

**Rhode Island Vaccine Advisory Committee
Meeting Minutes
10/29/2010**

Members in attendance: Elizabeth Lange, MD, RIVAC Committee Chair; Nathan Beraha, MD; Gail Skowron, MD; Sarah Fessler, MD; Boris Skurkovich, MD; Dinusha Dietrich, MD, David Chronley, MD; *Members unable to attend:* Penelope Dennehy, MD; Gail Davis, RN; Richard Ohnmacht, MD; Patricia Flanagan, MD; *HEALTH:* Peter Simon, MD; Patricia Raymond, Kathy Marceau, Sue Duggan-Ball, Heidi Wallace, Mark Francesconi; *Guests:* Claudia Kelly, Novartis; Rick Little, Novartis; Michelle Runyon, GSK; Dr. Marla Campbell, GSK; Dr. Liana Clark, Merck; Tim O'Hara, Merck; Matthew Badalucco, Richard Hughes, Cindy Dunaj

Open Meeting/Old Business

Dr Lange called meeting to order. Dr Lange noted that a correction is needed to a statement made in the committee's recommendation letter to the Director of Health dated April 30, 2010 following the March 19th Vaccine Advisory Committee (VAC) meeting. The statement—"HPV vaccine protects against transmission of disease from males to females" is not consistent with the FDA approval criteria of the vaccine and not an appropriate statement for this letter. This correction will also be noted in the next VAC recommendation letter to the Director.

Committee members asked for better follow-up communication of the meeting minutes, the VAC letters of recommendation and the outcome of recommendations to the Director of Health. HEALTH staff will verify and update committee contact information.

Announcements

CDC's Advisory Committee on Immunization Practices (ACIP) had quarterly meeting Oct 27-28. The ACIP approved a new recommendation for a booster dose of meningococcal conjugate vaccine at 16 yrs of age. CDC is expected to issue official guidance/recommendations from the ACIP's meeting in the next few weeks. The Department will communicate information to providers in the weekly Provider Briefing as soon as it is available.

HPV Vaccine Presentations

Glaxo Smith-Kline's (GSK) scheduled presenter was unable to attend the meeting to present on Cervarix vaccine due to a death in the family. It was mutually agreed that Merck would carry on with their formal power point presentation and the representatives that were present from GSK would provide a brief verbal presentation and participate in the Q&A portion of the meeting. Each company was given 15 minutes dedicated to their HPV vaccine, followed by 15 minutes of side-by-side questions from the committee.

Dr. Liana R. Clark, M.D., M.S.C.E., F.A.A.P., Regional Medical Director-US Adolescent Vaccine from Merck Vaccine and Infectious Diseases, Medical Affairs and Policy presented on Gardasil vaccine (see attached power point presentation) Following Dr Clark's presentation, Michelle Runyon (GSK) introduced Dr Marla Campbell (GSK) who gave a brief overview of Cervarix vaccine, followed by discussion generated by questions about Cervarix from the committee members.

Discussion

Questions raised – differences between Gardasil and Cervarix (see Table 1)

Interchangeability of vaccines – ACIP recommends completing the series with the same vaccine

Cost – (see table 1)

Additional data on duration of protection – Merck and GSK will provide additional information to committee

Further information about anal cancer – Merck will provide additional information

Other Business

Since time ran short, the committee members were asked to consider the following questions:

Going forward, how often should we meet? What topics should be on the agenda?

Is this meeting format helpful to the committee members?

Table 1. Compare Human Papillomavirus (HPV) Vaccine Formulations:

Age Indication:	9-26 years	10-25 years
Cost for Series:	\$ 326.18	\$ 288.24
Approved for Males:	Yes	No
HPV Types Covered:	6, 11, 16, 18	16, 18
Protects Against:	<p>Cervical cancer caused by HPV types 16 and 18; Vulvar cancer caused by HPV types 16 and 18; Vaginal cancer caused by HPV types 16 and 18</p> <p>Precancerous lesions caused by HPV types 6, 11, 16, and 18:</p> <ul style="list-style-type: none"> ▪ Cervical intraepithelial neoplasia (CIN) grade 2/3 ▪ Cervical adenocarcinoma <i>in situ</i> (AIS) ▪ Cervical intraepithelial neoplasia (CIN) grade 1 ▪ Vulvar intraepithelial neoplasia (VIN) grade 2 and 3 ▪ Vaginal intraepithelial neoplasia (VaIN) grade 2 and 3 <p>Genital warts caused by HPV types 6 and 11 in females and males</p>	<p>Cervical cancer caused by HPV types 16 and 18</p> <p>Precancerous lesions caused by HPV types 16 and 18:</p> <ul style="list-style-type: none"> ▪ Cervical intraepithelial neoplasia (CIN) grade 2 or worse ▪ Cervical adenocarcinoma <i>in situ</i> (AIS) ▪ Cervical intraepithelial neoplasia (CIN) grade 1
Excipients	Amino Acids, Amorphous Aluminum Hydroxyphosphate Sulfate, Carbohydrates, L-histidine, Mineral Salts, Polysorbate 80, Sodium Borate, Vitamins	3- <i>O</i> -desacyl-4'-monophosphoryl lipid A (MPL), Aluminum Hydroxide, Amino Acids, Insect Cell Protein, Mineral Salts, Sodium Dihydrogen Phosphate Dihydrate, Vitamins
Latex	No	Yes – Syringe; No – Vial
Thimerosal	No	No

Package inserts for both formulations of HPV vaccine are available at:

http://www.immunize.org/packageinserts/pi_hpv.asp

Excipients in vaccines: CDC Pink Book:

<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf>

CDC's Advisory Committee on Immunization Practices HPV Vaccine Recommendations:

<http://www.cdc.gov/vaccines/pubs/ACIP-list.htm#hpv>