

Vital Statistics Advisory Committee (VSAC)
Vital Records Protection Advisory Committee (VRPAC)
Joint Meeting
Meeting Minutes for Wednesday, November 3, 2010
9:00 AM to 11:00 AM

Attendees

Convener: Linette Scott

Committee Members:

Present: Jonathan Teague

Phone: Debbie Castanon, Peter Abbott, Sue Holtby, Erlinda Valdez,
Krista Hanni, Michelle Baas

CDPH Staff:

Present: Linette Scott, Jane McKendry, Debbie McDowell, Julie
Turner, Krista Christian, Cindy Tanaka-Fong

Phone: Dave Fisher

A. WELCOME

Krista Christian welcomed committee members. Debbie McDowell informed the committee that the use of a tape recorder would be an ongoing process but the tape would be destroyed after the notes were transcribed.

Both David Grant and Debbie Williams were unable to attend the meeting. They had no comments regarding the protocols but David had a question concerning the protocol, *Maternal Health after Fetal/Infant Death*.

B. Approval of minutes from the previous meeting

September 1, 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

4 projects (3 continuing project, 1 new project) were reviewed.

Project Title: "Thromboembolism I California: Who is at Highest Risk?"

Principle Investigator(s): Richard H. White, MD, UC Davis Division of General Medicine

Project Type: Continuing

CPHS Approval: Yes

Project No.: 05-08-60

Expiration: August 5, 2011

File(s) Requested: 2008 Death Statistical Master File

Requested Identifiers: Name, Certificate Numbers, SSN

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

Summary: The focus is on defining the epidemiology and risk factors associated with the development of thromboembolism, particularly deep-vein thrombosis and pulmonary embolism but also stroke associated with atrial fibrillation. Currently the focus is on identifying risk factors for hospital associated venous thromboembolism in medical patients.

There is a great deal of public (TJC) and private (Leapfrog group) pressure on hospitals to reduce the incidence of venous thromboembolism (VTE) among hospitalized patients by using medical prophylaxis (heparin). There is also a pressing need to determine who is at risk for post-operative stroke among patients with chronic atrial fibrillation. The current study may be able to help clinicians know which subgroups of hospitalized patients are at highest risk of developing wither VTE or arterial thromboembolism, both during a hospitalization, or in the ensuing 3-month period.

VSAC Discussion: No comments.

VSAC Recommendation: Approval

Project Title: Maternal Health after Fetal/Infant Death

Principle Investigator(s): Katherine J. Gold, MD, MS, MSN, University of Michigan

Project Type: Continuing

CPHS Approval: Yes

Project No.: 08-04-53

Expiration: April 1, 2011

File(s) Requested: OSHPD Linked PDD/Birth Data

Requested Identifiers: OSHPD files without identifiers

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

Summary: The project is a retrospective analysis of longitudinal health data to measure pre-existing maternal health and long-term maternal health diagnoses, hospitalizations, and health costs after stillbirth or infant death.

Objectives are (1) to evaluate the impact of a fetal or infant death on the mother's mental health; (2) to quantify the effect of fetal or infant death on maternal physical health, health care utilization, and health expenditures. The study will include mothers who have experienced stillbirth or infant death over a two-year period (1994 to 1995), of reproductive age (10-50), in California.

1989-1994 data used to provide pre-event data on medical status to be used to control for pre-existing medical conditions and prior pregnancy outcomes.

1994-1995 are the two years from which we will select mothers bereaved by stillbirth or infant death.

1995-2007 will provide 12 years of information post-event to look at health outcomes. (For some mothers, post-event data will start in 1995 or 1996.)

The research may provide societal benefits by improving understanding of how perinatal bereavement impacts subsequent health mothers and how changes in maternal health after a loss might affect subsequent pregnancies. Such information can be used to help improve interventions for grieving mothers and improve prenatal care in subsequent pregnancies.

VSAC Discussion:

- Clarification is needed on who has access to the data. The protocol mentioned three people having access to the data and subsequently mentioned that the study team and consultants would have access.
- Debbie C emphasized that the risk to participants of loss of confidentiality through disclosure of protected health information. of be minimized through the design study. There are no names in the data as they are removed through the linkage process. Names are available through Health Information and Research Section (HIRS).

- Another concern was the transmission of backup information. OSHPD uses an encrypted password. Data is sent on blank disks and followed up with the password and a description of what is on the disk. This system has been used for several years. OSHPD did not want to prescribe how to manage the security on wide range of computers. They set performance standards for the different types of computers.
- There has been no progress on the committees Debbie C has been working on relating to security issues as they have not regrouped and some of the members have retired. She suggested that VSAC could encourage the SB 13 committee to develop a standard. A generic question would be how to handle security data back-ups from computers? Debbie M suggested that we schedule time in a future meeting to discuss as a committee and look into options such as sending a formal letter to CPHS asking for guidance. Jonathan suggested that both CDPH and OSHPD Information Security Officers (ISO) be included.
- Peter wanted to know if private investigators have guidelines to describing their back up, security, and transmission of information between facility and systems. Jonathan said the OSPHD data request process has a set of guidelines which identifies what a secured environment should look like. OSHPD guidelines may be used as an example since the HIRS application does include detailed information on describing security measures. Peter suggested that an official recommendation of the committee would be to ask staff to be more specific in the descriptive instructions as to what would be presented to committee as part of the protocol.
- Action items:
 - 1) An agenda item in the next or following meeting relating to security and back up systems. The discussion should include information security officers and privacy officers to advise on the application process for data sets.
 - 2) Review the security steps of the OSHPD application for potential inclusion in the vital statistics application.

VSAC Recommendation:

Approval contingent on the following:

- 1) A list of those who will access the data and confirmation that the Principal Investigator will notify VSAC of changes in this list for duration of the project.
- 2) A more detailed description of the backup.

Project Title: The California Family Resource

Principle Investigator(s): Raymond H. White, PhD, Ernest Gallo Clinic and Research Center

Project Type: Continuing

CPHS Approval: Yes

Project No.: 05-08-54

Expiration: June 3, 2011

File(s) Requested: 2008 Birth Statistical Master File

Requested Identifiers: Name, Certificate Number

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

Summary: Ernest Gallo Clinic and Research Center (EGCRC) proposes to create a research resource consisting of a genealogical database of California families. This resource will provide a source of information for genetic, epidemiological, demographic, and public health studies. It will be used to identify families segregating a common genetic trait or disease susceptibility.

The work proposed here is the creation of a research resource and is not, itself, a research project. The purpose is to inform project investigators with respect to the familial relationships of their consented subjects. Each project requesting data will be individually subject to a review and approval process by their university institutional review board (IRB). In addition, projects must obtain prior review and approval from CPHS before approval is granted by the review group at EGCRC.

No subjects will be contacted from this database and project investigators will be provided only those familial relationships found among the individual subjects submitted by the project investigators. Subjects in the project will thus already be known to the investigators and will have been specifically consented with respect to linkage to the genealogical data prior to such linkage.

Project investigators will not have direct access to the database. The approved projects will submit names and other identifying information of their consented subjects and the familial relationships of the subjects will be confidentially reported to the PI.

The database will be password protected and stored in a locked facility accessible to only certified individuals. The database will not be a web-based

application, nor will it be accessible by the Internet or on a network that extends outside the resource facility.

VSAC Discussion:

- Committee members were concerned about rules governing the original product (original data files) vs. rules governing the new product (familial database) and that the new database is produced with significant amount of linkage that goes beyond the data files originally produced. Data files are requested by the PI and a new product is created. Current statute allows more disclosure than the committee is comfortable with.

A suggestion was made to look at protocols that are being prepared for EGRC information to see how the information is being used

VSAC Recommendation: Approval with release of data. The Principal Investigator will be contacted for the following additional information:

- 1) Number of requests received
 - 2) Frequency of database use
 - 3) Who has access to the data?
 - 4) A report on who uses the data and examples of actual requests
 - 5) Clarification of the institutional relationship between UCSF and Gallo
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Project Title: Bevan and Associates LPA, Inc.

Principle Investigator(s): Patrick M. Walsh

Project Type: New Research

CPHS Approval:

Project No.:

Expiration:

File(s) Requested: 2008 Death Statistical Master File

Requested Identifiers: Names, Certificate Numbers

Personal Contact: Yes

Identifiers Released: No

History: New Research Project

Summary: Bevan & Associates LPA, Inc (B&A) intends to use the information derived from this public request as follows:

- (1) Decedents with a particular cause of death will be identified;
- (2) B&A will order from the State of California death certificates related to the above deaths in order to obtain last known addresses for the decedents that have been identified.

(3) B&A will offer legal services to the estate of decedent, next of kin, etc., by sending a communication to the last known address provided on the California death certificate.

The information will only be installed on one PC. Both the CD and the file residing on the PC will be destroyed after the project is completed.

VSAC Discussion:

- This data request highlights the inconsistencies of the restrictions on data files and informational certificates as discussed in a presentation at an earlier meeting. A statutory change may be needed to change the way informational certificates are provided. The committee was uncertain on how this case would be handled without a statutory change. Comments were made that possibly this would result in a legislative proposal.
- This would be added to a future meeting as a formal agenda item in the context of potential alternatives to the current environment.

VSAC Recommendation: Approved with stipulation of contacting the requester for additional information regarding their security. A suggestion was made to ask the requester how many calls they receive from individuals who are not interested.

Questions should be sent to Krista Christian and include Julie Turner as a "cc".

The Health Information and Statistic Planning Division (HISP) has been reorganized to better match services we provide. Previously we had two branches – Center for Health Statistics and County Health Services. Currently, there are 5 branches:

- Vital Records Registration
- Vital Records Issuance and Preservation
- Public Health Policy and Research
- Public Health Informatics
- HISP Administrative Support

This will be the last meeting for Jane McKendry and Debbie McDowell as they will both be retiring at the end of December. They will fill behind but currently there is a hiring freeze.