



## Original Article

# FREQUENCY OF MISLABELED SPECIMEN IN A HISTOPATHOLOGY LABORATORY

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### Abstract:

**Background:** Mislabeled specimens are one of the most common pre-analytic errors in a histopathology laboratory. As histopathology provides the final diagnosis for most of the diseases, labeling errors can lead to serious consequences leading to wrong treatments.

**Objectives:** This study was carried out to find common pre-analytical errors of histopathology laboratory in the context of our country.

**Methods:** Data were collected on six points of container labeling and nine points of requisition papers through simple check list over a period of one week.

**Results:** Among 142 samples, labeling was found in 82.40% container. Among these labels, patients name, age, hospital registration number of the patients were absent in 19.01%, 26.06% and 90.85% samples respectively. Site of origin of the tissue in the container was absent in 71.83% samples. About 4.93% samples came to the laboratory without fixatives. Patients name, age, sex, site of origin of tissue, name of the referring physician and their contact numbers were found absent in 0.70%, 3.52%, 33.10%, 7.75%, 50% and 95.77% of requisition papers respectively. Clinical diagnosis was absent in 54.23% cases. A good proportion of container and requisition papers did not contain proper labeling, which is important not only for identification but also for histopathological diagnosis.

**Conclusion:** We believe that, these errors occur due to lack of standard histopathology requisition form. Association of Surgeons and Pathologists can collaboratively form a standard requisition form for sending histopathology samples to different laboratories, which could easily reduce mislabeling errors in histopathology.

**Key words:** Mislabeled specimen, Labeling errors, Histopathological diagnosis.

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### Introduction:

Medical error reduction has become a major focus for organized medicine since the publication of the Institute of Medicine's report on medical errors in 1999<sup>1</sup>. Mislabeled specimens are one of the most common pre-analytic errors in a histopathology laboratory. However, in a recent review of errors in histopathology, errors involving specimen labeling were only briefly mentioned<sup>2</sup>. Labeling errors can result in inappropriate therapy or the withholding of therapy in patients with unrecognized malignancies leading to

physical, mental and financial burden to the patient. Identification errors involving laboratory specimens may involve misidentification of a patient or the patient's specimen<sup>3</sup> or the site from which the specimen was obtained. Identification errors are frequent by anecdotal evidence<sup>3</sup>, but data on the frequency of such errors in the histopathology laboratory are extremely scattered in the literature.

A number of authors have worked with labeling errors in laboratory medicine, including Q-Probes analyses undertaken by the College of American Pathologists (CAP). These authors have also described methods for error reduction<sup>4-6</sup>. Of the Q-Probes accessioning errors, 10% were due to misidentification of samples. In majority of routine practice samples, labeling and specimen identification errors are probably underestimated and the frequency of occurrence of such errors, and many other errors may go undetected<sup>3</sup>.

One of the most common problems that a histopathologist encounter while reporting, is inadequate clinical information provided by the clinician in the requisition form. As most of the laboratories in our country do not have standard requisition form, it is one of the major causes of wrong histopathology report. We investigated the frequency of labeling errors in a famous histopathology laboratory, where the sample come from different regions of the country. We also tried to find out the most common labeling errors that a histopathologist faces during reporting.

**Materials and methods:**

This study was carried out at the histopathology department of Delta Hospital Limited, one of the most reputed histopathology referral centers for histopathology reporting in Bangladesh. Data were collected over a period of seven days on May 2012. We took data from the requisition forms that were sent along with the specimens and from the label of the containers that were attached with the respective container. Six fields were chosen for container labeling and nine fields were chosen for requisition form as an ideal sample (Table I). AST Recommended Standards of Practice for Handling and Care of Surgical Specimens were followed<sup>7</sup>. Data were recorded by simple check list. Frequency of presence and absence of different fields were analyzed by statistical software.

**Results:**

Data were taken from total 142 specimens and divided on two different categories, that is data from container label (Table II) and data from requisition form (Table III). Container label was found to be present in 82.40% specimens. Among this label name, age, hospital registration number of the patient was absent in 19.01%, 26.06% and 90.85% samples respectively. Name of the site from where the tissue was taken was absent in 71.83% samples. It was found that 4.93% samples come to the laboratory without fixatives.

Analysis of data from the requisition forms showed that name, age, sex, site from where the tissue has been taken, name of the referring physician and their contact numbers were found absent in 0.70%, 3.52%, 33.10%, 7.75%, 50% and 95.77% of requisition papers. Clinical diagnosis was absent in 54.23% cases.

**Table I**  
*Data collection sheet*

**A. Information provided on the container:**

Information	Present	Absent
1. Container labeling		
2. Name of the patient		
3. Age of the patient		
4. Hospital reg. no.		
5. Name of the specimen/ site of tissue		
6. Fixative (Formalin)		

**B. Information provided in the requisition paper:**

Information	Present	Absent
1. Name of the patient		
2. Age of the patient		
3. Sex- M ..... F .....		
4. Hospital reg. no.		
5. Name of the specimen/site of origin of tissue		
6. Name of the referring physician		
7. Contact no. of patient / physician		
8. Clinical Diagnosis		
9. Endoscopy/X-ray/ imaging.....reports		

**Table II***Frequency of information provided with the container*

Information provided : on the container	Frequency	Percentage
Container labeling	117	82.4%
Name of the patient	115	81.0%
Age of the patient	105	73.9%
Hospital reg. no.	13	9.2%
Name of the specimen/ site of tissue	40	28.2%
Fixative (Formalin)	135	95.1%

**Table III***Frequency of information provided with the requisition paper*

Information provided on the requisition form	Frequency	Percentage
Name of the patient	142	100%
Age of the patient	137	96.5%
Sex of the patient	95	66.9%
Hospital reg. no.	48	33.8%
Name of the specimen/site of origin of tissue	131	92.3%
Name of the referring physician	71	50%
Contact no. of patient / physician	6	4.2%
Clinical Diagnosis	65	45.8%
Endoscopy/X-ray/Imaging..... reports	19	13.4%

**Discussion:**

Histopathology provides the final diagnosis for most of the diseases and thereby helps to take decision about treatment plan. To reach the final diagnosis histopathologist needs to be informed about all the relevant clinical information. But unfortunately in our country there is no standard requisition form for sending histopathology samples to the laboratory for reporting. This study was carried out to give a snap of the problem to the medical community.

A few studies have documented error rates for specimen identification and information transmission in surgical pathology and cytopathology specimens<sup>8-9</sup>. In observational studies by Raab et al.<sup>8</sup> and Smith

et al.<sup>9</sup> it was found that, no specimen was found to be totally free of defect, although the frequency and type of defect varied considerably. In our study we found that about 17.6% of the samples enrolled to the laboratory without any label in the container. Goal 1 of the Joint Commission's patient safety goals (National Patient Safety Goal 01.01.01) emphasizes improved patient identification<sup>10</sup>. This encourages proper identification of specimens by instructing laboratories to "use at least two patient identifiers when providing laboratory services."<sup>11</sup> So it is ideal that at least two identification points should be present for each sample. The container as well as the requisition paper should be labeled with two identification points. But our study shows registration number of patients was present in only 9.2% of the containers and 33.8% of requisition forms. After name, registration number of patients is considered as second identification point. It should also be noted that many of the samples come to our laboratory from private clinics which actually do not have any provision with patients registration number. In such circumstances, age is considered as the second identifier. Our study found that age of the patient was absent in 26.1% of the containers and 3.5% of the requisition papers. Similar studies carried out by Raab et al. found that approximately 1.5% of specimen containers lacked an accurate patient name or second identifier<sup>8</sup>.

Fixative is a must in histopathology sample sent for routine reporting. But we found that about 4.9% sample comes to our laboratory without formalin. Most of these specimens show features of autolysis under microscope, making the sample unsuitable for reporting. This may be due to negligence or lack of awareness about the importance of formalin in tissue preservation. Unavailability of formalin and preparation of the specimen by non-medical personnel may contribute further to this problem.

Name of the site from where the tissue has been taken is one of the vital information that histopathologists need for reporting. But we found that about 7.7% samples sent to the laboratory without the name of the tissue in the requisition paper. Laboratory accreditation standards outlined by the Laboratory Accreditation Program of the College of American Pathologists (question 08.1105 of the 1998 Laboratory Checklist) and the Joint Commission on Accreditation of Healthcare Organizations 1998 Standard QC.2.1.1.<sup>12-13</sup> requires that each surgically removed

specimen is accompanied by pertinent clinical information and, to the degree known, by the preoperative and postoperative diagnosis<sup>14</sup>. We see in our study that only 13.4% of the specimens contain associated relevant investigation papers that are needed for final histopathological diagnosis. Study carried out by Raouf et al. found that no clinical history or clinical diagnosis was present on requisition slips in 2.4% of cases<sup>14</sup>. They studied 771 475 surgical pathology cases. Of these, 5594 (0.73%) required additional clinical information before the case could be completed. The median institutional rate of cases with inadequate clinical information for diagnosis was 0.62%, the rate at the 10th percentile was 3.01%, and at the 90<sup>th</sup> percentile, 0.08%. The highest rate of cases with inadequate clinical information was 20%<sup>14</sup>. In 59.4% of cases the additional clinical information confirmed the initial diagnostic impression, and in 25.1% of the cases it was not relevant to the pathologic diagnosis. In 4.2% of the cases the diagnosis was substantially changed because of the additional clinical information, and a revised report was issued in 1.9% of cases. Thus, 6.1% of cases that required additional clinical information for diagnosis were substantially changed or a revised report was issued once the adequate information was obtained. In 2.2% of cases no additional information could be obtained<sup>14</sup>. Our study found that physicians name and contact numbers were absent in 50% and 95.8% cases respectively. This made us unable to collect the additional information that was needed for histopathological diagnosis. In such cases reporting was done in a descriptive manner without providing a conclusive diagnosis.

### Conclusion:

The aim of this study is to create awareness among the physicians about the impact of mislabeling errors in histopathology laboratory which could be easily avoided. As accurate identification of patient specimens in histopathology plays a central role in the delivery of quality healthcare, patient's misidentification, mislabeling and specimen handling errors can lead to delayed or incorrect diagnoses. We believe that these errors occur due to lack of standard histopathology requisition form. Association of Surgeons and Pathologists can collaboratively form a standard requisition form for sending histopathology samples to different laboratories, which could easily reduce mislabeling errors in histopathology.

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