Practices of Family Physicians and Pediatricians in Administering Poliovirus Vaccine

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BACKGROUND. When the Advisory Committee on Immunization Practices added the sequential schedule to the poliovirus vaccine (PVV) recommendations in 1997, primary care physicians expressed concern about its implementation. This study examines the practices and factors influencing the administration of sequential, oral, or inactivated PVV schedules by family physicians and pediatricians.

METHODS. A random sample of Ohio family physicians and pediatricians was surveyed between January and April 1998. Primary outcome measures included physicians' awareness of the 1997 recommendations, their recommendations to parents and caregivers, administration of current PVV options, and the factors influencing their practices.

RESULTS. All physicians who immunize children (n = 263) reported awareness of the 1997 PVV recommendations. Family physicians were more likely to recommend and administer oral polio vaccine than pediatricians (50% and 63% vs 17% and 28%; P < .001). Pediatricians were more likely to recommend and administer the sequential schedule than family physicians (66% and 67% vs 31% and 28%; P < .001). Choice of sequential schedule was related to the risk of vaccine-associated paralytic poliomyelitis and liability ($P \le .05$). Choice of an all oral polio vaccine schedule was related to cost of inactivated PVV and increased number of injections ($P \le .05$). One hundred eighty-two physicians (69%) indicated that they personally discuss PVV options with parents or caregivers; only 41% have them read the required vaccine information sheets.

CONCLUSIONS. Differences exist between family physicians' and pediatricians' implementation of the 1997 PVV recommendations. Physician choice of PVV schedule is influenced by the risk of vaccine-associated paralytic poliomyelitis, increased number of injections, liability concerns, and vaccine cost. Physicians need to inform parents of vaccine benefits and risks to comply with federal regulations.

KEY WORDS. Vaccination; poliovirus vaccine; immunization schedule; child welfare. (J Fam Pract 1999; 48:594-600)

'n January 1997, the Advisory Committee on Immunization Practices (ACIP) revised the poliovirus vaccination schedule to include 3 options. The ACIP, an advisory group of the Centers for Disease Control and Prevention, recommended a sequential schedule of 2 doses of inactivated poliovirus vaccine (IPV) followed by 2 doses of oral poliovirus vaccine (OPV), but also considered the all OPV or IPV schedules acceptable.1 The recommendation was made on the basis of the following: (1) there had been no indigenously acquired case of wild-type poliovirus in the United States since 1979 or in the Americas since 1991; (2) the Western Hemisphere was certified to be free of indigenous wild poliovirus in 1994; (3) 8 to 9 cases of vaccine-associated paralytic poliomyelitis (VAPP) had occurred in the United States each year since 1980; and (4) the sequential schedule was expected to significantly decrease the risk of VAPP.¹

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From the Department of Family Medicine (S.R.K., S.P.) and the Department of Pediatrics (R.C.M., M.S.P.), Medical College of Ohio, Toledo. Reprint requests should be addressed to Sanford R. Kimmel, MD, Department of Family Medicine, Medical College of Ohio, 1015 Garden Lake Parkway, Toledo, OH 43614. E-mail: skimmel@mco.edu. An all OPV schedule was still acceptable and even preferred in certain circumstances, such as the need for accelerated protection.¹³ Both the American Academy of Family Physicians and the American Academy of Pediatrics recommended that parents and caregivers be offered a choice of one of the 3 schedules after the known risks and benefits had been explained.²⁴

Concerns expressed about the use of IPV include the additional injections, the cost of administration, the possibility of additional visits, decreased acceptability by parents, and subsequent decreased compliance.⁵⁸ Additional concerns were the limited availability of combination vaccine products, the potential need to continue the intestinal immunity induced by OPV,³⁸ and the effectiveness of the sequential schedule in preventing VAPP.⁶⁷

The additional costs of implementing the sequential schedule were estimated to total \$14.7 million or \$3.1 million for each case of VAPP prevented.⁹ For the practitioner, IPV requires more staff time and costs more to administer than OPV, even if the cost of the vaccine is similar. The costs associated with immunizations have been cited as a major barrier to delivery and a primary reason for referral of children to public health departments.^{10,11} Other factors may contribute to the hesitation to adopt the immunization recommendations by primary care providers. A 9-state survey found that family physicians were slower than pediatricians to adopt hepatitis B vaccine recommendations because of less demand for the vaccine by parents and perceived parental resistance to the vaccine or multiple injections.¹² A later 6-state study described the advantages and disadvantages of the all OPV schedule versus the sequential schedule to focus groups of low-income parents. Some parents expressed doubts and concerns about IPV, but a majority preferred the new schedule because of the risk of contracting VAPP with OPV only.¹³

Provider choice might also be an important factor in the actual administration of poliovirus vaccine (PVV). Focus groups of nurses in county health clinics in Georgia believed that provider recommendations regarding the polio schedules greatly influenced parental choice of which PVV schedule they wanted for their child.14 Six Georgia public health clinics informed parents of the 3 polio vaccination options, recommending the IPV-OPV schedule. Eighty-eight percent of infants received their first dose of PVV as IPV and 12% as OPV. Seventy-seven percent of infants receiving IPV returned for their second dose compared with 65% of those infants receiving OPV.¹⁵ Sixty-four percent of parents in 2 public health clinics indicated that the risk of VAPP was their greatest concern, 10% were concerned about the extra injection, and 12% were concerned about both.¹⁶

Since providers are likely to exert a major influence in the choice of PVV schedule, the purpose of our study was to describe the current awareness and practices of Ohio family physicians and pediatricians in implementing the 1997 recommendations for administration of PVV. The following hypotheses were tested: (1) There is a difference between family physicians and pediatricians in their awareness of the 1997 recommendations for the administration of PVV; (2) there are differences in practices between family physicians and pediatricians in their implementation of PVV recommendations; and (3) several factors (parent choice, additional cost of IPV, practice preference, difficulty obtaining IPV, liability concerns, risk of VAPP from OPV, increased number of injections per visit, and lack of combination DTaP-HIB vaccine for young infants) are associated with physicians' practices in administering poliovirus vaccine.

METHODS

STUDY DESIGN

We used a descriptive survey research design. An 18item questionnaire was specifically designed for our study. Along with basic demographic information, physicians were asked if they provided immunizations to children as part of their practice. They were asked if they followed the Centers for Disease Control and Prevention (CDC), American Academy of Family Physicians, or

American Academy of Pediatrics protocol for the administration of immunizations. Additionally, physicians were asked if they were aware of the 1997 recommendations regarding PVV. They were asked to select which of the various options for administering PVV they usually recommend in their practice. The options included: (1) all OPV; (2) all IPV; (3) sequential: 2 IPV plus 2 OPV, (4) all of the above; or (5) other. They were then asked to select which of the immunization options they most frequently administer in their practice. Physicians were asked how these options were presented to the child's parent or caregiver. The physician could select 1 or more of the following responses: (1) personally discuss each option with parent or caregiver; (2) office nurse or medical assistant discusses each option with the parent or caregiver; or (3) parent or caregiver reads information provided in handouts from the American Academy of Pediatrics or CDC vaccine information sheets. Finally, physicians were asked to indicate which factors influenced the actual administration of PVV in their practice: parent choice, additional cost, practice preference, difficulty obtaining IPV, liability concerns, risk of VAPP, increased number of injections per visit with IPV, or lack of a combination DTaP-HIB vaccine for infants.

SAMPLE

A sample of 480 Ohio family physicians and pediatricians was randomly selected to participate. Membership lists from the Ohio Academy of Family Physicians (OAFP) and the Ohio Chapter of the American Academy of Pediatrics (OAAP) were used to identify potential participants. Approximately 2000 family physicians, excluding residents and students, are included on the OAFP mailing list, and approximately 900 pediatricians, excluding subspecialists, residents and students, are included on the OAAP list. Both lists included approximately 90% of all physicians eligible for their professional society's membership. Simple random sampling was conducted using a random numbers table.

We estimated that 130 subjects per group would be required to perform the regression analyses (10 subjects per factor plus 50 additional subjects). ¹⁷ A sample size of 130 per group was determined to be adequate to detect a moderate effect size (.3) for the differences between the 2 groups using chi-square analysis with adequate power (.90) at $\alpha = .05$ (1-tailed). Family physicians were oversampled by 20% to account for previous research suggesting that approximately 20% of family physicians limit their care to adults only. Pediatricians were also oversampled by 20%, because the OAAP mailing list included some subspecialists that could not be clearly distinguished from the general pediatricians. A total of 480 questionnaires were originally sent in anticipation of at least a 60% response rate. We replaced 90 of the original subjects selected from the mailing list database with randomly selected subjects because of incorrect mailing addresses or retired or deceased members. Prior

approval was obtained from the investigators' Institutional Review Board.

The questionnaire was pilot tested among faculty and resident physicians from the investigators' respective residency programs. After revision, the final questionnaire was mailed in January 1998. The mailing included a brief introduction to the study and a request that the physician complete the questionnaire and return it in the enclosed preaddressed, prestamped envelope within a 3-week period. A reminder postcard was sent approximately 2 weeks after the initial mailing. A follow-up questionnaire was sent to physicians who had not responded by the deadline. Responses to the survey were anonymous.

DATA ANALYSIS

All data were scanned directly into a database and analyzed using SPSS-PC 8.0, a computer software package (SPSS Inc; Chicago, III). Data were carefully examined for nonrandom missing values. Comparability of the 2 physician groups was examined for all demographic and dependent variables. A logistic regression model was developed to identify the independent effect of factors most likely to influence the family physicians' and pediatricians' practices in administering PVV.

RESULTS

Three hundred nine physicians responded to the survey: 147 family physicians and 162 pediatricians. This represents a total response rate of 57.5% (65% for family physicians and 50% for pediatricians). Two hundred sixty-three (85%) of the responding physicians reported that they provide immunizations for children, 121 family physicians (46%) and 142 pediatricians (54%) (Table 1). Physician groups were similar across all demographic characteristics with the exception that more pediatricians were women and in hospital-based practice; more family physicians were in solo or 2physician practices; and family physicians' practices were more likely to be located in less-populated communities. This sample closely approximates the national demographic data reported for family physicians by the AAFP¹⁸ and for pediatricians by the AAP.¹⁹

Awareness of the 1997 Poliovirus Vaccine Recommendations

Ninety-eight percent of the physicians reported that they followed a standardized protocol provided by the CDC, AAP, or AAFP for the administration of immunizations. All physicians reported that they were aware of 1997 recommendations for the administration of PVV. Ninetythree (77%) of the family physicians reported that they

TABLE 1

Characteristics of Physicians Who Provide Immunizations for Children (n = 263)

| Characteristic | Family Physicians (n = 121) | Pediatricians (n = 142) |
|---|--------------------------------|-------------------------------|
| Sex, % Men Women* | 69 25 | 42 54 |
| Age (mean ± SD) | 42.8 ± 8.7 | 44.6 ± 10.8 |
| Practice years (mean \pm SD) | 12.4 ± 8.5 | 14.2 ± 10.4 |
| Board certified, % | 89 | 93 |
| Practice type,* % Group Solo or 2-physician Hospital based Medical school Health department Other | 51 34 2 15 2 2 | 60 20 13 9 4 4 |
| Practice location population,* % >500,000 50,000 - 500,000 25,000 - 50,000 <25,000 | 29 27 21 22 | 40 30 16 9 |

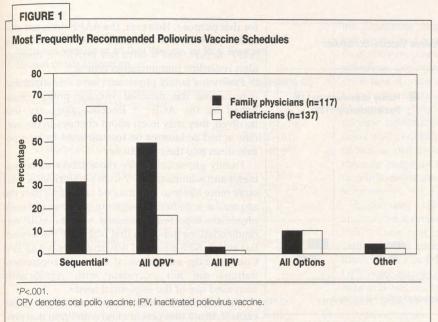
were aware of the 1997 AAFP PVV recommendations. One hundred forty (99%) of the pediatricians reported that they were aware of the 1997 AAP PVV recommendations. Family physicians (56%) were less likely than pediatricians (71%) to be aware of the 1997 CDC recommendations ($\chi^2 = 18.9, P = .000$).

Most Frequently Recommended Poliovirus Vaccine Schedule

One hundred thirty-one physicians (50%) reported that they most frequently recommend the sequential schedule for the administration of PVV to parents or caregivers; 84 (32%) usually recommend all OPV; and 3 (1%) usually recommend all IPV. Only 28 (11%) usually recommend all of the above. Eight (3%) indicated they recommend something other than those options indicated (usually the physician wrote in that they do not make a recommendation, rather it is the parent's choice); and 9 (3%) did not answer the question (Figure 1).

Most Frequently Administered Vaccine Schedule

One hundred twenty-nine physicians (49%) reported that they most frequently administer the sequential vaccine; 115 (44%) most frequently administer all OPV; 6 (2%) most frequently administer all IPV; 8 (3%) indicated they most frequently administer something other than



those options; and 5 (2%) did not answer the question (Figure 2).

How Physicians Discuss Vaccine Options with Parents or Caregivers

Physicians were asked how they make recommendations for administering poliovirus vaccine to the parent or care-

TABLE 2

Factors that Most Frequently Influence Administration of Poliovirus Vaccine by Physicians

| Factor | Family Physicians, % (n = 121) | Pediatricians, % (n = 142) |
|--|-----------------------------------|-------------------------------|
| Parent choice | 58 | 56 |
| Practice preference | 41 | 48 |
| Risk of VAPP | 27 | 48 |
| Increased number of injection per visit with IPV | ons 43 | 30 |
| Lack of combination DTaP- | HIB 21 | 13 |
| Liability concerns | 9 | 23 |
| Additional cost of IPV | 20 | 7 |
| Difficult to obtain IPV | | nga sun 1g |

Note: The total exceeds 100% because more than 1 factor could be selected. VAPP denotes vaccine-associated paralytic poliomyelitis; DTaP-HIB, diptheria tetanus acellular pertussis-Haemophilus influenzae type B vaccine; IPV, inactivated poliovirus vaccine.

giver (Figure 3). More than 1 option could be selected. One hundred eighty-two (69%) indicated that they personally discuss these options with the parent or caregiver; 57 (22%) indicated that their office nurse or medical assistant discusses each option; and 109 (41%) report that the parent or caregiver reads handouts provided by the AAP or CDC vaccine information sheets that describe these options caregivers. to parents and Pediatricians were more likely than family physicians to have parents read an information sheet ($\chi^2 = 6.23$; P = .013).

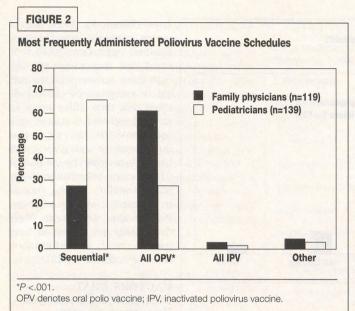
FACTORS THAT INFLUENCE PHYSICIAN PRACTICE IN THE Administration of Poliovirus Vaccine

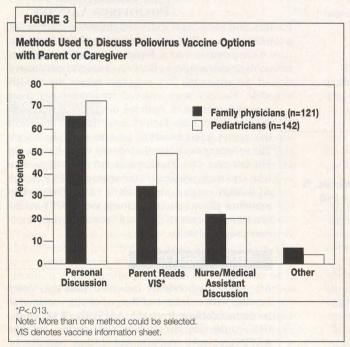
Factors that physicians indicated influence their actual administration of PVV are displayed in Table 2. All factors were entered into a logistic regression model to assess their independent effect on physician administration of the sequential PVV schedule versus the all OPV schedule. Factors were entered simultaneously using

stepwise regression analyses designed to maximize prediction of those factors most likely to influence the actual administration practices of physicians. The resulting models included only those factors significant at $\alpha \leq .05$. Factors that influence physicians who choose to administer the sequential PVV included liability concerns and risk of VAPP. Factors that influence physicians who choose the all OPV schedule included cost of IPV and increased number of injections (Table 3).

DISCUSSION

All survey respondents indicated that they were familiar with at least 1 of the poliovirus vaccination recommendations from the AAFP, the AAP, or the CDC. At the time our study was conducted, both the AAFP and AAP recommended that parents be offered a choice from all 3 schedules following an explanation of the risks and benefits. The ACIP recommended the sequential schedule but stated that the others were acceptable options. ¹ The vast majority of physicians in our study indicated that they followed 1 or more of the protocols recommended by the 3 organizations. Family physicians were less likely than pediatricians to be familiar with the ACIP recommendations.





Timely dissemination of vaccine information may contribute to pediatricians' greater awareness of the ACIP recommendations. The AAP sends out a member alert regarding new vaccines months before the recommendations are actually published in *Pediatrics*. In addition, these recommendations are published in the newsletter *AAP News*. The AAFP publishes the Recommended Childhood Immunization Schedule in *American Family Physician* as soon as it is available for that purpose. However, the AAFP does not currently publish this information in its newsletter *AAFP Report*, and it does not provide a member alert regarding immunization issues.

Practicing family physicians have less input into determining the national vaccine policy established by the ACIP. ²⁰ Because they are less involved, they may learn about changes in the vaccine schedule later or be less inclined to incorporate them into their practices.

Family physicians were more likely to recommend and administer OPV than pediatricians, who were more likely to recommend and administer the sequential schedule. A separate analysis of family physicians reporting familiarity with the ACIP recommendations indicated that 30% gave the sequential series, 63% gave all OPV, and 5% gave all IPV. Consequently, awareness of the ACIP recommendations did not correlate with significantly increased use of the sequential series.

Although both pediatricians and family physicians indicate that parent choice and practice preferences are factors that most frequently influence their actual administration of PVV, our study found that choosing the sequential schedule was significantly related to concern for the risk of VAPP and liability. Pediatricians more frequently cited the risk of VAPP and liability concerns as factors in their decision than family physicians. Choice of the all OPV schedule was significantly correlated with concern about the increased number of injections and cost. Family physicians' concerns about the cost of vaccines have also been cited by Zimmerman and others.^{10,11,20,21}

Although family physicians and pediatricians were both concerned about the number of injections, more family physicians cited this factor than pediatricians. A survey ²² of 32 Minnesota family practice clinics found that most parents, nurses, and physicians believed that 3 injections during 1 visit were too many. However, when parents were given an explanation of polio vaccine options with a recommendation for the sequential schedule, more than 90% chose the IPV vaccine for the first dose.¹⁶

Several recent studies support this study's findings of PVV usage among pediatricians. A Pediatric Research in Office Settings survey of 1424 pediatricians during the fall of 1997 found that 29% were

using all OPV, 5% all IPV, and 60% sequential IPV-OPV. ²³ In another study, risk of VAPP and evidence from vaccine trials were the reasons most frequently mentioned by primary care providers who had switched or planned to switch to the sequential schedule. Cost and legal concerns were not critical factors in their decision making. ²⁴

The finding that only 41% of all physicians have the parent read the information provided in handouts from the AAP or CDC is surprising because federal regula-

TABLE 3

Factors Influencing Physicians' Administration of Sequential Poliovirus Vaccine or All Oral Vaccine, by Most Frequent Method of Administration

| Factors | Odds Ratio (95% CI) |
|---|----------------------------|
| Physicians Administering Sequential PVV | nie is officially a second |
| Liability concerns | 22.16* (4.3-115.0) |
| Risk of VAPP | 9.09* (3.9-20.9) |
| Increased number of injections | .22* (.0951) |
| Additional cost of IPV | .23† (.0595) |
| Physicians Administering All OPV | |
| Increased number of injections | 4.63* (1.9-10.94) |
| Cost of IPV | 4.42† (1.0-18.65) |
| Risk of VAPP | .11* (.0525) |
| Liability concerns | .05 (.0123) |

PW denotes poliovirus vaccine; OPV, oral poliovirus vaccine; VAPP, vaccine-associated paralytic poliomyelitis; IPV, inactivated poliovirus vaccine; CI, confidence interval. *P <.001.

† P <.05.

tions require that "each health-care provider who administers a particular vaccine set forth in the Vaccine Injury Table shall provide a copy of the relevant information materials." ²⁵

Physicians may fail to provide the vaccine information sheet because they perceive that many caregivers either do not read or cannot understand the information. It has been demonstrated that the PVV information sheets increase caregivers' knowledge but are not as effective as a 15-minute videotape explaining the risks and benefits of IPV and OPV.²⁶ When given only the information sheet to read, more than 90% of the parents and guardians thought that it was an effective means of providing information. Failure to provide current and appropriate information about the different polio vaccines may constitute grounds for legal action in the event of a serious adverse reaction.²⁷

LIMITATIONS

This study may have overestimated physicians' awareness of the 1997 PVV recommendations. Physicians who were not familiar with these recommendations may have been less likely to respond to the survey. Consequently, the reported awareness and implementation of the 1997 poliovirus vaccine recommendations by primary care physicians at the time of this study may be less than indicated. It is also possible that this sample of Ohio pediatricians is not representative of this group of physicians nationally. However, the 67% reported administration of the sequential schedule by Ohio pediatricians is similar to the 60% reported in the 1997 Pediatric Research in Office Settings study.²³

CONCLUSIONS

This study demonstrates that family physicians more frequently recommend and administer the all OPV schedule. Concerns about cost and number of injections influence this recommendation. Pediatricians more frequently recommend and administer the sequential schedule. Concerns about VAPP and liability influence this recommendation. The majority of physicians report that although they personally discuss PVV options, they do not have the parent read the vaccine information sheet. Although family physicians and pediatricians most frequently cite parent choice as determining the PVV schedule, this study strongly suggests that the provider's recommendation influences the actual administration of the PVV schedule.

In January 1999, the ACIP, AAFP, and AAP announced a revision in their recommendations for PVV.²⁸ They now recommend that children in the United States receive IPV for the first 2 doses followed by IPV or OPV for the third and fourth doses. OPV is acceptable for the first 2 doses only if the parents will not accept the recommended number of injections, delayed onset of immunization requires an unacceptable number of injections, immediate travel is planned to areas where polio is endemic, or to control an outbreak of wild-type poliovirus infection.

Family physicians and pediatricians must provide current and appropriate information about vaccine benefits and risks. They must also provide parents with the current vaccine information sheet and document their actions to comply with federal regulations.

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