

Decision Brief

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

May 20, 2019
Defense Health Board

PREDECISIONAL



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Tasking

(1 of 2)

- 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, DHB was asked to make findings and recommendations on policies and practices in place to:
 - Determine where high-risk surgical procedures should be performed
 - Optimize safety and quality of surgical care provided
 - Enhance patient transparency related to surgical volumes and outcomes
 - Evaluate contribution of high-risk surgical procedures to medical readiness

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Tasking

(2 of 2)

- First report released November 2018
- Second report objectives and scope
 - Review array of low-volume high-risk surgical procedures performed on MHS beneficiaries in the Purchased Care System (TRICARE)
 - Evaluate potential for MHS to sign the “Surgical Volume Pledge”



Meetings Since Last Board Meeting

(1 of 2)

February 22, 2019	Teleconference to receive briefings regarding surgical volume and quality programs at Mayo Clinic and Defense Health Agency (DHA) participation with the Leapfrog Group
February 27, 2019	Teleconference to receive briefing regarding the American College of Surgeons (ACS) Advisory Council for Rural Surgery (ACRS)
February 28, 2019	Teleconference to receive briefing regarding the ACS approach to surgical volume and quality of care
March 18, 2019	Teleconference to receive briefing regarding several pilot efforts at Walter Reed National Military Medical Center (WRNMMC), examine the 10 “low-volume high-risk” surgical procedures data for TRICARE, and review report sections
March 26, 2019	Teleconference to review report sections



Meetings Since Last Board Meeting

(2 of 2)

March 28, 2019	Teleconference to receive briefings regarding medical force structure, TRICARE, and DHA updates since publication of the first report
April 4, 2019	Teleconference to receive updates regarding the Joint Trauma System (JTS), the Surgical Volume Pledge, and the Knowledge, Skills, and Abilities (KSA) program
April 16, 2019	Teleconference to review report sections
April 26, 2019	Teleconference to review report sections
May 1, 2019	Teleconference to review report sections
May 9, 2019	Teleconference to review report sections
May 10, 2019	Teleconference to review report sections



Introduction

- First report focused on direct care – care received at military medical treatment facilities (MTFs).
- Second report focuses on purchased care – care received in the TRICARE network.
- Note: the phrase “low-intensity surgical environments” conveys dynamic nature and impact of risk better than “low-volume high-risk” surgical procedures.
 - Such 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.



Surgical Outcomes are Direct Quality Measures (1 of 6)

Historical Approaches to Surgical Quality: The Volume Pledge

- In May 2015, Johns Hopkins Medicine, Dartmouth-Hitchcock Medical Center, and University of Michigan Health System created the Surgical Volume Pledge (“Volume Pledge”), vowing that their hospitals would meet annual volume thresholds for ten “low-volume high-risk” surgical procedures for both the hospital and the surgeon.
 - The Volume Pledge specifies that a facility that does not meet volume thresholds for specific procedures will direct surgical care for those procedures to alternate facilities that do meet thresholds.
 - The 10 surgical procedures were selected by roundtable consensus from six expert panels of six surgeons per panel from various specialties at the three institutions.

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



Surgical Outcomes are Direct Quality Measures (2 of 6)

*Historical Approaches to Surgical Quality:
The Volume Pledge*

- Three out of 6,210 U.S. hospitals have taken the Volume Pledge.
- These three institutions vary in adoption and execution of the Volume Pledge.
- There is limited evidence regarding the Volume Pledge impact on patient-centered quality and safety.
- No data regarding outcomes or impact on access to care could be obtained from the three Volume Pledge institutions.



Surgical Outcomes Are Direct Quality Measures (3 of 6)

Current Approaches to Surgical Quality

- **Department of Veterans Affairs (VA)** has not joined the Volume Pledge. The VA relies on facility infrastructure to engineer quality. This approach focuses on the entire surgical team, rather than volume alone.
- **Kaiser Permanente (Kaiser)** has not joined the Volume Pledge due to the need for flexibility and the unintended consequences of imposing strict thresholds below which surgeons must stop performing a procedure or increase their annual procedure volumes. Specifically, Southern California Permanente Medical Group addresses quality outcomes through simulation, systematic pre-operative patient optimization, peer review methods, and deliberate distribution of complex cases to low- and high-volume hospitals and surgeons.



Surgical Outcomes Are Direct Quality Measures (4 of 6)

Current Approaches to Surgical Quality

- **Mayo Clinic** did not join the Volume Pledge because internal quality assurance processes have been determined to be of more value.
 - Prefers electronic health record (EHR) data mining, use of risk-adjusted registries like the ACS National Surgical Quality Improvement Program (NSQIP), and rapid performance improvement processes
- **Massachusetts General Hospital (MGH)** did not join the Volume Pledge because of concern that the Volume Pledge was inconsistent with, and a potential distraction from, its institutional approach to optimizing operative outcomes.
 - Monitors outcomes closely through NSQIP and other national comparative registries for quality and outcome improvement, specifically when high-intensity cases are performed.



Surgical Outcomes Are Direct Quality Measures (5 of 6)

Summary: Approaches to Surgical Quality

- Studies of the level of surgical care experience and efforts to improve outcomes are not exclusive to the military and have been strong initiatives in the civilian healthcare sector for decades.
- Historically, better outcomes for specific complex operations have been associated with higher volumes of those specific operations among surgeons and hospitals.
- Assertions about the volume-outcome relationship are limited by weaknesses in study methodology, use of arbitrary cut-off volume thresholds, and exclusion of total surgeon/surgical team experience and level of patient risk as variables.
- The critical distinction between association and causation must be applied to volume-outcome relationship.
- Positive surgical outcomes reflect more than volume. Good surgical technique and judgment, team proficiency, proper support services, sound hospital structural processes, and appropriate surgical candidate selection are essential.



Surgical Outcomes are Direct Quality Measures (6 of 6)

Risk-Adjusted and Benchmarked Outcomes

- Surgical performance improvement requires looking at results that matter to patients and surgeons. Risk-adjusted and benchmarked surgical outcomes in morbidity and mortality are available through professional society programs.
 - Examples include the ACS NSQIP, Trauma Quality Improvement Program (TQIP), and the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP).
- NSQIP is a voluntary, “nationally validated, risk-adjusted, outcomes-based program to measure and improve quality of surgical care.”
- In 2014, 17 MTFs participated in NSQIP; in 2018 it was used in all 48 surgical inpatient MTFs.
- Purchased care network providers and facilities are not contractually required to use NSQIP. Those purchased care facilities that do use NSQIP are not required to share data with DHA clinical quality managers.



Comparison of Direct Care and Purchased Care Quality and Patient Safety Programs

(1 of 3)

- The DHA manages quality in direct care, whereas Managed Care Support Contractors (MCSCs) manage quality in purchased care with oversight by DHA clinical quality personnel.
- The MHS quality and patient safety metrics are tracked in separate dashboards for the direct and purchased care networks.
 - Direct care dashboard has 64 measures
 - Purchased care dashboard has 18 measures
 - 8 of the measures are the same, limiting comparisons at the enterprise-level
- There is no systematic method for connecting direct and purchased care data to risk-adjusted, benchmarked data in the deployed setting.



Comparison of Direct Care and Purchased Care Quality and Patient Safety Programs

(2 of 3)

- During this period of *NDAA FY 2017 Section 702* transition, existing DHA processes and staffing are insufficient for quality oversight across the direct and purchased care networks.
- Planning for an integrated and standardized quality assurance and patient safety capability across the direct and purchased care networks is underway.
 - The DHA Clinical Quality Management (CQM) procedures manual (intended release) July 2019 lists 6 CQM programs: 1) Patient Safety, 2) Healthcare Risk Management, 3) Credentialing and Privileging, 4) Accreditation and Compliance, 5) Clinical Measurement, and 6) Clinical Quality Improvement.
- The current TRICARE Operations Manual (TOM) governing purchased care requires contractors to have Clinical Quality Management Plans (CQMPs), though linkage to DHA is unclear.



Comparison of Direct Care and Purchased Care Quality and Patient Safety Programs

(3 of 3)

- In the first report, the Board reviewed the 10 “low-volume high-risk” surgical procedures performed by military surgeons at MTFs. Examination of quality was challenging due to inaccurate administrative data, personnel resources and coding tools.
- In this second report, the Board reviewed the same 10 procedures performed for MHS beneficiaries in the purchased care network. While it was possible to determine how many of the specified surgeries were performed on patients in purchased care, the data were otherwise unhelpful.
 - Purchased care patient data are derived from aggregated administrative claims data and represent only the care delivered through purchased care.
 - Because such patients make up only a portion of surgeon and facility cases, the volume of care by surgeon and facility is unknown.



Resources Relative to Workload in Oversight of Direct Care and Purchased Care Quality and Safety

- DHA leadership has high visibility on direct care quality and safety and reviews all sentinel events, but has lesser visibility of purchased care quality and safety and little to no visibility on quality and safety in deployed environments.
- For a system of 9.5 million beneficiaries:
 - There is limited staffing of the direct care quality program.
 - There is limited staffing of the newly developed DHA Policy and Integration Division for purchased care quality oversight of two large, complex TRICARE MCSCs, and the OCONUS contract.



Professional Society Initiatives in Infrastructure for Quality Care

- Patient safety and the quality of surgical care depend on training, experience, and skills of the surgeon, as well as the availability of institutional resources (i.e. facility infrastructure) and the ability to measure surgical outcomes.
- The American College of Surgeons *Optimal Resources for Surgical Quality and Safety* (i.e. the “Red Book”) delineates optimal resources and defines outcomes for surgical care.
 - This manual builds on successful models used across other ACS quality programs, including the Commission on Cancer, the Committee on Trauma, Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), NSQIP, and the Children’s Surgery Verification Program.
 - Based on the “Red Book,” the ACS developed the Surgical Quality Verification program, a hospital assessment program.
 - In 2018, WRNMMC was the first MTF to participate in the ACS Surgical Quality Verification pilot program.



Updates in DoD and DHA Medical Readiness

- The Knowledge, Skills, and Abilities (KSA) program was initiated by the Uniformed Services University Department of Surgery to provide a consistent method for quantifying surgical readiness by mapping relevant surgical skills from pre-deployment operations.
 - 3,790 KSAs have been mapped in eight critical wartime specialties.
 - 8 additional specialties will have KSAs completed in June 2019.
- The MHS approaches partnerships from multiple levels to include educational partnership agreements (EPAs), Service-specific agreements, and local MTF agreements. There is a lack of curricular consistency, inter-Service coordination, and verification of training outcomes across these partnerships.
- The Military Health System Strategic Partnership with the American College of Surgeon (MHSSPACS) is developing standards for military-civilian partnerships in the Blueprint Guidelines for Military-Civilian Partnerships in Training, Sustaining, Retention, and Readiness (i.e. the “Blue Book”), anticipated completion in 2019.



Finding 1

Finding 1:

- A) Surgical volume is an imperfect surrogate measure of surgical quality.
- B) Out of 6,210 hospitals in the U.S., only three academic institutions (Johns Hopkins Medicine, Dartmouth-Hitchcock Medical Center, and University of Michigan Health System) adopted a version of the Surgical Volume Pledge, and only one remains a strong proponent (Johns Hopkins Medicine). The 10 “low-volume high-risk” operations contained in the Surgical Volume Pledge were developed by roundtable consensus from only these three institutions.
- C) The ACS National Surgical Quality Improvement Program (NSQIP) is a nationally validated, clinical risk-adjusted, and outcomes-benchmarked program that improves the quality of surgical care.
 - i) NSQIP is used by all 48 surgical inpatient MTFs in the direct care network.
 - ii) NSQIP participation is not a requirement for surgical care organized through the TRICARE Managed Care Support Contractors (MCSCs).
 - iii) Purchased care facilities that use NSQIP are not required to share data with the DHA clinical quality managers.



Recommendation 1

Recommendation 1:

- A) The MHS should not use volume data as a sole measure of surgical quality or sole requirement for surgical privileging.
- B) The MHS should not join the Surgical Volume Pledge.
- C) The DHA must require that all institutions providing surgical care in the direct care and purchased care networks (1) participate in NSQIP; (2) assess outcomes through surgical specialty registries, patient safety programs with adverse event analysis, and peer-review programs; and (3) share findings from NSQIP, surgical registry, patient safety, and peer-review programs with the DHA.



Finding and Recommendation 2

Finding 2:

- A) The MHS does not have a comprehensive program for quality assurance and patient safety that covers the direct care, purchased care, and deployed care networks.
- B) The MHS purchased care network does not collect risk-adjusted outcomes data. Currently, patient population data from the purchased care network is derived from aggregated administrative claims data from submitted TRICARE claims.
- C) There are limited standard metrics and analytics for comparison of quality in direct care and purchased care institutions. Currently, the direct care quality dashboard has 64 measures, whereas the purchased care dashboard has 18 quality measures. Only eight of the measures are the same for direct care and purchased care.

Recommendation 2:

- A) The DHA must integrate direct care and purchased care quality management to ensure that care is of the highest quality in both networks and consider how to integrate care in the deployed environment into the MHS quality program.
- B) The MHS must use a standard quality framework for consistent analysis of risk-adjusted data and with a focus on patient outcomes. The DHA quality program must drive a continuously learning health care system for ongoing improvement in patient safety and quality.
- C) The DHA must standardize quality metrics for tracking of quality in both networks in a unified dashboard that is focused on risk-adjusted, benchmarked outcomes.



Finding and Recommendation 3

Finding 3:

The DHA is responsible for oversight of quality of care and patient safety for 9.5 million beneficiaries in both direct care and purchased care networks that include two large, complex TRICARE MCSCs and MTFs domestically and overseas. There is a very significant lack of staff and resources to oversee quality and patient safety across the enterprise.

Recommendation 3:

The DHA must provide adequate staff and resources equivalent to leading civilian health systems and managed care plans, to enable effective and efficient quality assurance across the purchased care and direct care networks.



Finding and Recommendation 4

Finding 4:

- A) Professional society verification of infrastructure relative to standards in trauma, cancer, and bariatric surgery centers has improved patient outcomes.
- B) The ACS has initiated a Surgical Quality Verification program, based on the ACS *Optimal Resources for Surgical Quality and Safety* (“the Red Book”) manual, to promote standards and better outcomes. The ACS Surgical Quality Verification program has been piloted at four facilities, including one military treatment facility (Walter Reed National Military Medical Center [WRNMMC]).

Recommendation 4:

The DHA should continue to evaluate and implement surgical quality verification programs by professional societies across facilities in direct care and purchased care networks.



Finding and Recommendation 5

Finding 5:

- A) The Knowledge, Skills, and Abilities (KSA) project continues to expand with the addition of eight KSAs for implementation in June 2019.
- B) *NDAA FY 2017 Section 717* permits civilians and veterans to be evaluated and treated at MTFs in order to support relevant patient care experiences that sustain medical readiness skills and competencies.
- C) The DHA has multiple pathways for military-civilian partnerships, including local agreements between MTFs and civilian institutions, Service agreements with civilian institutions, and educational partnership agreements (EPAs) between the DHA and other organizations (to include the VA, the Department of Health and Human Services, and the ACS). There is a lack of curricular consistency, inter-Service coordination, and verification of training outcomes across these partnerships.

Recommendation 5:

- A) The DoD must continue to support the KSA program with resources for expansion and tracking of outcomes that demonstrate improvement in medical readiness.
- B) The DHA must continue to expand civilian and VA partnerships that sustain surgical readiness through enhanced clinical experience.
- C) The DHA must promote inter-Service collaboration by developing a framework for consistent implementation, monitoring, and verification of all partnership agreements, to include education and training goals, curricula, and authentication of outcomes.



Questions?