DEP ARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Laboratory of Pathology, NCI, CCR

MEMORANDUM

January 12, 2024

TO: Laboratory of Pathology (LP) Clinical Staff

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

SUBJECT: **2023 Annual Review of Efficacy of the Quality Management Plan for the Laboratory of Pathology**

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. As has been the standard practice in LP, the 2023 QM Indicators assess pre-analytic, analytic, and post- analytic phases of testing. These have included: components to monitor turnaround times, intra-operative correlations, corrected reports, delays in obtaining surgical specimen orders, patient identification events, specimen processing and quality control (QC) errors.

RESIDENTS' QI PROJECTS

The LP QM program also incorporates "projects" that are planned, implemented, and monitored by LP's Clinical Residents and Fellows; these projects 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 CY2023 included: CAP cancer protocols reporting, accessioning errors for submitted surgical cases, reporting and follow-up of predictive markers, missing slides, clinical notification of unusual findings/revised or corrected reports, and compliance with IHC daily control QC. The residents' projects were reported quarterly to the QM Committee. Faculty advisors set meetings early in the year to provide background to the residents/fellows who are conducting these projects. Advisors reviewed data quarterly before presenting to the QM Committee. Projects were tracked and kept on task with documentation of new monthly findings and improved recommendations. A goal in CY2024 is to ensure faculty and clinical residents continue to participate in developing indicators, plans of assessment, and corrective actions for both monthly meetings and resident projects.

CUSTOMER SATISFACTION SURVEY

The LP Customer Satisfaction Survey (CSS) is on a biennial rotation and the most recent survey was completed in November 2023. 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 results from the Customer Satisfaction Survey will be reviewed with the Branch Chief, Medical Director, Clinical Laboratory Manager and discussed during a monthly Quality Management Committee meeting.

SUMMARY & RECOMMENDATIONS:

The 2023 QM program included monitoring of quality indicators from each clinical service, as well as common areas that affect the LP. The QM Committee also reviews and discusses issues affecting staff safety, environment of care, customer satisfaction and performance improvement efforts. The monthly QM program reviews and addresses quality indicators and identifies areas for improvement. The QM Committee's goal is to maintain at least 12, but no more than 20 indicators; this past year focused on 20 quality indicators.

SUBMITTED SURGICAL TURNAROUND TIMES:

Submitted surgical cases turnaround times were modified from 7 to 5 working days in CY2022. This threshold has posed challenges throughout CY2023, and the 5-day TAT was only successfully achieved in January 2023. The Medical Director, in consultation with the surgical pathologists in the QM Committee, opted to concurrently monitor the 7-day and 5-day turnaround times in the monthly reports with the long-term objective to reach the 5-day goal.

NCI-COMPASS:

The COMPASS program continues to increase in volumes, including increases with in-house and submitted consult cases received from physicians CONUS and internationally. The NGS pre-analytic and analytic QM indicators have demonstrated consistency with meeting thresholds, with only January failing to meet the threshold for turnaround time for the CY. The Methylation section also demonstrated consistency with meeting TAT thresholds, with only one outlier in February due to an increased number of cases requiring reflex testing.

SMALL BIOPSY TURNAROUND TIMES:

In mid-2022, the threshold for the Small Biopsy TAT was revised from 7 working days to 5 working days based on QM Committee discussions and with the approval of the Medical Director. The revision in TAT was difficult to meet; however, we were able to achieve this threshold for 5 months in CY23, with a positive trend of consistently meeting the threshold for the last four months. The 5-day TAT continues to be the goal for CY24.

COMPLEX CASES TURNAROUND TIMES:

The QM Committee revised the turnaround times for complex surgical cases from 10 days to 8 days in July 2022 due to consistency in improved turnaround times. This was attributed to better communication of the pending lists with residents and attendings, and evaluating each >10 day case with the involved pathologist(s). For CY 2023, the revised goal of an 8 day TAT in 90% of these cases was accomplished in 7 of the 12 months. The QM committee continues to address each >10 day outlier.

FAD TURNAROUND TIMES:

In the December 2022 meeting, the Medical Director and Chief of PostMortem Services agreed with the clinical residents' request that, while 45 days should be the goal, the 60-day mandated turnaround will be the expected threshold. The plan was later updated in mid-2023 to establish that a preliminary warning will be sent to the residents at the 45 day mark, and for cases over 60 days, the responsible resident would need to meet with the Branch Chief, Chief Resident, and the Residency Director to address this problem and plans for process improvement. During CY23, there were four months in which autopsy case TAT exceeded 60 days, these cases provided feedback and were discussed with our QM Committee and Technical Director for Post-Mortem Services.

SUMMARY:

Overall, there were more positive than negative outcomes for the CY2023 QM Program. The QM Committee will determine if any indicators can be removed and if other relevant indicators can be evaluated and/or added. During CY2023, the Laboratory of Pathology's clinical services demonstrated consistently good participation in performance improvement efforts from all clinical sections. All sections were routinely represented at QM meetings, and residents and fellows actively participated in monthly meetings and the biennial CAP accreditation self-inspection as inspectors. Residents provided important feedback on issues associated with pre-analytical issues, such

as reasons for solutions with missing IHC quality control reviews, and reasons for delays in the in-house and submitted services. The LP QM program encompasses all laboratory services and has been instrumental for process improvement in multiple aspects of LP's clinical services.

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