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Quality-of-care framework in urological cancers: where do we stand?

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Growing demands for patient safety, lower cost and quality of care have resulted in several initiatives of quality measurement across urological surgery. Although candidate indicators have been proposed in various procedures, the field still lacks a valid quality framework. Better understanding of the interplay between patient selection, surgical expertise, preoperative-, intraoperative, postoperative processes and outcomes is needed. Consensus needs to be achieved in which validated structural, process and outcomes measures to employ, how this data should be collected, which agencies to share this data with and how to use this data to effect change in health policy. Compliance with quality framework needs to be continuously audited with its outcomes frequently benchmarked against international standards. Pursuit of quality improvement schemes require significant investment and need to be weighed against current budgetary constraints.

What's known on the subject? and What does the study add?
Provision of high-quality care necessitates the identification and measurement of relevant quality indicators. Urological surgery currently does not have a validated quality-of-care framework to guide surgical quality improvement.

This article aims to delineate quality of care processes, current status of quality indicators for major urological cancers as well as recommend a provisional framework for evaluation of quality for urological procedures.

KEYWORDS

quality improvement, quality indicator, patient safety, urology

INTRODUCTION

The provision of high-quality care is a surgical prerogative. However, wide disparities in the quality of surgical care exist worldwide spurring an unprecedented interest in quality and safety in surgery [1,2]. In the key report, *Crossing the Quality Chasm*, the Institute of Medicine (IOM) defined quality care as '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]. This definition accurately summarises the complex nature of defining and measuring quality of care. Importantly, the phrase 'likelihood of desired health outcomes' shows quality is not synonymous with outcome, as other uncontrollable disease factors may affect outcome [4]. It also establishes that the pursuit of quality is a continuous process of self-improvement, where the goal is ever-evolving with the latest knowledge. Provision of such care must be safe, effective, equitable, timely and patient-centred [5].

To date, the focus of quality improvement efforts have focused on either regionalisation of care to high-volume centres or exporting effective processes from institutions with superior outcomes to their underachieving counterparts [6]. Improving quality of care necessitates the development of valid tools to measure it. However, most practice has been slow to identify, validate and implement quality indicators [4]. With the IOM report revealing 98 000 preventable deaths in the USA due to medical error, healthcare providers and patients alike have begun to demand the use of imperfect quality indicators rather than none at all [4].

In some specialities such as cardiothoracic surgery, the Quality Measurement Task Force of the Society of Thoracic Surgeons developed a comprehensive assessment methodology for quality of adult cardiac surgery. Within this framework, the quality of the principal procedure, coronary artery bypass grafting, was assessed by eleven individual indicators judging the quality of patient care in the perioperative, operative as well as postoperative setting [7]. These quality indicators satisfy multiple criteria for validity, are easily interpretable and readily actionable by healthcare providers [7]. In contrast, there is a lack of validated quality framework in rapidly evolving innovative disciplines such as urological surgery.

TABLE 1 Perioperative process measures listed according to strength of evidence and impact vs complexity of implementation

Strength of evidence/ impact/effectiveness	Cost/complexity of implementation		
	High	Medium	Low
Greatest	Patient self-management of anticoagulation using home monitoring devices	Continuous aspiration of subglottic secretions (CASS) to prevent ventilator-associated pneumonia	Appropriate venous thromboembolism prophylaxis
	Use of real-time ultrasound guidance during central line insertion	Use of pressure relieving bedding materials to prevent pressure ulcers	Appropriate use of antibiotic prophylaxis
High	Localising specialist procedures to high-volume centres	Changes in nursing staffing	Use of silver-alloy coated catheters
	Change in Intensive Care Unit structure promoting active management by intensivist	Computer monitoring for adverse drug events	Falls prevention using hip protectors
Medium	Use of suprapubic catheters in preventing hospital acquired UTIs	Barrier precautions in preventing nosocomial infections	H2-antagonists in preventing stress ulcers
	Computerised physician order entry to prevent adverse drug events	Perioperative glucose control in preventing surgical site infections	Limitations placed on antibiotic use
Lower	Limiting working hours in healthcare providers to reduce fatigue	Simulator-based training	Improving hand-washing compliance
	Implementing aviation-style crew resource management	Tunnelling short-term central venous catheters	Intraoperative monitoring of vital signs and oxygenation
Lowest	Changing catheters routinely	Marking of surgical site preoperatively	Use of pre-anaesthesia checklists
		Routine antibiotic prophylaxis	Counting sharps, instruments and sponges in surgery

Table developed from conclusions summarised in the review from Agency for Healthcare Quality and Research – Making Health Care Safer: A Critical Analysis of Patient Safety Procedures [11].

This article aims to: (i) delineate quality care process; (ii) highlight current status of quality indicators for major urological cancers; and (iii) recommend a provisional framework for evaluation of quality for urological procedures.

MEASURING QUALITY OF CARE

In pursuing quality improvement, health policy makers have traditionally employed Donabedian's widely accepted framework for quality focusing on the structure, process and outcome of healthcare provision [8].

Structure

Structural measures show the infrastructure or system in which care is provided [9]. This may include a hospital's physical resources, human resources or organisation. These measures often form the core of hospital accreditation surveys as they are easy and inexpensive to evaluate [1].For example, it would be logical for patients with RCC only to be managed at specialised centres with a high case volume, state-of-the-art equipment and multidisciplinary specialists. However, structural measures are an unreliable surrogate for outcome, as it can only be evaluated in observational studies and are prone to confounders [9]. In addition, such measures are not easily modifiable, limiting their value as the sole indicators of quality [10].

Process

Process variables directly reflect upon current care practices and are strongly associated to outcome but are as of yet, not routinely used in surgery [9]. In contrast, quality of care in primary practice is frequently assessed on proportion of patients who receive regular smoking cessation advice, diabetes reviews and flu vaccinations. In surgery, the Agency for Healthcare Research and Quality conducted a landmark review of current hospital practices and its effect upon patient safety [11]. A large number of perioperative processes including venous thromboembolism prophylaxis, use of prophylactic antibiotics and catheter management were evaluated and correlated to strength of evidence and complexity of their implementation (Table 1) [11].

Process measures are popular quality indicators as these have substantial potential benefits and are amenable to objective evaluation using randomised controlled trials [9].To illustrate this, Mangano *et al.* [12] showed patients receiving atenolol during and after major non-cardiac surgery had a significant reduction in 1 year mortality vs a control group (3% vs 14%, $P < 0.005$). Effective process measures such as this also allow for easy, systematic implementation and modification titrated according to continuous feedback of patient outcome [9]. As such, the main limitation of process measures lies in its specificity. Single processes might not be appropriate or effective in all patients and as each process is only correlated to a single outcome, other concurrent outcomes not directly investigated are neglected.

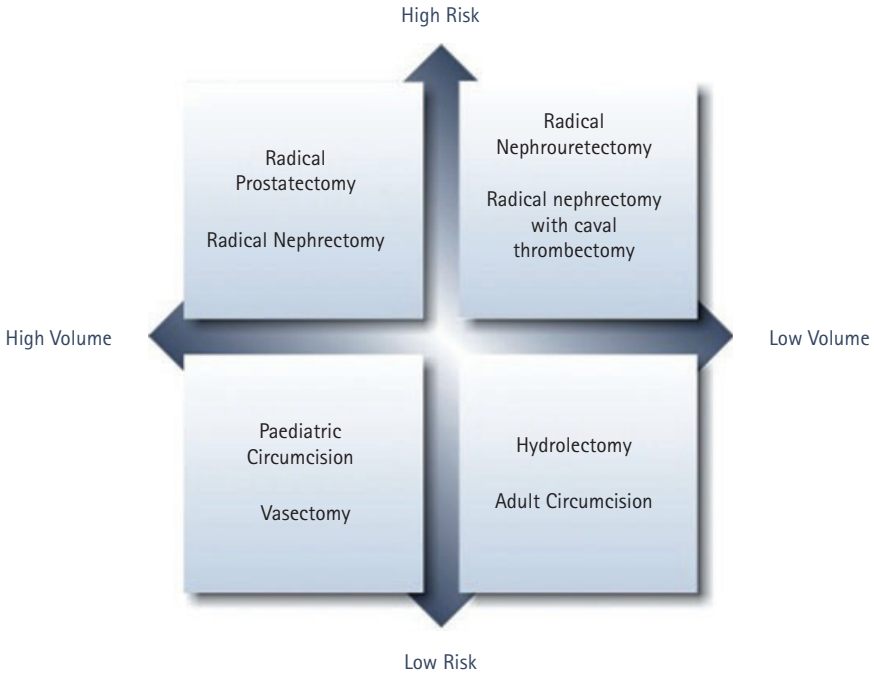
TABLE 2 Summary of structural, process and outcome measures

	Example	Outcome assessment	Strength	Weakness
Structure	Staffing ratio Procedure volume	Observational studies	Easy, inexpensive	Crude surrogate for outcome – prone to confounders Not readily modifiable
Process	Venous thromboembolism prophylaxis Antibiotic prophylaxis	Randomised controlled trials	Objective measurement Readily modifiable according to outcome	Procedure specific
Outcome	Mortality Morbidity Cost Quality of Life	N/A	Definitive measure 'Hawthorne effect'	Dependent on sample size

Outcome

Outcome measures have traditionally been considered the ultimate quality indicators as they reflect the result of care provided on the patient [13]. Operative mortality, morbidity, length of stay, cost, complication rate and health-related qualities of life (HRQL) are all established indicators of quality [9]. These measures possess undisputable face validity and hold great weight in healthcare improvement decisions [9]. Interestingly, the Hawthorne effect illustrates that the evaluation of these indicators alone have been shown to improve outcome [9]. However, outcome measures are vulnerable to inadequate sample size and statistical power [9]. In other words, outcomes of small numbers of high-risk procedures are less accurate than those of large numbers of low-risk common operations. Finally, if outcomes of healthcare providers are equal, utilizing outcome measures alone would suggest improvements in quality are not possible.

FIG. 1 Framework for selecting quality indicators based on procedural risk and case volume [14].



IDENTIFYING QUALITY INDICATORS

The ideal quality indicators in urological surgery need to incorporate a combination of structural, process and outcome measures with the exact composition determined by each procedure (Table 2) [1]. Miller *et al.* [14] introduced a novel framework for quality assessment where the selection of quality indicators are dependent on the risk of the procedure and volume of cases. In high-risk, low-volume procedures, e.g. radical nephroureterectomy, quality indicators based on structural measure would be most valid as the few cases prohibits an accurate evaluation of process and outcome measures [14]. Similarly, in high-risk yet high-volume procedures, e.g. radical prostatectomy (RP), the balance of quality indicators can be shifted in favour of process and outcome measures (Fig. 1) [1,14].

Selection of quality indicators also need to be based on their validity as judged by specialists and patients alike [9]. The most common question posed by patients is how often a certain procedure is performed by the surgeon. In cardiothoracic surgery, despite its many weaknesses, the volume-outcome relationship was recognised as sufficiently strong for the New York State Department of Health to publish annual volume and mortality rates for each cardiothoracic specialist [15]. In this case, procedural volume with accepted face validity to patients will significantly influence their choice of which hospital or surgeon to choose for elective surgery.

Finally, unlike collecting data for structural measures which are readily available, evaluating process and outcome measures incurs a significant cost [9]. Enrolment in the National Surgical Quality Improvement Program (NSQIP) of the Department of

Veterans Affairs, which assesses hospital-specific mortality and morbidity rates across a range of surgical operations costs ≈$40 per procedure [16]. Pursuing quality improvement through quality framework incurs a significant investment which care providers should be ready for. This section describes quality indicators for major urological cancers such as localised prostate, bladder and renal neoplasms.

LOCALISED PROSTATE CANCER

Adenocarcinoma of the prostate is the most common malignancy affecting men worldwide, with most having localised disease needing active management [17]. Patient outcome after RP and radiotherapy vary significantly from individual surgeons and institutions [18,19]. Accurate evaluations of this discrepancy across various institutions have been hindered by a lack of valid care quality indicators [19]. Interestingly, among the >200 quality indicators in the National Library of Healthcare Indicators, none evaluated care in prostate cancer management [17]. To address this issue, a specialist group of the non-profit organisation RAND combined literature review, expert panel and patient focus groups to identify and evaluate a group of 49 potential quality indicators for localised prostate cancer [17,20]. Each indicator was rated according to the level of evidence, validity and feasibility [17]. Of the 49 retained indicators, five reflected on structure (e.g. case volume, board certification), 23 on process (e.g. preoperative staging, PSA level, Gleason grade) and 16 on outcome (e.g. urinary, sexual, bowel function) (Table 3) [17]. The experts also proposed 14 variables (e.g. age, comorbidity) that would need to be considered to account for differences in patient populations across various institutions [17,20]. Although most of the indicators were chosen based on evidence from previous non-randomised controlled-, cohort- or case-control studies supporting their validity, other indicators were selected per the clinical experience of the experts [17].

One of the most significant qualities of care indicators is case volume. There is compelling evidence that high-case volume institutions have reduced mortality, morbidity, length of stay compared with their less specialist institutions in performing RP [21]. Other studies reaffirm this relationship even when controlling for age and case-mix [22].

In recent years, laparoscopic RP (LRP) has been popularised with an aim to achieve oncological efficacy whilst reducing hospital stay and morbidity [23]. In a preliminary study, Touijer *et al.* [23] proposed a set of quality indicators for LRP divided into long- or short-term. Long-term quality indicators address oncological efficacy (disease-free survival rate, nodal status, positive surgical margin rate, biochemical recurrence rate) and functional outcomes (continence, potency). Short-term quality measures describe factors such as length of stay, blood loss, transfusion rate and complication rate. Unfortunately, none of these indicators have been validated owing to the paucity of quality evaluation studies with this technique.

The initial report by RAND provided a rigorous initial infrastructure of evaluating quality of care indicators in localised prostate cancer. The method of using expert panel to identify candidate indicators is a validated and accepted method for providing recommendations [17,20]. However, additional studies are needed to clarify the strength of correlation between these quality indicators and clinical outcomes; especially in the form of level I evidence (randomised controlled trials). Similarly, further investigation into quality indicators are needed in robotic RP, LRP and brachytherapy, a method not accounted for by the initial framework of indicators.

LOCALISED BLADDER CANCER

Bladder cancer is the second most common genitourinary neoplasm in the Western world with an annual incidence of nearly 650 000 cases worldwide [24]. Unlike in prostate cancer, there are no formally studied quality indicators in the perioperative management of patients with bladder cancer [4]. After a literature review, Cooperberg *et al.* [25] have described a set of candidate measures of quality in line with Donabedian's framework (Table 4).

Amongst the structural variables identified, surgical volume has been the subject of close scrutiny in recent years, with most radical cystectomy cases being increasingly performed at high-volume centres [25]. Case volume represents a surrogate rather than direct measure of outcome, as it encompasses various factors including preoperative care, hospital services, anaesthetic expertise, surgical expertise and postoperative care [26]. The specific causal factors contributing to improved outcomes is not clear [4]. In a review by the Healthcare Cost and Utilization Project-Nationwide Inpatient Sample (HCUP-NIS), hospitals performing >12 cases of radical cystectomy annually vs those performing <2 cases annually had a significantly reduced postoperative mortality (2.9% vs 6%, adjusted odds ratio 0.46, 95% CI 0.37–0.58) [27]. The University Health System Consortium Clinical Database confirmed this finding, describing how centres performing <10 cases annually had a five-times higher mortality in comparison with high-volume centres performing ≥50 cases [28].

For radical cystectomy patients, it has been estimated that only ≈39% of beneficial effects from a high-volume centre can be attributed to increased surgeon volume alone [29]. Specialists performing more than four cystectomies annually possess a significantly lower mortality rate vs colleagues who only perform a single cystectomy (3.1% vs 5.5%) [4]. A trial by the Southwest Oncology Group (SWOG 8710) has shown that negative margins and the removal of ≥10 lymph nodes at cystectomy were independent predictors of increased survival [4]. The authors also showed that both of these aims were more likely to be achieved at high-volume centres with urological oncology specialists [4]. Although further studies are needed to identify the causal factors in the volume–outcome relationship, in the meantime, it would be prudent to concentrate high-risk procedures such as radical cystectomy to high-volume centres in view of reduced mortality and lower perioperative costs [25,30].

LOCALISED RCC

RCC accounts for ≈3% of all malignancies in men with most tumours detected at an early, potentially curative stage [31]. Traditional radical nephrectomy has an associated mortality rate of 2.04% and a complication rate up to 20% [31,32]. For small tumours (<4 cm) nephron-sparing surgery achieves preservation of renal

TABLE 3 Quality indicators in the management of localised prostate cancer [17]

Structure

System	Provider	Patient characteristics
• **Volume of cases** • **Availability of radiation oncology facilities** Availability of counselling	• Board certification of providers	• Patient knowledge of outcomes at institution

Process

Pre-operative	Intraoperative	Postoperative
• **DRE, preoperative staging, PSA level, Gleason grade** • **Documented assessment of comorbidity** • **Family history assessment** • **Use of clinical/pathological TMN staging** • Documented assessment of voiding Documented assessment of potency Documentation of pre-treatment urinary, sexual and bowel functioning via a validated survey instrument • Documentation of alternative treatment methods were offered to patient • Documentation that patient was offered a consult with a urologist or oncologist • Documentation that patient was informed of local rates of complications from treatment Documentation of communication with patient's primary care physician – continuing care	• Blood loss	• **Adherence to practice protocol of College of American Pathologists Cancer Committee for management of pathology specimens** • **Appropriate protection of rectal mucosa in high-dose 3D conformal treatment** • **Use of CT in conventional RT treatment planning** • **Immobilisation of patient during conventional (external beam) RT** • **Immobilisation of patient during conformal radiation treatment** • **Delivering recommended doses (68–72 Gy) for conventional external beam RT** • **Delivering escalated doses (70–80 Gy) with conformal RT** • **High-energy linear accelerator (>10 MV)** • **Use of CT in conformal (external beam) RT treatment planning** • At least two visits for follow-up by treating physician in the first postoperative year • Use of CT in conformal radiation therapy treatment planning

Outcome

Clinical endpoints	Functional endpoints
• **Primary treatment failure indicated by three consecutive increasing PSA values after primary treatment by RT** • **Primary treatment failure indicated by any confirmed detectable PSA after treatment by RP** • **Clinical detection of post-treatment local recurrence with biopsy confirmation** • **Hospitalisation for cystitis, proctitis, haematuria or rectal bleeding after primary treatment by RT** • **Surgical treatment for cystitis, proctitis, haematuria or rectal bleeding after primary treatment by RT** • **Medical treatment for cystitis, proctitis, haematuria or rectal bleeding after primary treatment by RT** • **Hospitalisation for bladder neck contracture or urethral stricture after RP or RT** • **Surgical treatment for bladder neck contracture or urethral stricture after RP or RT** • **Medical treatment for bladder neck contracture or urethral stricture after RP or RT**	• Patient assessment of urinary, sexual and bowel function after primary treatment by RT or RP using a reliable, valid survey instrument.

Bold, Evidence level (II), non-randomised controlled clinical trials, cohort, case-control studies; Bold, Evidence level (III), expert opinion; RT, radiation therapy.

function and improved HRQL without compromising on oncological outcome [32–34]. It is therefore surprising that the USA National Cancer institute's Surveillance, Epidemiology and End Results (SEER) program shows that up to 80% of patients with tumours of <4 cm, and up to 58% of patients with tumours of <2 cm, undergo radical rather than partial nephrectomy [35]. The gross underutilization of partial nephrectomy is a significant quality of care concern [32].

TABLE 4 Quality indicators in the management of localised bladder cancer [4,25]

Structure

System	Provider	Patient characteristics
Volume of cases	Subspecialists	Age/gender
Specialty mix	Years in practice	Disease severity (grade, stage)
Intensive care unit status (closed vs open)	Specialty training	Comorbidities
Availability of urological oncology pathologist	Age/gender	Health habits (smoking status)
Availability of enterostomal therapist	Job satisfaction	Preferences
Dedicated urology operating rooms and staff	Surgeon volume	Income
	Income/economic incentives	Insurance
	Functional results	Education
	Preferences	Race

Process

Preoperative	Intraoperative	Postoperative
Time to Cystectomy	Nodal yield/adequacy of lymphadenectomy	Use of validated clinical pathway
Re-review of outside pathology slides	Availability of orthotopic diversion	Check for uretero-ileal stricture
Re-resection of high-grade T1 tumours	Blood loss	Follow-up examination and laboratory radiological evaluation
Staging evaluation	Need for transfusion	Referral to medical oncology for high-risk cases
Appropriate use of neoadjuvant chemotherapy	Ability to perform nerve-sparing	
Evaluation of functional status (continence, potency, bowel habits)	Ability to perform multiple types of urinary diversion	
Characterisation of physiology (renal function, nutrition)	Intraoperative consultation (in case of major vascular/rectal injury)	
Nutritional supplementation	Expenditures	
Time between diagnosis and cystectomy	Margin status	
Expenditures		
Referral to tertiary centre for high-risk cases		

Outcome

Clinical endpoints	Functional endpoints
Length of stay	HRQL
30-day mortality rate	Continence
90-day mortality rate	Potency
Morbidity	Time to return to work
Cancer-specific survival	Satisfaction with care
Need for subsequent surgery	Financial coverage

In contrast to prostate and bladder cancers, an initial framework of quality assessment in RCC has not been described. Quality improvement efforts in RCC are impeded by a lack of understanding in to the essential processes of care. To streamline care, Chang *et al.* [36] have reported the introduction of a clinical pathway for radical nephrectomy, which evaluates the role of eight process and outcome measures. The measures included percentage of patients receiving preoperative tests before admission, appropriate duration of i.v. fluids, appropriate duration of acute pain management, complications and in-patient mortality [36]. Adoption of the clinical pathway resulted in significantly shortened hospital stay and reduced costs with no re-admissions in the short-term. Additional studies are needed to evaluate the validity of these indicators and additional quality measures in an effort of developing a comprehensive quality assessment framework in the care of patients with localised RCC.

Contrary to the other major urological procedures the volume–outcome relationship for nephrectomy is tenuous. A large review of 360 605 nephrectomies from the Nationwide Inpatient Sample, showed that low-volume centres had a protective effect on mortality [6]. A more complex case-mix for high-volume centres probably confounded the findings. In addition, the investigators included only a single outcome, surgical mortality, excluding critical outcomes including complications and functional measures.

Development of accurate and robust quality indicators in patients with RCC must be preceded by a basic understanding for the essential perioperative processes and outcomes. Future studies also need to address the lapse of quality measures in the rapidly emerging fields of laparoscopic nephrectomy and ablation therapy.

CURRENT CHALLENGES AND FUTURE DIRECTION

Establishing a comprehensive framework for quality assessment in urology necessitates understanding the complex care processes, division of care into its essential components (candidate indicators), rigorous validation of all candidate indicators, identification of processes that are associated with superior outcomes, and integration of these processes into a clinical pathway.

Care of urological patients is a complex interplay between patients, specialists, allied health professionals, institutions and commercial technology manufacturers. The potential benefit of investigating and measuring individual procedural quality indicators is limited. Instead, quality improvement efforts should strive to understand the complex relationship between these factors and how to employ optimal combinations of measures to achieve full potential.

Procedures need to be performed frequently enough to reliably identify hospitals with increased mortality rates. Identification of minimum number of hospital caseloads is necessary to detect a doubling of the mortality rate [37]. Therefore, quality measurement and improvement in high-risk, low-volume cases, e.g. radical nephrectomy, remains a challenge. Moreover, during the management of localised prostate cancer, the consequence of any intervention may not be reflected in outcome measures for many years. This entails a prolonged and costly follow-up process that is also prone to statistical bias and manipulation [1].

Patient-reported outcomes are increasingly being adopted in the quality improvement process. Improvement in patient satisfaction measured using indicators, such as HRQL, is a quality endpoint itself [2]. Addressing the patients' perspective guarantees a greater degree of compliance, reduced misuse of healthcare services, higher morale in healthcare workers and ultimately improves public perception of health care services [2]. Unfortunately, standardising such measures is challenging as patient-reported HRQL is highly variable depending on which instrument is used, as well as patient's clinical, cultural, social and educational background [1]. In urology, HRQL assessments on urinary and sexual function using a few standardised instruments are well documented for prostate cancer with a relative paucity for other conditions [38]. Sensitive and valid HRQL instruments measuring the outcomes most relevant to patients need to be readily available.

The pursuit of satisfying quality indicators may become an obsession and overshadow other aspects of care provision. As reporting systems become established, institutions and individuals may target specific indicators for pay-for-performance schemes with disregard of critical aspects of patient care that are not reported [1]. For instance in cardiac surgery, introduction of the public reporting system in New York has halved the number of high-risk patients undergoing angiographic intervention and those in need of cardiac bypass need to wait 10-times longer than in other states [15]. The benefits of concentrating care in high-volume specialist centres with public provider outcome data must be balanced against the limited access for high-risk patients and longer waiting times [1].

Even with established quality indicators the compliance is questionable. Miller *et al.* [19] identified 5230 cases of early-stage prostate cancer in the American Cancer Society–National Cancer Database with a compliance rate ranging from 40.7% to 97.4% with the established quality indicators in the management of localised prostate cancer. Improving quality of care is a continuing process with compliance with quality indicators frequently being audited to maintain best-practice standards.

CONCLUSIONS

Substantial variation exists in urology practice and outcomes. Before improving quality of care, procedural quality must be defined, measured and valid quality indicators need to be identified. An initial, comprehensive quality framework has been proposed in prostate cancer with a relative paucity of similar initiatives in other urological procedures. Further studies are needed to validate and integrate quality frameworks with current quality improvement policies. Importantly, standards must be continuously updated consistent with current best-practice and regularly audit established quality measures for compliance. Pursuing quality improvement through quality frameworks incur a significant investment which healthcare providers should prepare for.

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CONFLICT OF INTEREST

None declared.

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Abbreviations: **IOM**, the Institute of Medicine; **HRQL**, Health-related quality of life; **NSQIP**, National Surgical Quality Improvement Program; **(L)RP**, (laparoscopic) radical prostatectomy; **SEER**, National Cancer Institute Surveillance, Epidemiology and End Results program.