

Vital Statistics Advisory Committee (VSAC)
Vital Records Protection Advisory Committee (VRPAC)
Joint Meeting
Meeting Minutes for Wednesday, September 1, 2010
9:00 AM to 11:00 AM

Attendees

Convener: Linette Scott

Committee Members:

Present: Jonathan Teague, Debbie Castanon

Phone: Sue Holtby, David Grant, Krista Hanni, Peter Abbott

CDPH Staff:

Present: Linette Scott, Scott Fujimoto, Debbie McDowell, Julie Turner, Krista Christian, Karen Roth, Cindy Tanaka-Fong

A. WELCOME

Debbie McDowell welcomed committee members.

B. Approval of minutes from the previous meeting

July 7, 2010 minutes approved as written.

C. State Registrar's Response

1 continuing project and 7 new projects were approved for release of data.

D. New business

8 projects (1 continuing project, 7 new projects) were reviewed.

Project Title: Screening for Jevell and Lange-Nielsen Syndrome

Principle Investigator(s): Ruey-Kang Chang, MD, MPH, Harbor UCLA
Medical Center

Project Type: New

CPHS Approval: Yes

Project No.: 09-10-01

Expiration: File(s) Requested: October 1, 2010

Requested Identifiers: 2005-2008 Merged Death Files

Personal Contact: Yes

Identifiers Released: No

History: New Research Project

Summary: This is a research study funded by National Institute of Health (NIH). The purpose of the study is to determine if infants who died of undiagnosed Jervell and Lange Nielsen Syndrome (JLNS) could be labeled as Sudden Infant Death Syndrome (SIDS).

The investigator is hypothesizing that infants with undiagnosed JLNS who died of SIDS may have been potentially saved had their diagnosis been made early through cardiac screening.

Death data will be used to identify infants who died of SIDS, and matched with hearing screening data to identify which of these infants were hearing-impaired. These infants might have had JLNS which can be confirmed with genetic testing.

Study subjects are infants and children with severe-to-profound sensorineural hearing loss (SNHL) identified by the California Newborn Hearing Screening Program (NHSP). This is a 2-year project (October 2009 to September 2011), with a 2-year prospective cohort and a 4-year retrospective cohort.

The 2-year prospective cohort will be researched to determine the prevalence of JLNS in young infants with severe-to-profound SNHL, and evaluate the impact of early JLNS diagnosis on management and outcomes. Prospective cohort subjects will receive cardiac screening from 2 to 6 months of age.

The 4-year retrospective cohort includes all infants who were identified with severe-to-profound SNHL by the Newborn Hearing Screening Program (NHSP) in the preceding four years before the project starting date. The purpose is to estimate the number of infants with severe-to-profound SNHL who could have benefited from early cardiac screening. The age at cardiac

screening of the retrospective cohort will be 2 to 4 years of age, considerably older than for the prospective cohort.

Death data from CDPH will be used to find all infant deaths due to SIDS from 2005 to 2009, and match with Hearing Screening Program data. Families of hearing-impaired infants who died of SIDS will be contacted.

VSAC Discussion: No comments.

VSAC Recommendation: Approval

Project Title: Low Birth Weight and Segregation in Chicago and Los Angeles Neighborhoods

Principle Investigator(s): Michelle Debbink, Medical Scientist Training Program Fellow University of Michigan MD/PhD candidate, School of Medicine and School of Public Health

Project Type: New Project

CPHS Approval: Yes

Project No.: 10-08-61

Expiration: June 3, 2011

File(s) Requested: 2000-2008 Birth Statistical Master File

Requested Identifiers: Names, Certificate Numbers, and Addresses

Personal Contact: No

Identifiers Released: No

History: New Research Project

Summary: This project will explore links between racial residential segregation and low birth weight outcomes in Chicago and Los Angeles neighborhoods. Extensive and detailed data from the University of Michigan's Chicago Community Adult Health Study (CCAHS) and RAND's Los Angeles Families and Neighborhoods Study (LA-FANS) will be used in conjunction with Illinois Department of Public Health and California Department of Public Health Vital Records data in order to better understand the aspects of segregated neighborhoods that contribute to the association between racial segregation and low birth weight. By using data from Chicago and Los Angeles, this project will provide insight into the differences in these associations in different regions of the country. Three major aims will be researched in each location:

1) To confirm that local racial segregation measured at the census tract level is associated with rates of low birth weight. Using census and vital statistics data, the relationship between low birth weight and local segregation will be modeled, controlling for demographic and medical risk factors at the individual level (mother's age, income, education, health care status, prenatal care, and substance use) as well as income at the neighborhood level.

2) To investigate the mediating role of neighborhood disorder/decay, social networks, or health care availability to explain the association of local residential segregation with low birth weight for various population groups (African Americans, Whites, Black immigrants, and Hispanics), and potential

pathways in the relationship between low birth weight rates and segregation within and between racial and ethnic groups.

VSAC Discussion:

- The committee recommended the researcher separate US and foreign-born Hispanics.
- A suggestion was made to release only data requested instead of complete files. OHIR is moving towards this policy (“minimum-necessary” data sets).
- Debbie C wanted to make sure that researchers were meeting our standards of destruction. Linette responded that one of the committee’s roles is to make recommendations to adopt standards for security and data destruction.
- The committee recommends clarification on whether laptops would be encrypted or would contain personal information.

Linette suggested a future agenda item based on the committee’s recommendation will be to discuss informing researchers what level of standard they must follow for encryption and destruction after CPHS review.

VSAC Recommendation: Approval upon notification that the laptop contains de-identified or encrypted data. Only requested data will be released with a suggestion to separate results of US and foreign-born Hispanics.

Project Title: Memory Processes in Childhood

Principle Investigator(s): Simona Ghetti, PhD, University of California Davis,
Psychology Dept., Memory and Development Lab

Project Type: New Project

CPHS Approval: Yes

Project No.: 09-08-01

Expiration: April 1, 2011

File(s) Requested: 2006-2010 Birth and Infant Death Files obtained by
Dr. Lisa Oakes' project #07-07-06 for contact study

Requested Identifiers: Names, Certificate Numbers, and Addresses

Personal Contact: Yes

Identifiers Released: No

History: New Research Project

Summary: The Principal Investigator (PI) is requesting to use birth data (name, date of birth, residence address) obtained previously by Dr. Lisa Oakes, Center for Mind and Brain, at UC Davis.

The project description is "development of uncertainty monitoring during the preschool years." The proposed research investigates the development of metacognition (the awareness of one's cognitive abilities) in early childhood. Three experiments are being proposed to explore this possibility.

The PI is interested in examining developmental trends in uncertainty monitoring. Thus the stimuli are designed to elicit judgments that will be made with varying levels of uncertainty.

This research will contribute to understanding of memory development and how children learn; thus, the benefits are for the advancement of scientific knowledge. Many caregivers find it interesting to learn about memory development and to observe their child's responses to tasks that tap learning. This research will contribute to knowledge of how typically developing children learn. Understanding typical development may also contribute to a better understanding of atypical development and learning impairments in children, thus benefits to subjects outweigh the minimal risks of participation.

Recruitment efforts will be coordinated with Drs. Lisa Oakes, Susan Rivera, and Katherine Graf Estes whose protocols have been approved by CPHS and VSAC.

This project will enroll a total of 570 participants (480 children and 90 adults from Sacramento, Solano, and Yolo Counties--surrounding UC Davis). Experiments 1 and 2 will recruit children ages 2, 3, 4, and 5 years, as well as adults--a total of 300 participants. Experiment 3 will recruit children ages 2, 3, 4, 5, 7, 9, 11, and 16, as well as adults--a total of 270 participants.

Families will be contacted by periodically sending out recruitment letters. When children reach the appropriate age for participation, families will be contacted via telephone. Adult participants will be recruited through UC Davis' psychology department.

VSAC Discussion: The issue of data destruction was brought up. For future proposals, more specifics are needed on data destruction and protection.

VSAC Recommendation: Approval

Project Title: Understanding the Relation between Sleep and Memory in Infants

Principle Investigator(s): Angela Lukowski, PhD, University of California, Irvine

Project Type: New Project

CPHS Approval: Yes

Project No.: 10-02-03

Expiration: 02-04-2011

File(s) Requested: 2009 Birth Statistical Master File – Orange, Los Angeles, San Bernardino, Riverside, and San Diego

Requested Identifiers: Names, Certificate Numbers, Social Security Numbers, and Addresses

Personal Contact: No

Identifiers Released: Yes

History: New Research Project

Summary: The purpose of the present research is to determine whether napping facilitates long-term memory in infants tested near the end of the first year of life.

One behavior known to impact consolidation and storage processes is sleep. Whereas previous research conducted with both animals and human adults has established the influential effect of sleep on measures of memory and other cognitive abilities, the possibility that sleep-dependent performance has not yet been investigated in infants.

The proposed project is the first to attempt to determine the role of sleep-dependent consolidation on memory and related cognitive abilities in the first year of life.

In the present research, infants will participate in a two-session study that will take place at their residence. Infants will participate in behavioral assessments of memory at each session and their parents will be asked to complete online questionnaires inquiring about demographic information as well as the sleep habits and temperaments of their infants.

This work is important in that it has the potential to provide the first indication of the relation between sleep-dependent memory consolidation and long-term recall memory in infancy. This study will contribute significantly to the literature on cognitive development in infancy and will also serve as the first in a programmatic series of research projects designed to address the

relation between sleep and cognition in typically developing infants and children as well as in those with documented developmental disorders.

Infant birth records from CDPH will contain date the infant was born, first name he or she was given, first and maiden name of the mother, last name of the father, and residential address for the mother, including zip code. The death file will include date the infant was born, date the infant passed away, first name he or she was given, first and maiden name of the mother, last name of father, and residential address of mother, including zip code.

Records will be requested for Orange County and may be requested as well for portions of San Diego, San Bernardino, Riverside, and Los Angeles Counties. Data will be requested for years 2010 thru 2012 as available.

VSAC Discussion: Discussion included clarification of data retention and destruction and the lack of follow-up or confirmation when the project is completed to confirm data destruction. Questions are asked at the beginning but not followed up at the end as we do not have resources to do this. OSHPD has a similar procedure with data disclosures as they rely on reputational integrity.

VSAC Recommendation: Approval

Project Title: Racial and Ethnic Differences in Causes of Mortality

Principle Investigator(s): Latha Palaniappan, MD, MS, Palo Alto Medical Foundation Research Institute

Project Type: New Project

CPHS Approval: Pending CPHS approval

Project No.:

Expiration:

File(s) Requested: 2000-2008 Death Statistical Master File

Requested Identifiers: Certificate Numbers and Names, Social Security Numbers and Mother's Maiden Name

Personal Contact: No

Identifiers Released: No

History: New Research Project

Summary: This is an epidemiologic study designed to investigate the causes and predictors of mortality among different racial/ethnic groups and subgroups. The proposed study (1) uses California state death records to investigate the leading causes of mortality among Asian American subgroups compared to other racial ethnic groups in California, and (2) creates a record-linked data set of California state death records and clinical data from the Palo Alto Medical Foundation (PAMF) electronic health records (EHR) to examine predictors of mortality.

The Asian American population has grown dramatically in size and diversity in recent decades and there are wide gaps in knowledge of morbidity and mortality for this population. There is need for more racial/ethnic specific data in order to better understand the leading causes and predictors of mortality among Asian Americans in the United States.

The overall goal of this study is to address a substantial gap in existing knowledge regarding racial/ethnic differences in cause of mortality among Asian American subgroups and other racial/ethnic groups. This study will further enrich the body of knowledge regarding predictors and causes of mortality by linking California death records to PAMF EHR records.

The proposed research project is a data-only study and involves the use of death data for the years 2000 to current-2008 and will request additional data as updated death stat master files become available.

VSAC Comments: One of the committee members commented that this project would create a file for future possible research. Once created, a protocol would be put in place. Jonathan said that they were doing some research on racial and ethnic disparities in terms of healthcare outcomes. They were not able to determine how far the investigation would go and may set up a data file for further research. OSHPD does a similar thing as they create data file products for further research linking vital statistics and hospitalization data. They have projects where they construct those files, and will get requests for the information. The projects are approved by CPHS and management.

Debbie M clarified that information would be stored on a separate external hard drive which would be connected to the file server. Information would be deleted once the study is completed. The committee recommended determining the location of the file server.

VSAC Recommendation: Approval

Project Title: Neonatal Healthcare Utilization in California

Principle Investigator(s): Stephen B. Shew, MD, UCLA David Geffen School of Medicine, Division of Pediatric Surgery

Project Type: New

CPHS Approval: Yes

Project No.: 10-04-54

Expiration: April 1, 2011

File(s) Requested: 1999-2007 OSHPD linked PDD/Birth Cohort Data

Requested Identifiers: No Personal Identifiers

Personal Contact: No

Identifiers Released: No

History: New Research Project

Summary: The goal of this research is to use the linked Vital Statistics Birth Cohort/OSHPD Infant Encounters data to study the health outcomes of neonates in California with a focus on surgical diseases. From retrospective review of the data, they plan to study the epidemiology of these diseases, its outcomes in treatments, complications and mortality, the utilization of health care resources and associated disparity.

VSAC Discussion: Jonathan provided an explanation on OSHPD process used for data requests. Requestors receive a description from OSHPD on what is an adequate standard for security measures. Requestors must provide detailed information on how data is compiled, where the data resides, and how it is stored.

Also, clarification was given on power calculation and issues on page 3 concerning sample size, linking GIS data and merging or linking data.

VSAC Recommendation: Approval

Project Title: Proposal to Link Records from the patient Discharge Data Files with Records from California's Vital Statistics Birth and Death Files

Principle Investigator(s): Jonathan Teague; PI: Beate Danielsen, PhD, OSHPD, Health Information Division, (HID), Health Information Resource Center (HIRC)

Project Type: New

CPHS Approval: Yes

Project No.: 97-06-03

Expiration: April 1, 2011

File(s) Requested: 2009 Birth Statistical Master File

Requested Identifiers: No Personal Identifiers

Personal Contact: No

Identifiers Released: Yes

History: New Research Project

Summary: OSHPD Healthcare information Resource Center (OSHPD-HIRC) proposes to link OSHPD's 1983-2009 Patient Discharge Data (PDD) files with 1983 through 2009 CDPH birth cohort, birth statistical master, and fetal death files.

The goal of the linkage is to provide a non-public, linked file for each year beginning with 1983 that contains clinical data from the PDD, ER (2005 and later), and ambulatory (2005 and later) files, with the demographic and clinical data surrounding births from the vital statistics files.

This project is designed to produce a set of longitudinal data, which describes the clinical and demographic characteristics of mothers and babies during the period 1983 through 2009.

These data can be readily used for health policy analyses, research, and to address health program management issues. Observations of trends in quality, cost, and patterns of care can be analyzed across geographic, demographic, and socioeconomic lines. This library will provide for greater insight into maternity and neonatal care and birth outcomes, regional planning of hospital resources, health care infrastructure and provision of services, provide richer data for health care policy development, among many other uses.

VSAC Discussion: No comments.

VSAC Recommendation: Approval

Project Title: Vaccine Safety Data Link (VSD) Study

Principle Investigator(s): Wansu Chen, Stephen Jacobsen, Kaiser Permanente, Biostatistics and Data Development

Project Type: Continuing Research

CPHS Approval: Yes

Project No.: 08-10-60

Expiration: October 1, 2010

File(s) Requested: 2008 Birth Statistical Master File

Requested Identifiers: Names, Certificate Numbers, and Addresses

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

Summary: This request is for 2008 birth and death data. A list of variables is included in the protocol.

The Vaccine Safety Datalink (VSD) is a collaborative project that provides comprehensive medical and immunization histories for more than 5.5 million people annually, which are derived from participating managed care organizations (MCOs) that contain more than 9 million members. Kaiser Permanente Southern California (KPSC) is one of the largest sites in the VSD in terms of covered lives. The VSD was established in 1990 to monitor immunization safety and address the gaps in scientific knowledge about rare and serious side effects following immunization.

The VSD project includes a large linked database (LLDB) that utilizes administrative data sources at each MCO. Each participating site gathers data on membership, demographics, vaccination (vaccine type, date of vaccination, concurrent vaccinations), medical outcomes (outpatient visits, inpatient visits, emergency/urgent care visits), ancillary outcomes (labs, pharmacy, procedures), births, deaths and fetal deaths. Health service use information for each patient is computerized and continuously compiled by each MCO indexed by a unique identifier. Data is collected in a standardized VSD format (as identified by the Center for Disease Control (CDC), organized into files containing demographic information, covariate information, vaccination records, and various types of medical outcome data. Each site encodes their patients' clinical data with unique study identifiers before making the data available to the CDC with weekly and annual updates for merging and analysis, thereby preserving patient confidentiality. Only analyses with aggregate data are reported.

The goals and objectives of the VSD project are as follows:

- To conduct population-based research on immunization safety questions;
- To evaluate immunization safety hypotheses that arise from medical literature, passive surveillance systems, adjustments to immunization-schedules, and introduction of new vaccines;
- To guide national immunization policy decisions;
- To partner with healthcare providers, public health officials, and others to ensure the public has the best available information regarding the risks and benefits of immunizations;

Example VSD studies include: flu vaccine, SIDS, varicella and stroke, flu vaccine effectiveness.

VSAC Discussion: No comments.

VSAC Recommendation: Approval

A draft copy of Data Security Requirements was distributed by Debbie C.