

HPV Vaccine Mechanics Development, Practice and Support

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Vaccine Development

- Motivation and interest
 - severity and burden of disease
 - internal and external support for vaccine development
- Industry and government
 - Technical capability and capacity
 - Develop a candidate antigen
 - Rigorous scientific investment and investigation



Vaccine Development

- Animal studies (pre-phase1)
- IND application – proposed clinical trials protocol
- Phase 1,2,3 human vaccine trials
 - over several years, involve thousands of participants



Licensure

- FDA
 - Biologic License Application (BLA)
 - **Vaccines and Related Biological Products Advisory Committee (4x/yr.)**
 - HPV reviewed in May, 2006
 - recommended for approval
- Licensure
 - Official letter notifying company of licensure
 - HPV June 8, 2006
 - Letter details age groups etc. vaccine is “licensed for” and any restrictions, post vaccine reviews, modifiers from original BLA



- Merck & Co., Inc.
Attn: Dr. Patrick Brill-Edwards
Director
Worldwide Regulatory Affairs
Vaccines/Biologics
P.O. Box 4 , BLB-22
West Point , PA 19486-0004
- Dear Dr. Brill-Edwards:
- We have approved your biologics license application (BLA) for Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine under your existing Department of Health and Human Services U.S. License No. 0002. Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18)



Recommendations after Licensure

- Vaccine will generally be “recommended” based on scientific trial data and licensure.
 - Recommendations are medically, organizationally, and public health based
- Federal Advisory Committee on Immunization Practices (ACIP)
 - Provides recommendations on vaccines to CDC director
 - Powerful committee; recommendations are very seriously considered
 - ACIP meeting is June 29 &30



Recommendations after Licensure

- Various other organizations assemble recommendations (AAP, AAFP, ACOG)
 - they have not always matched
- Harmonizing recommendations among all organizations more ideally supports vaccine and funding



Pre-teen Visit

- Motivation is to have a comprehensive medical visit, including appropriate psycho/social discussion, as child turns to a teen
- Hepatitis B immunization served as important support for the pre-teen visit
- Recommended/required immunizations can serve as an incentive to accomplish the visit (Tdap, MCV4).
 - Sustainable immunization platform needs to be reestablished; current school law for hepatitis B no longer supports visit
 - Multi-dose vaccine series is a serious challenge



Required Vaccines

- Required is usually law or mandate (institution, local, school, organization)
 - CA school law (H&S Code 120225-120380)
 - Adding a new vaccine by law (code or regulation) is a serious process and takes several years
 - Vaccine supply must be stable
 - Adequate distribution mechanism
 - Informing and preparing providers, schools
 - Reinvites comment on vaccine mandates
 - » Public process
 - Requires state budget approval
 - Immediate laws for new vaccines are not generally appropriate



Vaccine Funding

- Public vaccine purchase and reimbursement is a complex mosaic,
 - mostly federal and almost entirely for children
- Main funding sources:
 - Vaccine for Children (VFC)
 - Federal 317 vaccine
 - infrastructure and vaccine
 - State and local funding
 - Infrastructure and vaccine
- Private funding including managed care
 - Healthy Families
 - Large HMO groups
 - Fee for service
 - Out of pocket



Vaccine Funding

- Public
 - **Vaccine for Children (VFC)** – provides included vaccines for eligible children under 19
 - ACIP votes to include vaccine in the program
 - **Federal 317 vaccine** – direct grant monies from CDC for state and local infrastructure and some vaccine procurement
 - **State** – limited direct general fund monies from state for immunization infrastructure and very limited vaccine procurement
 - **Local** – LHD or jurisdiction might buy some vaccines or invests in infrastructure



Vaccine Funding

- Private
 - HMO's – HEDIS includes immunization measures and therefore assures funding
 - New vaccines are not immediately added to HEDIS
 - Most large group practices, HMO's, include recommended vaccines
 - Short time lag from recommendation to implementation



Funding

- Private funding
 - Private payer insurance mandates
 - SB 686 (1996) – mandates health insurers cover ACIP recommended vaccines for children
 - SB 168 (2000) – mandates coverage for new vaccines for children not included in negotiated plans (2 year cycles)
 - Out of pocket



HPV vaccine challenges

- VFC funding will depend on recommendations and inclusion in program (June, 2006)
- Adult funding infrastructure for multi-dose vaccines is very shallow
- Uptake of vaccine may take some time; new vaccines and recommendations often take time to accommodate
- Necessary to have very high profile external support and participation (coalitions, champions, medical and nursing organizations etc.)

