Physician Concerns About Vaccine Adverse Effects and Potential Litigation

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Objective: To understand physician concerns about litigation and beliefs regarding vaccine safety.

Design: A stratified random sample of family physicians, pediatricians, and general practitioners younger than 65 years who were in office-based practices across the United States was selected from the American Medical Association list that includes nonmembers. A standardized telephone survey was conducted by trained interviewers in 1995.

Participants: Physicians seeing 5 or more patients per week younger than 6 years and having 50% or more primary care patients were eligible for the study.

Results: Of the 1236 physicians who were surveyed, 32% and 13% overestimated the risk for serious adverse effects related to pertussis and measles vaccines, respectively. Among physicians who thought that serious adverse effects from diphtheria and tetanus toxoids and pertussis vaccine (DTP) were unlikely, 15% were highly concerned about litigation; however, among those with higher ratings of the likelihood of serious adverse effects, 38% were highly concerned about vaccine litigation (P<.01). Of those aware of the Vaccine Injury Compensation Program, only 41% believed that it afforded a high level of liability protection; 22% believed that it gives little protection, and 37% gave an intermediate answer. Among physicians highly concerned about vaccine litigation, 22% were unlikely to recommend the third dose of DTP for a child with a fever of 39.4°C and no other symptoms after the second dose of DTP, whereas among those expressing little concern about litigation, only 12% were unlikely to vaccinate (P<.05). Although some physicians were concerned about litigation, most (86%) encouraged vaccination even if a parent was argumentative about possible adverse effects.

Conclusion: Physicians’ perceptions about the risk for adverse effects and protection afforded by the Vaccine Injury Compensation Program influence their concern about litigation and, to a lesser extent, their reported likelihood to administer immunizations.


Despite the availability of an effective vaccine, the United States experienced a major measles epidemic of 55,622 reported cases in 1989-1991.¹ According to the National Vaccine Advisory Committee, the principal cause of the epidemic was inadequate vaccination levels.² Forty-four percent of measles cases reported in 1990 were in unimmunized children old enough for immunization, ie, at least 15 months of age.³ Although this epidemic is over, a resurgence of pertussis occurred in 1993 and the National Vaccine Advisory Committee has predicted that future outbreaks of other vaccine-preventable diseases also will occur.⁴ To achieve the objectives stated in Healthy People 2000 of zero measles and rubella cases and fewer than 1000 cases of pertussis,⁵ we need to understand the knowledge, attitudes, and practices of primary care physicians because they are major providers of childhood vaccines.

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Fears about vaccine adverse effects, liability concerns, and underestimation of the risks for vaccine-preventable diseases may lead to an overly cautious approach to vaccination.⁶ Data from 1989 indicated that some physicians in private practice discontinued offering

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SUBJECTS AND METHODS

SUBJECTS

A stratified random sample of names and office telephone numbers of 3681 physicians in office-based practice in the 50 states of the United States was obtained from a commercial vendor of the American Medical Association's (AMA) physician list, which included nonmembers of the AMA. The sample of names consisted of equal-sized strata of 1227 physicians from each of the following 3 groups: general pediatricians, board-certified family physicians (FPs), and general practitioners (GPs), including noncertified FPs. Conceptually, the target population was physicians seeing at least moderate numbers of children, and who thereby could materially influence childhood immunization rates. Thus, physicians seeing 5 or more patients per week younger than 6 years and having 50% or more primary care patients were eligible for the study. Participants were offered a $30 honorarium for completing a 15-minute telephone interview.

QUESTIONNAIRE

The design of the questionnaire was based on suggestions from experts and on the health belief model, which has been used widely to explain compliance with preventive services.6-11 As adapted to vaccinations, the health belief model proposes that immunization use depends on perceptions of the risk of contracting disease, the severity of disease, vaccine safety and efficacy, and barriers to immunization. Many questions focused on measles and pertussis because of the outbreaks of these diseases in the 1990s. For many questions, respondents were asked to rate on a scale of 0 (very unlikely) to 10 (very likely) how likely they were to recommend immunization for a child in a particular clinical situation. A split-panel design was used with a common set of questions and 2 subsets; potential participants were randomly assigned to either subset 1 or subset 2 prior to being contacted. Details have been published previously.8 A partial listing of subset variables reported in this article includes: level of concern about litigation from injuries allegedly related to vaccination, physician estimate of the percentage of parents in their practice who ask about the safety of diphtheria and tetanus toxoids and pertussis vaccine (DTP), what happens in the physician's office when a child does not keep a well-child care appointment, and whether the childhood immunization rates have been calculated for their practice. Interviews were conducted from April 1995 to December 1995 by trained personnel using a standard questionnaire on a computer-assisted telephone interviewing system.6

DATA ANALYSES

To provide national estimates, we weighted some analyses by the estimated fraction of eligible physicians in each specialty in the target population.12,13 To facilitate display of results in tabular form, we grouped survey responses into 3 categories: unlikely/little concern (ratings of 0-3), intermediate (4-6), and likely/much concern (7-10). χ² Tests for association were performed on the resulting contingency tables.

Multiple linear regression analyses were performed with physicians' ratings of concern about potential litigation as the dependent variable, using physicians' responses on the scale of 0 to 10. From demographic characteristics (eg, physician age), practice characteristics (eg, percentage of immunizations personally administered), and attitudinal variables, forward selection regression analysis identified those that significantly (P<.01) contributed to the prediction of the dependent variable.

RESULTS

RESPONSE RATE

Introductory letters were sent to 3681 physicians, 2100 of whom were determined to be eligible for study. A member of the physician's office staff refused the inter-

immunizations despite the availability of the Vaccine Injury Compensation Program (VICP), which provides no-fault compensation to persons with a permanent injury that is temporally related to vaccination.2,7 These physicians referred children to health department vaccination clinics.7 This burdens an already taxed public system and creates additional delays in immunization as parents face an additional, unnecessary step by having to go to another clinic after seeing their physician for well-child care.

In this study, we quantified the knowledge, attitudes, and practices of a national sample of primary care physicians about the risks and benefits of childhood vaccines, the risks for the diseases they prevent, and concerns about liability.

DEMOGRAPHICS

The mean (±SD) age of the 1236 participants was 45±9 years; 71% were men. The racial breakdown was as follows: white (non-Hispanic), 82%; Asian, 10%; African American, 3%; Hispanic, 2%; and other, 3%. Overall, 86% of survey participants were board-certified and most (86%) worked in metropolitan or urban areas. Forty percent were in a 1- or 2-person practice, 33% worked in practices of 3 to 5 physicians, and 27% were in practices of 6 or more physicians. Additional demographic data for this study have been previously published.6
Table 1. Determinants of Physician Concern About Litigation From Injuries Allegedly Related to Vaccination

<table>
<thead>
<tr>
<th>Variable</th>
<th>Responses</th>
<th>Little Concern</th>
<th>Intermediate Concern</th>
<th>Much Concern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>64</td>
<td>19</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Belief that serious side effects from DTP are</td>
<td>Unlikely</td>
<td>66†</td>
<td>19</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Intermediate/likely</td>
<td>23</td>
<td></td>
<td>38</td>
</tr>
<tr>
<td>Level of protection afforded by VICP§</td>
<td>Low level</td>
<td>60‡</td>
<td>14</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>High level</td>
<td>71</td>
<td>15</td>
<td>14</td>
</tr>
<tr>
<td>Percentage of vaccines physician personally (actually) administers</td>
<td>0-33</td>
<td>67†</td>
<td>19</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>34-66</td>
<td>52</td>
<td>19</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>67-100</td>
<td>47</td>
<td>23</td>
<td>30</td>
</tr>
</tbody>
</table>

*Data are given as percentage of respondents. Data are weighted. DTP indicates diphtheria and tetanus toxoids and pertussis vaccine; VICP, Vaccine Injury Compensation Program.

†P<.01 by χ² test.
‡P<.05 by χ² test.
§Intermediate rows of 3×3 contingency tables not shown in the table.

LITIGATION CONCERN

Most physicians (85%) were aware of the federal VICP; however, only 41% of them believed that it afforded a high level of protection from liability. Fully 22% believed that it gives little protection, and 37% gave an intermediate response. More pediatricians (95%) were aware of the VICP than were FPs (71%) or GPs (61%) (P=.001). Among those who were aware of the VICP, there was no specialty difference in perceived protection it afforded; the percentage of respondents rating that it affords a high level of protection was 44% of FPs, 42% of GPs, and 40% of pediatricians (P=.91).

The majority (64%) of respondents reported a low level of concern about litigation from injuries allegedly related to vaccination, but more than one third expressed intermediate or high levels of concern (Table 1, row 1). To understand the basis for their concerns, we examined relevant knowledge, attitudes, and practices. Among physicians who believe that serious adverse effects from DTP are unlikely, few were concerned about vaccine litigation (15%; Table 1, row 2). By comparison, among physicians who believe that serious adverse effects from DTP occur commonly (ie, intermediate to likely), 38% were concerned about vaccine litigation (Table 1, row 3; P<.01; intermediate data are not shown). Beliefs about adverse effects attributable to measles, mumps, and rubella vaccine (MMR) and awareness of the VICP did not influence concern about litigation (data not shown). Among physicians who responded that the VICP gives little protection from liability, 26% were concerned about litigation from injuries allegedly related to vaccination (Table 1, row 4) whereas of those who believed that the VICP gives a high level of protection, only 14% were concerned about litigation (Table 1, row 5; P<.05). The higher the percentage of vaccinations personally (actually) administered by the physician, the higher the concern about litigation (Table 1, rows 6-8; P<.01). Physician concern about potential litigation from alleged vaccine-related injuries was not related to patient insurance status, as measured by the likelihood of referring an uninsured, insured, or Medicaid-insured child to the health department clinics for immunization (data not shown).

In regression analyses, the predictors of physician concern about litigation were, in order of importance, higher rating of serious adverse effects from DTP, higher percentage of vaccinations the physician administers personally, and nonwhite race. Taken together, however, these factors explained only 8% of the variance. These analyses were performed without inclusion of the question about the level of protection from the VICP, since this question was asked only of those who were aware of the VICP. We performed another set of regressions among the subset of physicians who were aware of the VICP, and found that the most important predictor of physician concern about litigation was again a higher rating of serious adverse effects from DTP (7% of the variance was explained). The other predictors were nonwhite race, a lower rating of the level of protection afforded by the VICP, and a higher percentage of vaccinations the physician administers personally, which together explained an additional 5% of the variance.

The primary payment source of the physicians’ practice was associated with concern about potential litigation from alleged vaccine-related injuries. Most physicians (77%) whose practice consisted predominantly (>50%) of health maintenance organization (HMO) patients had little concern about potential litigation from alleged vaccine-related injuries. By comparison, the percentage of physicians with little litigation concern was 66% for predominantly fee-for-service practices, 62% for practices without a dominant payment source, and 47% for predominantly Medicaid practices (P<.05).
When asked what percentage of the parents in their practice inquire about DTP safety, the median response reported by physicians was 20% with a range of 0% to 100%. Most physicians (86%) would encourage vaccination even if a child’s parent is argumentative about possible adverse effects (Table 2, row 1). Among physicians who had little concern about potential litigation (Table 2, row 2), only 4% were unlikely to encourage vaccination if the parent is argumentative about possible vaccine adverse effects whereas 11% of those who were highly concerned were unlikely to encourage vaccination (Table 2, row 3; P<.01). The likelihood of encouraging vaccination also varied by the level of perceived protection afforded by the VICP (Table 2, rows 4 and 5). Physicians’ likelihood to encourage vaccination if the parent is argumentative about vaccine adverse effects did not vary by awareness of the VICP, ratings of the likelihood of serious adverse effects, or likelihood of referring an insured child to the health department for immunization (data not shown).

HEALTH BELIEF MODEL

Physicians were asked a series of questions to assess their perceptions of the risks associated with measles and pertussis and the risks related to the vaccines to prevent them.
Physicians disagreed considerably on the likelihood of hospitalization from pertussis or measles and on the communicability of these diseases, as seen by the wide range of responses in Figure 1. They generally agreed on vaccine safety and efficacy, however (Figure 2). Given that serious adverse events after administration of DTP or MMR occur in fewer than 1% of recipients, it appears that many physicians overestimate the risk (Figure 2, bottom). The percentage overestimating the risk for serious adverse effects from pertussis vaccine and measles vaccine was 32% and 13%, respectively, when one considers a rating of 2 or higher as an overestimate (Figure 2).

**Physicians’ perceptions about the likelihood that a child with pertussis or measles would need hospitalization differed by the primary payment source of the practice.** Of those with a predominantly Medicaid practice, 84% responded that an unimmunized 4-month-old with pertussis was likely to require hospitalization, as compared with 74% in predominantly fee-for-service practices, 69% in HMO practices, and 67% in practices without a dominant payment source ($P < .05$). Of those with a predominantly Medicaid practice, 21% responded that an unimmunized 2-year-old with measles was likely to require hospitalization, as compared with 12% in predominantly fee-for-service practices, 7% in HMO practices, and 14% in practices without a dominant payment source ($P < .05$).

**PERTUSSIS VACCINE CONCERNS**

When physicians were asked how likely they were to administer the third dose of DTP to a child who had a fever of 39.4°C (103.0°F) and no other symptoms following the second dose, 78% were likely to immunize (Table 3, row 1). Among physicians who had little concern about potential litigation (Table 3, row 2, column 3), only 12% were unlikely to recommend administration of the third dose of DTP whereas 22% of those who were highly concerned were unlikely to recommend vaccination (Table 3, row 3, column 3; $P < .05$). More pediatricians (87%) were likely to immunize such a child than FPs (66%) or GPs (63%) ($P = .001$). Only 2% volunteered the information that they would administer a fractional dose in this situation.

Relatively few (13%) physicians recommended withholding the third dose of DTP during a well-child visit to a 7-month-old child who had a upper respiratory tract infection and a temperature of 37.5°C (Table 3, row 1, column 6). Among those with little concern about litigation (Table 3, row 2, column 6), only 10% were unlikely to recommend administration of the third dose of DTP whereas 19% of those who were highly concerned were unlikely to recommend vaccination (Table 3, row 3, column 6; $P < .01$).

Most (88%) physicians thought that there would be no increase in adverse effects after DTP when it is given...
during an upper respiratory tract infection. Among those expressing this opinion, only 8% said they were unlikely to administer the third dose of DTP during a well-child visit to a 7-month-old child who had an upper respiratory tract infection and a temperature of 37.5°C (Table 3, row 4, column 6). By comparison, 72% of those who thought there would be a marked increase in adverse effects were unlikely to vaccinate (Table 3, row 5, column 6; P<.01).

About three fourths (76%) of physicians said that they recommend acellular pertussis vaccine for all appropriately aged children without valid contraindications; there was no material difference by specialty. When asked what factors other than age are used in determining when to use acellular pertussis vaccine, 46% said that only age is considered. Other responses were previous reaction to DTP (35%), parental request (5%), insurance coverage or cost (5%), family history and patient's health (4%), and availability of acellular pertussis vaccine (3%). Six percent (6%) reported that they do not use acellular pertussis vaccine, and 5% gave other responses. (Because more than 1 answer could be given, the preceding total exceeds 100%.)

**HEPATITIS B VACCINE CONCERNS**

When asked to rate the importance of vaccinating all children against hepatitis B, 78% of physicians thought that it was highly important, 7% thought it was unimportant, and 15% rated it as intermediate. More pediatricians (85%) thought that routine hepatitis B vaccination was highly important than did FPs (65%) or GPs (70%) (P=.001). When asked about the percentage of the infants younger than 2 years in their practice for whom they recommended hepatitis B vaccine, 513 (82%) of the 626 respondents recommended it for all infants.

The concerns expressed about routinely vaccinating infants against hepatitis B were the limited duration of immunity (28%), the expense (18%), the low incidence of hepatitis B in their practice (10%), a preference for administering hepatitis B vaccine during adolescence instead of infancy (8%), safety and adverse effects (6%), number of injections required (5%), ethics (eg, vaccination might promote promiscuity) (0.5%), and other concerns (4%). More than one third (37%) reported that they had no concerns. (Because more than 1 answer could be given, the preceding total exceeds 100%.)

**COMMENT**

To our knowledge, this is the first national survey to address physician beliefs about vaccine safety and litigation in depth. The initiative with which physicians vaccinate children may be compromised by several factors addressed in our study: limited appreciation for disease communicability and severity, overestimation of the risks of vaccination, and concern about litigation from events allegedly related to vaccination. Nevertheless, 86% of participants encouraged vaccination even if parents were argumentative about potential vaccine adverse effects.

Appreciation of the communicability and severity of vaccine-preventable diseases in children has diminished with the success of the US childhood immunization program. The widespread use of vaccinations has led to the elimination in the United States of indigenous poliomyelitis due to wild-type virus and dramatically reduced the incidence of diphtheria, pertussis, tetanus, measles, mumps, and rubella. Thus, many physicians and parents lack firsthand experience with these diseases and may therefore underestimate their communicability and their potential harm. Measles and pertussis are highly communicable—under conditions of household exposure, 84% to 100% of susceptible contacts become infected. Most, but not all, survey respondents were aware of this fact. The hospitalization rate for pertussis is highest in early infancy—it is about 60% for 4-month-old children, as was understood by most respondents. For measles, the hospitalization rates reported in the literature vary, probably due to differences in patient socioeconomic status, diversity in treatment patterns, and the spectrum of clinical illness. Thus, we were not surprised to find that perception of a need for hospitalization was highest in physicians who treat mostly Medicaid-insured patients and lowest among physicians who treat mostly HMO patients.
Concerns about vaccine adverse effects have increased as the incidence of the diseases they prevent have declined. This has been fostered by a wave of antivaccine reports in the popular media (JAMA and Money Magazine. December 1996:148-164). Thus, we were not surprised to find that physicians in our survey estimated that 20% of parents ask about the safety of pertussis vaccine. Data from the literature indicate that the most common moderate to serious adverse effects from DTP, hypotonic-hyporesponsive episodes and seizures, each occur at a rate of 0.057% (1 in 1750 doses). The most common moderate to serious adverse effect from MMR is arthropathy, which may occur in 0.7% of recipients.

Many physicians who believe that adverse effects from DTP are likely were highly concerned about litigation from injuries allegedly related to vaccination. We previously reported that physician beliefs about adverse effects and vaccine efficacy influenced both the reported likelihood of recommending MMR during an upper respiratory tract illness and the likelihood of recommending simultaneous injections. Thus, it would appear that a consequence of overestimating adverse effects could be decreased age-appropriate vaccination rates.

Almost one fifth of participants indicated concern about the possibility of litigation from potential vaccine-related injury. This occurred despite the federal VICP. In reality, however, the litigation risk for the physician now may be higher for failure to vaccinate; there have been at least 2 successful lawsuits against physicians who failed to provide recommended immunizations. In our study, physicians who were highly concerned about litigation were less likely to encourage immunization if the parent was argumentative about vaccine adverse effects than were physicians with little litigation concern. In an increasingly litigious society, with media reports emphasizing even small problems with vaccine safety, these concerns are not unfounded. We were able to account for only a small part of this concern based on factors that we addressed. Although personal experience with litigation, which we did not inquire about in our survey, could affect concern about being sued, we suspect that most physicians’ concern is based on vicarious experience, resulting in fear and other normal emotional reactions. Standard theories that presume strictly logical reasoning are therefore unlikely to fully explain the effect. Despite concerns about litigation, 86% of physicians encouraged vaccination even if the parent was argumentative about potential adverse effects.

The VICP provides no-fault compensation to patients suffering a permanent injury temporally related to vaccination. Plaintiffs must apply to the VICP for compensation before using the tort system. The VICP affords protection to manufacturers and to vaccine providers and has already substantially reduced the number of cases processed in the tort system. However, only 41% of the physicians interviewed in our study believed that VICP affords them a high level of protection from liability. Perception of protection is key, because it was related in this study to concern about litigation and the likelihood of recommending vaccination when faced with a child with an upper respiratory tract infection, with a child who had a fever of 39.4°C after the second dose of DTP, or with a parent who is argumentative about adverse effects.

Our finding that litigation concern varied by predominant payment source, with the least concern being expressed by those whose practice consisted predominantly of HMO patients, has several possible explanations. First, malpractice insurance premiums are paid by the organization in staff-model HMOs, but by the individual physician or group in other settings; thus, the financial implications of increased premiums for settlements are felt more by physicians in solo or small-group practice. Second, HMOs often have courses on risk management and clinical pathways that offer a greater sense of safeguards. Third, physicians in large groups may feel less vulnerable due to the concept of safety in numbers, whereas solo practitioners or small-group practices do not have this large-group or large corporate backing.

PROVIDER EDUCATION NEEDS

We recommend the development of new educational materials for health care providers that concisely explain disease risk, vaccine safety, and the protection afforded by the VICP. These materials should include charts that clearly and succinctly compare the risks for disease with the risks and benefits of vaccination. We suggest these materials be incorporated in a national education program for providers about vaccine safety.

A refinement for provider education is the development of materials targeted to the needs and background of specific audiences. Although demographic factors such as specialty do not explain the majority of variation in reported vaccination concerns, there was a difference by specialty in awareness of the VICP, and this may be useful in targeting education. We recommend the development and evaluation of targeted educational products created by a team of educators, subspecialists, and primary care physicians who understand the needs of those on the front lines, particularly GPs and FP’s in 1- or 2-physician practices.

LIMITATIONS

The results of this study represent self-reports by physicians who see moderate to large numbers of preschool-aged children for primary care. Thus, our survey does not include physicians who see relatively few children, nor does it have a means of validating the physicians’ responses. Although self-report does not always correspond to actual practices, other studies using questionnaires that address knowledge about vaccine contraindications show that better physician knowledge is related to higher vaccination rates in the United States and Great Britain. The AMA master list is considered by many to be the best available, but it cannot be assumed to provide a complete listing of the physician population. For example, one study compared the AMA master list with a 1990 census of primary care physicians in Ohio. There were 283 physicians in the census who were not on the AMA list and 1835 who were common to both. Thus, we
must assume that some physicians were eligible for our study but were outside the sampling frame that was used to select participants. A related problem of “nonsampling errors” arises from nonrespondents: for example, 30% of eligible physicians with whom we made direct contact declined to participate in our survey. Although those who refused participation did not differ from survey participants on year of graduation from medical school or rural vs urban locale, they did differ somewhat by specialty—a higher proportion of eligible pedestrians participated than FPs or GPs (76%, 66%, and 63%, respectively; P<.001). It is, of course, impossible to know to what extent if any the nonrespondents differ with regard to their knowledge, attitudes, and practices concerning childhood immunizations.

**IMPLICATIONS**

Achievement of the Healthy People 2000 goals for childhood immunization is dependent on provider practices that take advantage of every clinical encounter to assess immunization status and bring preschool-aged children up-to-date according to the recommended vaccination schedule.\(^{\text{13}}\) We believe provider concerns about adverse effects and, to a lesser degree, litigation are hindrances to timely vaccination and recommend a national education program for providers about vaccine safety.

Accepted for publication July 28, 1997.

This study was funded by grant HS08068 from the Agency for Health Care Policy, Rockville, Md, and Research and the National Vaccine Program Office, Atlanta, Ga.

This work was presented in part at Prevention 96, Dallas, Tex, March 25, 1996, and the 30th Annual Spring Conference of the Society of Teachers of Family Medicine, Boston, Mass, May 5, 1997.

The authors thank Linda McCune, MEd, for assistance in survey management, Grace Lamson, PhD, for editorial comments, and Jeanette Trauth, PhD, and Ellen Wald, MD, for review of the questionnaire, Judy Ball, MS, for secretarial assistance, and the interviewing team.

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**REFERENCES**