Anatomic Pathologist’s Role in Error Reduction and Patient Safety

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Disclosure

• This presenter has no financial affiliations to disclose.
Topics

• Errors in Anatomic Pathology
• Error Reduction: Standardization, 2nd Opinion, etc.
• Critical Values
• GYN and NON-GYN Cytology
• Risk Management
• Strategies to Avoid Malpractice
• Summary
Audit Methods in Surgical Pathology

- Internal quality assurance
  - Consensus conference
  - Review all path reports
  - Selective review
- Intradepartmental consultation
- Extradepartmental consultation
- Clinicopathologic conferences
- External quality assurance-slide circulation
IOM Report
Deaths from Medical Errors

• Colorado & Utah studies – 44,000 deaths – NY study – 98,000 deaths
• 8th leading cause of death. More than MVA (44,000), Breast CA (43,000) & AIDS (17,000)
• Total national costs – lost income, lost household production, disability & health care costs of preventable adverse events (M.E. resulting in injury) – $17 – 29 billion, (1/2 of which is health care costs)
IOM Strategies & Goals

Strategies:

• Establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety:
• Identifying and learning from errors through mandatory reporting efforts
• Raising standards and expectations for improvements in safety
• Creating safety systems inside health care organizations through the implementation of safe practices at the delivery level.

Goal: 50% reduction in medical errors in 5 years

Pathology & Lab Testing

• 70% of medical decisions that affect or change clinical course related to lab data
• 60 million PAP tests/year. 240 million SP specimens
• >97% CA dx based on pathology specimen dx
• Also medical dx – GI, liver, etc.
Error, IOM Definition

• Failure of a planned action to be completed as intended (execution error)
• Use of wrong plan to achieve an aim (planning failure)
Error

Generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome.

Ronald L. Sirota, MD
CAP Companion Society Meeting
USCAP, March 22, 2003
Error

- Not a reality, but a judgment
  - A ruling made on human performance
- Always assigned after outcome is known
- Almost always affected by *hindsight bias*

Ronald L. Sirota, MD
CAP Companion Society Meeting
USCAP, March 22, 2003
Gold Standard for Correctness

• Fundamental scientific characteristic of disease state i.e., translocation or distinctive phenotype abn with very high dx sensitivity and specificity i.e., X:18 translocation – SS.

• Arbitrary Political Standards:
  - Most votes (normative standard)
  - Highest authority i.e., expert consultant

Foucar et al.
AJCP 82:116; S34, 2001
Interobserver Variability Among Experts

- Rosai J – 5 pathologists evaluated 17 proliferative breast lesions. No single case did all agree, and only 3 cases (18%) did 4/5 agree.
- Schnitt SJ, et al. – 6 pathologists reviewed 24 proliferative ductal breast lesions. Complete agreement – 58%, 5 or more in 71% and 4 or more in 92% following use of standardized criteria (Page)
- Farmer ER, et al. – 8 experts, 37 melanocytic cases: Kappa – 50 (moderate) with 62% unanimous or 1 discordant dx; 38% had 2 or more discordant dx.
What is “ERROR” in SP

• Clinical significant vs. academic
• Error defined by prospective versus retrospective review
• Error defined by “expert” 2nd opinion, intradept or inter-institutional review, etc.
• Judicial system – error as injury resulting from negligence (negligence defined by expert testimony as medical practice that falls below standard of care (national, not community standard))

Troxel, AJSP 28:1092, 2004
Types of SP Errors Based on Audit Method

• Review of consecutive cases – false negative.

• Consultation – false positive threshold errors – spectrum of typing and grading.

Renshaw, A.
AJCP 115:338, 2001
Logistics-Reporting Format

• Reporting surgical pathology errors – no standard

• Preliminary data suggests best method is to report errors/total slides reviewed NOT # of cases

A. Renshaw, MD
ADASP San Antonio, TX
Feb 2005
Errors in S.P.

ADASP Survey

- 41 questionnaires / 34 replies (academic dept.)
- Definitions, perceptions
- Measures discrepancy/errors
- Lack of uniformity/consistency
- Need for consensus

Kumarasen Cooper
ADASP, San Antonio, TX
Feb 2005
Errors in AP

• 1.2% of SP reports contained significant error (Ramsay et al 1992)

• 2\textsuperscript{nd} pathologist review, 7/5,397 (0.1%) had error affecting patient care (Safrin & Bark 1993) and 32/2,694 (1.1%) errors in bx’s (Lind et al 1995)

• Major error was 1/1,000 cases (DeMay 1996)

• AP errors (1-5%, range 0.5-43%); significant errors 0.25-8.8%, esp. neuropathology (Renshaw literature review AJCP 115:338, 2001)
Dx’s Errors in AP Organ Specific

- Prostate (Epstein, 1996) – 2.7%
- CNS (Bruner, 1997) – 8.8%
- GYN Tumors (Selman, 1999) – 4.7%
- Head & Neck (Westra, 2002) – 7%
Soft Tissue Consultative (Expert) 2nd Opinion

- 500 consecutive cases
- 266 (53.2%) accompanied by a dx
  - agreement – 68%
  - minor discrepancy – 7%
  - major discrepancy – 25%
- 65 major discrepancies
  - benign lesion dx as sarcoma (25%)
  - sarcomas dx as benign 23%)
  - nonmesenchymal dx as sarcoma (20%)
  - major grading diff (12%)

Arbiser,, Folpe, Weiss AJCP 116:473, 2001
Problematic Soft Tissue Lesions

- Lipoma (6 cases) & fasciitis (5), & their variants
- Desmoplastic neurotropic melanoma (5)
- Few lesions accounted for major portion of major discrepancies
- Few lesions needed IHC
- Needle bx’s more troublesome
In-house Prospective Peer Review Before Release of S.P. Report

- LIND, et al. – 32 errors (1.2% cases), 8 major errors.
- NOVIS – 1.3/1000 → 0.6/1000 following review
- WHITEHEAD, et al. – 7.8% disagreement with 2.2% changed dx (≈ 1% significant) (3,000 cases)
- SAFRIN & BARK – 14/5,397 (0.26% error); 7 significant. $7 per case, $2,700 per discrepancy
Which Cases Need 2nd Opinion (Consensus Conference)

• Highly critical or significant cases
• Problem prone cases
• Clinician flagged cases
• Patient flagged cases
• Rare disorders
• New procedures and specimen types
• New pathologist until competency proven and problem prone pathologist until competency issues resolved

Tomaszewski J., et al.  
AJCP 114:329, 2000
Consensus Conference on 2\textsuperscript{nd} Opinion Recommendations

“Formal policy on application of 2\textsuperscript{nd} opinion should be created in each pathology department.”

Tomaszewski et al.  
AJCP 114:329, 2000
Proposed Standards

• General surgical pathology
  - < 1% excellent
  - 1-2% acceptable

• Frozen Sections
  - > 3%
  unacceptable

• New Pathologists
  - < 1% keep

• Competency
  - > 5%
  incompetent

• Specialization
  - > 5% can’t sign it out

• Second Opinion
  - 10%
  unacceptable

A. Renshaw, MD
ADASP, San Antonio, TX
Feb 2005
CASE 1

• 65 M with fever, night sweats, cough and Rt. middle lobe of lung infiltrate

• Under went transbronchial bx at outside hospital, March 2007
Outside Hospital Dx

- **Rt. Middle lobe of lung biopsy**
  - Necrotizing granulomatosus inflammation with vasculitis
  - Special stains for fungus and AFB are negative
  - D/D- Wegener’s granulomatosis, Churg strauss syndrome, rheumatoid nodule, bronchocentric granulomatosis and diffuse pulmonary hemorrhage.
Case 1 (continued)

Patient was treated with cytoxan and prednisone with no improvement. The lung cultured Nocardia. In October 2007, skin lesions developed including a chest nodule which was biopsied and cultured Nocardia. Patient was then treated with roceptin followed by bactrim with improvement. The patient was referred for evaluation and treatment at AGH. Outside slides reviewed.
Final Diagnosis (AGH)

• Organizing pneumonia with associated BOOP like changes
Interinstitutional 2nd Review

- 777 patients / 9.1% discordant dx
- Change in Rxmet – 5.8%
- Cytology & FNA discrepant – 21%
- S.P. discordant – 7.8%

Abt et al.
Archives Pathol Lab 119:514, 1995
Mandatory Second Review

- Discordant dx – major modification in therapy or prognosis: benign vs. malignant or tumor classification
- 6171 cases: 86 changed dx (1.4%)
- Serosal surfaces (9.5%) & GYN (5.1%)

Kronz et al.
Cancer 86: 2426, 1999 (Johns Hopkins Hospital)
Incidence and Types of Discordant Diagnosis

1.4 – 5.8% - clinical impact (up to 30%, with mean 10% - clinical and non-clinical impact)

Higher in certain organ system – GYN, L.N., G.U. (5-13%). Also PAP smears, soft tissue FNA, serosal fluids.

Recent survey of 300 hospitals. ½ require mandatory review, but ¾ of academic centers require it (AJSP 24:280, 2000)
Mandatory Interinstitutional Pathology Consultation (IPCs) a.k.a. – Second Opinion

ADASP recommend adoption of IPC as “institutional policy” when patients are referred to a second institution. (AJSP 17:743, 1993)

No consensus or national guidelines due to perceived cost, delay and/or value

However, following Institute of Medicine’s 1999 report – 2\textsuperscript{nd} Conference – ASCP – June 2000 affirming ADASP recommendation supporting mandatory review of extramural dx “for which major therapeutic intervention are planned based on a tissue or cytologic dx” at the treating institution (AJCP 714:329, 2000).
RECOMMENDATIONS

2\textsuperscript{nd} opinion for:

Non-emergent cases for which Rxmet done based on outside tissue or cytology dx.

Second opinion done at treating institution.

Cases of dx discrepancy with outside institution need to be resolved before definitive Rxmet.
Cost Benefit of Second Review

• Decrease elective surgery in 11-19% cases
• Decrease unnecessary medical procedures i.e., angiography
• Saved $2-4 for every $1 spent (second review)

Kronz et al
Cancer 86: 2426, 1999
Second Review of Prostate Biopsies

- 1.3% bx’s reclassified as benign prior to radical prostatectomy
- Atrophy & adenosis msdx.
- Cancelled surgery in 6/535 cases
- Savings $1.91 for every $1 spent on 2nd review
- Cost savings – IHC, repeat bx’s, ultrasound, surgery

Epstein et al.  
AJSP 20:851, 1996
Health Mailbox

Columnist Tara Parker-Pope answers readers’ questions

Q: Can you provide a reference for your statement that pathology reports in cancer cases have errors from 1% to 20% of the time? Is this someone’s best guess, or is it documented by research? —D.O.
Pathology Errors
Wall Street Journal

• “Growing evidence that patients should always seek a 2nd opinion on lab work when cancer is suspected or dx”

• Johns Hopkins (1.4%)
  Dana Farber prostate dx (10%)
  Northwestern (8% of breast CA)

  etc. on 2nd review of outside pathology

  Tara Parker-Pope
  WSJ Feb 8, 2005
Value of Second Opinions Is Underscored in Study of Biopsies


Subjects: Cancer, Medical diagnosis, Medical research, Errors

Author(s): Laurie Tarkan

Document types: News

Section: F


Source type: Newspaper

ISSN/ISBN: 03624331
Errors in Surgical Pathology


Troxel. AJSP 28:1092, 2004
SP Claims – 1995-97

• 54% systematic cognitive errors – 52% of these false neg. dx, & 33% false positive

• False neg. breast FNA (sampling); melanoma misdx as Spitz nevi; failure to dx lymphoma in extranodal sites; frozen section misdx

Troxel. AJSP 28:1092, 2004
A Total of 218 Surgical Pathology Claims From 1995, 1996, and 1997

<table>
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<th>Specimen Category</th>
<th>Total Claims</th>
<th>% (no.) False Negative (Ca)</th>
<th>% (no.) False Positive (Ca)</th>
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Troxel. Am J Surg Pathol 28(8); 1092-95, 2004
SP Claims – 1998 - 2003

• 61% false neg. dx, 27% false positive
• Melanoma false neg.; breast bx’s, misdx ovarian tumors, operational errors, extranodal lymphomas, F.S.
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<td>Branchial cleft cyst</td>
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<td>-</td>
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</table>

Troxel. Am J Surg Pathol 28(8); 1092-95, 2004
Errors – Patterns & Trends

• Melanoma misdx increased from 11 – 16% of total claims – misdx as Spitz, unrecognized desmoplastic, etc.
• Breast bx, breast FNA, FS – most common cause of pathology malpractice claims
• Extranodal lymphomas
• Less FNA claims
• PAP smears decreased from 17 – 11% of total claims
• Operational errors increased from 1.8 – 8%
Melanoma Pitfalls

• Doctors Company malpractice claims 1995-2001 – 13% involved msdx of melanoma; 2nd most common following breast.
• 70% false negative.
• Problems – “classic” melanoma dx as nevus, nevoid melanoma, desmoplastic melanoma, dysplastic nevus, and Spitz nevus.
• Shave or punch biopsies.

Troxel DB
AJSP 27:1278, 2003
Spitz Nevus

• Spitz nevus in adult (>20 y.o.) send to consultant.

• All Spitz nevi should be completely excised (in young and adult).

Troxel – CAP
Meeting at USCAP
March 2003
Where AP Errors Occur
Pre-analytic

- Clinician – wrong information, no information, wrong specimen, inadequate or wrong sampling
- Specimen delivery
- Accessioning errors
- Histology errors
Errors in AP Analytic

- Gross Room – Poor gross examination – sampling, description, measurement, margins, sectioning, wrong studies ordered or proper studies omitted
- Frozen Section
- Microscopic Diagnostic: Cognitive mistakes in msdx or omitted dx.
- S.P. Report: Incorrect wording, typo’s, formatting
Analytic Error Analysis

SLIP
- wrong action to achieve goal
- unintended automatic action
- misapplying known knowledge

LAPSES
- inadvertent omission of automatic action
- skipping a slide
- mixing up cases

Knowledge gaps
Poor judgment
COGNITIVE DIAGNOSTIC ERRORS
(Acad. Med. Aug 03)

- Anchoring: Lock-in too early/fail to adjust to later information
- Confirmation: Look for confirming evidence to support Dx /not looking for refutation
- Diagnosis Momentum: One Dx label attached becomes stickier and stickier
- Ascertainment Bias: Thinking shaped by prior expectations/stereotyping
- Availability: If things rapidly come to mind/recent experience-more likely to occur
- Base rate neglect: Ignore prevalence of a disease
- Commission bias: tendency toward action
- Overconfidence: Universal tendency to believe we know more than we do
COGNITIVE ERRORS (CONT’D)

- Premature Closure: “when the diagnosis is made, the thinking stops”
- Fundamental Attribution Error: comorbid medical conditions overlooked
- Representativeness Restraint: Looking for prototypical manifestations of disease; leads to missing atypical variants
- Search Satisfying: Call off search once something is found
- Sutton’s Slip: When possibilities other than the obvious are not given sufficient consideration
- Sunk Costs: The more you invest in a Dx, less likely to release it, and consider alternatives
- Vertical Line Failure: Thinking in Silo’s: inflexible: what else could it be?
CASE 2

SP consultation slide from outside hospital

• 68 yr. old male, stomach Bx.
Final Diagnosis

Biopsy of stomach:

- Invasive poorly differentiated adenocarcinoma
CASE 2 (continued)

Patient then underwent resection of stomach, spleen and tail of pancreas for a 9.5 cm gastric mass
Final Diagnosis

- Metastatic malignant melanoma, invading into but not through the muscularis propria of distal stomach
- Eight of nine lymph nodes positive for metastatic malignant melanoma
CASE 3

• 40 yr. old female, with history of left breast carcinoma, status-post radiation following lumpectomy, underwent mastectomy
Final Diagnosis

Left breast mastectomy

- Rare atypical glands, consistent with residual ductal carcinoma, high nuclear grade
- Extensive fat necrosis
Amended Diagnosis

Left Breast, mastectomy:
- Rare atypical glands, consistent with radiation effect
- Extensive fat necrosis
CASE 4

- 81 yr. old male with history of bladder tumor underwent bladder neck and bladder biopsies
Bladder tissue
Preliminary Diagnosis

A. Left bladder neck tumor bx.:
   - invasive, moderately to poorly differentiated urothelial (transitional cell) carcinoma with focal glandular metaplasia

B. Bladder tissue:
   - Adenocarcinoma
   - Final diagnosis pending immunohistochemical studies
Immunostains

PSA

P504S

PAP

CK20
Amended Diagnosis

A. Left Bladder neck tumor, Bx.:
- Moderate to poorly differentiated adenocarcinoma consistent with prostatic carcinoma, Gleason score, 4+5:9

B. Bladder tissue:
- Prostatic adenocarcinoma Gleason Score 4+3:7
CASE 5

- 50 yr. old female with history of bilateral pneumothorax underwent edge resection of left upper and lower lobes
Final Diagnosis

A. Left lower lobe, wedge resection:
   - Emphysematous changes with bleb formation
   - Pleural fibrosis and granulation tissue
B. Lt. upper lobe, tissue excision
   - Emphysematous bleb
Immunostains

- SMA
- H-Caldesmom
- HMB-45
Amended Diagnosis

Lymphangioleiomyomatosis of lung
CASE 6

• 76 F with history of breast mass underwent right breast core bx
Final Diagnosis

Right breast core bx:
- Invasive ductal carcinoma, NOS type, nuclear grade 3
CASE 6 (continued)

• Patient then underwent core bx of 4.5 cm left leg mass approximately 1 week later
Preliminary Diagnosis

- Left leg soft tissue mass, touch preparation and core Bx.:
  - PD malignancy
  - Final diagnosis, pending immunostains
Final Diagnosis

Core bx and left leg soft tissue mass

- Poorly differentiated melanocytic malignancy c.w. clear cell sarcoma (melanoma of soft parts)
IHC then performed on breast core bx
Amended Diagnosis

Breast bx: Metastatic malignant melanocytic neoplasm c.w. metastatic melanoma of soft parts
CASE 7

• 7 y.o. male underwent cheek skin bx which was seen by pathologist / dermatopathologists
Diagnosis

Spitz Nevus
CASE 7 (continued)

- Patient then underwent FNA of parotid lymph node 1 1/2 years later
Post-Analytic

• TAT
• Delivery
• Critical Value Notification
• Misunderstood Report
Classification of Error in AP

- Henry Ford Hospital (2001-2003); 150,000 SP cases
- Amended report (2.3-3.3 amended reports/1,000 cases)
- Pre-analytic – patient/tissue identified; gross descriptions, measurements, sampling (31-48%)
- Analytic – overcall/undercall; misclassified (23-28%)
- Post-analytic – defective reports, typos, computer formatting errors (28-44%)

Meier et al.
Modern Pathol 185S:324A, 2005
USCAP Abstract #1506
Surgeons Comprehension of S.P. Report

- Questionnaires based on report given at surgical conference with scoring of attending physicians & trainees.
- Surgeons misunderstood path report 30% of the time.
- More experienced physicians did better.

Powsner SM et al.
Arch Pathol 124:1040, 2000
Formatting Pathology Reports

Applying Four Design Principles to Improve Communication and Patient Safety

A. PROSTATE, RIGHT BASE: ATROPHY AND CHRONIC INFLAMMATION. NO NEOPLASM IDENTIFIED.
B. PROSTATE, RIGHT MID: ACUTE AND CHRONIC INFLAMMATION. NO NEOPLASM IDENTIFIED.
C. PROSTATE, RIGHT APEX: ATROPHY. NO NEOPLASM IDENTIFIED.
D. PROSTATE, LEFT BASE: ADENOCARCINOMA, CONVENTIONAL TYPE, GLEASON 3+4=7, SIZE = 7 MM, PERINEURAL INVASION PRESENT.
E. PROSTATE, LEFT MID: SINGLE FOCUS OF ADENOCARCINOMA, CONVENTIONAL TYPE, GLEASON 3+3=6, SIZE = 2 MM.
F. PROSTATE, LEFT APEX: ATROPHY AND CHRONIC INFLAMMATION. NO NEOPLASM IDENTIFIED.

B

PROSTATE: ADENOCARCINOMA

Malignant locations: left base, left mid
Benign locations: left apex, right base, right mid, right apex
Gleason score: 3 + 4 = 7
Size: 7 mm (left base); 2 of 6 cores contain carcinoma
Histologic type: conventional prostatic adenocarcinoma
Perineural invasion is present

Paul N. Valenstein, MD, Arch Pathol Lab Med. 132;84-94, 2008
Challenge

• Converting data to useful information.
• Formatting the report.
• Grammar and word selection.
• Supporting text, comment, discussion.

Ruby SG
Archive Pathol 124:943, 2000
(Editorial)
Challenging Cases and Need For Effective Communication

- Dx should be based on accepted diagnostic criteria, which should be stated in the report. Even if incorrect dx, written report may show “prudent, careful and informed” pathologist.
- Communicate differential dx.
- Recommend appropriate follow-up or additional dx studies when appropriate.
- Document all verbal consultations with clinicians.

Troxel. In J of SP 9:305, 2001
Error Identification

Opportunity to:

• Identify sources of systematic errors in SP
• Create strategies for eliminating errors
• Structure QA program to identify & correct random and systematic errors
• Improve the system

Troxel. AJSP 28:1092, 2004
Error Prevention

- Build redundancy
- Data collection to identify problem
- Root cause analysis
- Benchmarking
- Design – simplification, standardization
Error Prevention

Systems approach:
- Don’t consecutive accession same specimen type
- Don’t put same type of cases consecutively in tray
- Mandatory 2\textsuperscript{nd} opinion on difficult/challenging types of cases
- Eliminate or decrease distractions – phone calls, physical plant improvement, etc.
System Error Prevention (continued)

• Compare # of tissue fragments in block with # in slides.
• Block/slide correlation by 2\textsuperscript{nd} histotech
• Gross description – dictate name or initials of patient.
• Don’t use “multiple” for gross # of fragments, unless >10.
• Bar-coding.

Jukic
PCR 10:88, 2005
Root Cause Analysis

• Root cause analysis helps identify what, how and why?
• Root causes are identifiable and allow for generation of recommendations.
• The process involves data collection, cause charting, root cause identification, recommendations and implementation.
Benchmarking Tools

- Q-Probes
- Proficiency testing (CAP PIP)
- Slide sets i.e., - California Tumor Registry, etc.
Safety & Quality Q-Probes (>30 AP)

- Amended report (1997)
- Necessity of clinical information in S.P.
- S.P. specimen identification & accessioning
- FS/permanent section correlation
- FS TAT (1995)
- Routine biopsy TAT (1992, 1993)
- Complex S.P. TAT (1993)
- # of organ specific S.P. adequacy Q-Probes
Amended Reports

- 1.3/1000 S.P. reports amended
- 38.7% change final dx; 15.6% change preliminary dx; 19.2% correct patient identification errors, 26.5% - other information

CAP Q-probe of 3147/1,667,547 S.P. reports from 359 path departments; Arch Pathol 122:303, 1998
CAP Q-Probe
Identification & Accessioning Errors

- 60,042/1,004, 115 cases (6%)
- Majority missing or inaccurate clinical info
- Specimen identification (9.6%), faulty or missing info (77%), specimen handling (3.6%)

Nakhle RE & Zarbo RJ
Arch Pathol 120:227, 2996
Quality Improvement Initiative

• 1999 IOM report – wide ranging disparities in quality of cancer care
• Improving quality of care, need high quality data
• High quality, reproducible data has decrease variation
Value of Standardization and Protocol Use in Reporting

• Clinical utility - data/outcome
• Completeness
• Accurate – rules based
• Uniformity
• Decrease variation
THYROID GLAND – PARTIAL OR TOTAL THYROIDECTOMY FOR TUMOR

Pl. Name ____________________________ Date: ____________

SP#: ____________________________

Surgical Procedure
- Partial thyroidectomy
- Total thyroidectomy
- With/without lymph node dissection

Histologic Type
- Follicular carcinoma
- Hurthle cell carcinoma
- Papillary carcinoma
- Papillary microcarcinoma (< 1 cm)
- Papillary carcinoma, follicular variant
- Medullary carcinoma
- Poorly differentiated (insular) carcinoma
- Undifferentiated (anaplastic) carcinoma
- Other _______

Tumor Location
- Right lobe
- Left lobe
- Isthmus
- Both lobes (with or without isthmus)

Tumor Multicentricity
- Present
- Absent

Dimensions
- Tumor size: _______ cm (maximum dimension)
- Tumor size, multifocal (each separately): _______ cm
- Cannot be assessed

Encapsulation
- Complete
- Partial
- Absent

Capsular Invasion
- Present (note extent: minimally vs. widely)
- Absent

Extrathyroidal Extension
- Present
- Absent
- Gross
- Micrscopic

Vascular/Lymphatic Invasion
- Present (note extent: minimally vs. widely)
- Absent
- Equivocal

Margins
- Positive (note extent)
- Negative

Lymph Nodes
- Lymph nodes (# with metastasis/total #): ___/___
- Regional lymph nodes cannot be assessed

Additional Pathologic Findings
- Nodular goiter
- Thyroiditis
- Therapy related changes
- Nodule/adenoma tumors
- Other _______

Other Tissues/Organs
- Parathyroid tissue

TNM Stage
- (AJCC Classification, 1997)

Primary Tumor (T)
- pT1 Primary tumor cannot be assessed
- pT0 No evidence of primary tumor
- pT1 Tumor 1cm or less in greatest dimension, limited to the thyroid
- pT2 Tumor greater than 1cm but not more than 4cm in greatest dimension, limited to the thyroid
- pT3 Tumor greater than 4cm in greatest dimension, limited to the thyroid
- pT4 Tumor of any size extending beyond the thyroid capsule

NOTE: All pT categories must be subdivided: (a) solitary tumor; (b) multifocal tumor (the largest determines the classification).

Regional Lymph Nodes (N):  
- pN0 No regional lymph node metastasis
- pN1a Metastasis in ipsilateral cervical lymph node(s)
- pN1b Metastasis in bilateral, midline, or contralateral cervical or mediastinal lymph node(s)

Distant Metastasis (M):  
- pM0 No distant metastasis
- pM1 Distant metastasis

1
## TNM STAGE GROUPINGS

### Papillary or Follicular Carcinoma

<table>
<thead>
<tr>
<th>Stage</th>
<th>Age &lt; 45 Years</th>
<th>Age ≥ 45 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Any T Any N</td>
<td>T1 N0 M0</td>
</tr>
<tr>
<td>II</td>
<td>Any T Any N</td>
<td>T2 N0 M0</td>
</tr>
<tr>
<td></td>
<td>M1</td>
<td>T3 N0 M0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>T4 N0 M0</td>
</tr>
<tr>
<td>III</td>
<td></td>
<td>Any T N1 M0</td>
</tr>
<tr>
<td>IV</td>
<td></td>
<td>Any T Any N M1</td>
</tr>
</tbody>
</table>

### Medullary Carcinoma (Any age)

<table>
<thead>
<tr>
<th>Stage</th>
<th>T1 N0 M0</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>T2 N0 M0</td>
</tr>
<tr>
<td></td>
<td>T3 N0 M0</td>
</tr>
<tr>
<td></td>
<td>T4 N0 M0</td>
</tr>
<tr>
<td>III</td>
<td>Any T N1</td>
</tr>
<tr>
<td>IV</td>
<td>Any T Any N M1</td>
</tr>
</tbody>
</table>

### Undifferentiated Carcinoma (All cases-stage IV)

<table>
<thead>
<tr>
<th>Stage IV</th>
<th>Any T Any N Any M</th>
</tr>
</thead>
</table>
1. Any case showing discrepancy between frozen section and permanent diagnosis.

2. Any case showing a discrepancy between preliminary FNA and final diagnosis.

3. Any case that has amended diagnosis with clinical significance.

4. Any change in diagnosis, based on outside consultation.

5. Any case showing significant discordance between cytology and surgical pathology diagnosis.

Silverman et al, Mod Path:1508, 2006
Pathology M & M  (Continued)

• Any case having major intradepartmental difference of opinion based on internal consultation, pathologists review for specialty conference differing from primary pathologist of record, or 1 o’clock conference differences, etc..

• Any physician complaint concerning a case.

• Any technical problems such as mislabeling, lost specimens, switch patient diagnosis, etc..

• Reporting issues.

• Terminology issues

• Staging TNM

Silverman et al, Mod Path:1508, 2006
Impact of Monthly A&P Quality and Safety Conference in the Pathology Practice

- 18 month review, two time periods 0-9 mo., 9-18 mo.
- Improvement in incomplete examination, incorrect tumor classification/TNM staging.
- Total # of cases increased due to terminology/clerical problems.
- Most cases in follow-up were minor discordance requiring no further action.

Pereira, TC et al.  
Mod Pathol, 2006
Critical Value

• Concept introduced by Lundberg (1972) – “pathophysiologica
derangement at such variance with normal as to be life-threatening if therapy is not instituted immediately”

• Standard of practice with well established guidelines for clinical pathology
Critical Values (Clinical Path)  
ASCP practice Parameters (Guidelines)  

• Generic critical values list derived from inter-laboratory surveys – starting point  
• Every lab must customize to meet the needs of their organization  
• Strict semantic interpretation of critical limits  
• Report by phone or alphanumeric page  
• Initially Institutional Committee approve and periodically review and revise  

Emancipator K. AJCP 108:247, 1997 ASCP Practice Assessment Committee & Board of Directors
# Representative Clinical Pathology Critical Values

<table>
<thead>
<tr>
<th>Test</th>
<th>Low Value</th>
<th>High Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td>&lt; 7 mg/dL</td>
<td>&gt; 12 mg/dL</td>
</tr>
<tr>
<td>Glucose</td>
<td>&lt; 50 mg/dL</td>
<td>&gt; 500 mg/dL</td>
</tr>
<tr>
<td>Potassium</td>
<td>&lt; 3.1 mmol/L</td>
<td>&gt; 5.9 mmol/L</td>
</tr>
<tr>
<td>Sodium</td>
<td>&lt; 121 mmol/L</td>
<td>&gt; 159 mmol/L</td>
</tr>
<tr>
<td>Fibrinogen</td>
<td>&lt; 50 mg/dL</td>
<td></td>
</tr>
<tr>
<td>PT-INR</td>
<td></td>
<td>&gt; 5.0</td>
</tr>
</tbody>
</table>
Clinical Laboratory Improvement Amendments of 1998 (CLIA 88)

Section 493.1109 (1) The laboratory must develop and follow written procedures for reporting imminent life-threatening laboratory results or panic values. In addition, the laboratory must immediately alert the individual or entity requesting the test or the individual responsible for utilizing the test results when any test results indicates an imminent life-threatening condition.

JCAHO & C.V.

- JCAHO Standard LD 3.2.1: Approved criteria are established for the immediate notification of the responsible practitioner when critical limits of specified test results are exceeded.
JCAHO 2005
National Patient Safety Goals

• Improve the accuracy of patient identification
• Improve the effectiveness of communication among caregivers. Measure, assess and, if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by responsible license caregiver, of critical test results and values
• Improve the safety of using medications
• Eliminate wrong-site, wrong-patient, wrong-procedure surgery
• Improve the effectiveness of clinical alarm systems
• Reduce the risk of health care-associated infections
2007 NPSGs

Goal 1    Improve the accuracy of patient identification.

1A    Use at least two patient identifiers when providing care, treatment or services.

1B    Prior to the start of any invasive procedure, conduct a final verification process (such as “time out,”) to confirm the correct patient, procedure and site using active not passive communication techniques.

Goal 2    Improve the effectiveness or communication among caregivers.

2A    For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person receiving the information record and “read back” the complete or test result.
2007 NPSGs (cont)

2B Standardize a list of abbreviations, acronyms, symbols, and dose designations that are not to be used throughout the organization.

2C Measure, assess and, if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the responsible licensed caregiver, of critical test results and values.

2E Implement a standardized approach to “hand off” communications, including an opportunity to ask and respond to questions.
• CAP Laboratory Accreditation Program – Laboratory General Checklist: Does the laboratory have procedures for immediate notification of a physician... when results of certain tests are within established “critical” ranges?
Critical Values in Surgical Pathology

• In Clinical Pathology there are well-established “critical values”
  – Very low or high serum potassium
  – Very low serum glucose…

• There are established guidelines to contact the clinician or nurse

• No guidelines in surgical pathology or literature
Anatomic Pathology

- The diagnosis are not measured in numbers
- However, certain diagnoses could require immediate treatment or evaluation of the patient:
  - Crescents in kidney biopsy
  - Absence of villi or trophoblasts in uterine contents
  - Organisms in immunocompromised
Prevalence and Perceptions of Critical Values in AP

- Surgical Pathology – (0.49%) based on review of 2,659 S.P. reports.
- Surveyed 11 pathologists (6) AGH, 5 national senior surgical and 5 clinicians.

Pereira, TC, Silverman, JF
AJCP 122: 201, 2004
Conclusions

- CV in SP are uncommon but not rare
- Majority of SP CV cases no documentation of phone call
- HX often not provided
- Range of opinions among pathologists, & between pathologists & clinicians about need for STAT phone call & degree of urgency
- Lack of consensus in identifying CV cases.
- No previous articles addressing CV in SP cases, although mentioned in texts (Rosai), or specific cases (fat in endo bx in Mazur & Kurman)
Prevalence of Cytology CV

2000 cytology reports from AGH and Mayo Clinic – 200 GYN, 400 non-GYN, 400 FNA each institution

CV cases: Unexpected malignancy, disagreement between preliminary FNA & final dx, orgs. in non-GYN & FNA

52 CV (2.6%), including 0.25% (1/400) GYN, 1.88% (15/800) non-GYN & 4.5% (36/800) FNA

Most (42 cases) were unexpected malignancies, 5 disagreement, 5 orgs.

30/52 documented phone call

Recommendations

• Currently CV cases managed on personal experience & common sense

• Some labs may have written policies, no established national guidelines

• Consensus conference of leaders in AP & key clinical specialists would be useful to establish guidelines

AJCP 122:201, 2004
Di Cy 34:447, 2006
ADASP AP Critical Value Survey Results

Surgical Pathology

• Survey 225 ADASP members for grading 17 possible S.P. CVs.
• No phone call necessary, call within 24 hrs, phone ASAP.
• List additional CVs.
• 68/73 supported AP CV concept.

Cytology

• Survey ADASP members for grading 18 CVs/57 responses.
• 53/57 supported CVs concept

Good agreement in many CVs, but differences in opinion for some diagnosis.

LiVolsi, Pereira, Fletcher, Frable, Goldblum, Swanson, Silverman
ADASP
Critical Diagnosis (Critical Values) in AP

- AdHoc Committee proposed guidelines based on ADASP surveys.
- Consultation with relevant clinical services is important.
- CV guidelines should be used as template, customized at individual hospitals requiring medical staff approval.
- Avoid overuse and eliminate non-critical diagnosis.

AJSP 30:897-899, 2006
ADASP Examples of Anatomic Pathology Critical Diagnoses

CASES THAT HAVE IMMEDIATE CLINICAL CONSEQUENCES

• Crescents greater than 50% of glomeruli in kidney biopsy
• Leukocytoclastic vasculitis
• Uterine contents without villi or trophoblast
• Fat in endometrial curettage
• Mesothelial cells in heart biopsy
• Fat in colonic endoscopic polypectomies
• Transplant rejection
• Malignancy in superior vena cava syndrome
• Neoplasms causing paralysis
ADASP Examples of Anatomic Pathology Critical Diagnoses

UNEXPECTED OR DISCREPANT FINDINGS

• Significant disagreement between frozen section and final diagnosis
• Significant disagreement between immediate interpretation and final FNA diagnosis
• Unexpected malignancy
• Significant disagreement and or change between primary pathologist and outside pathologist consultation
ADASP Examples of Anatomic Pathology Critical Diagnoses

INFECTIONS

- Bacteria or fungi in CSF cytology in immunocompromised or immunocompetent patients
- Pneumocystis, fungi or viral cytopathic changes in bronchoalveolar lavage (BAL), bronchial washing or brushing cytology specimens in immunocompromised or immunocompetent patients
- Acid-fast bacilli in immunocompromised or immunocompetent patients
- Fungi in FNA of immunocompromised patients
- Bacteria in heart valve or bone marrow
- Herpes in Pap smears of near term pregnant patients
- Any invasive organism in surgical pathology specimens or immunocompromised patients
Is there a policy regarding the timely communication, and documentation thereof, of significant or unexpected surgical pathology findings?

NOTE: Certain surgical pathology diagnoses may be considered particularly significant or unexpected. Such diagnoses may include: malignancy in an uncommon location or specimen type (e.g., hernia sac, intervertebral disk material, tonsil, etc.), absence of chorionic villi when clinically expected (potential ectopic pregnancy), change of a frozen section diagnosis after review of permanent sections, and/or mycobacterial, fungal or other significant infectious organisms identified on special stains. Diagnoses to be defined as “significant” or “unexpected,” if any, should be determined by the pathology department, in cooperation with local clinical medical staff. Consideration should be given to assuring, with reasonable effort, prompt communication of such results, by telephone, pager, or other system. There should be documentation of date and time of such special notification (which may be included in the pathology report or in laboratory files).
Critical Results (Diagnoses) in AP A CAP Survey of 1130 Labs

- 75% had written AP critical dx policy
- 30% of the policies included guidelines, but did not include specific examples
- 33% listed < 5 specific examples
- 18% listed > 5 examples
- 19% had specific defined list of critical dx i.e.,
  malignancies (48%)
  unexpected findings (45%)
  life threatening infections (45%)
  no chorionic villi in POC (37%)
  infl. or immunologic process (19%)
- Labs with ↑ # of specific examples, ↑ #’s of cases
- 25% HAD NO POLICY & <50% HAD SPECIFIC EXAMPLES

Nakhleh RE, et al.
Arch Pathol 132:1523, 2008
CAP-ADASP EFFComm Committee

- Barry R. DeYoung, MD
- Dina Rustom Mody, MD
- Jan F. Silverman, MD
- Jeffrey L. Myers, MD
- Patrick Fitzgibbons, MD
- Raouf E. Nakhleh, MD
- Timothy Craig Allen, MD
- William K. Funkhouser, MD, PhD
CAP-ADASP EFFComm Committee

• Urgent Dx & Significant, Unexpected Dx. Policy separate from critical result/panic value policy in CP with different timeframe for communication.
• Determination of specific urgent Dx’s with collaboration with clinical staff.
• Significant, unexpected Dx dependent on pathologist’s judgment but examples maybe given
• Each institution should establish reasonable time frame for UD (recommend same day) & SU Dx should occur as soon as it is practical, but pathologist exercise their judgement.

• Direct verbal communication desirable, but other forms of communication may be established.

• Communication of these Dx should be documented in the original SP/cytology report, or EMR or other mechanism.
Customer Satisfaction (Physician) in AP: CAP Q-Probe Study of 3065 Physicians From 94 Labs

- Professional interaction, dx accuracy, pathologist responsive to problems, f.s. accessibility, tumor board, courtesy of secretarial and technical staff, teaching conferences, communication of relevant info, TAT and notification of significant abnormal results.

   Arch Pathol 127:23, 2003
   Zarbo et al. (Quality Practice Committee)
CAP Q-Probe – Lowest Satisfaction

Poor Communication
- TAT
- Communication of relevant info
- Notification of significantly abnormal results
Diagnostic accuracy is an important, but not the only measure of safety and quality in anatomic pathology practice. Ineffectively communicating a correct diagnosis in an untimely fashion is an equally egregious and potentially dangerous event.

Jeff Myers – Archives of Pathology.130, 1103 – 1104, 2006
Barriers to Error-Free Medicine

“Complex rules being applied to complex biologic systems in complex environment by large number of people”.

Punitive Culture When Error
- Flawed individual
- Legal system

Foucar E.
AJCP 116:S34, 2001

“Healthcare represent the most complex safety challenge of any activity on earth”

Leape et al.
JAMA 280:1444, 1998
“First Do No Harm”

Hippocrates

“First Prevent No Harm”
“Building for safer health care means designing processes that respect human limits, promote effective teamwork, anticipate the unexpected, and celebrate errors as opportunities to learn.”

Institute of Medicine 2000
Summary: Strategies For Error Reduction & Patient Safety

• 2nd Opinion
  a. Intradepartmental-esp. error prone cases, etc.
  b. Outside consultation
  c. Interinstitutional review

• Systems Approach
  a. Build redundancy
  b. Standardize
  c. Simplify
  d. Collect data to identify problems
Summary: Strategies For Error Reduction & Patient Safety

- **Systems Approach** (continued)
  - e. Benchmark
  - f. Root cause analysis
  - g. Department “M&M”

- Timely Notification/Critical Diagnosis
- Create Environment to Learn from Errors
Pathologist is the Final Quality Assurance Officer, or “The Buck Stops Here”

Jukic
PCR 10:88, 2005