

# Low-Volume High-Risk Surgical Procedures



A REPORT BY THE DEFENSE HEALTH BOARD

INSIDE FRONT



DEFENSE  
HEALTH  
BOARD

**OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE  
HEALTH AFFAIRS**

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MEMORANDUM FOR PRINCIPAL DEPUTY ASSISTANT SECRETARY OF DEFENSE  
FOR HEALTH AFFAIRS

SUBJECT: Low-Volume High-Risk Surgical Procedures: Surgical Volume and Its Relationship to Patient Safety and Quality of Care

The Defense Health Board (DHB) is pleased to submit its report summarizing the findings and recommendations from its independent review of Low-Volume High-Risk Surgical Procedures: Surgical Volume and Its Relationship to Patient Safety and Quality of Care.

On March 28, 2018, the Acting Assistant Secretary of Defense for Health Affairs (ASD(HA)) requested that the DHB provide recommendations to improve policies for managing facility surgical capabilities and surgeon proficiency. Specifically, the Acting ASD(HA) requested the DHB address and develop findings and recommendations on the policies and practices in place to:

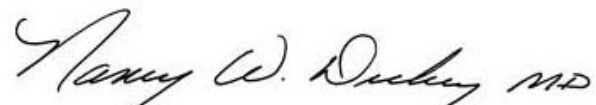
- Determine where high-risk surgical procedures should be performed,
- Optimize the safety and quality of surgical care provided,
- Enhance patient transparency related to surgical volumes and outcomes, and
- Evaluate the contribution of high-risk surgical procedures to medical readiness.

As the priority effort, the DHB Trauma and Injury Subcommittee was tasked to:

- Review the array of low-volume high-risk surgical procedures performed by military surgeons in the Direct Care system (i.e. MTFs).
- Evaluate policies, protocols, and systems for managing facility surgical capabilities and surgeon/staff proficiency across each of the Service branches.
- Develop recommendations to advance standardized policies on managing facility infrastructure capabilities and individual surgeon/supporting staff proficiency across all Service branches.
- Evaluate potential Military Health system (MHS) applicability of Veterans Health Administration (VHA) Operative Complexity Directives:
  - “Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures” (VHA 2010-018)
  - “Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center” (VHA 2011-037)
- Examine the contribution (Knowledge, Skills, and Abilities) of low-volume high-risk procedures to military medical readiness (e.g., surgeons, operating room staff).
- Provide recommendations on using the volume, errors, and outcome data to inform and enhance policies for managing surgical capabilities and surgeon currency.

The Subcommittee conducted literature reviews on key topics; received briefings from subject matter experts from within the MHS, other government agencies, and from the civilian sector; analyzed and interpreted volume, errors, and outcomes data; and reviewed current policies and practices related to patient safety and quality of care, including within MHS, the VHA, and civilian healthcare systems. The Subcommittee presented to the DHB on October 30, 2018, and following public deliberation of the findings and recommendations, the attached report was approved and finalized. The Subcommittee will continue to work on the secondary effort as outlined in the March 28, 2018 memorandum.

On behalf of the Board, I appreciate the opportunity to provide the Department with this independent review and hope that it provides useful information to promote and improve patient safety and quality of care across the MHS.

  
Nancy W. Dickey, MD, FAAFP  
President, Defense Health Board

Attachment:  
As stated



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## CHARGE TO THE DEFENSE HEALTH BOARD



**THE ASSISTANT SECRETARY OF DEFENSE**

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MAR 28 2018

**HEALTH AFFAIRS**

**MEMORANDUM FOR PRESIDENT, DEFENSE HEALTH BOARD**

**SUBJECT:** Request for Defense Health Board Review of "Low-Volume High-Risk Surgical Procedures"

Pursuant to the attached Terms of Reference (TOR) on "Low-Volume High-Risk Surgical Procedures," I request that the Defense Health Board (DHB) provide recommendations to the Department of Defense in order to improve policies for managing facility surgical capabilities and surgeon proficiency. Specifically, I request the DHB address and develop findings and recommendations on the policies and practices in place to:

- Determine where high-risk surgical procedures should be performed,
- Optimize the safety and quality of surgical care provided,
- Enhance patient transparency related to surgical volumes and outcomes, and
- Evaluate the contribution of high-risk surgical procedures to medical readiness.

The TOR for this review provides a detailed description and scope for this tasking. The point of contact for this action is Captain Juliann Althoff who can be reached at (703) 275-6060, or juliann.m.althoff.mil@mail.mil. Thank you for your continued support and commitment to optimizing the health and force-readiness of the military.

Tom McCaffery  
Acting

Attachment:  
As stated



## **ABSTRACT: LOW-VOLUME HIGH-RISK SURGICAL PROCEDURES: SURGICAL VOLUME AND ITS RELATIONSHIP TO PATIENT SAFETY AND QUALITY OF CARE**

The Military Health System (MHS) is one of the largest and most complex healthcare institutions, providing routine care to 9.4 million active duty personnel, their families, and retirees.<sup>1-3</sup> It is a global, comprehensive system that integrates health care delivery, public health and medical education, private sector partnerships, and medical research and development. The challenges of the MHS are unlike any other healthcare system in the world, carrying out mission requirements in both contingency and peacetime environments to include remote, deployed, and forward locations. The contingency mission includes ensuring that Service members are medically ready to deploy, and the medical force is ready and able to provide complex care in combat zones. The peacetime mission includes providing quality healthcare for military members, families, and other beneficiaries domestically and overseas.<sup>3,4</sup>

Recently, a series of U.S. News & World Report articles<sup>5-7</sup> reported on the quality and surgical volume relationship within the MHS. In response to these articles regarding patient safety, on March 28, 2018, the Acting Assistant Secretary of Defense for Health Affairs requested the Board conduct a review focused on high-risk surgical procedures in the MHS (see Appendix G).

The surgical care experience and outcome issue has been debated in the civilian healthcare sector for decades and is not exclusive to the military environment. The literature suggests a correlation between better patient outcomes for complex procedures when they are performed at high-volume hospitals and by high-volume surgeons.<sup>8-10</sup> However, correlation is not the same as causation. The volume and quality relationship may be more limited, citing weaknesses of statistical analysis, arbitrary cut-off points, and the lack of focus on the experience of the surgeon and interdisciplinary medical and surgical provider teams.<sup>11,12</sup> Further, the patient's level of risk also affects outcomes and must be considered.<sup>13</sup> The Board undertook and directed a thorough review of this topic, determining that volume alone is not a good measure of quality and outcomes.

The Board broadened its focus and identified the following themes as the approach to effectively assure the safety and quality of care delivered to patients within the MHS:

- (1) A culture of safety and quality is vital for building and sustaining infrastructure that provides safe and high-quality care. A sole focus on volume alone is not adequate to address patient safety or the quality of care and outcomes; there must be a standardized system in place to continuously monitor and proactively address quality and safety concerns in a transparent, non-punitive, data-driven learning environment across the Department of Defense (DoD). Further, the surgical team and organizational infrastructure, not only the surgeon, must be viewed as a system whose integrated operation is essential for strengthening safety and quality.
- (2) Data capture, optimization, and outcome measurements for quality of care, patient safety, and transparency efforts are essential to deliver safe and high-quality care to active duty personnel, military retirees, and their beneficiaries. The MHS must ensure appropriate information technology (IT) infrastructure and analytics are available to support enterprise leaders, providers, and patients, and maximize participation in and develop standardized



responses to risk-adjusted outcomes data, such as the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP), a benchmarked, clinical, risk-adjusted, outcomes-based program to measure and improve care across the surgical specialties.

- (3) A focus on the ready medical force is an imperative through utilization of Knowledge, Skills, and Abilities (KSAs), surgical simulation training, and military-civilian partnerships for peacetime and wartime care. The value of trauma experience and the integration of the entire surgical team are critical elements of success. Simulation training should be used to foster surgical team training and prepare teams for deployment operations. These models should be broadened and applied to other areas of surgical performance throughout the MHS.
- (4) There are standardization opportunities across the Services and at the Defense Health Agency (DHA)-level, spurred by the *National Defense Authorization Act Fiscal Year 2017 (NDAA FY 2017)*, specifically *Section 702 Reform of administration of Defense Health Agency and military medical treatment facilities*, which states that as of 1 October 2018, the Director of the DHA shall be responsible for the administration and management of the military medical treatment facility (MTFs). Successful practices and policies, such as already established through civilian and VA partnerships to increase both surgeon and surgical team proficiency, simulation training, and infrastructure requirements, should be leveraged.



## EXECUTIVE SUMMARY: SURGICAL VOLUME AND ITS RELATIONSHIP TO PATIENT SAFETY AND QUALITY OF CARE

The Military Health System (MHS) is a federated system of uniformed, civilian and contract personnel and additional civilian partners at all levels of the Department of Defense (DoD).<sup>14</sup> The Defense Health Agency (DHA), as part of the MHS, acts as a Combat Support Agency directing the execution of joint shared services enabling the Army, Navy, Air Force, and Marine Corps medical services to provide a medically ready force and ready medical force to Combatant Commands in both peacetime and wartime.<sup>15</sup> At the same time, the MHS acts as a health agency responsible for maintaining and caring for a very diverse population of young healthy people, families, and significant population of aging beneficiaries and their dependent families. These demographic characteristics accentuate the challenge of maintaining a ready medical force for wartime, while simultaneously and constantly demanding a high quality of care and optimal outcomes throughout the MHS whenever needed. Due to mission requirements, remote military medical treatment facility (MTF) locations, and deployed environments, some procedures are conducted in low frequencies. As part of its charge, the Board assessed the challenges presented in performing low-frequency procedures while ensuring that the facilities where these surgeries are performed are best equipped to provide a level of safety and quality of care that is consistent with the community standard of care.

The quality of combat casualty care demonstrates the advancements of military medicine. Informed by civilian trauma system outcome successes, the Joint Theater Trauma System (JTTS) was developed as a systematic and integrated approach to better organize, coordinate, and optimize battlefield care to minimize morbidity and mortality.<sup>16</sup> Created in 2004 as part of the JTTS, the Joint Theater Trauma Registry (JTTR) tracks combat casualty injury patterns, treatment, and final outcomes. In 2007, JTTR data were compared to civilian trauma systems using the American College of Surgeons (ACS) National Trauma Data Bank (NTDB).<sup>17</sup> The analysis demonstrated that survival and casualty outcome rates for Operation Enduring Freedom and Operation Iraqi Freedom (OEF/OIF) at Role IV sites and beyond appear comparable to the outcomes data in the NTDB.<sup>17</sup> Further, from derived standard calculations of Injury Severity Score (ISS), military ISS and probability of survival (Trauma and Injury Severity Score; [TRISS]), of the patients that incurred battle injuries, more survived these injuries than predicted (approximately 2.75 more patients survived than expected per 100 injured patients; from 2002 to 2007, a total of 788 more patients survived than expected).<sup>17</sup>

Additionally, the original tasking uses the phrase “low-volume high-risk surgical procedures.” However, while the Board acknowledges the intention of this phrase, it does not fully represent the surgical volume and outcome issue due to the dynamic nature of risk, which can vary in different environments. The Board instead uses the phrase “low-intensity” in this report. Low-intensity surgical environments perform procedures for healthier patients with few comorbid conditions, have a lower frequency of procedures, and/or exist with a more basic facility infrastructure and team expertise.



## BRIEF HISTORY OF THE SURGICAL CARE EXPERIENCE AND OUTCOME ASSOCIATION

The surgical care experience and outcomes issue is not exclusive to the military environment but is also a rural healthcare issue that has been debated in the civilian healthcare sector for decades. The literature showing a positive correlation to volume and quality (outcomes) is substantial. Increased hospital volume is often correlated with lower complication rates, lower re-operation rates, lower readmission rates, lower mortality rates, and lower costs.<sup>9,10,18-24</sup> However, certain procedures demonstrate a more robust relationship than others (see Appendix B.2). Similarly, there is a body of literature that indicates high-volume surgeons are likely to have better patient outcomes than low-volume surgeons.<sup>25,26</sup> The consensus of 30 years of literature indicates physicians and hospitals with the highest numbers of certain complex surgical procedures achieve the best results.<sup>5</sup>

Volume alone is not an absolute predictor of quality. “Volume should never be used by an accrediting organization as a measure of quality,” says Dr. Mark Chassin, President of The Joint Commission. Each facility and surgeon is unique.<sup>27</sup>

A series of U.S. News & World Report articles<sup>5-7</sup> reported on outcomes in the MHS of 10 Volume Pledge procedures<sup>i</sup> performed between 2012 and 2016 using administrative data from all MTFs. These 10 procedures were included in the Volume Pledge adopted in 2015 by Johns Hopkins Health System, Dartmouth-Hitchcock Medical Center, and the University of Michigan Health System, and were selected because they have the strongest correlation between hospital volume and patient outcomes in the literature.<sup>28</sup> The effectiveness of the Volume Pledge in promoting patient-centered quality and safety has not been demonstrated in the literature: There is no published outcomes data and no published analyses of effect on access to care<sup>11</sup> and no new sites have signed on to the pledge. The Volume Pledge is imperfect. By using absolute volume thresholds, it conveys a level of arbitrariness and does not account for longitudinal experience.<sup>11,12</sup> For example, if the threshold is 10 operations per year, a surgeon who performs nine is considered a low-volume surgeon, while a surgeon who performs 10 is a high-volume surgeon, regardless of experience. There are concerns that mandatory volume thresholds do not address the fundamental determinants of safety and quality. Further, a system that regionalizes complex operations to hospitals based on volume thresholds may lead to economic and social hardships for patients and families due to prolonged separation, disparities in access to care based on ability to travel, and worsening maldistribution of the surgical workforce due to practice limitations.<sup>10,29</sup> See Appendix B.2 for more information.

The Department of Veterans Affairs (VA) also examined the surgical volume and outcomes association. The VA National Surgical Quality Improvement Program (NSQIP), during the first two quarters of 2007, identified a mortality rate over four times the expected rate, as calculated by the Veterans Health Administration (VHA), at one medical center.<sup>30</sup> The Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) concluded that there were specific problems of quality of care, including pre-operative, intra-operative, and post-operative care for

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<sup>i</sup> Esophageal cancer resection, lung cancer resection, pancreatic cancer resection, rectal cancer resection, carotid artery stenting, complex abdominal aortic aneurysm repair, mitral valve repair, bariatric staple surgery, knee replacement, and hip replacement



veteran patients.<sup>30</sup> The review also concluded that, independent of physician expertise, the availability of support services may limit where certain operations should be performed.<sup>30</sup> To address the issue, in 2010, the VHA published the *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures* (VHA 2010-018) policy requiring each VHA medical facility with an inpatient surgical program to have an infrastructure-based surgical complexity designation.<sup>31</sup> In 2011, the OHI performed a retrospective review of the directive and found that the complex surgeries<sup>ii</sup> identified in the review were supported by the infrastructure at VHA facilities, as were referrals to non-VHA facilities, meaning the VHA had successfully implemented a system to ensure procedures were conducted at facilities that could support such surgeries.<sup>30</sup> See Appendix F.2 for more information.

## PATIENT SAFETY AND QUALITY OF SURGICAL CARE

Although the Board was tasked to evaluate transparency and public release of volume, errors, and outcomes data, these efforts are dependent on a culture that maximizes patient safety and quality of care and is rooted in principles of high reliability, which includes a focus on transparency. The DHA has targeted an opportunity for improvement across the MHS through a High Reliability Organization Operation Model (HROM), the focal point of which is care centered around the patient by Clinical Communities to continuously improve care quality and value, thereby contributing to readiness. DHA's Clinical Quality Management (CQM) functional capability provides enabling expertise to this effort. Professionals in CQM coordinate closely with DHA's Office of Strategy Management for the standardization of improvement processes with intent to integrate resourcing clinical quality improvement and transparency initiatives into MHS overall performance planning.<sup>32</sup> See Appendix D for more information.

The MHS has historically strived for a continuous learning path of improvement, informed by evidence-based practices and lessons-learned. Recently, on a larger scale, the Joint Trauma System (JTS) is an example that is directed at disseminating knowledge that could be used in other areas within the MHS.<sup>33,34</sup> The accomplishments of the JTS were reviewed and highlighted in the National Academies of Sciences, Engineering, and Medicine (NASSEM) *Zero Preventable Deaths* report.<sup>34</sup> The report asserted that the JTS is perhaps the best example of a learning health system that was distinctive by its use of real time data across the compendium of care from injury site to recovery.<sup>34</sup> The DoD JTS trauma registry fostered continual reflection and learning. The JTS adopted an approach known as forced empiricism and continuously delivered real-time performance improvement through the capture of and ongoing evaluation of care and outcomes. The JTS nimbly used the process to provide direct provider learning and correct system deficiencies. Through the acquisition of data, the JTS developed and, modified as needed, evidence-based practice guidelines, such as Tactical Combat Casualty Care (TCCC), designed to reduce variations in practice. The DoD JTS trauma registry data also informed the need for new research and ultimately improved capabilities and patient outcomes. Capitalizing on patient lessons learned and quality improvement processes, the JTS directed comprehensive combat casualty training using TCCC for its soldiers and medics.<sup>34</sup>

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<sup>ii</sup> Aortic aneurysm surgery, colectomy, craniotomy, esophagostomy, open heart surgery, pancreatectomy, and pneumonectomy



An example of this data-driven approach, with implications for civilian trauma systems, includes the 75th Ranger Regiment during combat, where they comprehensively implemented TCCC in Iraq and Afghanistan and realized better outcomes in case fatality and reduction of preventable deaths on the battlefield.<sup>35</sup> On a larger and systemic scale, the DoD JTS trauma registry data informed leaders in Afghanistan of delays in transport of wounded soldiers to forward MTFs. In 2009, this supported the Secretary of Defense directive that all helicopter transport of the critically wounded occur within 60 minutes. This resulted in more rapid arrival of the wounded from an average 90 minute time to 43 minutes and significantly improved survival from more severe injuries compared to that seen in earlier war years.<sup>35</sup>

The MHS has continued to evaluate its practices and to develop a more focused, data-driven way forward. In 2014, the Secretary of Defense ordered a comprehensive review of the MHS to assess access to medical care, quality of that care, and whether a culture of safety was present.<sup>36</sup> The findings from that report were followed by a number of recommendations, many of which were implemented and are further addressed in this report. Recommendations from this review aimed to foster the creation of a High Reliability Organization (HRO) across the MHS. Furthermore, evidence suggests that efforts and programs such as the DoD Patient Safety Program (DoD PSP), MHS Quality Assurance, the MHS Transparency Initiative, and the American College of Surgeons (ACS) NSQIP, now with all MTFs participating, lead to surgical quality improvements and the move to create a more synchronized system for standardization within the MHS.<sup>37-39</sup>

## DATA CAPTURE, OPTIMIZATION, AND OUTCOME MEASURES

As stated, accurately capturing data is critical for measuring patient safety and quality of care. ACS NSQIP<sup>40</sup> is a voluntary, “nationally validated, risk-adjusted, outcomes-based program to measure and improve quality of surgical care.”<sup>41</sup> In 2014, 17 MTFs participated in NSQIP; in 2018 it is used in all 48 inpatient MTFs. However, there is room for improvement and standardization of how the data are utilized across the Services. Further, opportunities for improving coding were identified across the Services. Currently, there is a lack of resources to accurately code, suggesting that an investment in experienced coding professionals and resourced analytics support could significantly improve coding accuracy.<sup>42</sup> Challenges for reporting accurate, total surgical volume also include missing data due to difficulty in identifying and capturing procedures conducted off-site (e.g., in a civilian partner hospital or in a VA facility).<sup>39,43-45</sup> See Appendices C and D for more information.

American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) uses data that are:

- From the patient’s medical chart, not insurance claims
- Risk-adjusted
- Case-mix-adjusted

## READY MEDICAL FORCE

The Board was tasked to “examine the contribution of KSAs of low-volume high-risk procedures to military medical readiness.” However, it was necessary to expand this focus area to include a



review of military medical readiness overall, since readiness is an essential theme for patient safety and quality. Being medically ready, including medical team readiness, is vital to successfully performing low-intensity procedures and critical to ensuring the establishment and maintenance of integrated team skills in both peacetime and wartime medical settings to reduced variability.

The Knowledge, Skills, and Abilities (KSA) program was created in 2017 to develop a methodology to measure the readiness of the MHS medical force by working in partnership with the ACS.<sup>2</sup> The KSAs identify and capture specific parts of the procedures that give readiness value. A readiness value is given for every procedure with more complex procedures yielding a higher KSA value. Thresholds are developed based on diversity, volume, and acuity.<sup>46</sup> It should be noted that the KSA scores do not determine deployment readiness, but assist leadership with readiness optimization at their clinics and MTFs. The Board acknowledged the KSA model is still in early stages as a pilot program and has only been linked to outcomes in the National Capital Region-Medical Directorate (NCR-MD). Thus far, results indicate MTF Commanders using the KSA metric find them feasible, without negative impact on other key aspects of healthcare delivery, such as access, safety, or cost, and able to focus the market on new approaches to improve readiness. In the first 90 days of the Proof of Concept, the NCR-MD increased total percentage of general surgeons meeting the KSA threshold from 26% to 30% and from 73% to 77% for orthopedic surgeons.<sup>47</sup> Conceptually, the KSAs have potential for creating an environment of standardization, accountability, and quantifiable results. See Appendix E for more information.

The Joint Trauma Readiness Training Program aims to link the various areas of medical readiness, including the KSAs, with the implementation of *NDAA FY 2017 Sections 707 and 708*, which align the JTS under the DHA. Thus, this model can be used for specific, elective, high-risk procedures. This program will include KSA metrics for clinical practice, formal psychomotor assessment of proficiency in expeditionary skills (Advanced Surgical Skills for Exposure in Trauma [ASSET<sup>®</sup>], Advanced Trauma Operative Management [ATOM<sup>®</sup>], etc.), and team-based training in hyper-realistic, field-based conditions.<sup>48</sup> See Appendix E for more information.

The DoD does not currently have a standardized, team-oriented training curriculum as a program of record. However, team-based training efforts are to be included in the Joint Trauma Readiness Training Program. Effective team training is critical for success in operational units and directly influences the quality of patient care.<sup>49,50</sup> Leveraging technologies, including the use of simulations, allows for maintenance and proficiency of surgical skills.<sup>33</sup> Simulation training is also important for improving team effectiveness specifically with low-frequency, high-acuity emergency situations as the success of these complex procedures depends on the entire surgical team, not just the surgeon.<sup>51</sup> If simulation continues to be reviewed and assessed, the planning discussion should also focus on locating simulation sites near MTFs with lower surgical volume caseload, many of which are located in rural areas.





## STANDARDIZATION

With its efforts centered on patient safety and the delivery of safe, high quality care, the MHS has the opportunity to improve the future of health, not only as an example for military healthcare but also as a leading force of innovation among all healthcare systems. The DoD recognizes the importance of modernizing the MHS through standardization of services across all facilities and integration of healthcare to improve and sustain operational medical force readiness and medical readiness of the Armed Forces, improve access and experience of care, improve health outcomes, and lower costs. The Board's recommendations on standardization align well with the *NDAA FY 2017*, specifically *Section 702 Reform of administration of Defense Health Agency and military medical treatment facilities*. Prior to 1 October 2018, each of the Services were managing their MTFs individually with variation in policies and procedures between the Services. See Appendix B for more information.

Variation and a lack of standardization also currently exists between the Services and the NCR-MD for managing facility surgical capabilities and surgeon/staff proficiency. For example, there is a lack of standardization in Service readiness-training models and partnership development between MTFs and civilian/VA facilities. These training models and partnerships increase case load and demonstrate potential to serve the community as part of the national trauma system.<sup>43-45</sup> This is in transition now with *NDAA FY 2017*, creating an opportunity for shared practices across the Services. Successful practices were identified in each of the Services for various areas, such as the Army's readiness efforts with its Level I Trauma Center, the Navy's Chief Medical Officer (CMO) position, the Air Force's partnership efforts, and the NCR-MD's efforts focused on the KSAs and market expansion/patient recapture. See Appendices C.3 and D.2 for more information.

## LIMITATIONS

The Board was tasked with seven specific charges during the first six months of the review addressing "low-volume high-risk" surgical procedures within the MHS (see Charge to the Defense Health Board and Appendix B). The Board believes that addressing the above four overarching themes, supplemented by research and data in the appendices, will address the seven charges. The Board was also tasked with two additional charges (review the array of low-volume high-risk surgical procedures performed on MHS beneficiaries in the Purchased Care System [TRICARE] and to evaluate the potential for the MHS to sign on to the "Surgical Volume Pledge") as a secondary six-month tasking to follow this report. However, the complexity of the initial tasking required an equally complex and multi-pronged analysis of a way ahead. Therefore, due to the expedited timeline of the report and its expansive scope, there may be certain constraints and a limited ability to fully address the scope in detail due to lack of data, such as an inability to complete a comprehensive product line assessment for surgical subspecialties and an inability to accurately compare civilian and military hospitals based on distinct characteristics of these two entities, including unique, economically driven civilian attributes. Finally, the broadening of the report response, due to a systems-based approach, included an assessment of factors beyond the narrowed focus of "low-volume high-risk surgical procedures." Thus, some aspects of this report may be addressed in further detail in the forthcoming second report.



## FINDINGS AND RECOMMENDATIONS

Throughout its review, the Board noted successful practices as well as opportunities to enhance current MHS practices to improve standardization of content and context across all Services for managing surgical capabilities and surgeon currency. Foundational themes emerged to guide the Board's findings and recommendations:

- (1) A culture of safety and quality is vital for building and sustaining infrastructure that provides safe and high-quality care. A sole focus on volume alone is not adequate to address patient safety or the quality of care and outcomes; there must be a standardized system in place to continuously monitor and proactively address quality and safety concerns in a transparent, non-punitive, data-driven learning environment across the DoD. Further, the surgical team and organizational infrastructure, not only the surgeon, must be viewed as a system whose integrated operation is essential for strengthening safety and quality.
- (2) Data capture, optimization, and outcome measurements for quality of care, patient safety, and transparency efforts are essential to deliver safe and high-quality care to active duty personnel, military retirees, and their beneficiaries. The MHS must ensure appropriate IT infrastructure and analytics are available to support enterprise leaders, providers, and patients, and maximize participation in and develop standardized responses to risk-adjusted outcomes data, such as the ACS NSQIP, a benchmarked, clinical, risk-adjusted, outcomes-based program to measure and improve care across the surgical specialties.
- (3) A focus on the ready medical force is an imperative through utilization of the KSAs, surgical simulation training, and military-civilian partnerships for peacetime and wartime care. The value of trauma experience and the integration of the entire surgical team are critical elements of success. Simulation training should be used to foster surgical team training and prepare teams for deployment operations. These models should be broadened and applied to other areas of surgical performance throughout the MHS.
- (4) There are standardization opportunities across the Services and at the DHA-level, spurred by the *NDAA FY 2017 Section 702*, which states that as of 1 October 2018, the Director of the DHA shall be responsible for the administration and management of the MTFs. Successful practices and policies, such as already established through civilian and VA partnerships to increase both surgeon and surgical team proficiency, simulation training, and infrastructure requirements, should be leveraged.

## CULTURE OF SAFETY AND QUALITY

### **Finding 1:**

- A) The DoD has periodically evaluated the medical health delivery system within the three Services and promoted continual learning to assure high quality and safety.
- B) The DHA, by direction of *NDAA FY 2017 Section 702* now has the authority to direct care, quality, and safety across all Services and MTFs. The alignment of all the military health delivery under a central locus of responsibility provides the MHS with the structure to optimize care, quality and safety.
- C) The trauma care system, specifically the JTS, has embraced and benefitted from the continuous learning system that delivers improved outcomes, an understanding of priorities,



and unique perspectives. The JTS, now a part of DHA, provides a model for expansion across other domains of the MHS.

- D) The MHS is well positioned to further enhance the system level characteristics necessary to promote continuous learning and improvement of an exceptional learning health system.

**Recommendation 1:**

- A) The Secretary of Defense, DHA Director, and Service leaders must establish an organization-wide culture of performance improvement that is patient-centered with aligned authority, accountability, and transparency as the highest priority.
- a. The Secretary of Defense, Combatant Commands, and Service Secretaries must support the efforts of the DHA to integrate and optimize healthcare delivery throughout the DoD.
- B) The Secretary of Defense should ensure that the DHA has capabilities to promote a culture of continuous learning and innovation.
- a. The DHA must establish a comprehensive, standardized, and non-punitive performance improvement process through peer review; root cause analysis; transparent, risk-based prioritization methodology; and ongoing assessment of systems of care to assure patient safety and optimize quality outcomes across the MHS.
  - b. Partnerships between MTFs, civilian medical centers, and VA medical facilities must be increased to provide optimal surgical care for all patients.
  - c. The DHA must have resources (to include personnel, IT, data analytics, and video teleconferencing) for an organization-wide learning system.

**Finding 2:**

- A) Volume is an imperfect standalone measure of quality.
- B) Robust quality and safety programs promote a culture of safety through accountability, verification, and an expansion of best practices.
- C) A learning health system holds great promise specifically for complex systems to deliver best care and optimize outcomes for patients across the system.

**Recommendation 2:**

- A) The MHS quality program must continue to use a quality assessment model that leverages risk-adjusted data, such as NSQIP, to focus on patient outcomes by institution and across the MHS.
- B) MHS leaders must regularly demonstrate that quality improvement and high reliability are valued at all levels of the MHS through openness to identify and address problems, engagement by surgical programs in professional society verification activities, and participation in inter-institutional collaborative to share best practices.
- a. The MHS quality program must continue to focus on a performance improvement model that leverages risk-adjusted NSQIP data, patient outcomes, and partnerships.
  - b. Regulation and policy barriers for confidentiality of patient safety and quality assurance records, such as *10 U.S.C. 1102* and associated policies must be modified so that safety and quality information cannot be used in a punitive way with regard to individuals, as it hinders open discussions of issues. The VHA has employed this non-punitive approach as facilitated by *38 U.S.C. 5705* and associated policies to ensure similar protection against punitive use of safety and quality data is mandated by the *Patient Safety and Quality Improvement Act of 2005*. Following the recommendations of *Optimal*



*Resources for Surgical Quality and Safety* by the ACS, the most effective surgical quality-improvement leaders seek to establish a culture where quality improvement and high reliability are valued and requires an explicit infrastructure including policies and procedures that facilitate the achievement of this goal that are built on accountability and fairness for all team members and encourages open and honest discussions of vulnerabilities and problems.

- C) The MHS must adopt a continuously learning healthcare system within the MHS to facilitate the improvement of patient safety and quality.
  - a. A comprehensive view of quality includes NSQIP data, registries and databases derived from electronic health records (EHR), identification of adverse events and care vulnerabilities through the DoD PSP, peer-review programs, and ongoing system analysis.

### **Finding 3:**

- A) MHS programs to inform patients about MTF quality are underutilized.
- B) Public resources are available to enhance patient engagement in shared decision making<sup>iii</sup> to include the online ACS Surgical Patient Education Program patient education handouts published in Journal of the American of Medical Association (JAMA).
- C) NSQIP, as a method of transparency within the MHS, is not user-friendly for patients.

### **Recommendation 3:**

- A) Patients in the MHS must be empowered in medical decision-making through access to understandable online information about MTF surgical quality and safety.
- B) Shared decision-making between patients and surgeons must be encouraged throughout the MHS. Transparency must be emphasized through patient consent to procedures and consultation on the risk of complex procedures at the facility where care is being recommended as compared to other available alternatives.
- C) Use of risk-adjusted data, such as NSQIP, for transparency with patients must enable patient-friendly comparisons between MTFs and potential civilian referral centers.

## DATA CAPTURE, OPTIMIZATION, AND OUTCOME MEASURES

### **Finding 4:**

- A) The NSQIP provides risk-adjusted outcome data for all 48 MTFs with surgical services. Results are used by the Services in different ways and to various degrees.
- B) Based on current governance and organizational structure, the NSQIP Steering Committee and MTF surgeon champions are limited in authority to act.
- C) MTFs are limited from participating in national risk-adjusted registries, such as, but not limited to, the ACS Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) and the Trauma Quality Improvement Program (TQIP).

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<sup>iii</sup> Shared decision making is a collaborative process in which at least two parties (the patient and provider) work together on treatment options and plans. This approach takes into account patient preferences in decision making and treatment as well as information and risk transparency on the part of the practitioner. Other parties, such as patient family members and allied health professionals, can also take part in this process.



- D) Current Procedural Terminology (CPT) codes are used in the MHS primarily for workload reporting and third-party billing. They are used secondarily in quality and safety metrics. There are discrepancies between surgical services, MTF, and MHS reported volumes due to inaccurate coding. There is a lack of resources for coding accuracy and analysis.
- E) MHS currently has a limited information management infrastructure, though pockets of excellence exist.

#### **Recommendation 4:**

- A) The DoD must standardize policy and practice regarding use of NSQIP results across the system.
- B) The MHS must empower MTF NSQIP leaders to act upon outcomes in conjunction with MHS NSQIP collaboratives.
- C) The MHS must support MTF participation in national risk-adjusted registries such as, but not limited to, MBSAQIP and TQIP.
- D) Coding must be resourced for improvement in accuracy. Training must be standardized across the MHS to ensure reporting based on CPT codes is as accurate as possible.
- E) The MHS must continue to optimize its IT infrastructure and analytics support, including MHS GENESIS and the MHS Management Analysis and Reporting Tool (M2).

### READY MEDICAL FORCE

#### **Finding 5:**

- A) Surgical outcomes are a reflection of surgeon and surgical support staff skill, team effectiveness, and facility capabilities.
- B) Within surgeon skill, experience may convey the greatest value toward quality outcomes. The KSA pilot program quantifies deployment-relevant operative skills for surgeons in peacetime operative experience and may drive clinical experience.
- C) Deployments or MTF assignments in low-intensity surgical environments influences readiness and surgical confidence. However, such deployments and remote MTF assignments cannot be avoided.

#### **Recommendation 5:**

- A) In collaboration with the Services, team training for the entire surgical team for pre-deployment readiness must be standardized in the DoD.
- B) The KSA program must be supported to validate its role in maintaining surgical readiness. The roles of telemedicine, telepresence, and telesurgery with specialists to fill KSA gaps must be explored.
- C) The MHS must address sustainment of surgical skills during and following deployments and assignments in low-intensity surgical environments.

#### **Finding 6:**

- A) Effective team training is critical for success in operational units and directly influences the quality of patient care. Simulation-based education and training may enable sustainment of surgical and teamwork skills.
- B) Simulation-based education and training throughout the MHS are limited by the lack of consistent funding and accreditation as programs of record.



- C) There is no system of readiness training to objectives through simulation. Most simulation-based activities are Service- or unit-specific.

**Recommendation 6:**

- A) Simulation activities, with associated outcomes data, must be used to prepare the entire surgical team for deployment operations.
- B) Simulation-based activities must align with the goals of the JTS program and be recognized as programs of record with explicit resourcing.
- C) The MHS must develop a more system-wide curriculum of simulation-based activities with measurable outcomes to support deployment timelines. The impact of these activities must be assessed through review of post-deployment care registries.

**Finding 7:**

The military has many operational deployments and remote locations that must be staffed for mission and readiness requirements. Deployment and stations in a low-intensity surgical environment influences readiness. Consistent placement of a surgeon at a rural, low-intensity facility can result in diminished skills for certain complex procedures.

**Recommendation 7:**

The DoD must develop a rotation system for surgeons and surgical teams stationed at low-intensity sites to high-intensity sites, even for short periods of time, to sustain skills. High-intensity civilian environments must be leveraged through expansion of military-civilian partnerships to provide opportunities for the rotation of military medical teams.

## STANDARDIZATION

**Finding 8:**

The policies, procedures, and systems of management are different between the Services; however, pockets of excellence exist. Following implementation of *NDAA FY 2017 Section 702 Reform of administration of DHA and MTFs*, the DHA has administrative and management responsibility for all MTFs and the opportunity to maximize standardization across MTFs.

**Recommendation 8:**

- A) The DHA must proceed with standardization of policies, procedures, and systems across Services and MTFs.
- B) The MHS must continue to identify successful practices and assess opportunities for dissemination through data-driven processes and metrics, such as the Army's Level I Trauma Center, Navy's CMO program, and Air Force's partnership efforts.

**Finding 9:**

- A) The decrease in direct care system enrollment within the MHS further exacerbates the ability to provide care providers with a case load that promotes competency. All Services have successful partnerships at different levels of maturity with civilian hospitals, medical centers, and the VA.
- B) Military healthcare systems in other countries have high capture of their beneficiary population and serve the civilian population, which positively influences caseload, provides



care to underserved populations, and supports clinical proficiency of the healthcare professionals.

**Recommendation 9:**

- A) The MHS must expand existing civilian and VA partnerships. *NDAA FY 2017 Section 717 Evaluation and treatment of veterans and civilians at MTFs* allows for civilians and veterans to be treated at MTFs.
- The MHS must leverage best practices from the Services, specifically the Air Force, and ensure providers' work in external facilities is accurately captured.
  - The MHS must consider templated partnership agreements at the enterprise-level.
  - The MHS must continue to evaluate business models that support qualified military personnel providing care in civilian trauma centers, and, where appropriate, involvement at selected military medical centers.
  - The DoD should seek engagement with international partners to increase experience in high-intensity environments.
  - MTF commanders must identify opportunities to partner with civilian and VA healthcare institutions to increase experience in high-intensity environments.
- B) The MHS must promote maintenance of competency and proficiency within MTFs by enhancing caseload recapture, and promoting exposure to high-intensity care environments.

**Finding 10:**

- A) The VA's robust quality systems, including a mechanism for evaluating safety mishap events when they occur, are integral to the VA's quality approach. The quality improvement approach is multi-layered with a focus on infrastructure, root cause analysis, peer-review, and NSQIP. These practices highlight the importance addressing the systems-based factors that are responsible for patient outcomes rather than inappropriately oversimplifying as a single issue such as volume.
- B) Through VHA Directive 2010-018, the VA has established a policy regarding the infrastructure requirements for VHA facilities providing in-house surgical services in relationship to the complexity of surgical procedures being performed. The directive is meant to ensure that the infrastructure where procedures are being performed meets the complete needs for good patient care and outcomes.

**Recommendation 10:**

- A) The MHS must adopt patient safety and quality programs similar to those within the VA. Quality programs that ensure collaboration of safety and a wider systems-approach with root cause analysis and the opportunity to respond to close calls (near misses) in real-time are critical for maintaining quality of care.
- B) The MHS must adopt an infrastructure approach similar to that within the VA (VHA 2010-018).



APPENDIX A. CROSSWALK BETWEEN TERMS OF REFERENCE OBJECTIVES AND REPORT RECOMMENDATIONS

Terms of Reference		Board Recommendations
I	Review the array of low-volume high-risk surgical procedures performed by military surgeons in the Direct Care system (MTFs).	<p><b>4D.</b> Coding must be resourced for improvement in accuracy. Training must be standardized across the MHS to ensure reporting based on CPT codes is as accurate as possible.</p> <p><b>4E.</b> The MHS must continue to optimize its IT infrastructure and analytics support, including MHS GENESIS and the MHS Management Analysis and Reporting Tool (M2).</p>
II	Evaluate policies, protocols, and systems for managing facility surgical capabilities and surgeon/staff proficiency across each of the Service branches.	<p><b>6A.</b> Simulation activities, with associated outcomes data, must be used to prepare the entire surgical team for deployment operations.</p> <p><b>6B.</b> Simulation-based activities must align with the goals of the JTS program and be recognized as programs of record with explicit resourcing.</p> <p><b>6C.</b> The MHS must develop a more system-wide curriculum of simulation-based activities with measurable outcomes to support deployment timelines. The impact of these activities must be assessed through review of post-deployment care registries.</p> <p><b>7.</b> The DoD must develop a rotation system for surgeons and surgical teams stationed at low-intensity sites to high-intensity sites, even for short periods of time, to sustain skills. High-intensity civilian environments must be leveraged through expansion of military-civilian partnerships to provide opportunities for the rotation of military medical teams.</p> <p><b>9A.</b> The MHS must expand existing civilian and VA partnerships. <i>NDA FY 2017 Section 717 Evaluation and treatment of veterans and civilians at MTFs</i> allows for civilians and veterans to be treated at MTFs.</p> <ol style="list-style-type: none"> <li>The MHS must leverage best practices from the Services, specifically the Air Force, and ensure providers' work in external facilities is accurately captured.</li> <li>The MHS must consider templated partnership agreements at the enterprise-level.</li> <li>The MHS must continue to evaluate business models that support qualified military personnel providing care in civilian trauma centers, and, where appropriate, involvement at selected military medical centers.</li> <li>The DoD should seek engagement with international partners to increase experience in high-intensity environments.</li> <li>MTF commanders must identify opportunities to partner with civilian and VA healthcare institutions to increase experience in high-intensity environments.</li> </ol> <p><b>9B.</b> The MHS must promote maintenance of competency and proficiency within MTFs by enhancing caseload recapture, and promoting exposure to high-intensity care environments.</p>
III	Develop recommendations to advance standardized policies on managing facility infrastructure capabilities and individual surgeon/supporting staff proficiency across all Service branches.	<p><b>1A.</b> The Secretary of Defense, DHA Director, and Service leaders must establish an organization-wide culture of performance improvement that is patient-centered with aligned authority, accountability, and transparency as the highest priority.</p> <ol style="list-style-type: none"> <li>The Secretary of Defense, Combatant Commands, and Service Secretaries must support the efforts of the DHA to integrate and optimize healthcare delivery throughout the DoD.</li> </ol> <p><b>1B.</b> The Secretary of Defense should ensure that the DHA has capabilities to promote a culture of continuous learning and innovation.</p>





Terms of Reference		Board Recommendations
		<p>a. The DHA must establish a comprehensive, standardized, and non-punitive performance improvement process through peer review; root cause analysis; transparent, risk-based prioritization methodology; and ongoing assessment of systems of care to assure patient safety and optimize quality outcomes across the MHS.</p> <p>b. Partnerships between MTFs, civilian medical centers, and VA medical facilities must be increased to provide optimal surgical care for all patients.</p> <p>c. The DHA must have resources (to include personnel, IT, data analytics, and video conferencing) for an organization-wide learning system.</p> <p><b>4A.</b> The DoD must standardize policy and practice regarding use of NSQIP results across the system.</p> <p><b>4B.</b> The MHS must empower MTF NSQIP leaders to act upon outcomes in conjunction with MHS NSQIP collaboratives.</p> <p><b>4C.</b> The MHS must support MTF participation in national risk-adjusted registries, such as, but not limited to, MBSAQIP and TQIP.</p> <p><b>8A.</b> The DHA must proceed with standardization of policies, procedures, and systems across Services and MTFs.</p> <p><b>8B.</b> The MHS must continue to identify successful practices and assess opportunities for dissemination through data-driven processes and metrics, such as the Army’s Level I Trauma Center, Navy’s CMO program, and Air Force’s partnership efforts.</p>
IV	<p>Evaluate potential MHS applicability of Veterans Health Administration (VHA) Operative Complexity Directives:</p> <ul style="list-style-type: none"> <li>• “Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures” (VHA 2010-018)</li> <li>• “Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center” (VHA 2011-037)</li> </ul>	<p><b>10A.</b> The MHS must adopt patient safety and quality programs similar to those within the VA. Quality programs that ensure collaboration of safety and a wider systems-approach with root cause analysis and the opportunity to respond to close calls (near misses) in real-time are critical for maintaining quality of care.</p> <p><b>10B.</b> The MHS must adopt an infrastructure approach similar to that within the VA (VHA 2010-018).</p>
V	<p>Examine the contribution (Knowledge, Skills, and Abilities) of low-volume high-risk procedures to military medical readiness (e.g., surgeons, operating room staff).</p>	<p><b>5A.</b> In collaboration with the Services, team training for the entire surgical team for pre-deployment readiness must be standardized in the DoD.</p> <p><b>5B.</b> The KSA program must be supported to validate its role in maintaining surgical readiness. The roles of telemedicine, telepresence, and telesurgery with specialists to fill KSA gaps must be explored.</p> <p><b>5C.</b> The MHS must address sustainment of surgical skills during and following deployments and assignments in low-intensity surgical environments.</p>



Terms of Reference		Board Recommendations
VI	Evaluate MHS policies related to surgical volume transparency and public release of volume, errors and outcomes data.	<p><b>3A.</b> Patients in the MHS must be empowered in medical decision-making through access to understandable online information about MTF surgical quality and safety.</p> <p><b>3B.</b> Shared decision-making between patients and surgeons must be encouraged throughout the MHS. Transparency must be emphasized through patient consent to procedures and consultation on the risk of complex procedures at the facility where care is being recommended as compared to other available alternatives.</p> <p><b>3C.</b> Use of risk-adjusted data, such as NSQIP, for transparency with patients must enable patient-friendly comparisons between MTFs and potential civilian referral centers.</p>
VII	Provide recommendations on using the volume, errors and outcome data to inform and enhance policies for managing surgical capabilities and surgeon currency.	<p><b>2A.</b> The MHS quality program must continue to use a quality assessment model that leverages risk-adjusted data, such as NSQIP, to focus on patient outcomes by institution and across the MHS.</p> <p><b>2B.</b> MHS leaders must regularly demonstrate that quality improvement and high reliability are valued at all levels of the MHS through openness to identify and address problems, engagement by surgical programs in professional society verification activities, and participation in inter-institutional collaborative to share best practices.</p> <ul style="list-style-type: none"> <li>a. The MHS quality program must continue to focus on a performance improvement model that leverages risk-adjusted NSQIP data, patient outcomes, and partnerships.</li> <li>b. Regulation and policy barriers for confidentiality of patient safety and quality assurance records, such as <i>10 U.S.C. 1102</i> and associated policies must be modified so that safety and quality information cannot be used in a punitive way with regard to individuals, as it hinders open discussions of issues. The VHA has employed this non-punitive approach as facilitated by <i>38 U.S.C. 5705</i> and associated policies to ensure similar protection against punitive use of safety and quality data is mandated by the <i>Patient Safety and Quality Improvement Act of 2005</i>. Following the recommendations of <i>Optimal Resources for Surgical Quality and Safety</i> by the ACS, the most effective surgical quality-improvement leaders seek to establish a culture where quality improvement and high reliability are valued and requires an explicit infrastructure including policies and procedures that facilitate the achievement of this goal that are built on accountability and fairness for all team members and encourages open and honest discussions of vulnerabilities and problems.</li> </ul> <p><b>2C.</b> The MHS must adopt a continuously learning healthcare system within the MHS to facilitate the improvement of patient safety and quality.</p> <ul style="list-style-type: none"> <li>a. A comprehensive view of quality includes NSQIP data, registries and databases derived from electronic health records (EHR), identification of adverse events and care vulnerabilities through the DoD PSP, peer-review programs, and ongoing system analysis.</li> </ul>
Secondary efforts to be addressed in the next six months following this report.		
VIII	Review the array of low-volume high-risk surgical procedures performed on MHS beneficiaries in the Purchased Care system (TRICARE).	
IX	Evaluate potential for the MHS to sign on to the “Surgical Volume Pledge” agreed to by Dartmouth-Hitchcock Medical Center, Johns Hopkins Medicine, and the University of Michigan.	



## APPENDIX B. BACKGROUND AND INTRODUCTION

### B.1 INTRODUCTION

#### REQUEST TO THE DEFENSE HEALTH BOARD

On March 28, 2018, the Acting Assistant Secretary of Defense for Health Affairs requested that the Defense Health Board (the Board) provide recommendations to improve policies for managing facility surgical capabilities and surgeon proficiency.

Specifically, the Board was asked to address and develop findings and recommendations on the policies and practices in place to:

- Determine where high-risk surgical procedures should be performed,
- Optimize the safety and quality of surgical care provided,
- Enhance patient transparency related to surgical volumes and outcomes, and
- Evaluate the contribution of high-risk surgical procedures to medical readiness.

To accomplish the above objectives, the Board's Trauma and Injury Subcommittee was specifically tasked to:

- Review the array of low-volume high-risk surgical procedures performed by military surgeons in the Direct Care system (i.e. MTFs).
- Evaluate policies, protocols, and systems for managing facility surgical capabilities and surgeon/staff proficiency across each of the service branches.
- Develop recommendations to advance standardized policies on managing facility infrastructure capabilities and individual surgeon / supporting staff proficiency across all service branches.
- Evaluate potential MHS applicability of Veterans Health Administration (VHA) Operative Complexity Directives:
  - "Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures" (VHA 2010-018)
  - "Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center" (VHA 2011-037)
- Examine the contribution (Knowledge, Skills, and Abilities) of low-volume high-risk procedures to military medical readiness (e.g., surgeons, operating room staff).
- Evaluate MHS policies related to surgical volume transparency and public release of volume, errors and outcomes data.
- Provide recommendations on using the volume, errors and outcome data to inform and enhance policies for managing surgical capabilities and surgeon currency.

Upon completion of the aforementioned objectives, the Board will address a secondary effort to:

- Review the array of low-volume high-risk surgical procedures performed on MHS beneficiaries in the Purchased Care System (TRICARE).



- Evaluate potential for the MHS to sign on to the “Surgical Volume Pledge” agreed to by Dartmouth-Hitchcock Medical Center, Johns Hopkins Medicine, and the University of Michigan.

## GUIDING PRINCIPLES

The Board adopted the following guiding principles as a foundation for its review (Figure 1).

**Figure 1.** Guiding Principles

**Overarching Principle:** It is the duty of the Department of Defense (DoD) to enhance patient safety and deliver safe and high-quality care to active duty personnel, military retirees, and their beneficiaries through services provided directly at Military Medical Treatment Facilities (MTFs) and through the TRICARE purchased care network.

**Guiding Principles:** These principles require that the recommendations by the Board must:

- (1) Consider the impact of the volume standards within the civilian sector and the applicability of such standards to MTFs;
- (2) Identify acceptable risk levels that ensure patient safety and quality of care;
- (3) Consider the contribution of high-risk surgical procedures to medical readiness especially as it relates to combat casualty care;
- (4) Describe the impact of assuring patient safety on readiness;
- (5) Recognize the systematic considerations that impact patient safety and quality of care;
- (6) Consider patient transparency related to surgical volumes and outcomes; and
- (7) Consider the suggestions of the healthcare community regarding implemented volume requirements.

## METHODOLOGY

To perform a comprehensive review of the surgical volume-outcome association and formulate findings and recommendations, the Board used several different sources to guide analysis. The Board:

- Conducted literature reviews on relevant topics;
- Received briefings from volume-outcome and/or military medic readiness subject matter experts (SMEs) from within the MHS and from the civilian sector;
- Requested, analyzed, and interpreted volume, errors and outcome data; and
- Reviewed current policies and practices related to patient safety and quality of care, including within the MHS, the VHA, and within the civilian healthcare systems.



## B.2 BACKGROUND

### OVERVIEW OF THE SURGICAL CARE EXPERIENCE AND OUTCOME ISSUE

The \$50-billion MHS's mission is to care for wounded combatants in conflict zones and provide routine care to 9.4 million active-duty personnel, their families, and retirees.<sup>1</sup> Military surgeons serve a relatively young and healthy population who do not often require surgery. However, to meet patient needs, some MTFs currently perform surgeries in lower volumes. For patient safety, it is important for the MHS to understand whether there are increased risks associated with low-intensity surgery and to develop policies and methods to prevent and mitigate such risks.

Recently, a series of U.S. News & World Report articles<sup>5-7</sup> reported on the quality and surgical volume relationship within the MHS. Moreover, 30 years of research indicates physicians and hospitals with the highest numbers of certain complex surgical procedures achieve the best results.<sup>5</sup> Due to mission requirements, remote MTF locations, and deployed environments, some procedures are conducted in low frequencies.

Concerned about the health and safety of military members and their beneficiaries, the Acting Assistant Secretary of Defense for Health Affairs requested that the Board examine the military's policies on complex procedures. A high-level, independent review of MHS practices in this area is likely to help improve both the safety and quality of MHS care and the confidence of patients in that care. By addressing these issues proactively, the MHS can maintain, improve, and enhance the safety and quality of care as well as the trust of its patients. Thus, the Board's Trauma and Injury Subcommittee evaluated the surgical care experience and outcome issue.

### HISTORY OF THE SURGICAL CARE EXPERIENCE AND OUTCOMES ISSUE

The medical field has debated the concept of quality of care for nearly a century. Beginning in the early 20<sup>th</sup> century, it was widely accepted to view the treatment of patients as primarily a financial benefit; thus, it was not necessarily the primary interest of the medical community to follow up, compare, analyze, or to standardize their results among surgeons.<sup>52</sup> The association between volume of surgical and medical procedures and outcomes of those procedures has been studied in the health and medical fields since the 1970s.<sup>53,54,25</sup> The debate has generally focused on such topics as whether regionalization of operations into large medical centers is better with high volumes of specific procedures than smaller hospitals which may not perform as many procedures. It is also extensively debated if high volume leads to better outcomes, commonly known as the "practice-makes-perfect" method, or if hospitals and surgeons with better outcomes attract more patients, known as the "selective-referral-program" method.<sup>54,55,10,56</sup> The "selective-referral-program" is not as largely held as a valid argument regarding the surgical care experience-outcome relationship; however, research in support of this model suggests that many patients could benefit from selective-referral based on the best available proxies for quality of care.<sup>57</sup>

Furthermore, the idea of "practice makes perfect" dominates the debate on whether hospital volume and surgeon volume equate to quality of care. For example, research conducted during



the 1990s by Farley and Ozminkowski examined whether patient outcomes were affected by variations in volume over time within hospitals and if this impact was consistent.<sup>58</sup> This often cited longitudinal study includes observations recorded from a national sample over the course of eight years with 500 community samples. The authors concluded that higher volume leads to better outcomes for certain groups of patients and outcomes varied by procedure.<sup>58</sup> Similarly, another early study found that the size of a hospital was the highest correlated variable with volume for a study based on data from 266,944 surgical patients and 227,107 medical patients treated in over 1,200 hospitals with the stipulation that size is also associated with several other factors such as organization of the facility and specialization of the staff.<sup>10</sup>

Early literature found hospital volume to be associated with outcome measures; modern research has drawn similar conclusions but these results vary dependent on the surgical procedure. In 2002, the widely cited study by Birkmeyer et al. suggested the relative importance of hospital volume varied by procedure for individual patients who were considering where to undergo various procedures.<sup>9</sup> The data for this study show proposed standards could reduce the surgical mortality associated with several procedures.

Livingston and Cao (2010) provide counterpoints to the claims that better outcomes occur at centers that perform higher volumes of surgical procedures, highlighting the limited quality of statistical analysis used to support these claims.<sup>12</sup> They identified serious flaws in the methods used to study the volume-outcomes association, emphasizing the criteria that should be used for a proxy variable include: It (volume) must have a strong (i.e., large effect) relationship with the outcome and must provide substantial explanation of the outcomes variance (i.e., the statistical model adequately fits the data). However, few publications using regression analysis (e.g., 3.6%) report on how well a model fits the data being studied. Guidance to address these concerns include capitalizing on the greater explanatory power of using volume as a continuous variable (as opposed to dichotomizing volume or categorizing volume into terciles or other groups). For example, if volume is dichotomized into the following groups, one with 2 to 149 cases per year and one with 150 cases or more per year, the low volume group would include surgeons that perform few procedures (e.g., 2 per year), along with surgeons that perform appreciable numbers (e.g., 100 per year). Further guidance includes reporting the proportion of variance explained by procedure volume to demonstrate the relative importance volume has in explaining outcomes relative to other potential sources for that variation.<sup>12</sup> Due to the methodology used in the Birkmeyer et al., 2002 article, the study becomes an outlier analysis and not a volume analysis, because the comparison focuses on the low outliers.<sup>11</sup>

Reoccurring corresponding implications open the opportunity to identify areas in need of growth and improvement throughout the health care system such as defining hospital and surgeon volume, cost-benefits analysis, marketing accreditations and referrals, medical training, and patient transparency while maintaining the quality of care.<sup>9</sup>

Additionally, higher hospital volume is often found to be correlated with lower complication rates, lower re-operation rates, lower readmission rates, lower mortality rates, and lower costs.<sup>9,10,18-24</sup> Furthermore, researchers argue that these findings support regionalizing healthcare. Nonetheless, there are many factors that influence whether patients are willing to take additional risks in receiving treatment at their local facility or if traveling to an arguably



more specialized, regionalized facility is the best option. For example, convenience of hospital location to the patient's home and family may be perceived by the patient to be more important than decreasing a probability of dying.<sup>10</sup> While there are options for family member accommodations through the Fisher House Foundation and Hotels for Heroes, criteria for eligibility are not standardized and are set by each site's commander. Further, these accommodations are not available for outpatient services, which include post-surgical care.<sup>59</sup> Flood et al. address the issue of differentiating between higher volume hospitals and simply larger hospitals, which must also be taken into consideration for regionalization.<sup>10</sup> Regionalization is the delivery of care at a limited number of selected provider sites.<sup>20</sup> Although regionalization is not defined in terms of cost, much of the literature links the two together: Regionalization should be considered as a means to ensure high-quality of care at low-cost. In particular, from the cost-effectiveness viewpoint, the economics of cancer surgery should benefit from encouraging patients to seek treatment from high-volume surgeons.<sup>60</sup>

Patients who travel longer distances to "high-volume" centers have significantly different treatments and better outcomes than patients who stay close to home at "low-volume" centers.<sup>61</sup> Furthermore, better patient outcomes for higher volume providers may indicate fewer complications, thus leading to lower hospital costs per patient. The results of this 2008 study suggest that the cost of reductions associated with higher surgeon volume became more established over time, and likely persist in current practice.<sup>60</sup> However, the biggest challenge to regionalization is the continuity of care for rural patients.<sup>24</sup> A 2017 study questioned if limiting operative care to "high-volume" hospitals would actually result in improved care or decreased access to care in at-risk populations. Authors concluded that volume standards would have a small impact on this already disadvantaged population.<sup>24</sup> Moreover, patients may have to travel intolerable distances, suffer longer wait times, and possibly experience mortality or complications before the surgery. Patients may not have the social support system to properly account for all of these disadvantages.<sup>62</sup> Literature suggests there is a further need to assess regionalization within rural hospitals and specific to rural patient needs.

In addition to the discussion about hospital volume, there is also the need to examine surgeon volume, including that of the surgical team and facility capabilities. As is the case of higher hospital volume leading to better outcomes, there is a body of research that demonstrates that "high-volume" surgeons are likely to have better patient outcomes than "low-volume" surgeons.<sup>25,26</sup> The caseload of a surgeon can be quantified similarly to that of an entire hospital; however, other factors can be considered regarding surgeons' outcome measures. There is little evidence to show several years of experience is more important than experience from a short period of time with a large number of operations.<sup>54</sup> Instead, a learning effect may explain the assumed better patient outcome. As hospitals or surgeons gain more experience performing operations, they improve their outcomes.<sup>60</sup> Some early research suggested physician volume may be more important than hospital volume,<sup>55,63</sup> while other research did not support the hypothesis that individual surgeon volume of patients is significantly related to patient mortality.<sup>22</sup> Moreover, recent researchers often review two factors together—hospital and surgeon volume—when examining the impacts on outcomes related to patient safety. Hence, the success of patient outcomes heavily relies on the surgical team and facility, not only the lead surgeon.<sup>3</sup> More surgeon experience may improve the utilization of resources in the operating



room (OR), shorten operative times, and produce better surgical techniques, which ultimately leads to minimizing cost.<sup>60</sup>

### B.3 TOP 10 “LOW-VOLUME HIGH-RISK” SURGICAL PROCEDURES

The top 10 surgical procedures often studied as having a positive association between higher volume and patient outcomes are divided into four categories: cancer resections (esophagus, lung, pancreatic, rectal), cardiovascular procedures (carotid artery stenting, complex abdominal aortic aneurysm, mitral valve repair), general procedures (bariatric staple surgery), and orthopedics (knee replacement, hip replacement). These procedures are shown to have a strong relationship between the number of times a hospital performs a specific surgical procedure and the outcomes of those patients, including death and complication rates.<sup>28</sup> Furthermore, these 10 procedures were adopted in May 2015 by Johns Hopkins Health System, Dartmouth-Hitchcock Medical Center, and University of Michigan Health System as part of their Volume Pledge that created annual volume minimums for each procedure. The 10 procedures identified by this group are those that are believed to have the strongest link between hospital volume and patient mortality.<sup>28</sup> Among the literature that examines at least one of these specific procedures, the consensus is these procedures were selected because they have a significant risk of serious postoperative morbidity and mortality.<sup>18</sup>

#### **Esophageal Cancer Resection**

In a 1998 study using low, medium, and high-volume categories for the number of procedures performed in a specific hospital with data from the Surveillance, Epidemiology, and End Results (SEER) Medicare linked database, the 30-day mortality dropped from 17.3% in the lowest-volume category to 3.4% in the highest-volume category for esophagostomy.<sup>18</sup> Similar results were found using the National Cancer Data Base from 2006 to 2011, where patients who travel longer distances to high-volume centers have significantly different treatment and better outcomes than patients who stay close to home at low-volume centers.<sup>61</sup> From 2009 to 2011 there were 1,324 esophagostomies performed in California, Florida, and New York, of which 82.1% were conducted at low-volume hospitals.<sup>64</sup> However, this study found no significant differences in in-hospital mortality between high- and low-volume hospitals, but high-volume facilities were less likely to have complications than the low-volume facilities.<sup>64</sup>

#### **Lung Cancer Resection**

Using data from 2009 to 2011 from California, Florida, and New York, 20,138 lung resections were performed, of which 38.3% were formed at high-volume hospitals.<sup>64</sup> This study found mortality for lung resections was significantly higher at low-volume hospitals, as was the presence of any postoperative complications, and costs were higher for patients at low-volume hospitals compared to those at high-volume facilities.<sup>64</sup>

#### **Pancreatic Cancer Resection**

The 30-day mortality dropped from 12.9% to 5.8% for patients at high-volume facilities compared to those at low-volume facilities for pancreatectomy in a study from 1998.<sup>18</sup> Similar results of a significant relationship between hospital volume and operative mortality was found





for a California study of 1,705 patients across 298 hospitals from 1990 to 1994 who underwent pancreatic resection.<sup>23</sup> Pancreaticoduodenectomy (Whipple procedure) was studied among patients in Maryland and came to the conclusion that the high-volume regional medical center (The Johns Hopkins Hospitals) achieved superior outcomes at a lower cost most likely due to the special expertise of the staff (including house and nurse staff) and large number of procedures performed.<sup>20</sup>

### **Rectal Cancer Resection**

A comprehensive 2010 meta-analysis examined all the current literature regarding the volume-outcome relationships and rectal cancer due to strong evidence supporting the importance of the volume-outcome relationship. Authors found no evidence that hospital caseloads demonstrated improved mortality or survival outcome for rectal cancer.<sup>63</sup> Additionally, a 2008 study reviewed 22 published studies on rectal cancer surgery and found that across all studies, high hospital volume and high surgeon volume have either a beneficial or neutral effect on patient care and outcomes.<sup>65</sup>

### **Carotid Artery Stenting**

A Nationwide Inpatient Sample (NIS) from the Healthcare Cost and Utilization Project was analyzed to identify patients undergoing carotid artery stenting (CAS) between 2005 and 2009. The stroke and death rate in the CAS high-volume operator tertile (2.27%), defined as 15 or more operator annual procedures, was nearly half of that observed in the low-volume operator tertile (4.43%), defined as fewer than 5 operator annual procedures.<sup>66</sup> Another study, using administrative data from Medicare beneficiaries undergoing CAS between 2005 and 2007, concluded that the observed 30-day mortality was higher among patients treated by operators with very-low annual volumes (2.5%), defined as fewer than 6 annual procedures, than among patients treated by operators with high annual volumes (1.4%), defined as 24 or more annual procedures.<sup>67</sup>

### **Complex Abdominal Aortic Aneurysm Repair**

Patients with an abdominal aneurysm are more likely to survive when their operations are performed in high-volume hospitals, as found in a national 1977 study.<sup>22</sup> A more recent sample from 2001 to 2007 included 47,033 patients who underwent intact abdominal aortic aneurysm (AAA) repair or presented with ruptured AAA found 5.6% of patients were treated at rural hospitals.<sup>68</sup> According to this study, patients with ruptured AAA who were not transferred to another facility had comparable mortality whether treated at a rural or urban hospital; however, the major risk at the rural facility is an inability to provide care at all, resulting in transfer and delayed repair.<sup>68</sup>

### **Mitral Valve Repair**

Using data from the Nationwide Inpatient Sample (NIS) from 1998–2011, patients who underwent both aortic and mitral valve repair or replacement were included in the 2015 study that found centers performing more than eight procedures a year were superior to those performing eight or fewer.<sup>62</sup> Similar results were found for Medicare beneficiaries from 2000 to



2009—hospitals with the lowest volume of mitral procedures had substantially worse short- and long-term survival than higher-volume hospitals and lower mitral valve repair rates annually were independently predictive of higher operative and long-term mortality.<sup>69</sup>

### **Bariatric Staple Surgery**

A New York study using 2003 data found an association between surgeon volume as well as hospital volume and the likelihood of postoperative complications for adult patients undergoing bariatric surgery.<sup>26</sup> Similarly, the association between hospital volume and surgeon procedure volume and complications following bariatric surgery was also found in a 2010 Michigan study.<sup>70</sup>

### **Knee Replacement**

A recent study found higher surgeon volume was associated with lower mortality, infections and transfusion rates for patients who underwent total knee arthroplasty, as well as shorter procedure times, decreased lengths of stay, and positive patient-reported outcomes.<sup>71</sup> However, another modern study did not draw the same strong relationship. Although hospital volume appeared to have more an impact on patient outcomes for total knee replacement than surgeon volume, the association was not strong according to a 2012 study.<sup>72</sup>

### **Hip Replacement**

There was a statistically significant association between low hospital volume and higher 1-year morbidity and higher risk of venous thromboembolism (VTE) for the study conducted using 2002 data from Pennsylvania.<sup>73</sup> Additionally, patients operated on at high-volume hospitals or by high-volume surgeons for total hip arthroplasty (THA) and total knee arthroplasty (TKA) are more likely to undergo shorter procedures than those in low-volume hospitals or by low-volume surgeons.<sup>74</sup>

## **NATIONAL DEFENSE AUTHORIZATION ACT FISCAL YEAR 2017**

The *NDAA FY 2017* provides the Board a unique opportunity to assist with shaping the future of military health, not only as an example for the military system, but also as a leading force of innovation among all healthcare systems. The DoD recognizes the importance of modernizing the MHS by standardization of services across all facilities and integration of healthcare to improve and sustain operational medical force readiness and medical readiness of the Armed Forces, improve access and experience of care, improve health outcomes, and lower costs. Table 1 shows the relevant sections that were considered when generating the Board's recommendations from this report.



**Table 1.** National Defense Authorization Act Fiscal Year 2017 (NDAA FY 2017) Provisions<sup>75</sup>

<b>NDAA FY 2017 Section</b>	<b>Summary</b>
<p><b>Section 702.</b>  <b>Reform of administration of Defense Health Agency and military medical treatment facilities</b></p>	<p>Beginning October 1, 2018, the Director of the Defense Health Agency shall be responsible for the administration of each military medical treatment facility, including with respect to—</p> <ol style="list-style-type: none"> <li>(1) Budgetary matters;</li> <li>(2) Information technology;</li> <li>(3) Health care administration and management;</li> <li>(4) Administrative policy and procedure;</li> <li>(5) Military medical construction; and</li> <li>(6) Any other matters the Secretary of Defense determines appropriate.</li> </ol> <p>The commander of each military medical treatment facility shall be responsible for—</p> <ol style="list-style-type: none"> <li>(1) Ensuring the readiness of the members of the armed forces and civilian employees at such facility; and</li> <li>(2) Furnishing the health care and medical treatment provided at such facility.</li> </ol> <p>In addition to the other duties of the Director of the Defense Health Agency, the Director shall coordinate with the Joint Staff Surgeon to ensure that the Director most effectively carries out the responsibilities of the Defense Health Agency as a combat support agency.</p>
<p><b>Section 703.</b>  <b>Military medical treatment facilities</b></p>	<p>The Secretary of Defense shall maintain medical centers in areas with a large population of members and covered beneficiaries who require comprehensive health care services that support medical readiness.</p> <p>Medical centers shall consist of the following:</p> <ol style="list-style-type: none"> <li>(1) Inpatient and outpatient tertiary care facilities that incorporate specialty and subspecialty care.</li> <li>(2) Graduate medical education programs.</li> <li>(3) Residency training programs.</li> <li>(4) Level one or level two trauma care capabilities.</li> </ol> <p>The Secretary may designate a medical center as a regional center of excellence for unique and highly specialized health care services, including with respect to polytrauma, organ transplantation, and burn care.</p> <p>The Secretary of Defense shall maintain hospitals in areas where civilian health care facilities are unable to support the health care needs of members of the Armed Forces and covered beneficiaries. Hospitals shall provide—</p> <ol style="list-style-type: none"> <li>(1) Inpatient and outpatient health services to maintain medical readiness; and</li> <li>(2) Such other programs and functions as the Secretary determines appropriate.</li> </ol> <p>Hospitals shall consist of inpatient and outpatient care facilities with limited specialty care that the Secretary determines—</p> <ol style="list-style-type: none"> <li>(1) Is cost effective; or</li> <li>(2) Is not available at civilian health care facilities in the area of the hospital.</li> </ol>
<p><b>Section 706.</b>  <b>Establishment of high performance military-civilian integrated health care delivery systems</b></p>	<p>No later than January 1, 2018, the Secretary of Defense shall establish military-civilian integrated health delivery systems through partnerships with other health systems, including local or regional in the private sector—</p> <ol style="list-style-type: none"> <li>(1) To improve access to health care for covered beneficiaries;</li> <li>(2) To enhance the experience of covered beneficiaries in receiving health care;</li> <li>(3) To improve health outcomes for covered beneficiaries;</li> </ol>



	<ul style="list-style-type: none"> <li>(4) To share resources between the Department of Defense and private sector, including such staff, equipment, and training assets as may be required to carry out such integrated health delivery systems;</li> <li>(5) To maintain services within military treatment facilities that are essential for the maintenance of operational medical force readiness skills of health care providers of the Department; and</li> <li>(6) To provide members of the Armed Forces with additional training opportunities to maintain such readiness skills.</li> </ul>
<p><b>Section 707. Joint Trauma System</b></p>	<p>No later than 180 days after the date of the enactment of this Act, the Secretary of Defense shall submit to the Committees on Armed Services of the House of Representatives and the Senate an implementation plan to establish a Joint Trauma System within the Defense Health Agency that promotes improved trauma care to members of the Armed Forces and other individuals who are eligible to be treated for trauma at a military medical treatment facilities.</p> <p>The Joint Trauma System shall include the following elements:</p> <ul style="list-style-type: none"> <li>(1) Serve as a reference body for all trauma care provided across the military health system;</li> <li>(2) Establish standards of care for trauma services provided at military medical treatment facilities;</li> <li>(3) Coordinate the translation of research from the centers of excellence of the Department of Defense into standards of clinical trauma care;</li> <li>(4) Coordinate the incorporation of lessons learned from trauma education and training partnerships pursuant to section 708 into clinical practice.</li> </ul>
<p><b>Section 708. Joint Trauma Education and Training Directorate</b></p>	<p>The Secretary of Defense shall establish a Joint Trauma Education and Training Directorate (in this section referred to as the “Directorate”) to ensure that the traumatologists of the Armed Forces maintain readiness and are able to be rapidly deployed for future armed conflicts.</p> <p>The Secretary may enter into partnerships with civilian academic medical centers and large metropolitan teaching hospitals that have level I civilian trauma centers to provide integrated combat trauma teams, including forward surgical teams, with maximum exposure to a high volume of patients with critical injuries.</p>
<p><b>Section 717. Evaluation and treatment of veterans and civilians at military treatment facilities</b></p>	<p>The Secretary of Defense shall authorize a veteran (in consultation with the Secretary of Veteran Affairs) or civilian to be evaluated and treated at a military treatment facility if the Secretary of Defense determines that—</p> <ul style="list-style-type: none"> <li>(1) The evaluation and treatment of the individual is necessary to attain the relevant mix and volume of medical casework required to maintain medical readiness skills and competencies of health care providers at the facility;</li> <li>(2) The health care providers at the facility have the competencies, skills, and abilities required to treat the individual; and</li> <li>(3) The facility has available space, equipment, and materials to treat the individual.</li> </ul>
<p><b>Section 726. Program to eliminate variability in health outcomes and improve quality of health care services delivered in military medical treatment facilities</b></p>	<p>Beginning no later than January 1, 2018, the Secretary of Defense shall implement a program—</p> <ul style="list-style-type: none"> <li>(1) To establish best practices for the delivery of health care services for certain diseases or conditions at military medical treatment facilities, as selected by the Secretary;</li> <li>(2) To incorporate such best practices into daily operations of military medical treatment facilities selected by the Secretary for purposes of the program, with priority in selection given to facilities that provide specialty care; and</li> <li>(3) To eliminate variability in health outcomes and to improve quality of health care services delivered at military medical treatment facilities selected by the Secretary for purposes of the program.</li> </ul>



*NDAA FY 2017* calls for significant administrative changes to the management of MTFs with transition of reform taking place in phases beginning 1 October 2018. *NDAA FY 2018* identified the DoD's lack of progress on the development of the implementation plan to transition MTFs to the DHA.<sup>76</sup> Initial interim reports to Congress outlined a "component model" with the Services maintaining command and control of MTFs through intermediary medical commands under two separate lines of authority—one from DHA and the other from the Services. After further analysis, the DoD decided that the component model did not adequately satisfy requirements and developed a new framework to ensure that the DHA would have direct control over MTFs while the Services would retain control over their uniformed personnel and non-health care delivery operational and installation-specific functions separate from MTF operations. The proposed implementation plan reflects a phased approach consistent with the Department's request for a three-year phasing period. However, concerns remain regarding if this model will lead to enhanced operational medical force readiness, improved access to care, improved quality of care, and a better experience of care.<sup>76</sup> Thus, while the transition continues, there is an opportunity for the Board to provide recommendations that align standardization with patient safety and enhancement of quality of care.<sup>57</sup>



## APPENDIX C. CURRENT STATUS OF SURGICAL CARE EXPERIENCE AND OUTCOMES IN MILITARY MEDICAL TREATMENT FACILITIES

### C.1 INTRODUCTION

Appendix C of this report addresses the current state of surgical care experiences and outcomes within the Military Health System (MHS) by Service (Army, Navy, Air Force) and the National Capital Region-Medical Directorate (NCR-MD). Specifically, this appendix addresses the following taskings in the Terms of Reference (TOR):

- Review the array of low-volume high-risk surgical procedures performed by surgeons in the direct care system (MTFs);
- Evaluate policies, protocols, and systems for managing facility surgical capabilities and surgeon/staff proficiency across each of the service branches.

While *National Defense Authorization Act Fiscal Year 2017 (NDAA FY 2017) Section 702* requires the Director of the Defense Health Agency (DHA) be responsible for the administration of MTFs beginning 1 October 2018, there is variability in surgical operations and training among Army, Navy, Air Force, and NCR-MD MTFs.<sup>75</sup> The proposed *Section 702* implementation plan reflects a focused, phased approach to standardization and efficiency; however, it is unclear how this model may lead to enhanced readiness, improved access to care, improved quality of care, and a better experience of care. Thus, it is useful to examine current individual Services approaches to monitoring surgical care and training.

### C.2 THE SURGICAL CARE EXPERIENCE AND OUTCOME ASSOCIATION IN THE MILITARY HEALTH SYSTEM

The MHS is one of America's largest and most complex health care systems with 9.4 million beneficiaries, as well as one of the nation's largest health benefit plans.<sup>77</sup> The mission of the MHS is complex: to ensure America's 1.4 million active duty and 331,000 Reserve Component personnel are medically fit to complete their national security missions; to ensure that all active and reserve medical personnel in uniform are trained and ready to provide medical care in support of operational forces around the world; and to provide a medical benefit commensurate with the service and sacrifice of active duty personnel, military retirees and their families.<sup>1</sup>

The challenges of the MHS are unlike any other healthcare system in the world; it must execute its mission requirements in both contingency and peacetime environments. The contingency mission includes ensuring military forces are a medically ready force and that the medical Service members deployed are a ready medical force, able to provide complex care in combat zones.<sup>3</sup> The peacetime mission includes providing healthcare for military members, families, and other beneficiaries stateside and overseas.<sup>3</sup> Although there appears to be a distinction between MHS's contingency and peacetime missions, a critical part of military readiness is assuring Service members that their families are well cared for while they are deployed.<sup>3</sup> Surgical procedure training and experience affects both contingency and peacetime-related mission requirements and, impacts millions of beneficiaries, while influencing overall medical readiness.

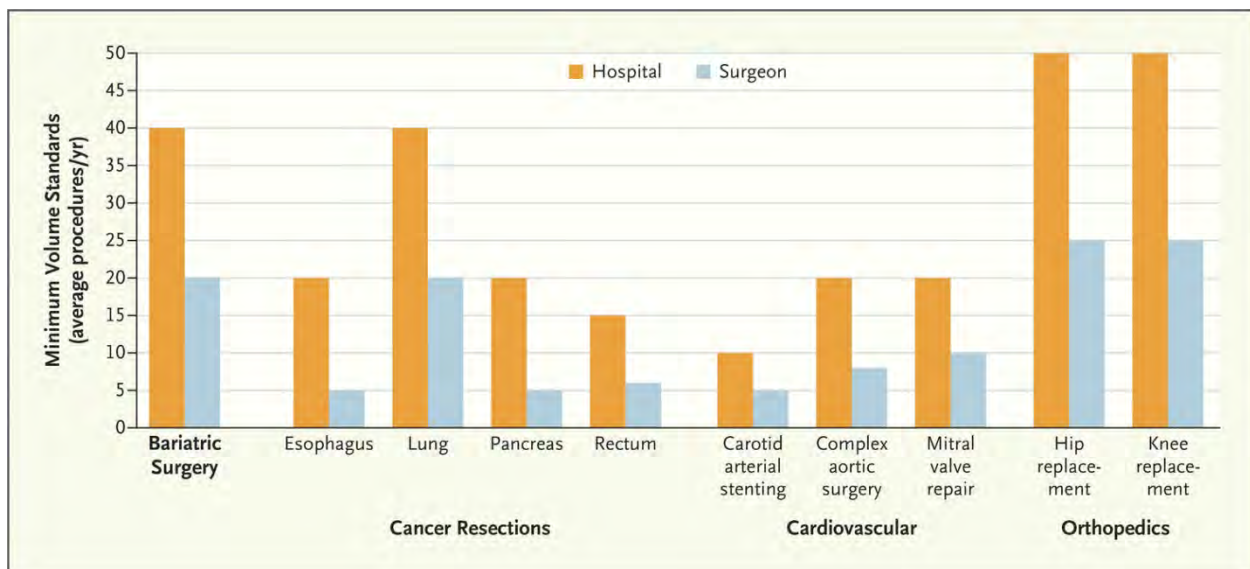


Underlying issues of operative experience are who performs the surgical procedure and where the procedure is performed.<sup>3</sup> The “who” refers to the surgeon and surgical team, which includes anesthesiologists, intensivists, nurse practitioners, physician assistants, nurses, and technicians. Surgical capabilities require technical and team skills for the performance of complex procedures.<sup>3</sup> The second aspect of the operative experience includes where the surgical procedure is performed. Within the MHS, Service MTF infrastructure and capabilities vary. Other large healthcare systems, such as the Department of Veterans Affairs (VA), have delineated designated required facility resources in order for procedures of tiered complexity to be performed through *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures* (VHA 2010-018).<sup>3</sup>

Operative experience is linked to patient safety and quality (see Appendix D). Transparency, specifically regarding safety and quality in MTFs, can promote improvement and enhance patient confidence. The sharing of information with patients so they can make informed decisions and be active participants in their healthcare choices is essential.<sup>3</sup> The MHS is making progress in parallel with civilian healthcare systems.

The MHS provided data to the U.S. News and World Report for the 10 procedures identified in the 2015 Volume Pledge adopted by Johns Hopkins Health System, Dartmouth-Hitchcock Medical Center, and University of Michigan Health System. The Volume Pledge proposed minimum volume standards for hospitals and surgeons.<sup>78</sup> As shown in Figure 2, the 10 surgical procedures are classified into four categories: bariatric surgery, cancer resections, cardiovascular, and orthopedics. The procedures, according to these three academic centers, have the strongest association between hospital volume and patient mortality.<sup>28,79</sup> However, the degree to which volume influences outcomes may be greater for certain procedures. See Appendix B.3 for more information.

**Figure 2.** Volume Pledge Minimum Volume Standards for Hospitals and Surgeons<sup>78</sup>





The 2017 MHS data for the 10 “low-volume high-risk” surgical procedures (identified by the Volume Pledge) by MTFs are shown in Figure 3. When considering the data for these specific 10 surgical procedures, it is important to note that the data are administrative and thus, subject to coding errors which understate MTF experience. At an enterprise-level, there are coding challenges related to the lack of availability of coding resources, such as staffing, education and training, and auditing of medical records.<sup>42</sup> Further, the new electronic medical record, MHS GENESIS, has a unidirectional interface requiring coders to manually input data and lacks certain coding tools, such as an anesthesia crosswalk.<sup>42</sup>

All the surgical procedures identified in the Volume Pledge are selective, complex, and elective. One of the concerns in directly applying these volume standards from the civilian sector to the military sector is that none of the procedures are emergent in nature. Thus, they do not represent high-intensity procedures within the MHS. Procedures within each category are not uniform: they vary greatly in complexity and prevalence. For example, the 2017 MHS complex aortic surgery data reflect 33 Current Procedural Terminology (CPT) codes, including open aortic aneurysm and endovascular repairs. The open aortic mortality rate is often higher than endovascular repair, which is less invasive than open surgery and the preferred treatment for most patients with an abdominal aortic aneurysm (AAA).<sup>80</sup> See Attachment One for a complete list of CPT codes for 2017 MHS data.

**Figure 3.** MHS Administrative Volume Data for 2017<sup>81</sup>

2017 Data: MTFs with one surgical procedure meeting or exceeding LVHR thresholds	Cancer Resections				Cardiovascular			General	Orthopedics	
	Esophagus Cancer Resection	Lung Cancer Resection	Pancreatic Cancer Resection	Rectal Cancer Resection	Carotid Artery Stenting	Complex Abdominal Aortic Aneurysm Repair	Mitral Valve Repair	Bariatric Staple Surgery	Hip Replacement	Knee Replacement
Low Volume / High Risk Thresholds	20	40	20	15	10	20	20	40	50	50
ACH EVANS-CARSON		§		§				101	48	155
AMC EISENHOWER-GORDON		11		5		§		40	54	93
ACH MARTIN-BENNING	11			§				21		
AMC TRIPLER-SHAFTER	§	19	§	8	5	16	4	37	44	79
ACH BLANCHFIELD-CAMPBELL								47	8	20
AMC WOMACK-BRAGG	§		§	10		7		76	35	61
AMC WILLIAM BEAUMONT-BLISS	4	8	6	8	§	22	§	150	52	118
AMC BAMC-FSH	10	34	28	32	6	42	14	203	95	150
AMC DARNALL-HOOD	§			§				173	25	50
AHC McDONALD-EUSTIS				9						
AMC MADIGAN-LEWIS	4	49	11	10	§	15		124	106	138
LANDSTUHL REGIONAL MEDCEN				5				44	15	28
AF-MC-60th MEDGRP-TRAVIS		7		4		18		75	98	184
AF-H-96th MEDGRP-EGLIN				7		8		33	53	54
AF-MC-81st MEDGRP-KEESLER				§	4	24		18	13	19
AF-MC-99th MEDGRP-NELLIS	§			§	§	6			60	91
AF-MC-88th MEDGRP-WRIGHT-PAT				11				§	63	144
NMC SAN DIEGO	13	47	4	16		13	6	72	84	163
NMC PORTSMOUTH	§	31	7	26		6	§	82	69	132
WALTER REED NATL MIL MED CNTR	4	17	10	6		7	18	67	133	98
FT BELVOIR COMMUNITY HOSP-FBCH				20	§			§	59	104

KEY: Percent of Hospital Volume Minimums <50% 50-99% 100-200% >200%





### C.3 CURRENT STATUS OF SURGICAL CARE EXPERIENCE AND OUTCOMES AMONG THE SERVICES

The next section will address the following objective: evaluate policies, protocols, and systems for managing facility surgical capabilities and surgeon/staff proficiency across each of the service branches. Currently, there is variability in training, partnerships, infrastructure, and efforts across the Services. However, standardization from the DHA level has begun to take place with the implementation *NDAA FY 2017 Section 702* that requires administrative changes to the management of MTFs from the Services to the DHA on 1 October 2018. The new management objectives are to address gaps between the policies and procedures of the Services, identify current effective approaches, and integrate these findings into standardized policies to ensure quality and safety across the MHS with the mitigation of risks whenever possible.

While there are many differences between the Services on policies and practices, regardless of Service, surgeons within the DoD are required to maintain certification. Further, *NDAA FY 2017 Section 749 Oversight of graduate medical education programs of military departments*<sup>75</sup> requires that: “No later than one year after the date of enactment of this Act, the Secretary of Defense shall establish a process to provide oversight of the graduate medical education programs of the military departments to ensure that such programs fully support the operational medical force readiness requirements for health care providers of the Armed Forces and the medical readiness of the Armed Forces.”<sup>82</sup> The assignment of responsibility of Graduate Medical Education (GME) to the DHA, under *10 U.S.C 1073* states that no later than 1 October 2018, the DHA “shall be responsible for policy, procedures, and direction of graduate medical education.”<sup>82</sup>

*NDAA FY 2017 Section 749* requires the Secretary of Defense provide a GME oversight process that includes:

- (1) To the extent practicable, such programs focus on operational medical force requirements and are conducted jointly;
- (2) Minimization of duplicate programs among the Military Departments (MILDEPs);
- (3) Coordination among the MILDEPs the assignment of faculty, support staff, and students;
- (4) Optimization of resources by appropriately using military treatment facilities (MTFs) as training platforms;
- (5) Reviewing and, if necessary, restricting or the realignment of programs to sustain and improve operational medical force readiness; and
- (6) A report that describes the process.<sup>82</sup>

Further, the Services and NCR-MD participate in several of the same programs and efforts, although to varying degrees and through different approaches. For example, the Joint Centralized Credentials Quality Assurance System (JCCQAS) is a worldwide interagency information technology (IT) system that supports both DoD and VA with credentialing, privileging, and risk management. Specifically, JCCQAS enables the military medical community to electronically manage provider credentialing centrally, while giving providers the ability to apply for privileges electronically. However, decision making authority for



privileging, which includes determination of scope of practice, remains at the MTF commander level, and is consistent with civilian hospitals.<sup>83</sup>

Aside from JCCQAS, the medical readiness efforts of the Combat Casualty Care (C3) Knowledge, Skills, and Abilities (KSA) were developed within the clinical readiness program at the Uniformed Services University of the Health Sciences (USUHS). The KSA program was designed to address the perishable skills problem acquired in combat zones and provides core metrics to focus the direct care system on readiness for the surgeon.<sup>46,84</sup> It is a joint venture with the American College of Surgeons (ACS). This is still a pilot program for three specialties with plans to expand to more facilities.<sup>46</sup> Additionally, all of the Services participate in the ACS National Surgical Quality Improvement Program (NSQIP), which is for measurement and improvement of quality of surgical care and provides facility-based assessments of surgical outcomes.<sup>39,85</sup> However, Services vary in how information is made available to patients, with decisions often made at the MTF-level. See Appendix D for more information.

Additionally, a 2018 study evaluated American Board of Surgery (ABS) Exam scores across surgical residency programs over 15 years. Programs in the first decile (rank 1 to rank 23) had more military and academic programs, whereas a majority of tenth decile programs were community programs. Of the 231 programs that were included in the analysis, eight were military residency programs, with three of the eight in the first decile—Madigan Army Medical Center ranking first, San Antonio Military Medical Center ranking third, and the National Capital Consortium ranking twenty-third overall. Moreover, there were more military programs in the first decile cohort and none in the tenth decile cohort. These data demonstrate the high quality of surgical training and the need to sustain these skills as junior military surgeons transfer from their residency programs to other duty stations.<sup>86</sup>

## ARMY

The Army has the only Level I Trauma Center in the DoD at Brooke Army Medical Center (BAMC) in San Antonio, Texas. This military-civilian partnership enhances combat readiness skills while avoiding duplicative efforts and extra costs.<sup>87</sup> It also serves as a medical readiness training platform for both the Army and Air Force.<sup>88</sup> The Army has also focused on two options for further addressing readiness: bringing the patient to the surgeon and bringing the surgeon to the patient. First, the *NDAA FY 2017 Section 717 Evaluation and Treatment of Veterans and Civilians at Military Treatment Facilities* supports the option of bringing the patient to the surgeon, enabling the Secretary of Defense to authorize non-military beneficiaries (veterans or civilians) to be evaluated and treated at MTFs if the Secretary determines treatment is necessary to attain the relevant mix and volume of casework; providers have the competencies required; and the facility has the available space and resources.<sup>75</sup>

Second, bringing the surgeon to the patient is accomplished through the Army's emerging civilian partnership programs, executed at command levels to mitigate proficiency gaps and promote readiness and access. The Army Medical Department Medical Skills Sustainment Program (AMSSP), a three-phase training program, provides access to Level I Trauma Centers across the nation based on location, capability, capacity, volume, and type of trauma (see Figure 4). The first phase, *Sustainment*, is long-term (one to three years) and focuses on embedding the surgical team into the civilian hospital, leveraging simulation training and fellowships. The



second phase, *Refresher*, is short-term (three to six months) and involves rotating individuals/teams; this phase may support pre- and post-deployment trauma and non-trauma skills training. The final phase, *Just in Time*, is near-term (one to three months) and focuses on pre-deployment training designed for individuals who require further skills.<sup>45</sup> The AMSSP began in October 2017, and the Army is still developing a standardized curriculum. The program is currently operational at two sites, Cooper Health in Camden, NJ, and Oregon Health and Science University in Portland, OR. The Army is planning to expand to another five sites in FY19.<sup>89</sup>

**Figure 4.** Army AMEDD Medical Skills Sustainment Programs (AMSSP)<sup>45</sup>

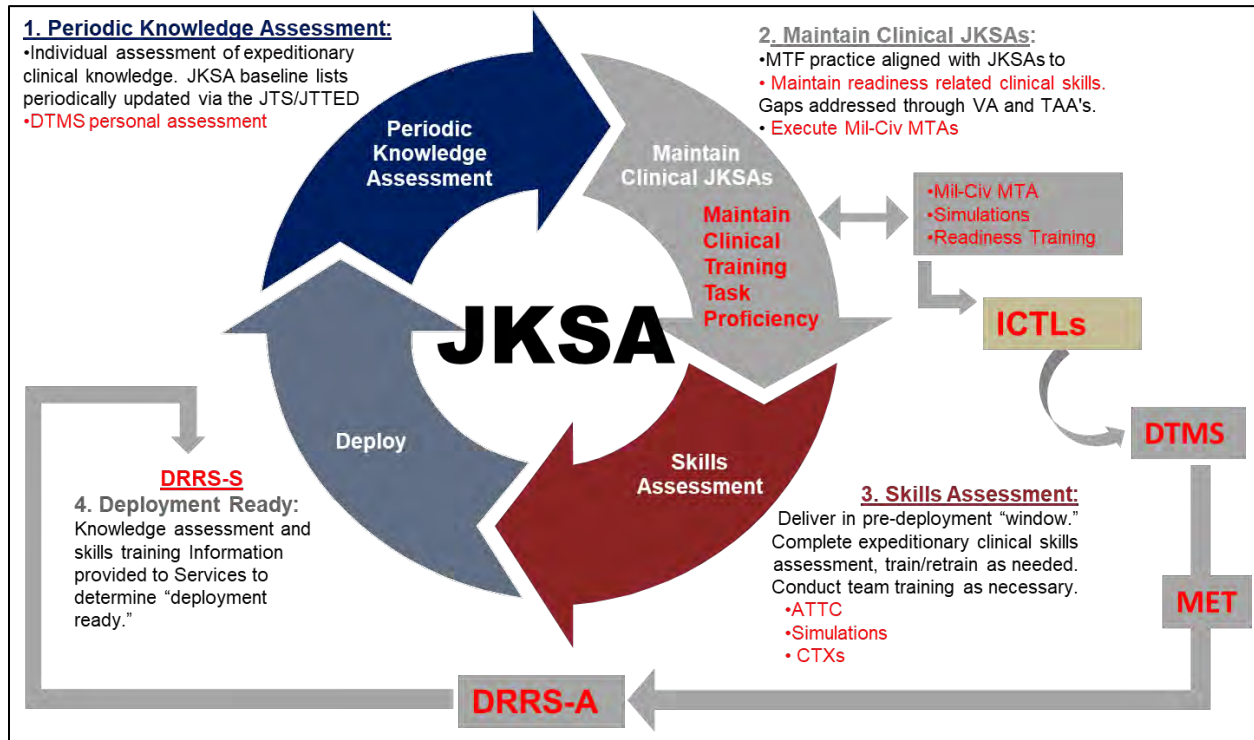


The Army also has VA partnerships at several facilities, including Eisenhower Army Medical Center (Fort Gordon), William Beaumont Army Medical Center (Fort Bliss), and Tripler Army Medical Center.<sup>88</sup> External resource sharing agreements (ERSAs) allow Army military surgeons to treat active duty/TRICARE patients at civilian facilities. To further address any gaps in readiness training and opportunities, the Army uses medical simulation systems. However, the Army recognizes there is no single simulation that replicates high-risk procedures with perfect fidelity.<sup>45</sup>

The Army’s Individual Critical Tasks (ICTs) specify the knowledge, skills, and attributes for each Operational Advanced Operations Course (AOC) and Military Occupation Specialties (MOS). Each Army Medicine soldier will be trained and ready as specified in the ICT for their AOC or MOS. This leverages the Joint Knowledge, Skills and Abilities (JKSAs) and allows the building of self-reported procedure information from moonlighting (working a secondary job) or outside cases performed at partnership sites. The Clinical Readiness Lifecycle, as shown in Figure 5, begins with phase one, *JKSAs* (baseline). Phase two, *Maintain Clinical JKSA*s, involves maintaining readiness by addressing gaps through the VA, Training Affiliation Agreements (TAAs), and military-civilian partnerships to include simulations. Phase three, *Skills Assessment*, takes place in the pre-deployment window with specific needs for the individual. The final phase (phase four; *Deployment Ready*) ensures the surgeon is deployment-ready with the appropriate knowledge and skills training.<sup>89</sup>



**Figure 5. Army Clinical Readiness Lifecycle<sup>89</sup>**



The Army recognizes the importance of surgical experience and quality outcomes and works to rotate low-volume surgeons from low to higher intensity surgical environments. However, this approach has limitations based on mission requirements and availability of surgeons to backfill low intensity surgical environments. Currently, the Army is working to backfill these positions through coordination with the Army Reserves, but there is no standard operating procedure (SOP) for this activity.<sup>45</sup> Additionally, all 19 Army MTFs participate in NSQIP which demonstrates a high level of quality even in low-volume centers. Overall, the Army is performing as well as or better than compared to civilian counterparts.<sup>45</sup>

## NAVY

The Navy addresses the surgical care experience-outcomes association through a High Reliability Organization (HRO) approach, taking into account several areas, such as development of the Chief Medical Officer (CMO) concept and establishment of several Clinical Communities to operationalize patient safety, quality care, and high reliability throughout the enterprise. Navy NSQIP data is tracked through the Navy-specific Safety and Quality Uniform Analytics Dashboard (SQUAD), where data are released quarterly to MTFs for review from the surgeon perspective and to the NSQIP Steering committee to identify levels of concern and document MTF outliers.<sup>44,90</sup> This reporting tool also aligns with the MHS Quadruple Aim Performance Plan (QPP). Furthermore, every MTF uses the patient safety reporting system, through which anyone may file a patient safety concern for evaluation. Although it is nonspecific, it is valuable for awareness of individual events and identification of trends that may become a safety problem. The Navy is implementing the Comprehensive Unit-Based Safety



Program (CUSP), a five-step program that improves patient safety culture through local ownership of patient safety and partnerships with leadership. This program began implementation at Naval Medical Center San Diego (NMCSD) and Naval Hospital Camp Pendleton.<sup>44</sup>

The Navy concentrates performance of complex surgical procedures in facilities with appropriate capabilities, staffing, and patient population. To do this, the Navy leverages the Right of First Refusal (ROFR) program. Under the ROFR program, when TRICARE Prime beneficiaries seek specialty care or treatment, they are directed first to Navy MTFs, provided that the service is available at that particular MTF.<sup>44</sup> The Navy recognizes this program as crucial to maintaining or recapturing patients who may seek treatment elsewhere. It is especially beneficial in optimizing the case mix index to return as many complex cases as possible to the MTFs to sustain surgical experience and readiness.<sup>44</sup>

The Navy also utilizes civilian and VA partnerships to provide care when capabilities are not available at a MTF, as well as to sustain surgeon trauma skills. Currently, partnerships are developed at the local level in memoranda of understanding (MOUs) formats. Larger partnerships are being developed to include other members of the surgical team, beyond physicians (such as nurses and corpsmen); these include Naval Medical Center Camp Lejeune with Vidant Medical Center, and Naval Hospital Jacksonville and with Shands Jacksonville and St. Vincent's. Naval Medical Center San Diego has made efforts to establish and sustain civilian and VA partnerships with Sharp HealthCare (Level II Trauma), University of California, San Diego (Neurosurgery), University of California, Irvine (Trauma Care Team), and the VA (Federal Cardiac Care Center).<sup>91</sup>

Furthermore, select Navy units, such as Fleet Surgical Teams, are pursuing unit-based simulation to train providers and nurses in a variety of scenarios to enhance perishable surgical skills. Simulation can address the continuum of care, from injury/pre-hospital care to the emergency room (ER), operating room (OR), and intensive care units (ICU). The training not only fosters individual skills, but also optimizes collaborative training by immersing an entire team into the simulation.<sup>44,51</sup>

The Navy's Office of the CMO oversees the quality, patient safety, and high reliability efforts throughout the enterprise. The Navy Bureau of Medicine and Surgery (BUMED) office is supported by regional CMO offices, which in turn support the CMOs at each facility. The CMOs oversee the quality and patient safety offices at each command, and the CMO reports directly to the Commanding Officer (CO) to maximize communication on all clinical quality and safety within a command. This is especially critical when advising the command on issues regarding complex surgery. The BUMED CMO office also runs the clinical communities. The Navy has seven clinical communities, to include Surgery. These communities are designed to provide a cross-organizational, bottom-up transfer of safety and quality information, and to minimize clinical silos.<sup>44</sup>



## AIR FORCE

The Air Force has been leveraging military and civilian partnerships for over 18 years. It recognizes the importance of sustaining currency by utilizing military and civilian partnerships, not just for surgeons, but for nurses, technicians, and other surgical team members. DoD and VA joint venture partnerships exist that result in veterans receiving care within the MTF where similar capability or capacity does not exist in the local VA system. Well-established joint ventures exist at Travis, Nellis, Keesler, Elmendorf, Eglin, and Wright-Patterson Air Force Bases. These partnerships involve high-acuity patients receiving specialty care services including Cardiac and Vascular surgery, Neurosurgery, Spine and Joint Replacement surgery, Surgical Oncology, and specialty medical services such as interventional and electrophysiological cardiology and pulmonology. These partnerships benefit the veterans who receive care and provide substantial currency opportunities for the multidisciplinary military medical teams involved in the care. The Air Force also has civilian partnerships that allow military medical personnel to perform clinical duties in a partner civilian facility. Several partnerships include GME programs in surgical specialties and may involve military surgeons working as faculty in these academic programs at both the MTF and the partner hospitals.<sup>43</sup>

The civilian-military partnership efforts of the Air Force are further exemplified through the Center for Sustainment of Trauma and Readiness Skills (C-STARS) program. C-STARS involves trauma and critical care readiness training.<sup>43</sup> The program addresses the needs of those medical technicians, nurses, and physicians who are expected to perform expeditionary medical duty including combat casualty care. The curriculum is divided between administrative needs, didactics, skills training, and clinical experience.<sup>92</sup> The program is located at Baltimore, St Louis, and Cincinnati civilian trauma centers and focuses on trauma and critical care training, aeromedical transport training (CCATT), research/injured warriors, and currency augmentation. Of note, the C-STARS program is not a team training program, as participants are integrated into the civilian care teams without distinct military team functions. There are, however, team exercises through simulation activities.<sup>43</sup>

The mutual benefit of these partnerships was demonstrated by the 99th Medical Group's (Mike O'Callaghan Military Medical Center) response to the mass shooting in Las Vegas, Nevada on October 1, 2017.<sup>93</sup> Eight surgeons and critical care professionals assigned to the 99th Medical Group responded to the University Medical Center (UMC) of Southern Nevada to treat casualties from the active shooter incident. The military surgeons were established members of the UMC team due to a long-standing readiness skills training program. This response illustrates the military's ability to easily perform surgeries in civilian hospitals, while enhancing civilian readiness for mass casualty care.<sup>87</sup>

The Comprehensive Medical Readiness Program (CMRP) is the expeditionary medical readiness program utilized by the Air Force (Figure 6). To achieve full spectrum readiness, the program relies on three categories of competency: Category I—*Clinical Currency for Readiness*, Category II—*Readiness Skills Training*, and Category III—*Unit Training Code (UTC) Training*. The KSAs are used only as an early part of CMRP because the KSA program is still in development and the Air Force has been using the CMRP checklist for several years.<sup>43</sup>



**Figure 6.** Air Force Comprehensive Medical Readiness Program (CMRP) Checklist Example<sup>43</sup>

Skill Set	Knowledge/ Performance	Frequency	Training Sources	Yes(Y) No(N)	Trainer Initials	Member Initials
<b>Category-1 Clinical Currency for Readiness</b> –Fundamental training and skills of an Airman, usually obtained through medical education and in-garrison care, that form a foundation on which to build readiness skills.						
1. Board Eligible/Certified	Knowledge	Initial/ Recert	N/A			
2. Surgical Cases: Perform a goal of 300 procedures per year including 50 procedures from the Consultant’s Currency CPT List.	Performance	Q12M	1. MTF, TAA/MOU, Regional Currency Site, C-STARS. * 2. ODE may be included. *			
3. Advanced Trauma Life Support (45S3K only)	Performance	Q48M	ATLS Course			
4. Trauma Critical Care Management (45S3K only): Perform a goal of 240 hours clinical practice at Level I or II Trauma Center.	Performance	Q12M	1. MTF, TAA/MOU, Regional Currency Site, C-STARS. * 2. ODE may be included. *			
<b>Category-2 AFSC Skills for Readiness</b> – Skills specific to an AFSC which allow an Airman to perform within the full scope of their AFSC in a deployed environment.						
1. Advanced Trauma Life Support (all 45S except K)	Knowledge	Q48M	ATLS Course			
2. Trauma management.	Knowledge	Q36M	Emergency War Surgery Course.			
3. Operative techniques in trauma surgery	Knowledge	Q36M	ATOM, ASSET, BEST, ESTARS, etc. List of approved courses maintained on Kx.			
4. Trauma/Critical Care management: Manage a goal of 40 critical care patient-days or 80 hours of clinical practice in trauma or critical care. (all 45S except K)	Performance	Q12M	1. MTF, TAA/MOU, Regional Currency Site, C-STARS. * 2. ODE may be included. *			
<b>Category-3 UTC Training</b> – Training specific to a UTC for which an Airman is assigned.						
			Per AFI 41-106, Chapter 5. Auto-populated in MRDSS upon assignment to a UTC.			

The Air Force created the Small Hospital Clinical Skills Enhancement Program to meet challenges faced by staff at small overseas hospitals. The tiered program is designed to increase quality and safety of care through Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS<sup>®</sup>), simulation training, critical skills enhancement (senior mentor rotation and currency augmentation), and limiting assignments to 2 years.<sup>43,94</sup>

NSQIP is used at all Air Force inpatient facilities. Local surgeon champions use the data to provide awareness of quality issues, and data are incorporated into performance analysis and planning.<sup>43</sup> Additionally, Air Force efforts are consistent with *VHA Directive 2010-018* for facility infrastructure requirements to perform standard, intermediate, or complex surgical procedures while there is no Air Force policy requiring this.<sup>95</sup> Facilities are divided into categories as shown in Table 2. For more information on the VHA Directives, see Appendix F.1.



**Table 2.** Air Force MTF Facility Infrastructure Capabilities<sup>43</sup>

Standard	Intermediate	Complex
Joint Base Langley-Eustis (Langley)	Mike O’Callaghan Military Medical Center (Nellis)	David Grant USAF Medical Center (Travis)
Royal Air Force (RAF) Lakenheath (Lakenheath)	Keesler Medical Center (Keesler)	
	Wright-Patterson Medical Center (Wright-Patterson)	
	Eglin Medical Center (Eglin)	
	Joint Base Elmendorf-Richardson (JBER)	

**NATIONAL CAPITAL REGION-MEDICAL DIRECTORATE**

The DHA’s NCR-MD was established to exercise authority, direction, and control over the Walter Reed National Military Medical Center (WRNMMC), Fort Belvoir Community Hospital (FBCH), and their subordinate clinics.<sup>96</sup> The NCR-MD has developed an initiative to improve medical force readiness, including the KSA program, as well as focusing on quality, patient recapture/market expansion, GME, and military trauma capabilities within the NCR-MD.<sup>97</sup> These efforts align with the DHA-wide FY 2019 QPP, which aligns MTF activities with the MHS Quadruple aim vision (Readiness, Better Health, Better Care, Lower Cost) (Figure 7). This fulfills part of the requirements for *NDAA FY 2017 Section 702*. Performance of all Markets and MTFs is monitored using QPP measures.<sup>98</sup>

**Figure 7.** MHS Quadruple Aim



The project plan for the NCR-MD’s Improving Medical Force Readiness initiative is focused on several cells. The surgical patient recapture and market expansion cell of the QPP is based on the KSA pilot program for general and orthopedic surgery. Current referral data demonstrate general surgery has lost workload for up to eight surgeons due to leakage of patients from the direct care system.<sup>97</sup> Orthopaedics has the opposite problem; it has the workload to support another 10 or more surgeons. Policies are being developed to standardize referral management across the market, create detailed monthly referral authorizations by specialty to enhance KSA- directed recapture, perform market analysis to provide specialty services to match demand, and centralize appointments to improve access. It is critical to have access to real time, accurate, granular patient referral data to make informed decisions to recapture the high-value KSA cases. The NCR-MD trauma readiness cell is designed to provide optimal trauma care for returning wounded service members and to deploy trauma-ready medical personnel to the battlefield.<sup>97</sup> Current trauma volume is inadequate for the NCR-MD to maintain readiness. Thus, to address this gap, development of a regionally integrated system, civilian-military collaborations, and infrastructure across the NCR-MD are





integral components.<sup>97</sup> Finally, the quality cell for the QPP initiative aims to standardize policies across all MTFs, such as surgical checklists, quality standards for surgery, and how outcomes data are collected, collated, and compared. By reducing variability, facilities look the same which increases practice, supports safety, and improves outcomes.<sup>97</sup> The scope of NCR-MD's Improving Medical Force Readiness initiative will be to focus on improving the number of General and Orthopedic Surgeons meeting the Clinical Currency Threshold (KSAs). Successes from this project will be disseminated to other MTFs in the MHS.<sup>97</sup>

#### C.4 OBSERVATIONS

The Board has assessed the Services' and NCR-MD's policies, protocols, and systems for managing facility surgical capabilities and surgeon/staff proficiency. Focus areas included surgical training, readiness/KSAs, civilian/VA partnerships, MTF capabilities, and transparency/NSQIP. These areas provide further direction in developing best practices to optimize standardization, maintain readiness, and improve access to care, quality of care, and experience of care. The following observations are made:

- (1) Readiness training models are Service-specific. Although there are joint standardization efforts, there is still great variation across the Services
- (2) There is an opportunity for coordination among the Services for surgical training. Aside from the GME program across Services, there are no shared initiatives or programs on how training should be implemented.
- (3) There is an opportunity for development of a systematic selection process for establishing or expanding civilian and VA partnerships between all Services.
- (4) Policies to determine the patient allocation in an established partnership between the DoD and VA/civilian systems with respect to surgical practice and volume caseload vary across the Services.
- (5) ERSAs exists for all Services with civilian facilities.
- (6) Information transparency for quality and safety could be enhanced by improving understanding of what metrics matter to the MHS patient population; implementing resource-based criteria similar to VA and publicizing these criteria; developing formal surgical quality programs at MTFs to engage in continuous quality improvement; and increasing resourcing of NSQIP and other data sources.
- (7) There is a lack of incentives and resources to accurately code, suggesting that an investment in experienced coding professionals and resourced analytics could significantly improve coding accuracy. Providers currently code, yet they are not always properly trained, incentivized or given adequate time to do this accurately.
- (8) The 10 "low-volume high-risk" surgical procedures do not include emergency or war-related surgeries and, instead, are elective and based on the civilian sector.
- (9) Challenges to reporting of accurate total surgical volume include missing data due to an inability to identify and capture procedures conducted off-site (e.g., in a civilian partner hospital or in a VA facility).
- (10) Performance improvement, quality assurance outside of trauma, and the Joint Trauma System (JTS) all provide an opportunity for adoption of successful practices to be used at the DHA-enterprise level.



## APPENDIX D. PATIENT SAFETY AND QUALITY OF SURGICAL CARE

### D.1 INTRODUCTION

This appendix examines patient safety and quality measures within the Military Health System (MHS) and civilian healthcare systems, surgical volume transparency efforts, and required surgical minimum volume thresholds adopted by academic institutions and non-profit patient advocacy groups. Specifically, Appendix D addresses the following objectives in the Terms of Reference (TOR):

- Evaluate MHS policies related to surgical volume transparency and public release of volume, errors, and outcomes data;
- Provide recommendations on using the volume, errors, and outcome data to inform and enhance policies for managing surgical capabilities and surgeon currency.

Although the TOR specifically states to evaluate transparency and outcomes data, assessment of a broader, more systemic approach is integral; this approach includes maximizing patient safety and quality of care, while preventing and mitigating risks. The Defense Health Agency (DHA) has targeted an opportunity for improvement across the MHS through High Reliability Organization Operation Model (HROM), the focal point of which is care centered around the patient by Clinical Communities to continuously improve care quality and value, thereby contributing to readiness. To fully execute and sustain this strategy, data analytics must be assessed for process optimization and accurate follow-up.

The first part of this appendix examines the current Department of Defense (DoD) and MHS safety and quality programs, including a brief background of the 2014 MHS Review, the American College of Surgeons (ACS) and MHS partnership, and the Joint Commission. The latter portion of the appendix explores how safety and quality are addressed in the civilian sector, including through initiatives such as the Volume Pledge and organizations like the Leapfrog Group.

The MHS continues to evaluate its practices to develop a more focused, data-driven way forward. For example, in 2014, the Secretary of Defense issued a memorandum directing a 90-day comprehensive review of the MHS to evaluate access to care, healthcare quality, and patient safety. This was the first enterprise-wide review and addressed a broad range of healthcare areas. The review assessed whether:

- (1) Medical care in the MHS meets defined access standards;
- (2) The quality of health care in the MHS meets or exceeds defined benchmarks; and
- (3) The MHS has created a culture of safety with effective processes for ensuring safe and reliable care of beneficiaries.<sup>36</sup>

The findings from that report were followed by several recommendations, many of which were implemented and are further addressed in this report. Recommendations from this review aimed to foster the creation of a High Reliability Organization (HRO) across the MHS. Further, the review found variation across the MHS and identified a need for better use of metrics to monitor



performance, specifically with regard to access to care, quality, and patient safety.<sup>99</sup> In addition, reliability, readiness, and access to care were identified as priority areas that will serve as the foundation to hold MHS leaders accountable.<sup>99</sup> The major recommendations in this review were directed at system enhancements to foster the creation of an HRO.<sup>36</sup> The MHS Review's established priorities form the impetus for MHS surgical quality improvement. However, a more in-depth, systematic examination of hospital volume data, quality and safety initiatives, and data utilization, including a review of processes and responses to outcomes data, will help inform effective methods for quality improvement as the MHS transitions to an HRO.

Infrastructure follows function (e.g., quality assurance and improvement activities).<sup>100</sup> Having the foundation support based on quality assurance, patient safety, and process improvement builds and sustains an infrastructure that includes a system of accountability, verification, and standardization. Furthermore, evidence suggests that efforts and programs such as the DoD Patient Safety Program (PSP), MHS Transparency Initiative, and the ACS National Surgical Quality Improvement Program (NSQIP) lead to surgical quality improvement and the creation of a more synchronized system for standardization within the MHS.<sup>37-39</sup>

## CULTURE OF SAFETY

According to the Agency for Healthcare Research and Quality (AHRQ), the largest barriers to achieving a culture of safety are poor teamwork, punitive environments for reporting, and lack of engagement from across the organization.<sup>101</sup> Some organizations, such as the Veterans Health Administration (VHA), have implemented a non-punitive approach toward safety reporting so that safety reports cannot be used in a personally punitive way and are protected by *38 U.S.C. 5705*.<sup>102</sup> Also, the *Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41)*<sup>103</sup> was enacted to allow organizations to perform safety and quality activities and protect individuals from inappropriate punitive actions. It established a voluntary reporting system to bolster patient safety and quality data available for use in assessment and quality improvement and provided Federal privilege and confidentiality protections for patient safety information.<sup>104</sup> The goal was to encourage reporting and analysis of close-call/near-misses to improve patient safety and also authorized AHRQ to list patient safety organizations and create a patient safety database network.<sup>104</sup> The act is in contrast to *10 U.S.C. 1102*,<sup>105</sup> and associated policies which currently do not prohibit safety and quality reports from being used internally in a punitive manner against individuals. The ability to use such reports in a punitive manner creates a barrier to developing and reinforcing an optimal culture of patient safety throughout the DoD.

AHRQ developed a commitment strategy that promotes a *culture of safety* centered on acknowledgement of high-hazard activities and the nature of healthcare, a supportive and blame-free environment for reporting, collaboration across ranks for solution development, and an organizational commitment of resources to address safety issues. AHRQ provides validated surveys on patient safety attitudes and safety culture for healthcare facilities to use for benchmarking and progress tracking.<sup>101</sup> The National Quality Forum's Safe Practices for Healthcare and the Leapfrog Group both mandate safety culture assessments. AHRQ also recommends yearly measurement of safety culture as one of its *10 patient safety tips for hospitals* and offers online tools such as Learn From Defects Tool, Staff Safety Assessment, Safety Issues Worksheet for Senior Executive Partnership, and the NOTICE Process



Checklist.<sup>106</sup> These tools are part of the Comprehensive Unit-based Safety Program (CUSP), a method that can help teams make care safer by combining improved teamwork, clinical best practices, and the science of safety.<sup>107</sup> Because a perceived poor safety culture has been linked to increased error rates,<sup>108</sup> many organizations establish executive walk arounds, team building activities, as well as safety champions to improve attitudes and organization culture issues.

However, blame culture is still prominent and presents a barrier to promoting safety culture. This is a particularly difficult issue because while non-punitive attitudes are necessary, there is still a need for accountability. The *just culture* concept focuses on root cause analyses to identify systems issues that lead employees to make unsafe decisions, while maintaining a zero tolerance policy for irresponsible behavior.<sup>109</sup> In contrast to a just culture approach, a response to an adverse event or close call/near miss is dependent on the type of behavior (e.g. deliberately performing an act they knew to be unsafe, such as refusing to perform a time out before surgery), versus the severity of the result. Safety culture attitudes can also be heterogeneous within an organization due to burnout variances and team cohesiveness.<sup>110</sup> Therefore, leadership must be attuned and responsive to worker needs and issues, as many safety culture determinants rely on successful inter-professional relationships.<sup>101</sup>

## THE MILITARY HEALTH SYSTEM STRATEGIC PARTNERSHIP WITH THE AMERICAN COLLEGE OF SURGEONS

The goals of the Military Health System Strategic Partnership with the American College of Surgeons (MHSSPACS) are to exchange information about: education/training, systems-based practice in trauma, quality initiatives, and DoD driven trauma research with translation to civilian sector.<sup>111</sup> Under the topic of education/training, the KSA clinical readiness project was created in partnership with the ACS as a method of measuring readiness for deployment for an expeditionary general surgeon. This methodology is being replicated by other groups who comprise the deployed surgical team (anesthesia, nurses, critical care providers etc.). (See Appendix E for more information on the KSAs.) This environment ensures that the military healthcare system operates in collaboration with civilian models of excellence while also sharing its own best practices. The goal of the quality initiative was to enroll all MTFs into the ACS NSQIP program with the formation of a military NSQIP consortium, allowing MTFs to share best practices and lessons learned throughout the enterprise.<sup>111</sup>

In the area of trauma systems, the partnership is responding to the National Academies of Sciences, Engineering, and Medicine (NASEM) report *Zero Preventable Deaths* by developing standards for selecting and evaluating military-civilian partnerships designed to train, sustain, and retrain military trauma teams.<sup>34</sup> This “Bluebook” of standards will be particularly important as grants for these partnerships become available through the MISSION Zero Act currently working its way through Congress.<sup>111</sup>

For research, the MHSSPACS assists in defining the gaps in combat casualty care research that are appropriate for investigation in civilian centers. One final project includes the re-birth of the Excelsior Surgical Society, a society of military surgeons now permanently housed within the ACS allowing for the exchange of information and research of relevance to military surgeons (active duty, reserves, or retired).<sup>111</sup>



## D.2 AMERICAN COLLEGE OF SURGEONS NATIONAL SURGICAL QUALITY IMPROVEMENT PROGRAM

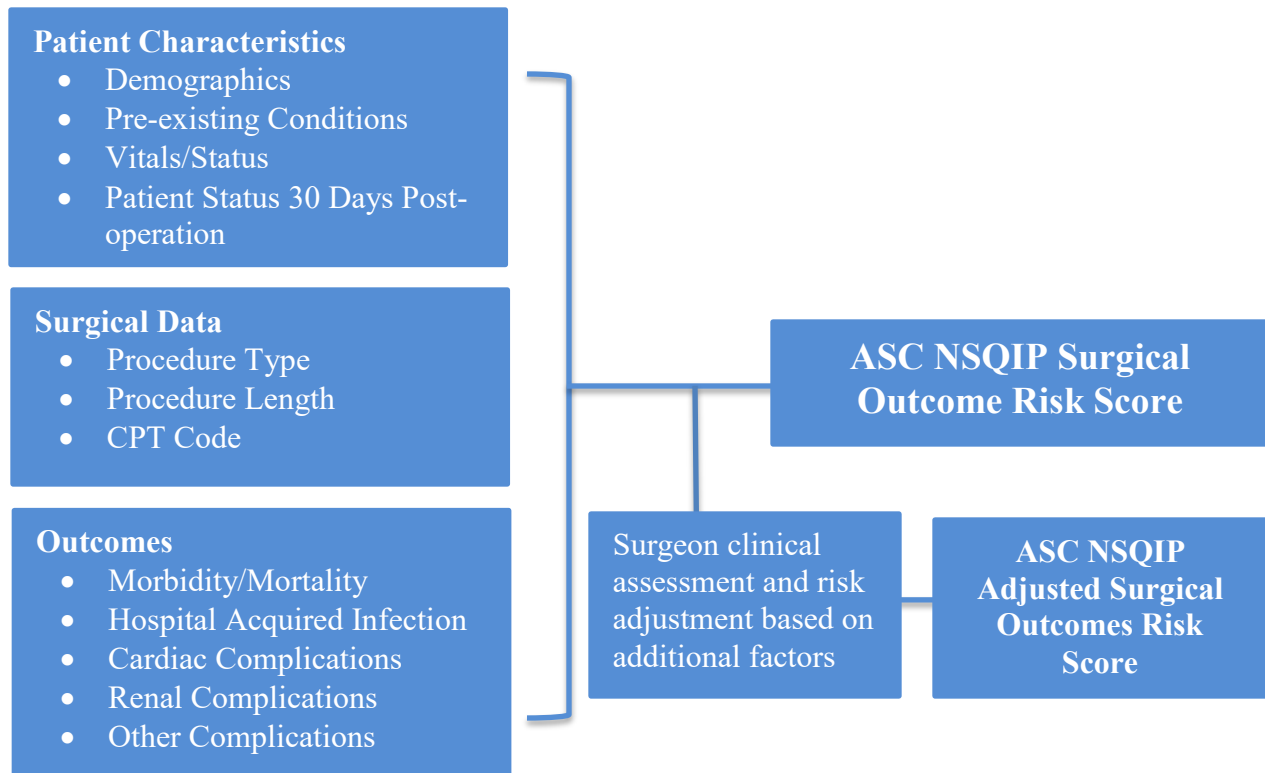
Patient safety and quality of surgical care goals include determining the minimally acceptable and maximally attainable criteria for surgical outcomes. Programs such as the ACS NSQIP provide data to compare over time, across hospitals, and between surgeons for quality assurance and monitoring of performance improvement. The ACS NSQIP is a “nationally validated, risk-adjusted, outcomes-based program to measure and improve quality of surgical care.”<sup>41</sup> Thus, it was created by surgeons for surgeons and provides participating hospitals with tools, analyses, and reports to make informed decisions about improving quality of care. The goal of NSQIP is to measure and improve the quality of surgical care and provide facility-based assessments of surgical outcomes.<sup>39,85</sup>

During the mid to late 1980s, the Department of Veterans Affairs (VA) came under public scrutiny over the quality of surgical care in some of its VA hospitals. The perception was that operative mortality rates in VA hospitals were significantly higher than the national average; however, these “national averages” did not exist.<sup>112</sup> In the early 1990s, researchers embarked upon the National VA Surgical Risk Study (NVASRS) in 44 VA medical centers. The success of the NVASRS study encouraged the VA to establish an ongoing program for monitoring and improving the quality of surgical care, which led to the creation of NSQIP.<sup>112</sup> As the VA focused on outcomes, outcomes improved: VA hospitals saw a 47% drop in postoperative mortality and a 43% drop in morbidity rates from 1991 to 2006.<sup>112</sup> The private sector became interested in NSQIP in 1999, with the ACS launching a pilot program funded by AHRQ in 2001 to demonstrate functionality in private sector hospitals. The ACS began enrolling additional hospitals in 2004.<sup>112</sup> Additionally, a two-year proof-of-concept was initiated at three DoD MTFs in 2004 (Walter Reed Army Medical Center, Naval Medical Center San Diego, and Wilford Hall Air Force Medical Center), with the addition of 13 DoD MTFs from 2009-2010.<sup>85</sup>

Currently, the ACS NSQIP includes 708 participating hospitals within the government and civilian sectors.<sup>113</sup> Understanding NSQIP’s value, the DHA *Procedural Instruction (PI) 6025.01 Implementing the ACS NSQIP Across the MHS*<sup>114</sup> assigns responsibilities and establishes uniform guidelines, standards, and procedures for all DoD MTFs providing healthcare services in the direct care system to comply with the final report to the Secretary of Defense, the “Military Health System Review, 2014” and *NDAA FY 2015 Section 713 Expansion of evaluation of effectiveness of TRICARE program to include information on patient safety, quality of care, and access to care at military medical treatment facilities*, directs the implementation of the surgical quality and reporting guidelines developed by ACS NSQIP.<sup>115</sup>



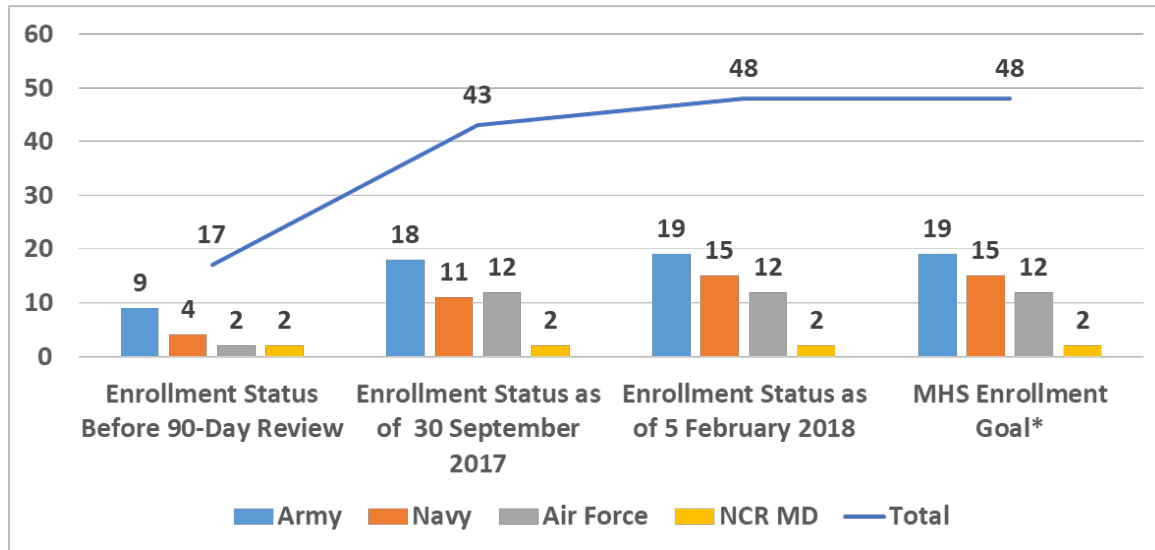
**Figure 8.** Hospital Submitted Data Flow for ASC NSQIP Surgical Outcomes Model



Since its inception, NSQIP has quickly expanded across the MHS from 17 participating MTFs in 2014, to all 48 inpatient MTFs in 2018, as shown in Figure 9.<sup>39</sup> The NSQIP statistical models within the MHS use Current Procedural Terminology (CPT) codes, length of operation, and 30-day post-operation status (Figure 8). A NSQIP facility team includes a surgical case reviewer (SCR) (generally 1.0 full-time equivalent [FTE]; varies by program selection/surgical volume) and a surgeon champion (approximately 0.1 FTE; varies).<sup>39</sup> Within the MHS, SCRs are registered nurses (RNs); other clinical reviewers may include physician assistants (PAs) or nurse practitioners (NPs). All clinical reviewers complete a one-month training for certification with annual certification renewal requirements.<sup>85</sup>



**Figure 9.** MHS NSQIP Enrollment Status by Service Since 2014<sup>85</sup>



A central programmatic feature of NSQIP are the semiannual reports (SARs). SARs use evaluations that are recalibrated with the incorporation of new data and the removal of old data on a semiannual basis, which results in a 6-month overlap of data reported. Each SAR contains results for 540+ models defined by combinations of outcomes, surgical specialties, individual operations or other surgical groupings, available predictors, and patient populations.<sup>39,115</sup> Participating hospitals are provided with the SAR, which benchmarks performance in comparison to how an estimated average NSQIP hospital would perform if doing the same procedures on the same patients.<sup>116</sup>

There are nuances of data abstraction. Within NSQIP, there are three sampling options to obtain data: 1) NSQIP Adult Program: Essential (General/Vascular and Multispecialty); 2) Targeted Procedure (DoD uses and is MTF specific); and 3) Small Rural (annual surgical volume less than 1,680).<sup>85</sup> Essentials Targeted Procedures may not capture 100% of surgical volume, dependent upon SCR resources. One full time equivalent (FTE) will abstract 1,680 cases annually. CPT codes are critical components of inclusion criteria for sampling.<sup>39,85</sup> The MHS originally established the NSQIP Steering Panel to coordinate the expansion of the program, which it successfully did. It now focuses on sustaining effective use of NSQIP across the DoD.<sup>39</sup> The NSQIP Steering Panel has the ability to recommend policy but these recommendations must go through the governance structure for final approvals.<sup>39</sup> If the Steering Panel decided that MTFs should review 100% of specific procedures, additional resources would be required since the vast majority of sites only have one FTE employee focused on this task.<sup>85</sup>

A consequence of this model is that performance is continuously reevaluated and has not yet been standardized across the Services. Hospitals are aware of present rankings in relation to other hospitals currently in the program but are unable to track or assess any necessary improvement due to the unstandardized processes across the Services. Also, the NSQIP surgeon champion may face challenges in identifying performance improvement and holding senior providers and staff accountable as the role is often assigned to junior surgeons.<sup>39</sup> Leveraging



NSQIP data to enhance performance can be influenced by the duration of participation and devoted response efforts to address concerns and properly direct quality improvement.<sup>116</sup>

One NSQIP indicator, mortality, is included as part of the MHS Transparency Initiative. However, while the data are publicly available on the MTF websites, the website navigation process to these indicators is not consistent across facilities, nor is the information readily available or user-friendly.<sup>85</sup> Transparency, in this context, is defined as the sharing of information with patients so they can make informed decisions and be active participants in their healthcare<sup>3</sup> as informed consent is a fundamental component of surgical care.<sup>117</sup> However, currently each Service utilizes and displays NSQIP data differently, as described in Appendix C.

NSQIP data are just the beginning and best practices should be identified.<sup>85</sup> Thus, NSQIP can provide the data, but not the solution.<sup>39</sup> In other words, high quality of care can be leveraged with the use of NSQIP, but cannot rely on NSQIP alone. Incorporating process data from electronic health records (EHR), standardized Enhanced Recovery After Surgery (ERAS) pathways, identifying adverse events, and utilizing an established external quality improvement/peer-review process to investigate root cause can be used together to create a system for maintaining and improving patient safety and quality of care.<sup>11</sup> The use of NSQIP along with other data registries, can be better utilized to enhance transparency, especially with regard to population health and to ensure a culture of continuous learning and growth is taking place. Moreover, success of NSQIP, including its implementation and use of outcomes data, is contingent on the surgeons' active participation in shared learning and quality analysis as well as robust facility support (personnel, informatics, and budgetary) for quality improvement.<sup>33,39</sup>

The use of public reporting of healthcare system performance programs, such as NSQIP, creates an environment that promotes and enhances the value of healthcare by improving quality, lowering costs,<sup>118</sup> and enabling patient engagement by creating transparency. The benefits of continuing to develop more robust, standard NSQIP transparency and quality improvement policies, in response to these data, may improve professionalism and physician engagement, spur competition among organizations and providers, and provide patients and their families with information that enables them to make important, educated medical decisions.<sup>118</sup>

### D.3 MILITARY HEALTH SYSTEM QUALITY ASSURANCE PROGRAM

The Joint Commission (TJC) seeks to continuously improve healthcare for the public, by evaluating healthcare organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.<sup>119</sup> According to the DoD Instruction (DoDI 6025.13) *Medical Quality Assurance (MQA) and Clinical Quality Management in the MHS*, which is currently under revision, "all fixed MTFs, as well as hospitals and other facilities used by managed care support contractors, shall meet or exceed the standards of appropriate external accrediting bodies. This includes accreditation of all hospitals by TJC and participation, as directed by the Assistant Secretary of Defense for Health Affairs (ASD[HA]), in all TJC quality management programs."<sup>120</sup> Moreover, DoDI 6025.13 states that fixed MTFs or facilities used by managed care support contractors may have a different accreditation source and operational healthcare units (not a component of an accredited MTF) are exempt from the accreditation requirement. Furthermore, the Services and NCR-MD shall each establish and implement





comparable quality-of-care oversight mechanisms for operational healthcare units under their cognizance, including, at a minimum, the functions of credentialing, risk-management, patient safety, and clinical performance improvement.<sup>120</sup>

DoD Manual (DoD 6025.13-R) *MHS Quality Assurance Program Regulation* regulates the principles of accountability, continuity of care, quality improvement, and medical readiness.<sup>121</sup> The ultimate goal of the quality assurance program is to ensure the provision of healthcare service is safe and effective. DoDI 6025.13, which will inform the forthcoming DHA- Procedural Manual and regulate all MTFs that, as of 1 October 2018, fall under the DHA for management and administration, addresses accreditation, credentials and clinical privileges, the Centralized Credentials Quality Assurance System (CCQAS), medical quality assurance reviews, sentinel events, patient safety, the national practitioner data base (NPDB) and healthcare integrity and protection data bank (HIPDB), and transparency. DHA's draft Procedural Manual updates Clinical Quality Management as a functional capability with the following six programs: 1) Patient safety; 2) Healthcare risk management; 3) Credentialing and privileging; 4) Accreditation and compliance; 5) Clinical measurement and analytics; and 6) Clinical quality improvement.<sup>32</sup> Recent completion of a proof-of-concept for the HROM and Clinical Communities provides the foundation for systematic optimization of patient care—data driven, evidence based, and integrated across the direct care, purchased care and operational environments for an integrated system for readiness and health.<sup>32</sup>

Integration of clinical quality improvement priorities into enterprise-wide performance improvement will ultimately inform DHA's strategic guidance. Several challenges remain, including continued collaboration with the Services for optimal standardization of processes that are robust enough to support CQM throughout all MHS' environments of care.<sup>32</sup> Each Service currently has their own quality-related policies with variances in processes or procedures for each of the six CQM programs, including how they report safety events. Further developments, such as MHS GENESIS provide opportunities to optimally manage and leverage clinical data. Combined with Clinical Community identification of leading clinical practices, such as quality improvement registry participation (e.g. NSQIP or the National Perinatal Information Center), activities such as these should enhance quality and optimize safety.<sup>32</sup>

#### D.4 DoD PATIENT SAFETY AND PERFORMANCE

NSQIP provides a direct link to evaluating surgical quality of care. In addition to this robust program, the MHS has several patient safety and performance improvement programs and efforts that, when used in synergy, create a systematic approach to patient safety and quality of care. The MHS promises to maintain active and effective organizational structures, management emphasis, and program activities to ensure quality, safe healthcare throughout the enterprise. Clinical quality management activities include clinical performance measurement and improvement, risk management, management of adverse actions, and patient safety; quality healthcare will be delivered consistently and effectively across the Military Departments and joint medical commands for all TRICARE beneficiaries with minimal surgical morbidity and mortality; and patients have the right to quality care and treatment that is consistent with available resources and generally accepted standards, including access to specialty care.<sup>114</sup>



## PARTNERSHIP FOR IMPROVEMENT

Creating an environment of quality built on process improvement leads to a system of accountability. As the DHA moves toward more standardization (following implementation of *NDAA FY 2017 Section 207*), accountability will be utmost importance to ensure the maximization of quality. Moreover, *NDAA FY 2017 Section 703* requires the DoD to incorporate measures of accountability for the performance of the MHS into the annual performance review for certain military and civilian leaders in the MHS.<sup>75</sup> The MHS maintains enterprise-wide measure sets—Partnership for Improvement (P4I)—to monitor system performance. The P4I measures serve as the primary reference source for evaluation of accountability in system performance<sup>75</sup> and directly addresses *NDAA FY 2017 Section 703* with regard to accountability in the MHS. Since the MHS is moving toward a more systems-based approach for all MTFs across the Services, it will be critical to maintain accurate monitoring to system performance.

MHS leadership relies on a P4I measure set of nine measures, of which two are related to surgery, *Unintended Retained Foreign Objects* and *Central Line Associated Bloodstream Infections*, as shown in Table 3 to ensure accountability. These nine measures are chosen specifically to drive dedicated annual improvement and keep the MHS focused on becoming an HRO. HROs, in general, are systems where harm prevention and quality improvement are second nature, where the organizations recognize the risk of over simplification of complex systems.<sup>36</sup> HROs focus on development and implementation of effective systems, transparency, and teamwork, as demonstrated by the ACS.<sup>122</sup> Most of the P4I measures are not unique to the MHS. The Principal Deputy Assistant Secretary of Defense for Health Affairs (PDASD [HA]) and Service Deputy Surgeons General review these measures on a monthly basis to enhance knowledge sharing and process improvement efforts.<sup>123</sup> The targeted areas of improvement and the associated P4I measures for each domain have remained consistent but can change based on MHS priorities. When targets are reached, the improved outcomes are not only maintained, but monitoring continues with the goal of continuous growth and improvement. This is an important principle to becoming an HRO. MHS senior leaders and MTF leadership are held accountable for meeting these established performance goals through an annual performance review. Many of these measures are required and reported to other organizations, such as The Joint Commission, for certification or comparison purposes.<sup>123</sup> In October 2018, as responsibility for the administration and management of the MTFs transitions to the DHA per *NDAA FY 2017 Section 702*, DHA will ensure accountability within the MTFs for meeting the performance objectives of the P4I measure set.<sup>123</sup>



**Table 3. Partnership for Improvement (P4I) Measures<sup>123</sup>**

P4I Measure	Description
Central Line Associated Bloodstream Infections	Percentile of Central line Associated Bloodstream Infections in DoD Intensive Care Units (ICUs) relative to other similar ICUs participating in Centers for Disease Control National Hospital Safety Network program.
Healthcare Effectiveness Data and Information Set (HEDIS®) Diabetes Composite	The percentage of members 18-75 years of age with diabetes (type 1 and type 2) who meet the criteria as specified below: The index includes 2 diabetes care measures for direct care: a process measure (annual A1C testing) and an outcome measure (A1C test results in good control [ $<8.0$ ]). Only one measure (annual A1C testing) is available in the purchase care claims data. The rate of compliance with the measures is converted to index points based on the HEDIS® national benchmarks. Data is displayed as percent of possible index points obtained for the measures.
Acute Conditions Composite	The composite includes HEDIS® measures for appropriate use of imaging studies for low back pain, use of antibiotics for upper respiratory infection and treatment of pharyngitis with antibiotics and strep test. The rate of compliance for each measure is converted to index points based on the HEDIS® national benchmarks. Data is displayed as percent of possible index points obtained for the three measures combined.
Satisfaction with Getting Care When Needed	Get Care When Needed: “In general, I am able to see my provider when needed.” (5-point scale, from “strongly agree” to “strongly disagree”; percent satisfied is “agree” and “strongly agree”).
Secure Messaging Enrollment	Measures the number of direct care beneficiaries who have registered to use secure messaging against the MTF’s Prime and Plus enrolled population.
Third Next Available 24hour	Measures the number of primary care clinics that have Third Available Appointments within the Acute (24 hours) Access to Care standards.
Third Next Available Routine (7 Days)	Measures the number of primary care clinics that have a Third Available Appointments within the Routine (Future) Access to Care standards.
Total Enrollment	The number of Prime, Reliant (only those enrolled to Op Forces), and TRICARE Plus beneficiaries for each MTF. This determines how many patients the MHS serves, which enables it to keep a medically ready force and ready medical force.
Unintended Retained Foreign Objects	The number of retained object events. A retained object is defined as a surgical object that is unintentionally left in the patient during a procedure.

### DoD PATIENT SAFETY PROGRAM

According to the ACS, “creating a culture that fosters quality, safety, and high reliability is ultimately our expression of professionalism. It is our responsibility to provide high-quality, safe, and reliable care to our patients; as surgeons, we must be accountable for establishing a culture that supports safety.”<sup>122</sup> In accordance with the ACS’s guidance, an enterprise-wide cultural focus that supports safety is essential to providing the best possible care.

The DoD PSP is uniquely positioned to assist the MHS and its surgeons and the surgical team, to foster a culture of safety and advance high reliability. The PSP is a comprehensive program providing products and services, as well as educational and training resources to promote safety and prevent harm for all aspects of patient care.<sup>38</sup>



The DoD PSP contributes to the MHS' focus to achieve the Quadruple Aim, aligned with DoD, MHS, and DHA strategic objectives, centered on Readiness—Ready Medical Force and Medically Ready Force—across all environments. Supporting this objective is the goal to achieve zero preventable harm and provide patient-centered, evidence-based care to improve patient outcomes. The DoD PSP provides a robust suite of products, services, and support to enable frontline surgical teams to eliminate harm and promote a culture of safety. The DoD PSP seeks to promote a strong culture of safety to eliminate preventable patient harm by engaging, educating, and equipping patient care teams to institutionalize evidence-based safe practices. To accomplish this the DoD PSP:

- *Manages Patient Safety (PS) Events.* Eliminating harm through identification, investigation, and mitigation of PS events.
  - By using data, knowledge management tools, and established resources, the DoD PSP develops actionable improvement steps that support the goal of achieving zero preventable harm. PS event reports are collected through various methods to include: 1) anonymous, self-reported PS events, through the Joint Patient Safety Reporting System, and 2) harm surveillance data, through the Global Trigger Tool. In addition, various tools are utilized to investigate, analyze and extract risk factors contributing to errors, develop and implement strong corrective actions to mitigate risks, and ensure that mitigation is sustained. This identification, investigation, analysis, reporting and learning from PS events is instrumental in ensuring a safe patient environment and achieving the Quadruple Aim. This PS information, along with culture survey results, is used for establishing strategies to address process failures and mitigate risks to improve clinical outcomes and eliminate preventable harm throughout the system.
- *Supports a Learning Organization.* Strengthening systems through the implementation of robust mitigations and providing education and training to all staff to promote concepts of high reliability in health care.
  - The DoD PSP sustains the health care learning organization by sharing safety-related information through numerous venues. These include data visualization applications, designed to allow for interactive, self-directed trend analysis for a variety of PS data. Formal competency-based training in PS principles and high reliability plays a key role, as well as many other types of learning resources. In addition, the PSP sponsors several publications designed to act as a catalyst for transparency, share success stories, highlight areas of improvement, and increase understanding of the network that contributes to patient safety in the MHS.
- *Fosters a Culture of Safety.* In the MHS, fostering a culture in which mistakes are acknowledged and lead to sustainable, positive change; respectful and inclusive behaviors are instinctive and serve as behavioral norms for the organization; and the physical and psychological safety of patients and the workforce are both highly valued and ardently protected.
  - A culture of safety is demonstrated by an organizational commitment to provide safe, high-quality and highly reliable patient care via a focus on collaborative teamwork, communication, and effective processes. This commitment must be shared by leadership and staff members at all levels. Organizations with a culture of PS acknowledge that medical errors can and will occur and strive to identify and reduce risk before it results in



harm. PS resources designed to evolve and sustain a culture of safety and are foundational to PS include TeamSTEPPS<sup>®</sup>, a system for maximally integrating teamwork principles into safe practice, and the Patient Safety Professional Courses, designed to prepare patient safety professionals for their role.<sup>38</sup>

In conjunction with the PSP, the Agency for Healthcare Research and Quality (AHRQ), developed TeamSTEPPS<sup>®</sup>, endorsed by the ACS. As displayed in Figure 1, this evidenced-based teamwork system is a training program designed for health care professionals to improve patient safety, communication, and teamwork skills for overall efficiency in health care.<sup>124</sup> The goal of TeamSTEPPS<sup>®</sup> is to:

- Produce highly effective medical teams that optimize the use of information, people, and resources to achieve optimal clinical outcomes,
- Increase team awareness and clarifying team roles and responsibilities,
- Resolve conflicts and improve information sharing, and
- Eliminate barriers to quality and safety.<sup>125</sup>

TeamSTEPPS<sup>®</sup> (Figure 10) has a three-phased process aimed at creating and sustaining a culture of safety. Phase one involves assessing the needs within the institution. Phase two

**Figure 10.** TeamSTEPPS<sup>®</sup> Model



involves planning, training, and implementing approaches tailored to the unique needs of the organization. Phase three is the sustainment and spread of improvement in teamwork performance, clinical processes, and outcomes resulting from the TeamSTEPPS<sup>®</sup> initiative.<sup>125</sup> The program also comprises strategies for four competencies, within which teamwork principles are translated into practices and checklists are used to enhance a shared mental model, mutual trust, and teamwork behaviors. These competencies include communication, leadership, mutual support, and situation monitoring.

Additionally, the PSP developed inpatient implementation guides for individual MTFs in order to prioritize specific patient safety improvement initiatives. Ninety-seven patient safety managers and champions were trained across the MHS, responsible for driving local patient safety improvement efforts to ensure the safe delivery of care. In 2017, the PSP designed a patient safety professional course focused on evidenced-based best practices, such as systems thinking, human factors engineering, leadership, and patient engagement, and emphasized the need for standardization and reduced variation to provide the best patient outcomes. Overall, the PSP boosts MHS priorities by building competencies and enhancing the skills of patient safety managers and champions to help foster a culture of safety and sustain the protection and health of patients.<sup>126</sup>



## D.5 MILITARY HEALTH SYSTEM TRANSPARENCY INITIATIVE

Maintaining and promoting transparency for surgical volume fosters awareness and trust and allows for the patients to be an active participant in their healthcare decisions. Moreover, transparency promotes patient safety, risk mitigation, and quality of care.<sup>33</sup>

The MHS Transparency Initiative developed a framework, adopting the National Patient Safety Foundation's (NPSF) four transparency domains:

- (1) *Transparency between clinicians and patients* is championed by the Clinical Quality Management Board (CQMB) and the Patient Experience Work Group for transparency in as risk-management of harm events, patient education, and health literacy.
- (2) *Transparency between clinicians themselves* is championed by the Patient Safety Improvement Collaborative for promoting and strengthening a culture of safety.
- (3) *Transparency between healthcare organizations* is championed by the CQMB for sharing leading practices and collaborative learning such as through participation in national or professional organization quality improvement registries.
- (4) *Transparency between clinicians, healthcare organizations, and the public* is championed by the Transparency Initiative Group (TIG) for transparency with the public as a service.<sup>37</sup>

MHS public reporting on its Health.mil/Transparency website allows patients to access MHS information with respect to each MTF for quality, patient safety, and access to care. The site allows comparison of measures for up to three MTFs, allowing patients to play a more active role in their healthcare decisions. Recent updates to the website also include allowing for addition or removal (if measure has been retired) of posted measures, and allows for patients to provide feedback on the site by email as well as tracking site visits and navigation.<sup>37</sup>

The ACS Surgical Patient Education Program provides a robust online resource for educating patients on preparing for surgical care as well as what to expect following the procedures.<sup>127</sup> Patient education handouts, such as those published by the Journal of the American of Medical Association (JAMA), detail key questions patients should ask before undergoing a procedure.<sup>128</sup> Additionally, patient engagement through informed consent and shared decision making<sup>iv</sup> are important aspects of a transparent culture. Promoting this kind of transparency between clinicians and patients through combined efforts of Clinical Communities, the Patient Experience Working Group, and the Transparency Initiative Group can enhance the MHS Transparency Initiative.<sup>37</sup>

The MHS is positioned with its model for an HRO to create conditions for high reliability at the point of care and to hold themselves accountable to MHS standards and clinical outcomes. The DHA is reviewing the next steps for its HROM following the proof-of-concept, to include stand up of the remaining Clinical Communities of which Surgical Services is proposed to be one.<sup>37</sup>

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<sup>iv</sup> Shared decision making is a collaborative process in which at least two parties (the patient and provider) work together on treatment options and plans. This approach takes into account patient preferences in decision making and treatment as well as information and risk transparency on the part of the practitioner. Other parties, such as patient family members and allied health professionals, can also take part in this process.



## D.6 TAKE THE VOLUME PLEDGE

The beginning of this appendix examined the various DoD and MHS programs for optimizing patient safety and quality of care. To examine potential best practices for maximizing patient safety and the quality of surgical care, the remainder of this appendix examines civilian programs regarding safety and quality. As the surgical volume issue is not exclusive to the military environment, efforts have been made in civilian healthcare to address and improve potentially adverse outcomes of low-intensity surgical procedures. The following will address the *Take the Volume Pledge* (Volume Pledge) implemented at three academic institutions, as well as review transparency and patient safety efforts from the Leapfrog Group. Of note, this section is not intended to be a comprehensive examination of the Volume Pledge's applicability to the MHS, as this will be addressed in stage two of this report.

In conjunction with the increased focus on overall patient care, quality, and safety within the MHS, there has been an added emphasis on surgical quality improvement due to the complexity and inherent risks associated with many surgical procedures.<sup>129</sup> Demands for improved healthcare quality in this domain have led to a closer examination of the relationship between surgical procedure volumes and patient outcomes.<sup>130</sup> Hospitals performing greater numbers of certain surgical operations have demonstrated significantly lower operative mortality and morbidity outcomes, presumably due to underlying mechanisms of increased surgeon/surgical team experience and/or selective referral patterns.<sup>131</sup> See Appendix B.2 for more information.

Some civilian healthcare systems across the U.S. are implementing various approaches in addressing the surgical volume issue. One such approach is the 2015 Volume Pledge involving the Johns Hopkins Health System, Dartmouth-Hitchcock Medical Center, and the University of Michigan Health System. Through this policy campaign, these institutions established mandatory volume thresholds for 10 complex surgeries at their main academic facility. A robust body of literature, including the widely cited article by Birkmeyer et al. (2002), suggest that greater volume is associated with better outcomes, including lower mortality rates for certain procedures.<sup>9</sup> These studies have encouraged movements to translate this evidence into practice, with the subsequent development of a “practice makes perfect” approach. The Volume Pledge encourages the use of specific volume thresholds for several procedures per year per hospital, as well as per surgeon, as shown in Table 4.<sup>132</sup> These procedures and thresholds were determined by six expert panels comprised of six members each, representing a diverse range of expertise from the three participating health systems, Johns Hopkins Health System, Dartmouth-Hitchcock Medical Center, and University of Michigan Health System.<sup>8</sup>



**Table 4.** Procedures and Thresholds defined by the Volume Pledge<sup>8</sup>

Procedure	Hospital Volume/Year	Surgeon Volume/Year
<b>Bariatric surgery</b>	40	20
<b>Cancer resections</b>		
<b>Esophagus</b>	20	5
<b>Lung</b>	40	20
<b>Pancreas</b>	20	5
<b>Rectum</b>	15	6
<b>Cardiovascular</b>		
<b>Carotid arterial stenting</b>	10	5
<b>Complex aortic surgery</b>	20	8
<b>Mitral valve repair</b>	20	10
<b>Orthopedics</b>		
<b>Hip replacement</b>	50	25
<b>Knee replacement</b>	50	25

Hospitals and surgeons that perform fewer than the set minimum volume would not be permitted to perform that specific procedure; patients would then be required to seek care at another center that meets the minimum volume threshold.<sup>132</sup> Although this minimum volume requirement could pose challenges, including career dissatisfaction for some surgeons, there are opportunities to maintain surgeon privileges and credentials for these complex procedures. These opportunities include senior surgeon mentoring and partnerships with other hospitals to meet volume thresholds;<sup>133</sup> however, by setting minimum standards, a surgeon’s years of past experience, advanced training, and case load complexity may be simplified to a minimum volume number, which may not accurately define the surgeon’s abilities.

The Volume Pledge institutions vary in their adoption and execution of the pledge. Johns Hopkins Health System consolidates hip and knee replacements at one center in their system.<sup>133</sup> Dartmouth-Hitchcock Medical Center monitors surgeon volumes through the privileging process and ensures that surgeons who fall below the volume thresholds participate in apprenticeships or reconfigure their practices to clear the thresholds.<sup>8</sup> The University of Michigan Health System uses surgeon attestation in the privileging process to confirm minimum volume requirements because of difficulty in tracking volumes for surgeons who perform operations at multiple hospitals.<sup>134</sup>

Although the intent of the establishment of mandatory volume thresholds is to improve patient safety and quality, there are concerns, including that this redirection of complex surgeries to fewer, centralized hospitals may lead to social disadvantages, such as prolonged patient/family separation, disparities in access to care, such as patients who are limited by their ability to travel. There may also be professional consequences, such as the impact on the career path of surgeons because it may narrow their scope of practice, influence their joy in practice, and reduce physician recruitment. Also, since the creation of the Volume Pledge in 2015, only the three original institutions have joined the initiative. Additionally, the efficacy of the Volume Pledge has not been fully demonstrated as outcomes are still being collected. Finally, because the





Volume Pledge, and the associated literature, use discrete categorization to define volume thresholds, an element of arbitrariness exists. For example, “low-volume” can be defined as 10 cases in one study and then defined as 50 cases in another study. Moreover, if the threshold is 10 surgeries, a surgeon who performs 9 surgeries is considered “low-volume,” while a surgeon who performs 10 surgeries is considered “high-volume.” Hence, there is a statistical concern when arbitrary cut-off points are created.

In general, there is a relationship between surgical volume and outcomes based on the peer-reviewed literature. While this relationship has been acknowledged, there is also evidence to suggest that volume is an imperfect standalone measure of quality. Volume is an imperfect standalone measure of quality.<sup>133</sup> The issue then may be better framed as a risk mitigation approach, where the multiple complexities inherent in surgical procedures are examined.<sup>33</sup>

## D.7 THE LEAPFROG GROUP

The Leapfrog Group is a national non-profit organization working to initiate breakthrough improvements in the safety, quality, and affordability of health care for Americans.<sup>135</sup> The organization focuses on measurement and public reporting. Other than the Centers for Medicare and Medicaid Services (CMS), Leapfrog is the only organization that collects hospital information and reports the data at no cost. Leapfrog does not provide services to hospitals; the organization does provide services to the purchasing consumers by collecting data from hospitals.<sup>79</sup> The Leapfrog Group has the following three programs:

- (1) The Leapfrog Hospital Survey is a voluntary survey on safety and quality completed by participating hospitals annually.
- (2) The Leapfrog Hospital Grade is a consumer-friendly letter grade system evaluating hospitals on patient safety.
- (3) The Leapfrog Value-based Purchasing Program is a pay-for-performance program that uses data from the Hospital Survey.<sup>135</sup>

Dr. John Birkmeyer, co-founder of the Volume Pledge, introduced the volume and quality relationship to Leapfrog, aligning the 2017 Hospital Survey content with the foundational elements of the Volume Pledge.<sup>79</sup> The 2017 Hospital Survey was the first time Leapfrog asked hospitals to report volume for the 10 procedures included in the Volume Pledge for hospitals and individual surgeons. Since 2017, 52% of eligible hospitals submitted data; of these hospitals, 1,582 are urban and 359 are rural. In 2018, hip and knee replacement procedures were excluded from the survey and are no longer considered a part of Leapfrog’s annual minimum volume standards. Additionally, minimum thresholds were established, and the focus shifted from reporting individual surgeon volume to reevaluating the privileging process. Changes are based on the advice from Leapfrog’s expert panel, and the content of the survey is continuously refined. There are plans to include broader definitions for procedures in the 2019 cycle of the Hospital Survey.<sup>79</sup>

Grades and scores can be found for all participating hospitals on Leapfrog’s website, by hospital volume and surgeon volume. Leapfrog does not collect patient outcomes data and relies on



volume as surrogate for quality. Each facility receives an overall value score as well.<sup>79</sup> All participating hospitals receive a detailed report regarding their results twice per year.<sup>135</sup>

Leapfrog public reporting has limitations. Because hospitals have to choose to participate, not all hospitals are represented on the Leapfrog hospital grade site. A patient query of the Leapfrog hospital grades is thus skewed to those hospitals that participate. This may or may not promote quality choices by patients. For example, the top two hospitals on U.S. News and World Report's Best Hospital List for cancer, MD Anderson Cancer Center in Houston, TX, and Memorial Sloan Kettering Cancer Center in New York City, NY, do not participate in Leapfrog, so they would not be visualized by patients on the Leapfrog site. Further, Leapfrog measures are self-reported by hospitals without external validation. Thus, there are concerns regarding the meaning of the grades derived from potentially inaccurate metrics.

Leapfrog's intention is to improve safety and encourage hospitals and surgeons to examine the contribution of volume to better patient care. However, numbers without associated outcomes do not provide a comprehensive analysis of surgical patient safety and quality. Moreover, by relying so heavily on a volume-outcome association and ignoring cumulative surgeon experience, this grading scheme may adversely impact surgical privileging and availability of surgical care in some communities. The Joint Commission notes that volumes are too blunt a metric to use as a proxy for quality. "Volume should never be used by an accrediting organization as a measure of quality" says Mark Chassin, President of the Joint Commission. Each facility and surgeon is unique.<sup>27</sup>

## D.8 OBSERVATIONS

As elucidated in *Crossing the Quality Chasm* (2002), reducing risk and ensuring safety require greater attention to systems that help prevent and mitigate errors.<sup>136</sup> Additionally, transparency efforts focused on providing information to patients and their families that allow them to make informed decisions when selecting a health plan, hospital, or clinical practice, or choosing among alternative treatments, is imperative. Further, culture change requires time, effort, and commitment from the leaders of an organization.<sup>137</sup> Continuing to develop and use evidence-based guidelines such as the ACS *Optimal Resources for Surgical Quality and Safety*, as well as identifying areas of excellence and successful practices from programs already in place, can spur positive and effective change. The following observations are made:

- (1) There is a continuous need to optimize data analytics. NSQIP data, in conjunction with registries and databases that use data directly from EHR, can be leveraged to provide a more comprehensive view of quality; NSQIP and EHR data, overlaid with peer-review and quality improvement programs, provide opportunities for continuous improvement.
- (2) For high-quality care to be maintained and increased, the system in place must be active in order to detect issues, such as near misses. The system must be comprehensive from the safety programs in place to the functionality of the surgical team. This includes the use of NSQIP as a responsive, pro-active tool.
- (3) NSQIP within the MHS is done through sampling and does not capture all data. A 100% sampling of select procedures may account for low numbers and provide a more informed understanding of procedural outcomes.



- (4) Robust quality and safety programs, within a culture of safety, allow for accountability, verification, and an expansion of best practices.
- (5) Management and supervision of low-intensity surgeons, including professional development and training, has been encouraged.
- (6) Leveraging high-volume civilian environments through expansion of military-civilian partnerships could provide opportunities for risk mitigation by allowing for the rotation of military medical teams. Personnel could spend time in a high-intensity site and rotate through low-volume sites, promoting the sharing of skills and creating a collaborative learning environment.<sup>33</sup>
- (7) Through the various DoD initiatives and programs, there has been an increased focus on collaborative learning environments, including establishing platforms where providers and team members can work across the Services to communicate best practices, share ideas, and problem-solve<sup>33</sup> (see Appendix E for more information).
- (8) The DHA focuses on a data-driven strategy, including all eligible MTFs participating in NSQIP. However, expansion to external registries such as the Metabolic Bariatric Surgery Accreditation and Quality Improvement Program (MBSQIP)<sup>42</sup> and the Trauma Quality Improvement Program (TQIP) may maximize the data analysis strategy.
- (9) Transparency includes not only the accessibility of data, but also the creation of an environment that emphasizes patient education in order for patients to make informed decisions.
- (10) There is limited outcomes data from the Volume Pledge. Of note, the adoption of the Volume Pledge within the DoD is part of the secondary efforts of this tasking and will be further evaluated at the conclusion of this report.
- (11) The current practice employed by the Leapfrog Group of only using volume data from voluntary surveys may be limited. Inclusion of risk-adjusted analyses and examination of the externalities for publishing may provide a more multidimensional approach to measuring patient safety and quality of care.
- (12) Although the volume-outcome relationship exists, the extent of this relationship varies by surgical procedure. Mitigation of risks can be emphasized to increase patient safety and quality of care with respect to low-intensity surgical procedures.
- (13) Based on current governance and organizational structures, the NSQIP Steering Committee and the MTF surgeon champions are limited in scope of authority.



## APPENDIX E. CONTRIBUTIONS TO MILITARY MEDICAL READINESS

### E.1 INTRODUCTION

Appendix E of this report examines the Combat Casualty Care (C3) Knowledge, Skills, and Abilities (KSA) program developed at Uniformed Services University of the Health Sciences (USUHS) within its Clinical Readiness Program and surgical simulation as they relate to medical readiness. This appendix will detail and examine the KSA program and simulation from the perspective of overall readiness within the MHS and how the KSAs can be utilized to define surgeon competencies in support of the complex surgical procedures issue. While not yet a program of record, this pilot effort has gained support and is expected to be directed as an enterprise-wide program in the near future. Appendix C.3 includes more KSA initiatives, such as plans to incorporate these KSAs within the training and readiness programs of the Services and the Defense Health Agency's (DHA) National Capital Region-Medical Directorate (NCR-MD). This appendix examines other areas of medical readiness such as the Joint Trauma System and simulation training.

Specifically, Appendix E addresses the following objective in the Terms of Reference (TOR): Examine the contribution of Knowledge, Skills, and Abilities (KSAs) of low-volume high-risk procedures to military medical readiness (e.g., surgeons, operating room staff).

In addition to the specific TOR objective, this appendix will examine if the KSA model can provide a template to ensure that the surgeon performing the procedure is highly proficient. Being ready medically is critical to the team specifically for complex procedures. It is important to consider if the KSA model mitigates risks by addressing surgeon and team deficiencies incurred due to low-volume and if the model sustains and enhances already established skills.

The *National Defense Authorization Act Fiscal Year 2017 (NDAA FY 2017) Section 702 Reform of Administration of the Defense Health Agency and Military Medical Treatment Facilities* states "Beginning October 1, 2018, the Director of the Defense Health Agency shall be responsible for the administration of each military medical treatment facility."<sup>75</sup> The Under Secretary of Defense Personnel and Readiness memorandum (USD[P&R]) *Construction for Implementation of Section 702*, dated May 22, 2018, states, "With the objective of ensuring a 'ready medical force' and a 'medically ready force,' MTFs will be the default choice for the assignment, allocation, detail, or other utilization of military medical personnel. Such default will be subject to the capacity of the MTF to afford military medical personnel opportunities to obtain and maintain currency in the clinical KSAs associated with their medical specialties and communities, at or above minimum established thresholds."<sup>138</sup> The *NDAA FY 2017* and the succeeding memorandum for implementation of *Section 702* enable standardization of the KSA program at the MHS level, requiring all surgeons regardless of Service to meet a set of thresholds as indicated through the clinical KSAs.

### E.2 DEVELOPMENT OF THE KNOWLEDGE, SKILLS, AND ABILITIES PROGRAM

In 2017, NCR-MD and USUHS led the KSA initiative to develop a methodology to measure the readiness of the MHS medical force.<sup>2</sup> This effort was undertaken to improve the MHS's



approach in addressing expeditionary specialty skills training, refinement, and retention, including providing standardization and metrics-driven processes in support of the maintenance of critical wartime C3 skill sets. Historically, pre-deployment training surveys, observations, insights, and lessons learned indicate that clinical specific pre-deployment training provided to deploying Service members does not consistently and/or adequately prepare individuals to quickly assume their medical duties while deployed.<sup>46</sup> It has not previously been tailored to individual skill levels, but rather a “one size fits all” approach.

Figure 11 shows the NCR-MD’s conceptual interpretation of knowledge currency across conflicts, from World War II to Operation Enduring Freedom and Operation Iraqi Freedom (OEF/OIF). This graph indicates the challenge of maintaining perishable skills between conflicts, and the military having to repeatedly “relearn” these skills during times of conflict.<sup>46</sup> Further, patient care may be impacted by the “dips” in knowledge currency due to surgeons having to relearn skills post conflict.<sup>46</sup> After each conflict, the ability to care for patients degrades. KSA adoption may assist medical personnel from losing skills during the post conflict periods. The KSA initiative focuses on refining and retaining knowledge currency during peacetime, while ensuring readiness of the medical force for the next conflict.<sup>46,111</sup>

**Figure 11.** Conceptual Interpretation of the Evolution of Knowledge Currency Across Conflicts<sup>46,111</sup>

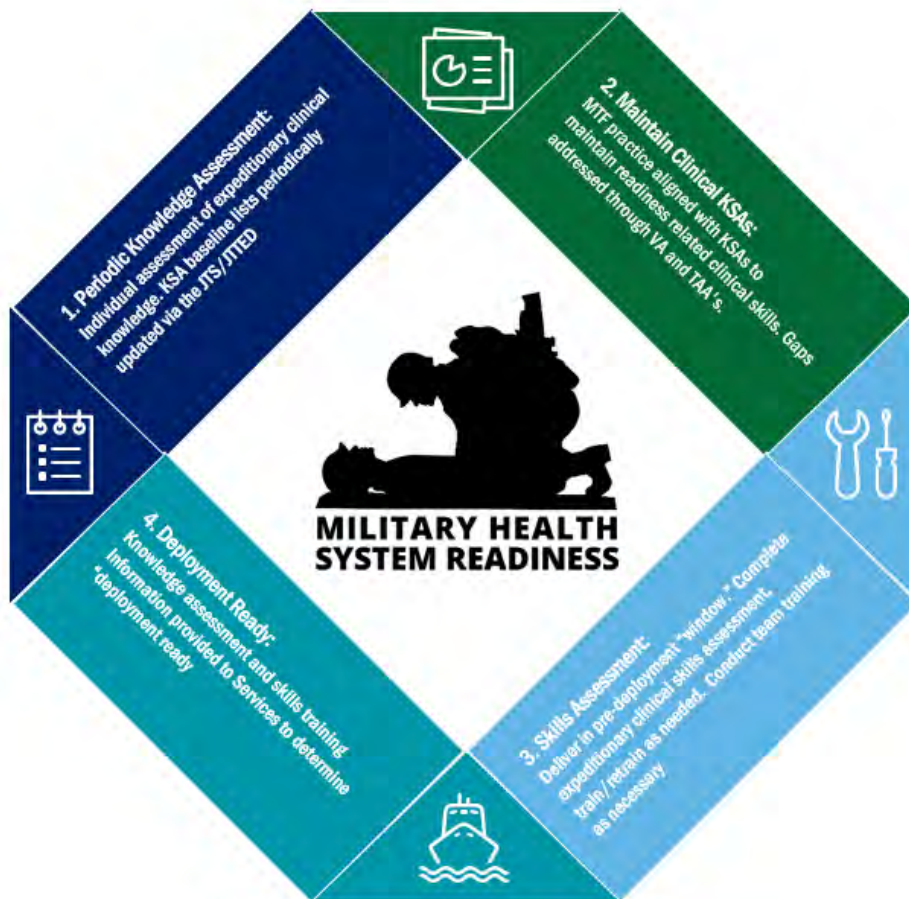


Although surgeons are expected to perform surgical procedures on the battlefield, at their MTFs they may not be exposed to enough procedures to maintain their medical readiness skills. Moreover, these procedures may not be the same ones that are required on the battlefield.<sup>46</sup> To address the challenge of knowledge currency and to improve the approach to skills maintenance, clinicians developed the Clinical Readiness Program with KSAs and Expeditionary Maintenance of Currency and Competency (MOC<sup>2</sup>) as a way to capture and sustain the skills necessary to meet expeditionary needs.<sup>46</sup> Based on the experience of war, Joint Trauma System (JTS) Clinical Practice Guidelines (CPGs), case registries, and relevant literature, the KSA formulation addresses the return on readiness for routine surgical care procedures, a methodology not previously developed.<sup>46,84</sup>



Within the Clinical Readiness Lifecycle, as shown in Figure 12, Phase 1, *Periodic Knowledge Assessment*, includes an individual assessment of expeditionary clinical knowledge with KSA baseline lists that are periodically updated. Phase 2, *Maintain Clinical KSAs*, involves aligning MTF practice with KSAs, with skill gaps addressed through partnerships with the VA and Training Affiliation Agreements (TAA)s. Phase 3, *Skills Assessment*, occurs during pre-deployment preparation with completion of expeditionary clinical skills assessment and training/retraining as needed for the individual surgeon. It also includes any necessary team training. The final phase of the clinical readiness lifecycle, Phase 4, *Deployment Ready*, provides the Services with data necessary to determine deployment readiness.<sup>46</sup> Incorporation of the KSAs into the Services’ readiness models is vastly different per Service. See Appendix C.3 for more information.

**Figure 12.** Clinical Readiness Lifecycle: Structured Readiness System<sup>46</sup>



## METHODOLOGY

The Army, Navy, and Air Force identified subject matter experts to assist in the development of KSAs for an expeditionary clinician. This Tri-Service Surgical Team, comprised of 14 military surgeons with deployment experience, and in partnership with the ACS, created the eight expeditionary domains initially for general surgery, which was later replicated for the remainder of the combat casualty care team (Figure 13). The Accreditation Council for Graduate Medical



Education (ACGME) methodology was used for domain creation because it is educationally based and exportable to all critical specialties. The medical specialties with KSA definitions include General Surgery, Anesthesia, Orthopedic Surgery, Trauma Surgery, Critical Care, and Emergency Medicine.<sup>46</sup> General surgery, the most developed specialty, has 487 KSAs, with over 3,000 KSAs across the combat casualty care team.<sup>46</sup> The KSA domains are extensive, but not exhaustive. Of note, there are no domains for chemical, biological, radiological, and nuclear (CBRN) and psychiatry problems such as post-traumatic stress disorder (PTSD) categories.

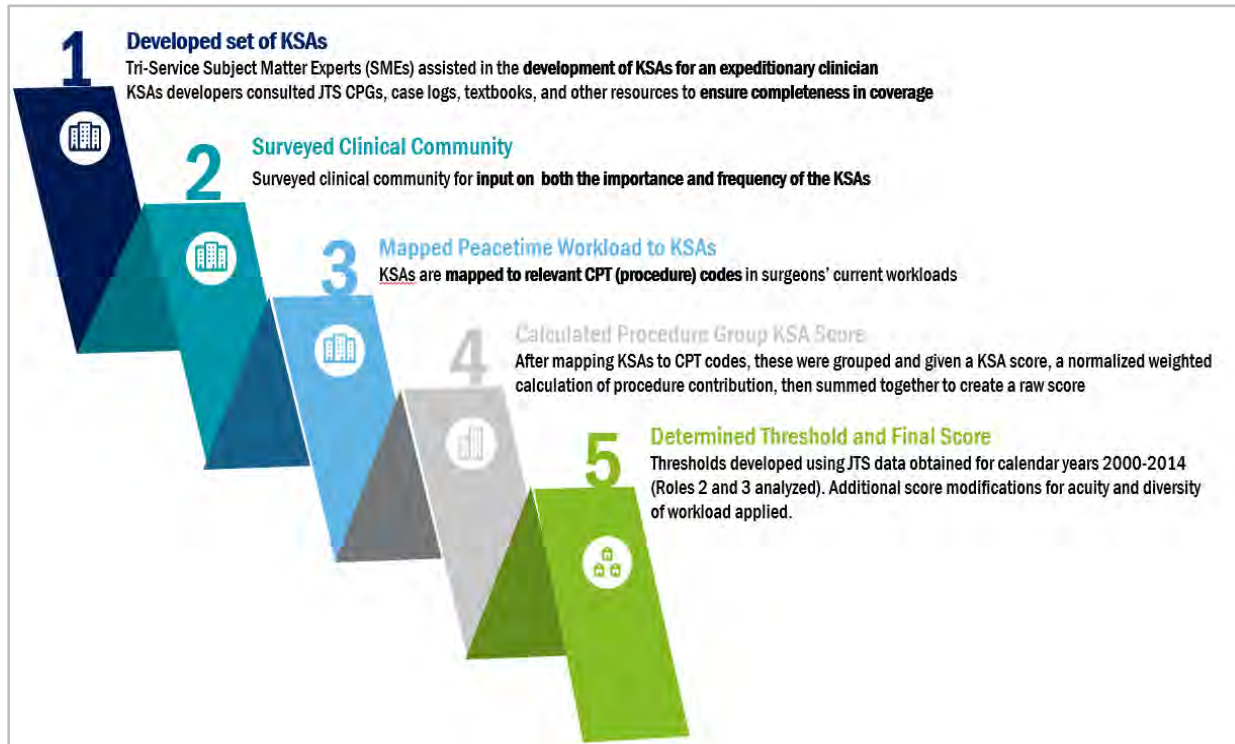
**Figure 13.** Domains of KSA Methodology<sup>46</sup>

Wound & Amputation /Fx Mgt	Head and Spine Injury	Torso Trauma
<a href="#">Management of War Wounds</a>	<a href="#">Cervical and TL Spine Injury</a>	<a href="#">Pelvic Fracture Care</a>
<a href="#">Compartment Syndrome and Fasciotomy</a>	<a href="#">Concussion/mTBI Management</a>	<a href="#">Blunt Abdominal Trauma</a>
<a href="#">Amputation</a>	<a href="#">Neurosurgical Management</a>	<a href="#">Damage Control Surgery (ABD)</a>
<a href="#">Burn Care</a>	<a href="#">Cervical Spine Evaluation</a>	<a href="#">Damage Control Surgery (Chest)</a>
<a href="#">High Bilateral Amputations</a>	<a href="#">Management of Severe Head Injury</a>	<a href="#">Damage Control Surgery (Neck)</a>
<a href="#">Extremity Trauma/Hands and Feet</a>	-	<a href="#">Thoracic Trauma</a>
-	-	<a href="#">Wartime Vascular Injury</a>
-	-	-
Transfusion and Resuscitation	<b>Domains for Assessment</b>	Critical Care/Prevention
<a href="#">Frozen Blood</a>		<a href="#">Hypothermia Prevention</a>
<a href="#">Damage Control Resuscitation</a>		<a href="#">Prevention of Venous Thromboembolism</a>
<a href="#">Fresh Whole Blood</a>		<a href="#">Catastrophic Care</a>
<a href="#">Inj Doc Resus Record</a>		<a href="#">Infection Control</a>
<a href="#">REBOA for Hemorrhagic Shock</a>		<a href="#">Management of Pain/Anxiety/Del</a>
<a href="#">Emergency Thoracotomy</a>		<a href="#">Critical Care additional</a>
-	-	-
Expeditionary Unique	Airway and Breathing	Universal Domains
<a href="#">UXO Management</a>	<a href="#">Trauma Airway Management</a>	<b>Systems Based Practice</b>
<a href="#">TCCC/Prehospital Care</a>	<a href="#">Acute Respiratory Failure</a>	Practice Based Learning and Improvement
<a href="#">EPW &amp; Detainee Care</a>	<a href="#">Trauma Anesthesia</a>	Interpersonal and Communication Skills
<a href="#">Pediatric Trauma</a>	<a href="#">Inhalational Injury</a>	<b>Professionalism</b>
<a href="#">Intratheater Transport</a>	-	
<a href="#">Clinical Mgt of Mil Working Dogs</a>	-	

The development of the KSA scores is shown in Figure 14. Clinical experts were surveyed for input on the importance and frequency of the KSAs. The KSA blueprint involves mapping KSAs to peacetime workload that yields a readiness indicator–KSA score–for each clinician, MTF, and market.<sup>46</sup> Specifically, KSAs are mapped to relevant Current Procedural Terminology (CPT) codes in surgeons’ current workloads. These KSAs identify and capture specific parts of the procedures that give readiness volume.<sup>46</sup> A readiness value is given for every procedure with more complex procedures yielding a higher KSA value. Thresholds are developed based on diversity, volume, and acuity. For example, in assessing volume thresholds, the 75<sup>th</sup> percentile of the Forward Surgical Team’s (FST) volume translated into a KSA score, which was used due to feasibility, understanding that there are many personnel performing low acuity procedures.<sup>46</sup>



**Figure 14.** How the KSA Scores are Developed<sup>46</sup>



In 2017, the USU staff worked with the Cost Assessment and Program Evaluation (CAPE) office within the DoD during development of the KSA methodology. During this partnership effort, KSA thresholds were compared to three civilian Level I trauma centers (a Northeastern suburban academic medical center, a Midwestern urban academic medical center, and a Southeastern urban medical center), confirming that the KSA metric within the MHS is achievable and that the KSA program is robust in general and emergent surgical procedures.<sup>46</sup>

It is important to note that KSA scores do not determine deployment readiness; instead, KSA scores assist leadership with readiness optimization at their clinics and MTFs. Additionally, the goal of the KSA program is to maximize the readiness of the MHS. Surgical skills toward readiness are measured through observation of the percentage of surgeons at or above the KSA threshold with the goal of 100% of surgeons at or above the KSA threshold.<sup>46</sup>

The KSA results are tracked through a visualization platform providing analytics at the individual and enterprise level. The dashboard allows for comparison between surgeons at the individual level and comparison of efforts provided in direct care versus purchased care at the facility and market levels. Additionally, the purchased care data section of the dashboard is used to understand the type, volume, and location of work referred to the network. Approaches for recapturing and expanding the market are more easily identified through the dashboard which shows the readiness value of cases lost when these procedures are sent to the purchased care network.<sup>46</sup>





## IMPLEMENTATION

The Under Secretary of Defense for Personnel and Readiness (USD[P&R]) memorandum *Construction for Implementation of Section 702* states “MTFs will be the default choice for the assignment, allocation, detail, or other utilization of military medical personnel. Such default will be subject to the capacity of the MTF to afford military medical personnel opportunities to obtain and maintain currency in the clinical KSAs associated with their medical specialties and communities, at or above minimum established thresholds.”<sup>138</sup> Appendix C.3 includes examples of how each Service is currently integrating the KSAs for skill maintenance and currency, with the Services appearing to be at different KSA implementation stages. With further management and implementation guidance expected to be released soon from the MHS level, all surgeons throughout the MHS, regardless of Service, will be required to meet the same set of standardized thresholds.

To understand the impact on MTFs that actively manage and attempt to improve KSA performance among their surgeons, the KSA program conducted a proof-of-concept at six MTFs: Walter Reed National Military Medical Center (WRNMMC), Fort Belvoir Community Hospital (FBCH), William Beaumont Army Medical Center (WBAMC), Naval Hospital Camp Pendleton (NHCP), 96<sup>th</sup> Medical Group (MDG) at Eglin Air Force Base (AFB), and the 60<sup>th</sup> Medical Group (MDG) at Travis AFB. The results of the proof-of-concept showed that three of the six MTFs improved in both KSA score and volume, when compared to their respective baseline. MTF Commanders using the KSA metric found them feasible, without negative impact on other key aspects of healthcare delivery, such as access, safety, or cost, and were able to focus the market on novel approaches to improve readiness.<sup>46</sup>

To explore the underlying factors behind KSA performance, the proof-of-concept team released an in-depth report analyzing the first 90 days of KSA performance within the National Capital Region (WRNMMC and FBCH).<sup>47</sup> Results show that the NCR-MD increased the total percentage of General Surgeons meeting the KSA threshold from 26% to 30% and from 73% to 77% for Orthopedic Surgeons. FBCH and WRNMMC collectively captured 50% of the total KSA points available in the market for General Surgery, which represents a two percent decrease. Orthopedics captured 42% of the total KSA points available in the market, which represents a two percent increase.<sup>47</sup>

The 90-day report also documented performance improvement activities to highlight potential best practices for the enterprise. The NCR-MD took the following steps to improve KSA performance:

- (1) Internal capacity and OR throughput: OR room utilization, turnover, and anesthesia and surgical procedure times were analyzed in an effort to assess areas for improvement and optimize case time estimation and scheduling. Additional perioperative nursing support staff has been approved to enable opening additional ORs at WRNMMC.
- (2) Deployment tempo and workload: FBCH and WRNMMC are working together to backfill deployments to minimize capability gaps and capitalize on patient demand with focus on the high-value KSA cases.



- (3) Patient recapture: Patient recapture and market expansion operations were initiated to target high KSA value procedures and for greater visibility of ROFRs.
- (4) Improved integration: Efforts are underway to reduce variance among coding personnel, software, and business rules to capture productivity consistently across the market.
- (5) Role of trauma care: The establishment of the NCR-MD Trauma Medical Director and associated project plan will help to drive readiness.<sup>46</sup>

The proof-of-concept also identified issues related to OR availability limitation due to staffing shortages of active duty nurses assigned to operational billets and inadequate integration between MTFs regarding coding personnel, software, and business rules.<sup>47</sup>

## KNOWLEDGE AND SKILLS ASSESSMENT

### Knowledge Assessment

Utilizing the KSA blueprint, a series of meetings of Subject Matter Experts (SMEs), guided by a psychometrician, were held to develop test items to evaluate the performance of the deploying General Surgeon (both knowledge and medical procedural-based).<sup>46</sup> This first phase of assessment development is complete with approximately 600 multiple-choice items with one correct answer developed. These have been developed utilizing 4-Item Writing Workshop with 40 SMEs participating to create strong, robust items that fit the blueprint and are written to the well-established item construction guidelines. Currently underway is beta testing utilizing previously deployed General Surgeons using two forms of the assessment of 200 questions each. The data from this pilot test will be scored and analyzed using appropriate item analysis and test construction software. From these results one form of the assessment will be developed. The final assessment will be validated by a panel of General Surgeons with expeditionary experience. The passing score will be determined by the SMEs who are familiar with writing and reviewing the items using a currently accepted Standard-Setting methodology. There will be one overall cut-score with diagnostic data for each of the domains with anticipated completion in February of 2019. This fully developed assessment will allow for the evaluation of the readiness for deployment into austere settings of expeditionary general surgeons, evaluate the effectiveness of training curricula, and help guide the development of future curricula.<sup>46</sup>

### Skills Assessment

The MHS has developed the Emergency War Surgery (EWS) Course that utilizes cadavers, didactic sessions, and live tissue to demonstrate critical skills.<sup>46</sup> The aim of this element of Clinical Readiness Program is to utilize the KSA Blueprint to update EWS and move from skills demonstration to direct assessment in an individualized manner. This three-year transition of EWS will leverage emerging simulation based approaches to achieve the following:

- A standardized comprehensive, consensus driven, validated, real time adaptable, distributable, multi-media curriculum for individualized surgical readiness training that leverages best in class educational concepts and tools.
- Evaluation tools and metrics that will allow for determination of skills readiness, durability and decay using 6-8 skills assessment stations.



- Individualized remediation process for surgeons unable to demonstrate currency and competency for required expeditionary surgical skills.<sup>46</sup>

### E.3 JOINT TRAUMA READINESS TRAINING PROGRAM

The Defense Medical Readiness Training Institute (DMRTI) is a Tri-Service organization under the Education and Training Directorate (J7) of the Defense Health Agency (DHA). The organization is staffed by Army, Navy, and Air Force professionals and offers joint medical readiness training courses as well as professional medical programs.<sup>139</sup> *NDAA FY 2017 Section 708 Joint Trauma Education and Training Directorate* and *DoD Instruction 1322.24 Medical Readiness Training (MRT)*<sup>140</sup> has directed the DHA to assume responsibilities for joint medical readiness training, enabling the opportunity for standardization of expeditionary trauma education and training programs across the DoD. This statute will also ensure the Services have medical forces ready to be rapidly deployed for future armed conflicts. Currently, each Service has their own individualized processes and programs for training trauma skills to their respective personnel, including various disparate methods for the delivery of CPGs, KSA-based cognitive skills, and team-based trauma training.<sup>48</sup> While each Service has developed areas of excellence as a result, training is uncoordinated and Service centric. This lack of standardization does not facilitate the interchangeable use of assets across a globally integrated theater of operations, leading to a disparity that could significantly limit medical capabilities downrange and thereby unacceptably increase risk to our deployed forces.<sup>48</sup> The Joint Trauma Education Directorate (JTETD) will serve to standardize these processes between Services, which will improve interoperability and shared efficiencies. Moreover, there has not been a formal link between the JTS, the DoD Trauma Registry, and informal trauma training programs, creating challenges for rapidly adapting training in order to address changing conditions on the battlefield.<sup>48</sup>

DMRTI, as the lead agent in this effort on behalf of the DHA, is developing the JTETD in conjunction with the JTS implementation plan for integration into the DHA. In addition to establishing criteria for military-civilian trauma partnerships, to include the effective incorporation of lessons learned from these partnerships, the JTETD will address these identified gaps in trauma-related expeditionary competencies by developing a Service neutral, comprehensive, standardized trauma training program of record that meets all statutory requirements and is consistent with current doctrine.<sup>141</sup> This effort will incorporate strategic civilian and military trauma center partnerships, including a curriculum with best practices, KSAs developed under the auspices of the MHSSPACS and technical innovation, including simulation and incorporation of modern learning theory and adult learning design.<sup>48</sup> Additionally, the program will take advantage of advanced, interactive learning methodologies, including smartphone applications that facilitate the performance of analytics that measure and verify trainees' understanding of the courses, providing for real-time modifications to the training curriculum as necessary to ensure optimal patient care across the continuum.<sup>48</sup>

The Joint Trauma Readiness Training Program aims to connect the various areas of medical readiness with the implementation of *NDAA FY 2017 Section 708*,<sup>75</sup> discussed above, and with *NDAA FY 2017 Section 707* which aligns the JTS under the DHA. Specifically, this program will include:



- (1) KSA metric for clinical practice;
- (2) Cognitive assessment of KSA domains by specialty, which applies toward maintenance of certification by American Board of Medical Specialties;
- (3) Formal psychomotor assessment of proficiency in expeditionary skills (Advanced Surgical Skills for Exposure in Trauma [ASSET<sup>®</sup>], Advanced Trauma Operative Management [ATOM<sup>®</sup>], etc); and
- (4) Team-based training in hyper-realistic, field-based conditions.<sup>48</sup>

#### E.4 SIMULATION-BASED SURGICAL TRAINING

The DoD currently lacks a standardized team-oriented training curriculum as a program of record. However, in *NDAA FY 2017 Section 707* mentioned above, this program will include a team-based training effort.

Effective team training is critical for success in operational units and directly influences the quality of patient care.<sup>49,50</sup> Leveraging technologies, including the use of simulations, allows for maintenance and proficiency of surgical skills.<sup>33</sup> Simulation training is also important for improving team effectiveness specifically with low-frequency, high-acuity emergency situations as the success of these complex procedures depends on the entire surgical team, not only the surgeon.<sup>51</sup>

The ACS Accredited Educational Institutes (ACS-AEI) Consortium was created in 2005 to set standards for simulation-based surgical training, as well as to improve patient safety, promote development of new techniques and technologies, promote research and collaboration, and identify best practices in simulation-based education.<sup>142</sup> Through a 2017 analysis of data from July 2011 to June 2016 from 149 ACS-AEI sites, 197 individual best practices were identified. Themes among simulation best practices include:

- Rigorous application of standardized curriculum development process, educational expert and/or learner involvement, and review by a curriculum review committee;
- Standardized processes for onboarding new faculty, faculty evaluation, and regular simulation instructor courses;
- Systematic process for simulator selection/acquisition and ability to develop custom simulators or modify simulators to meeting training needs; and
- Importance of garnering adequate and sustained institutional support, adequate space and equipment for training, efficiency and thoughtful design to meet the unique demands of simulation, and spaces that mimic clinical environments.<sup>142</sup>

#### SHIPBOARD SURGICAL TRAUMA TRAINING

Immersion training and stress inoculation in training has been a focus of the Naval Health Research Center (NHRC) since 2012. Utilizing immersion training and stress inoculation as a structure, the Navy Shipboard Surgical Trauma Training (S2T2) was developed five years ago as a research funded initiative with the intent to study the effectiveness of pre-deployment trauma team training to Fleet Surgical Teams (FST), with less emphasis on prerequisite individual skills.<sup>51</sup> It is Fleet funded and has provided training to West Coast FSTs with plans to expand to



East Coast teams in late 2018.<sup>51</sup> The focus of S2T2 is on improving team dynamics through maximizing efficiency and minimizing critical errors through a mixture of didactic sessions, hands-on skills sessions and multiple realistic trauma training scenarios.<sup>49</sup>

Establishing a cohesive team dynamic is critical prior to entering a combat zone.<sup>143</sup> Although not recognized as an ACS-approved simulation course, the S2T2 aligns with some of the best practices identified by the ACS-AEI, including its ability to develop customized simulation environments. The highlight of the course is its use of realistic trauma training scenarios that place students in a high-anxiety training “bubble” and a state of suspended disbelief.<sup>143</sup>

The immersed simulation training progresses in intensity and complexity throughout the week-long program to create a “crawl, walk, run” approach to learning.<sup>51</sup> This Hyper-realistic<sup>TMv</sup> field-based casualty scenario replicates battlefield conditions for point-of injury scenarios, Role 2 (resuscitative and surgical care), and en route care mock-ups. The training focuses on team management, medical logistics, and patient movement principles.<sup>51</sup> The teams typically spend one year together prior to deployment. U.S. Navy pre-deployment training typically includes three phases: 1) Individual; 2) Team (Shipboard); and 3) Integrated (such as training with Marines and integration of other ships).<sup>51</sup> Additionally, the S2T2 is intended to serve as a basis for the further development of standardized, KSA-based, Service-neutral expeditionary trauma training as stated in DoDI 1322.24<sup>140</sup> on Trauma Enterprise and Forward Resuscitative Care<sup>143</sup>

The content for S2T2 is based on TeamSTEPPS<sup>®</sup>, but in an accelerated environment (see Appendix D for more information on TeamSTEPPS<sup>®</sup>). The S2T2 emphasizes the use of subject matter experts (SMEs) who teach in a limited asset environment under the premise that personnel who train in a logistically challenged environment will be better prepared for all environments.<sup>51</sup> The S2T2’s dynamic curriculum also emphasizes the micro- and macro- level environments in a formative, rather than summative, training experience.<sup>51</sup> The training includes ship simulators for the Navy and Marine Corps, including an emergency room and two ORs (one which can simulate a ship board OR), a Navy/Marine Corps Shock Trauma Platoon (STP). Utilizing the same curriculum, the training scenario has also been successfully modified to train Army Forward Resuscitative Surgical Teams at multiple training sights.<sup>51,144</sup>

To measure team performance, the program has developed several quantified metrics to be collected and analyzed. A pre- and post-course written knowledge assessment is administered to measure understanding of the key principles of trauma care.<sup>144</sup> The reduction of patient resuscitation times and reduction of critical error made are both captured using standardized patient scenarios. Additionally, student bio-markers are collected and analyzed including reduction of cortisol stress response, increase in saliva Alpha amylase, and reduction of stress heart rate variability as measures of improved team performance.<sup>144</sup> A stressful situation will trigger the fight-or-flight response; thus, testing for stress requires accurate determination. Since

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<sup>v</sup> Hyper-realistic,<sup>TM</sup> a trademark of Strategic Operations, is defined as: such a high degree of fidelity in the replication of real world conditions in a training environment that participants so willingly suspend disbelief that they become totally immersed and eventually stress inoculated in a way that can be quantifiably and qualitatively verified.



surgeons must be able to perform critical tasks in real, life-threatening situations, stress immersion training may be essential to surgical simulation training.<sup>145</sup>

Qualitative data is also collected from pre- and post-longitudinal surveys to assess an individual's resilience and team cohesion that include an individual's perceptions of resilience, perceived stress, unit support, and interdisciplinary teamwork.<sup>144</sup>

A 2016 study assessed the outcomes of the S2T2 course with 25 shipboard medical teams receiving training over the span of three years.<sup>49</sup> Of the 25 teams, 11 were recaptured during the sustainment evaluation. Teams were assessed at the beginning and end of the course for disposition time and critical errors (defined as mistakes that had the potential to seriously compromise the survival of the patient or delay care) made during trauma management to assess skills sustainment.<sup>49</sup>

The efficacy of the study was determined based on 1) time to complete a patient interaction, and 2) the number of critical errors committed during the patient encounter. For the 11 teams examined, time to disposition improved significantly (11 minutes) and critical errors improved by 4 errors per encounter, from pre-test to post-test.<sup>49</sup> The S2T2 course has shown to be effective in preparing medical units for deployment by decreasing time to disposition and a reduction in the number of errors made during patient care; however, time to disposition increased minimally from post-test to sustainment testing, suggesting that some erosion of skills and knowledge had taken place, which shows the need for additional refresher training.<sup>49</sup>

Participants in the S2T2 program are able to obtain continuing medical education credits; however, since it is not a program of record, participants do not have completion documentation in their military records. Additionally, the program has become less Service-specific and the training concept and curriculum has been applied to pre-deployment Army Surgical Teams and Marine Corps Medical teams. The project is also mobile and can be scaled, as was successfully performed at Camp Bullis in San Antonio, Texas.<sup>51,143</sup>

## VETERANS HEALTH ADMINISTRATION MEDICAL TEAM TRAINING PROGRAM

Team training has also been executed in other governmental agencies, including the Veterans Health Administration (VHA). The VHA, as the largest integrated healthcare system in the U.S., began piloting Medical Team Training (MTT) in 2003 and then fully implemented a national team training program in 2006 that was aimed at improving care through better communication and uses checklists as a cognitive aid that facilitates open, thorough communication in the briefing prior to the procedure, open communication intraoperatively among the operating room (OR) team, and a debriefing following the procedure to capture lessons learned that occurred during the procedure.<sup>50</sup> The MTT program includes a two month preparation and planning phase with each facility's implementation surgical care team, followed by an onsite learning session (lecture, group interaction, and videos). The OR is closed to allow surgical staff to attend as a team (surgeons, anesthesiologists, nurse anesthetists, nurses and technicians). The program uses the crew resource management theory from aviation adapted for healthcare.<sup>50</sup>



A 2010 study examined the effects of the VHA training program by comparing the following between sites that participated and those that did not: rural or urban status, complexity, Veterans Affairs Surgical Quality Improvement Program (VASQIP) surgical volume, baseline observed and risk-adjusted mortality, the observed versus expected mortality ratio.<sup>50</sup> Data were used for 2006 to 2008 from 108 facilities. The VHA MTT program was found to be associated with a statistically significant reduction of 18% in surgical mortality rate, further showing that team training results in improved teamwork, safety attitudes, communication, and reduced errors. Moreover, the study also suggested that checklists guided briefings and debriefings associated with lower surgical mortality and morbidity and that the training program facilitated more open communication in the OR.<sup>50,146-148</sup>

## E.5 OBSERVATIONS

Military medical readiness through the KSA program supports standardization across the Services, while ensuring clinician skills and competency are managed and maintained at the DHA level. In addition to the KSA program's efforts on maintaining readiness, simulation based training is key for effective teamwork of the surgical team. The following observations are made:

- (1) Conceptually, the KSA program has the potential to create a standardized system of accountability and allow for the ability to quantify results.
- (2) By working closely with the ACS through an established partnership, successful practices, informed by evidence-based knowledge, have been incorporated in the KSAs.
- (3) Being deployed in a low-intensity surgical environment influences readiness. The KSA process acknowledges this and is building in competencies to address gaps.
- (4) Although there is a focus on quality of care at MTFs and on the battlefield, further research regarding the correlation between readiness and outcomes is required. The surgical checklist should be consistent between MTFs and combat zones.
- (5) There is an opportunity for return on investment as the military has acquired battlefield knowledge of how to save lives; in turn, the civilian sector could leverage military advancement in medicine and begin to apply this acquired knowledge, which aligns with recommendations from the 2016 National Academies of Sciences, Engineering, and Medicine (NASEM) *Zero Preventable Deaths* report.<sup>34</sup>
- (6) S2T2 provides a unique opportunity to teach team-based training and leadership in a standardized curriculum. However, limitations include consistent funding and accreditation as a program of record as an enterprise-wide requirement.<sup>143,149</sup>
- (7) A more systematic method to assess programs like S2T2 is needed, including identifying a way that S2T2 can take experienced teams, review care, correlate, and implement feedback into the program; currently, this is challenging due to not having a deployment care registry.



## APPENDIX F. COMPARISON OF FACILITY INTRASTRUCTURE MODELS WITHIN THE VETERANS HEALTH ADMINISTRATION AND CIVILIAN HEALTHCARE SYSTEM

### F.1 INTRODUCTION

This appendix examines the surgical volume issue from the perspectives of a governmental agency outside of the DoD and a large civilian healthcare system. Specifically, the appendix will review Veterans Health Administration (VHA) policies and practices, focusing on Operative Complexity Directives (VHA 2010-018<sup>95</sup> and VHA 2011-037<sup>150</sup>) which delineate facility infrastructure requirements, as well as the policies and practices of Kaiser Permanente.

The VHA is a large integrated health care system, providing care at 1,243 health care facilities, including 172 medical centers and 1,062 outpatient clinics of varying complexity, serving 9 million enrolled veterans each year.<sup>151</sup> Kaiser Permanente is a large not-for-profit health plan, serving 12.2 million members.<sup>152</sup> In comparison, the MHS serves over 9.4 million beneficiaries, including 1.4 million active duty and 331,000 Reserve Component personnel.<sup>1</sup> Due to the similar size and complexity of each of these integrated health care institutions, comparison to assess their approaches to the surgical volume and outcomes issue is deemed useful to inform and evaluate this issue and may identify best practices and policies.

This appendix will explicitly examine the facility infrastructure requirements for specific surgical procedures as developed within the VHA and the applicability for the MHS to implement such directives. Additionally, it will also examine current practices within Kaiser Permanente that may be transferable to the MHS beneficiary population.

Specifically, appendix F addresses the following objectives in the Terms of Reference (TOR):

- Develop recommendations to advance standardized policies on managing facility infrastructure capabilities and individual surgeon/supporting staff proficiency across all Service branches; and
- Evaluate potential MHS applicability of Veterans Health Administration (VHA) Operative Complexity Directives:
  - “*Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*” (VHA 2010-018)<sup>95</sup>
  - “*Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center*” (VHA 2011-037)<sup>150</sup>

### VETERANS HEALTH ADMINISTRATION DEVELOPMENT OF THE SURGICAL COMPLEXITY INITIATIVE

The Veterans Administration Health-Care Amendments of 1985 required the Secretary of the VA to maintain a quality assurance program to monitor and evaluate quality of healthcare provided by the VA. To meet this mandate, the VHA established the Veterans Affairs Surgical Quality Improvement Program (VASQIP) and the Continuous Improvement on Cardiac Surgery Program (CICSP).<sup>153</sup> The VHA first adopted facility complexity models in 1989.<sup>154</sup> Following





the 1996 reorganization, the VHA made a major institutional commitment to improve quality of care provided to veterans by building a nationwide electronic medical record system.<sup>155</sup> The EHR has facilitated the development of a performance measurement and feedback system that evaluates a variety of quality-of-care indicators such as access to care, adherence to evidence based guidelines, and both medical and surgical outcomes.<sup>155</sup> Moreover, these efforts focus on care that veterans obtain within the VHA system.

As shown in Appendix B.2, much of the research done in the civilian healthcare environment found patient outcomes are often associated with facility volume. Results are similar for the VHA patient population, as suggested in the aforementioned 2007 study. Furthermore, with a basic aim of effective and efficient healthcare to ensure the right match between the patient's condition and the setting for the patient's care that includes far more factors than the frequency of cases and extends to include such things as pre- and post-operative care, radiological capabilities, etc., the VA implemented the Surgical Complexity Initiative in 2010 to further improve the safety and quality of care for Veterans.<sup>31</sup> This was the first national effort to align the complexity of surgical procedures performed by a VHA facility with a facility's demonstrated infrastructure to ensure that VHA surgical programs practice within the scope of their available resources.

The initiative was developed in response to 2007 patient incidents at a VHA facility where performance of surgical procedures were conducted without the necessary supporting infrastructure, a factor that goes far beyond an overly simplistic assumption that volume alone is a causative factor. In 2007, the National Surgical Quality Improvement Program (NSQIP) identified a mortality rate over four times the expected rate as calculated by VHA during the first two quarters of 2007 at one VHA medical center.<sup>30</sup> The Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) concluded that there were specific problems of quality of care including pre-operative, intra-operative, and post-operative care for veteran patients.<sup>30</sup> The review also concluded that independent of physician expertise, the availability of support services may limit where certain operations should be performed.<sup>30</sup> Thus, the VHA took three steps to address the issue.

- (1) Develop two matrices. The Procedure Infrastructure Matrix designated the infrastructure requirements for a VHA facility with an inpatient surgical program as one of three levels: standard, intermediate, or complex; and the Surgical Complexity Matrix used the same designations to categorize surgical procedures based on Current Procedural Terminology (CPT) code.
- (2) Delineate the structural framework for nationwide implementation and monitoring. The Veterans Integrated Services Network (VISN) Surgical Workgroup was established in each of the VA's 21 VISNs (regional networks) and created 16 Surgical Advisory Boards composed of more than 90 subject-matter experts from key disciplines (such as cardiothoracic surgery, neurosurgery, transplant surgery).
- (3) Publish the *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures* (VHA 2010-018) policy to require each VHA medical facility with an inpatient surgical program to have an infrastructure-based surgical complexity designation. The designations are as follows:



- a) Standard facilities provide surgical procedures characterized as having minimal risk, such as breast biopsies, appendectomies, and hernia repair.
- b) Intermediate facilities provide more advanced procedures, such as gastric resections, prostatectomies, hip replacements, and spine surgery.
- c) Complex facilities provide procedures such as cardiac surgery, neurosurgery, complex thoracic procedures, and complex general surgery procedures.<sup>31</sup>

Each VHA facility is responsible for ensuring that scheduled, non-emergent surgical procedures do not exceed their infrastructure capabilities. Of note, the directive was designed to not interfere with either a surgeon's judgement in performing a surgical procedure beyond the surgical complexity designation of the facility, based upon new findings at the time of a planned procedure, or in managing an emergency condition where the patient's best interest is served by care and treatment on-site rather than being transferred to a more complex facility.<sup>31</sup>

Additionally, the CPT look-up tool, accessed via the intranet, provides an internal quality improvement mechanism. These CPT codes are reviewed annually to ensure accuracy.<sup>13</sup> Some of these processes have also been adopted by civilian healthcare systems.<sup>13</sup>

To ensure the VHA Directive CPT codes and that procedures were conducted at facilities that could support such procedures, the VA OHI performed a review of facility infrastructure capabilities with complex surgical procedures. The OHI conducted a 2011 retrospective review of intermediate and complex surgical procedures performed at VHA facilities and non-VHA facilities through fee basis arrangements prior to the release of VHA Directive 2010-018 on facility infrastructure.<sup>156</sup> It identified seven procedures as high-risk surgeries, identified because of an association with an increased risk for complications or death.<sup>151</sup> These procedures were identified as intermediate or complex and included:

- Aortic aneurysm surgery
- Colectomy
- Craniotomy
- Esophagostomy
- Open heart surgery
- Pancreatectomy
- Pneumonectomy

VHA facility infrastructure designations (standard, intermediate, or complex) were compared to surgical procedures performed at each facility during the OHI review in addition to review of outcomes for patients whose procedures were performed at VHA facilities with infrastructure designations less complex than would have been required by VHA Directive 2010-018 had it already been in place.<sup>156</sup> The review found that all procedures examined were performed at complex or intermediate facilities, with no adverse outcomes influenced by the facility infrastructure.<sup>156</sup> Additionally, fee basis facilities<sup>vi</sup> that performed esophagostomy, pancreatectomy, and pneumonectomy procedures were examined to determine if the infrastructure provided by the fee basis provided was comparable or exceeded that required for

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<sup>vi</sup> If a service cannot be provided in a timely manner due to capability, capacity, or accessibility, the service may, with approval, be provided outside of the VA through a fee basis.



VHA infrastructure. Nearly all of the procedures were performed at a Level I or II trauma designated facility or a cancer center (one pancreatectomy was not due to emergency surgery requirement and one pneumonectomy was not but was found to have no adverse outcomes). The review found that the complex surgeries identified in the review were supported by the infrastructure at VHA facilities, as were referrals to non-VHA facilities, meaning the VHA had successfully implemented a system to ensure procedures were conducted at facilities that could support such surgeries.<sup>156</sup>

**FACILITY INFRASTRUCTURE REQUIREMENTS TO PERFORM STANDARD, INTERMEDIATE, OR COMPLEX SURGICAL PROCEDURES**

The 2010 *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures* (VHA 2010-018, see Attachment Two) was “intended to establish policy and guidance regarding the infrastructure requirements for VHA facilities providing in-house surgical services in relationship to the complexity of surgical procedures being performed as well as the method for monitoring compliance.”<sup>95</sup> Regarding the procedure infrastructure matrix, VHA 2010-018 states “VHA facilities with an inpatient Surgical Program must have a written plan or policy for the safe and timely transfer of the patient who requires treatment or therapy which the facility is unable to provide or perform. Every effort must be made to medically stabilize the patient prior to a transfer, a process which may include the timely performance of a surgical procedure beyond the scope of the facility’s surgical complexity designation.”<sup>95</sup> A visual framework sample for the classifications of surgical procedures to operative complexity is shown in Figure 15. It should be noted that this VHA Directive expired May 31, 2015. However, published directives remain active until replaced and/or rescinded. The VHA is currently working on a concurrent draft for developing a combined specialty care complexity policy for invasive procedures in and out of the operating room.<sup>13</sup>

**Figure 15.** Sample of the VHA Directive 2010-018 Surgical Complexity Matrix<sup>95</sup>

Operative Category	Standard	Intermediate	Complex
Vascular - Intermediate		Carotid endarterectomy; Carotid subclavian bypass; Upper extremity graft or prosthesis, bypass or interposition; Lower extremity graft or prosthesis, bypass, or interposition; Infrarenal aortic surgery, bypass, or interposition, open or endovascular; Aortic renal or mesenteric, bypass, or interposition; Carotid or peripheral endovascular intervention; Venous surgery	
Vascular - Complex			Thoracoabdominal aortic reconstruction; suprarenal aortic reconstruction
Vascular Access	Central venous access; arteriovenous fistula, primary or graft		

*Note: Only samplings of surgical procedures are identified by surgical specialty.*

Together, in May 2015, Johns Hopkins Health System, Dartmouth-Hitchcock Medical Center, and University of Michigan Health System adopted 10 procedures believed to have the strongest



link between hospital volume and patient mortality as part of their Volume Pledge to establish annual volume minimum thresholds.<sup>28</sup> However, according to the standards developed by the VHA for surgical complexity, half of the 10 procedures identified in the Volume Pledge would be considered standard or intermediate, not complex.<sup>vii</sup> The allocation of patients and coding errors would improve with standardization of definitions that encompass not only the diagnosis but also the capabilities required in the treating facility to include not only professional skill and competence but also infrastructure capabilities.

## FACILITY INFRASTRUCTURE REQUIREMENTS TO PERFORM INVASIVE PROCEDURES IN AN AMBULATORY SURGERY CENTER

The 2011 *Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center* (VHA 2011-037, see Attachment Three) directive established “policy and procedures regarding the infrastructure requirements for VHA facilities providing surgical services in an Ambulatory Surgery Center (ASC) in relationship to the complexity of the surgical procedures being performed, as well as the method for monitoring compliance.” VHA 2011-037 does not impact or supersede VHA 2010-018.<sup>150</sup> The 2010 VHA Directive (VHA 2010-018) was established for inpatient VHA surgical procedures; however, approximately 80% of all surgical procedures performed by VHA facilities are done on the same day or on an outpatient basis. Thus, the VHA planned to expand the number of free standing ASCs. Each of these medical facilities must possess a surgical complexity designation of either basic or advanced, based on the facility’s infrastructure and by policy only perform surgical procedures that do not exceed the infrastructure capabilities of the facility.<sup>150</sup>

VHA facilities with ASC “must have a written plan or policy for the safe and timely transfer of a patient who requires treatment or therapy which the facility is unable to provide or perform. Every effort must be made to select appropriate patients who are suitable to have their procedure performed in an ASC.”<sup>150</sup> Furthermore, patients must be discharged from the ASC or transferred to a facility with 24 hour observation and inpatient surgical services. A visual framework sample for the classifications of surgical procedures to operative complexity is shown in Figure 16. It should be noted that this VHA Directive expired October 31, 2016.

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<sup>vii</sup> Standard or intermediate: lung cancer resection, rectal cancer resection, carotid artery stenting, knee replacement, and hip replacement

Complex: esophageal cancer resection, pancreatic cancer resection, complex abdominal aortic aneurysm, mitral valve repair, and bariatric staple surgery



**Figure 16.** Sample of the VHA Directive 2011-037 Ambulatory Surgery Complexity Matrix<sup>150</sup>

Procedure Category	Basic	Advanced
Amputation - Basic	Amputation, upper extremity, forearm, hand or digit; lower extremity, foot and digit	
Breast - Basic	Aspiration, cyst; drainage, abscess; biopsy or excision, breast lesion	
Breast - Advanced	Mastectomy	
Ear, Nose, and Throat (ENT) - Basic	Biopsy, soft tissue lesion or lymph node, head and neck; Biopsy throat; Excision, intranasal polyps or lesions or turbinates; septoplasty; repair of nasal defects; treatment of nasal fractures; treatment of nosebleeds; sinus surgery; nasal or sinus endoscopy with biopsy, polypectomy, debridement; laryngoscopy with biopsy or foreign body removal; drainage, biopsy, excision, repair of lip or mouth or tongue or gum or salivary, submaxillary, sublingual glands or external ear; excision neck cyst; construction of tracheoesophageal fistula for speech prosthesis; cleft lip repair; partial thyroidectomy; mastoidectomy; reconstruction of the external ear; tympanic membrane repair; myringoplasty	
ENT - Advanced	Drainage, deep abscess, neck; radiofrequency ablation base of tongue; sinus surgery--obliteration; palate reconstruction; oral vestibuloplasty-posterior; hemiglossectomy; uvulopalatopharyngoplasty; radical parotidectomy	
Eye - Basic	Blepharoplasty, corneal biopsy, cataract removal with lens insertion, vitrectomy, repair of ectropion	
Eye - Advanced	Enucleation of eye, insertion of ocular implant, repair of retinal detachment, strabismus surgery	
Facial - Basic	Treatment of nasal fracture, closed	
Facial - Advanced	Arthroscopy, Temporomandibular Joint and Muscle Disorders (TMJ); excision of tumor, benign or malignant, facial bones; preparation, facial prosthesis; Maxillofacial fixation; repair or revision or reconstruction, facial bones; Treatment of nasal fracture, open; treatment of complex fracture, nasal or maxillary or zygomatic arch or orbit, open or closed; Treatment of fracture,	

*Note: Only samplings of surgical procedures are identified by surgical specialty.*

## F.2 APPLICABILITY OF THE VHA FACILITY INFRASTRUCTURE MODELS

The National Surgery Office (NSO) is responsible for operational oversight and policy related to the VHA surgical programs, including outcomes data production and analysis. In 2009, the NSO underwent reorganization to enhance communication with the VISN and VHA facility leadership to enhance resources and develop and implement the VHA facility infrastructure policy for matching to surgical procedure complexity.<sup>153</sup> The NSO reviews outcomes data annually for coding assignments and confirmations in addition to reviewing comments from the field.<sup>13</sup> Additionally, a mechanism for evaluating patient and volume outcomes, root cause analysis and peer review could serve as proxies for quality in lieu of volume, as explained in Appendix D of this report.

To examine the implications of surgical complexity as defined by VHA 2010-018 in the civilian healthcare environment, a retrospective 2014 study examined 200 hospitals in Florida with 2009 data.<sup>157</sup> Hospitals were organized into quartiles based upon the number of complex surgical



procedures performed in each hospital to create a base analytic framework. Authors identified all discharges with a primary surgical procedure as standard, intermediate, or complex based on the *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures* matrix.<sup>157</sup>

Of the 2.5 million discharges from the sample year, 41% of the discharges involved no procedure and 18% involved non-surgical procedures.<sup>157</sup> Further, of the surgical procedures discharges, 14% were standard level, 20% intermediate level, and 5% in the complex level.<sup>viii</sup> Although complex surgeries represented only 5% of total discharges in Florida in 2009, authors found that they were highly concentrated and disproportionate even to the relative concentration of total discharges.<sup>157</sup> Additionally, there is a hierarchy of regionalization. Certain complex procedures are performed only in hospitals that are functionally able to achieve complex surgery volume thresholds. This leads to the overall composition of complex surgery caseload varying among hospitals as volume increases. Authors concluded that regionalization efforts in Florida are generally allocating complex surgeries among hospitals consistent with its facility capabilities.<sup>157</sup> Second, low-volume hospitals operating within the range of complex procedures appropriate to their capabilities were found to provide no increased risk of post-surgical mortality.<sup>157</sup> These practices highlight the importance of not inappropriately oversimplifying the issue as one of volume alone but instead addressing the systems-based factors that are responsible for patient outcomes.<sup>157</sup>

### F.3 CIVILIAN HEALTHCARE SECTOR VOLUME PERSPECTIVES

Civilian health care systems, such as Kaiser Permanente, use volume standards for physician referrals, patient care and quality, regulatory and accreditation requirements, and performance outcomes but does not only use volume in making decisions.<sup>29</sup>

Kaiser Permanente identifies two types of surgical procedures: 1) Those that are performed at only specialized Kaiser Permanente medical centers; and 2) Surgeries that are considered “high-volume low-risk,” such as hysterectomies and circumcisions.<sup>29</sup> Those performed at only specific medical centers are considered “low-volume high-risk” and may require expensive, specialized equipment. “High-volume low-risk surgical” procedures are usually performed at all Kaiser Permanente hospitals with generally low complications.<sup>29</sup>

In addition to volume, Kaiser Permanente considers other factors for addressing low-volume surgeons and surgeries. For example, it acknowledges member travel times, membership growth projections, hospital capacity, including the ability of a hospital to absorb patients, with consideration of operating room time, inpatient beds, intensive care unit beds, pathology, radiology, as well as surgeon satisfaction, recruitment of new surgeons, and workforce planning.<sup>29</sup> Some specialists, such as urologists, due to their specialty and need for robotic equipment, travel to other hospitals within the region to perform surgeries in higher volumes, while other surgeons are paired with high volume surgeons.<sup>29</sup>

Kaiser Permanente addresses quality outcomes through simulation, systematic optimization of

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<sup>viii</sup> Authors note that complex surgical procedures occur infrequently and therefore represent a low volume overall so that in the highest volume hospitals, some procedures will be performed a modest number of times.



patient pre-operation, peer review methods, review of surgical techniques through recordings, and a balanced distribution of complex cases to low and high volume hospitals and surgeons.<sup>29</sup> Additionally, Kaiser Permanente recognizes that flexibility in implementing volume recommendations is needed and it may be unnecessary to impose strict thresholds below which surgeons must stop performing a procedure or increase annual procedure volumes.<sup>130</sup> Using surgeon volume and outcomes data from Kaiser Permanente Southern California and Kaiser Permanente Northern California, a study was conducted using the concentration curve methodology to depict the relationship between surgeon procedure volumes and outcomes. The strength of this method is that it does not identify discrete volume thresholds for procedures like many other articles examining this area. Rather, the analysis was used as a foundation for facilitating conversations about surgeon volume.<sup>130</sup>

Questions remain around the complexity of creating policies for minimum volumes of surgeries dependent on the context of the practice and the continuous nature of the relationship between surgical volume and quality outcomes, rather than discrete intervals, should be considered in such policies and standards. Ultimately, every civilian healthcare system is uniquely structured and operates to serve its dynamic patient population and geographic region.

#### F.4 OBSERVATIONS

The VHA facility infrastructure model creates a standardized approach to managing surgical programs across VA medical facilities as well as its adoption into the civilian healthcare environment. The following observations are made:

- (1) The VHA system takes a more sophisticated approach than simply looking at volume alone. It looks at the entire facility capability including such factors as infrastructure and overall personnel training and competence in relation to the needs of the patient.
- (2) There is a vast difference between standard and intermediate operative complexity primarily due to the robust infrastructure, including the use of consultants, telehealth, and ICU at the intermediate level. Furthermore, the standard operative category surgical programs tend to reside in rural VHA facilities and not be affiliated with academic institutions for training.<sup>13</sup>
- (3) The majority of medical residents practice within intermediate and complex programs. Thus, the impact on surgical training is minimum when imposing an enterprise-wide surgical complexity directive.<sup>13</sup>
- (4) The VA utilizes partnerships with academic institutions; many VA clinicians also have academic appointments.
- (5) Partnerships between MHS, VHA, and civilian healthcare enterprises may optimize best practices, patient allocation, and resource sharing to better address volume issues, regionalization, and training opportunities.
- (6) Robust quality systems, including a mechanism for evaluating safety mishap events when they occur, are integral in VA's approach. The quality improvement approach is multi-layered with a focus on infrastructure, root cause analysis, peer review, and NSQIP.
- (7) Ensuring a mechanism to identify procedure complexity by CPT code and tracking facilities that exceed their designated level of complexity is integral in the VA's approach.



Further, the CPT look-up tool, accessed via the intranet, provides an internal quality improvement mechanism.

- (8) Half of the ten procedures identified in the Volume Pledge would be considered standard or intermediate, not complex, according to the VHA facility infrastructure directives. Standardizing definitions of surgical procedure complexities may improve the allocation of patients and reduce coding errors.
- (9) The VHA models focus on facility readiness.





## APPENDIX G: TERMS OF REFERENCE

These terms of reference establish the objectives for the Defense Health Board (DHB) review of the policies related to performance of complex surgical procedures within the Military Health System (MHS), the risks and mitigation strategies employed to ensure safe, high-quality, efficacious patient care, and the contribution of these procedures to military medical readiness. Specifically, I request the DHB, through the Trauma and Injury Subcommittee, address and develop findings and recommendations.

**Mission Statement:** The mission of the DHB is to provide independent advice and recommendations to maximize the safety and quality of, as well as access to, health care for members of the Armed Forces and other Department of Defense (DoD) beneficiaries.

**Issue Statement:** Research such as that presented in the 2015 U.S. News and World Report story “Risks Are High at Low-Volume Hospitals<sup>ix</sup>” suggests that patient outcomes are poorer when complex high-risk surgeries such as joint replacements are performed by surgeons who rarely perform such surgeries, in comparison to the same surgery performed by physicians/teams at hospitals where the surgeries are frequently performed using established protocols.

Several large medical systems, including the Johns Hopkins Health System, the University of Michigan Health System, and Dartmouth-Hitchcock Medical Center have recently pledged that their hospitals and surgical staff will meet a minimum annual volume of complex high-risk surgeries as a way of ensuring patient safety. The healthcare community is divided on the value of such an approach, as it suggests that such surgeries can only be safely performed in large urban medical centers, and may create a priori distrust of small and/or rural hospitals.

The MHS provides a broad array of medical services to Service members and their beneficiaries through both direct care Military Treatment Facilities (i.e., MTFs) and purchased care through TRICARE networks. To meet patient needs, some MTFs currently perform low-volume high-risk surgeries. For patient safety, it is important for the MHS to understand whether there are increased risks associated with low-volume surgery, and to develop policies and methods to prevent and mitigate such risks.

Many MHS facilities perform complex surgeries in low volumes, despite evidence that lower quality outcomes are associated with low-volume, high-complexity surgery. This presents a potential risk to patient safety and the MHS’s reputation for providing safe, high-quality care. There may also be a perception that military medical readiness requirements are driving the MHS to perform low-volume, high-risk procedures to build that readiness in ways that expose patients to elevated risk. It is also unclear to what extent shifting of high-complexity procedures to the purchased-care system, where civilian facilities may likewise perform complex surgeries in low volumes, may place patients at risk. A high-level, independent review of MHS practices in this area is likely to help improve both the safety and quality of MHS care and the confidence of patients in that care. By addressing these issues proactively, the MHS can maintain and enhance the trust of its patients.

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<sup>ix</sup> <https://www.usnews.com/news/articles/2015/05/19/hospitals-move-to-limit-low-volume-surgeries>



## **Objectives and Scope:**

As priority effort, the Trauma and Injury Subcommittee should:

- Review the array of low-volume high-risk surgical procedures performed by military surgeons in the Direct Care system (MTFs).
- Evaluate policies, protocols, and systems for managing facility surgical capabilities and surgeon/staff proficiency across each of the service branches.
- Develop recommendations to advance standardized policies on managing facility infrastructure capabilities and individual surgeon / supporting staff proficiency across all service branches.
- Evaluate potential MHS applicability of Veterans Health Administration (VHA) Operative Complexity Directives:
  - “Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures” (VHA 2010-018<sup>x</sup>)
  - “Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center” (VHA 2011-037<sup>xi</sup>)
- Examine the contribution (Knowledge, Skills, and Abilities) of low-volume high-risk procedures to military medical readiness (e.g., surgeons, operating room staff).
- Evaluate MHS policies related to surgical volume transparency and public release of volume, errors and outcomes data.
- Provide recommendations on using the volume, errors and outcome data to inform and enhance policies for managing surgical capabilities and surgeon currency.

As secondary effort, the Trauma and Injury Subcommittee should:

- Review the array of low-volume high-risk surgical procedures performed on MHS beneficiaries in the Purchased Care system (TRICARE).
- Evaluate potential for the MHS to sign on to the “Surgical Volume Pledge” agreed to by Dartmouth-Hitchcock Medical Center, Johns Hopkins Medicine, and the University of Michigan<sup>xii</sup>.

## **Methodology:**

1. Trauma and Injury Subcommittee’s assessment will be conducted in compliance with the Federal Advisory Committee Act, Department of Defense Instruction 5105 and the DHB’s Charter.
2. The Trauma and Injury Subcommittee’s assessment should focus on improving the policies and practices currently in place to (1) determine where high-risk surgical procedures should be performed and (2) optimize the safety and quality of surgical care provided.

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<sup>x</sup> [http://www.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=2227](http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2227)

<sup>xi</sup> [http://www.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=2452](http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2452)

<sup>xii</sup> <http://www.nejm.org/doi/full/10.1056/NEJMp1508472>.



3. The Trauma and Injury Subcommittee may conduct interviews and site visits as appropriate.
4. As appropriate, the Trauma and Injury Subcommittee may seek input from other sources with pertinent knowledge or experience.

**Deliverables:** The Trauma and Injury Subcommittee will complete all phases of its work within one year of receiving the tasking. Primary effort will be priorities for completion within six months of receiving the tasking. Primary effort will be related to Direct Care (MTF) areas of review while secondary effort will focus on Purchased Care (TRICARE) review. The Trauma and Injury Subcommittee will, in accordance with its Charter, report to the Assistant Secretary of Defense for Health Affairs, who has been delegated the authority to evaluate the independent advice and recommendation received from the Trauma and Injury Subcommittee and evaluate, in consultation with the USD (P&R), what actions or policy adjustments should be made by DoD in response. Progress updates will be provided at each Board meeting.

**Required Support:**

1. The Defense Health Board Support Division will provide any necessary research, analytical, administrative, and logistical support for the Trauma and Injury Subcommittee.
2. Funding for this review is included in the division's operating budget.



## APPENDIX H. MEETINGS AND PRESENTATIONS

### **April 17, 2018 – Trauma and Injury Subcommittee Teleconference**

Members reviewed the tasking, discussed suggested briefers, discussed the timeline and report outline.

### **May 30, 2018 – Trauma and Injury Subcommittee Teleconference**

Members received an overview of the issue of low-volume, high-risk surgical procedures within the Military Health System (MHS) and reviewed the data for the ten surgical procedures identified by the Volume Pledge as low-volume high-risk surgical procedures.

Subject matter experts in attendance included:

- Dr. Paul Cordts, Deputy Assistant Director, Strategy, Plans, and Functional Integration, J-5, Defense Health Agency (DHA)
- Mr. Steve Hill, Senior Advisor, program analysis and strategic communication support to J-5, DHA

### **June 20-21, 2018 – Trauma and Injury Subcommittee Meeting**

Falls Church, VA

Members received an overview from the Services and DHA on the current state of affairs regarding surgical volume and readiness, a briefing on the MHS Modernization study, the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP), and the Combat Casualty Care Knowledge, Skills, and Abilities (KSA) Program.

Subject matter experts in attendance included:

- Col Jeffery Bailey, Director of Surgery, Walter Reed National Military Center, and Professor of Surgery, Uniformed Services University
- CDR David Barrows, Action Officer, Office of the Chief Medical Officer, Bureau of Medicine and Surgery
- Col Michael Charlton, Division Chief, Defense Medical Readiness Training Institute (DMRTI)
- Maj Amanda Davis, Action Officer, Air Force Medical Operations Agency (AFMOA)
- Dr. Paul Doan, Chief of Specialty Care Support Office, DHA
- CAPT Christine Dorr, Deputy Assistant Chief for Healthcare Operations, Bureau of Medicine and Surgery
- Lt Col Peter Learn, Chair, DoD NSQIP Steering Panel, and Associate Chair of Surgery for Quality and Outcomes, Uniformed Services University
- Ms. Patti Lederer, Surgical Quality Assurance, Medical Affairs (J-3), Clinical Support Division, DHA
- CAPT Jamie Lindly, Chief, Decision Support Division, DHA
- CAPT Andrew Plummer, Chief, Advanced Clinical Analytics for Quality Management within Healthcare Operations, DHA
- Mr. Frank Salazar, 3SL Analyst Health System Specialist, MEDCOM



- Col James (Jay) Sampson, Chief Surgical Consultant to the Air Force Surgeon General (SG), AFMOA
- LTC Cleve Sylvester, Chief, Surgical Services Service Line (3SL), OTSG/MEDCOM
- Lt Col Richard Zavadil, Action Officer, AFMOA

### **June 29, 2018 – Trauma and Injury Subcommittee Teleconference**

Members reviewed sections of the draft report. There were no briefings on this teleconference.

### **July 9, 2018 – Trauma and Injury Subcommittee Teleconference**

Members reviewed sections of the draft report. There were no briefings on this teleconference.

### **July 18-19, 2018 – Trauma and Injury Subcommittee Teleconferences**

Members received an overview of the volume-quality relationship, the Veterans Health Administration (VHA) infrastructure model, and the KSA program.

Subject matter experts in attendance included:

- Col Jeffery Bailey, Director of Surgery, Walter Reed National Military Center, and Professor of Surgery, Uniformed Services University
- CAPT Eric Elster, Chairman, Department of Surgery, University Services University of the Health Sciences and Walter Reed National Military Medical Center (WRNMMC)
- Dr. William Gunnar, National Director of Surgery, VHA
- Dr. Edward Livingston, Deputy Editor for Clinical Content for the Journal of the American Medical Association (JAMA)

Members also reviewed sections of the draft report.

### **July 30, 2018 – Trauma and Injury Subcommittee Teleconference**

Members reviewed sections of the draft report. There were no briefings on this teleconference.

### **August 6, 2018 – Trauma and Injury Subcommittee Teleconference**

Members received an overview of low-volume high-risk issue from a civilian systems perspective.

Subject matter expert in attendance included:

- Dr. Donald Berwick, President Emeritus and Senior Fellow, Institute for Healthcare Improvement (IHI)

### **August 14, 2018 – Trauma and Injury Subcommittee Teleconference**

Members reviewed sections of the draft report. There were no briefings on this teleconference.



**August 27, 2018 – Defense Health Board Meeting**  
San Diego, CA

The Trauma and Injury Subcommittee Chair provided a tasking update to Board members.

**August 28-29, 2018 – Trauma and Injury Subcommittee Meeting**  
San Diego, CA

Members joined Board members for a site-visit to Strategic Operations, Inc. for observation of the pre-deployment Fleet Surgical Team Shipboard Surgical Trauma Training (S2T2). Members then received an overview of the Chief Medical Officer (CMO) perspective and Navy surgeon's perspective on surgical volumes.

Subject matter experts in attendance included:

- Col Michael Charlton, Division Chief, DMRTI, DHA
- CAPT Christopher Chisholm, CMO, NMCS
- Dr. Mitchell Cohen, Director of Surgery, Denver Health Medical Center, and Professor of Surgery, University of Colorado School of Medicine
- CDR Ian Fowler, Director of Surgical Services, NMCS
- Dr. Reginald Franciose, Trauma Surgeon, Vail Health
- CAPT Richard Green, Director of Professional Education, NMCS
- CAPT Tuan Hoang, S2T2 Director for Commander, Surface Forces Pacific
- Dr. Matthew Pena, Anesthesiologist and Assistant Professor, University of California Davis

**September 11, 2018 – Trauma and Injury Subcommittee Teleconference**

Members received an overview of the low-volume perspective from the civilian health system.

Subject matter expert in attendance included:

- Dr. Michael Kanter, Regional Medical Director of Quality & Clinical Analysis for the Southern California Permanente Medical Group, Executive Vice President and Chief of Quality Officer of the Permanente Federation, Associate Dean of Quality Science in the Kaiser Permanente School of Medicine

Members also reviewed sections of the draft report.

**September 13-14, 2018 – Trauma and Injury Subcommittee Teleconferences**

Members received an overview of the German healthcare system, the Johns Hopkins affiliation and application of the Volume Pledge, the Leapfrog Group Volume Standards, the Quadruple Aim Performance Plan (QPP), the MHS Strategic Partnership American College of Surgeons and the Clinical Readiness Program, the Dartmouth Hitchcock Volume Pledge, the TRICARE health plans and the use of MTFs, the DoD Patient Safety Program, and closed with the MHS Transparency Initiative.

Subject matter experts in attendance included:



- Dr. Matt Austin, Assistant Professor of Anesthesiology and Critical Care Medicine, Johns Hopkins University School of Medicine
- Dr. John Birkmeyer, Chief Clinical Officer, Sound Physicians
- Ms. Missy Danforth, Vice President of Health Care Ratings, Leapfrog Group
- CAPT Eric Elster, Chairman, Department of Surgery, USUHS, WRNMMC
- Dr. James Ficke, Professor of Orthopedic Surgery, Director of the Department of Orthopedic Surgery, Johns Hopkins School of Medicine
- LTC Danielle Holt, Chief of General Surgery, Walter Reed National Military Medical Center
- Dr. Peggy Knudson, Medical Director, Military Health System Strategic Partnership American College of Surgeons
- Lt Col Peter Learn, Associate Chair of Surgery for Quality and Patient Outcomes, Department of Surgery, Uniformed Services University of the Health Sciences
- COL Kyle Remick, Associate Chair, Trauma in the Department of Surgery, Uniformed Services University and Walter Reed National Military Medical Center
- Dr. Daniel Ross, Chief of the Patient Safety Program, DoD, DHA
- Col Kai Schlolaut, German Health Liaison Officer, Office of the Assistant Secretary of Defense Health Affairs (OASD [HA])
- CAPT Edward Simmer, Chief Clinical Officer for TRICARE and Health Plans, DHA
- Dr. Jill Sterling, Chief of the Integrated Clinical Quality Support Branch, Clinical Support Division of the DHA

### **September 21, 2018 – Trauma and Injury Subcommittee Teleconference**

Members received an overview of the Volume Pledge from the University of Michigan Healthcare System.

Subject matter expert in attendance included:

- Dr. Justin Dimick, Director, Center for Healthcare Outcomes & Policy, George D. Zuidema Professor of Surgery, Chief of the Division of Minimally Invasive Surgery, Associate Chair for Strategy & Finance, University of Michigan

### **September 24, 2018 – Trauma and Injury Subcommittee Teleconference**

Members received an overview of the DHA Coding Working Group and MHS coding efforts.

Subject matter experts in attendance included:

- Dr. Paul Doan, Chief of Specialty Care Support Office, DHA
- Ms. Michele Gowen, Medical Coding Program Manager, Patient Administration Office, Clinical Support Division, DHA

Members also reviewed sections of the draft report.

### **October 3, 2018 – Trauma and Injury Subcommittee Teleconference**

Members received an overview of medical readiness from the Joint Staff Surgeon perspective.



Subject matter expert in attendance included:

- RADM Colin Chinn, Joint Staff Surgeon, Joint Staff

Members also reviewed sections of the draft report.

#### **October 9, 2018 – Trauma and Injury Subcommittee Teleconference**

Members reviewed sections of the draft report. There were no briefings on this teleconference.

#### **October 15, 2018 – Trauma and Injury Subcommittee Teleconference**

Members received an overview of medical readiness from the DHA Director.

Subject matter expert in attendance included:

- VADM Raquel Bono, Director, DHA

Members also reviewed sections of the draft report.

#### **October 16, 2018 – Trauma and Injury Subcommittee Teleconference**

Members reviewed the draft report. There were no briefings on this teleconference.

#### **October 18, 2018 – Trauma and Injury Subcommittee Teleconference**

Members reviewed the draft report. There were no briefings on this teleconference.

#### **October 25, 2018 – Trauma and Injury Subcommittee Teleconference**

Members reviewed the draft report. There were no briefings on this teleconference.

#### **October 30, 2018 – Defense Health Board Meeting**

Falls Church, VA

The Trauma and Injury Subcommittee Chair provided a decision brief to Board members. Board members voted to approve the report and its findings and recommendations.





## APPENDIX I. ACRONYMS

AAA: Abdominal Aortic Aneurysm  
ABS: American Board of Surgery  
ACGME: Accreditation Council for Graduate Medical Education  
ACS: American College of Surgeons  
ACS-AEI: American College of Surgeons Accredited Educational Institutes  
AFB: Air Force Base  
AFMOA: Air Force Medical Operations Agency  
AHRQ: Agency for Healthcare Research and Quality  
AMSSP: Army Medical Department Medical Skills Sustainment Program  
AMEDD: Army Medical Department  
AOC: Advanced Operations Course  
ASC: Ambulatory Surgery Center  
ASD(HA): Assistant Secretary of Defense for Health Affairs  
ASSET<sup>®</sup>: Advanced Surgical Skills for Exposure in Trauma  
ATOM: Advanced Trauma Operative Management  
BAMC: Brooke Army Medical Center  
BUMED: Navy Bureau of Medicine and Surgery  
C3: Combat Casualty Care  
CAPE: Cost Assessment and Program Evaluation  
CAS: Carotid Artery Stenting  
CBRN: Chemical, Biological, Radiological, and Nuclear  
CCATT: Critical Care Training, Aeromedical Transport Training  
CICSP: Continuous Improvement on Cardiac Surgery Program  
CPG: Clinical Practice Guidelines  
CPT: Current Procedural Terminology  
CMO: Chief Medical Officer  
CMRP: Comprehensive Medical Readiness Program  
CMS: Centers for Medicare and Medicaid Services  
CO: Commanding Officers  
C-STARS: Center for Sustainment of Trauma and Readiness Skills  
CSA: Combat Support Agency  
CSC: Clinical Steering Communities  
CUSP: Comprehensive Unit-Based Safety Program  
DEROS: Date Estimated Return from Overseas  
DHA: Defense Health Agency  
DHB: Defense Health Board  
DMRTI: Defense Medical Readiness Training Institute  
DoD: Department of Defense  
DoDI: Depart of Defense Instruction  
DoD-REs: Department of Defense Reportable Events  
EHR: Electronic Health Records  
ER: Emergency Room  
ERSA: External Resource Sharing Agreements



EWS: Emergency War Surgery  
FBCH: Fort Belvoir Community Hospital  
FRSS: Forward Resuscitative Surgical System  
FTE: Full-Time Equivalent  
FST: Fleet Surgical Team  
FY: Fiscal Year  
GME: Graduate Medical Education  
HA: Health Affairs  
HEDIS: Health Effectiveness Data and Information Set  
HRO: High Reliability Organization  
HROM: High Reliability Organization Operation Model  
ICT: Individual Critical Tasks  
ICU: Intensive Care Unit  
IHI: Institute for Healthcare Improvement  
IOM: Institute of Medicine  
ISS: Injury Severity Score  
IT: Information Technology  
JAMA: Journal of the American of Medical Association  
JCCQAS: Joint Centralized Credentials Quality Assurance System  
JPSR: Joint Patient Safety Report System  
JTETD: Joint Trauma Education Directorate  
JTS: Joint Trauma System  
JTTR: Joint Theater Trauma Registry  
JTTS: Joint Theater Trauma System  
JV: Joint Ventures  
KSA: Knowledge, Skills, and Abilities  
M2: MHS GENESIS and MHS Managements Analysis and Reporting Tool  
MBSAQIP: Bariatric Surgery Accreditation and Quality Improvement Program  
MDG: Medical Group  
MHS: Military Health System  
MILDEP: Military Departments  
Military Services: Army, Navy, and Air Force  
MOC<sup>2</sup>: Maintenance of Currency and Competency  
MOS: Military Occupation Specialties  
MOU: Memoranda of Understanding  
MQA: Medical Quality Assurance  
MTF: Military Medical Treatment Facilities  
MRT: Medical Readiness Training  
NAM: National Academies of Medicine  
NCR-MD: National Capital Region-Medical Directorate  
NHRC: Naval Health Research Center  
NMCSO: Naval Medical Center San Diego  
NDAA: National Defense Authorization Act  
NDAA FY 2017: National Defense Authorization Act for Fiscal Year 2017  
NDAA FY 2018: National Defense Authorization Act for Fiscal Year 2018  
NHCP: Naval Hospital Camp Pendleton



NIS: Nationwide Inpatient Sample  
NP: Nurse Practitioner  
NPSF: National Patient Safety Foundation  
NSO: National Surgery Office  
NSQIP: National Surgical Quality Improvement Program  
NTDB: National Trauma Data Bank  
OASD(HA): Office of the Assistant Secretary of Defense Health Affairs  
OEF/OIF: Operation Enduring Freedom and Operation Iraqi Freedom  
OIG: Office of Inspector General  
OGC: Office of General Counsel  
OHI: Office of Healthcare Inspections  
OR: Operating Room  
P4I: Partnership for Improvement  
PA: Physician Assistants  
PACFLT: U.S. Navy Pacific Fleet  
PDASD(HA): Principal Deputy Assistant Secretary of Defense for Health Affairs  
PI: Procedural Instruction  
PTSD: Post-Traumatic Stress Disorder  
PSAC: Patient Safety Analysis Center  
PSP: Patient Safety Program  
QPP: Quadruple Aim Performance Plan  
RN: Registered Nurse  
ROFR: Right of First Refusal  
S2T2: Shipboard Surgical Trauma Training  
SAR: Semiannual Report  
SEER: Surveillance, Epidemiology, and End Results  
SCR: Surgical Case Reviewer  
SME: Subject Matter Expert  
SOP: Standard Operating Procedure  
SQUAD: Safety and Quality Uniform Analytics Dashboard  
STP: Shock Trauma Platoon  
TAA: Training Affiliation Agreements  
TeamSTEPPS<sup>®</sup>: Team Strategies and Tools to Enhance Performance and Patient Safety  
TCCC: Tactical Combat Casualty Care  
THA: Total Hip Arthroplasty  
TIG: Transparency Initiative Group  
TJC: The Joint Commission  
TKA: Total Knee Arthroplasty  
TOR: Terms of Reference  
TQIP: Trauma Quality Improvement Program  
TRICARE: Military Health System purchased care system  
TRISS: Trauma and Injury Severity Score  
TXA: Tranexamic Acid  
UMC: University Medical Center of Southern Nevada  
USD(P&R): Secretary of Defense Personnel and Readiness  
USUHS: Uniformed Services University of the Health Sciences



UTC: Unit Training Code

VA: Department of Veterans Affairs

VASQIP: Veterans Affairs Surgical Quality Improvement Program

VHA: Veterans Health Administration

VISN: Veterans Integrated Services Network

VTE: Venous Thromboembolism

WRNMMC: Walter Reed National Military Medical Center



## APPENDIX J. DEFENSE HEALTH BOARD SUPPORT STAFF

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# ATTACHMENTS

## ATTACHMENT ONE: 2017 CPT CODES USED IN M2 DATA EXTRACTION



Scope: Esophagus CPTs (10a)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
43100	EXCISION OF ESOPHAGUS LESION	EXCISION OF LESION, ESOPHAGUS, WITH PRIMARY REPAIR; CERVICAL APPROACH
43101	EXCISION OF ESOPHAGUS LESION	EXCISION OF LESION, ESOPHAGUS, WITH PRIMARY REPAIR; THORACIC OR ABDOMINAL APPROACH
43107	REMOVAL OF ESOPHAGUS	TOTAL OR NEAR TOTAL ESOPHAGECTOMY, WITHOUT THORACOTOMY; WITH PHARYNGOGASTROSTOMY OR CERVICAL ESOPHAGOGASTROSTOMY, WITH OR WITHOUT PYLOROPLASTY (TRANSHIATAL)
43108	REMOVAL OF ESOPHAGUS	TOTAL OR NEAR TOTAL ESOPHAGECTOMY, WITHOUT THORACOTOMY; WITH COLON INTERPOSITION OR SMALL INTESTINE RECONSTRUCTION, INCLUDING INTESTINE MOBILIZATION, PREPARATION AND ANASTOMOSIS(ES)
43112	REMOVAL OF ESOPHAGUS	TOTAL OR NEAR TOTAL ESOPHAGECTOMY, WITH THORACOTOMY; WITH PHARYNGOGASTROSTOMY OR CERVICAL ESOPHAGOGASTROSTOMY, WITH OR WITHOUT PYLOROPLASTY
43113	REMOVAL OF ESOPHAGUS	TOTAL OR NEAR TOTAL ESOPHAGECTOMY, WITH THORACOTOMY; WITH COLON INTERPOSITION OR SMALL INTESTINE RECONSTRUCTION, INCLUDING INTESTINE MOBILIZATION, PREPARATION, AND ANASTOMOSIS(ES)
43116	PARTIAL REMOVAL OF ESOPHAGUS	PARTIAL ESOPHAGECTOMY, CERVICAL, WITH FREE INTESTINAL GRAFT, INCLUDING MICROVASCULAR ANASTOMOSIS, OBTAINING THE GRAFT AND INTESTINAL RECONSTRUCTION
43117	PARTIAL REMOVAL OF ESOPHAGUS	PARTIAL ESOPHAGECTOMY, DISTAL TWO-THIRDS, WITH THORACOTOMY AND SEPARATE ABDOMINAL INCISION, W W/O PROXIMAL GASTRECTOMY; WITH THORACIC ESOPHAGOGASTROSTOMY, W W/O PYLOROPLASTY (IVOR LEWIS)
43118	PARTIAL REMOVAL OF ESOPHAGUS	PARTIAL ESOPHAGECTOMY, DISTAL 2-3RDS, W THORACOTOMY&SEPARATE ABDOMINAL INCIS, WWO PROX GASTRECTOMY; W COLON INTERPSTN/SM INTSTINE RECONSTRUCTION, INCL INTSTINE MOBILIZATION, PREP,&ANASTOMOSIS(ES)
43121	PARTIAL REMOVAL OF ESOPHAGUS	PARTIAL ESOPHAGECTOMY, DISTAL TWO-THIRDS, WITH THORACOTOMY ONLY, WITH OR WITHOUT PROXIMAL GASTRECTOMY, WITH THORACIC ESOPHAGOGASTROSTOMY, WITH OR WITHOUT PYLOROPLASTY
43122	PARITAL REMOVAL OF ESOPHAGUS	PARTIAL ESOPHAGECTOMY, THORACOABDOMINAL OR ABDOMINAL APPROACH, WITH OR WITHOUT PROXIMAL GASTRECTOMY; WITH ESOPHAGOGASTROSTOMY, WITH OR WITHOUT PYLOROPLASTY



Scope: Esophagus CPTs (10a)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
43123	PARTIAL REMOVAL OF ESOPHAGUS	PARTIAL ESOPHAGECTOMY, THORACOABDOMINAL/ABDOMINAL APPROACH, WWO PROXIMAL GASTRECTOMY; W COLON INTERPOSITION/SM INTESTINE RECONSTRUCTION, INCLUDING INTESTINE MOBILIZATION, PREPARATION,&ANASTOMOSIS(ES)
43124	REMOVAL OF ESOPHAGUS	TOTAL OR PARTIAL ESOPHAGECTOMY, WITHOUT RECONSTRUCTION (ANY APPROACH), WITH CERVICAL ESOPHAGOSTOMY
43130	REMOVAL OF ESOPHAGUS POUCH	DIVERTICULECTOMY OF HYPOPHARYNX OR ESOPHAGUS, WITH OR WITHOUT MYOTOMY; CERVICAL APPROACH
43135	REMOVAL OF ESOPHAGUS POUCH	DIVERTICULECTOMY OF HYPOPHARYNX OR ESOPHAGUS, WITH OR WITHOUT MYOTOMY; THORACIC APPROACH
43289	LAPAROSCOPE PROC, ESOPH	UNLISTED LAPAROSCOPY PROCEDURE, ESOPHAGUS
43310	REPAIR OF ESOPHAGUS	ESOPHAGOPLASTY, (PLASTIC REPAIR OR RECONSTRUCTION), THORACIC APPROACH; WITHOUT REPAIR OF TRACHEOESOPHAGEAL FISTULA
43320	FUSE ESOPHAGUS & STOMACH	ESOPHAGOGASTROSTOMY (CARDIOPLASTY), WITH OR WITHOUT VAGOTOMY AND PYLOROPLASTY, TRANSABDOMINAL OR TRANSTHORACIC APPROACH
43360	GASTROINTESTINAL REPAIR	GASTROINTESTINAL RECONSTRUCTION FOR PREVIOUS ESOPHAGECTOMY, FOR OBSTRUCTING ESOPHAGEAL LESION OR FISTULA, OR FOR PREV ESOPHAGEAL EXCLUSION; STOMACH,W W/O PYLOROPLASTY
43361	GASTROINTESTINAL REPAIR	GASTROINTSTINAL RECONS, PREVIOUS ESOPHAGECTOMY, OBSTRUCTING ESOPHAG LES/FIST,/FOR PREVIOUS ESOPHAG EXCLUSION; W COLON INTERPSTN/SM INTSTINE RECONS, INCL INTSTINE MOBILIZATION, PREP,&ANASTOMOSIS(ES)
43415	REPAIR ESOPHAGUS WOUND	SUTURE OF ESOPHAGEAL WOUND OR INJURY; TRANSTHORACIC OR TRANSABDOMINAL APPROACH
43499	ESOPHAGUS SURGERY PROCEDURE	UNLISTED PROCEDURE, ESOPHAGUS





Scope: Lung CPTs (10b)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
32440	REMOVAL OF LUNG,PNEUMONECTOMY;	REMOVAL OF LUNG, PNEUMONECTOMY;
32442	REM,LNG,PNEUMON;SLEEVE PNEUMON	REMOVAL OF LUNG, PNEUMONECTOMY; WITH RESECTION OF SEGMENT OF TRACHEA FOLLOWED BY BRONCHO-TRACHEAL ANASTOMOSIS (SLEEVE PNEUMONECTOMY)
32445	REM,LUNG,PNEUMONECT;EXTRAPLEUR	REMOVAL OF LUNG, PNEUMONECTOMY; EXTRAPLEURAL
32480	LOBECTOMY	REMOVAL OF LUNG, OTHER THAN PNEUMONECTOMY; SINGLE LOBE (LOBECTOMY)
32482	BILOBECTOMY	REMOVAL OF LUNG, OTHER THAN PNEUMONECTOMY; 2 LOBES (BILOBECTOMY)
32484	SEGMENTECTOMY	REMOVAL OF LUNG, OTHER THAN PNEUMONECTOMY; SINGLE SEGMENT (SEGMENTECTOMY)
32486	SLEEVE LOBECTOMY	REMOVAL OF LUNG, OTHER THAN PNEUMONECTOMY; WITH CIRCUMFERENTIAL RESECTION OF SEGMENT OF BRONCHUS FOLLOWED BY BRONCHO-BRONCHIAL ANASTOMOSIS (SLEEVE LOBECTOMY)
32488	COMPLETION PNEUMONECTOMY	REMOVAL OF LUNG, OTHER THAN PNEUMONECTOMY; WITH ALL REMAINING LUNG FOLLOWING PREVIOUS REMOVAL OF A PORTION OF LUNG (COMPLETION PNEUMONECTOMY)
32491	REM,LNG,NOT PNEUM;RES-PLI,EMPH	REMOVAL OF LUNG, OTHER THAN PNEUMONECTOMY; WITH RESECTION OF EMPHYSEMATOUS LUNG(S) (BULLOUS/NON-BULLOUS) FOR LUNG VOLUME REDUCTION, STERNAL SPLIT/TRANS THORACIC APP, INCL ANY PLEU PROC, WHEN PERFORMED
32501	REPAIR BRONCHUS ADD-ON	RESECTION AND REPAIR OF PORTION OF BRONCHUS (BRONCHOPLASTY) WHEN PERFORMED AT TIME OF LOBECTOMY OR SEGMENTECTOMY (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
32503	RESECT,APICAL LNGTUMR;WO/CHSTWA	RESECTION OF APICAL LUNG TUMOR (EG, PANCOAST TUMOR), INCLUDING CHEST WALL RESECTION, RIB(S) RESECTION(S), NEUROVASCULAR DISSECTION, WHEN PERFORMED; WITHOUT CHEST WALL RECONSTRUCTION(S)
32504	RESECT,APICAL LNGTUMR;W/CHSTWAL	RESECTION OF APICAL LUNG TUMOR (EG, PANCOAST TUMOR), INCLUDING CHEST WALL RESECTION, RIB(S) RESECTION(S), NEUROVASCULAR DISSECTION, WHEN PERFORMED; WITH CHEST WALL RECONSTRUCTION
32505	THORACOT;THER WEDGE RESEC,INIT	THORACOTOMY; WITH THERAPEUTIC WEDGE RESECTION (EG, MASS, NODULE), INITIAL

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Scope: Lung CPTs (10b)  
Source: DS Method 4



Scope: Lung CPTs (10b)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
32506	THORACOT;WEDG RESEC,EA AD,IPSI	THORACOTOMY; WITH THERAPEUTIC WEDGE RESECTION (EG, MASS OR NODULE), EACH ADDITIONAL RESECTION, IPSILATERAL (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
32507	THORACOT;DX WEDG,ANA LNG RESEC	THORACOTOMY; WITH DIAGNOSTIC WEDGE RESECTION FOLLOWED BY ANATOMIC LUNG RESECTION (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
32540	REMOVAL OF LUNG LESION	EXTRAPLEURAL ENUCLEATION OF EMPYEMA (EMPHYEMECTOMY)
32663	THORACOSCOPY,SURG;W LOBECTOMY	THORACOSCOPY, SURGICAL; WITH LOBECTOMY (SINGLE LOBE)
32666	THORACOS,SX;WEDG RES,INITL UNI	THORACOSCOPY, SURGICAL; WITH THERAPEUTIC WEDGE RESECTION (EG, MASS, NODULE), INITIAL UNILATERAL
32667	THORACOS,SX;WED RES,EA AD,IPSI	THORACOSCOPY, SURGICAL; WITH THERAPEUTIC WEDGE RESECTION (EG, MASS OR NODULE), EACH ADDITIONAL RESECTION, IPSILATERAL (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
32668	THORACOS,SX;WEDG RES,ANAT LNG	THORACOSCOPY, SURGICAL; WITH DIAGNOSTIC WEDGE RESECTION FOLLOWED BY ANATOMIC LUNG RESECTION (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
32669	THORACOS,SX;REMOVAL,1 LUNG SEG	THORACOSCOPY, SURGICAL; WITH REMOVAL OF A SINGLE LUNG SEGMENT (SEGMENTECTOMY)
32670	THORACOSCOPY,SURG;REMOV,2 LOBES	THORACOSCOPY, SURGICAL; WITH REMOVAL OF TWO LOBES (BILOBECTOMY)
32671	THORACOSCOPY,SURG;REMOVAL,LUNG	THORACOSCOPY, SURGICAL; WITH REMOVAL OF LUNG (PNEUMONECTOMY)
32672	THORACOS,SRG;RES-PLI,EMPHY,UNI	THORACOSCOPY, SURGICAL; WITH RESECTION-PLICATION FOR EMPHYSEMATOUS LUNG (BULLOUS OR NON-BULLOUS) FOR LUNG VOLUME REDUCTION (LVRS), UNILATERAL INCLUDES ANY PLEURAL PROCEDURE, WHEN PERFORMED
32998	ABL,RED,1+ PULM TUM,PLE/CH WAL	ABLATION THERAPY FOR REDUCTION OR ERADICATION OF 1 OR MORE PULMONARY TUMOR(S) INCLUDING PLEURA OR CHEST WALL WHEN INVOLVED BY TUMOR EXTENSION, PERCUTANEOUS, RADIOFREQUENCY, UNILATERAL

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Scope: Lung CPTs (10b)  
Source: DS Method 4





Scope: Pancreas CPTs (10c)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
48000	DRAINAGE OF ABDOMEN	PLACEMENT OF DRAINS, PERIPANCREATIC, FOR ACUTE PANCREATITIS;
48001	PLACEMENT OF DRAIN, PANCREAS	PLACEMENT OF DRAINS, PERIPANCREATIC, FOR ACUTE PANCREATITIS; WITH CHOLECYSTOSTOMY, GASTROSTOMY, AND JEJUNOSTOMY
48020	REMOVAL OF PANCREATIC STONE	REMOVAL OF PANCREATIC CALCULUS
48100	BIOPSY OF PANCREAS, OPEN	BIOPSY OF PANCREAS, OPEN (EG, FINE NEEDLE ASPIRATION, NEEDLE CORE BIOPSY, WEDGE BIOPSY)
48102	NEEDLE BIOPSY, PANCREAS	BIOPSY OF PANCREAS, PERCUTANEOUS NEEDLE
48105	RESECT,PANCREAS,ACT NECROTIZ	RESECTION OR DEBRIDEMENT OF PANCREAS AND PERIPANCREATIC TISSUE FOR ACUTE NECROTIZING PANCREATITIS
48120	REMOVAL OF PANCREAS LESION	EXCISION OF LESION OF PANCREAS (EG, CYST, ADENOMA)
48140	PARTIAL REMOVAL OF PANCREAS	PANCREATECTOMY, DISTAL SUBTOTAL, WITH OR WITHOUT SPLENECTOMY; WITHOUT PANCREATICOJEJUNOSTOMY
48145	PARTIAL REMOVAL OF PANCREAS	PANCREATECTOMY, DISTAL SUBTOTAL, WITH OR WITHOUT SPLENECTOMY; WITH PANCREATICOJEJUNOSTOMY
48146	PANCREATECTOMY	PANCREATECTOMY, DISTAL, NEAR-TOTAL WITH PRESERVATION OF DUODENUM (CHILD-TYPE PROCEDURE)
48148	REMOVAL OF PANCREATIC DUCT	EXCISION OF AMPULLA OF VATER
48150	PARTIAL REMOVAL OF PANCREAS	PANCREATECTOMY, PROXIMAL SUBTOTAL WITH TOTAL DUODENECTOMY, PARTIAL GASTRECTOMY, CHOLEDOCHOENTEROSTOMY AND GASTROJEJUNOSTOMY (WHIPPLE-TYPE PROCEDURE); WITH PANCREATICOJEJUNOSTOMY
48152	PANCREATECTOMY	PANCREATECTOMY, PROXIMAL SUBTOTAL WITH TOTAL DUODENECTOMY, PARTIAL GASTRECTOMY, CHOLEDOCHOENTEROSTOMY AND GASTROJEJUNOSTOMY (WHIPPLE-TYPE PROCEDURE); WITHOUT PANCREATICOJEJUNOSTOMY
48153	PANCREATECTOMY	PANCREATECTOMY, PROXIMAL SUBTOTAL WITH NEAR-TOTAL DUODENECTOMY, CHOLEDOCHOENTEROSTOMY AND DUODENOJEJUNOSTOMY (PYLORUS-SPARING, WHIPPLE-TYPE PROCEDURE); WITH PANCREATICOJEJUNOSTOMY
48154	PANCREATECTOMY	PANCREATECTOMY, PROXIMAL SUBTOTAL WITH NEAR-TOTAL DUODENECTOMY, CHOLEDOCHOENTEROSTOMY AND DUODENOJEJUNOSTOMY (PYLORUS-SPARING, WHIPPLE-TYPE PROCEDURE); WITHOUT PANCREATICOJEJUNOSTOMY
48155	REMOVAL OF PANCREAS	PANCREATECTOMY, TOTAL

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Scope: Pancreas CPTs (10c)  
Source: DS Method 4



Scope: Pancreas CPTs (10c)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
48160	PANCREAS REMOVAL/TRANSPLANT	PANCREATECTOMY, TOTAL OR SUBTOTAL, WITH AUTOLOGOUS TRANSPLANTATION OF PANCREAS OR PANCREATIC ISLET CELLS
48400	INJECTION, INTRAOP ADD-ON	INJECTION PROCEDURE FOR INTRAOPERATIVE PANCREATOGRAPHY (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
48500	SURGERY OF PANCREATIC CYST	MARSUPIALIZATION OF PANCREATIC CYST
48510	DRAIN PANCREATIC PSEUDOCYST	EXTERNAL DRAINAGE, PSEUDOCYST OF PANCREAS
48520	FUSE PANCREAS CYST AND BOWEL	INTERNAL ANASTOMOSIS OF PANCREATIC CYST TO GASTROINTESTINAL TRACT; DIRECT
48540	FUSE PANCREAS CYST AND BOWEL	INTERNAL ANASTOMOSIS OF PANCREATIC CYST TO GASTROINTESTINAL TRACT; ROUX-EN-Y
48545	PANCREATORRHAPHY	PANCREATORRHAPHY FOR INJURY
48547	DUODENAL EXCLUSION	DUODENAL EXCLUSION WITH GASTROJEJUNOSTOMY FOR PANCREATIC INJURY
48548	PANCREATICOJEJUNOSTMY,ANASTMS	PANCREATICOJEJUNOSTOMY, SIDE-TO-SIDE ANASTOMOSIS (PUESTOW-TYPE OPERATION)
48550	DONOR PANCREAT,W/WO DUODNL	DONOR PANCREATECTOMY (INCLUDING COLD PRESERVATION), WITH OR WITHOUT DUODENAL SEGMENT FOR TRANSPLANTATION
48551	BACKBNCH STD PRP,PANCREAS ALLO	BACKBENCH STANDARD PREPARATION OF CADAVER DONOR PANCREAS ALLOGRAFT PRIOR TO TRANSPLANTATION
48552	BACKBNCH RECS,PANCREAS ALLOGRF	BACKBENCH RECONSTRUCTION OF CADAVER DONOR PANCREAS ALLOGRAFT PRIOR TO TRANSPLANTATION, VENOUS ANASTOMOSIS, EACH
48554	TRANSPL ALLOGRAFT PANCREAS	TRANSPLANTATION OF PANCREATIC ALLOGRAFT
48556	REMOVAL, ALLOGRAFT PANCREAS	REMOVAL OF TRANSPLANTED PANCREATIC ALLOGRAFT
48999	PANCREAS SURGERY PROCEDURE	UNLISTED PROCEDURE, PANCREAS

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Scope: Pancreas CPTs (10c)  
Source: DS Method 4





Scope: Rectal CPTs (10d)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
44145	PARTIAL REMOVAL OF COLON	COLECTOMY, PARTIAL; WITH COLOPROCTOSTOMY (LOW PELVIC ANASTOMOSIS)
44155	REMOVAL OF COLON/ILEOSTOMY	COLECTOMY, TOTAL, ABDOMINAL, WITH PROCTECTOMY; WITH ILEOSTOMY
44207	L COLECTOMY/COLOPROCTOSTOMY	LAPAROSCOPY, SURGICAL; COLECTOMY, PARTIAL, WITH ANASTOMOSIS, WITH COLOPROCTOSTOMY (LOW PELVIC ANASTOMOSIS)
44208	LAP COLECTOMY/COLOPRCTOSTOMY	LAPAROSCOPY, SURGICAL; COLECTOMY, PARTIAL, WITH ANASTOMOSIS, WITH COLOPROCTOSTOMY (LOW PELVIC ANASTOMOSIS) WITH COLOSTOMY
45110	REMOVAL OF RECTUM	PROCTECTOMY; COMPLETE, COMBINED ABDOMINOPERINEAL, WITH COLOSTOMY
45111	PARTIAL REMOVAL OF RECTUM	PROCTECTOMY; PARTIAL RESECTION OF RECTUM, TRANSABDOMINAL APPROACH
45112	REMOVAL OF RECTUM	PROCTECTOMY, COMBINED ABDOMINOPERINEAL, PULL-THROUGH PROCEDURE (EG, COLO-ANAL ANASTOMOSIS)
45113	PARTIAL PROCTECTOMY	PROCTECTOMY, PARTIAL, WITH RECTAL MUCOSECTOMY, ILEOANAL ANASTOMOSIS, CREATION OF ILEAL RESERVOIR (S OR J), WITH OR WITHOUT LOOP ILEOSTOMY
45114	PARTIAL REMOVAL OF RECTUM	PROCTECTOMY, PARTIAL, WITH ANASTOMOSIS; ABDOMINAL AND TRANSACRAL APPROACH
45116	PARTIAL REMOVAL OF RECTUM	PROCTECTOMY, PARTIAL, WITH ANASTOMOSIS; TRANSACRAL APPROACH ONLY (KRASKE TYPE)
45119	PRCTECT,COMBN ABDOMINOPERINEAL	PROCTECTOMY, COMBINED ABDOMINOPERINEAL PULL-THROUGH PROCEDURE (EG, COLO-ANAL ANASTOMOSIS), WITH CREATION OF COLONIC RESERVOIR (EG, J-POUCH), WITH DIVERTING ENTEROSTOMY WHEN PERFORMED
45120	REMOVAL OF RECTUM	PROCTECTOMY, COMPLETE (FOR CONGENITAL MEGACOLON), ABDOMINAL AND PERINEAL APPROACH; WITH PULL-THROUGH PROCEDURE AND ANASTOMOSIS (EG, SWENSON, DUHAMEL, OR SOAVE TYPE OPERATION)
45121	REMOVAL OF RECTUM AND COLON	PROCTECTOMY, COMPLETE (FOR CONGENITAL MEGACOLON), ABDOMINAL AND PERINEAL APPROACH; WITH SUBTOTAL OR TOTAL COLECTOMY, WITH MULTIPLE BIOPSIES
45123	PARTIAL PROCTECTOMY	PROCTECTOMY, PARTIAL, WITHOUT ANASTOMOSIS, PERINEAL APPROACH
45126	PELVIC EXENTERATION	PELVIC EXENTERATION FOR COLORECTAL MALIG, W PROCTECTOMY (WWO COLOSTOMY), W REMOVAL OF BLADDER & URETERAL TRANSPLANTATIONS, &/HYSTERECTOMY/CERVICETOMY, WWO REM OF TUBE(S), OVARY(S)/ANY COMB THEREOF
45130	EXCISION OF RECTAL PROLAPSE	EXCISION OF RECTAL PROCIDENTIA, WITH ANASTOMOSIS; PERINEAL APPROACH

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Scope: Rectal CPTs (10d)  
Source: DS Method 4



Scope: Rectal CPTs (10d)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
45135	EXCISION OF RECTAL PROLAPSE	EXCISION OF RECTAL PROCIDENTIA, WITH ANASTOMOSIS; ABDOMINAL AND PERINEAL APPROACH
45136	EXCISE ILEOANAL RESERVOIR	EXCISION OF ILEOANAL RESERVOIR WITH ILEOSTOMY
45150	EXCISION OF RECTAL STRICTURE	DIVISION OF STRICTURE OF RECTUM
45160	EXCISION OF RECTAL LESION	EXCISION OF RECTAL TUMOR BY PROCTOTOMY, TRANSACRAL OR TRANSCOCYGEAL APPROACH
45171	EXC,REC TUM,TRANSAN;NO MUSC PR	EXCISION OF RECTAL TUMOR, TRANSANAL APPROACH; NOT INCLUDING MUSCULARIS PROPRIA (IE, PARTIAL THICKNESS)
45172	EXC,REC TUM,TRANSAN;MUSC PROPR	EXCISION OF RECTAL TUMOR, TRANSANAL APPROACH; INCLUDING MUSCULARIS PROPRIA (IE, FULL THICKNESS)
45395	LAP,SURG;PRCTECT,COMBO,W/CLST	LAPAROSCOPY, SURGICAL; PROCTECTOMY, COMPLETE, COMBINED ABDOMINOPERINEAL, WITH COLOSTOMY
45397	LAP,SRG;PROCTECT,PULL-THRO,RES	LAPAROSCOPY, SURGICAL; PROCTECTOMY, COMBINED ABDOMINOPERINEAL PULL-THROUGH PROCEDURE (EG, COLO-ANAL ANASTOMOSIS), W CREATION, COLONIC RESERVOIR (EG, J-POUCH), W DIVERTING ENTEROSTOMY, WHEN PERFORMED
45400	LAP,SURG;PROCTOPEXY(PROLAPSE)	LAPAROSCOPY, SURGICAL; PROCTOPEXY (FOR PROLAPSE)
45402	LAP,SURG;PROCTOPEXY,W/SIGMOID	LAPAROSCOPY, SURGICAL; PROCTOPEXY (FOR PROLAPSE), WITH SIGMOID RESECTION
45499	UNLISTED LAP PROC, RECTUM	UNLISTED LAPAROSCOPY PROCEDURE, RECTUM
45540	PROCTOPEXY;ABDOM APPR	PROCTOPEXY (EG, FOR PROLAPSE); ABDOMINAL APPROACH
45541	PROCTOPEXY;PERINEAL APPR	PROCTOPEXY (EG, FOR PROLAPSE); PERINEAL APPROACH
45550	PROCTOPEXY,W/SIGMOID RESCT,ABD	PROCTOPEXY (EG, FOR PROLAPSE); WITH SIGMOID RESECTION, ABDOMINAL APPROACH
45560	REPAIR OF RECTOCELE	REPAIR OF RECTOCELE (SEPARATE PROCEDURE)
45562	EXPLORATION/REPAIR OF RECTUM	EXPLORATION, REPAIR, AND PRESACRAL DRAINAGE FOR RECTAL INJURY;
45563	EXPLORATION/REPAIR OF RECTUM	EXPLORATION, REPAIR, AND PRESACRAL DRAINAGE FOR RECTAL INJURY; WITH COLOSTOMY
45800	REPAIR RECT/BLADDER FISTULA	CLOSURE OF RECTOVESICAL FISTULA;
45805	REPAIR FISTULA W/COLOSTOMY	CLOSURE OF RECTOVESICAL FISTULA; WITH COLOSTOMY
45820	REPAIR RECTOURETHRAL FISTULA	CLOSURE OF RECTOURETHRAL FISTULA;
45825	REPAIR FISTULA W/COLOSTOMY	CLOSURE OF RECTOURETHRAL FISTULA; WITH COLOSTOMY
46700	REPAIR OF ANAL STRICTURE	ANOPLASTY, PLASTIC OPERATION FOR STRICTURE; ADULT

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Scope: Rectal CPTs (10d)  
Source: DS Method 4







Scope: Rectal CPTs (10d)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
46705	REPAIR OF ANAL STRICTURE	ANOPLASTY, PLASTIC OPERATION FOR STRICTURE; INFANT
46706	REPR, ANAL FIST W FIBRIN GLU	REPAIR OF ANAL FISTULA WITH FIBRIN GLUE
46707	REP,ANORECTAL FISTULA W PLUG	REPAIR OF ANORECTAL FISTULA WITH PLUG (EG, PORCINE SMALL INTESTINE SUBMUCOSA [SIS])
46710	REPR,ILEOANAL POUCH;TPRNL APPR	REPAIR OF ILEOANAL POUCH FISTULA/SINUS (EG, PERINEAL OR VAGINAL), POUCH ADVANCEMENT; TRANSPERINEAL APPROACH
46712	REP,ILEOANL POUCH;TRANSPER/ABD	REPAIR OF ILEOANAL POUCH FISTULA/SINUS (EG, PERINEAL OR VAGINAL), POUCH ADVANCEMENT; COMBINED TRANSPERINEAL AND TRANSABDOMINAL APPROACH
46715	REPAIR OF ANOVAGINAL FISTULA	REPAIR OF LOW IMPERFORATE ANUS; WITH ANOPERINEAL FISTULA ("CUT-BACK" PROCEDURE)
46716	REPAIR OF ANOVAGINAL FISTULA	REPAIR OF LOW IMPERFORATE ANUS; WITH TRANSPOSITION OF ANOPERINEAL OR ANOVESTIBULAR FISTULA
46730	CONSTRUCTION OF ABSENT ANUS	REPAIR OF HIGH IMPERFORATE ANUS WITHOUT FISTULA; PERINEAL OR SACROPERINEAL APPROACH
46735	CONSTRUCTION OF ABSENT ANUS	REPAIR OF HIGH IMPERFORATE ANUS WITHOUT FISTULA; COMBINED TRANSABDOMINAL AND SACROPERINEAL APPROACHES
46740	CONSTRUCTION OF ABSENT ANUS	REPAIR OF HIGH IMPERFORATE ANUS WITH RECTOURETHRAL OR RECTOVAGINAL FISTULA; PERINEAL OR SACROPERINEAL APPROACH
46742	REPAIR OF IMPERFORATED ANUS	REPAIR OF HIGH IMPERFORATE ANUS WITH RECTOURETHRAL OR RECTOVAGINAL FISTULA; COMBINED TRANSABDOMINAL AND SACROPERINEAL APPROACHES
46744	REPAIR OF CLOACAL ANOMALY	REPAIR OF CLOACAL ANOMALY BY ANORECTOVAGINOPLASTY AND URETHROPLASTY, SACROPERINEAL APPROACH
46746	REPAIR OF CLOACAL ANOMALY	REPAIR OF CLOACAL ANOMALY BY ANORECTOVAGINOPLASTY AND URETHROPLASTY, COMBINED ABDOMINAL AND SACROPERINEAL APPROACH
46748	REPAIR OF CLOACAL ANOMALY	REPAIR OF CLOACAL ANOMALY BY ANORECTOVAGINOPLASTY AND URETHROPLASTY, COMBINED ABDOMINAL AND SACROPERINEAL APPROACH; WITH VAGINAL LENGTHENING BY INTESTINAL GRAFT OR PEDICLE FLAPS
46750	REPAIR OF ANAL SPHINCTER	SPHINCTEROPLASTY, ANAL, FOR INCONTINENCE OR PROLAPSE; ADULT
46751	REPAIR OF ANAL SPHINCTER	SPHINCTEROPLASTY, ANAL, FOR INCONTINENCE OR PROLAPSE; CHILD
57300	REPAIR RECTUM-VAGINA FISTULA	CLOSURE OF RECTOVAGINAL FISTULA; VAGINAL OR TRANSANAL APPROACH
57305	REPAIR RECTUM-VAGINA FISTULA	CLOSURE OF RECTOVAGINAL FISTULA; ABDOMINAL APPROACH

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Scope: Rectal CPTs (10d)  
Source: DS Method 4



Scope: Rectal CPTs (10d)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
57307	FISTULA REPAIR & COLOSTOMY	CLOSURE OF RECTOVAGINAL FISTULA; ABDOMINAL APPROACH, WITH CONCOMITANT COLOSTOMY
57308	FISTULA REPAIR, TRANSPERINE	CLOSURE OF RECTOVAGINAL FISTULA; TRANSPERINEAL APPROACH, WITH PERINEAL BODY RECONSTRUCTION, WITH OR WITHOUT LEVATOR PPLICATION

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Scope: Rectal CPTs (10d)  
Source: DS Method 4





Scope: Carotid CPTs (10e)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
37215	TRNSCATH,IV STNT,CERV;DIST EMB	TRANSCATHETER PLACEMENT OF INTRAVASCUL STENT(S),CERVICAL CAROTID ARTERY,OPEN/PERCUTANEOUS,INCLUDING ANGIOPLASTY,WHEN PERFORMED,AND RADIOLOGICAL SUPERVISION &INTERPRETATION;W DISTAL EMBOLIC PROTECTION
37216	TRNSCATH,IV STNT,CRV;WO DIS EM	TRANSCATHETER PLACEMENT OF INTRAVASCUL STENT(S),CERVICAL CAROT ARTERY,OPEN/PERCUTANEOUS,INCLUDING ANGIOPLASTY,WHEN PERFORMED,AND RADIOLOGICAL SUPERVISION &INTERPRETATION;W/O DISTAL EMBOLIC PROTECTION
37217	TRANSCATH,INTRAVAS STN,CCA,RET	TRANSCATHETER PLACEMENT OF INTRAVASCUL STENT(S),INTRATHOR COM CAROT ART/INNOV ART,RETROGRAD TREAT,OPN IPSILATERAL CERV CAROT ART EXPOS,INCL ANGIOPLASTY,WHEN PERFORM,& RADIOLOGICAL SUPERVIS &INTERPRET
37218	TRANSCATH,INTRAVAS STNT,CA/INN	TRANSCATHETER PLACEMENT OF INTRAVASCUL STENT(S),INTRATHORACIC COMMON CAROTID ARTERY/INNOV ARTERY,OPEN/PERCUT ANTEGRADE APP,INCLUDING ANGIOPLASTY,WHEN PERFORMED,AND RADIOLOGICAL SUPERVIS & INTERPRET

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Scope: Carotid CPTs (10e)  
Source: DS Method 4



Scope: Aortic CPTs (10f)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
33875	THORACIC AORTIC GRAFT	DESCENDING THORACIC AORTA GRAFT, WITH OR WITHOUT BYPASS
33877	THORACOABDOMINAL GRAFT	REPAIR OF THORACOABDOMINAL AORTIC ANEURYSM WITH GRAFT, WITH OR WITHOUT CARDIOPULMONARY BYPASS
33880	EVASC REPR,DTA;CVRAGE,L SUBCL	ENDOVASC REPR,DESCNDNG THORAC AORTA(ANRYM,PSEUDOANRYM,DISSECT,PENETRATNG ULCER,INTRAMRL HEMTMA,TRTIC DSRPTN);CVRGE,L SUBCLAVIAN ARTRY ORIGN,INT ENDOPROS-DSCNDNG THRAC AORT XTEN(S),CELIAC ARTRY ORIGN
33881	EVASC REPR,DTA;NOCVRGE,L SUBCL	ENDOVASC REPR,DESCNDNG THORAC AORTA(ANRYM,PSEUDOANRYM,DISSECT,PENETRATNG ULCER,INTRAMRL HMTMA,TRTIC DSRPTN);NO CVRGE,L SUBCLAVIAN ARTRY ORIGN,INT ENDOPROS-DSCNDNG THRAC AORT XTEN(S),CELIAC ARTRY ORIGN
33883	PLCMNT,EVASC REPR,DTA;INT XTEN	PLCMNT, PROXIMAL EXTEN PROSTHESIS, ENDOVASCULAR REPAIR, DESCENDING THORACIC AORTA (EG, ANEURYSM, PSEUDOANEURYSM, DISSECTION, PENETRATING ULCER, INTRAMURAL HEMATOMA, /TRAUMATIC DISRUPTION); INIT EXTEN
33884	PLAC,EX PROS,REP DES TH AOR;AD	PLACE PROX EXTENS PROS,ENDOVASC REPAIR DESC THOR AORTA (EG,ANEURYSM,PSEUDOANEURYSM,DISSECT,PENETRAT ULCER,INTRAMURAL HEMATOMA,TRAUM DISRUPT);EA ADD PROX EXTENS (LIST SEP IN ADD TO CODE FOR PRIM PROC)
33886	PLCMNT,DIA,AFTER EVASCREPR,DTA	PLACEMENT OF DISTAL EXTENSION PROSTHESIS(S) DELAYED AFTER ENDOVASCULAR REPAIR OF DESCENDING THORACIC AORTA
34800	ENDVS REP AB ARTC ANRYSM;AORTO	ENDOVASCULAR REPAIR OF INFRARENAL ABDOMINAL AORTIC ANEURYSM OR DISSECTION; USING AORTO-AORTIC TUBE PROSTHESIS
34802	ENDOV REP ABD AOR ANRYM;1 DOCK	ENDOVASCULAR REPAIR OF INFRARENAL ABDOMINAL AORTIC ANEURYSM OR DISSECTION; USING MODULAR BIFURCATED PROSTHESIS (1 DOCKING LIMB)
34803	ENDOV REP ABD AOR ANRYM;2 DOCK	ENDOVASCULAR REPAIR OF INFRARENAL ABDOMINAL AORTIC ANEURYSM OR DISSECTION; USING MODULAR BIFURCATED PROSTHESIS (2 DOCKING LIMBS)
34804	ENDV REP AB ART ANRYM;UNIB BIF	ENDOVASCULAR REPAIR OF INFRARENAL ABDOMINAL AORTIC ANEURYSM OR DISSECTION; USING UNIBODY BIFURCATED PROSTHESIS
34805	ENDOVASC ABDO REPAIR W/PROS	ENDOVASCULAR REPAIR OF INFRARENAL ABDOMINAL AORTIC ANEURYSM OR DISSECTION; USING AORTO-UNILIAC OR AORTO-UNIFEMORAL PROSTHESIS

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Scope: Aortic CPTs (10f)  
Source: DS Method 4





Scope: Aortic CPTs (10f)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
34825	EXTEND PRSTH ENDVSC,INIT VESEL	PLACEMENT OF PROXIMAL OR DISTAL EXTENSION PROSTHESIS FOR ENDOVASCULAR REPAIR OF INFRARENAL ABDOMINAL AORTIC OR ILIAC ANEURYSM, FALSE ANEURYSM, OR DISSECTION; INITIAL VESSEL
34826	EXTEND PRSTH ENDVSC,ADDL VESEL	PLACEMENT, PROXIMAL/DISTAL EXTEN PROSTHESIS, ENDOVASCULAR REPAIR, INFRARENAL ABDOMINAL AORTIC/ILIAC ANEURYSM, FALSE ANEURYSM,/DISSECTION; EA ADDITION VESSEL (LIST SEPARATELY ADDITION CD, 1 PROCEDU
34830	OPEN REP AORT ANRYSM/DISS;TUBE	OPEN REPAIR OF INFRARENAL AORTIC ANEURYSM OR DISSECTION, PLUS REPAIR OF ASSOCIATED ARTERIAL TRAUMA, FOLLOWING UNSUCCESSFUL ENDOVASCULAR REPAIR; TUBE PROSTHESIS
34831	OPN REP AORT ANRYS/DISS;A-BI-I	OPEN REPAIR OF INFRARENAL AORTIC ANEURYSM OR DISSECTION, PLUS REPAIR OF ASSOCIATED ARTERIAL TRAUMA, FOLLOWING UNSUCCESSFUL ENDOVASCULAR REPAIR; AORTO-BI-ILIAC PROSTHESIS
34832	OPN REP AORT ANRYS/DISS;AOR-BI	OPEN REPAIR OF INFRARENAL AORTIC ANEURYSM OR DISSECTION, PLUS REPAIR OF ASSOCIATED ARTERIAL TRAUMA, FOLLOWING UNSUCCESSFUL ENDOVASCULAR REPAIR; AORTO-BIFEMORAL PROSTHESIS
34841	ENDOVAS REP,VIS AORT;1 ENDOPRO	ENDOASC REP,VISCERAL AORTA (EG,ANEUR,PSEUDOANEUR,DISSECT,PENETRAT ULCER,INTRAMUR HEMATOMA/TRAUM DISRUPT),DEPLOY OF FENEST VIS AORT ENDOGRFT &ALL ASSOC RAD SUP &INT; 1 VISCERAL ART ENDOPROSTHESIS
34842	ENDOVAS REP,VIS AORT;2 ENDOPRO	ENDOASC REP,VISCERAL AORTA (EG,ANEUR,PSEUDOANEUR,DISSECT,PENETRAT ULCER,INTRAMUR HEMATOMA/TRAUM DISRUPT),DEPLOY OF FENEST VIS AORT ENDOGRFT &ALL ASSOC RAD SUP &INT; 2 VISCERAL ART ENDOPROSTHESIS
34843	ENDOVAS REP,VIS AORT;3 ENDOPRO	ENDOASC REP,VISCERAL AORTA (EG,ANEUR,PSEUDOANEUR,DISSECT,PENETRAT ULCER,INTRAMUR HEMATOMA/TRAUM DISRUPT),DEPLOY OF FENEST VIS AORT ENDOGRFT &ALL ASSOC RAD SUP &INT; 3 VISCERAL ART ENDOPROSTHESIS
34844	ENDOVAS REP,VIS AORT;4+ENDOPRO	ENDOASC REP,VISCERAL AORTA (EG,ANEUR,PSEUDOANEUR,DISSECT,PENETRAT ULCER,INTRAMUR HEMATOMA/TRAUM DISRUPT),DEPLOY OF FENEST VIS AORT ENDOGRFT &ALL ASSOC RAD SUP &INT;4/MORE VISCERAL ART ENDOPROSTHESES
34845	ENDOVAS REP,VIS &INF AB AORT;1	ENDOASC REP,VIS AORT&INFRAREN AB AORT W FENES VIS AORT ENDOGRAFT &CONCOMIT UNIBDY/MOD INFRAREN AORT ENDOGRAFT &ALL RAD SUP&INT,TARGET ZONE ANGIOPLASTY,WHEN PERFORM; 1 VISCERAL ART ENDOPROSTHESIS

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Scope: Aortic CPTs (10f)  
Source: DS Method 4



Scope: Aortic CPTs (10f)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
34846	ENDOVAS REP,VIS &INF AB AORT;2	ENDOASC REP,VIS AORT&INFRAREN AB AORT W FENES VIS AORT ENDOGRAFT &CONCOMIT UNIBDY/MOD INFRAREN AORT ENDOGRAFT &ALL RAD SUP&INT,TARGET ZONE ANGIOPLASTY,WHEN PERFORM; 2 VISCERAL ART ENDOPROSTHESIS
34847	ENDOVAS REP,VIS &INF AB AORT;3	ENDOASC REP,VIS AORT&INFRAREN AB AORT W FENES VIS AORT ENDOGRAFT &CONCOMIT UNIBDY/MOD INFRAREN AORT ENDOGRAFT &ALL RAD SUP&INT,TARGET ZONE ANGIOPLASTY,WHEN PERFORM; 3 VISCERAL ART ENDOPROSTHESIS
34848	ENDOV REP,VIS &INF AB AORT;4/+	ENDOASC REP,VIS AORT&INFRAREN AB AORT W FENES VIS AORT ENDOGRAFT &CONCOMIT UNIBDY/MOD INFRAREN AORT ENDOGRAFT &ALL RAD SUP&INT,TARGET ZONE ANGIOPLASTY,WHEN PERFORM;4/MORE VISCERAL ART ENDOPROSTHESES
35081	REPAIR DEFECT OF ARTERY	DIRECT REPAIR OF ANEURYSM, PSEUDOANEURYSM, OR EXCISION AND GRAFT INSERTION, WITH OR WITHOUT PATCH GRAFT; FOR ANEURYSM, PSEUDOANEURYSM, AND ASSOCIATED OCCLUSIVE DISEASE, ABDOMINAL AORTA
35082	REPAIR ARTERY RUPTURE, AORTA	DIRECT REPAIR OF ANEURYSM, PSEUDOANEURYSM, OR EXCISION AND GRAFT INSERTION, WITH OR WITHOUT PATCH GRAFT; FOR RUPTURED ANEURYSM, ABDOMINAL AORTA
35091	REPAIR DEFECT OF ARTERY	DIRECT REPAIR, ANEURYSM, PSEUDOANEURYSM/EXCISION&GRAFT INSERTION, WITH/WITHOUT PATCH GRAFT; F OR ANEURYSM, PSEUDOANEURYSM,&ASSOCIATED OCCLUSIVE DISEASE, ABDOMINAL AORTA INVOLVING VISCERAL VESSELS
35092	REPAIR ARTERY RUPTURE, AORTA	DIRECT REPAIR OF ANEURYSM, PSEUDOANEURYSM, OR EXCISION AND GRAFT INSERTION, WITH OR WITHOUT PATCH GRAFT; FOR RUPTURED ANEURYSM, ABDOMINAL AORTA INVOLVING VISCERAL VESSELS
35102	REPAIR DEFECT OF ARTERY	DIRECT REPAIR, ANEURYSM, PSEUDOANEURYSM, OR EXCISION&GRAFT INSERTION, WITH OR WITHOUT PATCH GRAFT; FOR ANEURYSM, PSEUDOANEURYSM,&ASSOCIATED OCCLUSIVE DISEASE, ABDOMINAL AORTA INVOLVING ILIAC VESSELS
35103	DIR REP,ANEU;RUPT,ABD AOR,ILIA	DIRECT REPAIR OF ANEURYSM, PSEUDOANEURYSM, OR EXCISION AND GRAFT INSERTION, WITH OR WITHOUT PATCH GRAFT; FOR RUPTURED ANEURYSM, ABDOMINAL AORTA INVOLVING ILIAC VESSELS

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Scope: Aortic CPTs (10f)  
Source: DS Method 4





Scope: Aortic CPTs (10f)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
35361	THROMBOEND;COMBINED AORTOILIAC	THROMBOENDARTERECTOMY, INCLUDING PATCH GRAFT, IF PERFORMED; COMBINED AORTOILIAC
35363	THROMBOEN;COMBINE AORTOILIOFEM	THROMBOENDARTERECTOMY, INCLUDING PATCH GRAFT, IF PERFORMED; COMBINED AORTOILIOFEMORAL

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Scope: Aortic CPTs (10f)  
Source: DS Method 4



Scope: Mitral Valve CPTs (10g)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
33418	TRANSCATH MITR VAL REP;INITIAL	TRANSCATHETER MITRAL VALVE REPAIR, PERCUTANEOUS APPROACH, INCLUDING TRANSSEPTAL PUNCTURE WHEN PERFORMED; INITIAL PROSTHESIS
33419	TRANSCATH MITR VAL REP;ADD PRO	TRANSCATHETER MITRAL VALVE REPAIR,PERCUTANEOUS APP,INCLUDING TRANSSEPTAL PUNCTURE WHEN PERFORMED;ADDITIONAL PROSTHESIS(ES) DURING SAME SESSION (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROC)
33420	REVISION OF MITRAL VALVE	VALVOTOMY, MITRAL VALVE; CLOSED HEART
33422	REVISION OF MITRAL VALVE	VALVOTOMY, MITRAL VALVE; OPEN HEART, WITH CARDIOPULMONARY BYPASS
33425	REPAIR OF MITRAL VALVE	VALVULOPLASTY, MITRAL VALVE, WITH CARDIOPULMONARY BYPASS;
33426	REPAIR OF MITRAL VALVE	VALVULOPLASTY, MITRAL VALVE, WITH CARDIOPULMONARY BYPASS; WITH PROSTHETIC RING
33427	REPAIR OF MITRAL VALVE	VALVULOPLASTY, MITRAL VALVE, WITH CARDIOPULMONARY BYPASS; RADICAL RECONSTRUCTION, WITH OR WITHOUT RING
33430	REPLACEMENT OF MITRAL VALVE	REPLACEMENT, MITRAL VALVE, WITH CARDIOPULMONARY BYPASS
33600	CLOSURE OF VALVE	CLOSURE OF ATRIOVENTRICULAR VALVE (MITRAL OR TRICUSPID) BY SUTURE OR PATCH
92987	REVISION OF MITRAL VALVE	PERCUTANEOUS BALLOON VALVULOPLASTY; MITRAL VALVE

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Scope: Mitral Valve CPTs (10g)  
Source: DS Method 4





Scope: Bariatric CPTs (10h)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
43644	LAPARO,SX,GASTRIC RESTRICT PROC	LAPAROSCOPY, SURGICAL, GASTRIC RESTRICTIVE PROCEDURE; WITH GASTRIC BYPASS AND ROUX-EN-Y GASTROENTEROSTOMY (ROUX LIMB 150 CM OR LESS)
43659	LAPAROSCOPE PROC, STOM	UNLISTED LAPAROSCOPY PROCEDURE, STOMACH
43775	LAP,SRG,GAS RESTR, LONG GASTREC	LAPAROSCOPY, SURGICAL, GASTRIC RESTRICTIVE PROCEDURE; LONGITUDINAL GASTRECTOMY (IE, SLEEVE GASTRECTOMY)
43846	GASTRC RSTRC PRC,BP,SHORT LIMB	GASTRIC RESTRICTIVE PROCEDURE, WITH GASTRIC BYPASS FOR MORBID OBESITY; WITH SHORT LIMB (150 CM OR LESS) ROUX-EN-Y GASTROENTEROSTOMY
43847	GASTRIC BYPASS FOR OBESITY	GASTRIC RESTRICTIVE PROCEDURE, WITH GASTRIC BYPASS FOR MORBID OBESITY; WITH SMALL INTESTINE RECONSTRUCTION TO LIMIT ABSORPTION
43848	REV,GAS REST,MORB OBES,NOT ADJ	REVISION, OPEN, OF GASTRIC RESTRICTIVE PROCEDURE FOR MORBID OBESITY, OTHER THAN ADJUSTABLE GASTRIC RESTRICTIVE DEVICE (SEPARATE PROCEDURE)

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Scope: Bariatric CPTs (10h)  
Source: DS Method 4



Scope: Hip CPTs (10i)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
27120	RECONSTRUCTION OF HIP SOCKET	ACETABULOPLASTY; (EG, WHITMAN, COLONNA, HAYGROVES, OR CUP TYPE)
27122	RECONSTRUCTION OF HIP SOCKET	ACETABULOPLASTY; RESECTION, FEMORAL HEAD (EG, GIRDLESTONE PROCEDURE)
27125	PARTIAL HIP REPLACEMENT	HEMIARTHROPLASTY, HIP, PARTIAL (EG, FEMORAL STEM PROSTHESIS, BIPOLAR ARTHROPLASTY)
27130	TOTAL HIP ARTHROPLASTY	ARTHROPLASTY, ACETABULAR AND PROXIMAL FEMORAL PROSTHETIC REPLACEMENT, WITH OR WITHOUT AUTOGRAFT OR ALLOGRAFT
27132	TOTAL HIP ARTHROPLASTY	CONVERSION OF PREVIOUS HIP SURGERY TO TOTAL HIP ARTHROPLASTY, WITH OR WITHOUT AUTOGRAFT OR ALLOGRAFT
27134	REVISE HIP JOINT REPLACEMENT	REVISION OF TOTAL HIP ARTHROPLASTY; BOTH COMPONENTS, WITH OR WITHOUT AUTOGRAFT OR ALLOGRAFT
27137	REVISE HIP JOINT REPLACEMENT	REVISION OF TOTAL HIP ARTHROPLASTY; ACETABULAR COMPONENT ONLY, WITH OR WITHOUT AUTOGRAFT OR ALLOGRAFT
27138	REVISE HIP JOINT REPLACEMENT	REVISION OF TOTAL HIP ARTHROPLASTY; FEMORAL COMPONENT ONLY, WITH OR WITHOUT ALLOGRAFT

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Scope: Hip CPTs (10i)  
Source: DS Method 4





Scope: Knee CPTs (10j)

Low Volume | High Risk Surgical Procedures

CPT	Description Short	Description Long
27440	REVISION OF KNEE JOINT	ARTHROPLASTY, KNEE, TIBIAL PLATEAU;
27441	REVISION OF KNEE JOINT	ARTHROPLASTY, KNEE, TIBIAL PLATEAU; WITH DEBRIDEMENT AND PARTIAL SYNOVECTOMY
27442	REVISION OF KNEE JOINT	ARTHROPLASTY, FEMORAL CONDYLES OR TIBIAL PLATEAU(S), KNEE
27443	REVISION OF KNEE JOINT	ARTHROPLASTY, KNEE, FEMORAL CONDYLES OR TIBIAL PLATEAUS; WITH DEBRIDEMENT AND PARTIAL SYNOVECTOMY
27445	REVISION OF KNEE JOINT	ARTHROPLASTY, KNEE, HINGE PROSTHESIS (EG, WALLDIUS TYPE)
27446	REVISION OF KNEE JOINT	ARTHROPLASTY, KNEE, CONDYLE AND PLATEAU; MEDIAL OR LATERAL COMPARTMENT
27447	TOTAL KNEE ARTHROPLASTY	ARTHROPLASTY, KNEE, CONDYLE AND PLATEAU; MEDIAL AND LATERAL COMPARTMENTS WITH OR WITHOUT PATELLA RESURFACING

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Scope: Knee CPTs (10j)  
Source: DS Method 4





## ATTACHEMENT TWO: VHA DIRECTIVE 2010-018

Department of Veterans Affairs  
Veterans Health Administration  
Washington, DC 20420

VHA DIRECTIVE 2010-018

May 6, 2010

**FACILITY INFRASTRUCTURE REQUIREMENTS TO PERFORM STANDARD,  
INTERMEDIATE, OR COMPLEX SURGICAL PROCEDURES**

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive is intended to establish policy and guidance regarding the infrastructure requirements for VHA facilities providing in-house surgical services in relationship to the complexity of surgical procedures being performed as well as the method for monitoring compliance.

**2. BACKGROUND**

a. In the spring of 2008, the Under Secretary for Health established the Operative Complexity and Infrastructure Workgroup.

b. In October 2008, the Under Secretary for Health approved the recommendations of the Operative Complexity and Infrastructure Workgroup establishing the Procedure Infrastructure Matrix (PIM) and the Operative Complexity Matrix (OCM). The PIM documents the infrastructure requirements for a VHA facility with an inpatient surgical program to be designated as standard, intermediate, or complex. The OCM establishes a complexity assignment of standard, intermediate and complex to all surgical procedures by Current Procedure Terminology (CPT) code.

c. A detailed analysis of the facility infrastructure and the surgical procedures performed for each of the VHA Surgical Programs was performed. Resolution of any gap in infrastructure identified in relationship to the complexity of the surgical procedures performed, was resolved prior to March 15, 2010.

d. On or before March 15, 2010, the Veterans Integrated Service Network (VISN) Director notified the Office of the Deputy Under Secretary for Health for Operations and Management and the National Director of Surgery (NDS) of surgical complexity designation for each inpatient VHA Surgical Program located within their respective VISN. This declaration signified that all components of the PIM had been satisfied in relationship to the operative complexity designation for the facility.

**3. POLICY:** It is VHA policy that each VA medical facility with an inpatient Surgical Program have: (1) surgical complexity designation of either standard, intermediate, or complex based upon the facility infrastructure; and (2) that the scheduled (non-emergent) surgical procedures performed, are not to exceed the infrastructure capabilities of the facility. *NOTE: This policy does not interfere with the judgment of the surgeon to perform a surgical procedure beyond the operative complexity designation of the facility, based upon new findings at the time of a planned procedure or in managing an emergency condition where the patient's best interest is served by care and treatment on-site rather than through transfer to a more complex facility.*

**THIS VHA DIRECTIVE EXPIRES MAY 31, 2015**



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**4. ACTION**

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for designating the operative complexity of each VA medical facility with an inpatient VHA Surgical Program.

b. **National Director of Surgery (NDS).** The NDS is responsible for:

(1) The content of the PIM (see Attachment A) and the OCM (see Attachment B) and for ensuring that both documents are reviewed on an annual basis. In performing this review, the NDS considers modifications to the CPT codes, the standard of care, the clinical outcomes data from the Veterans Affairs Surgical Quality Improvement Program (VASQIP), the emergence of new technology, and the opinion of Surgical Advisory Boards (SAB).

(2) Providing timely notification to the Office of the Deputy Under Secretary for Health for Operations and Management and the VISN Chief Surgical Consultants located within the VISN offices of any modification to the PIM or the OCM.

(3) Providing oversight to the VASQIP, which:

(a) Monitors all surgical procedures performed by an inpatient VHA Surgical Program by the complexity designation of the facility.

(b) Reports all surgical procedures performed beyond facility complexity designation.

(c) Notifies the VISN and the facility whenever a surgical procedure has been performed beyond the operative complexity designation.

c. **VISN Director.** The VISN Director is responsible for:

(1) Ensuring that each VA medical facility in the VISN with a Surgical Program has Surgical Complexity Designation based upon analysis of the PIM requirements.

(2) Providing the Deputy Under Secretary for Health for Operations and Management and the NDS with appropriate notification and documentation of any future request by a VA medical facility to modify the surgical complexity designation consistent with current VHA policy on restructuring VHA clinical programs. *NOTE: In this manner, an intermediate program adding additional resources may request a complex designation. Alternatively, the loss of key medical staff members may require an intermediate facility to request a change in surgical complexity designation to standard designation.*

(3) Submitting all waiver documentation to the Deputy Under Secretary for Health for Operations and Management and the NDS for concurrence when any component of the PIM is provided outside the VA medical facility. The waiver must include:

(a) The component of the PIM for which the waiver is requested:





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- (b) The name of the facility performing the procedure;
  - (c) The travel distance between the VA medical facility and the facility performing the procedure;
  - (d) The procedure by which the Veteran patient receives care and treatment;
  - (e) A copy of either the Memorandum of Understanding or a contractual agreement between the VA medical center and the facility performing the procedure; and
  - (f) A plan for monitoring and reviewing the quality of care being provided.
- (4) Ensuring that all appropriate documentation is submitted and procedures followed, according to current VHA policy, "Restructuring VHA Clinical Programs," anytime a significant increase or decrease in surgical services is anticipated or realized at any given facility sufficient to result in a change in the facility operative complexity designation.
- d. **Facility Director.** The facility Director is responsible for:
- (1) Ensuring that the infrastructure requirements for the facility, as identified by the PIM, are accounted for and communicated to the VISN Director;
  - (2) Ensuring that the VISN Director is notified if, and when, there is a failure to maintain the infrastructure appropriate for the surgical complexity designation of the facility;
  - (3) Initiating the request for a change in clinical services to the VISN Office according to current VHA policy, "Restructuring VHA Clinical Programs," anytime the facility infrastructure significantly changes, resulting in a decrease or increase in the surgical services being provided; and
  - (4) Ensuring that the scope of surgical procedures being performed is within the capabilities of the facility.
- e. **Facility Chief of Surgery.** The facility Chief of Surgery is responsible for:
- (1) Ensuring that the scheduled (non-emergent) surgical procedures performed by the facility are within the scope of facility operative complexity designation;
  - (2) A timely review of any surgical procedure performed beyond the facility operative complexity designation; and
  - (3) Timely notification of the VISN Chief Surgical Consultant within the VISN Office of any concern regarding a Veteran having received or requiring a level of care beyond the operative complexity designation for the facility.



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**5. REFERENCES:** Office of the Inspector General Report 07-03386-65. Quality of Care Issues. VA Medical Center, Marion, Illinois. January 28, 2008.

**6. FOLLOW-UP RESPONSIBILITY:** The National Surgery Office (10NC2), is responsible for the contents of this Directive. Questions may be referred to the National Director of Surgery at 202-461-7148.

**7. RESCISSIONS:** None. This VHA Directive expires May 31, 2015.

Robert A. Petzel, M.D.  
Under Secretary for Health

**DISTRIBUTION:** E-mailed to the VHA Publications Distribution List 5/10/2010



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## ATTACHMENT A

### PROCEDURE INFRASTRUCTURE MATRIX

Veterans Health Administration (VHA) facilities with an inpatient Surgical Program must have a written plan or policy for the safe and timely transfer of the patient who requires treatment or therapy which the facility is unable to provide or perform. Every effort must be made to medically stabilize the patient prior to transfer, a process which may include the timely performance of a surgical procedure beyond the scope of the facility's surgical complexity designation.

#### 1. DEFINITIONS

a. **Board Eligible.** Board eligible implies that a physician has completed a training program approved by the specialty specific Residency Review Committee and is eligible to sit for specialty's certifying examination. Individuals who are no longer eligible to sit for the certifying examination are not board eligible. *NOTE: Individuals trained outside the United States may have credentials equivalent to board eligibility, a fact to be considered and evaluated by the facility credentialing and privileging the provider.*

b. **Intensivist.** An intensivist is a physician provider specializing in critical care of the surgical patient; this may include a surgeon, anesthesiologist, cardiologist or pulmonologist.

c. **Interventional Cardiology.** Interventional Cardiology is the performance of diagnostic and therapeutic interventions by a qualified cardiologist in an accredited cardiac catheterization laboratory.

d. **Written Policy or Procedure.** A written policy or procedure for a fee or contract procedure should provide for the transfer and placement of the patient in the procedure room at the fee or contract facility within 60 minutes.

#### 2. FACILITY COMPLEXITY DESIGNATION REQUIREMENTS

a. **Standard Surgical Complexity.** A facility is designated a standard VHA Surgical Program when the following infrastructure is made available:

##### (1) Pre-operative and Post-operative Diagnostic Evaluation

(a) **Electrocardiogram (EKG):** In-house weekdays dayshift, available on-call 24 hours a day, 7 days a week, 365 days a year (24/7) within 30 minutes.

(b) **Basic Laboratory:** In-house weekdays dayshift, available on-call 24/7 within 30 minutes.

(c) **Basic Radiology:** In-house weekdays dayshift, available on-call 24/7 within 30 minutes.

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**(2) Pre-operative Risk Assessment and Post-operative Consultation and Services**

- (a) Pre-operative Medical Consultation (elective): In-house weekdays dayshift.
- (b) Pre-operative Medical Consultation (emergency): In-house weekdays dayshift, available on-call 24/7 within 15 minutes by phone or 60 minutes in person.
- (c) Post-operative Medical Consultation: In-house weekdays dayshift, available on call 24/7 within 15 minutes by phone or 60 minutes in person.
- (d) Anesthesia Pre-operative Assessment: In-house weekdays dayshift, available on-call 24/7 within 15 minutes by phone or 60 minutes in person, may be provided by Certified Registered Nurse Anesthetist (CRNA) or mid-level provider.

**(3) Surgical Physician Staffing**

- (a) General Surgeon: One Full-time Equivalent (FTE) employee, who may be provided by contract.
- (b) Specialty Surgeons: Variable depending upon the clinical services offered.
- (c) Surgical Assistant: Available 24/7 on call within 60 minutes.
- (d) Inpatient Coverage: Written plan or policy for the availability of a qualified surgeon 24/7 on-call within 60 minutes. Service may be provided by fee or contract at the facility.

**(4) Operating Room (OR)**

- (a) Staffing: There must be a minimum staffing to include a circulating Registered Nurse (RN) and scrub technician or RN. A policy or protocol defining training and competencies consistent with the Association of Operating Room Nurses (AORN) and the Association of Surgical Technicians (AST) must be maintained.
- (b) Instrument Sets: There must be a duplication of all major instrument sets including one vascular set available for emergency purpose.
- (c) Equipment required in each OR: There must be an anesthesia machine, the OR must have the capability for basic physiological monitoring including EKG, end-tidal Carbon Dioxide (CO<sub>2</sub>), an electrocautery unit.
- (d) Equipment required for the OR Area: There must be a code cart and defibrillator, flash sterilizer, and intraoperative c-arm.
- (e) Coverage: Nursing and operating room must be available 24/7 within 60 minutes.

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(f) Radiology: There must be a technician available for intraoperative radiology in-house weekdays dayshift, on-call 24/7 within 60 minutes.

(5) **Anesthesia Services**

(a) Provider: Anesthesiologist or CRNA.

(b) Assistance: Written plan or policy for physician provider skilled in airway management, as necessary.

(c) Coverage: In-house weekdays dayshift, on-call 24/7 within 60 minutes.

(6) **Post Anesthesia Care Unit (PACU)**

(a) Area: There must be a designated PACU or equivalent; local policy may require specific specialty procedures or after-hours care to be directly transferred to the Intensive Care Unit (ICU).

(b) Staffing: Minimum staffing of two licensed providers with a 1to1 provider-to-patient ratio as required, consistent with the American Society of PeriAnesthesia Nursing (ASPAN) guidelines.

(c) Staffing Outside the PACU: There must be a RN with demonstrated competencies available when the patient is recovered outside the PACU, consistent with ASPAN guidelines.

(d) Discharge Guidelines: Patients must be discharged from the PACU based upon defined protocol.

(7) **Intensive Care Unit (ICU)**. ICU Level: Level 4 or Level 3 without intensivist (for explanation of Levels see Web site at: <http://chestjournal.chestpubs.org/content/132/5/1455.full.pdf.html> ).

(8) **Ward**. Nurse competencies must be in alignment with the types of surgical procedures being performed. In addition, there must be:

(a) Monitored Beds (EKG): Capability and defined criteria for the use of beds remotely monitored by EKG.

(b) Monitored Beds (Pulse Oximetry): Capability and defined criteria for the use of beds remotely monitored by pulse oximetry.

(9) **Support Services**

(a) Respiratory Therapy: In-house weekdays dayshift, on-call 24/7 within 60 minutes, service must be provided by a credentialed respiratory therapist.



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(b) Pharmacy: Pharmacy services in-house 12 hours a day within 15 minutes by telephone and 60 minutes on site.

(c) Blood Bank: There must be packed red blood cells, fresh frozen plasma, and platelets available within 60 minutes weekdays dayshift.

(d) Physical Therapy: In-house weekdays dayshift.

**(10) Supply, Processing, and Distribution (SPD)**

(a) Availability: There must be a re-processing capability on-site or immediately available appropriate sterile instrument sets should be on-site for all scheduled procedures.

(b) Equipment: There must be a flash sterilizer available 24/7 with competent personnel.

b. **Intermediate Surgical Complexity**. A facility is designated an Intermediate VHA Surgical Program when the following infrastructure is made available:

(1) **Pre-operative and Post-operative Diagnostic Evaluation**. There must be:

(a) EKG: In-house 24/7 by competent technician or personnel.

(b) Basic Laboratory: In-house 24/7, alternative may be point of care testing for basic laboratory studies including complete blood count, electrolytes, and arterial blood gas.

(c) Basic Radiology: In-house 24/7.

(d) Cardiac Stress Testing: Available in-house during day tour, may be through fee or contract.

(e) Pulmonary Function Test (PFT) Studies: Available in-house during day tour, may be through fee or contract.

(f) Computerized Tomography (CT) Scan: In-house weekdays dayshift, on-call 24/7 within 30 minutes.

(g) Vascular Ultrasound: In-house weekdays dayshift.

(h) Radiology Interpretation: In-house weekdays dayshift, on-call 24/7 within 30 minutes.

(i) Interventional Cardiology: To be provided 24/7 in-house or by fee or contract within 60 minutes.

(j) Vascular Interventional Radiology: To be provided 24/7 in-house or by fee or contract within 60 minutes.

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(k) Non-vascular Interventional Radiology: To be provided 24/7 in-house or by fee or contract within 60 minutes.

**(2) Pre-operative Risk Assessment and Post-operative Consultation and Services**

(a) Pre-operative Medical Consultation (elective): In-house weekdays dayshift.

(b) Pre-operative Medical Consultation (emergency): In-house weekdays dayshift, available on-call 24/7 within 15 minutes by phone or 60 minutes in person.

(c) Post-operative Medical Consultation: In-house weekdays dayshift, available on-call 24/7 within 15 minutes by phone or 60 minutes in person.

(d) Specialty Consultants: The following specialty consultants must be available 24/7:

1. Cardiology and Pulmonary within 15 minutes by phone and 60 minutes in person. For specialty services, such as PFTs and cardiac catheterization provided by fee or contract, the patient may be seen either on-site or off-site.

2. Gastroenterology, Hematology, Infectious Disease, Interventional Radiology, Nephrology, Neurology, Orthopedic Surgery, Pathology, Thoracic Surgery, Urology, Vascular Surgery within 15 minutes by phone or 60 minutes in person.

(e) Anesthesia Pre-operative Assessment: In-house weekdays dayshift, available on-call 24/7 within 15 minutes by phone or 60 minutes in person, may be provided by CRNA or mid-level provider.

**(3) Surgical Physician Staffing**

(a) General Surgeon: There must be a two or more FTE employees who may be provided by contract.

(b) Specialty Surgeons: Variable depending upon in-house clinical services offered.

(c) Surgical Assistant: Available 24/7 on call within 60 minutes.

(d) Call Schedule: Formal General Surgery and Specialty Service Call Schedule, availability 24/7 within 60 minutes. The call schedule must incorporate only board certified or board-eligible surgeons.

(e) Inpatient Coverage: There must be coverage by surgical staff, resident, or fellow 24/7 within 15 minutes by phone or 60 minutes in person.

**(4) Operating Room (OR)**

(a) Staffing: There must be:



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1. Minimum staffing to include a circulating RN and scrub technician or RN. A policy or protocol defining training and competencies consistent with the AORN and the AST must be maintained at the facility.

2. Staff competencies for specialty specific surgery.

3. A plan or policy for staffing based upon procedural complexity.

4. A plan or policy for supplemental staffing for intraoperative emergencies.

(b) Instrument Sets: There must be a duplication of all major instrument sets, including one vascular set available for emergency purpose.

(c) Equipment Required in each OR: There must be an anesthesia machine, an electrocautery unit, and the OR must have the capability for advanced physiological monitoring, including EKG, end-tidal CO<sub>2</sub>, central venous pressure, and arterial pressure.

(d) Equipment Required for the OR Area: There must be a code cart and defibrillator, flash sterilizer, cell saver, and intraoperative c-arm.

(e) Coverage: There must be nursing staff and an OR available 24/7 within 60 minutes.

(f) Radiology: There must be a technician available for intraoperative radiology in-house weekdays dayshift, on-call 24/7 within 60 minutes.

**(5) Anesthesia Services**

(a) Provider: There must be an Anesthesiologist, or CRNA available for all cases 24/7 within 60 minutes.

(b) Chief of Anesthesia: The anesthesia service must be managed by a board certified or board eligible anesthesiologist.

(c) Assistance: There must be a written plan or policy for a physician provider skilled in airway management, as necessary.

(d) Coverage: In-house weekdays dayshift, on-call 24/7 within 60 minutes.

**(6) PACU**

(a) Area: There must be a designated Post-Anesthesia Recovery Area or equivalent; local policy may require specific specialty procedures or after-hours care to be directly transferred to the ICU.





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(b) Staffing: There must be a minimum staffing of two licensed providers with a 1 to 1 provider to patient ratio as required, consistent with ASPAN guidelines.

(c) Staffing Outside the PACU: There must be a RN with demonstrated competencies available when the patient is recovered outside the PACU, consistent with ASPAN guidelines.

(d) Competencies for Recovery of Specialty Patients: There must be specific competencies for recovery of specialty patients as indicated.

(e) Skills: There must be ventilator management, and management of physiologic monitoring.

(f) Discharge Guidelines: Patient's discharge from the PACU must be based upon defined protocol.

(7) **ICU**

(a) ICU Level: Level 2 or Level 3 with intensivist (for explanation of Levels see Web site at: <http://chestjournal.chestpubs.org/content/132/5/1455.full.pdf+html> ).

(b) Medical Co-management of Surgical Patients: There must be a written policy or plan for co-management 24/7.

(8) **Ward**. Nurse competencies must be in alignment with the types of surgical procedures being performed, and specialty specific competencies must be defined. There must be:

(a) Monitored Beds (EKG): Capability and defined criteria for the use of beds remotely monitored by EKG.

(b) Monitored Beds (Pulse Oximetry): Capability and defined criteria for the use of beds remotely monitored by pulse oximetry.

(9) **Support Services**

(a) Respiratory Therapy: In-house 24/7; service must be provided by a credentialed respiratory therapist.

(b) Pharmacy: Pharmacy services in-house 16 hours a day; on-call or available within 15 minutes by telephone and 60 minutes on site.

(c) Blood Bank: There must be packed red blood cells, fresh frozen plasma, and platelets available within 60 minutes 24/7.

(d) Physical Therapy: In-house weekdays dayshift; weekends if necessary for specialty specific recovery.

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- (e) Dialysis: In-house weekdays dayshift; it must be available on-call 24/7 within 6 hours.
- (f) Pathology: There must be a capacity for frozen section studies in-house weekdays dayshift; on-call 24/7 within 60 minutes.
- (g) Biomedical Engineering: In-house weekdays dayshift.
- (10) **SPD**
  - (a) Availability: There must be processing on-site; personnel in-house weekdays dayshift; on-call 24/7. or materials available within 15 minutes by written policy or protocol.
  - (b) Equipment: There must be a flash sterilizer available 24/7 with competent personnel.
  - c. **Complex Surgical Complexity**. A facility is designated a Complex VHA Surgical Program when the following infrastructure is made available:
    - (1) **Pre-operative and Post-operative Diagnostic Evaluation**
      - (a) EKG: In-house 24/7 by competent technician or personnel.
      - (b) Basic Laboratory: In-house 24/7.
      - (c) Basic Radiology: In-house 24/7.
      - (d) Cardiac Stress Testing: Available in-house during day tour, may be through fee or contract.
      - (e) PFT: Available in-house during day tour, may be through fee or contract.
      - (f) CT Scan: In-house weekdays dayshift, on-call 24/7 within 30 minutes.
      - (g) Vascular Ultrasound: In-house weekdays dayshift.
      - (h) Magnetic Resonance Imaging (MRI) and Magnetic Resonance Angiography (MRA): In-house weekdays dayshift, on-call 24/7 within 30 minutes if necessary for specialized programs.
      - (i) Radiology Interpretation: In-house weekdays dayshift, on-call 24/7 within 30 minutes.
      - (j) Interventional Cardiology: To be provided 24/7 in-house or by fee or contract within 60 minutes.
      - (k) Interventional Neuroradiology: In-house or written plan and/or policy for fee or contract, 24/7 within 60 minutes.



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(l) Vascular Interventional Radiology: To be provided 24/7 in-house or by fee or contract within 60 minutes.

(m) Non-vascular Interventional Radiology: To be provided 24/7 in-house or by fee or contract within 60 minutes.

**(2) Pre-operative Risk Assessment and Post-operative Consultation and Services**

(a) Pre-operative Medical Consultation (elective): In-house weekdays dayshift.

(b) Pre-operative Medical Consultation (emergency): In-house weekdays dayshift, available on-call 24/7 within 15 minutes by phone or 60 minutes in person.

(c) Post-operative Medical Consultation: In-house weekdays dayshift, available on-call 24/7 within 15 minutes by phone or 60 minutes in person.

(d) Specialty Consultants: The following specialty consultants must be available 24/7:

1. Cardiology, Gastroenterology, Hematology, Infectious Disease, Interventional Radiology, Nephrology, Neurology, Orthopedic Surgery, Otolaryngology, Pathology, Pulmonary, Thoracic Surgery, Urology, Vascular Surgery on staff; available 24/7 within 15 minutes by phone or 60 minutes in person.

2. Cardiovascular Surgeon, Interventional Neuroradiologist, Neurosurgeon as indicated by approved clinical programs; on staff or by fee or contact, available 24/7 within 15 minutes by phone or 60 minutes in person.

3. There must be a board-certified or board-eligible anesthesiologist in-house weekdays dayshift, available 24/7 within 15 minutes by phone or 60 minutes in person.

(e) Anesthesia Pre-operative Assessment: In-house weekdays dayshift, available on-call 24/7 within 15 minutes by phone or 60 minutes in person, may be provided by CRNA or mid-level provider.

**(3) Surgical Physician Staffing**

(a) General Surgeon: There must be a three or more FTE who may be provided by contract.

(b) Specialty Surgeons: Variable depending upon in-house clinical services offered.

(c) Surgical Assistant: Available 24/7 on call within 60 minutes.

(d) Call Schedule: Formal General Surgery and Specialty Service Call Schedule, availability 24/7 within 60 minutes. The call schedule must incorporate only board-certified or board-eligible surgeons.



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(e) In-patient Coverage: There must be a dedicated in-patient coverage in-house available 24/7, which may be provided by resident, fellow, hospitalist, critical care specialist, or mid-level provider without responsibility to another institution (cannot be provided by physician assigned to the Emergency Department or the Medical Officer of the Day).

**(4) Operating Room**

(a) Staffing: There must be:

1. Minimum staffing to include a circulating RN and scrub technician or RN. A policy or protocol defining training and competencies consistent with the AORN and the AST must be maintained at the facility.

2. Staff competencies for specialty specific surgery.

3. Plan or policy for staffing based upon procedural complexity.

4. Plan or policy for supplemental staffing for intraoperative emergencies.

(b) Instrument Sets: There must be a duplication of all major instrument sets, including one vascular set available for emergency purpose.

(c) Equipment Required in each OR: There must be an anesthesia machine, an electrocautery unit, and the OR must have the capability for advanced physiological monitoring including EKG, end-tidal CO<sub>2</sub>, central venous pressure, and arterial pressure.

(d) Equipment required for the OR Area: There must be a code cart and defibrillator, flash sterilizer, cell saver, and intraoperative c-arm.

(e) Coverage: There must be nursing staff and an OR available 24/7 within 60 minutes.

(f) Radiology: There must be a technician available for intraoperative radiology in-house weekdays dayshift, on-call 24/7 within 60 minutes.

**(5) Anesthesia Services**

(a) Provider: There must be an anesthesiologist, or CRNA available for all cases 24/7 within 60 minutes.

(b) Chief of Anesthesia: The Anesthesia Service must be managed or supervised by a board-certified or board-eligible anesthesiologist.

(c) Assistance: There must be a written plan or policy for a physician provider skilled in airway management, as necessary.

(d) Coverage: In-house weekdays dayshift, on-call 24/7 within 60 minutes.

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(6) **PACU**

(a) Area: There must be a presence of designated Post-Anesthesia Recovery Area or equivalent; local policy may require specific specialty procedures or after-hours care to be directly transferred to the ICU.

(b) Staffing: There must be a minimum staffing of two licensed providers with a 1 to 1 provider-to-patient ratio as required, consistent with ASPAN guidelines.

(c) Staffing Outside the PACU: There must be a RN with demonstrated competencies available when the patient is recovered outside the PACU, consistent with ASPAN guidelines.

(d) Competencies for Recovery of Specialty Patients: There must be specific competencies for recovery of specialty patients as indicated.

(e) Skills: There must be ventilator management, and management of physiologic monitoring.

(f) Discharge Guidelines: Patient's discharge from the PACU must be based upon defined protocol.

(7) **ICU**

(a) ICU Level: Level 1 or Level 2 (for explanation of Levels see web site at: <http://chestjournal.chestpubs.org/content/132/5/1455.full.pdf+html> ).

(b) There must be a pharmacist available in-house to ICU, weekdays dayshift tour.

(c) Medical Co-management of Surgical Patients: There must be a written policy or plan for co-management 24/7.

(8) **Ward**. Nurse competencies must be in alignment with the types of surgical procedures being performed, and specialty specific competencies must be defined. There must be:

(c) Monitored Beds (EKG): Capability and defined criteria for the use of beds remotely monitored by EKG.

(d) Monitored Beds (Pulse Oximetry): Capability and defined criteria for the use of beds remotely monitored by pulse oximetry.

(9) **Support Services**

(a) Respiratory Therapy: In-house 24/7, service must be provided by a credentialed respiratory therapist.

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(b) Pharmacy: Pharmacy services in-house 24/7, clinical pharmacy services can be available off tour on-call within 15 minutes by telephone and 60 minutes on site.

(c) Blood Bank: There must be packed red blood cells, fresh frozen plasma, and platelets available within 60 minutes 24/7.

(d) Physical Therapy: In-house weekdays dayshift; weekends if necessary for specialty specific recovery.

(e) Dialysis: In-house weekdays dayshift; it must be available on-call 24/7 within 6 hours.

(f) Pathology: There must be a capacity for frozen section studies in-house weekdays dayshift; on-call 24/7 within 60 minutes.

(g) Biomedical Engineering: In-house weekdays dayshift.

**(10) SPD**

(a) Availability: There must be processing on-site; personnel in-house weekdays dayshift; on-call 24/7, or materials available within 15 minutes by written policy or protocol.

(b) Equipment: There must be a flash sterilizer available 24/7 with competent personnel.



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**ATTACHMENT B**

**SURGICAL COMPLEXITY MATRIX**

1. The Surgical Complexity Matrix (OCM) is the assignment of each surgery procedure by Current Procedure Terminology (CPT) code to an operative complexity designation of standard, intermediate, or complex. Alternatively, the Veterans Administration Surgical Quality Improvement Program (VASQIP) has made available a Web-based tool, the CPT Look-Up, to allow any individual with Intranet access to identify the complexity assignment for any individual surgical procedure, available at:  
<https://vhadennsqipweb.v19.med.va.gov/NSQIP/Dev/CPTLookup.aspx>.

2. To provide a visual framework for classification of surgical procedures to operative complexity category, the following table is included in this document. Note: Only samplings of surgical procedures are identified by surgical specialty.

Operative Category	Standard	Intermediate	Complex
Amputation - Standard	Amputation, upper extremity, arm or forearm or hand; Amputation, lower extremity, above knee or below knee or ankle		
Amputation - Intermediate		Amputation, forequarter or hindquarter; Disarticulation, hip	
Breast - Standard	Aspiration, cyst; Drainage, abscess; Biopsy or Excision, breast lesion; Mastectomy, radical with implant		
Breast - Intermediate		Mastectomy, complex; reconstruction with muscle flap; malignancy; Chest wall resection or reconstruction	
Cardiac - Complex		Coronary artery bypass; cardiac valve replacement; procedures requiring extracorporeal bypass; cardiac Electro Physiology (EP) procedures	
Ear, Nose, and Throat (ENT) - Standard	Biopsy, soft tissue lesion or lymph node, head and neck; Biopsy throat; Excision, intranasal polyps or lesions or turbinates; Septoplasty; Repair of nasal defects; Treatment, nasal fractures; Treatment, nosebleeds; Sinus surgery; Nasal or sinus endoscopy with biopsy, polypectomy, debridement; Laryngoscopy with biopsy or foreign body removal; Drainage, biopsy, excision, repair of lip or mouth or tongue or gum or salivary, submaxillary, sublingual glands or external ear; Excision neck cyst; Tonsillectomy; Myringotomy; Tympanoplasty		
ENT - Intermediate		Drainage, deep abscess, neck; Excision, soft tissue tumors; Sinus surgery, obliteration or excision; nasal or sinus endoscopy with resection; Laryngoscopy with tumor removal or intervention; Construction of tracheoesophageal fistula for speech prosthesis; cleft lip or palate reconstruction; Oral vestibuloplasty; Partial glossectomy; Uvulopalatopharyngoplasty; Parotidectomy; Esophageal diverticulectomy; Thyroidectomy; Parathyroidectomy; Masteoidectomy; Reconstruction of the external ear; Tympanic membrane repair; Myringoplasty; Cochlear Implant	

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Operative Category	Standard	Intermediate	Complex
ENT - Complex			Maxillectomy; Laryngectomy; Tracheal reconstruction; Nasal or oral or pharyngeal or laryngeal resection with radical neck dissection; Pharyngectomy
Eye - Standard	Any procedure except those restricted to 'Eye - intermediate,' requiring Intermediate or Advanced Infrastructure		
Eye - Intermediate		Corneal Transplant; Retinal surgery; Exploration, excision, decompression of the orbit	
Facial - Standard	Treatment of nasal fracture, closed		
Facial - Intermediate		Arthrotomy, Temporomandibular Joint and Muscle Disorders (TMJ); Excision of tumor, benign or malignant, facial bones; Preparation, facial prosthesis; Maxillofacial fixation; Repair or revision or reconstruction, facial bones; Treatment of nasal fracture, open; Treatment of complex fracture, nasal or maxillary or zygomatic arch or orbit, open or closed; Treatment of fracture, palatal or maxillary or mandibular; Arthroscopy, jaw; Complex surgery, nose	
Foot - Standard	Incision; Excision; Repair; Revision; Reconstruction; Fracture; Dislocation; Arthrodesis; or Amputation of the foot and ankle		
General Surgery (GS) - Standard	Biopsy skin or soft tissue or muscle or nerve or lymph nodes; Gastrostomy, jejunostomy, open or laparoscopic; Appendectomy, open or laparoscopic; Liver biopsy; Cholecystectomy, open or laparoscopic; Diagnostic laparotomy or laparoscopy; Lysis of adhesions, open or laparoscopic; Hernia repair, inguinal or femoral or ventral or umbilical, open or laparoscopic; Drainage, rectal abscess		
GS - Intermediate		Complex soft tissue resection; Splenectomy, open or laparoscopic; Retroperitoneal lymph node dissection, open or laparoscopic; Gastroesophageal surgery, subtotal gastric resection, open or laparoscopic; Vagotomy and pyloroplasty; Gastroenterostomy; Small bowel resection, open or laparoscopic; Colectomy, open or laparoscopic; Proctocolectomy; Repair vesicoenteric fistula; Proctectomy; Repair of rectal prolapse; Ablation of liver tumor, open or laparoscopic or percutaneous; Common bile duct exploration; Cholecystoenterostomy; Drainage, pancreatic pseudocyst; Pancreatic cyst-enterostomy; Abdominal exploration; Drainage, abdominal abscess Total gastrectomy; ; Ileo-anal pull through; Abdominal perineal resection; Proctectomy; Bile duct resection; Adrenalectomy, open or laparoscopic	

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Operative Category	Standard	Intermediate	Complex
GS - Complex			Esophagectomy; Hepatectomy; Total Pancreatectomy; Bariatric Surgery, including laparoscopic bands
General Urology (GU) - Standard	Kidney biopsy, percutaneous; Cystoscopy and renal endoscopy; Ureteral endoscopy, procedures or treatment; Lithotripsy; Placement of suprapubic catheter; Urodynamics; Cystoscopy, procedures or treatment; Transurethral resection prostate; Urethral surgery, dilatation or repair or treatment of lesions; Biopsy or excision or repair of penis; Circumcision; Penile prosthesis, placement or removal; Orchiectomy; Biopsy or exploration or removal of the testes, epididymis, scrotum; Vasectomy; Hydrocele, drainage or repair or excision Prostate, biopsy or ultrasound		
GU - Intermediate			Exploration or drainage or resection of the kidney, ureter, open or laparoscopic; Kidney biopsy, open; Treatment of kidney stones, open or laparoscopic; Ureterolysis; Urinary diversion; Construction of a neobladder; Cystectomy; Repair of bladder fistula; Complex reconstruction of the urethra; Prostatectomy, open or laparoscopic ; Pelvic lymphadenectomy; Penectomy
Gynecology - Standard	Incision and Drainage (I&D) superficial abscess or lesion; Laser or chemical destruction of vulvar lesion; Biopsy or excision vulva; Repair vagina or perineum; Colposcopy or colpotomy; Destruction, vaginal lesion; Vaginal examination, biopsy or excision or destruction of lesion; Examination or treatment of cervix; Cervical dilatation; Endometrial biopsy or ablation; Insertion or removal Intrauteran Device (IUD); Tubal ligation; Salpingo-oophorectomy; Drainage ovarian cyst or abscess; oophorectomy; Repair of vaginal fistula; Removal of cervix; Myomectomy; Hysterectomy, abdominal or vaginal; Surgery, fallopian tube; Laparoscopic hysterectomy or myomectomy; Hysteroscopy; Laparoscopy with adnexal intervention; Repair fallopian tubes		
Gynecology - Intermediate			Radical vulvectomy; Vaginectomy; Repair of urethra or bladder or vagina or pelvic floor; Resection for ovarian malignancy
Hand - Standard	Incision; Excision; Repair; Revision; Reconstruction; Fracture; Dislocation; Arthrodesis, forearm or wrist or hand or digits		
Neurosurgery - Complex			Twist drill or burr hole for subdural or extradural hematoma; Cerebral Spinal Fluid (CSF) shunts; Craniectomy or craniotomy for decompression, biopsy, excision; Skull based surgery; Twist drill or burr hole for ventricular access or device implantation or biopsy; Hypophysectomy, craniectomy or transnasal or transseptal; Surgery for aneurysm or arteriovenous malformation or vascular disease; Stereotactic surgery; Implantation of neurostimulator; Neuroendoscopy



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Operative Category	Standard	Intermediate	Complex
Ortho - Standard	Debridement skin or muscle or bone; Bone Biopsy, open or excisional or percutaneous; Injection, tendon or ligament; Drainage or injection, joint, bursa; Placement or removal, fixation device; Removal, implant or wire or pin or rod (except for long bone implants); Harvest of tendon or cartilage for transplant; I & D, shoulder; Biopsy or excision, soft tissue lesion shoulder; Excision or Curettage, bone lesion or foreign body; Muscle transfer or tenotomy, shoulder; Humerus, nailing or plating or pinning or wiring; Clavicular fracture, closed treatment; Treatment, humerus fracture; Treatment shoulder dislocation, closed; Surgery of the arm or elbow; Surgery of tendons or ligaments, upper extremity; Fractures of the upper extremity; Soft tissue surgery of the hip; Hip dislocation, closed reduction; Soft tissue surgery, thigh; Surgery knee, not including arthroplasty; Curettage, femur; Thigh fracture, closed treatment; Treatment of patellar and knee fracture; Treatment of fracture or dislocation of the leg and ankle; Casting or splint		
Ortho - Intermediate		Arthrotomy, shoulder or clavicle; Claviculectomy; Repair, biceps tendon; Shoulder reconstruction; Clavicular reconstruction; Clavicular fracture, Open Reduction Internal Fixation (ORIF); Shoulder dislocation, ORIF Hip dislocation, ORIF; Thigh fracture, ORIF; Complex tibia or fibula reconstruction; Osteotomy, scapula or humerus or clavical; Shoulder reconstruction; Complex reconstruction, humerus or elbow or radius; Excision tumor or osteotomy, pelvis or hip or thigh; Acetabuloplasty; Hip arthroplasty; Treatment of pelvic fracture; Treatment of thigh fracture; Arthrodesis, hip; Exploration, reconstruction of the kneeComplex reconstruction, leg and ankle; Revisional hip arthroplasty; Revisional knee arthroplasty	
Plastic or Reconstructive -Intermediate		Fascia or muscle graft for face nerve palsy; Excision excessive skin or subcutaneous tissue, face or trunk or extremity, including liposuction; Excision coccyx, with or without flap; Treatment pressure ulcer, sacrum or ischium or trochanter by excision or osteotomy or closure, Mohs surgery; Omental flap, intraabdominal or extraabdominal, without microvascular anastomosis; Neuroorrhaphy, nerve graft, face or arm or leg	
Plastic or Reconstructive - Complex		Replantation, arm or hand or foot or digit; Bone or osteocutaneous graft, with microvascular anastomosis; Jejunal transfer, with microvascular anastomosis; Omental flap, intraabdominal or extraabdominal, with microvascular anastomosis	
Proctology - Standard	Treatment of pilonidal cyst, rectal lesion, rectal abscess, anal fissure, hemorrhoids, anal fistula; anoscopy		

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Operative Category	Standard	Intermediate	Complex
Skin or Subcutaneous Tissue - Standard	Incision, drainage, removal, abscess or pilonidal cyst or foreign body or hematoma; Remove mesh, abdominal wall; Debridement, skin, subcutaneous tissue, muscle, bone; Paring callus; Biopsy, skin lesion; Remove, skin tags; Shave, skin lesions; Excision, skin lesion, benign or malignant; Excision, hidradenitis, axillary or inguinal or perineal; Excision, skin lesion, benign or malignant; Surgery of the nails or nail bed; Introduction or removal, tissue expanders; Insertion or removal, drug delivery system; Simple or complex or layer closure, wounds; Tissue transfer (Z-plasty, rotation flap, advancement flap); Skin grafts, autografts or allografts or xenograft; Free flaps; Hair transplant; Dermabrasion, chemical peel, simple facial plastic surgery; Removal excessive skin; Destruction lesion, laser or electrosurgery or cryosurgery or chemosurgery; Incision, abscess		
Skin or Subcutaneous Tissue - Intermediate		Complex debridement; Complex skin grafts, large surface area or head and neck; Skin or deep tissue flaps, face or trunk or arm or leg; Destruction malignant lesion, laser or electrosurgery or cryosurgery or chemosurgery	
Spine - Intermediate		Incision or drainage, deep abscess, cervical, thoracic, lumbar spine; Excision or osteotomy, cervical, thoracic, lumbar spine; Spinal fracture, closed or open treatment; Vertebroplasty; Kyphoplasty; Arthrodesis, cervical, thoracic, lumbar spine; Laminectomy for exploration or decompression or excision; Implantation or removal of spinal catheter or neurostimulator	
Spine - Complex			Complex cervical spine procedures; procedures with open dura
Thoracic - Standard	Pacemaker insertion; reposition or repair of lead		
Thoracic - Intermediate		Pericardiectomy; placement or removal of epicardial pacemaker leads; Exploration, biopsy, excision of chest wall; Repair of pectus or sternal separation; Exploration or biopsy of chest, lung, pleura, open, or thoracoscopic; Pleurodesis; Lobectomy; Thoracoscopy, diagnostic, or therapeutic; Repair of hiatal or paraesophageal hernia, open or thoracoscopic; Esophageal diverticulectomy; Thymectomy; Pneumonectomy	
Thoracic - Complex			Completion Pneumonectomy; Sternal debridement; Repair of trachea or bronchus; Esophagectomy
Tracheostomy - Standard	Unrestricted		
Transplant - Complex			Kidney transplant; Liver transplant; Stem cell harvest or transplant; Cardiac transplant; Lung transplant



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<b>Operative Category</b>	<b>Standard</b>	<b>Intermediate</b>	<b>Complex</b>
Vascular - Intermediate		Carotid endarterectomy; Carotid subclavian bypass; Upper extremity graft or prosthesis, bypass or interposition; Lower extremity graft or prosthesis, bypass, or interposition; Infrarenal aortic surgery, bypass, or interposition, open or endovascular; Aortic renal or mesenteric, bypass, or interposition; Carotid or peripheral endovascular intervention; Venous surgery	
Vascular - Complex			Thoracoabdominal aortic reconstruction; suprarenal aortic reconstruction
Vascular Access	Central venous access; arteriovenous fistula, primary or graft		

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## ATTACHMENT THREE: VHA DIRECTIVE 2011-037

Department of Veterans Affairs  
Veterans Health Administration  
Washington, DC 20420

VHA DIRECTIVE 2011-037

October 14, 2011

**FACILITY INFRASTRUCTURE REQUIREMENTS TO PERFORM INVASIVE  
PROCEDURES IN AN AMBULATORY SURGERY CENTER**

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive establishes policy and procedures regarding the infrastructure requirements for VHA facilities providing surgical services in an Ambulatory Surgery Center (ASC) in relationship to the complexity of the surgical procedures being performed, as well as the method for monitoring compliance. *NOTE: This Directive does not impact or supersede in any way VHA Directive 2010-018.*

**2. BACKGROUND**

a. VHA Directive 2010-018 established the facility infrastructure requirements to perform standard, intermediate, or complex surgical procedures by inpatient VHA Surgical Programs.

b. Approximately 80 percent of all surgical procedures performed by VHA are done so on a same day or outpatient basis. In accordance with the demand for outpatient services, VHA has plans to expand the number of free standing ASCs.

**c. Definitions**

(1) **Ambulatory Surgery.** Ambulatory surgery refers to surgical or invasive diagnostic procedures performed by qualified providers in an inpatient surgical suite or ASC with pre-procedural and immediate post-procedure care completed on the same day, or observation without hospitalization.

(2) **Ambulatory Surgery Center (ASC).** An ASC is a free standing VHA facility separate from an inpatient VHA Surgery Program. Outpatient (same day) surgery performed in a separate building on a VHA campus with an inpatient VHA Surgery Program would be considered an ASC if community paramedics are used to respond to emergencies according to current VHA policy on Out-of-Operating Room Airway Management.

(3) **Post-anesthesia Care Unit (PACU).** The PACU is an area dedicated to receive patients following general anesthesia, regional anesthesia, or monitored anesthesia care. Phase I requires close monitoring, including airway, ventilator, and hemodynamic support. Phase II allows preparations to be made to progress the patient towards discharge to home. Phase I PACU and Phase II PACU may be combined.

(4) **Ambulatory Surgery Program.** An Ambulatory Surgery Program provides surgical procedures on an outpatient basis in an ASC; distinguishable from an inpatient VHA Surgery Program performing surgical procedures on an a same-day or outpatient basis at a VA medical center.

**THIS VHA DIRECTIVE EXPIRES OCTOBER 31, 2016**



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(5) **VHA Facility.** A VHA facility includes any one of the following: VA medical center, community based outpatient clinic, long-term care facility, or Ambulatory Surgery Center. **NOTE:** *Invasive procedures performed outside the inpatient surgical suite or ASC (i.e., clinics, procedure rooms), utilizing local anesthesia or moderate sedation, are not defined as ambulatory surgery. For specific guidelines refer to VHA's current policy on Moderate Sedation by Non-Anesthesia Providers.*

**3. POLICY:** It is VHA policy that each Department of Veterans Affairs (VA) medical facility with an ASC must possess a surgical complexity designation of either basic or advanced, based on the facility's infrastructure and will only perform surgical procedures that do not exceed the infrastructure capabilities of the facility.

**4. ACTION**

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for designating the surgical complexity of each VHA medical facility with an Ambulatory Surgery Program.

b. **National Director of Surgery (NDS).** The NDS is responsible for:

(1) The content of the Ambulatory Surgery Center Infrastructure Matrix (ASCIM) and the Ambulatory Surgery Complexity Matrix (ASCM), and for ensuring that both documents are reviewed on an annual basis. In performing this review, the NDS must consider modifications of the Current Procedure Terminology (CPT) codes, the standard of care, the clinical outcomes data from the Veterans Affairs Surgical Quality Improvement Program, the emergence of new technology, and the opinion of the Surgical Advisory Boards within the National Surgery Office (NSO). **NOTE:** *For information regarding these forms see Attachments A and B.*

(2) Providing timely notification to the Office of the Deputy Under Secretary for Health for Operations and Management and the Veterans Integrated Service Network (VISN) Chief Surgical Consultants located within the VISN offices, of any modification to the ASCIM and ASCM.

(3) Providing oversight to the NSO, which:

(a) Monitors all surgical procedures performed by a VHA Ambulatory Surgery Program by complexity designation of the facility,

(b) Reports all surgical procedures performed beyond facility complexity designation, and

(c) Notifies the VISN and the facility whenever a surgical procedure has been performed by a VHA Ambulatory Surgery Program beyond the complexity designation of the facility.

c. **Veterans Integrated Service Network (VISN) Director.** The VISN Director is responsible for:



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(1) Ensuring that each VHA medical facility in the VISN with an Ambulatory Surgery Program has an ASC Complexity Designation based upon an analysis of the ASCIM requirements.

(2) Providing the Deputy Under Secretary for Health for Operations and Management and the NDS with appropriate notification and documentation of any future request by a VA medical facility to modify the surgical complexity designation of an ASC consistent with current VHA policy on restructuring VHA clinical programs. *NOTE: In this manner, a basic ASC adding additional resources may request an advanced designation. Alternatively, the loss of key infrastructure may require an advanced ASC to request a change to basic designation.*

(3) Submitting all waiver documentation to the Deputy Under Secretary for Health for Operations and Management and the NDS for concurrence when any component of the ASCIM is provided outside the VA medical facility. The waiver must include:

- (a) The component of the ASCIM for which the waiver is requested;
- (b) The name of the facility performing the procedure;
- (c) The travel distance between the ASC and the facility performing the procedure;
- (d) The process by which the Veteran patient receives care and treatment;
- (e) A copy of either the Memorandum of Understanding or a contractual agreement between the VA medical facility performing the services; and
- (f) A plan to monitor and review the quality of care provided.

(4) Ensuring that all appropriate documentation is submitted and procedures followed, according to current VHA policy regarding restructuring VHA clinical programs, anytime a significant increase or decrease in surgical services is anticipated or realized at any given facility sufficient to result in a change in the facility surgical complexity designation.

d. **Facility Director.** The facility Director is responsible for:

(1) Ensuring that the infrastructure requirements for the facility, as identified by the ASCIM, are accounted for and communicated to the VISN Director;

(2) Ensuring that the VISN Director is notified if, and when, there is a failure to maintain the infrastructure appropriate for the surgical complexity designation of the ASC;

(3) Initiating the request for a change in clinical services to the VISN Office according to current VHA policy regarding restructuring VHA clinical programs, anytime the facility infrastructure significantly changes, resulting in a decrease or increase in the services being provided; and



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(4) Ensuring that the scope of surgical and invasive procedures being performed is within the capabilities of the ASC.

e. **Facility Chief of Surgery.** The facility Chief of Surgery is responsible for:

(1) Ensuring that the scheduled surgical procedures performed by the ASC are within the scope of the facility ambulatory surgery complexity designation.

(2) A timely review of any surgical procedure performed beyond the ambulatory surgery complexity designation.

(3) Ensuring that all surgical procedures performed by the ASC are entered into the Veterans Health Information Systems and Technology Architecture (VistA) Surgical Package. *NOTE: The facility may choose whether or not to enter non-surgical procedures into the VistA Surgical Package, e.g., colonoscopy.*

(4) Timely notification of the VISN Chief Surgical Consultant within the VISN Office of any concern regarding a Veteran having received or requiring a level of care beyond the surgical complexity designation of the ASC.

**5. REFERENCES:** American Society of Anesthesiologists, Standard for Post anesthesia care (2009), available at [www.asahq.org/](http://www.asahq.org/)

**6. FOLLOW-UP RESPONSIBILITY:** The National Surgery Office (10NC2), Office of the Deputy Under Secretary for Health and Operations and Management is responsible for the contents of this directive. Questions may be referred to the National Director of Surgery at (202) 461-7148.

**7. RESCISSIONS:** None. This VHA Directive expires October 31, 2016.

Robert A. Petzel, M.D.  
 Under Secretary for Health

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October 14, 2011

## ATTACHMENT A

### AMBULATORY SURGERY CENTER INFRASTRUCTURE MATRIX

Veterans Health Administration (VHA) facilities with an Ambulatory Surgery Center (ASC) must have a written plan or policy for the safe and timely transfer of the patient who requires treatment or therapy which the facility is unable to provide or perform. Every effort must be made to select appropriate patients who are suitable to have their procedure performed in an ASC. Patients must be discharged from the ASC according to an established protocol, or must be transferred to a facility with 24 hour observation and inpatient surgical services.

**1. DEFINITION OF BOARD ELIGIBLE.** Board eligible implies that a physician has completed a training program approved by the specialty specific Residency Review Committee and is eligible to sit for that specialty's certifying examination. Individuals who are no longer eligible to sit for the certifying examination are not board eligible. *NOTE: Individuals trained outside the United States may have credentials equivalent to board eligibility, a fact to be considered and evaluated by the facility credentialing and privileging the provider.*

#### 2. ASC FACILITY COMPLEXITY DESIGNATION REQUIREMENTS

a. **Basic Surgical Complexity.** A facility is designated a basic VHA ASC Program when the following infrastructure is readily available:

##### (1) Pre-operative and Post-operative Diagnostic Evaluation

- (a) Electrocardiogram (EKG). Available within 30 minutes during hours of operation.
- (b) Basic Laboratory. Available within 30 minutes during hours of operation.
- (c) Basic Radiology. Available within 30 minutes during hours of operation.

##### (2) Pre-operative Risk Assessment and Post-operative Consultation and Services

- (a) Anesthesia Pre-operative Assessment. Available during hours of operation, may be provided by Certified Registered Nurse Anesthetist (CRNA), or appropriately trained advanced nurse practitioner or physician assistant.
- (b) Post-operative General Surgery Surgical Consultation. Available within 15 minutes by phone and 60 minutes in person, during the hours of operation.

##### (3) Surgical Physician Staffing

- (a) General Surgeon. One Full-Time Equivalent (FTE) employee, board eligible or certified, who may be provided by contract.
- (b) Specialty Surgeon. Variable depending upon the clinical services offered.

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**(4) Operating Room (OR)**

(a) Staffing. Each facility OR must meet the minimum staffing requirement to include a circulating Registered Nurse (RN), scrub technician or Registered Nurse (RN). A policy or protocol defining training and competencies consistent with the Association of Operating Room Nurses (AORN) and the Association of Surgical Technicians (AST) must be maintained.

(b) Instrument Sets. There must be a duplication of all major instrument sets, including one vascular set available for emergency use.

(c) Equipment required in each OR. There must be suction, an electrocautery unit, an anesthesia machine, and the capability for basic physiological monitoring including EKG, end-tidal carbon dioxide (CO<sub>2</sub>), and pulse oximetry. At all times, there must be at least one functioning anesthesia machine in excess of the number of ORs scheduled for procedures.

(d) Equipment required for the OR Area. There must be a code cart and defibrillator, flash sterilizer, and intra-operative c-arm in the OR.

(e) Radiology. There must be a Radiology Technician on call, available within 30 minutes during the hours of operation.

**(5) Anesthesia Services**

(a) Provider. Anesthesiologist or CRNA.

(b) Assistance. There must be a written plan or policy for the physician provider skilled in airway management, as necessary.

(c) Coverage. Coverage must be available within 30 minutes during the hours of operation.

**(6) Post Anesthesia Care Unit (PACU)**

(a) Area. There must be a designated PACU or equivalent.

(b) Phase I PACU Staffing. Minimum staffing of two licensed providers with a 1 to 1 provider to patient ratio as required, consistent with the American Society of Peri-Anesthesia Nursing (ASPAN) guidelines.

(c) Phase II PACU Staffing. There must be a registered nurse with demonstrated competencies available, consistent with ASPAN guidelines.

(d) Discharge Guidelines. Patients must be discharged from the Phase I PACU and Phase II PACU based upon a defined protocol.



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(7) **Support Services**

(a) Pharmacy. Pharmacy Services must be available within 15 minutes by phone, and within 60 minutes on site during the hours of operation.

(b) Blood Bank. There must be packed red blood cells, fresh frozen plasma, and platelets available within 60 minutes during the hours of operation.

(c) Social Work. Social Work must be available within 15 minutes by phone, and within 60 minutes on site during hours of operation.

(8) **Supply, Processing, and Distribution (SPD)**

(a) Availability. Sterile instrument sets must be available on site for all scheduled procedures.

(b) Equipment. There must be a flash sterilizer available with competent personnel during hours of operation.

(9) **Back-up 23 Hour Observation and In-patient Surgical Services**. Protocols to transfer patients within 60 minutes to a VHA acute care facility with an Inpatient Surgery Program or community provider must be established through Memorandums of Understanding. *NOTE: Timeliness of patient transfer in any given situation is dictated by the clinical condition of the patient.*

b. **Advanced Surgical Complexity**. A facility is designated an advanced VHA Ambulatory Surgery Program when the following infrastructure is made available:

(1) **Pre-operative and Post-operative Diagnostic Evaluation**

(a) Electrocardiogram (EKG). Available within 30 minutes during the hours of operation.

(b) Basic Laboratory. Available within 30 minutes during the hours of operation.

(c) Basic Radiology. Available within 30 minutes during the hours of operation.

(d) Radiology Interpretation. Available within 30 minutes during the hours of operation.

(2) **Pre-operative Risk Assessment and Post-operative Consultation and Services**

(a) Anesthesia Pre-operative Assessment. Available during the hours of operation, may be provided by Certified Registered Nurse Anesthetist (CRNA) or appropriately trained advanced nurse practitioner or physician assistant.

(b) General Surgery Surgical Consultation. Available on-site during the hours of operation.



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(c) Medical Consultation. Available within 15 minutes by phone, and within 60 minutes in person during the hours of operation.

(d) Specialty Consultation. Cardiology and Vascular Surgery within 15 minutes by phone and within 60 minutes in person, during the hours of operation.

**(3) Surgical Physician Staffing**

(a) General Surgeon. There must be two or more FTE employees, who may be provided by contract. At least one must be board eligible or certified.

(b) Specialty Surgeon. Variable depending upon the clinical services offered.

(c) Surgical Assistant. Available within 60 minutes during the hours of operation.

**(4) Operating Room (OR)**

(a) Staffing. There must be:

1. There must be a minimum staffing to include a circulating Registered Nurse (RN) and scrub technician or RN. A policy or protocol defining training and competencies consistent with the AORN and the AST must be maintained.

2. Staff competencies for specialty specific surgery.

3. A plan or policy for staffing based upon procedural complexity.

4. A plan or policy for supplemental staffing for intra-operative emergencies.

(b) Instrument Sets. There must be a duplication of all major instrument sets, including one vascular set available for emergency purpose.

(c) Equipment required in each OR. There must be suction, an electrocautery unit, an anesthesia machine, the capability for basic physiological monitoring including EKG, end-tidal carbon dioxide (CO<sub>2</sub>), and pulse oximetry. There must be at all times at least one functioning anesthesia machine in excess to the number of operating rooms scheduled for procedures.

(d) Equipment required for the OR Area. There must be a code cart and defibrillator, flash sterilizer, and an intraoperative c-arm.

(e) Radiology. There must be a Radiology Technician on call, available within 30 minutes during the hours of operation.

**(5) Anesthesia Services**

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- (a) Anesthesiologist. There must be one or more FTE employees, board eligible or certified anesthesiologist on site during hours of operation.
- (b) Provider. There must be an Anesthesiologist or CRNA available for all cases.
- (6) **Post Anesthesia Care Unit (PACU)**
  - (a) Area. There must be a designated PACU or equivalent.
  - (b) Phase I PACU Staffing. Minimum staffing of two licensed providers with a 1 to 1 provider to patient ratio as required, consistent with the ASPAN guidelines.
  - (c) Phase II PACU Staffing. There must be a RN with demonstrated competencies available, consistent with ASPAN guidelines.
  - (d) Discharge Guidelines. Patients must be discharged from the Phase I PACU and Phase II PACU based upon a defined protocol.
- (6) **Support Services**
  - (a) Pharmacy. Pharmacy Services must be available on site during the hours of operation.
  - (b) Blood Bank. There must be packed red blood cells, fresh frozen plasma, and platelets available within 60 minutes during hours of operation.
  - (c) Social Work. A Social Worker must be available within 15 minutes by phone, and within 60 minutes on-site during the hours of operation.
- (7) **Supply, Processing, and Distribution (SPD)**
  - (a) Availability. Sterile instrument sets must be available on site for all scheduled procedures.
  - (b) Equipment. There must be a flash sterilizer available with competent personnel during the hours of operation.
- (8) **Back-up 23 hour Observation and In-patient Surgical Services**. Transfer to VHA acute care facility with an intermediate or complex inpatient Surgical Program (see current VHA policy) or equivalent community provider through established memorandum of understanding within 60 minutes. *NOTE: Timeliness of patient transfer in any given situation is dictated by clinical condition of the patient.*



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**ATTACHMENT B**

**AMBULATORY SURGERY COMPLEXITY MATRIX**

1. The Ambulatory Surgery Complexity Matrix (ASCM) is the assignment of each surgery procedure by Current Procedure Terminology (CPT) code to an operative complexity designation of basic or advanced. Alternatively, the National Surgery Office has made available a Web-based tool, the CPT Look-Up, to allow any individual with Intranet access to identify the complexity assignment for any individual surgical procedure, available at:

<http://vawww.medicalsurgical.va.gov/surgery/index.asp>. *NOTE: This tool identifies procedures that must not be performed in an ASC. This is an internal Web site and is not available to the public.*

2. To provide a visual framework for classification of surgical procedures to operative complexity category, the following table is included in this document. *NOTE: Only samplings of surgical procedures are identified by surgical specialty.*

Procedure Category	Basic	Advanced
Amputation - Basic	Amputation, upper extremity, forearm, hand or digit; lower extremity, foot and digit	
Breast - Basic	Aspiration, cyst; drainage, abscess; biopsy or excision, breast lesion	
Breast - Advanced	Mastectomy	
Ear, Nose, and Throat (ENT) - Basic	Biopsy, soft tissue lesion or lymph node, head and neck; Biopsy throat; Excision, intranasal polyps or lesions or turbinates; septoplasty; repair of nasal defects; treatment of nasal fractures; treatment of nosebleeds; sinus surgery; nasal or sinus endoscopy with biopsy, polypectomy, debridement; laryngoscopy with biopsy or foreign body removal; drainage, biopsy, excision, repair of lip or mouth or tongue or gum or salivary, submaxillary, sublingual glands or external ear; excision neck cyst; construction of tracheoesophageal fistula for speech prosthesis; cleft lip repair; partial thyroidectomy; mastoidectomy; reconstruction of the external ear; tympanic membrane repair, myringoplasty	
ENT - Advanced	Drainage, deep abscess, neck; radiofrequency ablation base of tongue; sinus surgery—obliteration; palate reconstruction; oral vestibuloplasty-posterior, hemiglossectomy; uvulopalatopharyngoplasty; radical parotidectomy	
Eye - Basic	Blepharoplasty, corneal biopsy, cataract removal with lens insertion, vitrectomy, repair of ectropion	
Eye - Advanced	Enucleation of eye, insertion of ocular implant, repair of retinal detachment, strabismus surgery	
Facial - Basic	Treatment of nasal fracture, closed	
Facial - Advanced	Arthrotomy, Temporomandibular Joint and Muscle Disorders (TMJ); excision of tumor, benign or malignant, facial bones; preparation, facial prosthesis; Maxillofacial fixation; repair or revision or reconstruction, facial bones; Treatment of nasal fracture, open; treatment of complex fracture, nasal or maxillary or zygomatic arch or orbit, open or closed; Treatment of fracture,	

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Procedure Category	Basic	Advanced
	palatal or maxillary or mandibular; Arthroscopy, jaw; Complex surgery, nose	
Foot - Basic	Incision; Excision; Repair; Revision; Reconstruction; Fracture; Dislocation; Arthrodesis; or Amputation of the foot and ankle	
General Surgery (GS) -Basic	Biopsy skin or soft tissue or muscle or nerve or lymph nodes; Hernia repair, inguinal, femoral or umbilical, open or laparoscopic; drainage, rectal abscess	
GS - Advanced	Gastrostomy, jejunostomy, open or laparoscopic; laparoscopic cholecystectomy; open or laparoscopic ventral hernia repair	
General Urology (GU) - Basic	Kidney biopsy, percutaneous; Cystoscopy and renal endoscopy; Ureteral endoscopy, procedures or treatment; lithotripsy; placement of suprapubic catheter; urodynamics; cystoscopy, procedures or treatment; Urethral surgery, dilatation or repair or treatment of lesions; biopsy or excision or repair of penis; circumcision; penile prosthesis, placement or removal; orchiectomy; biopsy or exploration or removal of the testes, epididymis, scrotum; vasectomy; hydrocele, drainage or repair or excision prostate, biopsy or ultrasound	
GU - Advanced	Transurethral resection prostate; laparoscopic orchiectomy	
Gynecology - Basic	Pelvic exam under anesthesia; vaginal biopsy or excision or destruction of lesion; placement of Intrauterine Device (IUD), I & D perineal abscess; colposcopy; hysterosalpingography; hysteroscopy; amniocentesis; treatment of the cervix, including dilatation; superficial abscess or lesion; laser or chemical destruction of vulvar lesion; biopsy or excision vulva	
Gynecology - Advanced	Vulvectomy, anterior or posterior colporrhaphy, fallopian tube ligation or transaction, oophorectomy	
Hand - Basic	Incision; excision; repair; revision; reconstruction; fracture; dislocation; arthrodesis, forearm or wrist or hand or digits	
Ortho - Basic	Debridement skin or muscle or bone; bone biopsy, open or excisional or percutaneous; injection, tendon or ligament; drainage or injection, joint, bursa; placement or removal, fixation device; removal, implant or wire or pin or rod (except for long bone implants); Harvest of tendon or cartilage for transplant; I & D, shoulder; biopsy or excision, soft tissue lesion shoulder; excision or curettage, bone lesion or foreign body; muscle transfer or tenotomy, shoulder; humerus, nailing or plating or pinning or wiring; clavicular fracture, closed treatment; treatment, humerus fracture; treatment shoulder dislocation, closed; surgery of the arm or elbow; surgery of tendons or ligaments, upper extremity; Fractures of the upper extremity; soft tissue surgery of the hip; hip dislocation, closed reduction; Soft tissue surgery, thigh; Surgery knee, not including arthroplasty; Curettage, femur; Thigh fracture, closed treatment; treatment of patellar and knee fracture; treatment of fracture or dislocation of the leg and ankle; Casting or splint	
Ortho - Advanced	Ablation of bone tumor; clavectomy; Open repair of proximal humeral fracture; open treatment of shoulder dislocation; arthroplasty radial head; ligamentous reconstruction of the knee	

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Procedure Category	Basic	Advanced
Plastic-Basic	Breast implant placement, local skin flaps <5cm; skin grafting <100 sq. cm	
Plastic or Reconstructive - Advanced	Fascia or muscle graft for face nerve palsy; excision excessive skin or subcutaneous tissue, face or trunk or extremity, including liposuction	
Proctology - Basic	Treatment of pilonidal cyst, rectal lesion, rectal abscess, anal fissure, hemorrhoids, anal fistula; anoscopy	
Skin or Subcutaneous Tissue - Basic	Incision, drainage, removal, abscess or foreign body or hematoma; debridement, skin, subcutaneous tissue, muscle, bone; paring callus; biopsy, skin lesion; Remove, skin tags; shave, skin lesions; excision, skin lesion, benign or malignant; excision, hidradentiis, axillary or inguinal or perineal; Excision, skin lesion, benign or malignant; Surgery of the nails or nail bed; Introduction or removal, tissue expanders; Insertion or removal, drug delivery system; Simple or complex or layer closure, wounds; Skin grafts, autografts or allografts or xenograft; dermabrasion, chemical peel, simple facial plastic surgery; Removal excessive skin; destruction lesion, laser or electrosurgery or cryosurgery or chemosurgery; Incision, abscess	
Spine - Advanced	Incision or drainage, deep abscess, cervical, thoracic, lumbar spine; excision or osteotomy, cervical, thoracic, lumbar spine; spinal fracture, closed or open treatment; vertebroplasty; kyphoplasty; arthrodesis, cervical, thoracic, lumbar spine; laminectomy for exploration or decompression or excision; Implantation or removal of spinal catheter or neurostimulator	
Thoracic- Basic	Bronchoscopy; chest tube placement; thoracentesis; percutaneous pleural biopsy	
Thoracic - Advanced	Pacemaker placement; implantable defibrillator placement	
Vascular- Basic	Central venous access; arteriovenous fistula, primary or graft; endovenous ablation; sclerotherapy	
Vascular-Advanced	Venous excision	



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