



Public Health Subcommittee

Decision Brief:

Improving Defense Health Program Medical Research Processes

Defense Health Board

February 9, 2017

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Overview

- Tasking
- Membership
- Timeline
- Process
- Meetings/Briefings
- Structure of the Written Report
- Findings & Recommendations



Tasking

(1 of 3)

“I request that the Defense Health Board (DHB). . . provide recommendations to the Department regarding approaches that would optimally support military medical professionals who oversee and conduct DHP medical research.”

- Acting Under Secretary of Defense (Personnel & Readiness) (USD(P&R)) Memo dated September 30, 2015



Tasking

(2 of 3)

Request that the Defense Health Board address and develop findings and recommendations on the following:

- Determine how DoD may improve visibility on Defense Health Program (DHP) medical research supported through separate funding sources (research, development, test, and evaluation (RDT&E) and operations and maintenance (O&M)) to enhance coordination of effort, oversight, and collaboration.
- Determine the major challenges that DoD investigators face in initiating, funding, conducting, and publishing DHP medical research.
- Determine how DoD may facilitate more efficient initiation and conduct of high-quality DHP medical research without compromising safety or data protection standards.



Tasking

(3 of 3)

Request that the Defense Health Board address and develop findings and recommendations on the following:

- Determine how DoD may improve Institutional Review Board processes to facilitate more efficient approval of multicenter studies and clinical trials.
- Determine cost-effective mechanisms to encourage more professionals to become engaged in medical research.
- Determine mechanisms to improve acknowledgement in public communications by other government agencies and industry of DoD's contributions to products it has funded or partially developed and subsequently handed off.



Public Health Subcommittee Membership

- There are 10 members of the Public Health Subcommittee, including one member as chair.



Timeline

October 2015: Subcommittee begins investigation.

December 2015 – December 2016: Members receive briefings and hold roundtable discussions with Department of Defense (DoD) medical research leadership; junior-, mid-, and senior-level investigators (active duty and civilian); and representatives from a non-profit foundation.

April 2016 – January 2017: Members develop draft report and findings and recommendations for the Defense Health Board's (DHB's) consideration.

February 2017: Subcommittee presents pre-decisional draft to DHB.



Process

- 5 in-person, roundtable discussions with DoD medical research leadership and investigators
 - Over 130 participants
- 4 teleconferences with DoD medical research leadership and investigators
- 5 teleconferences with Subcommittee members only (draft report review)



Meetings/Briefings

(1 of 2)

Participation from:

- Office of the Under Secretary of Defense for Personnel and Readiness
- Office of the Assistant Secretary of Defense for Health Affairs
- Office of the Assistant Secretary of Defense for Research and Engineering
- Defense Health Agency Research and Development Directorate
- Uniformed Services University of the Health Sciences



Meetings/Briefings

(2 of 2)

Participation from (continued):

- Army, Navy, Air Force:
 - Human Research Protection Programs
 - Clinical Investigation Programs
 - Medical Research and Development
- National Capital Region Medical Directorate
- San Antonio Uniformed Services Health Education Consortium
- Henry M. Jackson Foundation for the Advancement of Military Medicine
- National Institutes of Health



Structure of the Written Report

- History of the Defense Health Program
- Request to the Defense Health Board
- Strategic Role of Medical Research in the Department of Defense*
- Defense Health Program Medical Research Oversight and Execution*
- Infrastructure for Defense Health Program Medical Research*
- Professional Development of Department of Defense Investigators*
- Attribution of Department of Defense Medical Research Successes*
- Findings and Recommendations

* Appendices provide further information on these sections.



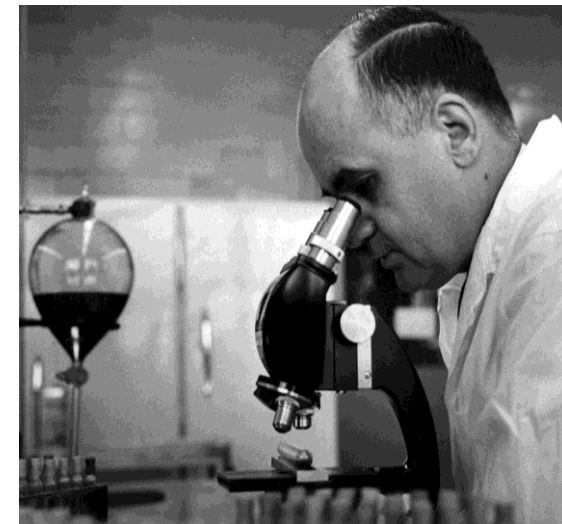
DoD Medical Research: Historical Contributions (1 of 2)



William Beaumont: The father of gastric physiology; early (1832) example of compensation for inconvenience



Walter Reed: Proof that mosquitoes transmit yellow fever; early (1900) use of informed consent



Maurice Hillerman: As civilian head of the Walter Reed Army Institute of Research (1948-57), discovered adenovirus as a cause of respiratory infections

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DoD Medical Research: Historical Contributions

(2 of 2)

1950s to 1970s	Adenovirus	Adenoviruses isolated at Fort Leonard Wood (1952). Burden of adenovirus infection on hospitalizations measured. Inactivated vaccines developed (1956). Live vaccines developed in 1960s-70s	Maurice R. Hilleman, COL Edward L. Buescher, COL Franklin H. Top, Jr. COL (later MG) Phillip K. Russell
1961	Rubella	Rubella virus isolated from trainee hospitalized at Fort Dix, New Jersey	CPT Paul D. Parkman, Malcom S. Artenstein, COL Edward L. Buescher
1960s-1970s	Meningococcal disease	Immune responses to bacteria described. First meningococcal polysaccharide A (1970) and C (1976) vaccines developed	Malcolm S. Artenstein, CPT Irving Goldschneider, CPT Emil C. Gotschlich, MAJ Ronald Gold
1960s, 1970s	Hepatitis B	Advances in viral subtyping. Protective effect of antibodies demonstrated	COL William H. Bancroft, COL Marcel E. Conrad
1960s	Japanese encephalitis	Efficacy of two JE vaccines compared in Thailand	COL Charles H. Hoke, Jr.
1980s	Gonorrhoea	Gonococcal pilus vaccine produces measurable genital mucosal antibody, but not effective in field trial	COL Edmund C. Tramont COL John W. Boslego
1980s	Respiratory syncytial virus	Polyvalent high-titer anti-RSV Immune globulin effective prophylaxis in infants	MAJ Gerald W. Fischer, Val G. Hemming, Greg A. Prince
1980s to present	Human immunodeficiency virus	gp160 vaccine immunogenic, but did not effect disease progression	COL Edmund C. Tramont, LTC Robert R. Redfield
1985-1995	Hepatitis A	Prototype hepatitis A vaccine developed. Army conducts pivotal efficacy trial in Thailand	Leonard N. Binn, COL Charles H. Hoke, Jr., LTC Bruce L. Innis, MAJ Stanley M. Lemon
1980s-1990s	Tick-borne Encephalitis	American experience with European-licensed vaccines	
1990s	Plague	Recognition of F1 and V antigens on virulence and immunity	COL Arthur M. Friedlander
1990s	Cholera	Oral WC/rBS cholera vaccine tested with Peruvian Army and Navy	COL Jose L. Sanchez, COL David N. Taylor
1990s to present	Anthrax	Animal challenge studies of vaccine efficacy. Cohort studies of anthrax vaccine safety	COL Arthur M. Friedlander, COL John F. Brundage, Others



Combat Casualty Care

(e.g., tourniquets, blood products)

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FINDINGS AND RECOMMENDATIONS



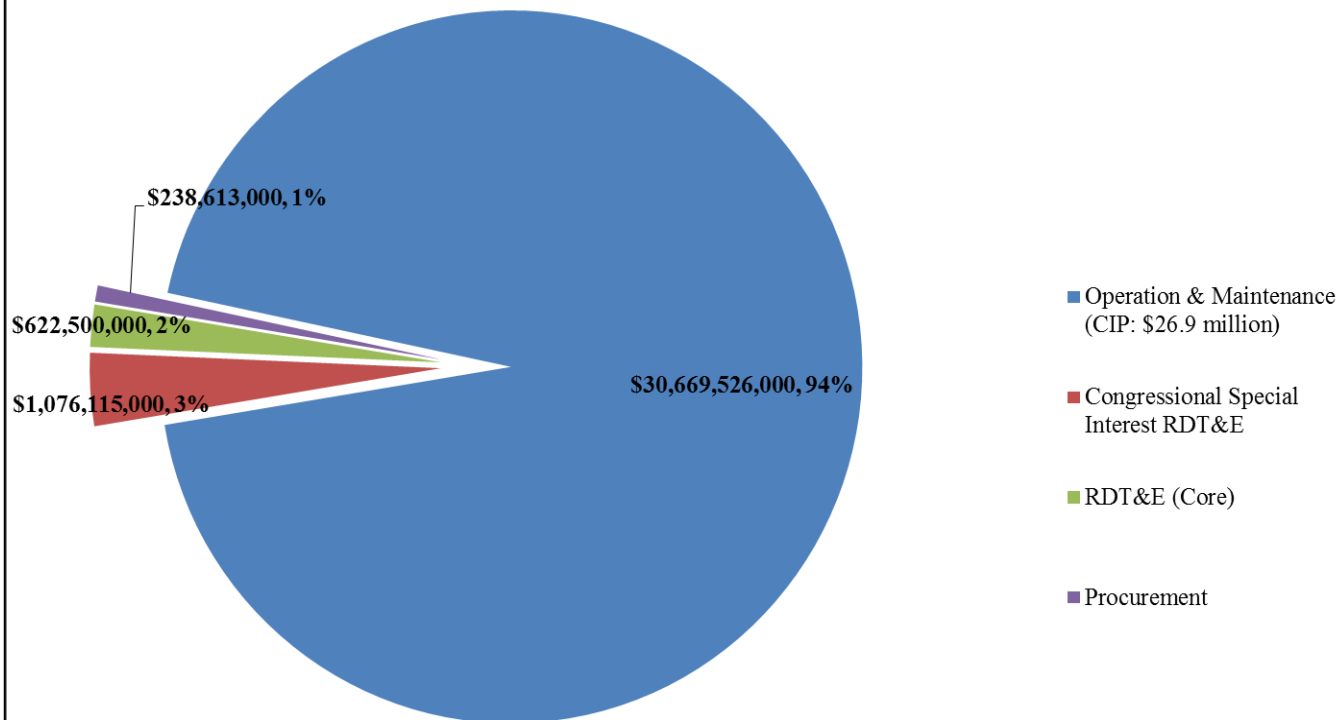
Objective #1

Determine how the Department of Defense may improve visibility on Defense Health Program medical research supported through separate funding sources (Research, Development, Test & Evaluation and Operations and Maintenance) to enhance coordination of effort, oversight, and collaboration.



Defense Health Program Medical Research Funding

Fiscal Year 2015 Total Enacted DHP Budget



Congressional Special Interest research accounted for 63% of RDT&E funded directly by the DHP.

The Subcommittee was not able to determine the entire level of expenditure on biomedical research within the DHP.

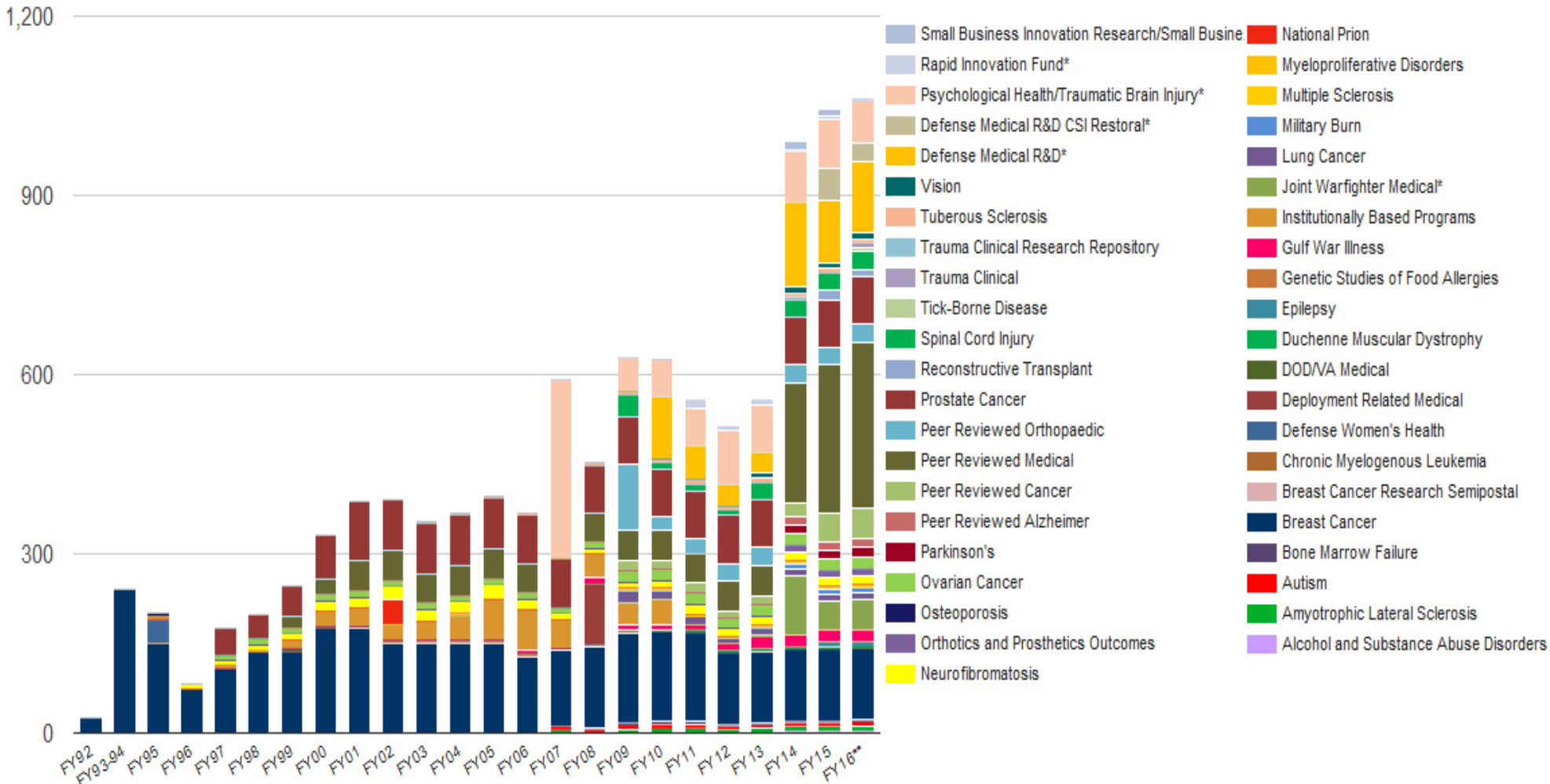
Source: Defense Health Program FY 2016 Budget Estimates, Vol I, February 2015.

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Congressionally Directed Medical Research Programs

Congressional Appropriations

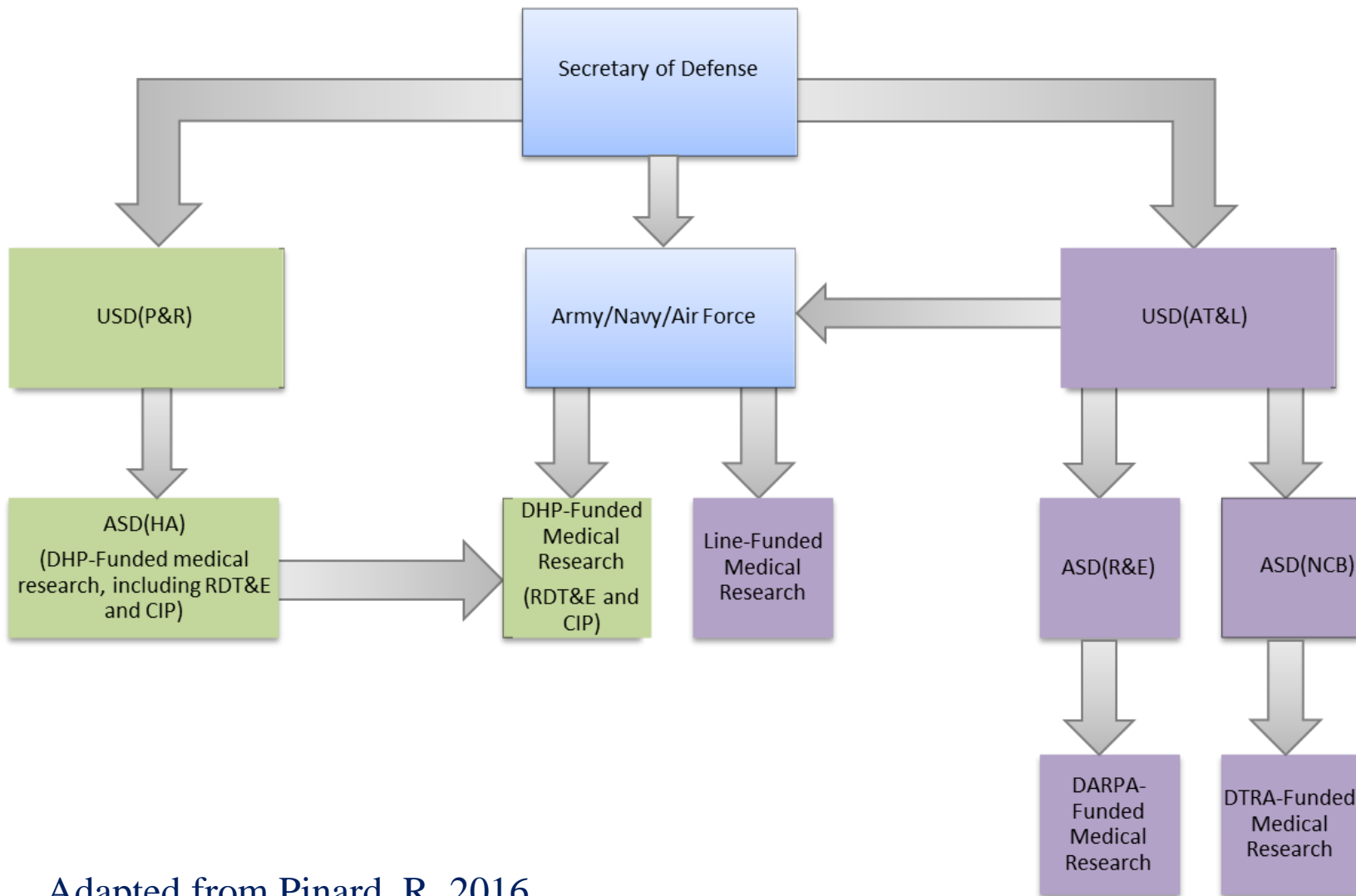


Source: <http://cdmrp.army.mil/about/fundinghistory>; Updated 1/27/2017

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DoD Medical Research



Adapted from Pinard, R. 2016.

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Finding 1

(1 of 4)

Finding 1: The Department of Defense’s medical research enterprise is fragmented across the Services with an array of different approaches to accomplish common goals. Despite clear direction in Department of Defense Instruction 6000.08 stating that one of the objectives of the Defense Health Program-funded medical research and Clinical Investigation Programs is to “maintain a medical research portfolio that is responsive to the needs of the MHS [Military Health System] and the dynamic nature of the health sciences,” there is no comprehensive top-down strategy to ensure that this is accomplished.



Finding 1

(2 of 4)

Specifically:

- The periodic Capabilities Based Assessments are one attempt to try to provide a comprehensive view of ongoing medical research and set priorities. However, it is not clear how follow up takes place in the interim to assure research activities are aligned with these priorities.
- While there are annual Joint Program Committee reviews of capability gaps and *ad hoc* Armed Services Biomedical Research and Evaluation Management Community of Interest reviews, it is not clear how well these evaluations map to overall decision-making regarding approval of research activities.



Finding 1

(3 of 4)

Specifically (continued):

- Although the Defense Health Agency Research and Development Directorate plans to roll out integrated program plans for Defense Health Program research, development, test, and evaluation-funded research in 2017 aligned to validated, prioritized capability gaps, there is no external, independent oversight of both Defense Health Program-funded medical research and Clinical Investigation Programs as a whole. This lack of independent, comprehensive oversight compromises the ability to provide long-term strategic guidance.



Finding 1

(4 of 4)

Specifically (continued):

- Defense Health Program-funded medical research is only a portion of all Department of Defense-conducted medical research. Visibility of all Department of Defense-conducted medical research would help facilitate the best use of Department of Defense medical research funding to support the mission of the Military Health System.



Recommendations 1a & 1b

Recommendation 1a: The Director of the Defense Health Agency Research and Development Directorate **should develop an overall strategy for health research with particular attention to the needs of the warfighter. This should include but not be limited to programs funded through** research, development, test, and evaluation and Clinical Investigation Programs **and be** in accordance with the spirit of the Fiscal Year 2017 National Defense Authorization Act.

Recommendation 1b: The Defense Health Agency Research and Development Directorate should issue a comprehensive biennial report **that includes key metrics with respect to progress on the strategy outlined in Recommendation 1a** on the status of Department of Defense-conducted **health** research taking highlights from the different programs across the Services. This report should be made readily available to the public.



Recommendations 1c & 1d

Recommendation 1c: The Defense Health Agency Research and Development Directorate should ensure that all Defense Health Program research, development, test, and evaluation-funded medical research is entered into Federal RePORTER.

Recommendation 1d: The Defense Health Agency Research and Development Directorate should ensure that all clinical trials conducted with Department of Defense funds, both internal and external, are listed on ClinicalTrials.gov.



Recommendation 1e

Recommendation 1e: The Department of Defense should create a platform, overseen by the Defense Health Agency Research and Development Directorate, which provides visibility of all Department of Defense-conducted **health** research, including Defense Health Program-funded **health** research and Clinical Investigation Programs, line-funded research, other Department of Defense-funded research (e.g., Defense Threat Reduction Agency and Defense Advanced Research Projects Agency), and extramurally-funded research.

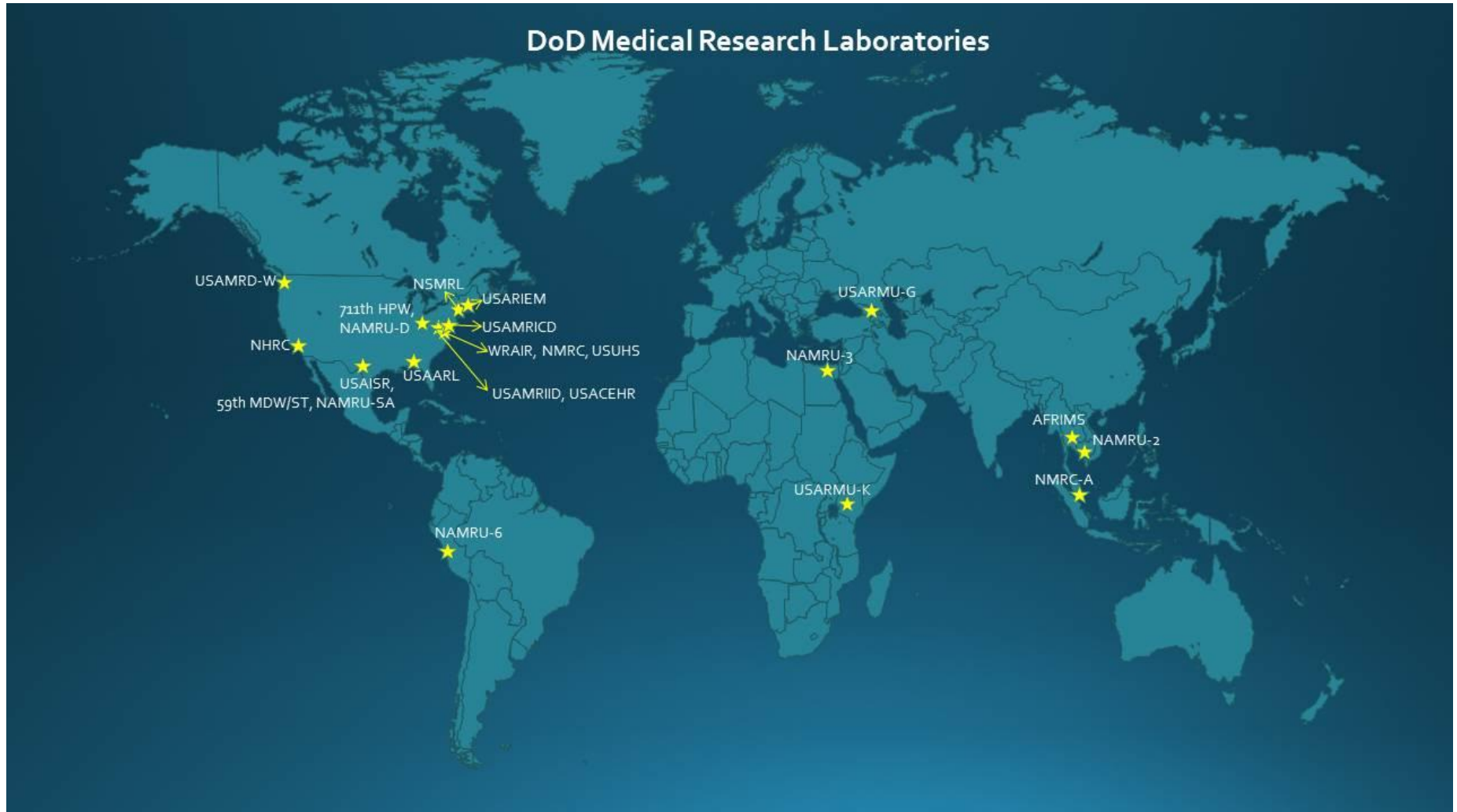


Objective #2

Determine the major challenges that Department of Defense investigators face in initiating, funding, conducting, and publishing Defense Health Program medical research.



DoD Medical RDT&E Laboratories

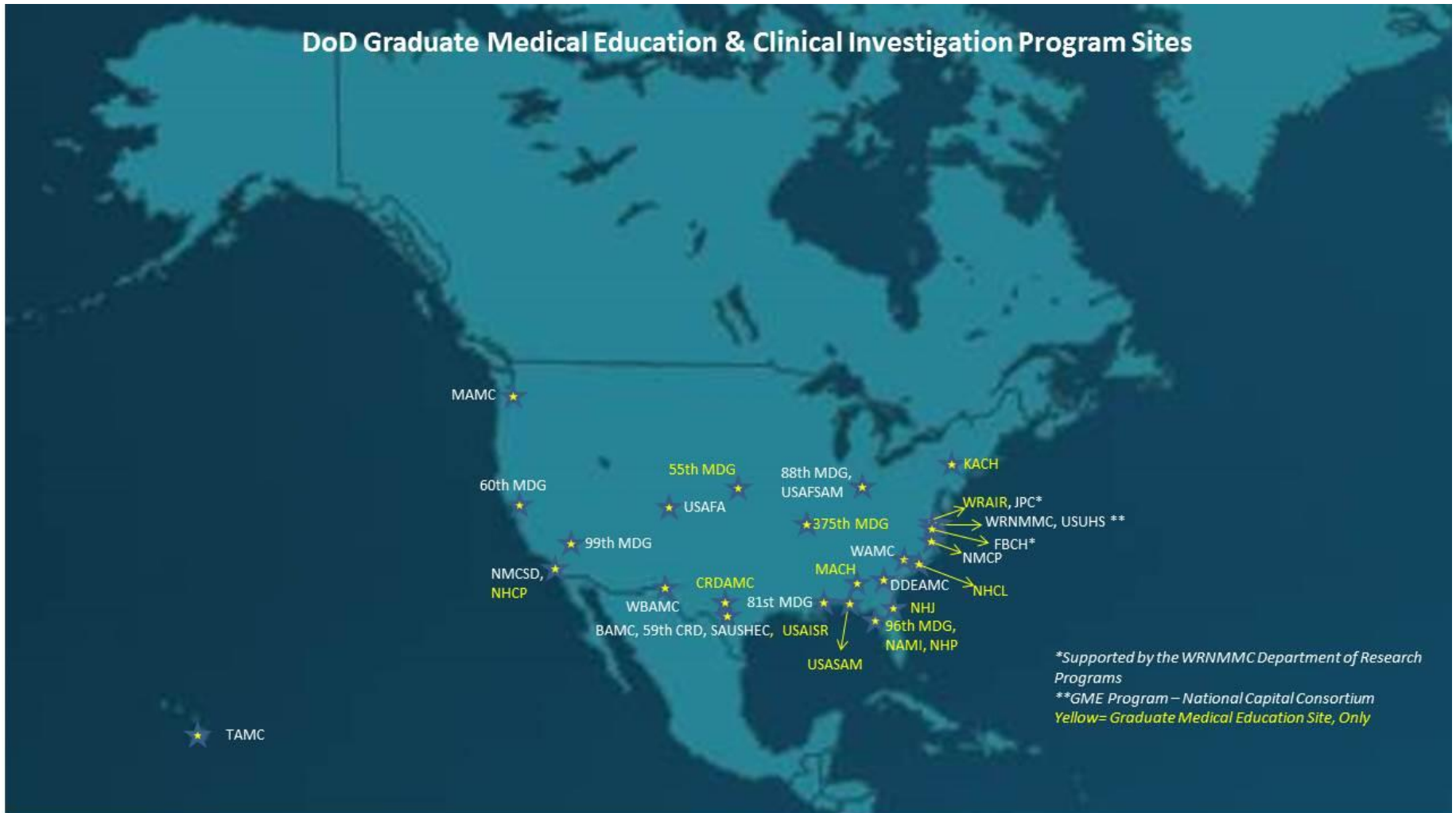


Adapted from USAMRMC, NMRC, and AFRL.

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DoD CIP and GME Sites



Adapted from information provided by DHA Education and Training; Army, Navy, Air Force CIP leadership.

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Finding 2

(1 of 3)

Finding 2: Despite the Department of Defense Instruction 6000.08 to maintain a medical research portfolio responsive to the needs of the Military Health System, there is no clear evidence that medical research has been embraced as a clear mission for the Department of Defense. Specifically:

- There is a lack of a clearly defined career path for officers skilled in medical research, an exodus of current officers with this skill set, and, as a result, a shortage of mentors for junior officers with this interest.
- There is no intentional recruitment of officers with medical research training. Individuals are recruited because of their clinical skills with little or no thought given to their research qualifications.



Finding 2

(2 of 3)

Specifically (continued):

- Given the primary focus of commanders on clinical care relative value units, there is variable and generally limited command support for Clinical Investigation Programs research with investigators often taking this task on after required duty hours.
- While it was often stated that Defense Health Program research, development, test, and evaluation and operations and maintenance funds could not be combined to support Clinical Investigation Programs research, the Board could find no such restriction and, in fact, instruction to the contrary.



Finding 2

(3 of 3)

Specifically (continued):

- While Defense Health Program research, development, test, and evaluation funds are used to support the basic infrastructure for research, development, test, and evaluation laboratory facilities such as the U.S. Army Medical Research Institute of Infectious Diseases, there are no funds directly allocated to the research in these facilities with the scientists needing to obtain additional funding for their actual research. These funds may come from the Defense Health Program or other Department of Defense or non-Department of Defense sources. Accordingly, the research agenda is at risk of being driven by funding opportunities as opposed to the genuine needs of the warfighter.



Recommendations 2a & 2b

Recommendation 2a: The Services should develop a clear career and leadership path for officers with an interest in **health** research with appropriate education, training, and opportunities to experience different aspects of **health** research with the potential for eventual command opportunities at the **health** research, development, test, and evaluation facilities.

Recommendation 2b: The Services should include in the performance evaluation of military treatment facility commanders, and by extension their Department Heads, an evaluation of the research carried out in their military treatment facilities and Departments.



Recommendations 2c & 2d

Recommendation 2c: The Military Health System should establish a relative value unit for **health** research at the military treatment facilities.

Recommendation 2d: The Services should enhance ways to use Defense Health Program research, development, test, and evaluation funds across the Department of Defense **health** research enterprise to support **health** research at the military treatment facilities and to support a core amount of research at the research, development, test, and evaluation facilities.



Recommendation 2e

Recommendation 2e: The Services should recruit officers with medical research training and offer training opportunities (e.g., research fellowships) to those without such training who are interested in a research career path.



Objective #3

Determine how Department of Defense may facilitate more efficient initiation and conduct of high-quality Defense Health Program research without compromising safety or data protection standards.



Finding 3

Finding 3: The Department of Defense’s current approach and support for medical research have not kept pace with the vast changes that have taken place in the practice of medical research, and, as such, the infrastructure support (administrative, scientific, and technical) for medical research in general, and human subjects research at the military treatment facilities in particular, is seriously inadequate. These shortcomings have been recognized repeatedly over the years without being adequately addressed; one cannot conduct high-quality research safely without this type of support.



Recommendation 3

Recommendation 3: The Department of Defense should establish several regional, tri-Service research infrastructure support centers under the Defense Health Agency within the military treatment facility system and require that anyone conducting human subjects research be affiliated with one of these centers. The centers should be used by all military treatment facilities within their designated region and provide the necessary competencies and oversight (e.g., those shown in Table 3 of Appendix C.6) to ensure high-quality, regulatory compliant, and safe research.



Objective #4

Determine how Department of Defense may improve Institutional Review Board processes to facilitate more efficient approval of multicenter studies and clinical trials.



Finding 4

Finding 4: The Institutional Review Board process is currently fragmented across the Services with different protocol templates, requirements, and methods of implementation. The current move to a uniform electronic Institutional Review Board system is a significant step forward, but it does not address the lack of consistency across the Services. As is current National Institutes of Health policy, a single Institutional Review Board of record is the most efficient way to streamline the approval of multi-center studies.



Recommendations 4a & 4b

Recommendation 4a: The Department of Defense should designate the Director of the Defense Health Agency Research and Development Directorate as the single Institutional Official for all of the Department of Defense human subjects research to provide uniform oversight for all Department of Defense Institutional Review Boards.

Recommendation 4b: The Department of Defense should establish policies and procedures to require a single Institutional Review Board to serve as the Institutional Review Board of record for multi-center studies.



Recommendations 4c & 4d

Recommendation 4c: The Department of Defense should consolidate Institutional Review Board functions at the regional tri-Service research infrastructure support centers envisioned in Recommendation 3 and ensure that they receive the adequate resources to carry out their role.

Recommendation 4d: The Institutional Official should establish standardized metrics of performance for Department of Defense Institutional Review Boards and ensure compliance to those metrics.



Objective #5

Determine cost-effective mechanisms to encourage more professionals to become engaged in medical research.



Finding 5

Finding 5: As noted under Findings 2 and 3, there is a lack of clear command support for medical research at the military treatment facilities; inadequate infrastructure support to conduct research at the military treatment facilities; and, often, no core funding for the actual research at the medical research, development, test, and evaluation facilities. These are essential elements of cost-effective research. In addition, the pay scales for civilian medical researchers are not comparable to either the private sector or other governmental agencies. Given the lack of adequate core funding for research infrastructure and lack of career opportunities, medical research is not seen as an attractive career option.



Recommendations 5a, 5b, & 5c

Recommendation 5a: The Department of Defense must provide the necessary research infrastructure support to conduct research and instruct the commands to embrace medical research as an essential part of the mission of the Department of Defense.

Recommendation 5b: The Department of Defense should pursue the appropriate authority to incorporate the civilian pay scales present in other federal agencies through Titles 38 and 42 to provide adequate pay incentives for Department of Defense civilian health professionals engaged in military medical research.

Recommendation 5c: Medical research must be viewed as a career track and competency with special pays for research analogous to other specialty fields.



Objective #6

Determine mechanisms to improve acknowledgement in public communications by other government agencies and industry of Department of Defense contributions to products it has funded or partially developed.



Finding 6

Finding 6: The Department of Defense has an extraordinary history of accomplishments in medical research including confirmation of routes of transmission of infectious diseases such as typhoid fever and yellow fever, as well as development of anti-malarial agents. Most recently, they have been key contributors to combat casualty care research and emerging infectious diseases, such as Ebola. However, the majority of the public is unaware of this history and current accomplishments. There are a series of meetings that could facilitate communication of Department of Defense medical research successes and recruit Department of Defense investigators, such as the Military Health System Research Symposium and other professional meetings. However, current conference attendance restrictions impede the ability to do so.



Recommendation 6a

Recommendation 6a: The Department of Defense should ensure that the annual Military Health System Research Symposium contains a section highlighting accomplishments of the past year and perhaps a review of a key medical research area to facilitate recognition across the Department of Defense of medical research successes and contributions. This should be done in concert with appropriate press briefings.



Recommendations 6b, 6c, & 6d

Recommendation 6b: Department of Defense scientists should be allowed and encouraged to present their findings at national and international specialty and subspecialty meetings.

Recommendation 6c: Department of Defense scientists should be expected to publish their findings in national, peer-reviewed journals in a timely manner, with appropriate acknowledgment of Department of Defense funding.

Recommendation 6d: The Department of Defense should ensure broad distribution of the biennial report discussed in Recommendation 1b.



Questions?