

Second-Opinion Pathologic Review Is a Patient Safety Mechanism That Helps Reduce Error and Decrease Waste

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Abstract

Purpose: We have a crisis in health care delivery, originating from increasing health care costs and inconsistent quality-of-care measures. During the past several years, value-based health care delivery has gained increasing attention as an approach to control costs and improve quality. One proven way to control costs and improve the quality of health care is subspecialty pathologic review of patients with cancer before initiation of therapy. Our study examined the diagnostic error rate among patients with cancer treated at a tertiary care hospital and demonstrated the value of subspecialty pathologic review before initiation of treatment.

Methods: From September 1 to September 30, 2011, all patients seeking a clinical consultation had pathology submitted to and reviewed by a pathologist with subspecialty expertise and correlated in our pathology database.

Results: A total of 2,718 patient cases were reviewed during September 2011. There was agreement between the original pathologist and our departmental subspecialty pathologist in 75% of cases. In 25% of cases, there was a discrepancy between the original pathology report and the subspecialty final pathology report; 509 changes in diagnosis were minor discrepancies (18.7%), and in 6.2% of patients (169 reports), the change in diagnosis represented a major discrepancy that potentially affected patient care.

Conclusion: Second review of a patient's outside pathology by a subspecialist pathologist demonstrates the value of multidisciplinary cancer care in a high-volume comprehensive cancer center. The second review improves clinical outcomes by providing patients with evidence-based treatment plans for their precise pathologic diagnoses.

Introduction

Our nation is in the midst of a crisis in health care delivery. Most agree that the root of the crisis lies in increasing health care costs and suboptimal and inconsistently followed quality-of-care guidelines. During the past several years, value-based health care delivery has gained increasing attention as an approach to control costs and improve the quality of health care.¹ In the context of health care delivery, value is defined as health outcomes achieved per cost of the care delivered. In a value-based system, health care programs aim to measure and improve outcomes of care while measuring and reducing costs. Another hallmark of value-based programs is that care is organized around integrated practice units, wherein health care specialists focus on patients with a single medical condition, thus affording care providers with subspecialty expertise the opportunity to provide the highest quality evidence-based care.

Cancer care can be administered according to a model of value-based care delivery. Our institution has been organized around integrated practice units since 1992, with specialists and subspecialists in various medical disciplines providing care to patients in multidisciplinary care centers. Pathologists with subspecialty experience are essential members of each multidisciplinary care team. We consider obtaining the correct diagnosis and treatment plan on the initial visit to our facility critical to the outcome for each patient. We undertook this study to demonstrate the value of conducting a second review of pathologic specimens obtained and analyzed at another institution.

Our institution routinely performs a second-opinion review of pertinent outside pathologic material. Before a patient's first appointment in a multidisciplinary care center, a pathologist with subspecialty expertise routinely performs a complete review of the patient's outside pathology. This practice, mandated by our institutional bylaws, is similar to that of many other major academic centers that require or strongly encourage pathologic review of all diagnostic material to ensure appropriate treatment. This review is distinct from our direct pathologist-to-pathologist consultation practice for second opinions on challenging cases. A second review of the outside pathology allows our clinicians to have accurate diagnosis and staging information before multidisciplinary planning conferences that establish the course of treatment a patient will receive. Additionally, in this era of personalized cancer medicine, many subtleties exist in diagnoses that may be more amenable to subspecialty pathologic review and that enable a patient to be eligible for a clinical trial based on pathologic findings. The primary purposes of this study were: first, to demonstrate the frequency with which we made clinically significant changes in pathologic diagnosis as a result of second-opinion pathologic review, and second, to estimate the effect of that improved outcome of care on the cost of care in patients with breast cancer.

Although discrepancies after second pathologic review have been reported, these studies tend to be retrospective and anatomic site specific.²⁻⁶ Our study is comprehensive in that it

reviews the diagnostic error rate across all organ systems in surgical pathology.

Methods

From September 1 to September 30, 2011, all pathology patient cases (referrals and consultations) submitted to the department were reviewed by a pathologist with subspecialty expertise and correlated in our pathology database. Subspecialty expertise is defined as having sufficient knowledge in an organ system–based disease as demonstrated by prior subspecialty fellowship and/or academic and clinical concentration and intensity in a disease site. The correlation was performed either prospectively at the time of signout or retrospectively within the month of completion based on comparison of the final diagnosis and the referring pathologist's diagnosis (Table 1).

Patient cases were categorized as in agreement, major disagreement, or minor disagreement. A major disagreement was a change in diagnosis that affected patient care (eg, tumor *v* no tumor, positive *v* negative margin, or change in pathologic stage that affected treatment). A minor disagreement was a change in diagnosis that did not affect patient care (eg, additional positive lymph nodes in patient who was node positive, change in tumor grade that did not affect treatment, additional positive margins in patient scheduled for additional surgery or radiation therapy, or presence of lymphovascular space involvement that did not affect therapy). It is a policy in our pathology department that all changes in diagnosis that affect patient care be reviewed by another pathologist for concordance before signing out the patient case (in effect, third pathologic review). In all cases, original slides or recut sections from the paraffin block were used to render diagnosis. If there was a discrepancy based on additional material obtained, or if recut sections elucidated a diagnosis not present when compared with the original stained section, the change in diagnosis was not included in this data set, because the change would be based on additional material not available to the original pathologist at the time of initial signout. Addi-

tionally, true second-opinion consultations without a prior or tentative diagnosis that were sent to our department for difficult or challenging patient cases were not included in this study as discrepancies. A pathologic report of the second review was made part of the patient's electronic medical record and was reviewed by the treating oncologist formulating treatment recommendations. Results were entered and stored in our laboratory information system (PowerPath; EMC², Hopkinton, MA), extracted, and reported using Crystal Reports (SAP, Waldorf, Germany) and Microsoft Excel (Redmond, WA). All major discrepancies were then rereviewed by a pathologist for the purposes of this article and ensuring accuracy of the concordance.

Because breast cancer treatment is highly standardized across institutions, and two coauthors have interest and expertise in breast cancer, the subset of patients with known or suspected breast cancer who had diagnoses that yielded discordant results with potential clinical impact were additionally studied. Data were extracted, and a summary was prepared with the original and reviewed consultation reports. This summary information was provided to a coauthor medical oncologist with breast cancer subspecialty expertise (R.W.), who reviewed the clinical impact of the changed diagnosis. Discordant cases were then reviewed by a multidisciplinary care team to determine the care plan the patient would have undergone had we acted on the incorrect diagnosis.

There were eight patients evaluated who had a breast diagnosis at our institution that differed from the referred outside diagnosis (Table 2; Appendix, online only). For these eight patients, the change in diagnosis at our institution resulted in a change in the care plan and therefore a change in the costs that would have been incurred or avoided by each patient. In this scenario, costs to the patient are identified as hospital-billed charges minus any payments made by a private or public payer on the patient's behalf. The potential cost savings or additional costs incurred were determined by comparing the estimated

Table 1. Correlation of Second Review of Pathology by Subspecialty

Subspecialty	Total No. of Patient Cases	Correlated Patient Cases		Major Discrepancies		No. of Minor Discrepancies	Total Discrepant Patient Cases	
		No.	%	No.	%		No.	%
Breast	297	296	99.7	14	4.73	26	40	14
Cytology	395	369	93.4	4	1.08	43	47	13
GI	404	403	99.8	28	9.95	107	135	33
Genitourinary	304	304	100	19	6.25	73	92	30
Gynecology	293	293	100	21	7.17	63	84	29
Head and neck	144	140	97.2	9	6.43	56	65	46
Hematopathology	336	334	99.4	29	8.68	42	71	21
Neurology	60	59	98.3	6	10.17	4	10	17
Skin	303	293	96.7	23	7.85	71	94	32
Soft tissue	25	25	100	4	16	6	10	40
Thoracic	157	155	98.7	12	7.74	18	30	19
Total	2718	2,671	98.3	169	6.63	509	678	25

Table 2. Clinical and Financial Review of Eight Patients With Breast Cancer Who Had Documented Changes in Therapy Based on Pathologic Second Review*

Initial Diagnosis	Second Review Diagnosis	Change in Management	Added Cost or Savings
DCIS	Multifocal IDC	Additional OR time, SLN biopsy, detailed pathologic review of SLN	\$18,560 added cost
DCIS	DCIS and IDC with positive margins	Additional OR time, SLN biopsy, detailed pathology of SLN	\$105,277 added cost
IDC, ER positive	IDC, ER negative	No hormonal therapy, additional chemotherapy, WBC enhancers	\$115,832 added cost
Invasive metaplastic carcinoma	IDC	Change to standard chemotherapy without platinum	\$42,488 added cost
Paget's disease, completely excised	Paget's disease, close margin	Additional surgery (image-guided lumpectomy) revealed residual tumor	\$99,187 added cost
ADH on core biopsy	UDH and ALH	Surveillance, no surgery	\$18,560.05 cost savings
DCIS	ADH	Surveillance, no 6-week standard radiation therapy	\$72,082.00 cost savings
DCIS and LCIS	LCIS	Surveillance, no 6-week radiation therapy or additional surgery	\$90,642.05 cost savings

Abbreviations: ADH, atypical ductal hyperplasia; ALH, atypical lobular hyperplasia; DCIS, ductal carcinoma in situ; ER, estrogen receptor; IDC, invasive ductal carcinoma; LCIS, lobular carcinoma in situ; OR, operating room; SLN, sentinel lymph node; UDH, usual ductal hyperplasia.

* Significant pathologic changes in remaining six patients did not affect patient care or result in change of therapy, because they were either historical patient cases, in which treatment had already been rendered, or there were mitigating factors or comorbid conditions that superseded the change in diagnosis.

cost of care associated with the outside diagnosis with the estimated cost of care associated with the diagnosis made in our institution. Costs to each patient were queried using the enterprise information warehouse (EIW) at our institution. Data that were queried from the EIW for this study included both hospital and clinic charges, physician charges, patient diagnosis information, procedures performed, data on surgeries, and pharmacy data. To estimate the costs associated with our institutional diagnosis, the available EIW data were reviewed by a medical oncologist with breast cancer subspecialty expertise who verified which patient costs were associated with the treatment plan related to our diagnosis. To estimate costs associated with the original diagnosis, a medical oncologist with breast cancer subspecialty expertise described the care plan the patient would have undergone with the original diagnosis. This care plan was then queried by either a matched patient who received the same care plan or procedures that would have been performed. The estimated change in cost was then determined to be either an added cost or avoided cost based on the change in care.

Results

A total of 2,718 patient cases were reviewed in the pathology department during September 2011. Of these, 98.3% (n = 2,671) were correlated, and contributor diagnoses and our diagnoses were compared. Neoplasia, either diagnosed or suspected, was the basis of the referral in 100% of the patient cases submitted for referral and consultation. There was agreement between the original pathologist and our institution subspecialty pathologist in close to 75% of cases. In 25% of cases, there was a discrepancy between the original pathology report and the final pathology report of our institution; 509 changes in diagnosis were minor discrepancies (19.1%), and in 6.3% of patients (169 reports), the change in diagnosis represented a major

discrepancy that affected patient care. By subspecialty, there was most agreement with review of cytologic specimens (87.3%), followed closely by breast specimens (86.5% concordance). Conversely, 46% of head and neck pathology reports rereviewed at our institution had discrepancies when reviewing the original pathology report in comparison with the final report used for patient care.

Soft tissue and neuropathology had the least number of patient cases reviewed but showed the highest percent of major discrepancies: 16% and 10%, respectively. Glioblastoma multiforme was the most common revised diagnosis in brain tumors (100%), whereas classification of liposarcoma was the most common major diagnostic discrepancy in soft tissue (50%). Review breast outside pathology during the month of September 2011 showed 4.7% of major discrepancies. Review of the electronic medical records documented changes in either therapy or clinical evaluation in 57% of the patients with discrepant breast cancer diagnoses; some of the recorded changes in diagnosis occurred after the commencement of initial therapy. The most common added cost was from additional surgery for sentinel lymph node evaluation and the cost of changing chemotherapeutic regimens. Cost avoidance occurred when lesions were downgraded, and patients were dispositioned to surveillance rather than surgery or radiation therapy.

Discussion

In the prospective review of all surgical pathology cases accessioned at our institution during the month of September 2011 with mandatory electronic correlation, discrepancies were identified in 25% of patient cases. A majority of these discrepancies were considered minor and did not affect patient care, but there was a significant change in diagnosis that affected patient care in 6% of cases. These 6% of cases with major discrepancies correspond to 169 patients who had substantial changes in their



Figure 1. Flow diagram illustrating diagnostic concordance (agreement) and discordance (disagreement) of referral and consult patient cases reviewed in September 2011. ADH, atypical ductal hyperplasia; DCIS, ductal carcinoma in situ; ER, estrogen receptor; IDC, invasive ductal carcinoma; LCIS, lobular carcinoma in situ; UDH, usual ductal hyperplasia.

pathology that altered their course of treatment. On the basis of the number of new patients we see annually at our institution, extrapolation of these data would result in potentially more than 2,000 patients per year with a major change in diagnosis. In addition to this profound effect on clinical care in these patients, these significant patient diagnostic errors translate into substantial downstream revenue enhancements for the hospital, with patients being triaged to additional surgery or complete resections and/or adjuvant chemotherapy or radiotherapy. Be-

cause the treating hospital is responsible for the assigned diagnosis used for therapeutic decision making, we and others conclude that it is rational and wise that all patient cases be reviewed where major therapeutic interventions are planned based on the interpretation of tissue.⁷ Our study benefited from the development of a postanalytic quality improvement structured report that allowed for prospective data collection and the ability to study the differences between opinions by subspecialty.

These results on changing the contributor's diagnosis are substantially higher than the rate of outside pathologists changing the diagnoses of pathologists at our institution. In comparison, our pathology department sent out 240 cases for a second opinion in 2011. There was a significant change in diagnosis in one (0.4%) of these 240. This difference may be secondary to the practice of subspecialty signout by pathologists at our institution and added value of both concentration and intensity of expertise. There is likely a benefit of redundancy—that is, a benefit of review of a high volume of a particular pathologic entity that facilitates accurate and complete pathologic diagnoses. Moreover, the value differentiator may be that clinical follow-up is available and the outcomes of the patients are known, providing important feedback to the diagnostic pathologist.

In 1992, the Association of Directors of Anatomic and Surgical Pathology published its recommendation that complete review of outside pathology be a standard quality improvement policy before commencement of treatment at a different institution.⁸ This quality improvement initiative was recommended so that hospitals would have tissue confirmation of diagnosis before commencing therapy. Gupta et al⁹ surveyed 300 hospitals in 2000 and ascertained that approximately half of all responding institutions had similar requirements for in-house review of outside material before surgery.

Numerous studies have reported the clinical management benefits of a pathologic second-review process when patients are referred for treatment from a different hospital, and several large studies of interinstitutional pathology review have reported overall discordance rates of 1.4% to 9%.¹⁰⁻¹³ The lower rate of 1.4% is from a study of more than 6,000 patient cases referred to Johns Hopkins Hospital in the late 1990s. In this study, a changed diagnosis was defined as “a discordant diagnosis resulting in a major modification therapy or prognosis.”^{10(p2)} Using a similar definition of major and minor diagnosis changes, Manion et al¹¹ observed a 9.0% minor discordance rate and 2.3% major discordance rate for 5,629 patient cases reviewed after submission to the pathology department in Iowa City, Iowa. A review of pathology submitted to the Cancer Center in Taiwan documented major discordance in 6% of institutional pathologic consultations submitted for review.¹² Weir et al,¹³ in reviewing the pathologic consultations submitted to the University Health Network (Toronto, Ontario, Canada), observed a 6.8% discordance rate in 1,000 randomly selected consultations. Abt et al,¹⁴ in reviewing 777 pathologic cases submitted to the Hershey Medical Center (Hershey, PA), identified discrepancies that resulted in a change in patients' evaluation and treatment in 45 cases (5.8%). Our results of 6% major discrepancies in review of outside pathologic material are thus congruent with those reported in the medical literature.

In a recent study of patients with breast cancer, Price et al¹⁵ reported an 11% rate of discrepancy with high or medium clinical impact in pathology reports of 100 randomly selected patients. For the purposes of this study, high or medium clinical impact was defined as pathologic changes with the potential to lead to a change in the intent of treatment, treatment modality,

type or duration of treatment within a modality, or emphasis placed on a recommendation modality as determined by oncologist review. The similarity of discrepancy rates between this study and ours is most likely attributable to similar patient populations; both studies were performed in a major referral center with a high volume of patients with cancer. Kennecke et al,¹⁶ in reviewing the pathology of 405 patients with node-negative breast cancer, documented pathologic changes in 20% (81 patients). The most frequent change elements were tumor grade (40%) and lymphovascular (26%), nodal (15%), and margin (12%) status. With results similar to this study, the authors found that the changes in diagnosis resulted in treatment modifications in 6% of patients. In reviewing prostate biopsies of patients referred for definitive treatment, Epstein et al¹⁷ studied the clinical and cost impact of second review and found that second review resulted in a cost savings for their institution.

Routine second review of patients' pathologic material is time consuming, and its value and utility is routinely questioned by hospitals and third-party payers. However, our study and others have shown that pathologic second review can reduce health care costs by preventing inappropriate therapy (harm) and identifying correct therapy, especially when pathologists with subspecialty expertise are responsible for second review.

A secondary purpose of this study was to document the return on investment of a second pathologic review in a tertiary-care setting. Breast cancer was chosen both because of national standardization of treatment and because of the breast cancer expertise among our investigators. We analyzed how changes in therapy affected patients' outcomes and costs by reviewing patient cases with significant changes in diagnosis after second review. Over the last 3 years, our institution has worked to examine the cost of providing multidisciplinary care through the use of time-driven activity-based costing. This methodology allowed us to reach an estimate regarding the cost to provide second pathologic review, including technical and professional aspects of care. The value of a second review is evident in the patients who were triaged to either additional surgery or chemotherapy and in the patients with atypia and lobular carcinoma in situ who needed no additional interventional treatment. Our results indicate that although clinically significant differences in opinion represented a small fraction of all our patient cases reviewed, these differences affected patient management, resulting in either additional therapeutic interventions or surveillance. For three of the patients in this study, the net outcome was a cost savings, but for the remaining five patients, there were added charges reflecting appropriate patient care.

A reasonable question is whether all types of pathologic specimens need to be reviewed. This study and prior studies from tertiary-care hospitals show that the overall change in diagnosis is similar for all major types of surgical pathology. No organ system or pathologist is immune from diagnostic errors. Therefore, it is crucial that systems be in place to help mitigate such errors. Second pathologic review should not be limited to pa-

tient cases from community-based hospitals or private laboratories not affiliated with a teaching hospital, because we have shown that on occasion, cases signed out by our pathologists also contain errors. Rather, all patient cases submitted to a hospital for a second clinical opinion, a transfer, or initiation of care should undergo rereview as an error-reduction strategy.⁷

Our results indicate that clinically significant disagreements in pathologic opinion can affect patient management and protocol eligibility. Although 93.8% of patient cases did not have a major variance, extrapolation of our data shows that in the absence of pathologic second review, potentially more than 150 patients treated at our institution each month could receive inappropriate therapy based on incomplete or inaccurate pathologic information. This level of harm is preventable.

We believe that a second review of a patient's outside pathology by a subspecialty pathologist demonstrates the value of multidisciplinary cancer care in a high-volume comprehensive cancer center. The second review improved clinical outcomes by providing patients with evidence-based treatment for their precise pathologic diagnoses. We also demonstrated the cost implications of this practice and compared them with the costs of treatments avoided. Applied nationally, this added step be-

fore cancer treatment could improve the quality of cancer care in the United States.

Authors' Disclosures of Potential Conflicts of Interest

The authors indicated no potential conflicts of interest.

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Appendix

Clinical and financial review of eight patients with breast cancer who had documented changes in therapy based on pathologic second review. One patient who had her pathology reviewed in September 2011 was initially given the diagnosis of ductal carcinoma in situ (DCIS) and was found to additionally have multifocal invasive ductal carcinoma (IDC) on rereview. This change in diagnosis resulted in additional operating room time, sentinel lymph node (SLN) biopsy, and detailed pathologic review to include levels and cytokeratin immunohistochemical staining of the nodes.

A second patient, presented to our institution after undergoing lumpectomy that showed DCIS with tumor at the margins on initial review, was found to also have invasive carcinoma with IDC at the margin. This patient additionally underwent SLN biopsy, necessitating surgery, with additional operating room time and additional pathologic evaluation of her specimen.

For a 45-year-old patient with an outside diagnosis of a 1.8-cm estrogen receptor (ER) –positive IDC, it was found on review that her tumor was in fact ER negative. This change in diagnosis saved the patient the cost of hormonal therapy but added the cost of appropriate chemotherapy and WBC enhancers (pegfilgrastim).

One patient received an outside diagnosis of invasive metaplastic carcinoma, a carcinoma in which the glandular elements have undergone metaplasia or transformation into an alternate cell type rather than retaining luminal type epithelium. Invasive metaplastic carcinomas are frequently chemoresistant and are treated with platinum-based chemotherapies. On pathologic review, it was found that the patient had conventional IDC, so she benefited from standard chemotherapy.

Another patient presented with a superficial biopsy of Paget's disease of the nipple, which by the outside pathology report was considered completely excised. Pathologic second review confirmed Paget's disease of the nipple, with a comment in the report that the additional margins were scant and probably not diagnostic. On the basis of this interpretation, the patient underwent re-excision, which confirmed the suspected residual carcinoma.

Three patients were downgraded after second pathologic review, resulting in a cost savings. The first patient with a core biopsy diagnosis of atypical ductal hyperplasia (ADH) warranting excision was downgraded to usual ductal hyperplasia and atypical lobular hyperplasia and triaged to surveillance at our institution rather than undergoing additional surgery, for a cost savings of \$18,560.05.

The second patient, who had undergone lumpectomy with the outside diagnosis of DCIS, was reclassified as having ADH, with no histologic evidence of DCIS, and was dispositioned to surveillance rather than 6 weeks of standard radiation therapy, for a cost savings of \$72,082.00.

The third patient, who initially had the core biopsy diagnosis of DCIS and lobular carcinoma in situ (LCIS) rendered by the contributing pathologist, was found only to have LCIS. This patient was also dispositioned to surveillance rather than lumpectomy and radiation therapy, for a cost savings of \$18,560.05.

Significant pathologic changes in the remaining six patients did not affect patient care or result in a change of therapy, because they were either historical patient cases, in which treatment had already been rendered, or there were mitigating factors or comorbid conditions that superseded the change in diagnosis.