LAP Audioconference
How to Prepare and Comply with Your Quality Management Plan*
February 18, 2009

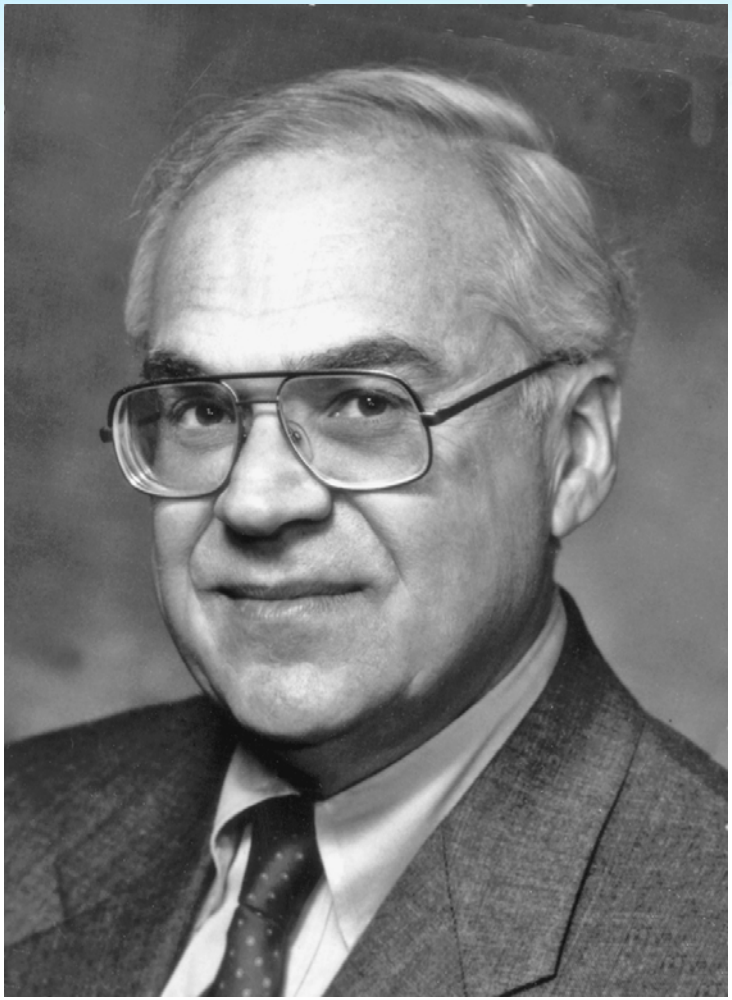
Paul Bachner, MD, FCAP
Professor & Chair
Department of Pathology & Laboratory Medicine
University of Kentucky College of Medicine

* With much appreciation
to Elizabeth Wagar, MD; UCLA

cap
Advancing Excellence
www.cap.org

CAP Headquarters, Northfield, IL

Paul Bachner, MD, FCAP



Chair, UK Department of Pathology & Laboratory Medicine & Director of Hospital Laboratories

Commission on Laboratory Accreditation
Regional Commissioner
For KY, TN, IL

CAP Council on Accreditation

CAP Past President & Member of Board of Governors

FIRST LAB ACCREDITATION INSPECTION IN 1969
(MANY SINCE)

University of Kentucky, Lexington, KY

New UK HOSPITAL (2011)

Audioconference Objectives

- Why is the QM Plan important?
  - CAP and CLIA accreditation requirement
  - Will improve patient care and safety
  - Will help you to improve lab services (money, time)
  - Ensures continuing surveillance and management
  - Always ready for inspection
- What are the key compliance issues?
  - Plan format
  - Components (entire analytic cycle, all sections)
  - Metrics, benchmarks and indicators
  - Corrective action and follow-up to problems
  - How does plan contribute to patient safety?
- Template for QM Plan Design and Implementation

CAP Accreditation Requirement

- Ensure that the laboratory participates in the monitoring and evaluation of the quality and appropriateness of services rendered within the context of the quality assurance program appropriate for the institution, regardless of testing site(s).

CAP Accreditation Requirement

- Director must assume responsibility for implementation of the quality management plan. The director and professional laboratory personnel must participate as members of the various quality management committees of the institution.

Quality Management Basics

- High emphasis by CAP (critical deficiency)
- Written Quality Plan (CAP & CLIA)
- Annual review & approval by director
  - 2.2% of CAP labs had not performed!
- Specify information/reporting method
- Accuracy of results (analytic)
- Integrity of pre & post-analytic processes in all sections

Quality Management Formats

- Format may be Laboratory designed
- CLSI (NCCLS) guidelines (GP-22 or GP-26)
- ISO 9000 series
- ISO 15189 accreditation and standards
- JC model for improvement of organizational performance
- AABB quality program
- Safety plan integrated or separate

Key Quality Management Components

- Statement affirming commitment to quality and patient safety
- Risk assessment
- Monitoring and Control activities (identify indicators and metrics)
- Response to identified problems
- Information and communication
- Continuous improvement

Essentials of Quality Management Implementation

- Implement as designed
- Explicit delegation of responsibility
- Specify frequency of activities
- Create quality committee(s)
- Evidence and documentation
  - Committee minutes
  - QI reports
  - Documents responding to complaints, problems, adverse events

What Will the Inspectors be Looking For?

- Written QM Plan
- Lab Director Involvement
- Monitoring of process and improvement
- Communication within organization

What Will the Inspectors be Looking For?

- Incorporation of PT data & corrective action
- Attention to employee and “client” concerns
- Use of incident reports to improve process and practice
- All shifts, All sections

Quality in Laboratory and Pathology Services

- Laboratory & pathology are the traditional quality focus for the hospital
- 60-80% of patient management decisions are based on laboratory data
- Longest history in medicine of experience in elements of quality:
  - What should we do? (Policies)
  - How will we do it? (Procedures)
  - Have we done it? (Documentation)

Lab Quality Management*

- Correct sample obtained in the correct way from the correct patient
- Correct test performed in the correct way
- Correct results obtained
- Understandable report created
- Report delivered to the correct individual(s)
- Timely, convenient service
- Correct and timely billing
- Cost effective and efficient
- Compliance with all regulations

* Mike Cibull, MD, FCAP

12 Key Quality Elements*

1. Organization
2. Personnel Resources
3. Equipment
4. Supplier and Customer Issues
5. Procedure Control (QC, PT)
6. Documents and Records

* Elizabeth Wagar, MD, UCLA

12 Key Quality Elements*

7. Occurrence Management
8. Assessments and Audits
9. Process & Performance Improvement
10. Facilities and Safety
11. Information Management
12. Customer Service and Satisfaction

* Elizabeth Wagar, MD, UCLA

1. Organization

- Scope & location of services
  - Which labs are covered, off-site, satellites, POC
- Describe organization
  - Org charts
  - Medical/administrative directors
  - Managers/supervisors

2. Personnel Resources

- CLIA (CAP) definitions
- Employee orientation, training, annual competency assessment, CE, safety training
- Summarize educational resources
- Where is documentation of employee assessments and competencies kept?

3. Equipment

- Briefly describe that equipment policies exist for selection, acquisition, installation, validation, maintenance, malfunction response and disposal.
- Keep it simple - We all have lots of equipment!

4. Suppliers and Customers (Supplies)

- Who is responsible for supporting lab operations?
- Uninterrupted flow of supplies and services?
- Quantity, quality, right time, price
- Procedure for supply recall

4. Suppliers and Customers (Referral Labs)

- Selection of referral labs is the responsibility of director in consultation with medical staff
- Annual review of referral lab
  - Provision for audit of results
  - Service and support
  - Contracts

4. Suppliers and Customers (Customer Surveys)

- Physicians and nurses
  - TAT, critical values, phlebotomy response, test menus, consultation, courtesy
- Employee satisfaction
  - Communication, work environment and facilities, pay & promotion, “morale”
- Patients (phlebotomy, wait times, courtesy, complaints)

5. Procedure Control (QC, Process Control)

- Define as analysis of substance of known composition in tandem with patient sample analysis
- Measure of precision (maintenance of calibration)
- QC frequency and levels
- Process for QC outliers, shifts, drifts
- QC retention policy (manual, electronic, how long?)

5. Procedure Control (Proficiency Testing)

- Define as periodic analysis of substance of unknown composition, usually from outside source
- Measure of accuracy
- Required by CLIA and CAP
- Referral or inter-lab communication forbidden (harsh penalties!)
- Integration into routine workflow required
- “Alternate” semi-annual assessment required if external PT not available

5. Procedure Control (Test Validation)

- Formal validation for:
  - LDT (laboratory-developed tests)
  - LMT (laboratory-modified tests)
- Formal validation minimum requirements:
  - Test performance (accuracy, precision)
  - Intended use
  - Applicable specimens
  - Clinical validity
  - Periodic external verification (PT)

6. Documents and Records

- Describe document control policy for your laboratory & institution
- May use master list and other SOPs for document management
- Who is responsible for management, review, signatures (frequency)
- Document retention and discard

7. Occurrence Management

- Rich opportunity for improvement
- Need to identify and analyze non-conforming events to identify serious, common, recurring and systems problems
- Capturing non-conforming events:
  - Random review
  - Lab/technologist determined
  - External detection (doctors, nurses)
- Review and document data and trends at Quality Committees

7. Occurrence Management
(Options for Non-Conforming Events)

- Paper-based
- Electronic
- Trend analysis for frequent events
- Classify by patient harm (develop form)
- Serious events (patient harm) should be thoroughly investigated and subjected to root cause analysis

CAP Patient Safety Goals*

- Improve patient & sample identification
- Improve verification and communication of life threatening information (critical values, tests)
- Improve identification, communication and correction of errors
- Improve integration & coordination of the laboratory patient safety role within the healthcare organization
- Utilize data within system to improve care

* CAP Patient Safety & Performance Measures Committee

cap Advancing Excellence
www.cap.org

8. Assessments and Audits

- List external assessments (CAP, CMS, FDA, AABB, JC, state agencies)
- Who is responsible? The Lab Director!
  - If delegated, specify!
- Describe internal audits (CAP interim, competency assessments, quality indicators, periodic audit of QM Plan)
- Keep Brief; refer to SOPs for details

9. Process/Performance Improvement

- Authority, Responsibility & Delegation
- Director & Quality Management Team
- Define and describe process
- Must involve all lab sections/shifts and encompass preanalytic, analytic and postanalytic activities and processes

9. Process/Performance Improvement

- List hospital or other committees
  - Infection control
  - Transfusion
  - Safety
  - Quality Committee(s)
  - Never forget that nurses run the hospital
- Interdisciplinary involvement critical to improvement and to demonstrate lab integration with institutional QM programs

9. Process/Performance Improvement (How to do it)

- Identify problem or improvement
- Appoint team that knows the process
- PDCA
  - Plan the improvement
  - Do (try it, but may need resources)
  - Check (what happened?)
  - Act (implement)

9. Process/Performance Improvement (Sample QM Indicators*)

- Diabetes monitoring (system)
- Hyperlipidemia screening (system)
- Test order accuracy (preanalytic)
- Patient identification (preanalytic)
- Blood culture contamination (preanalytic)
- Adequacy of specimen information (system/preanalytic)

* The Institute for Quality in Laboratory Management; CAP TODAY, June 2005

9. Process/Performance Improvement (Sample QM Indicators*)

- Accuracy of point-of-care testing (analytic)
- Cervical cytology/biopsy correlation (analytic)
- Critical value reporting (postanalytic)
- Turnaround time (postanalytic)
- Clinician satisfaction (system & postanalytic)
- Clinician follow-up (system & postanalytic)

* The Institute for Quality in Laboratory Management; CAP TODAY, June 2005

10. Facilities and Safety

- May be preferable to keep separate
- Refer to Safety Manual
- Annual safety audit of lab sections
- Metrics/scoring of lab sections may stimulate competition – Annual Pizza Party (UCLA)

11. Information Management

- Authority to approve users & access
- Statement: SOPs in place for data security and integrity of data transfer
- List security measure categories (passwords, security levels, access)
- Document audit of data transfer
- HIPAA compliance
- Frequency of system checks (? quarterly)
- Annual summary report system integrity

12. Customer Service and Satisfaction

- State frequency of surveys
- Physicians and nurses
  - TAT, critical values, phlebotomy, test menus, consultation, courtesy
- Employee satisfaction
  - Communication, work environment, pay & promotion, “morale”
- Patients (phlebotomy, wait times, courtesy, complaints)

References

- Application of a Quality Management System Model for Laboratory Services: Approved Guideline, 3rd Ed. PP26-A3 CLSI, 2004
- Quality Management in Clinical Laboratories: Promoting Patient Safety Through Risk Reduction And Continuous Improvement, P. Valenstein, CAP, 2005
- CAP Laboratory Accreditation Manual: http://www.cap.org/apps/docs/laboratory_accreditation/standards/lapmanual_0707.pdf

Assistance

http://www.cap.org

Email: accred@cap.org

800-323-4040, ext. 6065

bachner@email.uky.edu