DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MEMORANDUM

February 15, 2019

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: **2018 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 CY2018 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 2018 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.

During the 2018 QM period, the Laboratory of Pathology's clinical services saw increased participation in performance improvement efforts with all departments. This past year, more residents and fellows attending QM meetings, and participated in the annual CAP accreditation self-inspection as inspectors. Residents provided important feedback on issues associated with pre-analytic variables (e.g. missing CRIS orders), and for turnaround time issues for inhouse and submitted surgicals.

The 2018 QM Plan continued with the previous year's indicators based on feedback of sections' technical directors and QM Committee members; however, the 2018 QM Plan expanded to include new indicators that will address turnaround times of Submitted Service cases and Medicolegal and Return Material requests from outside sources.

Positive outcomes in 2018 included:

- Overall consistent improvement in turnaround times for Cytology and Large Surgicals.
- Improvement in reporting delayed CRIS orders by surgical accession staff, which helped identify specific clinical areas of the hospital.

- Submitted service turnaround times was relatively new this year. Although the threshold was not consistently met, there was significant discussions during monthly QM about the system outliers. Most often, residents identified that they had to wait for additional material from outside sources, and we identified that the SS (submitted for consideration to admission on protocols) was mixed with personal consults (ST). The accession staff was trained to separate the two case types, which will help future tracking of the relevant SS turnaround times to monitor how quickly LP provides an interpretation / final report for patients awaiting admission to NIH protocols.

Areas for continuous improvement needed:

- This was the first full year of Immunohistochemistry process improvement quality indicators. The year started with consistent outliers to pre- and analytic- procedures, but the latter part of the year resulted in improved compliance evident of process improvement and more accountability by the section's personnel.
- Requisition not submitted continue to be a challenge. The LP surgical pathology staff and residents routinely must request orders from surgical fellows. A recurring response is that the fellow is in another procedure and will enter the order(s) after the current case, or the fellow is attending to the patient. The LP has worked with the hospitals Quality Improvement committee, OR Nursing Leadership, Interventional Radiology and OR Medical Staff to address these issues. It appears the eventual solution will be the implementation of the SoftPath DX system, which will require real-time orders during the surgical procedure. We will continue to monitor this indicator next year and continue to enter hospital incident reports (STARS) when appropriate.

EVALUATION OF POTENTIAL NEW INDICATORS

Turnaround Times for new Molecular Services (NCI-COMPASS Illumina Sequencing Facility)

The LP's NCI-COMPASS program is set to launch the TSO-500 NGS sequencing platform in late 2018. When that methodology launches, the entire Molecular Diagnostics QM program will be re-evaluated to ensure inclusion of all Molecular methodologies. The TSO500 is LP's plan to implement a next-generation sequencing (NGS) assay that analyzes cancer-relevant genes from both DNA and RNA in one integrated workflow. With simultaneous analysis of both DNA and RNA, various types of biomarkers relevant to a given tumor type (single nucleotide variants (SNVs), indels, fusions, splice variants, tumor mutation burden (TMB), and microsatellite instability (MSI)) will be assessed from the same sample in a single assay. The RNA panel will use a probe design that enables capture of both known fusions and novel fusion partners. The TSO500 panel includes 523 genes for DNA mutation detection and 55 genes for fusion and splice variant detection. The molecular pathology report is also incorporated with reporting software for clinical actionability as Tier levels

of FDA-approved drug and clinical trials, and pathogenicity based on AMP/ASCO/CAP/ACMG guidelines. Turnaround times to include processing, testing and reporting will be a valuable quality indicator for this new paradigm in LP's molecular testing program.

Methylation Arrays Turnaround Time: The new methodology will launch in 2018. The NCI Laboratory of Pathology recently began to evaluate implementation of a clinically-reportable diagnostic tool that uses genome-wide DNA methylation profiling as a diagnostic for tumors of the central nervous system. The validated tool is based, in part, on data published in a recent Nature study that showed tumor methylation profiles can provide definitive evidence to complement and refine morphology-based diagnostics in tumors of the brain and spinal cord. The NCI Laboratory of Pathology is poised to become a diagnostic reference center to implement this tool for diagnostically challenging neuropathology cases. Because there is only one other healthcare facility in the US performing this testing, the LP will be the industry guide on quality thresholds but will establish thresholds based on ideal processing, extraction, profiling and analysis times.

RESIDENTS' QM 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 CY2018; 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.

CAP CANCER PROTOCOLS COMPLIANCE

1) *****REVISED** 08/21/2017***

ANP.12350 Cancer Protocols Phase II

All data elements required in applicable CAP Cancer Protocols are included with appropriate responses in at least 90% of the surgical pathology reports from definitive resection specimens for primary invasive malignancies, as well as cases of ductal carcinoma in situ of the breast, with an audit performed annually to ensure that all required elements are included.

2) *****REVISED** 08/21/2017***

ANP.12385 Synoptic Reporting Phase I

Data elements required by applicable CAP Cancer Protocols are reported using a synoptic format in at least 90% of the eligible surgical pathology reports.

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CAP cancer protocol project, as of 04/12/2018

2016	Jan-16	Feb-16	Mar-16	Apr-16	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16	Dec-16
CAP protocol required	14	14	20	25	17	15	18	29	24	19	13	27
Entered	14(100%)	14 (100%)	16 (84.2%)	25 (100%)	17 (100%)	14 (93.3%)	18 (100%)	27 (93.1%)	24 (100%)	19 (100%)	11 (100%)	26 (96.3%)
Not entered	0	0	3 (15.8%)	0 (0%)	0 (0%)	1 (6.7%)	0 (0%)	2 (6.9%)	0 (0%)	0 (0%)	0%	1 (3.7%)
CAP not required	49	58	78	53	46	38	37	50	42	35	61	52
# Corrective Action	N/A	N/A	Corrected	N/A	N/A	Corrected	N/A	Corrected	N/A	N/A	N/A	Corrected
Total	63	72	97	78	63	53	55	79	66	54	72	79

2017	Jan-17	Feb-17	Mar-17	Apr-17	May-17	Jun-17	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17
CAP protocol required	18	18	11	7	11	12	17	25	24	8	24	6
Entered	18 (100%)	18 (100%)	11 (100%)	7 (100%)	11 (100%)	12 (100%)	16 (94.1%)	25 (100%)	24 (95.9%)	8 (100%)	24 (100%)	6 (100%)
Not entered	0 (0%)	0	0	0	0	0	1	0	1	0	0	0
CAP not required	40	47	75	53	49	48	39	46	35	48	46	41
# Corrective Action	N/A	N/A	N/A	N/A	N/A	N/A	Corrected	N/A	Corrected	N/A	N/A	N/A
Total	58	65	86	60	60	60	56	71	59	56	70	47

2018	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
CAP protocol required	21	11	21	Sally	Sally							
Entered	21 (100%)	11 (100%)	20 (95.2%)									
Not entered	0	0	1									
CAP not required	21	37	44									
# Corrective Action	N/A	NA	Corrected									
Total	42	48	65									

Attending: Dr. Kleiner
Residents: Sun A Kim, Christopher Trindade, Sally Tanakchi

Assessment / Recommendations:

Check specimen type and procedure in the quick guide to find out whether CAP checklist is required.

Remember that some biopsy requires CAP checklist in the report. However, CAP protocol template is not always necessary if required items are included in the pathology report (e.g. tumor site, size, grade etc.).

CAP checklist is always required if the primary tumor is initially resected or it is resected as a recurrent tumor after previous curative resection.

Exclusion (we don't need CAP checklist)

- Resection or biopsy of metastatic tumor
- Multiple partial nephrectomy for multiple RCC of hereditary nature (ex> VHL, HLRCC, hereditary papillary RCC)
- Excision/resection that is for tissue procurement and not of curative purposes