

# Clinicopathological Diagnostic Discrepancies: An Analysis of 1703 Surgical Pathology Specimens

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## Abstract

**Background:** Evaluation of error occurrence is a vital component of laboratory-quality assurance. One method of the measuring errors is by an assessment of discrepancies in clinical and pathology diagnosis. This study was carried out to determine the occurrence of such differences in our institution and to find out if any association exists between clinical diagnostic reasoning and the nature of the lesion. **Materials and Methods:** A 3-year retrospective analysis of surgical pathology specimen records was performed for report contents, clinical diagnosis, clinical suspicion, or diagnostic questions. Discrepancy index (*Di*) was calculated as the number of incompatible cases/total number of cases  $\times 100$ . **Results:** An analysis of 1703 cases showed complete agreement between the clinical and pathology diagnosis in majority of the cases (1514, 89.9%) while discordance occurred in 189 (11.1%). There was more discrepancy in benign cases (12.3%,  $n = 1144$ ) than malignant conditions (8.6%,  $n = 559$ ). Using Chi-square test of independence, there was association between the nature of the lesion (benign or malignant) and diagnostic concordance ( $\chi^2 = 5.24$ ,  $P = 0.02207$ ) at 0.01 level of significance. There was more discordance in diagnosis of soft tissue lesions ( $Di = 23.8$ ,  $n = 1587$ ). **Conclusion:** This study suggests that greater discrepancies are likely to occur in the diagnoses of benign conditions than malignant diseases.

**Keywords:** Diagnostic errors, discrepancy index, quality assurance

## INTRODUCTION

A discrepancy in diagnosis has occurred when there is a difference in the diagnosis rendered, of a disease condition, by two or more competent physicians. Theoretically, the attendant consequence is that the patient will be subjected to completely different therapeutic decisions, all of which may be inappropriate. In an ideal setting, all the activities involving patient care, from the clinic to the laboratory, commencement, and monitoring of therapy should resonate in a concordant diagnostic stream, and within the limits of logic, yield a predictable treatment outcome. Discrepancies in diagnosis or diagnostic reasoning raise the questions of accuracy. Accuracy in diagnosis is the product of an appropriate diagnostic reasoning which is, in turn, a complex cognitive synthesis of the doctor's knowledge and experience base, observation, and interpretation of the information received from the patient and the faithful transfer of information between other members of the diagnostic team. There is an emerging emphasis on the relevance of the analysis and collection of error data to

be used later to guide the development and implementation of institution-based quality improvement and intervention strategies. Intervention strategies to enhance interpretive accuracy have been shown to have undisputed potential to improve patient care and safety.<sup>[1]</sup> Reports from the pathology laboratory are expected to be accurate and reliable. Diagnostic errors in pathology potentially bears serious consequences, the gravity of which may not be easily fathomed at the point of decision-making. The results of evaluation of 316,589 incidents in the National Incidents Reporting System in the UK by Sevdalis *et al.* aptly underscore the importance of accurate diagnosis. This group found that 1674 (0.5%) of the reported incidents were basically diagnostic, and they concluded that

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**How to cite this article:** Vhritherire RA, Ngbea JA, Akpor IO, Gyenger D, Ajetumobi O, Adekwu A, *et al.* Clinicopathological diagnostic discrepancies: An analysis of 1703 surgical pathology specimens. *Ann Trop Pathol* 2018;9:50-4.

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**DOI:**  
10.4103/atp.atp\_10\_18

diagnostic incidents were more likely than others to cause serious harm or death of patients.<sup>[2]</sup>

Discrepancy studies are conducted to evaluate the occurrence of interpretive errors. It is a measure of the difference in diagnostic reasoning, based on available data sources, between two or more observers of a phenomenon. This may be done within the surgical pathology department in the form of periodic inter-observer or intra-observer reviews of past cases, an activity which also doubles as an internal-quality assurance assessment. Discrepancy studies have been conducted to assess the extent to which histology has confirmed cytopathology diagnosis with a view to improving skills. For instance, a histology follow-up of fine needle aspiration of 4703 thyroid nodules yielded a discrepancy rate of 15.3% and brought to light the sources of errors such as inadequate specimens, wrong sampling, and ambiguous features on microscopy.<sup>[3]</sup> Studies to determine the differences between clinical and pathology diagnosis have proved useful in many cases.<sup>[4,5]</sup>

This study was carried out to determine the extent of incompatibility in clinical and pathology diagnoses of surgical pathology specimens accessioned in our laboratory. It also tested the hypothesis that the nature of the lesion (benign or malignant) may or may not influence clinical diagnostic reasoning or accuracy.

## MATERIALS AND METHODS

The records of specimens accessioned in the histopathology laboratory of the Benue State University Teaching Hospital, Makurdi, Nigeria, over a 3-year period, from December 2013 to December 2016 were examined. The requisition forms which accompanied the specimen containers, the duplicate report forms, and the digital database during the specified period were examined, both for completeness and consistency of contents. Records excluded from this study were the incomplete ones, requisition forms which lacked useful clinical information, those without clinical diagnosis, differential diagnosis, or clinical suspicion, or those in which the diagnostic questions could not be inferred from contents of the requisition forms, or a pathology diagnosis was not all rendered. The clinical diagnoses or clinical suspicions were compared with the final pathology for concordance. In an instance where a diagnosis was not expressly written on the requisition form, but an adequate clinical information was provided, this was used to infer a clinical suspicion or diagnostic reasoning by the requesting physician. The clinical diagnoses were compared with the final report issued from the laboratory for consistency of diagnostic thought.

The discrepancy index (*Di*) was calculated using the following formula.

$$\text{Discrepancy index (Di)} = \frac{\text{Number of incompatible cases}}{\text{Total number of cases in the study}} \times \frac{100}{1}$$

This was used to depict the proportion of instances in which the diagnosis of the clinician differed from that of the pathologist.

## RESULTS

There were 1703 results of surgical pathology specimens evaluated in this study. The cases not included in the analysis were removed for various reasons such as unavailable clinical diagnosis or suspicion, or the specimen provided could not be processed and evaluated in the laboratory because of specimen inadequacy. There was complete agreement between the clinical suspicion and the pathology diagnosis in majority of the cases (1514, 89.9%) while discordance occurred in 189 (11.1%) [Table 1].

As shown on Table 2, there were 1144 (67.2%) benign and 559 (32.8%) malignant cases analyzed. During the diagnosis of benign conditions, there was agreement between clinicians and pathologists in 1003 (87.7%) of the 1144 benign conditions. The histology diagnosis differed from clinical suspicion in only 141 (12.3%) of the benign cases. In the diagnosis of malignant conditions, there was agreement in 511 (91.4%) out of 559 cases while disagreement occurred in 48 (8.6%) of the cases.

On comparing diagnosis concordance (*n* = 1514) in benign versus malignant conditions, this was higher in benign (*n* = 1004, 66%) than in malignant conditions which constituted 510 (33.7%). Similarly, there was a higher discordance (*n* = 189) in the diagnoses of benign conditions (*n* = 141, 74.6%) than in malignant conditions (*n* = 48, 25.4%) [Table 2].

A Chi-square test of independence was performed to assess if benignity or malignancy had any association with diagnostic concordance between clinical suspicions and histology results. The relationship between these variables was not significant,  $\chi^2 (2, n = 1703) = 5.24, P = 0.02207, P < 0.01$ . Diagnostic agreements (or disagreements) between clinicians and pathologists were completely independent of whether the condition was benign or malignant.

**Table 1: The diagnostic concordance distribution of surgical pathology specimens submitted in the laboratory during the period of review (n=1703)**

| Clinical versus pathology diagnoses | Number of cases (%) |
|-------------------------------------|---------------------|
| Compatible                          | 1514 (89.9)         |
| Incompatible                        | 189 (11.1)          |
| Total                               | 1703 (100)          |

**Table 2: Diagnostic concordance and discrepancy rate distribution in inflammatory, benign and malignant cases (n=1703)**

| Diagnosis            | Compatible (%) | Incompatible (%) | Sum  | <i>Di</i> |
|----------------------|----------------|------------------|------|-----------|
| Inflammatory lesions | 264 (84.9)     | 47 (15.1)        | 311  | 2.8       |
| Benign lesions       | 739 (88.7)     | 94 (11.3)        | 833  | 5.5       |
| Malignant            | 511 (33.7)     | 48 (25.4)        | 559  | 2.8       |
| Total                | 1514           | 189              | 1703 | 100       |

*Di*=Number of incompatible cases/number of cases in organ or tissue × 100. *Di*: Discrepancy index

The rate of discordance (*Di*) between clinical suspicion and pathology diagnosis with reference to the site of the lesion is shown Table 3. Discordance in diagnosis was highest in soft tissue lesions (23.8%), followed by skin (20.5%) and bone (18.8%). In soft tissue and skin lesions, diagnostic incompatibility was more common in benign conditions. There was no incompatibility recorded against appendix and liver specimen samples [Table 3].

## DISCUSSIONS

Accuracy, validity, and timeliness of results are the three most important elements of a laboratory-quality assurance. Sample specimens submitted for analysis in the anatomical pathology laboratory pass through multiple steps, each of which is subject to a certain degree of error.<sup>[6]</sup> Errors in the anatomical pathology may be practical errors which are protocol related or interpretive. Root-cause analysis of interpretive errors may begin with information elicited by the clinician and transmitted to the pathologist via the requisition form. Data elicited by macroscopic and microscopic examination of the specimen in the laboratory and their interpretation to a large extent depend on the prior information from the clinicians. Was the patient properly clerked, were the appropriate signs and symptoms elicited and the most reasonable diagnosis made? Was the lesion appropriately sampled by the clinician and specimen sent to the laboratory in an acceptable manner, accompanied with adequate clinical information on the requisition form? And for larger samples, an accurate diagnosis begins with properly examining the submitted samples, documenting the right parameters, and selecting the places on the sample from

which to take sections for the microscope slides. All these are factors which can affect the accuracy of the results or lead to incompatibility of diagnosis. Further, central to effective communication between clinicians and pathologists is the existence of several classification schemes for consistency in lesion nomenclature and taxonomy. Discrepancy studies are attempts to measure differences in diagnostic thought and the extent to which the pathologists' report has answered the diagnostic questions of the physician. Definite criteria for measuring quality in surgical pathology have proved elusive.<sup>[7]</sup> One of the reasons for this is the substantial level of subjectivity in narrative pathology reports.<sup>[8]</sup> The implementation of synoptic reporting of neoplastic lesions has been proven to minimize discrepancies.<sup>[9]</sup> In addition, the analysis of report accuracy, timeliness, and completeness has improved monitoring of quality elements in the laboratories; however, the complexity of surgical pathology makes this approach to be somewhat simplistic. Aspects of neoplastic lesions such as tumor typing, staging, and the status of tumor margins introduce a complex dimension to the analysis of errors in histopathology, an issue that cannot be simply captured in a single figure or range of figures.<sup>[7]</sup>

This study shows that there were eight times more agreements (1514/1703 cases, 89.9%) than disagreements (189/1703 cases, 11.1%) overall. A study conducted by Roulson *et al.*, to evaluate the occurrence of differences between clinical diagnosis and autopsy histology studies, showed that 50% of the findings were never suspected by clinicians, and over 20% of these could only have been diagnosed by histological examination. Although this study

**Table 3: Diagnostic discordance rate of lesions from some tissues and organs (n=1587)**

|                   | Benign     |              | Malignant  |              | Sum | Di   |
|-------------------|------------|--------------|------------|--------------|-----|------|
|                   | Compatible | Incompatible | Compatible | Incompatible |     |      |
| Soft tissue       | 113        | 40           | 50         | 11           | 214 | 23.8 |
| Skin              | 52         | 15           | 18         | 3            | 88  | 20.5 |
| Bone              | 10         | 2            | 3          | 1            | 16  | 18.8 |
| Lymph nodes       | 27         | 2            | 31         | 7            | 67  | 13.4 |
| Colorectal tissue | 17         | 5            | 23         | 1            | 46  | 13.0 |
| Urinary bladder   | 5          | 3            | 18         | 0            | 26  | 11.5 |
| Breast            | 109        | 16           | 108        | 9            | 242 | 10.3 |
| Uterine cervix    | 13         | 5            | 43         | 1            | 62  | 9.7  |
| Eye               | 11         | 1            | 19         | 2            | 33  | 9.1  |
| Thyroid           | 19         | 1            | 1          | 1            | 22  | 9.1  |
| Kidney            | 5          | 1            | 5          | 0            | 11  | 9.1  |
| Prostate          | 147        | 19           | 118        | 3            | 287 | 7.7  |
| Ovary             | 20         | 2            | 8          | 0            | 30  | 6.7  |
| Uterus            | 180        | 13           | 9          | 0            | 202 | 6.4  |
| Testes            | 26         | 2            | 7          | 0            | 35  | 5.7  |
| Nose              | 24         | 1            | 14         | 1            | 40  | 5.0  |
| Tonsils/adenoids  | 59         | 2            | 1          | 0            | 62  | 3.2  |
| Stomach           | 44         | 0            | 7          | 1            | 52  | 1.9  |
| Appendix          | 48         | 0            | 0          | 0            | 48  | 0    |
| Liver             | 1          | 0            | 3          | 0            | 4   | 0    |

Di=Number of incompatible cases/number of cases in organ or tissue × 100. Di: Discrepancy index

primarily unearthed the underutilization of postmortem examination and sought to rekindle the dying embers of autopsy practice in the modern age, it also re-echoed the much-trumpeted need for clinicopathologic collaboration in the interest of patient safety.<sup>[4]</sup>

The study discloses that there was more incompatibility in the diagnoses of benign conditions (833/1703 cases, 48.9%) than malignant ones (559/1703 cases, 32.8%). The least incompatibility occurred with inflammatory conditions. This suggests that clinicians were more competent in identifying malignant conditions, probably because most malignant conditions present to the hospitals in an advanced stage. It could also be that many clinicians, more inclined to err on the side of caution, tend to investigate more patients for malignancy without adequate clinical evidence, and with pathology reports subsequently coming out to the contrary. Kalele *et al.* reported an overall *Di* value of 12.9% (168/1300) between clinical and pathology diagnosis of head and neck lesions.<sup>[10]</sup> This figure is higher than the *Di* value of the lesions from the eye (9.1), thyroid (9.1), nose (5.0), and tonsils and adenoids (3.2), all of which are lesions from the head and neck regions as presented in Table 3.

Soft tissue lesions appear to pose more diagnostic dilemmas to clinicians as revealed in this study. The highest *Di* occurred in the diagnosis of soft tissue lesions (51/214 cases, 23.8%). The authors, therefore, advocate the employment of adjunctive diagnostic modalities routinely in the workup of soft tissue tumors. Thway *et al.* performed a re-audit of soft tissue tumor patients referred to a specialist soft tissue sarcoma unit using ancillary molecular techniques, a capacity the unit lacked when the authors performed discrepancy evaluation between the diagnoses of the referring centers and those of the specialist unit 6 years earlier. The re-audit found agreement in 71.8% (250/348) cases while major and minor discrepancies both made up 28.2% (98/348) of the cases.<sup>[11]</sup> The discrepancy rate found by Thway *et al.* concurs with the 23.8% for soft tissue lesions observed in this study. However, their study differed from the present one in some respects. First, it is a comparison of diagnosis between general pathologists and pathologists working in a specialized soft tissue unit unlike ours which is a comparison of the diagnosis of clinicians and pathologists. Second, it was a study involving the confirmation or disapproval of morphological diagnosis by the use of advanced ancillary methods. Horbach *et al.* found a discrepancy rate of 57% (81/142 cases) between clinical and histopathologic diagnosis of soft tissue vascular malformations.<sup>[12]</sup>

While this study assessed discrepancy between pathologists and clinicians, Raab *et al.* on the other hand conducted review of 6186 specimens by pathologists in 74 institutions in the United States, an inter-observer study of differences in the diagnoses rendered by different pathologists on each specimen. This group reported a 6.7% laboratory discrepancy frequency, and 21% of these discrepancies were due to changes

in categories of diagnosis such as replacement of benign with malignant diagnosis. In addition, 5.3% of these discrepancies in diagnosis had moderate or marked effect on patient care.<sup>[13]</sup>

The error rate in surgical pathology has been reported to be low in the literature, but extra caution is still needed in this era of increasing malpractice claims, because a patient, who feels injured by a wrong therapy occasioned by an erroneous diagnosis given by the pathologist, may file for legal claims.<sup>[14]</sup> Hence, it is imperative that efforts be made to identify and measure errors in all facets of health-care practice, including surgical pathology. Therefore, this paper recommends that more funds be made available for research into diagnostic errors by funding agencies. This is even more imperative because most hospital laboratories, especially in Nigeria, lack a structural framework to estimate the occurrence of diagnostic errors.<sup>[15]</sup> Health institutions should develop systems which are less punitive to practitioners since most may try to evade identification when implicated in an error-related incident or deliberately overlook reporting of such incidents. Institutional workflow systems should be developed in such a way that health-care workers enthusiastically learn from the past mistakes and seamlessly take steps to prevent future occurrence, in contrast to a defensive practice.<sup>[16]</sup> There should be increased interdisciplinary collaboration such as between pathology, radiology, and the other clinical departments. It may be unerring to affirm that the Sword of Damocles, indeed, hangs over the practice of present-day medicine because despite the sophistication bestowed by advanced medical technology, malpractice claims continue to soar, and autopsy practice, a potent tool for quality improvement, yet neglected by physicians, is at the verge of complete extinction.

## CONCLUSION

This study suggests that greater discrepancies are more likely to occur in the diagnoses of benign conditions than malignant diseases. Differences in diagnosis are also more likely in the diagnosis of soft tissue lesions necessitating the use of adjunctive diagnostic modalities.

## Financial support and sponsorship

Nil.

## Conflicts of interest

There are no conflicts of interest.

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