DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health
Laboratory of Pathology, NCI, CCR

MEMORANDUM

February 15, 2016

TO: Laboratory of Pathology Staff

FROM: Frederic G. Barr, MD, PhD (Medical Director)

Armando Filie, MD (Quality Management Chair)

Joseph Chinquee, DHSc, MT(ASCP)DLM (Clinical Manager)

SUBJECT: ***Addendum (new Medical Director review):***
Annual Review of Efficacy of the Quality Management Plan for the Laboratory of Pathology, NCI

In accordance with the College of American Pathologists' (CAP) Laboratory General Checklist GEN.16902, the Quality Management (QM) Plan must be implemented as designed and reviewed annually for effectiveness. The Laboratory of Pathology (LP) has identified several revisions to the CAP's most recent updated checklists requirements for QM (Attachment A), and the QM plan has been revised to address revisions to more relevant quality indicators and based on the CAP's 2015 checklist revisions. The 2015 LP QM Indicators included preanalytic, analytic, and post-analytic indicators for turnaround times, intraoperative correlations, corrected reports, patient identification events, and specimen errors.

Based on review of the relevance of our quality indicators and for relevance, industry recommendations, occurrence of incidents, and to be inclusive of LP's extent of services, the following revisions have been made to the 2065 Quality Management Plan:

I. REMOVE: It is the determination of the QM Committee that the analytic indicator to monitor the post-mortem provisional autopsy diagnosis (PAD) is no longer necessary because we have demonstrated more than two years of good performance.

II. REVISE: Molecular Diagnostics Turnaround Time: It was determined by the Technical Director that the Molecular service continued to meet TAT compliance of 11 days for two consecutive years. Because TAT is a valuable quality indicator, the Director will retain the indicator with a more strict threshold. The 2016 Quality Management Plan will change the TAT for Molecular Diagnostics from 11 days to 8 days.

III. ADD TWO (2) NEW INDICATORS

NEW: Immunohistochemistry Pre-Analytic Errors (e.g. Patient Identification)

According to CAP Checklist item ANP.21050, the identity of every specimen must be maintained through each step of tissue processing and block and slide preparation. This indictor in intended to monitor and address potential patient identification events, such as: mislabeled slides, incorrect block cut, or incorrect slides pulled. Determining the threshold: In laboratory medicine, typical acceptable range for quality control is a +/- 2 std. deviation to allow a 95% confidence interval and in some cases, a 99.5% confidence for 1 standard deviation. As we implement this new quality indicator, we will use the 2 s.d. threshold of ≤5% allowable errors for patient identification events against total IHC cases stained for the month.

Threshold: There will be ≤0.5% patient identification errors out of all IHC requests per month

NEW: Analytic Errors (e.g. Requests for Repeat Immunohistochemical Stains, QC issues)

ANP.22900 requires immunohistochemistry stains be of acceptable technical quality, and this indicator aims to monitor and improve upon factors in processing and staining procedures that might lead to poor quality slides. Whether an IHC request for repeat is due to technical, clerical, or procedural error, the reasons for repeat stain requests should be reviewed for trends to determine if there is/are system errors that could/should be implement to prevent recurring quality failures that result in repeat stains. The IHC laboratory has developed a form that must be completed by Pathologists for each request for repeat (Attachment B) to document the reasons(s) for repeat stain requests, and an IHC QA tracking sheet (AttachmentC) will be used by Laboratory staff to monitor repetitive errors in order to identify system solutions to prevent potential future errors.

Threshold: There will be ≤0.5% of repeat requests for Immunohistochemical stains per month

IV. EVALUATION OF TWO (2) POTENTIAL NEW INDICATORS

a. Lost Slides: Objective

The Quality Management Committee requested assessment of the number of times slides are not immediately located in the Lektriever or long-term storage when requested by submitting facilities for return or LP pathologists attempt to find a case for additional review.

Plan:
Data collection from staff (pathologists, archivist, and surgical pathology patient care coordinators) unable to locate slides. See *Attachment B* for worksheet example.

Data Elements:

- Lost Slides
    - Case(s) lost
    - If located: How long to find? Where were the slides?
    - If not located: Were we able to recut blocks?
    - Final comments – disposition? (e.g. communication with requesting facility)
    - Any potential prospective solutions to prevent this from future recurrence?
- Lost Blocks
    - Case(s) lost
    - If located: How long to find? Where were the block(s)?
    - If not located: Final comments – disposition? (e.g. communication with requesting facility)
    - Any potential prospective solutions to prevent this from future recurrence?

Outcomes: This could potentially be a qualitative quality indicator because there is no reasonable denominator (e.g. total LP surgical or submitted cases not feasible).

Threshold(s) will be recommended:

- 0 (zero) lost case slides, unable to be recut from blocks
- ≤1 lost slides, but we were able to recut from blocks

b. Submitted Surgicals (SS) and Submitted Hemepath (SJ) Turnaround Times

The QM Committee suggested monitoring the viability of adding Submitted Surgicals (Consults) to the Turnaround Times to QM repots. There are known variables not under the control of LP, but the committee asked to at least evaluate efficacy of the quality indicator.

Variables to consider:

- Purpose for the Consult (e.g. some second opinion rather than protocol-driven)
- Type of Consult:
    - Patient being considered for protocol
    - Personal consultation – second opinion for a specific pathologist
    - General second opinion
- Additional documents requested from submitting facility (NIH staff or submitted outside source) is not within the scope of control of LP staff
- Submitted Case for patient protocol review without accompanying paperwork from nurse

V. Annual Quality Management Projects

a. Biennial Customer Satisfaction Survey
b. Pending Supplemental Reports
c. Annual Quality of Water
d. Biennial Report Format and Content Review
e. Residents Projects:
    i. CAP Cancer Protocol Reporting
    ii. Immunohistochemistry Intra-observer Variability
    iii. Predictive Marker Annual Results
f. Patient Confidentiality QM (newly added 2015)

New Annual QM Project: Patient Confidentiality QM

In order to satisfy the College of American Pathologists' (CAP) revised standard GEN.41303, Patient Confidentiality QA, the Laboratory of Pathology will conduct an annual audit of compliance with the NIH and LP patient confidentiality policies. LP policies dictate that: 1) requests for release of patient reports must initiate from the NIH Clinical Center's Medical Records department, or based on the distribution list provided by the submitting clinician for consultative and submitted cases; and 2) any report released electronically will be encrypted when released to internal NIH health care providers, and/or password protected file(s) when submitting reports to the patients' non-NIH health care provider(s).

In order to satisfy the annual audit, LP staff will:

I. Review no less than 3 random Medico-legal requests from the previous calendar year to ensure that there is proper patient authorization to release the patient's repot to the requested provider or facility. The quality reviewer will:

a. Ensure the Medlegal request includes the patient signed authorization, and
b. The pathology report was submitted to the intended audience (e.g. patient's own request, submitting health care provider, and/or facility), and
c. The transmission of the pathology report was secure encrypted and/or password protected file if transmitted electronically, and
d. If possible, contact the facility to ensure the report was received securely.

II. Review no less than 3 random submitted surgicals (SS) cases with distribution that included at least 1 internal NIH provider and at least 1 external facility. The quality reviewer will:

a. Ensure the name(s) and address(es) of the distribution list is correct by reviewing the original submitted case documents, and
b. Ensure the internal NIH email was encrypted (the reviewer can print the senders' sent email file as evidence), and
c. The distribution to the external health care provider or facility was password protected and password did not accompany the same email as the report. This review can also be done via reviewing the Surgical Pathology Patient Care Coordinator's sent emails.

All evidence (emails and reports) will be submitted to the Clinical Manager, and the results of the audit will be submitted to the Quality Management Committee and Medical Director with appropriate investigations and corrective actions if necessary.

VI. Other Quality Issues to Consider

a. Bone Marrow specimens continue to be a struggle
b. No requisitions / delayed continues to take a lot of time for the Residents

MEMORANDUM

Attachment A

Material Referenced

CAP Laboratory General and All Common Checklists, rev. 7/28/2015

COM.04000 Documented QM/QC Plan **Phase II**

The laboratory has a written quality management/quality control (QM/QC) program.

NOTE: The program must ensure quality throughout the pre-analytic, analytic, and post-analytic (reporting) phases of testing, including patient identification and preparation; specimen collection, identification, preservation, transportation, and processing; and accurate, timely result reporting. The program must be capable of detecting problems in the laboratory's systems, and identifying opportunities for system improvement. The laboratory must be able to develop plans of corrective/preventive action based on data from its QM system.

All QM requirements in the Laboratory General Checklist pertain to the laboratory.

Evidence of Compliance:

✓ Records reflecting conformance with the program as designed **AND**
✓ Results of quality surveillance

GEN.16902 QM Implementation **Phase II**

For laboratories that have been CAP accredited for more than 12 months, the QM plan is implemented as designed and is reviewed annually for effectiveness.

NOTE: Appraisal of program effectiveness may be evidenced by an annual written report, revisions to laboratory policies and procedures, or revisions to the QM plan, as appropriate.

Evidence of Compliance:

✓ Evidence that the plan has been implemented as designed requires all of the following:
- quality measurements/assessments specified in the plan are being substantially carried out;
- there is evidence of active review of quality measurements;
- if target performance levels are specified in the plan and the targets are not being met, there is documented follow-up action;
- any interventions/changes to operations that are specified in the plan have been carried out as scheduled, or the reason for delay documented; **AND**
- any communication of information that is required by the plan have taken place

GEN.20100 QM Extent of Coverage **Phase II**

The QM program covers all areas of the laboratory and all beneficiaries of service.

NOTE: The QM program must be implemented in all areas of the laboratory (e.g. chemistry, anatomic pathology, satellite, point-of-care, consultative services, etc.). The program must include all aspects of the laboratory's scope of care, such as inpatient, outpatient, and reference laboratory services.

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REVISED* *07/29/2013*

GEN.20316 QM Indicators of Quality **Phase II**

The QM program includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases.

NOTE: Key indicators should monitor activities critical to patient outcome and/or affect many patients. The laboratory must document evaluation of indicators by regularly comparing performance against available benchmarks. The number of monitored indicators should be consistent with the laboratory's scope of care. Special function laboratories may monitor fewer indicators; full-service laboratories should monitor multiple aspects of the testing process appropriate to their scopes of service.

While there is no requirement to monitor any specific laboratory monitor, the following key quality indicators listed below have been commonly used to measure laboratory performance in a consistent manner and are important to clinicians and patients as indices of care.

1. *Patient/Specimen Identification: Percent of patient wristbands with errors, percent of ordered tests with patient identification errors, or percent of results with identification errors*
2. *Test Order Accuracy: Percent of test orders correctly entered into a laboratory computer*
3. *Specimen Acceptability: Percent of specimens accepted for testing*
4. *Stat Test Turnaround Time: Collection-to-reporting turnaround time or receipt-in-laboratory-to-reporting turnaround time of tests ordered with a "stat" priority (e.g. emergency department or intensive care unit specimens), mean or median turnaround time, or the percent of specimens with turnaround time that falls within an established limit*
5. *Critical Value Reporting: Percent of critical results with documentation that results have been reported to caregivers; percent of critical results for which the primary clinician cannot be contacted in a reasonable period of time*
6. *Customer Satisfaction: Standardized satisfaction survey tool with a reference database of physician, nurse, or patient respondents*
7. *Corrected Reports – General Laboratory: Percent of reports that are corrected*
8. *Corrected Reports – Anatomic Pathology: Percent of reports that are corrected*
9. *Surgical Pathology/Cytology Specimen Labeling: Percent of requisitions or specimen containers with one or more errors of pre-defined type*
10. *Blood Component Wastage: Percentage of red blood cell units or other blood components that are not transfused to patients and not returned to the blood component supplier for credit or reissue*
11. *Blood Culture Contamination: Percent of blood cultures that grow bacteria that are highly likely to represent contaminants*

Performance of indicators should be compared with benchmarks, preferably from multi-institutional studies conducted within ten years of the laboratory's use of the monitor, where such surveys are available.

ANP.21050 Specimen Identity **Phase II**

The identity of every specimen is maintained through each step of tissue processing and block and slide preparation.

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***REVISED** 07/28/2015*

GEN.41303 Patient Confidentiality **Phase II**

The laboratory ensures that internal and external storage and transfer of data maintains patient confidentiality and security.

NOTE: Written procedures must address patient confidentially during transfer of data to external reference laboratories or other service providers. This must include cloud based computing (e.g. for storage of confidential data), as appropriate

The laboratory must audit compliance with the procedures at least annually.

Evidence of Compliance:

✓ Records of patient privacy audit for compliance with the Health Insurance Portability and Accountability Act (HIPAA)

REFERENCES

1) Title 45 – Code of Federal Regulations – Parts 160, 162, and 164, Health Insurance Reform: Security Standards; Final Rule, *Federal Register*, Published Feb. 20, 2003, http://www.cms.hhs.gov/HIPAAGenInfo

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Attachment B

Lost Slides QM Worksheet

In Process:						
Date Requested	Case #	Located (Y/N)	Where Located?	When (how long delayed = days)	Recuts Done? (Y/N/NA)	Disposition (f/u with requester)
Lost - Able to be recut:						
Date Requested	Case #	Located (Y/N)	Where Located?		Recuts Done? (Y/N/NA)	Disposition (f/u with requester)
Lost - Unable to recut:						
Date Requested	Case #	Disposition (f/u with requester)				