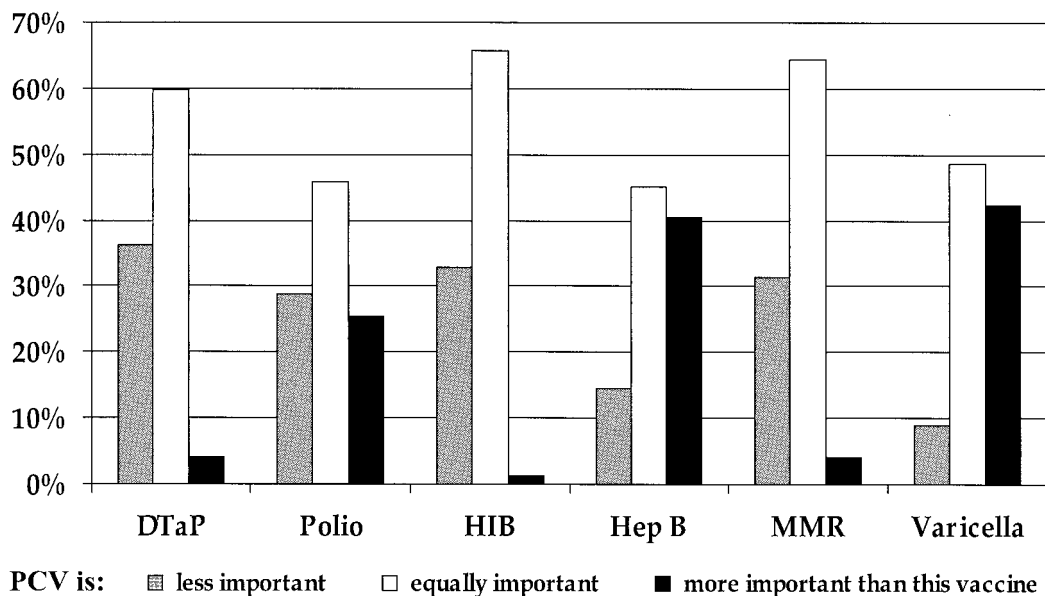


Fig 3. Relative perceived importance of PCV compared with other childhood vaccines.

were significantly more likely to offer PCV to their patients than were physicians who had not had similar experiences (90% vs 76%; $P < .01$).

Finally, multiple logistic regression was performed to determine which factors (eg, locality, specialty, primary insurance type, having had a patient who died or had severe sequelae after pneumococcal disease) independently predicted whether physicians would be early or late adopters of PCV. Physicians were likely to be early adopters of PCV for their privately insured patients (ie, began providing it before August 1, 2000) when most of their patients were privately insured (odds ratio [OR]: 15.0; 95% confidence interval [CI]: 7.3–30.9; $P < .001$), when they were pediatricians (OR: 5.4; 95% CI: 2.7–11.1; $P < .001$), or when a patient in their practice previously had severe sequelae as a result of invasive pneumococcal disease (OR: 2.1; 95% CI: 1.1–4.3; $P = .03$). Similarly, physicians were likely to be early adopters of PCV for their VFC-eligible patients when most of their patients were privately insured (OR: 3.8; 95% CI: 2.0–7.0; $P < .001$), when they were pediatricians (OR: 4.3; 95% CI: 2.2–8.4; $P < .001$), or when they practiced in Monroe County (OR: 2.6; 95% CI: 1.5–4.5; $P = .001$). In contrast, physicians with large proportions of VFC-eligible patients were particularly likely to be late adopters of the PCV recommendation for any of their patients.

DISCUSSION

Adoption of the PCV Recommendation

The results of this survey clearly indicate that, in the communities surveyed, the vast majority of physicians quickly adopted and strongly supported the recommendations for the use of the PCV. Physicians also generally seemed to emphasize appropriate reasons for PCV immunization when discussing the vaccine with parents.

PCV is the latest of several vaccines (including hepatitis B vaccine, varicella vaccine, and rotavirus vaccine) that the ACIP recommended for routine use for infants and young children during the past decade.^{15–17} Not all vaccines have met with the same rapid acceptance that PCV has received. In contrast to most physicians' quick, widespread implementation of the recommendation for use of PCV, the recommendations for routine vaccination of young children with hepatitis B vaccine and varicella vaccine initially were met with a great deal of skepticism, leading many physicians to delay introduction of these vaccines.^{18–23} It is likely that physicians' rapid implementation of the PCV recommendation can primarily be attributed to the greater perceived importance of PCV relative to these other vaccines. Physicians who have seen the devastating sequelae of invasive pneumococcal infections are among the strongest proponents of PCV vaccination for their patients, just as physicians who have encountered varicella-related fatalities have been reported to be among the strongest proponents of varicella vaccine.²⁴ Thus, it is also not surprising that large majorities of the physicians surveyed rated the strength

of their recommendation for PCV as strong or very strong.

In this study, physician specialty was found to be a significant determinant of whether providers were early or late adopters of PCV. This finding mirrored the pattern noted in several previous studies that evaluated other vaccines and found that pediatricians were more likely than family physicians to adopt new vaccine recommendations quickly.^{18,24–29} It therefore may be advisable for the CDC to work closely with the AAFP to develop new initiatives to inform family physicians about the availability of newly licensed vaccines and to stress the importance of adopting new vaccine recommendations.

Financing Vaccination

Of particular concern to many physicians was the lag time between February 2000, when the vaccine was licensed by US Food and Drug Administration; June 2000, when the ACIP recommended routine vaccine use; and October 2000, when the recommendations were published in the *Morbidity and Mortality Weekly Report*. Early in this period, most private-sector managed care and indemnity health insurance plans in Rochester and Nashville began reimbursing providers for PCV, whereas publicly funded vaccine was not widely available until the late summer or fall. Because physicians generally were eager to begin providing PCV as soon as possible, for many physicians this resulted in an ethical dilemma: Could they withhold a valuable new vaccine from some patients while offering it to others? Physicians responded in various ways. Some physicians delayed providing PCV to any of their patients until they could provide it to both their privately insured patients and their patients who qualify to receive vaccines through VFC. Others began providing PCV to all of their patients, including those who were VFC eligible, several months before the vaccine was available through the VFC program, thereby absorbing the cost of the vaccine for VFC-eligible patients themselves. Minimizing delay in the availability of public-sector vaccine would reduce similar future dilemmas faced by health care providers.

Expanded Immunization Recommendations for High-Risk Groups

The ACIP, AAP, and the AAFP recommended that children who are 2 to 5 years of age and have chronic illnesses (eg, sickle cell disease, diabetes mellitus, immunodeficiencies) that increase their risk of invasive pneumococcal disease should receive PCV. They also suggested that, as a result of their somewhat increased risk of invasive pneumococcal disease, PCV should be considered for most children 2 to 3 years of age as well as for children who are 3 to 5 years of age and are black, are Native American, or attend out-of-home child care.^{5,14} In both cities where physicians were surveyed, most 2- to 5-year-old children with chronic medical conditions that predispose them to invasive pneumococcal infections were being offered PCV, although few of these children were being recalled for vaccination. However, few physicians in these communities were rou-

tinely offering PCV to any other groups of 2- to 5-year-old children. This finding suggests that permissive vaccination recommendations—even for a pathogen widely considered by physicians as important—are unlikely to lead to substantial vaccine administration. As insurance companies may not reimburse for vaccine under a permissive recommendation, providers may face a dilemma of wanting to provide vaccine but having to consider a child's insurance status or their parents' ability to pay.

Multiple Simultaneous Immunizations

As the number of recommended childhood immunizations has increased, many physicians have become concerned about the need to give multiple immunizations simultaneously.^{30,31} With the introduction of PCV, as many as 4 or 5 simultaneous immunizations are recommended for infants during some visits. Although many physicians surveyed responded to this challenge by administering hepatitis B vaccine at birth and at 1 month of life or by turning to combination vaccines, some physicians reacted by postponing other recommended immunizations, particularly hepatitis B vaccine, polio vaccine, or varicella vaccine. Such actions are counterproductive because they result in periods when children are not protected and may eventually lead to lower immunization rates for these vaccines.

Study Limitations and Strengths

We could not determine whether the reported practices of the surveyed physicians reflected their actual clinical practices, and we were unable to confirm whether survey respondents had practices and attitudes that differed significantly from those of nonresponders. However, the high response rate decreased the potential for response bias. Also, although this study illustrates physician practices in 2 communities, it is possible that practices differ elsewhere. It is interesting that the physicians' PCV immunization practices were remarkably similar in Rochester and Nashville. In addition, 2 previous immunization surveys of the same group of Rochester-area physicians and a national survey of pediatricians and family physicians found that, in general, the immunization practices of Rochester physicians mirrored practices nationwide.^{26,27}

Implications

The findings of this study have several implications:

- Physicians strongly support and rapidly adopt new vaccines (eg, PCV) that prevent infections with common pathogens that are often associated with significant morbidity.
- ACIP, CDC, and state health departments should recognize the impact that delayed availability of public-sector vaccine may have on vaccine providers and should attempt to identify ways to accelerate the process of getting that vaccine to private providers and public clinics.
- Because some groups of physicians may be slower adopters of new vaccines, systematic educational

strategies targeted to these groups should be implemented in conjunction with national professional organizations.

- As more new vaccines are approved, physicians may begin delaying administration of existing vaccines that they perceive to be less important. Therefore, the development of combination vaccines should be strongly encouraged.

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