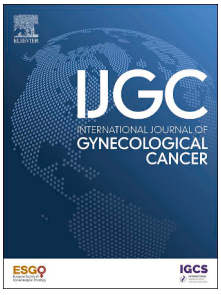
ORIGINAL RESEARCH

Rethinking certainty: a retrospective study on diagnostic revisions in gynecologic pathology



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ABSTRACT

Objective: Expert pathology review plays a crucial role in gynecologic oncology, where diagnostic complexity can substantially affect patient management and medico-legal accountability. This study aimed to assess the frequency, nature, and impact of diagnostic revisions arising from second opinion evaluations of gynecologic lesions.

Methods: We retrospectively analyzed 319 consecutive cases of gynecologic lesions submitted for second opinion review by a senior gynecologic pathologist at a tertiary referral center between 2018 and 2024. Each case was categorized as concordant, minorly discrepant, or majorly discrepant compared with the referring diagnosis. Clinical impact and medico-legal relevance were systematically evaluated.

Results: Of the 319 reviewed cases, 47.0% were fully concordant with the original diagnosis, whereas 34.5% exhibited major discrepancies and 18.5% minor discrepancies. The most frequent sources of diagnostic disagreement involved tumor histotype, grade, and determination of the primary site. Ovarian and endometrial specimens accounted for most revisions. Diagnostic reinterpretation led to changes in clinical management in 54.9% of cases, and potential medico-legal implications were identified in 11.3%.

Conclusions: Expert second opinion pathology in gynecologic oncology revealed a high rate of diagnostically and clinically significant revisions. Routine implementation of specialist review for complex or high-risk gynecologic lesions is strongly recommended to improve diagnostic accuracy, guide appropriate patient care, and reduce medico-legal risk.

Keywords:
Second Opinion; Gynecologic Pathology; Endometrial Cancer; Ovarian Cancer; Cervical Cancer

WHAT IS ALREADY KNOWN ON THIS TOPIC

Diagnostic discrepancies in gynecologic pathology are not uncommon and may significantly influence treatment decisions. However, few studies have systematically evaluated the clinical and medico-legal impact of second opinion pathology in this field.

WHAT THIS STUDY ADDS

In a large retrospective series of 319 second opinion reviews, over half of the cases resulted in diagnostic revisions, one-third of which were major and directly altered patient management. More than 11% of consultations were linked to medico-legal proceedings, emphasizing the dual clinical and legal importance of expert review.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

Routine expert pathology review should be considered a standard component of gynecologic oncology practice to enhance diagnostic accuracy, improve patient safety, and strengthen medico-legal defensibility.

INTRODUCTION

Second opinions in surgical pathology are a well-established practice, especially for complex or rare lesions. In gynecologic pathology, they are pivotal in optimizing diagnostic accuracy and ensuring appropriate patient management, given that therapeutic decisions often depend critically on histopathologic interpretation. Multiple studies have shown that second opinions may reveal significant discrepancies, including changes in grade, stage, or even fundamental diagnostic categories.[1-6] Such differences are not always attributable to error but often reflect subjective interpretation or variable application of diagnostic thresholds, particularly, in borderline or ambiguous cases.[7]

From a medico-legal standpoint, second opinions are increasingly relevant. In countries such as Italy, litigation related to diagnostic discrepancies is not uncommon, particularly, when such variation results in over-treatment, under-treatment, or delayed therapy.[8-10] The Italian Gelli-Bianco Law (2017) redefined professional liability, placing patient safety at the center of medical

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practice and emphasizing adherence to evidence-based guidelines and best practices.[11,12] In this framework, seeking a second opinion in complex cases may be not only prudent but a professional obligation, and failure to do so may be interpreted as a breach of the duty of care[13-15] Recent jurisprudence confirms that not all diagnostic errors constitute malpractice. However, negligence may be established when a physician fails to take reasonable measures to reduce diagnostic uncertainty, particularly, when expert review is readily available.[16] Judges increasingly emphasize clinical documentation and adherence to diagnostic-therapeutic pathways as safeguards for patients and providers.[13-16]

Another important aspect is informed consent.[17] Although second opinions usually occur between professionals, their implications for patient care require transparent communication.[13-17] Patients have the right to be informed about diagnostic uncertainties, the rationale for additional review, and possible consequences, such as treatment delays, transfer of materials, or significant diagnostic revisions.[13-17] Properly documented consent not only supports patient autonomy but also provides medico-legal protection for clinicians and institutions. This study analyzed second opinion consultations for the histopathologic diagnosis of gynecologic tumors at a tertiary referral center between 2018 and 2024, quantifying diagnostic discrepancies. It also integrates medico-legal considerations to highlight the implications of diagnostic variability and the need for standardized review processes.

METHODS

Study Design and Setting

This retrospective, monocentric study was conducted at the Anatomical Pathology Unit of the Fondazione Policlinico Universitario A. Gemelli IRCCS (Rome, Italy). It includes all second opinion pathology consultations for gynecologic lesions received and reported by Professor Gian Franco Zannoni between January 1, 2018 and March 31, 2024.

Case Selection and Diagnostic Review

Eligible cases were identified from departmental consultation records. Included were all second opinion requests related to the female genital tract, submitted either from external institutions or internally by gynecologic oncologists. Each case was reviewed on hematoxylin and eosin—stained slides, with additional immunohistochemical stains performed when necessary.

All consultations were jointly conducted by at least 2 senior pathologists.. This collaborative review ensured expert consensus in all cases.

Data Extraction and Classification

A structured database was used to capture the following data: year of consultation, anatomical site (cervix, endometrium, ovary), type of lesion (carcinoma, borderline tumor, dysplasia), initial diagnosis (as per referring pathologist), final diagnosis (after expert review), presence and type of diagnostic discrepancy (major, minor, none), clinical impact (change in therapeutic management), and medico-legal implications (if applicable and explicitly documented)

Cases were categorized according to the type of the diagnostic discrepancy as follows: major discrepancy: diagnostic changes with potential impact on treatment (benign vs malignant, tumor grading, histotype change); minor discrepancy: differences with no expected impact on treatment or follow-up (descriptive terminology, classification nuances); and concordant diagnosis: full agreement between original and second opinion diagnoses.

A revision was deemed to have clinical impact when it led to changes in surgical planning, extent of resection, indication for adjuvant therapy, or oncologic follow-up.

Potential medico-legal relevance was recorded only when explicitly mentioned in the consultation request or accompanying clinical documentation. No systematic medico-legal classification was applied; thus, related findings are limited to descriptive observations.

Ethical Considerations

The study was reviewed and approved by the local ethics committee of the Fondazione Policlinico Gemelli IRCCS. Given its retrospective design and use of anonymized data, the ethics committee determined that no formal protocol number was required. All procedures were conducted in accordance with the principles of the Declaration of Helsinki (2013 version).

In accordance with the journal's guidelines, we will provide our data for independent analysis by a selected team by the Editorial Team for the purposes of additional data analysis or for the reproducibility of this study in other centers if such is requested.

RESULTS

Between January 2018 and March 2024, a total of 319 second opinion pathology consultations concerning gynecologic lesions were reviewed and signed by Professor Gian Franco Zannoni at the Fondazione Policlinico Universitario A. Gemelli IRCCS. These cases were referred primarily from external institutions across Italy, with a high volume of requests coming from regions outside Lazio (68%), reflecting the national recognition of the institution's expertise in gynecologic pathology.

Patients ranged in age from 20 to 88 years, with a median age of 57 years. Most consultations involved epithelial neoplasms of the ovary (35.4%, n = 113) and endometrium (28.5%, n = 91), followed by cervical lesions (16.6%, n = 53) (Table 1). The remaining cases (19.4%, n = 62) included tumors of the vulva, vagina, fallopian tubes, peritoneum, uterus not otherwise specified, and metastatic tumors involving gynecologic organs. A broad spectrum of histopathologic entities was represented, ranging from common high-grade endometrial carcinomas and borderline ovarian tumors to diagnostically complex or rare lesions such as

Table 1 Distribution of Consultation Cases by Anatomical Site.

Anatomical Site	No. of cases	Percentage (%)
Ovary	113	35.4
Endometrium	91	28.5
Cervix	53	16.6
Other (vulva, vagina, tubes, uterus NOS, peritoneum)	62	19.4

Abbreviation: NOS, not otherwise specified.

perivascular epithelioid cell tumor, mesonephric carcinoma, and uterine tumors resembling ovarian sex cord tumor.

A comparative analysis between the referring diagnosis and the second opinion revealed diagnostic concordance in 150 of 319 cases (47.0%), where the expert review confirmed the original interpretation without relevant variations in terminology, histotype, or grading. Conversely, 169 cases (53.0%) showed some level of discrepancy, including 110 cases (34.5%) classified as major discrepancies (defined as changes with potential implications for patient management) and 59 cases (18.5%) considered minor discrepancies, which involved terminological adjustments, subclassification refinements, or borderline interpretative issues not affecting treatment plans (Table 2).

When stratified by site of origin, ovarian tumors accounted for the highest proportion of major discrepancies, mainly due to challenges in distinguishing borderline from invasive carcinomas; confusion between Brenner, endometrioid, and serous tumors; or mature versus immature teratomas. Treatment modifications (surgery vs chemotherapy) occurred in approximately 35% of these cases (Table 3). Endometrial tumors also showed frequent discordance, particularly, regarding the diagnostic threshold between atypical hyperplasia and well-differentiated endometrioid carcinoma, grading shifts (G1 vs G3), and misinterpretation of stromal sarcomas versus leiomyosarcomas; in several cases, the second opinion upgraded the lesion, directly impacting adjuvant therapy decisions. Cervical cancer revisions involved the distinction between human papillomavirus–related and mesonephric carcinoma, CIN3, AIS, and invasive carcinoma, as well as recognition of neuroendocrine morphology, with changes influencing prognosis and surgical management. In vulvar tumors, discrepancies included clarifications between severe dysplasia and invasive squamous carcinoma or benign stromal lesions, with surgical management being the main therapeutic implication. Mesenchymal tumors frequently showed misclassifications between leiomyomas, smooth muscle tumor of uncertain malignant potential, and leiomyosarcomas, with relevant consequences for follow-up and adjuvant treatment. Finally, uterine and other rare tumors, such as adenomatoid tumor, hydatidiform mole, and undifferentiated carcinoma with sarcomatoid features, were also subject to revision, where the second opinion refined diagnostic categorization and therapeutic strategy.

Histologically, the most frequently revised features involved the following: histotype: 26.3% of all discrepancies; tumor grade: 21.0%; tumor origin: 5.3%; multiple concurrent changes: 47.4%.

These findings highlight the complexity of gynecologic pathology and the importance of experienced, consensus-based review.

A diagnostic revision was considered to have a clinical impact in 175 of 319 cases (54.9%) (Table 4). These cases directly influenced patient care, including revision from benign to malignant or vice versa, prompting major changes in the therapeutic strategy; re-assessment of surgical indications (from conservative surgery to radical resection or avoidance of overtreatment); modification or initiation of adjuvant treatment such as chemotherapy, radiotherapy, or hormonal therapy; re-definition of follow-up protocols, especially in low-grade lesions or precancerous conditions.

Notably, in several instances, the second opinion spared patients from unnecessary aggressive treatments, whereas in others, it enabled timely escalation of care based on revised risk stratification. The highest clinical impact was observed in cases where grading or histotype re-classification altered the oncologic approach.

In 36 of 319 cases (11.3%), the consultation was explicitly linked to medico-legal concerns, as documented in the referral

Table 2 Distribution of Diagnostic Discrepancies.

Discrepancy type	No. of cases	Percentage (%)
Concordant diagnosis	150	47.0
Minor discrepancy	59	18.5
Major discrepancy	110	34.5

Table 3 Category of Discrepancy.

Category of discrepancy	No. of cases	Clinical impact
Ovarian tumors (borderline vs invasive; Brenner vs endometrioid; serous vs mucinous; teratomas)	34	Therapy changes (surgery ↔ chemotherapy), prognostic implications
Endometrial tumors (hyperplasia vs carcinoma; grading discrepancies; stromal sarcoma vs leiomyosarcoma)	20	Upstaging led to CT or surgery + CT in several cases
Cervical cancer (CIN3 vs AIS vs invasive; HPV-related vs mesonephric; neuroendocrine variants)	10	Modified prognosis, surgical management, systemic therapy
Vulvar tumors (dysplasia vs. invasive squamous carcinoma; benign fibrous lesions)	2	Surgical management adjustment
Mesenchymal tumors (leiomyoma vs STUMP vs leiomyosarcoma)	15	Prognostic re-assessment and adjuvant therapy
Rare uterine/other tumors (adenomatoid, mole, undifferentiated carcinoma with sarcomatoid features)	3	Diagnostic refinement and therapeutic reorientation

Abbreviations: CT, computed tomography; HPV, human papillomavirus; STUMP, smooth muscle tumor of uncertain malignant potential.

Table 4 Cases with Clinical Impact and Medico-Legal Relevance.

Impact type	No. of cases	Percentage (%)
Cases with clinical impact	175	54.9
Cases with medico-legal relevance	36	11.3

request or accompanying clinical notes (Table 4). These included requests for forensic evaluation in the context of legal disputes or insurance claims; internal audit cases with suspected diagnostic errors; and, in nearly all medico-legally relevant cases, a major discrepancy was identified, and a change in diagnosis was deemed retrospectively significant in terms of patient safety or treatment outcome.

DISCUSSION

Summary of Main Results

Among 319 second opinion consultations, diagnostic discrepancies were identified in 53.0% of cases, with 34.5% classified as major. More than half of the cases demonstrated direct clinical impact, primarily affecting tumor type, grade, or primary site, particularly, in ovarian and endometrial lesions. From a medico-legal standpoint, 11.3% of consultations were explicitly requested for forensic reasons, and nearly all of these involved major diagnostic revisions. Among the 110 cases with major discrepancies, 45.5% caused no legal damage, 17.3% produced over-treatment, 23.6% represented loss of chance of survival, and 4.5% were classified as wrongful death. These findings illustrate the spectrum of liability outcomes, ranging from no compensable harm to fatal consequences.

Results in the Context of Published Literature

These findings mirror previous studies showing discrepancy rates of 10% to 40%, depending on subspecialty and referral setting.[1-4,13-16] Clinically, second opinions altered surgical planning, indications for adjuvant therapy, or follow-up strategies, thereby reducing over-treatment and under-treatment. Although time-intensive and resource-intensive, second opinions clearly enhance patient safety, as confirmed by previous studies demonstrating reduced morbidity, better therapeutic alignment, and avoidance of unnecessary interventions.[1-4,13-16] Variability is not always error-driven but often reflects interpretative subjectivity, different diagnostic thresholds, or limited ancillary testing at referring institutions.[13-16,18]

The medico-legal implications of diagnostic discrepancies between an initial histopathologic report and a second opinion depend primarily on their clinical consequences.[13-16] Three main scenarios can be distinguished. First are discrepancies without clinical impact, where no harm or liability arises.[13-16] Second are errors causing biological damage through over-treatment (eg, misclassifying a benign lesion as malignant, leading to unnecessary interventions) or under-treatment (eg, missing malignancy and delaying therapy).[13-16] Within under-treatment, medico-legal outcomes include "loss of chance of survival," when prognosis is compromised, and "wrongful death," when diagnostic error directly leads to a fatal outcome.[13-16] Differentiating between hypothetical consequences and documentable harm underscores the central role of second opinion pathology in patient care and in medico-legal evaluation.

Responsibility for diagnostic errors must be assessed on a case-by-case basis. Individual liability arises when avoidable errors are made without appropriate verification.[1-4,13-16] Conversely, when cases are inherently complex and the initial diagnosis followed best practices, the variability between experts does not imply malpractice.[1-4,13-16] Systemic responsibility is also relevant because institutional deficiencies, such as lack of ancillary tests, absence of review protocols, or excessive workloads, may contribute to errors.[1-4,13-16] Courts increasingly acknowledge that discrepancies do not automatically equal negligence but emphasize the duty to minimize uncertainty through expert review when appropriate.[19–23]

Strengths and Weaknesses

Despite several limitations, this study provides valuable insights into the diagnostic and medico-legal implications of second opinion pathology. Its primary weaknesses include referral enrichment because the cases submitted for second opinion were likely those already perceived as diagnostically challenging or disputed, potentially inflating the observed rate of discrepancies. The inclusion rationale was also unclear because the criteria for external case referral and acceptance were not standardized or prospectively defined. Moreover, medico-legal relevance was recorded only when explicitly mentioned in referral documentation, without application of a systematic or validated forensic classification framework. The impact assessment was indirect, with "clinical impact" inferred from theoretical treatment modifications rather than from verified patient outcomes, such as survival, morbidity, or quality of life. The absence of longitudinal data further limits the ability to determine whether diagnostic revisions improved clinical management or mitigated subsequent litigation risk. From a methodological standpoint, the study relied solely on descriptive analyses without inferential statistics, regression modeling, or inter-observer agreement testing, restricting the depth of analytical interpretation.

Nonetheless, key strengths include the relatively large case series and the integration of detailed medico-legal assessment within a real-world diagnostic setting, offering a meaningful contribution to the understanding of how expert pathology review influences clinical and legal decision-making.

Implications for Practice and Future Research

Beyond clinical and legal dimensions, second opinions provide value at the health care system level. Integrating them into multidisciplinary tumor boards and diagnostic-therapeutic care pathways promotes consistency, transparency, and fairness while providing defensive documentation in case of litigation.[1-4,13-16] The act of formally seeking expert review demonstrates prudence, adherence to standards, and commitment to patient safety. Moreover, second opinions reinforce patient trust, support communication, and serve as a valuable tool for professional education, reducing inter-observer variability and fostering continuous improvement.[1-4,13-16] Future research should explore digital pathology and artificial intelligence to support second opinion workflows and evaluate patient perspectives.[24–27] National databases of medico-legal claims may further clarify the legal consequences of diagnostic variability.[28,29] This study confirms the importance of structured second opinion pathways in gynecologic pathology, particularly, for diagnostically complex lesions.

CONCLUSIONS

Second opinion pathology is essential in gynecologic oncology, with over one-third of cases showing major discrepancies and

more than half influencing treatment. Expert review enhances diagnostic accuracy, patient safety, and medico-legal protection. Integrating second opinions into standard workflows promotes transparency and quality assurance. Informed consent (clearly documenting the rationale for review) upholds patient autonomy and professional accountability, reinforcing trust and shared responsibility in care.

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