

Contents

Chapter 1	Introduction	1
	Historical perspective, 1	
	Focus on patient care, 2	
	The systems approach to quality improvement, 3	
	Developing a quality program, 3	
Chapter 2	Designing a quality improvement plan	5
	The plan, 5	
	A mission statement, 5	
	The test cycle (preanalytic, analytic, and postanalytic), 5	
	Priorities, 5	
	Individual responsibility and timetable, 6	
	Institutional concerns, 6	
	External and internal benchmarks, 6	
	Figure 2-1. Example of an anatomic pathology quality improvement plan, 7	
Chapter 3	Regulatory compliance	9
	Introduction, 9	
	Preanalytic phase compliance, 11	
	Guidelines for specimen submission, 11	
	Exempted and gross-only specimens, 12	
	Specimen labeling and rejection, 12	
	Requisition form retention, 12	
	Analytic phase compliance, 13	
	Gross examination personnel, 13	
	Tissue distribution, 13	
	Specimen integrity during processing, 13	
	Intradepartmental and extradepartmental consultations, 13	
	Correlation of ancillary studies, including immunohistochemistry, with pathologic findings, 14	
	Intraoperative consultation and frozen sections, 15	
	Postanalytic phase compliance, 15	
	Pathology reporting, 15	
	Slide/tissue retention and send-out, 16	
	Tissue disposal, 17	
	Reports and records retention, 17	
	Miscellaneous regulatory items, 18	
	Summary, 18	

Table 3-1. Checklist regulatory items arranged by phase in the test cycle, 19
 Table 3-2. Checklist regulatory items arranged by numerical order, 21
 Table 3-3. Minimum requirements for surgical pathology retention, 23
 Exhibit 3-1. Safe Medical Devices Act of 1990, 24
 Exhibit 3-2. Analyte specific reagents, 25
 Exhibit 3-3. Surgical specimens to be submitted to pathology for examination, 26
 Exhibit 3-4. Stewardship of pathologic specimens, 28

Chapter 4 Strategies for error reduction and prevention in surgical pathology 33

General principles of error reduction, 34
 System solutions, 34
 Personnel solutions, 36
 Methods that may reduce errors in surgical pathology, 37
 Entire test cycle, 37
 Preanalytic phase: specimen delivery and accessioning, 37
 Analytic phase: technical factors, 38
 Analytic phase: diagnostic factors, 39
 Postanalytic phase: transcription, 39

Chapter 5 Defining and handling errors in surgical pathology 41

Mechanisms for discovery of error, 42
 Definitions of diagnostic discrepancies, 42
 Relative risks by time of discovery, 43
 Nearly immediate identification of discrepancy, 43
 Intermediate time to identification of discrepancy, 43
 Extended time to identification of discrepancy, 43
 Response to error discovery, 43
 Summary, 44

Chapter 6 Quality improvement plan components and monitors 45

Overview, 45
 Preanalytic variables: specimen submission and handling, 45
 Background, 45
 Specimen procurement, transport, and accessioning, 46
 Correct identification of submitted specimens, 46
 Data collection, 46
 Benchmark data, 47
 Requisition form, 47
 Background, 47
 Data collection, 48
 Benchmark data, 48
 Fixation, 48
 Background, 48
 Data collection, 49
 Timeliness of delivery to the laboratory, 49

Analytic variables: diagnostic accuracy, 50
Correlation of intraoperative and final diagnoses, 50
Background, 50
Data collecting and reporting, 51
Benchmark data, 52
Diagnostic accuracy: intradepartmental peer review, 52
Background, 52
Data collecting and reporting, 55
Benchmark data, 56
Diagnostic accuracy: interinstitutional peer review, 59
Background, 59
Data collection and reporting, 60
Benchmark data, 60
Postanalytic variables: report adequacy and integrity, 61
Report adequacy, 61
Background, 61
Data collection and reporting, 62
Benchmark data, 64
Report integrity, 64
Background, 64
Data collection and benchmark data, 65
Turnaround time, 65
Introduction, 65
Frozen sections, 66
Background, 66
Data collection and reporting, 66
Benchmark data, 66
Surgical pathology specimens, 68
Background, 68
Data collection and reporting, 68
Benchmark data, 69
Further considerations, 69
Customer satisfaction, 70
Background, 70
Data collection and reporting, 71
Benchmark data, 72
Table 6-1. Specimen rejection log, 47
Table 6-2. Requisition form monitor, 48
Table 6-3. Adequacy and appropriateness of fixation, 49
Table 6-4. Comparison of characteristics and results of Q-Probes studies, 53
Table 6-5. Institutional percentile from frozen section studies, 53
Table 6-6. Diagnostic performance: false-negative and false-positive diagnoses for neoplasms, 53
Table 6-7. Summary of error rates in surgical pathology, 57
Table 6-8. Number (%) of surgical pathology errors according to type, 57

- Table 6-9. Interinstitutional review: summary of error rates detected by mandatory second opinion, 60
- Table 6-10. Interinstitutional review: summary of error rates by organ system, 60
- Table 6-11. Monitors used to gauge report adequacy, 62
- Table 6-12. Rectal cancer reports, 64
- Table 6-13. Breast cancer reports, 64
- Table 6-14. Lung cancer reports, 64
- Table 6-15. Urinary bladder cancer reports, 64
- Table 6-16. ADASP benchmarks and thresholds for surgical pathology turnaround times, 68
- Table 6-17. CAP LAP guidelines and Q-Probes results for surgical pathology, 68
- Table 6-18. Distribution of institutional overall satisfaction scores, 72
- Table 6-19. Distribution of institutional percentiles with respect to the percentage of excellent/good rating for each service category, 72
- Figure 6-1. American College of Surgeons Commission on Cancer compliance monitoring template, 63
- Figure 6-2. Frozen section turnaround time report, 67
- Figure 6-3. Surgical pathology turnaround time report, 67
- Figure 6-4. Sample anatomic pathology customer satisfaction survey, 71

Chapter 7 Quality management in the histology laboratory

77

- Quality control techniques, 77
- Daily checklists, 77
 - Temperature and humidity checks, 78
- Production and review of controls, 78
- Special stain controls, 80
 - External quality assessment, 81
- Performance improvement monitors in histology, 81
- Turnaround times, 81
 - Quality of histologic sections, 81
 - “Lost” specimens, 82
 - Flootation errors, 83
 - Extraneous tissue, 84
 - Assessing pathologist satisfaction, 85
- Conducting a failure mode effects analysis in histology, 86
- Exhibit 7-1. Frozen section area documentation, 88
- Exhibit 7-2. Histology quality improvement, 89
- Exhibit 7-3. Quality assurance quarterly indicators, 90
- Exhibit 7-4. Histopathology worksheet, 91

- Overview, 93
- Preanalytical phase, 93
 - Tissue fixation and processing, 93
- Analytical phase, 94
 - Standardization and procedures, 94
 - Antibody evaluation and validation, 95
 - Validation of new reagent lots, 96
 - Routine quality control, 96
 - Daily controls, 97
 - Positive tissue controls, 97
 - Negative tissue controls, 98
 - Negative reagent controls, 98
 - Interpretation, 99
 - External quality assessment, 100
- Postanalytical phase, 101
 - Reporting, 101
- Quality assurance monitors, 101
 - Repeat slides, 101
 - Turnaround time, 102
 - Audits of pathology reports, 102
- Table 8-1. Key parameters that may have an adverse effect on staining quality, 96
- Table 8-2. Examples of common problems, 102
- Exhibit 8-1. Antibody lot-to-lot comparison, 103
- Exhibit 8-2. Antibody staining patterns and controls, 104
- Exhibit 8-3. Analyte specific reagent disclaimer, 106
- Exhibit 8-4. Repeat stains, 107
- Exhibit 8-5. Turnaround time, 108

- Introduction, 111
- Definitions, 111
- Quality assurance in cytopathology and CLIA '88, 112
 - Historical overview, 112
 - CLIA '88 and accreditation monitors, 113
- General cytology laboratory procedures, 113
 - Specimen acceptance and adequacy, 113
 - Specimen preparation and staining, 114
 - Workload monitors in cytology, 115
 - Personnel standards, 116
 - Cytopathology reports and records, 116

Gynecological cytology quality assurance, 117
Specimen acceptance and adequacy, 117
Screening and reporting of gynecological specimens, 118
Review of abnormal gynecological cases, 119
Rescreening of negative cases, 119
Cytological/histological correlation and clinical follow-up, 120
Retrospective reviews, 121
Measures of quality of screening/interpretive performance, 121
Review of discrepancies between individuals, 124
Consultations, 124
Review of unknown cases, 125
Descriptive statistics of interpretations, 125
Turnaround time, 125
Interlaboratory comparison data, 125
New technologies in gynecologic cytopathology, 127
Liability issues/risk management in gynecologic cytopathology, 128
Non-gynecological cytology quality assurance, 129
Sign-out and review of non-gynecological cases, 129
Descriptive statistics, 130
Peer review, 130
Cytology/histology correlation and follow-up, 131
Turnaround time, 132
Continuing education and benchmarking, 132
Fine-needle aspiration cytology quality assurance, 132
Informed consent, 132
Specimen procurement, 133
Specimen adequacy, 133
Guidelines for interpretation, 133
Report, 134
Correlation studies, 134
Table 9-1. Cytopathology rejected specimen log, 135
Table 9-2. Cytopathology problem log, 136
Table 9-3. Cytopathology stain quality evaluation, 136
Table 9-4. Cytopathology stain maintenance, 137
Table 9-5. Cytotechnologist daily slide totals, 137
Table 9-6. Daily cytotechnologist interpretation log, 138
Table 9-7. Monthly cytotechnologist gyn statistics, 139
Table 9-8. Cytotechnologist workload assessment, 140
Table 9-9. Cytotechnologist competency assessment, 141
Table 9-10. Cytopreparatory personnel competency assessment, 142
Table 9-11. Gyn cytology/histology correlation log, 143
Table 9-12. Cytology follow-up correlations, 143
Table 9-13. Cytopathology 5-year retrospective reviews, 144
Table 9-14. Cytopathology statistics: gyn and non-gyn, 145
Table 9-15. Focused cytologic/histologic correlation, 146
Table 9-16. Cytopathology quality improvement plan, 147

- Turnaround time, 154
- Sample checklists and components: technical and quality control of autopsy, 155
- Sample checklists and components: professional quality assurance in autopsy, 156
- Sample checklists and components: communication, 158
- Sample checklists and components: quality integration of autopsy, 158
 - Case-specific clinical and autopsy diagnosis comparison and correlation, 158
 - Case-specific review and incorporation into institutional quality assurance programs, 159
 - Cumulative review of cases, 159
 - Organ-based or diagnostic-based reviews, multiple cases, 162
 - Service-based review, multiple cases, 162
 - Additional activities for quality improvement, 162
- Information systems, database development, and de-identified data sets, 163
- Table 10-1. Performance assessment areas of autopsy quality assurance, 154
- Table 10-2. Autopsy quality management scheme, 155
- Table 10-3. Turnaround times: case-based format, 157
- Table 10-4. Community Hospital “X”: autopsy summary review form, 160
- Table 10-5. Case analysis for year 4, 161
- Table 10-6. Data sets for autopsy correlation and quality improvement activities, 163
- Checklist 10-1. Autopsy permit, 165
- Checklist 10-2a. Postmortem care (prior to autopsy/no autopsy done), 166
- Checklist 10-2b. Postmortem care (after autopsy), 167
- Checklist 10-3. Autopsy/morgue facility, 168
- Checklist 10-4. Histology, technical, 169
- Checklist 10-5. Photography, imaging, 170
- Checklist 10-6. Gross dissection and examination, 171
- Checklist 10-7. Organ-specific evaluations: examples for gross and microscopic heart examination, 172
- Checklist 10-8. Microscopic assessment, 174
- Checklist 10-9. Ancillary testing and suitability review, 175
- Checklist 10-10. PAD and FAD correlation, 176
- Checklist 10-11. Total pathology case review, 177
- Checklist 10-12. Preautopsy review of clinical information, 178
- Checklist 10-13. Postautopsy review of clinical information, 179
- Checklist 10-14. Family and other communication, 180
- Checklist 10-15. Clinical diagnosis and autopsy diagnosis correlation table, 181