Blank Vs. X
Definitions and Data Interpretation for AJCC Staging

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Definition of TX and NX

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AJCC Chapter 1 Principles of Cancer Staging

Unknown Designation: X

The X designation is used if information on a specific T or N category is unknown; such cases usually cannot be assigned a stage. Therefore, TX and NX should be used only if absolutely necessary. Of note, there is no MX category.

Tumor category…	Is assigned when there is…
TX	No information about the T category for the primary tumor, or it is unknown or cannot be assessed *Note*: Use of the TX category should be minimized.

Regional node category…	Is assigned when there is…
NX	No information about the N category for the regional lymph nodes, or it is unknown or cannot be assessed *Note:* Use of NX should be minimized.

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AJCC Chapter 1 Principles of Cancer Staging

Assigning Stage: Role of the Managing Physician

Although the pathologist and the radiologist provide important staging information, and may provide important T-, N-, and/or M-related information, stage is defined ultimately from the synthesis of an array of patient history and physical examination findings supplemented by imaging and pathology data. Only the managing physician can assign the patient's stage, because only (s)he routinely has access to all the pertinent information from physical examination, imaging studies, biopsies, diagnostic procedures, surgical findings, and pathology reports.

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Definition of X

- X
  - Defined by AJCC as cannot be assessed
  - Only managing physicians assess patients by exam, imaging, procedures, surgery
  - Managing physician must assign X or describe they do not have information
  - X must only be managing physician perspective of patient's story
- If X definition not met, only option for registrar is leave it blank
  - No other AJCC values available to assign if X, 0, 1, 2, 3, 4 are not correct
  - No choice left for registrar except to NOT assign a category
  - If registrar cannot assign a category, it is left blank
  - Registrar would not assign any other AJCC category if definition not met
  - Would a registrar assign T2 or N1 if that definition not met?
  - Don't change rules for X, if definition not met it cannot be assigned
  - X is ***not*** the same as unknown to registrar

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AJCC Staging Rules for X

- AJCC staging rules only include criteria for X
  - Written for physicians to use in patient care
  - No rules written for registrar to use blank, intuitive, if no info leave it blank
  - Managing physicians document information about cancer in staging
    - Including TX or NX as appropriate
  - Pathologists no longer use X
    - pT or pN not assigned if cannot be determined
- Tell patient's story through staging (from managing phy perspective)
  - X = managing physician has no exam/imaging/procedure results or results cannot be quantified
  - Blank = registrar had no access to managing physician information or no valid T or N category information provided

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Physician Use of X

- Managing physician – may use X
  - Performs assessment of patients
  - Responsible for patient staging
  - X is for patient, using all available information
- Pathologists and radiologists – may NOT use X
  - Do not assess patients
  - Cannot assign staging for patients, only provide helpful information
  - Limited information: one imaging or one specimen
  - X is for patient, ***not*** just one imaging or one specimen
  - AJCC & CAP agreed to no longer allow pathologists to use TX or NX – June 2021
    - CAP protocols updated
    - Change made to AJCC Chapter 1
    - Pathologists agree do not have access to all information, not appropriate to use X

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Stage Classification: Blank or X

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Does Patient Meet Stage Classification Criteria?

- Yes – patient meets classification criteria
  - If managing physician could not assess T or N for patient
  - Registrar may use TX or NX
- Yes – patient meets classification criteria
  - No info in chart on diagnostic workup, operative findings, or resection pathology
  - Registrars do ***not*** use X
    - Implies physician did not assess or have info on patient's T or N
  - Registrars use blank
    - Indicates registrar could not find information in chart

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Does Patient Meet Stage Classification Criteria?

- No – patient does NOT meet classification criteria
  - Registrars do NOT use X
    - Indicates patient eligible for staging
    - Implies physician did not assess or have info on patient's T or N
  - Registrar must use blanks
    - Indicates patient did not meet classification criteria

- No – patient does NOT meet classification criteria
  - No diagnostic workup = no clinical staging
    - Not cTX or cNX, must be blank
  - No surgical resection = no pathological staging
    - Not pTX or pNX, must be blank
  - No surgical resection after neoadjuvant = no posttherapy path staging
    - Not ypTX or ypNX, must be blank

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Clinical & Pathological Staging

- Tell patient's story through staging
  - X = managing physician has no assessment/results or results cannot be quantified

  - Clinical staging – story of pt's diagnostic workup
    - cTX = managing phys has no exam/diagnostic workup results or results cannot be quantified
    - cNX = managing phys has no exam/diagnostic workup results or results cannot be quantified

  - Pathological staging – pt's story from diagnosis through surgical treatment
    - pTX = specimen cannot be evaluated, maybe fragmentation or destroyed, and no clinical info or operative findings can quantify T category
    - pNX = no regional node microscopically examined at any time from dx through resection

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Registrar Blank Usages

- Blank used by registrar when

  - No information available in chart

  - Registrar has no access to physician info on patient

  - Cannot be assigned a valid AJCC category (according to definition/criteria)
    - Valid AJCC categories include X, 0, 1, 2, 3, 4 and any subcategories

  - Patient not eligible for stage classification
    - cT blank = no workup for pt, incidental finding at surgical treatment
    - pT blank = pt didn't have surgical treatment
    - ypT blank = pt didn't have surgical treatment after neoadjuvant therapy

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Clinical & Pathological Staging – M Category

- X does *NOT* exist for M category
- Blank
  - Registrar had no access to managing physician information or no valid M category information provided
- cM0
  - Requires history and physical exam (H&P) by managing physician
  - Does not mean registrar must find H&P on chart
  - If managing physician suspects mets
    - It will be mentioned in chart
    - Treatment plan will be different

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Harm from using TX or NX

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Issues with Registrars Using X

- Examples of physician interpretation of registry data
- Registry data should reflect
  - Information in medical record
  - Managing physician care of patient
- Examples showcase importance of accurate use of X
  - Differentiate physician cannot assess (X) and registrar doesn't know (blank)
  - Illustrate how data is interpreted
  - Registry data leads to false/erroneous conclusions based on registrar use of X

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Breast cTX cM1 – Physician Questions

- Breast cTX cM1 cases in NCDB PUF
- Physician concerns
  - Once patient distant mets identified
  - Breast exams or imaging not being performed
  - cTX means no exam/imaging assessment or results cannot be quantified
- Physician plans writing medical journal article
  - Data showing complete workup *not* being performed
  - Convince physicians important to assess breast
- Physician asked questions of AJCC to verify findings

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Breast cTX cM1 in Registry Database

- My explanation - more likely registrar issue
  - Registrar not finding data
  - Registrar inaccurately using cTX
- cTX indicates
  - No breast assessment by exam/imaging, pt refused/phy didn't order
  - Exam/imaging results can't be quantified
- Issues
  - Registrar did not have access to information, not cTX
  - cTX may not represent what physician knew about patient
  - Some registrars incorrectly use cTX if can't find info or don't ask physician
  - Registrar using X and not blank skews data for physician researchers
  - Registrar X could lead to incorrect conclusions on pt care being published

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Melanoma cNX – Physician Questions

- Melanoma cNX cases in NCDB PUF
- Physician concerns
  - Nodal area clinical/physical exams or imaging not being performed
  - Nodal area assessment part of national workup guidelines
  - Must be assessed for lymph nodes, satellites, and in-transit lesions
- Physician plans medical journal article and lectures
  - Data showing complete workup *not* being performed
  - Convince physicians important to assess nodal area
- Physician asked questions of AJCC to verify findings

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Melanoma cNX in Registry Database

- My explanation - more likely registrar issue
  - Registrar not being able to find data
  - Registrar inaccurately assigning cNX
- cNX indicates
  - No nodal area assessment by exam/imaging, pt refused/phy didn't order
  - Exam/imaging results can't be quantified
- Issues
  - Registrar did not have access to information, not cNX
  - cNX may not represent what physician knew about patient
  - Some registrars incorrectly use cNX if can't find info or don't ask physician
  - Registrar using X and not blank skews data for physician researchers
  - Registrar X could lead to incorrect conclusions on pt care being published/lectured

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Rectum cTX – Physician Questions

- Rectum cTX cases in NCDB PUF
- Physician concerns
  - No appropriate imaging assessment being done
  - Especially problem since NAPRC guidelines very clear about workup
- Physician plans working with NAPRC and accredited centers
  - Data showing appropriate imaging *not* being performed
  - Convince physicians important to follow NAPRC guidelines
  - Determine if issue with physician care or registrar staging
  - Choose appropriate next steps depending on source of problem
- Physician asked questions of AJCC to verify findings

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Rectum cTX in Registry Database

- My explanation - more likely registrar issue
  - Registrar not being able to find data
  - Registrar inaccurately assigning cTX
- cTX indicates
  - No rectal assessment by exam/imaging, pt refused/phy didn't order
  - Exam/imaging results can't be quantified
- Issues
  - Registrar did not have access to information, not cTX
  - cTX may not represent what physician knew about patient
  - Some registrars incorrectly use cTX if can't find info or don't ask physician
  - Registrar using X and not blank skews data for physician researchers
  - Registrar X could lead to incorrect conclusions on pt care & accreditation status

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Example from Past Registrar Data Collection Issues

- 1998-2011 Registry definition of sentinel node procedure
  - Sentinel nodes – all must contain dye or tracer
  - Sentinel node and regional nodes – if any node does not contain dye or tracer
- 2011 analysis of NCDB breast data
  - 28-29% of pts undergoing axillary dissection without preceding sentinel node bx
  - Breast patients with negative sentinel nodes going on to have axillary dissections
- Data presented at national physician conference
  - Potential evidence of inappropriate patient care
  - Physicians in attendance questioned the findings
- Validity of data called into question by 3 separate groups

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Example from Past Registrar Data Collection Issues

- 3/9/12 Letter sent from NCDB
  - Acknowledged
    - Registrars given wrong definition of sentinel nodes
    - Wrongly told to code from pathology report
    - Wrongly code as axillary dissection if non-sentinel nodes also removed
  - Provided remedy
    - Changes in coding instructions
    - Registrars instructed to review operative report to code information
    - Registrars instructed nodes without dye/tracer are
      - Non-sentinel nodes
      - Part of sentinel node procedure
- 14 years of inaccurate data – learn from this, prevent future mistakes
  - Must consult with physicians actively involved in patient care
  - Only way for registry data to help physicians improve patient care & outcomes

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Physician Data Interpretation

- Physician data interpretation of X
  - Managing physician did *not* perform exam or imaging
  - Managing physician ordered tests but results were *not* clear
  - Meets AJCC definition of TX and NX
  - Examples from physician data questions about appropriate workup
    - Breast cTX cM1: phy concerned breast exams or imaging not performed
    - Melanoma cNX: phy concerned no nodal area clinical exam or imaging
    - Rectum cTX: phy concerned no imaging assessment
- Physician data interpretation of blank
  - Registrar did not have access to information

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Registrar Use of X and Blank

- Registrars
  - Assign X
    - Managing physician clear they do not know
    - Managing physician has not or could not assess primary tumor or nodes
    - Managing physician has assessed but results did not provide definitive information
  - Leave category blank
    - Registrar does not have information
    - No evidence managing physician did not assess
    - Physician using uncertainty rule with main categories (e.g. T3/T4)

- Prioritize **accuracy** over completeness
  - Registrar must leave data items *blank* if necessary info not available
  - Can't get around this, can't fill in every data item with "meaningful" code
  - Skews data, causes misinterpretation by physicians and researchers

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Understanding the Significant Difference: Blank Vs. X

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Blank vs. X – The Issue

- Correct use of blank or X
  - Causing data analysis issues, misinterpretation by physicians and researchers

TX Primary tumor cannot be assessed NX Regional lymph nodes cannot be assessed

- Blank makes more sense, usually more accurate
  - Why registrar reluctance to use blank?
  - Potential harm coming from X
  - Registrars do ***not*** assess patients and cannot make the call to assign X
  - Need to refine and reinforce instructions for clear data
  - Makes a difference to physicians using the data

Guiding principle
- Always tell patient's story from managing physician's perspective

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Blank vs. X – Risks & Benefits

X

- Risks
  - Is registrar confident physician did ***not*** know
  - May ***not*** accurately represent physician information
  - May lead to misinterpretation of data if physician knew
  - No advantage to using X instead of blank
- Benefits
  - Clearly conveys physician did ***not*** know – if that is accurate

Blank

- Risks
  - None, no information is lost
- Benefits
  - Registrar not penalized for blanks
  - Using blank instead of X ***does not lose any information***
  - No advantage to using X instead of blank
  - Better to err on side of caution by using blank
  - Best if not sure physician does ***not*** know

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Blank vs. X – The Solution

- Solution clear from the data evidence and benefits/risk
- Critical for registrars to
  - Assign T, N, and M according to definitions in AJCC staging system
  - When necessary information **not** available
    - Registrars cannot assign TX and NX
    - Registrars must leave data items blank
    - No other valid AJCC TNM category can be assigned
  - Discriminate between blank and X usage
    - Assign X *ONLY* according to AJCC rules
    - Protect accuracy and integrity of the data
    - Must value **accuracy** over completeness

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Information and Questions on AJCC Staging

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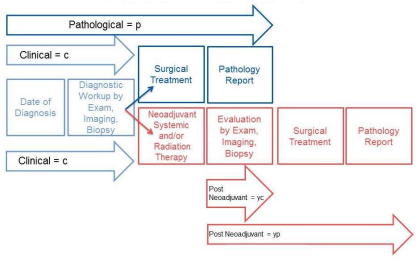
Timing is Everything

AJCC Stage Classifications

Defining Time Frame and Criteria



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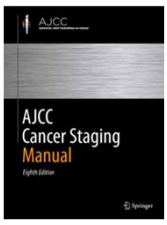
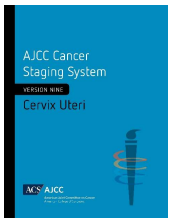
AJCC Web Site

- https://cancerstaging.org
- https://www.facs.org/quality-programs/cancer-programs/american-joint-committee-on-cancer/
- General information
  - Overview
  - Version 9
  - Cancer Staging Systems
    - AJCC 8th edition Chapter 1: Principles of Cancer Staging
  - Cancer Staging Education
  - FAQ & Resources





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CAnswer Forum

- Submit questions to AJCC Forum
  - Version 9 Forum
  - 8th Edition Forum
  - Located within CAnswer Forum
  - Provides information for all
  - Allows tracking for educational purposes
- http://cancerbulletin.facs.org/forums/

ACS CAnswer

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