QUALITY MANAGEMENT IN ANATOMIC PATHOLOGY

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Laboratory Goal

The right test to right patient,
The right result at the right time,
“systematic approach”
….. 70% of all clinical decisions are based on the lab results
Even using the lower estimate, preventable medical errors in hospitals exceed attributable deaths to such feared threats as motor-vehicle wrecks, breast cancer, and AIDS.

Institute of Medicine, Nov 1999
Not a “bad apple” problem

More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them.

Institute of Medicine, Nov 1999
Pre-analytic errors

Analytic errors

Post-analytic errors
Laboratory errors happen

**Patient and system impact?**
- Inadequate / inappropriate patient care
- Inappropriate public health action
- Undetected communicable disease outbreaks
- Wasting of resources
- Death of an individual

**Root causes?**
- Training
- Competence
- Environment
- Policies and procedures
- Test system performance
What does a quality laboratory, effectively managed look like?

- Report delivered to correct individual(s)
- Timely, convenient
- Cost effective, efficient
- In compliance with all regulations
- Client service oriented
- Appropriate sample correctly obtained from the right patient
- Correct test(s) performed properly
- Accurate, precise results obtained
- Understandable report created with an effective interpretation
CAP’s Accreditation Program helps laboratories realize these outcomes

- 360 international laboratories
- >50 countries
- Hospitals, independent commercial laboratories, clinics and contract research organizations

Among the Best Laboratories in the World
What are labs aspiring to achieve by pursuing CAP accreditation?

- Ensure the best Dx solutions; identify problems before they occur
- Be recognized among the best in the world
- Meet treatment requirements of foreign tourists and multinational companies
- Meet international standards and cooperate with foreign labs; qualify to conduct clinical trial work
- Fulfill government requirements
- Strengthen and maintain leadership edge
- Deal with competitive pressure

...and laboratorians
- Professionally grow
- Be recognized
- Gain differentiating credentials
CAP’s Standards are the core of the program

I  Director & Personnel

II  Physical Resources—Facilities & Safety

III  Quality Management—QC, PT/EQA & Performance Improvement

IV  Inspection Requirements
CAP 2-year accreditation cycle covers the entire lab

1. Application
2. Onsite Inspection
3. Report Inspection Results to CAP
4. Deficiency Responses
5. CAP Review of Deficiency Responses
6. Accreditation Decision
7. Self Inspection

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CAP Checklists provide the roadmap

• General and discipline-specific guidelines for lab policies, procedures and processes

• Guide the inspection
  o Ensure focus on patient and employee safety
  o Over 2,600 Checklist requirements
  o Reflect best practices; input from experts in the field—Updated annually
  o Help ensure accurate, reliable test results
Guidance across the lab and to the bench level

- **Team Leader Checklist**
- **Laboratory General**
- **All Common Checklist**
- Hematology & Coagulation
- Chemistry & Toxicology
- Urinalysis
- Microbiology
- Transfusion Medicine
- Diagnostic Immunology
- Flow Cytometry

- Anatomic Pathology
- Cytopathology
- Cytogenetics
- Forensic Drug Testing
- Histocompatibility
- Molecular Pathology
- Point of Care
- Clinical Biochemical Genetics
- Reproductive Lab (Embryology & Andrology)
All reagents are used within their indicated expiration date.

NOTE: The laboratory must assign an expiration date to any reagents that do not have a manufacturer-provided expiration date. The assigned expiration date should be based on known stability, frequency of use, storage conditions, and risk of deterioration.

For laboratories not subject to US regulations, expired reagents may be used only under the following circumstances: 1. The reagents are unique, rare or difficult to obtain; or 2. Delivery of new shipments of reagents is delayed through causes not under control of the laboratory. The laboratory must document validation of the performance of expired reagents in accordance with written laboratory policy. Laboratories subject to US regulations must not use expired reagents.

Evidence of Compliance:
✓ Written policy for evaluating reagents lacking manufacturer’s expiration date

REFERENCES
CAP requirements and inspection cover the entire process

Pre-Analytic  Analytic  Post Analytic

FOLLOW THE SPECIMENT
ROAD: a “process” to focus on the “Big Picture”
Lab has 30 days to address non-conformances

- New or revised policy/procedures
- QC records with evidence of review
- Instrument printouts; log sheets
- Purchase orders
- Photographs
Accredited after meeting all requirements
Continuous compliance means **high quality**…

- Self inspection
- Maintain accurate activity test menu
- Quality management monitoring
- Participate in CAP’s PT/EQA
- Continuous compliance with all QA requirements

...**not just on the inspection day**
CAP accreditation requirements are the same worldwide

- Monitors continuous compliance through PT
- Peer-based; requires inspectors to be from CAP-accredited labs
- Educational and objective
- Focuses on technical procedures
- Provides detailed, focused checklists
- All lab disciplines
COM Table of Contents

• Proficiency testing
• Quality management
• General QC issues
• Procedure manuals
• Results reporting
• Reagents
• Instruments & equipment*
• Test method validation /verification
• Method performance specifications
• Reference intervals
What will inspectors look for: QC

- Written QC policy/plan
- Documentation of reviews:
  - Before reporting patient results
  - Secondary review at least monthly
  - Corrective action documented
- Validation of target range
- Defined tolerance limits
- Statistics, graphs, etc., organized to detect problems
What will inspectors look for: Procedure Manuals

• Documentation of thorough review at least every two years by Laboratory Director or designee
• Scientific validity
• Clinical relevance
• Documentation of staff knowledge/review
• Practice matches policy/procedure
• Reviewed by new director
• New procedures reviewed by Laboratory Director
Patient Result

- 13 Requirements in Lab Gen
- Report elements in GEN. 41096
- Critical result notification in All Common
  - Lab has procedures for immediate notification of a physician (or other personnel responsible for the patient’s care) when results of designated tests exceed established “alert” or “critical” values that are important for prompt patient management decisions
  - Lab Director and physicians define “critical”
What will inspectors look for: Reagents

- All reagents used within expiration date
- Parallel testing of new reagent lots
- Labeling of secondary containers
- Appropriate storage
- Labeling of hazardous chemicals
What will inspectors look for: Instruments/Equipment

- Glassware chipped, cracked?
- Certified thermometer
- Certified weights for scales
- Secondary review of temperature and maintenance records
  - Corrective action documented
- Maintenance/repair records kept:
  - Near/at instrument
  - For life of instrument
Test Method Validation vs. Verification

• Validation - A defined process by which a laboratory confirms that a laboratory developed or modified FDA-cleared/approved test performs as intended or claimed.

• Verification - The process by which a laboratory determines that an FDA-cleared/approved test performs according to the specifications set forth by the manufacturer.
Calibration/Verification

Definitions

• Calibration: Relationship between reagent system/instrument response and the corresponding concentration/activity values of an analyte

• Calibration verification: Confirmation that current calibration settings remain valid
Calibration/Verification

• Calibrate according to manufacturer’s instructions

• Criteria for calibration verification:
  o At least every six months
  o At complete change of reagents
  o When indicated by QC data
  o After major maintenance
  o When recommended by manufacturer

• Verify Analytical Measurement Range
What will inspectors look for: Calibration/Verification

- Three levels - low, medium, high
- Patient results outside of AMR verified by dilution or alternate method
- Criteria for Calibration Verification followed
- Lab has acceptance criteria
- Manufacturer’s guidelines followed
- Corrective action documented
What will inspectors look for: Method Performance Specifications

• Lab should have data for every test’s:
  o Sensitivity, precision, specificity, interferences
  o Established/verified reference intervals (normal ranges)

• Source of data may be:
  o Laboratory’s own studies, or
  o Manufacturer, published studies

• Comparisons:
  o Between instruments
  o Between methods
Reference Intervals

• Lab must establish or verify reference intervals

• Lab must evaluate appropriateness of reference intervals and take corrective actions if necessary
  o Introduction of new analyte, method or change in patient population
Most Common Deficiencies: All Common

ALL COMMON (grouped by category)

- COM.40000 Method Validation/Verification Approval
- COM.50000 Reference Intervals Established/Verified
- COM.01100 Ungraded PT Evaluation
- COM.01200 Activity Menu
- COM.01400 PT Attestation
- COM.01500 PT Alternative Performance
- COM.01700 PT Evaluation
- COM.30350 Reagent Storage
- COM.30400 Reagent Expiration Date
- COM.30450 New Reagent Lot Acceptability
- COM.10100 Procedure Review
Laboratory General Checklist

• QM/ Document Control
• Safety
• Computer
• Personnel
<table>
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<th>1. Organization</th>
<th>7. Occurrence Management</th>
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</tr>
<tr>
<td>5. Procedure Control</td>
<td>11. Information Management</td>
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</tbody>
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Document Control Is…

- The process by which the instructions in use can be assured to be current, correct, and available.
  - Instructions for tasks (procedures)
  - Instructions for behaviors (policies)
  - Instructions for organization (processes)
  - Any associated material related to these instructions (job aids or posted instructions)
  - Electronic or paper
  - Approved by Director on CLIA certificate before implementation
  - Reviewed biennially by director or designee (or annually per state/laboratory requirements)
What will inspectors look for: Laboratory Safety

- Written policies and procedures
- May be facility-wide but must be site specific, as applicable
- Disaster preparedness
- Fire safety
- Occupational safety
- Bloodborne pathogens, PPE
Laboratory Safety (cont.)

- Injury/exposure reporting, evaluation and follow-up
- Chemical safety
- Electrical safety
- Waste disposal
- Radiation safety
- Audits, Safety Committee review, and/or annual reports
What will inspectors look for: Environmental Safety

- Chemical storage
- Proper warning labels on chemicals
- Availability of MSDS
- Fire extinguisher placement
- Alarms
- Evacuation routes
- Blocked exits

- Signs (e.g. biohazard, radioactive)
- Availability of PPE, eyewashes, gloves
- Lighting
- Space, clutter
- Audits, reports, corrective action
Data Handling and Reporting (Computer Requirements)

• Inspector’s role
  o Finding the answers:
    Data output reliable?
    Data confidential?
    Records preserved?
What to Look for: Reliability of Data Output

• Evaluate:
  o Original data to video display to final report
  o Original worksheet or instrument printout to final report
  o Table of reference ranges and comments
  o Calculation checks
  o Documented review/approval of lab reports
What to Look for: Confidentiality of Data, Security

- Explicit policies limiting access
- Use and security of access codes
  - Access confined to job duties
  - Best practices
What to Look for: Preservation of Records

- Procedures to protect data and equipment
- Back up methods
- Storage of back up data
- Fire proof storage for record backup in lab and LIS
- Paper documents - most are two year retention - need to meet state or local requirements if longer, such as Transfusion Medicine and Anatomic Pathology and Cytology
Personnel

- Each individual must have a personnel file.
- File is held by human resources or laboratory
- File must contain items identified in GEN.54400
- Key documents to check:
  - Job description
  - Transcript or academic diploma
  - Certification if required by employer or state
  - License if required by state
  - Summary of training and experience
Employee Health Records

- Visual color discrimination (can be done by lab)
- Hepatitis and other vaccinations
- TB skin testing
- Exposure incident records/follow-up
  - Above records may not be available for review without employee authorization
- Review of procedures and interview with employee health nurse may be used to assess compliance
New Employees

• Documentation of training and what test systems the individual is deemed competent to perform, signed by the Laboratory Director

• Semi-annual competency assessments the first year of hire (two)

• Annual competency each successive year of employment

• Laboratory Director must ensure staff who perform competency meet defined regulatory requirements
How Lab Assesses Competency

• Required elements for non-waived test methods
  o Direct observation (routine test performance)
  o Test result recording/reporting
  o Review documentation- QC, PT, PM, results/worksheets
  o Direct observation (performance of instrument maintenance)
  o Assess test performance (previously analyzed specimens)
  o Evaluate problem-solving skills
Competency for Tests that are Waived Complexity

- Personnel must have documented training and be deemed competent prior to performing testing
- Competency is assessed annually or if problems are identified
- Six elements of competency are not required- lab may define mechanism to determine competency
Record Selection

• All new testing staff hired within last two years
• Senior staff
• Testing personnel
• Supervisors
• Work different shifts or departments
• Different job descriptions
What will inspectors look for: Competency Assessment

- Records must indicate what, how, and when skills were assessed
- Documentation for all testing personnel
  - Competency assessment on non-testing personnel is a best practice
- Evaluations must be specific for each job description
- Retraining and reassessment if problems identified
Top Ten Deficiencies – GEN Checklist

- GEN.55500  Competency
- GEN.20375  Document control
- Gen.54400  Personnel files
- GEN.75400  Fire drills
- GEN.77400  Eye wash

- GEN.16902  QM Plan
- GEN.76000  Chemical Hygiene
- GEN.26791  Terms of Accreditation
- GEN.41042  Refrigerator/freezer temperature
- GEN.41096  Report elements
Conclusions

Understanding how to prepare for key quality activities that are common to all checklists will result in more consistent and efficient inspections and aid in continuous compliance.
CAP Accreditation

- A Partnership with the Laboratory
- A Partnership devoted to the best patient care
- Checklists contain the best laboratory Practices
- Checklists are updated annually
- Laboratory must provide an engaged director and an enthusiastic staff
On Site

- CAP Inspectors are not Policemen
- CAP Inspectors will assist the Staff in improving the Laboratory

Self Inspection

- By lab staff with CAP Checklists often finds more deficiencies than CAP Inspectors.
- Promotes the implementation of best laboratory practices for the benefit of patients more quickly
Laboratory Director and Employees

- Director is responsible for implementing the best practices as outlined in the CAP Checklists.
- Employees have the responsibility to follow the best practices outlined in the CAP Checklists.
Post Inspection

- All CAP inspections are reviewed by a Technical Specialist at the CAP home office.
- All inspections are reviewed by the International Commissioner before Accreditation is recommended or denied.
- The Post Inspection Critiques are reviewed by the Commissioners and CAP staff.
- The Accreditation Committee has the final review and the authority to approve or deny accreditation.
Complaint & Investigation Process

• CAP will address patient care problems which are reported by an employee.

• CAP will not let a disgruntled employee use the CAP against a Lab or a Lab director.

• CAP is in partnership with the hospital, the Lab Director and the staff to provide the best possible care for patients.
Special Aspects of Anatomic Pathology

- Test result is not a quantitative value
  - Medical consultation
  - Test validation not commonly performed
- Proficiency testing:
  - For Gyn Cytopathology
  - Limited PT requirements for ANP tests
  - Anatomic Pathology and Non-Gyn Cytopathology: “Peer educational program”
- Few defined performance benchmarks
Anatomic Pathology
Scope of Testing Activities

- Surgical Pathology/Histology
- Immunohistochemistry
- Immunofluorescence
- FISH / ISH
- Autopsy pathology
- Electron microscopy
- Cytopathology
Anatomic Pathology
Quality Activities Common to All Areas

• Method Performance Specifications (Validation/Verification)
• Quality Improvement/Quality Control
• Safety and Environment
• Professional Role of the Pathologist
• Quality of the Diagnostic Report
Method Performance Specifications (Validation/Verification)

- Applicable to stains, antibodies, tissue processors (including changes in programs), digital image analysis, as in clinical laboratory
- Scope must include range of tissues expected
Method Performance Specifications (Validation/Verification)

- ANP.22976 ER/PgR Validation – 40 cases required for new or existing assays
- ANP.22978 HER2 Assay Validation – minimum of 40 cases for new or existing assays (2014 edition - increase from 25)
Quality Improvement

- All sections of Anatomic Pathology
- Periodically change monitors to cover entire spectrum of activities
- *Focused on patient outcome*
- Benchmarks, with evaluation and corrective action, as required
- Feedback to institution
Examples of Quality Indicators

• Frequency of un/mislabeled specimens
• Sub-optimal specimens
• Frozen vs. permanent section diagnosis
• Corrected/revised reports
• Turnaround time for final reports
  o Surgical pathology reports
  o Autopsy reports
• Peer review of completed reports
• Immunostain & FISH/ISH Predictive Markers - annual result comparison
Quality Control
Pre-analytic Phase

- Specimen procurement
  - Collection procedure manual
  - Safety instructions for fixatives
- Maintenance of specimen identity
  - Patient and specimen identity
  - Specimen accessioning
  - Block and slide labeling
Quality Control
Analytic Phase

• Non-Pathologist grossing
  o Qualifications & Supervision
  o Specimen types; extent of examination
  o Annual evaluation

• Histologic preparations
  o Daily review by Pathologist
  o Slide review by inspector

• Maintenance and equipment
  o Schedule, review of records
  o Availability of records
Quality Control
Post-analytic Phase

• Report communication
  o Communicable diseases
  o Significant/unexpected findings

• Report retrievable by patient identifier

• Record retention
  o QC records - 2 years
  o Blocks and slides - 10 years
  o Reports - 10 years
  o Procedure for referral & retrieval
Safety and Environment
Key Quality Procedures

• Hazardous & flammable reagents
  o Handling/cleanup procedures posted

• Biohazard control and disposal

• Radioactive specimens

• Air quality
  o Formaldehyde & xylene

• Storage space

• Ergonomics
Professional Role of the Pathologist

Key Quality Activities

- Correlation with prior reports
- Correlation with Cytology
- Consultation and peer review
- Teaching and Committees
- Continuing education, performance improvement and self-assessment
Quality of the Diagnostic Report
Key Quality Indicators

• Clinical information
• Adequacy of descriptions
• Data for staging of tumors
• Correlation of special studies
• Documentation of consultations
• Signed/verified by Pathologist
• Turnaround time
Quality Activities by Section

• Intraoperative Consultations
• Special procedures:
  o Immunohistochemistry
  o Immunofluorescence
  o FISH / ISH
• Autopsy pathology
• Electron microscopy
• Cytopathology
Intraoperative Consultations (Frozen Section Diagnosis)

• Frozen section, touch prep, gross-only

• Reporting and documentation:
  o Contemporaneous written/signed report
  o Diagnosis included in final report

• Slides retained with final report slides

• Residual tissue processed and correlated with frozen slides
Special Procedures
Immunostains & FISH/ISH

• Procedures for fixation, antigen retrieval
• Daily positive and negative controls
  o Negative reagent control
  o Negative tissue control
• New reagent lot confirmation of acceptability
• Reporting of “analyte-specific reagents”
• Reporting of predictive/prognostic tests
Electron Microscopy

• Specimen identification
  o Blocks, slides, photographs

• Maintenance of electron microscope
  o Calibration
  o X-ray leakage

• Reagent handling and disposal
  o Documented procedures
  o Safety hood
Electron Microscopy
Common Deficiency

• Is the magnification calibrated after major maintenance, as appropriate?
Cytopathology
Cytopathology

Gyn Cytology - most heavily regulated

- Screening only in an approved laboratory
- PT plus interlaboratory peer comparison required
- Workload requirements
- Rescreen requirements
- Intralaboratory screening performance required
- Statistical record evaluation with evaluation of outliers
Cytopathology

- CAP inspection
  - Separate checklist
  - Inspector qualifications
  - Time requirement
  - Slide review for diagnostic accuracy
Cytopathology
General Requirements

• Personnel qualifications

• Slide screening maximum:
  o 100 slides in an 8-hour day (or local law/regulations)
  o Prorated by time spent screening
  o Includes Pathologist screening of Gyn

• Standard descriptive terminology

• Slide retention: 5 yrs. (FNA - 10 yrs.)
Gyn Cytology

- Papanicolau (Pap) stain required
- Feedback on unsatisfactory specimens
- Pathologist review of all but normal
- Follow-up histology for HGSIL
- 5-year lookback
- Screener performance evaluation
Automated Screening Instruments

• Implementation and verification
• Technical & interpretive training
• Corrective action when tolerance limits exceeded
• Procedure for unsuccessful slides
• Procedure for handling workload when instrument not available
Non-Gyn Cytology

• Separate processing of specimens with high likelihood of cross-contamination
• Cytology/Histology correlation
• All reviewed by a Pathologist
Conclusions

• Quality requires attention to detail

• Anatomic Pathology can learn from Clinical Pathology

• A credible accreditation process is essential for laboratory quality