

**Task Force to Study Cervical Cancer Prevention,
Detection and Education
August 24, 2006 - Meeting**

MEETING SUMMARY

Members in attendance: Senator Nancy Sullivan (co-chair), Representative Lisa Marrache (co-chair), Representative James Campbell, Dr. Kolawole Bankole, Bob Downs, Dr. Jonathan Fanburg, Sharon Jerome, Dr. Michael Jones, Evelyn Kieltyka, Janet Miles, Dr. James Raczek, Dr. Molly Schwenn, Dr. James Wilberg

Members absent: Dina Cole, Dr. Susan Miesfeldt

1. HPV Vaccine - Gardasil

- Liana R. Clark, MD, Medical Director, Merck, Vaccine Division

Key Points Made in Presentation/Discussion:

- Dr. Clark provided an overview of its HPV vaccine, Gardasil, and the clinical studies that Merck conducted on Gardasil.
- Gardasil is a *quadrivalent* vaccine that targets HPV 6, 11, 16, and 18; types 6 and 11 cause 90% of genital warts; types 16 and 18 cause 70% of cervical cancer.
- Merck's clinical studies of Gardasil included 26,000 young women ages 16-26 years; the effectiveness of the vaccine for younger girls was inferred through "bridging" studies of the safety and immune response to this vaccine in girls ages 10-15 (safety trials).
- Gardasil does *not* treat existing HPV infection; it is *preventive only*; therefore it is ideal to administer the vaccine before exposure to HPV.
- The CDC Advisory Committee on Immunization Practices (ACIP) at its June 2006 meeting voted to recommend routine vaccination of girls ages 11-12 years of age.
- The vaccine does *not* substitute for cervical cancer screening; screening recommendations have not changed.

Comments/Questions:

- Are there racial differences in the effectiveness of Gardasil? Merck commented that it works equally well in different racial groups.
- The vaccine is likely to have a greater impact on cervical cancer rates in parts of the world where there is less access to screening / Pap tests (e.g. developing countries).
- Did Merck look at the risk of HPV in lesbians in its Gardasil studies? This was not examined; lesbians do tend to have similar rates of HPV as rest of the population.
- Implications of vaccine for pregnant women? It is not recommended for use in pregnant women; based on clinical studies to date, there is no evidence of causal relationship

between the vaccine and adverse outcomes; there is a pregnancy registry to collect data on exposure to the vaccine during pregnancy.

- Could vaccine be given at even younger ages? Merck reported that they do not yet know how long the vaccine will last / duration of immune response; they are starting with the age preceding significant increase in risk of HPV exposure and expect to bring it to younger children as gather more evidence on the duration of efficacy (from studies that are following recipients of vaccine).
- What are the contraindications for the vaccine? According to the ACIP recommendations, the vaccine is not recommended for use in pregnancy and it is contraindicated for people with “a history of hypersensitivity to yeast or to any vaccine component”; it *can* be given to individuals with a compromised immune system (expect lower response).
- What about vaccinating women in their 40s? Vaccine is not approved for anyone over 26 years of age; off-label use may occur; Merck is currently doing a study of 27-45 year old women.
- Other vaccines in the pipeline? GlaxoSmithKline has a bivalent vaccine, Cervarix, in development that targets HPV 16 and 18; Merck has a vaccine in the pipeline that will cover 8 types of HPV (expect to see in 2010).
- Potential for reducing number of doses from 3 to 2 based on “immune memory” findings? Merck noted it will be another 3 years or so until there will be enough data; noted that with Hepatitis B vaccine the decision that there was no need for a booster was based on 10 years of data.
- Cost-benefit issues related to vaccination.
 - Merck noted that CDC/ACIP did examine cost-effectiveness research as part of its decision making; vaccinating 11-12 year old girls shown to have relatively low cost per quality adjusted life year (QALY); Merck modeling has shown that adding “catch-up” vaccination of 13-26 year olds makes vaccination even more cost-effective.
 - Members noted the need to consider avoided costs related to colposcopies, LEEP, treatment of genital warts, abnormal Paps and precancerous conditions.
 - Some discussion regarding whether it would be cost-effective to give the vaccine to a woman who is 40 and is getting regular Pap tests; “under examined” group of single/divorced women in their late 30s and 40s with new exposure to HPV; Merck noted that there are biological factors (cervical transformation zone) that increase the risk in younger population.

2. Maine Immunization Program

- Sally Lou Patterson, Division Director, Division of Infectious Disease, DHHS
- Jiancheng Huang, Program Director, Maine Immunization Program, DHHS
- Handout provided: “Human Papillomavirus (HPV) and its Vaccine” Sally Lou Patterson, August 24, 2006

Key Points Made in Presentation/Discussion

- Maine has a universal purchase policy for vaccines; the state purchases all the recommended vaccines and distributes them to private providers and public health departments.

- Funding for immunization comes from four sources:
 - Federal Vaccines For Children (VFC) program
 - Federal 317 Grant program
 - HMO contributions
 - Fund for a Healthy Maine (*for flu vaccine only*)
- VFC funding for children to receive recommended vaccines at no cost if they are younger than 19 and are:
 - Eligible for Medicaid, or
 - Have no health insurance, or
 - Native American or Alaskan Native, or
 - Have health insurance that does not cover childhood immunization and receive services at an federally qualified health clinic (FQHC) or rural health clinic.

VFC funds are limited to children in these specific groups and are limited to specific vaccines.

- Section 317 grants provide funds for state and local health departments to purchase ACIP-recommended vaccines through CDC's consolidated vaccine purchase contracts:
 - There are no restrictions on the use of vaccine purchased with Section 317 funds;
 - States are expected to pay 30-35% of vaccine costs when they use 317 funds to purchase vaccines, but there is not a requirement of a state match;
 - The Maine Immunization Program has not received General Fund money for some time;
 - Maine uses 317 funds to cover vaccines for children that are not covered under the VFC program.
- Maine is waiting for the formal recommendation from the CDC regarding the HPV vaccine (current status is "provisional recommendation"); after the formal recommendation is issued then will need to see the CDC budget and funding provided to state, and then the CDC negotiated price for the vaccine.
- As the number of required vaccines increase, the gap between the cost of what Maine Immunization needs to purchase and what it gets in federal funds (VFC and 317) grows; the gap is currently \$2.5 million for 0-5 year olds. When adolescents are added in, the gap is \$4.5-5.0 million.
- The current ACIP recommendation is to vaccinate girls aged 11-12 years. The start up cost is high because of the need to catch up the 13-26 year old population.
- The percentage of 0-2 year olds fully vaccinated in Maine is at 80%; in 1994, Maine was a national leader in vaccination rates, but is now falling behind; vaccination rates are related to acceptance and outreach as well; anti-vaccine movements have had an effect.

Comments/Questions:

- Who will get the vaccine? Depending on what happens with recommendations and funding for the HPV vaccine, the issue of who gets the vaccine will have to be addressed; one possibility is to start with current 11-12 year olds and go from there; it was noted that 9-11 year olds are often easier to catch in the health system; Merck's health economics modeling suggests that it is cheaper in the long-run to add the "catch-up" group of 13-26 year olds at the outset.

- Vaccination rates are falling and funding for vaccines is facing crisis; the addition of the HPV vaccine may add to existing challenges.
- With limited funds, could MIP be put in the position of having to decide which vaccines are more/less important?
- MIP funding gap:
 - Request to MIP to provide specific breakdown of the program's budget gap for vaccines (funding sources and amounts vs. expenditures / vaccine costs)
 - Are there other potential sources of funding for MIP?
 - Could the Legislature impact funding for MIP?

3. Family Planning Association of Maine / Pap Test Data

- Evelyn Kieltyka, Senior Vice President of Program Services
- Handout provided: PowerPoint presentation slides (dated July 18, 2006)

Key Points Made in Presentation/Discussion:

- Family Planning Association of Maine (FPAM) provides clinical family planning services through over 30 clinics across the state; FPAM also operates a statewide Family Life Education program and advocates for progressive family planning policies.
- FPAM follows the American Cancer Society (ACS) screening guidelines for the onset of Pap testing (3 years after onset of sexual activity or 21 years old).
- Demographics of Family Planning clients: 46% age 18-24 years; 28% age 19 or younger; 52% are in poverty (at or below 100% of federal poverty level).
- Pap tests provided by Family Planning have a 13.5% rate of atypical squamous cells (ASC) results; this is higher than the rate in the private sector but expected due to higher risk population.

4. Task Force Discussion/Work Session

- Handouts: "Cervical Cancer Task Force Meeting Handouts 8-24-06"

Staff Review of New Materials:

- *Fund for a Healthy Maine.* Task Force members had asked whether the Fund could be a source of funding for cervical cancer initiatives. Staff provided a quick overview of the Fund. It is likely that cervical cancer initiatives would meet statutory restrictions on the use of FHM dollars for health-related purposes. (See item 1 in meeting handouts packet).
- *Cervical Cancer Rates by County.* Task Force members reviewed new data from the Maine Cancer Registry on cervical cancer incidence, including incidence rates by county. The rate of cervical cancer is significantly higher than the state average in Washington and Somerset counties and is significantly lower than the state average in Cumberland County. (See item 2 in meeting handouts packet).

- *State Task Force Recommendations.* Staff provided a quick overview of the recommendations of cervical cancer task forces in 5 other states, and outlined a draft list of potential recommendations from the Maine task force based on comments made at previous meetings. (See chart entitled “Status and Recommendations of State Cervical Cancer Task Forces” / part of August 17, 2006 mailing to Task Force members).
- *State Legislation.* Staff summarized recent cervical cancer-related legislation from other states, focusing on laws that have not been enacted in Maine. These laws include insurance mandates for HPV testing, public awareness campaigns, and income tax checkoffs to fund cervical cancer initiatives. (See chart entitled: “Sampling of Recent State Legislation Related to Cervical Cancer” / part of August 17, 2006 mailing to Task Force members).

Discussion:

Task force members identified the following areas of interest as the group moves into its development of recommendations:

- **Medicaid Family Planning Waiver.** The cervical cancer task force in Virginia has recommended that the state examine the possibility of modifying the state’s family planning waiver to cover additional diagnostic and/or treatment services for cervical cancer and precancerous conditions. It was noted that under a Medicaid family planning waiver there is a 90%/10% match (for every \$1 in state costs, the federal government covers \$9 in costs); task force members requested that staff obtain additional information about the Medicaid Family Planning Waiver option.
- **Cancer screening education/awareness.**
- **Provider education for working with immigrant and minority populations; culturally sensitive/appropriate practice.**
- **Reaching younger women through MBCHP.** Caution about extending to much lower ages (such as 18); redundancy with Title X funding/services through Family Planning for the younger ages; MBCHP recommends considering a shift of minimum age from 40 years to 35 years and noted that they are seeking grant funding (Susan G. Komen foundation) for diagnostic mammograms and if obtained that would free up more of the CDC funding for Pap tests.
- **Framework for Recommendations.** Suggestion made that the recommendations of the Task Force be generated from a framework organized around identified system failures, including:
 - Failure to get screened for cervical cancer -> recommendations to reach women who are not getting screened
 - Failure of screening technology -> recommendations to improve technology (for example: endorse HPV testing; thin prep vs. conventional)
 - Other screening failures (e.g. loss to follow-up)
 - Failure to prevent HPV infection -> recommendations to reduce infection (vaccine; smoking cessation)

5. Information Requests

Task Force members requested the following information or follow-up work:

- Cost-effectiveness studies/results for the HPV vaccine / Gardasil
 - The following presentation provides a summary of the cost-effectiveness research: *"The Potential Cost-Effectiveness of HPV Vaccination in the United States: A review of published and ongoing studies"* a presentation by Dr. H. Chesson made at the June 2006 meeting of the CDC Advisory Committee on Immunization Practices (ACIP). See <http://www.cdc.gov/nip/acip/slides/jun06/hpv-5-chesson.pdf>
 - Additional cost-effectiveness information has been requested from Merck
- Maine Immunization Program information regarding the program's budget "gap" for vaccines including a breakdown of program revenue and expenditures
- Information regarding Medicaid Family Planning Waivers

6. Initial Planning for Next Meeting

- The next meeting (Tuesday, 9/26/06) will be devoted to discussing and developing the recommendations of the Task Force / creating its Cervical Cancer Prevention Plan.
- *Please see attached page for questions to consider in preparation for the next meeting.*

Future Meetings of the Task Force
Tuesday, September 26, 2006, 1:30-4:30pm
Tuesday, October 17, 2006, 1:30-4:30pm
Room 214, Cross Office Building, Augusta

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