

Immunization Advisory Committee
Michael A. Bilandic Building Room N505
160 N. LaSalle Street, Chicago, Illinois
July 22, 2009
Summary of Minutes

Members Present:

M.D.Shafiqul Azam
Rashmi Chugh, M.D
Robert Daum, M.D
Nancy Khardori, M.D
Stephen Laker, M.S
Julie Morita, M.D
Susanna Roberts, R.N, M.S.N

Rita Rossi-Foulkes, M.D, F.A.A.P
Penny Roth, M.S., R.D., L.D.N
Margaret Page Saunders, M.S.
Lorraine Schoenstadt, M.S., R.N
Tina Q. Tan, M.D
Dennis Vickers, M.D., M.P.H
Kathy Swafford, M.D
Ellen Wolff, R.N.M.P.H

Others in Attendance:

Jeannin Alamed, Sanofi Pasteur
Jan Daniels, IDPH
Lynnae Godsell, Sanofi Pasteur
Paula Jimenez, Sanofi Pasteur
Michael Kimak, Wyeth
Lisa Kritz, Chicago Area Immunization Campaign
Janet Larson, IDPH
Andrew Maniotis, UIC

Rita Sand Maniotis, IVAC
Karen McMahon, IDPH
Leslie McMillian, Merck
Barbara A Mullarkey, IVA
Madhu Nappi, IDPH
Dave Nardone, Merck
Ketul Patel, GSK
Josefina P. Procharkova, Student
Doug Rock

1. Welcome and introductions

Dr. Khardori called the meeting to order and asked for introductions of the committee.

2. Old Business and approval of Minutes

Dr. Khardori called for a motion for approval of the minutes. There was a motion and a second to approve the minutes.

3. New Business

Legislative Rule Update: Karen McMahon indicated that packets included sample language from other states pertaining to Tdap rules and regulations. Explanation was provided that we have discussed changing the existing rules since Tdap is the vaccine that most providers utilize for school students. Moving the requirement to 11 and 12 year old students provides consistency with current physical exam requirements and is also consistent with the ACIP recommendations on Tdap. Dr. Morita inquired if Tdap was covered under the Vaccines for Children Program and Karen indicated that it was covered under the Plus portion. Dr. Morita inquired about the process to change rules or regulations. Karen indicated that once language is approved, it is then proposed to the State Board of Health (SBoH) which meets four or five times a year. The SBoH determines if the proposal should be acted upon and make a recommendation to the Director to do so. If the recommendation is to move forward with rule making, the SBoH is required to convene a series of three public hearings. Following the hearings, SBoH meet to review the findings and make the recommendation to the

Director to move forward. At this time, the rule making process begins. Final rulemaking concludes with the Joint Committee on Administrative Rules (JCAR)

Dr. Morita asked if we had any pending legislation and Karen indicated that we did not. She indicated that a committee member or small group may launch a forum to do some draft language for the October meeting.

ACIP Update: Dr. Julie Morita (Please see attached power point presentation)

H1N1 Update: Karen McMahon: Karen indicated that the packets included the H1N1 updated key points. Through our electronic disease surveillance system we captured all cases that were reported. The numbers that we are reporting are strictly those that had laboratory confirmation. Early on we had to report to CDC daily and we communicated with them on everything that was coming through INEDSS (Illinois National Electronic Disease Surveillance System). Karen stated that she would like to open this up to discussion on how to get the H1N1 vaccine out to public and private providers. CDC planned to have centralized distribution such as the system currently used for the VFC Program. We would be hoping to engage hospitals and OB/Gyn providers throughout the state in this process. Dr. Tan suggested engaging local chapters such as the American College of Obstetrician and Gynecologist (ACOG) and Illinois Chapter American Academy of Pediatrics (ICAAP) on ways to get the vaccine to their patients. Steve Laker explained how the system worked in 1976 with swine flu and how they used six large dairies to store the since they had the capacity. Karen indicated that IDPH has continued to maintain the former vaccine warehouse that was used prior to centralized distribution. We would be able to utilize the warehouse for a designated provider site for a centralized depot.

Steve Laker made a motion to state health department's immunization program be the manager for the receipt and distribution of the H1N1 vaccine. Dr. Chugh moved that IDPH Immunization program provide a weekly update in conjunction with CDC guidance as issued to local health departments to private providers, schools, on specific guidance during H1N1. Rita Rossi-Foulkes seconded the motion.

Hepatitis B in newborns (Daum): Dr. Daum indicated that they had a conference call with Dr. Vickers, Salaeha Shariff (ICAAP) and a representative of the Chicago Area Immunization Campaign. It was the consensus of the committee not to get parallel legislation such as the HIV law but to try an education program or an education intervention. Dr. Daum explained that Chicago Department of Health has such a program in place that provides education and follow up to birthing units with the aim of increasing Hepatitis B. Karen McMahon indicated that IDPH was taking on the same model as Chicago has done with their hospitals. ICAAP had conducted a Hepatitis Birth dose survey in 2007 but IDPH felt that they should conduct one in 2009 to obtain updated information from the hospitals. Dr. Daum indicated that the unit of intervention is the birthing unit policy in the hospital. Dr. Daum indicted that identifying the team within each hospital of the right people to assemble for the visit is crucial and takes time. Dr. Morita indicated that it was easier to do the visits in Chicago because they are geographically confined. Karen McMahon indicated the next step is to ensure that IDPH can get in the hospital and start the process so that we have some baseline data available. Dr. Daum indicated that wanted to emphasize not the coverage level but the buy in from the hospital that this is their policy.

4. Open meeting speaker Barbara Mullarkey, President, Illinois Vaccine Awareness. Coalition presented the following questions:

- What is the history of the swine flu vaccine?
- Why was the 1976 swine flu vaccine killed?
- How can the Mercury-Free Vaccine Act passed in 2005 and signed by the governor become effective when the IDPH director keeps signing declaration of exemptions?
- How has the IDPH worked to implement the 2005 Mercury-Free Vaccine Act?
- How has the IDPH advised the legislators on the purchase of mercury-free vaccines instead of 13 mercury-based vaccines ranging from vaccines for flu, tetanus, to meningitis?
- How many other laws by name and date have the IDPH circumvented by a declaration of exemption?
- How has the IDPH/IAC alerted Illinois parents that mercury still exists in vaccines for their children?
- When will meeting minutes of the IAC appear on the web site?
- Could you have open comment at the beginning of each meeting instead of at the end?

Speaker Rita Sand Maniotis presented a picture of a child who had the Hepatitis B vaccine and within hours he was covered with a rash. She stated that her child also experienced this after having received the Hepatitis B vaccine. Rita indicated that the PTA passed in 2004 a resolution to rescind the mandate for Hepatitis B. She stated to recommend not mandate the Hepatitis B vaccine. Rita handed out information on Hepatitis B and gave to IAC members.

Speaker Andrew Maniotis from UIC had a couple of question for the IAC.

- Is this committee going to take the adjuvanted vaccine or are they going to recommend a non-adjuvanted vaccine?
- There has been evidence for many years now since 1992 that Hep B vaccine caused false positive Hib test results and wanted to know if IAC was aware of it?

3. Future topics: Steve Laker indicated that we will still be talking about H1N1 vaccine.

4. Adjourn: Dr. Daum made a motion to adjourn the meeting and Margaret Saunders seconded the motion.

ACIP Update June 24-26, 2009

Recommendation Changes

- Rabies vaccine
- Inactivated Polio vaccine
- Measles, Mumps, Rubella (MMR) and MMR-Varicella (MMRV) vaccines
- Meningococcal Conjugate vaccine
- Japanese Encephalitis vaccine
- *Haemophilus influenzae* type B vaccine
- Human Papillomavirus vaccine

Rabies Vaccine

- Supply update
 - sanofi- pasteur
 - Post-exposure prophylaxis only
 - Password required
 - Novartis
 - Pre-exposure and post-exposure prophylaxis
 - Password not required
- Post exposure prophylaxis recommendation
 - 5 dose series decreased to 4 dose series

Inactivated Polio Vaccine (IPV)

- **No change in recommended timing of doses**
 - If 4 doses administered before 4 years of age, additional dose required at 4-6 years of age
- **Intervals for Polio-containing vaccines**
 - Minimum interval from dose 3 to dose 4 is extended from 4 weeks to 6 months
 - Minimum interval from dose 1 to dose 2 and dose 2 to dose 3 remains 4 weeks.
 - Minimum age for dose 1 remains 6 weeks of age

Evidence of Immunity: MMR for Healthcare Personnel

- Documentation of appropriate vaccination against measles, mumps, and rubella
 - Administration on or after the first birthday of two doses of live measles and mumps vaccine separated by ≥ 28 days and one dose of live rubella vaccine
- Laboratory evidence of immunity or laboratory confirmation of disease
 - Eliminated MD diagnosed disease
- Born before 1957

Footnote for ROUTINE circumstances

- For unvaccinated personnel born before 1957 who lack laboratory evidence of measles, mumps and/or rubella immunity or laboratory confirmation of disease, healthcare facilities should consider recommending two doses of MMR vaccine (for measles and mumps) and one dose of MMR vaccine (for rubella)

Footnote for OUTBREAKS

- For unvaccinated personnel born before 1957 who lack laboratory evidence of measles, mumps and/or rubella immunity or laboratory confirmation of disease, healthcare facilities should recommend two doses of MMR vaccine during an outbreak of measles or mumps and one dose during an outbreak of rubella

MMRV

- Increased risk for febrile seizures 7- 10 days after dose 1 at 12-15 months of age
 - Increased risk not seen after dose 2 at 4-6 years
- For the first dose of measles, mumps, rubella, and varicella vaccines at ages 12 to 15 months either MMRV vaccine or separate MMR and varicella vaccines can be used
 - Benefits and risks of both vaccination options should be discussed with the parents or caregivers

Human Papillomavirus Vaccines

- Bivalent vaccine (types 16/18)
 - Submitted to FDA in March, 2009
 - ACIP recommendations: possibly October, 2009
- Quadrivalent vaccine (types 6/11/16/18) for males
 - Submitted to FDA in December, 2008
 - ACIP recommendations: possibly October, 2009

Meningococcal Conjugate Vaccine

- Persons aged 7-55 yrs who remain at increased risk for meningococcal disease 5 yrs after vaccination with MCV4 or MPSV4 should be revaccinated with MCV4
 - Persistent complement component deficiencies*
 - Anatomic or functional asplenia
 - Microbiologists who are routinely exposed to isolates of *N. meningitidis*
 - Frequent travelers to or people living in areas with high rates of meningococcal disease

* e.g., inherited or chronic deficiencies such as C3, properdin, factor D, or late complement components

Meningococcal Conjugate Vaccine

- College freshmen living in dorms who were previously vaccinated against meningococcal disease at age 11-18 yrs are not recommended to be revaccinated with MCV4
- Children who received their first MCV4 or MPSV4 at age 2-6 yrs and remain at increased risk for meningococcal disease should be revaccinated with MCV4 3 yrs after their first meningococcal vaccine

Hib Vaccine Supply

- sanofi pasteur:
 - Increased supply available beginning July 2009
 - Reinstate 4th dose and begin catch-up
- GSK has applied for licensure of their monovalent Hib vaccine (Hiberix®)
 - Booster dose

Hib Vaccine Supply

- Merck is working with FDA toward the following goals:
 - Limited supply of PedvaxHIB available in late 2009
 - Full availability of PedvaxHIB® expected in early 2010
- The return of Comvax® dependent upon supply situation for both Hib and hepatitis B vaccine components

Hib Vaccine Recommendations

- **Hib-containing vaccines currently available include monovalent Hib (ActHib) and DTaP-IPV/Hib (Pentacel)**
 - Increased number of doses starting July 1, 2009
- **Hib supply sufficient to:**
 - Reinstated on time booster dose of Hib vaccine at 12-15 months for all children who completed primary 3 dose series
- – Limited catch catch-up

Hib Vaccine Recommendations

- **Limited catch-up**
 - Older children whose booster dose deferred should receive dose at next routinely scheduled visit or medical encounter
- **Supply constraints do not permit mass recall of all children whose booster deferred**
 - Active notification process to contact all children with deferred booster doses not recommended

Novel Influenza A Vaccine

- ◎ Vaccine production
 - Seed strains provided to manufacturers (5)
 - Clinical trials due to begin in late July
 - Efficacy
 - Safety
 - Results anticipated in late August
- ◎ Decision to vaccinate
 - Novel influenza activity in US
 - Novel influenza activity in southern hemisphere

What is known?

- ◎ Two different vaccines
 - Pandemic
 - Seasonal
- ◎ Pandemic vaccine production
 - 600 million doses expected
 - 2 doses per person (< 50 years of age)
- ◎ Season vaccine production projections
 - 120 million doses expected
 - Mid-August ~15 million doses
 - September 1 ~40 million doses
 - November 1 ~108 million doses

What is not known?

- Pandemic vaccine
 - How much vaccine will be available?
 - When will vaccine be available?
 - Who will receive vaccine first?
 - How will disease activity correlate with vaccine availability?
 - Healthcare resources
 - Demand for vaccine

Scenario-Based Plans

⦿ Amount of vaccine

- 40 to 160 million doses available mid-fall
- Disease peaks before, during or after vaccine available
- Demand high, demand low

⦿ Routes for distribution/administration

- Public sector provision (CDPH)
 - Mass vaccination
- Private sector provision of vaccine
 - Hospitals, clinics, retail pharmacies

Private Sector Planning

- Hospitals/LTCFs
 - Administer vaccine to employees and patients
- Private and public clinics
 - Administer vaccine to employees and patients
- Retail pharmacies
 - Administer vaccine to the public

Stay Tuned for More Information