

The Vaccine Safety Datalink (VSD) Data Sharing Program

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VSD Data Sharing Program: Background

- Heightened public interest for access to VSD data
- In direct response to public interest, NIP developed a data sharing program to provide external researchers access to Vaccine Safety Datalink (VSD) data
- Program developed in collaboration with:
 - Department of Health and Human Services (HHS)
 - Congressman Dan Burton and staff
 - Managed Care Organizations (MCOs) participating in the VSD



Challenges in Creating VSD Data Sharing Program

- **Several challenges at the time of creation:**
 - No established CDC data sharing policy
 - Dual objectives of providing access to VSD data while assuring privacy of personal medical records at MCOs
 - Many datasets from previous published VSD studies had not been archived in a standard manner



Challenges in Creating VSD Data Sharing Program

- VSD data cannot be “deidentified” and still be useful for vaccine safety studies
 - Vaccine safety analyses require date of birth, date of vaccination , specific administration of vaccines, date of medical visit and medical diagnosis
 - Having all this information could permit identification of individual patients



Mechanism to Protect Privacy Within the VSD Data Sharing Program

- Given the need for protection of the private medical records, the VSD data sharing program was developed to make use of existing infrastructure at CDC, using the NCHS Research Data Center



VSD Data Sharing Program: Background

- **August 2002: Guidelines for Data Sharing Program for External Researchers: Access to CDC's Vaccine Safety Datalink Data**
- **Types of studies that can be conducted using VSD data:**
 - **New studies of vaccine safety from VSD data files that reside at CDC**
 - **Re-analyze study-specific datasets from VSD published studies**



VSD Data Sharing Program: A 3-Step Process

- **Step 1: Submission of Proposals to NIP**
- **Step 2: Submission of Proposals to MCO IRBs for approval**
- **Step 3: Use of the NCHS RDC, after signing 308(d) confidentiality protection forms**



Step 1: Submission of Proposals to NIP

- External researcher submits a proposal in format as required in the Guidelines
- As stated in Guidelines, NIP's role is to verify:
 - Proposals are complete
 - Variables requested by external researcher to conduct new vaccine safety studies exist
 - Requested final dataset for re-analysis of VSD published study is available
- If proposal is complete and data are available, external researcher is provided IRB contact information for relevant sites



Step 2: Submission of Proposals to MCO IRBs for Approval

- CDC does not have role in MCO IRB formal review process
- External researcher must request IRB application from relevant IRBs
- Each MCO IRB has own rules, regulations and fees
- Completed IRB application is reviewed by IRBs
- Application is either approved or disapproved
 - Disapproved applications provide opportunity for external researchers to respond to IRB questions
- External researcher must provide final IRB dispositions to NIP so that datasets can be created



Step 3: Use of NCHS RDC

- Upon IRB approval, datasets created and delivered to NCHS RDC
- Datasets uploaded on RDC computers
 - VSD data analyzed with SAS software
- Technical monitor
 - Performs disclosure review of all output produced (no line listings, no cells < 5, etc) to assure confidentiality



Status of VSD Data Requests: Research Group 1

- Submitted new vaccine safety studies (13 hypotheses) and re-analyses (11 studies) of CDC published studies
- Have accessed data twice at RDC
- Time from NIP receipt of first proposal to first RDC visit 9/02 – 10/03



Status of VSD Data Requests: Research Group 2

- Submitted re-analysis of 1 CDC published study
- Current status:
 - Step 2 - Submission of proposals to MCO IRBs



Challenges Encountered With VSD Data Sharing Program

- Limited experience outside of NCHS using the data enclave approach to access data
- Learning along the way:
 - Revision of data sharing guidelines
 - More explicit
 - Not all IRBs approved proposals
 - Some VSD final datasets not available



Next Steps for Data Sharing at CDC

- **VSD Data Sharing Program transferred from NIP to NCHS**
- **Plan to enhance CDC website to list available datasets from published studies**
- **Given need for more transparency, process being developed for creation of public use datasets in the future**

