Precision Medicine: Understanding How Genomics and Big Data Are Enabling the Right Care for the Right Person at the Right Time

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Disclosures

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- Foundations and Non-profits: Board member Aspirin Foundation
- Advisory Boards: UKBiobank, TOPMed (chair), Alberta Tomorrow Project (chair)
- Society membership: AMA, ACC, AHA, Royal College of Physicians

- Sports teams: WVU Mountaineers, Patriots, Red Sox, Celtics, Bruins, Revolution
- Hobbies: running, biking, swimming, cooking, wood working, wine making

Transformative "Big Data" Problems in Science

What is Big Data?
Information with high volume, high velocity and/or high variety that requires new forms of processing to allow enhanced knowledge generation, decision making and process optimization.

FINANCIAL SERVICES — RETAIL — EDUCATION — ENERGY — HEALTHCARE — ENTERTAINMENT — COMMUNICATIONS — GOVERNMENT — MANUFACTURING — TRANSPORTATION — NATURAL RESOURCES — INSURANCE
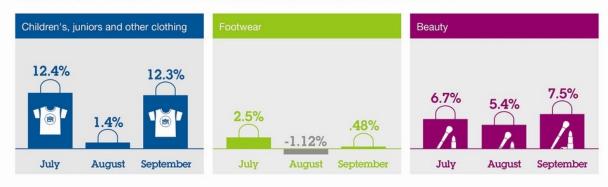
Health care is a late comer to using big data analysis

Example: Retail
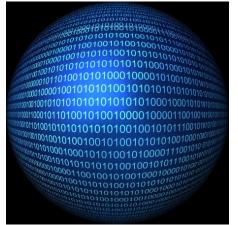
Riding lawn mower owner phenotype

Example: Credit card companies

Call to collect info about transaction – within 30 seconds

Questions:
- Do you have your card? yes
- Are you in Ireland buying gas at….? yes
- Would you like to keep your card active? yes

Using data beyond its intended purpose: identification of US special forces

- Fitness tracking app Strava gives away location of secret US army bases

- **Data about exercise routes shared online by soldiers can be used to pinpoint overseas facilities**

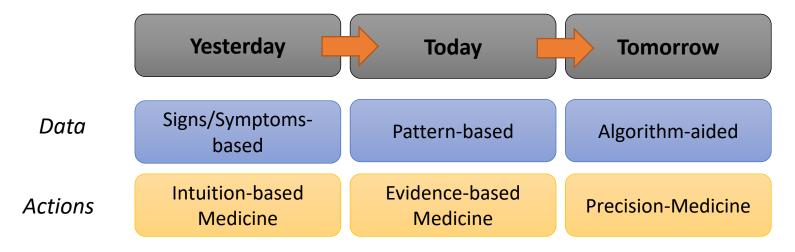# The promise of big health data: To improve health, prevent and treat disease by empowering providers, patients and health systems with better access to and use of health information.

	Yesterday →	Today →	Tomorrow
Data	Signs/Symptoms-based	Pattern-based	Algorithm-aided
Actions	Intuition-based Medicine	Evidence-based Medicine	Precision-Medicine

Electronic Health Records

Big Health Data

Community Health Workers
Primary Healthcare
Diagnostic Labs
Hospitals
Pharmacies
Patients / Consumers

Single Sign-On

Electronic Health Record

Patient Index
Provider Index
Public Health / Regional / National Systems

Sequencing

Biotechnology

Genotype

Proteomics

Big Omics

Metabolomics

Metabolomics

Proteomics

Genomics

Physiological Influence

Environmental Influence

Metabolome

Proteome

Genome

Big Computing

Moore's Law - 2005

Transistors Per Die

10^{10}
10^9 — 1G 2G
10^8 — 512M, Itanium™ 2 Processor
10^7 — 256M, Itanium™ Processor
10^6 — 64M 128M, Pentium® 4 Processor
10^5 — 16M, 4M, Pentium® III Processor
10^4 — 1M, Pentium® II Processor
10^3 — 256K, Pentium® Processor
10^2 — 64K, 486™ Processor
10^1 — 16K, 386™ Processor
10^0 — 4K, 80286

8080 8086
8008
4004

◆ 1965 Data (Moore)
■ Memory
◆ Microprocessor

1960 1965 1970 1975 1980 1985 1990 1995 2000 2005 2010

Source: Intel
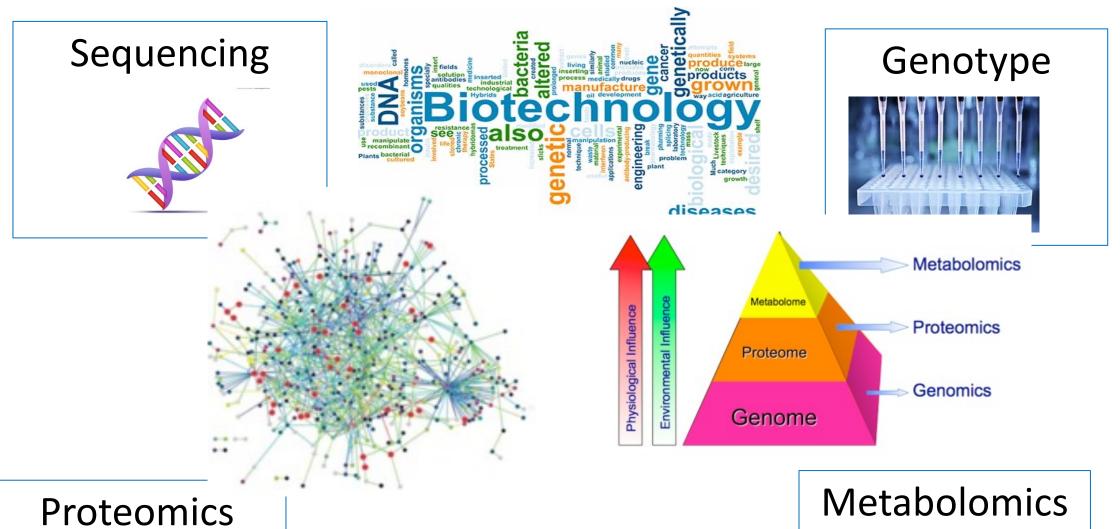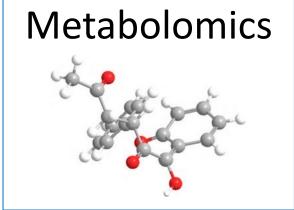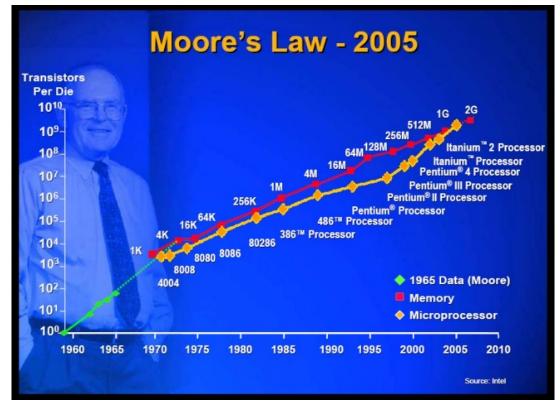
Precision Medicine

- A brief history of data science
- Big data analytics in an integrated health care system:
    - Discovery
        - Observational Epidemiology, Trials
    - Quality Improvement
    - Building mega cohorts for research and clinical care (MVP)
- Challenges in using big data (Data challenges, AI, etc.)
- The future

Evolution of Data in Understanding Disease Relationships

- **Descriptive phase**

- **Pre-analytic phase:**
  - **Cases, Early interventions**

- **Analytic phase**
  - **Case-control, Cohort studies, RCTs**
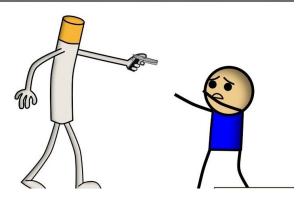
- **Super Analytic Phase**
  - **Scalable**
  - **Big health**
  - **Super c**
  - **Mega-c**

The Black Death

Smoking Kills

BRITISH MEDICAL
LONDON SATUR

STREPTOMYCIN TREATMENT
A MEDICAL RESEAR
The following gives the short-term results of a c
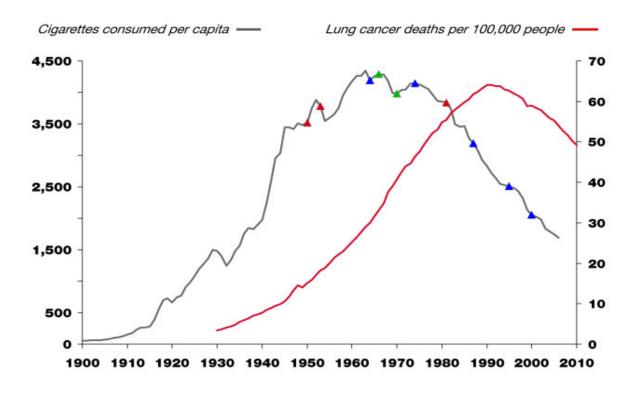
SMOKING KILLS

Which industry first figured out that smoking took years off your life?

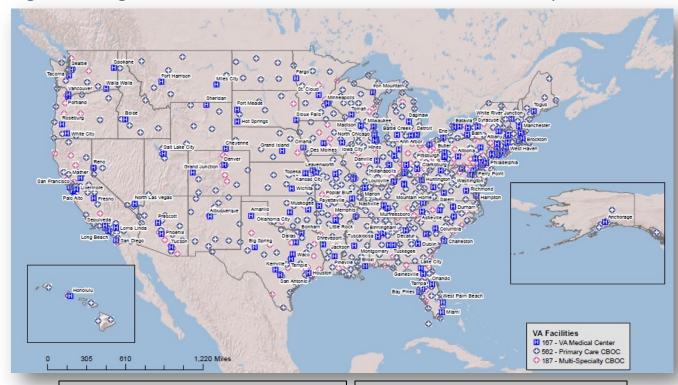Cigarette consumption & lung cancer deaths in the United States

Building a population data center in a large, integrated health system

Veterans Health Administration (VHA)

The Largest Integrated Healthcare Network in the Country

VHA Points of Care (1,748)
- Integrated Healthcare Networks: 21
- Major Medical Centers: 152
- Outpatient Clinics: 990
- Vet Centers: 370
- Domicillaries: 102
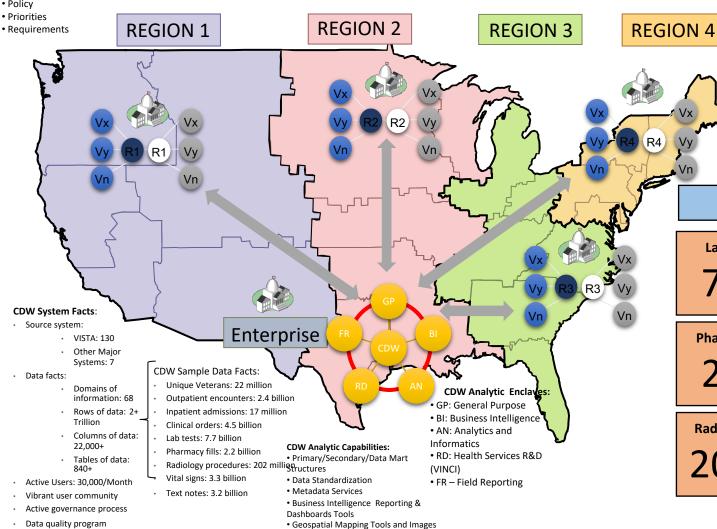- Community Living Centers: 134

Patient Population
- Enrollees: 8.8M
- Active Patients: 6M
- All Time Patients: 22M
- FY15 Outpatient Visits: 84M
- FY15 Inpatient Admissions: 703K

VA Analytic Ecosystem (2015)

Common Data ♦ Common Infrastructure ♦ Common Tools ♦ Common Security

Governance Board
- Strategy
- Policy
- Priorities
- Requirements

REGION 1 REGION 2 REGION 3 REGION 4

Enterprise

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 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

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

The EHR data available in the CDW and other data sources is among the best in the world.

Patients: 22 M

Lab Results	Clinical Orders	Immunizations	Appointments
7.7B	4.5B	71M	1.4B

Pharmacy Fills	Clinical Notes	Health Factors	Encounters
2.2B	3.2B	2.2B	2.4B

Radiology Proc	Vital Signs	Consults	Admissions
202M	3.3B	315M	17M

Surgeries	Oncology
14M	1.3M

Domains: 15/68

MASSACHUSETTS VETERANS EPIDEMIOLOGY RESEARCH AND INFORMATION CENTER (MAVERIC) -
funded in 1997 with the mission

"*To enhance health care delivery in the VA system by promoting the conduct of VA based population research relevant to the needs of veterans and to facilitate the transfer of vital epidemiologic information to VHA providers and administrators*".

MAVERIC is a national resource to foster epidemiologic research in the VA with:

- *a community of Ad hoc consultants and faculty with expertise in all disciplines of epidemiology*

- *the necessary infrastructure to support a highly relevant epidemiologic research agenda including a core computing facility and core laboratory for biological specimen processing and storage*

- *a clearing house for VA and non-VA databases and the expertise to harvest them for epidemiologic research projects and pilot studies*

- *a training center to educate both young and established VA investigators in epidemiologic research methods*

- *an information dissemination center for transfer of relevant epidemiological information to VA health care providers and administrators system wide*

MAVERIC's History

MVP β — MVP Beta Phase Launched

Population Genomics Center Created

All of Us RESEARCH PROGRAM — AoU Created

CDW for Widespread Use
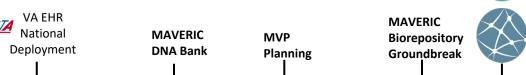
IOM - Envisioning transformed clinical trials enterprise

VA POC DCP Launched

VA EHR National Deployment

MAVERIC DNA Bank

MVP Planning

MAVERIC Biorepository Groundbreak

VA POC Insulin Pilot Launched (closed 2014)

VA POP Clinical & Research program Created

| 1985 | 1997 | 2001 | 2003 | 2008 | 2010 | 2011 | 2012 | 2014 | 2015 | 2016 | 2018 | 2020 |

MAVERIC Funded (Epidemiology Center)

MAVERIC Awarded Clinical Trial Coordinating Center

VA CDW Established

Murray & Frenk- "US Healthcare 37th in quality

IOM - Transforming Clinical Research in US

POC presented to VA CSP

MVP Launched

MVP Alpha Phase Launched

VA POC DCP Funded

VISN 1 POP Created
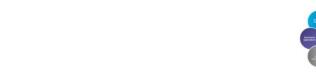
Data and Computational Sciences Created

MVP-DoD Partnership Launched

All of Us RESEARCH PROGRAM — AoU Launch
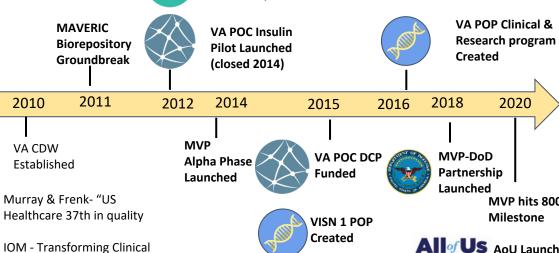
MVP γ — MVP Gamma Phase Launch

Big Data Science VA-DOE Champion Partnership Launched

MVP hits 800K Milestone

VA Cooperative CSP Studies Program

MAVERIC Components

- Epidemiology research center
- Trial coordinating center
- National biorepository
- National Quality Improvement initiatives
- Million Veteran Program (MVP)
- Phenomics research center and CIPHER
- Computing: Informatics cores / DOE collaboration
- Advanced analytics core
- Training programs

Cardiovascular Benefit of Magnitude of Low-Density Lipoprotein Cholesterol Reduction

A Comparison of Subgroups by Age

Catherine R. Rahilly-Tierney, MD, MPH; Elizabeth V. Lawler, MPH, ScD; Richard E. Scranton, MD, MPH; J. Michael Gaziano, MD, MPH

Table 4. Unadjusted and Multivariate-Adjusted* HRs (95% CI) for Each Category of LDL-C Reduction, by Age Quartile

Category of LDL-C Reduction	<61.1 y	61.1 to 69.3 y	69.3 to 75.3 y	≥75.3 y
Small: 10–40 mg/dL				
Unadjusted	0.87 (0.76–1.00)	0.69 (0.59–0.79)	0.77 (0.66–0.90)	0.72 (0.61–0.85)
Multivariate adjusted	0.73 (0.64–0.84)	0.67 (0.58–0.78)	0.70 (0.60–0.82)	0.64 (0.54–0.76)
Moderate: 40–70 mg/dL				
Unadjusted	0.68 (0.59–0.79)	0.57 (0.48–0.67)	0.65 (0.55–0.77)	0.73 (0.60–0.87)
Multivariate adjusted	0.50 (0.43–0.58)	0.45 (0.37–0.52)	0.45 (0.39–0.56)	0.53 (0.44–0.64)
Large: ≥70 mg/dL				
Unadjusted	0.73 (0.61–0.87)	0.57 (0.47–0.69)	0.53 (0.43–0.66)	0.54 (0.43–0.70)
Multivariate adjusted	0.37 (0.31–0.45)	0.29 (0.24–0.37)	0.26 (0.20–0.34)	0.38 (0.30–0.49)

*Adjusted for age, gender, current smoking status, body mass index, statin use, nonstatin cholesterol-modifying therapy use, hypertension, cerebrovascular disease, thyroid disease, and renal disease.

Among 326,981 US veterans ≥75 without ASCVD, statin therapy was significantly associated with a lower risk of mortality.

Table 2. Association Between Statin Use, All-Cause Mortality, and Major Cardiovascular Events in 326 981 US Veterans 75 Years and Older Free of Atherosclerotic Cardiovascular Disease at Baseline, After Propensity Score Overlap Weighting

Outcome	Weighted rate/1000 person-years		Weighted incidence rate difference/1000 person-years (95% CI)[a]	HR (95% CI)	P value
	Statin user (N = 57 178)	Statin nonuser (N = 269 803)			
Primary outcomes					
All-cause mortality (n = 206 902)	78.7	98.2	−19.45 (−20.38 to −18.52)	0.75 (0.74 to 0.76)	<.001
All CV death (n = 53 296)	22.6	25.7	−3.09 (−3.63 to −2.55)	0.80 (0.78 to 0.81)	<.001
Secondary outcomes					
ASCVD composite (n = 123 379)[b]	66.3	70.4	−4.05 (−5.09 to −3.02)	0.92 (0.91 to 0.94)	<.001
Myocardial infarction (n = 24 951)	13.2	12.6	0.56 (0.13 to 0.98)	0.99 (0.97 to 1.03)	.94
Ischemic stroke (n = 35 630)	18.4	18.2	0.25 (−0.26 to 0.76)	0.98 (0.96 to 1.01)	.20
CABG surgery/PCI (n = 74 362)	35.2	39.2	−3.38 (−4.12 to −2.64)	0.89 (0.88 to 0.91)	<.001

Abbreviations: ASCVD, atherosclerotic cardiovascular disease; CABG, coronary artery bypass graft; CV, cardiovascular; HR, hazard ratio; PCI, percutaneous coronary intervention.

[a] Weighted incidence rate difference comparing statin users to nonusers after overlap weighting was applied.

[b] ASCVD composite: time to first MI or ischemic stroke or CABG/PCI. There were fewer composite ASCVD events compared with total individual events, as participants were censored at first event of interest.

Orkaby AR … Gaziano JM … et al. JAMA 2020.

Developing a VA CVD Risk Calculator in the VA Health Care System

Table 3. Harrell C Statistics for Composite ASCVD Events

| | C statistic (SD) | | | |
| | Men | | Women | |
Model	White	Black	White	Black
Overall cohort of 1 672 336 veterans				
ASCVD events, No.	54 550	10 575	1154	326
No. at risk	1 314 938	260 225	69 055	28 118
Model 1, 2013 PCE	0.66 (0.004)	0.72 (0.007)	0.78 (0.020)	0.79 (0.036)
Model 2, 2013 PCE with cohort-derived β	0.67 (0.004)	0.72 (0.007)	0.80 (0.018)	0.80 (0.030)
Model 3, 2013 PCE with cohort-derived β and statin therapy	0.67 (0.004)	0.72 (0.007)	0.80 (0.018)	0.80 (0.029)
Subset aged 40-79 y with 1 415 057 veterans				
ASCVD events, No.	48 169	9609	847	285
No. at risk	1 136 161	218 463	44 399	16 034
Model 1, 2013 PCE	0.63 (0.004)	0.68 (0.008)	0.72 (0.022)	0.72 (0.045)
Model 2, 2013 PCE with cohort-derived β	0.64 (0.004)	0.68 (0.008)	0.73 (0.023)	0.73 (0.038)
Model 3, 2013 PCE with cohort-derived β and statin therapy	0.64 (0.004)	0.68 (0.008)	0.73 (0.023)	0.73 (0.036)

Developed at VA specific risk equation for prediction of intermediate and long-term CVD risk using EHR data.

This enables automated estimation of CVD risk in real time using EHR data for use in clinical practice.

Abbreviations: ASCVD, atherosclerotic cardiovascular disease; PCE, Pooled Cohort Equation.
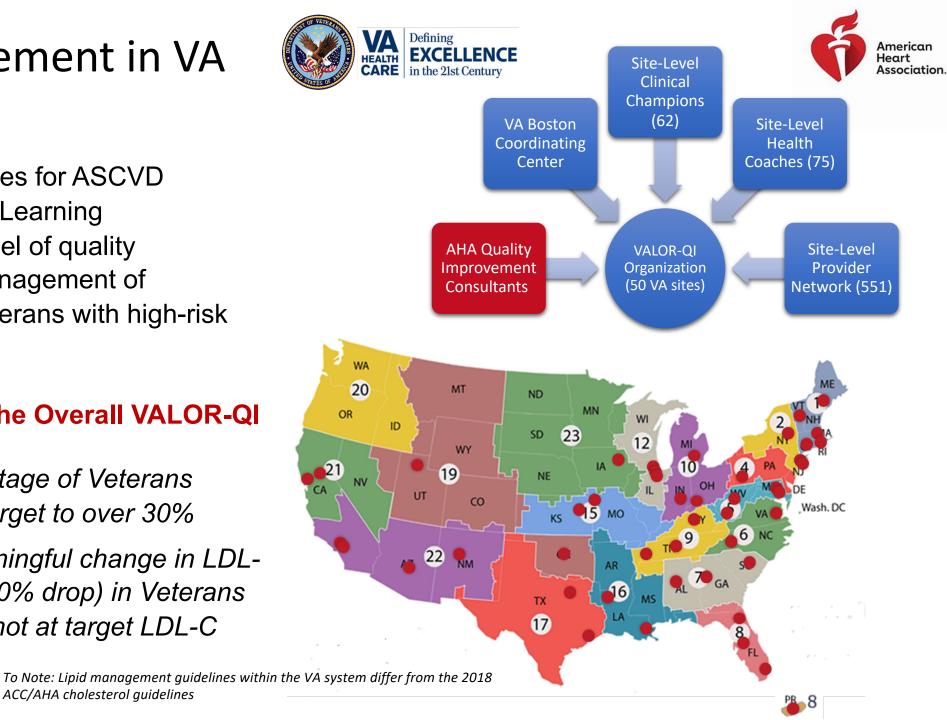
Quality Improvement in VA

VALOR-QI Vision

Improve clinical processes for ASCVD management through a Learning Healthcare System model of quality improvement for the management of dyslipidemia among Veterans with high-risk ASCVD.

Clinical Objectives for the Overall VALOR-QI Program:

✓ *To increase the percentage of Veterans achieving the LDL-C target to over 30%*

✓ *To demonstrate a meaningful change in LDL-C from baseline (i.e., 10% drop) in Veterans with ASCVD currently not at target LDL-C*

To Note: Lipid management guidelines within the VA system differ from the 2018 ACC/AHA cholesterol guidelines
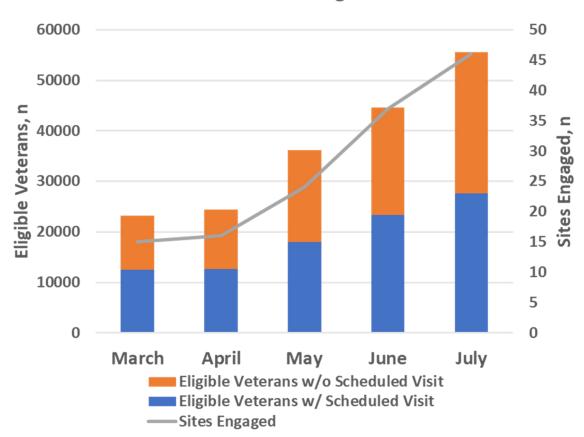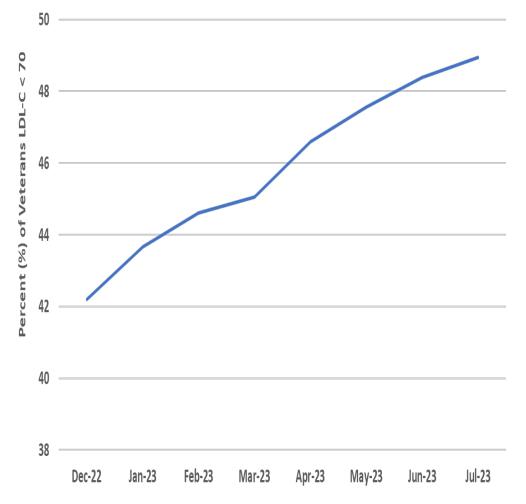
Percent of Veterans Achieving LDL-C <70mg/dl

THE GERONTOLOGICAL SOCIETY OF AMERICA®

OXFORD

Research Article

The Burden of Frailty Among U.S. Veterans and Its Association With Mortality, 2002–2012

Ariela R. Orkaby, MD, MPH,[1,2,3] Lisa Nussbaum, MA, MBA,[2] Yuk-Lam Ho, MPH,[2] David Gagnon, MD, PhD,[2,4] Lien Quach, PhD,[2,5] Rachel Ward, MPH, PhD,[2] Rachel Quaden, MA,[2] Enzo Yaksic, BS,[2] Kelly Harrington, PhD,[2,6] Julie M. Paik, MD, MPH, MSc,[1,7] Dae H. Kim, MD, MPH, ScD,[8,9] Peter W. Wilson, MD,[2,10,11,12] J. Michael Gaziano, MD, MPH,[2,3] Luc Djousse MD, ScD,[2,3] Kelly Cho, PhD,*[2,3] and Jane A. Driver, MD, MPH*[,1,2,3]
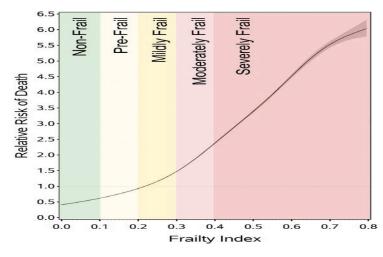
Table 4. Twelve Years' Median Survival Time According to FI Level for U.S. Veterans of age at least 65 Years
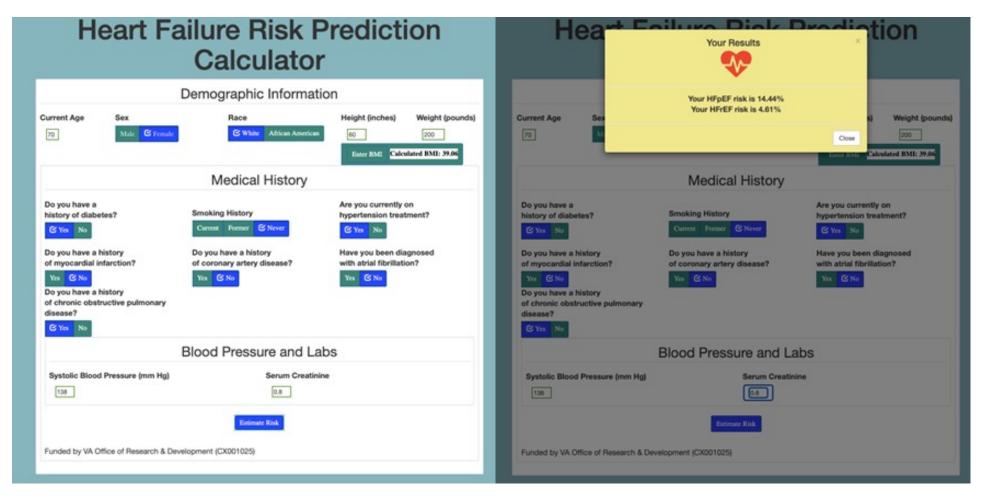
2002	Median Survival Time (years)					
	Men			Women		
	Age[†]	Age[†]	Age[†]	Age[†]	Age[†]	Age[†]
Frailty Score	65–74	75–84	≥85	65–74	75–84	≥85
FI ≤ 0.1	13.0	10.4	6.4	19.2	11.6	7.4
>0.1 to ≤0.2	12.4	8.7	5.7	15.1	10.5	6.5
>0.2 to ≤0.3	9.5	7.0	4.8	12.0	8.8	5.6
>0.3 to ≤0.4	6.8	5.4	3.8	8.5	7.0	4.5
FI > 0.4	4.6	3.8	2.8	6.0	5.1	3.7
All FI	12.9	8.0	4.9	15.6	9.5	5.7

Note: FI = Frailty Index.

[†]From Kaplan–Meier estimates.

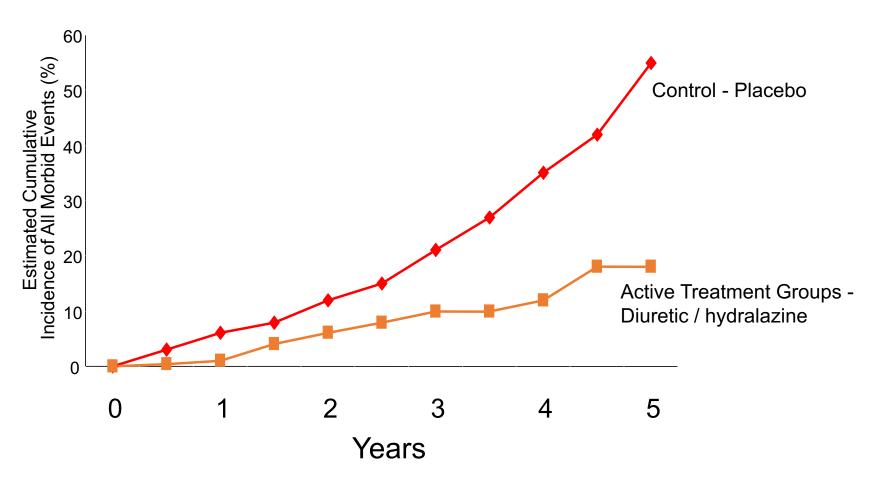[‡]From gamma model because median had not been achieved by the end of the study.

Developing a HF Risk Prediction Calculator (HF, HFrEF, HFpEF)

Liam Gaziano, et al., ESC Heart Fail. 2021 Dec;8(6):4893-4903.

First Hypertension Treatment Trial: Reduced Mortality and Morbidity in the VA Cooperative Study (CSP) - 1970
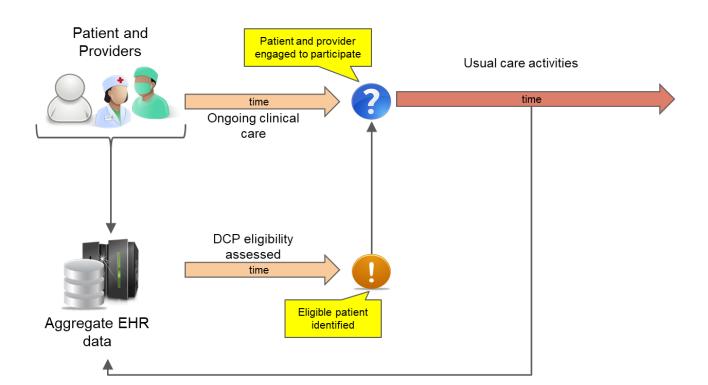

Veterans Administration Cooperative Study Group on antihypertensive agents *JAMA* 1970;213(7):1143-1152.

Boston CSP Trial Center: Traditional and pragmatic trials.

VA Diuretic Comparison Trial

Advanced Analytics Using EHR Data

Causal inference modeling / Target Emulation Trial: Head-to-head comparison of COVID Vaccines

Slide 1

COVID Cumulative incidence curves for the study outcomes in each vaccine group during the period marked by alpha-variant predominance.

Building MVP

MVP's Journey

2009 Planning meeting
2011 First veteran enrolled
2014 MVP reaches 250,000
2016 MVP reaches 500,000
2018 First results published
2019 MVP reaches 750,000
2023 MVP reaches 1 million
20?? MVP hits 2 million

VA Population

21 Million Veterans

↓

9-10 Million VHA Enrollees

↓

Most Are Eligible for MVP

MVP Sites (5M)   Non-MVP Sites (3M)
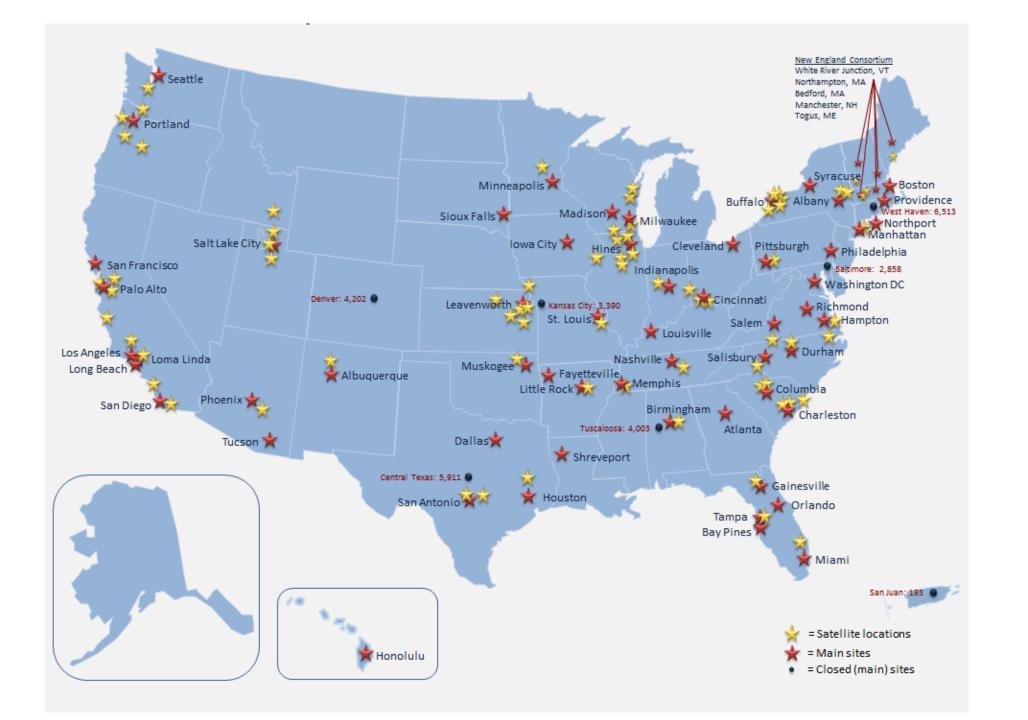
Million Veteran Program (MVP)
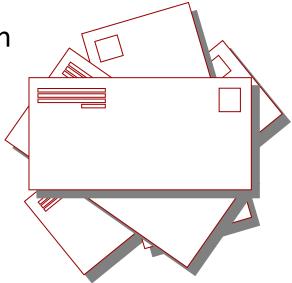
- **Goal: Enroll up to one million users of the VHA into an observational mega-cohort**

  o **Collect health and lifestyle information**

  o **Blood collection for storage in biorepository**

  o **Access to electronic medical record**

  o **Ability to recontact participants**

MVP

New England Consortium
White River Junction, VT
Northampton, MA
Bedford, MA
Manchester, NH
Togus, ME

Seattle
Portland
Salt Lake City
San Francisco
Palo Alto
Los Angeles
Loma Linda
Long Beach
San Diego
Phoenix
Tucson
Albuquerque

Denver: 4,202

Minneapolis
Sioux Falls
Madison
Milwaukee
Iowa City
Hines
Indianapolis
Leavenworth
Kansas City: 3,390
St. Louis
Muskogee
Fayetteville
Little Rock
Memphis
Nashville
Louisville
Cincinnati
Cleveland
Pittsburgh

Syracuse
Buffalo
Albany
Boston
Providence
West Haven: 6,513
Northport
Manhattan
Philadelphia
Washington DC
Baltimore: 2,858
Richmond
Hampton
Salem
Durham
Salisbury
Columbia
Charleston
Birmingham
Atlanta
Tuscaloosa: 4,003
Dallas
Shreveport
Central Texas: 5,911
San Antonio
Houston
Gainesville
Orlando
Tampa
Bay Pines
Miami

San Juan: 193

Honolulu

= Satellite locations
= Main sites
= Closed (main) sites

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
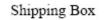
Building the VA National Biorepository

Packing Slip

Shipping Box

Secondary Container (with absorbent)

Primary Container (Blood tubes)

VA Central Biorepository: Processing
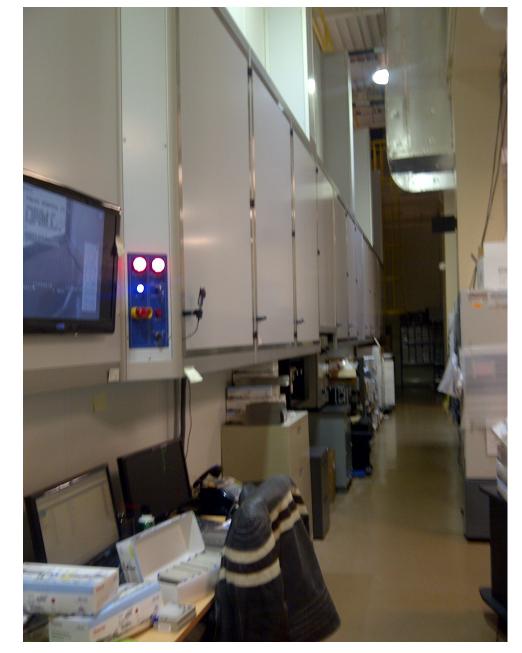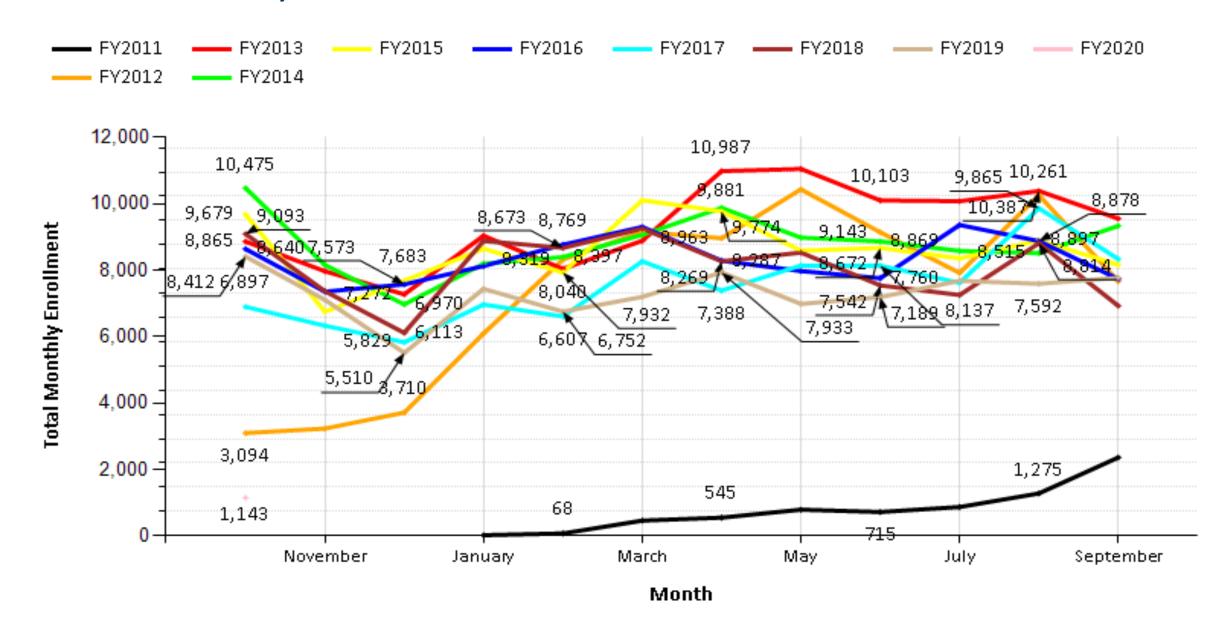
VA Central Biorepository: Storage
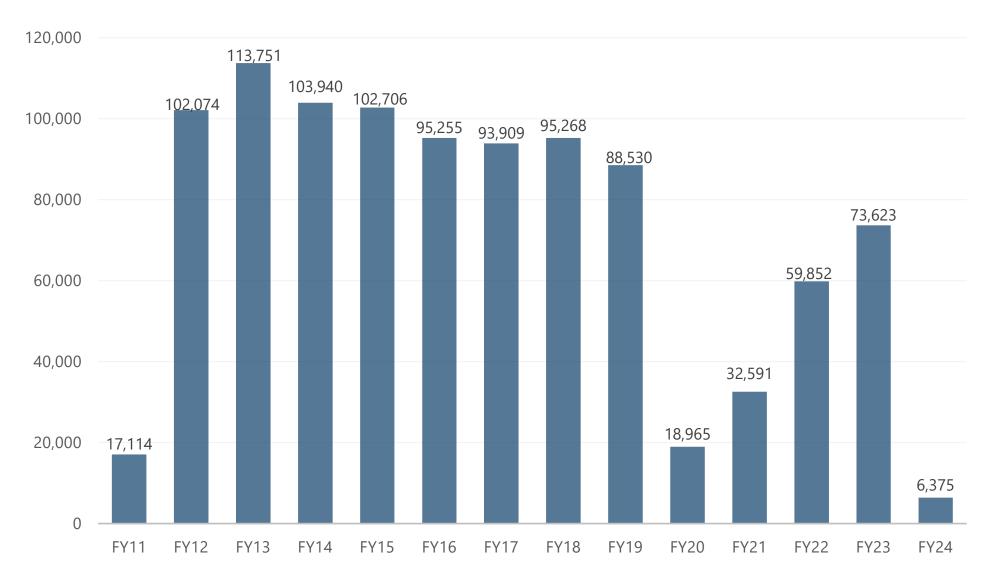
MVP Monthly Enrollment Across Years

MVP Enrollment by FY
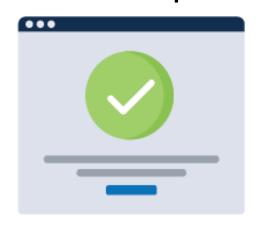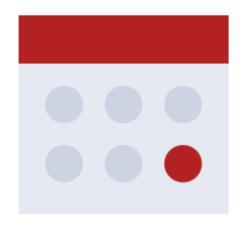
MVP Online For Expanded Enrollment

SIGN IN
using the same credentials as other VA partners (such as My HealtheVet or eBenefits).

COMPLETE
the consent process and allow access to health records.

SCHEDULE
an MVP visit to provide a blood sample.

FILL OUT
surveys about health and lifestyle.

mvp.va.gov
Launched 09/19
6,500 Enrolled Online

Biospecimen Expansion:
What are we doing in terms of biospecimens expansion?
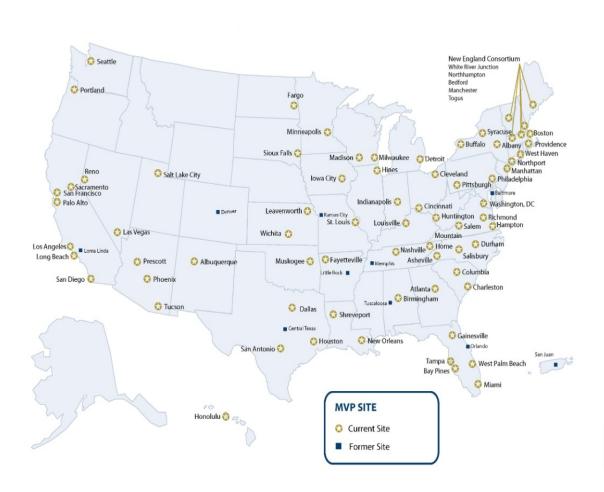
MVP Site Stats

Current

- **147 total**
  - 68 main sites
  - 79 satellite sites
- **279 MVP site staff**
  - 106 LSIs
  - 173 research staff

New England Consortium
White River Junction
Northhampton
Bedford
Manchester
Togus

Seattle
Portland
Fargo
Minneapolis
Sioux Falls
Madison
Milwaukee
Detroit
Syracuse
Boston
Buffalo
Albany
Providence
West Haven
Northport
Manhattan
Reno
Salt Lake City
Hines
Cleveland
Philadelphia
Sacramento
San Francisco
Palo Alto
Iowa City
Pittsburgh
Baltimore
Denver
Leavenworth
Kansas City
Indianapolis
Cincinnati
Washington, DC
St. Louis
Louisville
Huntington
Richmond
Las Vegas
Wichita
Salem
Hampton
Los Angeles
Long Beach
Loma Linda
Mountain Home
Nashville
Durham
Prescott
Albuquerque
Muskogee
Fayetteville
Asheville
Salisbury
San Diego
Phoenix
Memphis
Little Rock
Columbia
Atlanta
Charleston
Tucson
Tuscaloosa
Birmingham
Dallas
Shreveport
Central Texas
Gainesville
San Antonio
Houston
New Orleans
Orlando
San Juan
Tampa
Bay Pines
West Palm Beach
Miami
Honolulu

MVP SITE
⭐ Current Site
■ Former Site

Ever

- **228 total**
  - 85 main sites
  - 143 satellite sites
- **932 MVP site staff**
  - 181 LSIs
  - 751 research staff

MILLION VETERAN PROGRAM

Hitting a Million: Nov 8, 2023 at 3:42 pm

MVP: Current Status

598K+ Baseline Surveys

1.02M+ Enrolled

476K+ Lifestyle Surveys

62 Active Sites

77 Sites Ever

25M+ Total Mailings

8.5M+ Individuals Contacted

MVP SITE
- ⬡ Current Site
- ■ Former Site

MVP Enrollment Map

Enrollees (N)

0	10 - 15
1	16 - 26
2 - 3	27 - 47
4 - 5	48 - 93
6 - 9	94 - 1977

▲ Active MVP Enrollment Site
▲ Inactive MVP Enrollment Site

0   375   750   1,500 Miles

Who's in MVP?

Key health and demographic stats

Below are selected statistics from a recent review of the demographic, military, and health characteristics of Veterans enrolled in VA's landmark Mill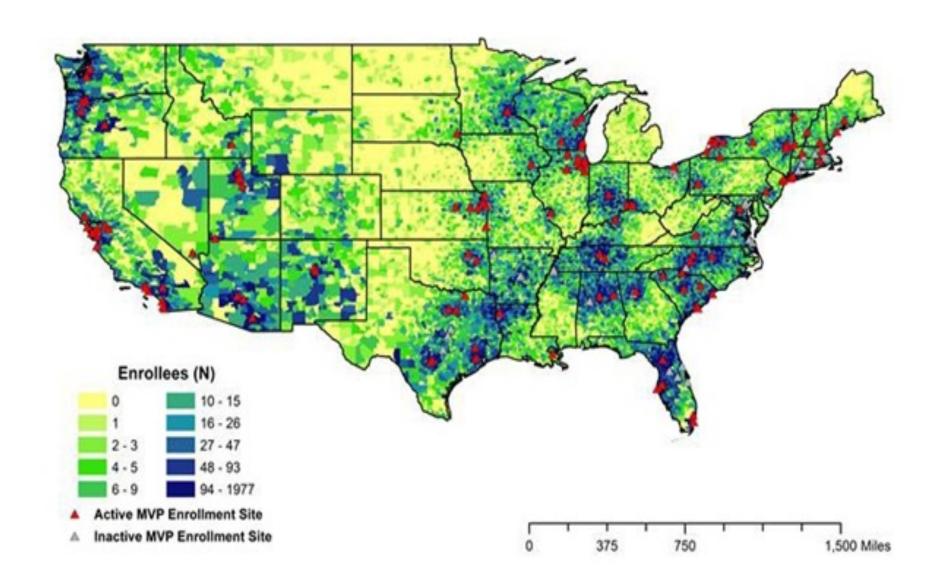ion Veteran Program, which has become one of the world's largest databases of health and genomic information. The researchers concluded that the demographic make-up of the MVP cohort—which has nearly 700,00 Veterans enrolled to date—is similar to that of VA patients on the whole.

90.4% of the MVP cohort is **male**

The **average age** is **61.9**

73.9% of the cohort is **White, 19% Black,** and **6.5% Hispanic**

The most common self-reported disease among **men** is hypertension **(64.6%)**

The most common self-reported disease among **women** is depression **(47.5%)**

38.2% of the MVP cohort is obese, and **42.3%** is overweight

PTSD was reported by **18.3% of men,** and **26% of women**

Tinnitus was reported by **34.2% of men,** and **20% of women**

Diversifying the Cohort Beyond a Million

Stacey Whitbourne, Director, MVP Cohort Management

MILLION VETERAN PROGRAM

MVP 100K Re-Contact

- Invitation
  - Implement re-contact for additional research process
    - Sample: more than 5 years since enrollment
    - Mailings/emails with invitation to participate
    - Follow-up phone calls

  - Engage existing MVP sites/staff for re-contact visit
    - Additional consent
    - Blood collection
    - Update and new self-report data / New data: cognition, military exposure, etc.
- Blood Specimen
  - Standard EDTA tube/biorepository processing and PAXgene
  - Processing of other types of specimens as needed
- Timeline
  - Begin pilot efforts in late 2023
  - 33K per year

Priorities:

Time in MVP
Baseline data
Diversity
Exceptional Age

MILLION VETERAN PROGRAM