DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MEMORANDUM

January 22, 2020

TO: Laboratory of Pathology Clinical Staff

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

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SUBJECT: **2019 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 two new indicators in CY2019 in order to satisfy GEN.20316 (monitor of key indicators for pre-analytic, analytic, and post-analytic phases), while also adopting the need to address GEN.20100 (extent of coverage) to ensure that all clinical sections of LP were included in the QM Program. The 2019 LP QM Indicators included preanalytic, analytic, and post-analytic indicators; which, included components to monitor turnaround times, intraoperative correlations, corrected reports, delays in obtaining surgical specimen orders, patient identification events, specimen processing and quality control (QC) errors, and the evaluation of a new indicator for a newly implemented clinical test mid-year- Methylation Arrays. A preliminary plan to revise the Molecular Diagnostics turnaround time to include all aspects of processing, extraction, analysis, informatics and final pathology report was discussed, but will be delayed until the new platforms (TSO-500, RNASeq, etc) has been active for a period of time.

Methylation Arrays Turnaround Time: The NCI Laboratory of Pathology implemented a clinically-reportable diagnostic tool that uses genome-wide DNA methylation profiling as a diagnostic for tumors of the central nervous system in 2019. The validated tool is based, in part, on data published in a *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 LP 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.

Turnaround Times for new Molecular Services (NCI-COMPASS Illumina Sequencing Facility): The LP's NCI-COMPASS program launched the TSO-500 NGS sequencing platform in the third quarter of 2019, and there are several new clinical genomic methods being validated for

implementation. The TSO500 is 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.

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; or c) recurring issues in LP's sections that may pose a risk to quality management. Projects identified for CY2019 included: determining common causes of >10-day outliers; missed CAP cancer reporting; interobserver variability; and predictive marker annual result comparison. Residents' Projects were not consistently reported to QM Committee. Faculty advisors were not proactive with setting meetings with their fellow(s), and there was no accountable QM staff to ensure follow up on QA findings. In CY2020, a new shared ClinOps/OOTC admin staff has been assigned to track and keep the projects on task. Faculty are asked to develop the indicators, plans of assessment and corrective actions must have an end goal.

2019/2020 CUSTOMER SATISFACTION SURVEY

The 2019 Customer Satisfaction Survey was delayed and completed in early 2020. This survey polled NIH professional and support level staff utilizing LP clinical, research, and academic services. Respondents included branch chiefs, staff clinicians, clinical and research fellows, physician assistants, nurse practitioners, nursing staff, and clinical and research support customers. The 2019 survey shows consistent performance in most areas regarding how LP's customers view services and interactions with LP. Composite data about interactions with staff, faculty and residents/fellows and quality and timeliness of clinical work will be presented to the LP QM Committee. The QM Committee will discuss and address recurring issues identified in the survey in the first quarter of CY2020, and make determinations if there are actionable items in the individual comments. In particular, already accomplished was a meeting with the Surgical Pathology administrative staff regarding the perception about customer service provided. The intent of the QM Committee is to discuss the summary of responses and address those items that are actionable.

CONCLUSION & RECOMMENDATIONS:

The 2019 QM program was all-encompassing and addressed indicators from each clinical service, and common areas that affect the LP as a whole. The QM Committee also oversaw issues affecting staff safety, environment of care, customer satisfaction and investigating and addressing performance improvement efforts. The basis of the monthly QM program is to review and address quality indicators, and identify areas for improvement. The QM Committee's goal is to maintain at least 12, but no more than 20 indicators. This past year resulted in 18 initial, 2 assessed, and a final 19 quality indicators. The QM Committee section participants opted to maintain indicators relevant to their service, and we retained LP-wide indicators addressed as industry best practices (e.g. surgical turnaround times, identification events, and revised reports).

Overall, there were more positive than negative outcomes for the CY2019 QM Program. The QM will be tasked with maintaining no more than the maximum 20 indicators in CY2020, which will be reassessed at the end of the calendar year to determine if any may be removed and/or other relevant indicators evaluated and/or added. An assessment of effectiveness for certain indicators and QA efforts for 2019 include:

- Overall consistent improvement in turnaround times for medical/gyn cytology, surgical biopsies, and large surgicals; however, there is no consistency with meeting the thresholds. These monitors will continue.

- As of the close of CY2019, the autopsy service consistently exceeded compliance with the 60-day turnaround time standard. A 2016 resident project resulted in several years of consistent compliance, but 2019 ended with numerous outliers and several post-mortem cases remain on the pending list. The branch chief made an edict that the cases be signed out, and the QM committee will continue to track compliance.

- IOC correlations compliance improved over previous years as residents consistently completed their IOC correlations, and there were a handful that required discussion about each case in QM Committee meetings. This monitor has been a beneficial learning and QA tool, and will continue.

- Improvement in reporting delayed CRIS orders by surgical accession staff, which helped identify specific clinical areas of the hospital. LP staff met with hospital QA members, nursing and OR medical staff to address the issues, but we continued to have issues with delayed CRIS orders. The new LIS upgrade – Softpath DX – is slated to go live in 2020, and this system requires real-time order entry which is expected to resolve this issue.

- Submitted service turnaround times was relatively new this year. Although the threshold was not consistently met in the first quarter, there was significant discussions during monthly QM about the system outliers and there was improvement throughout the remainder of the year. In the previous year, we identified that the SS (submitted for consideration to admission on protocols) was mixed with personal consults (ST). The accession staff were trained to separate the two case types, which resulted in accurately capturing the relevant SS turnaround times to monitor how quickly LP provides an interpretation / final report for patients awaiting admission to NIH protocols. Although improved, there is consistency with outliers, so this indicator will be continued to be monitored in CY2020. This indicator may be considered to be removed at the end of the year.

- 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.

- The QM Committee stopped monitoring PAD turnaround times at the end of CY2016 due to consistent compliance. Due to the CAP standards, this indicator will be added to the CY 2020 QM plan.

CONCLUSION:

During the 2019 QM period, the Laboratory of Pathology's clinical services had consistently good participation in performance improvement efforts from all departments. This past year, all sections were routinely represented, and 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: preanalytic issues, such as reasons and solutions with missing IHC quality control reviews; analytic delays for inhouse and submitted service, such as cases that required additional outside material or multiple consults; and post-analytic variables. The LP QM program is robust and has demonstrated success with process improvement in multiple aspects of LP's services.