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THE ANATOMY OF A RESEARCH PROTOCOL: TEACHING PROTOCOL WRITING TO MEDICAL STUDENTS THROUGH AN AUDIT OF CLINICAL DOCUMENTATION IN HISTOPATHOLOGY REQUISITION FORMS

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ABSTRACT **Background:** Histopathology requisition forms are a critical clinicopathological communication between clinicians and pathologists. Incomplete forms represent an ethical lapse, as they compromise diagnostic accuracy, delay appropriate management, and increase the risk of patient harm, thereby undermining patient safety and quality of care. Despite international guidelines emphasizing complete documentation, deficiencies remain common, particularly in high-volume healthcare settings in low- and middle-income countries. **Objective:** To assess the quality and completeness of clinical and demographic information in histopathology requisition forms in a tertiary care teaching hospital. **Methods:** This retrospective audit will be conducted in the Department of Pathology of a tertiary care teaching hospital. A total of 1000 histopathology requisition forms will be evaluated using a structured 20-item checklist covering patient, specimen, clinical, and physician details. Each item will be scored as present (1) or absent (0), with total scores categorizing forms as adequate (16–20), partially complete (11–15), or inadequate (≤10). Descriptive statistics will summarize completeness, and analytical tests will assess associations with variables such as clinical department and key clinical details. **Expected Results:** The study will identify key gaps in form completeness, including clinical history, diagnosis, and investigations, and highlight departmental variations. **Conclusion:** This audit will provide evidence on deficiencies in documentation practices and underscore the need for targeted interventions, including clinician sensitization, standardized requisition formats, and quality assurance measures.

KEYWORDS : Histopathology, requisition forms, clinical information, pre-analytical errors, quality audit, diagnostic accuracy, patient variation

BACKGROUND AND RATIONALE

Histopathological examination plays a crucial role in the diagnosis and management of many diseases. The histopathology requisition form is an important communication tool between the clinician and the pathologist, providing essential information such as patient details, clinical history, provisional diagnosis, and relevant investigations. Adequate clinical information is necessary for accurate interpretation of tissue specimens and proper clinicopathological correlation. However, in routine practice, requisition forms are often incompletely filled, with missing or inadequate clinical details. Such deficiencies may lead to diagnostic difficulties, delays in reporting, and reduced efficiency in laboratory workflow.

Globally, incomplete laboratory and pathology requisition forms are recognized as a major contributor to laboratory errors. (1, 2) International audits conducted in Europe, North America, and Africa have reported that 20–50% of requisition forms are missing key parameters such as patient age and sex, clinical history, provisional diagnosis, or physician contact details, while in some institutions fewer than 10% of forms are fully completed.(3, 4) The absence of relevant clinical information can compromise the interpretive accuracy of pathologists, necessitate additional clarification from clinicians, and delay the diagnostic process.(5)

Evidence from South Asian countries suggests that the problem of incomplete requisitioning may be particularly pronounced in high-volume healthcare settings where paper-based systems and heavy clinical workloads persist.(6) Studies from the region have reported frequent omissions of essential information such as clinical history, clinician contact details, and relevant investigations, with some audits documenting clinical information missing in more than 80–95% of requisition forms in certain departments. Audits from countries such as India, Pakistan, Sri Lanka, Uganda, (8)and Malaysia have documented incomplete requisition forms, with frequent omissions including clinical history, duration of illness, provisional diagnosis, and relevant laboratory findings. (9-11) Incomplete documentation can lead to delays in specimen processing, difficulty in correlating histopathological findings with clinical context sometimes leading to errors, and increased communication burdens between laboratories and clinicians.(7))(10)These findings highlight persistent gaps in documentation practices and underscore the need for systematic evaluation and corrective strategies to improve the completeness of histopathology requisition forms and strengthen communication between clinicians and pathologists. Despite these concerns, systematic investigations examining the ethical implications and patient safety consequences of incomplete pathology requisition forms remain limited in many South and Southeast Asian healthcare systems. International standards and accreditation guidelines strongly emphasize the importance of complete and accurate laboratory requisition forms as a fundamental component of quality assurance in diagnostic services. The World Health Organization (WHO) laboratory quality management system highlights proper test request documentation as a critical step in minimizing pre-analytical errors and ensuring patient safety. (12)Similarly, the ISO 15189 standards for medical laboratories mandate that adequate clinical information must accompany specimens to ensure accurate interpretation and reliable reporting.(13) The College of American Pathologists (CAP) and the National Health Service (NHS) guidelines also recommend that histopathology request forms include comprehensive patient details, clinical history, and relevant investigations to facilitate effective communication between clinicians and pathologists. (14, 15)These international recommendations underscore that complete requisition forms are not merely administrative requirements but essential tools for reducing diagnostic errors, improving laboratory efficiency, and ensuring appropriate and timely patient care.

Beyond operational concerns, the completeness of histopathology requisition forms raises important ethical considerations in clinical practice. Accurate documentation reflects the physician's professional duty of care and supports the ethical principles of beneficence and non-maleficence, as adequate clinical information enables pathologists to interpret specimens correctly and minimizes the risk of diagnostic error. Incomplete or poorly filled requisition forms may compromise patient safety by increasing the likelihood of misinterpretation, delayed diagnosis, or inappropriate management, thereby shifting the risk–benefit balance unfavorably for the patient. From the perspective of justice, incomplete documentation can lead to inequities in care, as patients whose clinical information is inadequately conveyed may receive less accurate or delayed diagnostic evaluation compared to those whose information is properly communicated. Furthermore, the ethical principle of professional accountability requires clinicians to ensure that laboratory requests are accompanied by sufficient information to allow meaningful clinicopathological correlation.

In this context, the act of properly completing requisition forms is not merely an administrative task but an ethical responsibility that supports patient safety, fairness in healthcare delivery, and the integrity of diagnostic decision-making.

A commentary by A.E John highlighted the importance of adequate clinical information in pathology requisition forms. The author emphasized that the requisition form serves as the primary communication link between clinicians and pathologists. Incomplete forms lacking clinical history, provisional diagnosis, or relevant investigations can create diagnostic challenges for pathologists. The article stresses that adequate clinical details are essential for clinicopathological correlation and accurate interpretation of histopathological findings, ultimately improving diagnostic accuracy and patient care. (16)

A study conducted by Prabin Gyawali evaluated pre-analytical errors associated with inadequacies in laboratory requisition forms. The study found that many forms were incompletely filled, with missing information such as patient identification, clinical details, and physician information. These deficiencies were identified as significant contributors to pre-analytical errors in laboratory practice. The author emphasized that accurate and complete requisition forms are essential to ensure effective communication between clinicians and laboratory personnel and to maintain the reliability and quality of laboratory diagnostic services. (17)

Similarly, Sandeep Sehgal and colleagues analyzed laboratory requisition forms received in a cytopathology laboratory of a tertiary care center in their study. The audit revealed that many requisition forms lacked essential clinical information, including patient history, relevant investigations, and clinician details. The study highlighted that incomplete forms can adversely affect diagnostic interpretation and laboratory workflow. The authors recommended improved awareness among clinicians and the use of standardized requisition formats to enhance the completeness of clinical information. (18)

Previous studies have highlighted that incomplete or inadequately filled laboratory requisition forms are a common issue and may contribute to diagnostic challenges and pre-analytical errors in laboratory practice. Studies such as those by A E John, Prabin Gyawali, and Sandeep Sehgal have reported deficiencies in the completion of requisition forms and emphasized the importance of adequate clinical information for accurate interpretation and effective communication between clinicians and pathologists.(16-18)

Given the documented deficiencies in laboratory and histopathology request documentation, periodic evaluation of requisition forms becomes an important component of quality assurance in diagnostic services. Auditing pathology requisition forms allows laboratories to systematically assess the completeness and adequacy of information provided by clinicians, identify recurring gaps in documentation, and understand how these deficiencies may affect diagnostic interpretation and workflow efficiency. Therefore, assessing the adequacy and completeness of information provided in histopathology requisition forms is important to identify gaps and improve the quality of diagnostic services.

Such audits also serve as an educational and feedback mechanism, helping clinicians recognize the importance of providing relevant clinical details to facilitate meaningful clinicopathological correlation. From an ethical and patient safety perspective, lapses in documentation may compromise diagnostic accuracy, delay patient care, or create inequities in service delivery. Despite the recognized importance of this issue, published studies examining the completeness and ethical implications of histopathology requisition forms remain relatively limited in many parts of South and Southeast Asia, including India, where high patient volumes and resource constraints may further influence documentation practices. The adequacy of clinical information provided in histopathology requisition forms may vary across institutions, and local data regarding this issue are limited.

Beyond addressing an important quality assurance issue in pathology services, this study also serves as an educational model for undergraduate medical students learning research methodology. Protocol writing is a fundamental competency in medical education, as it teaches students how to transform a clinical observation into a structured and scientifically sound research question. Through the process of literature review, formulation of objectives, selection of appropriate study design, development of data collection tools, planning of statistical analyses, and consideration of ethical principles, students gain practical experience in the conduct of research. Early exposure to protocol development fosters critical thinking, evidence-based decision-making, scientific writing skills, and an appreciation of research ethics. Using a real-world clinical problem such as incomplete histopathology requisition forms provides students with an opportunity to understand how research can be applied to improve healthcare quality and patient safety. This protocol is therefore intended not only as a blueprint for the proposed audit but also as a teaching example to guide novice researchers in the development of rigorous biomedical research protocols.

Therefore, conducting a structured audit of histopathology requisition forms is an essential step toward improving communication between clinicians and pathologists, strengthening diagnostic quality, and promoting accountable and ethically responsible clinical practices. By presenting a complete protocol from conception this article aims to serve as a practical resource for medical students, interns, and early-career researchers undertaking their first research project

RESEARCH QUESTION

What proportion of histopathology requisition forms received in a tertiary care teaching hospital contain adequate clinical information?

STUDY OBJECTIVE

The objective of this study is to assess the adequacy and completeness of clinical and demographic information provided in histopathology requisition forms received in the pathology department of a tertiary care teaching hospital.

METHODOLOGY

1.Study design

A retrospective cross-sectional study of the nature of an audit is planned.

2.Study setting

Department of Pathology, Pushpagiri Institute of Medical Sciences and Research Center

3. Data

Histopathology requisition forms accompanying tissue specimens received in the Department of Pathology during the study period.

4.Inclusion criteria

- Histopathology requisition forms submitted along with tissue specimens to the pathology laboratory during the study period.
- Requisition forms received from all clinical departments of the hospital.

5.Exclusion criteria

- Requisition forms associated with cytology specimens or other investigations not related to histopathology.
- Duplicate requisition forms for the same specimen.

6.Sampling method

Using convenient sampling, 1000 requisition forms that come to histopathology lab will be collected and evaluated using a 20-item checklist

7.Data collection tools

The structured 20-item checklist used in this study has undergone content validation by subject experts from pathology and community medicine to ensure its relevance, clarity, and comprehensiveness in capturing essential components of histopathology requisition forms. A pilot study will be conducted on approximately 10–20% of the sample to refine the data collection process and identify any ambiguities in the checklist. Based on pilot findings, necessary modifications will be made to improve clarity and applicability. Face validity will be established through the pilot testing.

To ensure reliability, inter-rater agreement will be assessed by having two independent reviewers evaluate a subset of requisition forms using the checklist. Reviewers will be blinded to each other's assessments. Agreement between reviewers will be quantified using Cohen's kappa statistic, calculated using SPSS version 25 or equivalent statistical software. Kappa values will be computed for selected checklist items and/or overall completeness categories. A kappa value of ≥ 0.61 will be considered indicative of substantial agreement. Internal consistency of the checklist will also be assessed using Cronbach's alpha. Any discrepancies identified will be resolved through discussion, and the checklist will be finalized prior to the main study.

Using convenient sampling, 500 requisition forms that come to histopathology lab will be collected and evaluated using a 20-item checklist derived from laboratory quality guidelines and previously published studies.

Each parameter will be scored as 1 if present and 0 if absent. The maximum score obtainable is 20.

Forms scoring 16–20 will be considered adequate, 11–15 partially complete, and ≤10 inadequate.

Statistical Analysis Plan

Data collected from the histopathology requisition forms will be entered into Microsoft Excel and analyzed using statistical software such as SPSS version 25 (or equivalent statistical package). Descriptive and analytical statistical methods will be applied. This will be automatically created through the Google Forms.

Data Preparation

Each requisition form will be evaluated using the 20-item checklist, with each parameter scored as 1 if present and 0 if absent. The total completeness score for each form will be calculated by summing the individual item scores, with a maximum possible score of 20.Based on the total score, requisition forms will be categorized as:

- Adequate: 16–20
- Partially complete: 11–15
- Inadequate: ≤10

2. Descriptive Statistics

Descriptive statistics will be used to summarize the completeness of requisition forms.

The following will be calculated:

- Frequency and percentage of forms containing each checklist parameter (patient details, specimen details, clinical information, and requesting doctor details).
- Mean, median, standard deviation, and range of the total completeness score.
- Distribution of forms according to completeness categories (adequate, partially complete, inadequate).

Results will be presented using:

- Tables summarizing completion rates of individual parameters
- Bar charts or pie charts showing the distribution of completeness categories.

3. Domain-wise Analysis: The completeness of information will also be evaluated by domain:

- Section A – Patient details
- Section B – Specimen details
- Section C – Clinical information
- Section D – Requesting doctor details
- Section E – Overall form quality

For each section:

- A section score will be calculated.
- The percentage completeness of each section will be determined.

4. Department-wise Analysis

Since the clinical department/unit is recorded, the completeness of forms may be compared between different departments submitting specimens.

- Mean completeness scores across departments will be compared.
- The proportion of adequate vs incomplete forms by department will be calculated.

Where appropriate, statistical tests such as:

- Chi-square test for association between department and adequacy category
- ANOVA or Kruskal–Wallis test for differences in completeness scores between departments may be applied.

5. Association Analysis: Associations may also be explored between overall completeness score and specific parameters, such as:

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- Presence of clinical history
- Presence of provisional diagnosis
- Legibility of handwriting
- Signature of requesting doctor

Categorical variables will be compared using the Chi-square test or Fisher's exact test.
A p-value <0.05 will be considered statistically significant.

6. Identification of Common Deficiencies

The most frequently missing parameters will be identified by ranking checklist items according to the percentage of forms in which they are absent. This will help identify key areas requiring improvement in documentation practices.

7.Presentation of Results

Results will be presented using frequency tables, cross-tabulations, and graphical representations such as bar charts and pie charts to clearly illustrate patterns of completeness and deficiencies in requisition form documentation.

ETHICAL CONSIDERATIONS

1.Consent Process

As this is a retrospective study evaluating the completeness of information in histopathology requisition forms and does not involve direct patient interaction or any intervention, a waiver of individual patient consent will be sought from the Institutional Ethics Committee. Patient identifiers will not be recorded, and confidentiality of data will be maintained throughout the study.

2.Confidentiality

Patient identifiers such as name, hospital number, and contact details will not be recorded in the data collection sheet. Each requisition form will be assigned a unique study code. All collected data will be stored in a password-protected electronic database accessible only to the investigators.

3.Risk–Benefit Ratio

This study involves minimal risk as it only analyzes existing records and does not involve any clinical intervention. The potential benefit includes identification of deficiencies in requisition forms, which may help improve the quality of clinical information provided to pathologists and enhance diagnostic accuracy.

4. Ethical Approval

The Institutional Review Board of the Institute has reviewed and approved the protocol as a minimal-risk study and waived the requirement for signed informed consent through letter PIMSRC/E1/388A/425/2026.

TIMELINE AND BUDGET

1.Gantt Chart

TASK NAME	START DATE	DAY OF MONTH*	END DATE	DURATION* (WORK DAYS)	DAYS COMPLETE*	DAYS REMAINING*	TEAM MEMBER	PERCENT COMPLETE
Proposal writing								
Proposal Writing	3/1	1	3/8	7	7	0	S	100%
Review of literature	2/28	28	3/8	8	6.4	0	S	80%
Sending protocol for review by guides	3/9	9	4/9	31	18.6	12.4	S	60%
Review of protocol by guides	3/9	9	4/9	31	12.4	18.6	A, LK	40%
Sending protocol for ethical review	4/10	10	4/15	5	0	5	S	0%
Data collection								
Ethical approval	4/16	16	4/17	1	0	1	Admin	0%
Data collection	4/18	18	5/18	30	0	30	S, S, A	0%

Data entry into Excel	5/19	19	5/31	12	0	12	S, S, A	0%
Analyze Results	6/1	1	6/12	11	0	11	Biostatistician	0%
Writing and presenting results								
Review results	6/13	13	6/14	1	0	1	A, A, S	0%
Writing results	6/15	15	6/20	5	0	5	S, S, A	0%
Finalize Presentation	6/21	21	6/30	9	0	9	S, S, A, A, LK	0%
Write manuscript	7/1	1	8/1	31	0	31	S, S, A, A, LK	0%
Send for publication	8/15	15	8/30	15	0	15	A	0

2.Budget:

Budget head	Description	Estimated cost
1. Stationery	Printing of consent related documents, submission copies, final reports	1,000
2.Internet/ data usage	Mobile data for literature search, Google forms, data entry, communication	1,000
3.Data entry and analysis	Software usage, Excel/SSPS support, data management	1,000
4.Publication charges	Journal submission /publication fees /partial article processing charges	12,000

QUESTIONNAIRE

Section A: Patient Details

1. Patient name mentioned
2. Age mentioned
3. Sex mentioned
4. Hospital number / registration number mentioned
5. Ward / OPD / department mentioned

Section B: Specimen Details

6. Type of specimen mentioned (biopsy/excision etc.)
7. Anatomical site of specimen mentioned
8. Number of specimens mentioned (if applicable)
9. Date of specimen collection mentioned
10. Time of specimen collection mentioned

Section C: Clinical Information

11. Clinical history mentioned
12. Provisional clinical diagnosis mentioned
13. Relevant investigation / imaging findings mentioned
14. Previous biopsy or treatment mentioned

Section D: Requesting Doctor Details

15. Name of requesting doctor mentioned
16. Department/unit mentioned
17. Signature of requesting doctor present
18. Date of request mentioned

Section E: Overall Form Quality

19. Handwriting legible
20. All essential fields (patient identification, specimen details, clinical information, and requesting doctor details) are completed

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