

What is quality, and can we define it in lung cancer? – the case for quality improvement

Farhood Farjah¹, Frank C. Detterbeck²

¹Division of Cardiothoracic Surgery, Surgical Outcomes Research Center, University of Washington, Seattle, USA; ²Section of Thoracic Surgery, Yale Thoracic Oncology Program, Yale University School of Medicine, New Haven, USA

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Correspondence to: Farhood Farjah, MD, MPH. Division of Cardiothoracic Surgery, Surgical Outcomes Research Center, University of Washington, Seattle, Washington, 98195, USA. Email: ffarjah@uw.edu.

Abstract: Decades worth of advances in diagnostics and therapeutics are associated with only marginal improvements in survival among lung cancer patients. An obvious explanation is late stage at presentation, but gaps in the quality of care may be another reason for stifled improvements in survival rates. A framework for quality put forth by Avedis Donabedian consists of measuring structures-of-care, processes, and outcomes. Using this approach to explore for potential quality gaps, there is evidence of inexplicable variability in outcomes across patients and hospitals; variation in outcomes across differing provider types (structures-of-care); and variation in approaches to staging (processes-of-care). However, this research has limitations and incontrovertible evidence of quality gaps is challenging to obtain. Other challenges to defining quality include scientific and clinical uncertainty among providers and the fact that quality is a multi-dimensional construct that cannot be measured by a single metric. Nonetheless, two facts compel us to pursue quality improvement: (I) both empirically and anecdotally, actual care falls short of expected care; and (II) evidence of potential quality gaps is not ignorable primarily on ethical grounds.

Keywords: Lung cancer; quality improvement; outcomes research

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Introduction

Despite considerable advances in diagnostics and therapeutics, overall survival rates for lung cancer have increased by only 4% over the last three decades (1). A common explanation for this observation is late-stage at presentation. There is no doubt that patient disease overshadows medical advances when cancer is incurable. Fortunately, lung cancer screening is expected to usher in a new era of early-detection and cure leading to better survival rates for the overall population of lung cancer patients (2). However, it is important to temper our expectations of screening because one-fifth of lung cancer patients are never smokers and only an estimated 5-10% of all smokers are eligible for screening (3,4). It is also

important to wonder if there are other explanations for the modest improvements in lung cancer survival over time.

An alternative explanation for modest survival gains over time is suboptimal care delivery. Invoking this explanation assumes that advances in diagnostics and therapeutics have been demonstrated to improve outcomes, patients remain eligible and willing to undergo these interventions, and that providers willingly deviate from established standards. Verifying these assumptions directly is difficult, if not impossible. Nonetheless, there remains a strong interest in understanding whether gaps in quality pose barriers to achieving better outcomes for lung cancer patients.

The goal of this review is to (I) present a standard framework for conceptualizing quality; (II) provide evidence

of quality gaps in lung cancer care using this framework; (III) briefly identify some challenges of defining quality; and (IV) make a simple case for quality improvement.

Framework for quality assessment

One of the greatest barriers to improving quality is the lack of a universal definition for it. In 1990, the Institute of Medicine (IOM) proposed the following definition for healthcare quality: “The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (5). Nearly a decade later, the IOM provided a more granular description of quality through six aims—safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. Despite this well-intended effort to define quality, the task of measuring it remains challenging.

Well before the IOM definition of quality, Avedis Donabedian put forth a model for quality measurement that remains relevant today (6). This model consists of evaluating processes, structures-of-care, and outcomes. It is the most widely used framework for studying and measuring quality. Below are some definitions and examples of processes, structures-of-care, and outcomes, as well as a brief discussion of advantages and disadvantages of each.

Outcomes

Outcomes refer to a broad set of endpoints that characterize the effect of healthcare delivery on patients, populations, health care delivery systems, and society. Given this definition, it is important to clearly understand the perspective (i.e., patient, surgeon, healthcare system, etc.) of an outcomes-based analysis. For instance, a patient-centered outcome is one that matters most to the patient. Examples include, but are not limited to, survival after lung cancer treatment, health-related quality-of-life (HRQOL), cancer recurrence, pain, functional status, decisional-regret, and satisfaction with care. A health plan-centered outcome is one that matters to the payer or insurer. Examples include healthcare utilization and costs. Importantly, outcomes may be relevant to multiple perspectives. For instance, in the prior example, the payer and society both have a stake in healthcare costs. It is also important to understand that outcomes may account for varying themes. For example, the effectiveness of pulmonary resection for lung cancer is often measured in terms of overall survival, whereas safety

is often measured in terms of morbidity and mortality. Other concepts captured through outcomes measurement include resource utilization [e.g., length-of-stay (LOS), readmission], costs, HRQOL, patient satisfaction, and value (e.g., health benefits divided by costs).

One advantage of measuring outcomes is that they are easily interpreted as the “bottom-line”. In other words, if one wants to know if hospitals are providing safe and effective surgery for lung cancer, the most straightforward approach would be to measure hospital-specific morbidity and long-term survival rates. Another advantage is some outcomes are easy to measure, for example inpatient deaths. However, outcomes can also be difficult to measure. For instance, survival measurement requires time and money for complete follow-up. In contrast, HRQOL requires a validated instrument, patient cooperation, and resources to collect data. Another disadvantage of outcomes assessment is that they require statistical adjustments to account for variation in case-mix and to discriminate between signal and noise (i.e., chance) (7). Because different hospitals and providers may care for different patient populations with varying risk profiles, risk-adjustment is necessary to ensure “apple-to-apples” comparisons of outcomes. Some outcomes are rare, making it difficult to discern random variation from true departures (good or bad) from expected outcomes (8). Statistical techniques are available to optimize the “signal-to-noise” ratio (9,10). The added burden of collecting additional clinical variables for the purposes of risk-adjustment and hiring statisticians is expensive.

Processes-of-care

Processes-of-care are healthcare related activities provided for, or on behalf of, a patient. Specific examples include low-dose computed tomography (CT) for lung cancer screening (2) and adjuvant therapy for locally-advanced resectable lung cancer (11,12). In order for processes-of-care to be relevant, they must be linked to a specific outcome of interest.

Several advantages of processes-of-care are that they are relatively easy to measure; are not influenced by case-mix; may serve as a surrogate for measuring long-term outcomes; and are potentially actionable from a provider perspective. The disadvantages of processes-of-care are that they seldom have a well-established causal link to outcomes supported by evidence from randomized trials; appropriateness of use is difficult to assess because the denominator—patients with an indication and without a contraindication for the intervention—can be difficult to measure; and patient

compliance is necessary but not mandatory because of the ethical principle of autonomy.

Structures-of-care

Structures-of-care refer to the context or environment in which a patient receives healthcare. Examples of structures-of-care include facilities, equipment, healthcare personnel, reimbursement guidelines, healthcare policy, and cultural and sociopolitical characteristics of a population. Like processes-of-care, in order for structures-of-care to be relevant they must be linked with a specific outcome of interest.

Several advantages of structures-of-care are that they are relatively easy to measure; are not influenced by case-mix; and may serve as surrogates for measuring long-term outcomes. Disadvantages of structures-of-care are that they seldom have a well-established causal link to outcomes and they are often not easily modifiable. For instance, if high-volume surgery is considered a quality measure, hospitals cannot readily change their volume status.

Evidence of quality gaps

Using Donabedian's measurement framework, investigators have provided evidence of quality gaps. Although by no means an exhaustive account of the literature in lung cancer, the examples below feature several prominent and/or new studies that have investigated quality in terms of outcome, structure, and process.

Outcomes

In the late 20th century, researchers showed that black patients with early-stage lung cancer had lower long-term survival rates than white patients (13). These investigators also showed that blacks underwent curative lung resections less often than whites. The significance of these observations is that there may be inequity in how lung cancer patients are cared for in the United States (US)—an unpopular hypothesis among providers dedicated to high quality patient care but a plausible one given this country's checkered past of racial inequity. Subsequent research showed that a myriad of factors could explain these observations. A growing body of evidence suggests that perceived and/or real barriers to accessing care (despite insurance) are an explanation for differential care and outcomes by race (14,15). Supporting this view are

investigations demonstrating an association between greater access to primary and sub-specialty care and better care and outcomes (16,17). Another common hypothesis is that blacks have more comorbid conditions precluding resection and confounding the relationship between race and outcomes. Several studies demonstrate a higher distribution of comorbidities among blacks, but comorbidities did not fully account for lower rates of resection among blacks (14,18). However, these investigations were limited in their ability to characterize the severity of underlying comorbid conditions—a more likely predictor of optimal therapy. Interestingly, a prospective study was unable to identify racial differences in the severity of underlying lung disease measured by pulmonary function tests (14)—one of the most important determinants of surgical therapy. Another potential explanation for outcomes differences (but not treatment differences) is differential response to therapy. However, neither tumor registry data nor a secondary analysis of clinical trials supports this view (13,19). Finally, perceived and observed communication gaps between patients and providers also appear to be a factor influencing the receipt of optimal care (14,20,21). Thus, in summary, the data supporting differences in the patients (comorbidities) or the tumor biology as associated with racial differences in outcomes is weak, whereas associations with access, type of facility, communication are better supported. This body of research raises serious concerns about a likely gap in quality.

In addition to demonstrating variation in outcomes across patients, researchers have also provided evidence of variation in outcomes across hospitals. Using a clinical registry designed and maintained by the Society of Thoracic Surgeons (STS), investigators have demonstrated over five-fold variation in a composite measure of morbidity and mortality after pulmonary resection for lung cancer (22). This work is notable for three reasons. First, having a clinical registry with granular details allows for robust risk-adjustment increasing the possibility of an apples-to-apples comparison of outcomes regardless of case-mix across hospitals. Second, the researchers used advanced statistical methods (e.g., reliability adjustment) to mitigate the influence of chance inflating (or deflating) rates of adverse events at lower volume centers (9,10). Finally, only 10% of centers were poor performers. One explanation for the paucity of poor performance is the voluntary nature of the STS database and the high likelihood that participants are the best performers in the US committed to quality improvement. A subsequent study compared unadjusted

discharge mortality rates between patients in the STS database to those in the Nationwide Inpatient Sample (NIS) (23). This study demonstrated that patients included in the STS database account for only 8% of all lung resection patients in the US. It also showed that the discharge mortality rate was 66% higher in the NIS compared to the STS. Without risk-adjustment it is difficult to make strong conclusions, but these two findings suggest that the STS may not be generalizable to the rest of the nation, and that the paucity of variation revealed by the STS likely grossly underestimates the degree of variability in outcomes across hospitals, as well as the proportion of poor performing outliers. Again, inexplicable variability in outcomes is a sign of suboptimal care delivery.

Structures-of-care

In the 1970s, Harold Luft, PhD suggested that surgical care should be regionalized based on the observation that higher-volume centers had lower mortality rates (24). Several decades later, the LeapFrog Group—a coalition of employers advocating for higher quality health care—attempted to steer their employees who needed to undergo one of five high-risk operations to seek care at higher volume centers. In an effort to provide evidence of this relationship in the modern era, several groups evaluated the volume-outcome relationship among Medicare beneficiaries undergoing high-risk cancer operations, including pulmonary resection. Researchers demonstrated that higher volume hospitals were associated with lower operative mortality rates, lower complication rates, and higher long-term survival rates (25,26). These findings led to renewed interest in regionalization but also skepticism about the findings and concerns over unintended consequences of centralizing care. Researchers subsequently demonstrated that the volume-outcome relationship is sensitive to how hospital volume is modelled in regression analyses and the limited ability to risk-adjust using administrative data. With more rigorous modelling of hospital volume there was no evidence of a volume-outcome relationship among lung cancer patients (27,28), and a clinical registry with robust risk-adjustment failed to demonstrate a relationship between volume and short-term outcomes after lung resection (29). Another important criticism of regionalization was that volume-outcome relationships were based on averages and not individual hospital performance. As a potential consequence, some low or medium hospitals that performed well might not be allowed to provide care. This concern

was further amplified by research demonstrating that lower volume hospitals were more likely to care for minorities, Medicaid patients, and the uninsured (30), suggesting that a policy of regionalization could further marginalize these groups. Other lines of research showed that greater knowledge of volume-outcome relationships would not necessarily steer patients towards higher volume centers. Medicare beneficiaries who had undergone high-risk operations, including lung resection, were interviewed and half reported that they would not change hospitals even if they knew there was an alternative center nearby with a 1% lower mortality rate (31). Recently, investigators conducted two different national studies evaluating the potential impact of regionalization over decades. Over time more patients were being cared for at higher volume centers, and operative mortality rates were decreasing (32,33). However, improvements in outcomes over time could not be attributed to shifts to higher volume centers because operative mortality rates were decreasing across all type of hospitals. Although the high-visibility nature of the volume-outcome relationship has raised concerns about the quality of care at low-volume centers, the relationship between volume and outcomes remains controversial at best among lung cancer patients.

Interest in regionalizing patients to hospitals also spurred interest in centralizing care based on surgeon specialty. Investigators subsequently demonstrated that board-certified thoracic surgeons with a practice predominantly dedicated to general thoracic surgery were associated with lower operative mortality rates and higher long-term survival rates (34-37). This relationship between subspecialty care and better outcomes was observed even after accounting for the potentially confounding effects of hospital characteristics (e.g., teaching status, bed size, etc.) and surgeon volume. Although not formally investigated, many of the same concerns about regionalizing to specific hospitals have been raised about restricting surgical care to only board-certified thoracic surgeons.

Processes-of-care

Cancer stage is one of the most important determinants of treatment selection, and therefore suboptimal staging has profound consequences for the patient and the provider team. In collaboration with the Commission on Cancer of the American College of Surgeons, Alex Little, MD and associates conducted a national 'patterns of surgical care' study among lung cancer patients (38). This paper is widely

perceived to show that invasive mediastinal staging was being performed far too infrequently (in ~27% of patients). Even more disturbing was the finding that less than half of all patients who underwent mediastinoscopy had tissue specimens submitted for pathological examination. In her discussion of this paper at the 42nd annual meeting of the STS, the late Dr. Carolyn E. Reed said that “the results are an indictment of the present care of patients with non-small cell lung cancer”. These perspectives led to a series of subsequent studies that showed apparent underutilization of both invasive and non-invasive staging modalities in the community-at-large (38-41). Practice guidelines have provided recommendations for performing CT and positron emission tomography (PET) on all patients with suspected or confirmed non-small cell lung cancer, as well as criteria for when to perform invasive staging and the thoroughness of invasive mediastinal staging (42-45). Large tumor registries do not contain sufficient granularity to evaluate the appropriateness of invasive staging. Recent single-institution studies reveal that the expected rate of invasive staging is roughly 75%, and that actual rates are disparate across high-volume, academic, cancer centers ranging from 10% to 97% (46,47).

An anticipated criticism of adopting staging as a process-of-care quality metric is uncertainty about the relationship between diagnostic tests and patient outcomes. Five randomized trials have investigated the use of PET in evaluating patients with lung cancer (48-52). Although none of the studies evaluating survival were adequately powered to do so, no study showed a clinically relevant survival difference (48,49,52). Several trials reported dramatic reductions (by 50%) in stage-inappropriate surgery; however, the rates of futile thoracotomy were so high (20-40%) they were not felt to be acceptable representations of usual care. To the extent that PET identifies occult nodal and distant metastatic disease not detected by physical exam and CT, patients would not want surgery for stage IIIB/IV disease or to be denied a choice of one of several multi-modality options. In this way PET is likely linked to better patient outcomes, even though there is no published scientific evidence demonstrating this relationship. However, the converse is equally important, though frequently ignored: there is a risk of false positive PET findings, with the result that patients are erroneously denied curative treatment. The actual value of PET is influenced by the context in which it is used (53); thus, simply tracking PET utilization rates is unlikely to provide a measure of actual quality and appropriateness of care.

The challenges of defining quality

There are at least two prevailing challenges to defining quality for lung cancer. One is that providers often cannot agree on optimal care because of scientific and clinical uncertainty. Another is that quality is a multi-dimensional concept. In other words, there will never be a single measure of quality, and attempts to improve quality using one metric may have unintended consequences.

Scientific and clinical uncertainty

Debates over what constitutes quality stem from both scientific and clinical uncertainty. For instance, practice guidelines from the American College of Chest Physicians (ACCP) and National Comprehensive Cancer Network (NCCN) recommend invasive mediastinal evaluation for patients with suspected or confirmed non-small cell lung cancer who have PET positive nodes, lymphadenopathy, and tumors that are larger than 3 cm or centrally located (42,43). However, the ACCP recommends endobronchial ultrasound (EBUS) for first-line invasive staging and the NCCN allows for either mediastinoscopy or EBUS as a first-line strategy. This discrepancy was the subject of a recent debate and remains unresolved (54,55). Discordance among experts likely contributes to uncertainty and variable practice patterns. This example was not intended to dismiss one stakeholder groups' perspective, but to highlight variability among experts and the challenges that clinical and scientific uncertainty pose to defining quality.

Quality is a multi-dimensional construct

Quality is a multi-dimensional construct. If quality is too narrowly defined and measured, efforts to improve it may have unintended consequences on other dimensions of quality. The example above about regionalization of care to high volume hospitals demonstrates this concept. Specifically, a policy mandating centralized care could result in wider disparities in care and potentially replace suboptimal care with no care if patients are unwilling to change hospitals (30,31). Another potential example is evident by examining hospital LOS and readmission rates after pulmonary resection. Two different investigative groups have demonstrated a u-shaped relationship between readmission rates and LOS (56,57). In other words, above a threshold LOS, readmission rates tend to increase. Similarly, below the threshold LOS, earlier

discharges are associated with higher readmission rates. To the extent that LOS and readmission are considered markers of quality, aggressive efforts to reduce LOS could paradoxically increase readmission rates. Although it would seem that quality has improved if only LOS is measured and it has decreased over time, measuring both LOS and readmissions may reveal higher readmission rates. It is unlikely that any one measure, or type of metric (structure, process, outcome), is sufficient to “capture” quality. A multi-dimension concept requires multi-dimensional measures.

The case for quality improvement

It is important not to “overthink” the case for quality improvement despite the challenges of defining and measuring it. If we wait until we have the perfect quality measure and intervention, we will never take a single step. There are at least two facts that compel us to pursue quality improvement. First, reality does not meet expectation. A growing body of evidence shows us that actual care is different from what most would consider the standard of care. The limitations of research tempt some to dismiss claims that there are problems with delivery of lung cancer care. However, all of us have some anecdote of patients who have not received the best care, and most of us “know it when we see it” regardless of whether it is extraordinarily high or low quality care. The combination of research findings and clinical experience do not allow us to dismiss the high likelihood that real care falls short of expectations. Another reason to pursue quality improvement is that the available evidence, regardless of its limitations, is not ignorable. For example, to the extent that racial disparities may be due to providers and/or the healthcare system, we have an obligation to eliminate disparate care. This obligation arises from the ethical principle of distributive justice and a society that has declared equity to be a value. While there are harms (e.g., resource utilization) of pursuing quality improvement in the absence of a true quality gap, the harms of not pursuing quality improvement are greater where there are likely disparities and gaps in care.

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Footnote

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