

Management of the Air Force Health Study's Research Assets

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Presenter Disclosures

David A. Butler, PhD

(1) The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:

No relationships to disclose.



The National Academy of Sciences

Chartered by the U.S. Congress in 1863 as an independent non-governmental institution.



"... the Academy shall, whenever called upon by any department of the Government, investigate, examine, experiment, and report upon any subject of science or art...."



The Institute of Medicine

Component of the National Academies (along with the National Research Council and the National Academy of Engineering).



Chartered in 1970 "to enlist distinguished members of the medical and other professions in the study of problems that affect the public's health."



The Air Force Health Study (AFHS)

Study instigated by US Air Force (USAF) in June 1979.

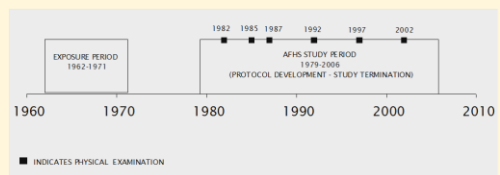
Protocol subjected to ten rounds of review and revision; final version (11) published in January 1982.

Protocol called for a 20-year morbidity study with up to six physical examination cycles in years 1, 3, 5, 10, 15, and 20, plus companion mortality and reproductive studies.

Total study cost (through FY 2006): ~\$143M



AFHS timeline



Source: Disposition of the Air Force Health Study, Figure 2-1, p. 33 (IOM, 2006)



Morbidity study clinical examination health endpoints

- general health
- endocrine
- pulmonary
- immunologic
- neurologic
- renal
- gastrointestinal
- hepatic
- hematologic
- dermatologic
- psychiatric
- neoplasia (cancer)
- cardiovascular
- reproductive

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Morbidity study clinical examination data gathering

- blood draws
- urine and semen collection
- skin and fat biopsies
- stool smears
- spirometry
- chest X rays
- electrocardiograms (ECGs)
- dermatology examinations
- peripheral vascular exams
- neurological assessments
- psychological testing
- many other clinical endpoints

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Morbidity study questionnaire data gathering

- education
- employment
- income
- marital and fertility history
- spirometry
- child and family health
- health habits
- physical activities
- toxic substances exposure
- neurologic health
- military experience
- wartime herbicide exposure

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Morbidity study data assets

Detailed physical, mental, laboratory, and demographic data from 2,758 subjects who participated in at least one exam, including

- ~15,000 chest X-rays
- ~51,000 serum samples
(~2,000 serum dioxin assays)
- ~20,000 whole blood samples
- ~7,000 urine samples
- ~9,000 semen samples
- ~300 adipose tissue samples

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Reproductive outcomes study

Comprehensive reproductive histories ascertained through interviews of current and former wives or partners.

Medical records data gathered from partner and offspring health providers.

Offspring followed through age 18.

Medical data collected and verified for 9,921 conceptions and 8,100 live births.

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Mortality study

Mortality data collected through periodic status queries to major databases: Social Security Administration, DVA, IRS, USAF, National Death Index.

Date of death and reported primary and secondary underlying cause of death coded.

Data collected and analyzed on ~20,000 subjects.

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AFHS contributions to the scientific literature

Papers on

- pharmacokinetics of TCDD and its half-life in humans.
- Vietnam veterans health status.

Papers and reports have influenced determinations of the association between herbicide exposure and health effects in Vietnam veterans.

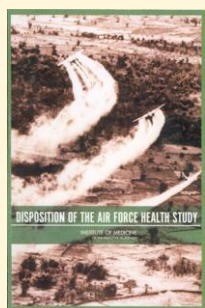
- Type 2 diabetes (diabetes mellitus)
- spina bifida in the children of veterans

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The charge to the IOM committee in Pub. L. 108-183 §602(c) [excerpt]

[Evaluate the] "scientific merit of retaining and maintaining the medical records, other study data, and laboratory specimens collected in the course of the Air Force Health Study after the currently scheduled termination date of the study in 2006".

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2006 IOM report content

Conclusions and recommendations were offered on several topics including ...

- the value of the AFHS research assets,
- alternatives for the future of the assets,
- characteristics of a good custodian of the assets,
- establishing the assets as a resource for researchers, and
- future review of support for the assets.

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Value of the research assets – report conclusions

The AFHS data assets are unique: no other epidemiologic dataset on Vietnam veterans contains as detailed information over as long a time period.

The data collected by the AFHS appear to be of high quality and the specimens appear to be well preserved.

Analysis of the AFHS data assets has contributed to the literature addressing the health of Vietnam veterans.

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Value of the research assets – report conclusions

It follows that there is scientific merit in retaining and maintaining these resources after the study's currently scheduled termination date.

Further study of the AFHS medical records, other study data, and laboratory specimens is thus advisable.

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Events since the release of the 2006 IOM report

Public Law 109-364 directed the Air Force to transfer custodianship of the AFHS's data and biospecimens to the Institute of Medicine at the conclusion of the AFHS.

AFHS sought permission from the Study cohort to transfer the data assets to IOM; over 95% consented.

AFHS transferred study data to IOM shortly before ceasing operations on 30 September, 2007.

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Events since the release of the 2006 IOM report

Because IOM does not have an in-house capability to maintain biospecimens, it sought an alternative location to securely store them; the Air Force Research Laboratory at Wright Patterson Air Force Base (Dayton, OH) agreed to assume this responsibility.

AFHS biospecimens are being maintained at AFRL-WPAFB under the aegis of the IOM.

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Events since the release of the 2006 IOM report

The *Veterans Benefits Improvement Act of 2008* (Public Law 110-389, §803):

- asks IOM to maintain and manage the AFHS assets
- allows "such additional research on the assets ... as [IOM] considers appropriate toward the goal of understanding the determinants of health, and promoting wellness, in veterans."
- directs VA to provide funding to support the maintenance, management and research.

IOM obtained funding from the VA to support an AFHS research assets dissemination initiative in summer 2011.

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IOM's management of the Ranch Hand assets

IOM is implementing a program to promote new and innovative research on the AFHS assets under the sponsorship of the US Department of Veterans Affairs, ...

- soliciting proposals from qualified researchers,
- subjecting submissions to rigorous scientific and IRB review,
- seeking collaborative relationships with successful applicants,
- disseminating available support money to promising proposals, and
- promoting publication of research results.

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IOM's management of the Ranch Hand assets

The first RFP soliciting proposals was posted in May, 2012.

- Proposals were submitted by academic, government, and private sector researchers.
- Successful applicants were notified during summer 2012.
- IOM is currently working with successful applicants to obtain IRB approval of study protocols.
- When all proposals have completed the IRB approval process, information on successful applicants and studies will be posted.

A second solicitation was posted in October 2012; proposals are currently being evaluated.

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Additional information on the AFHS project

A webpage outlining the research facilitation effort and providing links to data dictionaries, applications for data and biospecimen access and other information may be found at:

<http://www.iom.edu/Activities/Veterans/AirForceHealthStudyResearchAssets.aspx>

Expressions of interest in research and questions may be sent to: AFHS-study@nas.edu

The 2006 *Disposition...* report is available for reading and download at:

<http://www.iom.edu/Reports/2006/Disposition-of-the-Air-Force-Health-Study.aspx>

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