Anatomical pathology errors and the classic laboratory test cycle at Muhimbili National Hospital, Dar es salaam, Tanzania

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Abstract:

Backbround: Due to its complex nature, anatomical pathology practice is inherently error prone. Currently, there is a tendency towards an increase in errors in pathology which stems out from medical practices of other medical disciplines at Muhimbili National Hospital and thus there is a need to have error reduction strategies combined with an attempt to apply these strategies.

Objective: To determine errors in anatomic pathology in relation to the classic laboratory test cycle and discuss factors contributing to these errors.

Study design: The study was a descriptive cross-sectional one in which the information analyzed was obtained from pre-analytic, analytic and pot-analytic phases of the anatomical pathology laboratory test cycle.

Study setting: Muhimbili National Hospital in Dar es Salaam, Tanzania.

Methodology: During the pre-analytic phase of the laboratory test cycle, request forms and specimen containers containing information of patients for histological analysis of the biopsy specimens were analyzed for important parameters which had a bearing in the diagnosis. Also parameters in the analytic phase of the laboratory test cycle were analyzed for errors. The parameters analyzed here were mainly those which occurred during the histologic specimen processing, in the taking-in room, at the microscope and by clerical personnel in the laboratory. Errors which were analyzed in post-analytic phase of testing related mainly to those which resulted from delivery of the reports or information to the clinician, untimely delivery of the reports and failure of the caregiver to see the reports at all.

Results: In the pre-analytic phase of laboratory testing, errors were derived and analyzed from request forms for investigation from clinicians and from information on the containers containing biopsy specimens. Out of 13 variables analyzed from the request forms, 11 (84.6 %) had errors which differed in magnitude. The highest errors were those which arose from misleading clinical information (90%), and missing of relevant clinical information of patients (90%). However, 8 variables were also analyzed from containers and the errors which ranked highest included mislabeling on the container (85%) followed by illegibly labeling of the container (75%) and others. On the part of the analytic phase of laboratory test cycle, there were 11 variables analyzed for analytic errors and 9 (81.8 %) variables had errors, among them typographic errors had the highest frequency (45%) followed by block mislabeling (35%). In the post-analytic phase of laboratory testing, there were 3 variables which were analyzed for errors. The variables analyzed and the errors which were found included; delivery of the report or information to wrong clinician (10%), untimely delivery of report to the clinician (35%) and failure of the caregiver to see the report at all was (15%).

Conclusion and recommendations: The numerous errors amounted in the pre-analytic, analytic and post-analytic phases of laboratory test cycles in Anatomical pathology reinforces the need for effective quality control and quality assurance at all steps in laboratory test cycle. This will be possible only and only if factors that contribute to errors be reduced to an absolute minimum through error reduction strategies combined with an attempt to apply these strategies. Additionally, incremental adoption of information technology and automation along with improved training in patient safety and quality management can help reduce errors.

Key words: Anatomical pathology, Pre-analytic, Analytic, Post-analytic, Errors, Laboratory test cycle

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Introduction

It is difficult to judge and define error in anatomic pathology. The judgment of a pathology error must relate to the clinical circumstances of the case and, to the extent possible, must relate to whatever objective standards exists at the time the error is committed [1,2,3]

Errors committed in anatomic pathology may be major or minor. A major error is an error that has major effect on the therapy that can alter the prognosis of a disease that has a major effect on the prognostication exclusive of the therapy. A minor error is one that does not have a major effect on prognostication, exclusive of therapy.[3]

The test cycle in anatomic pathology, just as in any other clinical laboratory, can be broken down into the pre-analytic phase, the analytic phase and the post-analytic phase of testing.[4] The pre-analytic phase of testing begins with clinical encounter in which the specimen is obtained and ends with the specimen receipt and accessioning in the laboratory. The analytic phase pertains to those processes and steps that are performed to analyze the specimen and to generate a report. The post-analytic phase encompasses those steps necessary to communicate the results in the analytic phase to proper clinicians so that the information can be used effectively to patient care. Errors in one part of the test cycle can cause significant errors in a subsequent parts of the test cycle.[5,6,7]

In order to reduce anatomic pathology errors, there must be a dramatic paradigm shift in the processing of tissue specimens in surgical pathology otherwise error reduction is unlikely to occur without a sustained comprehensive effort addressing all areas of the test cycle. [8] The adoption of new technologies as they become available is a key to addressing may of these error reduction strategies. A comprehensive computer system may facilitate many of these issues, particularly if the system includes features such as remote order entry, barcode technology, facilitates block and slide labelers, automatic order-generating capabilities for histology and other ancillary studies, and synchronization with an electronic medical record. If possible, use of automated instruments, such as stainers and block and slide labelers, is desirable and eliminates error-prone tasks. Other important aspects of reducing errors include a comprehensive, meaningful training and educational program for workers, one that addresses the skills and knowledge necessary to complete work, but also addresses training in error reduction, quality assurance, and actions when mishaps occur.

Problem statement and the rationale of the study

The anatomic pathology error in the laboratory test cycle has increasingly been observed to occur at Muhimbili National Hospital (MNH) at different levels of the laboratory test cycle (pre-analytic, analytic and post-analytic phases) and has a major impact to the patient care and treatment, thus, evaluation of the situation is needed in

order to know the magnitude of the problem and to look for solutions to arrest the situation.

Errors in the pre-analytic phase of testing have been observed to arise from clinicians (clinician error) and this is a major source of this phase at MNH. This type of error often causes major errors in other parts of anatomic pathology test cycle, Unfortunately, the laboratory team has often been held accountable for these errors.

Errors in the analytic phase of the anatomic test cycle has also been observed to occur during histologic and specimen processing in the taking-in room (Gross room), at the microscope and by clerical personnel in the laboratory. In the post-analytic phase of testing, the result of this phase of testing are communicated to caregivers so that they can be used for patient care. Untimely delivery of the report or information to the clinician leads to delay in treating the patient and this may result in tragedy in such cases.

Objectives

Broad objective

To determine errors in anatomic pathology in relation to the classic laboratory test cycle and evaluate factors contributing to these errors at Muhimbili National Hospital, DAR ES SALAAM.

Specific objectives

(i) To determine errors in pre-analytic phase in anatomic pathology in relation to classic laboratory test cycle
(ii) To determine errors in analytic phase of the anatomic pathology test cycle in the laboratory
(iii) To determine errors in post-analytic phase of testing in anatomic pathology in relation to the classic laboratory test cycle.
(iv) To evaluate factors contributing to errors in anatomic pathology in relation to classic laboratory test cycle and suggest solutions.

Materials and methods

Study design

The study was a descriptive cross-sectional one in which the information was obtained from pre-analytic assessment of all request forms for histopathological analysis including their corresponding specimen containers and by analyzing pre-analytic errors written on the forms or containers and those observed in the containers holding the specimen/biopsy, also from the analytic phase of the laboratory test cycle which was followed- up and analyzed for errors which might occur at different levels of this test cycle. Finally errors occurring during post-analytic phase of the laboratory test cycle were documented and analyzed

Source of information

Request forms containing information of the biopsies from patients including their specimens and containers were obtained at the Central Pathology Laboratory (CPL)and from departments of surgery, obstertrics/ Gynaecology, orthopedics/Trauma, neurosurgery, internal medicine, peadiatrics/Childhealth and outpatient clinics at Muhimbli National hospital and Muhimbili Orthopedic institute respectively and were documented and evaluated during the pre-analytic phase of the laboratory test cycle for a period of 3 months.(July – September, 2008).

Pre-analytic phase

(i) Request forms:

Request forms from clinicians containing information for a particular patient for histopathological analysis of the biopsy specimens were scrutinized and documented for important parameters which had a bearing in the diagnosis. The parameters included; name of the patient, hospital registration number, sex, age, relevant clinical information (history of the patient, examination findings of the lesion, other investigations done included; providing misleading or inadequate clinical information which subsequently may lead to poor diagnostic formulation in analytic phase of testing), site of biopsy, type of biopsy (incisional or excisional), and in the case of endometrial curettings, date of LMP where applicable and Full name of the clinician and address. These parameters mainly covered the pre-analytic phase of anatomic pathology test cycle in order to uncover any errors.

(ii) labels, containers and fixatives:

Also in this phase, labels on the containers including the specimen and fixative they hold were checked for errors and documented. The aim was mainly to match parameters with those of the corresponding patient in the request form. The parameters here included mislabeling or labeling illegibly on the container, name of the patient, hospital registration number, site/type of biopsy, the size of container in relation to the size of biopsy and the amount of fixative in relation to the size of biopsy and adequacy of the tissue biopsy for diagnosis.

Analytic phase

Also parameters in the analytic phase of the anatomical pathology laboratory test cycle were evaluated in order to observe for any errors. The parameters which were evaluated here mainly occured during histologic specimen processing, in the taking-in room (gross room), at the microscope, and by clerical personnel in the laboratory.

(i) Histologic errors included those arising from slide labeling, specimen contaminations (e.g. floaters, pickups).
(ii) Errors in the taking-in room:
These included incomplete or incorrect gross examination, poorly worded description of the gross examination of the specimen were picked-up from the hand-written pathology report forms retrieved from the files.
(iii) The pathology report:
Finally, analytic phase errors which occurred during the transcription and generation of the pathology report were evaluated and documented. Mistakes here included assignment of a report to the wrong patient or clinician and typographical errors. Here, the typed pathology reports forms were retrieved from the files and were evaluated for errors or mistakes which occurred during the analytic phase.

Post-analytic phase

In the post-analytic phase of testing, the results of the analytic phase of testing were communicated to caregivers so that they could be used for patient care. Errors here related to the delivery of reports or information to the wrong clinician. Before the posting of results was done from the department of pathology, the reports were scrutinized for the correctness of the address (ward) and name of the clinician. Some of the reports had no address and even name of the clinician ordering the investigation. Untimely delivery of reports to the wards was also evaluated. The date of receiving the specimen to the date of delivery of the report was used as a yardstick in documenting the time taken. Any duration of delivery of the pathology report beyond one week was evaluated as untimely.

Results

In the pre-analytic phase of the laboratory testing, the pre-analytic errors which were analyzed were picked up from the request forms and specimen (biopsies) containers submitted to the laboratory. There were 13 variables analyzed from the request forms (table 1). Out of these 13 variables, 11 had errors which differed in magnitude. The highest pre-analytic errors were those arising from misleading clinical information of the patient (90%) and missing relevant clinical information of particular cases (90%) . Also there was lack of examination findings of lesions examined (80%) of cases. Relevant clinical history of patients was missing in 90 (45%) of the patients. Likewise the site and type of biopsies were not indicated in 15% and 40% of the patients respectively. The age of patients were not indicated in the request forms in 20% of cases while sex (gender) was not shown in 10%. Out of 200 names of clinicians requesting investigations as seen in the request forms, 140 (70%) names were not written in full and of these, 120 (85.7%) gave their first names and 20 (14.3%) had signatures only. It was also noted that in 10% of request forms of patients, the address of the ward or clinician where the specimens were coming from were not indicated.

There were 8 variables analyzed for pre-analytic errors arising from information picked up from the specimen containers as shown in table 2. The errors included those arising from mislabeling on the container, which was the highest (85%) followed by illegibly labeling of the container (75%), no indication of site and type biopsy on the container in 25% and 50% respectively. The sizes of the containers were inadequate to accommodate the specimens (biopsies) in 15% while the amount of fixative for the biopsy was also inadequate in 15% of biopsy specimens. There was insufficient (inadequate) amount of biopsy specimen in the container for diagnosis in 15% of cases.

In the analytic phase of laboratory test cycle, there were 11 variables analyzed for analytic errors. In these; 9 out 11 variables, errors which arose were of differing magnitudes. The errors which were found included typographic errors which had the highest frequency (45%) followed in frequency by block mislabeling (35%), incorrect slide labeling (25%), incorrect gross examination of the specimen (20%), specimen contamination (10%), Incomplete gross of the specimen (5%), poorly or incorrect worded description of the gross specimen (5%), assignment of the report to wrong patient (5%) and assignment of the report to the wrong clinician (5%).

In the post-analytic phase of laboratory testing, there were 3 variables which were analyzed for errors. The variables analyzed and the errors found (table 4) were; delivery of the report or information to wrong clinician (10%), untimely delivery of report to the clinician (35%) and failure of the caregiver to see the report at all was (15%).

Table 1: Pre-analytic errors arising from request forms information.

SN	Variable	Present	Absent	Total
1.	Name of the patient	200 (100%)	0	200
2.	Sex of the patient	180 (90%)	20 (10%)	200
3.	Age of the patient	60 (80%)	40 (20%)	200
4.	Registration number of the patient	200 (100%)	0	200
5.	Relevant clinical history of the patient	110 (55%)	90 (45%)	200
6.	Examination findings of the lesion	40 (20%)	160 (80%)	200
7.	Misleading clinical information of the patient	20 (10%)	180 (90%)	200
8.	Inadequate clinical information of the patient	160 (80%)	40 (20%)	200
9.	Other clinical information of the patient done	20 (20%)	180 (90%)	200
10	Site of biopsy	170 (85%)	30 (15%)	200
11.	Type of biopsy	120 (60%)	80 (40%)	200
12. *	Full name of the clinician	60 (30%)	40 (70%)	200
13.	Address of the ward or clinician	180 (90%)	20 (10%)	200

*** First name only: 120 out of 140 (85.7%) * Signature only : 20 out of 140 14.3%)**

Table 2: pre-analytic errors arising from containers

SN	Variables	Present	Absent	total
1.	Mislabeling on the container	30 (15%)	170 (85%)	200
2.	Labeling the container illegibly	50 (25%)	150 (75%)	200
3.	Name of the patient on the container	200 (100%)	0	200
4.	Site of biopsy	150 (75%)	50 (25%)	200
5.	Type of biopsy	100 (50%)	100 (50%)	200
6.	Adequacy size of container in relation to biopsy	170 (85%)	30 (15%)	200
7.	Adequacy of fixative amount in relation to biopsy	170 (85%)	30 (15%)	200
8.	Adequacy of biopsy for diagnosis	170 (85%)	30 (15%)	200

Table 3. Analytic errors

SN	Variables	Present	Absent	Total
1.	Correct slide labeling	150 (75%)	50 (25%)	200
2	Specimen contamination	20 (10%)	180 (90%)	200
3.	Incomplete gross examination	10 (5%)	190 (95%)	200
4.	Incorrect gross examination	40 (20%)	160 (80%)	200
5.	Poorly or incorrect worded description of gross specimen	10 (5%)	190 (95%)	200
6.	Poor or incorrect sampling of tissue for microscopic examination	0	200 (100%)	200
7.	Block mislabeling	70 (35%)	130 (65%)	200
8.	Microscopic examination done	200 (100%)	0 (0%)	200
9.	Typographic errors	90 (45%)	110 (55%)	200
10.	Assignment of report to wrong patient	10 (5%)	190 (95%)	200
11.	Assigniment of report to wrong clinician	10 (5%)	190 (95%)	200

Table 4: Post-analytic errors

SN	Variables	Present	Absent	Total
1.	Delivery of report or inform to wrong clinician	20 (10%)	180 (90%	200
2.	Untimely delivery of report clinician	70 (35%)	130 (65%	200
3.	Failure of the caregiver to s the report at all	30 (15%)	170 (85%	200

Discussion

Clinician error is a major source of pre-analytic error, and this type of error often causes major errors in the other parts of the anatomic pathology test cycle. Unfortunately, the laboratory team is often held accountable for these errors.[3] In this study, clinician error included providing inadequate tissue for diagnosis, mislabeling or labeling illegibly a specimen which may lead to incorrectly identifying the specimen as to the patient or site of origin of the specimen e.g. right versus left ovary or breast, providing misleading or inadequate clinical information that subsequently leads to poor diagnostic formulation in the analytic phase of testing. Significant pre-analytic error also occurred in the receipt and accessioning phase of the pre-analytic phase of testing in the current study. These errors included those that stemmed from clinician labeling error and those that originated from incorrect order entry and accessioning by laboratory workers (e.g. assigning a specimen to the wrong patient, misidentifying the site of origin of a specimen, and assigning a specimen to the wrong clinician). Similar to clinician error, these failures can engender errors in the analytic and post analytic phases of testing.[3]

Errors in the analytic phase of the anatomic test cycle in this study occurred during histologic processing, in the taking-in (gross) room, at microscope, and by clerical personnel in the laboratory. Errors at the microscope include slide mix-ups (e.g. assigning a diagnosis from a given slide to the wrong patient), numerous types of mistakes that are caused by cognitive problems, and generation of poorly worded or poorly formulated report. Pathologists believe that they are particularly responsible for these types of errors because they are almost always directly involved in the processes that engender them.[5] The effects of these range from almost inconsequential to devastating. Finally, like in other studies, the analytic phase errors in this study occurred during the transcription and generation of the pathology report. Mistakes here included assigning of a report to the wrong patient or clinician and typographic errors. Typographic errors in particular which ranged highest in the analytic phase in this study, can be difficult to detect especially when proofreading numerous reports in the same sitting.[7] Even minor typographic errors can profoundly alter the meaning of a report (e.g. "no malignancy is seen" versus "malignancy is seen).

In the post-analytic phase of testing, the results of the analytic phase of testing are communicated to caregivers so that they can be used for patient care. Errors here relate the delivery of the reports or information to the wrong clinician, untimely delivery of reports, misunderstanding on the part of the treating physician as to the significance of the information in the report, and failure of the caregiver to see the report at all. Some of these errors stem from pre-analytic labeling and accessioning error, some stem from poorly formulated reports generated in the analytic phase, some relate to clinician office practices. These problems are often magnified when critical result is anticipated by the clinician, because in those cases the treating physician will not be looking for the report and the entire patient encounter can easily be put out of mind.[10,11]

Factors that might have contributed to errors at Muhimbili Medical National Hospital included those which stemmed from errors in the pre-analytic, analytic and post-analytic phases of the laboratory test cycle as already indicated the result section. They included variable inputs such as incorrect or improper patient identification and incomplete or incorrect clinical history of the patient. Also the complexity of steps in the process of the surgical pathology test cycle tended to increase the chance of errors. Additionally, inconsistent use of diagnostic criteria for the diagnosis of cancer and other conditions contributed to the creation of confusion and reduced the level of confidence in pathology and might have lead to errors in surgical pathology. Lack of timely and accurate information access, for example of not knowing patient's history, including previous pathology report and radiographic studies or lack of electronic medical record greatly enhanced the increase in the chance of error occurrence.

Conclusion

Anatomical pathology is a complex system with ample opportunity for error. Significant error reduction is unlikely to occur without a sustained comprehensive program of quality control and quality assurance. Incremental adoption of information technology and automation along with improved training in patient safety and quality management can help reduce errors.

Recommendations

The numerous errors amounted in the pre-analytic, analytic and post-analytic phases of laboratory test cycles in Anatomical pathology reinforces the need for effective quality control and quality assurance at all steps in laboratory test cycle. This will be possible only and only if factors that contribute to errors be reduced to an absolute minimum through error reduction strategies combined with an attempt to apply these strategies. Timely, accurate information access is vital to decision making; this is particularly critical at the time of diagnosis. Knowing the patient's history, including previous pathology reports and radiographic studies allows the pathologist to focus on the question at hand. Although clinical information is required for specimen submission, it is often incomplete or inaccurate. Access to electronic medical record greatly would enhance the prospects of having correct clinical information at the correct time. It also saves time spent having the clinician to get answers.

Errors can also be consistently reduced when systems are modified to reduce reliance on memory. Introduction of checklists for example in reporting and daily worksheets to ensure that routine tasks are completed, including daily maintenance of laboratory equipments; would reduce errors. Automation at any point in the process is not

memory aid, but does eliminate the need to remember multi-step procedures and therefore, reduces reliance on memory. With regard to the issue of personnel in the laboratory, one should choose the correct staff for the correct job. It is not uncommon to find an individual's job title to include multiple duties and responsibilities but with the same basic qualification. Such an individual will have strengths and weaknesses with respect to their various duties and responsibilities. It is optimal that individuals be placed in jobs in which they are strong. Without adequate training, assigning individuals to duties in their areas of weakness is a set-up for failure and may result in errors.

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