

Interagency Work Group to Address Content of National Children's Study

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NVAC and the NCS

- At the February NVAC meeting, NVAC members discussed the adequacy of collecting vaccine histories from the primary caretaker
- Recommended contacting NCS director to discuss alternatives
- Draft NVAC Vaccine Safety Recommendations
 - “The NVAC strongly urges further consideration of incorporating provider-verified immunization histories into standard NCS data collection”



HHS Update

- Briefing with the Assistant Secretary for Health, March 13th 2009 on immunization data collection
 - Interest in collecting as accurate immunization information as feasible
 - Charge to create an interagency Working Group to discuss vaccine issues



Interagency Working Group

- NVPO, FDA/CBER, CDC/NCIRD, NIH/NCS
- Charge
 - What immunization information will and will not be captured in the NCS (validity of currently planned data)
 - The federal immunization community needs for the NCS (are there important questions that can't be answered by the current protocol, and if so, the priority of such studies)
 - What other means are there to collecting needed immunization information (registries, changing protocols for NCS, etc)



Discussion of Data Elements Collected by Medical Care Log

- Vaccine trade name (lot numbers may not be specific to a manufacturer)
- In the context of a current vaccine adverse event, asking for a history/family history of vaccine adverse event
- Current medications during each acute and well visit
- Column for vaccinations during sick visits (as is done for well visits)
- Immunizations for older ages
- Allowing space for new (not yet licensed) types of vaccines or new age indications for existing vaccines



Linking NCS with VAERS

- Systematic reporting by study personnel of all vaccine adverse events to VAERS with inclusion of 'NCS participant'



Additional Considerations

- Active surveillance (e.g., by phone) for adverse events occurring within 6-8 weeks of vaccination
- Validity study of Caretaker-provided Medical Logs in sub-sample
 - Provider-verified immunization histories would be collected retrospectively regardless



Next Steps

- Additional discussion by the Interagency Working Group
- Working Group will make recommendations to NCS
- Report back to NVAC



**VACCINATIONS**

Vaccine	Protects against	Recommended age	Date received	Lot #	Reaction
Hepatitis B	Hepatitis B virus (chronic inflammation of the liver, life-long complications)	Birth to 2 months	____/____/____		
		1 to 4 months	____/____/____		
		6 to 18 months	____/____/____		
Diphtheria, Tetanus, and Pertussis (DTaP)	Diphtheria, tetanus and pertussis (whooping cough)	2 months	____/____/____		
		4 months	____/____/____		
		6 months	____/____/____		
		15 to 18 months	____/____/____		
H. Influenza Type B (Hib)	Infections of the blood, brain, joints, or lungs (pneumonia)	2 months	____/____/____		
		4 months	____/____/____		
		6 months	____/____/____		
		12 to 15 months	____/____/____		
Inactivated Polio (IPV)	Polio	2 months	____/____/____		
		4 months	____/____/____		
		6 to 18 months	____/____/____		
Pneumococcal Conjugate (PCV7 or PPV)	Infections of the blood, brain, joints, inner ears, or lungs (pneumonia)	2 months	____/____/____		
		4 months	____/____/____		
		6 months	____/____/____		
		12 to 15 months	____/____/____		
		24 months or older	____/____/____		
Measles, Mumps, and Rubella (MMR)	Measles, mumps, and rubella (German measles)	12 to 15 months	____/____/____		
Varicella	Chickenpox	12 to 15 months	____/____/____		
Hepatitis A	Hepatitis A virus (inflammation of the liver)	12 to 23 months	____/____/____		
		18 to 29 months	____/____/____		
Influenza	Flu and complications	6 to 59 months (during flu season)	____/____/____		
			____/____/____		
			____/____/____		
Rotavirus	Rotavirus diarrhea (and vomiting)	2 months	____/____/____		
		4 months	____/____/____		
		6 months	____/____/____		
Meningococcal	Meningitis	24 months or older	____/____/____		



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