Advisory Commission on Childhood Vaccines
(ACCV or Commission)

July 29, 2010

Minutes of Teleconference on Vaccine Information Statements

Members Present
Charlene Gallagher, J.D., Chair
Sherry K. Drew, J.D., Vice Chair
Tawny Buck
Thomas Herr, M.D.
Sarah Hoiberg
Magda Castro-Lewis
Jeffrey M. Sconyers, J.D,

Executive Secretary

Geoffrey S. Evans, M.D., Director, DVIC

Staff Liaison

Andrea Herzog, Principal Staff Liaison

Proceedings

Ms. Gallagher called the meeting to order and explained that the purpose of the special meeting was to review Vaccine Information Statements (VISs) developed by the Centers for Disease Control and Prevention (CDC) in accordance with the Public Health Service Act. The ACCV is one of the federal entities charged by the Secretary of Health and Human Services (HHS) with review of the VISs. Dr. Gallagher announced that the text of the VISs to be reviewed could be found on the HRSA web site at www.hrsa.gov/vaccinecompensation.

After introductions, Mr. Skip Wolfe explained that the drafts under review were based on last year's approved VISs for the same vaccines, including updates and some revisions made internally within CDC. He reminded the Commission that the VISs are designed to inform parents and not practitioners or health care providers. Ms. Jennifer Hamborsky commented that CDC's panel of subject matter experts had reviewed and approved the documents. She suggested beginning with review of the inactivated influenza VIS.

Ms. Castro-Lewis offered the first comment, the statement that explains in English that the VIS is available in "Spanish and many other languages" might not be helpful to an individual who does not speak or read English. The statement should at least be included in Spanish along with a web link that would lead to additional information. She offered to provide a Spanish language statement if desired. Mr. Wolfe agreed that the translation would be welcomed. Asked about similar statements in other languages, Ms. Castro-Lewis commented that the Hispanic population in the U.S. is of significant size and merits the statement in every VIS. She suggested that it would be up to CDC to decide on whether other languages should be included. Mr. Wolfe commented that there was an assumption that the health care provider would probably ensure that the proper translation was provided to his or her patients who did not read English with ease. Even the less common language translations are available on the Internet.

Ms. Hoiberg noted that, under the heading "Why Get Vaccinated," the sentence, "Other illnesses can have the same symptoms and are often mistaken for influenza," is a statement of fact and not a rationale for obtaining the vaccine. She suggested that it be placed just after the symptoms in the same section as an explanatory statement. Ms. Gallagher noted that Commission member Meg Fisher, who was unable to attend, sent a comment that the flu virus spreads by coughing, sneezing, etc., but can also be deposited on an individual's hand and spread in that manner – hand contact with another individual. Mr. Wolfe commented that adding hands to the list suggested a preventive hand-washing measure, which was not really related to the vaccine. He felt the sentence was sufficient to explain the vector of infection. Dr. Fisher also recommended amending the last sentence of the section to read "Influenza vaccine can prevent influenza or make the illness milder," at the end of the first section. Dr. Carolyn Bridges (CDC) commented that the evidence for that has not been established by large-scale studies. Mr. Wolfe suggested that he could talk to Dr. Fisher about the recommended change. Dr. Marion Gruber added that the words "can prevent transmission" may be too strong since no studies have been conducted to determine whether that is true or not. She suggested using the words "may prevent transmission." Ms. Gallagher restated the final sentence of the first section: Influenza vaccine can prevent influenza and may help prevent transmission to others. The Commission members present agreed.

There was a suggestion that , since vulnerable populations often have more serious flu experiences, that it would be appropriate to add to the "why get vaccinated" section that by being vaccinated an individual is reducing the chance that individuals in those vulnerable populations would contract the illness. Mr. Wolfe felt the suggestion was appropriate.

In the second section, Inactivated Influenza Vaccine, Ms. Hoiberg suggested that the last paragraph omit any mention of autism, but explain that since some vaccines contain thimerosol that there are thimerosol-free vaccines available. Then parents would know that the thimerosol-free vaccine is available on request. There was a suggestion that the VIS include a statement that parents should talk to their physicians about the issue. There was a suggestion that the following sentence be added at the end of that paragraph: Ask your doctor about options.

Ms. Buck considered the third paragraph of Section 2 confusing. After discussion, the Commission agreed that the second sentence, which mentions potential protection when the vaccines strains selected are a close match to other influenza strains, should be deleted, and the third sentence should be slightly revised to read: But even when there is not a close match the vaccine may provide some protection. There was also a suggestion to delete the last sentence about protection from other viruses. Mr. Sconyers added that sentence that identifies the three 2010-2011 strains should more accurately describe the pandemic virus as influenza A/H1N1. Mr. Wolfe agreed, noting that the strain should be so identified throughout the document.

There were no comments by the members present on Section 3, Who Should Get Inactivated Influenza Vaccine and When? However, Ms. Gallagher stated that Dr. Fisher had recommended the following wording: All people 6 months of age and older who cannot or choose not to receive the live attenuated influenza vaccine (LAIV). There was agreement that the mention of the LAIV could be confusing and that the statement should not be included.

In Section 4, Some People Should Not Get Inactivated Influenza Vaccine or Should Wait, there was a comment that the statement under the second bullet should be more proactive –Your doctor should help you make the decision about whether the vaccine is right for you, if there's have a history of Gullain-Barre Syndrome (GBS). There was agreement that such wording was more effective. In addition, there was also a comment concerning the description of the individual in the health care system who is involved with administration of vaccines -- doctor, doctor and nurse, and health care provider, all of which are used in

the VIS. It was noted that in many cases a person receiving the vaccine may never come in contact with a doctor, so the term “health care provider” might be the most appropriate descriptor. Mr. Wolfe commented that the observation had been made many times in the review of VISs that using the term doctor might appear to exclude other health care providers and the fact that the term “doctor” is understood by most to mean those in the doctor’s office who administer inoculations. He added that the VIS should continue to refer individuals to his or her doctor when a severe reaction or a life threatening event occurs. There was agreement expressed by Commission members.

Ms. Hoiberg expressed concern that with the increase in availability of vaccines in storefront locations, the warnings become especially important, particularly the caution about an individual allergic to eggs avoiding vaccines without consulting a doctor. Ms. Hamborsky commented that vaccines in storefront locations are administered by legally authorized health care providers and that there is an assumption that they follow the regulations to distribute the VIS materials and to provide the required verbal warnings during the process. There was a suggestion that the warning about egg allergy could be printed in bold typeface.

In Section 5 Ms. Buck commented that the three signals identified by the Vaccine Risk Assessment Workgroup -- Bell’s palsy, GBS and thrombocytopenia – might be mentioned in the section. Mr. Wolfe noted that the risks included are usually those identified by the Advisory Committee on Immunization Practices (ACIP). Ms. Buck expressed the opinion that even the preliminary signal should be included in the VIS. Dr. Jane Gidudu stated that the three conditions have only reached the preliminary stage with regard to being signals related to flu vaccine and were termed “weak” signals in the Workgroup’s report. Mr. Wolfe stated that providers should certainly be aware of developing information about risks and there should be consideration of methods to provide this information, but the VIS may not be the proper place to discuss it. There was general agreement among the Commission members that these risks should at least be mentioned on the VIS and the individual would then have the opportunity to ask the health care provider about the risks. Ms. Buck maintained that the three risks should be mentioned, including the fact that the risks were seen in the monovalent vaccine during the last flu season but have not been fully researched, especially with regard to the trivalent flu vaccine, and that there is continuing effort to research the issue. Mr. Wolfe stated that he was reticent to include the three specific risks in a VIS until there is more confirmation, although he expressed agreement that there should be a more aggressive effort to advise the providers about the signals during this flu season, encouraging them to discuss pertinent risks with patients. Ms. Gallagher stated that the CDC should develop language for the VIS based on the discussion.

There was a brief discussion about the apparent repetition of a caution about GBS in Section 5, and Mr. Wolfe stated that the purpose of the paragraph was to provide an assurance that the GBS associated with the 1976 (swine flu) vaccine was no longer a risk in the current vaccines. There was agreement that the statement should remain in the VIS for the time being. It was noted that the warning was not mentioned in the live attenuated (nasal) vaccine, partly because that vaccine did not exist is 1976. Dr. Gidudu noted that there have been no claims currently for that vaccine.

There was a comment that in Section 6, concerning severe reactions, the first sentence should include numbness, tingling or usual bruising.

Ms. Gallagher, noting the end of discussion related to the inactivated influenza vaccine, invited comments on the live attenuate nasal vaccine. The members present commented that the recommendations discussed earlier would also apply to the nasal vaccine.

Ms. Gallagher invited public comment and one individual, Ms. Lynne Redwood, representing SafeMinds, commented that federal agencies must comply with the Data Quality Act which would suggest that the information on thimerosol in flu vaccines should be fully reported. It was her contention that manufacturers had stated that most, not some, flu vaccines contain thimerosol. Thimerosol is 49.4% ethyl mercury, a neurotoxin. Secondly there should be information on whether or not the flu vaccine presents any risk to pregnant women. Finally, Ms. Redwood noted that the VIS warns against accepting the vaccine if an individual is allergic to any component in the vaccine, but no list of such components is included in the VIS. Ms. Hoiberg emphasized the importance of encouraging the individual to discuss the issue with the health care provider. Mr. Wolfe affirmed that the VIS advises the individual to consult the health care provider concerning labeling.

Adjournment

There being no other business, on motion duly made and seconded, the meeting was adjourned by consensus at 2:15 p.m.

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Charlene Gallagher, ACCV Chair

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Sherry K. Drew, ACCV Vice-Chair

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Geoffrey Evans, M.D.
Executive Secretary, ACCV

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Date