



**Scope of Regional Lymph Node Surgery:
A Review of Data Validity, Revised Coding Directives, and Agency Transition Plans**

Hospital and central cancer registries have been collecting information on sentinel lymph node biopsies among patients diagnosed with breast cancer using the registry data item “Scope of Regional Lymph Node Surgery”. Clinical investigators working in collaboration with staff at the National Cancer Data Base raised concerns regarding the validity of reported data describing the type of regional lymph node surgery performed for patients undergoing breast cancer operations. Multiple agencies/organizations, including the American College of Surgeons Commission on Cancer (CoC), National Cancer Institute’s Surveillance Epidemiology and End Results (SEER) program, the Centers for Disease Control and Prevention’s National Program for Cancer Registries (NPCR), and the North American Association of Central Cancer Registries (NAACCR) have concluded that under coding instructions in use by registry abstractors, sentinel lymph node biopsies for breast cancer have been significantly under-reported. In a collaborative effort, these agencies have designed new instructions and clarifications to guide the coding for this data element for implementation for cases diagnosed January 1, 2012 and later. The CoC tested the clarifications in over a dozen hospitals.

This report provides additional background describing the origin and scope of the problem, how each agency plans to address the issue moving forward, and the changes in coding instructions for items RX Hosp--Scope Reg LN Sur (NAACCR Item # 672) and RX Summ--Scope Reg LN Sur (NAACCR Item # 1292).

The Commission on Cancer supports a broad set of quality initiatives. Among these are the National Cancer Data Base’s Quality Measure Groups, charged with the identification, development and specification of quality of care process measures that can be feasibly applied across the spectrum of CoC accredited cancer centers for the purpose of local monitoring and assessment of care provided to cancer patients. In the spring of 2011 the Breast Quality Measure Group (BQMG) was interested in defining a measure that would allow the CoC to track the clinical adoption of recently reported findings from an ACOSOG trial reporting that breast conservation surgery paired with a sentinel lymph node dissection for small primary breast cancers was as efficacious as an operation that removed axillary nodes. The group started by examining lymph node dissection patterns for AJCC clinically node negative breast cancers that underwent surgical care and had regional lymph nodes pathologically examined. This analysis suggested that 28-29% of women were undergoing an axillary dissection (ALND) without a preceding sentinel lymph node biopsy (SLNBx), contrary to clinical expectation. The validity of the data was called into question, with a specific focus on the cancer registry item “Scope of Regional Lymph Node Surgery”.

At almost the same time, two meeting abstracts, one using data from the NCDB and the other using data from the California Cancer Registry, reported similar findings. The findings reported in these papers indicated that the anomaly observed by the BQMG was wide-spread across patient cohorts of different demographics, tumor size, provider type, and geographic region of the country.

The CoC initiated two reviews:

The first review consisted of clinical members of the BQMG reviewing breast cancer cases coded in their own cancer registries. This review served to provide preliminary confirmation that the registry item “Scope of Regional Lymph Node Surgery” was being miscoded by hospital registrars. Results from this limited four-center review showed that ALND rates reported in registry data dropped from 10%, 5%, 34%, and 38% to 0%, 4%, 2%, and 8%, respectively, upon clinical review of AJCC clinically node negative invasive breast cancers that underwent surgical care and had regional lymph nodes pathologically examined.

The preliminary conclusions from this limited review were: 1) The data element “Scope of Regional Lymph Node Surgery” was under-reporting SLNBx and SLNBx with ALND; 2) the issue centers on how the data element has been defined over time, and how registries have been guided to code the item (see Appendix A for a brief history of the data item), and that any erroneous data should NOT be blamed on the registrar; 3) coding directives did not provide a mechanism to report failed mapping of SLNs, and that if non-sentinel LN were removed in addition to SLN then registries often coded these as ALND; 4) this problem likely exists across all registry operations, Hospital and Central Registries and impacts the CoC, SEER, NPCR, NAACCR, and the state central registries; and 5) these data affect the interpretation of papers published from many registry sources. For reference, Appendix A provides a ‘history’ of the evolution of the item “Scope of Regional Lymph Node Surgery” in cancer registries.

The second review consisted of selecting 12 CoC accredited cancer program registries to perform a re-coding exercise. 103,095 non-diffuse, invasive, AJCC cN0 cM0 breast cancers diagnosed in adult women in 2008 who underwent surgery for their disease, excluding those treated with neo-adjuvant therapy, were selected from the NDCB. The 1,292 CoC accredited programs with cases meeting these criteria were stratified by their respective reported ALND rate and three programs were selected from the lowest quartile (ALND rate <10%), six randomly selected from the middle two quartiles (ALND rate 10.1% – 46%) and three from the highest quartile (ALND rate >46%). The aggregate ALND rate reported from these 12 hospitals was 29.4%. A total of 479 cases were requested to be re-coded, ranging from 28 to 49 per hospital. Selected hospitals were located across the country (MA, NY, NC, GA, FL, OH, MI, TX, WA, and CA). Each hospital was contacted, and provided a list of cases to re-code and a set of coding instructions (Appendix B) that had been developed following the four hospital review described above. An attending clinician reviewed the registry re-coded cases to confirm the correct interpretation of documented surgical procedure. The results of this re-coding study showed that the ALND rate fell to 10.4%, and that this could be attributed to two changes in the way registries coded surgical lymph node procedures: 1) cases originally reported as ALND alone were found to have had a SLNBx; and 2) cases originally reported as having undergone SLNBx with ALND were found to have only undergone SLNBx.

The conclusions from this more systematic review were: 1) The data element “Scope of Regional Lymph Node Surgery” has been under-reporting SLNBx and SLNBx with ALND; 2) the revised coding rules employed in the re-coding study put emphasis on securing information from the operative report, in contrast to the standing coding rules which privileged information drawn from the pathology report, and that these new directions were comprehensive and clear; 3) the problem of mis-coded regional lymph node procedures exists

across all registry operations; and 4) the availability of these data in widely distributed data sets and the use of these data in published work needs to be assessed.

Complementary reviews by NCI/SEER of their data indicated findings similar to those noted in the NCDB. CDC/NPCR reviewed data from re-abstracting studies and confirmed that mis-coding of the “Scope of Regional Lymph Node” item was a recurring issue.

Representatives of the cancer registry surveillance agencies (CoC, SEER, NPCR, and NAACCR) have met on numerous occasions between April and October of 2011 and reviewed the results of the two CoC studies, discussed the respective findings of the two federal agencies, and reviewed the working draft of the revised coding directives developed and implemented by the CoC in its 12-center re-coding study. These agencies have agreed that a coordinated communication to its respective constituents describing the severity of the identified problem and their plans for collecting data describing lymph node procedures moving forward will be released by late November or early December 2011. There is consensus among these agencies that while retrospective re-coding of breast cancer cases was not feasible or desirable and that historical data was irretrievably lost, it was important to take corrective action and implement new coding directives starting as soon as possible.

The transition plans for each agency below, address the handling of the data already collected in the item “Scope Regional Lymph Node Surgery”, the implementation of the revised coding instructions for the item, training for hospital and central registry staff, and communications with the research community regarding the findings summarized above. Appendix B provides the revised coding instructions for this item that all agencies have agreed to implement for cases diagnosed January 1st, 2012 and later.

ACoS/CoC:

- The Commission on Cancer plans to implement the revised coding instructions (Appendix B) beginning with cases diagnosed in 2012. The instructions will be incorporated in **FORDS: Revised for 2012** and this statement will be posted.
- CoC accredited program registries will be involved in a mandatory on-line re-coding exercise based on applicable breast cancer cases diagnosed in 2009. This exercise will closely follow the procedures described in the 12 program re-coding study. Cancer Program Liaison Physicians (CLPs) or breast cancer surgeons at each program will review the revised codes against the surgical reports for accuracy, this will serve as an additional education element to ensure that registrars and their programs learn how to use the new coding instructions and understand the effects the new instructions have on their data.
- The CoC has been in contact regarding this issue with investigators that are known to have used data from the NCDB in submitted meeting abstracts and published papers that used the item “Scope of Regional Lymph Node Surgery”. A copy of this statement will be shared with these investigators, who will be advised to review their work and determine the potential impact of these finding. If appropriate, they will be advised to communicate with the respective meeting planning committees and/or journal editors if these findings are determined to have jeopardized their reported results.
- Moving forward, CoC use of the item “Scope of Regional Lymph Node Surgery” for cases diagnosed 2011 or earlier will be curtailed. The item will only be used to identify whether or not a patient underwent regional lymph nodes surgery, effectively removing any distinction between the type or extent of surgical intervention.

NCI/SEER:

- The National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) Program plans to implement the revised coding instructions (Appendix B) beginning with cases diagnosed in 2012. The instructions will be incorporated into the SEER Coding Manual for 2012 and this statement will be posted on the SEER website (<http://seer.cancer.gov>).
- Dissemination to SEER Data Collection Staff:
 - Data collection staff in SEER registries will attend a mandatory training via web or videoconference in early 2012. The training will emphasize the use of the operative report as the priority source to code Scope of Regional Lymph Node Surgery. The SEER registries will be asked to send any concerns about these guidelines to SEER.
 - Reliability study: Because we have a mutual interest in ensuring that these new guidelines are uniformly applied, we will conduct a reliability study. The study will be done to evaluate the data collector's ability to follow the guidelines. After reconciliation with the SEER registries, we will discuss the results at a future SEER QI or manager's videoconference. Feedback on the guidelines will be shared with the CoC, NPCR, and NAACCR.
- Dissemination to SEER Researchers:
 - The SEER Principal Investigators have been apprised of this issue.
 - The SEER Program will issue a statement to all users of SEER data on-line through SEER*Stat and the SEER research files on DVD regarding this issue. Investigators who have used the data item "Scope of Regional Lymph Node Surgery" should evaluate the impact of this issue on their analytic results and conclusions. For SEER data files which have been linked to other data files, the investigators will also be informed of this issue.
- The data item "Scope of Regional Lymph Node Surgery" for cases diagnosed in 1998+ will be changed to a '9' (unknown) on the SEER research data base for breast cancer.

CDC/NPCR:

- The Centers for Disease Control and Prevention's National Program of Cancer Registries (NPCR) plans to implement the revised coding instructions beginning with cases diagnosed in 2012.
- Dissemination to NPCR Central Cancer Registries:
 - A blast e-mail will be distributed all to Program Directors/Registry Contacts informing them of the issue and revised coding instructions. The revised coding instructions will be attached to the e-mail.
 - A conference call with all Education and Training Coordinators and Quality Assurance Coordinators will be held to review the revised coding instructions.
 - A reminder of the revised coding instructions will be included in the next NPCR newsletter.
- This data item is not included in files submitted to NPCR's Cancer Surveillance System and, therefore, the issue does not affect NPCR analytic databases.
- CDC's Division of Cancer Prevention and Control will be informed of this issue as it may affect analyses they conduct using SEER and/or NCDB data files.

NAACCR:

Disseminate information to NAACCR membership.

- Present an overview of the problem, a summary of standard setter plans to address the issue and the updated coding instructions as agenda items for specific NAACCR Committees: Uniform Data Standards, Registry Operations, and Education (at October and November 2011 meetings). All other committees will be provided with a written summary of the relevant information.
- Distribute listserv to membership noting the change in coding instructions for the data item, scope of regional lymph node surgery, applicable for cases diagnosed 1/1/2012 stating that the coding instructions can be found in the SEER 2012 Coding Manual and 2012 FORDS.
- Print an article in the winter issue of the NAACCR Narrative describing the validity issues and including agency implementation plans.
- Provide education on coding instructions.
 - Present revised coding instructions for the data item, scope of regional lymph node surgery, that are applicable for cases diagnosed 1/1/2012 and after in a coding moments segment of a monthly NAACCR webinar (winter 2012).
 - Create a training module presenting the revised coding instructions for the data item, scope of regional lymph node surgery, that are applicable for cases diagnosed 1/1/2012 and after and post the module on the Education/Training page of the NAACCR website (winter 2012).

Appendix A

Breast Cancer Surgery and Scope of Regional Lymph Node Surgery – A History

Prior to 1998 types of lymph node dissections were not distinguished by registry coding. While labels appearing in the coding guidelines distinguished between procedures WITHOUT and procedures WITH axillary lymph node dissections, there were no separate codes to separate surgical procedures that did or did not include ALND. In the early coding guidelines there are directives that indicate that if the pathology report indicates that 1-3 nodes were examined then the registry should take this to mean the lymph nodes were taken for staging purposes not for cure. The implication being that a more extensive pathological examination of nodes (≥ 4) was indicative of an ALND and curative intent. This distinction may have its roots in very early AJCC directives (2nd edition) indicating that "pathologic staging required at least a modified radical mastectomy (the entire breast and all three levels of axillary lymph nodes)".

Beginning in 1998 with the release of the ROADS manual, the CoC and SEER implemented a new set of surgery items for registries to use. These included separate items that described the surgical procedure (eg. lumpectomy or mastectomy) as well as the type of lymph node surgery (SLN, ALND, or the combination of the two). These items were coded and defined separately for each organ site. Thus, for example, the code definitions for breast were different than those for melanoma. This second item was paired with a surgery-specific count of the number of nodes removed. The number of nodes reported in this surgery-specific item was separate from the item recording the total # of nodes pathologically examined.

The most recent change in the registry coding standards occurred in 2003 with the release of the CoC FORDS manual. Here, in an attempt to simplify the coding requirements for registries generally, the Scope Lymph Node Surgery item was re-crafted so that it could be applied across all organ sites. This item is defined as: "[i]dentifying the removal, biopsy, or aspiration of regional lymph node(s) at the time of surgery of the primary site or during a separate surgical event." The applicable directives given to the registrar are:

- The scope of regional lymph node surgery is collected for each surgical event even if surgery of the primary site was not performed.
- Record surgical procedures which aspirate, biopsy, or remove regional lymph nodes in an effort to diagnose or stage disease in this data item.
- Codes 0–7 are hierarchical. If only one procedure can be recorded, code the procedure that is numerically higher.

The codes and definitions can be found in the CoC FORDS manual and the SEER Coding and Staging Manuals. In its design, the "Scope of Regional Lymph Node Surgery" was carried forward the distinction between 1-3 vs. ≥ 4 nodes, to accommodate the registry community's desire to ensure data were longitudinally consistent. In FORDS the CoC has emphasized that the node count distinction does not carry any clinical significance: "One important use of registry data is the tracking of treatment patterns over time. In order to compare contemporary treatment to previously published treatment based on the former codes, or to data still unmodified from pre-1998 definitions, the ability to differentiate surgeries in which four or more regional lymph nodes are removed is desirable. The compromise incorporated in the Scope of Regional Lymph Node Surgery codes separates removal of one to three nodes (code 4) from removal of four or more nodes in the response categories (code 5). It is very important to note that this distinction is made to permit comparison of current surgical procedures with procedures coded in the past when the removal of fewer than four nodes was not reflected in [the registry] surgery codes. The distinction between fewer than four nodes and four or more nodes removed is not intended to reflect clinical significance when applied to a particular surgical procedure."

Appendix B

Scope Regional Lymph Node Surgery
Revised Coding Directives for Implementation January 1, 2012
 RX Hosp--Scope Reg LN Sur (NAACCR Item # 672)
 RX Summ--Scope Reg LN Sur (NAACCR Item # 1292)

The following instructions should be applied to all surgically treated cases for all types of cancers. The treatment of breast and skin cancer is where the distinction between sentinel lymph node biopsies (SLNBx) and more extensive dissection of regional lymph nodes is most frequently encountered. For all other sites, non-sentinel regional node dissections are typical, and codes 2, 6 and 7 are infrequently used.

		General Instructions Applying to All Sites	Additional Notes Specific to Breast (C50.x)
Code	Label	Use the operative report as the primary source document to determine whether the operative procedure was a sentinel lymph node biopsy (SLNBx), or a more extensive dissection of regional lymph nodes, or a combination of both SLNBx and regional lymph node dissection. The operative report will designate the surgeon's planned procedure as well as a description of the procedure that was actually performed. The pathology report may be used to complement the information appearing in the operative report, but the operative report takes precedence when attempting to distinguish between SLNBx and regional lymph node dissection or a combination of these two procedures. Do not use the number of lymph nodes removed and pathologically examined as the sole means of distinguishing between a SLNBx and a regional lymph node dissection.	Use the operative report as the primary source document to determine whether the operative procedure was a sentinel lymph node biopsy (SLNBx), an axillary node dissection (ALND), or a combination of both SLNBx and ALND. The operative report will designate the surgeon's planned procedure as well as a description of the procedure that was actually performed. The pathology report may be used to complement the information appearing in the operative report, but the operative report takes precedence when attempting to distinguish between SLNBx and ALND, or a combination of these two procedures. Do not use the number of lymph nodes removed and pathologically examined as the sole means of distinguishing between a SLNBx and a ALND.
0	No regional lymph node surgery	No regional lymph node surgery.	

1	Biopsy or aspiration of regional lymph node(s)	Review the operative report of to confirm whether an excisional biopsy or aspiration of regional lymph nodes was actually performed. If additional procedures were performed on the lymph nodes, use the appropriate code 2-7.	Excisional biopsy or aspiration of regional lymph nodes for breast cancer is uncommon. Review the operative report of to confirm whether an excisional biopsy or aspiration of regional lymph nodes was actually performed; it is highly possible that the procedure is a SLNBx (code 2) instead. If additional procedures were performed on the lymph nodes, such as axillary lymph node dissection, use the appropriate code 2-7.
2	Sentinel Lymph Node Biopsy	<ul style="list-style-type: none"> • The operative report states that a SLNBx was performed. • Code 2 SLNBx when the operative report describes a procedure using injection of a dye, radio label, or combination to identify a lymph node (possibly more than one) for removal/examination. • When a SLNBx is performed, additional non-sentinel nodes can be taken during the same operative procedure. These additional non-sentinel nodes may be discovered by the pathologist or selectively removed (or harvested) as part of the SLNBx procedure by the surgeon. Code this as a SLNBx (code 2). If review of the operative report confirms that a regional lymph node dissection followed the SLNBx, code these cases as 6. 	<ul style="list-style-type: none"> • If a relatively large number of lymph nodes, more than 5, are pathologically examined, review the operative report to confirm the procedure was limited to a SLNBx and did not include an axillary lymph node dissection (ALND). • Infrequently, a SLNBx is attempted and the patient fails to map (i.e. no sentinel lymph nodes are identified by the dye and/or radio label injection) and no sentinel nodes are removed. Review the operative report to confirm that an axillary incision was made and a node exploration was conducted. Patients undergoing SLNBx who fail to map will often undergo ALND. Code these cases as 2 if no ALND was performed, or 6 when ALND was performed during the same operative event. Enter the appropriate number of nodes examined and positive in the data items <i>Regional Lymph Nodes Examined</i> (NAACCR Item #830) and <i>Regional Lymph Nodes Positive</i> (NAACCR Item #820).

3	Number of regional lymph nodes removed unknown or not stated; regional lymph nodes removed, NOS	<ul style="list-style-type: none"> • The operative report states that a regional lymph node dissection was performed (a SLNBx was not done during this procedure or in a prior procedure). • Code 3 (Number of regional lymph nodes removed unknown, not stated; regional lymph nodes removed, NOS). Check the operative report to ensure this procedure is not a SLNBx only (code 2), or a SLNBx with a regional lymph node dissection (code 6 or 7). 	<p>Generally, ALND removes at least 7-9 nodes. However, it is possible for these procedures to remove or harvest fewer nodes. Review the operative report to confirm that there was not a SLNBx in addition to a more extensive regional lymph node dissection during the same procedure (code 6 or 7).</p>
4	1-3 regional lymph nodes removed	<ul style="list-style-type: none"> • Code 4 (1-3 regional lymph nodes removed) should be used infrequently. Review the operative report to ensure the procedure was not a SLNBx only. 	
5	4 or more regional lymph nodes removed	<ul style="list-style-type: none"> • Code 5 (4 or more regional lymph nodes removed). If a relatively small number of nodes was examined pathologically, review the operative report to confirm the procedure was not a SLNBx only (code 2). If a relatively large number of nodes was examined pathologically, review the operative report to confirm that there was not a SLNBx in addition to a more extensive regional lymph node dissection during the same, or separate, procedure (code 6 or 7). • Infrequently, a SNLBx is attempted and the patient fails to map (i.e. no sentinel lymph nodes are identified by the dye and/or radio label injection). When mapping fails, surgeons usually perform a more extensive dissection of regional lymph nodes. Code these cases as 2 if no further dissection of regional lymph nodes was undertaken, or 6 when regional lymph nodes were dissected during the same operative event. 	

6	Sentinel node biopsy and code 3, 4, or 5 at same time, or timing not stated	<ul style="list-style-type: none"> • SNLBx and regional lymph node dissection (code 3, 4, or 5) during the same surgical event, or timing not known • Generally, SLNBx followed by a regional lymph node completion will yield a relatively large number of nodes. However it is possible for these procedures to harvest only a few nodes. • If relatively few nodes are pathologically examined, review the operative report to confirm whether the procedure was limited to a SLNBx only. • Infrequently, a SNLBx is attempted and the patient fails to map (i.e. no sentinel lymph nodes are identified by the dye and/or radio label injection.) When mapping fails, the surgeon usually performs a more extensive dissection of regional lymph nodes. Code these cases as 6. 	<ul style="list-style-type: none"> • Generally, SLNBx followed by ALND will yield a minimum of 7-9 nodes. However it is possible for these procedures to harvest fewer (or more) nodes. • If relatively few nodes are pathologically examined, review the operative report to confirm whether the procedure was limited to a SLNBx, or whether a SLNBx plus an ALND was performed.
7	Sentinel node biopsy and code 3, 4, or 5 at different times	<ul style="list-style-type: none"> • SNLBx and regional lymph node dissection (code 3, 4, or 5) in separate surgical events. • Generally, SLNBx followed by regional lymph node completion will yield a relatively large number of nodes. However, it is possible for these procedures to harvest only a few nodes. • If relatively few nodes are pathologically examined, review the operative report to confirm whether the procedure was limited to a SLNBx only. 	<ul style="list-style-type: none"> • Generally, SLNBx followed by ALND will yield a minimum of 7-9 nodes. However, it is possible for these procedures to harvest fewer (or more) nodes. • If relatively few nodes are pathologically examined, review the operative report to confirm whether the procedure was limited to a SLNBx only, or whether a SLNBx plus an ALND was performed.
9	Unknown or not applicable	<ul style="list-style-type: none"> • The status of regional lymph node evaluation should be known for surgically-treated cases (i.e., cases coded 19-90 in the data item <i>Surgery of Primary Site</i> [NAACCR Item #1290]). Review surgically treated cases coded 9 in <i>Scope of Regional Lymph Node Surgery</i> to confirm the code. 	