DEFENSE HEALTH BOARD
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AUG 1 8 2010

DHB

MEMORANDUM FOR: CHARLES L. RICE, PERFORMING THE DUTIES OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

SUBJECT: Review of the Department of Defense Center for Deployment Health Research

1. References

   a. Presentation: Review of the Department of Defense Center for Deployment Health Research, 11 May 2010, by Dr. Tyler C. Smith, Deployment Health Research Center.

   b. Presentation: Review of the Department of Defense Center for Deployment Health Research, August 2009, by Dr. Tyler C. Smith, Deployment Health Research Center.

   c. Memorandum, Assistant Secretary of Defense for Health Affairs, 17 September 2002, Public Health Advisory Board to the Centers for Deployment Health.

   d. Memorandum, Assistant Secretary of Defense for Health Affairs, 30 September 1999, Policy – Establishment of DoD Centers for Deployment Health.

   e. Institute of Medicine. Adequacy of the Comprehensive Clinical Evaluation Program, 1997.

BACKGROUND

2. In accordance with Section 743 of the Strom Thurman National Defense Authorization Act (NDAA) for Fiscal Year 1999 (FY99), the Secretary of Defense was authorized to establish a Center devoted to "longitudinal study to evaluate data on the health conditions of members of the Armed Forces upon their return from deployment."

3. In a memorandum dated 30 September 1999, the Assistant Secretary of Defense (ASD(HA)) endorsed and directed the establishment of three Centers for Deployment Health. Each Center Director is to provide an annual report to the Assistant Secretary of Defense for Health Affairs (ASD(HA)) on the status and progress, limitations, and accomplishments of the Center's efforts.

4. In a memorandum dated 17 September 2002, the Defense Health Board (DHB), formerly the Armed Forces Epidemiological Board (AFEB), was charged by the ASD(HA) with providing ongoing programmatic review to the Department of Defense (DoD) Centers for Deployment Health, to include, the Center for Deployment Health Research at the Naval Health Research Center in San Diego, California; the Deployment Health Clinical Center at Walter Reed Army Medical Center in Washington, DC; and the Armed Forces Health Surveillance Center at the U.S. Army Center for Health Promotion and Preventive Medicine in Aberdeen Proving Ground, Maryland. The focus of this report is the Naval Health Research Center (NHRC) in San Diego, California, designated as the Center for Deployment Health Research, which has primary responsibility for the Millennium Cohort Study (MCS).

5. The DoD established the Center for Deployment Health Research in response to recommendations that the DoD investigate the impact of military service, in particular, deployment, on the long-term health of military Service members. The current portfolio at the Center for Deployment Health Research includes post-immunization studies, deployment and healthcare studies, the Birth and Infant Health Registry, the Recruit Assessment Program, and the MCS. The recommendation and endorsement for a prospective cohort study, the MCS, has roots in the following documents:

   a. In 1997, the Institute of Medicine (IOM) published a report on the Adequacy of the Comprehensive Clinical Evaluation Program, and recommended establishment of a report.

   b. Section 743 of the Strom Thurmond NDAA FY99 directed the Secretary of Defense to establish a Center devoted to a longitudinal study to evaluate data on the health conditions of members of the Armed Forces upon their return from deployment.

   c. In a memorandum dated 30 September 1999, the ASD(HA) issued a policy in establishing a DoD Center for Deployment Health. The NHRC was designated as the DoD Center for Deployment Health Research and specifically charged with a number of research initiatives including epidemiologic studies investigating the longitudinal health experience of previously deployed military personnel.

   d. Few epidemiological studies have examined the impact of deployment on family members and family functioning. Family relationships play an important role in the functioning and well-being of U.S. military Service members. In late 2010, the Family Millennium Cohort Study will enroll approximately 10,000 spouses in order to assess the impact of deployment and military service on spouses and children of Service members.

e. The Family survey will include topics such as impact of deployment and service on spouse and family, services received, family cohesion, and behavior and development of children.

f. The Family Millennium Cohort Study is supported by the DoD, and the Military Operational Medicine Research Program.

6. The IOM committee further recommended that an independent advisory board, known as the Scientific Steering Advisory Committee (SSAC), oversee the conduct of the Millennium Cohort Study. In addition to subject matter experts, members of SSAC should include Active Duty military scientists, retired officers, and enlisted senior leaders. As recommended by the IOM, the SSAC should be an independent, scientific, and policy-oriented body composed of experts in: clinical medicine, epidemiology, health status, and health outcomes assessment; veterans' health issues; health services research; statistics; national health databases; health policy; and members of the public who represent veterans.

7. SSAC membership is reviewed yearly by Co-Investigators at the Center for Deployment Health Research. In the past 10 years, six members have served on the Committee and chose not to be reappointed, and one member was not reappointed based upon their review. The SSAC serves solely for the MCS; advisory committees are currently being planned for the Recruit Assessment Program, the Birth and Infant Health Registry, and the Family Millennium Cohort Study. It is unclear where the mandate for the SSAC resides. However, the SSAC is structured with a fixed number of advisors from the military services, veterans groups, and scientists. The members meet periodically to review scientific protocols, and data analysis. The DHB did not request a summary of problematic areas and the suggestion for remediation developed by the SSAC, nor is it known whether such a document exists.

8. The American Institute of Biological Sciences (AIBS) is sponsored by the United States Army Medical Research and Material Command (USAMRMC), by way of the Military Operational Medicine Research Program (MOMRP), to ensure that United States resources are adequately utilized. The AIBS conducts periodic reviews of the Center for Deployment Health Research; the focus of the review is on the quality of the science, staffing, and review priorities.

9. Members of the Defense Health Board Military Occupational/Environmental and Medical Surveillance Subcommittee framed questions regarding the Center for Deployment Health Research, which were sent to the Subcommittee Chair. The Subcommittee Chair and the Defense Health Board Executive Secretary traveled to San Diego, California on 5 October 2009 and met with a Principal Investigator of the Center for Deployment Health Research, Dr. Tyler Smith, along with several staff. The Subcommittee Chair then drafted a preliminary report as a result of the site visit to the Center.

10. The Subcommittee held telephonic meetings on 20 August 2009, and 22 December 2009 to establish a plan for review of the Center, and to discuss the preliminary report. The Subcommittee held a meeting on 11-12 May 2010 at the Center for Deployment Health Research to finalize their review of the Center; an agenda was developed representing a prioritized list of issues identified for more in-depth evaluation.

FINDINGS

11. The Center for Deployment Health Research is responsive to the needs of the ASD(HA), the Chief of Naval Operations (CNO), and additional tri-Service commands. The organizational structure and the designation of various entities within the Center remain unclear and difficult to understand; however, clear organizational charts are now available, including the MCS which is part of the Center for Deployment Health Research. The organizational charts delineate the supervisory structure for scientific and financial matters, but it is not always clear that these are aligned and parallel.

12. The Center for Deployment Health Research receives funding through the U.S. Army, ASD(HA), Congressionally Directed Medical Research Program (CDMRP), the Office of Naval Research, and Unfunded Requirement approaches. The largest source of funding is provided by the U.S. Army, with additional funds provided by the Services. Some funding for the Center is in line item from the federal budget, while other funding is the result of competition for intramural funds within the DoD. How funding streams relate to specific strategic goals is not evident based on the preliminary visit. A review of the Center for Deployment Health Research business plan was deferred by the DHB to follow-up meetings.

13. There are two types of requests to the Center for Deployment Health Research. The first requires a rapid response and often comes from members of Congress, by way of Force Health Protection and Readiness (FHP&R). On the other hand, there are long-term issues, such as the long-term incidence and determinants of depression associated with deployment and combat experience. These long-term issues are often stimulated by observations of the Center for Deployment Health Research by the Armed Forces Health Surveillance Center. Similarly, it is expected that the Birth and Infant Health Registry and the Recruit Assessment Program will focus both on short-term turn around questions, and long-term projects.

14. The Center for Deployment Health Research is subject to a review by a number of groups, these include the DHB, AIBS, and SSAC. In subsequent reviews by the DHB, we will assess the potential for redundancy. Efforts should be made to minimize redundancy.

BROAD ISSUES

15. Several profound issues of importance exist in regard to the diverse work of the Center for Deployment Health Research. These issues manifest in many of the narrower concerns that will follow.

16. Adequate staffing is critical to accomplishing the mission of the Center for Deployment Health Research. The Center has a seemingly adequate number of epidemiologists, statisticians, and others, almost all of whom are contractors. More staff would be useful in the area of survey research, including cohort, recruitment, retention, and questionnaire design. There is a dearth of senior level uniformed military medical professionals who have the depth of knowledge of the disease and injury experience of military personnel is vital.

17. Short-term management focuses on the problems at hand. Examples may include meeting yearly programmatic deadlines for fiscal execution, managing the budget, and completing specific analysis; all are necessary for success. However, the long-term value of longitudinal studies depends, as well, on long-term issues, such as an insightful choice of questions for research, adequate sustained funding, and insightful investment in information that will be useful to answer questions in the future.

18. The mandate and vision held by the scientists entrusted with the MCS will determine the value that is added by the enterprise. If viewed as a national treasure with the potential for addressing major issues affecting health of the military, as well as the general population, the effect will be to search for study ideas, staffing, and government and civilian collaborations that will facilitate achieving results that are broadly applicable to the military community. At the other extreme, if success is conceived as mainly answering more immediate and pragmatic questions of more limited consequence, or if the enterprise becomes isolated from cutting edge science, or for other pragmatic reasons, the prospect of producing answers of major importance are diminished. A challenging issue for the Center for Deployment Health Research is that it has accrued an outstanding staff; however, the staff largely has regional roots.

SPECIFIC ISSUES

19. Currently, the Center for Deployment Health Research sets its priorities in response to directives from the ASD(HA). In addition, ideas for research initiatives are generated by the research staff and Co-Investigators.

20. Administratively, the Center for Deployment Health Research is in the management chain of the Department of the Navy Bureau of Medicine and Surgery (BUMED). However, in practice authority for the Center stems from the ASD(HA). Potential ambiguities that may result from this command structure have been averted and have not resulted in practical problems. The administrative

complexity should be monitored and reconsidered if it results in practical problems.

21. The Center for Deployment Health Research lists its publications in summary documents and gives short synopses that are useful. Numbers of publications and synopses do not demonstrate the significant impact of the Centers research products. It will also be important to assess the impact of the research or productivity on military health policy and practice.

22. The protocol for the peer review of major studies is developed by the researchers with participation and signed off by the Principal Investigator of the Center for Deployment Health Research. It then is submitted to the Institutional Review Board (IRB) and upon review and approval would be implemented.

23. The SAC should develop guidelines for the extent of the peer review of manuscripts. Currently, completed publications have to go through various levels of review, ranging from technical editing to review by the Commanding Officer.

24. The availability of data sets for extramural analysis is an issue faced to varying degree by all federal researchers and non-federal researchers supported with federal resources. It is unclear when a data set should be made available for analysis by external investigators, if ever. This issue has not been resolved by the Center for Deployment Health Research. External requests sometimes result in investigators participating in research conducted at the Center, but have so far not resulted in the creation of a public use data set for external investigators. On the one hand, availability of federal data sets will result in an increase in data utilization; however, premature release of data, especially when data is not sufficiently vetted, may result in erroneous results. Premature release may also dissuade the Center for Deployment Health Research staff from spending large blocks of time in development of data sets if they do not have preferential access to its analysis.

25. Internal staffing at the Center is staffed as follows: nine with a doctoral degree; 15 with a master's degree; 11 with a bachelor's degree; and 3 administrators. There are few senior investigators on the staff; however, more participate as Co-Investigators. The Center currently has 25 protocols in process and has one principal investigator; contract professionals can not be principal investigators. This reflects the preponderant youth of most MCS investigators.

26. There are different philosophies in the stability of staffing in different Services. There are variations among the Services in availability of staffing at the Center for Deployment Health Research. For example, Air Force investigators may be assigned to the Center for many years, while Navy officers are rotated frequently. In this context, the issue is how to build stability in the Center for Deployment Health Research. The current approach appears to be to utilize civilian employees of the military, as the use of long-term military officers with the Center for

Deployment Health Research has not been utilized. There appears to be a lack of career growth for military personnel who spend a substantial number of years in the Center for Deployment Health Research.

27. The MCS produces annotated lists of publications that are helpful to understand past research activity. The MCS does not further explore productivity by assessing impact through a citation index or some other means, nor does it track or quantify the impact of research findings on military policy.

CONCLUSIONS

28. Future assessments will spend more time on funding sources and review of the business plan for the Center for Deployment Health Research. Review in the future with a view towards the maintenance of long-term stability of resourcing to ensure the stability of the cohorts.

29. The MCS has major epidemiologic and bio-statistical expertise. In contrast, access to bio-medical investigators is usually through extramural collaborations. This issue should be addressed in a more in-depth review. The success of the MCS in recruiting and retaining participants and other aspects of project management has not been reviewed and it is unclear if expertise in this area is insufficient. It is urged that the Center for Deployment Health Research contact other federal agencies to explore mechanisms by which health professionals can have temporary assignments, fellowships, sabbaticals, individual mobilization augmenters, and other means of joining the research team. In the long-term it would be valuable for the DoD to develop a career path for training, retention, and promotion of military research scientists.

30. The Center for Deployment Health Research appears to balance short-term demands with making progress towards long-term goals. An opportunity exists for more emphasis on visionary thinking about the possible long-term contributions that could be made by the Center for Deployment Health Research. This issue should be addressed through a more in-depth review.

31. Providing access of the Center's data sets to external investigators is one method to enrich its use. Release of data must conform to established policies for data protection and must also protect the Center for Deployment Health Research investigators for a reasonable time before data collected at federal expense is made available for re-analysis. The DHB could review a policy if it were developed by the DoD.

32. In contrast to the National Institute of Health (NIH) or the Centers for Disease Control and Prevention (CDC), it appears that there are fewer senior investigators at the Center for Deployment Health Research. The implications of this distribution should be assessed not just for its etiology but also to assess its impact. There are structural impediments, such as the relationship of

advancement in rank and frequency of rotation, to involving military officers as senior scientists. This issue should be pursued with the goal of having a broader distribution of investigators at all stages of seniority.

33. The Board endorses the following recommendations based on a comprehensive evaluation of the Center for Deployment Health Research.

RECOMMENDATIONS

34. The Board recommends the revision and restructuring of the Scientific Steering Advisory Committee (SSAC) into a Scientific Advisory Committee (SAC) that is responsible for overseeing all activities at the Center for Deployment Health Research. Among individuals whom the DoD might include are senior leaders of the Active Duty and retired, officer and enlisted, military, regional and national subject matter experts, and DHB representatives. The DoD might also consider including the Commanding Officer (CO), along with at least one senior leader from the Department of Veterans Affairs (VA), to serve as ex-officio members on the SAC due to the implications for veterans.

35. The DHB recognizes that there is redundancy between the Scientific Advisory Committee (SAC) that is being recommended and the American Institute of Biological Sciences (AIBS). The AIBS is employed by the United States Army Medical Research and Material Command (USAMRMC) to review the Center of Deployment Health Research, amongst other organizations. The review by the AIBS appears redundant with the proposed SAC and does not fulfill vital roles that the Board recommends of the SAC. The Board recommends that the DoD consider opportunities to combine the indicated reviews into a single, more comprehensive assessment.

36. The DHB recommends that there be coordination meetings between the three Centers for Deployment Health at least twice a year, coordinated by, and attended by the ASD(HA), or designee.

37. When additional staff requirements are needed, strong consideration should be given to a national recruitment effort.

38. In the future, we recommend that the Scientific Advisory Committee (SAC), mentioned above, play a significant role in establishing research priorities. At that time it would be appropriate to assess whether the funding is adequate to meeting the research needs.

39. Mandated studies require only Institutional Review Board (IRB) review. The Board recommends that in the future, research protocols should be reviewed and approved, at the very least, by the advisory committee.

40. The Center for Deployment Health Research should explore the development of a program for recruiting graduate students or external faculty for months to year-long assignments.

41. The DoD should explore the development of a military career path within the area of epidemiology.

42. The above recommendations were unanimously approved.

FOR THE DEFENSE HEALTH BOARD:

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