

Charge To The IOM On Sharing Preliminary Findings From The Vaccine Safety Datalink

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Types of Information

- Preliminary data
- Preliminary findings
- Final data
- Published findings



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Preliminary Data

- Data are the underlying elements of information that lead to findings but are not the findings per se. They permit analyses or reanalyses.
- Preliminary data are the underlying elements of information of a study or investigation which are still incomplete or subject to change.



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Preliminary Findings

- Initial results obtained from investigations or studies often expressed in summary statements or summary-like form such as tables and graphs. These results are incomplete and subject to change prior to peer-reviewed publication.



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Twofold Charge to the IOM by the National Immunization Program

1. Review and make recommendations about the Data Sharing Program—Mtg August 2004
2. Review and make recommendations about whether, when, and how to share preliminary findings from the Vaccine Safety Datalink Project (VSD)—Mtg Oct 2004

Types of Information

- Preliminary data
- Preliminary findings (focus for task 2)
- Final data (focus for task 1)
- Published findings



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Charge to the IOM Regarding Preliminary Findings

2a) Review the approaches to conducting analyses that are characteristic of studies using the complex, automated data from the VSD project (e.g., thimerosal and asthma studies)

Charge to the IOM Regarding Preliminary Findings (con't)

2b) Review whether, when, and how preliminary findings about potential vaccine related risks obtained from the VSD should be:

- Shared with other scientists
- Communicated to the public
- Used to make policy or recommendations to CDC

2c) Make recommendations to NIP regarding sharing preliminary findings in the future

Charge to the IOM Regarding Preliminary Findings (con't)

- Guidance is sought by NIP for NIP
 - not intended for other groups such as CDC as a whole, FDA, NIH, and other government agencies

Sharing Preliminary Findings

- Current process of sharing preliminary findings at NIP:
 - Routine Public Health Concerns
 - VSD Asthma Study
 - Non-Routine Public Health Concerns
 - VSD Thimerosal Screening Analysis
 - NIP Rotavirus Experience



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5 Step Process: Routine Public Health Concerns

1. Presentations at scientific meetings (work in progress)
2. Internal peer review and clearance
3. External peer review prior to publication (confidential)
4. Publication in journal
5. Sharing of final dataset for published study

10 Step Process : **Non-Routine Public Health Concerns**

1. Consultations with internal scientists
2. Consultations with external scientists, including those from the vaccine industry
3. Presentations to standing advisory committees for policy recommendations
4. Communication with the public
5. Release of presented findings in summary form
6. Presentations at scientific meetings
7. Internal peer review and clearance
8. External peer review (confidential)
9. Publication in journal
10. Sharing of final dataset in published study

Challenges Associated With Sharing Preliminary VSD Findings

- How best to consult with outside experts and vaccine industry representatives about preliminary findings (e.g., the Simpsonwood consultation on thimerosal)

Challenges Associated With Sharing Preliminary VSD Findings (Con't)

- Whether to and how best to retrieve and release to the public preliminary findings which have been superceded by later findings (either still preliminary or final)
- “Works in progress”

Challenges Associated With Sharing Preliminary VSD Findings (Con't)

- How best to release to the public preliminary findings upon which rapid public health decisions are often based
- In what form should preliminary findings be shared

Challenges Associated With Preliminary VSD Information

- How best to communicate public health actions when based on preliminary findings
 - May be difficult when:
 - the quality of the data is not optimal
 - there is a low level of certainty about the findings
 - there is a higher than average degree of public interest, at least in some segments of the population

Type Of Recommendations Being Sought From The IOM

- Specific to the NIP
- Relevant to findings requiring public health action in advance of normal publication
- Relevant to the evolving findings from the VSD on the safety of vaccines
- Relevant to findings with a degree of uncertainty

Timetable

- A report must be completed in a timely fashion as the topics under review are the subject of concern in some public and Congressional groups.
 - Task A (Data sharing report)
 - 120 days from date of award (extended to mid-December 04)
 - Task B (Preliminary findings report)
 - 270 days from date of award (Feb 05)