SPECIAL CONFERENCE CALL

THE ADVISORY COMMITTEE

ON

IMMUNIZATION PRACTICES

September 28, 2000

KNOWN PARTICIPANTS OF CONFERENCE CALL:

MEMBERS
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Richard Clover
Fernando Guerra
Charles Helms
David Johnson
John Modlin
Paul Offit
Margaret Rennels
Bonnie Word

Executive Secretary
Dixie Snider

Ex Officio
Dand Bradshaw
James Cheek
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Randolph Graydon
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William Schaffner
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Richard Zimmerman

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Nancy Cherry
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Ronald Goodman
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Kathy Zoon

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Lynn Bahta, Immunization Action Coalition
Michele Bailey, American Social Health Association
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Sue Lovelace, District Health Department #2
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Taousik Mabrouk, Biochempharma
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Catrina Manzano, Member of the public
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Ed Marcuse, University of Washington
Michele Marill, Hospital Employee Helath Newsletter
William Martone, NFID
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Karen Midthun, Food and Drug Adminsitration
Kit Mikovitz, Grand Traverse County Health Department
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Ann Moen, Centers for Disease Control and Prevention
Rich Mullins, CVS pharmacy
Maria Murray, Self employed (recorder)
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Peggy Webster, Wyeth-Ayerst Pharmaceuticals
Harold Weiss, Delmarva Foundation
Rick Weiss, Washington Post
Bruce Weniger, Centers for Disease Control and Prevention
Deborah Wexler, Immunization Action Coalition
Melinda Wharton, Centers for Disease Control and Prevention
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Carla Wohl ABC
Luana Wojcik, Aventis Pasteur
Laurel Wood, Alaska Department of Health and Social Services
Jane WorthyHowlett, Washtenaw County Public Health
Michelle Yang, National Asian Women's Health Organization
Jan Zucker, Centers for Disease Control and Prevention

Centers for Disease Control and Prevention
Advisory Committee on Immunization Practices
Record of the Teleconference Call
September 28, 2000

A teleconference call was held by the Centers for Disease Control and Prevention (CDC) on September 28, 2000, to discuss the 2000-2001 influenza recommendations. Public participation in this call was invited by publication in the Federal Register, and was only limited by the availability of telephone ports. The call was convened at 3:15 p.m.by Dr. Dixie Snider, CDC'S Associate Director of Science and Executive Secretary, ACIP.

Those calling in included ACIP members, ex-officio and liaison members, federal agency (CDC, FDA) staff, media representatives, and members of the public. Public questions and comment, with names listed in order by the conference call operator, were taken after the committee's vote.

Dr. Snider called for the members' statements of potential conflicts of interest, including relationships with the relevant vaccine manufacturers (Aventis Pasteur, Inc.; Medeva; Parkedale; and Wyeth Lederle). All members, even those with conflicts, may discuss the matters considered, as long as the conflicts are revealed, but those members may not vote. Payment of honoraria of <$1000 and travel support (considered *de minimus* interests) did not prevent voting.

The members participating and their statement of conflicts of interest were:
John Modlin, M.D.: none
Fernando Guerra, M.D.: His department is conducting vaccine studies for Aventis Pasteur and is in discussions of same with Wyeth Lederle, but none of these are influenza-related.
Dennis Brooks, M.D., Johns Hopkins University: none
Charles Helms, M.D., University of Iowa: none
Paul Offit, M.D., Children's Hospital of Philadelphia: none
David Johnson, M.D., Michigan Department of Community Health: none
Bonnie Word, M.D.: none
Richard Clover, M.D.: University of Louisville School of Medicine: Conflict with Wyeth-Lederle
Margaret Reynolds, M.D.: University of Maryland School of Medicine: none

The list of all those who called in to listen and/or participate in this conference is attached (Attachment #1).

Proceedings of the Teleconference
ACIP Chair Dr. John Modlin reviewed the meeting agenda. Presentations of the issues related to this season's influenza immunization activities were provided, as described in a draft document distributed to the members. Discussions followed among the committee members, liaisons and ex-officios, and federal agency staff. Public comment or inquiry was then invited. The goal of

the teleconference was for the ACIP to deliberate the draft document and to approve it as amended during this call.

Presentations

National Immunization Program.

Dr. Walter Orenstein, Director of the National Immunization Program (NIP) recalled discussion during the last June ACIP meeting that either a) the availability of influenza vaccine would likely be substantially delayed for the 2000-2001 season, or b) a shortfall in supply could occur. The vaccine is the best preventive of influenza-related death among the elderly in the U.S. On July 14, 2000, notice of an expected delay in the vaccine supply was published in CDC's *Morbidity and Mortality Weekly Report (MMWR)*. Physicians were urged to make appropriate plans and a delay of mass vaccine campaigns was advised. If needed, CDC guaranteed the production of >9 million doses, to make up for the manufacturers' possible shortfall and to reduce the potential risk of a severe shortage to vulnerable populations. Nonetheless, a substantial portion of vaccine is expected to be available later in the season than normally. This meeting was called to discuss the supplies available and the impact of delays on influenza vaccination efforts.

Dr. Orenstein shared data on the vaccine's possible target populations and past influenza immunization experience. Currently in the U.S., about 50% of the 76 million at high risk of serious complications from influenza routinely choose to be vaccinated; 35 million of those are aged 65 years or older, and 33-39 million are under age 65 with high risk medical conditions. Another approximately 2 million women could be in the 2nd-3rd trimester of pregnancy during the influenza season, and be at higher risk of complications from influenza than the general population.

In the 1999-2000 season in the U.S., 77 million doses of influenza vaccine were distributed and 3 million were returned, for a net distribution of 74 million doses. This was the largest distribution ever, an increase of >11 million doses over the 1998-1999 season. About half of those were administered to those with high risk conditions and to health care workers, and the balance was to healthy people aged <65. Therefore, the 74 million doses is being used as the baseline of adequacy for this year. But, Dr. Orenstein noted, the baseline has not always been stable; there has been substantial variation between years.

Influenza vaccine is normally administered between October and mid-November, but it is also beneficial if received later in the year. In the last 18 influenza seasons, peak influenza activity has been in January through March. Assuming a two week interval to establish vaccine immunity, even a December vaccination has impact. If the influenza activity peaks in February and March, as it has in ten of the past 18 years, vaccination even in January could be beneficial.

Manufacturers' Vaccine Production to Date and Future Projections:

Aventis Pasteur

Mr. Len Lavinda, Director of Public Relations for Aventis Pasteur, provided an update on their distribution. Their influenza vaccine shipments began a month later than normal (September) and will continue another month later than normal (through the end of November). The extension, and overtime work for Aventis Pasteur staff since May, was spurred by the low yield for this year's vaccine. In addition, in response to CDC's request, they will extend the production of the influenza vaccine Fluzone through November in order to produce another 9 million doses. Manufacture of other vaccines originally planned for production will be delayed, but not threaten their supply. Aventis Pasteur is working with CDC to develop procedures to ensure that the distribution of the additional doses matches the nation's health needs. They expect in the near future to issue specific instruction on ordering those added doses.

Wyeth-Lederle Vaccine

Ms. Elizabeth McKee Anderson, of Wyeth-Lederle Vaccine, predicted their release of 24 million doses of influenza vaccine over October (3 million doses), November (12 million), and December (9 million). The scheduled depends on the release of each individual lot, its inspection, and successful completion of quality assurance/control. They have sent two letters and telephoned their (Flushield) vaccine customers, advising of the anticipated delays compared to prior years, and emphasizing the July 14th ACIP recommendations.

Henry Shine Company

Mr. John Trizzino, Vice President of the Henry Shine Company, which distributes the Medeva vaccine, reported that they had not been scheduled to participate in this teleconference. Therefore, they had no comments, but offered to answer questions as they were able.

Discussion

Dr. Orenstein asked the total number of doses expected to be distributed by Aventistus and Medeva. Mr. Lavinda reported 35 million, including the additional doses from CDC contract. Mr. Trizzino was unable to respond for Medeva.

FDA Report

Dr. Catherine Zoon, Director, Center for Biologics Evaluation and Research (CBER),FDA, provided the FDA's best estimate of the total available dose numbers, based on data gathered from the manufacturers on the previous day (or, for one manufacturer, last August). With the currently scheduled 66.3 million doses, and the additional 9 million potentially available with CDC's additional purchase, FDA expects the availability of 75.3 million doses. Of these, 27 million are expected by end of October; another 30.3 million by the end of November; and 9 million (or 18 million, with CDC's contracted doses) by the end of December. She thought these release estimates to be probable, but the individual lot approvals depend on their achievement of the manufacturers' quality control and specifications, as well as CBER's review and approval.

ACIP Influenza Workgroup Report

Dr. Bonnie Word, Chair of the ACIP Influenza Workgroup, reported NIP's receipt on August 30th of additional information suggesting there may be a delay in production and a shortfall of vaccine. The extent of the shortage and potential contingency plans were addressed by the ACIP Influenza Workgroup and NVAC's Pandemic Influenza Workgroup. Two conference calls (September 11 and 18) were held to develop alternative recommendations for ACIP review for vaccine administration. Extensive interactions with others also occurred.[1]

The question addressed by the workgroup included: 1) Define "shortage:" CDC suggested anything <65 million doses; should contingency recommendations be based on a severe shortage or just a delay?; 2) should a prioritization list be developed for those previously recommended for vaccination; and if so, who?' 3) should the prior recommendation to vaccinate otherwise healthy adults aged 50-60 be postponed or suspended?; is it feasible to control vaccine distribution? (The quick answer was "no."); 4) how directive should recommendations to providers be ("should" or "could")?; 5) what are the roles of state health departments?; 6) are the recommendations regarding vaccine campaigns realistic?; 7) and, once all that was decided, how could the use of influenza vaccine be enhanced after its later delivery?; 8) once the recommendations were finalized, how fast could they be disseminated to practitioners and state health departments?; 9) what best method should be used to advise practitioners and patients about vaccine availability? (i.e., without raising safety concerns, to diminish vaccine utilization and cause a post-season surplus; or causing increased vaccine demand by those not at high risk but buying to avoid shortage). Also discussed was vaccine use (Fluvirion) among pediatric patients.

With NIP staff help, the Workgroup developed two scenarios, for a delay and a shortage of vaccine. With the most recent vaccine availability information, they proposed using a model of delayed availability rather than shortage.

Proposed Influenza Vaccine Usage Model

Dr. Melinda Wharton outlined the proposed model and recommendations for the ACIP members, as outlined in the document which they had already received.

1. As vaccine first becomes available, vaccine efforts should be focused first on persons at high risk of complications associated with influenza disease and on health care workers. These efforts should continue into December and later, as long as influenza vaccine is available.
2. Mass vaccination campaigns should be scheduled later in the season as availability of vaccine is assured. Given projected vaccine distribution, the campaigns in most areas will be scheduled in November or later. Efforts should be made to increase participation

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[1] (e.g., CDC Influenza Branch, NIP, NIH, CSTE, FDA, NACCHO, IDSA, AAP, AAFP, ACOG, ACP, AHA, and the Departments of Defense and Veterans Administration).

by high-risk persons and their household contacts, but other persons need not be turned away.

3. Special efforts should be undertaken in December and later to vaccinate persons 50-64 years of age who are not at high risk and are not household contacts of high risk persons.
4. Immunization efforts for all groups (i.e., high risk persons, health care workers, household contacts of high-risk persons, other persons 50-64 years of age, and other people who wish to decrease their risk of influenza) should continue into December and later as long as vaccine is available.
5. Fluviron, from Medeva Pharma Ltd., is licensed for use in children 4 years of age and older. Efficacy has not been demonstrated among younger children. Another influenza vaccine licensed for use among children 6 months of age and older should be used in this age group.

Committee discussion was also requested about a further recommendation for the use of pneumococcal polysaccharide vaccine to reduce the risk of complications among many of the same high-risk persons for whom influenza vaccine is recommended. Assuring pneumococcal vaccination of these high-risk persons early in the influenza season, in accordance with ACIP recommendations, could confer substantial protection from the major complications of influenza such as pneumococcal pneumonia.

Dr. Wharton summarized that the recommendation:

- Focuses initial work to those at high-risk, and health care workers;
- With more vaccine available (November), conduct mass vaccination campaigns including the general public, but focusing on increasing participation by those at high risk and their household contacts.
- Non-implementation of the new recommendation on vaccination of otherwise healthy persons 50-64 years of age until December was proposed.
- Immunization of all age groups should continue to December or later as long as vaccine is available.

Also in the recommendation text was specific guidance for providers and health care organizations on possible steps to increase vaccine uptake by high-risk persons, and the role of state and local health departments. However, there was insufficient time in this conference call to discuss that language.

Discussion/Recommendations. Dr. Modlin requested discussion of the first four proposed recommendations relating to the possible delay. Several members expressed agreement and found it to be well written. Other suggestions included:

- Insert explicit language to clearly state that no shortage is expected, using the distribution data from previous seasons as support; and clarify #4 to avoid possible confusion among providers who may end up with duplicate orders and excess inventory of vaccine. (Dr. David Johnson)

- Perhaps through the CDC Website, try to direct the many physicians holding Medeva vaccine inventory to exchange it. (Dr. Reynolds)
- The exploration of possible vaccine stockpiling (e.g., in Mexico) and redistribution was suggested (Dr. Guerra). However, while re-importation legislation is being discussed, it only addresses large quantities; personal importation cannot be addressed.
- Recommend pneumococcal vaccination, without specifying polysaccharide, to be inclusive of conjugates as well. The pneumococcal polysaccharide vaccine statement will be published on the same day as this recommendation (October 6), so the statements could be cross-referenced. There was general committee agreement that the benefits of including the statement outweigh any possible conflicts, due to the two diseases' links.
- Nonetheless, it was acknowledged that confusion could result, since the pneumococcal vaccine prevents pneumonia. A clear statement was suggested that the pneumococcal vaccine "is not a substitution for influenza vaccine, which still should be administered when it becomes available."

Public Comment/Discussion

Mr. Steve Mitchell, of Reuter's Health, asked if the pneumococcal vaccine was intended for children or everyone. Dr. Modlin emphasized that this discussion was on influenza vaccine. But because many patients for whom influenza vaccine is recommended due to high risk of complications are also at increased risk from pneumococcal disease, that reminder is being added.

Mr. Rick Weiss, of the Washington Post, asked if the product that physicians should exchange was Parkedale's Fluogen, and if CDC's additional 9 million dose purchase was previously announced, or new on this day. Dr. Modlin clarified that the Medeva vaccine, not licensed for children aged <4, should be exchanged for vaccine licensed for children that age. He declined to answer the second question, since this was an NIP issue, and not pertinent to this ACIP meeting.

Dr. Snider announced that CDC's Press Office would remain open to 6:30 p.m. to answer questions and provide copies of the draft recommendations as written. Since this was a committee meeting to produce a policy recommendation, he asked that media questions be deferred if possible. Several reporters deferred their questions.[2]

Mr. William Atkinson, of the NIP, reported organizations' inquiries to the NIP as to whether they should prioritize vaccinating their health care workers or out-patient high-risk individuals (e.g., as in VA medical centers). Since the draft had grouped those, he requested the document's guidance for such prioritization.

Dr. Word reported the workgroup's preference to prioritize the health care worker, who has the most contacts to expose to the illness. However, Dr. Fukuda advised the organizations to try to

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[2] Steven Sternberg, USA Today; Gary Evans, Hospital Infection Control; Lisa Levine: Orange County Register.

get as much vaccine as possible and to make plans to vaccinate both. Since the goal is to protect high-risk populations, in the case of an absolute need to choose, he would lean toward vaccinating high-risk people first, then health care workers.

Dr. Modlin expressed some discomfort about inserting that level of detail in this statement, but leaned toward vaccinating the high-risk individual. Dr. Zoon agreed, and thought it important to provide guidance in this area. But Dr. John Abramson pointed out the complexity of issues involved. He cited the vulnerable population of bone marrow transplant patients, and expressed the opinion that they would be better served by vaccinating the health care workers. He thought that this might have to be approached on a case-by-case basis.

Dr. Modlin suggested adding text that, in certain individual situations during an immediate shortage, organizations may require flexibility in prioritizing between high-risk individuals and health care workers. He expected that this may cause some confusion, since the ACIP has emphasized the immunization of health care workers to avoid transmission. Dr. Nichol agreed, noting literature citing the immunization of health care workers in long-term care facilities as much more predictive of reducing mortality.

The difficulty of deciding prioritization to protect high-risk patients was generally acknowledged by the committee members. Dr. Guerra suggested that guidance be offered at the local level (e.g., target health care workers in oncology or pulmonolgy settings early, as opposed those in a general pediatric office).

Dr. Fukuda again emphasized that only a delay, not a shortage, is expected. In view of that, he suggested continuing the past ACIP general guidelines' trend of prioritizing first the protection of the high-risk patient. Dr. Wharton summarized that the statement would reflect that and add the reminder that sufficient vaccine should be available later in the season to vaccinate all those at high risk and health care workers.

Mr. Landis Crockett, of the Florida Department of Health and Disease Control, asked if or how King Pharmaceuticals' (the Parkedale proprietor) discontinuation of Fluogen production would affect the situation. Dr. Zoon did not expect this to affect the FDA's projections at all.

Ms. Margie Green, of the Wisconsin State Immunization Program, asked if the ACIP still recommended that the states develop clearing houses for vaccine distribution. Dr. Wharton expected this to be less of an issue than if a major shortage was expected. But since it will be some time before an adequate supply is issued, all state and local health department help in aiding distribution will be very useful. Dr. Orenstein added that the October 6th *MMWR* will address the state and local health department role.

Ms. Kerry Ann Murray, of the Pennsylvania Department of Health, asked if household contacts of the high-risk individuals are included in the initial vaccination group, or if they should wait to the mass campaign. She also asked if the recommendation would address antiviral prophylaxis

(e.g., among those in long-term care facilities who have not yet received vaccine). Dr. Wharton identified those at high risk and the contacts with most potential to spread to most people – health care workers – as those in the first vaccination. Household contacts, though a large group, were felt to pose less of a risk, and able to wait until more vaccine is available.

Dr. Fukuda reported some discussion of antiviral usage in the July 14th updated recommendations. Although they state no new recommendations for antiviral use, some circumstances could suggest their use for prophylaxis (e.g., in a nursing home with influenza activity before vaccine is available). Such a population offers a sufficiently circumscribed population of high-risk people, as do bone marrow recipients.

Ms. Laura Wood, of the Alaska Department of Social Services, asked if the statement could explicitly advise whether the FDA restrictions against specific manufacturers were lifted (including Wyeth), and whether their projections no longer considered that an issue. Dr. Zoon reiterated that FDA numbers reflected the manufacturers' expected distribution of safe and effective vaccines to the public, and offered to discuss this further at another time.

Ms. Susanne Whiting, of the Ohio Department of Mental Health, purchases influenza vaccine and other pharmaceuticals for 70 state facilities. Her vendor had given her a 10% cut, and put her on a waiting list, but was not optimistic she would get more. She was confused by these mixed signals, having just notified the 70 institutions that they would be cut as well. At this point, Ms. Whiting was disconnected by the operator, who apologized but could not reconnect her.

Dr. Modlin regretted that, as her question went to the heart of the discussion. He wished to reassure her that the production of the amount of vaccine used in past years, coupled with more efficient vaccine use this year, would constitute only a delay, not a shortage. Dr. Orenstein reiterated that, while this year's overall number of vaccine doses will be comparable to those available last year, inferring no national problem, demand is fluid. Past years have also had problems in individual procurement as well.

Dr. Modlin closed the discussion to take a vote. He summarized the changes, none substantial, offered to the influenza statement: 1) to drop "polysaccharide" as a modifier to "pneumococcal", or to include "conjugate vaccines" as an added advisory; 2) to add language to the statement that certain situations may require some prioritization among health care workers' and high-risk individuals' vaccinations; and 3) to provide suggestions as to what to do operationally if vaccine runs out. Dr. Wharton added 4) emphasis that pneumococcal vaccine is not a substitute for influenza vaccine, and 5) that prioritization should be a short-term need since vaccine will become available over time.

Committee Vote

Dr. Johnson called the question, moving to accept as ACIP policy, the statement sent to the committee with the modifications as just discussed. The eligible voting members were Drs. Modlin, Brooks, Helms, Johnson, Offit, and Word, all of whom voted for approval. Those abstaining were Drs. Clover, Guerra, and Reynolds. The **motion passed.**

Dr. Modlin expressed his particular thanks to staff members Ms. Gloria Kovach and LaTarsha Hall for executing the difficult task of arranging this teleconference, and Dr. Word for taking over and leading the Influenza Workgroup to craft this statement on short notice. Dr. Snider thanked the committee members and members of the public for their involvement and help. He requested their continuing help as CDC tries to get the word out and take appropriate action in the upcoming influenza season.

With no further comment, Dr. Modlin adjourned the teleconference at 4:50 p.m.

I hereby certify that, to the best of my knowledge, the foregoing Minutes are accurate and complete.

John F. Modlin, M.D., Chair

1 Nov 00

Date