Controversies in prostate cancer staging implementation at a tertiary cancer center

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Objective: *To assess accuracy of recorded prostate cancer stage after implementation of a quality assurance staging improvement plan.*

Methods and materials: *Genitourinary multidisciplinary TNM staging guidelines were prospectively implemented. Educational programs for health records technicians (HRT) and clinicians preceded implementation of the new guidelines. Patient stage information was entered into the Oncology Patient Information System (OPIS) as part of the usual operations of the cancer center by an HRT. Physician and HRT auditors performed a subsequent quality assurance audit on 97 prostate cancer patients seen over a 2-month period. Assessment of staging accuracy and reasons for discrepancies between the OPIS stage and auditor stage were analyzed and reported.*

Results: *Fifty-four (52%) charts showed discrepancies between auditors. Of the fifty-four, twelve (22%) had discrepancies between OPIS and auditor, thirty (56%) showed discrepancies between auditors, and twelve (22%) had discrepancies between OPIS, physician auditor, and HRT auditor. Forty-three (41%) cases had no discrepancies. Reasons for discrepancies included: misinterpretation of the digital rectal examination (16/54), inappropriate use of TRUS/MRI (9/54) in staging, stage not assigned at initial diagnosis (9/54), misinterpretation of pathology (7/54), TNM staging confusion (4/54), OPIS update not performed (3/54), inappropriate use of biopsy data (3/54), disagreement between consultants (2/54), and misinterpretation of TURP result (1/54). Overall staging accuracy was 76% for OPIS, 65% for the physician auditor and 62% for the HRT auditor.*

Conclusions: *Despite guidelines and educational interventions, computer registry staging accuracy remains an issue. On-going audit procedures are proposed to identify and correct both published and institutional staging guidelines.*

Key Words: prostate cancer, staging, audit, quality assurance

Introduction

Institutional computerized cancer databases typically capture pre-defined patient information such as demographics, tumor site, histology and tumor stage. This potentially allows for the development of strategies and policies for cancer prevention, treatment and control. Poor compliance and/or inaccuracies in database information can lead to incorrect conclusions and poor treatment decisions. The recording of tumor stage in particular has previously been identified as an area of weakness in regards to local, regional and national cancer registries.[1,2]

The determination of stage is based on guidelines such as the TNM staging classification published by the International Union Against Cancer (UICC)[3] and the American Joint Committee on Cancer (AJCC).[4] These guidelines classify tumors based on the extent of tumor at the primary site (T category), the involvement of regional lymph nodes (N category) and the presence of metastasis (M category) and can be used for both clinically and pathologically staged patients.[3,4]

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Stage, Gleason score and PSA are the most powerful known predictors of patient survival in prostate cancer; therefore accurate staging is critical for many reasons. It facilitates treatment decision-making and assists in the evaluation of both screening and treatment programs; thus optimizing the effectiveness of cancer control programs.[1] In addition, accurate staging is also crucial for the success and interpretation of both prospective and retrospective clinical trials. Within a clinical trial, staging allows for the generation of new information through the observation of groups of patients with similar staged cancers and it allows for integration of information about similar patients from different sources.[2,5]

Although it is universally accepted that staging is an essential component of cancer management, relatively little research is performed on the application of the TNM staging guidelines in practice. In response to a previously published cancer staging audit,[6] we decided to perform a targeted staging audit on prostate cancer patients at the London Regional Cancer Program after a multidisciplinary team educational intervention had been implemented.

Materials and methods

Genitourinary multidisciplinary 1997 TNM staging guidelines[3] were prospectively implemented at the London Regional Cancer Program (LRCP) through an educational program aimed at health record technicians (HRT) and clinicians who were part of the genitourinary multidisciplinary team (GU MDT). First, in-house guidelines, Figure 1 and Figure 2, were developed based on the 1997 UICC TNM staging manual,[3] Figure 3, and presented to the GU MDT for discussion and approval.

Apart from the following exceptions, all new cases to the centre should be staged within three months of initial consultation:

Small cell lung	Pediatric
Non-melanomatous skin	Thymomas
CNS	Nasal cavity
Myeloma	Primary unknown
Leukemias	Sarcoma

Note: Three months is a CCO coding requirement, as all OPIS staging information in OPIS is frozen after three months.

- Cases should be confirmed microscopically if at all possible.
- Clinical or pathological (TNM) stage should be used to describe each tumor site (TNM values and overall stage grouping) (with the exception of melanomas which are staged according to Clark Levels). If surgery was performed, pathological stage is required. If no surgery, clinical stage should be reported.
- The stage assigned should reflect the extent of disease present at the time of initial diagnosis. When stage at presentation to the Centre for the first time is different than stage at diagnosis, both stage at diagnosis (if enough information is present to determine it) and stage progression should be captured. If there is not enough information present to determine stage at diagnosis, the case should be staged as X.
- Tumor stage remains unchanged once established.
- If there is doubt concerning the correct TNM category to which a case should be assigned, then the lowest appropriate TNM category assignment should be chosen.
- In the case of multiple simultaneous tumors in one organ, the tumor with the highest T category should be classified and the multiplicity or the number of tumors should be indicated in parentheses. In the case of simultaneous bilateral cancers of paired organs, each tumor should be classified independently.
- In case of discrepancy between referring physician staging and LRCP physician staging, the LRCP physician staging will take precedence. Exceptions to this rule include patients that have been staged and treated at another cancer centre or patients who have received neo-adjuvant treatment (i.e. hormonal manipulation) prior to LRCP assessment.

When assigning TNM values, an "X" should only be used when the TNM cannot be assessed.

Figure 1. General staging guidelines for the London Regional Cancer Program.

The 1997 UICC TNM staging guidelines will be used for the assignment of stage (beginning April 1, 2002).
Prostate cancer specific guidelines:

- Clinical examination (i.e. DRE) is to be utilized for determination of clinical T stage. **Biopsy positive lobes do not influence assignment of T stage (i.e. T2a vs. T2b)[1]**
- Pathological examination (i.e. prostatectomy specimen, lymph node dissection) is to be utilized for the determination of pathological T and N stage.
- The use of the prostate worksheet in order to communicate stage, grade, and PSA with the HRT is encouraged.
- The community PSA reading prior to consultation will be recorded unless unavailable (then use LRCP PSA).
- The team recognizes that physicians may decide that it is not clinically necessary to assess specific TNM categories to confirm absence of disease, and will not report a value for these cases. HIS staff will enter a "0" in OPIS, unless otherwise specified.
- When T, N, or M categories have not been assessed (i.e. Tx, Nx or Mx), categories will be reported (in OPIS) as T0, N0, or M0 unless otherwise specifically stated/requested by the dictating physician in the dictation or on the prostate database sheet.

Figure 2. Genitourinary (site) specific staging guidelines for the London Regional Cancer Program.

T-Primary tumor
- Tx-primary tumor cannot be assessed
- T0-no evidence of primary tumor
- T1-clinically inapparant tumor not palpable or visible by imaging
  - T1a-tumor incidental histological finding in 5% or less of tissue resected
  - T1b-tumor incidental histological finding in more than 5% of tissue resected
  - T1c-tumor identified by needle biopsy (eg., because of elevated PSA)
- T2-tumor confined within the prostate[1]
  - T2a-tumor involves one lobe
  - T2b-tumor involves both lobes
- T3-tumor extends through the prostatic capsule[2]
  - T3a-extracapsular extension (unilateral or bilateral)
  - T3b-tumor invades seminal vesicle(s)
- T4-tumor is fixed or invades adjacent structures other than seminal vesicles: bladder neck, external sphincter, rectum, levator muscles, and/or pelvic wall

1. Tumor found in one or both lobes by needle biopsy, but not palpable or visible by imaging is classified as T1c.
2. Invasion into the prostatic apex or into (but not beyond) the prostatic capsule is not classified as T3, but as T2.

N-regional lymph nodes (pelvic nodes below the bifurcation of the common iliac arteries)
- NX-regional lymph nodes cannot be assessed.
- N0-No regional lymph node metastasis.
- N1-regional lymph node metastasis.

M-distant metastasis
- MX-distant metastasis cannot be assessed
- M0-No distant metastasis
- M1-distant metastasis
  - M1a-non-regional lymph node(s)
  - M1b-bone(s)
  - M1c-other site(s)

Figure 3. 1997 TNM staging guidelines for prostate cancer.[3,4]

Guidelines for all genitourinary sites were developed; but based on the high volume of prostate cancer patients seen at the center, the GU MDT decided to focus the audit on prostate cancer patients only.

Although the 2002 staging guidelines had just been published at the time of the audit, most physicians were more familiar with the 1997 guidelines and in order to minimize errors that could occur with the introduction of a new staging system, the 1997 staging guidelines were used until completion of the audit.

In addition, the use of TRUS and MRI investigations as part of the recorded T stage was also discussed. Although the use of imaging in clinical staging was allowed according to the UICC TNM staging manual,[3] its prognostic value has not yet been proven; therefore its use for staging purposes was prohibited in this staging audit.[7-9] The time at which stage should be assigned was also discussed at the GU MDT. It was decided that stage should be assigned at the time of diagnosis due to potential delays in referral and the common use of neoadjuvant hormones prior to cancer center referral.

Seven LRCP radiation oncologists, one medical oncologist and one HRT were trained in the use of the final staging guidelines. Special GU MDT rounds and small group sessions were used to educate the team. All participants received a copy of the in-house guidelines and the 1997 UICC TNM staging guidelines.[3]

Next, patient stage information was entered into the Cancer Care Ontario Oncology Patient Information System database (OPIS) as part of the usual operations of the cancer center by the trained HRT for 2 months (September 1 - October 31, 2002). The staging information included all available clinical and/or pathological TNM staging information. After the designated 2-month period, the charts of all new prostate cancer patients seen over the study period were then retrospectively examined by both a physician auditor and an HRT auditor who were not part of the GU MDT but who underwent the educational intervention outlined above. The charts were staged according to the 1997 TNM staging criteria, Figure 3, and the in-house guidelines, Figure 1 and Figure 2. A clinical TNM and/or a pathological TNM were assigned for each patient. The overall stage was also determined, Figure 4. The auditors did not have access to the TNM categories assigned by each other or OPIS at the time of stage assignation.

The clinical and pathological TNM stage entered into OPIS or recorded by the physician auditor and the HRT auditor were later compared by the study investigators (TS and GR). Discrepancies between auditors recorded stage and OPIS were noted and the charts were subsequently examined in order to determine the reason(s) for the discrepancies. For charts with discrepancies, the study investigators assigned a final stage according to consensus agreement using the chart, in-house guidelines, UICC 1997 TNM guidelines[3] and the auditors staging information.

Stage I	T1a	N0	M0	grade 1
Stage II	T1a	N0	M0	grade 2-4
	T1b	N0	M0	any grade
	T1c	N0	M0	any grade
	T1	N0	M0	any grade
	T2	N0	M0	any grade
Stage III	T3	N0	M0	any grade
Stage IV	T4	N0	M0	any grade
	AnyT	N1	M0	any grade
	AnyT	anyN	M1	any grade

Figure 4. Overall TNM stage (1997).[3,4]

The level of accuracy was determined for each of the clinical and/or pathologic TNM categories. Assessments of accuracy included comparing the clinical and pathological TNM stage with that assigned by OPIS and each of the auditors. Accuracy was defined as the total proportion of charts that were in agreement with the six components of stage (clinical T, N and M and pathologic T, N and M) and the final stage (stage I, II, III, IV).

Interobserver agreement was also determined by performing kappa statistics (to adjust for chance agreement) for the physician auditor, HRT auditor, OPIS and the final consensus stage. Agreement within individual T categories (T1 versus T2 versus T3 versus T4) was compared as well as agreement within the following T groupings: T1 - T2 (organ confined disease) versus T3 - T4 (locally advanced disease).[10]

Results

Overall staging accuracy

A total of 97 new prostate cancer patients were registered over a period of 2 months and subsequently audited by a physician auditor and an HRT auditor. Of these, 43 (44%) showed agreement amongst the physician auditor, the HRT auditor and OPIS in regards to all six components of the clinical and pathological TNM stage (cT,cN,cM,pT,pN,pM). There was disagreement in at least one of the six staging categories between the auditors and/or OPIS in 54 (56%) charts. The ability of the auditors to accurately assign an overall stage (stage I, II, III or IV) was 76% for OPIS, 65% for the physician auditor and 62% for the HRT auditor. All disagreements occurred in terms of the T category. No disagreements in N or M category occurred in this audit.

TABLE 1. **Kappa statistic (95% CI) showing interobserver agreement between physician/HRT auditors, OPIS and final stage for individual T categories (T1 versus T2 versus T3 versus T4)**

	Physician auditor	HRT auditor	OPIS	Final stage
Physician auditor	X			
HRT auditor	0.44 (0.29-0.60)	X		
OPIS	0.48 (0.34-0.63)	0.54 (0.40-0.69)	X	
Final stage	0.63 (0.50-0.76)	0.55 (0.41-0.69)	0.76 (0.65-0.87)	X

HRT = health record technician; OPIS = oncology patient information system

Interobserver agreement

Kappa statistics showed substantial agreement[10] (0.55-0.76 for individual T category and 0.63-0.81 for organ confined versus non-organ confined T category) between the final T category assigned and the category assignment by the physician auditor, HRT auditor and OPIS, Table 1 and Table 2. Moderate agreement[10] between both auditors and OPIS was seen for individual T category (0.44-0.54) and for organ confined versus non-organ confined T category (0.47-0.57), Table 1 and Table 2.

Areas of disagreement

In 54 charts, there were discrepancies in regards to the recorded stage. There was total disagreement between OPIS, the physician auditor and the HRT auditor in 12/54 (22%) of cases. In the case where there was only one disagreement, OPIS and the physician auditor disagreed in 12/54 (22%) cases and the physician auditor and HRT auditor disagreed in 30/54 (56%) cases. There was no disagreement solely between the HRT auditor and OPIS, Figure 5.

Major versus minor discrepancies

Table 3 lists the types of discrepancies seen in the recorded stage. A major discrepancy is defined as a disagreement in T, N or M category that results in a change in overall stage or risk stratification[11] (e.g. T1-2 versus T3-4). A minor discrepancy is defined as a disagreement between T categories, which does not change the overall stage (e.g. T1 versus T2). Discrepancies within a T category (e.g. T2a versus T2b) were classified as not clinically significant (NCS). In 11/54 charts (20%), there were NCS discrepancies seen and in 23/54 charts (43%) there were minor discrepancies, all in distinguishing T1 from T2. In 20/54 cases (37%) there was a major discrepancy such that the overall stage was in disagreement.

Reasons for disagreement

The charts with staging discrepancies were examined by the study investigators in order to assess potential reasons for the discrepancies. In many of these charts there was a significant time delay between the initial diagnosis of prostate cancer and referral to the cancer center. This was due to watchful waiting approaches, neoadjuvant hormone use or consultation delay. The reasons for staging discrepancies can be found in Table 4.

The main reason for staging disagreement was a misinterpretation of the digital rectal examination (DRE) results based on the dictated notes available in the chart. This occurred in 29.6% of cases. The next most common reasons for discrepancies included the use of magnetic resonance imaging (MRI) or trans-rectal ultrasound (TRUS) information when it had been agreed that this

TABLE 2. **Kappa statistic (95% CI) showing interobserver agreement between physican/HRT auditors, OPIS and final stage for combined T categories (T1-T2 versus T3-T4)**

	Physician auditor	HRT auditor	OPIS	Final stage
Physician auditor	X			
HRT auditor	0.52 (0.30-0.75)	X		
OPIS	0.47 (0.25-0.70)	0.57 (0.35-0.80)	X	
Final stage	0.66 (0.48-0.84)	0.63 (0.44-0.82)	0.81 (0.67-0.95)	X

HRT = health record technician; OPIS = oncology patient information system

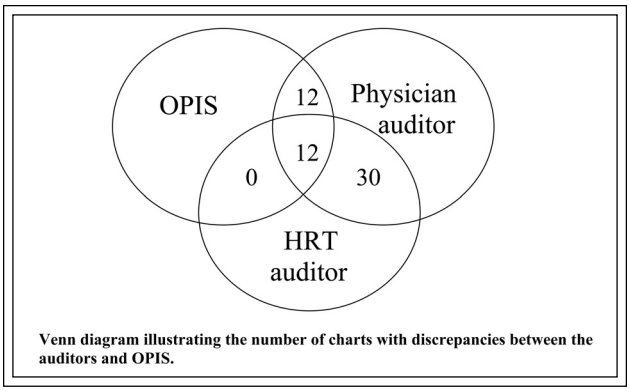

Figure 5. Areas of staging discrepancy between OPIS, HRT auditor and physician auditor (n = 54).

information was not to be used in clinical staging (16.7%) and stage assignment being made at consult rather than at initial diagnosis (16.7%). Other reasons for stage disagreement included misinterpretation of pathology results (13%), TNM staging confusion (7.4%), OPIS update not being performed within 6 months of consultation (5.6%), the use of biopsy data in clinical staging (5.6%), disagreement between consultants (3.7%) and misinterpretation of transurethral resection (TUR) pathology reports (1.9%).

TABLE 4. **Assigned reasons for staging discrepancies**

Reasons	**Number of discrepancies (%)**	
Misinterpretation of DRE[a]	16	(29.6)
Use of MRI/US data	9	(16.7)
Stage not assigned at initial diagnosis	9	(16.7)
Misinterpretation of pathology	7	(13.0)
TNM staging confusion	4	(7.4)
OPIS update not performed[b]	3	(5.6)
Use of biopsy data in clinical staging	3	(5.6)
Disagreement between consultants	2	(3.7)
Misinterpretation of TURP[c]	1	(1.9)
Total	**54**	**(100)**

[a]DRE = digital rectal exam; [b]OPIS = oncology patient information system; [c]TURP = transurethral resection of prostate

TABLE 3. **Frequency and type of T category discrepancies**

Type	**Number of discrepancies (%)**	
Non-clinically significant		
T1 versus T1	2	(3.7)
T2 versus T2	7	(13)
T3 versus T3	2	(3.7)
Overall	**11**	**(20.0)**
Minor		
T1 to T2	7	(13.0)
T2 to T1	16	(29.6)
Overall	**23**	**(43.0)**
Major		
T1 versus T3	4	(7.4)
T1 versus T4	2	(3.7)
T2 versus T3	11	(20.0)
T2 versus T4	3	(5.6)
Overall	**20**	**(37.0)**

Discussion

Overall staging accuracy

Accurate staging is an important issue but one for which there are no agreed upon guidelines or quality standards. In fact, until the late 1990's, stage information was rarely recorded and was not readily available at a provincial or national level. Many physicians felt that they had enough information to make treatment decisions and were initially resistant to complete forms to document the stage formally.[12]

In order to address this issue, the Ottawa Regional Cancer Center (ORCC) performed a retrospective review looking at their accuracy in capturing stage information in their center's Oncology Patient Information System (OPIS). They analyzed 390 charts from 1994 to 1996 and found that 71.5% had been staged completely. Physician related staging errors occurred in 2%-5% of cases and in 3%-6% of cases there were data entry errors. Their overall staging accuracy was between 89%-95%.[12] This overall accuracy; however, did not include the charts that were excluded due to lack of information thus potentially artificially elevating the overall staging accuracy.

In 1997, an audit was performed at Princess Margaret Hospital in order to determine the accuracy of staging at their center. This audit was intended to act as a baseline prior to the implementation of an education program. There was agreement between the health record stage and the final overall stage in 80% of clinically staged patients and 90% of

pathologically staged patients. However, if all the components of stage (clinical TNM and pathologic TNM) were considered, then only 45.5% of charts were in full agreement. Since there is no reference standard for staging accuracy, the audit panel at PMH arbitrarily decided that a local standard of 90% accuracy was reasonable. The audit also demonstrated the importance of objective guidelines and suggested that educational programs may improve staging accuracy.[6]

The London Regional Cancer Program (LRCP) audit was undertaken in order to see if an educational intervention prior to a staging audit would have an impact on staging accuracy. Our control group was the GU site data from the PMH audit. Our audit demonstrated an overall staging accuracy between 62% and 76%, slightly lower than the 78% seen at PMH. Our in-house staging guidelines were different from those used at PMH and may have lead to differences in accuracy rates. For example, excluding the use of MRI and TRUS information and relying entirely on digital rectal examination information may have resulted in more staging errors in our population.

However, our accuracy of staging all six categories was 45.5%, which is not significantly different from the 50% achieved at PMH for their GU patients. In the LRCP audit, both auditors staged all of the charts, whereas at PMH only 10% of the charts were reviewed by each auditor.[6] PMH found that their intrarater reliability was low; therefore, it is likely that with only two auditors at LRCP reviewing all charts that the intrarater reliability for all six categories was potentially better, thus leading to results similar to that seen at PMH.

Our interobserver agreement ranged from moderate to substantial, with the best agreement between the stage assigned in OPIS and the final stage while substantial agreement was seen between the auditors assigned stage and the final stage.

Reasons for staging discrepancies

In the ORCC retrospective review, there were two main reasons for staging errors. The first was the assignation of stage at the time of consult to the cancer center, rather than at initial diagnosis and the second was recording the stage too early before all the information was available.[12] In the LRCP audit, 16.7% of the discrepant charts were the result of stage assignment being made at time of consult rather than at initial diagnosis and 5.6% were due to lack of OPIS updates. The educational intervention did not impact on these errors as expected. The staging guidelines and teaching were clear on the issue of staging at time of diagnosis, but the study investigators noted that in many cases there were long delays between diagnosis and consult due to a watch and wait approach or a consultation delay. On examining the charts with delays, there appears, in many cases, to be a lack of information needed for adequate staging dating from the time of the initial diagnosis. This makes staging more subjective and prone to interobserver variability.

Our audit found that in over 50% of cases there were problems interpreting data within the chart, which is consistent with the ORCC and PMH audit experiences. Most often it was misinterpretation of the notes pertaining to the digital rectal exam, but there was also confusion in interpreting the TNM staging guidelines and the pathology results. This was not surprising. On re-examining the charts after the audit, the study investigators saw that the notes from the time of initial diagnosis rarely included a recorded stage and the digital rectal examination descriptions tended to be ambiguous. The terminology used tended to be general such as "firm" or "enlarged", but specific terms such as "induration" or "nodule" were often missing. Since stage is assigned at the time of the initial diagnosis of the patient and most of these patients were diagnosed prior to being referred to LRCP, the primary referring physicians would not have had the benefit of the educational intervention.

Sixteen percent of discrepant charts were due to the use of TRUS or MRI data in staging. Furthermore, all of the cases of down staging were due to the use of TRUS data and should have been prevented with the educational intervention. If one looks at the TNM staging manual, Figure 2, it states that imaging may be used in staging but it is not specified whether imaging can be used to define extracapsular extension or seminal vesicle involvement. The sixth edition of the UICC cancer staging manual attempts some clarification of this issue but obvious questions still remain.[13] The T1 category is defined as "clinically inapparent tumor neither palpable nor visible by imaging". The type of imaging allowed and whether imaging can be used to define other T categories is not clarified. The text further states that "investigators should specify_whether clinical staging into the T1c category is based on DRE only or on DRE plus TRUS".[13] No mention is made of imaging for defining T3 disease or the use of biopsy data for T staging. The use of TRUS in assessing extracapsular extension has been recently explored by Yoon et al.[7] They concluded that TRUS could not be used as an independent prognostic factor in staging and that the DRE should be used instead to define the clinical T category.[7] Other investigators have likewise found that TRUS defined T category does not add additional prognostic information.[8,9]

Study limitations

There were a number of limitations of this study. The most important is the lack of a reference standard for staging. Unfortunately, this is a common problem amongst staging audits. In our audit, we chose to rely on a consensus agreement between two independent study investigators to determine a final stage for charts with discrepancies. However, consensus agreement amongst individuals is also subjective and prone to bias. We attempted to limit the problem by using an independent panel not involved in the initial audit to assign the final stage.

The accuracy rates amongst the ORCC, PMH and LRCP audit were quite different. If one examines these audits in greater detail, it can be seen that all three employed their own local guidelines and rules to assess staging accuracy. Therefore, it is not surprising that all three audits achieved different levels of accuracy. International and national standardization of the development of "in-house" guidelines would help to reduce these types of discrepancies and errors.

Finally, the LRCP audit was limited to prostate cancer patients, rather than all sites as in the PMH audit. However, while our conclusions are only directly applicable to the staging of prostate cancer patients, we can use the information to make some general recommendations regarding staging in general and prostate cancer staging in particular.

Study recommendations

General staging

1. Ongoing audit procedures followed by educational programs should be carried out at an institutional, regional and national level in order to maintain accurate cancer registries.
2. Clear and unambiguous TNM guidelines and implementation procedures should be developed for each site at a national and international level.
3. Recording of TNM stage information should be incorporated into the referral process when appropriate.

GU specific staging

1. Guidelines clarifying the use of imaging such as TRUS and MRI in clinical staging should be developed.
2. Guidelines clarifying the use of bilaterally positive biopsy data in clinical staging when only one lobe contains a palpable/imagable lesion should be developed.
3. Clear and consistent use of specific terms to describe the digital rectal exam should be employed by referring physicians and oncologists.

Conclusion

Despite guidelines and educational interventions, computer registry staging remains an on-going issue. In order to maximize accuracy of staging, it is important to implement ongoing audit procedures with feedback to the treating physicians followed by re-education. Community physicians and urologists should also take part in educational interventions in order to improve the accuracy of recording digital rectal information at the time of initial diagnosis, which should ultimately improve our overall staging accuracy. □

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