DEPARTMENT OF HEALTH & HUMAN SERVICES

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Laboratory of Pathology, NCI, CCR

MEMORANDUM

February 15, 2017

TO: Laboratory of Pathology Staff

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

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SUBJECT: **2017 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) evaluated new indicators in CY2016 in order to satisfy GEN.20316 (monitor of key indicators for pre-analytic, analytic, and post-analytic phases), while also realizing the need to address GEN.20100 (extent of coverage) to ensure that all clinical sections of LP were included in the QM Program. The 2016 LP QM Indicators included preanalytic, analytic, and post-analytic indicators; which, included components to monitor turnaround times, intraoperative correlations, corrected reports, patient identification events, and specimen errors.

The 2017 QM Plan will continue with the previous year's indicators based on feedback of sections' technical directors and QM Committee members; however, the 2017 QM Plan will expand to include new indicators that will address turnaround time of the final signout of submitted service cases, turnaround time for Medlegal requests and to return submitted material. In addition, the Medical Director has requested that the 2017 QM Committee address recurring issues with delayed receiving of CRIS orders with specimens, and the accurate documentation of specimen source on the CRIS orders.

The 2017 Plan also addresses two new hospital-wide Clinical Center (CC) programs that aim to identify and evaluate errors, incidents and other problems that may interfere with patient care services (GEN.20208). These quality initiatives allow LP staff a mechanism to report concerns to the hospital-wide community that may benefit from external involvement – e.g. the issues affect LP, but contributing factors or corrective actions are not LP-specific. The CC is developing a new Occurrence Reporting System (ORS) that will allow timely feedback to the reporting staff, and the CC has already adopted a a 'Morning Huddle' at 08:20 each weekday morning, which is

attended by each clinical department, nursing units representatives, and support services representatives and is a forum for any healthcare professional to report on concerns that may benefit from other hospital departments.

The following revisions have been made to the 2017 Quality Management Plan Based on review of the relevance of our quality indicators relating to: industry best practices and recommendations; occurrence of incidents (system errors); regulatory standards (new CAP / JCAHO standards); and to ensure all of LP's clinical servicesare represented in QM Committee.

I. REVISED THE FOLLOWING INDICATORS

a. Cytopathology Turnaround Time: Rather than reporting Cytopathology GYN and Medical Cytology turnaround times in different reports, it was determined in the latter part of CY2016 that the quality indicator would involve total Cytopathology cases (CM and CG) as a better indicator of section TAT performance. The combined indicator is reported as Medical and GYN Cytology Comprehensive Turnaround Time for the 2017 QM Program.

b. REVISED: The Intraoperative Turnaround Time: The IOC TAT indicator previously evaluated the time that specimens were received by the pathologist until time reported to the surgeon. Based on clinician customer feedback, this quality indicator is being evaluated for relevance of adding another variable: time of notification by the O.R. until time Pathologist arrives in the TPPF. If the data reflects a benefit to revising the QM report, time of pathologist arrival from notification could potentially be added to the monthly QM reports.

c. REVISED: Immunohistochemistry Errors: The IHC preanalytic and analytic errors were initially evaluated at ≤0.5% of total slides. LP QM committee discussed whether using a denominator of 'patient slides' would be a better indicator than 'total slides', but it was determined that all slides, including QC slides, are included in the preanalytic and analytic totals. Rather than changing the denominator used, the threshold was decreased from ≤0.5% to ≤0.1%.

II. ADD TWO (2) NEW INDICATORS & (1) BIMONTHLY/PERIODIC REPORT

a. (NEW) - Submitted Service (SS / SJ) Turnaround Time (Analytic)

An integral component of the LP clinical service is review of submitted surgical materials for patients being considered for an NIH research protocol. Additionally, LP pathologists are considered experts in certain disciplines, and their consultative services are requested by non-NIH institutions for the rendering of a second opinion. Variables to consider while assessing issues with the submitted service turnaround times include: Identifying the purpose for the Consult (e.g. some second opinion rather than protocol-driven); The type of Consult - Is the patient being considered for protocol – is it a personal consultation or second opinion for a specific pathologist; Were there additional documents requested from submitting facility (NIH staff or submitted outside source) is not within the scope of control of LP staff; or consideration if the submitted Case for patient protocol review received without accompanying paperwork from the submitting clinic. This indicator is implemented in order to determine if there are system errors, or specific variables, that contribute to extended turnaround times that might be addressed.

Threshold determination: According to Volmar, K., et. al., (2015, median turnaround times in government institutions was 6.06 days for complex surgical specimens (based on a 2012 CAP Q-Probes Study of 56 Institutions repoted on 2,763 large or complex cases). Considering there are potential processing issues, such as requesting additional material or missing paperwork, and also considering this includes routine consults that are less time-critical are mixed with consults for protocol consideration. Initially, 90% within 10-days was evaluated, similar to the turnaround time indicator for complex surgicals; however, initial data demonstrates that 90% within 7 days is a more effective threshold. This, and all thresholds, are reviewed periodically by the QM Committee and the Medical Director, and can be revised to strive for furthur improvement.

Threshold: ≥90% withing 7 days

b. (NEW) - Medlegal and Return Material TAT (Post-Analytic)

LP's Surgical Pathology routinely receives requests to have non-NIH stained and unstained slides recut or whole blocks (less frequently) returned to the submitting facility. Medlegal requests include patient-authorized requests to forward LP case material on to another facility for medico-legal purposes, or if that patient is being treated, or being considered for another protocol in that facility. Because of our research mission, it is important that LP processes patient requests

to forward pathology material to other facilities. Additionally, patients who are on multiple protocols in various health care organizations routinely ask that their material be returned to the submitting facility so that they can send on to other facilities. Past customer satisfaction surveys provided feedback that having material sent to other facilities may take too long, so this indicator was created to monitor the turnaround times for return material requests.

Threshold determination: Numerous factors can contribute to the time it takes from receipt of a request for material until the time it is mailed to the requesting facility. A formal requisition is needed, determination if material can be released to that facility, availability of the material (time to recut if necessary), release by the attending pathologist, and administrative staff availability to process the paperwork and physically mail the material. For the purpose of evaluating an initial threshold, we referenced Giannini et al. (2011), of the Mayo Dept of Lab Medicine and Pathology, which esablished expected return of their submitted material at 14 days for clinical cases and 6 months for materials requsted for research or education. A focus on the clinical expectation, and based on LP's initial QM data which suggests that 7 to 10 days from receipt of request would be a more appropriate target, the Medical Director has requested setting the threshold at the lower limit and eventually strive to improve even that threshold.

Threshold: ≥90% withing 7 days

c. (NEW) - Bi-monthly Reporting of >30 day outliers to Section Head (Analytic)

During the CY2016 QM review, the Medical Director requested a periodic review of cases in all clinical sections that had exceeded 30 days. Contributing factors included: research cases being entered into the LIS and never signed out; two clinical sections closed and research reports remained unresolved; and occasionally there might be pending submitted or inhouse clinical cases. As a result of an audit of cases that exceeded 30-days without a final report, the pending report will be printed bimonthly and the pending case(s) communicated directly with the assigned pathologists, as well as the to the section head. Outliers that repeat in more than one report cycle are also communicated with the Medical Director.

III. EVALUATION OF POTENTIAL NEW INDICATORS

a. Research IHC in Diagnostic Line (consider as QM Indicator)

In addition to the clinical antibodies that have been developed, validated, implemented and have routine proficiency testing performed, the Laboratory of Pathology has a

applications or to support research protocols. CAP Lab GEN.41350 references research testing: For laboratories subject to US regulations: for tests in disciplines covered by CLIA, specimens and materials for testing must be referred only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. With respect to patients on research protocols, whose tests are referred to a research laboratory: if those test results are used for patient management decisions, the research laboratory must be CLIA-certified, or meet equivalent requirements as determined by CMS.

Plan: This indicator is being considered to ensure research or developmental antibodies that have not yet been validated and implemented for clinical use are not referenced in the diagnostic line of the pathology report. Initial data collection q1 year to determine compliance, and document potential limiting factors. Clinical Residents, an Attending Mentor, and IHC Technical Staff to develop plan of action based on data.

b. Lost Slides: Objective (continued evaluation from past year for QM Indicator)

The Lost Slides QM effort has been discussed at several committee meetings, and it is determined that there is a potential issue with staff having to search for lost/misplaced slides. However, there was limited data received from staff regarding the numbers of lost slides, therefore we cannot determine thresholds / metrics with the limited evaluation data. This indicator will continue on for assessment during the 2017 QM Program.

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.

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
- ≤ lost slides, but we were able to recut from blocks

IV. Annual Quality Management Projects

a. Biennial Customer Satisfaction Survey is due Nov 2017

b. Pending Supplemental Reports due March 2017

c. Annual Quality of Water due March and October 2017

d. Biennial Report Format and Content Review due October 2017

e. Immunohistochemistry Intra-observer Variability

f. Patient Confidentiality QM due March 2017

g. Annual Medical Director Review of Effectiveness of QM Program due February 2017

V. Residents Projects:

The LP QM program also incorporates "projects" that are planned, implemented, monitored, by LP's Clinical Residents and Fellows, and the projected are to address: a) specific CAP checklist requirements; b) areas that need further monitoring and improvement based on the results of indicators monitored in CY2016; or c) recurring issues in LP's sections that may pose a risk to quality management. Areas previously identified as potential projects to be adopted by the QM committee include: determining common causes of >10 day outliers, delays in autopsy, missed CAP cancer reporting, and clotted bone marrow samples.

As of the close of CY2016, the autopsy service was consistently in compliance with the 60-day turnaround time standard. This Resident Project has been CLOSED.

By the close of CY2017, the bone marrow clotted samples project resulted in compliance with the threshold for several months. Although there are outlier months, the Resident Project contributed to repeated compliance for an indicator that routinely exceeded allowable thresholds for compliance every month for three years consistently. Based on the improvement, the Resident Project has been CLOSED.

Resident Projects for 2017

a. CAP Cancer Protocol Reporting
b. SS case patient ID/accession error
c. Ensuring compliance with Immunohistochemistry daily Quality Control

Proposed Resident Project (To be developed in 2017):

a. Accuracy of CRIS Orders to Actual Specimens Received

While reviewing the incidents of cases received without CRIS orders, the Histology technicians and residents indicated that there are occasions that a CRIS order (placed by the treating clinician) doesn't always match the actual specimen received in Histology (will also be different in Softpath). Additional resources in Attachment A: Referenced Material. CRIS orders differ from actual specimen The Medical Director is concerned that this variance is our regulatory standards, in particular with GEN.20316 and GEN.40750, accuracy of orders placed by the clinicians and he asked that this be a Resident project.

Plan: The Medical Director has requested that a Resident, under the supervision of a surgical pathologist, develop a Resident QM Project to identify: the problem; the number of incidents involved in CRIS order differences; types of incidents (wrong site, wrong procedure, used the wrong CRIS order); contributing factors; develop and monitor metrics (from standards, cited best practices, publications); how outliers are addressed; and a proposed outcome.

b. Delayed CRIS Orders

Delayed CRIS orders continues to be an issue for the clinical residents as their work is delayed as they wait for attending clinicians to place CRIS orders. There are considerations that some cases will have delayed orders if the surgeon is still in the Operating Room, but there are cases that it's unclear who is responsible for entering the CRIS orders. It has been recommended by the QM committee that a resident take on a QM project to identify the issues, investigate, evaluate, report, and propose solution(s) to the delays in receiving CRIS orders with specimens.

Plan: The Medical Director has requested that a Resident, under the supervision of a surgical pathologist, develop a Resident QM Project to identify: the problem; the number of incidents involved in CRIS order differences; types of incidents (wrong site, wrong procedure, used the wrong CRIS order); contributing factors; develop and monitor metrics (from standards, cited best practices, publications); how outliers are addressed; and a proposed outcome.

REFERENCES

Giannini, C., et al.,. (2011, March). Maintaining Clinical Tissue Archives and Supporting Human Research: Challenges and Solutions. Arch Pathol Lab Med; 135, 347-353.

Volmer, K., Idowu, M., Souers, R., Karcher, D., & Nakhleh, R. (2015). Turnaround Time for Large or Complex Specimens in Surgical Pathology: A CAP Q-Probes Studey of 56 Instituions. Arch Pathol Lab Med; 139, No. 2, pp. 171-177.

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CAP Checklist Items Referenced

CAP Laboratory General and All Common Checklists, rev. 8/17/2016

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 are records of 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 recorded; **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). The program must include all aspects of the laboratory's scope of care, such as inpatient, outpatient, and referral laboratory services.

*****REVISED**** ***08/17/2016***

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 or that may affect many patients. The laboratory must evaluate its indicators by comparing its performance against available benchmarks. The laboratory should also evaluate the effectiveness of each corrective action. 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 scope of service.

For laboratories that have implemented one or more individualized quality control plans (IQCPs), the quality management program must include a review of the ongoing monitoring of the effectiveness of each IQCP. While there is no requirement to monitor any specific laboratory indicator, the following key quality indicators 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 written record 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*

***REVISED** 08/17/2016

ANP.21395 Special Stains/Studies **Phase II**

For special stains, including histochemical stains, and studies using immunologic and ISH methodology, positive and negative controls are verified and recorded as acceptable prior to or concurrent with the reporting of patient results and records maintained.

NOTE: Controls must be verified and recorded as acceptable by a pathologist or designee (provided the designee meets high complexity testing qualifications).

Positive tissue controls must contain the component specific to the special stain that is being applied to the specimen.

Immunohistochemical tests using polymer-based detection systems (biotin-free) are sufficiently free of background reactivity to obviate the need for a negative reagent control and such controls may be omitted at the discretion of the laboratory director following appropriate validation.

If interpretation of the special stain or study is performed by a different laboratory, there must be a procedure for the laboratory performing the stain or study to verify the acceptability of the controls before transfer, if the controls are not sent with the patient slides (regardless of the outside laboratory's accrediting organization). Records of this verification must be readily available to the laboratory performing the interpretation.