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Preanalytical Errors in the Histopathology Laboratory: How an Incompletely Filled Requisition Affects Histopathology Reporting and Patient Care

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ABSTRACT

Introduction: Histopathology reports are considered the gold standard for the diagnosis of most diseases. Studies have demonstrated that many of the errors contributing to a sub optimal report occur in the pre-analytical phase. This phase involves procedures that are not within the control of laboratory personnel, such as specimen collection, filling of the laboratory requisition forms (LRF) and transportation of the specimen to the laboratory. Out of these, the greatest number of preanalytical errors were found to be in filling out the LRF. **Materials and Methods:** A retrospective, cross-sectional study was carried out on all histopathology LRFs received at the histopathology laboratory of University Hospital KDU (UH KDU) from 2020 to 2024. Statistical analysis was done using Microsoft Excel. **Results:** A total of 7308 histopathology LRFs were analysed. None of them were completely filled. The name, age, patient registration number and specimen type were present in all the requisition forms. The gender was absent in 5% (365), and the ward/ clinic was absent in 16% (1169). The patient's contact number was absent in 31% (2265). Details of previous biopsies were absent in 28% (2046). The working diagnosis was lacking in 32% (2339). Specimen orientation was not given in 46% (3362). **Conclusion:** This study revealed significant deficiencies in filling certain fields in the histopathology requisition form that are crucial for reporting. The lack of these parameters will result in a sub-optimal report that will in turn, cause difficulties in patient management by the clinician.

Keywords: Histopathology laboratory, pre-analytical errors, laboratory requisition forms

INTRODUCTION

Laboratory medicine comprises a complex set of medical sub-specialities that cover a wide range of diagnostic testing. Approximately 70% of all

patient management and monitoring decisions are made based on laboratory reports (1,4).

Therefore, reliable and timely laboratory diagnoses are a fundamental and essential component in patient management.



The laboratory testing process comprises pre-analytical, analytical and post-analytical phases. A general belief is that the majority of laboratory errors occur in the analytical phase (2). However, analysis of the testing process reveals that approximately 50% – 70% of laboratory errors occur during the pre-analytical phase (3,6). This phase involves procedures that are not within the control of the laboratory personnel, such as specimen collection, specimen fixation, filling the laboratory requisition form and transportation of the specimen to the laboratory (1). Out of these, the majority of pre-analytical errors were found to be due to errors in filling out the laboratory requisition form (2).

The laboratory requisition form is the initial link between the clinician managing the patient and the laboratory staff (4). At present, in most hospitals in Sri Lanka, this form is filled out manually. At a minimum, these forms should include patient details such as patient name, gender, age, patient identification number, ward, date of specimen collection, sampling site,

An incomplete requisition form may compel the laboratory to reject and return the specimen unprocessed or delay processing of the specimen till the required information is received. This will delay the issue of the report and, in turn, delay decisions critical in patient management (4). A wrongly filled requisition form will affect the final diagnosis (5). This is especially so where histopathology reports are concerned. Histopathology is, in most diseases, considered the gold standard for diagnosis. It is crucial that the histopathology requisition form contains all relevant information needed to aid the pathologist in making an accurate diagnosis, as well as to ensure that the correct patient gets the correct report at the correct time.

Therefore, to prevent errors in diagnosis as well as rejection and return of specimens and to pave the way for optimal patient management, it is vital that laboratory requisition forms are filled correctly.

METHODOLOGY

A retrospective, cross-sectional study was carried out on all histopathology requisition forms

received at the histopathology laboratory of University Hospital, Kotelawala Defence University (UH KDU) from 2020 to 2024. UH KDU is a 700-bed tertiary care hospital located in the suburbs of Colombo. The histopathology requisition form used by our hospital is a structured form where all parameters (fields) required are specifically stated (Figure 1). Patient confidentiality was maintained throughout the study. A descriptive statistical analysis was done using Microsoft Excel.

The form is titled "Request form for Histopathology / Cytology / Immunohistochemistry" and includes the following sections:

- 1. Patient's Name:** Contact No., Age, Gender (Male/Female), Ward, BHT No., Name of Surgeon, Oncologist.
- 2. Specimen Type & Site:**
- 3. Relevant Clinical History (Duration ect) & Findings (eg-Lymphadenopathy, Hepatosplenomegaly):**
- 4. Probable diagnosis/Differential diagnosis:**
- 5. Relevant radiological findings (including USS/CT/MRI/Mammography):**
- 6. If a previous biopsy was done (including FNAC/PAP) please give details:** If done at UH-KDU, Lab Ref No., or Date:
- 7. Pre Op CT given:** Not given, RT given, Not given.
- 8. Relevant operative findings/Endoscopic findings:**
- 9. Specimen Orientation:**
- Date:** **Signature:** **Name and Designation:**

Figure 1: The histopathology requisition form used at UH KDU

RESULTS

A total of 7308 histopathology requisition forms were analysed. None of them were completely filled. The name, age and patient registration number were present in all the requisition forms. The gender was absent in 5% (365) of the forms, and the ward/ clinic was absent in 16% (1169). The patient's contact number was present in only 69% (5043). While the specimen type was entered in all request forms and the relevant clinical history was present in 96% of the forms, only 73% gave details of previous biopsies or cytology that had been done for the same lesion. The working diagnosis was lacking in 32% (2339) of the requests. Specimen orientation was the field showing the lowest

number of entries, with only 54% (3946) of the requisition forms showing completeness. The attending clinician's name and the date of sample collection were absent in 3% of the forms. The signature, name and designation of the doctor filling the requisition form were absent in 12%, 28% and 34% of the forms, respectively (Figure 2).

analysed 7308 requisition forms were completely filled.

Filling in the required demographic data, such as patient name, age, gender, patient identification number (BHT or clinic) and ward number, is essential to ensure that the correct report goes to

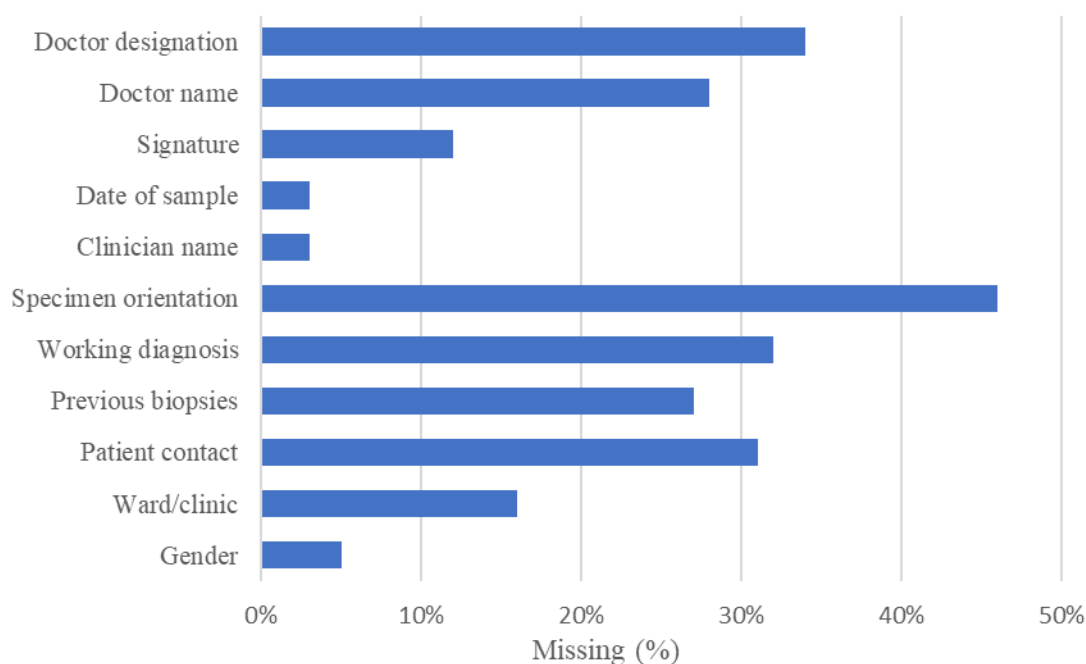


Figure 2: Percentage of missing data in different fields of histopathology requisition forms

DISCUSSION

Incorrect or incomplete data submitted to the laboratory could have a crucial impact on patient diagnoses (5). The majority of studies analyse requisition forms submitted to the haematology, microbiology and biochemistry laboratories. The studies analysing histopathology requisition forms are few. Unlike other laboratory testing, which is mainly automated, the pathologist relies heavily on the information submitted in the requisition form to arrive at a diagnosis and formulate the final pathology report.

This study analysed all histopathology request forms received at the histopathology laboratory, UH KDU, for the completeness of the required parameters. A study done by Kipkulei and Lotodo in 2019 (4) revealed that only 1% of the laboratory requisition forms contained all the required information. However, in our study, none of the

the correct patient. The lack of parameters such as patient name and identification number may result in sample rejection at the specimen reception counter itself (7). A study done to analyse preanalytical errors in five Portuguese hospitals by Roque et al in 2015 revealed that 1.2% of requisition forms lacked patient identification [8]. Our study revealed that all requisition forms contained the patient's name, age and BHT/clinic number. However, 16 % of our request forms lacked information regarding the patient's location (ward/clinic). Which is a higher percentage compared to the study done by Kipkulei et al in 2019 (4), in which this parameter was missing in only 4.1% of the forms. Such reports are usually kept in the laboratory if no other means are available to find out the patient's location. This, in turn, will result in delays pertaining to patient management.

It is good clinical practice to inform patients when reports are ready, especially those that should be urgently shown to the clinician, such as malignancies. Usually, the patient is discharged from the hospital by the time the histopathology report is ready. Therefore, it is vital that the patient's contact number is available to inform when a report is ready for collection. Furthermore, any urgency to show the report to the clinician could also be conveyed to the patient via a phone call. The patient contact number may also be required during the analytical phase, if the pathologist requires additional details regarding the patient's clinical problem or previous biopsy or radiology reports. Our study showed that only 69% of the requisition forms contained this parameter.

Clinical data and a working diagnosis are essential for the interpretation of histopathology slides. Histopathology involves the diagnosis of diseases in a large variety of tissues. The clinical data that should be entered in the requisition form differs depending on the specimen. If a surgical specimen with a malignancy has been submitted, it is essential that details regarding previous biopsies/cytology/excisions, relevant radiological information as well as information regarding neoadjuvant therapy, etc., are included. This information is required not only to enable standardised reporting of the specimen but also to make decisions regarding additional testing, such as immunohistochemistry. Lack of information regarding relevant investigations done may result in repeating tests, which will be an additional, unnecessary cost to the government or the patient.

The working diagnosis of the clinician is important. This is especially so with regard to small biopsies, e.g. skin biopsies. This is because, to arrive at a diagnosis, not only the microscopic appearance but also the macroscopic appearance of a lesion is taken into consideration. Hence, the importance of the working diagnosis.

Lack of clinical data was identified as one of the commonest failures with regard to filling of the requisition form by Roque et al, following a study that analysed over 10,000 cases, over a period of 20 days, in five hospitals in Portugal (8). Clinical data and a working diagnosis were also detected as the most lacking information in studies done by Nutt et

al in 2008 (5), Kipkulei et al in 2019 (4) and Bhatia et al in 2017 (2), with 99%, 76.42% and 14.7% of the requisition forms deficient of this information, respectively.

When clinical data is lacking, the laboratory should take the initiative to obtain the pertinent data [9]. However, this will undoubtedly lead to delays in finalising the report. In our study, the relevant history was present in 96% of the requisition forms, which was well over the figures reported by Olumide et al in 2019 [10] and Olayemi et al in 2011 (11). However, the provisional diagnosis was lacking in 32% of the request forms in our study compared to the 8% of the requisition forms in the study done by Olumide et al in 2019 (10).

Nakhleh et al did a study in 1999 using 771,475 surgical pathology cases from 341 institutions (12). He reported that in 59.4% of cases, the additional clinical information confirmed the initial diagnosis, and in 4.2% of the cases, the diagnosis was substantially changed because of the additional clinical information

Specimen orientation was the parameter that was most lacking from the requisition forms in our study, with only 54% of the requisition forms complying. Specimen orientation is essential to report the margin status of specimens with malignancies and is, therefore, an important determinant of patient management. Specimen orientation is done during the surgery where the surgeon marks at least two margins with sutures, e.g. short suture for the superior margin and long suture for the anterior margin, etc. This will, in turn, enable the pathologist to identify these margins as well as the other margins of the specimen. The reporting of the distances from the lesion to each margin is crucial when it comes to making decisions regarding the management of oncology patients. The absence of specimen orientation is noticed only when the specimen is taken for grossing, usually on the day following the surgery. Proceeding with specimen grossing and processing is not possible till details regarding specimen orientation are available. As such, there will be a delay in issuing the final report. As the orientation details will only be obtained from the surgeon, many hours following the surgery, there is also an increased risk of error.

It is important that the name of the attending clinician is included in the requisition form. This enables the pathologist to contact the clinician to obtain additional clinical information as well as to clarify issues pertaining to sampling. Knowing who the attending clinician is also enables the laboratory to convey details regarding urgent reports. The attending clinician's name was absent in 3% of the requisition forms submitted to our laboratory. This is an improvement compared to the findings of Roque et al, where an error rate of 13% was documented (8).

It is essential that the date of specimen collection is included in the completed requisition form. The date of specimen collection is important to ensure that adequate time has been given for tissue fixation. Usually, surgical samples, especially the larger excision biopsies and the resection specimen, are taken for grossing one day after the surgery. This enables ample time for tissue fixation. Processing of the specimen without adequate fixation will result in poor quality tissue sections on slides, where the cellular architecture will not be clear for diagnostic interpretation. This can result in delays as well as suboptimal reporting. 3% of the requisition forms received at the histopathology laboratory did not have the date of sampling.

The histopathology requisition form should always be filled out by a clinical doctor. This is to ensure that the necessary clinical information, as well as specimen information, is recorded. Once the form is filled, the doctor should write his/her name as well as the designation and put his/her signature. This is required as accuracy regarding patient details is essential, and accountability is imperative. Lack of this information may also result in laboratory staff being unable to contact a clinical staff member with knowledge pertaining to the patient's clinical details, to answer queries, as well as to communicate regarding matters relevant to the patient. Analysis of the request forms received in our laboratory revealed a lack of name in 28%, a lack of designation in 34% and a lack of signature in 12% of the requisition forms.

CONCLUSION

Histopathology reports are considered the final, definitive and in most diseases, the gold standard

for diagnosis. Studies have demonstrated that pre-analytical errors are an important contributory factor for a suboptimal report. This laboratory-based study revealed deficiencies in filling certain fields in the requisition form that provide essential information for histopathology reporting. Most of the deficiencies identified in this study were related to clinical information regarding the patient as well as surgical details of the specimen. These omissions will cause misdiagnosis, delayed diagnosis and prolonged turnaround times, as well as delays in patient treatment and suboptimal patient management.

Recommendations

The information obtained from this study should be utilized to implement measures to mitigate these deficiencies in the future. Suggested measures include the establishment of a Health Information Management System in all hospitals so that it will be mandatory to fill all parameters in the requisition form as well as educational sessions for all newly recruited doctors regarding proper filling of the requisition form and their role in preventing pre-analytical laboratory errors.

Author declaration

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Authors' contributions:

Conceptualization, Planning, Supervision of Data Collection, Literature Search, Manuscript Writing and Final Revision: IHSK; Data Collection and Verification, Final Revision and Editing: PHIP, KK; Literature Search, Final Revision and Editing: PHIP, IHSK; Statistical Data Analysis, Final Revision and Editing: WASIF.

Conflicts of interest:

The authors declare that there is no financial or non-financial conflict of interest.

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Ethics statement:

Ethical clearance was obtained from the ethics review committee of the Faculty of Medicine, KDU. (RP/2021/09). Anonymity was maintained throughout the study. The participants were informed that they were free to withdraw from the study at any time, and voluntary participation was ensured. The confidentiality of information was assured by the PI, and only for publication in scientific publications as summarized data. Informed consent was obtained prior to data collection.

Statement on data availability:

Data of this study is available with the principal investigator and can be handed over on request.

<https://10.34297/AJBSR.2019.06.001056>>

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