

**Staging Workgroup
Approvals Committee – Commission on Cancer
September, 2007**

Proposals for Revision of Standards Related to Cancer Staging

The Approvals Committee established a Workgroup to examine the mechanisms for collecting staging data in approved programs, and the standards that regulate this work. This was prompted by problems at many programs with collecting physician generated stage and with the perceived variation in the accuracy of stage. The Workgroup is making the following proposals for implementation in the current interpretation and survey of the standards, and for the upcoming future revision of the standards.

Background:

The collection of information on treatment and outcome is central to monitoring and improving the quality of care of cancer patients. Therefore, maintaining an efficient and complete cancer registry is a core component of program approval by the American College of Surgeons Commission on Cancer. One key aspect of the registry process is accurate definition of the extent of cancer at the time period of cancer diagnosis. The TNM cancer staging system used in cancer registries accounts for the size and extent of the tumor, the degree of involvement of the draining regional lymph nodes, and the presence or absence of distant metastases.

Collecting and recording cancer staging data requires the coordinated efforts of treating physicians, pathologists, and cancer registrars. In many practice settings, it is difficult for the cancer registry to collect the requisite documentation from some of the required parties. A combination of factors contribute to these problems including lack of knowledge of the details of staging among some physicians, increasing demands and decreasing resources for cancer registry operations, and the increasingly fragmented cancer care system largely oriented around the outpatient setting. In addition, difficulties in obtaining physician documentation of staging at many centers uses a large fraction of registrar time and in some settings creates an adversarial relationship between registrars and physicians that detracts from the effectiveness of the cancer program. To address these concerns, the Approvals Committee established the Staging Workgroup to examine the requirements for cancer staging data collection and the CoC approval standards regulating these practices.

In addressing any modification of the standards for staging data collection, it is important to identify the goals for the Approvals Program related to cancer staging. There are two primary goals:

- Goal 1:** Promote and document physician use of cancer stage in the course of treatment decisions.
- Goal 2:** Collect in the cancer registry the most accurate information on the stage and extent of cancer in a timely and efficient manner.

Current Standards for CoC-Approved Programs Related to Staging:

The current Approvals Program standards addressing cancer staging are Standard 4.3 and 2.10. The purpose of these two standards is to ensure that documentation exists in the patient record that records the stage of disease with the understanding that “proper staging of cancer allows the physician to determine appropriate treatment” (p.55); and to ensure that high quality data exist in the cancer registry (p.35).

Standard 4.3 addresses the collection of staging information in the medical record. It requires that “Staging appropriate to the category is assigned by the managing physician, or other approved medical professional, and is recorded in a standardized location(s) in the medical record for 90% of eligible annual analytic cases” (p.55). Further, the definition and requirements for this standard state, “Proper staging of cancer allows the physician to determine appropriate treatment. Staging enables the reliable evaluation of treatment results and outcomes reported from various institutions on a local, regional and national basis.”

Standard 2.10 requires the implementation of a plan to assess the quality of cancer registry data. With respect to staging information, this standard requires a check of the accuracy of the representation of staging information appearing in the cancer registry, given physician documentation (p.35).

This standard also includes a recommendation that the accuracy of physician documented staging information be reviewed: “[Establishment] of minimum quality benchmarks [of which a] recommended accuracy [of] 90% of AJCC staging assigned by the managing physician is accurate” (p.35). The workgroup recognizes that this recommendation is misplaced within a standard calling for quality control of cancer registry data. Additionally, the workgroup recognizes that no objective mechanism currently exists to assess the accuracy of documented staging information.

The goal of improving physician use of cancer staging in treatment is not addressed by any of the standards. Specifically, documentation of staging information in a standardized location in the medical record does not equate with use of staging during treatment decisions or the course of treatment planning. Staging may be documented by the physicians as long as 6 months after diagnosis. Furthermore, the documented staging information is the summary of the overall cancer staging and includes all data from diagnosis through 4 months after diagnosis as defined by TNM staging. It does not always capture the information available and used by physicians at the time of treatment decisions.

The current program survey reviews the percentage of cases for which the managing physician provides staging. The only measure of the completeness of staging is a review of a minimum of 25 abstracts and medical records at the time of survey. The standard related to use of cancer staging in treatment is not addressed at survey and the accuracy of staging is also not considered.

The requirement of the physician to record stage in the medical record is a major issue for some programs because of the burden of achieving compliance, and questions as to the accuracy of physician generated staging. The process is accomplished in some programs with relative ease. There are some institutions where the physician provides data not otherwise available to the registrar, such as that from imaging studies done outside the hospital system. However, in many programs this process consumes an enormous proportion of the cancer registrar’s time to get the staging information recorded, and to proof and correct errors made by the treating physician.

In addition, obtaining compliance from the physicians in some cases creates an adversarial relationship between registrars and physicians.

There are no data to demonstrate cancer staging data recorded in the medical record by the managing physician is more accurate than that collected by registry using available medical records. Exceptions to this include situations where the treating physician may have access to medical records not available to the registrar. For this reason, some form of physician oversight remains important in collecting staging data. This oversight is not necessarily well addressed by assessing the staging as recorded in the medical record for completeness, and not accuracy, nor by enforcing use of the AJCC Staging Form. However, a recent study shows that physician generated staging (proofed by registrars) provides comparable data to that of the Collaborative Staging System (CSS).

Proposal of the Workgroup:

To address these issues, the Staging Workgroup makes the following proposals regarding the current standards and upcoming standard revisions. None of these proposals require changes to the existing standards. The CoC will issue directives regarding how each of the following standards will be interpreted and surveyed. The objective is to emphasize a shift from assessing staging completeness to the accuracy of staging.

Standard 2.10:

Staging data appearing in the cancer registry will be evaluated by the cancer committee to ensure that it is the correct stage as defined by the Collaborative Staging System. At the time of survey the cancer committee chair and other cancer committee members will discuss the process for evaluating staging accuracy in the registry with the surveyor.

Standard 3.2:

The CoC will issue a directive regarding how this standard shall be surveyed, whereby a shift from assessing staging completeness to assessing accuracy of staging will be emphasized:

- a. Registries shall continue to collect staging data using the Collaborative Staging System (CSS), and transmit the input and derived items to NCDB.
- b. AJCC clinical T, N, and M elements must be entered into the cancer registry for submission to the NCDB. These elements must represent the stage of the patient prior to definitive surgery, or if surgery is not performed as the initial treatment, of the stage of the patient prior to start of systemic or radiation therapy. The registrar should record the clinical staging elements as documented by the managing physician(s) in the medical record [see Standard 4.3]. If the managing physician has not recorded the clinical stage, registrars *may* complete the clinical stage elements based on available data, without a requirement to further contact the managing physician.

Standard 4.3:

The CoC will issue a directive regarding how this standard shall be surveyed, whereby a shift from assessing staging completeness to assessing accuracy of staging will be emphasized:

- a. During 2008 the surveyor will discuss with the cancer committee processes that are being developed to set and evaluate the accuracy of the Collaborative Staging System (CSS) recorded in the registry database. The cancer committee should identify the processes for review and correction. During 2008 this will not be surveyed.

Additionally, surveyors will discuss with the cancer committee the processes being developed to promote and document use of physician staging in treatment planning. During 2008 this will not be surveyed.

- b. The CoC recognizes that completion of staging data including the Collaborative Staging elements requires data from the medical record and other sources that may include communication from physicians. Approved programs that use the AJCC Staging Form or similar strategies to communicate information from the managing physicians to the registry are encouraged to continue to use these successful communication and data identification strategies.
- c. The survey process is a retrospective review of program activity for the last 3 years (eg. 2005, 2006, and 2007 for surveys conducted during 2008). Evaluation of the standard to assess the completeness of staging and rating program compliance will no longer take place.
- d. The program will have the option to have staging completeness evaluated in order to receive a commendation rating for this standard. As a result, each surveyor shall discuss this evaluation option with programs when establishing the survey agenda, and survey activity will be modified to reflect the program's choice.

Discussion of Proposal:

Summary:

The proposed changes provide for improved efficiency of registry operations while assuring that accurate data is included in the registry. It is expected that these directives and the shift in surveying will reduce the timely iterative process with physicians and save substantial registrar time, while at least maintaining, if not improving accuracy. Further, recording of clinical stage as defined by the clinical records (including physician recording), will be a major enhancement of the registry data while again improving efficiency. However, the Workgroup recognizes that a major emphasis of Approvals is to foster use and documentation of use of staging during treatment decisions. A subcommittee will be established to work quickly but thoroughly to define the best mechanisms to do this in the context of the approvals and survey process. This work will culminate in a revised Standard 4.3 for implementation effective January 1, 2009. The standard will specifically include options and/or directives for documentation of physician use of staging and prognostic information in treatment decisions, and to define mechanisms to assess the compliance with these standards at the time of survey. These directives will be coupled with

enhanced educational programs targeting physicians on the use and documentation of staging and prognostic information in the management of cancer patients.

The current system overburdens registry staff with no enhancement in the value of the registry. Any changes recommended for Standard 4.3 should enhance the use of staging in practice and help streamline registry operations. Therefore, the registry must continue to collect and report stage using the Collaborative Staging System (CSS). All oversight agencies agree that CSS provides a measure of the extent of disease that is documented by information available from the day of diagnosis through 4 months after diagnosis in the absence of systemic or radiation therapy and/or in the absence of progression of disease. However, this may include information that is not available to the managing physician at the time the treatment decisions are made. It is important that the cancer registry provide the final stage as defined by the 4 month time window both for population incidence studies and long-term comparisons to patient groups.

Collection of the final stage in the form of CSS does not address the goal of promoting physician use of staging during treatment nor does it address the ability to know the pre-treatment stage of disease. The Staging Workgroup has discussed a number of options for promoting physician use of staging in treatment decisions, and for documenting this use.

The current Standard 4.3 requires that the managing physician record staging. The changes recommended by this Workgroup do not alter this requirement. Moving forward, the standard, or a modification will be used to require the managing physician to record stage as part of treatment planning, possibly in the form of the “working stage”, discussed below, as a mechanism to promote the use of staging in treatment. The concept of “working stage” addresses the reality that treatment decisions are made in an environment of limited information on the extent of the cancer. The scope of information increases as treatment progresses until all information is available by the time period set for formal staging.

“Working stage” is the extent of disease known at the time of treatment decisions on the basis of clinical, imaging and pathologic information. For example, a surgeon making a treatment decision related to the colon cancer surgery makes that decision based on available clinical data. However, at the time of surgery, that surgeon may identify liver metastases. The final stage for this patient would therefore be ultimately classified as “M1.”. However, the surgeon treated the patient based on data available before surgery (e.g. “working stage” cT3 cN0 cM0).

There may be other proposals for improving physician knowledge and use of staging. The Workgroup stresses that strategies to address this should be defined and evaluated in the coming months to work toward concrete changes in the Standards. In addition to the concepts put forth by the Workgroup, the CoC may want to solicit comments on this concept and suggested strategies from Approved Programs nationwide.

Finally, a key element that needs to be addressed is physician education. These changes are intended to underscore the need for physicians to use and document staging and prognostic information. The AJCC and CoC have put a great deal of effort into physician education. These changes will place heightened importance on the need for these efforts.

Implications for Implementation of this Change of Standard:

There are several internal implications that need to be addressed immediately in order to implement the directives concerning the interpretation and survey of standards 4.3, 3.2, and 2.10 that will become effective January 1, 2008.

Listed in priority order:

- If approved by the Executive Committee, an October conference call will need to be held with the Committee on Approvals to affirm the Executive Committee's decision. On that call, formation of a subgroup of the Staging Workgroup, or request for new volunteers, would be initiated to begin work on defining benchmarks to measure the use of staging in defining appropriate treatment. This work would need to take place between November 2007 and April 2008; culminating in a proposal to the Committee on Approvals in May 2008 for implementation in cancer programs January 1, 2009.
- A meeting of the QIC by conference call to review and consider the recommended changes in recording and reporting staging information to the NCDB.
- A detailed notification about the changes will need to be communicated to the CoC surveyor and consultant teams; followed by a presentation at their November 7-9, 2007 training meeting.
- A detailed notification about the changes will need to be first communicated to the CoC membership, followed by NAACCR, cancer registry software vendors, and CoC constituents in approved and non-approved programs.
- Explanatory information will need to be posted on the CoC web site.
- A web conference program reviewing the changes will need to be held in November 2007 and January 2008 to inform and educate cancer programs about the change.
- Guidelines for standards implementation supported through NAACCR were agreed to by the Executive Committee of the CoC in May, 2004. Following from this, changes in data recording and reporting requirements for January 1, 2008 were to be documented and disseminated to the broad community of cancer registries no later July 1, 2007.
 - Changes in data requirements for recording and reporting staging information will have to be reviewed by the Uniform Data Standards Committee (UDSC) of NAACCR. Changes to FORDS item definitions will be viewed, at the very least as "minor changes", and will require approval of this body.
 - It is unknown which state registries routinely collect physician staging information, and if the change in cancer program standards by the CoC will cause disruptions among other data collectors.
 - It is unknown what the impact of this change in data recording and reporting requirements will have on registry software vendors' product support and maintenance over the next six to nine months.

- Preliminary discussions with the UDSC will be initiated during the last week of September, 2007.
- The FORDS manual will have to be updated to replace the current rules for assigning stage, per the recommendations of this workgroup, once approved by the QIC.

The following implications would need to be considered for a broader change in the standard that would become effective January 1, 2009.

- Release communications about the staging change to CoC surveyors, members, and all cancer programs (CoC-approved and non approved).
- By July 1, 2008, release revised pages for *Cancer Program Standards 2004, Revised Edition* that set forth the new staging standard.
- If new data items are determined to be required, revision of the FORDS manual must reflect new data reporting requirements. This may involve the Uniform Data Standards (UDS) committee of NAACCR. Implementation of new data items, if any, will be effective starting January 2010 and used for cases diagnosed and/or treated in 2010 and beyond.
- Convert NCDB products (benchmark reports, eQuIP, CP3R) and FIPS level II tables to display CS derived stage, *where appropriate and supported by available data*. Modify the data warehouse and related analytic tools for use with CS derived stage.
- Design and conduct training programs for both cancer program constituents, and surveyors and consultants that detail the new requirements and methods for evaluation at the facility level as well as during the survey. Training programs may include national meeting presentations (NCRA April 2008), web conferences and/or face to face workshops.
- Develop tools for surveyor use during on-site visits and introduce these during the November 2008 surveyor/consultant training meeting. Prepare and publish new or revised materials for the surveyor and consultant tool kits.
- Create best practice documents for the best practices repository to assist facilities with successful implementation and compliance.