ORIGINAL ARTICLE

Local Audit of Diagnostic Surgical Pathology as a Tool for Quality Assurance

***Sani Abubakar Malami** *FMCPath, MIAC,* ****Yawale Iliyasu** *FMCPath, FICS*
**Faculty of Medicine, Bayero University, Kano, Nigeria, **44 Nigerian Army Reference Hospital, Kaduna, Nigeria*

Abstract

Background: *Internal audit has been rarely done for quality assurance of histology laboratories in Nigeria. We reviewed the steps involved in the production of reports with a view to assessing the performance of the histopathology laboratory of Aminu Kano Teaching Hospital, Nigeria.*

Methods: *A randomly selected 2 per cent sample of the total histology workload of the center for the year ending December 2005 amounting to 2877 cases was systematically reviewed.*

Results: *Analysis of the accumulated data showed a concordance rate of 94.8% between the original and review histological diagnoses, comparable to other published studies. Significant defects were observed to be due to missing demographic information on request forms (22.8%), poor technical quality of slide sections (18.4 %) and typographical errors by typists (12.3 %) In a minority of cases microscopic description was inadequate or inappropriate (7.0 %) and some were inaccurate (2.7 %). The turnaround time ranged from 2 to 16 days (mean 6.2 days) with results of 75.8 per cent of the specimens completed within 7 days.*

Conclusion: *From the study we have shown that local audit is feasible in Nigerian laboratories and is an excellent method for detecting errors and improving performance in Surgical Pathology to optimize the scarce resources available to patient care in our country.*

Keywords: Quality control; Audit; Histopathology.
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Introduction

Surgical pathologists intuitively accept the necessity for quality control and assurance because they know that major therapeutic decisions are based on their histological diagnoses.[1,2,3,4] Even in the hands of superbly trained and conscientious histopathologists, false-positive and false-negative results can occur. Obviously, surgical pathology has inherent limitations, and recognition that it is not infallible could greatly improve the end product which would guarantee optimal patient care.[1]

"Audit" belongs to the etymological class of primitive (root) words. It is derived from the Latin *auditum* meaning to hear a statement; hence to examine an account. It follows that an auditor is simply one who hears, or simply a hearer.[5] Periodic audit of the performance of pathology providers has been promoted as a necessary component of total quality management in surgical pathology laboratories.[3,4]

In Britain, the National Health Service (NHS) reforms of 1989 required all doctors to adopt medical audit in their clinical practice.[6] It was stipulated that time was to be allocated for audit work within each consultant's job plan.[7] In 1993, the term 'medical audit' was replaced by 'clinical audit', covering audit activity carried out by all health care professionals, including doctors.[8] In 1997, the Royal College of Pathologists UK published guidelines entitled *Clinical audit in Pathology.*[9] In the same year, the General Medical Council (GMC) UK, in response to public concerns, ruled that in order to maintain their registration, *"all doctors must be able to demonstrate that they can practice in their chosen field"* [10] It is therefore apparent that evidence is required of each doctor to satisfy the corporate accountability for quality and demonstrate his / her own fitness to practice. In both cases, a large part of this evidence would be provided by formal review of practices and clinical performance; the tool for producing that evidence would be clinical audit.[11]

Regulations abound in other parts of the world which have been enacted to promote uniform quality and standards among all testing sites with the aim to minimize the laboratory component of diagnostic errors and highlight the need for histopathologists to maintain and improve their professional competence.[12, 13] Notably, the Congress of the United States passed the Clinical Laboratory Improvement Amendment in 1988 which replaced the less stringent CLIA 67 Act, thereby establishing higher standards for clinical laboratory testing and mandated the Centers for Medicare and Medicaid Services (CMS) with its strict enforcement.[12] The intent of CLIA'88 is to ensure quality testing through a combination of minimum quality practices that incorporate total quality management concepts.[14]

However, enforcement of uniform standards for clinical laboratory services in Nigeria has been bedeviled by problems. Ojo et al lamented that a policy of clinical audit at professional, governmental or institutional level

Correspondence to **Dr S A Malami,** E-mail: malamisa@yahoo.co.uk

does not exist in Nigeria and no laboratory in the country was conducting audit in a sustained or sustainable manner.[3] This is inspite of the mandate given to the Medical and Dental Council of Nigeria (MDCN) to regulate laboratory testing and conduct validation surveys in the country.[15] As a consequence, the frequency and clinical impact of errors in anatomical pathology laboratories in Nigeria have been poorly characterized to date. The present study analyzed a number of critical performance parameters including accuracy of reports, technical proficiency and turn-around times in the histopathology laboratory of the Aminu Kano Teaching Hospital (AKTH) with the aim to identify problems and introduce corrective measures.

Materials and Methods

An internal audit was devised and developed to meet the particular needs of the Histopathology Department of Aminu Kano Teaching Hospital, with a total histology workload for the one-year period January to December 2005 of 2877 cases. The system used in the present study was fashioned after previously described schemes of histopathology audits, but with modifications to suite the peculiarities of our own centre.[1,2,4]

The hospital is a designated tertiary referral centre for Kano in North western Nigeria and the clinical school of the Bayero University is located on the hospital campus. The work of the laboratory is partially automated. Medical staffing consists of three full-time consultants, one senior registrar and one registrar. Comprehensive peer review was done on a random sample of 2 per cent of the total surgical cases. We adopted the value 2% as the minimum number of cases for effective peer review in surgical pathology recommended by the groups headed by Ramsay and Zuk respectively.[1,2] To select the sample size of 58 surgical pathology cases a systematic sampling method was used. Following selection, all material relevant to each case was retrieved, including request cards, microscopic slide sections and the report. Cases were then re-examined sequentially by the authors, both being specialists in histopathology with five years (SAM) and eleven years (YI) post qualification experiences. These two auditors had not been involved with the cases being reviewed. An assessment checklist (Figure 1) for completion accompanied each case. Sixteen (16) variables were individually scored per case. The review process examined the aspects of the cases pertaining to completeness of patient demographics, typing errors, adequacy of clinical history, technical quality and labeling of slides, macroscopic description, coding of paraffin blocks, microscopic reports, and discordant diagnoses. Turn around times, adequacy of specimen sampling, and use of special stains were also assessed. Diagnostic discrepancies were classified into those that would not affect the line of management (minor) and those ones which have serious implications for patient management and require issuing a supplementary report (major).

A numerical scoring system was applied to account for the seriousness of omissions or errors. Total scores were calculated with the maximum being 16 points.

Results

The study involved a review of 2 per cent (58) of the 2877 surgical pathology specimens received in the department during the period of study. Nine hundred and twenty eight pieces of data were generated from the 58 pathological samples and analyzed.

In 12.3 % of these cases, we noted significant defects in various aspects of the requisition, laboratory handling and diagnostic evaluation of the specimens. Table I shows the frequency and percentage of the observed errors for each of the variables under investigation. In a third of all the cases (28.9%) the incompleteness of clinical data supplied by the requesting physician was observed. The next most important group consisted of cases in which critical demographic information on the patients was missing (22.8%), followed by observations related to the technical quality of slide sections made in the laboratory (18.4 %), typographical errors (12.3 %), and the absence of clinical history (9.7 %). Others were observations on defective microscopic description (7.0 %), and diagnostic inaccuracies (2.7 %). When the quality of microscopic sections was interpreted further to determine its true impact on laboratory performance, the defects were found out to be of minor nature, as only 2.7% of them were bad enough to require re-processing. The histological discrepancies, also, were minor in nature and related to issues of subjectivity, including adequacy of sample and diagnostic threshold for tumour. Details of the three discordant cases are shown in Table II. The turnaround times in the present study ranged from 2 to 16 days (mean, 6.2 days). The study also showed that the turnaround times for 75.8 % of the specimens submitted to the laboratory was within 7 working days, and for 17.2 % it was within 3 days. Typist performance was assessed through frequency of typographical errors in the final reports. 24.1 % of the reports had these errors but none was of a serious nature.

Under a miscellaneous category, we recorded 2 errors (3.4%) due to negligent storage by the requesting

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FIGURE 1 DIAGNOSTIC SURGICAL PATHOLOGY AUDIT CHECKLIST

Laboratory Number.....
Assessment Date.....
Assessors.....

ITEMS ASSESSED		SCORE
I.	*Completeness of Request form*	*Complete / accurate 1; Incomplete / Inaccurate - 0*
	1. Patients name, age, sex, unit number, ward	
	2. Nature of specimen, date of collection	
	3. Clinical history, salient findings, provisional diagnosis	
	4. Requesting consultants name and signature	
	5. Miscellaneous: fixation, appropriate form, gynae history	
II.	*Pathologists performance*	*Complete / accurate 1; Incomplete / Inaccurate - 0*
	1. Clerical details	
	2. Specimen identification	
	3. Block selection	
	4. Clarity and accuracy of macroscopic description	
	5. Clarity and accuracy of microscopic description	
	6. Final diagnosis	
	7. Turnaround time (excluding Sat, Sun, public holidays)	
III.	*Technical performance*	*Good / satisfactory 1; Poor / Unsatisfactory - 0*
	1. Quality of microscopic section	
	2. Quality of staining	
	3. Labeling of sections	
IV.	*Typist performance*	*Present 1; Nil 0*
	1. Typographical errors (specify minor / major)	

Subtotal
Completeness of requesting form (maximum = 5).....
Pathologists performance (maximum = 7).....
Technical performance (maximum = 3).....
Typist performance (maximum = 1).....
TOTAL SCORE (maximum = 16).....