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Knowledge and Attitudes Regarding Category B ACIP Recommendations Among Primary Care Providers for Children

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Abstract

Objective—In 2015, the Advisory Committee on Immunization Practices (ACIP) made a category B recommendation for use of serogroup B meningococcal (MenB) vaccines, meaning individual clinical decision-making should guide recommendations. This was the first use of a

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Authors' contributions: Dr. Kempe conceptualized and designed the study, contributed to the data collection instrument design, drafted the initial and final manuscript; Drs. O'Leary, Allison, and Hurley and Ms. MacNeil, Liang, Albert, and Lindley assisted in study design and creation of the data collection instrument and reviewed and revised the manuscript; Dr. Smith assisted with data interpretation and reviewed and revised the manuscript. Dr. Crane conceptualized and designed the study, designed the data collection instrument, and reviewed and revised the manuscript; Ms Beaty contributed to the study design, carried out the initial and further analyses, and reviewed and revised the manuscript; Ms. Brtnikova contributed to the study design and data collection instrument design, coordinated and supervised all data collection, and reviewed and revised the manuscript. All authors approved the final manuscript as submitted.

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category B recommendation pertaining to a large population and the first such recommendation for adolescents. As part of a survey regarding MenB vaccine, our objectives were to assess among pediatricians (Peds) and family physicians (FPs) nationally: 1) knowledge of the meaning of category A versus B recommendations and insurance coverage implications; and 2) attitudes about category A and B recommendations.

Design/Methods—We surveyed a nationally representative sample of Peds and FPs by e-mail and mail from 10–12/2016.

Results—The response rate was 72% (660/916). Although >80% correctly identified the definition of a category A recommendation, only 24% were correct about the definition for category B. Fifty-five percent didn't know that private insurance would pay for vaccines recommended as category B, and 51% didn't know that category B-recommended vaccines would be covered by the Vaccines for Children program. Fifty-nine percent found it difficult to explain category B recommendations to patients; 22% thought ACIP should not make category B recommendations; and 39% were in favor of category B recommendations because they provide leeway in decision-making.

Conclusions—For category B recommendations to be useful in guiding practice, primary care clinicians will need to have a better understanding of their meaning, their implications for insurance payment and guidance on how to discuss them with parents and patients.

Keywords

immunization; meningitis B; Advisory Committee on Immunization Practices (ACIP); vaccination recommendations; primary care

INTRODUCTION

The Advisory Committee on Immunization Practices (ACIP), established in 1964, is a federal advisory committee charged with developing recommendations for vaccines for the civilian population of the United States.[1] Although ACIP recommendations have always been data-driven, in 2012, ACIP recommended to CDC the use of an explicit evidence-based framework based on GRADE (Grading of Recommendations Assessment, Development and Evaluation)[2,3] as one of the important processes guiding recommendations. Key factors considered in development of recommendations using GRADE include balance of benefits and harms, type or quality of evidence, and values and preferences of the people affected. Two categories of vaccination recommendations are stipulated; category A recommendations are made for all persons in an age- or risk-factor-based group and category B recommendations are made for individual clinical decision-making. Conceptually, these categories were not entirely new; prior to implementation of the GRADE process ACIP recommendations included terms such as "should" or "routine" for a recommendation that would have been classified as category A (e.g., use of 13-valent pneumococcal conjugate vaccine in infants and children)[4] and "may" or "consideration may be given" (unofficially referred to as "permissive") for those that would have been classified as category B (e.g., use of herpes zoster vaccine in adults 50–59 years of age).[5] However, prior to implementation of GRADE, the criteria were not as explicit and the category A and B designations had not been used in CDC vaccine recommendations. Currently, the Affordable Care Act requires

non-grandfathered federal and commercial insurance plans to pay for all vaccines routinely recommended by ACIP when administered by an in-network provider, regardless of whether they are designated as a category A or category B recommendation[6] and all routinely recommended vaccines, regardless of recommendation category, are covered by the Vaccines for Children program (VFC) if ACIP has voted to include them.[7]

The first time ACIP used the term “category B recommendation” for a large group, and the first such recommendation for adolescents, was for serogroup B meningococcal (MenB) vaccines in adolescents and young adults in 2015.[8] Prior to this, Category B had been used only once pertaining to the use of hepatitis B vaccine in a subgroup of adults[9]. Two MenB vaccines are licensed by the Food and Drug Administration for use in the United States and approved for use in persons aged 10–25 years: MenB-FHbp (Trumenba®) and MenB-4C (Bexsero®).[8] Both vaccines were given a Category B recommendation for persons 16–23 years of age, with a preferred age for administration of 16–18 years. Because this was the first broad use of a Category B recommendation and its first use for adolescent populations, we sought to examine the following among pediatricians and family physicians nationally: 1) knowledge of the meaning of category A versus B ACIP recommendations and insurance coverage implications of such recommendations and 2) attitudes about ACIP category A and B recommendations.

METHODS

We conducted a survey between October and December 2016 among pediatricians and family physicians who were part of sentinel networks within each specialty. The human subjects review board at the University of Colorado Denver approved this study.

Study Population

The survey was created and conducted in collaboration with the Centers for Disease Control and Prevention (CDC) as part of the Vaccine Policy Collaborative Initiative, a rapid turnaround survey project to gain insight into physician attitudes about vaccine-related issues. In conjunction with the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP), we recruited national networks of primary care physicians from each specialty. Quota sampling[10] was utilized to ensure that network physicians were representative of the AAP and AAFP memberships with respect to region, practice location, and practice setting. Providers were excluded from participation of they practiced < 50% primary care, practiced outside of the United States, or were in a training program. The survey methodology used has been previously described.[11] We have demonstrated in prior work that survey responses from network physicians compared to those of physicians randomly sampled from American Medical Association physician databases had similar demographic characteristics, practice attributes, and attitudes about a range of vaccination issues.[10]

Survey Design

We developed the survey in collaboration with CDC, and with input from AAP and AAFP leadership. The survey included questions about knowledge and attitudes regarding ACIP

category A and B recommendations in general which are the focus of this manuscript. These questions were part of a larger survey that also focused on issues related to serogroup B meningococcal disease and MenB vaccine specifically. We used “true,” “false,” and “I would have to look this up” responses for knowledge questions and 4-point Likert scales (strongly agree, somewhat agree, somewhat disagree and strongly disagree) as well as a “don’t know” category for questions assessing attitudes about category A and B recommendations. A national advisory panel of pediatricians and family physicians pre-tested the survey. The survey was then piloted among 45 pediatricians and 13 family physicians nationally and further modified based on this feedback.

Survey Administration

We surveyed physicians by Internet (Verint, Melville, New York, www.verint.com) or by mail, based on their preference which was collected in the initial network recruitment survey. We sent the Internet group an initial e-mail with up to 8 reminders, and we sent the mail group an initial mailing and up to 2 additional reminders. We sent Internet survey non-respondents a mail survey in case of problems with e-mail correspondence. We patterned the mail protocol on Dillman’s tailored design method.[12]

Statistical Analysis

We pooled Internet and mail surveys together for analyses because studies have shown that physician attitudes are similar when obtained by either method.[12,13] Comparisons between specialties regarding their knowledge of Category A and Category B recommendations were made using Pearson’s chi-squared or Fisher’s chi-squared tests, as appropriate. To compare attitudes between specialties, we used the Kolmogorov-Smirnov test to see if there was evidence that the data were from the same empirical distribution. We conducted a multivariable logistic regression with the outcome of higher number of correct answers on knowledge questions [0–3 out of 5 questions correct (73%) versus 4–5 out of 5 questions correct (27%)] and independent variables including provider specialty, age and gender; practice setting, census location and region of the U.S. and proportion of practice patients 16–23 years of age, percentage of patients who were black or of Hispanic ethnicity and percentage of patients on Medicaid or SCHIP. Factors significant at $p<0.25$ in bivariate analyses were tested in the multivariate model by using a backward elimination procedure in which the least significant predictor in the model was eliminated sequentially. At each step, estimates were checked to make sure other variables were not largely affected by dropping the least significant variable. This resulted in the retention of only those factors that were significant at $p<0.05$ in the final model. All tests were two-sided and p values<0.05 were considered significant. Analyses were performed using SAS software, version 9.4 (SAS Institute, Cary, NC).

Results

The overall response rate was 72% (660/916); 79% (374/475) of pediatricians and 65% (286/441) of family physicians. Overall, 68% responded by e-mail and 32% by mail. Table 1 describes the surveyed physician population including demographic characteristics of providers, their practices and practice patient populations.

Knowledge of Category A versus B ACIP Recommendations and Insurance Coverage Implications

With respect to awareness of the differences between Category A and B vaccine recommendations before taking the survey, 26% of pediatricians and 15% of family physicians reported being “very aware”, 54% and 57% “somewhat aware” and 20% and 28%, respectively, “not at all aware.” Figure 1 depicts the percentage of pediatricians and family physicians who understood the definitions of category A or B recommendations and whether vaccines recommended as category A or B would be covered by different types of payers. Although the vast majority of pediatricians and family physicians correctly identified the definition of a category A recommendation, only 56% of pediatricians and 38% of family physicians correctly identified the definition of a category B recommendation. Only 19% of pediatricians and 31% of family physicians knew that when subgroups of patients are routinely recommended to receive a vaccine this is a category A rather than a category B recommendation. Overall, the majority of all respondents did not know that vaccines recommended as A or B would be covered by both private insurance and by VFC if ACIP voted to include them in the VFC resolution. Slightly over one-half of pediatricians did know that all routinely recommended vaccines should be covered by VFC. Of note, for most true and false questions over a third to one-half of providers reported they would need to look the answers up. In multivariable analysis, only urban compared with suburban/rural location [Odds Ratio 1.94 (95% confidence interval 1.35–2.80)] and having a proportion of the practice that was ≥10% in the 16–23 year old range versus less than this [OR 2.07 (1.30–3.31)] were significantly associated with higher knowledge of the definitions of Category A and B recommendations and insurance coverage implications.

Attitudes about ACIP Recommendation A and B Categories

As shown in Figure 2, the majority of physicians either strongly or somewhat agreed that category B recommendations require more discussion than category A recommendations and that they needed more information regarding category B recommendations and how to discuss them with parents and patients. Sixty-four percent of pediatricians and 60% of family physicians reported understanding the difference between A and B recommendations; however, among physicians who reported understanding the difference, 55% of pediatricians and 35% of family physicians incorrectly thought that a routine recommendation in a patient subgroup was a category B recommendation (data not shown). A minority of respondents, 26% of pediatricians and 16% of family physicians, thought ACIP should not make category B recommendations. Less than half of pediatricians and family physicians were in favor of category B recommendations because they provide more flexibility for individual clinical decision-making.

Discussion

Results of this study demonstrate a high level of understanding by most primary care providers regarding ACIP category A recommendations, but poorer understanding of category B recommendations and of the implications of either type of recommendation on coverage of vaccines by VFC or private insurance. Most physicians reported needing

additional information about the meaning of category B recommendations and how to explain them to parents and patients.

Given the fact that category B recommendations have not previously been applied to any large group of children, it is not surprising that many of the providers we surveyed did not understand what such a recommendation means. The most common misunderstanding was thinking that a routine recommendation in a subgroup of patients was a category B rather than a category A recommendation. In addition, many physicians were not aware that private insurance plans, unless grandfathered, must pay for all vaccines routinely recommended by ACIP, regardless of whether they are included in a category A or category B recommendation. There were also many physicians who were not aware that all ACIP routinely recommended vaccines, whether category A or B, are covered by VFC[7] for patients through 18 years of age if included in an ACIP VFC resolution.

There were significant differences between pediatricians and family physicians on several of the knowledge questions, although one specialty was not consistently more knowledgeable than the other. Given the fact that adolescents in the 16–18 year old age group may be roughly equally likely to see pediatricians or family physicians,[14] both specialties need to be aware of the distinctions between types of recommendations, particularly with respect to MenB vaccine. Young adults 18–23 years of age would be most likely to see family physicians, obstetricians-gynecologists or internal medicine physicians,[14] highlighting the importance of knowledge of category B recommendations in all primary care specialties.

These data include both strengths and limitations. We surveyed large, nationally representative samples of pediatricians and family physicians and achieved high response rates. The responses of our sentinel physicians may not be fully generalizable, however, although previous work has demonstrated the sampling methods described yield similar responses to the most commonly employed method of sampling physicians nationally.[10] Non-respondents may have had different views than respondents, although the high reported response rates somewhat mitigate this potential source of bias. We did not specifically exclude insurance plans that were grandfathered in our question about insurance coverage, which might have resulted in some providers responding that vaccines would not be routinely covered by private insurance. However, the vast majority of insurance plans do not fall into this category, therefore it is unlikely that many providers would include consideration of grandfathered plans in responding to a question about “routine” coverage. Finally, reported attitudes and knowledge related to category B recommendations may be influenced by physicians’ knowledge and attitudes about MenB vaccination recommendations as this category B recommendation covers the largest population group to date.

Primary care physicians’ attitudes and gaps in understanding about category B ACIP recommendations may impact how they implement these recommendations in practice. For example, physicians’ belief that category B-recommended vaccines would not be covered by insurance or that a category B-recommended vaccine requires more time to discuss than a category A-recommended vaccine might deter them from discussing the vaccine with their patients and families or providing the vaccine at all. On the other hand, providers’ lack of

understanding of the difference between category A and B recommendations might result in the incorporation of a category B vaccine into a practice's routine vaccine administration schedule via standing orders with little or no discussion of patients' individual circumstances, which is not the intention of a category B recommendation.

Our data clearly reflect providers' need for additional guidance on how to present Category B recommendations to patient and families. The original guidance for presenting recommendations included use of the word "recommend" for A and "may" recommend for B recommendations.[15] It suggested that Category B recommendations should be considered in the context of a clinician-patient interaction and that discussion include the balance between desirable (benefits, savings) and undesirable effects (harms, costs) of the vaccine in question. Although the AAP's Committee on Infectious Diseases[16] has more directly addressed how to discuss the MenB vaccine specifically, additional guidance about how to communicate with patients and families about Category B recommendations in general is lacking.

ACIP's Evidence-Based Recommendations Workgroup has adapted the GRADE framework[17] to improve transparency and clarity of how evidence is considered when formulating vaccine recommendations. The adapted framework was formally adopted in February, 2018; the terms "category A" and "category B" will be replaced by language where the meaning of the recommendation may be clearer. However, there will continue to be situations where "permissive" recommendations are deemed appropriate by ACIP. Successful implementation of permissive, or non-routine, recommendations will rest on increasing providers' understanding of what these recommendations mean and how to discuss them with patients and parents. The CDC and national physician organizations, such as the AAP and AAFP, could be key in providing talking points to providers about how best discuss "permissive" or Category B vaccination recommendations with patients and families.

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WHAT'S NEW?

A minority of primary care providers understand the meaning of Category B recommendations from the Advisory Committee on Immunization Practices (ACIP), the implications of such recommendations for insurance coverage for vaccines or how to discuss them with parents and patients.

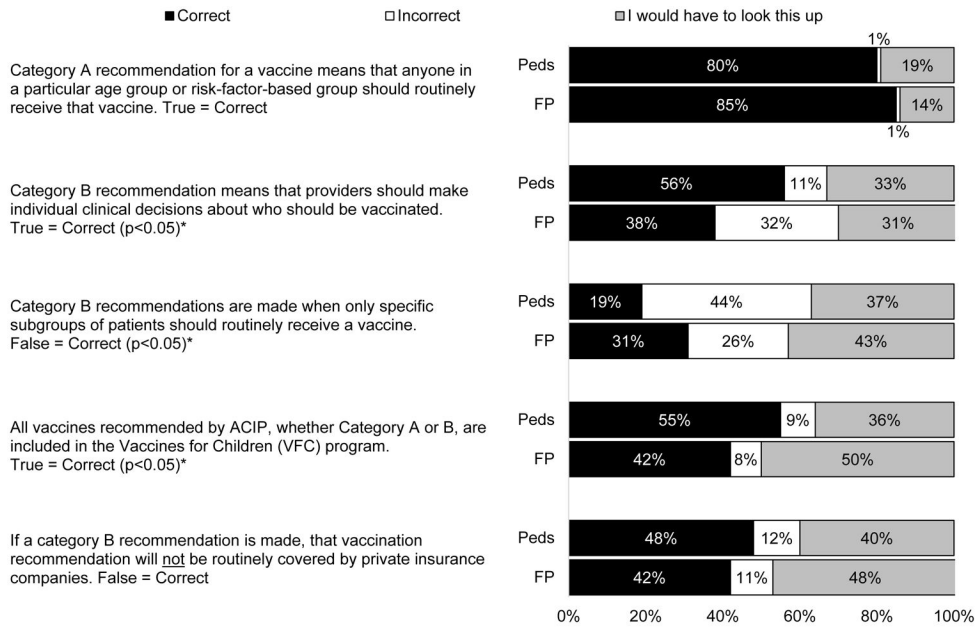

Figure 1. Knowledge of Category A and B Recommendations (Peds n=374, FP=286)

Peds = pediatricians; FP = family physicians

* $p<0.05$ for difference between Peds and FP using Kolmogorov-Smirnov test

Study conducted in the US from October to December 2016.

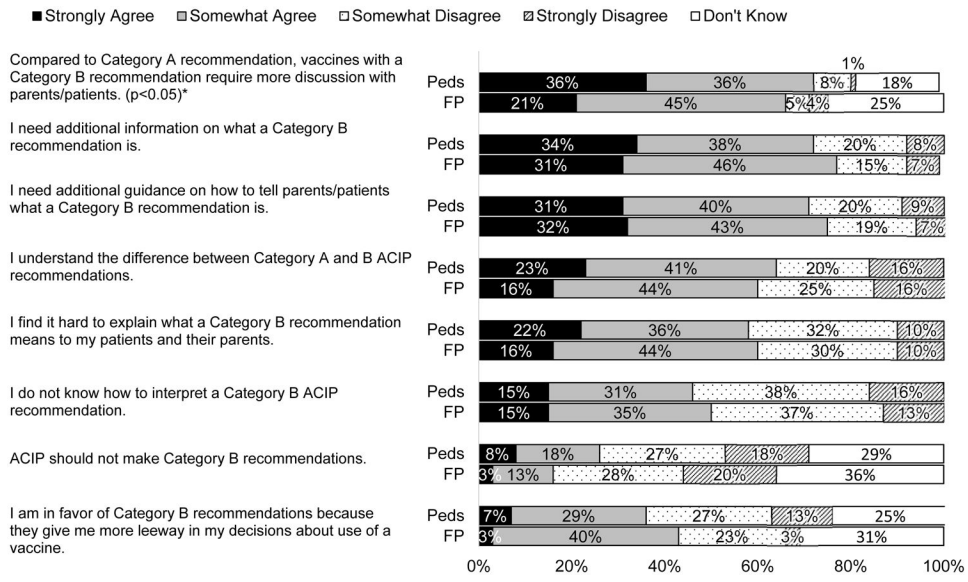

Figure 2. Attitudes about Category A and B Recommendations (Peds n=374, FP =286)

Peds = Pediatricians; FP = Family physicians

* $p<0.05$ for difference between Peds and FP using Kolmogorov-Smirnov test

Study conducted in the US from October to December 2016.

Table 1

Respondent Characteristics

	Total Respondents* (n=660)
Age in years, mean (SD)	51.8 (9.5)
Male, % (n)	42.6 (281)
Region, % (n)	
Midwest	25.6 (169)
Northeast	19.2 (127)
South	33.9 (224)
West	21.2 (140)
Location of Practice, % (n)	
Urban	47.1 (311)
Suburban	48.2 (318)
Rural	4.7 (31)
Setting, % (n)	
Private practice	73.3 (484)
Hospital/clinic	20.5 (135)
HMO	6.2 (41)
Proportion of patients age 16–23 years old, % (n)	
<10%	33.0 (213)
10–19%	35.5 (229)
≥20%	31.5 (203)
Proportion of Black or African American patients, % (n)	
0–24%	80.4 (511)
25–49%	15.9 (101)
≥50	3.8 (24)
Proportion of Non-Hispanic white patients, % (n)	
0–24%	16.8 (107)
25–49%	24.9 (159)
≥50%	58.3 (372)
Proportion of patients with Medicaid or CHIP, % (n)	
0–24%	53.1 (337)

	Total Respondents* (n=660)
25–49%	24.6 (156)
≥50%	22.4 (142)
Proportion of patients with private insurance, % (n)	
0–24%	20.1 (128)
25–49%	21.2 (135)
≥50%	58.8 (375)

*pediatricians and family physicians combined