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Quality assurance of anatomic pathology diagnoses: Comparison of alternate approaches

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ABSTRACT

Objectives: Traditionally, a 10% review has been the basis for quality assurance programs in anatomic pathology. The effectiveness of such reviews has been questioned and alternative methodologies suggested. The study investigates the error detection rates for four quality assurance protocols.
Methods: The detection rate for diagnostic errors in surgical pathology was calculated over a one year period using four different review procedures comprising: random 10% review, correlation of internal and external diagnoses following solicited external expert opinion, correlation of internal diagnoses with outside diagnoses in cases sent for review at a second institution treating the patient along with a focused review of dermatopathology cases over a 3 month period. Error rate was expressed as percentage of reviewed cases where the initial diagnosis differed from the review diagnosis. Error rates detected by each method were compared among the methods
Results: The 10% random review detected seventeen errors in 2147 cases (0.8%). Solicited case consultations requested by clinicians or internal pathologists detected five diagnostic errors in seventy cases (7.1%). Unsolicited reviews by outside institutions in the course of patient care detected three diagnostic errors in 190 cases (1.6%). Review of the dermatopathology material disclosed 5 diagnostic errors in 59 cases (8.5%).
Conclusions: Focused reviews initiated by diagnostic concerns of a clinician or pathologist, unsolicited reviews because of treatment at another institution and sub-specialty based reviews appear to be more effective in detecting diagnostic errors than the 10% random review. Quality assurance programs should include focused reviews in addition to 10% random review to maximize error detection.

1. Introduction

Quality assurance programs are an important component of laboratory management and are recommended by the College of American Pathologists (CAP) [1]. While a number of methodologies may be utilized, a 10% random review of both surgical pathology and cytopathology cases has been a standard approach [2,3]. However, a number of studies have demonstrated that a 10% random review of cytology cases may underestimate the false-negative rate associated with the sign-out of cervical cytologies [4]. Some studies have shown that rapid rescreening of cervical cytologies is a more successful technique for quality assurance that the 10% random review [5–10].

Alternate strategies to a 10% random review have been proposed for surgical pathology specimens including the utilization of video microscopy, external consultation, 100% review of frozen section – permanent section correlation, 100% histopathologic review for certain specimen types and directed peer review for specific case types or anatomic locations for monitoring diagnostic accuracy in surgical pathology [1,11–14].

We reviewed our experience with a variety of quality assurance review procedures to assess their ability to detect diagnostic errors. These quality assurance procedures included 10% random review, focused organ specific review, review of outside consultations requested by pathologists or clinicians and finally review of correlations between initial in-house diagnosis and review by an outside institution following patient referral for treatment elsewhere. Herein we report the results of that comparison.

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Table 1
Descriptions of errors made and assessment of clinical impact by review type.

Review Type	Error Description		Category[a]
	Original Diagnosis	Review Diagnosis	
Random 10% Review	Simple endometrial hyperplasia	Disordered Proliferative Pattern	B
	Colonic ulcer with no dysplasia	Ulcer with possible fistula	B
	Chronic cholecystitis & cholelithiasis	Chronic cholecystitis & cholelithiasis & liver with mild fatty change	A
	Soft tissue with mild chronic inflammation and fibrosis	Chronic inflammation & foreign body giant cell response	A
	Chronic cholecystitis	Chronic cholecystitis & cholesterolosis	A
	Ileostomy stoma with chronic inflammation	Ileostomy stoma with chronic inflammation and foreign body giant cells	A
	Cutaneous cyst	Epidermal inclusion cyst	A
	Adenocarcinoma	Papillary Adenocarcinoma	A
	Dermal cyst	Epidermal inclusion cyst	A
	Fibroadenoma	Fibroadenoma & calcification	B
	Benign proliferative pattern	Early secretory endometrium	A
	Simple hyperplasia	Disordered proliferative pattern	B
	Actinic Keratosis	Squamous cell carcinoma in situ	D
	Endocervical tissue with no evidence of dysplasia	Endocervical tissue with no evidence of dysplasia No endometrial tissue identified	A
	VIN III	Reactive Atypia	D
	Degenerative joint disease	Degenerative joint disease and synovial cyst	A
	Seborrheic keratosis	Seborrheic keratosis and dermal nevus	A
External Solicited	VIN II	Reactive atypia and inflammation	C
	CIN II	Reactive atypia and inflammation	C
	Benign verrucoid hyperplasia	Benign verrucoid hyperplasia with atypia	A
	Superficial basal cell carcinoma	Nodular basal cell carcinoma	A
	Cyst with acute & chronic inflammation	Ruptured epidermal inclusion cyst with acute and chronic inflammation	A
External Unsolicited	Vocal cord: invasive squamous carcinoma	Carcinoma in situ	D
	3 negative lymph nodes	4 negative lymph nodes	A
	1 lymph node – no evidence of malignancy	1 lymph node with micro metastases	D
Organ Based	Solar lentigo	Junctional nevus	A
	Benign atypical keratosis	Squamous cell carcinoma	B
	Mycosis fungoides	Subacute spongiotic dermatitis	D
	Mild chronic inflammation	Lichen sclerosis	B
	Atypical squamous proliferation	Squamous cell carcinoma	D

[a] Category A–Minor disagreement with no effect on patient care; Category B–Disagreement with some but not major consequence for patient care; Category C–Major disagreement with serious impact on patient care; Category D–Major disagreement without serious impact or with unknown impact on patient.

2. Materials and methods

The Department of Pathology and Anatomical Sciences at the University of Missouri has five quality assurance programs focusing on diagnostic accuracy in surgical pathology. One of these quality assurance programs correlates final pathologic diagnosis with frozen section intraoperative consultation diagnosis. The remaining four review protocols focus on accuracy of final diagnosis. The results of these quality assurance programs are reviewed monthly at a quality assurance conference. Errors are classified by the definitions in Table 1. Errors are discussed with the responsible faculty and the outcomes of the review process are documented in a permanent record.

The quality assurance protocols include a random 10% review of all surgical pathology cases. The cases in the 10% review are randomly selected by case number only. Tissue site, diagnosis and case size are not used in the selection process. Cases identified as diagnostically difficult or of concern to the treating clinician are sent to outside expert pathologists for review. The internal diagnosis and the expert consultant diagnosis are compared and any discrepancies noted. Cases requested by outside medical centers for review in conjunction with their treatment of the patient have the external review diagnosis correlated with the internal final diagnosis. Discrepancies are reviewed. Finally, three-month duration focused reviews are undertaken by organ system with specific reviews of gynecologic, gastrointestinal, and dermatopathology specimens.

In a one year period (January 1–December 31, 2014), all cases undergoing review by any of the protocols except the focused review were included in the present study. The cases used for each of the review methods were drawn from the identical set of cases (all cases accessed in the one year period). The tissue focused review (three month period) was for dermatopathology cases, the majority of which were initially diagnosed by a board certified dermatopathologist. Following the dermatopathologist's review, the cases were over read by an in-house surgical pathologist. Subsequent review by an external "expert" dermatopathologist occurred when disagreements were detected between the review surgical pathologist and the dermatopathologist. Unsolicited consults by outside institutions were defined as consultations received from outside institutions which reviewed University of Missouri material in conjunction with treatment of a patient at the second institution. Error rate was expressed as percentage of reviewed cases where the original diagnosis differed from the review diagnosis. The percentage of cases with diagnostic errors detected by each of the methods was calculated and compared among the methods. The clinical significance of the diagnostic errors is defined in Table 1.

3. Results

The results of the review process are listed in Tables 1 and 2. The 10% random review detected seventeen errors in 2147 cases (0.8%). Selected case consultations requested by clinicians or an internal pathologist detected five diagnostic errors in 70 cases (7.1%).