• The Power of Multisite Research
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The Power of Multisite Research

- Largest integrated health care system in U.S.
- State-of-the-art electronic health record
- Geographic, demographic diversity
- Large datasets
- Embedded researchers who are also faculty members at nation’s top universities
- **Ability to rapidly self-fund multisite clinical studies to answer important and urgent clinical questions**
The Power of Multisite Research

- Gold standard for providing evidence of safety and effectiveness
- Veterans—especially those with conditions beyond routine clinical care—gain access to potentially life-saving or life-enhancing treatments otherwise not available
- Highly regulated to ensure participants are informed of risks and provided protections
- VA clinical trials registered at www.clinicaltrials.gov
VA’s research program “…has the most innovative clinical trials center in the world…”

– (Then) Vice President Joe Biden upon conferring the Malcolm Baldrige National Quality Award to the VA Cooperative Studies Program Clinical Research Pharmacy Coordinating Center, 2009
VA Research: Strategic Priorities

- VA research has three overarching strategic priorities:
  - Increase Veterans’ access to high-quality clinical trials
  - Increase the real-world impact of VA research
  - Put VA data to work for Veterans
Increase Access to Clinical Trials

Goals:
1. Provide Veterans and VA investigators with more opportunities to participate in multi-site clinical trials of new therapies
2. Establish an organized national VA clinical research enterprise to better partner with industry & other federal sponsors
   - Create efficient processes and capabilities

Main activities:
- Access to Clinical Trials (ACT) for Veterans – processes to more efficiently start up industry-sponsored trials
- NAVIGATE – National Cancer Institute and VA model for starting up and overcoming barriers in cancer clinical trials
Deploy our research resources to deliver meaningful outcomes, ranging from validated knowledge generation to policies to products.

- Shift from an individual award focus to the series of steps necessary to achieve a desired outcome (e.g., roadmaps)
- Translate VA inventions into licensed products.
- More rapidly implement effective interventions into routine care
Between July 21, 2021 and January 21, 2021, the number of COVID-19 research projects rose to 292 across 70 VHA sites.

To help meet recruitment goals for clinical trials, ORD developed a registry of Veterans who wanted to volunteer for COVID-19 trials.

- 58,000 Veterans and other US adults enrolled
- Close to 90 percent (89.7) indicated Veteran status
- Nearly a quarter are from minority groups
ORD COVID-19 Goals

Keep research staff and participants safe

Support the clinical mission:
• Provide access to investigational therapies that are available only through research
• Evaluate scientific literature and real-world evidence to support operational decision-making
• Contribute to national research to combat the pandemic
VA Research and COVID-19: Sample Studies

• **Epidemiology, Immunology and Clinical Characteristics of COVID-19** (EPIC3) is a collaboration with DOD on an observational, natural history study being coordinated by VA’s Cooperative Studies Program.

• Four VA sites are part of an NIH-sponsored adaptive trial of the **antiviral drug remdesivir** plus the **anti-inflammatory drug baricitinib** for hospitalized patients with COVID-19.

• The wide-reaching **“VA CURES” master protocol** will enable a series of clinical trials across VA. The first, now underway, is examining the effects of convalescent plasma.
VA has been part of two major national research initiatives on COVID-19 vaccines and therapeutics: Operation Warp Speed (OWS) and the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiative.

Through OWS and other efforts, VA has been an active participant in several clinical trials designed to evaluate potential COVID-19 vaccines. These trials have included:

- The Moderna/COVE trial, which took place at one VA site and is now closed to enrollment.
- The Janssen ENSEMBLE trial, which included 17 VA sites and is now closed to enrollment.
- The Pfizer trial, in which one VA site participated.
Big Data and Informatics

- Creating a high-quality database of people who have tested +/- for COVID-19, in partnership with VA operations.
- Coordinating a VA research/operations group to examine safety and effectiveness of different treatments.
- Million Veteran Program deploying COVID-19 survey to its diverse population of more than 800K Veteran enrollees.
VA Listening Sessions with Veterans of Color (Late Summer/Early Fall 2020) revealed that to overcome vaccine hesitancy, information would need to:

- Come from a trusted source, e.g., their physician or fellow veteran
- Address specific concerns, e.g., infamous Tuskegee study
- Discuss current data on vaccine effectiveness
- Be delivered via already used technology, i.e., mobile device
- Link directly to a specific action, e.g., scheduling a vaccination appointment.
Vaccine Hesitancy: VA Response to Listening Sessions

- VHA doctors discussed the benefits of vaccination months before the first vaccines became available
- VHA developed targeted messaging to address medical mistrust and Tuskegee
- VHA issued Internet-connected devices to the many Veterans and communicated with less bandwidth-intensive channels, such as VEText
- Facilities leveraged VHA’s centralized electronic health records to identify eligible Veterans, contact them, and schedule appointments
Vaccine Hesitancy: VA Response

10 ways to get the care and support you need from VA during COVID-19

A coronavirus disease (COVID-19) resource for Black, Hispanic, and Native American Veterans

We know that COVID-19 is severely impacting Black, Hispanic, and Native American communities across the country. We’re here to connect you with the information and resources you need to stay healthy during this time.

Here are 10 ways to get care and support from VA:

1. If you’re not enrolled in VA health care, find out if you’re eligible and how to apply. If you weren’t eligible for VA health care in the past but you’ve had a decrease in income, you may be eligible now. Find out at www.va.gov/health-care/eligibility/.


3. Get care when you need it. Please don’t delay routine health appointments. And keep up with recommended health screenings based on your age and other risk factors. Screenings are tests that help to find health problems (like heart issues or certain cancers) early, when they’re easier to treat.

4. Make sure you have enough of your prescription medicines. Order your new prescription as soon as you can. Always order at least 10 days before you need more. Learn more about refilling VA prescriptions online at www.va.gov/health-care/refill-track-prescriptions/.

Veterans from Communities at High Risk of COVID-19:

What you need to know about getting the COVID-19 vaccine

“VA is providing the COVID-19 vaccine first to Veterans and high-risk health care personnel, so we can flatten the curve and stop the devastation that COVID-19 is causing in our communities across the country. I look forward to getting the vaccine as soon as I am eligible.”

Kameron Leigh Matthews, MD, JD, FAAFP
Chief Medical Officer
Veterans Health Administration

VA’s goal is to provide vaccine for all health care personnel and Veterans who want to be vaccinated in 2021.