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# Candidate quality of care indicators for localized bladder cancer

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**Abstract**

The surgical management of clinically localized bladder cancer is challenging, and the quality of care delivered to patients with bladder cancer is a subject of increasing interest. Multiple large studies have examined the association between surgical volume and outcomes after radical cystectomy. These studies generally find lower mortality and complication rates at high-volume centers, though interpretation of the data must be tempered by limitations of the datasets driving the studies. Benefits of regionalization of care also must be weighed against other measures proven to predict outcomes; a delay in time to cystectomy beyond 3 months, for example, is strongly associated with increased mortality. Other candidate process measures supported by existing literature include adequacy of lymphadenectomy as measured by nodal yield and availability or offering of orthotopic diversion when appropriate. Assessment and reporting of bladder cancer outcomes should be risk adjusted based on oncologic risk factors and patient comorbid illness. Perioperative morbidity and mortality, cause-specific survival, and overall survival are all key measures. Assessment of health-related quality of life after bladder cancer treatment should also be standardized for reporting. Multiple survey instruments have been developed in recent years, but none has yet been well validated or widely adopted. In particular, capturing variation in quality of life outcomes between patients undergoing bladder-sparing protocols vs. continent diversion vs. incontinent diversion is an important but difficult goal that has not yet been met. The urologic oncology community should take a strong lead in achieving consensus regarding the definition, assessment, and reporting of quality of care data for bladder cancer. 

*Keywords:* Bladder neoplasms; Radical cystectomy; Quality of health care; Health care quality indicators; Surgical volume; Outcome assessment (health care); Process assessment (health care); Quality of life

## Introduction

With 68,810 diagnoses and 14,100 deaths expected in 2008, bladder cancer in the United States is second only to prostate cancer among genitourinary malignancies in terms of both incidence and mortality [1]. Over 9,000 radical cystectomies are performed annually in this country [2]. The pre-, peri-, and postoperative care of men and women undergoing this procedure is challenging by any measure, and the quality of care delivered to these patients is a subject of increasing interest. In this review, we present candidate structure, process, and outcome measures, which might be appropriate for inclusion in a set of quality indicators for bladder cancer care.

## Structural measures

Structural aspects of care often are supported as quality metrics by common sense if not by high-level, disease-specific clinical evidence. For example, for patients requiring care beyond straightforward transurethral resection and/or intravesical therapy, availability of multidisciplinary consultation, including medical oncology, radiation therapy, and psychological and other supportive care is important at an intuitive level. Other basic structural measures specifically relevant to radical cystectomy include adequacy of operating room and patient care unit facilities, certification of surgeons and other providers, etc. Some of these measures are included in a set of quality of care indicators

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proposed by an expert panel specifically for early stage prostate cancer care [3], but they have not yet been formally evaluated in the context of bladder cancer.

## Surgical volume

One structural aspect of cystectomy quality that has been the focus of significant scrutiny in recent years is surgical volume, both surgeon- and hospital-based. The general parameters of the debate surrounding the volume-outcomes association were reviewed in a prior article of this issue [4]. For cystectomy, as for other operations, most insight gained to date has resulted from the analysis of large administrative databases. Birkmeyer et al. first identified the impact of both hospital [5] and surgeon [6] volume on radical cystectomy, using data from Medicare and the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS).

They found that hospitals in the highest quintile of volume had lower postoperative mortality than those in the lowest quintile (2.9% vs. 6.4%, adjusted OR 0.46, 95% confidence interval 0.37–0.58). Of note, hospitals in the lowest quintile performed fewer than 2 cases annually on average, while 12 cases or more per year were sufficient to place a hospital in the highest quintile [5]. In an analysis of Medicare data, the authors found that surgeon volume accounted for approximately 39% of the effect of hospital volume on outcomes; tertiles of surgeon volume were $<2$, 2–3.5, and $>3.5$ cases annually [6].

A more recent analysis of NIS data focused on radical cystectomies reported on 13,824 cases between 1988 and 1999, examining patients by age group and correcting for year of surgery. In this study, overall in-hospital mortality (2.9%), hospital volumes (tertiles defined by 1.5 and 2.75 cases annually), and surgeon volumes (tertiles defined by 1.0 and 1.5 cases annually) were all lower. Mortality varied significantly with hospital volume (4.7, 3.3, and 2.7% by tertile, $P < 0.001$), and surgeon volume predicted mortality only among patients 50–69 years old (2.5%, 1.8%, and 1.4% mortality by tertile, $P = 0.046$). In multivariable analysis, the statistical significance of hospital volume faded in a model, which also included surgeon volume—presumably due to covariance between surgeon and hospital volume—along with patient age, length of stay, and total number of hospital procedures. Furthermore, lower surgeon volume predicted longer length of stay and higher hospital volume was associated with lower average charges [7].

Another NIS analysis examined complication rates from 1998 to 2002, reporting a slightly lower overall mortality rate (2.6%) and complication rate (28.4%); on multivariable analysis, patient factors including age and comorbidity predicted outcomes, as did hospital factors including urban location, size, and teaching status. High volume hospital (HVH) status per se in fact exerted a weaker protective effect for complications (OR 0.83, 95% CI 0.69–1.01) than did classification as a large-bed, urban, teaching hospital (OR 0.71, 95% CI 0.63–0.82) [8]. NIS data have also demonstrated markedly lower charges for cystectomy if performed by a high-volume surgeon and/or in a HVH [9]. Another NIS study recently found that HVH status defined as $>3$ cases annually for radical cystectomy predicted reduced mortality (multivariable OR 0.59, 95% CI 0.36–0.97), but neither broader urologic specialty classification, based on HVH status for multiple urologic procedures, nor HVH status for other surgical procedures were significantly associated with outcome [10]. A final analysis from this data source, conversely, found that much of the volume-outcomes association for cystectomy could be explained by adjustment for specific hospital characteristics such as staffing levels and availability of open heart surgical services [11].

In a study of volume-outcomes associations using Texas administrative data, Etling et al. defined 3 volume groups, not by tertile but rather by requiring that at least 25% of patients and 5 hospitals fall into each group, yielding thresholds of $\leq 3$, 4–10, and $>10$ cases annually to define low, moderate, and high volume centers. Using these much more stringent definitions for HVH compared with the prior studies (only 23 and 5 hospitals met criteria, respectively, for moderate and high volume); they reported mortality rates of 3.1, 2.9, and 0.7% at each volume level ($P = 0.04$) and complication rates of 15.9, 12.1, and 9.0% ($P = 0.01$) [12].

On multivariable analysis, hospital volume, patient age, patient comorbidity, and nurse-to-bed ratio are all strong predictors of outcomes. Teaching status per se was not a predictor of outcome, but for-profit centers had mortality and complication rates of 2.6% and 13.4%, respectively, compared with 0.4% and 6.3% for non-profits. Of note, all 5 HVHs were academic medical centers, accounting for 33% of the cases overall [12]. However, an analysis of nearly 6,728 cystectomy cases reported by academic medical centers to the University Health System Consortium Clinical Database found that hospital volume was a strong predictor of mortality even among academic centers, with those performing fewer than 10 cases a year reporting a 5-fold increase in mortality compared with those reporting 50 or more cases per year [13].

However strong or weak the association between volume and outcomes may in fact be, the effects of volume-based referrals are already evident in national treatment trends. The proportion of United States hospitals performing cystectomy varied from 45% to 50% from 1988 to 1996, but between 1996 and 2000 fell to 39% [2]. With the greatest attention to surgical volume developing in the last few years, particularly with respect to cystectomy, this trend might be expected to continue. A recent analysis of NIS data found that from 1998 to 2002 the proportion of discharges from HVHs for surgical care of bladder cancer rose from 67% to 70%, while the proportion of discharges from HVHs for nonsurgical bladder cancer care rose from 70% to 72% [14].

Another variable that may be accelerating concentration of cystectomy care may be reimbursement, which has either remained stagnant or declined relative to various office and ambulatory surgical procedures in urology. Non-Caucasian patients and those with Medicaid or no insurance are significantly less likely to undergo radical cystectomy at HVHs [15], and any policies that potentiate trends toward regionalization must avoid worsening the already profound disparities in health care quality across sociodemographic groups [16,17]. Surgical volume may be a proxy structural measure indicating availability of certain essential resources, such as qualified personnel, adequate number of beds, etc. to deliver advanced bladder cancer care, and may only be useful in that context.

## Process measures

Process measures for early stage bladder cancer care might include adequate staging via obtaining a good sample of muscle during transurethral resections, rates of complications such as bladder perforation, and appropriate use of bacillus Calmette-Guérin (BCG) intravesical therapy. Regarding cystectomy care, likely to be a greater focus of quality improvement efforts, assessable metrics may include general aspects of perioperative care including preoperative assessment including cardiac risk profile and albumin level, appropriate use of thromboembolic prophylaxis measures and antibiotics, early ambulation, and enteral nutrition. Other indicators will be specific to cystectomy, potentially including documentation of adequate staging and upper tract evaluation, intraoperative placement of ureteric stents, and appropriate use of neoadjuvant or adjuvant chemotherapy. Potential process measures, which have received particular attention in the recent literature, are discussed in detail.

## Time to cystectomy

Invasive bladder cancer may frequently exhibit an aggressive natural history; multiple studies have in fact confirmed the importance of minimizing the time interval between diagnosis of invasive disease and radical cystectomy. In one report, 81% of patients with a delay of >90 days from diagnosis to surgery, compared with 52% of those with a delay of ≤90 days, were found to have pT3 or greater disease ($P = 0.01$); conversely, the average delays for those with organ-confined and extravesical disease, respectively, were 48 and 75 days ($P = 0.02$) [18]. These results assume equivalent distribution of clinical stages at diagnosis, and do not necessarily account for clinical understaging. In a larger analysis of 265 cystectomy patients, Sanchez-Ortiz et al. found that a delay of >12 weeks vs. ≤12 weeks yielded nearly a doubling of risk of both extravesical tumor extension (84% vs. 48%) and all-cause mortality at 3 years (75% vs. 38%), with a hazard ratio (HR) for mortality if 2.5 (95% CI 1.3–4.8, $P = 0.006$). An important finding was that even with adjustment for tumor and nodal stage, the HR for a >12 week delay was 1.9 (95% CI 1.0–3.8, $P = 0.05$) [19].

These findings are not universal; another study found a more modest difference of 34% vs. 55% for progression-free survival among those with a delay >3 months vs. ≤3 months ($P = 0.04$); this difference was not statistically significant after adjustment for stage and grade [20]. On the other hand, a population-based analysis of cystectomy patients in Quebec found that those with a delay >12 weeks faced an increased risk of all-cause mortality (HR 1.2, 95% CI 1.0–1.5, $P = 0.05$). This study also reported the concerning finding that the median delay increased from 23 to 50 days between 1990 and 2002 [21]. Patient factors such as advanced disease and/or comorbidities requiring workup and/or medical optimization prior to surgery may contribute to delays both to surgery and to outcome ascertainment. This may be an important source of potential confounding in these series, particularly with respect to mortality outcomes. However, the preponderance of evidence suggests that time to surgery should be an important process indicator for quality care.

## Nodal yield/adequacy of lymphadenectomy

Lymphadenectomy is a critical part of radical cystectomy, both because accurate nodal staging can help guide subsequent treatment, and because excision of micrometastatic nodal disease can yield long-term cure among some patients. Multiple series have found that lymph node density—the number of positive nodes related to the total number retrieved—is an independent predictor of survival after cystectomy [22,23]. A large analysis from the SEER registry found that among 1,923 cystectomy patients, 40.3% had no nodes removed and/or analyzed, 12.7% had 1 to 3 nodes analyzed, and 47.0% had at least 4 nodes examined. Those with a limited lymphadenectomy (<4 nodes examined) had significantly greater disease-specific mortality across all stages than those with more nodes examined. While relatively few patients in most reported series have <4 nodes removed, this study is particularly important because it proved the importance of nodal yield in the setting of multi-institutional data accessioned from many different surgeons and pathologists [24]. Secondary analysis of a cooperative group trial involving 268 patients found on multivariate analysis that a nodal yield <10 was associated with a nearly doubled risk of mortality (HR 1.96, $P = 0.0001$) [25]. Parallel study of two large American and European cohorts found that extended rather that limited lymphadenectomy yielded superior local and distant disease control and survival for both node-negative and node-positive patients across various pathological stages [26].

In another recent study, among patients with nodal involvement found at cystectomy, removal of at least 13

nodes was associated with improved disease-specific survival; moreover, those who had < 4 nodes positive but had removal of <13 nodes had outcomes comparable to those with a more extended lymphadenectomy and found to have at least 4 nodes positive [27]. Finally, Koppie et al. analyzed 1,121 cystectomy patients, with a median of 9 nodes removed (range 0–53). The authors could not identify a threshold above which outcomes reached a plateau; rather, there was a continuous dose-response relationship between more extensive lymphadenectomy and greater probability of survival [28].

There are acknowledged limitations to the use of nodal yield as a proxy for quality of lymphadenectomy, as the count depends on fixation and analysis by the pathology department as well as on the surgeon's technique. One analysis, for example, found that submitting lymphatic tissue in multiple anatomic packets rather than as a single specimen increased mean nodal yield from 2.4 to 8.5 for standard template, and from 22.6 to 36.5 for extended template lymphadenectomy [29]. A followup study found that by dividing the nodes among 13 anatomic packets, the median yield was increased to 68, lowering the nodal density significantly [30].

Assuming standardization of surgical technique and pathologic analysis, nodal yield does seem to be a potentially valuable indicator of cystectomy quality. A final caveat, however, is how well nodal yield can be assessed using administrative data; a recent SEER-Medicare analysis divided hospitals into tertiles based on frequency of analyzing at least 10 nodes, and found that patients at those hospitals least likely to analyze at least 10 nodes had a 25% higher likelihood of 5-year mortality than those treated at hospitals most likely to analyze at least 10 nodes. With adjustment for measurable patient and hospital factors, this difference fell to 12%, and ranged from 8% to 15% when the nodal yield threshold was varied between 5 and 20 nodes [31].

## Availability/utilization of orthotopic diversion

Existing literature does not prove a quality of life benefit for continent over incontinent diversion, at least in part because quality of life outcomes following bladder cancer treatment are not yet well-defined or standardized. Although many experts consider orthotopic neobladder to be the optimal diversion in terms of functional and cosmetic outcomes for appropriately selected patients [32], the decision on type of diversion ultimately should be driven by patient factors: personal preferences as well as functional status and biology. Appropriately tailoring the type of diversion to the patient's desires and physiology may be regarded as an indicator of high quality care, albeit one that may be difficult to measure.

A study of diversion following cystectomy among Medicare patients found that over an 8 year period, 19.9% of 3,611 patients received a continent diversion. Patient factors were strong drivers of treatment selection; older age, greater comorbidity, female gender, and lower educational level were all associated with lower likelihood of continent diversion on multivariable analysis, as was African-American race and surgery in the early rather than later years of the study. The strongest predictor of continent diversion, however, was surgery at a designated comprehensive cancer center (OR 5.50, 95% CI 4.20–7.22). Others included treatment at an academic center (OR 1.43, 95% CI 1.14–1.81) and treatment at a high-volume center, defined by ≥5 cases per year (OR 1.49 compared to <5 cases per year, 95% CI 1.19–1.86) [32]. Another analysis of cystectomy trends among Medicare patients identified on average 370 continent and 2,433 incontinent diversions annually, with significant regional and annual variation and no clear trends over time [33].

An ongoing study comparing diversion approaches in the United States (NIS data) and Sweden (population-based registry data) found much more prevalent use of continent diversion in Sweden (34% in 2002) than in the United States (7.4% in 2002). Interestingly, while this study found an increase in continent diversion use in the United States from 4.4% in 1997, over the same 5-year interval continent diversion fell from 38% of cases in Sweden in 1997 (Konety et al., unpublished data). A high volume tertiary center in the United States likewise recently reported decline from 2000 to 2005 in rate of continent diversion from 47% to 21% ($P < 0.01$) [34].

These data in aggregate suggest that a proportion of otherwise eligible patients, especially those treated at lower volume or non-cancer center designated hospitals, may not be offered the option of continent diversion. Alternatively, it may be that significant differences exist in preferences among patients living near or seeking referral to these designated centers. While there is clearly no optimal rate of continent diversion indicative of high-quality care, offering continent diversion with appropriate counseling to a patient without contraindications may be an important process indicator.

## Outcomes

A consideration of measurement of health outcomes for quality assessment must be tempered by the recognition that outcomes tend to reflect patient factors at least as much as quality of care per se; outcomes are nonetheless important aspects of quality assessment and improvement. Perioperative morbidity and mortality are important markers of quality care, but their evaluation as quality metrics carries the nontrivial requirement of adequate mechanisms for risk adjustment. In a large analysis of 2,538 cystectomies, Hollenbeck et al. reported that 30.5% of the patients had one or more postoperative complication. Surgeon training level and perioperative factors such as operative time and trans-

fusion requirement predicted likelihood of complications, but equally important were patient factors including age, functional status, preoperative pulmonary and renal disease, and American Society of Anesthesiologists (ASA) score [35].

In a followup study, the authors reported 30- and 90-day mortality of 2.9% and 6.8%, respectively, noting that 30-day mortality may inadequately capture late development of perioperative morbidity. Multivariable analysis demonstrated that age, ASA class, functional status, and serum albumin consistently predict both prolonged length of stay and mortality, and potentially could be used in development of case mix adjustment for outcomes reporting [36]. Furthermore, others have found that obesity is an independent predictor of increased blood loss, operative time, and complication rates, with yet a stronger predictive effect than ASA status [37,38].

Beyond perioperative morbidity and mortality, cause-specific and overall mortality are both important measures. While the latter is influenced more by nontreatment-related patient factors, it will also capture relatively subtle treatment-related morbidity. If a patient dies of sequelae of a hip fracture due to accelerated osteoporosis resulting from pelvic radiation therapy, the death may not be classified as cancer-specific, but would be reflected in overall mortality figures. Again, mortality outcomes must be adjusted appropriately for cancer stage and grade, use of additional therapy such as radiation and chemotherapy, and relevant patient factors.

Most men and women undergoing radical cystectomy today should expect at least 5-year survival after surgery; increasing attention is therefore being focused on patient-centered health related qualify of life (HRQOL) as an important outcome to be measured and potentially reported. Experience in the prostate cancer literature has demonstrated definitively that accurate HRQOL measurement requires direct patient report rather than physician assessment [39]. Instruments for patient report of HRQOL following treatment for bladder cancer have not yet been developed to the same level of accuracy and validation as those for prostate cancer. Nonetheless, three bladder cancer-specific patient-reported HRQOL instruments have been developed in recent years.

The Functional Assessment of Cancer Therapy-Vanderbilt Cancer Index (FACT-VCI) assesses general and disease-specific HRQOL via a 45-item questionnaire, which assesses domains including physical, social/family, emotional, and functional well-being as well as "additional concerns," incorporating questions on urinary, sexual, and bowel function [40]. The Bladder Cancer Index (BCI) is a 34-item instrument assessing disease-specific HRQOL in 6 domains: sexual, urinary, and bowel function, and bother [41]. The Functional Assessment of Cancer Therapy-Bladder Cancer (FACT-Bl) adds several questions on bladder function to the well-validated FACT [42]. These instruments have the potential to standardize HRQOL assessment after cystectomy, but neither has yet been externally validated or widely accepted. Two additional instruments for superficial and invasive cancer, the European Organization for Research and Treatment of Cancer (EORTC)'s Quality of Life Questionnaires EORTC-QLQ-BLS24 and EORTC-QLQ-BLM30, respectively, have been described but not formally assessed or validated [43]. Studies to date have used a variety of different approaches to HRQOL assessment, complicating comparisons among different analyses.

In a recent review of the HRQOL following urinary diversion, Gerharz et al. appropriately concluded that the available literature is "rather extensive but generally of questionable quality" [44], and reiterated the need for prospective, controlled studies of HRQOL outcomes. No such randomized trials have yet been completed, and none of the nonrandomized studies published to date adequately captures pretreatment HRQOL, so results must be interpreted with caution. Patients electing incontinent diversion, for example, may have more medical comorbidity, functional limitation, and/or social isolation than those choosing orthotopic diversion, and may therefore have lower HRQOL scores based on issues unrelated to choice of diversion. Results will also vary markedly based on which questions are asked.

Hart et al. used modifications of 4 general HRQOL surveys assessing mood, sexual history, body image, urinary problems, and overall quality of life, finding no significant differences among patients undergoing ileal conduit, continent cutaneous diversion, or orthotopic diversion [45]. Fujisawa et al. surveyed patients using the general HRQOL Short Form-36 (SF-36) with the addition of several questions on micturition, again demonstrating no significant differences between ileal conduit and orthotopic neobladder patients [46]. Other studies using the SF-36 found no differences between ileal conduit and orthotopic neobladder patients [47] or between continent cutaneous and orthotopic diversion patients [42]. Allareddy et al. reported a long-term questionnaire study using the FACT-BL, and found at median of 100 months since diagnosis, no differences between those with an incontinent or continent diversion across any of the general or disease-specific HRQOL domains; moreover, there were no significant differences between radical cystectomy patients and bladder cancer patients with intact bladders [48].

Using the EORTC-QLQ-C30 and locally-determined urinary questions, in contrast, Hobisch et al. found markedly better HRQOL among orthotopic neobladder patients compared with ileal conduit patients in terms of both general and disease-specific domains as well as satisfaction. In this series, however, conduit patients were older, less educated, and less likely to be married [49]. Saika et al., conversely, also using the QLQ-C30, found no significant differences in any domain among 109 elderly ileal conduit, cutaneous ureterostomy, and orthotopic neobladder patients; neobladder patients were more likely to report disappointment with HRQOL outcomes, but, like those in the

other groups, generally reported that in retrospect they would choose the same diversion if offered the choice again [50].

Using the SF-36 and FACT-General to measure general and cancer-related HRQOL, respectively, Dutta et al. found more modest HRQOL advantages to neobladder over ileal conduit diversion, mostly in terms of emotional well-being, with high satisfaction among both groups. Their conduit patients again were older on average than the neobladder patients [51]. On the other hand, Gilbert et al. found using the BCI that urinary function in particular is superior among ileal conduit patients compared with neobladder patients. The BCI has not yet been published in full length form, however, making interpretation of these results difficult [41]. In general, no instrument has yet been shown able to compare HRQOL outcomes following bladder-sparing treatment vs. continent diversion vs. incontinent diversion [52]. An important caveat to reiterate with respect to all of these studies is that none of the HRQOL instruments used to date has been well validated, and may imperfectly capture the HRQOL domains relevant to patients with bladder cancer.

## Conclusions

A fair assessment of cystectomy quality of care must evaluate a mix of structure, process, and outcome measures, and should focus on the structures and processes most closely and reliably associated with relevant outcomes. We have reviewed a number of potential process measures, including time to cystectomy, nodal yield, and availability of orthotopic diversion, which are relatively well supported by extant literature. Surgical volume will remain controversial as a structure measure, but likely has a place on a candidate list of quality indicators for cystectomy care in particular, as may appropriate use of intravesical and/or systemic neoadjuvant chemotherapy. Clearly, outcomes of interest include perioperative, cancer-specific and overall mortality; disease- and treatment-related morbidity, and general and disease-specific HRQOL.

Essential elements of a reporting system for these measures, however, are still lacking. A sufficiently accurate system of case-mix adjustment must be generally accepted by both surgeons and payors. No patient-reported HRQOL instrument for bladder cancer has yet to be validated and widely used. It is quite possible, in fact, that the absence of consensus regarding the HRQOL impact of continent vs. incontinent diversion reflects lack of sensitivity of bladder cancer HRQOL instruments published to date with respect to outcomes most relevant to patients.

There also exist inherent conflicts in the bladder cancer quality literature to date, which illustrate the overlapping challenges of selecting and implementing quality metrics. If payors or regulatory agencies were to determine, for example, that cystectomies should be performed only by high-volume surgeons, patients would almost certainly face longer wait-times between diagnosis and surgery, and it is far from clear that the benefit of surgery in a high volume center would outweigh the known adverse impact of a longer delay. Moreover, identifying a measure as a quality indicator for assessment and reporting will naturally drive providers to focus quality improvement efforts on that measure, at the likely expense of other aspects of quality, perhaps more important but unreported.

With respect to regionalization trends, perioperative cancer care is increasingly resource-intensive, yet reimbursements have fallen significantly over the past decade. Cancer surgery is generally perceived now to be under-compensated compared with other urologic procedures, particularly in the case of cystectomy [53]. This perception will tend to increase further referrals from smaller community hospitals to larger medical centers. As a result, HVHs in general—and in particular high-volume non-profit medical centers that treat regardless of insurance status—face the prospect of increasing levels of un- or under-reimbursed care, despite providing relatively cost-efficient care compared with lower volume centers [9].

Much work will need to be done to define and validate a reliable and meaningful set of quality indicators bladder cancer, but it is essential that consensus must be achieved regarding which processes and outcomes should be measured, how these data should be collected, with whom they should be shared, and how they should be reported to the public, to payors, and to regulatory agencies. These decisions will be made one way or another in coming years; it will be incumbent upon the urologic oncology community to assume and retain the leadership of the process of defining quality care for bladder cancer.

## References

[1] Jemal A, Siegel R, Ward E, et al. Cancer statistics, 2008. CA Cancer J Clin 2008;58:71–96.
[2] Taub DA, Dunn RL, Miller DC, et al. Discharge practice patterns following cystectomy for bladder cancer: evidence for the shifting of the burden of care. J Urol 2006;176:2612–8.
[3] Spencer BA, Steinberg M, Malin J, et al. Quality-of-care indicators for early-stage prostate cancer. J Clin Oncol 2003;21:1928–36.
[4] Cooperberg MR, Birkmeyer JD, Litwin MS. Defining high quality health care. Urol Oncol 2009;27:411–6.
[5] Birkmeyer JD, Siewers AE, Finlayson EV, et al. Hospital volume and surgical mortality in the United States. N Engl J Med 2002;346:1128–37.
[6] Birkmeyer JD, Stukel TA, Siewers AE, et al. Surgeon volume and operative mortality in the United States. N Engl J Med 2003;349:2117–27.
[7] Konety BR, Dhawan V, Allareddy V, et al. Impact of hospital and surgeon volume on in-hospital mortality from radical cystectomy: Data from the health care utilization project. J Urol 2005;173:1695–700.
[8] Konety BR, Allareddy V, Herr H. Complications after radical cystectomy: Analysis of population-based data. Urology 2006;68:58–64.
[9] Konety BR, Dhawan V, Allareddy V, et al. Association between volume and charges for most frequently performed ambulatory and

nonambulatory surgery for bladder cancer. Is more cheaper? J Urol 2004;172:1056–61.
[10] Konety BR, Allareddy V, Modak S, et al. Mortality after major surgery for urologic cancers in specialized urology hospitals: Are they any better? J Clin Oncol 2006;24:2006–12.
[11] Hollenbeck BK, Daignault S, Dunn RL, et al. Getting under the hood of the volume-outcome relationship for radical cystectomy. J Urol 2007;177:2095–9.
[12] Elting LS, Pettaway C, Bekele BN, et al. Correlation between annual volume of cystectomy, professional staffing, and outcomes: A statewide, population-based study. Cancer 2005;104:975–84.
[13] Barbieri CE, Lee B, Cookson MS, et al. Association of procedure volume with radical cystectomy outcomes in a nationwide database. J Urol 2007;178:1418–21.
[14] Cooperberg MR, Modak S, Konety BR. Trends in regionalization of inpatient care for urological malignancies, 1988 to 2002. J Urol 2007;178:2103–8.
[15] Konety BR, Allareddy V, Carroll PR. Factors affecting outcomes after radical cystectomy in African Americans. Cancer 2007;109: 542–8.
[16] Felix-Aaron K, Moy E, Kang M, et al. Variation in quality of men's health care by race/ethnicity and social class. Med Care 2005;43:I72–81.
[17] Nawal Lutfiyya M, Bhat DK, Gandhi SR, et al. A comparison of quality of care indicators in urban acute care hospitals and rural critical access hospitals in the United States. Int J Qual Health Care 2007;19:141–9.
[18] Chang SS, Hassan JM, Cookson MS, et al. Delaying radical cystectomy for muscle invasive bladder cancer results in worse pathological stage. J Urol 2003;170:1085–7.
[19] Sanchez-Ortiz RF, Huang WC, Mick R, et al. An interval longer than 12 weeks between the diagnosis of muscle invasion and cystectomy is associated with worse outcome in bladder carcinoma. J Urol 2003; 169:110–5, Discussion 15.
[20] May M, Nitzke T, Helke C, et al. Significance of the time period between diagnosis of muscle invasion and radical cystectomy with regard to the prognosis of transitional cell carcinoma of the urothelium in the bladder. Scand J Urol Nephrol 2004;38:231–5.
[21] Mahmud SM, Fong B, Fahmy N, et al. Effect of preoperative delay on survival in patients with bladder cancer undergoing cystectomy in Quebec: A population based study. J Urol 2006;175:78–83; discussion 83.
[22] Stein JP, Cai J, Groshen S, et al. Risk factors for patients with pelvic lymph node metastases following radical cystectomy with en bloc pelvic lymphadenectomy: Concept of lymph node density. J Urol 2003;170:35–41.
[23] Steven K, Poulsen AL. Radical cystectomy and extended pelvic lymphadenectomy: Survival of patients with lymph node metastasis above the bifurcation of the common iliac vessels treated with surgery only. J Urol 12007;78:1218–23, Discussion 23–4.
[24] Konety BR, Joslyn SA, O'Donnell MA. Extent of pelvic lymphadenectomy and its impact on outcome in patients diagnosed with bladder cancer: Analysis of data from the Surveillance, Epidemiology, and End Results Program data base. J Urol 2003;169:946–50.
[25] Herr HW, Faulkner JR, Grossman HB, et al. Surgical factors influence bladder cancer outcomes: A cooperative group report. J Clin Oncol 2004;22:2781–9.
[26] Dhar NB, Klein EA, Reuther AM, et al. Outcome after radical cystectomy with limited or extended pelvic lymph node dissection. J Urol 2008;179:873–8.
[27] Honma I, Masumori N, Sato E, et al. Removal of more lymph nodes may provide better outcome, as well as more accurate pathologic findings, in patients with bladder cancer–analysis of role of pelvic lymph node dissection. Urology 2006;68:543–8.
[28] Koppie TM, Vickers AJ, Vora K, et al. Standardization of pelvic lymphadenectomy performed at radical cystectomy: Can we establish a minimum number of lymph nodes that should be removed? Cancer 2006;107:2368–74.
[29] Bochner BH, Herr HW, Reuter VE. Impact of separate versus en bloc pelvic lymph node dissection on the number of lymph nodes retrieved in cystectomy specimens. J Urol 2001;166:2295–6.
[30] Stein JP, Penson DF, Cai J, et al. Radical cystectomy with extended lymphadenectomy: Evaluating separate package versus en bloc submission for node positive bladder cancer. J Urol 2007;177:876–81, Discussion 81–2.
[31] Hollenbeck BK, Ye Z, Wong SL, et al. Hospital lymph node counts and survival after radical cystectomy. Cancer 2008;112:806–12.
[32] Gore JL, Saigal CS, Hanley JM, et al. Variations in reconstruction after radical cystectomy. Cancer 2006;107:729–37.
[33] Konety BR, Joyce GF, Wise M. Bladder and upper tract urothelial cancer. J Urol 2007;177:1636–45.
[34] Rumohr JA, Lowrance WT, Chang SS, et al. Examining contemporary urinary diversion: A review of changing practice patterns diversion selectivity. J Urol Suppl 2007;177:60.
[35] Hollenbeck BK, Miller DC, Taub D, et al. Identifying risk factors for potentially avoidable complications following radical cystectomy. J Urol 2005;174:1231–7.
[36] Hollenbeck BK, Miller DC, Taub DA, et al. The effects of adjusting for case mix on mortality and length of stay following radical cystectomy. J Urol 2006;176:1363–8.
[37] Chang SS, Jacobs B, Wells N, et al. Increased body mass index predicts increased blood loss during radical cystectomy. J Urol 2004; 171:1077–9.
[38] Lee CT, Dunn RL, Chen BT, et al. Impact of body mass index on radical cystectomy. J Urol 2004;172:1281–5.
[39] Litwin MS, Lubeck DP, Henning JM, et al. Differences in urologist and patient assessments of health related quality of life in men with prostate cancer: Results of the CaPSURE database. J Urol 1998;159: 1988–92.
[40] Cookson MS, Dutta SC, Chang SS, et al. Health related quality of life in patients treated with radical cystectomy and urinary diversion for urothelial carcinoma of the bladder: Development and validation of a new disease specific questionnaire. J Urol 2003;170:1926–30.
[41] Gilbert SM, Wood DP, Dunn RL, et al. Measuring health-related quality of life outcomes in bladder cancer patients using the Bladder Cancer Index (BCI). Cancer 2007;109:1756–62.
[42] Mansson A, Davidsson T, Hunt S, et al. The quality of life in men after radical cystectomy with a continent cutaneous diversion or orthotopic bladder substitution: Is there a difference? BJU international 2002;90:386–90.
[43] Botteman MF, Pashos CL, Hauser RS, et al. Quality of life aspects of bladder cancer: A review of the literature. Qual Life Res 2003;12: 675–88.
[44] Gerharz EW, Mansson A, Hunt S, et al. Quality of life after cystectomy and urinary diversion: An evidence based analysis. J Urol 2005;174:1729–36.
[45] Hart S, Skinner EC, Meyerowitz BE, et al. Quality of life after radical cystectomy for bladder cancer in patients with an ileal conduit, cutaneous or urethral kock pouch. J Urol 1999;162:77–81.
[46] Fujisawa M, Isotani S, Gotoh A, et al. Health-related quality of life with orthotopic neobladder versus ileal conduit according to the SF-36 survey. Urology 2000;55:862–5.
[47] Hara I, Miyake H, Hara S, et al. Health-related quality of life after radical cystectomy for bladder cancer: A comparison of ileal conduit and orthotopic bladder replacement. BJU international 2002;89:10–3.
[48] Allareddy V, Kennedy J, West MM, et al. Quality of life in long-term survivors of bladder cancer. Cancer 2006;106:2355–62.
[49] Hobisch A, Tosun K, Kinzl J, et al. Quality of life after cystectomy and orthotopic neobladder versus ileal conduit urinary diversion. World J Urol 2000;18:338–44.
[50] Saika T, Arata R, Tsushima T, et al. Health-related quality of life after radical cystectomy for bladder cancer in elderly patients with an ileal conduit, ureterocutaneostomy, or orthotopic urinary reservoir: A

comparative questionnaire survey. Acta medica Okayama 2007;61: 199–203.

[51] Dutta SC, Chang SC, Coffey CS, et al. Health related quality of life assessment after radical cystectomy: Comparison of ileal conduit with continent orthotopic neobladder. J Urol 2002;168: 164–7.

[52] Porter MP, Penson DF. Health related quality of life after radical cystectomy and urinary diversion for bladder cancer: A systematic review and critical analysis of the literature. J Urol 2005;173: 1318–22.

[53] Soloway MS. Bladder carcinoma: Where are the patient advocates? Cancer 2005;104:1559–62.