DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MEMORANDUM

March 18, 2021

TO: Laboratory of Pathology Clinical Staff

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

Armando Filie, MD (Quality Management Chair)

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

SUBJECT: **2020 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.20326, the Quality Management (QM) Plan must be implemented as designed and reviewed annually for effectiveness. The Laboratory of Pathology (LP) evaluated a new indicator in CY2020 in order to satisfy ANP.33100 (monitor of preliminary autopsy gross examination reports), 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 2020 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.

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. After a year of data collection, the committee had decided to establish a turnaround time threshold of 21 days.

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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. The turnaround times were monitored under the Molecular Diagnostics indicator during CY2020.

Preliminary Autopsy Turnaround Time: The NCI Laboratory of Pathology has begun to monitor the turnaround-time for preliminary autopsy gross examination reports due to the CAP Checklist ANP.33100. The threshold was established at 2 calendar days from receiving the specimen to sign-out, in regulation with the CAP. The indicator only tracks full post-mortem cases, with the AU prefix.

Final Autopsy Turnaround Time: The LP QM Committee decided to decrease the FAD turnaround-time threshold to 45-days in March of CY2020. In CY2019, there were numerous non-compliant outlier cases which we hoped to eliminate with a tighter threshold. The residents cleared out the overdue pending cases that rolled over from the previous year, per the branch chief's decision. A member of Office of the Chief began sending out the pending case list on a weekly basis to provide a consistent reminder to residents and pathologists with pending cases. Since the implementation of the new threshold, there has only been 1 post-mortem report that was not compliant. We are very pleased with the improvement and hope to continue compliance into future years.

Switch to SoftPath DX: The NCI Laboratory of Pathology went live with the new LIS platform, SoftPath DX, in June 2020. The new system requires real-time order entry, which resolved LP's prominent issue of delayed CRIS orders. Since the system went live, there have been 0 cases that were submitted without a CRIS order. This is drastic improvement compared to CY2019 where an average of 2-10% of cases were submitted monthly without the corresponding CRIS order.

RESIDENTS' QI 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 CY2020 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 clinical residents and fellow(s), and there was no accountable QM staff to ensure follow up on QI findings. In CY2020, a new shared ClinOps/OOTC admin staff has been assigned to track and keep the projects on task. Faculty along with clinical residents and fellows 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. Areas with the most significant decrease in satisfaction include: Overall speed for the notification of significant normal results and the overall satisfaction level with customer service provided. These areas will be a priority focus in the LP Quality Management Committee. Areas that have shown improvement over the last two years include: Quality of professional interaction and communication with the secretarial, technical, and management staff, Communication of relevant information regarding cases submitted, Staff pathologist responsiveness to problems and the Availability of staff pathologist.

SUMMARY & RECOMMENDATIONS:

The 2020 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 20 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).

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The NCI-COMPASS Program continues to grow, causing an increase in submitted consult cases from clinicians world-wide. Because of the dramatic increase, the Medical Director suggests separating different thresholds for the Molecular Diagnostics program from receipt, processing, extraction, testing, variant report to report sign-out. We will identify more specific indicators and establish thresholds that will be reevaluated mid-year.

As we have begun preparation for the upcoming College of American Pathologist Biennial Self-Inspection for 2021, there were many documents pending signatures in MediaLab. MediaLab has been implemented as the new Document Control tool for LP and will now be used for all accreditation inspections. The Medical Director recommends a quality indicator for accreditation readiness related to document management control ensuring timely review of policies and procedures by the technical director designee and/or new or significant revised policies to the medical director for review.

Overall, there were more positive than negative outcomes for the CY2020 QM Program. The QM will be tasked with maintaining 21 indicators in CY2021, to more deeply evaluate the NCI-COMPASS program, which will be reassessed at the end of the calendar year, and 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 2020 include:

- Overall consistent improvement in turnaround times for medical/gyn cytology, surgical biopsies, and large surgicals.

- As of the close of CY2020, the autopsy service was consistently compliant with the 60-day turnaround time standard. A majority of cases were also compliant with the new 45-day standard that was established by the Committee in March of CY2020. All previous overdue cases were signed-out, per the branch chief's request. This was a huge improvement compared to CY2019. We will continue to send out the pending cases on a weekly basis to provide Pathologists and Residents with consistent reminders and continue to require accountability when thresholds are not met.

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

- Flow Cytometry turnaround times were consistently successful in CY2020. There was always less than 5% of Bone Marrow cases clotted, with 100% compliance for the year.

- Submitted service turnaround times were consistently successful in CY2020. In CY2018, 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. Due to the increase in volume of submitted cases and abridged work amid the pandemic, the Medical Director recommends continuing to monitor the submitted cases for patients being admitted on protocol to detect if there are any system issues that may be improved.

- This was the second full year of Immunohistochemistry process improvement quality indicators. The laboratory stayed compliant almost the entire year, except for July, when there were a few pre-analytic errors. Pre-analytic errors occurred due to Softpath requests not appearing on the daily worksheet or interfacing on our stainers. Manual requests with poor handwriting were also factors. Overall, there were only a handful errors that occurred during CY20.

- Requisition not submitted was a large challenge for LP in previous years. The LP surgical pathology staff and residents routinely needed to 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. The issue was finally resolved with the new implementation of LIS software, SoftPath DX. Since the new software, there have been zero (0) cases received without a CRIS order. Due to the success of the new system, we have decided to stop monitoring this indicator in CY21.

- The QM Committee stopped monitoring PAD turnaround times at the end of CY2016 due to consistent compliance. Due to the CAP standard ANP.33100, this indicator was added to the CY 2020 QM plan and we will continue to monitor in CY21. There were only 3 PAD reports that were signed out past the 2-calendar-day requirement, out of 70 PADs that were completed in CY2020.

2021 PLANS:

- The CY2021 QM Plan was reviewed with input of the Quality Management Committee in February of 2021 and was approved by the Medical Director on March 02, 2021.
- New or revised indicators that will be reviewed for effectiveness for further evaluation at the end of this year include;

- COMPASS- Single Test Turnaround Time
- COMPASS- NGS Test Turnaround Time
- Policies and Procedures Mandatory Review in MediaLab

- The QM committee will continue to review the necessity for new quality indicators needed to address industry norms or variances within the department.

CONCLUSION:

During the CY2020 QM period, the Laboratory of Pathology's clinical services had consistently good participation in performance improvement efforts from all clinical sections. This past year, all sections were routinely represented, and residents and fellows attending QM meetings participated in the biennial 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 in-house 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.

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Quality Management Chair: Armando Filie, MD Date

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Medical Director: Frederic G. Barr, MD, PhD Date