



DEFENSE HEALTH BOARD
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DEC 19 2008

DHB

MEMORANDUM FOR: The Honorable S. Ward Casscells, Assistant Secretary of Defense for Health Affairs

SUBJECT: Defense Health Board Review of the Joint Pathology Center Work Group Concept of Operations for the Establishment of the Joint Pathology Center

REFERENCES

- a. Memorandum, DASD (C&PP), 16 June 2008, Defense Health Board Review and Recommendations Regarding the Establishment of a Joint Pathology Center (JPC)
- b. 2005 Defense Base Realignment And Closure (BRAC) Commission Report
- c. P.L. 110-181, National Defense Authorization Act for Fiscal Year 2008
- d. Joint Task Force National Capital Area Medical Joint Pathology Center Concept of Operations (ConOps), dated 27 August 2008
- e. Presentation: Joint Pathology Center Concept of Operations and Implementation Plan, to the Defense Health Board (DHB), 05 September 2008, by Col Thomas Baker, Joint Task Force National Capital Area Medical

BACKGROUND

In a memorandum dated 16 June 2008, the Deputy Assistant Secretary of Defense for Health Affairs Clinical and Program Policy, Dr. Joseph Kelley, requested that the Defense Health Board (DHB) review the Department of Defense (DoD)'s implementation plan for the establishment of the Joint Pathology Center (JPC) and comment on the plan's appropriateness and feasibility for DoD within the context of the 2005 Base Alignment and Closure (BRAC) Commission Report and subsequent legislation.

H.R. 4986, the National Defense Authorization Act for Fiscal Year 2008, became Public Law 110-181 on 28 January 2008; P.L. 110-181, § 722 directs the President to establish a Joint Pathology Center. The law directs the JPC "shall function as the reference center in pathology for the Federal Government." The statute also recognizes the substantial and significant contributions of the Armed Forces Institute of Pathology (AFIP) to military and civilian medicine.

The JPC Working Group (JPCWG) was formed by the Office of the Secretary of Defense for Health Affairs and tasked to create options for the establishment of the JPC within DoD. The

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JPCWG recommended the JPC be established within the Joint Task Force National Capital Region Medical (JTF CapMed) in collaboration with the Uniformed Services University of Health Sciences (USUHS) after consideration of eight options, as indicated to the Board. A Concept of Operations (ConOps) plan was subsequently developed to reflect the JPCWG's consensus recommendations. The ConOps includes the Working Group's vision of the JPC as "the Federal Government's premier pathology reference center supporting the military health system (MHS), DoD and other Federal agencies" through its mission statement that the "JPC will provide world-class diagnostic subspecialty consultation, education, training, research, and maintenance/modernization of the Tissue Repository in support of the mission of the DoD and other Federal agencies."

On September 5, 2008, the DHB was briefed on the Department's ConOps plan and was asked to provide comments and recommendations regarding the establishment of the JPC. While the Board concurs with the JPC ConOps' Vision and Mission, it has provided a number of findings and recommendations the Department should consider as it develops its more extensive strategic plan for the JPC. The comments below reflect the Board's review of the ConOps plan.

SPECIFIC FINDINGS

The Board believes, through the establishment of the JPC, the DoD has an opportunity to develop the structure for a world-class center of excellence.

Clinical Scope of Service

While the ConOps states the diagnostic (consultative) service of the JPC will provide subspecialty pathology care for the MHS and other Federal agencies, the subspecialties are not specified. Further investigation revealed that the DoD intends to prioritize subspecialty establishment based primarily on subspecialty case volume, although some subspecialties with low volume but high case complexity would be included. Defining the scope of subspecialty services is foundational to the design and operation of the JPC and should be reflected in the strategic plan along with details on the process of handling individual cases to include accession, triage, disposition, flow reporting, and quality assurance. Competency in subspecialty pathology relevant to current DoD force health protection needs and adaptability to future requirements should be addressed.

Within the JPC's clinical scope of services, the ConOps includes pathology telemedicine (telepathology) services to military treatment facilities (MTFs) and pathologists in theater. The plan, however, does not include the development of supporting diagnostic technologies that can be utilized in combat environments supported via telepathology services from the continental United States (CONUS). Inclusion of such supporting services in a more detailed strategic plan would help to define the military support and reference center mission of the JPC as well as the needs of other Federal agencies. For example, the employment of telepathology would potentially enhance the Department of Homeland Security in the event of a national disaster, the

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Federal Bureau of Investigation (FBI) in national security investigations to protect and defend the nation against terrorist threats, and the National Transportation Safety Board as it pursues its accident investigation role.

The Board believes that the JPC should function as the primary pathology reference center for services for the Armed Forces Medical Examiner (OAFME). The Board deems the identification of appropriate support for the OAFME as critical, since with the disestablishment of AFIP, specific mission-induced expertise required by the OAFME in future investigations might not be available for acquisition outside the Department. Furthermore, the Board advises further elaboration of the force health protection support aspects of the JPC services be included in the strategic plan.

The JPC ConOps does not address collaboration with the world of civilian medicine, for research or educational activities. Historically, DoD medicine has fostered and grown from rich collaborations with other Federal agencies and the civilian community in the area of pathology. These collaborations have resulted in significant advancements in medical knowledge. Robust collaborations with other Federal agencies, both within and outside of DoD, for example, Department of Veterans Affairs (DVA), the National Institutes of Health (NIH), the National Cancer Institute (NCI), Indian Health Services, and Centers for Disease Control (CDC) could help ensure that the JPC functions as a "Federal reference center." Similarly, the Board believes civilian collaborations should be encouraged and embraced to the extent they serve to fulfill and advance the successful execution of the Center's mission.

The Board recognizes that funding streams have a potential to impact scope of service. In concert with the JPC's Federal mission, the Board recommends the Department pursue funding approaches that may involve other Federal agency stakeholders. In this manner, other Federal agencies could help ensure annual financial support that would be appropriate for a Federal reference center.

POSITIONING OF THE JPC WITHIN COMMAND STRUCTURE

In acknowledgment of the Federal statute pertaining to the JPC, the Board provides its comments based on the establishment of the Center within the DoD. The establishment of the JPC within JTF CapMed is a logical choice to the extent that JTF CapMed is a joint medical organization and can facilitate the coordination of management policies and practices supporting the JPC mission.

As an important Federal asset, however, the Board believes JPC should possess high visibility to ensure its activities are mission-supported. Consequently, the Board believes establishing the JPC more directly under JTF CapMed leadership represents a more desirable approach, rather than the organizational structure outlined in the ConOps in which it is embedded as a component of a hospital-based pathology department. The priorities, mission and focus of a hospital-based pathology department are intrinsically different from that of a state-of-

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the-art pathology reference entity as depicted in the Department's ConOps. Concerns arise as to whether the priorities of the Chair of the WRNMMC Department of Pathology may conflict with the intended mission of the JPC. The organizational alignment under the Department of Pathology does not appear to be consistent with the vision, mission, or presumed goals of the JPC. If the DoD decides that the JPC will remain organizationally aligned as a sub-department in a medical center, the Board looks forward to reviewing the detailed strategic plan containing specifics on how the JPC would operate under the proposed line of authority.

Governance

Given the JPC mission of serving as a Federal resource providing specialty pathology support to DoD and other Federal agencies, the Board believes there is value to establishing a governance board consisting of members of Federal agencies receiving significant support from the JPC to annually review the operations of the JPC and evaluate the success of the management support to the JPC mission. This Board should include recognized leaders in pathology with possible representation from civilian medicine and industry, and provide active oversight and advocacy for funding. As the DoD further develops the JPC strategic plan, further consideration should be given to issues of chain of command and a governance board. Additionally, the Board will request and expect reports from the JPC. The Board further recommends JPC performance metrics be developed for which the Director of the JPC is accountable.

Organizational Structure

As indicated in the ConOps, the proposed organizational structure includes five civilian positions in the Project Management Office, and three civilian positions for Research and Education. Adequate resourcing for these important functions should be periodically assessed as the JPC becomes fully operational and workload requirements clarify. The Board advises that business principles and practices such as LEAN design and 6-Sigma methods be utilized to simplify and streamline all administrative functions for the JPC to make support activities within the JPC as cost efficient as possible.

Staffing

The ratio of professional staff to administration support seems inadequate when the variety and complexity of the laboratories of the JPC are taken into consideration, and poses the potential risk of not fully capitalizing on the special skills and talents of the highly trained and highly paid personnel. If this staff ratio is maintained, the JPC should expect retention problems for a talented professional workforce, and consequently experience insufficient research and education support to maintain high levels of productivity. In addition, the support provided by the proposed staffing ratio may be exacerbated by the fact that activities will be divided between the Bethesda and Fort Glenn Annex locations. The Board strongly advises that appropriate technological laboratory staffing be included in order to provide the necessary support for

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specialty pathology personnel, and the JTF CAPMED, as an operational command and control entity, should conduct a full man-power allocation review.

Staffing issues also need to address level of experience (staffing by junior relatively inexperienced pathologists versus seasoned established pathologists) and competitive salary levels. Compared to salaries that can be obtained at academic institutions, the salary levels suggested in the ConOps are not competitive for "world class" pathologists.

Projected Workload

The multi-year historical data, upon which the projected JPC workload is based, includes cases submitted by the MHS and DVA. Work from other Federal agencies, such as the NCI, CDC, or NIH is not included in the JPC projected workload analysis. The Board believes the Department should survey other Federal agencies in order to determine their current and future pathology needs. As JPC becomes fully operational, the Board envisions that the Departments of Justice, Homeland Security, Health and Human Services, and others may desire to adjust their existing pathology support services and take advantage of the JPC's expertise and capabilities. By better understanding the needs of other Federal agencies, the DoD can better plan for and structure the JPC. The Board also recommends the issue of case complexity also be considered when determining projected workload since the metrics of a non-specialized general pathology practice can not be applied to a subspecialty consultative practice.

Tissue Repository

Although the ConOps indicates the JPC will include the AFIP Tissue Repository assets and will actively "maintain and modernize" the repository on a continual basis to provide the MHS and other Federal entities access to prior surgical and autopsy materials for clinical care, research, and education, the nature, extent, and mechanisms for access to Tissue Repository assets by the MHS and Federal entities are not clearly defined. The Board advises the DoD, as it further details the JPC strategic plan, to consider the legal issues that may arise in situations where non-DoD entities may have access to and utilize some of these assets. It is essential that the plan clearly delineate the access and usage limits of the resources available through the Tissue Repository. The Board advises DoD to thoroughly define the route of access to specimens for civilian sector research and include a direct communication mechanism to ensure a facilitated process for interagency and civilian avenues of approach.

The Board strongly believes the Tissue Repository is an irreplaceable national and international treasure and resource from which significant potential for research and advances in medical care will result, particularly with recent developments in genomics and individualized medicine as well as initiatives to establish a human biobank. Every effort must be pursued to guarantee that the Tissue Repository is preserved, implements world-class modernization, and is utilized appropriately. A recent independent report by Asterand (Detroit, MI) submitted to USUHS found the repository to have a commercial value of \$3.0 – 3.6 Billion, which, in the

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appropriate context, may provide significant funding streams from future collaborative research efforts with industry and non-Federal agencies.

Research

Research activities within the JPC must be aligned with and approved through DoD's health research management process for all DoD elements performing and/or funded to conduct health research. The Board believes the research agenda should not be developed autonomously, and the process, including criteria for consideration, inclusion and prioritization for protocol approval must be clearly defined in the strategic plan.

Education and Training

The Board envisions numerous potential benefits the Uniformed Services University for the Health Sciences (USUHS) will glean from the expertise of the JPC staff through its partnership with the Center. However, since this effort is collaborative in nature, the contributions provided by USUHS to the JPC relative to its missions need to be defined. The current plan also describes educational support to Accreditation Council for Graduate Medical Education (ACGME)-approved residency training in pathology without mention of other ACGME-accredited subspecialty fellowship pathology training programs such as dermatopathology or neuropathology. A more complete outline of medical training support, particularly where it will impact continuing accreditation, should be outlined and described.

The Board believes opportunities for collaboration and development with other professional organizations should be fostered. In order to ensure the structure of the JPC is flexible to support education and training, the Board would advise the Department to incorporate a method for adopting educational programs into the organizational plan. The Board recognizes the Department's long and distinguished history of providing highly specialized pathology training to include radiology, neuropathology and other pathology subspecialties, but also advises the consideration of a broad spectrum of interest areas, for example, aviation and accident forensics and investigation. The educational offerings of the JPC should be periodically reconciled with the military treatment priorities and challenges, especially those arising from in-theater, combat support experience. As a Federal resource, the JPC should coordinate and collaborate with other Federal agencies needing support: where the agencies may manage their education programs, the JPC can serve as the locus for such training.

Major Equipment and Special Design Requirements

In order to ensure and maintain the world-class and state-of-the-art pathology services, the JPC strategic plan should include measures to procure equipment necessary to carry out these functions. Simply relocating existing and potentially outdated equipment to new locations will not necessarily assure that appropriate current technology is available to JPC staff. Dividing the JPC assets between the Bethesda and Forest Glen Annex locations is not an ideal situation and

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logistical requirements imposed by the physical location of the operational JPC and Tissue Repository at Forest Glenn are potentially problematic. In particular, separation of the physical location of histology laboratories and transcription services at the Bethesda campus from the working pathologists at the Forest Glenn Annex may significantly impede efficiency and the ability to provide timely consultations. These issues are neither adequately addressed by a 15-30 minute transit time between campuses nor by the use of courier services. Consequently, the Board advises that workflow considerations and a physical location that would allow consolidation at least all of the consultative services be included in the JPC strategic plan.

CONCLUSIONS

The Board recognizes the enormous contributions of the DoD to the field of medicine and the importance of the continuation of its legacy in providing world-class consultations in pathology and innovative state-of-the-art research, as well as exceptional educational offerings. The Board believes that Congress in establishing the JPC has provided the visionary opportunity to establish a world-class medical entity that will benefit future generations of mankind, particularly as advances in medical genomics and individualized medicine become more important.

The Board is thankful for the opportunity to review and provide advice on the Department's Concept of Operations for the establishment of the JPC, and looks forward to reviewing the Department's more detailed strategic plan.

RECOMMENDATIONS

In addition to the findings detailed above, the Board provides the following recommendations:

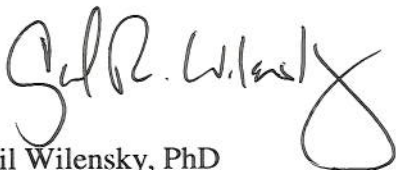
- 1. Within the constraints of the law, the Board believes an exceptional opportunity exists for the DoD to build a center of excellence that will meet the needs of all Federal agencies. The strategic plan should therefore include a structure for the JPC that is sufficiently adaptable and flexible in order to meet future requirements of the DoD and other Federal agencies as they arise. The plan should ensure that the equity of *all* Federal agencies is considered in the services provided by the JPC.**
- 2. Federal agencies supported by the JPC should identify subspecialty areas regarding clinical scope of service in order for the Center to achieve a premier level of support.**
- 3. The Board encourages the organizational structure of the JPC to be sufficiently flexible to allow for methods to establish collaborative relationships with non-Federal entities, as well as to provide an education and training component.**

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4. A governance structure should be developed to ensure various stakeholder interests (including those Federal agencies receiving significant support from the JPC and the DoD) are addressed and considered in a systematic and rationalized process agreed to by all parties, and to ensure their commitment to, as well as the preservation of the required mission of the JPC.
5. Performance metrics should be developed for the successful operation of the Center.
6. In order to ensure and sustain the world-class and state-of-the-art service and achieve the goals for the JPC, satisfactory assurance of adequate resources to include funding, staff, space, equipment, and facilities is vital and should be a key component of the strategic plan.
7. While the basic budget outlined in the ConOps may not be sufficient to meet the needs of all Federal agencies, funding for the JPC should take these needs into consideration. If a Federal agency survey results indicate a substantial workload, cost-sharing to meet those needs should be part of the strategic approach. Funding opportunities and collaborative efforts with other Federal agencies supported by JPC should be pursued. Funding issues must be resolved and mechanisms developed that will allow the JPC to thrive and meet its mission of serving as the reference center in pathology for the Federal Government. Funding opportunities with non-Federal agencies and Industry also should be explored and considered.
8. The Board strongly believes the Tissue Repository is a national treasure and resource from which significant potential for research and advances in medical care will result; subsequently, every effort must be pursued to guarantee this resource is preserved, implements world-class modernization, and is utilized appropriately.
9. The Board welcomes the opportunity to participate in the design of and the review of the JPC strategic plan as it is developed.

The above conclusions were unanimously approved.

FOR THE DEFENSE HEALTH BOARD:



Gail Wilensky, PhD
President, Defense Health Board



Joseph Parisi, MD
Chair, Scientific Advisory Board for
Pathology and Laboratory Services

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cc:

DHB Members and Consultants
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Joint Staff Surgeon
Library of Congress