QUALITY MANAGEMENT (QM) PROGRAM
Laboratory of Pathology: 2014

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.

Method of Implementation:

General Requirements

The QM program is an LP-wide initiative and quality indicators and reports cover all clinical areas. 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. College of American Pathologists 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 2014 plan to complement the LP-wide QM quality indicators' to present at QM Committee are:

1. Clinical Cytogenetics Section
2. Flow Cytometry Unit

- 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 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).

- This quality monitor has been recommended to address the 2011 Customer Satisfaction Survey, identifying customer complaints or incidents that can affect patient care timely in QM Committee to impact all LP sections; and also addresses the CAP's GEN.20365, the current 2011 CAP Laboratory Patient Safety Goal (most current) – Improve identification, communication, and correction of errors in a timely manner. Specific criteria approved by QM Committee require that all sections establish and define what 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 QM Committee.

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.

The QM program for 2014 will continue address issues raised during the 2011 and 2013 customer satisfaction surveys, in which physicians and other healthcare providers in the Clinical Center were polled on quality issues relevant to LP's mission: clinical, research, and academia. The QM Chair and LP Medical Director have recommended (based on the survey): to continue to improve turnaround time for all clinical sections; to implement a mechanism for addressing external submitted complaints or incidents; and Infectious Diseases physicians have been added to the autopsy notification list, as well as implemented turnaround time monitoring for post-mortem services with documentation of reasons for outliers in compliance with CAP and JCAHO recommendations.

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) an AP resident.

A 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 to participate 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: 2014

Defined Laboratory/Unit/Section Head:

Autopsy - David Kleiner
Chromosome Pathology Unit – Svetlana Pack
Cytogenetics - Diane Arthur
Cytopathology – Armando Filie
Flow Cytometry - Maryalice Stetler-Stevenson
Hematopathology - Elaine S. Jaffe
Histology - David Kleiner
Immunohistochemistry - Mark Raffeld/Markku Miettinen
Molecular Pathology - Mark Raffeld
Surgical Pathology – Markku Miettinen
In Situ Hybridization - Stefania Pittaluga

The Section Head (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. Turn around time**

When relevant, what is the acceptable turn around 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.

2014 QM Program - AP QI Plan
Method of Implementation:

Specific Requirements

The LP QM program also incorporates the AP QI plan to review and discuss the quality reports of at least 10 indicators chosen by the committee. 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. Quality indicators are reviewed for relevance by the QM committee at least annually. The following quality indicators have been approved by the QM committee as the 2014 Quality Indicators will be in effect from January 1 through December 31, 2014. 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. 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)***
Analytic:	7. Autopsy PAD (Provisional Autopsy Diagnosis)***
Post-Analytic:	8. Intraoperative Correlation (Frozen Sections)***
Post-Analytic:	9. Revised (Corrected) Reports***
Pre-Analytic:	10. Patient Identification Error, Unlabeled Cases or Missing Patient Information
Pre-Analytic:	11. Requisitions Not Submitted***
Analytic:	13. Molecular Diagnostics Turnaround Time
Pre-Analytic:	13. Molecular Diagnostics Specimen Adequacy
Pre-Analytic:	14. Chromosome Pathology Unit Specimen Adequacy
Analytic:	15. Chromosome Pathology Unit Turnaround Time (TAT)
Pre-Analytic:	16. Flow Cytometry Bone Marrow (BM) Specimen Adequacy

In addition to these quality indicators, the QM Committee engaged the in-training pathology physicians (residents and fellows) in 2013 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 2014, 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.

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.[2] 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.[3] 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. GYN Cytology 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.[4] 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.

Threshold: 95% of 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.

7. Provisional Autopsy Diagnosis (PAD)

CAP (ANP.33100) establishes a standard for completing Preliminary Autopsy Diagnosis (PAD). The standard requires that a documented preliminary report of the gross pathologic diagnosis is submitted to the institutional record in 90% of the cases within two working days. As a result, the QM committee will monitor the number of cases that fall outside this standard, investigate the cause, and make recommendations for process improvement. At the NIH, one patient can be assigned two autopsy cases numbers, one for the brain (AN-prefix) and the other for the body (AU-prefix). PADs are reported per patient, not per autopsy case number, so AN-cases with corresponding AU-cases are not included in the PAD standard. PADs are not entered for submitted cases. Submitted cases include those received as bodies or slides/blocks from outside institutions.

Threshold: 90% of autopsies that have PAD will have that PAD entered into the LIS within two working days of the autopsy.

8. 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.

Threshold: < 2% of major discrepancies

9. 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

10. 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.

Threshold: ≤ 5% of total SB/SI cases.

11. 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.

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 11 working days of receipt.

13. 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

14. 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

15. 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

16. 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

2013 / 2014 RESIDENT & CLINICAL FELLOW PROJECTS

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 2012 and 2013. 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 2013 QM plan, and will continue in the 2014 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 Attachements).

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.

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.

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. During 2012, 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 affect 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.

References

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8. American College of Medical Genetics, E.6.5.3.2 (2009).