Health Equity and Diversity in Clinical Trials

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*The VA Office of Health Equity (OHE) was created in 2012 to champion reduction of health and healthcare disparities and galvanize efforts, enhance synergy across the VA and spur actions towards achieving health equity for all Veterans*
LEARNING OBJECTIVES

- Identify Veteran-related factors that place Veterans at risk for health disparities
- Describe Office of Health Equity and efforts to advance health equity for Veterans
- Explain the importance of including Veterans, while accounting for diversity, in clinical trials
- Describe reasons why Veterans are motivated to participate in clinical trials and why some populations are apprehensive about participating in clinical trials
VA OVERVIEW

- VA Mission
- Quick facts
  - Established 1930
  - Elevated to Executive Level 1989
  - 2nd largest Federal Govt. Department
  - Full Time VA Employees: >300,000
  - U.S. Department of Veterans Affairs has 3 arms:
    - **VHA** - Veterans Health Administration
    - **VBA** - Veterans Benefits Administration
    - **NCA** - National Cemetery Administration
VETERANS AS A UNIQUE POPULATION

- <2% of US Population in military service
- ~9 million of the estimated 22 million Veterans alive use VA
- Military service is unique
- Experiences during military service are unique
- Challenges & exposures may vary by era/period of service
- Some health challenges may be more prevalent or related to military service
- Veterans & Non-Veterans may be members of a vulnerable group
- Military service adds vulnerability for health and health care disparities
- Combination may increase likelihood of health disparities/inequities
- Intersection of vulnerability ⇒ +/-
HEALTH EQUITY – CROSS CUTTING

Conceptual framework for prioritization: Institute of Medicine, 2010

Components of Quality Care
- Effectiveness
- Safety
- Timeliness
- Patient/family-centeredness
- Access
- Efficiency

Type of Care
- Preventive Care
- Acute Treatment
- Chronic condition management

Crosscutting Dimensions
- Care Coordination
- Health Systems Infrastructure Capabilities

U.S. Uchendu, MD @ FDA Lecture Series 11.20.2017. Source: NAM (formerly IOM)
OHE along with key partners developed the HEAP which Aligns with Sec VA Priorities, My VA, the VHA Strategic Plan (see Objective 1E Quality & Equity), and other agency and national strategic goals. The HEAP focal areas are

- **Awareness**: Crucial strategic partnerships within and outside VA

- **Leadership**: Health equity impact assessed for all policies, executive decision memos, handbooks, procedures, directives, action plans and National Leadership Council decisions

- **Health System Life Experience**: Incorporate social determinants of health in personalized health plan

- **Cultural and Linguistic Competency**: Education & training on health equity, cultural competency to include unconscious bias, micro inequities, diversity & inclusion

- **Data, Research and Evaluation**: Develop common definitions and measures of disparities and inequities; Develop strategies for capturing data on race, ethnicity, language, and socioeconomic status and other variables needed to stratify the results for all quality measures and to address disparities; Incorporate health equity into Strategic Analytics for Improvement and Learning (SAIL)

http://www.va.gov/HEALTHTHEQUITY/Health_Equity_Action_Plan.asp
SECVA PRIORITIES & HEALTH EQUITY

- **Greater Choice**
  - Consider any disparate impact on vulnerable Veteran populations
  - Empower Veterans through transparency of information

- **Improve Timeliness**
  - Consider any disparate impact on vulnerable Veteran populations

- **Suicide Prevention**
  - Apply equity lens to 2016 suicide mortality report to inform culturally appropriate and tailored prevention strategies for vulnerable Veteran populations as appropriate. More details in the FHEA 07.17.2017 Archive

- **Accountability /Efficiency**
  - Implement Commission on Care Recommendation #5 – Eliminate Health Disparities among Veterans: Make Health Equity a Strategic Priority by Implementing the HEAP
  - Data transparency by assessing any disparate impact and making data on vulnerable Veterans publicly available.
  - Go beyond collecting and analyzing disparities to actually addressing them in order to diminish or eliminate the gaps

- **Modernization**
  - Embed HEAP implementation into foundational services.
  - Incorporate social determinants of health in the new EHR with connection to DoD & actionable data for vulnerable groups
  - Consider disparate impact of appeals on the vulnerable
  - Develop partnerships with community organizations to improve health equity

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Poll Question 1
These factors put Veterans at risk for health disparities? Select all that apply.

- Age
- Gender/Sex
- Military Era/Period of Service
- Rural/Urbn Living
- None of the Above
VISION

Office of Health Equity champions the advancement of health equity and reduction of health disparities.

MISSION

- Position Veterans Health Administration (VHA) as a national leader in achieving equity in health care and health outcomes among vulnerable populations.
- Champion efforts to address health disparities through education, training, communications, programs, projects, and initiatives that bring synergy and break down silos within the organization.
- Capitalize on the existing network of Department of Veterans Affairs (VA) Offices and Veteran advocates to coordinate and harness efforts to advance health equity and achieve equitable health care.
- Represent VA and serve as a liaison to other governmental and non-governmental organizations working to achieve health equity.

VA has health and benefits under one umbrella which permits VA to address both health care and social determinants of health that influence overall health and well-being.

https://www.va.gov/HEALTHEQUITY
The FDA Office of Minority Health (OMH) works to build a world where **health equity is a reality for all**...

**Goals**
- Improve regulatory science by *increasing the amount of clinical trial data* available on racial and ethnic minorities; improve the data quality to determine *how minorities react to medical products*; and *increase transparency* and access to available data

- Strengthen FDA’s ability to respond to minority health concerns

- Promote health and safety communication to minority populations who often experience low health literacy and/or speak English as a second language

Source: [www.FDA.gov/MinorityHealth](http://www.FDA.gov/MinorityHealth)
OMH @ FDA - PROGRAMS

- **Research & Collaboration**
  - Partner with academia, minority serving organizations, and other Federal agencies to strengthen research in minority health and health disparities with regulatory significance
  - Support FDA’s research efforts to advance regulatory science in health disparities

- **Communications & Outreach**
  - Improve FDA’s communication and outreach with minority and underserved people
  - *Partner with stakeholders to identify and reduce health disparities*

- **Key Priority Areas**
  - *Clinical Trials* * Language Access * Cancer * **Cardiovascular Disease** * **Hepatitis** * HIV/AIDS * **Diabetes** * Sickle Cell Disease

Source: www.FDA.gov/MinorityHealth
FDA OMH Key Priority Areas striking alignment with VA and Veteran health conditions:

- Clinical Trials - Inclusion of diverse Veteran groups in clinical trials - OHE bringing Focus to Veterans as part of November Veteran Month activities
- Cardiovascular Disease - Includes Hypertension which is one of the top 3 prevalent diagnosis among Veterans + disparate impact on African American Veterans, Native Hawaiian and Other Pacific Islanders Veterans (NVHER)
- Diabetes - Among the top 3 prevalent diagnosis for all Veterans + disparate impact all racial/ethnic minority groups except Asians (NVHER)
- Hepatitis - An area of disparate impact among Vietnam Veterans most of whom are in the 1945-1965 birth cohort impacted by Hepatitis C

VA has made great strides in the management of Hepatitis C - unleashed unprecedented care with support of funds from U.S. Congress to ensure appropriate Hepatitis C Virus screening, diagnosis and treatment of Veterans
National Veteran Health Equity Report - Online & ePub with ISBN*

Virtual Training Modules - created with Veterans’ stories on Simulation Platform that applied Flipped Classroom model

Translating research into action with Journeys with High Blood Pressure Videos – virtual peer to peer Veteran stories

Focus on Health Equity and Action Cyberseminar with over 2,300 registrants (does not include archive accessed post session)

Twenty bulletins via the OHE listserv to over 380k total recipients

OHE website had over 15k page views and 12k unique page views

OHE Applying the Equity Lens graphic on Visualize Health Equity Online Gallery by National Academy of Medicine

Collaborations to advance health equity – e.g., FDA Veteran inclusion Clinic Trials video coming soon

http://www.va.gov/HEALTHEQUITY/Tools.asp

*International Standard Book Number
Modalities Applied by OHE in Projects:

- Publications with open access & Presentations in multiple formats
- Data Visualization
  - Dashboards - Hepatitis C Virus Disparities
  - Data Story - National Veteran Health Equity Report
- Virtual Patient Health Equity Modules
  - Simulation Platform
  - Application of Stories
  - Flipped Classroom Model
- Video - Messaging & Products
  - Clinical Look at Unconscious Bias
  - Journeys with High Blood Pressure
- Cyberseminar Series – FHEA
- Reports including e-Pub & ISBN
- Website & Listserv
- FDA Veteran inclusion Clinic Trials video
- Virtual Medical Center - Health Equity Learning Hub

FHEA - Focus on Health Equity and Action

**https://www.va.gov/HEALTHEQUITY/Tools.asp**
VA-VMC - HEALTH EQUITY HUB

- Sneak – Peek

- Official launch coming soon

Register Now @: www.vavmc.com
‘APPLYING THE EQUITY LENS’ ON NATIONAL ACADEMY OF MEDICINE GALLERY

- News! Thursday 11.09.2017 - Applying the Equity Lens graphic and blog selected for NAM Visualize Health Equity Permanent Online Gallery

- Concept intended for
  - Communicating health equity
  - Understanding how equity differs from equality
  - Applying the equity lens in order to address/eliminate disparities

NAM Gallery - http://visualizehealthequity.netlify.com/#/artwork/11
Health Equity and Diversity in Clinical Trials:

Poll Question 2

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Examples of Office of Health Equity initiatives/products to advance health equity among Veterans include all of the following except:

- Using Veteran Stories to create training on Social Determinants of Health
- Funding contractors to map a path for Veterans
- VA Health Equity Roadmap - The HEAP
- Collaboration with FDA-OMH


CLINICAL TRIAL PARTICIPATION BARRIERS & MOTIVATORS

- **BARRIERS**
  - Costs
  - Biases
  - Cultural factors
  - History of discrimination
  - History of exploitation
  - Lack of awareness of trials
  - Language differences
  - Mistrust
  - Social determinants not often accounted for by the research design
  - Trial designs not amenable to inclusion
  - Participants as subjects

- **MOTIVATORS**
  - Altruism
  - Community context
  - Ease of participation
  - Family impact/connection
  - Matter of importance to participants or someone they care about
  - Seeking answers/solution to health issues including unique exposures like Agent Orange & TBI
  - Potential benefits to the participant
  - Participants as partners enriches the study beyond inclusion in numbers only
US MILITARY SERVICE MEMBERS’ REASONS FOR PARTICIPATING

- US Military Service Members’ Reasons for Deciding to Participate in Health Research
- Service members described participation decisions for 34 individual research experiences in 27 separate studies

**Reasons for Participation**

- For Others - Altruism
  - Contribute to science
  - To make things better for others
  - To improve an organization
  - To help researchers
  - Giving back to the medical community who care for them

- Self - Treatment they need

- Fit Focused - Understanding how they fit in studies

**Conclusion** - Findings may help researchers, study sponsors, ethicists, military leaders, and military decision-makers better understand service members’ reasons for participating in research and improve future recruitment of service members in health research

~Wendy A. Cook et al
2007 study published in Military Medicine

- Compared Veterans & Non Veteran reasons for participation in clinical trials
- Provided a preset group of reasons to choose from
- 146 respondents out of which 135 provided usable responses defined as >80% complete

**Results**

- Veterans *valued Altruism and giving back more* and *Financial Compensation less* for engagement compared to non-Veterans
- Veterans involved in armed conflict have the same reasons for participating as Veterans as a whole, but value them more strongly

**Conclusion** - Knowledge of the varying reasons for participation could potentially aid recruitment efforts and marketing materials for clinical trials

~Dennis Raisch et al
Engaging Veterans with substance abuse disorders into a research trial: success with study branding, networking, and presence

The goal was to enroll 200 participants over a 25-month period, and to exceed 70% follow-up for all treatment arms

- To meet these goals, a four-pronged strategy was developed
  - Branding
  - Outreach/networking
  - Onsite presence
  - Incentives

Implications

- **Practice** - Consider multiple strategies for outreach and ongoing engagement
- **Research** - Use multipronged approach for efficient recruitment & strong retention to maximize external validity of research findings
- **Policy** - Factor planning and resources for outreach and ongoing engagement into investment cost/plan

~Anne Kathryn Michalek et al
VETERAN INCLUSION IN CLINICAL TRIALS – WHY?

- Participation in research and clinical trials makes it possible for scientists to identify solutions to the health challenges Veterans face as a result of military service.

- Psychotherapy for Military-Related PTSD: A Review of Randomized Clinical Trials
  
  **Objective** - To examine the effectiveness of psychotherapists in Military and Veteran Populations.

  **Conclusion** - There is a need for improvement in existing PTSD treatments for development and testing of novel evidence-based treatments, both trauma-focused and non-trauma-focused.

  **IMPORTANCE** - Posttraumatic stress disorder (PTSD) is a disabling psychiatric disorder common among military personnel and Veterans. First-line psychotherapies most often recommended for PTSD consist mainly of “trauma-focused” psychotherapies that involve focusing on details of the trauma or associated cognitive and emotional effects.

~Maria M. Steenkamp et al
Health Equity and Diversity in Clinical Trials

Poll Question 3
Veterans participation in clinical trials makes it possible for scientists to identify solutions to health challenges as a result of military service

☐ True
☐ False
• Important to understand the risks & benefits involved in the particular clinical trial

• There are applicable laws to protect participants

• Participation is completely voluntary

• Best care for Veterans includes clinical trials to hone in on the best possible treatments and products
For Participants and those considering to become volunteers

- VA - https://www.research.va.gov/programs/csp/participation.cfm

- FDA - https://www.fda.gov/ForConsumers/ByAudience/MinorityHealth/ucm472295.htm

For Researchers

- VA - https://www.research.va.gov/resources/ORD_admin/clinical_trials/
The following information describes what clinical trials are and gives additional information to help you decide if participating in a clinical trial is right for you.

- **What Is a Clinical Trial?**
- **What Types of Clinical Trials Are There?**
- **What Are Clinical Trial Phases?**
- **Why Are Clinical Trials Important?**
- **Why Would a Person Be Interested in a Clinical Trial?**
- **What Protections Exist for People Who Participate in Clinical Trials?**
- **What Is Informed Consent?**
- **What Should You Know Before Participating in a Clinical Trial?**
- **Who Sponsors Clinical Trials?**
- **Who Can Participate in a Clinical Trial?**
- **What Is It Like to Participate in a Clinical Trial?**
- **Why Is Patient Adherence to the Clinical Trial Treatment Plan Important?**
- **In Conclusion**

For Participants & those considering to become volunteers -

- [https://www.research.va.gov/programs/csp/participation.cfm](https://www.research.va.gov/programs/csp/participation.cfm)
IMPERATIVE FOR VETERAN INCLUSION IN CLINICAL TRIALS

- Specifically for Veterans and Service Members - Unique experiences and exposures in the military makes it imperative that a good cross section of Veterans participate in clinical trials for themselves, their colleagues and their families.

- VA and DoD and others are investing a lot on war related illnesses and some of the known exposures like Agent Orange, blast injuries etc. (Refer & link VA military history taking pocket card)

- In order to fully understand and tackle these, it is important that Veterans, Service Members & their families participate in research and clinical trials.

- To support Veterans, VA OHE & FDA OMH partnered to produce and launch the recent campaign on Veterans participation in clinical trials.

- Release in November 2017 in support of the WH & SECVA call to make November Veterans Month beyond the one day National Veterans Day Holiday...
President Donald J. Trump
Proclaims November 2017 as National Veterans and Military Families Month

During National Veterans and Military Families Month, we honor the significant contributions made by American service members, their families, and their loved ones. We set aside this month surrounding Veterans Day to hold observances around the country to honor and thank those whose service and sacrifice represent the very best of America. We renew our Nation’s commitment to support veterans and military families. They deserve it.

Our veterans are our heroes. Our Armed Forces have preserved the security and freedom that allow us to flourish as a Nation. They have braved bitter winters, treacherous jungles, barren deserts, and stormy waters to defend our Nation. They have left their families to face danger...
Video: Veteran Inclusion in Clinical Trials
Where can you sign up?

Who can you contact?

Listen to a Veteran

VIDEO CLIP HERE
REMEMBER …

- Equity is a cross cutting theme along with value
- Other elements of quality can differ based on who (vulnerable characters) and it is important to consider those differences and account for them
- Diverse populations participating in clinical trials ensures that those differences are part of the research and findings that inform Effective + Safe + Personalized + Prevention Strategies as well as Treatment for Acute and Chronic conditions
- Take Action – Include Veterans while accounting for *Diversity in Clinical Trials*

![Conceptual framework for prioritization: Institute of Medicine, 2010](image)

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REMEMBER ...

- Lack of meaningful inclusion & participation of diverse populations ➔ disparities in health and healthcare

- Studies that do not include implications and impact on the minority groups because they were not included/adequately represented have far reaching implications

- If the findings, treatments and/or products are deployed to all, it translates to the testing occurring in the broader members of the groups that were underrepresented in the controlled/regulated trial environment, without the protection that the clinical trial protocol provides

- If the impact is negative in those not included in the clinical trial, there is passage of time in the post release phase before it is identified and/or rectified

- If the drug or product is ineffective in certain populations who were not a part of the study, members of these subgroups treated with it do not reach desired goals ➔ loss of quality of life & loss of funds they expended on the drug or product etc.
In some scenarios where the groups that were not a part of the trial end up becoming test cases without the monitored protocols that usually accompany clinical trials

For instance, if a drug or product was not checked for efficacy and side effects in enough numbers of people from racial/ethnic minority and women, the result of analysis will not account for the underrepresented group. As a result, they may end up manifesting untoward response/reaction to the product after it is released.

Fortunately, there is the post release reporting of untoward effects which allows the regulatory bodies to take action if need be -- BUT these actions do not reverse impact on those who already experienced the post release unanticipated complication (Lawyers may get settlements for those impacted - how much is enough to pay for the harm?)

Discussions continue about how some groups may react to or respond to certain drugs and/or products... *Inclusion and adequate participation from all the groups in the clinical trials will positively inform this dialogue*
Consistently report, monitor, trend, and track key metrics along vulnerability lines to include gender/sex, race/ethnicity, rural/urban, military era/period of service, etc.

- Doing so will allow transparent monitoring of the progress for the vulnerable groups, support accountability, agency priority and bolster trust
- Got ideas for innovative health equity projects to tackle disparities among Veterans? Send your ideas to OHE: healthequity@va.gov

The pursuit of Health Equity should be everyone’s business.

It is a journey that takes time and sustained effort.

What can you do today in your area of influence to improve health equity?

At a minimum - in all your actions - do not increase the Disparity.

https://www.va.gov/HEALTHEQUITY/Tools.asp
LEARNING OBJECTIVES - REWIND

- Identify Veteran-related factors that place Veterans at risk for health disparities
- Describe Office of Health Equity and efforts to advance health equity for Veterans
- Explain the importance of including Veterans, while accounting for diversity, in clinical trials
- Describe reasons why Veterans are motivated to participate in clinical trials and why some populations are apprehensive about participating in clinical trials
Poll Question 4
Which of the following represent an accurately ordered pairing of a reason for apprehension & a motivating factor for participation in clinical trials:

- Altruism & Fear of death
- Historical misunderstanding & Altruism
- Spirit of service & Family ties
- Lack of awareness of trials & Mistrust
- All of the above
OFFICE OF HEALTH EQUITY

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- OHE Listserv sign up link: http://www.va.gov/HEALTHEQUITY/Updates.asp

- Next FHEA Cyberseminar 12.18.2017 : 3-4PM EST


Health Equity and Diversity in Clinical Trials

- Questions 1 - 4
- These factors put Veterans at risk for health disparities? Select all that apply.

- Age
- Gender/Sex
- Military Era/Period of Service
- Rural/Urban Living
- None of the Above
Examples of Office of Health Equity initiatives/products to advance health equity among Veterans include all of the following except:

- Using Veteran Stories to create training on Social Determinants of Health
- Funding contractors to map a path for Veterans
- VA Health Equity Roadmap - The HEAP
- Collaboration with FDA-OMH
Veterans participation in clinical trials makes it possible for scientists to identify solutions to health challenges as a result of military service.

- True
- False
QUESTION 4

Which of the following represent an accurately ordered pairing of a reason for apprehension & a motivating factor for participation in clinical trials

- Altruism & Fear of death
- Historical misunderstanding & Altruism
- Spirit of service & Family ties
- Lack of awareness of trials & Mistrust
- All of the above
○ Make the connection!

○ The work is far from over