pTX and pNX should not be used in tumor staging

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June 2021—For the June 2021 release of updates for the CAP cancer protocols and the corresponding electronic cancer checklists used by electronic health record vendors, pTX and pNX will no longer be selectable options for use by pathologists when assigning pathologic staging based on definitive surgical resection (pTNM). This change is coming after extensive discussions with the American Joint Committee on Cancer (AJCC) and with its unanimous endorsement. Why are we making this change?

In our view, and that of the AJCC as the standard-setting organization for tumor staging, assigning pathologic T and N requires an integration of multiple sources of clinical data in addition to the pathologic staging data derived from the definitive surgical resection. Since assigning pTX and/or pNX renders a tumor unstageable, they should be used only when there is an absence of information necessary to determine pT or pN. Final tumor staging is ultimately the responsibility of the managing physician who takes into consideration all the appropriate clinical information, including imaging studies, operative findings, and other clinical data, when assigning the final pathologic TNM and group stage.

This is not a trivial point. We have identified at least 22 stageable cancers in the eighth edition of the AJCC *Cancer Staging Manual* that may require clinical information such as imaging studies or operative findings to appropriately assign pathologic T or N categories. While many of these involve higher stage tumors that may not be surgically resected, we can cite numerous instances in which this would affect surgically resectable tumors (and require assignment of T and N by the pathologist). While pathologists in some health care systems may have immediate access to all the information needed to assign pathologic T and N categories, others practice in health care systems in which access to the entirety of the patient's health care records is not available. Erroneous use of pTX or pNX by the pathologist in this setting will make the tumor unstageable if carried over into the final tumor staging.

There is a precedent for removing the "X" designation from tumor staging. As of the AJCC sixth edition, pMX was removed from the TNM tumor staging system. While pMX is no longer used for staging across the entire continuum of tumor staging, pTX and pNX still have an important role for clinical care and for the cancer surveillance community, and they continue to be used by the managing physician when appropriate. The only difference is that the pathologist will no longer be using pTX and pNX on definitive surgical resection specimens.

We anticipate that this will improve tumor staging through the entire continuum of cancer staging, reduce cancer staging errors or ambiguities, and strengthen the quality of staging information for tumor registrars and the cancer surveillance community. In the upcoming updates to the cancer protocols, the CAP will provide alternative wording that may be used when the lack of clinical information precludes us from assigning pathologic T or N categories. Your opinion and experiences matter to us, and we welcome feedback on this change at <u>cprotoc@cap.org</u>.

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