Department of Veterans Affairs
National Research Advisory Council Meeting
Room 730, 810 Vermont Avenue NW, Washington, DC
June 7, 2017

Minutes

**Members Present**
Feussner, John R., Chair
Grody, Wayne W
Guccione, Andrew A.
Rauch, Terry M.
Steinwachs, Donald M.
Washington, Donna L.
West, Barbara F.
Young, David

**VA Staff Present**
Atkins, David
Bever, Christopher
Breeling, Jim
Cody, Marisue
Cooper, Melissa
DePalma, Ralph (VANTS)
Dorn, Patricia
Jaeger, Robert
Kaplan, John
Kilbourne, Amy
Moser, Jennifer
Ramoni, Rachel
Smyth, Miriam
Huang, Grant
Kalasinsky, Victor
Thompson, Caitlin
Call to Order – Melissa Cooper
Mrs. Cooper called the meeting to order at 9:08 a.m.

Introductions – John R. Feussner, MD, MPH, Chair
The members and other attendees introduced themselves.

Brief by ACMO – Jeff Moragne, Director, ACMO
Mr. Moragne briefed the Council on the role of the Federal Advisory Committee Act, the Council charter, and the Council balance plan; and asked members to review those documents. The VA is expanding its portfolio by adding five new advisory committees.

Strategy Review – Rachel Ramoni, DMD, ScD, CRADO
Dr. Ramoni mentioned distributing one and five-year action plans from various directors to the Council. The VA has established five VA priorities:
1. suicide prevention
2. modernizing VA systems
3. improving timeliness of service
4. focusing resources more efficiently
5. creating greater choice for veterans

Acting USH wants greater accountability with specific milestones and timelines. ORD is looking for independently meaningful milestones for investigator-directed research, and faces challenges in achieving goals because of the hiring freeze and proposed budget cuts, especially the 90% cut to IT, requested 21 million, budget reduced to 2 million, 2017 budget was 20 million. Because funds have already been committed for projects running for several years, the cut critically limits new awards. ORD has opportunity to increase efficiency through big data, technology transfer, enhancing the efficiency of clinical trials, and tracking impact, and active portfolio management.

Discussion question 1: What are paths through which research could better integrate with operations at the VA?

Dr. Ramoni responded to questions regarding shared NCI trials and milestones for the cancer research portfolio, and opened the floor to discussion.

It's important to track impact separately from milestones, and create realistic expectations for research outcomes. Substantial impacts on practice may be the cumulative result of multiple studies. Chairman Feussner encouraged ORD to tell the VA about its successes, including Tim Wilt’s upcoming 20-year follow-up on PIVOT in the New England Journal. Research by the VA can be performed either because of a problem unique to veterans, or because of the VA’s unique ability to contribute to the knowledge base (as with the clinical trial on a herpes zoster vaccine and research into prostate cancer). Integration should be built into funding requirements.

*Operations, executives, clinicians, and research should jointly develop a research agenda on high priority high visibility projects.
Caitlin Thompson – Executive Director, Suicide Prevention
The veterans’ issue with suicide is also a general population issue, but numbers on suicide have increased more for veterans between 2001 and 2014 than for the general population. Veterans who have not deployed have a higher rate than those who have, and 65% of veteran suicides occur in veterans age 50 or older.

Veterans who use VA health services have lower rates of suicide than those who do not. The veteran suicide issue is a problem for private practice as well as the VA, particularly with the CHOICE program. The VA should perform outreach to civilian providers, and is working toward collaborations with SAMHSA and NIMH to bolster the suicide prevention portfolio with research from outside providers.

Research has shown that reducing access to lethal means, educating primary care providers on suicide issues, and structured follow-up after a suicide attempt are effective means of reducing the risk of suicide. The VA is exploring home visits, text messages, and letters as means of follow-up. The VA has worked to reach veterans at risk for suicide through strategic partnerships, integrated suicide prevention coordinators at every facility, REACH VET, and the Veteran Crisis Line. The VA can distribute gun locks, but is unable to collect data to confirm that this prevents suicide. The REACH VET program, piloted last summer, uses an algorithm to identify veterans in the VA system with the highest risk of suicide and reach out to them through their providers.

Dr. Thompson discussed the program with the Council. Chairman Feussner, David Atkins, and David Young discussed possible methods of expanding the use of the algorithm used by REACH VET to reach veterans who have never used the VA health system through partnership with DoD. Research into the effectiveness of programs like REACH VET is as important as research that precedes new programs.

Big Data Update – Jim Breeling, MD, PhD, Director of Biometrics
ORD held its first big data summit in 2017, although the VA has been invested in big data for some time. The VA has formed a partnership with the Department of Energy, which has greater computer science staffing capabilities and industry partnerships, to create a hybrid cloud to meet VA’s data needs as defined by program directors at the 2017 Data Summit. The partnership is funded for five years, has an interagency board, and has expanded the concept of national strategic computing to include healthcare data. The hybrid cloud architecture is ideal because of its compatibility to VA’s needs for management, security and privacy; and will form a system that promotes enhancements to the knowledge base to improve veteran outcomes.

VA aims to create a data structure that will allow genomic case files to be passed to hospitals to use in direct decision support in real time. The Department of Energy partnership is an opportunity to improve the way data is exchanged with other agencies, such as the NIH; although the partnership’s biggest challenge thus far has been breaking down policy barriers to data sharing. Collaboration with the Department of Energy opens the VA to research that will analyze the full sample of genomic data,
whereas VA’s RFAs have typically used ‘villages of data’ of around 20,000. Centralizing VA’s imaging data has proven challenging, as Cerner has no native imaging capability and imaging data is often held in local proprietary systems because the VA computer system was initially designed to be decentralized.

**Jennifer Moser, Program Manager, Million Veteran Program**
The Million Veteran Program (MVP) currently has 51 sites enrolling and has enrolled 570,000 veterans. Enrollment is currently being done in person; but a contract will be awarded this year to create a web portal for enrollment, recruitment, and engagement. A partnership with the Department of Defense to enroll Millennium Cohort Study participants through VHA has been established. Every participant in MVP contributes a blood sample, which undergoes DNA genotyping. MVP hopes to have a genome sequencing sample of 25,000 this fiscal year, and is piloting other omics such as metabolics, proteomics, and methylation this year.

MVP has eight ongoing scientific “alpha” and “beta” projects of high priority for research, funded by CSP and BLRD. MVP is reviewing “gamma” applications, with funding decisions to be made in August, ideally approving eight projects. The MVP program had a summit with the Department of Energy in April, and selected prostate cancer, suicide prevention, and cardiovascular disease as projects to pursue jointly.

Discussion question 2: How can we make the most of our VA-DOE partnership?
- Need OMB budget line for FY19 for Healthcare IT
- DOD/VA Joint initiative agreement that Service Members will have a paper record
- Leverage DOE Research on DNA repair
- DOE Data Scientists may be good source of suggested research

**LUNCH BREAK**

**John Kaplan, Ph.D., J.D., Director, Technology Transfer Program (TTP)**
The Technology Transfer Subcommittee identified training as an issue. Technology Transfer has created an online TTP training course targeted towards investigators and Associate Chiefs of Staff (ACOSs). The web-based training moves through a script and questions on the basics of technology transfer and its disclosure forms, and takes about twenty minutes. TTP has conducted 36 site visits since July 2016, and is distributing investigators’ notebooks and tailored posters.

TTP’s increased staffing has allowed for better engagement, resulting in better cooperation and information from universities under CTAAs as well as revenues through licensing and royalties. VA used to have national organizations for ACOSs and other chiefs that allowed VA’s central office to communicate directly and identify priorities. ACOSs need to know how to set up a system in their offices to manage the legal obligations associated with tech transfer.
Chairman Feussner asked whether GAO had made progress investigating growth for the tech transfer program. Dr. Kaplan replied that GAO is constantly engaged but is still investigating, as tech transfer is highly complex.

Chairman Feussner noted that integrating programs that overlap in suicide prevention, opioid abuse, and homelessness may be opportunities to bring together clinical folks with ORD. Dr. Atkins noted that in addition to its investigator-initiated programs, QUERI has 12 partnered evaluation centers where the partner provides 80% of the funding and drives the agenda more.

**Patricia Dorn, Ph.D., Director, Rehabilitation Research and Development**

Dr. Dorn asked the Council members for input on creating metrics for the small projects program that has replaced the pilot program. At the moment RRD has close to 500 funded awards across the funding mechanisms. The Luke arm has commercialization, and purchasing is in the works. After significant research funded by VA, DoD, and NIH; VA is doing the first in-human USA trial for lower extremity implants. After FDA approval, RRD hopes to move on to a safety study for upper extremity implants.

Chairman Feussner suggested asking FDA to advance to the efficacy trial for upper extremity based on the lower extremity safety trial; and incorporating European research with VA research, as upper and lower extremity implants are already available in Europe.

Progressive tinnitus management was built, developed, and has launched an EES; and is being used at VA audiology clinics, DoD clinics, and private sector providers. Chairman Feussner emphasized the importance of highlighting this success in communications with the Secretary.

Dr. Dorn asked for input on the SPIRE program. Dr. Guccione expressed optimism for SPIRE because he has reviewed are not exclusively devices. Rehabilitative devices create interest and serve veterans with high cost injuries such as limb loss; but non-device rehabilitation is also critical to the well-being of veterans.

**Chris Bever, M.D., Director, Biomedical Laboratory Research and Development**

To investigate concerns at the loss of clinician researchers raised at the last meeting, surveys were sent to VA clinicians who had had funding and are no longer funded. Of the 139 who responded, 60% no longer have funding, and 35% cited loss of personnel during the renewal process as a significant factor when unable to renew awards. Any clinician investigator at a VA medical center losing funding with this round of renewals will be able to participate in a pilot bridge funding program.

ORD is continuing to look into balancing its workforce, but will not be requiring medical centers to fund a clinician for every non-clinician investigator. Overall, clinicians are almost as effective in research as non-clinicians, but are twice as likely to drop out of research when they lose funding. Dr. Bever discussed the VA’s unique position to perform discovery research because of its clinician investigators and large pool of long-term data.
Dr. Bever moved on to discuss infrastructure. He suggested shifting the portfolio balance to emphasize special areas of veteran need, and to look within aging research at how the particular problems faced by veterans play out as veterans age. VA is forming a research plan to make burn pit registry better coordinated for research.

*May be value in listing portfolio by Veteran cohort/era.

**Miriam Smyth, Acting Director, Clinical Science, Research and Development**
CSR&D’s top three research priority areas are suicide prevention, PTSD, and traumatic brain injury (TBI). CSR&D established a PTSD psychopharmacology initiative in December 2016 by establishing an executive committee of field experts in PTSD; which has produced a white paper in the *Society of Biological Psychiatry Journal*. The initiative has selected Tonix and Corcept to provide PTSD medication for research, and is performing site surveys to identify VAs that are well-positioned for clinical trials of PTSD medication. CSR&D has initiated meetings to discuss comparing PTSD portfolios with Cohen Veteran Biosciences.

ORD rolled out a specific RFA in Fall 2016 focused on suicide prevention, and funded two submissions from the Fall round. Dr. Smyth expressed concern that the RFA received very few submissions. Dr. Bever recommended that ORD specify an amount of money committed to the RFA, to clarify the advantages of applying to the ORD as well as the VA. Suicide prevention research is challenging, and goals are not clearly defined, and multiple studies compete for a limited population.

**Discussion - John R. Feussner, MD, MPH, Chair**
Discussion question 3: How should ORD measure its success?

Chairman Feussner invited the Council to discuss success metrics for processes and outcomes. System outcomes are important, and studies that find a cheaper drug to be as effective as its more expensive counterpart can save money for the health system. Dr. Young asked how VA as a body can seek research based on new demographic information on specific topics to fill knowledge gaps. The main mechanisms would be an annual state-of-the-art conference, or an RFA. RFAs have a faster turnaround, but a state-of-the-art conference focusing on the population being served could inform a research consortium.

Chairman Feussner suggested the enumeration of partnerships as a possible system metric. Metrics for partnership could include contact with prospective partners, implemented partnerships, contributions of money or assets from a partner, or progress toward partnership goals. Because VA is known to be difficult to partner with, informing Congress of its successful partnerships is important.

Chairman Feussner turned the discussion to Council action items.

Chairman Feussner recommended the Council task the CRADO with reviewing and evaluating the VA’s research infrastructure needs, including wet labs. As VA labs
deteriorate, more VA investigators ask for waivers to do VA research at universities, which takes the investigator out of the VA.

Chairman Feussner asked that ORD identify its top ten impacts from the last five years and its communications strategies inside and outside of the VA, and report back in September. Examples such as the success of the Research Day event on the Hill.

Chairman Feussner recommended integrating the suicide prevention research group using the QUERI model, and to identify the five top priority areas to develop.

Chairman Feussner recommended VA create more effective collaboration that includes DoD and takes advantage of the new Cerner initiative to create common EMR, work with the Department of Energy to improve computer security, and resolve the longitudinal and imaging data issues with Cerner and Vista. Merging the health record is a multiyear initiative, and must be approached strategically. Chairman Feussner’s final recommended action item was the establishment and distribution of best practices within VA.

Chairman Feussner asked the Council for further potential recommendations. Dr. Young asked the group for their sense of the burn pit, Agent Orange, and Gulf War registries. There is tension between the owners of data, who are outside of ORD, and those who would curate and use the data. Dr. Young highlighted the importance of visibility for these veteran-specific health issues.

*Patient Outcomes
*System Outcomes
*Partnerships – successful private and public

Recommendations/Action Items
- Research infrastructure - personnel, physical infrastructure, IT Infrastructure. What are the positive impacts?
- Integrate suicide research using QUERI model, identify the five top priority areas to develop a research agenda in the next 6-12 months.
- DOE – how do we get VA/DOE to create a more effective collaboration with DoD and EMR?
  - DOE excellence in computer science, what can we learn?
  - Image data issue with Cerner
  - Longitudinal data with VISTA
  - Time to get initiatives on the table is now
- Best practices
  - ACOS/TTP system in Baltimore – expand to 10 sites
- Burn pit, Gulf War, AO repositories registries, where do they reside? How to coordinate standardize registries? (They belong to Patient Care)
- Identify ORDs top ten impacts from the last five years, then communications can identify its communications strategies inside and outside of the VA, and report back in September. Fostering expedited communication through VHA communications
Adjournment
The motion to adjourn was made and seconded. Chairman Feussner adjourned the meeting at 2:30 p.m.

Melissa Cooper  
Designated Federal Officer  

John R. Feussner, MD  
Chair