QUALITY MANAGEMENT (QM) PROGRAM
Laboratory of Pathology: 2016

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 and by assisting each individual laboratory with the QM plan. 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. In accordance with the College of American Pathologists (CAP) standards, Laboratory GEN.13806 – GEN.20208, 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.

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. LP areas that will devise a section-specific 2016 plan to complement the LP-wide QM quality indicators' to present at QM Committee include supplements for the Clinical Cytogenetics Section and Flow Cytometry Unit.

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.

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.

The QM Committee will include: (1) the Chief of the Laboratory of Pathology; (2) the QM Committee Chairman, (3) the Clinical Laboratory 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.

A minimum of one pathology resident will attend QM committee meetings as a “resident member” on a rotational basis for the purpose of providing an educational experience and an opportunity to contribute to the ongoing improvement efforts of the QM committee. Other residents are encourage participating at the meetings and will attend the meetings as “guests”. 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: 2016

Defined Laboratory/Unit/Section Head:

Medical Director – Frederic Barr
Autopsy - David Kleiner
Chromosome Pathology Unit – Svetlana Pack
Cytogenetics - Diane Arthur
Cytopathology – Armando Filie
Flow Cytometry - Maryalice Stetler-Stevenson
Hematopathology - Elaine S. Jaffe
Immunohistochemistry – Armando Filie/Markku Miettinen
Molecular Pathology - Mark Raffeld
Surgical Pathology – Markku Miettinen
In Situ Hybridization - Stefania Pittaluga
Clinical Operations / Histology - Joseph Chinquee (Manager) / Michael Newford (Supervisor)

The Section Head 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.

2016 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 10 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 2016 Quality Indicators will be in effect from January 1 through December 31, 2016, and may be extended into the next calendar year if not revised by the QM committee and Medical Director.

The indicators relating to the CAP Laboratory General Checklist[1] are marked with (***) and are also the components of the AP QI plan:

Analytic:	1. Medical Cytology Turnaround Time (TAT)
Analytic:	2. Comprehensive Cytology (Medical and GYN Cytology TAT)
Analytic:	3. Small Biopsy TAT***
Analytic:	4. Complex Cases TAT***
Analytic:	5. Intraoperative (Frozen Section) TAT***
Analytic:	6. Autopsy TAT (Final Autopsy Report)***
Post-Analytic:	7. Intraoperative Correlation (Frozen Sections)***
Post-Analytic:	8. Revised (Corrected) Reports***
Pre-Analytic:	9. Patient Identification Error, Unlabeled Cases or Missing Patient Information
Pre-Analytic:	10. Requisitions Not Submitted***
Pre-Analytic:	11. Molecular Diagnostics Specimen Adequacy
Analytic:	12. Molecular Diagnostics Turnaround Time
Pre-Analytic:	13. Chromosome Pathology Unit Specimen Adequacy
Analytic:	14. Chromosome Pathology Unit Turnaround Time (TAT)
Pre-Analytic:	15. Flow Cytometry Bone Marrow (BM) Specimen Adequacy
Pre-Analytic:	16. Immunohistochemistry Pre-Analytic Errors
Analytic:	17. Immunohisto Analytic Errors (Requests for Repeat Stains, QA issues)
Analytic:	18. Submitted Surgicals Turnaround Time (2016 Evaluation)
Post-Analytic:	19. Lost / Misplaced Slides (2016 Evaluation)

1. Medical Cytology 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.

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

2. 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 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.

3. 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.

4. 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.

5. 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

6. 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

7. 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

8. 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

9. 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.

10. 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.

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

11. 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

12. 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.

13. 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

14. 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

15. 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

16. 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.

17. 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 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 histochemical stains are 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: $\leq 0.5\%$ of IHC stains will be repeated due to analytic errors

18. Submitted Surgicals 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. The QM committee suggested monitoring the viability of adding Submitted Surgicals (Consults) to the Turnaround Times to QM repots. There are known variables not under the control of LP, but the committee asked to at least evaluate efficacy of the quality indicator. 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) is not within the scope of control of LP staff; or Was the submitted Case for patient protocol review received without accompanying paperwork from nurse

Threshold: Being evaluated for 2016

19. Lost Slides (Post-Analytic)

LP has a significant archive of past patients surgical slides, both for inhouse cases and slides received for the submitted service. There are routine requests from the submitting facility to return the slides for continuum of their patient care, and there are requests by the patient or submitting NIH investigator for additional material to be sent to other facilities for additional research. Because of the department's research and academic functions, there are occasions that slides may be removed from the slide storage system and it creates some effort to identify where these slides are located. In other situations, the slides are not located and recutting the block is the solution. In the worst-case scenarios, no slides are blocks are available. As a result of the critical nature of patient slides in the continuum of patient care, the QM committee requested the evaluation of lost or misplaced slides as a quality indicator.

Threshold: Being evaluated for 2016

ANNUAL QUALITY MANAGEMENT PROJECTS – REGULATORY COMPLIANCE (RC)

RC-I. Biennial Customer Satisfaction Survey – GEN.20335

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

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

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

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 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

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 identifier. 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: Intra-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 interobserver 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.

2015/ 2016 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 2013 and 2014. Areas identified as potential projects to be adopted by the QM committee include: >10 day outliers, delays in autopsy, CAP cancer report criteria, switch of residents, and clotted bone marrow samples. The QM committee chair decided that initially three of these areas were be adopted as projects for the 2014 QM plan, and will continue in the 2015 QM program: clotted bone marrow samples, delays in autopsy and CAP cancer report criteria. Each of these projects will be design, implemented and monitored by an attending and a fellow(s) and/or a resident(s); and reported to the QM committee on time intervals specified in the project plan (See Attachments). Annual Residents and Clinical Fellows Projects

In addition to the LP Quality Indicators, the QM Committee engaged the in-training pathology physicians (residents and fellows) in 2015 to implement three projects and involve the in-training pathology physicians in quality management and improvement. These projects were selected because they involve recurring quality issues affecting LP and required monitoring. These projects will continue through 2016 with an addition of a new project, and include:

Clotted Bone Marrow Aspirates:

A collaborative QM project by the Hematopathology fellow(s), Flow Cytometry, and Cytogenetics aimed to decrease the number of clotted aspirates received by LP sections due to collection techniques.

CAP Cancer Protocols Review:

To address CAP Anatomic Pathology Checklist requiring that all data elements required in applicable CAP Cancer Protocols are included in the surgical pathology report.

Final Autopsy Report Turnaround Time:

CAP- and Joint Commission-regulated turnaround time requirements for final autopsy diagnosis has been a long-standing issue for LP due to its education program and research missions.

CFP-I: Clotted Bone Marrow Aspirates

I. Problem: Increased incidence of clotted BM aspirate samples, insufficient samples, contaminated samples being submitted to Flow cytometry, Clinical Cytogenetics and Molecular diagnostics. This is above QA/QC cutoff limits for these studies and needs to be reduced to be in compliance with regulations/ recommendations

II. Project Plan

1. From LP- Revised, clear and consistent procedure manuals- print and online, laminated versions available easily in the procedure/ in-patient units

2. Coordinate with DLM- heparin and EDTA as anticoagulants, pre-filled syringes and collection tubes

3. Presented data to NCI MOB fellowship program director, Dr. Sanjeeve Bala and a clinical fellow Dr. Manisha Bhutani- discussed plans for training clinical fellows/ procedure unit nurses/ PA's
4. Discussion with NHLBI fellowship program director Dr. Charles Bolan regarding training of clinical fellows

5. Eventually present data to the office for patient safety

III. Outcome

1. Reduction in number of clotted/ contaminated BM aspirates for flow cytometry, cytogenetics and molecular diagnostics.

2. Relatively standardized protocols for submission of BM aspirates for ancillary tests

3. Increased awareness of clinical fellows to this problem and better technique to reduce its occurrence.

IV. Monitoring

1. Continue monitoring of BM aspirate quality (as is being done presently) by Flow cytometry, cytogenetics and molecular diagnostics.

2. Present data at LP QA/QC committee meeting.

3. Updating sample requisition forms/ procedure manual as required.

4. Yearly in-service training of clinical fellows/ PA's.

CFP-II: CAP Cancer Protocols Reporting Project

I. Issue: 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

All data elements required in applicable CAP Cancer Protocols are included in the surgical pathology report.

1. *The use of these protocols is encouraged, but not required, providing that the data elements required by the protocols are present in the report.*

2*. Data elements not applicable to the specimen need not be included in the report. (For example, if a mastectomy specimen does not include lymph nodes, no reference to lymph nodes is required.)*

3*. This checklist requirement is not applicable to cancer reports for which no CAP Cancer Protocol applies (for example, incisional biopsy of the breast) nor to reports on specimens that do not contain cancer.*

4*. Reports must include the required data elements from the current edition of the CAP Cancer Protocols. Laboratories may use the previous edition of the Protocols for up to 8 months after publication of the current edition.*

This checklist requirement should be cited by the inspector only if there is a pattern of repeated failure to include all requirements in multiple reports.

Resource: College of American Pathologists. Practicing Pathology: Cancer Protocols. http://www.cap.org/cancerprotocols/protocols/intro.html

II. Project Plan Objective

The objective is to have 100% compliance with the reporting of CAP cancer protocols for those tumors that such protocol exist and should be included in the final surgical pathology report. In order to achieve this goal the proposed plan would include:

1. Email link for the CAP website containing the CAP cancer protocols to all residents and attendings

2. Provide a table listing all tumor types requiring the reporting of CAP cancer protocols to residents and attending

3. Utilize SoftPath to alert residents and attendings about the possibility of having to include a CAP cancer protocol by including in the SI cases template a header for "CAP Cancer Checklist"

4. Explore the possibility of updating the CAP cancer protocol checklist that already exists in SoftPath and make it available to residents and attendings

III. Expected Outcome

The expected outcome is to familiarize residents and attendings with the CAP cancer protocol reporting checklist and to alert them to the need of having the cancer protocol reporting incorporated in cases that such reporting is necessary according to the CAP checklist question mentioned above.

IV. Monitoring

Monitoring the of compliance of including the CAP cancer protocol reporting in the surgical pathology reports will be performed on an ongoing basis and the results will be reported to the QM committee at least biannually.

CFP-III: Autopsy FINAL Turnaround Time QM Project

I. The problem

The sign-out of final autopsy reports is consistently delayed past the expected turn-around time. Up until 2013, out of 80 reports, 29 reports were signed out more than 60 working days from the time of autopsy. However, because of the inherent complexity of autopsy performance and reporting it is unclear what steps are contributing most to the delay of the report. The purpose of this project is to identify the root causes for delays in the final diagnosis for autopsies?
CAP Standards

Preliminary report: "A documented preliminary report of the gross pathologic diagnoses is submitted to the attending physician and the institutional record in 90% of the cases within a reasonable time." NOTE: For preliminary reports based on gross examination only, two working days is the recommended TAT. For cases with complicated dissections or rush histology, up to 4 working days is recommended. For some cases such as single organ only examination or slide consults, a Provisional Report may not be appropriate or required.

Final report: "The final autopsy report is produced within 60 working days in 90% of the cases." NOTE: The 90% threshold is used in recognition of the fact that occasional unusual cases may require more than 60 days for completion, particularly when external consultation is required. If cases exceed 60 days, there should be documentation of the reason for the delay and of ongoing review of this information by the director of the service.

Final report content: "The final autopsy report contains sufficient information in an appropriate format so that a physician may ascertain the patient's major disease process and probable cause of death"

II. Quality Plan Objective

Residents will prospectively collect quantifiable data to identify causes of delay at specific points in the autopsy evaluation and report preparation. Residents will keep a log of dates corresponding to several check points.

Residents should also make note of unusual events that may have effect on the final report. These include out-of-town rotations, cases sent out for consultation, etc.

III. Expected outcome

- The goal remains that all cases will be signed out by 60 days.
- A possible benefit of this project is that merely by recording events in the history of the case, sign-out may occur more quickly.
- In the event that cases are delayed there will be better documentation for the deficiencies on a case by case basis.
- Detailed information will be gathered on individual steps of the process.

IV. Reporting will be done Bi-annually

At six month intervals (starting with the December QM meeting), the data will be collected and analyzed for trends. If there are obvious delays that can be acted upon, specific recommendations can be made to the process. Subsequent tracking can be used to monitor the effectiveness of recommendations.

Potential Future Resident Projects to Consider

Proposal 1 – The Medical Directed requested the QM committee conduct a biannual review of all pending supplemental reports in SoftPath, to determine if the supplemental reports were added erroneously or if these cases still require sign out and were missed. The pending supplementals will be reported to the QA committee for CY2016, and the Medical Director will consult the QM committee chair to determine if there is a need to include this as a quality indicator in CY2017.

Proposal 2 – Delayed CRIS orders continues to be an issue for the clinical residents as their work is delayed as they wait for attending clinicians to place CRIS orders. There are considerations that some cases will have delayed orders if the surgeon is still in the Operating Room, but there are cases that it's unclear who is responsible for entering the CRIS orders. It has been recommended by the QM committee that a resident take on a QM project to identify the issues, investigate, evaluate, report, and propose solution(s) to the delays in receiving CRIS orders with specimens.

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