

VA Genomic Medicine Program

An Overview

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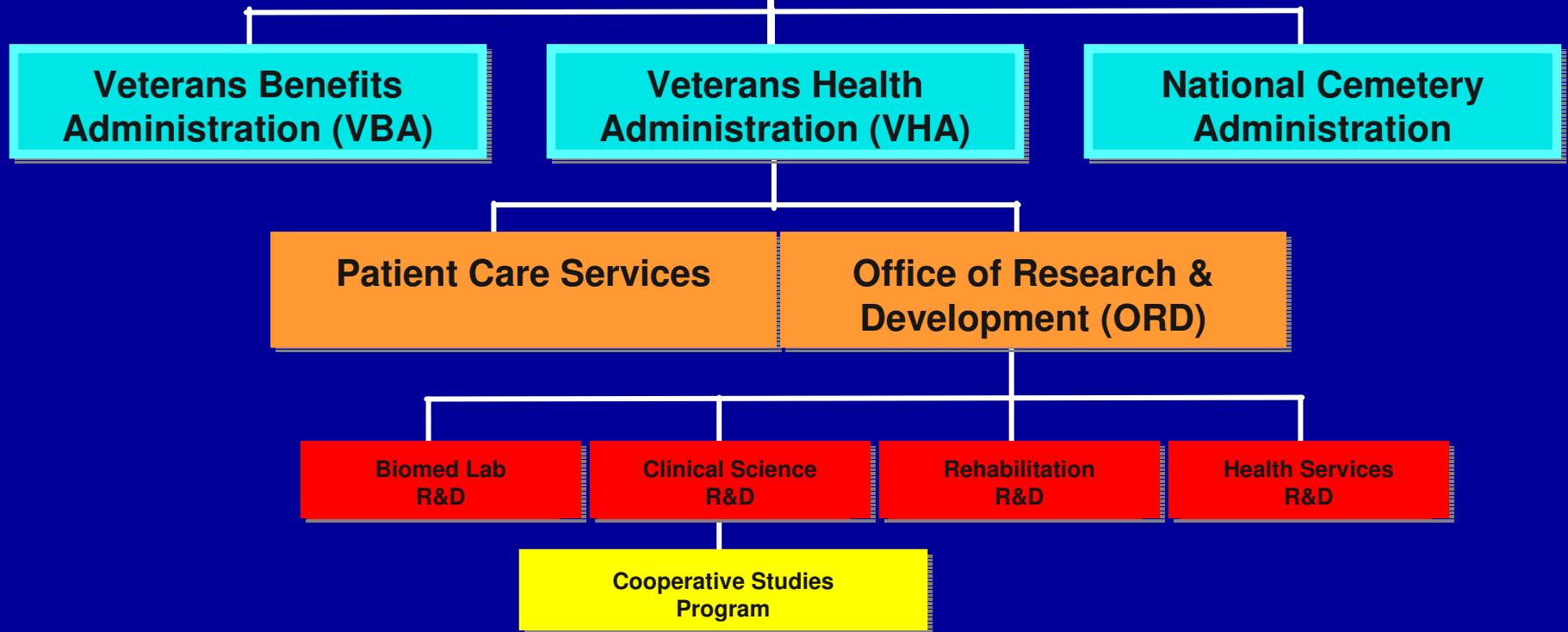
Scientific Program Manager, Genomic Medicine
VHA Office of Research and Development



Facts About VA

- § Largest healthcare system in the US
- § 5.5M unique patients treated in FY 07
- § 153 hospitals, 745 CBOCs, 245 Vet Centers
- § Electronic medical record system
- § Stable population
- § Affiliation with academic institutions
- § Major training hospitals for clinicians

VA Organizational Chart





VA Genomic Medicine Program

- § In 2006, the Department of Veterans Affairs formally launched the Genomic Medicine Program
 - to examine the potential of emerging genomic technologies to optimize medical care for veterans



Advisory Committee

- § As a first step, the Secretary established a distinguished 13-member Genomic Medicine Program Advisory Committee (GMPAC), a FACA committee, to lay the groundwork for the program
- § Members include leaders in the fields of genetics research and medical genetics, genomic technology, health information technology, healthcare delivery, policy, program administration, legal counsel; they come from the public and private sectors and academia; representative of a VSO



GMPAC Members

Wayne Grody, MD, PhD (Chair), Professor & Director of Molecular Pathology Laboratory, UCLA

Michael S. Watson, PhD, FACMG, Exe. Director, American College of Medical Genetics

Geoffrey S. Ginsburg, MD, PhD, Director, Center for Genomic Medicine, Duke University

Muin J. Khoury, MD, PhD Director, NOPHG, CDC

Daniel R. Masys, MD, Prof. & Chair of Biomedical Informatics, Vanderbilt University

Jonathan B. Perlin, MD, PhD, MSHA, FACP, CMO and Senior Vice-President, HCA Healthcare

Margaret McGovern, MD, PhD, Prof. Human Genetics at Mount Sinai

Peter G. Traber, MD, President & CEO, Baylor College of Medicine

Annette Taylor, MS, PhD, President, Director, Founder, Kimball Genetics

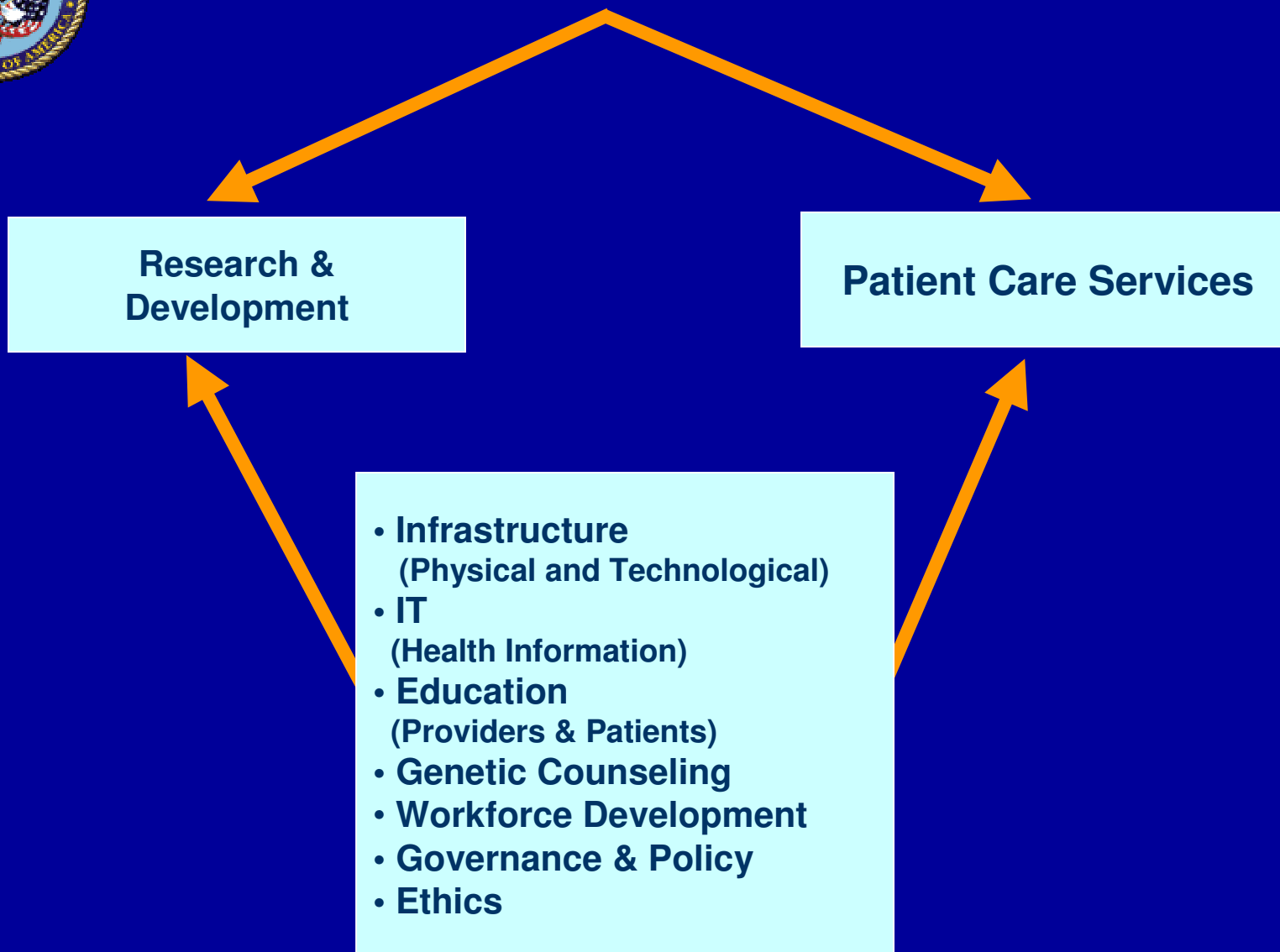
Brion C. Smith, Col USA (Ret.) DDS, DOD Defense DNA Registry

David S. Gorman, Exe. Director, Disabled Veterans of America

Christine Q. Burt, President CQB Associates, Denver, CO



Implementation





Challenges

- § Large operationally decentralized system
- § Variability in infrastructure, operations, capabilities
- § OIT distinct from VHA
- § Budget constraints
- § Rapidly evolving technologies
- § Will veterans participate?



Veteran Consultation Project

- § In 2007, VA launched a consultation project to assess veterans' knowledge and attitudes about genomic medicine
 - Interagency agreement with NHGRI and conducted under a cooperative agreement by the Genetics and Public Policy Center (GPPC) at Johns Hopkins University
 - PI Kathy Hudson
 - Focus Groups and Survey



Assessing Veteran's Attitudes About the Genomic Medicine Program

- § 10 focus groups in five locations of diverse participants in 2007
 - Solicit a wide range of perspectives
 - Identify themes and issues
- § Survey of 931 participants in 2008
 - To test themes and messages from focus groups
 - Paper describing findings in press in the journal *Genetics in Medicine*



Survey Results

- § 83% said program should be done
- § 71% said they would participate
- § 61% also said they would:
 - Attend a 1/2 day exam
 - Allow medical records from non-VA health care to be added to the database
 - Have follow up exams over time



Survey Results Con't

- § Willingness to participate was associated with
- Attitudes about research
 - Attitudes about helping and history of previous “altruistic behaviors”
 - Curiosity about genetics
 - Satisfaction with VA



Where Do We Start?

- § What is available within the VA system?
- § Build in house capability or leverage infrastructure at affiliated universities and contract with industry?
- § Research agenda?



Cooperative Studies Program

- § Large multisite clinical trials
- § Four clinical trials coordinating centers
- § Four Epidemiology Research and Informatics Centers (ERICs)
- § Health economics research center
- § Pharmacy coordinating center
- § Central IRB



Infrastructure Development

- § DNA Bank/Biorepository (Boston VA)
 - About 30,000 blood samples collected as part of multi-site VA clinical trials (Cooperative Studies Program), with capacity for banking 100,000 samples
 - 6000 DNA samples
 - RTS storage system and robotics
 - Shadow bank
- § DNA Coordinating Center at Palo Alto VA (link to clinical information and data analysis)
- § Tissue repository (Tucson VA)
 - Brain collection, tissue blocks



Infrastructure Development Con't

- § Established Pharmacogenomics Analysis Laboratory in Little Rock, AR
 - Clinical Laboratory Improvement Amendments (CLIA) certified research genomics laboratory
 - Illumina platform

- § Genomics Research Core at the San Antonio VAMC (funded)



Infrastructure Development



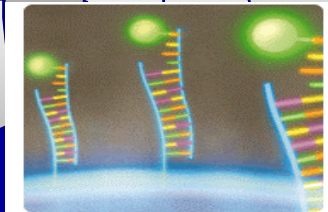
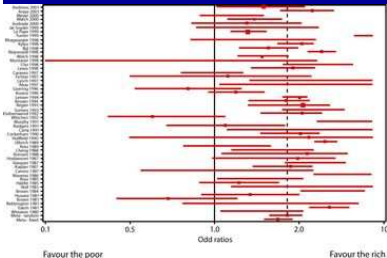
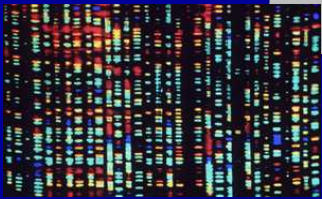
Palo Alto, CA

Philadelphia, PA

Tucson, AZ

Little Rock, AK

Boston, MA





IT Infrastructure Development

§ GenISIS

- Genomic Information System for Integrative Science
- Louis Fiore, MD

§ VINCI

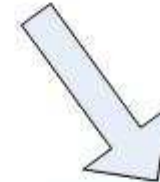
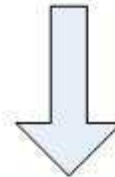
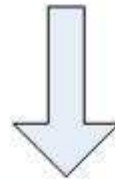
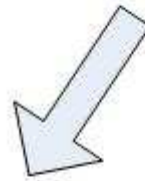
- Veterans' Informatics, Information & Computing Infrastructure
- Jonathan Nebeker, MS MD



GenISIS

MAVERIC

MASSACHUSETTS VETERANS EPIDEMIOLOGY
RESEARCH AND INFORMATION CENTER



Epidemiology
(ERIC)



Core Specimen
Repository



Clinical Trials
Coordinating Center
(CSP CC)



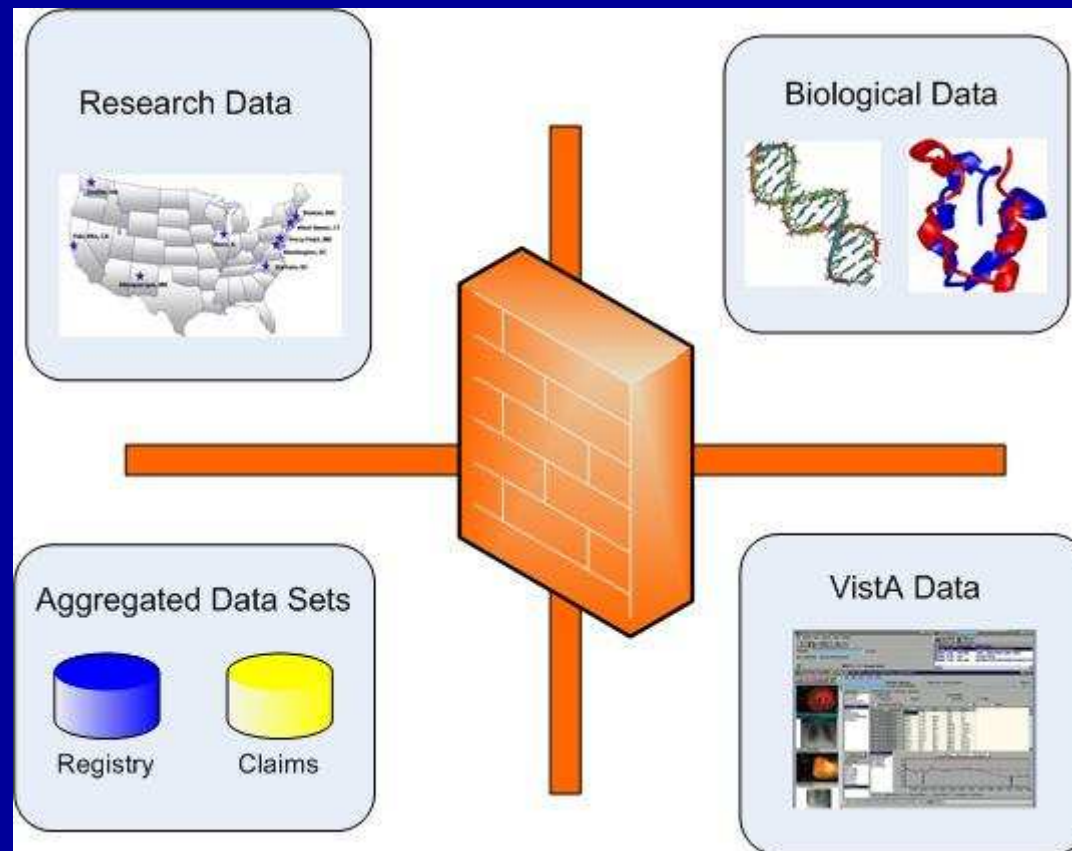
Biomedical
Informatics





GenISIS

Current Research Paradigm





Current Model

- Hypothesis testing
- Discipline-driven
- Targeted data collection
- Single use of “owned” data in silos

Emerging Model

- Comprehensive data collection and retention
- Data analyses
- Hypothesis ***generation (and validation)***
- Interdisciplinary (Team science)
- Reuse of data



GenISIS

- § Securely gather, integrate, and analyze patient information
- § Facilitate discovery research through shared expertise
- § Repurpose data and results for secondary analyses
- § Validate genomic medicine findings
- § Integrate findings into clinical medicine



GenISIS Vision Statement

§ Short Term (Research focused):

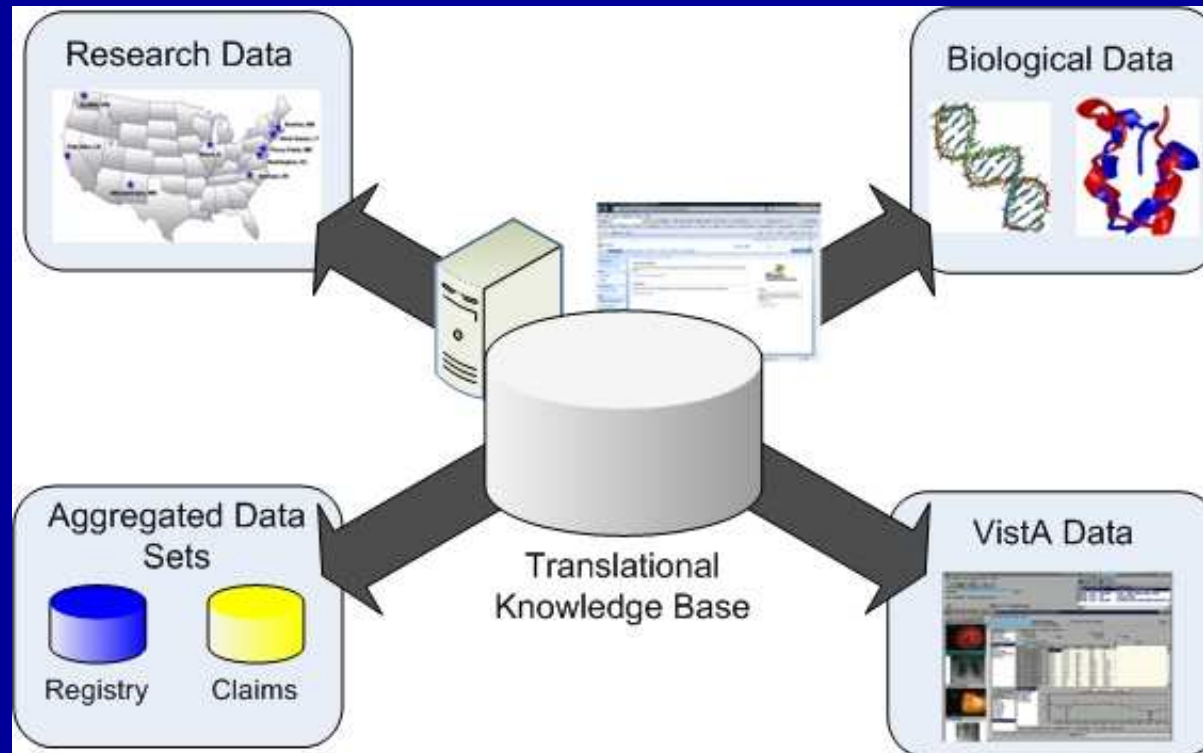
- To create and support a knowledge base that will facilitate independent research projects and allow for collaborative repurposing of data and results.

§ Long Term (Patient care focused):

- Integration of clinical care and research activities for improved patient outcomes and research efficiencies



GenISIS



Database, Query Interface, Analysis Environment, Governance



VINCI



Veterans'
Informatics,
iNformation, &
Computing
Infrastructure



VINCI Objectives

- § Integrate existing data bases
- § Integrate new data
 - Extracted information
 - Extracted meaning
- § Provide a secure, high-performance computing environment
- § Provide access to data
- § Maintain customer support and outreach programs



Research Agenda

- § Informed by healthcare needs of veterans
- § GMPAC
- § Scientific Advisory and Working Groups (HNPPCC, endocrine tumors)
- § Workshops
- § Investigator initiated as well as Program directed



Genomic Research Projects

- § Genetic epidemiology of ALS (ongoing)
- § Genetics of PTSD (pilot funded)
- § Serious mental illness cohort
 - Schizophrenia & Bipolar Disorder (in review)
 - Reference Cohort (pilot funded)
- § Diabetes
- § Pharmacogenomics



Ongoing Genomics/ Genetics-Related Projects

- § VA funds 142 investigator-initiated Merit Review projects related to genetics/genomics
 - wide spectrum of conditions prevalent in veterans such as schizophrenia, PTSD, bipolar disorder, Alzheimer's, cardiovascular disease, diabetes, cancer (prostate, breast, colon, bladder, lung), substance abuse, stroke, chronic viral infections, autoimmune disorders, Gulf War Illness, etc.
 - Genetic-association, pharmacogenomics
 - Candidate gene analysis, SNP analysis, linkage studies, microarrays, siRNA, gene expression

GenISIS

Research



Translational

Pharmacogenomics



HNPCC

Education

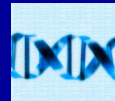
Stats



Spent samples



DNA bank



VINCI



Short-term goals

- PTSD
- ALS
- Schizophrenia/
mental illness

Long-term goals

- Diabetes
- Pharmacogenomics
- Women's Health

GWAS

Patient
care
services



VistA
My HealthVet



Challenges Going Forward

- § Launching an integrated system to facilitate genomics research as well as translation to clinical care of veterans
- § Governance and policy (access to samples and data etc)
- § Education (effect on patient outcome; point of care tools)
- § Interoperability



Education Initiative

- § Development of educational programs and tools for physicians and other health professional
 - Collaboration between VA Employee Education Services and National Coalition for Health Professional Education in Genetics (NCHPEG)
 - Web-based tool for heritable colorectal cancer
 - Health-provider centric



Interactions With Other Organizations

§ The VA interacts, discusses and actively participates in:

- Pharmacogenetic Research Network
 - supported by several NIH Institutes
- National Human Genome Research Institute (NHGRI)
- The Institute of Medicine Roundtable on Translating Genomic-Based Research for Health
- The American Health Information Community (AHIC) and AHIC Successor (AHIC2)
- HHS and CDC- Family History Tool Working Group