PEDIATRICS PERSPECTIVES

Understanding the Category B Recommendation for Serogroup B Meningococcal Vaccine

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Published recommendations of the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention, which carry the approval of the Secretary of Health and Human Services, provide guidance on how licensed vaccines should be used. Professional organizations such as the American Academy of Family Physicians and the American Academy of Pediatrics (AAP) also develop immunization recommendations. Since 1995, the recommendations of the ACIP, the American Academy of Family Physicians, and the AAP have been harmonized, although minor differences have surfaced from time to time. In the end, some vaccines are recommended for universal use and some are not, despite approval from the US Food and Drug Administration and commercial availability.

Deliberations of the recommending bodies have always been methodical, data-driven, and comprehensive, but they were not always codified or, for that matter, entirely transparent. A change in that direction took place in 2010, when the ACIP adopted the modified GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach.[1] In this formal process, the evidence germane to a particular disease and vaccine is ranked according to type and quality (Table 1). Key factors (eg, the balance between benefits and harm, the evidence type, values and preferences, health economic analyses) are used to refine the recommendation and to determine ultimately what category of recommendation is made, either Category A or Category B (Table 2).

Category A (formerly known as "universal") recommendations apply to all persons in an age- or risk-based group. These recommendations may be for or against use of the vaccine. A timely example of a Category A recommendation is the June 2015 ACIP recommendation that certain persons ≥10 years of age at increased risk for meningococcal disease be given a serogroup B meningococcal (MenB) vaccine.[2] The AAP recently released similar recommendations.[3] These are Category A recommendations because they state that members of defined populations (eg, those with persistent complement component deficiencies or anatomic or functional asplenia) should be vaccinated.

Category B (formerly known as "permissive") recommendations are a call for individual clinical decision-making. Specifically, they

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are used in the context of clinician–patient interaction to determine if vaccination may be appropriate for that patient.[4] It is important to understand that a Category B recommendation is a "recommendation," as opposed to a "non-recommendation," silence on the topic, or something that can be ignored. The October 2015 ACIP recommendation that the MenB vaccine "may be given" to persons 16 to 23 years of age, with the preferred age being 16 to 18 years, is an example of a Category B recommendation.[5] Why was the MenB vaccine assigned Category B rather than Category A for healthy adolescents? Simply speaking, there was not enough evidence to recommend that all 16- to 18-year-olds receive the vaccine, but there was enough evidence to recommend that adolescents and young adults be given the choice of vaccination, in the context of the provider–patient relationship and joint decision-making. Factors that favored Category B included the low burden of disease and the high cost per quality-adjusted life year saved of a universal program (which would have been implemented with a Category A recommendation), as well as a lack of information about duration of protection, effects on carriage, herd immunity, and strain coverage (serogroup B strains are antigenically diverse).

"Individual clinical decision-making" cannot occur if a patient does not know about the vaccine and the disease. The AAP acknowledges this caveat by encouraging pediatricians to discuss the availability of the MenB vaccine with families,[3] in essence providing the first real guidance on implementing the Category B recommendation. In the absence of such a discussion, disparities could arise between the "information haves" (families who know about the disease and seek vaccination) and the "information have-nots" (those who do not know about the disease or the vaccine). Under Category B, patients should have a choice between being vaccinated or not being vaccinated, a choice that boils down to, at the individual level, the tradeoff between a sore arm and continued vulnerability to a rare but potentially devastating disease. It is noteworthy that, generally speaking, the patient's choice is not whether to spend his or her money; the Patient Protection and Affordable Care Act directs insurance companies to pay first-dollar for both Category A and Category B recommendations,[6] and both categories of recommendations are generally covered under the Vaccines for Children Program.

Providers need to decide how they will approach initiating the discussion about the MenB vaccine (and, indeed, vaccines yet to come that may carry a Category B recommendation). Should they recommend that every 16- to 18-year-old in the practice be vaccinated (a presumptive approach)? Should they present vaccination as an option (a participatory approach) and ask the patient and family to decide? One problem with the latter approach is that there is no way to predict, short of exposure during an outbreak, which healthy adolescents are at risk for invasive serogroup B disease (even college attendance is not a risk factor[5]). Should the whole practice or health care system adopt a standard, consistent approach or leave the process up to each provider? Either way, we agree with the implication from the AAP's statement: not discussing MenB disease and the vaccine that is currently available should not be an option.

TABLE 1 Evidence Base for GRADE Process

Evidence Type	Source
1	Randomized controlled trials
	Overwhelming observational evidence
2	Randomized controlled trials with important limitations
	Exceptionally strong observational evidence
3	Observational studies
	Randomized controlled trials with notable limitations
4	Clinical experience
	Controlled or observational studies with major limitations

GRADE, Grading of Recommendations, Assessment, Development, and Evaluation. See Ahmed et al.[1]

TABLE 2 Categories of ACIP Recommendations

Category	Application	Language
A	All persons in an age- or risk-based group	Recommend
		Recommend against
		Should
		Should not
B	Individual clinical decision-making	May
		Suggest against

See Ahmed et al.[1]

ABBREVIATIONS

AAP: American Academy of Pediatrics
ACIP: Advisory Committee on Immunization Practices
MenB: serogroup B meningococcal

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