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# Vaccine Safety Implementation Plan

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## Some Vaccine Safety Concerns

- Hib vaccines and diabetes
- Oral polio vaccine (OPV) and VAPP
- Measles vaccine and thrombocytopenia
- Measles vaccine and autism
- OPV and CFS (the "stealth" virus)
- Inactivated polio vaccine and SV40 contamination
- Hepatitis B vaccine and multiple sclerosis
- Rotavirus vaccine and intussusception
- Mumps vaccine and aseptic meningitis
- Smallpox vaccine and progressive vaccinia

## Vaccine Safety Concerns

- Associated with vaccine (OPV and VAPP) or vaccine strain (aseptic meningitis and Urabe mumps strain; not known with Jeryl Lynn)
- Adventitious viral agent in vaccine (IPV and SV40); no known adverse effect
- Additives or adventitious materials (proteins, LPS, DNA, antibiotics, etc.) in vaccine (measles vaccine and thrombocytopenia)
- Causality established, evidence against, evidence uncertain

## Vaccine Safety Action Plan

- Task Force on Safer Childhood Vaccines established by the Secretary, DHHS, at the direction of Congress.
- Comprehensive report from the Task Force approved by the Secretary, DHHS, in January of 1997.
- NVPO charged by the Secretary to implement the recommendations of the Task Force
- Interagency group drafted a VSAP; presented to NVAC and Surgeon General

## Vaccine Safety Implementation Plan

- Presented to the Deputy Secretary, Health and Human Services, October 26 (VSAP) and December 10, 1999 (VSIP).
- Highest Priority activities identified; to the extent possible these will be initiated this FY.
- Stable funding being sought through various mechanisms.

## VSIP Goals

- **I.** Increase efforts to detect potential vaccine safety problems
- **II.** Improve the response to and understanding of vaccine safety concerns
- **III.** Improve the risk management of vaccines in clinical setting
- **IV.** Increase and improve communications about vaccine risks and benefits
- **V.** Obtain and maintain a “state of the art” vaccine supply

## I. Detect Potential Safety Problems

- Improve the laboratory testing and evaluation of vaccine safety and purity
- Develop new approaches to testing for the presence of unknown or previously undetected agents in vaccines

## II. Improve response and understanding of vaccine safety concerns

- Evaluate VAERS reports more adequately to improve scientific understanding of the reports
- Carry out timely review of newly hypothesized vaccine safety concerns
- Study possible causal links between vaccines and specific diseases in expanded Vaccine Safety Datalink populations

### III. Improve risk management of vaccines in clinical settings

- Finalize new Decision Rules for Vaccination policies to reduce unnecessary repeat doses
- Update the NVAC Standards for Pediatric Immunization Practices to include a focus on safety related practices

### IV. Increase/improve communications about risks and benefits

- Improve the exchange of information between providers and parents

## V. Obtain and maintain a “state of the art” vaccine supply

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- Develop safer alternatives for current vaccines