Cancer Surgery Standards PROGRAM
AMERICAN COLLEGE OF SURGEONS

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Cancer Surgery Standards Program (CSSP)
Webinar on CoC Standard 5.8: Pulmonary Resection

Background

- The ACS launched the CSSP in June 2020, recognizing growing evidence that adherence to specific operative techniques in cancer surgery leads to:
    - Better surgical outcomes
    - Improved patient quality of life
    - Longer patient survival

Rationale for Standard 5.8

- Standards for invasive nodal staging in lung cancer surgery are important because:
    - Accurate pathologic staging (1) depends upon surgeons performing adequate N1 & N2 lymph node harvesting and (2) more precisely determines prognosis and guides further treatment
    - Malignant lymph node involvement is detected more reliably with systematic node harvesting as opposed to selective (limited) node harvesting
    - Although data suggests that gathering MORE lymph nodes → more accurate staging and even increased survival, relying upon a simple number count is fraught with inconsistencies and has remained a controversial means of quality measurement in the thoracic oncology community
    - Clearly defined "minimum thresholds" for meeting what expert consensus considers to be quality invasive lymph node staging allows for more meaningful measurement of care delivery
- Optimizing documentation and standards of node gathering processes improves concordance of reporting between surgeons, pathologists, and registrars → ultimately leads to higher quality research that will serve as the evidence base for even higher quality future standards

Operative Standard 5.8 Measure of Compliance

- The following two criteria must be met for a program to achieve compliance:
    1. Pulmonary resections for primary lung malignancy include lymph nodes from at least 1 (named and/or numbered) hilar station & at least 3 distinct (named and/or numbered) mediastinal stations
    2. Pathology reports for curative pulmonary resection document the nodal stations examined by the pathologist in synoptic format.
- Standard 5.8 applies to all pulmonary resections performed with curative intent for non-small cell lung cancer, small cell lung cancer, or carcinoid tumors of the lung, and applies to all operative approaches.
    - Compliance will be assessed upon review of synoptic pathology reports for curative intent pulmonary resections.
- Single digit stations are mediastinal (2-9) and double-digit stations are hilar (10 or higher).
- Surgeons are encouraged to harvest as many lymph nodes as is safely possible. This standard is intended to define the MINIMUM THRESHOLD number of lymph nodes removed at the time of curative intent pulmonary resection for lung cancer.

Compliance Timeline

- Programs should aim to achieve compliance rates of
    - **70%** for 2021
    - **80%** for all subsequent years
- Site visits in 2022 will begin to review synoptic pathology reports for 2021 compliance

Tips to Achieve Compliance

- Ensure pathology utilizes College of American Pathology synoptic reports, and denotes specific nodal stations by hilar vs. mediastinal location
- Documenting lymph nodal sampling method and appropriately labeling specimens in the operative report will help pathologist documentation
- Encourage communication amongst surgeons, pathologists, and registrars to optimize documentation for appropriate cases. Standard 5.8 applies to all operations conducted with curative intent. Intent should be assigned postoperatively by the operating surgeon on the basis of preoperative evaluation and intraoperative management and should be clearly documented in the operative report. Institutional checklists and pre-labeled specimen cups may help improve concordance between surgeons and pathologists.

Frequently Asked Questions

Question	Answer
If a mediastinoscopy/EBUS is performed prior to the curative resection, can these procedures qualify for Standard 5.8 and do they have to be included within the curative resection pathology report or can they remain in a separate report to qualify?	As endobronchial ultrasound (EBUS) does not remove nodes, those nodes do not count toward the requirements of Standard 5.8. Nodes biopsied during EBUS should be removed at surgery as additional confirmation of benign versus malignant pathology. Nodes from mediastinoscopy must be included on the same pathology report as the lung resection to count toward the requirements of Standard 5.8. If nodes are sampled at the time of mediastinoscopy performed at a separate operation on a separate day prior to surgery, then those nodes would satisfy the requirement only if documented within the pathology report from the curative intent operation. In general, the surgeon should always strive to obtain lymph nodes from at least one hilar station and at least three distinct mediastinal stations. However, we recognize that there may be infrequent clinical situations in which the standard is not able to be achieved, which is why the threshold compliance rate is less than 100%.
Do they count the hilar nodes evaluated in the lobe with hilar nodes as N1?	Yes (which encourages pathology to do due diligence in their specimen dissection). Surgeons should not rely solely upon hilar nodes being found by their pathology colleagues and should conduct interlobar hilar nodal dissection as well (levels 10 and 11).
Is needle biopsy with EBUS equivalent to removal or sampling of the nodes?	Rarely, if ever, would EBUS (endobronchial ultrasound) be performed at the same setting as curative intent pulmonary resection because one cannot accurately rely upon needle specimen assessment with ROSE (rapid on-site evaluation) to change management in the minutes prior to moving on to major surgery. Furthermore, a negative EBUS assessment of a lymph node does not satisfy the requirement for surgical lymph node harvesting at the time of surgery (EBUS and mediastinoscopy always carry a risk of false negative sampling). This is, in fact, a specific intent of Standard 5.8; surgical lymph node harvesting minimizes the risk of false negatives by confirming nodes are truly benign or are in fact malignant despite preoperative clinical staging efforts. If an ipsilateral mediastinal lymph node is sampled at

	the time of mediastinoscopy performed at a separate operation on a separate day prior to surgery, then this lymph node would satisfy the standard only if it is documented within the pathology report from the curative intent operation. In this situation, communication between the surgeon and pathologist is required to ensure accurate documentation in the synoptic portion of the CAP pathology report. We are aware that some institutions are capable of combining pathology reports from separate procedures for this specific purpose.
If the 2R and 4R packet is sent together, does this count as one N2 or two N2?	The packet should be separated and labeled appropriately if the surgeon believes the nodes have been harvested from two separate lymph node stations (i.e. separate the 2R portion from the 4R portion if at all possible, and label accordingly). If the surgeon ultimately obtains mediastinal lymph nodes from at least 2 other stations (7, 8R, or 9R) then the point is moot given the goal of harvesting at least 3 different mediastinal nodal stations has been accomplished. The surgeon must take responsibility for appropriately and specifically labeling lymph nodes.
If you send a fat pad from a station and label it but no nodes are found, does this count or not count as an N2 node?	This will not satisfy the requirement for harvesting an N2 lymph node but is a realistic occurrence during these operations (one cannot always know for sure if a lymph node exists within a particular fat pad). Occasionally, lymph nodes will not be present or safely accessible during the conduct of an operation. The threshold compliance rate is less than 100% to take this infrequent occurrence into consideration. Surgeons should ideally document where they looked to harvest nodes, even if none were found in a particular station, to provide clarity to the extent of thoroughness during the surgery (e.g., “no lymph nodes were visible within the level 9L inferior pulmonary ligament station despite thorough dissection”).
A pathologist-dissected intrapulmonary node is really quite different than a surgeon-dissected hilar node from a surgical quality metric. Can you confirm whether the pathologist-dissected intrapulmonary node satisfies the requirement?	Yes, nodes dissected out from the primary lung specimen by the pathologist count as hilar lymph nodes for Standard 5.8. Ideally, however, the surgeon would obtain additional nodes from levels 10 and 11.
When the 4R/2R packet is sent to pathology, surely it has to have a marker to determine the highest node and orientate?	It is the surgeon’s responsibility to ensure harvested lymph nodes are labeled appropriately to allow for accurate pathologic assessment and documentation.

If the criteria are not met, and the nodes sampled are negative, is it reported as N0 or indeterminate?	The final pathologic stage will be based upon the lymph nodes that have been assessed. If lymph nodes have been harvested and are negative for metastatic disease, N0 will be documented. Nx should be reserved for cases in which lymph nodes were not resected. Meeting the criteria does not change the pathologic staging process. The standard is a quality metric that insures the most accurate and clinically meaningful staging is achieved but it does not change the conduct of pathologic staging.
We have found some situations where it was not appropriate to remove nodes (such as a small peripheral lesion wedged out in in a patient with significant comorbidities, or when nodes are densely adherent to a major vessel). Do you plan to publish some exceptions for these types of scenarios?	We have set the threshold of compliance at 70% in the first year, and 80% in subsequent years to account for the inevitable and infrequent clinical situations in which the standard is not able to be achieved. Surgeons should always document when/why they could not obtain more lymph nodes (it happens to all of us on occasion, just as is implied in this particular question).
Will a fully completed CAP Pathology Checklist serve as compliance for 5.8? Are all the critical data elements in the CAP report?	Programs must meet ALL measures of compliance under Standard 5.8 to satisfy the standard. This includes the surgical removal of the lymph nodes from the specific nodal stations listed in the standard.