WASHINGTON VACCINE ASSOCIATION

Vaccine Committee Meeting Minutes

May 17, 2013, 12:00 - 1:30 PM Location: Ellis Li McKinstry

I. **Attendance** The following individuals participated in the meeting.

Committee:
Janna Bardi
Jeffrey Gombosky (T)
Jan Hicks-Thomson
Dr. Ed Marcuse
Fred Potter (T)
Norm Seabrooks

Consultants & Others:
Margaret Lane, WVA
Dr. John Dunn, consultant
Chad Murphy (T), consultant
Dr. Rachel Wood, consultant

Absent:
Laura McMillan

II. Minutes

At 12:00 PM, a quorum having been established, Dr. Ed Marcuse, Chairman of the Vaccine Committee, opened the meeting.

Welcome, Introductions and Changes in Committee Membership

Dr. Marcuse welcomed committee members and recognized new committee consultant Dr. Rachel Wood, who will add the important perspective of local health officers.

Ed reported that Laura McMillan had resigned from the Vaccine Committee due to taking on the Audit Committee chairmanship. Laura could not be replaced on the committee by Dr. John Dunn from Group Health because the statute creating the WVA and setting out Vaccine Committee membership requires that the carrier positions on the Vaccine Committee be held by voting WVA board members. A solution was approved so that John could participate on Laura's behalf but Laura will remain on the committee and if there is a critical vote Laura would need to participate. (*Note: Subsequent to this meeting Laura informed WVA Board Chair Brian Ancell, WVA Executive Director Fred Potter, and Vaccine Committee Chair Ed Marcuse that she was retiring from Group Health. A process is underway to appoint a Group Health representative to the WVA Board.)*

Second, Dr. Mary Kay O'Neill has served as Vice Chair of the Vaccine Committee but recently left Cigna. However, it is likely that Dr. O'Neill will continue in the industry in the local area and may be able to continue her relationship with WVA and possibly the Vaccine Committee. *(Note: Subsequent to this meeting Mary Kay informed Brian, Fred, and Ed that she was leaving Cigna. She subsequently joined Regence and has been appointed their representative to WVA and will continue to serve on the Vaccine Committee.)*

Update on Vaccine Selection

Jan Hicks-Thomson reported that DOH just completed the first cycle of its Vaccine Selection Process for 2013 at the end of April. This was the third cycle in the last 18 months for providers to decide if they wanted to continue or change their brand of vaccine for those that have multiple brands.

Twenty-six providers opted to change their formulary out of 1,160 providers. This was a less than 1% change in market share for any individual product. Jan noted that there are several reasons why the change rate is so low. First, practices try to limit the number of changes in order to make it easier for medical staff traveling from one location to another. Limiting the number of changes in brand also decreases the possibilities of medical error. Finally, Dr. Dunn noted that there were not new brands of vaccine this time and Jan agreed that new brands of vaccine have not been introduced in a long time.

Each cycle the DOH has seen fewer changes requested by providers who want to make a change for a brand. The first time it was about a 17% change, the second time 5%, and now it's less than 1%.

Jan added that the process occurs entirely within the DOH Immunization Information System (IIS). The DOH also conducts a provider satisfaction survey where they can ask broader questions about using the provider immunization ordering system. Providers have reported that they find the system easy to use and are happy with the twice a year frequency of the vaccine selection process.

Dr. Wood asked how the vaccine manufacturers felt about this frequency. Jan responded that at the beginning of the process the manufacturers wanted vaccine selection to occur more frequently, even monthly. The DOH explained that this created an administrative burden for them because they needed to balance the vaccine monthly spending plan to the vaccine brand across three fund sources, among other tasks. Jeff Gombosky responded that the vaccine manufacturers are comfortable with the current direction of the WVA and frequency of vaccine selection.

The next vaccine selection cycle will be in October, 2013. Jan reviewed the process for the committee: the choice window is opened for 15 days in the IIS, the DOH does proactive communications to provider professional organizations and sends a blast fax to all providers in the program with information about the process. The process is an "opt-in" so they select to make a change but are not required to go into the system.

Jan noted that a provider had inquired whether it could have multiple brands of the meningococcal vaccine. The DOH position has been to select one brand. Dr. Marcuse suggested that Jan ask the provider what was the rationale was for requesting multiple brands. Jan thinks that the Menactra meningococcal vaccine is licensed to 9 months and Menveo does not yet have that licensure but may be licensed to two years. Jan responded that if a provider has a specific need to have vaccine in the refrigerator for these high-risk infants 9 – 23 months of age, we could allow them to order individually rather than creating additional rounds of order sets. Dr. Dunn said that this practice is not standard, even a large pediatric practice would want the vaccine only for specific kids. Jan has received only this one call in 18 months so it is not a frequent issue.

Ed clarified for the committee that there are multiple serotypes of meningococcus; there is no licensed US vaccine for serotype B that affects kids under two years. We can't protect these kids against the serotype that is most likely to make them ill, so neither the ACIP nor AA P recommend routine use of currently licensed meningococcal conjugate vaccines in this age group. However if there is someone at very high risk we would.

Menhibrix – new Meningococcal Conjugate Vaccine Combination

Jan explained that Menhibrix is a combination Meningococcal CY– Hib b tetanus toxoid conjugate vaccine, it is not currently available nor is it on the CDC contract. This vaccine is for a limited number of high-risk infants, not as an option for Hib immunization of all infants. The DOH isn't sure when it will become available. Janna noted that the ACIP had added footnotes to their documentation about this vaccine, including recommendations in the national schedule as well as the VFC resolution, that providers need to use the vaccine only when they are trying to protect against all components of the vaccine. The lack of an ACIP recommendation for broader use dampens the market for the vaccine, so the manufacturers are less enthusiastic about promoting it. Dr. Marcuse noted that the judgment about what risk is worth vaccinating against is somewhat arbitrary.

Margaret noted that this vaccine is on the grid, even though it is not currently available. The Operations Committee discussed this vaccine and because the Operations Committee had good information about pricing and understands that CDC will put it on the contract agreed it should be listed on the grid.

Jan stated that the key to this vaccine is that its licensure is to two months and can be given as early as six weeks of age. This gives a physician the opportunity to make a decision for a child who is a younger age than any of the quadrivalent vaccines allow for. However it only covers two serotypes (C,Y), not all four (A,C,Y W). So when a child is 9 months of age you can use a quadrivalent that can protect against more serotypes. The state Vaccine Advisory Committee (VAC) discussed how the state would manage this so providers understand that this will be for a very limited number of kids. VAC will put together draft clinical guidance on this vaccine.

Influenza

Jan Hicks-Thomson referred to the Childhood Influenza Vaccine Update PowerPoint distributed to the Vaccine Committee that she had also distributed to the VAC. This year there may be more confusion about flu vaccines, there are some quadrivlaent flu vaccines available, one brand that is injectable, and all LAIV is quadrivalent. Ed explained for the committee that in recent years US influenza vaccines have had two type A's and one type B component , and the quadrivalent will have two type A's and two type B's, because half the world has one type B circulating and the other half has the other type B, and no one knows which will hit the U.S.

Each year the DOH does a pre-book with the CDC to determine which products will be made available in WA State. This year the CDC guidance was that 25% of flu vaccine would be available in quadrivalent . At its meeting in March, the VAC suggested booking more flu-mist, which would be 100% quadrivalent. DOH asked

for guidance about distribution, and which populations to target. The most common recommendation was to distribute vaccine to providers and then prioritize the high-risk patients who cannot tolerate flu mist vaccine. Flu mist is not for every child. Generally children who have asthma are not supposed to have flu mist.

Jan referred to the table on unordered flu vaccine. Last flu season was a mild season and there was quite a bit of unordered vaccine. The 2011-2012 season started out similarly then in January during one 2-week period the DOH shipped over 40,000 doses of flu vaccine. The next slide previews the vaccine ordered for the 2013-2014 season. DOH is booking flumist again, this has continued to see good growth. The .25ML is the only product licensed for 6 – 35 months of age which meets WA standards for thimerisol, it is preferred by providers.

More .25ML sanofi preservative free vaccine was ordered than available. DOH managed this by working with its network across the country to either swap vaccine or seek donations of unused product to our state. This was also the process used for the multi-dose vial vaccine. The FluMist vaccine came in at about what was ordered. Overall, DOH did very well and the percentage of unordered vaccine was the lowest it has been in several years. The returns process is not yet complete; all the vaccine expires at the end of June and DOH has paperwork for unused vaccines that are returned for excise tax, after which DOH will have an even better idea of what was really used.

Jan's presentation also shows what's being pre-booked for 2014. DOH is pre-booking more than what was distributed last year and they have increased the amount of quadrivalent LAIV by 40,000 doses. Jan thinks they could still have challenges because they were not able to prebook 100% quadrivalent. Roughly half the vaccine is quadrivalent. However, each manufacturer is in a different place with their licensure – sanofi still doesn't have a licensed quadrivalent; GSK is still the only manufacturer with a licensed quadrivalent injectable. Ed asked whether providers asked for quadrivalent when they pre-booked, and, is there a plan to communicate to providers on this topic

Jan responded that the provider flu survey is not a prebook, one of the caveats is that the survey doesn't represent the number of doses and type of vaccine they will receive because the response rate is not 100%. It is guidance for the DOH, it is information that allows the DOH to pre-book. At the time of the survey, quadrivalent was on the horizon and no one knew what the outcome would be. Even at the time of the pre-book, GSK was the only manufacturer and others were saying they would get licensure in June. DOH had to do the pre-book in March so there was no way to pre-book quadrivalent vaccine that was not licensed. CDC could allocate some portion of vaccine to grantee states to offset their trivalent but this isn't clear as of yet. This will be an ongoing communication challenge for the DOH, to tell providers what they ordered, and what they received. The strains that are circulating may be covered by the trivalent vaccine. Dr. Marcuse noted that most of vaccine is given prior to December and we don't really know where we are with flu viruses before January.

Jan noted that the VAC is convening a sub-committee to talk about clinical guidance, quadrivalent, LAIV, etc. Hopefully this will offer some support for providers, but it may still be a challenging.

Ed next addressed a JAMA article that he distributed, *Influenza Vaccines, Time for a Rethink*. The focus of the article is more on adults than children but he was struck by the following phrase: "but as current influenza

vaccine campaigns are based on information asymmetries--in which the public's understanding of potential vaccine benefit and potential harms is incompatible with the evidence—the public trust is risked by a continuation of the status quo." He doesn't see uptake of flu vaccine being impacted in the short-term by this kind of commentary but it has a potential to put a damper on advisory committee recommendations. Rachel inquired how old the author of the article is. There was another article suggesting that younger physicians view vaccine preventable diseases as less severe and are more conscious of the negative effects of vaccines.

Jeff noted he had not shared the article with manufacturers but the general thrust of the article is an ongoing concern for the industry and they are trying to find ways to proactively address the issues raised.

Vaccine Assessment Grid

Margaret reported that the Operations Committee has drafted a policy and procedure to ensure a repeatable process for the annual update to the Assessment Grid. Criteria are set out and identify what we do when exceptions come up and a mid-year assessment grid update is necessary or when a vaccine is taken off the grid. The policy and procedure discusses the roles of the Vaccine Committee, the Board, and the Operations Committee. The Operations Committee does the work of putting the grid together using the experience of the people on the committee. There is a goal to do this work annually. Dr. Marcuse asked where we are compared to the CDC prices. We were significantly below the CDC prices and even after raising the vaccine levels on April 1, 2013 we are about 20% below CDC levels. There was some discussion about how the WVA funding program benefits the public as well as providers and payers.

317 Funding Resource

Janna Bardi explained that Section 317 is a funding resource for immunizations, at a national level decisions are made about how much 317 funding comes to states for operations support. About half of DOH funding for office support is from 317, as opposed to entitlement dollars related to the VFC program. A portion of 317 dollars is carved out as direct assistance and is referred to as vaccines in lieu of cash. DOH can order vaccine against this account. A few years ago, this was as much as $5 million and today it's $2.6 million. DOH had instruction to use 317 for low-income children in state sponsored programs like Apple Health. VFC represents Medicaid, AK Native American Indians, kids who are uninsured for vaccines and kids who are underinsured and vaccinated in an Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC), this is about 65% of kids. The next largest category is WVA financing for privately insured kids, and the remaining percentage is through 317direct assistance, about 1%. At the federal level there's a desire for states to shift the use of this resource from children to adults. The VFC program covers a high percentage of children, and the assumption is that the Affordable Care Act will assure that children who are not VFC eligible have first dollar coverage for vaccines. The CDC doesn't see why 317 is needed. Theoretically, this is true but everything is not in place yet to make this happen. Also there is a question whether the Affordable Care Act requirements for first dollar coverage are the same as the requirements for public insurance first dollar coverage. Last year CDC made a national change for the use of federal 317 DA funds. For WA this meant 317 could not be used for kids in the State Child Health Insurance Program (S-CHIP). The state had to find the funds for these kids.

Now the President's budget reformulates 317 so it's focused on adults. It may be a different amount of money that is specific to the population of uninsured adults. This could result in a different amount for states and it could also require the funds to be used in a different way. There's no change yet and DOH hasn't been informed that there will be a change, so right now the funds are still used for Apple Health kids. Currently, the kids who are only covered by 317 are the undocumented kids in the Apple Health program. Medicaid doesn't allow coverage of undocumented kids nor does the ACA. DOH has a meeting in June with the Health Care Authority staff to discuss this issue. For Washington state this is 24,532 kids at an annual cost of $2,382,110. If the state doesn't find new funding the entire vaccine system that the state has created is vulnerable. The vulnerability would result because providers would have to order, store and use vaccine specifically for this group of children, thus effectively creating a two tier, rather than universal childhood vaccine system.

Related to the fragility of the system and importance of WVA funding continuing, Dr. Marcuse noted that he has received some concerns from practices about the costs of generating two bills to generate the DBA. Providers have reported that costs range from $2500 - $10,000 a year. Their point is that this removes an income stream for them.

Janna also reported that new Secretary John Wiesman has been effective at communicating to the department about himself and his priorities. He has been working hard with the HCA and DSHS to determine the role of public health. He has created think tanks in the DOH around four key areas to focus on and determine a strategy. Key areas of focus include The Affordable Care Act and health reform, assuring the agenda for change is implemented, the obesity epidemic, and climate change. The Secretary is using the first 90 days to listen, learning and assess. On June 7 the Secretary will have a special briefing with the DOH.

Closing Section

The Committee's second meeting for 2013 will be in the fall, in October or November. Ed suggested that the meeting be in November so it can follow the next cycle of Vaccine Selection.

There being no further business for the Committee, the meeting was adjourned at 1:25 PM.

WASHINGTON VACCINE ASSOCIATION

What:	WVA Vaccine Committee Meeting
Date and Time:	May 17, 2013, / 12:00 – 1:30 PM
Place of Meeting:	Law office of Ellis, Li & McKinstry, PLLC, Market Place Tower, PH-A, 2025 First Avenue, Seattle
Call in Numbers:	(local) 206.925.3583; (long distance/toll-free) 877.826.6967; Part code: 1981457183#

AGENDA for Vaccine Committee Meeting (in person attendance requested if possible)

Approximate Time		Topic/Anticipated Action	Presented by
12:00 – 12:05		1. Welcome a. Introductions b. Purpose of Meeting c. Committee membership	E. Marcuse
12:05 – 12:15		2. Vaccine Selection a. Update on April, 2013 Vaccine Selection b. Vaccine Selection cycle for 2013-2014	J. Hicks-Thomson
12:15 – 12:30	*	3. Influenza a. New types of vaccine for 2013-14 b. Flu pre-book c. Vaccine Advisory Committee Discussion	J. Hicks-Thomson
12:30 – 12:40		4. Updated Vaccine Assessment Grid a. Review Operations Committee policy and procedure b. New vaccines: MenHibrix – meningococcal hib vaccine combo c. Vaccine Advisory Committee Discussion	M. Lane J. Hicks-Thomson
12:40 – 12:55		5. Updates: a. Section 317 federal funding b. New Secretary	J. Bardi
12:55 – 1:10		6. Closing section a. Public comment b. Report at WVA Board May 23, 2013 meeting c. Meeting Schedule 2013-2014 (2 meetings/year, one in fall and one spring)	E. Marcuse

* Document posted on Sharepoint