

National Research Advisory Council
U.S. Department of Veterans Affairs
Office of Research and Development (ORD)
1722 "I" Street, NW, Room GL 20
Washington, DC

April 14, 2008

Members present:

Marie Bernard, MD, Chair
Jeffrey Drazen, MD
Robert Kelch, MD
Col. Aaron Butler, USMC, Ret.
Dudley Childress, PhD
David Korn, MD
Richard Wenzel, MD, MSc
Albert Reese, MD, PhD, MBA

Guest Presenter:

David Vesely, MD, VA Medical Center Tampa

VA Staff:

David Atkins, MD
Gina Clemons
Patricia Dorn, PhD
Seth Eisen, MD, MSc
Jay Freedman, PhD
Sandra Isaacson
Joel Kupersmith, MD
Jeff Moore, PhD
Timothy O'Leary, MD, PhD
Ron Przygodzki, MD
Cheryl Oros, PhD
Doug Young

Guests:

Louis E. Antosck, MD, J-7, Joint Task Force, National Capital Region
Robert Jasak, Esq., American Association of Orthopedic Surgeons
Dane Christensen, The Digestive Disease National Coalition

The meeting was called to order by Dr Bernard at 8:30 a.m. followed by all the attendees introducing themselves. NRAC members were asked to review the minutes from the last meeting and approved them unanimously.

Report from CRADO –Dr. Kupersmith:

Currently, there are thirteen master Cooperative Research and Development Agreements (CRADA – to be discussed by Dr. Moore) – two have already been signed. Novartis was the first to join.

The online grant application process is moving forward. Congressionally Directed Medical Research Programs (CDMRP) has allocated \$300M over 5 yrs for Post Traumatic Stress Disorder (PTSD) & Spinal Cord Injury research. Of special note was a \$60M research grant to Dr. Mary Stein of San Diego VAMC.

Dr. Kupersmith mentioned the gains made recently in Office of Research and Development's (ORD) communication efforts:

- Upcoming research and development week activities at VA Central Office on May 23rd with various celebrities, including Bob Feller;
- National media attention to VA research on:
 - Flat polyps as cancerous;
 - Cordoma;
 - Alzheimer's disease;
 - Diabetes;
 - Post Traumatic Stress Disorder (PTSD) gene;
 - Parkinson's disease.

“Cardiac Hormones in the Treatment of Congestive Heart Failure (CHF), Renal Failure (RF) and Cancer (CA).” – Dr. David Vesely

Dr. Vesely gave a presentation describing the different ways that four cardiac hormones can be used to treat CHF, RF and several different types of cancer. Treatment of CHF and RF in humans has had significant success with the cardiac hormone therapy. Treatment of CA in animals using these hormones has had excellent results. Testing of CA in humans has not begun.

BLR&D and Genomics – Dr. Przygodzki

Dr. Przygodzki briefed the council on status and progress in genomics. He discussed a recent VA survey to assess ongoing genomic/genetic activities at one hundred fifty-four VAMCs. The results:

- Of one hundred fourteen responding VAMCs, ninety-nine perform genetic testing.
 - Genomic/genetic testing
 - Clinical, predominantly heritable
 - A combination of in-house and off-site
- Educational tools and materials were few. Only about 25% of the facilities had and were using educational materials.
- Genetic counseling was being done both in-house and off-site, predominantly the latter.

Dr. Przygodzki discussed planned studies and resource development:

- Development of educational programs and tools for physicians and other health professionals:
 - Collaboration between VA Employee Education Services and the National Coalition for Health Professional Education in Genetics
 - Introduction of web-based heritable colorectal cancer program
- Health Services Genomics Workgroup
 - To review and begin the process of developing a healthcare delivery model;
 - To provide a framework for planning and delivery of genomic services to the VA population.

Clinical Science Research and Development Service – Dr. O’Leary

Dr. O’Leary discussed CSR&D activities:

- Longitudinal cohorts in PTSD (May be helpful in studying non-genomic disease);
- ACE inhibitors for treatment of diabetes mellitus;
- Transcranial treatment of mental diseases; electromagnetic pulses for the treatment of depression;
- Use of “Prazocin” for the treatment of nightmares associated with PTSD;

CSP Study Updates:

- Two new studies approved at the December 2007 Cooperative Studies Scientific Merit Review Board (CSSMRB):
 - CSP 566 – Longitudinal mental health and neurological outcomes in OEF/OIF veterans
 - CSP 560 – Education and case management for COPD (Full trial)
- A CSP for colon cancer tissue repository is being established at the VAMC in Durham, NC.
- There are several studies in the planning stage:
 - Three genome-wide association studies:
 - Schizophrenia/bipolar disorder
 - PTSD
 - ALS
- Four clinical trials:
 - Non-acute coronary syndrome;
 - Saphenous vein grafts;
 - GERD;
 - Community-acquired pneumonia.
- One demonstration project:
 - Brain-computer interface for patients with ALS

ORD has several CSP initiatives:

- Development of small/early phase clinical trial mechanisms;

- Enhance clinical research methodological expertise:
 - Biostatisticians
 - Genetic statisticians
 - Informaticists

Administrative Review – Ms. Isaacson

Ms. Isaacson discussed the recent administrative review of ORD. Its purpose is to review and identify methods to ensure the best possible outcomes for VA research, through robust management and an appropriate field-based administrative structure. ORD is responsible to provide guidance, a template and support systems to assist VA facilities in achieving these goals. To further these efforts, ORD is convening a steering committee and two work groups:

- Governance, will:
 - Clarify, with regard to research and development, the roles of those in key leadership positions – VISN director, medical center director, chief medical officer, ACOS for R&D, and Administrative Officer.
 - Identify the lines for reporting within and between local research centers, medical center, VISN and VACO.
 - Define the R&D committee's role in governance.
- Human Capital, will identify:
 - Candidates for which local positions should be referred to ORD for concurrence.
 - Mechanisms to recruit and mentor young scientists.
 - Management of time practices for research.
 - Succession planning for key research administrative positions.
 - Duties, responsibilities and reporting requirements regarding research compliance.
 - Standard elements related to R&D to be included in VHA leaders' performance expectations.

The committee and both work groups have been identified. Issues related to financing, science and stakeholders will be addressed separately. ORD will assist in the development of data collection strategies for the research center and summarize the data. The data gathering strategy meeting will be April 16, 2008. This information will be used by the work groups to develop recommendations for the steering committee which will review and make recommendations to the CRADO.

Cooperative Research and Development Agreement (CRADA) – Dr. Moore:

February 20, 2008, NAVREF hosted a CRADA conference. Over fifty people attended from thirty pharmaceutical companies. Dr. Kussman, Paul Hutter and Dr. Kupersmith all spoke at the event. The remainder of the day was spent going through the CRADA clause by clause. There were many questions, comments

and recommendations from the attendees. General Council accepted some of the recommendations and some have been implemented. The overall impression is that the CRADA is better; it helps the pharmaceutical companies and provides them with rights and boundaries. Currently, there are thirteen master CRADAs under review. CRADAs were mandated on Mar 26. Novartis is VA's first master CRADA.

Communications – Ms. Clemons

Ms. Clemons highlighted the upcoming “VA Research Week” scheduled to be celebrated at VA medical facilities from May 11-17, 2008. VACO will celebrate it on May 23, 2008. Ms. Clemons noted that among several celebrities who are attending the celebration will be Bob Feller (Veteran and Baseball Hall of Famer). She distributed the most recent RR&D handouts and pamphlets and gave the VA Research and Development's website address: www.research.va.gov.

Quality Enhancement Research Initiative (QUERI) –Dr. Atkins:

Mission: To enhance the quality, outcomes and efficiency of VA health care by systematically facilitating the implementation of evidence-based research findings into routine clinical practice.

Dr. Atkins gave an overview of QUERI's ten year history, its research/implementation pipeline and identified QUERI coordinating centers. He described strengthening connections and collaboration:

- Implementation Resource Center
 - Provide consultation/support/evaluation to implementation efforts in patient care;
 - Facilitate hand-off in national rollouts;
 - Strengthen inter-QUERI collaboration.
- New leadership (OQP, Primary Care) – a chance to align priorities
- National QUERI meeting, December 2008 – focus on connections to patient care.
- Many important issues for policy and implementation cut across conditions
 - Health IT (CPRS, MyHealth-eVet, secure messaging);
 - Healthy behaviors;
 - Complex, comorbid patients;
 - Care coordination, transitions in care.
- There is a need to capitalize on shared learning across QUERI centers as QUERI is both a research and clinical quality improvement program.

VHA & OI&T: Center for Scientific Computing (CSC) – Dr. Eisen:

Dr. Eisen discussed the background of IT barriers for researchers within the VHA system to include:

- Multiple permissions required for data access;

- Local ISO and PO required;
- Data security and privacy risks;
- Data transfer is usually complex;
- Medicare data is not available;
- OEF/OIF data is not available.

He further explained the CSC concept and objectives:

- Establish high-performance computing, national research database;
- Enhance data security;
- Facilitate data access;
- Permit remote data access and analysis;
- Disseminate research informatics products to investigators and operations;
- Develop database partnerships with DoD, CMS, etc.

Dr. Eisen explained how the CSC Governance Board would be chaired by ORD and OI&T with members from both offices, as well as ORO. He identified advantages to the CSC concept:

- Enhanced relations between ORD and OI&T;
- Enhanced data security and privacy;
- Make more data available than previously;
- Standard analysis scripts may be shared with all users;
- Real time data mirror with VISTA permits real time clinical applications;
- Enhanced dissemination of research informatics products will facilitate research progress.

There are some potential disadvantages:

- Mechanisms must be developed to merge investigators' data with CSC's database;
- Security and privacy risks may be reduced but perhaps not completely eliminated;
- Software development may be complicated;
- It will be expensive

Implementation sequence:

- Develop a services and support agreement;
- Allocate funds from ORD's IT budget;
- Medical informatics investigators will develop CSC with OI&T;
- Following successful implementation, CSC oversight will be transferred to ORD.

Rehabilitation Research and Development (RR&D) Service – Dr. Selzer (by telephone):

Dr. Selzer discussed several ongoing RR&D programs.

Prosthetics

- Collaboration among DARPA, VA scientists and industry may restore fine upper limb control to VA amputees;
- Advanced prosthetic ankle/foot is improving ambulation among those VA amputees

Merit Review Applications. Of one hundred sixteen applications received, The plan is to fund thirty-two of which seven are for high priority projects. Regarding career development applications (CDA), thirty-nine of all types were received. The plan is to fund sixteen (scores <18):

- CDA-1
 - Sixteen applications reviewed
 - The plan is to fund six of which two are for high priority areas
- CDA-2
 - Twenty-one applications were reviewed
 - The plan is to fund eight of which one is for a high priority area
- CDTA
 - Two applications were reviewed
 - One application will be funded.
- Four applications were received for research career scientist projects:
 - Two applications were for Research Career Scientist (scores <13)
 - Plan to fund two.
- Two applications for Senior Career Scientist were reviewed
 - Plan to fund one.

New RR&D staff scientists were introduced:

- J. Thomas Pierce, PhD, MBBS
- Robert Jaeger, PhD
- Audrey Kalehua, PhD
- Sunil Sengupta, PhD, MPH

The meeting adjourned at 1:00 p.m.

I hereby certify that, to the best of my knowledge, the foregoing minutes are an accurate and complete record of the substance of the meeting.

Jay A. Freedman, PhD
Designated Federal Officer
National Research Advisory Council

Marie A. Bernard, MD
Chair
National Research Advisory Council

These minutes will be formally considered by the Council at its next meeting, and any corrections or notations will be incorporated in the minutes of that meeting.