Influenza Vaccine: Delays and Shortages and How to Address Them

Co-Sponsored by the AMA and the CDC

March 27, 2001

(Summary prepared for AIM members)

David Lynch, NY, and Diane Peterson, MN, represented AIM at the meeting. What follows is their summary of the meeting, which is also enhanced by notes from a subsequent ASTHO-sponsored conference call held on March 28, 2001.

- Those present included representatives from national and state medical associations, the AAP, AAFP, the vaccine manufacturers and distributors, vaccination contractors, pharmacy groups, HCFA, FDA, CDC-NIP, NACHO, and AIM.

- Four major issues were discussed:
  - Need to enhance the flu vaccine supply.
  - Need better systems to prioritize high-risk patients.
  - Cost of vaccine.
  - Need for a timeline and more rapid communication

- Enhanced Supply:
  - The manufacturers stated that they could produce more vaccine if the vaccination season were extended through the end of November with promotion of vaccination of healthy persons in December. (Note: the 2001-02 ACIP recommendation will state that the optimum time for organized campaigns lasts until the end of November.)
  - We need to do a better job of communicating with the public and with providers that "It's never too late to vaccinate." Influenza peaked in late January to the beginning of February during this past flu season, yet very few people wanted vaccine once it became available in December.
  - The NIH is continuing their studies of ½ doses in healthy persons. This study however might not have any impact on flu vaccine availability for 2001-2002.
  - The manufacturers agreed to reveal "red flags" when they experience an indication of a possible problem at any of the various "milestones" in the production process. They would inform either CDC or the FDA (although this information would likely still be proprietary.)

- Prioritization of High Risk:
  - Manufacturers, distributors, government, and providers need to more efficiently identify high-risk patients and target vaccine accordingly. One suggestion was to identify high-risk patients through their pharmaceutical records for other drugs.
  - If prioritization is left to ordering facility, there is a great potential for errors (intentional and unintentional).
  - With so many non-traditional providers holding public flu clinics, it's difficult to categorize where high-risk are being served.

- Our communication efforts with providers must be improved. The messages must penetrate and be understood beyond upper management, e.g., medical organizations, reaching the provider and consumer levels.

- Cost of Vaccine:
  - The cost of the vaccine is a significant issue and everyone should be prepared for price increases this year.
  - Concern was expressed over current Medicare reimbursement for vaccine and its administration. It is now formula-based on the average wholesale price as published in the other "Red Book" (95% of new AWP of cheapest vaccine). Will this be sufficient to cover the increased cost of vaccine? (States should contact their carriers to determine the reimbursement for the state.)

- Timeline and Communications
  - The fact that public health and other providers weren't given all the facts on problems with the manufacturers last year until very late in the summer was identified as a serious problem
  - Dr. Orenstein specifically asked the FDA and the manufacturers to come back to the group with a timeline for 2001
  - The timeline would identify critical points in the manufacturing and approval process that could become stumbling blocks
  - Those involved would let the CDC and know immediately when problems arose, thereby maximizing everyone's ability to respond appropriately

- The outlook for the 2001-02 flu vaccination season:
  - Strain selection:
    - There was only 1 change in the strain selection for the coming season (unlike the 00-01 season when 2 of the virus strains changed).
    - The 3rd strain was selected on March 9th, one month earlier than 00-01.
    - It appears to be growing well.
  - The manufacturers:
    - Wyeth is committed to produce 24 million doses. However, they are operating under a consent decree from the FDA and the impact of this action is not yet known.
    - Evans is committed to selling 11 million doses in the U.S. market; they could possibly increase that to 15 million.
    - Aventis is committed to producing 38 million doses; however, they are purchasing additional incubators and other equipment to potentially increase their production by another 17 million doses (dependent on FDA's approval and market demand).

  - The possible scenarios for flu vaccine supplies:

    Best case:
    - API: 38 (+ 17) = 55 million doses
    - Wyeth: 24 million

- Evans: 15 million
- Total 94 million doses

Worst Case:

- API: 38 million (if FDA doesn't approve new equipment)
- Wyeth: 0 (if Wyeth fails to get FDA approval)
- Evans: 11 million (if Evans can't get approval to ship the additional 4 million doses to the U.S.)
- Total 49 million doses

- Options for planning for another delay and possible shortage:
  - Potential legislation that would empower the Federal government to take over entire supply. Questions remain, however, as to how to deal with this? Public sector purchase of flu vaccine is too small to affect overall distribution in times of shortage.
  - Where to find funding? States cannot "re-sell" vaccine to the private sector.
  - Concern that any strategies to deal with immediate crisis may be counter-productive to long term goals (e.g., increasing rates of high-risk persons to reach 2010 goal of 90%, expanding routine immunization among persons 50-64 years of age and also healthy children under 5 years, etc.)
  - The best option may be a voluntary collaborative approach.

 So, what is the outlook? There are still many questions to be answered but, at least we have an opportunity to know about the issues in March, rather than just hearing of them in mid-summer.

Dr. Orenstein gave everyone an assignment – What can your agency (i.e., AIM) do if there is another flu vaccine delay or shortage? All states should develop and be prepared to implement contingency plans based on potential delays or shortages in influenza vaccine.

Other tidbits:

API will be shipping 25-50% of each order beginning in September (smaller orders of <1,000 doses may get 100%). The remainder will be shipped in October and November.

Wyeth has also expressed an intent to do staged shipping for vaccine purchased under the Minnesota-Multistate Purchasing Alliance.

Wyeth's FluMist may not be ready for the 01-02 season. When it is licensed, it will initially target children >1 year.