Million Veteran Program (MVP): A Mega-Cohort within a Healthcare System

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Professor of Medicine, Harvard Medical School
Transformative “Big Data” Problems
Evolution of Epidemiology

• Descriptive phase

The Black Death

Bruegel's
*Triumph of Death*

C. 1556
Evolution of Epidemiology

- Descriptive phase

The Black Death

Bruegel's
Triumph of Death
c. 1556
Evolution of Epidemiology

- Descriptive phase

The Black Death

Bruegel's
Triumph of Death
c. 1556
Evolution of Epidemiology

- Descriptive phase
- Pre-analytic phase
Evolution of Epidemiology

- Descriptive phase
- Pre-analytic phase
- Analytic phase
Evolution of Epidemiology

- Descriptive phase
- Pre-analytic phase
- Analytic phase
  - Case-control, Cohort studies, RCTs
Evolution of Epidemiology

• Descriptive phase
• Pre-analytic phase
• Analytic phase
  – Case-control, Cohort studies, RCTs

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Evolution of Epidemiology

- Descriptive phase
- Pre-analytic phase
- Analytic phase
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Evolution of Epidemiology

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Evolution of Epidemiology

• Descriptive phase
• Pre-analytic phase
• Analytic phase
  – Case-control, Cohort studies, RCTs
• Super Analytic Phase: Mega-Biobanks
Nesting Population Research in the VA Healthcare System

VA ideal setting for nested large-scale population research

- Stable and willing veteran population of 8 million using the system each year
- Outstanding electronic medical record; fully integrated; data reaching back as far as 20 years; access to CMS and NDI data
- Research infrastructure with diverse expertise
- Prototypes for health system based research:
  - Million Veteran Program
  - Pragmatic trial of HCTZ vs Chlorthalidone
Million Veteran Program (MVP)

- Enroll up to one million users of the VHA into an observational mega-cohort
  - Collect health and lifestyle information
  - Blood collection for storage in biorepository
  - Access to electronic medical record
  - Ability to recontact participants
MVP Organizational Structure

Million Veteran Program (MVP): A Partnership with Veterans

02/07/2011

VA Central Office / Office of Research and Development

- Genomic Medicine Program
- GMPAC
- Cooperative Studies Program
- Genetics CSSEC
- VA Central IRB
- VA Communications
- MVP Executive Committee

MAVERIC

- Recruitment Center
- Mailing Center
- Call Center

GenISIS

- Project Management
- VA Central Biorepository

Participating VAMC

- Local Site Investigator, Research Coordinator, Research Assistant

Outside Vendor

- Mailing/Scanning Center

Study Planning

- ERIC’s
- CSP CC’s

Albuquerque CRPCC

- Admin Center
- Scanning Center

Investigators VA Non-VA

- PAL Keck Lab
- Other laboratories

Veteran

Data Sources: VA, Medicare, etc.
MVP Design and Implementation

• Recruitment and Enrollment
• Biorepository
• Biochemical Analysis
• IT/Informatics
• Epidemiology and Phenotyping
• Current Projects
MVP Recruitment and Enrollment

• Invitational Mailing
  – Invitation letter, Baseline Survey, MVP Brochure

• Appointment Mailing
  – Appointment letter, Informed consent language

• Study visit procedures
  – Informed consent/HIPAA, Blood collection

• Thank you Mailing
  – Thank you letter, Lifestyle Survey
Baseline Survey

Collects basic demographic, health, and lifestyle information including:

- Health status
- Military experience
- Medical history
- Healthcare utilization
- Family pedigree
- Family history of disease
MVP Study Visit

• Study visit procedures
  – Obtain consent/HIPAA
  – Collect blood specimen
  – Walk-ins given printed baseline form
  – Given MVP pin

• All aspects are automated using SharePoint and GenISIS.
Thank You / Lifestyle Survey

- Thank you letter
- Lifestyle Survey
  - Occupational history
  - Combat history
  - Exercise habits
  - Mental health
  - Environmental exposures
  - Dietary habits
Open at a total of 58 sites

- Wave rollout
- Active facilities
  - 51 main sites
  - 60 satellite facilities
- 5 sites launching in 2016
  - Fayetteville, Muskogee, Providence, Salem, San Francisco

= Actively Recruiting
= Closed to Recruitment
# MVP Recruitment to Date

<table>
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<tr>
<th>Metric</th>
<th>Value</th>
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<tr>
<td>Invitation mailings sent</td>
<td>3.7 Million</td>
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<tr>
<td>Expressed interest by mail</td>
<td>16%</td>
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<tr>
<td>Optout</td>
<td>13%</td>
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<tr>
<td>Completed Baseline Surveys</td>
<td>580,000</td>
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<tr>
<td>Consented Veterans</td>
<td>509,000</td>
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<tr>
<td>Specimens in Lab</td>
<td>506,000</td>
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<tr>
<td>Unscheduled (proportion)</td>
<td>40%</td>
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<tr>
<td>Upcoming appointments</td>
<td>8,000</td>
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<tr>
<td>Call volume</td>
<td>Over 650,000</td>
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MVP Enrollees: Age and Gender

**Age**

- The bar chart shows the age distribution of MVP Enrollees compared to the VHA Population.
- The vertical axis represents the percentage, and the horizontal axis represents different age groups.

**Gender**

- The bar chart compares the gender distribution of MVP Enrollees to the VHA Population.
- The blue bars represent VHA Population, and the green bars represent MVP Enrollees.
- The chart indicates that the majority of MVP Enrollees are male.

**VHA Population**

- MVP Enrollees: Age and Gender
- (n=145,270)
MVP Enrollees: Top 15 Self-Reported Diseases and Conditions

- Coronary artery/heart disease: 13%
- PTSD: 14%
- Enlarged prostate: 16%
- Other skeletal/muscular problem: 16%
- Colon polyps: 17%
- Sleep apnea: 19%
- Other arthritis: 18%
- Cataracts: 21%
- Diabetes: 21%
- Depression: 22%
- Tinnitus: 25%
- Hearing loss: 24%
- Acid reflux/GERD: 26%
- High cholesterol: 44%
- Hypertension: 49%

n=145,270
Biorepository

- Full service biorepository
- Study planning to analysis
- Develop study specific SOPs
  - Pilot studies
  - Collection kits
  - Trained sites coordinators
  - Process specimens and prepare shipment to analytic laboratory
Specimen Collection

- 4 ice packs must be in the freezer the day before bloods will be drawn
- After obtaining consent, scan barcode on EDTA blood tube to enter blood ID into blood collection form
- Draw blood filling the tube
- Rescan tube
- Refrigerate until shipping
Ongoing Genetic Analyses

• Whole genome sequencing: 2K
  – ALS, Exceptional age
• Whole exome sequencing: 24K
  – Schizophrenia, Bipolar disorder, African Americans
• SNP array (750K SNPs): 500K (2014, 2015, 2016)
  – Randomly chosen from current enrollees
Axiom MVP Biobank Array

23K eQTLs Markers
- Selected from 1000 Genomes database, NCBI/NIH GTEx eQTL database and Axiom Genomic Database
- ~7K tiled and ~23K pair-wise tagged

70K Novel Exome/LOF Variants
- New Exome/LoF Content from 26K Exome Sequencing initiative
- High Confidence LOFs
- No Singletons
- Known disease-causing mutations
- Potential Splice Variants
- 30K INDEL/45K SNPS

400K multiethnic Grid
- polymorphic CEU, YRI, LAT
- Impute v2-based Selection

eQTLs

New Exome/LoF Content

Imputation GWAS grid

2K variants
- selected from:
  - Pharmaadme.org
  - PharmaGKB.org

ADME Content

VA Custom Disease Specific Variants

Exome Content

264K cSNPs & InDels Variants
- 197K non-synonymous
- 18K InDels
- 15K compatibility SNPs
  - GWAS, ESP, HLA, Fingerprint, mtDNA, Y chr, miRNA targets, AIMS

Axiom MVP Biobank Array
723K
CDW System Facts:
- Source system: VISTA: 130, Other Major Systems: 7
- Data facts: Domains of information: 68, Rows of data: 2+ Trillion, Columns of data: 22,000+, Tables of data: 840+
- Active Users: 30,000/Month, Vibrant user community, Active governance process, Data quality program

CDW Sample Data Facts:
- Unique Veterans: 22 million, Outpatient encounters: 2.4 billion, Inpatient admissions: 17 million, Clinical orders: 4.5 billion, Lab tests: 7.7 billion, Pharmacy fills: 2.2 billion, Radiology procedures: 202 million, Vital signs: 3.3 billion, Text notes: 3.2 billion

CDW Analytic Enclaves:
- GP: General Purpose, BI: Business Intelligence, AN: Analytics and Informatics, RD: Health Services R&D (VINCI), FR – Field Reporting

CDW Analytic Capabilities:
- Primary/Secondary/Data Mart Structures, Data Standardization, Metadata Services, Business Intelligence Reporting & Dashboards Tools, Geospatial Mapping Tools and Images, SAS/Grid High Performance Compute Grid, Natural Language Processing Engines, Hadoop Cluster
Patients: 22 M

- Lab Results: 7.7B
- Clinical Orders: 4.5B
- Immunizations: 71 M
- Appointments: 1.4B
- Pharmacy Fills: 2.2B
- Clinical Notes: 3.2B
- Health Factors: 2.2B
- Encounters: 2.4 B
- Radiology Proc: 202 M
- Vital Signs: 3.3B
- Consults: 315 M
- Admissions: 17 M

68 Blocks

Domains: 15/68
The Future: “Big Data”

More and more data is becoming available for health care research: is it a blessing or a curse?
The Future: “Big Data”

More and more data is becoming available for health care research: is it a blessing or a curse?

- Sometimes, data warehouses resemble landfills more than libraries
- Apply the 4 C’s: collect, catalogue, clean and curate.
MVP Data Universe

Self-reported MVP surveys

VA - Clinical VINCI, CDW/NDS

MVP Participant

Biospecimen

Molecular Data

Non-VA NDI, CMS
Data Sources

MVP Data

• Self-Reported Survey Data:
  – Lifestyle Survey Data (Personal Information, Well-Being, Activity, Health, Military Experience, Dietary Intake, Medication, Habits)
  – Baseline Survey (Health, Military Experiences, family medical history)
• Genetic Data
  – Genotype data
  – Sequence data

Other Data

• VA Healthcare System Data
• Other Data
  – National Death Index (NDI)
  – Centers for Medicare and Medicaid Services (CMS)
  – Department of Defense
VA Data Sources

- Corporate Data Warehouse Databases
- National Patient Care Databases
- Vital Status
- Decision Support System
- National Data Extract
- Beneficiary Identification Records Locator (BIRLS) death file
- New England VISN-1 Pharmacy files
- Outpatient Clinic File (OPC)
- Patient Treatment File (PTF)
- Inpatient and Outpatient Hospitalizations

- Clinic Inpatient and Outpatient Visits
- Diagnosis (ICD-9) codes
- Procedure (CPT) codes
- Pharmacy data and laboratory data

- Pharmacy Benefit Management (PBM) system database
- OEF/OIF and OND Roster
- VA Clinical Assessment Reporting and Tracking (CART)
- Veterans Affairs Surgical Quality Improvement Program (VASQIP)
- Veterans Affairs Central Cancer Registry (VACCR)

National Data Systems (NDS)

Special Data Access w/ Data Steward
System Architecture

Data Warehouse

- Survey Data
- Clinical Data
- NDI, CMS
- Molecular data

Vendor

VA

Non VA

Molecular Lab

Honest Broker

Consent Manager

Query Mart

Query Portal

Analysis Environment

Study Mart

Access Authorization by Governance System

Researcher
MVP Phenotyping Activities

Core Variables
- Demographics
  - Age
  - Sex
  - Race
- Laboratory values
  - Total cholesterol
  - HDL, LDL
  - Albumin
  - Serum creatinine
  - Triglycerides
- Medications
- Other characteristics
  - Blood pressure
  - Height/weight/BMI
  - Smoking
  - Alcohol consumption
  - Combat exposure

Complex Phenotypes
- Disease
  - Myocardial infarction (MI)
  - Stroke
  - Unstable angina with revascularization
  - Acute congestive heart failure
  - Death from cardiovascular disease
  - Vascular procedure
  - Posttraumatic stress disorder (PTSD)
  - Schizophrenia
  - Bipolar disorder
  - Traumatic brain injury
  - Depression
  - Vascular dementia
  - Cognitive impairment
  - Type 2 diabetes mellitus
- Other
  - Creatinine trajectory
  - Glucose trajectory

Algorithm Development
Validation Methods
3-Tier 7-Step Phenotyping Process

Tier I
Algorithm (T1A)

1. Initial cohort (Likely cases, possible cases, likely non-cases)
2. Literature Search
3. Structured Data
4. Phenomic Database
5. Data Processing Pipelines (NLP, data curation, extraction, augmentation, etc.)
6. Refined Algorithm (T2A)
7. Refinement of T1A and Phenomic database to derive T2A

Tier II
Algorithm (T2A)

1. Step 1: Define initial working algorithm (T1A)
2. Step 2: Create study cohort and apply T1A
3. Step 3: Create Annotation Data Set
4. Step 4: Create Phenomic Database through Data Processing Pipelines
5. Step 5: Derive T2A
6. Step 6: Evaluate T2A to formulate T3A
7. Step 7: Develop probabilistic model and assign caseness

Tier III
Algorithm (T3A)

1. Development of a probabilistic model
2. Assignment of quantitative “caseness”

Prior Knowledge

Table:

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<th>Step 1: Define initial working algorithm (T1A)</th>
<th>Step 5: Derive T2A</th>
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<tr>
<td>Step 3: Create Annotation Data Set</td>
<td>Step 7: Develop probabilistic model and assign caseness</td>
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<tr>
<td>Step 4: Create Phenomic Database through Data Processing Pipelines</td>
<td>Deposit resulting algorithms to a central Phenotype Library</td>
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Our Vision for Phenotyping in MVP: A New Approach

Semi-automated phenotyping combines features of manual and automated phenotype development.
Overview of semi-automated method for developing EMR phenotypes

**Step 1:** Create “Phenotype X Mart”

**Step 2:** Develop gold standard training set

**Step 3:** Identify variables important for predicting Phenotype X
   - Codified + narrative data (extracted using natural language processing)

**Step 4:** Develop algorithm
   - Logistic regression with LASSO

**Step 5:** Validation

Current Projects

• Alpha test
  – Schizophrenia and Bipolar Disorder
  – PTSD
  – Gulf War illness

• Beta test
  – Funding approved for 5 consortia of qualified VA investigators using only MVP Chip genotype data (200K+)
  – Research focus on:
    • Cardiovascular risk factors
    • Cardio-metabolic disorders
    • Kidney disease progression
    • multi-substance use
    • Macular degeneration
Hypertension Treatment Significantly Reduced Mortality and Morbidity in the VA

Veterans Administration Cooperative Study Group on antihypertensive agents *JAMA* 1970;213(7):1143-1152.
Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Care providers using EMR
Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Care providers using EMR

Cohort Identification Centrally
Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Care providers using EMR

Cohort Identification Centrally → Phone Enrollment & Consent
Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Cohort Identification Centrally → Phone Enrollment & Consent → Randomize

Care providers using EMR
Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Care providers using EMR

1. Cohort Identification Centrally
2. Phone Enrollment & Consent
3. Randomize
4. Intervention Delivered by mail
Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Care providers using EMR

Cohort Identification Centrally → Phone Enrollment & Consent → Randomize → Intervention Delivered by mail

Data Capture By EHR & CMS
Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Cohort Identification Centrally

Phone Enrollment & Consent

Randomize

Intervention Delivered by mail

Data Capture By EHR & CMS

Study DB

Analysis

Care providers using EMR

Study team using traditional scientific tools
Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Care providers using EMR

Cohort Identification Centrally → Phone Enrollment & Consent → Randomize → Intervention Delivered by mail

Data Capture By EHR & CMS → Clinical Decision Support

Study DB → Analysis

Study team using traditional scientific tools
Collaboration with PMI-Cohort Program
eMERGE Phenotypes

- ACE Inhibitor (ACE-I) induced cough
- ADHD phenotype algorithm
- Appendicitis
- Atrial Fibrillation
- Autism
- Cardiac Conduction (QRS)
- Cataracts
- Clopidogrel Poor Metabolizers
- Crohn's Disease
- Dementia
- Diabetic Retinopathy
- Drug Induced Liver Injury
- Heart Failure
- Height
- Herpes Zoster
- HDL
- Hypothyroidism
- Fibromyalgia in an RA cohort
- Lipids
- MidSouth CDRN CHD Algorithm
- Multiple Sclerosis
- Peripheral Arterial Disease
- Red Blood Cell Indices
- Rheumatoid Arthritis
- Severe Early Childhood Obesity
- Sleep Apnea Phenotype
- Type 2 Diabetes – 2 phenotypes
- Warfarin dose/response
- White Blood Cell Indices
CHARGE Consortium Working Groups

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<td>Blood Pressure</td>
<td>Lipids</td>
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<td>Musculoskeletal</td>
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<td>Depression</td>
<td>Natriuretic Peptides</td>
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Large-Scale Biobanks

Europe
- UK Biobank
- Icelandic Biobank
- Banco Nacional de ADN
- GenomEUtwin
- Finnish biobank
- Swedish biobank
- German biobank, KORA
- UK DNA Banking Network & British biobank
- Estonian biobank
- Generation Scotland
- HUNT (cardiovascular) & Biohealth
- EPIC, European (cancer)
- Danubian Biobank Consortium
- GATiB Genome Austria Tissue Bank
- Biobank Hungary

United States
- MVP
- PMI CP
- Kaiser
- Geisinger
- BioVU
- Marshfield Clinic
- American Cancer Society
- Academic Medical Centers: Howard University African Diaspora, Mayo Clinic, Partners Healthcare, Chicago area consortium, etc.
- Health system consortia: eMERGE
- Large scale cohorts in consortia: CHARGE, NCI Cancer Cohort Consortium

International
- Kadoorie (China)
- Mexico City
- Gambian National DNA Bank (Africa)
- H3 Africa
- KHCCBIO (Jordan)
Acknowledgments

VA Central Office
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MVP Steering Committee and Subcommittees

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MVP Information Center – Canandaigua, NY
Annie Correa; Melissa Juhl; George Barzac III; Liam Cerveney; Anne Van Patten; Jonathan Martinez; Eileen Loh-Fortier; Jessica Marino

MVP Local Site Investigators
“I enrolled in The MVP because I thought it would help Veterans get even better healthcare in the future.”

Gennaro F. Carbone
U.S. Marine Corps
Gulf War Era
VA Connecticut Healthcare System
“I have always known someone in the family with Diabetes or Hypertension. I eagerly volunteered to participate in MVP so I can help medical researchers better understand how genes influence diseases. One blood draw is all it took... yet the potential to contribute to scientific discoveries is enormous!”

Priscilla Bryant
U.S. Army
1974 - 1994
VA Palo Alto Health Care System
“Knowing that I would be helping other GI’s is the reason I am part of the Million Veteran Program.”

Mons S. Sjaastad
U.S. Army
Korean War Era
VA Connecticut Healthcare System
“With malice toward none, with charity for all, with firmness in the right as God gives us to see the right, let us strive on to finish the work we are in, to bind up the nation’s wounds, to care for him who shall have borne the battle and for his widow, and his orphan, to do all which may achieve and cherish a just and lasting peace among ourselves and with all nations.”

Lincoln, March, 1865

Thank You!
Thank You!