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Volume standards and outcomes measurement—Complementary strategies to improve surgical quality

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Precis: This Editorial argues that minimum volume standards are a necessary qualifying criterion for complex oncologic surgical delivery, and once met, should be combined with other methods for measuring and improving surgical performance improvement. These two practices are not mutually exclusive.

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In the last twenty years, expanding research has consistently demonstrated that surgeon and hospital volume are associated with short- and long-term outcomes for high risk surgery, especially complex oncologic surgery. [1-4] The Leapfrog Group, a national organization centered on quality improvement for hospitals, created the Volume Pledge in 2015. The Volume Pledge set minimum volume standards for esophageal, lung, pancreatic and rectal cancer resection for hospitals and surgeons with the goal of establishing a floor, below which hospitals would be unlikely to have the clinical experience, tacit knowledge, and resources required for optimal performance.[5]

This Editorial argues that minimum volume standards are a necessary qualifying criterion for complex oncologic surgical delivery, and once met, should be combined with other methods for measuring and improving surgical performance improvement—we believe the two are not mutually exclusive.

In this issue of Cancer, Aquina and colleagues report variation in postoperative complications and 90-day mortality among surgeons meeting the Leapfrog volume standards for esophagectomy, lung resection, pancreatectomy, and proctectomy among two distinct patient cohorts. The authors should be commended for a methodologically sound analysis addressing a topic of significant policy and clinical importance. Consistent with prior studies, the authors found that high-volume surgeons at high volume hospitals were associated with lower adjusted odds of complications and 90-day mortality for all procedures. However, among surgeons who met the volume criteria, the authors noted a two-fold variation in complication rates for all surgeries (esophagectomy 28-55%, lung resection 7-21%, pancreatectomy 16-35%, proctectomy: 16-28%). Wide variation in 90-day mortality was only found for esophagectomy and pancreatectomy.[6]

Based on these findings of variation across surgeons meeting minimum volume standards, the authors conclude that while a volume-outcome association exists, volume minimums should not be used as the sole measure of quality. We agree with the authors that minimum volume standards should not be the only approach used to improve surgical outcomes. However, we believe it is important to note that these findings in no way invalidate the use of minimum volume standards. There is no need to create a false dichotomy between volume standards and other approaches to quality improvement. In fact, minimum volume standards and other approaches, such as rigorous outcome measurement and improvement, as the authors note, can be complementary. Volume standards ensure that surgeons (or hospitals) achieve a baseline level of competency after which measures of outcomes can be used, where reliable, in feedback mechanisms for quality improvement to further reduce the variation pointed out by Aquina and colleagues.

When applied to individual surgeons, hospitals and healthcare systems, volume minimum standards serve as a threshold to filter out surgeons and surgical delivery environments who lack the volume to maintain clinical competence, the necessary resources to rescue from complications, and interdisciplinary teams required for complex post-operative care. While the effect of surgeon versus hospital volume varies by procedure, higher volumes for both factors are associated with better outcomes.[7] Higher individual surgeon volume for cancer resections has been associated with lower perioperative mortality, perioperative complications, recurrence and long term survival through mechanisms including technical skill and intra-operative decisions making and processes. [3,7-8] High volume hospitals have similar association with outcomes due to the presence of specific hospital-based

services (ex. distribution of hospital bed types, technology, and nurse staffing) which contribute to lower failure to rescue rates and improved short term outcomes.[9] Additionally, surgical resection at high volume hospitals has been associated with higher uptake of adjuvant therapy and presence of multi-disciplinary oncologic teams, which contributes to the long-term outcome of survival.[10] We believe this persistent replication of the volume-outcome association, across numerous conditions and outcomes, serves as the basis for to implement volume standards as a screening tool for hospitals and surgeons that meet a bare minimum in terms of experience.

The role of minimum standards is not mutually exclusive from the importance of collecting, maintaining and addressing outcome measures, when reliable, for oncologic surgery. However, it is important not to treat "measuring outcomes" as a gold standard that is always the ideal approach. Outcomes measurement has its own Achilles heel—namely, small sample size for most surgeons and hospitals. We tend to readily understand that statistical power is essential for randomized trials, but we forget the same forces are at play when measuring outcomes. For individual surgeons, and particularly for rare, complex operations (e.g., pancreatic and esophageal resection), there is very little "signal" and a lot of "noise" when measuring outcomes. In fact, volume is actually a much better measure of quality than outcomes for such procedures.[11] When proven to reliably profile providers, outcome metrics such as complications, mortality, and readmission should be used in conjunction with long-term oncologically-relevant outcomes (e.g., margin status, adequate lymphadenectomy, survival, recurrence, survivorship) to monitor and improve performance.

There are strong precedents for systematically combining volume standards and outcomes monitoring to optimize outcomes. Transplant Surgery serves as an example of using volume standards followed by rigorous data collection, monitoring and reporting for ensuring a high quality of care. In 2007, CMS issued a Conditions of Participation (COP) for solid organ transplantation specifically outlining volume and quality standards. To be considered for initial approval by the Center for Medicaid and Medicare Services (CMS), organ specific transplant centers must perform a minimum volume (e.g., 10 transplants for lung, liver, and heart) over the course of a year.[12] In addition to this volume minimum, transplant centers must adhere to strict policies regarding data collection and reporting on several outcome measures including mortality, patient, and graft survival. These are closely monitored to identify outliers which are then targeted for improvement efforts. Each center is required to have a Quality Assessment and Performance Improvement (QAPI) program that allows for monitoring and evaluation of performance of transplant services outcomes including patient and donor management, technique for organ recovery and patient satisfaction.[12] While complex cancer operations have similar operative risk, and there is wide variation in longer term outcomes, no such intentional structure has been applied to cancer care.

An intentional program to monitor and improve cancer care could also address longstanding disparities in quality of care within complex oncologic surgery. It is well documented that certain sociodemographic factors, including race, insurance status, and geographic residence, are specifically associated with receipt of cancer surgery at low volume hospitals.[13,14] The disproportional receipt of surgical care at low volume centers by racial/ethnic minorities, uninsured or Medicaid patients, and individuals who live in geographical areas with high levels of social deprivation provides the opportunity to reconceive the role of volume standards in combination with quality improvement programs as tools for surgical equity. The often-cited unintended consequence of increased social and economic barriers to surgical care potentially associated with volume minimum standards does not justify the avoidance of implementation of volume standards but rather highlights the concurrent need for increased structures centered on the surgical determinants of health(SDOH) to achieve equity in surgical delivery. The improvement in complex surgical oncology for vulnerable populations can be achieved with implementation of volume standards with rigorous quality assessment including measures centered on disparities along with creation of targeted interventions addressing the effect of SDOH on surgical access and outcomes.

In summary, we believe minimum volume standards are an important tool for reducing the prevalence of low performing surgeons and hospitals. As noted by Aquina and all in this issue of Cancer, such volume standards alone are not enough. We also need to build outcomes monitoring systems that provide feedback, when and where it is reliable enough, to profile and improve the quality of care for all patients who require complex cancer surgery.

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