DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MEMORANDUM

January 18, 2022

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: **2021 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 2021 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.

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 CY2021 included: missed CAP cancer reporting; accessioning errors for submitted surgical cases; interobserver variability; missing slides; notification of unusual findings; 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 CY2022, 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.

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2021 CUSTOMER SATISFACTION SURVEY

The 2021 Customer Satisfaction Survey was completed in December of 2021. 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 were reviewed with the Branch Chief, Medical Director, Clinical Laboratory Manager and Quality Management Chair. The survey results will also be presented and discussed at the next LP Senior Staff Meeting. Areas with the most significant decrease in satisfaction include: Availability of staff of staff pathologist and the quality of professional interaction and communication with the staff pathologists. 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 fellow and resident pathologists, Quality of professional interaction and communication with the secretarial, technical, and management staff, Availability of fellow and resident pathologists, Quality of presentations and conferences and Overall turnaround time of final report.

SUMMARY & RECOMMENDATIONS:

The 2021 QM program was all-encompassing and addressed indicators from each clinical service, and common areas that affect the LP. 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 21 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).

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 suggested separating different thresholds for the Molecular Diagnostics program from receipt, processing, extraction, testing, variant report to report sign-out. Two new indicators were implemented in CY21 including the turnaround time of COMPASS-Single Test Cases and the turnaround time of COMPASS-Next Generation Sequencing Cases to monitor cases more accurately. Thresholds were established and outlier feedback was provided from both the laboratory and pathologist to properly document where delays occurred. The Branch Chief addressed the importance of signing out cases in a timely manner with Molecular Pathologist during a COMPASS meeting, and the pending case

list is now reviewed weekly with the Molecular Pathologist during the COMPASS meetings to prevent outlier cases.

While preparing for the College of American Pathologist Biennial Self-Inspection for 2021, there were many documents pending signatures in MediaLab. MediaLab was implemented as the Document Control tool for LP and is used for all accreditation inspections. We began tracking pending employee signatures as an indicator in CY21 to ensure timely review of policies and procedures by the technical director designee and/or new or significant revised policies to the medical director for review. The intent of the indicator was to keep MediaLab in our forefront as all LP staff were adjusting the MediaLab format. As we have become more familiar with this platform, the QM Committee and Medical Director determined this monthly indictor should be removed and reviewed annually.

The QM Committee monitors revised reports as a monthly indicator. When a report is modified with information that impacts clinical care, it is required that the treating clinician be notified of the revision. A significant issue the QM Committee observed during CY2021 was insufficient documentation of the notification of revisions to the treating clinician. To prevent this from reoccurring, a Call Request and canned message were added to the revised report template, which needs to be completed prior to sign-out of the revision. This helps the QM Committee ensure all treating physicians were properly notified, while also accurately documenting the notification in the final revised report.

Overall, there were more positive than negative outcomes for the CY2021 QM Program. The QM will be tasked with maintaining 20 indicators in CY2022, to continue to evaluate the NCI-COMPASS program deeper. The QM Committee will determine if any indicators may be removed and/or other relevant indicators evaluated and/or added.

2022 PLANS:

- The CY2022 QM Plan will be reviewed with input of the Quality Management Committee in February of 2022 with final approval from the Medical Director.
- There will be no new indicators added in CY2022 as the program already encompasses the Laboratory of Pathology.
- The Policies and Procedures Mandatory Review in MediaLab indicator will be removed and monitored annually in October, as staff have become more familiar with the platform.
- The QM committee will continue to review the necessity for new quality indicators needed to address industry norms or variances within the department.

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CONCLUSION:

During the CY2021 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: preanalytical 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.

Reviewed and discussed in January 15, 2022 QM Committee meeting

Quality Management Chair: Armando Filie, MD

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

Medical Director: Frederic G. Barr, MD, PhD