Department of Veterans Affairs
National Research Advisory Council (NRAC) Meeting
Room 730, 810 Vermont Avenue NW, Washington, DC
June 5, 2019

Minutes

Members Present
Young, David G., Chair
Bitsui, LeManuel Lee
Farmer, Carrie M. (by phone)
Guccione, Andrew A.
Lee, Jerry S.H.
Lillard, James W.
Lima, Maria F.
Ling, Geoffrey
Lushniak, Boris
Maddox, Yvonne T.
McKinney, Jr., Ross

Members Absent
Catherine A. L. Wicklund

VA Staff Present
Rock, Avery, Designated Federal Officer (DFO)
Huang, Grant, Alternate DFO
Robinson, Rashelle, Alternate DFO
Ramoni, Rachel
Moragne, Jeffrey
Dorn, Patricia
Gurland, Jonathan
Singh, Hardeep
Souden, Maria
Byrne, James

Public Attendees
Anderson, Lauren
Charalambakis, Naomi
Starrs, Rick
Stewart, Julie
Taylor, German
Call to Order/Opening Remarks – Avery Rock, Designated Federal Officer (DFO); Grant Huang, Alternate DFO; Brig. Gen. David G. Young, Chair; Rachel Ramoni, DMD, ScD, Chief Research and Development Officer

Ms. Rock and Dr. Ramoni called the Committee to order at 9:07 a.m. as Dr Young, NRAC Chair, was delayed in Security. Ms. Rock was introduced as the new DFO for the committee and she provided statements regarding the committee, its purpose and the process for public comments. Dr. Ramoni welcomed and thanked the committee members for their service. She highlighted agenda items while describing key goals and objectives for the meeting including getting input on:

1) Electronic Health Record (EHR) Modernization and its impact on research – discussions and recommendations on how to mitigate those impacts will be an important area for the Office of Research and Development (ORD) going forward;

2) ORD Strategic Priorities on access to clinical trials, having substantial real-world impact of results and a priority related to making data work for Veterans;

3) Collaborations particularly with the Department of Defense.

Dr. Huang reminded the NRAC that some members will have terms expiring and requested that NRAC think about potential nominations. He solicited views from the NRAC on experience and expertise that would be valuable in addition to scientific and subject matter experts that would help with a diverse representation of health services, biomedical, clinical, rehabilitation, and other types of areas, such as informatics/information science and “Big Data”. With the current issues the VA and the nation are facing regarding the opioid crisis, suicide and limited mental health care access, it was suggested that special efforts be made to recruit a qualified mental health researcher to the NRAC.

Remarks from the Office of the Deputy Secretary – The Hon. James Byrne

While awaiting Mr. Byrne’s arrival, Dr. Maddox previewed the partnership discussion by describing a recent meeting at the Uniformed Services University that was also attended by Dr. Ramoni. At this meeting, topics focused on how to foster research collaborations with partners on the West Coast and in the Pacific. These partnerships involve DoD military treatment facilities and academic institutions in these areas. It was noted that given shared interests between VA and the Department of Defense (DOD), there may be some opportunities to pursue.

When Mr. Byrne joined the meeting, he thanked Council members for their service, noting the importance of federal advisory committees. He gave the top priorities for the Secretary which are:

1) Customer service – There is to be a focus on serving Veterans and those who serve the Veterans.

2) Implementation of the MISSION Act – While VA provides care in the community, consolidation of that care, making it more efficient, user friendly and helping providers will help add to the experience of care.

3) Modernization – Efforts are focused on Information Technology modernization across the country, improving activities involving the supply chain and financial management business systems.

4) DOD collaboration – VA has a natural relationship with the DoD that should be built up.

VA priorities on suicide prevention were discussed, especially regarding the need to address the stigma associated with mental health issues and seeking care.
NRAC members raised questions including how to obtain IT support for activities such as the Million Veteran Program (MVP). Mr. Byrne noted that VA has a new Chief Information Officer, Mr. Gfrerer, and encouraged talking to him.

NRAC Chair Dr. Young suggested the following recommendations which could be accomplished with no new resources:

1. Seek to expand the number of mental health professionals available to provide care for veterans by conducting a critical review of scope of practice limitations, and type of professional degree limitations acceptable for employment currently within the VA (e.g., PhD, PsyD and Masters in Counseling). Many states have expanded practitioner scope of practice limitations to address the critical shortage of mental health practitioners nationwide, especially in light of the opioid overdose epidemic. This would be similar to scope of practice expansion for nurse practitioners and physician assistants, optometrists and nurse anesthetists.

2. Address critically the barriers to care for Veterans, who should be encouraged to seek care for mental health issues, yet find negatives at their first encounter. For example, screening questions to obtain a permit or license to purchase a firearm often include a question such as “Have you ever sought treatment for a mental health problem?” This very question will dissuade veterans from seeking help as their legitimate concern is that answering in the affirmative may prevent them from exercising their Second Amendment rights. Further, a common concern within the active duty military force is that seeking help and receiving treatment ends up with a “Scarlet Letter” on their records which follows them from assignment to assignment even if the treatment was successful and has no further impact on duty performance.

3. Registries and various offices within the VA and the DoD working with post-deployment health concerns, e.g., Agent Orange-the Air Force Health Study, Gulf War syndrome and burn pit registries, seem to be managed by a multitude of offices. The stand-up of the Defense Health Agency (DHA) would seem to be an opportunity to bring these efforts together for a more unified and systematic approach, especially as relates to opportunities for clinical research.

Comments from the Advisory Committee Office (ACMO) and Ethics Training - Jeff Moragne, Director, ACMO & Jonathan Gurland, General Counsel Ethics Specialty Team

Mr. Moragne briefed the Council on the role of the Federal Advisory Committee Act and VA's efforts regarding its advisory committees. Additionally, the Council charter and balance plan were discussed and members were asked to review those documents. Dr. Young suggested that ACMO consider a summit for recognizing VA's contributions, particularly in research, that have brought substantial gains to the practice and understanding of healthcare to the benefit of all of our citizens.

Mr. Gurland provided the annual ethics training to NRAC members. He emphasized the role of special government employees and that members should feel free to call the Ethics Specialty Team with any questions. A copy of the VHA Code of Integrity will be provided to NRAC.

Discussions on EHR Modernization – Maria Souden, Ph.D., MSI Acting Director, VA Information Resource Center

Following a suggestion from the March NRAC meeting to discuss EHR activities, Dr. Souden was invited to provide an update on EHR Modernization (EHRM) efforts centering on the transition to Cerner and its implementation within VA. She noted that Seattle and Spokane will
receive the Cerner system first, by next March or April. The system will be implemented in a cycle around the country as a 10-year rollout. While 10 years is a long period, VA medical centers will have the opportunity to learn from each other over this time to help implementation go smoother.

Dr. Souden also discussed how the Office of EHRM has created 18 national councils that are tasked with specifying VA’s requirements with the Cerner system. Councils cover clinical, ancillary support, and business and support services. Research is under the Quality Safety Value workgroup, and concerned with the quality of data and how they are used analytically to meet research goals. The research workgroup is composed of members representing ORD services. Near-term efforts of the research workgroup are focused on mitigation plans for any initial risks when going live at first. Longer term goals will address next generation application/product development to push research further. The workgroup also will have a “go-live” strategy to assess risks, implement mitigation strategies, assess effectiveness and impact, and will continue to refine the strategy for the next go-live. The issues the workgroup would like to address include: 1) data syndication; 2) standing up research to help improve the implementation; 3) opportunities to invest in quality research, with a goal of improving it.

NRAC raised questions including:
- Each research group has their own sets of data, legacies, etc. How will they be handled?  
  Reply: There is a reports & registries workgroup addressing this to look at all the different items. These items will be inventoried and accounted for and their owners identified.
- What happens to VINCI? 
  Reply: VINCI isn’t going anywhere; it will work with Cerner data throughout the process. 
  NRAC then further questioned whether there would be adequate infrastructure support.
- What does interoperability of systems mean? 
  Reply: Community care and other groups can be provided opportunities for interoperability; also interoperability with DOD is facilitated as Cerner is their contractor as well.

NRAC discussed the need to touch on these issues at future meetings with an eye to developing an approach to studying these impacts in a way that will not be too burdensome.

NRAC was supportive of research on Cerner, its utility and impacts noting that it is primarily a clinical/billing platform. They indicated the importance of prioritizing data/research activities and needs, especially for “Big Data” research. We should not lose opportunities simply because they were not thought of initially.

2021 Proposed Priorities for ORD Budget – Rachel Ramoni, DMD, ScD

Dr. Ramoni presented recent ORD efforts on preparing the budget request and priorities for 2021. She highlighted ORD’s three strategic priorities related to access to clinical trials, making real-world impact and having data work for Veterans, and provided brief updates on these priorities. Dr. Huang noted that written updates were provided to NRAC members as specified in the annual plan, and in the interest of time, welcomed feedback via email.

NRAC members followed with questions and suggestions including:
- Consideration should be given to the appropriateness of biomarker research in light of MVP efforts.
- There is a need to look at diversity in genomics/genetics research.
Dr. Ramoni noted that while diversity considerations are a part of planned activities, it can be more clearly highlighted. An example of research results known to be a factor of a diverse population is to gain a better understanding as to why African Americans have a higher rate of prostate cancer.

- How can priorities be addressed in an environment of limited funds? Also, what is the impact on making the key priorities more visible?
- There is a need for mental health research efforts to be front and center. How can VA ensure mental health issues get an appropriate share of research funding?
- In context of the 21st Century CURES Act VA was left out; how can that be changed?
  - It was further noted that given VA's impact from its smaller research budget compared to NIH, VA needs to consider how to ensure research is included in overall budget discussions. How can decision makers be made to understand the impact of VA's translational research activities given return on investment?
- the VA ecosystem allows comparing the signaling cascades, phenotypes, etc. inherent within various health issues. How does VA leverage this system?
  - Patients own their own data under 21st Century Cures; VA has the opportunity to teach other systems about how to handle such issues
- Data/data science is a common link among all of the areas. Who else will partner to do the work, especially given VA's particular strengths in this area?
- There has been a tendency to look at things backwards. There needs to be a way to align funding with areas where there have been successes. For example, an evaluation of the portfolio should help with investing in those things that have been going well based on outcomes, while also turning to forward-looking projects.
- What can be done to trumpet where VA research has made a huge difference in healthcare for all Americans? What has VA done that no one else has done, and that wouldn't have been done elsewhere?
- ORD should consider engaging younger people in research; some beneficiaries of VA are members of underrepresented individuals and communities – how can we engage them into our system? Is there a way to formalize such programs within VA R&D?
  - This topic may be a good opportunity for collaboration with the NAAC and a potential area to explore. It was further suggested that a subcommittee on training/education be established.

Facilitating ORD Research Collaborations – Drs. Maddox and Ramoni

Discussion continued from earlier meetings regarding collaborations with others, including the DOD. It was suggested that ORD also needs to consider looking at the Public Health Service (PHS). The PHS has several qualities and priorities that align with those outlined previously. Another suggestion was to look at what is known about research activities and how well they reflect the populations they were intended to serve. What can ORD do to have researchers align with those groups?

The following idea was proposed: Pick 5 sites (e.g., locations where there is a VA and DOD healthcare facility and possibly PHS site) and target their use of Cerner/EHR-informatics for opportunities for research collaborations. Such an approach may help with more proactive directions on requirements development. San Antonio, Seattle, Tidewater, Las Vegas and the Washington, DC regions were suggested. Following a request for priorities in 2021 from Dr. Ramoni, it was proposed that ORD should consider having a certain number of VA/DOD collaborations driven by EHR activities. Another consideration was to identify locations where there are VA and DOD sites to be focal points for doing data science research.
Questions arose regarding work in toxic exposures and whether future meetings should discuss recommendations from the National Academies for Science, Engineering and Medicine. Also, does ORD need to operationalize a response to that report? It was suggested that someone be invited from an appropriate DOD service or from the DHA to a future meeting to speak about it. NRAC members should provide input on the types of information they would like to hear at a future meeting. Another idea was for ORD to consider how to potentially include beneficiaries/children of veterans as future investigators interested in addressing problems faced by their parents. This topic was proposed as an agenda item for the next meeting.

**VA Investigator Presentation - Hardeep Singh, MD, MPH – Chief, Health Policy, Quality and Informatics Program, Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey VA Medical Center**

Dr. Singh presented his work involving the EHR and the related challenges and best practices within healthcare facilities. Examples highlighted multiple socio-technical issues that related to health IT safety implementation issues. His research suggested the need for more interagency operability and collaboration on best practices. Implications are related to diagnostic activities, medication overdoses and the clinician's roles in healthcare delivery. Activities should target regulatory and policy requirements.

**Wrap-up and Adjournment**

Closing comments from Dr. Ramoni and Dr. Young summarized activities for future meetings. Work on toxic exposures and bringing young investigators into VA research who have personal connections for doing this work were re-emphasized. It was also requested that ORD topic areas and funding amounts be presented to help with context on the ORD 2021 budgetary priority discussion. Regarding collaborations, the discussions related to DOD opportunities were raised. An attempt to identify agreements (e.g., in prostate cancer, suicide prevention, Cerner/EHR) and to identify what outcomes have been successful and noteworthy should be undertaken. The alignment of VA’s efforts with the Defense Health Agency were also recommended as a focus for future discussion.

Public comment came from the National Association of Veterans' Research and Education Foundations regarding their and VA affiliated non-profit corporations being available to assist with any future collaborative opportunities.

The meeting was adjourned at 3:17 p.m.

David G. Young III, M.D., FACP, Brig. Gen. USAF (Ret.)
Chair, National Research Advisory Council