

# The Use of Health Plans' Data for Vaccine Safety Research

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\* These are the speaker's opinions. They have not been reviewed or approved by health plans. <sup>1</sup>

# Vision/Mission Of VSD Datalink Project

- Powerful, cost-effective resource for the ongoing evaluation of vaccine safety.
- Monitor vaccine safety through planned studies and timely investigations of new hypotheses.
  - Via collaborations between CDC and health-plan based researchers.

# Health Plans' Reasons for Participation in Vaccine Safety Datalink

- Public benefit resulting from their unique ability to provide relevant information on large numbers of people.
- Interest in being good partners to public health.

# Data Types Used for Medical Research

- Data collected with public funds for research
  - NHANES, clinical trials
- Data collected for other purposes by public agencies
  - Drivers' licenses, census
- Data collected by private organizations for other purposes, such as patient care and business operations
  - Vaccine Safety Datalink

# Vaccine Safety Datalink Data

- Uses membership, health services, and electronic medical records data of 8 private not-for-profit health plans.
- These are data routinely collected as part of health plans' patient care and business operations.
  - Confidential patient data
  - Proprietary business data
  - Characteristics are atypical of data collected specifically for research

# VSD Data Use Provisions

- A “limited rights/limited use” data set is created for each approved VSD study for use by specific investigators.
- 4 confidentiality provisions apply
  - HIPAA Privacy Rule “Limited Use Data”
  - Federal Acquisitions Regulations 52.227-14: “Limited Rights Data”
  - Section 308(d) of the Public Health Services Act
  - Contract with VSD health plans

# Confidentiality of Data - 1

- HIPAA Privacy Rule - Applies to Health Plans
  - VSD data contain Protected Health Information (“PHI”)
  - PHI may be used and disclosed for research without patients’ Authorization only in limited circumstances:
    - **As a “limited data set” with a data use agreement,**
    - Under a waiver of the Authorization requirement,
    - Preparatory to research,
    - For research on decedents' information.

# Confidentiality of Data - 2

- “Limited Rights Data” FAR\* 52.227-14
  - Data will not, without written permission of the Health Plan, be used or disclosed outside the Government.

\* Federal Acquisitions Regulations

# Confidentiality of Data - 3

- 308(d) of the Public Health Services Act
  - “No information, if an establishment or person supplying the information or described in it is identified, ... may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented ... to its use for such purpose...”
  - “... information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable ...”

# Confidentiality of Data - 4

- Contract with VSD health plans
  - “Existing raw data or databases in whole or in part shall be considered confidential information to Research Organization (Health Plan).” \*\*

# Data Protection Employed by Health Plans: All VSD Projects

- Their own institutional review boards assess protection of patient confidentiality.
- They have separate processes to assess protection of proprietary data.
- They release to specific investigators the “Limited Rights/Use” data necessary to address questions specifically approved by health plan.
- They maintain ownership and ongoing control over the data they provide.

# VSD Project Guidelines for Data Sharing: Proposals from External Researchers

- Health plans' regular research approval processes apply.
- “Limited rights/use”, and 308(d) data provisions apply.
- Uses the Research Data Center (RDC) at the National Center for Health Statistics.
- Investigator must sign agreement to abide by standard practices of RDC.
  - Maintain confidentiality of data
  - Only copies of summary results can leave RDC
- For approved studies, RDC prepares study-specific data set for analysis.
- Data must be used at RDC with supervision by a technical monitor.

# Impact of Removing “Limited Rights” and Other Confidentiality Protections

- Potential breach of confidentiality of patient records.
  - Protected Health Information in Research Data Center is difficult to de-identify.
    - Birthdate, census tract residence information
    - Dates and diagnoses of all health care services/encounters
- Members may believe their personal information is shared inappropriately.
- Potential release of proprietary data.
  - Plan-specific data in RDC is difficult to de-identify.
    - Locations, dates, volumes, and modalities of care provided by individual health plans
- Risk that data may be subpoenaed in litigation.
- Risk of inaccurate conclusions about care.

# Conclusion 1

- Immunization policies affecting the health of our nation depend on the consistent monitoring of vaccines' use and assessment of immunization benefits and risks.
- The Vaccine Safety Datalink project is one of our most important tools to ensure the safety and efficacy of vaccines.

## Conclusion 2

- The VSD health plans support the continuation of this important public health program, provided that --

data use “satisfies all requirements concerning patient confidentiality and the protection of the proprietary interests of the research organizations”\* (health plans).