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

October 30, 2018
Defense Health Board

Overview

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- Meetings

- Overview of Surgical Volume and Its Relationship to Patient Safety and Quality of Care

- Opportunities for Standardization and Transformation: National Defense Authorization Act Fiscal Year 2017 (NDAA FY 2017)

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- Findings and Recommendations

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

- Specifically, the DHB 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.

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Objectives and Scope – Initial Six Months

- Review the array of low-volume high-risk surgical procedures performed by military surgeons in the Direct Care system at 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);

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- Examine the contribution (Knowledge, Skills, and Abilities) of low-volume high-risk procedures to military medical readiness (e.g., surgeons, operating room staff);

- Evaluate Military Health System (MHS) policies related to surgical volume transparency and public release of volume, errors and outcomes data.; and

- Provide recommendations on using the volume, errors and outcome data to inform and enhance policies for managing surgical capabilities and surgeon currency.

Objectives and Scope – Second Six Months

- 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.

The T&I Subcommittee has worked to gather information and review the draft report through the following in-person briefings and teleconferences:

August 28, 2018	Meeting to receive briefings regarding simulation training, MTF surgeons' perspective on surgical volume, Navy Chief Medical Officer (CMO) role, and to review report sections
September 11, 2018	Teleconference to receive a briefing regarding a large civilian health system's policies and procedures
September 13-14, 2018	Teleconference to receive briefings regarding Volume Pledge institutions (Johns Hopkins, Dartmouth Hitchcock), German military healthcare system, Leapfrog, National Capital Region-Medical Directorate (NCR-MD), American College of Surgeons (ACS) partnership with the military, TRICARE, DoD Patient Safety Program, and MHS Transparency Initiative
September 21, 2018	Teleconference to receive a briefing regarding Volume Pledge implementation at the University of Michigan Health System

Meetings Since Last Board Meeting

September 24, 2018	Teleconferences to receive briefings regarding DHA coding efforts and to review report sections
October 3, 2018	Teleconference to receive briefing regarding readiness and to review report sections
October 9, 2018	Teleconference to review report sections
October 15, 2018	Teleconference to receive briefing from DHA leadership and review report sections
October 16, 2018	Teleconference to review report sections
October 18, 2018	Teleconference to review report sections
October 25, 2018	Teleconference to review report sections

PREDECISIONAL

- The phrase "low-volume high-risk surgical procedures" is used in the tasker. However, it does not fully represent the surgical volume-outcome issue due to the dynamic nature of risk, which can vary in different environments. Instead the phrase "low-intensity" is used in this report.

    - Low-intensity surgical environments perform operations for healthier patients with few comorbid conditions, have a lower frequency of operations, and/or exist with a more basic facility infrastructure and team expertise.

- The surgical care experience and outcome issue is not exclusive to the military environment and has been debated in civilian healthcare sector for decades. The literature showing a positive relationship 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. Certain procedures demonstrate a more robust relationship.

- Volume alone is not an absolute predictor of quality. It may help to identify or predict success, but is not a measure itself.

- Other literature suggests using caution when making conclusions about the volume and quality relationship, citing the limitations of statistical analysis used for some of the surgical volume research, including arbitrary cut-off points and the lack of focus on the experience of the surgeon.

- The patient's level of risk also affects outcomes and must be considered.

- Due to several current MHS requirements related to readiness, remote MTF locations, and deployment environments, some procedures are conducted in low frequencies.

Opportunities for Standardization and Transformation: NDAA FY 2017

- 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.

- In conjunction with *NDAA FY 2017*, specifically *Section 702 Reform of administration of Defense Health Agency and military medical treatment facilities*, the Board's recommendations to focus on standardization align with DHA policies for implementation by 1 October 2018.

- 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, pro-active, 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.

- **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.

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- 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.

- There are **standardization** opportunities across the Services and at the DHA-level, spurred by *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 MTFs. Successful practices and policies, such as already established civilian and VA partnerships to increase both surgeon and surgical team proficiency, simulation training, and infrastructure requirements, should be leveraged.

Patient Safety and Quality of Surgical Care

- 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.

- The MHS has historically strived along a continuous learning path of improvement, informed by evidence-based practices and lessons-learned.

  - The Joint Trauma System (JTS) is an example that is directed at disseminating knowledge in a manner that could be used in other areas within the MHS. The accomplishments of the JTS were reviewed and highlighted in the National Academies of Sciences, Engineering, and Medicine (NASEM) *Zero Preventable Deaths* report.

- 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. Recommendations from this review aimed to foster the creation of a High Reliability Organization (HRO) across the MHS.

  - Efforts and programs such as the DoD Patient Safety Program (DoD PSP), MHS Quality Assurance Program, MHS Transparency Initiative, and ACS NSQIP, now with all MTFs participating, may lead to surgical quality improvements and the move to create a more synchronized system for standardization within the MHS.

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Data Capture, Optimization, and Outcome Measurements

- Accurately capturing data is critical for measuring patient safety and quality of care.

- ACS NSQIP is used in all 48 MTFs; however, there is room for improvement and standardization of how the data are utilized 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.

- Challenges for reporting accurate total surgical volume also 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).

Ready Medical Force

- Being medically ready, including medical team readiness, is vital to successfully performing low-volume procedures and critical to ensuring the establishment and maintenance of integrated team skills in both peacetime and wartime medical settings to reduced variability.

- The KSA pilot program has the potential for creating an environment of standardization, accountability, and quantifiable results.

- The Joint Trauma Readiness Training Program aims to link the various areas of medical readiness, with the implementation of *NDAA FY 2017*, which aligns the JTS under the DHA.

- 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. Leveraging technologies, including the use of simulations, allows for maintenance and proficiency of surgical skills and may be able to be used for low-frequency procedures.

PREDECISIONAL

Standardization

- Variation and a lack of standardization exists between the Services and NCR-MD for managing facility surgical capabilities and surgeon/staff proficiency, including readiness-training models and development of partnerships between MTFs and civilian/VA facilities, which increase case load and demonstrate potential to serve the community as part of the national trauma system.

- 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:
  - Army's readiness efforts with its Level I Trauma Center
  - Navy's Chief Medical Officer (CMO) position
  - Air Force's partnership efforts and utilization of the VA's surgical complexity matrix
  - NCR-MD's efforts on the KSAs and market expansion/patient recapture

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.

Culture of Safety and Quality: Finding and Recommendation 2

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 ~~NSQIP~~ 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.

Recommendation 2:

b) Regulation and policy barriers for confidentiality of patient safety 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.

Culture of Safety and Quality: Finding and Recommendation 3

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[1] 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. ~~Patient t~~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 ~~NSQIP~~ risk-adjusted data, such as NSQIP, for transparency with patients must enable patient-friendly comparisons between MTFs and potential civilian referral centers.

[1] 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.

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).

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.

Data Capture, Optimization, and Outcome Measures: Recommendation 4

Recommendation 4:

A) The ~~DHA~~ 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).

Finding 5:

A) Surgical outcomes are a reflection of surgeon and surgical support staff skill, team effectiveness, and ~~as well as~~ 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.

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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.

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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 ~~MHS~~ 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.

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 ~~loss of beneficiaries~~ 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.

   a) The MHS must leverage best practices from the Services, specifically the Air Force, and ensure providers' work in external facilities is accurately captured.

   b) The MHS must consider templated partnership agreements at the enterprise-level.

   c) 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.

   d) The DoD should seek engagement with international partners to increase experience in high-intensity environments.

   e) 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).

Questions?