QUALITY MANAGEMENT (QM) PROGRAM
Laboratory of Pathology: 2018

Purpose:

The Quality Management (QM) program is designed to continually evaluate the quality of clinical services generated throughout the Laboratory of Pathology (LP). This is accomplished by: monitoring and evaluating quality improvement indicators for the LP; ensuring continuous compliance with quality control and preventative maintenance policies by LP sections; addressing quality outliers and incident reports (addressing system issues); and ensuring all LP Clinical Sections are in compliance with the College of American Pathologists (CAP) standards and guidelines to ensure compliance with the Clinical Laboratory Improvement Amendments (CLIA-88) statutes that govern clinical laboratory medicine. The LP QM Committee oversees the program.

General Requirements

The QM program is an LP-wide initiative and quality indicators and reports cover all clinical areas. According to the College of American Pathologists, LabGEN Checklist, v. 8/17/2016, the laboratory must have a written quality management program to systematically ensure the quality of laboratory services. In laboratories that are part of a larger institution (e.g. a hospital), the laboratory quality management program must be integrated with the institutional program. In accordance with the CAP standards, GEN.13806, GEN.20100, GEN.20208, and GEN.20316, the laboratory has a written quality management program that covers the extent of all clinical services and establishes policies and procedures to identify and evaluate errors or issues that may interfere with patient care, and the QM program includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases.

A list of indicators is provided below. Some clinical sections can opt to devise additional QI plans to monitor and document a set of relevant indicators based on their section's regulatory standards (e.g. CAP standards for turnaround times). Indicators for individual sections' quality reports should include pre-analytical, analytical, and post-analytical variables.

QM Plan Overview

- All clinical sections are given the opportunity to report their section specific quality plans and subsequent end-of-year reports to QM Committee to share quality initiatives across clinical sections.

- In addition to the annual report for these sections, General Anatomic Pathology (AP): Autopsy and Histology Laboratory's QA Sheets, and LP and the Clinical Center's Environment of Care will be reviewed during each QM Committee meeting.

  (Histology is the primary clinical processing laboratory, therefore monthly monitoring of quality issues are important to report to QM committee).

– Improve identification, communication, and correction of errors in a timely manner. Specific criteria approved by QM Committee require that all sections establish and define any incidents/complaints to address, monitor and report to QM Committee on a monthly basis. The objective is to identify and resolve consistent or recurrent complaints or incidents that affect all LP clinical laboratories. Action items will be addressed by the QM Committee.

- The QM program must include a process to identify and evaluate errors, incidents and other problems that may interfere with patient care services (GEN.20208). LP staff have several mechanisms to identify and report any quality issues or concerns: a) LP currently participates in the Clinical Center's Occurrence Reporting System (ORS), which is a mechanism to report hospital-related incidents to Clinical Center clinicians, nurses, and allied health professionals; b) LP's internal Incident Reports, where LP staff reports internal and/or external quality concerns to the QM committee or Clinical Manager; and c) the Clinical Center has adopted a 'Morning Huddle' at 08:20 each weekday morning, which is attended by each clinical department, nursing units representatives, and support services representatives and is a forum for any healthcare professional to report on concerns that may benefit from other hospital departments.

Method of Implementation

The LP QM program will be devised and monitored by the QM committee. Indicators to be monitored and reported include: pre-analytical (number of cases without requisitions), analytical (turnaround time for SI and SB cases), and post-analytical (number of revised reports). Detailed specifications for the LP QM program and AP QI plan are listed below. The QM committee recommends that each laboratory/ section/ unit devise and monitor quality indicators specific to their discipline. The section's QM plan should improve patient safety and the quality of services provided by LP. Although a formal written and verbal report will not be required, updates on individual efforts to improve patient safety and quality of services will be requested by the QM committee.

The QM committee will monitor the process related to patient safety (CAP and JCAHO Laboratory Patient Safety Goals) on an annual basis. The committee will utilize several parameters in this process including the annual QM reports from the required LP laboratories/units/sections; outcomes of events reported to the QM committee via QI tracker/QI log or directly to either the QM committee chair or Clinical Lab Manager; participation of QM committee chair in the Surgical Administrative Committee (SAC); and reporting of relevant LP QM findings to Clinical Center/NIH office(s) involved in patient care and safety.

The QM committee will monitor the process related to occupational injury/illness in the LP at least on a quarterly basis. Each Unit/Section/Laboratory will submit all OMS reports to the Clinical Laboratory Manager. The OMS reports must not contain any personal identifiers. The OMS reports will be reviewed by the Clinical Laboratory Manager and reported to the QM committee to identify any common issues that could potentially impact other LP Units/Sections/Laboratories.

General Requirements of the QM Committee

The QM Committee will meet to review the effectiveness of the QM program and to follow-up on any corrective actions taken. Minutes of each QM Committee review will be generated to document the effectiveness of the QM program and to include any recommendations made to improve the QM program. However, overall review and approval of the QM program is the responsibility of the Laboratory of Pathology's Medical Director.

The QM Committee will include: (1) the Chief or Deputy Branch Chief of the Laboratory of Pathology; (2) the QM Committee Chairman (a physician representative), (3) the Clinical Manager, (4) the LIS Administrator, (5) a representative from each LP laboratory/unit/section, and (6) members of the AP residency and clinical fellowship programs.

All pathology residents onsite are expected to attend QM committee meetings for the purpose of providing educational experience and an opportunity to contribute to the ongoing improvement efforts of the QM committee. Hematopathology and Cytopathology fellows will attend the QM committee meetings as "guests" with the purpose of providing an educational experience with issues related to quality assurance, quality improvement and quality management.

PROCEDURE FOR IMPLEMENTATION OF QM PROGRAM
Laboratory of Pathology: 2018

Defined Laboratory/Unit/Section Head:

Medical Director – Kenneth Aldape
Autopsy - David Kleiner
Chromosome Pathology Unit – Svetlana Pack
Cytopathology – Armando Filie
Flow Cytometry - Maryalice Stetler-Stevenson
Hematopathology - Elaine S. Jaffe
Immunohistochemistry –Markku Miettinen/Armando Filie
Molecular Pathology - Mark Raffeld
Surgical Pathology – Markku Miettinen
Clinical Operations - Joseph Chinquee (Clinical Manager)
Histology - Michael Newford (Supervisor)

The Section Head, Technical Director or Chief Medical Officer for each LP laboratory/section/unit is responsible for establishing section-specific quality plans and for overseeing the section's overall quality plan and indicators. Each plan should include at least one pre-analytical, one analytical and one post-analytical indicator. Suggested indicators are listed below (indicators marked with [*] are related to patient safety). For each indicator monitored, the following should be documented:

(1) **Goal/Threshold**...What is the goal for the monitored indicator? For example specimen adequacy, what constitutes an adequate (or inadequate) specimen? An indicator for specimen adequacy might be *tissue viability*. The Goal/Threshold for an adequate specimen might be "viability of sample should exceed 40%."

(2) **Events not meeting goal/threshold**...For each indicator, raw data is collected monthly and events not meeting goal/threshold may require further investigation. Using the above example, all samples with viability below 40% are documented.

(3) **Corrective action taken**...Corrective actions should include both **reactive** and **proactive** actions. Using the above example, contacting the physician who obtained the sample to report problems with viability would be a reactive action. A proactive action might include sending out an annual memo to physicians instructing them how to procure samples with the best possible viability.

Suggested QI Indicators

Section quality indicators should include pre-analytic, analytic, and post-analytic variables. Monitors should incorporate elements to identify areas for improvement with patient safety issues and improve the accuracy of results reported on our patients.

1. Specimen adequacy

To generate excellent data for patient care, specimens analyzed must be adequate and appropriate for analysis. Each chief/director should address the issue of what determines an adequate/appropriate specimen for his or her respective service (goal).

II. Appropriateness of test(s) ordered

When relevant, are the tests ordered appropriate? For example, a clinician ordering daily cytogenetics on bone marrow biopsies for the purpose of monitoring minimal residual disease is inappropriate.

*III. Turnaround time**

When relevant, what is the acceptable turnaround time for a given test/analysis?

*IV. Patient/Specimen Identification**

This indicator will include identification errors with specimens submitted by nursing/medical staff, labeling errors (or unlabeled specimens) received in the lab; misspelled or incorrect demographics on specimen or requisition labels; and laboratory labeling errors to include blocks, slides, or records.

V. Test Order Accuracy

Percent of test orders correctly entered into a laboratory computer.

*VI. Revised Reports**

Percent of reports that are revised - relative to the total workload. For example, total revised reports for routine small biopsies that impacted, or had the potential to impact patient care, are important to monitor.

VII. Quality Control / Preventative Maintenance Review

To ensure staff perform required test quality control procedures and preventative maintenance as required per standard operating procedure.

2018 QM Program - AP QI Plan
Method of Implementation:

Specific Requirements

The Quality Management program includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases (GEN.20316). These indicators aim to monitor activities critical to patient outcomes or that may affect the patient care. Although the CAP does not mandate specific indicators, the LP QM program has adopted some of the key quality indicators that are commonly used to measure laboratory performance in a consistent manner and that are important to clinicians and patients as indices of care (e.g. specimen identification, customer satisfaction, and corrected reports).

The LP QM program also incorporates the AP QI plan to review and discuss the quality reports of at least 12, but no more than 20, Quality Indicators (QI) chosen by the committee and reviewed/approved annually for effectiveness by the Medical Director. The plan for each indicator is listed on the monthly reports and updated as necessary by the committee. Actions taken if goals are not met will be documented in the minutes. The following quality indicators have been approved by the QM committee as the 2018 Quality Indicators will be in effect from February 1, 2018 through January 31, 2019, and may be extended into the next calendar year if not revised by the QM committee and Medical Director.

The majority of indicators for the AP QI plan relate to the CAP Laboratory General and Section-Specific Checklists, or are derived from best-practice indicators for clinical laboratories:

Analytic:	1. Comprehensive Cytology (Medical and GYN Cytology TAT)
Analytic:	2. Small Biopsy TAT
Analytic:	3. Complex Cases TAT
Analytic:	4. Intraoperative (Frozen Section) TAT
Analytic:	5. Autopsy TAT (Final Autopsy Report)
Post-Analytic:	6. Intraoperative Correlation (Frozen Sections)
Post-Analytic:	7. Revised (Corrected) Reports
Pre-Analytic:	8. Patient Identification Error, Unlabeled Cases or Missing Patient Information
Pre-Analytic:	9. Requisitions Not Submitted
Pre-Analytic:	10. Molecular Diagnostics Specimen Adequacy
Analytic:	11. Molecular Diagnostics Turnaround Time
Pre-Analytic:	12. Chromosome Pathology Unit Specimen Adequacy
Analytic:	13. Chromosome Pathology Unit Turnaround Time (TAT)
Pre-Analytic:	14. Flow Cytometry Bone Marrow (BM) Specimen Adequacy
Pre-Analytic:	15. Immunohistochemistry Pre-Analytic Errors
Analytic:	16. Immuno Analytic Errors (Requests for Repeat Stains, QA issues)
Analytic:	17. Submitted Service (SS/SJ) TAT
Post-Analytic:	18. Medicolegal & Return Material TAT

1. Medical and GYN Cytology Comprehensive Turnaround Time

The quality of services provided by a laboratory may be measured by the TAT of tests done by the lab. A recent study collected data on TAT for medical (non-gynecological) cytology from 180 laboratories. Results showed that labs in the top 50 % of participants would have 90% of medical cytology cases with TAT (receipt to report) of 3 calendar days. It was not mentioned what types of laboratories participated in the study; however, it is likely that a large portion of participants were nonacademic labs. LP provides anatomic pathology services for the Clinical Center as well as 21 different Institutes of the National Institutes of Health (NIH). NIH is a large clinical/research institution where all patients participate in protocol studies for various diseases and disorders including rare syndromes and cancers. Only a minority of patients requires a primary diagnosis. A significant number of medical cytology cases require additional ancillary studies and/or further workup to confirm primary diagnosis exclude secondary malignancy/disorder or include additional studies mandated by protocol. Therefore, the process involved in signing out medical cytology cases at the NIH is more complex and does not reflect the medical cytology cases seen at more "conventional" cytology labs where primary diagnosis is often the main concern. In addition, the NIH LP is a teaching department with accredited residency and fellowship programs in anatomic pathology. These facts must be taken into consideration when defining a threshold for medical cytology TAT. As reported by ADASP for TAT in surgical pathology cases, extra time should be allowed for cases requiring recuts, immunohistochemistry, etc. The same principal is valid for medical cytology cases. The threshold established for medical cytology TAT was based on the above information and also in accordance with expectations of SAC. A prospective study on the TAT for gynecologic cytology specimens including 371 laboratories showed that half of the participating labs were able to sign out 90% of the cases within 8 calendar days. Typically these labs have a large volume of gynecologic cytology specimens. The number of gynecologic cytology cases seen at LP is low. Based on this observation and also in accordance with SAC expectations, the TAT for gynecologic cytology established by the committee is within the expected TAT for our patient population. The volume of GYN cases is limited; therefore, a more relevant quality monitor is the comprehensive turnaround times for Medical and GYN cases for the month.

Threshold: 90% of medical and gynecologic cytology cases signed out within 5 working days.

2. Small Biopsy Turnaround Time

The quality of services provided by a laboratory may be measured by the TAT of tests done by the lab. A recent study collected data on TAT for routine biopsy specimens (small biopsy) from 157 small private and public hospitals in the U.S. (153) and abroad. Results showed that approximately 86% of cases were signed out within 2 working days.5 LP provides anatomic pathology services for the Clinical Center as well as 21 different Institutes of the National Institutes of Health (NIH). NIH is a large clinical/research institution where all patients participate in protocol studies for various diseases and disorders including rare syndromes and cancers. Only a minority of patients requires a primary diagnosis. A significant number of biopsy cases require additional ancillary studies and/or further workup to confirm primary diagnosis, exclude secondary malignancy/disorder or include additional studies mandated by protocol. Therefore, the process involved in signing out biopsy cases at the NIH is more complex and does not reflect the biopsy cases seen at more "conventional" surgical pathology labs where primary diagnosis is often the main concern. In addition, the NIH LP is a teaching department with accredited residency and fellowship programs in anatomic pathology. These facts must be taken into consideration when defining a threshold for small biopsy TAT. As reported by ADASP for TAT in surgical pathology cases, extra time should be allowed for cases that needed recuts, immunohistochemistry, etc.3 Therefore, the threshold established for small biopsy TAT was based on the above information and also in accordance with expectations of SAC.

Threshold: 90% of small biopsy cases signed out within 7 working days.

3. Complex Cases Turnaround Time

The quality of services provided by a laboratory may be measured by the TAT of tests done by the lab. A study collected data on TAT for complex surgical pathology cases from 489 laboratories in the U.S. and abroad. Results showed that 60 % of complex special-handling cases were signed out within 2 working days. The median TAT was 2.6 days with a range of 0-13.5 days.6 LP provides anatomic pathology services for the Clinical Center as well as 21 different Institutes of the National Institutes of Health (NIH). NIH is a large clinical/research institution where all patients participate in protocol studies for various diseases and disorders including rare syndromes and cancers. Therefore, the LP surgical pathology complex cases are considered special handling complex cases. In addition, a significant number of complex cases require additional ancillary studies and/or further workup to confirm primary diagnosis, exclude secondary malignancy/disorder or include additional studies mandated by protocol. The NIH LP is also a teaching department with accredited residency and fellowship programs in anatomic pathology. These facts must be taken into consideration when defining a threshold for complex cases TAT. As reported by ADASP for TAT in surgical pathology cases, extra time should be allowed for cases requiring overnight fixation, resubmission, recuts, immunohistochemistry, etc.3 The threshold established for complex surgical pathology cases was based on the above information and also in accordance with expectations of SAC.

Threshold: 90% of complex cases signed out within 10 working days.

4. Intraoperative (Frozen Section) Turnaround Time

Frozen Section (IOC) is an essential tool for patients undergoing surgery to aid the surgeon with a rapid diagnosis; therefore, IOC turnaround time (TAT) might have direct impact on patient's therapy and safety during and after surgery. This indicator results from the CAP's Anatomic Pathology checklist question ANP.11820, supported by a CAP Q-Probe study of 32,868 frozen sections in 700 hospitals (Archives of Pathology Lab Medicine, 1997; 121:559-567) which suggests that 90% of frozen sections should be completed within 20 minutes. Twenty minutes is intended to apply to the typical single frozen section, and cases involving multiple sections on a single specimen or case (e.g., resection margins) should expect longer TATs. The threshold is established in accordance with the CAP standard and all outliers will be evaluated by the QM committee and recurring reasons will be addressed with the residents and faculty.

Threshold: 90% of frozen sections will be completed within 20 minutes average

5. Autopsy Turnaround Time

Autopsy reporting is an important part of the quality management of medical care. It may be the only tool for answering questions and is the gold standard for determining the cause of death. Autopsies serve to identify diseases that were unknown at the time of death. The NIH Clinical Center Medical Records Department, in line with JCAHO standards has set a goal for all final autopsy reports to be returned within 60 calendar days of the autopsy. The CAP's standard is set at 60 working days and requires ongoing review of cases failing to meet this deadline. Accordingly, the QM committee will review the TAT on all final autopsy reports, and assess possible resolutions to prevent similar future outliers.
Threshold: All autopsy Final Autopsy Diagnosis (FAD) must be signed out within 60 calendar days of the performance date of the autopsy. Outliers must have documentation to identify the reason for the delay, and an evaluation by the chief medical officer to determine future corrective actions to prevent similar delays.

Threshold: 100% within 60 working days

6. Intraoperative Correlation (Frozen Sections)

Discrepancies between frozen section and final diagnosis that significantly impact on patient's treatment and/or management (major discrepancies) will be tracked and reported to the committee. The QM committee will address major discrepancies and compliance with IOC review during each QM meeting. Through CAP's Q-Probe program, which survey 90538 ICs performed in 461 institutions and found a case disagreement rate of 2% when uncorrected for deferred cases. A recent study of IOC and final diagnosis looked at 2812 specimens, which had a 96.75% agreement. Findings from the CAP's W-Tracks and Q-Probes show those who monitor this as a quality indicator have a IC/FD disagreement rates close to 2% with improved performance over time.

Threshold: ≤2% of major discrepancies

7. Revised (Corrected) Reports

The number of revised reports for reasons that significantly impact on patient's care (major reasons) will be tracked for AP as well as for all other LP sections/units/labs and reported to the committee. In accordance with the CAP's 2008 National Laboratory Safety Goals, all inaccuracies will be documented and communicated as soon as an inaccuracy becomes known. Significant impact to patient care will be assessed by a pathologist, and in accordance with the CAP Safety Goals, the pathologist should discuss the matter with the physician who ordered the consultation to determine how best to communicate the result to the patient. Compliance of this quality indicator will be assessed by reviewing all corrected reports and documentation.

Threshold: 0 with significant negative impact to patient care

8. Patient Identification Errors, Unlabeled Cases or Missing Patient Information

Another relevant CAP National Laboratory Safety Goal is to improve patient and sample identification at specimen collection, analysis, and reporting. LP staff documents identification errors with mislabeled specimens, slides, unlabeled cases, or reports and records with missing or inaccurate patient information. For 2010 quality indicators, SB (small biopsy) and SI (complex cases) for surgical pathology specimens will be tracked and system improvements addressed by QM Committee in partnership with section chiefs. A CAP study focused on 136 laboratories, with 427,255 reviewed cases where 0.4% (1811 cases) had some sort of mislabeling. The overall mislabeling rates per 1000 were 1.1 cases, 1.0 specimen, 1.7 blocks, and 1.1 slides. .00

Threshold: ≤ 5% of total SB/SI cases.

9. Requisitions Not Submitted for SB/SI cases

The number of small biopsy cases and complex cases that are submitted to the Surgical Pathology Section without a requisition will be tracked. The requisition should accompany the cases or should be forwarded to Surgical Pathology to prevent processing delays. According to CAP GEN.40700, All specimens are to be accompanied by an adequate requisition. Nakhleh & Fitzgibbons (CAP QM for AP, 2005) state that a requisition must accompany all specimens, and all identifying information on the request must match that on the specimen container. Further recommendation includes monitoring a subset of requisitions at least quarterly for completeness.

Threshold: ≤ 5% of cases without a requisition for more than 24 hours.

10. Molecular Diagnostics Specimen Adequacy

The quality of services provided by the laboratory is related to the condition of the sample received and the receipt of correct documentation. The molecular diagnostics laboratory assesses the adequacy and documentation of all specimens received. Blood and bone marrow samples must be received with adequate anticoagulation and should not be clotted. All blood and bone marrow specimens must have at least 1 ml of sample. Unstained slides and paraffin blocks must contain sufficient tissue for analysis. The sample must be labeled with the patient's name or other clear identifier, and must be accompanied by a CRIS or Softpath order specifying the specific test.

Threshold: 0 specimen submission and processing errors

11. Molecular Diagnostics Turnaround Time

The quality of services provided by a laboratory may be measured by the TAT of tests done by the lab. The Molecular Diagnostics laboratory continues to strive to improve and maintain satisfactory report time from specimen receipt through final report. There are currently no industry standards or norms for the turnaround time of Molecular tests. Based on our patient population (research based) and expectations of our medical staff, eleven working days is established as the initial threshold. As this indicator is monitored, future consideration to decrease the threshold will be considered.

Threshold: 90% of cases reported within 8 working days of receipt.

12. Chromosome Pathology Unit Specimen Adequacy

The quality of services provided by the laboratory is related to the condition of the sample received and the receipt of correct documentation. The Chromosome Pathology Unit assesses the adequacy and documentation of all samples received. In most cases, one H&E stained and four unstained slides per patient/sample are required. H&E stained should be reviewed by a pathologist who may designate tumor area(s) for analysis. Unstained slides must contain sufficient tissue for analysis. The sample must be labeled with the patient's name or other clear identifier, and all cases must be accompanied by a CRIS or Softpath order specifying the specific test.

Threshold: 0 specimen submission and processing errors

13. Chromosome Pathology Unit Turnaround Time (TAT)

The quality of services provided by a laboratory may be measured by the TAT of tests done by the lab. The Chromosome Pathology Unit (CPU) continues to make every effort to improve and maintain satisfactory report time from specimen receipt through the final report. The current industry standard for the turnaround time of FISH tests for formalin fixed paraffin-embedded (FFPE) tissues is 7 days [8]. Based on this observation, the TAT for the FFPE FISH established by the QM committee is within the expected TAT for our patient population.

Threshold: 90% of cases reported within 7 working days of receipt

14. Flow Cytometry Bone Marrow (BM) Specimen Adequacy

Optimal specimen quality is vital for successful flow cytometric immunophenotyping. Clotted specimens may result in loss of the cells of interest and may compromise test result accuracy. The technologist performs gross inspection on all specimens to detect non-optimal specimen conditions. Clots in all specimens are noted upon specimen receipt in the Softpath Specimen Source Modifier field during accessioning on in the Gross Section of the Final Report. The QM committee will monitor the number of clotted specimens received by Flow Cytometry.

Threshold: ≤ 5% of BM specimens received with clots

15. Immunohistochemistry Pre-Analytic Errors (e.g. Patient Identification, Processing issues)

A 1994 Q-Probes study involving over one million cases from 417 institutions documented identification and accessioning deficiencies in 6% of total cases accessioned, with a median deficiency rate of 3.4%. Errors related to specimen identification accounted for 9.6% of these deficiencies, discrepant or missing information were present in 77%, and 3.6% involved specimen handling[6]. This quality indicator was established in CY2015, and the initial threshold established for allowable errors for pre-analytic variables (e.g. patient identification, processing, and handling events) measured against total IHC cases stained for the month was consistently less than 5 percent. CAP checklists (GEN.40490), (ANP. 11950), (ANP. 11950) establish a standards for Patient Identification.

Threshold: ≤ 0.5% of all IHC stains ordered per month will have no pre-analytic errors. This is a preliminary threshold, and will be reassessed for possible 99% confidence interval mid-year.

16. Immunohistochemistry Analytic Errors (e.g. Requests for Repeat IHC Stains, QC issues)

An inadequate immunohistochemical stain may be the result of less than optimal tissue fixation, selection and/or processing, antibody failure, or technical factors. It is important that the lab document all requests for repeat stains, the reason for the request, the corrective action performed, and final outcome[6]. Whether an IHC request for repeat is due to technical, clerical, or procedural error, the reasons to repeat stain requests should be reviewed for trends to determine if there are system errors that should/could be implement to prevent recurring quality failures that result in repeat stains. The IHC laboratory has developed a tracking sheet to document. CAP checklist (ANP.21450) Special Stain quality, all immunohistochemical stains should be of adequate quality, and daily controls are demonstrated on each day of use for the tissue components or organisms for which they were designed. Some examples of common problems include: high background, periphery staining, no or weak staining, and tissue detachment. All analytic errors and repeat requests will be reported and assessed.

Threshold: ≤ 0.5% of repeated IHC stains

17. Submitted Surgical Pathology Cases (SS & SJ) Turnaround Time (Analytic)

An integral component of the LP clinical service is review of submitted surgical materials for patients being considered for an NIH research protocol. Additionally, LP pathologists are considered experts in certain disciplines, and their consultative services are requested by non-NIH institutions for the rendering of a second opinion. Variables to consider while assessing issues with the submitted service turnaround times include: Identifying the purpose for the Consult (e.g. some second opinion rather than protocol-driven); The type of Consult - Is the patient being considered for protocol – is it a personal consultation or second opinion for a specific pathologist; were there additional documents requested from submitting facility (NIH staff or submitted outside source) that is not within the scope of control of LP staff; or consideration if the submitted case for patient protocol review was received without accompanying paperwork from the submitting clinic. This indicator is implemented in order to determine if there are system errors, or specific variables, that contribute to extended turnaround times, that might be addressed.

Threshold determination: According to Volmar, K., et. al., (2015), median turnaround times in government institutions was 6.06 days for complex surgical specimens (based on a 2012 CAP Q-Probes Study of 56 Institutions reported on 2,763 large or complex cases). Considering there are potential processing issues, such as requesting additional material or missing paperwork, and also considering this includes routine consults that are less time-critical are mixed with consults for protocol consideration. Initially, 90% within 10-days was evaluated, similar to the turnaround time indicator for complex surgicals; however, initial data demonstrates that 90% within 7 days is a more effective threshold. This, and all thresholds, are reviewed periodically by the QM Committee and the Medical Director, and can be revised to strive for further improvement.

Threshold: ≥90% within 7 days

18. Medicolegal and Return Material Turnaround Time (Post-Analytic)

LP's Surgical Pathology service routinely receives requests to have non-NIH submitted patient material (stained, unstained slides recut or whole blocks (less frequently)) returned to the submitting facility or forwarded on to another facility at a patient's request if that patient is being treated or being considered for another protocol in that facility. It's an important responsibility that LP staff process patient requests to forward pathology material to other facilities. Additionally, patients who are on multiple protocols in various health care organizations routinely ask that their material be returned to the submitting facility so that they can send on to other facilities. Historic customer satisfaction surveys provided feedback that having material sent to other facilities may take too long, so this indicator was created to monitor the turnaround times for return material requests.

Threshold determination: Numerous factors can contribute to the time it takes from receipt of a request for material until the time it is mailed to the requesting facility. A formal requisition is needed, determination if and/o how much material can be released to that facility, availability of the material (time to recut if necessary), release by the attending pathologist, and administrative staff availability to process the paperwork and physically mail the material. For the purpose of evaluating an initial threshold, we referenced Giannini et al. (2011), of the Mayo Dept of Lab Medicine and Pathology, which esablished expected return of their submitted material at 14 days for clinical cases and 6 months for materials requsted for research or education. A focus on the clinical expectation, and based on LP's initial QM data which suggests that 7 to 10 days from receipt of request would be a more appropriate target, the Medical Director has requested setting the threshold at the lower limit and eventually strive to improve even that threshold.

Threshold: ≥90% withing 7 days

ANNUAL QUALITY MANAGEMENT PROJECTS – REGULATORY COMPLIANCE (RC)

RC-I. Biennial Customer Satisfaction Survey – GEN.20335 (due November 2019)

The Laboratory of Pathology measures the satisfaction of healthcare providers with laboratory services every two years. Satisfaction metrics are important for understanding the needs of clients (physicians, patients, referring laboratories, nurses, etc.) to improve laboratory services. Experience has shown that surveys are more informative if they are conducted anonymously and allow for open ended comments. The sample size should be adequate. A numeric satisfaction scale allows for calculation of statistics.

RC-II. Quality of Water – GEN.41500 (due March / October 2018)

The quality (specifications) of the laboratory's water, whether prepared in-house or purchased, must be checked and recorded at least annually. The frequency and extent of checking may vary, according to the quality of source water and specific laboratory needs. Corrective action must be recorded if water does not meet acceptability criteria. LP conducts biannual PMs and tests for maximum microbial content (CFU/mL) <10.

RC-III. Biennial Report Format and Content Review (due October 2019)

The laboratory director (or a designee who meets CAP qualifications for laboratory director) must review and, at least every two years, approve the content and format of laboratory patient reports (whether paper or computer screen images) to ensure that they effectively communicate patient test results, and that they meet the needs of the medical staff (GEN.41067).

RC-IV. Patient Confidentiality QM Review (due March 2018)

In order to satisfy the CAP revised standard GEN.41303, Patient Confidentiality QA, the Laboratory of Pathology will conduct an annual audit of compliance with the NIH and LP patient confidentiality policies. LP policies dictate that: 1) requests for release of patient reports must be initiate from the NIH Clinical Center's Medical Records department, or based on the distribution list provided by the submitting clinician for consultative and submitted cases; and 2) any report released electronically will be encrypted when released to internal NIH health care providers, and/or password protected file(s) when submitting reports to the patients' non-NIH health care provider(s).

RC-V. Pending Supplemental Reports (due March 2018)

Because of the nature of LP's patient workload, there are occasions that supplemental reports are added to case(s) without having been signed out. Examples of reasons can include: duplicative orders; the result was reported with an associated clinical case (e.g. Molecular result reported with the Surgical case); or the supplemental could have been delayed for sign-out. Because the supplemental reports do not show up on pending lists, the QM program will review pending supplemental pathology reports at least annually. Pending supplemental reports will be resolved as soon as identified. However, if recurring issues are demonstrated or if there is the potential to impact patient care based on the annual review, the project could potentially become a recurring quality indicator.

RC-VI: Intradepartmental-Observer Variability – Predictive Markers

For immunohistochemical and FISH/ISH tests that provide independent predictive information, the laboratory at least annually compares its patient results with published benchmarks, and evaluates inter-observer variability among the pathologists in the laboratory. NOTE: Individuals interpreting the assay must also have their concordance compared with each other and this concordance should also be at least 95%. (Reference: ANP.22970)

With specific reference to estrogen and progesterone receptor studies: in general, the overall proportion of ER-negative breast cancers (invasive and DCIS) should not exceed 30%. The proportion is somewhat lower in postmenopausal than premenopausal women (approximately 20% vs. 35%). The proportion is considerably lower in well-differentiated carcinomas (<10%) and certain special types of invasive carcinomas (<10% in lobular, tubular, and mucinous types). The proportion of PgR-negative cases is 10-15% higher than for ER-negative in each of these settings. Investigation is warranted if the proportion of negative cases is significantly lower in any of these settings.

RC – VII: Patient Confidentiality QA

In order to satisfy the College of American Pathologists' (CAP) revised standard GEN.41303, Patient Confidentiality QA, the Laboratory of Pathology will conduct an annual audit of compliance with the NIH and LP patient confidentiality policies. LP policies dictate that: 1) requests for release of patient reports must initiate from the NIH Clinical Center's Medical Records department, or based on the distribution list provided by the submitting clinician for consultative and submitted cases; and 2) any report released electronically will be encrypted when released to internal NIH health care providers, and/or password protected file(s) when submitting reports to the patients' non-NIH health care provider(s).

In order to satisfy the annual audit, LP staff will:

Review no less than 5 random Medico-legal requests from the previous calendar year to ensure that there is proper patient authorization to release the patient's repot to the requested provider or facility. The quality reviewer will ensure: a) Medicolegal request includes the patient signed authorization; b) The pathology report was submitted to the intended audience (e.g. patient's own request, submitting health care provider, and/or facility); c) The transmission of the pathology report was secure encrypted and/or password protected file if transmitted electronically; and d) If possible, contact the facility to ensure the report was received securely.

Review no less than 5 random submitted surgical (SS) cases with distribution that included at least 1 internal NIH provider and at least 2 external facilities. The quality reviewer will ensure: a) Ensure the name(s) and address(es) of the distribution list is correct by reviewing the original submitted case documents; b) Ensure the internal NIH email was encrypted (the reviewer can print the sender' sent email file as evidence); and c) The distribution to the external health care provider or facility was encrypted and/or password protected and password did not accompany the same email as the report. This review can also be done via reviewing the Surgical Pathology Patient Care Coordinator's sent emails.
All evidence (emails and reports) will be submitted to the Clinical Manager, and the results of the audit will be submitted to the Quality Management Committee and Medical Director with appropriate investigations and corrective actions if necessary.

RESIDENT & CLINICAL FELLOW PROJECTS (CFP)

The LP QM program will also incorporate "projects" that will address specific CAP checklist requirements and areas that need further monitoring and improvement based on the results of indicators monitored in CY2017 and based on 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. As of the close of CY2016, the autopsy service was consistently in compliance with the 60-day turnaround time standard. By the close of CY2017, the bone marrow clotted samples project resulted in compliance with the threshold.

As our clinical residents and fellow train to be future pathology lab directors, all are required to participate in at least one resident/fellow QM Project. In addition to the LP Quality Indicators, the QM Committee is engaged the in-training pathology physicians (residents and fellows) by implementing new projects for 2018. These projects were selected because they involve recurring quality issues affecting LP and require monitoring and corrective action.

Guidelines for Residents/Fellows QM Projects

- Identify an issue or area of LP's clinical services that require process improvement
- Suggestions might include examples such as:
  Pre-analytic Variables – specimen collection, requisitions, transport, receiving
  Analytic Variable – turnaround times, grossing, procedures, strains, interpretations, reporting
  Post-Analytic Variables – supplementals, customer complaints, corrected reports, physician notification of abnormal reports
- Discuss the issue(s) with the sections' technical staff or director
- Develop a plan: Identify metrics, data sources, how to report, how to address system issues
- Coordinate with a mentor – e.g. Lead Technologists, Medical Officers, Clinical Manager
- Implement the Plan(s), Monitor Metrics, Quarterly Reports to LP QM Committee
- The most important consideration when developing your Project Plan: there MUST be an end to the project – there must be a SOLUTION

2018 QM PROJECTS

CAP Cancer Protocols Reporting

Sun A Kim, Christopher Trindade, Sally Tanakchi (Dr. David Kleiner attending faculty)

CAP cancer reporting protocols should be incorporated in the final surgical pathology report for those cases that such protocols exist and are made available by CAP. Anatomic Pathology CAP Checklist# ANP.12350. Consistency in reporting was less than 80% for mandated reporting when this project stated. The LP Residents focused on having 100% compliance with the reporting of the CAP cancer protocols for those tumors that such protocol exists by providing all Residents and Attendings CAP cancer protocols table listing all tumor types that require reporting. SoftPath was also utilized by alerting Residents and Attendings about including a CAP cancer protocol by including it in the SI cases template header.

SS Case Patient ID/Accession Errors

Astin Powers (Dr. Chinquee faculty advisor)

Over the past two years, Residents raised a concern that there was an increase in clerical entry errors by the Accession staff for submitted and consult cases. The Resident project is to collect data (clerical errors by type, stratify significance of errors, and identify system solutions).

Missing CRIS Order

Hong Jiang (Dr. Pittaluga attending faculty, Michael Newford)

The surgical pathology specimens without CRIS order received in histology lab delay accession, postpone the process of tissue and case evaluation. Because of the nature of cases received, surgical fellows typically enter CRIS orders post-surgery but often orders are delayed or missed due to other responsibilities. LP Residents will aim to decrease the missing order rate by remaining consistent in reporting these issues by Histology, including notification of Hospital Office of Quality, reporting to the Clinical Center nursing and medical staff through STARS reports, and holding attending clinicians accountable for their fellows.

Duplicate Entries in SoftPath

Osorio Lopes (Dr. Kleiner attending faculty)

To review duplicate entries in SoftPath (patients with more than one MRN) and issuing merge orders. The LIS coordinator created a database query listing all potential duplicates (the initial number is 7,500), and over the months the Resident will review each. The goal is to progressively reduce the number of duplicates over time, until we reach zero. After this is achieved, the Resident can use the query to identify only the newly introduced duplicates.

Reporting and Follow-up of Predictive Markers

Kelly Brenan, Tanupriya Agrawal, Neda Mirzamani (Dr. Filie attending faculty)

Regulatory compliance requires that the reporting of the predictive marker Her2 should be done either by using the manufacture's instructions or the ASCO/CAP scoring criteria. Similarly, the reporting of the predictive markers estrogen and progesterone receptors should be done by using the ASCO/CAP scoring criteria. In addition, as per LP policy, all Her2 cases reported as "Score 2+" should also have FISH studies for HER2 performed. This project will start by retrospectively looking if pathology reports are in compliance with these requirements in order to determine if there is/are any issue(s) that require corrective action(s).

Missing Slides

Cara Monroe (Dr. Chinquee faculty advisor)

Residents and staff routinely seek slides I blocks for additional testing or requests for recuts for TRCs or return/medicolegal requests that are unable to be located. Dr. Monroe worked with Dr. Chinquee to identify tools for data collection, developed metrics, and will monitor data for the first few months of 2018. Data will drive potential corrective actions and system solutions.

Receipt to Accession Turn Around Time

Irena Manukyan (Dr. Kleiner attending faculty)

Dr. Kleiner suggested that it might be beneficial to track the time it takes from specimen receipt for submitted cases-to-the time the case is accessioned. There is no current data if there is a delay, so this project is to start with data collection to determine if there is an actionable issue.

Clinical Notification

Astin Powers (Dr. Chinquee faculty advisor)

Regulatory compliance requires notification of treating clinician and staff any unusual findings and revised or corrected reports. This project will focus on the notification (name and date) and 'read-back' that must be documented in the LP report. The Resident and Faculty advisor will be documenting the notification and read-back for both critical/unexpected and revised (potential patient impact on minor) categories.

Compliance with IHC Daily Control QC

Hot seat resident (All Residents; Dr. Filie attending faculty)

IHC control slides review and QC must be completed daily and slides and paperwork returned to the Immunohistochemistry lab daily. There are days that IHC controls are not documented. The objective is to have I00% compliance with the Control Slide Review item. For the beginning months of 2017, IHC control review was consistently deficient.

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