UW Medicine - Pathology

100-01-01-04

Quality Management Plan

Adopted Date: 08/13/01
Revision Date: 06/05/13

PURPOSE

The UW Medicine Pathology Department is committed to providing outstanding consultative and diagnostic services, and it maintains a continuous program of quality management with particular attention to optimal patient care and safety.

SCOPE

Provide diagnostic pathology services; support and engage in education, quality assurance, and research activities. Advise clinical care providers on available pathology services, optimal specimen handling & safety precautions, and appropriate special studies.
The Laboratories included in UW Medicine Pathology are:

A) **Surgical Pathology:** Macroscopic evaluation, intraoperative consultation with or without frozen section diagnosis, microscopic evaluation, special studies, including Immunohistochemistry, and generation of a diagnostic report. Surgical pathology will be further divided into subspecialties.

B) **Neuropathology:** Macro- and microscopic evaluation of nervous system surgical specimens with/without frozen section diagnosis and special studies. Diagnosis of nerve and muscle pathology through histologic examination and appropriate special studies. Gross and microscopic post-mortem examination of the brain and generation of diagnostic reports.

C) **Cytopathology:** Diagnostic microscopic evaluation and reporting of GYN and Non-GYN cytology specimens. Performance and diagnostic evaluation of fine needle aspiration cytology of palpable lesions. Immediate interpretations and generation of final diagnostic reports.

D) **Autopsy Pathology:** Macroscopic and histologic post-mortem examination. Generation of provisional and final anatomic diagnostic reports.

E) **Molecular Diagnostics:** Human papilloma virus (HPV) detection in cytologic cell suspensions and biopsies. HPV Genotyping - Type specific detection in cytologic cell suspensions and biopsies. Fluorescent in-situ hybridization. Generation of diagnostic reports.

F) **Electron Microscopy:** Ultra microscopic analyses of cellular structure and content. Generation of photos and diagnostic reports.

G) **DNA Flow Cytometry:** Diagnostic analyses of DNA in tissue. Generation of diagnostic report

H) **Cytogenetics:** Analyses of chromosomes to determine genetic abnormalities. Generation of diagnostic report.

I. Quality Indicators (General)

A) Technical and procedural elements:

- Specimen identification / acceptance
- Specimen processing, sectioning and staining
- Prevention of cross-contamination
- Equipment function
- Safety / incident reports
- Quality controls

B) Professional elements:

- Review of pertinent previous histologic and cytologic material, when available and appropriate
- Frozen section correlation with final diagnosis
- Appropriateness of frozen section diagnosis deferrals
- Diagnostic reports review through consultation, internal peer review, and clinical-pathologic conferences
- Correlation of GYN cytologic and histologic diagnoses
- HGSIL-prompted review of prior negative GYN cytology cases (5 year retrospective)
- Non-GYN histo-cyto correlation, when available

C) Diagnostic report review criteria:

- Accuracy and completeness of diagnostic information
- Adequacy of clinical and demographic information
- Adequacy of gross / microscopic descriptions
- Accuracy of transcription / typography
- Timeliness of reports

Thresholds: For each of these quality indicators, each major discrepancy (QCS ≥ 3, see section V.A.) is addressed in a timely fashion upon discovery. The threshold for formal analysis of major discrepancies and corrective action is 90%.

II. Monitoring

Data are reviewed at least quarterly and major discrepancies discussed during the QA Review segment of the monthly Pathology QI departmental meeting at each facility. The supervisors of each laboratory section collect and report technical/procedural quality indicator data to the Administrative Director and/or Lab Directors at each site.

Supervisors and QA Support Staff report trends, problems, successes and any safety concerns at the monthly Pathology departmental QI meeting at their specific facility.

Professional/diagnostic review is conducted by the pathologists, with the support provided by QA Support Staff. Lab Directors summarize the quality review to each facility's respective quality improvement committees.

Surgical Pathology- Faculty:

A) When possible and appropriate, pertinent previous cytologic or histologic material is reviewed in correlation with current material. Histologic biopsy findings are correlated with prior or concurrent cervical cytology diagnosis, at the time of biopsy diagnosis, when possible. When histologic follow-up for cytologic diagnosis of dysplasia is not evident from pathology data within 4 months, then a letter requesting explanation is sent to the clinic, and replies are monitored to ensure a response is received.

B) Non-GYN histologic material is correlated with cytologic findings when possible, but is not often available. Quality is monitored by peer review of Non-GYN cytology cases and may be recorded in the diagnostic report or in the electronic pathology record as a case note by the reviewing or verifying pathologist.

C) Peer review: The pathologists are encouraged to submit cases of new malignancy (except basal cell carcinoma and squamous cell carcinoma) of skin, breast, prostate, thyroid, testis (if biopsied/resected for tumor) and ovary (if removed for tumor or cyst) and any other cases they wish to have reviewed to another pathologist for peer review. The data is collected by QA Support Staff or the pathologist in charge of QA and summarized at the monthly QA Review.

D) Clinical-pathologic correlation: Review of cases at clinical-pathologic conferences is annotated on the conference quality assurance sheets, indicating any significant discrepancies. The data is collected by QA Support Staff or the pathologist in charge of QA and summarized at the monthly QA Review.

E) Frozen section-to-final diagnosis correlation of surgical pathology and neuropathology cases for each month are reviewed by the assigned pathologist. Significant discrepancies are reconciled either in the surgical pathology report or in the quarterly departmental QA report.

F) Internal and external consultation: Documentation of intradepartmental consultation is not required but may be done on the diagnostic report or in the Notes tab of the pathology information system by either the verifying or the consulting pathologist. Difficult or controversial cases may be referred to specialists for expert consultation. Formal outside consults are reported as an addendum, maintained with the pathology report, and may be filed in the medical record, if deemed appropriate by the pathologist. These cases are reviewed for any discrepancy and reported to QA Support Staff or the Pathologist in charge of QA.

G) The expected turn-around time (TAT) for single frozen sections is 20 minutes from receipt (assessed annually). Expected TAT is 2 working days (from accessioning date) for final diagnosis of uncomplicated biopsy cases and 4 working days for larger cases. Exceptional cases requiring special procedures, such as decalcification, histochemical stains, immuno-cytochemical evaluation, or consultation, may exceed these intervals but should be verified promptly upon completion. Some TAT is determined by the testing process time needed.

H) The department subscribes to the College of American Pathologists' Performance Improvement Program (unknowns with subsequent published discussion) for self-monitoring and continuing medical education.

I) Accuracy of Molecular Diagnostic reports: All reports are double checked within a week of signout by the Laboratory Supervisor or another Clinical Technologist if the supervisor is unavailable. Findings are documented and reviewed by the Administrative Director or Lab Director.

J) For Surgical NP cases, including ocular lesions, all cases of neoplasm and non-neoplastic lesions that have a differential diagnosis of neoplasm or are of unusual histology are peer reviewed at a weekly conference attended by neuropathologists and trainees. Discrepancies and action taken are recorded in the electronic Case Review Conference Log. Any major discrepancies (QCS $\geq$ 3) are discussed at the monthly Quality Review.

K) A 5-year retrospective review of prior negative cervical cytologies is conducted when a new diagnosis of high-grade squamous intraepithelial lesion (HGSIL) is made.

L) GYN cytology cases with current abnormal results are reviewed by a pathologist. A random 10% of cases with negative diagnosis and all cases with current negative diagnosis and prior abnormal GYN cytology are reviewed by a qualified cyto-technologist. Results of these reviews are recorded electronically and monitored by the section supervisor. Major discrepancy rate over 2% threshold for a cytotechnologist triggers corrective action.

M) Refer to Cytopathology policies and procedures for additional information regarding quality assurance/quality control and annual cytology quality assurance report.

N) <u>Autopsy Pathology (including Neuropathologic autopsies)</u>

1. Peer review: Slides, provisional and final report of at least one autopsy per quarter of the year is peer reviewed.

2. Clinical-pathologic correlation: A clinical-pathologic correlative comment is included in the autopsy report, and should highlight any clinically

inapparent but important findings. Select cases are presented at didactic interdepartmental conferences, when requested clinically.

3. The expected turn-around time is 2 working days for provisional anatomic diagnostic reports and 60 working days for final anatomic diagnosis. Cases open for > 60 working days require ongoing review by the Laboratory director and the Autopsy Director. Reason for the delay is documented.

   Referring providers will be notified of excessive delay in test results. An excessive delay is one that exceeds the above expected turn-around times by more than 2 days and is expected to have substantial impact on clinical patient care in the judgment of the attending pathologist.

4. Formal intra- and extra-departmental consultations are documented and the reports maintained with the patient's autopsy report.

5. The Autopsy Director and/or the Clinical Autopsy Coordinator briefly review the medical record (chart) of all deceased, to determine whether in-house autopsy or referral to medical examiner should be suggested, if none was requested.

6. Findings from autopsies are incorporated in the institutional quality management program through the Mortality Review by the HMC & UWMC Medical Quality Improvement Committee.

III. Patient Safety Net (PSN)

Incidents that place employee or patient safety at risk are to be reported to hospital administration for proper corrective action. PSNs are reviewed by faculty and/or Lab Directors monthly. Incidents with a University HealthSystems Consortium (UHC) harm score of ≥4 are expedited for immediate director review.

A UHC harm score of 4 is defined as an event having reached the patient, resulting in mild and transient anxiety or pain or physical discomfort without the need for additional treatment other than monitoring (such as by observation; physical examination; laboratory testing including phlebotomy, and/or imaging studies). Distress/inconvenience since discovery and/or expected in future as a direct result of event.

IV. Proficiency Testing

Cytology, Neuropathology, Immunohistochemistry, Cytogenetics, DNA Flow Cytometry, and Molecular Diagnostic Lab currently participate in Proficiency Testing for certain tests. PT testing is not referred to other laboratories, and inter-laboratory communication on proficiency testing data before results reporting is not permitted.

V. Customer Satisfaction Surveys

At two-year intervals, Cytology, Surgical Pathology, Neuropathology, Autopsy, Cytogenetics, DNA Flow Cytometry, Electron Microscopy and Molecular Diagnostics surveys will be distributed to submitting providers. The feedback will be summarized at the monthly UWMC and HMC Pathology Departmental Meeting.

VI. Evaluation of Indicators

Results of the monitoring of quality indicators are collated monthly by the section supervisors, QA Support Staff, QA pathologist and/or Lab Directors. Above-threshold quality indicator results, trends, and all relevant incident reports are reviewed during the quality review segment of the monthly UWMC and HMC Pathology Departmental Meeting. For major discrepancies or events, quality concern scores, comparison comment, and attribution classification are assigned according to the system recommended by the HMC Medical Staff QA Committee (see below). Corrective action, when appropriate, is implemented by the Lab Director at the respective facility.

A) Quality Concern Scores (QCS)

The relationship between the identified variation in practice, delayed diagnosis or medical error and any actual or potential adverse event is categorized as follows:

QCS	Description
0	No quality of care concerns evident (*No variation from a generally agreed-upon standard of care, no delayed diagnosis, and/or no medical error)*
1	Reached patient or near-miss with low risk to patient (*Variation in practice, delayed diagnosis or medical error did not affect hospital course or well-being AND was not associated with clinically significant risk to the patient)*
2	Near miss with high risk to patient (*Variation in practice, delayed diagnosis or medical error did not affect hospital course or well-being BUT was associated with a clinically significant increased risk to patient)*
3	Event reached patient and required additional care *(Variation in practice, delayed diagnosis or medical error reached the patient and resulted in escalation of care, e.g., additional monitoring, new drugs, ventilator, specialty consult, new or prolonged ICU/recovery room or hospital stay)*
4	Event reached patient and was potentially life-threatening or caused disability *(Variation in practice, delayed diagnosis or medical error resulted in extended or permanent disability or was potentially life-threatening)*
5	Event reached patient and was life-threatening or caused death (*Variation in practice, delayed diagnosis or medical error resulted in death or was life-threatening)*

B) (Optional): Given the same findings, another case would be handled/diagnosed similarly

- (a) Virtually all the time,

- (b) Much of the time, but with variability among pathologists, or
- (c) Infrequently

C) (Optional): The variation in practice, delayed diagnosis or medical error was due to an issue of: judgment, technique, management, communication, system, sampling variation, etc.

D) Summary score example: "QCS 3c – Management"

VII. Effectiveness of actions

Results of implemented corrective action will be reviewed at the monthly meeting. Any major changes in the department's Quality Management program will be included in the quarterly QA report, and will result in revision of the Quality Management Plan.

VIII. Results communication

UWMC and HMC Pathology QA reports are compiled quarterly and presented at the UWMC and HMC Pathology Departmental Meetings by the Lab Directors (or designees).

IX. Compliance

UWMC and HMC Departments of Pathology maintain accreditation by the College of American Pathologists and comply with guidelines issued by CAP and JCAHO, with state, federal and local regulations, and with the policies and bylaws of Harborview Medical Center and UW Medical Center.

UW Medicine Administrative Director:
(Signature and Date)

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