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Defining high quality health care

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Abstract

Most health care quality improvement efforts target measures of health care structures, processes, and/or outcomes. Structural measures examine relatively fixed aspects of health care delivery such as physical plant and human resources. Process measures, the focus of the largest proportion of quality improvement efforts, assess specific transactions in clinical-patient encounters, such as use of appropriate surgical antibiotic prophylaxis, which are expected to improve outcomes. Outcome measures, which comprise quality of life endpoints as well as morbidity and mortality, are of greatest interest to clinicians and patients, but entail the greatest complexity, as the majority of variance in outcomes is attributable to patient and environmental factors that may not be readily modifiable. Selecting among structure, process, and outcome measures for quality improvement efforts generally will be dictated by the specific clinical situation for which improvement is desired.

One aspect of health care quality that has received a great deal of attention in recent years is the relationship between surgical volume and health outcomes. Volume, an inherent characteristic of a health care facility or provider, is generally considered a structural measure of quality. Many studies have demonstrated a positive association between volume and outcomes, and policymakers in the private and public sectors have begun to consider volume in certification and reimbursement decisions. The volume-outcome association is not without controversy, however. Most studies in the field are limited by the nature of the administrative data on which they are based, and some studies have found that variation in quality within volume quantiles exceeds differences between quantiles. Moreover, regionalization driven by a focus on volume may exert adverse effects on access to care.

The movement for health care quality improvement faces substantial methodological, clinical, financial, and political challenges. Despite these challenges, it is a movement that is gaining momentum, and the emphasis on quality in health care delivery is likely only to increase in the future. It is crucial, therefore, that physicians assume increasing leadership roles in efforts to define, measure, report, and improve quality of care.

Keywords: Quality of health care; Health care quality assurance; Health care quality indicators

Introduction

Health policy decisions and interventions focus for the most part on one or more aspects of the triumvirate of cost for, access to, and quality of health care [1]. While cost and access remain intractable problems in the United States and elsewhere, the current decade has witnessed an unprecedented focus on health care quality. Galvanized by the Institute of Medicine (IOM)'s 2001 report, Crossing the Quality Chasm [2], health care researchers and policymakers at local, regional, and national levels are devoting increasing effort and resources to the assessment, reporting, and improvement of quality.

Although defining quality care is not straightforward, the definition adopted by the IOM—"the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" [3]—is frequently repeated and constitutes a useful operational framework. The IOM further identifies 6 domains of quality clinical care (Table 1). While the first 2 domains—safety and efficacy—receive the most attention, particularly in quality reporting efforts, all are important, and each has been studied to some extent in recent years in relation to care of patients with urologic tumors.

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Table 1
Domains of quality care defined by the IOM [2]

1. Safety: minimizing medical errors and adverse events
2. Effectiveness: maximizing intended health outcomes
3. Patient-centeredness: focusing on patient and family comprehension, preferences, goals, and priorities in making treatment decisions
4. Timeliness: minimizing delay between onset of illness and initiation of treatment
5. Efficiency: providing maximally cost-effective care
6. Equity: providing care of equal quality regardless of gender, ethnicity, region, socioeconomic status, or insurance coverage.

One additional domain not explicitly incorporated in the IOM framework is appropriateness—to what extent the decision to perform or omit a given intervention is supported by best evidence and practice guidelines. Appropriateness may be considered to reflect effectiveness, safety, and efficiency, but likely should be considered in its own right in assessing quality care [16].

Assessing quality

Efforts by health care organizations to assess, report, and improve health quality are frequently considered in relation to Donabedian's well-established paradigm of structure, process, and outcomes [4], recently reviewed in depth in the context of surgical procedures [5]. Structural measures of quality are typically concrete and relatively easy to measure. They may include aspects of health care delivery, such as physical plant adequacy; nursing ratios; board certification of providers; and availability of specific expertise, diagnostic tests, and interventions. Structural measures are the focus, for example, of much of the Joint Commission's hospital accreditation surveys. They are relatively easy and inexpensive to assess, but tend to be only weakly associated with outcomes, and are often difficult for providers to influence. Structural measures often work best at establishing a minimal threshold for quality—for example, suggesting that radiation therapy for prostate cancer should be provided at centers with access to intensity modulated delivery systems [6]—thus distinguishing good from inferior but not good from superior. One structural aspect of health care delivery that is the subject of much ongoing debate in urologic oncology and across multiple other fields in medicine is the extent to which hospital and clinician case volume predict outcomes, which will be discussed in more detail below and elsewhere in this seminar [7].

Outcome measures represent the health care delivery endpoints of greatest interest to both clinicians and patients, but are the most complex both to assess and interpret. Outcomes comprise both beneficial and adverse impacts of health care on survival, complications, functional status, and both general and disease-specific health-related quality of life (HRQOL). Improvement in outcomes is the focus of most clinical trials and evidence-based medical guidelines, and there is some evidence that simply measuring outcomes tends to improve them [5]. In practice, however, the majority of variance in outcomes across clinical sites and contexts is attributable to factors external to health care delivery processes [1,8]. For example, in addition to clinical decision-making and quality of care, morbidity and mortality outcomes reflect patient factors such as comorbid illness and compliance as well as random variation [9], and absent a broadly accepted risk-adjustment system, outcomes-based reporting may drive clinicians to turn away higher-risk patients.

Furthermore, important outcomes—perioperative mortality around radical nephrectomy, for example—may be infrequent, such that even a relatively large proportional change may translate to small numbers of observable events in a given year. Indeed, in a large study of hospital mortality rates for 8 major surgical procedures, with the exception of cardiac bypass, most hospitals did not perform sufficient numbers of operations to detect increased mortality rates reliably [10]. The interval between intervention and event may also stretch into years, as is certainly the case for treatment of localized prostate cancer. The large numbers of observations and complex analyses therefore required become costly, and may be prone to statistical manipulation [8].

A strong argument can be made that it is in fact patients who should define which outcomes are critical and whether these outcomes have been achieved [3]. Standardizing such patient-reported outcomes for reporting can be even more challenging, however, as these outcomes depend heavily on who records the assessment; in what setting; using what methods and instruments; and with what corrections for cultural, educational, social, and clinical variability. Direct patient report provides more accurate measurement of HRQOL than clinician assessment [11], but psychometric development and adequate validation of instruments are complex tasks, and for many important HRQOL domains such as urinary and sexual function, multiple competing instruments exist, with varying degrees of overlap and little agreement on standards. HRQOL assessment in urologic oncology is best defined for prostate cancer, where a relatively limited number of instruments are becoming widely used standards [12]; patient-reported HRQOL assessment for bladder cancer outcomes, on the other hand, is gathering increasing interest but remains a relatively nascent field [13]. Outcomes reporting would in theory allow the most appropriate selection of high quality hospitals and providers for referrals. However, such reporting at this point remains problematic for the reasons described above, and one of the few large-scale experiences reported to date confirms that access for high-risk patients may be adversely impacted [14].

Given these barriers to outcomes assessment, most quality improvement efforts focus instead on processes of care, particularly in nonsurgical settings. Process measures generally evaluate the proportion of instances in which an intervention known to correlate with favorable outcomes is undertaken. Examples in surgery include administration of prophylactic antibiotics within an hour of surgical incision, prescription of β-blockers for patients at risk for perioperative myocardial infarction, and appropriate use of thromboprophylaxis [5]. Processes can by further divided into

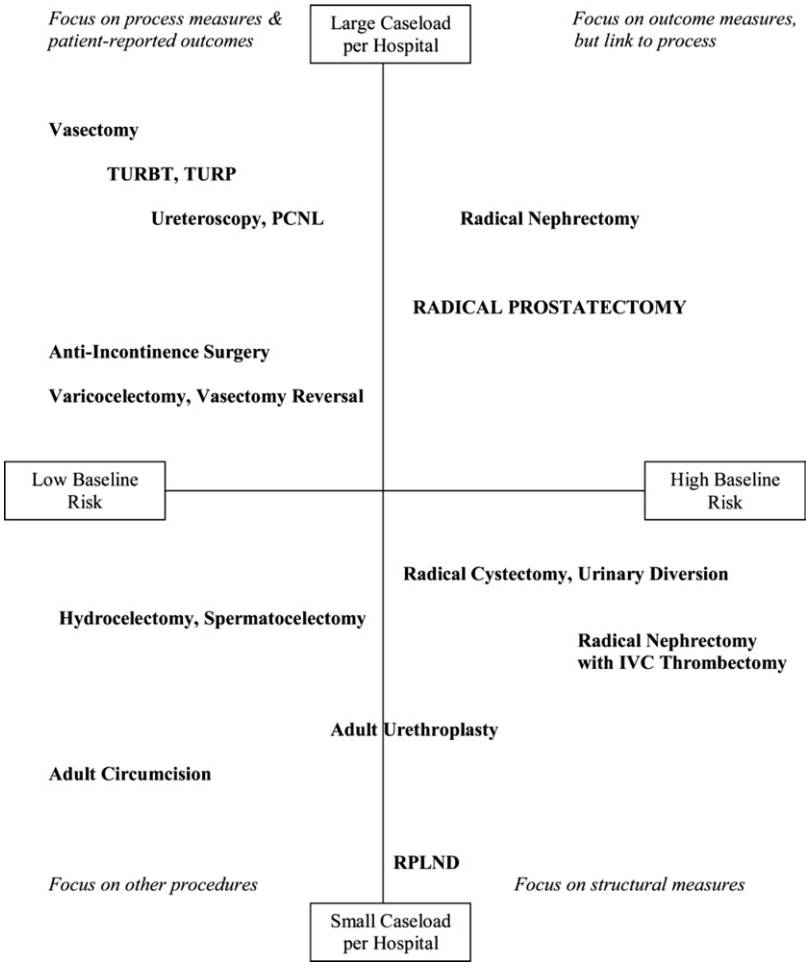

Fig. 1. A conceptual approach to focusing quality improvement efforts based on procedure risk and volume. Reprinted from Miller et al. [16] TURBT = transurethral resection of bladder tumor; TURP = transurethral resection of prostate; PCNL = percutaneous nephrolithotomy; IVC = inferior vena cava; RPNLD = retroperitoneal lymph node dissection. (Reprinted with permission [16]).

interpersonal and technical processes. Interpersonal processes are those which relate to aspects of the clinician-patient interaction such as communication skills, often amenable to assessment via patient surveys. Technical processes relate to whether medical interventions are appropriate and are delivered in a timely and skillful manner. Technical process assessments underlie the development of reportable quality indicators. Processes targeted for improvement ideally should be demonstrated to predict better outcomes reliably based on high-level clinical evidence.

Process measures generally form the basis for most extant quality assurance efforts, including the National Center for Quality Assurance's Health Plan Employer Data and Information Set (HEDIS), and will likely underlie much development of so-called pay-for-performance (P4P) reimbursement incentive systems [15]. However, quality assessment efforts ideally should incorporate structure, process, and outcome measures, with the balance dictated by the specific clinical question. Birkmeyer et al. have suggested a framework, [5] adapted for urology by Miller et al., [16] under which quality metrics are driven by the risk a procedure poses to a patient and the average hospital caseload for the procedure (Fig. 1). For high-risk, low-volume procedures such as nephrectomy with caval thrombectomy, structural measures may be most appropriate, as samples will be too small to properly assess processes and outcomes. For high-risk, high-volume procedures such as radical prostatectomy, a greater focus may be directed to processes and outcomes. One appealing framework applicable to the latter situation is the National Surgical Quality Improvement Program (NSQIP) developed by the Department of Veterans Affairs (VA) [17] and recently extended to non-VA hospitals [18]. Spencer et al., likewise, have developed a set of quality indicators specific to surgical and radiation-based treatment of localized prostate cancer, which incorporates a mix of structure, process, and outcomes measures [6].

The question of surgical volume

Evidence has accumulated over the past quarter-century linking surgical volume with outcomes across multiple dis-

ease conditions, and has engendered animated debate regarding the explanations for and significance of the findings. The volume-outcomes relationship was first noted in 1979 [19], and has been extensively explored in a number of areas in surgery and medicine. A systematic review of the United States and European literature commissioned by the Institute of Medicine analyzed 135 studies concerning 27 different diagnoses and procedures. The authors of the review found that in general higher volume does associate with better outcomes, but that the magnitude of the relationship varies widely, as does the methodological quality of the studies [7].

Dudley et al. analyzed claims data for admissions in California in 1997 and concluded that of among 58,000 admissions for 11 selected conditions, low-volume hospital status could account for 26% (95% CI 13%–37%) of the 2,315 deaths observed [20]. Begg et al. were the first to focus on cancer care; they analyzed 5 major cancer operations in the linked Surveillance, Epidemiology, and End Results (SEER)-Medicare database and found a significant association between volume and short-term outcomes in 4 of the 5 [21]. A more recent analysis from the same data source confirmed that hospital volume influences longer term cancer outcomes as well, though the magnitude of the influence varied markedly by operation. Actuarial 5-year overall survival after radical cystectomy, for example, was 39.0% at high-volume hospitals vs. 35.4% at low-volume hospitals, whereas survival following esophagectomy was 33.7% and 17.4% at high- and low-volume hospitals, respectively [22]. In urologic oncology specifically, most of the focus on volume and outcomes to date has been on radical prostatectomy and radical cystectomy, with fewer studies to date on radical nephrectomy and testis cancer management [23]; these will be discussed in further depth in the articles that follow.

Surgical volume has gained traction at the health policy level as a marker of surgical quality. In the 1990s, the volume-outcome relationship in cardiac surgery was judged to be sufficiently strong that the New York State Department of Health now publishes annual volume and mortality rates for every cardiac surgeon and interventional cardiologist in the state [14]. The Leapfrog Group, a coalition of 160 large payors who purchase insurance for over 34 million Americans, has created formal designations for high-volume centers for 5 complex procedures and high-risk obstetric care, and explicitly encourages volume-based hospital referral among other initiatives [24]. The federal Centers for Medicare and Medicaid Services (CMS) is likewise piloting programs to provide surgical volume and quality information to patients, and as of early 2006 only provides coverage for bariatric surgery performed at high-volume centers with low mortality rates [25].

Despite these policy trends, however, a causal association between higher volume and better outcomes is not universally acknowledged. Welke et al. analyzed nearly 950,000 Medicare patients undergoing coronary artery bypass graft surgery at 850 hospitals between 1996 and 2001. They found that hospital volume predicted mortality at a statistically significant but clinically marginal level of accuracy (concordance index 0.52), and that the mortality ranges for each hospital-volume quintile were broader than the difference even between the highest and lowest quintiles (mortality ranges from lowest to highest quintiles: 1%–17%, 2–12%, 2%–10%, 2%–9%, 3%–11%) [26].

Analyzing mortality outcomes in another large administrative database, Ward et al. likewise found that hospitals meeting the Leapfrog Group's volume standards for 5 procedures had in-hospital mortality rates, which were not substantially different from those of hospitals not meeting the standards, and that applying volume standards would significantly impact revenue for low-volume hospitals and substantially impair patients' access to care [27]. Indeed, many rural areas simply lack the referral base to support even a single high-volume center for some procedures [28]. In the NSQIP registry, which comprises clinical data entered prospectively by trained nurses rather than administrative claims data, careful analyses have failed to demonstrate significant associations between hospital volume and outcomes [29].

A recent study of cardiac bypass outcomes using NIS data found that over a period of declining bypass volumes—during which, in particular, the proportion of high-volume hospitals fell by 50%—mortality rates declined consistently, with the greatest decline in mortality among the lowest volume hospitals [30]. To the extent, then, that surgical volume as a structural measure does predict outcomes, it is clearly a surrogate for perioperative and operative processes, and does not itself denote high-quality care. Some of these processes should be measurable with improved accuracy as hospitals gradually move to electronic medical record systems, which will facilitate collection of more accurate data than that available in claims-based databases. Others, however, such as intraoperative surgical decision-making, are by nature intangible and will remain difficult to measure reliably. There exist some low-volume hospitals and low-volume surgeons that yield excellent outcomes; it would be a disservice to these providers and the patients they serve to exclude them based on regulation or reimbursement from performing complex procedures.

Challenges and conclusions

Most large studies to date examining health processes and outcomes in relation to quality of care rely heavily on databases populated from Medicare, private insurance claims, and other administrative sources. While these are excellent sources of population-based data, they are not without limitations. Claims data tend to include few clinical variables and are prone to inaccuracies, at times severe, due to the manner in which such data are collected [31]. Conversely, accumulating sufficient clinical data to report accurate and

effectively risk-adjusted outcomes is expensive and time-consuming, and must address privacy concerns.

Several studies have contrasted the NSQIP approach with claims-based analysis for risk-prediction, yielding mixed results [32–35]. Best et al. compared NSQIP data to the VA's ICD-9 code-based administrative database, finding that the administrative data performed poorly in predicting both preoperative risk factors (positive predictive value [PPV] 0.34) and postoperative outcomes (PPV 0.23) identified in NSQIP [32]. Atherly et al. likewise found that NSQIP outperformed both the Charlson Comorbidity Index and a proprietary risk model developed by DxCG (Boston, MA) [33]. Conversely, Hall et al. compared NSQIP with a sophisticated ICD-9-based algorithm developed by Solucient (Stamford, CT), and found that while both performed well, the claims-based algorithm predicted mortality with greater accuracy than NSQIP ($P = 0.008$), at approximately one-third the estimated cost. Of note, the Solucient algorithm tended to slightly overestimate risk of mortality, thus yielding a more favorable impression of actual results, while NSQIP tended to slightly underestimate risk, yielding a less favorable impression of results [35].

Studies of hospital-level risk-adjusted mortality rates have likewise found at best mixed performance of extant disease severity assessment tools, with marked variation in performance across available tools and disease states [36,37]. Furthermore, even if a patient-level risk factor be a strong driver of outcomes, it will not prove useful for hospital-level risk adjustment if there is insufficient variation across hospitals in distribution of the risk factor [36]. The details of implementing a risk-adjustment system, then, may be more important than its conceptual underpinnings, and clearly much work must be done to develop broadly acceptable standards for variable definition, assessment, and reporting.

The statistical models underlying report cards and other quality reporting tools are complex, and results can vary dramatically depending on which among multiple potentially valid data modeling strategies is used [38,39]. Models must be accurate and robust, and agreed to be the best available by a consensus of clinicians, statisticians, and policymakers. Another caveat for reporting efforts is that the identification of a measure as a quality indicator may drive providers to game the reporting system, i.e., to focus on the measured indicator for quality improvement efforts, maybe at the expense of other (perhaps more important) aspects of quality, which are not reported.

Significant public interest exists regarding the issues surrounding surgical volume and surgical outcomes. However, given the limitations of administrative data discussed above, results of currently available volume-outcomes studies should be applied to policy decisions cautiously; ideally, high-quality providers should have the opportunity to be evaluated by their outcomes data regardless of their volume. As volume and outcomes reporting is incorporated into health policy decision-making, either explicitly or de facto by means of reimbursement pressures, complex care may become regionalized to high-volume centers. The results must be monitored carefully, both to verify that quality is actually improving, and to ensure that any gains in quality are not offset excessively by declines in access for patients who are high-risk and/or who are geographically or socioeconomically disadvantaged. A recent paper, for example, offers a caveat to public reporting of provider data, noting that since the advent of New York's reporting system for cardiac intervention, high-risk myocardial infarction patients in New York are half as likely as those in other states to receive angiographic intervention, and wait 10 times as long as those in other states for cardiac bypass [14]. In bladder cancer, likewise, concentration of treatment in higher volume centers may be expected to yield improved outcomes, but these improvements must be weighed against the risks entailed by potentially longer delays to cystectomy.

Finally, policy decisions with respect to health care quality should reflect the multi-dimensional nature of health care quality. Of the 6 IOM quality domains (Table 1), safety, effectiveness, and efficiency tend to attract most research focus; while patient-centeredness, timeliness, and equity receive less attention. Indeed, improvements in one domain may be won at the expense of another (for example, improved effectiveness yielding decreased timeliness, or improved safety won at the cost of lost efficiency); therefore changes in the various domains should all be considered in weighing the impact of changes in policy.

Health care payors—and the businesses and government purchasers who bear the cost of health care premiums—clearly have a strong vested interest in reducing complications, and their interest in predictors of adverse outcomes can only grow with ongoing increases in health care costs. The pay-for-performance movement is a reflection of this trend. Moreover, the American public is increasingly aware of substantial differences in quality of care across providers, and likely will expect in the near future more publicly-available data on provider-specific volumes and outcomes, particularly in the surgical fields. Given the substantial unresolved challenges and the consequences facing patients, physicians must assume leadership roles in defining the terms of quality reporting and improvement efforts.

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